

Guidelines for the translation of Rome Foundation research and diagnostic questionnaires

Pediatric questionnaires

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The following are the Rome Foundation guidelines for the translation of questionnaires to be used for research, clinical trials and the diagnosis of functional gastrointestinal disorders (FGIDs). This is a rigorous process that must be carried out with professional translators with experience in medical translation who are native speakers of the target language and fluent in English with the accompaniment of a Rome-Foundation appointed clinician monitor who is fluent in the target language. The translation will only be approved as an official RF translation if the guidelines are fully adhered to.

In separate documents we provide guidelines for:

- The translation of Rome Foundation questionnaires for *adults*.
- The translation of Rome Foundation material that are *not questionnaires*. These materials include books and other non-questionnaire documents.
- The “localization of Rome material (*adult questionnaires and others*) into the same language as the original document with adaptation for the local dialect/culture.
- The “localization” of Rome Foundation *pediatric questionnaires* into the same language as the original document with adaptation for the local dialect/culture.

Introduction

Translation is the most common method for preparing study instruments for use in research in other countries and cultures. However, cross-cultural translation has pitfalls that threaten validity. Some of these pitfalls are very difficult to detect unless a rigorous and standardized methodological process is adopted. Failing to do this could have unrecognized, deleterious effect on study results.

Cross-cultural translation is a process that looks at both language and cultural adaptation issues in the process of preparing an instrument for use in another culture. The challenge is to adapt an instrument so that it retains the meaning and intent of the original instrument (the source language) and is culturally relevant and comprehensible. Thus, the aim is to achieve a "cultural" rather than a "literal" translation into a target language.

To this end the Rome Foundation has formulated the appended guidelines for the translation of its material from English into other languages. In order to gain official approval for the translation the guidelines have to be followed and documentation of adherence to the process has to be provided during its course and at its conclusion. A central contact person from the Rome Foundation will be appointed to accompany the process and a clinician from the country involved, who is affiliated with the Rome Foundation and is a native speaker of the "target" language, will be available for consultation at all stages of the process ("clinician monitor").

The Rome Foundation itself will be preparing official versions of its material in several central languages. When completed, those versions will be the officially sanctioned versions of the Rome Foundation and should be used in all cases. Translation into other languages will have to be conducted in accordance with the appended guidelines.

Guidelines

The head of the group conducting the translations signs the guidelines confirming that they will follow them rigorously and returns the signed guidelines to the Rome Foundation.

The translation process begins with the original instrument in the source language. The following steps are required in order to obtain Rome Foundation approval for the final target version:

1. Forward translations

Two forward translations into the target language will be completed by two **professional** translators with experience in medical translation, working independently of each other. These translators have to be native speakers of the target language and fluent in English.

Product: forward versions 1a and 1b (target language)

2. Reconciliation

The two translators who participated in step 1, together with the Rome Foundation-appointed clinician monitor, compare the two target-language versions (1a and 1b), identify differences and conduct a reconciliation process.

Product: forward version 2 (target language)

3. Backward translation

Forward version 2 (target language) is translated back into English by a professional translator, with experience in medical translation, who is a native speaker of English and fluent in the target language. This translator should not have been involved in steps 1 and 2 in any way.

Product: backward version 1 (English)

4. Comparison of the two English versions and validation of the translation

The original instrument and the back-translated version 1 (both in English) are compared, item-by-item, on two dimensions, i.e., similarity of language (literal translation) and comparability of interpretation (cultural adaptation). The translators together with the clinician monitor can do this step.

Product: Final target language version for cognitive debriefing

5. Cognitive debriefing

Children may use different words at different ages for the same concept. Thus in the pediatric age group the cognitive debriefing stage is of particular importance. In this stage the questionnaire is presented to one girl and one boy (10-18 years of age), or to two parents of children younger than 10. The children or parents are asked individually to explain each question back to the physician and suggest changes in wording in case they find it beneficial. Any suggested changes are then tested with a new group of children (with the similar characteristics) to assess their understanding. If the level of agreement is 90% or above the changes are adopted. If the level of agreement is below 90%, the process is repeated until an agreement level of at least 90% is reached.

Product: Final target language version for Rome Foundation for proofreading.

6. Proofreading

Proofreading of the final version before submission to the Rome Foundation for approval.

7. Approval

Submission of the final version of the target language version together with all translation process documents (see below) to the Rome Foundation with a letter of recommendation by the Rome Foundation-appointed clinician monitor.

• Required documentation

- Files of the two forward translations
- File of the backward translation
- File of the target language version for cognitive debriefing
- A file documenting the comments made for each item (if any) during cognitive debriefing.

- A file with the final, proofread translation

8. The Rome Foundation Board of Directors then approves the final target language version.

Product: Rome Foundation approved instrument

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I acknowledge that I have read and understand the guidelines.

Signature _____

Date: _____