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TRANSLATION, CULTURAL ADAPTATION AND VALIDATION OF THE LIVING WITH MEDICINES QUESTIONNAIRE INTO THREE REGIONAL LANGUAGES (TAMIL, TELUGU AND HINDI) IN INDIA

Helen W⁽¹⁾, Srinivasan R⁽²⁾

(1) Research Scholar, Department of Pharmacy Practice, Faculty of Pharmacy, Bharath Institute of Higher Education and Research (BIHER), Chennai, Tamil Nadu, India

(2) Research Supervisor, Department of Pharmaceutical Chemistry, Faculty of Pharmacy, Bharath Institute of Higher Education and Research (BIHER), Chennai, Tamil Nadu, India

Abstract

INTRODUCTION : To assess, from a patient's point of view, the issues related to the burden resulting from the use of medicines, the Living with Medicines Questionnaire version 3 has been developed in English.

OBJECTIVE : To translate and culturally adapt the LMQ version 3 into three regional languages in India.

METHODOLOGY : Permission to translate the LMQ-3 was obtained from the original developers, and a translation and adaptation protocol based on the International Society of Pharmacoeconomics and Outcomes Research guidelines has been developed using patient-reported outcome measures. To produce the first reconciled version, translated back into English, two forward translations from English into the Indian regional language (Tamil, Telugu, and Hindi) have been developed and compared.

RESULTS : Rewording of certain items within this instrument has addressed the issues found and those relating to Cultural and Conceptual equivalence with respect to some terms. The translation process and cognitive debriefing exercise generated comments regarding the original tool's construct and its Tamil, Telugu and Hindi equivalents, which were communicated to the developers of the LMQ for their consideration while conducting further comparative studies.

CONCLUSION : To be able to use it in research and clinical practice in Tamil, Telugu and Hindi-speaking people in India, a culturally appropriate translation of the LMQ version 3 has been developed. It is recommended and envisaged that this developed version of these languages will continue to be validated.

KEYWORDS : Translation, Cultural Adaptation, Validation, Living with Medicines Questionnaire, three regional languages.

INTRODUCTION

In the managing of chronic diseases, medicines constitute the most commonly used form of treatment.¹ Multiple medicinal products, especially for patients with multimorbidity, are often prescribed for the clinical management of different chronic conditions. The routine of taking medicines, adverse reactions, nature of the medication, regimen challenges associated with the healthcare system, access to medications, and interference with social activities often result in medication-related burdens for patients.² The burden of medication may be detrimental to an individual's social, psychological, and physical well-being.⁵ A critical humanistic dimension that needs to be evaluated in all patient-centered interventions is the social, psychological, and physical impact of medication therapy on patient's lives. To assess aspects related to patient's use of medicine, several instruments have been created. However, there are still insufficient evidence-based tools in the literature to evaluate the burden on patients from a patient's point of view regarding medication use. Krska et al. have developed and validated the Living with Medicines Questionnaire (LMQ), which is intended to examine several aspects related to

the burden of medicine use from a patient's point of view. Based on earlier qualitative investigations, the LMQ was developed for patients with chronic morbidities. Validations for comparative psychometric evaluations of this tool were conducted in several countries, including England, Australia, Ireland, and the Netherlands.^{10,11} Feedback from patients to date indicates that the questionnaire is an effective tool in assessing a range of problems, such as adherence to treatment plans, patient relationships with healthcare providers, and concerns related to drug side effects.⁹ To our knowledge, tools are not available for assessing patient's perceptions of the burden related to the use of medicinal products in an Indian language (Tamil, Telugu, Hindi) context. Additionally, there has not been a third version of the LMQ in these languages, which are among the most commonly spoken languages in India. To that end, this study aims to participate



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Corresponding Author: Helen W
e-mail : whelen2712@gmail.com

in international instrument development efforts to make culturally acceptable tools available. This will be a valuable tool to help us assess how patients feel about their treatment and its effects on their lives. In this way, tailored interventions designed to reduce the use of medicines in patients with chronic illnesses who receive multiple medicinal products will also be facilitated.

METHODOLOGY

Description of LMQ 3:

The LMQ version 3, developed by Krska et al., contained 41 statements with which the respondents indicated their level of agreement using a five-point Likert-type scale (from strongly agree to disagree). Furthermore, the patient was able to add any additional pertinent issues that did not appear on the questionnaire by means of a freely readable question. Eight domains covered by the tool include interactions with healthcare professionals, practicalities, information, effectiveness, adverse reactions, attitudes, impacts, and control. Additionally, a visual analogue scale (VAS) was used, which allowed the patient to express how much of a burden they felt from their entire medicine regimen on a range of 0 (no burden at all) to 10 (very burdensome). Initial versions of this VAS did not have distinct points with scores ranging from 0 to 10, However, the developers later accepted the scoring.¹³

