



Harmonisation as Part of the Translation and Linguistic Validation Process: What is the Optimal Method?

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Background and introduction

During the PRO translation and linguistic validation process, harmonisation is of the utmost importance; it ensures conceptual equivalence of the translations across all languages, allowing trial data to be pooled across cultures.

The 2005 ISPOR Principles of Good Practice paper describes harmonisation as a key objective in the translation and linguistic validation of PROs. It outlined two methods for achieving harmonisation, which are presented in Table 1 below.

Table 1 – Harmonisation Methods

Option 1: Formal meeting	Option 2: Ongoing process
<ul style="list-style-type: none"> Formal meeting with the project coordinator(s), translators from each target language and the instrument developer (extracts from a harmonisation meeting are presented in table 3). This can take place either in person or by teleconference or webinar. During the meeting, the project co-ordinator and developer elaborate on the meaning of each item, and the lead translators in each target country can discuss areas of concern. The meeting or teleconference usually occurs after back translation review, though if necessary and if time and budget allows, it can occur additionally at other points in the translation process. 	<ul style="list-style-type: none"> An ongoing process, whereby solutions to common problems are conveyed to all translators through rigorous quality control. This method requires the use of a detailed concept elaboration document (presented in table 2 below) as an aid to help translators to find the optimum translation. The concept elaboration document contains a definition and explanation of every item, and if possible should be developed in collaboration with the questionnaire developer. The concept elaboration document is referred to by lead translators and project co-ordinators at all stages of the project. Furthermore, where problems arise in one language the difficulty and its resolution can be added to the concept elaboration document as a reference for the translators or project coordinators of other languages.

Table 2 : Example item definition/concept elaboration document (IWQOL-lite):

Wording of Original (Source Text)	Concept and Possible Alternatives for Wording
<p><u>Part 2</u> Self-esteem</p>	<p>Second theme: the way obesity affects self-esteem.</p> <p>"Self-esteem" = the opinion one has of oneself. 'Self-evaluation' seems to be a bit weak with respect to "self-esteem". However, if this is the simplest and clearest way to express this notion, then it is fine.</p>
<p><u>Item 1</u> Because of my weight I am self-conscious.</p>	<p>"self-conscious": 'having complexes' would adequately convey the original meaning as it refers to feeling shy, uncomfortable, awkward as if everyone was looking at you and judging you. The solution "being too conscious of myself" also is a good one</p> <p>Because of my body weight I am too conscious of myself.</p> <p>Would "extremely conscious of myself" and "uncomfort-able with myself" be appropriate alternatives to render "self-conscious"?</p> <p>Developer: "extremely conscious of myself" seems to imply an <u>extreme</u> degree of self-consciousness rather than self-consciousness in general. As a result, I would not recommend the use of the term "extremely conscious of myself."</p> <p>"Uncomfortable with myself" is not exactly the same as "self-conscious," either. The following are definitions of the term "self-conscious" from the Encarta English dictionary:</p> <ol style="list-style-type: none"> "highly conscious of the impression made on others and tending to act in a way that reinforces this impression" "feeling acutely and uncomfortably aware of failings and shortcomings when in the company of others and believing that others are noticing them too" <p>I believe that these definitions do a good job of conveying the intended meaning of this item.</p> <p>Perhaps more words are needed in the translations in order to convey the full meaning of the term "self-conscious" (according to definitions number 1 and 2 above). For example, "Because of my weight I am uncomfortably aware of myself and highly conscious of the impression I am making on others."</p>

© Copyright 2000. Duke University Medical Center. Direct all correspondence to Ronette L. Kolotkin, Ph.D., Obesity and Quality of Life Consulting, 1004 Norwood Avenue, Durham, NC 27707, USA; (919) 493-9995; Fax: (919) 493-9925 (email address: rkolotkin@yahoo.com) IWQOL-Lite – English (US).

