



Translation & Validation Procedure

Guidelines and Documentation Form

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Appendix

1 Introduction

Included in this manual are guidelines and a description of the translation methodology for the DISABKIDS instruments, propositions for a validation study and an outline of topics which should be addressed in a translation and validation report.

2 The translation methodology for the DISABKIDS questionnaires

2.1 Overview

The focus of the translation process should lie on achieving conceptual equivalence amongst all versions rather than on achieving linguistic / literal equivalence. As a translation methodology the forward-backward-forward technique should be applied.

In a first step, two independently working translators should translate the English DISABKIDS questionnaire into the respective target language. Thus, for the research group of the translating country two different translation versions should be acquired (Forward Translation 1 and Forward Translation 2). Rather than solely being professionals in translation, the translators must have experience in test development and the research fields concerning Health-related Quality of Life in Children and Adolescents (cp. Fig. 1 step1).

In the following reconciliation step the two forward translators and one member of the research group will review the two forward translations in order to create the Reconciled Forward Translation, meeting all demands of conceptual equivalence with the original English DISABKIDS questionnaire (cp. Fig. 1 step 2a & 2b).

Afterwards, the Reconciled Forward Translation should be translated back into English by a third translator meeting the criteria as described above (cp. Fig. 1 step 3).

In a next step two members of the research group (and if available external experts with experience in instrument development and translation) as well as the forward translator will compare the Backward Translation with the original English DISABKIDS questionnaire, thus reviewing the Reconciled Forward Translation and thereby generating the Final Forward Translation (cp. Fig. 1 step 4a & 4b).

Subsequent to the generation of the Final Forward Translation all reviews and translation data will be sent to the German study centre of the DISABKIDS Group for documentation. The objective of the following telephone conference with one member of the DISABKIDS group (which will be held in English language) is to resolve inadequate concepts of translation as well as all discrepancies between alternative versions (cp. Fig. 1 step 5).

To ensure the feasibility of the translation, a pre-test including cognitive interviews should take place in the respective country. Six children, six adolescents and eight parents should be asked to evaluate comprehensibility and acceptance of the items (cp. Fig. 1 step 6).

A telephone-conference (which is to be held in English language) between members of the respective research group and one member of the DISABKIDS group will serve as a platform for international harmonisation and to ensure conceptual equivalence amongst the target language versions. This way, all discrepancies due to item translation processes can be discussed (cp. Fig. 1 step 7).

The thus created Final Questionnaires for the respective target populations should be tested (if possible) in a validation study.

In order to ensure cross-cultural comparability of the questionnaire versions in the respective target languages, the following aspects have to be taken into account (Hui & Triandis, 1985):

Functional Equivalence

Items cross culturally similar in meaning?

Operational Equivalence

Procedures used to obtain information comparable?

Scale Equivalence

Do individuals respond to similar items in similar way?

Metric Equivalence

Individuals ordered on measure in cross-culturally comparable way?

The presented manual is based on:

- The MAPI Linguistic Validation Process provided on the website <http://www.mapi-researchinst.com/lvprocess.asp>
- Ulrike Ravens-Sieberer and Eva Noack 1996: The Translation of the English Colorectal Cancer Module into German; EORTC Study Group on Quality of Life.
- Report from the EUROHIS Mid-Term Review, 2-4 Nov. 2000, WHO Regional Office for Europe, Copenhagen
- MOS Translation Criteria, Medical Outcomes Trust, July 1997 BULLETIN; <http://www.outcometrust.org/bulletin/0797bull.htm>
- The International Quality of Life Assessment (IQOLA) Project, <http://www.iqola.org>
- WHOQOL
- see also references

2.2 Forward Translation

Rather than solely being professionals in translation, the respective translators must have experience in test development and/or the research fields concerning Health-related Quality of Life in Children and Adolescents.

The translators need to have the following qualifications:

- Native speakers of the respective target language
- Knowledge of both English and the target language
- Familiarity with the cultures, both of English speaking countries as well as of the target countries
- Experience in test development and/or in the content of the research fields concerning Healthrelated Quality of Life in Children and Adolescents.

