

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

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ABSTRACT

In 1999, ISPOR formed the Quality of Life Special Interest group (QoL-SIG)—Translation and Cultural Adaptation group (TCA group) to stimulate discussion on and create guidelines and standards for the translation and cultural adaptation of patient-reported outcome (PRO) measures. After identifying a general lack of consistency in current methods and published guidelines, the TCA group saw a need to develop a holistic perspective that synthesized the full spectrum of published methods. This process resulted in the development of Translation and Cultural Adaptation of Patient Reported Outcomes Measures—Principles of Good Practice (PGP), a report on current methods, and an appraisal of their strengths and weaknesses. The TCA Group undertook a review of evidence from current practice, a review of the literature and existing guidelines, and consideration of the issues facing the pharmaceutical industry, regulators, and the broader

outcomes research community. Each approach to translation and cultural adaptation was considered systematically in terms of rationale, components, key actors, and the potential benefits and risks associated with each approach and step. The results of this review were subjected to discussion and challenge within the TCA group, as well as consultation with the outcomes research community at large. Through this review, a consensus emerged on a broad approach, along with a detailed critique of the strengths and weaknesses of the differing methodologies. The results of this review are set out as “Translation and Cultural Adaptation of Patient Reported Outcomes Measures—Principles of Good Practice” and are reported in this document.

Keywords: cultural adaptation, good practice, guidelines, linguistic validation, patient reported outcomes measures, translation.

Background and Rationale

At ISPOR Second Annual European Congress, which took place in 1998 in Edinburgh, Scotland, a meeting was held about quality of life in general and the need for a greater presence at ISPOR. At this meeting, a list of possible topics was generated by the group and the attendees identified the topic that was of interest. From there, the working groups were formed based on the areas of interest.

When the working groups of the Quality of Life Special Interest Group (QoL-SIG) were set up in

1999, a separate chair was asked to lead each working group. The groups were given no specific remit, rather they were intended to offer a forum, in which ISPOR members could meet to share thoughts and discuss issues pertinent to the particular research interests of the group. Open meetings were scheduled to take place at each of the European and International ISPOR conferences so that ISPOR members were free to join any group at any stage, depending on their own particular research interests at any given time. Information can be found about other QoL-SIG working groups on the ISPOR's Web site at <http://www.ispor.org>

The Translation and Cultural Adaptation (TCA) group met for the first time at the ISPOR Third Annual European Congress in Antwerp in 1999.

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The Congress was attended by representatives of the pharmaceutical industry, academia, and contract research organizations (CROs); all participants were either interested or involved in the translation and cultural adaptation of patient-reported outcomes (PRO) measures for use in clinical trials or other forms of outcomes research. Some members had no prior knowledge of the translation process and had come expecting to have their questions answered during the meeting, while other members, with first-hand experience of managing translations, had come expecting to discuss some of the difficult issues they faced as practitioners. Discussions at this meeting demonstrated that there were no definitive answers to many methodological questions and confirmed that differing methodologies were being employed in current practice.

The TCA group concluded that better definitions were required for the following reasons:

1. In practice differing methodologies are employed by consulting groups to perform similar tasks, making consistency and comparison difficult to achieve.
2. Different terminology is used to refer to the same aspects of the translation process, making it harder to achieve clarity.
3. Instrument developers have sometimes developed their own translation guidelines for use with a specific instrument that may be inconsistent and/or out of date compared to current research requirements.
4. Poorly translated instruments threaten the validity of research data and the safe aggregation of global data sets. There is no practical means to assess the validity and conceptual equivalence of new or existing translations except by post hoc psychometric validation. Quality assurance is therefore heavily dependent on the methodology used.

