

CHEST[®]

Official publication of the American College of Chest Physicians



Dangers in Using Translated Medical Questionnaires : The Importance of Conceptual Equivalence Across Languages and Cultures in Patient-Reported Outcome Measures

Raoul Breugelmans

Chest 2009;136;1175-1177
DOI 10.1378/chest.09-1684

The online version of this article, along with updated information and services can be found online on the World Wide Web at:
<http://chestjournal.chestpubs.org/content/136/4/1175.full.html>

Chest is the official journal of the American College of Chest Physicians. It has been published monthly since 1935. Copyright 2009 by the American College of Chest Physicians, 3300 Dundee Road, Northbrook, IL 60062. All rights reserved. No part of this article or PDF may be reproduced or distributed without the prior written permission of the copyright holder.
(<http://chestjournal.chestpubs.org/site/misc/reprints.xhtml>)
ISSN:0012-3692

A M E R I C A N C O L L E G E O F



P H Y S I C I A N S[®]



Dangers in Using Translated Medical Questionnaires

The Importance of Conceptual Equivalence Across Languages and Cultures in Patient-Reported Outcome Measures

Raoul Breugelmans, MA

(*CHEST* 2009; 136:1175–1177)

The editorial in this issue of *CHEST* by Juniper¹ stresses the importance of using only authorized versions of medical questionnaires that are designed to measure patients' subjective health status. Such questionnaires generally are referred to as *patient-reported outcome (PRO) measures*, and research on their development, validation, and cultural adaptation has grown into a field of study in its own right. The US Food and Drug Administration² has defined a PRO as a measurement of any aspect of a patient's health status that comes directly from the patient (*ie*, without the interpretation of the patient's responses by a physician or anyone else). PRO measures can be used in a clinical trial or clinical setting to assess different aspects of patients' health status, including symptoms, functioning, health-related quality of life, and satisfaction with treatment. They can provide valuable information on how patients feel that would be difficult or impossible to obtain by conventional clinical measurements, particularly when different treatments have comparable effects with regard to disease control but different effects on health-related quality of life, or when changes in clinical measurements do not translate directly into recognizable patient benefit. Regulatory agencies increasingly recognize the importance of PRO measures, as illustrated by the US Food and Drug Administration

draft guidance² on the use of PRO measures in medical product development to support labeling claims and the European Medicines Agency³ reflection paper on the use of health-related quality-of-life measures in the evaluation of medicinal products.

MAIN POINTS TO CONSIDER

As Juniper mentions, well-developed PRO measures are precision instruments that accurately assess patients' health status, and must meet certain standards in terms of development and psychometric validation. Developing a new questionnaire is a complex, time-consuming, and often expensive undertaking, not simply a matter of a physician writing up some questions on the basis of his or her clinical knowledge and experience. The first essential step is to identify the concepts that need to be measured. Although expert opinion and reviews of the literature are important in developing the conceptual framework, it cannot be completed without patient input, which usually is gained through patient interviews and focus groups. Patients are selected to represent, as well as possible, the population that the new PRO measure will target. Trained interviewers conduct the interviews and focus groups according to a carefully designed guide, and complete transcripts are produced of each interview and focus group. These transcripts are then analyzed and used for the generation of draft items to be included in the questionnaire.

At a later stage in the development process, patients are involved again through cognitive debriefing interviews to test their understanding of the draft questionnaire. This step is particularly important because all items must convey to patients exactly what they are intended to convey, and the items must be interpreted in the same way by all patients

Manuscript received July 15, 2009; accepted July 17, 2009.

Affiliations: From the Department of International Medical Communications, Tokyo Medical University, Tokyo, Japan.

Correspondence to: Raoul Breugelmans, MA, Department of International Medical Communications, Tokyo Medical University, 6-7-1 Nishishinjuku, Shinjuku-ku, Tokyo 160-0023, Japan; e-mail: rb@imcc-tmu.jp

© 2009 American College of Chest Physicians. Reproduction of this article is prohibited without written permission from the American College of Chest Physicians (www.chestjournal.org/site/misc/reprints.xhtml).

DOI: 10.1378/chest.09-1684

in the target population, regardless of age, gender, or ethnicity. Although this may appear obvious, in reality it can be very challenging to word an item in such a way that all patients interpret it as intended, and cognitive debriefing interviews sometimes reveal interpretations that the developers of the instrument had not imagined possible. The transcripts of these cognitive debriefing interviews are analyzed, and items are reduced or modified based on the results. In addition to the wording of the items, it is necessary to develop instructions to go with the items, to carefully consider the format of the questionnaire and its mode of administration, and to set the scoring method.

Even when these steps have been completed, the questionnaire is not yet ready for use. It first has to go through psychometric validation to assess measurement properties, such as reliability, validity, and ability to detect change.

A questionnaire that has gone through rigid development steps is, as Juniper states,¹ truly a precision instrument, and even small modifications can compromise its reliability and validity. Modifications that may appear innocent, such as changing the format or layout of the instrument, changing the order of items, or rewording the instructions, may alter the patients' responses. Therefore, it is important to administer only the exact version used in the validation process, however tempting it may be to make small modifications to better suit the specific purpose of the study at hand.

Regulatory agencies are likely to evaluate an instrument that was modified from an existing validated instrument as they would a completely new one. For modified instruments, the US Food and Drug Administration² recommends additional validation studies, including small nonrandomized or randomized studies (depending on the degree of modification), particularly when changes have been made in measurement concept, patient population or condition, item content or questionnaire format, or mode of administration or when the instrument has been adapted to a different language or culture. Translation of PRO measures for use in another language or culture is particularly problematic because too often clinicians and researchers believe incorrectly that it is acceptable to simply translate an existing questionnaire into another language and consider the resulting version to be a validated instrument as long as the original has been validated.