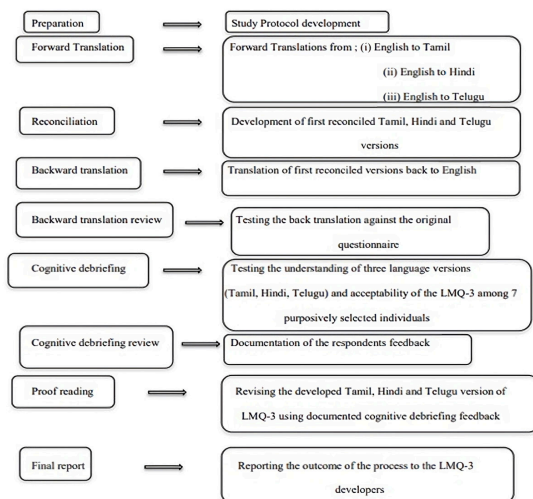


Figure 1: Steps for the translation and cultural adaptation of the LMQ 3 into Tamil, Hindi and Telugu (based on ISPOR guidelines).

The Translation and Cultural Adaptation Process: In this study, the ISPOR Guidelines for adaptation, validation and translation of questionnaires regarding PRO measurement have been used by the International Pharmacoeconomics and Outcomes Research Society. (Figure 1)

Preparation

The original authors of the questionnaire i.e., Krska et al. have given their permission to use the LMQ version 3. A comprehensive study protocol has been drawn up and shared with the developers, giving them a clear overview of the design, methodology and anticipated project results. Throughout the development of a Tamil version of the questionnaire, developers have provided detailed information and explanations where necessary. The multistage process for the developing of a three-languages (Tamil, Hindi and Telugu) version of the questionnaire is illustrated in Figure 1, which shows results at each stage.

Forward translation

Two independent, multilingual, and trained translators carried out two different translations of the LMQ-3 from (i) English to Tamil, (ii) English to Hindi, and (iii) English to Telugu. The contents of this tool have not been informed to the translator with experience working in PROs before their translation.

Reconciliation

A panel composed of five study investigators (Four of whom were fluent in English, Tamil, Hindi and Telugu) and the translators convened on several occasions to develop three language versions of the LMQ-3 translations. This was done to eliminate any discrepancies in translation and to ensure cultural equivalence. This generated the first reconciled Tamil, Hindi and Telugu versions of the LMQ-3.

Back translation and review

A third independent, bilingual and qualified translator who was not familiar with the original English version 3 of the LMQ has translated the first reconciled Tamil, Telugu and Hindi versions back into English to test the quality of the translation and to ensure that the intended meanings of all the items were maintained. A review of the results in this step has resulted in further enhancement of the three languages questionnaire and a second harmonised language version. A step of harmonization was taken at this point in time, as indicated by the ISPOR (The International Society for Pharmacoeconomics and Outcomes Research) Guidelines to guarantee equivalence between differing versions of the developed texts. It is advisable to harmonize when a tool of interest is transferred over to multiple languages. In this work, steps are undertaken to ensure comparability between all three language versions through joint discussions among translators.

Cognitive debriefing and review

Each Ten Tamil, Hindi and Telugu-speaking people were purposively chosen for the cognitive debriefing. To give equal

representation between the sexes, ages, and occupation, these participants have been selected (Table 2,3,4). Although it was intended to ensure that the developed version of Tamil could be understood by the general population, a large proportion of those selected had at least one chronic condition. Respect comprehension, time pressures and acceptability they gave their comments on the 2nd corrected version of the LMQ-3 Tamil, Hindi, Telugu languages. In this review of the cognitive debriefing procedure, discussions have resulted in a revising of previous steps to deal with cultural and linguistic issues. Investigators could also able to evaluate whether the original LMQ version 3 content was acceptable and communicate it to developers of an initial version through a cognitive debriefing process.

Proofreading and final report

To provide a final translation, investigators of the study have carried out careful reviews of the English version 3 of the LMQ. A final report was developed and submitted to the LMQ developers on the original version of the LMQ-3 with three languages (Tamil, Hindi, Telugu) translations, methods for generating a translated version as well as its findings during linguistic validation.

RESULT

Translation and Cultural Adaptation

Statements of the instrument were evaluated carefully by the study investigators at the semantic, conceptual, and cultural levels. In that regard, certain words have been modified to retain the intended meaning and heading of the statement to be able to meet the regional language context. (Table 1)

Table 1: Issues resolved in the translation and cultural adaptation of the LMQ 3

Item	Translation Issue	Action
Item 11 - I can vary the dose of the medicines I take	A literal translation may change the direction of the item and may give the meaning that the patient will change the dose regardless of the need.	It was translated to express the confidence that respondents would have to tailor the dose as per their needs, which is the intended meaning of the item.
Item 4 - I am comfortable with the times I should take my medicines.	When back-translated into English, the term "comfortable" became "relieved". This would change the meaning and the direction of the item.	The word 'comfortable' has been converted into a phrase indicating acceptance.
Item 17 - I am concerned that my medicines interact with alcohol	Cultural adaptations have been made to ensure that the respondents can answer this question because alcohol consumption, despite its widespread occurrence in Indian society, particularly for women, is not a normal part of their culture.	This was translated into Tamil which meant "I am concerned that my medicines interact with my nutritional habits (other foods, alcohol, drinks)." The same translations were applied to Hindi and Telugu languages.
Item 41 - My life revolves around using my medicines.	It would be difficult to understand and convey different meanings and directions of the item if translated literally.	The sentence "using medicinal products constitutes a substantial part of the patient's life" was added to this item.