TCA group discussions at subsequent ISPOR meetings focused on the evaluation of existing translation guidelines, their current relevance to outcomes research, and possible forms that any new guidelines might take. After it became apparent that the open nature of those meetings was causing little progress to be made, it was decided in May 2001 to form a core group of regular meeting attendees in order to complete a draft of a new guidance document. The remaining group of interested members could then act as a reference group to review and comment on the new guidance as it progressed. This core group began work in June 2001.

Problem Statements

The main problems initially identified by the TCA group were:

1. Lack of consistency in terminology. For example, the terms “pilot testing” and “cognitive debriefing” are both used to describe the testing of a new translation on a small group of five or six patients. In addition, the term “pilot testing” is also used to refer to the testing of an instrument on a larger group of 30–40 patients to gather some initial data.
2. Lack of consistency in methodology. While most practitioners agree that the overall aim of translation is to produce a new language version, which is both conceptually equivalent with the original and relevant to the new target culture, the actual methods employed differ. For example, some methods do not include a “back translation” to further refine the translation, while some methods include one or two “back translations.” While the literature expresses the preference of individual authors, there is a lack of published research studies that demonstrate the superiority of any one approach.
3. The scope of future guidance. In particular should it prescribe language-specific methodology or translation methods for specific types of PRO instruments (e.g., symptom checklists, diaries, and components of case report forms)?
4. The extent to which any new guidance should be prescriptive or descriptive, i.e., whether it should describe the way in which the process can be undertaken or should it set out criteria, standards, or requirements that must be met.
5. The target audience for the new guidance needs to be defined in order to determine how results should be presented.

The scope of the new guidance document was explored during initial TCA group discussions. It was determined early on that each particular type of “language to language” translation process (e.g., English to German, or French to Russian) should be dealt with separately from “same language adaptations” (e.g., adapting a Spanish for Spain translation for use in Argentina, or English for the United States being adapted for use in South Africa). The TCA group chose to begin by reviewing existing translation guidelines for “language to language” translations, and decided that “same language adaptations” merited their own guidelines.

In addition, there was discussion about the different methodologies employed for different types of patient-reported outcome measures. It was decided that the discussion around whether some types of PRO measures (e.g., diaries) require a less rigorous approach to fully validate health-related quality of life (HRQoL) measures should wait until after further discussion had taken place.

When discussing the style in which the new guidance document would be written, the working group also considered its target audience. It was decided that it should be produced with the entire ISPOR membership in mind, as it was intended to benefit the interests of outcomes research. It needed to be written in a user-friendly format and from a very practical point of view for all interested parties—whether they be from industry, academia, or contract research. It was agreed that, because of the subjective nature of language and the range of PRO instruments in current use, resulting guidance should not be overly prescriptive. However, if guidance were purely descriptive, readers without experience in the area might be unable to effectively select an appropriate translation method. The TCA group therefore decided that it should aim to publish good practice “guidance” that set basic standards but allowed flexibility. It would provide a description of the process in a step-by-step format that would be clear enough for anyone to follow and understand, without using ill-defined labels or jargon. An additional section was to be provided to inform readers about the risks they would face if they chose to omit any one of the steps in the process.

The final work would therefore not be presented as a set of rigid procedures, but rather set out the principles of good practice in the area of translation and cultural adaptation, making clear both the rationale for including each step and the risks of omission.

Methods

The TCA working group of ISPOR’s QoL-SIG carried out a review of the following 12 major sets of guidelines available for translation and cultural adaptation:

1. American Association of Orthopaedic Surgeons (AAOS) [1];
2. Association of Test Publishers [2];
3. EORTC group [3];
4. Euro QoL group [EuroQoL Group, unpublished];

5. Evidence: Clinical and Pharmaceutical Research [4];
6. FACIT group [5];
7. Health Outcomes group (HOG) [6];
8. Health Utilities Inc. (HUInc) [7];
9. International Quality of Life Assessment (IQOLA) group [8];
10. Kidney Disease Quality of Life (KDQOL) [9];
11. Medical Outcomes Trust (MOT) [10]; and
12. World Health Organization [11].