Two translators are to translate the English DISABKIDS questionnaire independently from each other into the respective target language. The translators are asked to use natural and acceptable language for the broadest audience and to be simple, clear and concise in their formulations.

The following guidelines may be given to the translators:

- The translators should always focus on conceptual equivalence rather than on literal word-for-word translation. The translators should always try to grasp the most relevant meanings of the English terms and translate them accordingly.
- The translators should try to be simple, clear and concise in their formulations - long sentences with many clauses should be avoided.
- The translators should take into account what the typical respondents (children and parents) will understand when they read the items.
- The translators should take the age of the respondents into consideration and thus should not use any jargon or terms that would be difficult to understand. The translation has to be clear, simple and comprehensible. Double negatives should be avoided.

The two forward translators provide two forward translations; the Forward Translation 1 and Forward Translation 2, which have to be documented together with the source document in the provided *Form 1 "Documentation of Forward-Backward-Procedure and Review"* (see Appendix). The two versions are then to be reconciled in the next step.

2.3 Reconciliation of items

Participants in the reconciliation procedure review the two forward translations. Participants in the reconciliation procedure should be:

- The two forward translators
- One member of the research group of the respective country with good knowledge both of English and of the target language.

To reconcile the two independent forward versions a reconciliation meeting should be held, so that the two translations can be compared and assessed in regard to their conceptual equivalence, comprehensibility

and clarity of speech relative to the English questionnaire. Participants in the reconciliation procedure should document their assessments item-by-item and select the best translation or (if neither is adequate) suggest another translation. They should focus on differences in culture and linguistics which may cause difficulties when transforming the English version into the target languages. A reconciled version is to be derived by means of a subsequent discussion between the participants.

Derived by means of the reconciliation procedure, the Reconciled Forward Translation consists of the best fitting translations of the items. The reconciliation procedure may also produce valuable hints to differences in culture and / or linguistics, relevant for the whole translation process. Reconciled items are to be documented in *Form 1 "Documentation of Forward-Backward-Procedure and Review"* (see Appendix).

2.4 Backward Translation

Designed to assess the conceptual equivalence of the Reconciled Forward Translation and the English DISABKIDS questionnaire, the Backward Translation serves as an instrument to measure the quality of the Reconciled Forward Translation. The Backward Translation and the English DISABKIDS questionnaire are supposed to be very similar and if they are not, discrepancies, such as problematically translated items, will thus be indicated and can be corrected.

The backward-translator must have the following qualifications:

- Native English speaker
- As to all other qualifications see above (forward translator)

The Reconciled Forward Translation is back-translated into English by the backward translator. The backward translator is not supposed to have worked with the DISABKIDS questionnaire before. The guidelines as described above (guidelines for forward translators) may also be given to the backward translator. The result of the backward-translation-process is a back-translated version of the Reconciled Forward Translation. The back-translation process has to be documented in *Form 1 "Documentation of Forward-Backward-Procedure and Review"* (see Appendix).

2.5 Review of the Forward and Backward Translation

The review is designed to assess the entire forward-backward-process in order to provide a Final Forward Translation. Participants in the review procedure should be:

- Two members of the research group with good knowledge of both English and the target language
- One of the forward translators
- If available, external experts with experience in instrument development and translation.

Focusing on conceptual differences, the backward translation is to be compared with the English DISABKIDS questionnaire. The participants review the translation process item-by-item by comparing the back-translated items to the English source items and suggesting a version for the Final Forward Translation. This is done either by confirming the results of the reconciliation process or by suggesting an alternative translation if necessary. All changes in wording or meaning of the items are to be undertaken in the process of generating the Final Forward Translation.

Thereby the review board is expected to make sure that the translation is simple, clear and concise and most importantly, that there are no conceptual discrepancies between the English Original and the Final Forward Translation. The focus lies on achieving conceptual equivalence and clarity as well as using colloquial language. This process has to be documented in the *Form 1 "Documentation of Forward-Backward-Procedure and Review"* (see Appendix).

