

Guidelines for the Translation of Rome Foundation Material

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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 enclosed 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.

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 enclosed guidelines.

Guidelines

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

1. Forward translation

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.

The product of this step: forward versions 1a and 1b (target language)

2. Reconciliation

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

The product of this step: 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.

The product of this step: 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) will be 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.

The product of this step: Final target language version for cognitive debriefing

5. Cognitive debriefing

Test of the final target language version with a panel of patients (5-8) to assess the translation in terms of clarity, cultural adaptation, language level, and acceptability. This step requires familiarity with the cognitive debriefing process, usually with the help of a professional company or an academic institution.

Final product of this step: 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 (pdf) together with all translation process documents (pdf's) to the Rome Foundation with a letter of recommendation for approval of the final language by the Rome Foundation-appointed clinician.

The product of this step: Rome Foundation approved instrument

I have read, understand and agree to abide by the Rome Foundation Translation Guidelines.

Signature

Date