Each of these was broken down into different steps in the process (e.g., forward translation, reconciliation, back translation, pilot testing), and each member of the working group reviewed the content of published guidelines for each key step. For some steps, there was a great deal of consistency in approach, while for other steps there was considerable disparity. The resultant reviews were evaluated in terms of current practice and research needs and agreement was reached regarding what should be included in the methodological description of each step.

Agreement was also reached on the need for additional information that would provide assistance to outcomes researchers in implementing the suggested methods. These other areas included:

1. the rationale for each step;
2. a description of the actors to be involved in each step; and
3. an outline of the risks associated with not including that step in the process. For clarity and ease of use, the information was to be presented in a tabular format, with a list of clear definitions.

The PGP working paper resulted from this process and was circulated to the TCA QoL-SIG reference group for review. Suggestions for changes or additions were subsequently discussed by the working group and implemented as appropriate. Two further rounds of review and revision were carried out until the working and reference groups agreed on the current document.

The Translation and Cultural Adaptation—Principles of Good Practice are presented over the following pages, beginning with definitions of each step in the process and the actors involved at each step. The framework for describing each step in the translation process is:

1. Preparation;
2. Forward Translation;
3. Reconciliation;
4. Back Translation;

5. Back Translation Review;
6. Harmonization;
7. Cognitive Debriefing;
8. Review of Cognitive Debriefing Results and Finalization;
9. Proofreading; and
10. Final Report.

Each step is described in the following ways:

1. Step identification;
2. Critical components;
3. Rationale;
4. Who should do this; and
5. What are the risks of not doing this?

For each of the 10 steps, a summary of the TCA Group discussions and revisions that lead to the current PGP are also included.

ISPOR Principles of Good Practice: The Cross-Cultural Adaptation Process for Patient-Reported Outcomes Measures

Part 1: Definitions

For clarity, the following explanations are provided for the terms most often used to label each step in the translation process and the key actors involved in each step. They are not deemed to be definitive labels, but an aid to understanding and evaluating the content of each step.

Explanation of the labels used to describe each step in the process

- Preparation—initial work carried out before the translation work begins;
- Forward translation—translation of the original language, also called source, version of the instrument into another language, often called the target language;
- Reconciliation—comparing and merging more than one forward translation into a single forward translation;
- Back translation—translation of the new language version back into the original language;
- Back translation review—comparison of the back-translated versions of the instrument with the original to highlight and investigate discrepancies between the original and the reconciled translation, which is then revised in the process of resolving the issues;
- Harmonization—comparison of back translations of multiple language versions with each other and the original instrument to highlight discrepancies between the original and its derivative translations, as well as to achieve a consistent approach to translation problems;
- Cognitive debriefing—testing the instrument on a small group of relevant patients or lay people in order to test alternative wording and to check understandability, interpretation, and cultural relevance of the translation;
- Review of cognitive debriefing results and finalization—comparison of the patients' or lay persons' interpretation of the translation with the original version to highlight and amend discrepancies;
- Proofreading—final review of the translation to highlight and correct any typographic, grammatical or other errors;
- Final report—report written at the end of the process documenting the development of each translation.

Description of the key actors involved in the process

- Client—the person or group of people requiring or commissioning the translation of an instrument;
- Instrument developer—person or group of people who developed the original instrument being translated, and who may be responsible for the management of the instrument;
- Project manager—the person coordinating the translation project, working at a CRO or other similar organization. He or she provides oversight at each stage of the process;
- Key in-country consultant—the main contact person managing the process in the target country. This person is responsible (sometimes) for developing the first forward translation. He or she should be a native speaker of the target language, fluent in the source language, usually English, and should reside in the target country. He or she should come from a medical/health/psychology/social science background and have experience in translating/managing the translation of PRO measures;
- Forward translators—the people who develop the second and subsequent forward translations. They should be professional translators, native speakers of the target language and fluent in the source language, usually English. It is preferable that forward translators reside in the target country and have experience in the translation of PRO measures;
- Independent translator—a translator who may be used to carry out the reconciliation. He or she should be a native speaker of the target language, be fluent in the source language, and