Table 2: Participants (Tamil native speakers) selected for cognitive debriefing

Participants (Tamil Native Speakers)	Sex	Age (y)	Occupation	Interview place	Interview duration (min)
P1	Female	27	Pharmacist	Hospital	45
P2	Female	42	Software engineer	Home	60
P3	Male	48	Private bank Manager	Bank office	50
P4	Female	23	Housewife	Home	60
P5	Female	32	Lecturer	Home	60
P6	Male	56	Real estate	Participant office	45
P7	Male	50	Laborer	Worksite	45
P8	Female	36	Customs officer	Home	40
P9	Male	60	Professor	Home	70
P10	Female	55	Professor	Home	75

Table 3: Participants (Telugu native speakers) selected for cognitive debriefing.

Participants (Telugu Native speakers)	Sex	Age (y)	Occupation	Interview place	Interview duration (min)
P1	Male	45	Business	Home	45
P2	Male	32	Sales development	Participant Office	45
P3	Female	56	Housewife	Home	50
P4	Male	47	Business	Participant Office	50
P5	Female	29	Accountant	Home	40
P6	Female	39	Housewife	Home	45
P7	Male	60	Mechanic	Work site	30
P8	Male	42	Driver	Home	45
P9	Female	57	Housewife	Home	40
P10	Female	62	Retired Professor	Home	60

Table 4: Participants (Hindi native speakers) selected for cognitive debriefing

Participants (Hindi Native speakers)	Sex	Age (y)	Occupation	Interview place	Interview duration (min)
P1	Male	28	Building Worker	Home	70
P2	Female	39	Housewife	Participant Office	45
P3	Female	54	Housewife	Home	60
P4	Male	45	Business	Participant Office	65
P5	Male	31	Building Worker	Home	45
P6	Female	37	House wife	Home	60
P7	Male	53	Business	Worksite	60
P8	Male	47	Business	Home	70
P9	Male	34	Sale representative	Home	45
P10	Female	48	Assistant Professor	Home	70

Visual Analogue Scale and Cognitive Debriefing

A decision was made, through discussions among the research investigators, to change the VAS to one with discrete graduation between 0 (no burden at all) and 10 (extremely burdensome).

The recommended change has been communicated to the developers of the first instruments has been approved by them. The rationale behind adding discrete ratings to the VAS was that they could be used as a basis for providing an overall global assessment of the burden of medicine use. This would enable measuring associations with the entire LMQ version 3 scores and their respective domains.

Almost all of the interviewed individuals commented on the length of the questionnaire (41 items) and the presence of some items that clustered around similar meanings. For instance, item 3, "I am pleased with the efficacy of my medicines," and item 25, "My medicinal products are in line with my expectations" were used by some respondents to measure their effectiveness. However, there were no suggestions to modify those issues since they have slight differences in their very close relationship.

DISCUSSION

The first attempt to introduce an instrument to assess the burden of the use of medicinal products from the patient's point of view was made with the development of the LMQ. This study adds to evidence that compared to healthcare providers, patients have different perceptions of issues relating to the use of medicines.¹⁷

Although methodologies may differ, we have undertaken to follow the best practices laid down by ISPOR to ensure reliable and robust results in studies concentrating on cultural adaptation measures. Before conducting the forward-backward translation, the investigators tried to characterize the concept tool of interest measures among the target population (English-speaking).

Apart from the diverse types of instruments adapted, this diversity can be attributed to enormous differences between languages, cultures and places where these studies were carried out. To help interpret the findings resulting from using this tool, which was supported by the development community, the researchers of that study favoured a grade VAS with scores between 0 and 10; an option endorsed by the developers. And to assess the comprehension and duration of the questionnaire, cognitive debriefing interviews have been carried out.¹² Given the development of the LMQ, which is based on qualitative patient opinions about medication issues, a general good level of understanding was expected

achieved about nearly all statements in the tool. In most of the guidance on translation and cultural adaptation to PRO instruments, native speakers of the original language who are also fluent in their target language should be used for back translations. It was hard to find a person in our area with that those characteristics. A qualified bilingual translator, whose mother tongue was Tamil, Telugu and Hindi and who was familiar with Western culture, had translated our study back to translation. In addition, before its use for research and medical practice, it is essential to conduct out further studies to establish the psychographic characteristics of the produced Tamil version amongst Tamilian populations in Tamil Nadu, state of India. Similarly for Telugu and Hindi version among the Telugu and Hindi speaking populations. It is necessary to measure in particular the validity of construction and its internal consistency.¹⁹

CONCLUSION

It is our belief that the translation and cultural adaptations of the LMQ-3 beyond English to other language countries will have a significant input, complementing work already carried out by LMQ developers in other languages. This work also provides for the release to the public, in a strong translation process, a Tamil, Telugu and Hindi versions of the LMQ-3 which is functionally similar to the English language tool.

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