EXPLICATION

What, then, does it take to translate a validated instrument for use in a different language or culture?

The complex process is commonly referred to as *cultural adaptation*, and its purpose is to ensure that all of the resulting language versions are conceptually equivalent to the original version and to one another while being relevant and culturally acceptable to the target populations. Producing a translation that is conceptually identical while culturally relevant and acceptable is a dauntingly difficult task because most existing instruments were developed with only one culture in mind and with little thought given to translatability. How do you translate, for example, "Have you been feeling blue?" into Korean or "shoveling snow" for use in Malaysia? Literal translations are highly unlikely to work, but often the problem is not immediately obvious.

Consider the following example: "How difficult was it to sit without losing your balance?" This item appears to be straightforward and easy to translate unambiguously into any language. When translating it into Japanese, however, a problem occurs. Traditionally, Japanese people sit on the floor, and although chairs now are used frequently both at home and at work in Japan, many opportunities still exist to sit on the floor, and many elderly people prefer sitting on the floor over sitting on a chair. A literal Japanese translation of the word "sit" would include both sitting on a chair and sitting on the floor. Whether this ambiguity is acceptable depends on the concept that the item is designed to measure, in this case, the degree of difficulty maintaining one's balance when seated on a chair. As the degree of difficulty maintaining one's balance while sitting on a chair differs from that when sitting on the floor, the latter should be excluded. The item therefore should be translated as, "How difficult was it to sit on a chair without losing your balance?" To identify and solve this type of problem, it is essential to assess the various ways in which patients might interpret the meaning of a translated item and then assess whether these meanings are in line with the concept the item is intended to measure.

A multistep methodology⁴ has been developed that is now generally accepted, albeit with considerable variations in the details of the various steps. In the development of any translated instrument, it is necessary to translate the questionnaire from the source language into the target language (called *forward translation*), and most methodologies call for a quality-control step in which the resulting target language version is translated back into the source language (called *back translation*). A common misperception, however, is that as long as the back translation of a translated instrument is produced, the translation can be considered to be a validated version of the original validated questionnaire. Unfortunately, it is not that simple. Cultural adaptation

requires a collaborative effort that involves input from professional translators of both the source language and the target language, clinicians, the developers of the original instrument, and the patients. Although variations exist, the following paragraph outlines the steps that are commonly present in most cultural adaptation methodologies.

As with the development of an original instrument, the cultural adaptation process starts with an analysis of the concepts underlying the items. Once the concepts are well understood, the questionnaire is translated independently by two or more translators who are native speakers of the target language. After the resulting translations have been synthesized into a single draft translation, this version is back translated into the source language by one or more translators who are native speakers of the source language in order to check for equivalence with the original version. Often, a clinician or expert panel review is included. Probably the single most important step is pilot testing the questionnaire with patients who represent the target population. As with the original version of the instrument, pilot testing can be performed through cognitive debriefing interviews to identify exactly how patients interpret the items and to ensure that no discrepancies with the intended meanings of the items exist. Finally, it is important to document each step in sufficient detail to serve as evidence that the instrument has been validated properly and to ensure that any issues that may arise later can be addressed. Following these steps will lead to a translated PRO measure that

meets regulatory requirements and avoids loss of time, effort, money, and valuable patient data.

TAKE-HOME LESSON

Leave translation of PRO measures to PRO experts who are experienced in the process.

ACKNOWLEDGMENTS

Financial/nonfinancial disclosures: Mr. Breugelmans is a consultant to the MAPI Research Institute, Lyon, France, the services of which are discussed in Dr. Juniper's editorial in this issue of *CHEST*.¹

REFERENCES

- 1 Juniper E. Medical questionnaires are copyrighted to ensure that validity is maintained. *Chest* 2009; 136:951–952
- 2 US Food and Drug Administration. Guidance for industry: patient-reported outcome measures; use in medical product development to support labeling claims [draft]. Available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm071975.pdf>. Accessed September 8, 2009
- 3 European Medicines Agency. Reflection paper on the regulatory guidance for the use of health-related quality of life (HRQL) measures in the evaluation of medicinal products. Available at: <http://www.emea.europa.eu/pdfs/human/ewp/13939104en.pdf>. Accessed September 8, 2009
- 4 Acquadro C, Conway K, Hareendran A, et al. Literature review of methods to translate health-related quality of life questionnaires for use in multinational clinical trials. *Value Health* 2008; 11:509–521

**Dangers in Using Translated Medical Questionnaires : The Importance
of Conceptual Equivalence Across Languages and Cultures in
Patient-Reported Outcome Measures**

Raoul Breugelmans
Chest 2009;136; 1175-1177
DOI 10.1378/chest.09-1684

This information is current as of January 25, 2011

Updated Information & Services

Updated Information and services can be found at:
<http://chestjournal.chestpubs.org/content/136/4/1175.full.html>

References

This article cites 2 articles, 1 of which can be accessed free at:
<http://chestjournal.chestpubs.org/content/136/4/1175.full.html#ref-list-1>

Permissions & Licensing

Information about reproducing this article in parts (figures, tables) or in its entirety can be found online at:
<http://www.chestpubs.org/site/misc/reprints.xhtml>

Reprints

Information about ordering reprints can be found online:
<http://www.chestpubs.org/site/misc/reprints.xhtml>

Citation Alerts

Receive free e-mail alerts when new articles cite this article. To sign up, select the "Services" link to the right of the online article.

Images in PowerPoint format

Figures that appear in *CHEST* articles can be downloaded for teaching purposes in PowerPoint slide format. See any online figure for directions.