- reside in the target country, preferably with experience in the translation of PRO measures;
- Back translators—the people who develop the translations from the target language back to the source language. They should be professional translators, native speakers of the language of the source measure, and fluent in the target language. They should have no prior knowledge of the measure, and should not see the source or any other language version before or during back translation;
- In-country consultant—an in-country person who may be used to carry out the cognitive debriefing interviews. He or she should be a native speaker of the target language, be fluent in the source language, and reside in the target country, preferably with experience in qualitative interviewing and/or cognitive interviewing techniques; and
- Proof readers—the people who check the final translation for typographic, grammatical, or other errors. They should be native speakers of the target language.

Part 2: The Translation and Cultural Adaptation Process

Step 1—preparation. Although this is usually omitted from translation guidelines, the TCA group recognized that there is a good deal of preparatory work to be done before the translation work can begin. Therefore, a step was included to outline what this preparation work involves.

The TCA group agreed that it is usually the project manager who both develops the explanation

of the concepts with the developer if available/interested, and also recruits the key in-country persons. However, there was some discussion regarding who should take responsibility for contacting the developer for permission to use the instrument and to invite them to become involved in the process. In practice, this was sometimes carried out by the client requiring the translations, while at other times the client had often not obtained permission before requesting that the project manager carry out the translations. It was therefore decided that to reflect current practice, and to avoid being too prescriptive, the PGP maintains that initial contact with the developer to obtain permission for translation should be carried out, by either the client or the project manager. In some cases, an independent researcher may wish to undertake the translation of an instrument, and in such cases, the researcher would need to contact the developer for permission before beginning any translation work (Table 1).

Step 2—forward translation. There was general agreement in the existing guidelines regarding the need for more than one forward translation. Ensuing discussions centered on the qualifications required for the people carrying out the forward translation. It is clear that culture is a primary determinant of language and that native speakers within a given culture have advantages with language ability that second language speakers do not, and thus it was agreed that all forward translators should be native speakers of the target language with prior experience in the translation of PRO measures. However, there was some disagreement about the need for all forward translators to be resident in the

Table 1 Step 1—Preparation

| Critical components | Rationale | Who should do this? | What are the risks of not doing this? |
|--------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|
| 1. Obtain permission to use instrument | 1. To respect copyright | 1. The client or the project manager contacts the instrument developer to ask for permission to use and translate the instrument | 1. Being prosecuted for unauthorized use of copyright material |
| 2. Invite instrument developer to be involved | 2. If the instrument developer is involved, he/she is often able to clarify any ambiguities, and clarify the concepts behind the items | 2. The project manager or the client invites the instrument developer to be involved in the translation process. The extent of their involvement is dependent on their own level of interest in the instrument | 2. Misinterpretation of items or concepts |
| 3. Develop explanation of concepts in instrument | 3. To strengthen the conceptual equivalence of the forward translations, and help to avoid any ambiguities | 3. The project manager works with the instrument developer (where possible) to produce information about the conceptual basis for the items in the measure, for use by the translators in the process | 3. Misinterpretation of items or concepts |
| 4. Recruit key in-country persons to the project | 4. To have a key person in the target country to work closely with the project manager for the duration of the translation process | 4. The project manager recruits a key in-country person for each target language | 4. Not applicable |

