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Linguistic Validation Process

Linguistic Validation (LV) and adaptation work is usually carried out by commercial LV companies. The process may take between 4 - 8 months, depending on the language and questionnaire. When commercial funding is available, LV and adaptation work can be done by professional translators and typically takes 4 months to complete. Translations may be done non-commercially, but a rigorous protocol must be adhered to so that we can maintain HPR's high LV standards.

The following process is important in order to ensure a high standard of translation into a new target language and its LV. The comments and discussions at the various stages are needed for our records of the translation history, so that we can refer to reasons why certain decisions and choices were made. This record is especially important if subsequent psychometric evaluation suggests that improvements to the translation are needed. The linguistic validation process is divided into the following parts: 1) Forward and back translation, 2) Clinician and/or psychologist reviews, 3) Cognitive debriefing with patients, 4) Proofreading and finalisation. For the second part, a condition-specialist physician or nurse is generally needed. However, a psychologist may be included in addition, or even instead of a specialist clinician when the psychologist has a clinical role in managing the condition. Who contributes at this stage will depend on project-specific conditions.

For linguistic adaptations

Part 1 is not needed when adapting a language for use in another country or community. However, the existing language version must be reviewed first by someone who is a native speaker of the required language and resident in the relevant country. They should also be fluent in English. For English adaptations (e.g. for Australia, India) it should be sufficient for the person wishing to use the questionnaire to carry out this review, as long as English is their first or native language (e.g. someone who has been educated throughout in English in the target country).

The other parts of the LV process are still required.

Forward and Back Translation

Languages which require reformatting of the questionnaires

For languages which are written other than from left to right, LV teams must include a member who can layout the questionnaires to the required standard of HPR. The LV team member formatting the questionnaires must be able to save the questionnaire file in a file format that is fully readable by Microsoft Word. Target language versions of the questionnaires are required from the FT stage until formatting of the final versions.

Forward Translation (FT)

1) Two parallel forward translations by native speakers of the target language, fluent in English and resident in the country where the translation is to be used. Ideally one person should be a professional translator and the other a psychologist with experience of designing psychological questionnaire measures. Familiarity with the subject of the questionnaire would be an advantage. We provide Concept Translation Guidelines (CTGs) which offer guidance on words, phrases and structures which may cause problems for translators.

2) Review of discrepancies and reconciliation of the two forward translations into **1st reconciled forward translation** by a third person, who is a native speaker of the target language and fluent in English.

3) Notes on difficulties found, decisions made and reasons for those decisions during Step 2 for the forward translation report.

Back Translation (BT)

4) Two parallel back translations of the 1st reconciled forward translation, done completely blind (i.e. with no help or information about the original English questionnaires) and independently of each other. These should be done by people who are native speakers of English and fluent in the target language.

5) Review and discussion of discrepancies with back translators.

6) Notes on issues raised during Step 5 for back translation report.

7) Review of back translation report by a member of HPR, who highlights any concerns.

Any revisions to Forward Translation

8) Review by forward translators / reconciler of any concerns or discrepancies noted during the BT. Retranslation where necessary.

9) Notes on decisions made in revisions, together with notes on any items needing particular attention and possible testing of alternatives during clinician review and cognitive debriefing.

10) Review of revisions and notes by a member of HPR.

Review by psychologist and/or clinician

1) **By psychologist:**
This step may be particularly useful if the questionnaire is a generic one (e.g. the WBQ12) and there is no reason for a clinician review. Where one of the forward translators is a psychologist (particularly one with experience of questionnaire design) then step 2 is not necessary.

2) **By clinician:**
Where the questionnaire is condition-specific, review of the revised intermediate translation by a clinician practising in the relevant field (e.g. diabetes, renal disease, ophthalmology) is important. In particular, review of any phrases relating to the nature of the treatment or name of the disorder or associated symptoms. It is important to identify the name the clinician gives to the disorder when talking to patients (i.e. not necessarily the terms used between health professionals). If one of the forward translators is just such a clinician, this step would not be necessary. If the clinician is simply providing a brief review of the questionnaire and not acting as one of the translators themselves, they may not wish to spend time studying the CTG, but these guidelines should nevertheless be made available to them along with the translation (in case they have questions about an item). Many questions can be answered by these documents.

3) Notes on suggestions and decisions resulting from both the above steps and notes on any items needing particular attention (or testing of alternatives) during cognitive debriefing need to be included in the psychologist/clinician report.

4) Review by HPR and discussion of any proposed revisions.

Cognitive debriefing with patients

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1) Interviews of approximately five patients with as good a mix as possible, e.g. for the DTSQs & c, ADDQoL, HypoSRQ we would aim for the following:

a) a minimum of 5 people
b) all with diabetes
made up of a mixture of the following:
c) men and women
d) across a good age range
e) with Type 1 and 2 diabetes
f) the Type 2 patients would ideally include someone on diet alone, someone on tablets and someone on insulin.

2) Report by person conducting the interviews using the CD report template provided, and listing:

a) demographic and known clinical / treatment details of interviewees (these may have a bearing on any notes relating to (b) below);
b) account of patients' understanding of all items, even where the interviewer doesn't think there is a problem. If there are any problematic items, a note of which patient(s) found it problematic and in what way.
c) selected scores for any of these patients where particularly relevant (e.g. on the DTSQ, if the patients' scores appeared to contradict what they were saying in the interview).

3) Review by translation co-ordinator:

a) Review of any problematic words/phrases/items with forward translators following CD interviews.
b) Retranslation and back-translation where necessary.
c) Notes on changes, plus explanations to be given on the CD report template.

4) Review by HPR and discussion of any proposed revisions.

Proofreading and finalisation

Languages which require reformatting of the questionnaires

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1) **Formatting**

Please ensure you keep to the original format. We will give you a Word document of the original English that you can use as a template. As you will see from your agreement, you need to keep strictly to this template and not add extras into the header or make any changes to the style. This includes font and font size, unless you are producing e.g. Chinese and you have to produce a translation in a different script. If you need to add e.g. patient number and completion date somewhere, we suggest that you do as others have done and have a separate cover sheet in front of the questionnaire.

2) **Treatment Satisfaction Questionnaire: Change – generic and trial specific versions**

When you are translating the Change version, please ensure that you start by producing the generic version of the introduction. If you need to change the wording to be specific to your study, please produce this as a separate version and send both questionnaires to us on completion.

3) **Proofreading**

An important step sometimes forgotten! A new translation/adaptation needs to be proofread by at least one native speaker of the target language.

4) The questionnaire also needs to be proofread for formatting issues, using the original English format as a template and checked subsequently by HPR. HPR will finalise the footer and copyright statement.