2.6 Assessment of Conceptual Equivalence / First Harmonisation of Problematic Items in a Telephone Conference

International Harmonisation serves to assure and, if necessary, generate inter-conceptual equivalence. The back-translations will thereby be used as instruments to evaluate the national Final Forward Translations in respect to the Draft. A telephone conference will provide the necessary international platform. This process has to be documented in *Form 1 "Documentation of Forward-Backward-Procedure and Review"* (see Appendix).

2.7 Pre-test (Cognitive Interviews)

The Pre-test is expected to show whether all items are comprehensible and acceptable. Tested individuals should be 3 children of both sexes (8-11 years old), 3 adolescents of both sexes (12-17 years old) and 2 parents of both sexes and both age-groups. Test participants should be provided a quiet place. In regard to their contribution to the test development procedure, tested individuals are to be informed about the objective of the pre-test.

The proposed Pre-Test conduction is widely based on the work report of the German ZUMA Researchcentre (see references).

Pre-testing is critical for identifying questionnaire problems such as misunderstandings about the intended meaning of items. Problems concerning item content, including confusion about the overall meaning of items, as well as misinterpretation of individual terms or concepts can also be identified. Pre-testing incorporates many different methods. For the DISABKIDS questionnaire we propose a cognitive interviewing method based on **Paraphrasing** as a variant of the **Think Aloud Method** (asking the respondent to repeat the item in their own words, immediately after answering the item). This technique permits the researcher to learn whether the respondent understands the question and interprets it in the manner intended. It may also reveal better wordings for items.

Additionally, using the **General Probing Method** respondents will be asked whether the items can be considered comprehensible and clear and whether they were difficult to answer. The outcomes of all interviews have to be documented in the documentation *Form 1 “Documentation of Forward-Backward-Procedure and Review”* (see Appendix) and are to be sent together with the entire translation procedure documentation to the German study centre.

2.8 International Harmonisation

International Harmonisation is intended to ensure the comparability between the translated questionnaire versions. Participants in the International Harmonisation procedure should be one or two members of the research group - if possible those who have already been involved in the review procedures. A telephone conference with one member of the DISABKIDS group is to serve as a platform to discuss all questions concerning conceptual and cultural aspects of the item translations. The Final Questionnaire versions are generated in the process of International Harmonisation. This procedure will be documented again in *Form 1 “Documentation of Forward-Backward-Procedure and Review”* (see Appendix). The Final Questionnaires should subsequently be tested in a validation study.

3 Validation study

It is recommended to test the final translation of the DISABKIDS instrument in a validation study in order to obtain more information about the psychometric properties of the instrument in the respective language. Besides the DISABKIDS instrument, sociodemographic information should be assessed. If possible another generic HRQOL instrument for children and adolescents should be included in the validation study.

The validation study should be a cross-sectional study including at least 100 children and adolescents with a chronic health condition aged 8 – 18 in the respective country, as well as parents and clinicians. The study population should include mainly children and adolescents with chronic health conditions.

The study can take place health care centres in both ambulatory and inpatient care with a range of clinical characteristics. Although convenience sampling can be used (i.e. the sample does not have to be nationally representative), it is important to ensure a good spread of respondent characteristics in the sample. The sample should consist of children and adolescents aged 8-18 of both genders. Within each group, children from higher and lower socio-economic backgrounds/areas should be included. An exclusion criterion is when parents and/or children and adolescents refuse consent to participate in the study.

Researchers in the translating country should decide on the most appropriate means of selecting schools or health care centres in socio-economic categories.

3.1 Field tasks

3.1.1 Contact health care centres or schools

Health care centres or schools chosen for the validation study should be sent an information letter, explaining the study objectives and the activities which will be carried out (s. table 2).

Table 1. Field tasks

Activities to carry out in each school or health care centre

1. Interview with the authority in school/centre: authorisation and selection of the courses or sampling of the population
 2. Delivery of the letter asking for parents' consent
 3. Questionnaire administration:
 - Clinician administration in health care centres
 - Health care centres questionnaire administration by mail to children and parents
 4. Collection of parents' questionnaires in health care centres and schools.
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In the case of schools, teachers will be asked to help with the field work; their duties will be:

- to be present when researchers administer the questionnaire (or only at the beginning of the activity),
- to obtain written informed consent from parents,
- to collect questionnaires completed by parents.