Table 3: Example extract formal harmonisation meetings

Source Text	Comments from Harmonisation	Comments
Signing up for this study has made me feel better	<p>Project coordinator: There are some issues for translators with the term for "signing up", could you elaborate please?</p> <p>There was also an issue with "has made me feel better" – does this mean more the psychological boost from the actual act of signing up in the study, or does it mean a real improvement in the condition?</p>	<p>Developer 1: just signing up to participate and whatever impact that has (psychological or otherwise).</p> <p>Developer 2: I think "made me feel better" could refer either to a psychological boost, an improvement in symptoms, or both. In either case I think it refers to the decision to participate in the study (sign up for the study).</p>

(table continued overleaf)

Table 3: Example extract formal harmonisation meetings (Continued)

I will make myself better during this study	Project coordinator: Some languages need to add “through definite efforts of my own” or even “I will try to become better” – is this what the original means?	Developer 1: yes
Day center / drop-in / social club	Project coordinator: All languages are struggling to find equivalent terms for this item; some countries do not have such centers or clubs, and “social” often implies “state provided” in other countries. Alternatively, can it be removed entirely where it is not culturally appropriate.	Developer: Please change the item to read: Other Care: (please specify) _____

*extracts taken from various questionnaires

Methods:

Eight projects were reviewed. Four included a harmonisation meeting via teleconference with translators from each target language and the instrument developer. The other four projects were harmonised through a detailed concept elaboration as shown in table 2, created in collaboration with the developer. This document was continually updated; wherever problems arose, the resolution was incorporated. The document was consulted by translators at every step of the process, for example it was added into the translation grid at reconciliation stage, then at back translation review stage, and was consulted during the cognitive debriefing reviews.

Both methods were evaluated by the project coordinators and with feedback from the lead translators involved, to determine the optimal process.

Results:

Both methods achieved harmonised translations, but some differences in the process became apparent as presented in table 4.

Table 4: Differences in harmonisation methods

	Option 1: Formal meeting	Option 2: Ongoing process
Advantages	<ul style="list-style-type: none"> Translators felt it useful to speak with the developer, and this method allows a clear channel of communication between the translators and developer, facilitated by the project coordinator. 	<ul style="list-style-type: none"> Cost and timelines less than option 1 Lack of logistical problems relating to time zones. Harmonisation occurs at every stage of the project (e.g. after linguistic validation interviews) Sharing translation problems throughout the project is very useful The developer’s input is still included. Logistical advantages in that the same harmonisation process can be utilised for a project where new languages are added at a later point; the same item definition report is simply re-used ensuring better harmonisation across different projects as well as within a project. Because the harmonisation procedure is implemented from the start of the project, fewer alterations are made at a later stage as in option 1, therefore ensuring consistency throughout the project.
Disadvantages	<ul style="list-style-type: none"> Addition of at least a week to the project timeline Higher cost to the sponsor Logistical problems if many countries involved, particularly if these cross time zones (e.g. encompassing Australia, Latin America and the UK), meaning that several teleconferences had to take place per project rather than having all translators and the developer in the one conference, which would be preferable. Harmonisation meeting usually takes place after back translation review; the translation can be altered after this point, for example at clinician review or after linguistic validation interviews. Higher number of changes suggested both to the translations themselves and even at times the source text. 	<ul style="list-style-type: none"> Translators do not have direct contact with developer. Lack of a formalised harmonisation report, which may be preferred by some sponsors. However, a formal report is not a regulatory requirement so this should not pose a problem.

As shown in the tables, there were great differences in the two processes; the first proved useful in that it clearly provided a means for the developer to convey their intended concepts to the translators, but was costly in terms of both time and budget, and applied to only one point of the translation and linguistic validation process. The second option appeared to offer some positive aspects which cannot be achieved with option 1, such as providing ongoing support and shared problem solving. Furthermore, less harmonisation alterations were needed in option 2, because of the consistency of the harmonisation documents provided to translators right from the start of the project.

Conclusions:

The harmonisation procedure is key to the translation process, and both methodologies achieved harmonised translations. However, the less formal approach shortened the timeline and reduced the cost for the sponsor and provided other additional benefits, without sacrificing harmonisation.

References:

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, Wild et al, 2005