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Ten-language translation and harmonization of the International Prostate Symptom Score: developing a methodology for multinational clinical trials.

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Abstract

OBJECTIVE:

Production of cross-culturally adapted and harmonized translations of the International Prostate Symptom Score (I-PSS) into 10 languages (Canadian French, Danish, Dutch, Flemish, French, German, Italian, Norwegian, Spanish, Swedish) by means of an appropriate methodology.

METHODS:

A method based on state-of-the-art guidelines about translation of questionnaires was developed which consisted of forward-translation, rating of clarity, common language and cultural adequacy, group discussion and consensus, testing for comprehension in lay subjects, back-translation and rating for conceptual equivalence.

RESULTS:

The study lasted 3 months. Items 1-7 scored high for clarity, common language and cultural adequacy (mean range 5.3-9.8) as also did item 8 (5.1-9.7). Only 10% of items were rated less than 5.0. Comprehension tests in lay subjects produced comments in 10% of items, most frequently in items 2, 7, and 8, and response categories for items 1-6. Comparisons between the back-translations and the source version showed that 84% of all items, 88% of response categories for items 1-6, 100% of response categories for item 7, and 75% of response categories from item 8 were conceptually equivalent.

CONCLUSION:

The present set of 10 translations plus the original I-PSS questionnaire can be used in multi-country studies in which benign prostatic hyperplasia symptoms are to be assessed using the I-PSS and the data collected from different countries can be legitimately aggregated.

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