Table 2 Step 2—Forward Translation

| Critical components | Rationale | Who should do this? | What are the risks of not doing this? |
|-----------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| 1. Development of at least two independent forward translations | 1. Translations can be compared, enabling detection of errors and divergent interpretation of ambiguous items in the original, thus reducing the potential bias of each key in-country person and forward translators | 1. Two or more forward translators carry out independent forward translations of the instrument. It is preferable that one forward translation be carried out by the key in-country person | 1. A translation which includes too much of one person's own style of writing |
| 2. Provision of explanation of concepts in the instrument to the key in-country persons and forward translators | 2. To provide key in-country persons and other forward translators with a clear explanation of the basic concepts, with the intention that the translations will capture the conceptual meaning of the questions rather than being a literal translation | 2. The project manager provides the key in-country person and the other forward translators with background information about the conceptual basis of the measure. The project manager should instruct them to produce colloquial translations that will be easily understood by the general lay population. In some circumstances it may be necessary to ask that wording is kept compatible with certain reading levels or ages | 2. Lack of conceptual equivalence in translations due to misinterpretation of items |

target country. Bearing in mind that the aim of the PGP was to present practical guidance rather than prescriptive rules, it was agreed that as the key in-country person would reside in the target country, it was acceptable for any second or subsequent forward translators to live in another country. However, it was felt that the PGP should indicate that residence in the target country was preferable (Table 2).

Step 3—Reconciliation. There was relatively little concurrence between existing guidelines about how the reconciliation of the forward translations should be carried out. There are three approaches:

1. a translation panel consisting of the key in-country person, all forward translators, and the project manager;
2. an independent native speaker of the target language who had not been involved in any of the forward translations; and

3. an appointed in-country investigator who may have prepared one of the forward translations, who will also conduct pilot testing and cognitive debriefing.

TCA group discussions agreed to accept more than one way to achieve reconciliation, suggesting that it could be achieved by the key in-country persons working with their own and any other forward translations or by an independent translator without prior knowledge of the translation, but also concluding that it is preferable for the key in-country person to work with the other forward translator(s) and the project manager. Most importantly, reconciliation decisions should be reviewed by or referred to the project manager. This allows for a degree of consistency and harmonization with other translated versions (Table 3).

Step 4—back translation. The existing guidelines suggested a variety of approaches to back transla-

Table 3 Step 3—Reconciliation

| Critical components | Rationale | Who should do this? | What are the risks of not doing this? |
|------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|
| Reconciliation of the forward translations into a single forward translation | Reconciliation resolves discrepancies between the original independent translations, and seeks agreement between individual speech habits and preferences. A consensus may require alternative translations to be produced but results in one final reconciled forward translation ready for back translation | Where possible, reconciliation should be carried out via discussion with the key in-country person and the second forward translator, with input from the project manager. Alternatively an independent translator may be used to perform the reconciliation. As a minimum requirement, the key in-country person may compare the two forward translations and reconcile them via discussions with the project manager, with reference to the second forward translator for difficult items | A biased translation that is written in one person's own personal style or speech habit; misinterpretations remaining in the translation |

Table 4 Step 4—Back Translation

| Critical components | Rationale | Who should do this? | What are the risks of not doing this? |
|-------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Back translation of the reconciled translation into the source language | <ol style="list-style-type: none"> 1. The primary purpose of the backward translation process is to provide a quality-control step demonstrating that the quality of the translation is such that the same meaning can be derived when the translation is moved back into the source language 2. Some constructs (e.g., medical symptoms) might require a more literal back translation while more subjective constructs (e.g., QoL items) might need to be rendered more conceptually | Back translators should be used to carry out at least one backward translation. Depending upon the nature of the content of the measure, it should be made clear by the project manager whether a literal or conceptual back translation is required | <ol style="list-style-type: none"> 1. A translation in the new language version, which has a different content to and/or conceptual basis from the source measure (and therefore less likely to maintain the psychometric performance that source measure demonstrated) 2. A translation that does not respect the normal speech patterns and colloquialisms of the target culture |

tion. There was a general agreement on the need for back translators to be native speakers of the original language, but little agreement regarding how the back translation should actually be carried out. Some guidelines included more than one back translation, to be carried out either in parallel or sequentially; others suggested a back translation panel and many included a single back translation.

