The Living with Medicines Questionnaire: Translation and Cultural Adaptation into the Arabic Context

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A B S T R A C T

Background: The Living with Medicines Questionnaire (LMQ) was developed in English language to assess, from a patient's perspective, issues related to the burden resulting from the use of medicines. **Objectives:** To translate and culturally adapt the LMQ into the Arabic language and context. **Methods:** Permission to translate the LMQ was obtained from the original developers, and a protocol for its translation and cultural adaptation was developed using the International Society for Pharmacoeconomics and Outcomes Research guidelines for the translation and cultural adaptation of patient-reported outcome measures. Two forward translations (from English into Arabic) were developed and compared to produce the first reconciled version, which was back-translated into English. The resulting English version was compared with the original questionnaire leading to the second reconciled version. The emerged Arabic questionnaire was then cognitively tested among purposively selected individuals to assess the linguistic and cultural equivalence, and produce the final Arabic version. **Results:** Issues identified and related to cultural and conceptual equivalence of some terms were resolved by rewording some items in the tool. The translation process and cognitive debriefing exercise generated comments regarding the original tool's construct and its Arabic equivalent, which were communicated to the developers of the LMQ for their consideration while conducting further comparative studies. **Conclusions:** A culturally suitable translation of the LMQ was generated for potential use in research and clinical practice in Arabic-speaking countries. Further validation of the developed Arabic version is recommended and planned.

Keywords: cultural adaptation, medication burden, questionnaire, polypharmacy, translation.

Highlights

- Medication burden has a negative effect on patients' lives and is associated with adverse drug events.
- In this study, a culturally adapted Arabic version of the Living with Medicines Questionnaire was developed. This questionnaire was originally developed in English to assess medication burden from a patient's perspective.
- The translated version could be used in clinical practice and/or research where it is important to assess burden related to medication intake. This, in turn, could inform designing of interventions aiming at providing minimally disruptive health care.

Introduction

Patients on multiple drug therapy and those with comorbidities are highly prone to drug-related problems [1]. The number of these at-risk patients is on the rise worldwide [2]. Polypharmacy, which is the use of several medications simultaneously, has been associated with increased morbidity and mortality, hospitalizations, and demand for nursing home care [1,3]. Polypharmacy could also increase medication burden and may result in drug-related consequences, such as poor adherence, adverse drug reactions, and unnecessary drug therapy [4,5]. Medication burden could still occur in patients using any number of medications, when considering the negative feelings and experiences related to those medications [6].

Identification, prevention, and resolution of drug-related problems are considered the main responsibilities of a pharmaceutical care (PC) provider [7]. Consequently, an effective PC practice, with its patient-centered philosophy and outcome-oriented tenets, should, hypothetically, lead to reduced burden of drug therapy. Given that patients' perspectives on issues related to the use of medicines are arguably different from those of health care providers, more attention has been drawn toward assessing the burden of drug therapy from the perspective of the patient in recent years [6,8,9]. Consequently, the assessment of the burden of medicine use from the patient's viewpoint is an important element in providing PC because it will help to identify

the most vulnerable patients affected by the burden of therapy so that appropriate interventions could be provided to reduce this [6].

Several instruments have been developed to evaluate the aspects of medication use practices of patients [10]. This is not the case with regard to measures that assess the burden associated with medication use from the patient's perspective, where there is still paucity of validated tools in the literature. Krska et al. [6] developed and validated the Living with Medicines Questionnaire (LMQ), a measure that aims to investigate several aspects of the burden of medicine use from the patient's perspective. The LMQ was derived from earlier qualitative investigations among patients diagnosed with chronic morbidities [8]. Validations for comparative psychometric evaluations of this tool were conducted in several countries including England, Australia, Ireland, and the Netherlands [6,11]. Patients' feedback, so far, suggests the value of the questionnaire in assessing various issues such as adherence to treatment plans, patients' relationships with health care providers, and concerns about adverse drug reactions [6].

Different approaches for adaptation, validation, and translation of questionnaires related to the measurement of patient-reported outcomes (PROs) have been described in the literature [12–14]. To our knowledge, there are no tools available to assess patients' perspectives on the burden associated with medicine use in the Arabic context. Similarly, an Arabic version of the LMQ had not been previously developed. Therefore, the aim of this study was to join the international efforts in instruments development to make available a culturally acceptable Arabic version of the LMQ for potential use in Arabic-speaking countries. This shall produce an invaluable tool to help assess perceptions of patients on drug therapy and the impact on their lives. This will, in turn, help to design tailored interventions that will decrease the burden of medicine use, especially among patients with chronic illnesses receiving multiple medications.

Methods

Description of the LMQ

The LMQ, developed by Krska et al. [6], contained 41 statements with which the respondents indicated their level of agreement using a five-point Likert-type scale (from strongly agree to strongly disagree). In addition, a free text (open-ended) question allowed the patient the freedom to add any other relevant issues that were not covered in the questionnaire [6]. The tool comprised eight domains: relationships with health professionals, practicalities, information, efficacy, side effects, attitudes, impact, and control. A visual analogue scale (VAS) that allowed the patient to express his or her overall perceived medication burden on a scale of 0 (no burden at all) to 10 (extremely burdensome) was also included [6]. This VAS originally contained no discrete scored points between 0 and 10, but the scoring was later proposed to the developers and approved.

