

Linguistic Validation of the ICIQ Male Sexual Matters associated with Lower Urinary Tract Symptoms Questionnaire (ICIQ-MLUTSsex) in 7 Languages

Shawn McKown*, Mary C. Gawlicki**, Vasudha Vats***

*Corporate Translations, Inc., Chicago, IL; **Corporate Translations, Inc., East Hartford, CT; ***Pfizer Inc., New York, USA

Objective

The objective of the linguistic validation process was to create culturally valid translations which were conceptually and linguistically equivalent to the original ICIQ Male Sexual Matters associated with Lower Urinary Tract Symptoms Questionnaire (ICIQ-MLUTSsex) instrument.

Background

ICIQ Male Sexual Matters associated with Lower Urinary Tract Symptoms Questionnaire (ICIQ-MLUTSsex):

The ICIQ Male Sexual Matters associated with Lower Urinary Tract Symptoms Questionnaire (ICIQ-MLUTSsex) is a 4-item patient-administered scale that assesses health-related quality of life, symptom bother, and the impact of lower urinary tract symptoms on sexual matters in male patients.¹

¹ Frankel S, Donovan J, Peters T, Abrams P, Dabhoiwala N, Osawa D, Tong Long Lin A. Sexual dysfunction in men with lower urinary tract symptoms. *J Clin Epidemiol.* 1998; 51(8): 677-685

Countries and Languages

Asia:

- Korea (Korean)

Africa:

- South Africa (Afrikaans, English)

Europe:

- Slovakia (Slovak)

North America:

- Canada (English)

- USA (English)

- Mexico (Spanish)



Methods

Harmonization

- Two professional translators who were native speakers of the target language and were experienced in translating health questionnaires independently translated the ICIQ-MLUTSsex.
- The two translators compared their translations and together produced a third harmonized translation.

Back-translation

- The harmonized translation was back-translated into English by a native English-speaking translator.
- A project manager compared the original English to the back-translation and either approved or questioned each item in the back-translation. The project manager discussed concerns with the three translators, who then changed the translation and/or the back-translation, or justified their solution for problem items.

Review

- A survey research expert compared the original English to the back-translation and either approved or questioned each item. The translation and/or back-translation were revised as necessary.
- In-country representatives reviewed the translation to judge its acceptability. If the local user requested changes, previous steps were repeated until all issues were resolved and all revisions were approved by the survey research expert.

Cognitive Debriefing

- Five native speakers of each target language residing in the target country and who were not involved in the translation process were recruited as debriefing subjects. Subjects were selected to be diverse as to age, gender, and educational level.
- Trained bilingual interviewers (English and target language) conducted debriefing interviews to assess the clarity and acceptability of the translations.

Finalization

The survey research expert made recommendations for approval or re-translation. Harmonization and review were repeated as necessary until the survey research expert, project manager, translators and interviewers were in agreement.

Results

Harmonization and Back-translation

During the harmonization and back-translation of the ICIQ-MLUTSsex, translation issues were encountered related to the concepts “ejaculation of semen” and “normal rigidity.” Translators in several languages noted that the phrase “ejaculation of semen” was somewhat redundant; after discussion, the decision was made to maintain the phrase “of semen” in all translations, despite its redundancy, to maintain conceptual equivalence across translations. Several translation teams noted that “normal rigidity” of erection was an ambiguous concept, asking whether “normal” referred to the subject’s average rigidity, or to the average person’s rigidity. The decision was made to maintain this ambiguity in all translations.

Translators in all languages devoted significant attention to clarifying the above concepts while maintaining appropriate levels of conceptual equivalence with the original English instrument. Overall, the harmonization and back-translation processes were completed without the appearance of any significant problems.

Cognitive Debriefing

Five in-country, native-speaking subjects were interviewed for each of the languages tested. Subjects (n=35) ranged in age from 18 to 70 years, with a mean age of 39 years. Their academic education ranged from 9 to 24 years, with a mean of 15 years; 60% of the subjects were male.

Overall, the translations were well understood by subjects in all languages. The comprehension rate for the ICIQ-MLUTSsex was 94.3%. One concept in question #4C caused confusion in two English variants (South Africa and Canada); subjects noted the ambiguous referent for “this”, i.e., whether “this” refers to “sex life” or “no sex life” in the question “If you have no sex life, how long ago did this stop?” This ambiguity was not identified as a problem in the non-English translations because the translations were constructed to elicit information about the cessation of sexual activity.

The Korean translation was the only language to require further text changes as a result of the cognitive debriefing interviews. These changes are as follows:

- The translation for the word “year” was changed from “연” to “년” throughout the Korean questionnaire for improved clarity.
- The translation of the “rigidity” of the erection in question #1A was considered potentially confusing by 4 of 5 subjects. The following changes were made as a result:
 - The translation for “yes, with normal rigidity” was changed to “보통으로 단단하게 발기됩니다”.
 - The translation for “yes, with reduced rigidity” was changed to “그러나 단단한 정도는 덜합니다”.
 - The translation for “yes, with severely reduced rigidity” was changed to “그러나 단단한 정도는 크게 줄었습니다”.

These changes were suggested by subjects to improve the clarity of the Korean translation, and were reviewed and approved by the interviewer, translation team, project manager, and survey research expert.

Except for these minor issues, subjects in all target languages demonstrated their understanding of the concepts and the task of selecting a response.

CONCLUSIONS

The 7 translations of the ICIQ-MLUTSsex instrument are linguistically and conceptually equivalent to the original UK English questionnaire and generally understood by subjects. Linguistic validation of the translations will facilitate inter-country comparisons of sexual matters in patients with bladder conditions and the pooling of data in multi-country studies.