The focus of the TCA working group's discussions, however, was on what style of back translation should be recommended—i.e., should the back translations be literal or conceptual. It was agreed that, for practical purposes, a more literal back translation would prove more useful when compared with the original language version. However, further discussion highlighted the potential need for more conceptual back translations in the case of more subjective items, such as those dealing with QoL issues. Thus the PGP report highlights the need to determine which back translation approach is most appropriate to a specific situation (Table 4).

Step 5—back translation review. The TCA group felt that this was one of the most important com-

ponents of the cross-cultural adaptation process, but one that most of the existing guidelines had not specifically addressed.

There was considerable agreement within the TCA group on this aspect of the process, with review of the back translation against the original being the key function. There was also recognition that discrepancies identified in this way would lead to further assessment of the reconciled version and to possible revisions of it to eliminate the discrepancies. It was also agreed that this review should be carried out by the project manager and any revision of the translation be agreed upon by the project manager and the key in-country person. Clarification should be sought from the developer whenever this was possible (Table 5).

Step 6—harmonization. The TCA Group agreed that harmonization was a key objective of the translation and cultural adaptation process. Harmonization across different translations is essential to ensuring intertranslation validity, and allowing for reliable pooling of data from randomized controlled trials. However there is great disparity in the process through which harmonization is achieved. It is

Table 5 Step 5—Back Translation Review

| Critical components | Rationale | Who should do this? | What are the risks of not doing this? |
|-------------------------------------------------------------|---------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| Review of the back translations against the source language | To ensure the conceptual equivalence of the translation | <p>The project manager and the key in-country person should review the back translations against the source instrument to identify any discrepancies</p> <p>The project manager should address the problematic items and, in liaison with the key in-country person, refine the translation</p> <p>It may also be useful to involve the developer to help resolve difficult issues</p> | A mistranslation or omission may be overlooked and therefore remains in the translation |

Table 6 Step 6—Harmonization

| Critical components | Rationale | Who should do this? | What are the risks of not doing this? |
|------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| Harmonization of all new translations with each other and the source version | To detect and deal with any translation discrepancies that arise between different language versions, thus ensuring conceptual equivalence between the source and target language versions and between all translations. This provides an additional quality-control step and further ensures that data from global trials can be safely aggregated | Harmonization can be achieved in two main ways: 1. A harmonization meeting chaired by the project manager, where back translators representing each language provide a verbal back translation of each item in the measure. Close attention should be paid to the correspondence of each back translated item to the original version as well as to any instances or trends of differences between language versions in their rendering of the concepts 2. The project manager identifies items, which are found to be conceptually problematic in one or more languages. He/she then shares translation solutions for those items with all other key in-country persons working on the measure at the same time. These solutions can be shared at any point during the translation process, but are mainly communicated at the point of back translation review. It may also be useful to refer difficult items to the developer for clarification | Translations that include differences between language versions may make it difficult to aggregate the global data set |

perhaps not surprising therefore, that it has been omitted from the majority of existing guidelines.

Some practitioners believe that harmonization can only be achieved via a harmonization meeting, in which key in-country consultants, or back translators representing each language, compare all translations with each other and the original. Other practitioners do not advocate a specific harmonization step, but integrate a harmonization component within each major step of the translation process. With the need for a specific harmonization step unproven, and the expense of hosting a full harmonization meeting prohibitive for many clients, it was decided that, to maintain a practical approach, the PGP should not support a single approach to harmonization. Instead the PGP should inform the reader of its importance and to describe alternative methodologies for achieving it.

This is an issue that requires further investigation by the TCA group to obtain empiric evidence (Table 6).

Step 7—cognitive debriefing. Although there is broad agreement within the existing guidelines on the purpose and necessity of a cognitive debriefing aspect in the process, each set of guidelines differs slightly in terms of the number and types of people they suggest should be included.