3.1.2 Asking for consent

A letter should be sent to parents/guardians explaining the objectives of the study, asking for their child's consent to take part in it, and guaranteeing the confidentiality of the information gathered. In the letter addressed to parents, their participation will also be requested and they will be informed about how the questionnaire is administered. This communication should take place approximately one week before the administration of the questionnaire.

3.1.3 Questionnaire administration

The questionnaires for children and adolescents should be administered either individually in the clinic or by mail (health care centre samples). Parent questionnaires should be self-administered and sent back in both types of samples. Children and adolescents should be reminded that the questionnaire is not an exam, and that there are no incorrect answers. We are interested in the opinion of the child/adolescent regarding his/her state of health. The answers they provide us will neither be made known to their teachers or their parents.

3.2 Data entry and management

The collected data will be entered by the research group. In order to ensure a standardised data entry process, the DISABKIDS study centre will provide a data entry manual and an SPSS data entry mask. A plausibility check using the double entry method for 10% is strongly recommended. The research centre will be responsible for the plausibility of its data.

3.3 Ethical issues

Ethical issues such as the participants' consent and the confidentiality of data have to be regarded in the validation study and special efforts need to be taken to fulfil these issues. This means that in all cases parental consent for children to participate in the study should be sought. It is recommended to use a standard informative letter which parents are asked to sign and return if they do or do not wish their child to participate in the study (depending on country specific legal aspects). The letter to parents should briefly explain the study objectives and assure parents of the confidentiality of the data. In addition, the child's consent to participate should be applied for. Concerning confidentiality, all questionnaires will be identified by a number, which will be kept separate from the personal identification of participants. The number corresponding to each participant will only be available to the responsible investigators in the study centre while the study is in progress. Afterwards, the number is to be eliminated.

4 Documentation of translation and validation study

4.1 Documentation of the translation process and a copy of the questionnaire

For the documentation of the translation procedure a table is enclosed in the Annex. The results of each translation step (e.g. forward translation, backward translation) should be included in the respective column. In its completed form, this table gives an overview of the whole translation procedure in the respective language. This table and a copy of the DISABKIDS instrument in the respective language should be sent to the DISABKIDS study centre for documentation purposes.

4.2 Documentation of the validation study

4.2.1 Study design, sampling, questionnaire distribution, and administration

The introduction of the validation report should give an overview of the objectives, the validation study design and the time period of the validation study.

In the next paragraph the preparation of the study (e.g. criteria for sample collection) and more practical aspects of sampling, questionnaire distribution and administration should be addressed: how the participants were contacted (through schools or health care centres), as well as the number of participating schools, children, adolescents, and parents. It should be reported whether informed written consent from parents was necessary or only the consent of teachers and children. A description of the questionnaire administration in classes with the number of interviewers per class should be given. The process of administration and difficulties during administration should also be documented.

Not only should the number of participants in the validation study be provided, but the number of nonresponders and data on the response rate as well. The sample description should be provided in a table (s. 4.2.3).

4.2.2 Data entry and plausibility check

The data entry process should be summarised, stating how data entry was managed in the respective country. Further specifications should be made on how correct data entry was tested. Were data and questionnaires compared or was a double entry procedure employed?

4.2.3 Documentation of national data analysis

The results of the national data analysis should include

- a sample description (sex, age, sociodemographic data) and if possible a comment on the sample's representativeness
- basic scale characteristics of the DISABKIDS dimensions (means, SD, missing, floor/ceiling effect)
- internal consistency of DISABKIDS dimensions (Cronbach's Alpha)
- relationship between the DISABKIDS dimensions and other features (gender, socio-economic status)
- correlation between DISABKIDS scales and other generic HRQOL measures
- reference data should be provided if possible.

5 References

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