The Translation and Cultural Adaptation Process

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines for adaptation, validation, and translation of questionnaires related to the measurement of PROs were used in this study (Figure 1) [12].

Preparation

Permission to use the LMQ was obtained from the original developers of the questionnaire (i.e., Krska et al.). A comprehensive study protocol, which contained detailed information about the design, methods, and expected results of the project, was developed and shared with the developers. The developers provided details and explanations as needed throughout the process of developing the Arabic version of the questionnaire.

Forward translation

Two translations of the LMQ from English to Arabic were conducted by two independent, bilingual, and qualified translators. The translators, who were experienced in translating PROs, were not informed about the content of the tool before the translation process.

Reconciliation

A panel composed of three study investigators (two of whom were fluent in English and Arabic) and the translators convened on several occasions to develop a single Arabic version of the LMQ translations. This was done to eliminate any discrepancies in translation and to ensure cultural equivalence. This generated the first reconciled Arabic version of the LMQ.

Back translation and review

The first reconciled Arabic version of the LMQ was back-translated into English by a third independent, bilingual, and qualified translator who was not familiar with the original English version of the LMQ. This new English translation was compared with the original LMQ by the study investigators to test the quality of the translation and to ensure that the intended meanings of all the items were maintained. A review of the outcome of this step led to further refinement of the Arabic questionnaire and to the second reconciled Arabic version. According to the ISPOR guidelines, this step should be followed by a step of "harmonization." Nevertheless, harmonization is recommended when the tool of interest is translated into more than one language to ensure equivalence between the different developed versions. This was not the case in the present work.

Cognitive debriefing and review

Seven Arabic-speaking people were purposively selected for cognitive debriefing. These participants were selected to obtain a balanced sex, age, educational level, and nationality representation. Although the purpose of this step was to ensure that the developed Arabic version was comprehensible to the general population, most of the selected participants had at least one chronic condition. They provided feedback on the second reconciled LMQ Arabic version in areas related to comprehension, time burden, and acceptability. Discussions during this review of the cognitive debriefing process resulted in refining the changes made in the previous steps pertaining to cultural and linguistic issues. The cognitive debriefing process also allowed investigators to assess the acceptability of the content of the original LMQ, and to communicate this to the developers of the original version.

Proofreading and final report

The Arabic version of the LMQ was revised carefully by the study investigators to produce the final translation. A final report regarding the original LMQ and the Arabic translation, the methods used to generate the translated version, and the
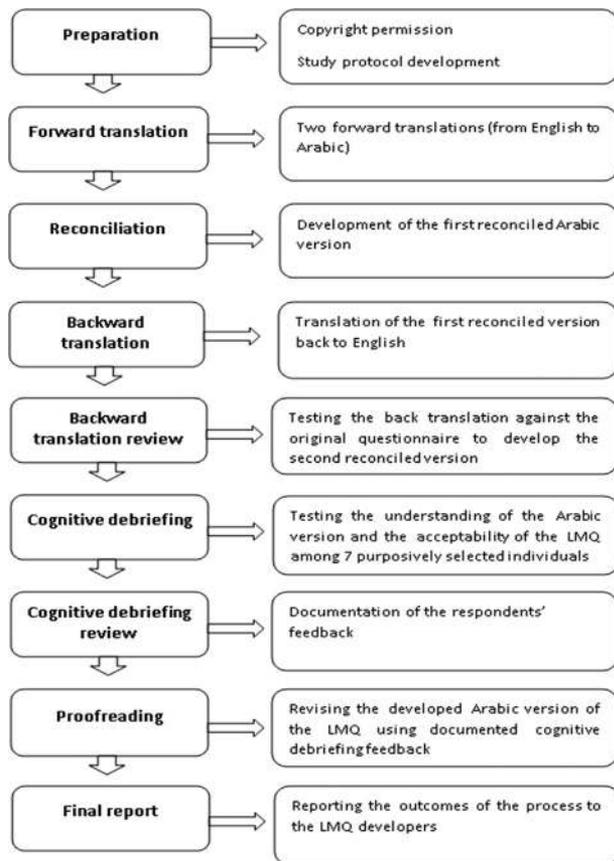
Figure 1 – Steps for the translation and cultural adaptation of the LMQ into Arabic (based on ISPOR guidelines).

findings arising during the linguistic validation process was generated and shared with the LMQ developers.

The flow diagram in Figure 1 shows the multistep process and the outcomes of each stage in the development of the Arabic version of the questionnaire.

Results

Title and Instructions Translation

The instrument's title and the instructions were translated with no need for changes. Questions about demographic characteristics, which were at the end of the original LMQ, were moved to the first page to avoid missing important demographic data. The question about the ethnic group of the respondent was replaced by a question about nationality.