The TCA group was very much aware of the need to avoid setting strict criteria which would be difficult to meet in real-world situations, while making sure that the recommendations were rigorous enough to ensure that the purpose of including this step (e.g., ensuring that the translation is comprehensible to the general or patient population) could be met. It was therefore decided to suggest a range for the number of patients that should be included, and give a clear recommendation that these should match the target population for as many criteria as reasonably practical (Table 7).

Step 8—review of cognitive debriefing results and finalization. As with the back translation review

Table 7 Step 7—Cognitive Debriefing

| Critical components | Rationale | Who should do this? | What are the risks of not doing this? |
|-----------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Cognitive debriefing of the new translation, usually with patients drawn from the target population | To assess the level of comprehensibility and cognitive equivalence of the translation To test any translation alternatives that have not been resolved by the translators To highlight any items that may be inappropriate at a conceptual level To identify any other issues that cause confusion | The newly translated measure should be tested for cognitive equivalence by the key in-country person (or another in-country consultant) on a group of 5 to 8 respondents in the target country Respondents should be native speakers of the target language who adequately represent the target population (sex, age, education, diagnosis) In certain circumstances it may be appropriate to include healthy respondents | Missing or inaccurate data resulting from respondents' misunderstanding of items |

Table 8 Step 8—Review of Cognitive Debriefing Results and Finalization

| Critical components | Rationale | Who should do this? | What are the risks of not doing this? |
|-------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Cognitive debriefing results are reviewed and the translation finalized | To incorporate findings of the debriefing process to improve the performance of the translation | <ol style="list-style-type: none"> 1. The project manager reviews the results from cognitive debriefing and identifies translation modifications necessary for improvement. Items and response options may be reworded where respondents' comments justify such changes 2. Following agreement on changes between the project manager and the key in-country person, the translation can be finalized | <p>Translation may include words or phrases that are not familiar to or commonly used by the respondents</p> <p>Subsequent data collected may include a high level of missing data, or may be inappropriate to aggregate</p> |

step, this is an aspect of the process, which even though included in cognitive debriefing exercises, is not often specifically described.

A review of the cognitive debriefing results against the original version of the instrument is a key to assure cultural relevance. The review should be carried out by the project manager. Revisions to the translation should be agreed between the project manager and the key in-country person. Finally, it was agreed that clarification should be sought from the developer whenever possible (Table 8).

Step 9—proofreading. Even though the proofreading of final translations is likely to be carried out at the end of most projects, few of the existing guidelines included it as a step in the process. The working group agreed that its inclusion was important because it is an important opportunity to ensure that any minor errors are corrected before the translated instrument is approved for use among the target population. Also, those PGP

users who may be unfamiliar with translations would be aware that even though a translation has been taken through many rigorous steps, there is still a need for this final quality-control step (Table 9).

Step 10—final report. Again this is an important aspect of the translation process, which the TCA working group agreed needed to be included here, although it is often not clearly explained in the existing guidelines. The Final Report provides a description of all translation and cultural adaptation decisions, which may be useful when interpreting derivative data sets or informing other future translations of the same instrument, especially with regard to harmonization (Table 10).

Discussion

PRO measures are included in the majority of global clinical trials and other research studies

Table 9 Step 9—Proofreading

| Critical components | Rationale | Who should do this? | What are the risks of not doing this? |
|----------------------------------------|---------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| The finalized translation is proofread | To check for minor errors which have been missed during the translation process | The key in-country person and/or a proof reader checks the final translation and corrects any remaining spelling, diacritical, grammatical, or other errors | A final translation that contains spelling, grammatical, and/or other errors |

