

Guidelines for the localization of Rome Foundation material in one language for use in another country/dialect/culture where the same language is spoken

Pediatric questionnaires

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The following are the Rome Foundation guidelines for the “localization” of Rome Foundation material from one language (example: Spanish for Mexico) into the same language for another locale (example: Spanish for Spain) *for pediatric questionnaires*.

The following explanation of language localization has been adapted and abridged from Wikipedia (https://en.wikipedia.org/wiki/Language_localisation):

Language localization is the process of adapting a product that has been previously translated into multiple languages to a specific country or region. It is the second phase of a larger process of product translation and cultural adaptation (for specific countries, regions or groups) to account for differences in distinct markets, a process known as internationalization and localization.

Localization is done for regions or countries where people speak the same language: for instance, different dialects of Spanish, with different idioms, are spoken in Spain and in Latin American countries.

Examples include:

English for US localized into English for Australia, Canada, UK, South Africa, etc.

Spanish for Mexico localized into Spanish for Argentina

French for France localized into French for Canada or Belgium

Bengali for India localized into Bengali for Bangladesh

Arabic for Egypt localized into Arabic for Saudi Arabia, Israel, etc.

Guidelines

The head of the group conducting the “language localization” signs the guidelines confirming that they will follow them strictly and returns the signed guidelines to the Rome Foundation.

The localization process begins with the official, approved version of the Rome Foundation pediatric questionnaire in the source language (this could be the original English or a Rome-Foundation approved translation).

No material will be approved for localization that is not an original Rome Foundation approved source material (usually English) or a Rome Foundation approved translation of source material.

The following steps, are required in order to obtain Rome Foundation approval for the final localized version:

1. Forward adaptation

Two experts (native speakers of the local language and usually senior clinicians) go over the original document ***independently*** and make revisions to adopt it to their local language/culture.

2. Reconciliation

The two clinicians then go over the two versions together, compare them and reconcile them producing a final version. **Product: Reconciled forward localization**

3. 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 localized language version for proofreading.

4. Proofreading

The head of the group proofreads the final version and submits it, together with the required documentation (see below) to the Rome Foundation with his/her recommendation for official approval.

Product: Final localized version for Rome Foundation approval.

5. Submission for approval

Submission of the final version of the target language version together with all required documents of the localization process to the Rome Foundation with a letter of recommendation by the head of the localization group.

Required documentation

- Files of the two independent adaptations
- A file of the reconciled version
- A file documenting the comments made for each item (if any) during cognitive debriefing.
- A file with the final, proofread adaptation

6. Approval

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

Product: Rome Foundation approved localization of existing material

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I acknowledge that I have read and understand the guidelines.

Signature _____

Date: _____