Table 10 Step 10—Final Report

| Critical components | Rationale | Who should do this? | What are the risks of not doing this? |
|---------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Report is written on the development of the translation | <ol style="list-style-type: none"> 1. To clearly explain the reasons for all translation/ wording choices made throughout the translation process 2. This is essential for future translations of the same measure to be harmonized with language versions previously developed | The project manager writes the final report, which should include a full description of the methodology used, plus an item-by-item representation of all translation decisions undertaken throughout the process | <ol style="list-style-type: none"> 1. Translations of measures that may not be used because of inadequate reporting of methods used in development 2. Development of subsequent translations that are not harmonized with previous language versions |

throughout the world. This usually means that at least some of the measures included in the research have been translated into other languages from a single original language and the data obtained from each country using these translated measures is often pooled or aggregated and analyzed and reported as a single data set. The quality of the data derived from those translated measures relies on the accuracy of the translation. It is therefore surprising that no current set of quality assurance guidelines exist, given the risks that poor translation methods can present to research data.

It is in this context that the need for some generic guidance in the area of translation and cultural adaptation was identified very early on in the discussions of the TCA group. These PGP are based on a comprehensive review of existing guidelines, identifying areas of common agreement and areas of disparity. They synthesize published guidelines to achieve, to the greatest degree possible, a comprehensive and universally acceptable document.

During the review of existing guidelines, the TCA Group noted four main problems:

1. lack of consistency—in the use of both terminology and methods;
2. gaps or insufficient information in the literature about several areas of importance, including harmonization and proofreading;
3. little information on why each step should be followed, and nothing identifying the risk of omitting key parts of the TCA process; and
4. emphasis on theoretical ideals for translation and cross-cultural adaptation rather than what is actually feasible in research practice.

Based on their work and discussion of these issues, the TCA working group in consultation with the wider TCA reference group decided to take a new approach to guidance by creating an all-encompassing methodology that describes how each step can be undertaken, and the benefits and risks of undertaking, or omitting each step.

Overall, we found more areas of agreement on principles of good practice than disagreement. The areas of most disparity were reconciliation and approaches to harmonization because of the widely differing approaches to carrying out those steps. The approach in this case to address the disparity was to present all the differing viewpoints so that it was clear that all were acceptable under these guidelines. Because of the consensus-building approach, we sought to be as inclusive as possible in providing options for how the various steps can be carried out. As long as agreement was found on the broader

steps of what was essential to developing a high-quality, linguistically valid translation, the details of how to actually carry out each step were not as critical as ensuring that each step was carried out in one form or another.

During the same period that the current guidance document was being developed, similar work was being undertaken by the ERIQA Group. The group was established in 1998 and brings together HRQoL researchers, representatives from pharmaceutical companies, and health care authorities with the objective of establishing HRQoL as a credible criterion for evaluation in clinical trials. The ERIQA Group aims at establishing principles and practice guidelines for the integration of HRQoL outcomes in the regulatory process. At the same time that the ISPOR group was working on its guidance document, the ERIQA group conducted a literature review of existing guidelines and developed a draft checklist of recommended steps in the process of developing questionnaires of cross-cultural adaptations[13]. The steps identified in the ERIQA checklist mirror those identified in the guidance document presented in this paper and appear as a checklist, which includes a description of steps in the process, the team involved, and the minimal requirements. The ERIQA group plans to disseminate and publish the checklist and to discuss the applicability of the checklist to all types of PROs.

Conclusion

This study has shown that it is indeed possible to find consensus on PGP in translation and cultural adaptation by looking for the areas of agreement in broader terms and allowing for different ways to achieve the same goal for each step in the process of translation. Building on the success of these principles, the TCA working group plans to investigate other areas for future research including “same language adaptation,” methods for translating non-validated instruments such as diaries, symptom checklists, and new analytical approaches such as Item Response Theory and Differential Item Functioning to better demonstrate the validity of translated measures. The group anticipates that addressing these issues will once again involve collecting different points of view from various sources, and consolidating them based on areas of agreement while allowing for some disparities in practice. We will also investigate ways to address the need for empiric evidence of what approaches to translation may yield better results.

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