Items Translation and Cultural Adaptation

Statements of the instrument were evaluated carefully by the study investigators at the semantic, conceptual, and cultural levels. In this respect, some words were changed to retain the intended meaning and direction of the statement and to suit the Arabic context (Table 1).

The backward translation review revealed no major issues in the translation. Only a few statements were rearranged to be easier for and closer to the Arabic respondent's understanding while maintaining the intended meaning of the original sentences. Details of the issues raised were reported to and discussed with the LMQ developers. Issues which arose during the process of translation and cultural adaptation are presented in Table 1.

The Visual Analogue Scale

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). This proposed change was communicated to (and approved by) the original instrument developers. The rationale for adding discrete scores to the VAS was to help in providing a global self-assessment of the burden of medicine use and to allow measuring associations with the overall LMQ score and with each of its domains.

Cognitive Debriefing

The characteristics of the individuals who participated in the cognitive debriefing interviews are presented in Table 2. The

Item no.	Item	Translation issue	Action
4	"I am comfortable with the times I should take my medicines."	When back-translated into English, the term "comfortable" became "relieved," which would change the meaning and the direction of the item.	The word "comfortable" was translated into a word in Arabic that meant "accept."
11	"I can vary the dose of the medicines I take."	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.
17	"I am concerned that my medicines interact with alcohol."	Cultural adaptations were performed to ensure acceptance of the respondents to answer such an item because alcohol consumption, even though common, is not a norm in the Arabic culture.	This was translated into Arabic that meant "I am concerned that my medicines interact with my nutritional habits (other foods, alcohol, drinks)."
41	"My life revolves around using my medicines."	If translated literally, it would be hard to understand and would deliver a different meaning and direction of the item.	This item was translated into a sentence that meant using medicines takes a major part of the life of the patient.

Table 1 – Major issues resolved in the translation and cultural adaptation of the LMQ.

LMQ, Living with Medicines Questionnaire.

Participant	Sex	Nationality	Age (y)	Occupation	Interview place	Interview duration (min)
P1	Female	Syrian	26	Physical therapist	Home	60
P2	Female	Qatari	35	Red Crescent volunteer	Coffee shop	50
P3	Male	Lebanese	57	Manager	Participant's office	60
P4	Female	Syrian	23	University student	Researcher's office	75
P5	Female	Libyan	28	University student	Researcher's office	45
P6	Male	Qatari	58	Real estate expert	Participant's office	40
P7	Male	Egyptian	45	Laborer	Construction work site	45

Table 2 – Characteristics of the participants selected for cognitive debriefing.

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interviews conducted revealed an overall good understanding of most of the questionnaire's statements and their Arabic translation. 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 meaning. For example, item 3, "I am satisfied with the effectiveness of my medicines," and item 25, "My medicines live up to my expectations," were, to some respondents, measuring the effectiveness of their medications. No changes, however, were suggested regarding these items, because these closely related questions have subtle differences between them. Respondents' suggestions and comments regarding not only the Arabic but also the original version were reported to the LMQ developers in detail.

Discussion

The development of the LMQ was the first attempt to introduce an instrument that assesses the burden related to the use of medicines from a patient's perspective [6]. This work adds to the growing evidence that issues related to medication intake are perceived differently by patients when compared with health care providers [15]. Although studies concentrating on culturally adapting measures may vary in their methodologies, we committed to follow best practices provided by the ISPOR to ensure credible and robust outcomes.

Present recommendations in the literature exist for adopting already existing tools for use in different study environments and settings [14,16,17]. Nevertheless, achieving cultural equivalence of measurement tools in practice is important to enhance the comparability of results generated from the use of these tools in different cultures [17]. Among societies with different cultures, questionnaires should be used only after previous testing within the target environment [16].

Diverse approaches have been used to conduct translation and cultural adaptation processes [16,18,19]. For example, Santo et al. [16] have adapted the Brazilian-Portuguese version of a self-report measure for dry eye from the US English version. Within their nine-step approach in cultural adaptation, they performed the back translation on the final adapted version after it had been tested for comprehension. Tran et al. [18] have developed an English version of the French Treatment Burden Questionnaire. Before conducting the forward-backward translation, the investigators tried to characterize the concept that the tool of interest measures among the target population (English-speaking). This diversity is due to the enormous differences in languages, cultures, and settings where these studies have been conducted, in addition to the diversity of the types of the tools adapted.

Because the statements of the LMQ were derived from earlier qualitative investigations among patients diagnosed with chronic morbidities [8], they were found to be clear and easy to understand by participants of different backgrounds. Our study revealed no major challenges during the translation process. This may have been because guidelines were carefully followed to maintain the cultural equivalence besides the questionnaire's intended meaning.

Similarly, decisions regarding the addition, elimination, or rewording of the items of instruments to maintain the cultural equivalence in questionnaire translation and validation processes have been described in the literature [18,20]. In this study, several issues were raised; most notably was a question in the demographic information page that asked participants about their ethnic group. A decision was made to replace the question on ethnic group with a question on nationality to act as a better differentiator among the Arabic-speaking people. Moreover, there was an item that asked respondents about concerns related to interactions between alcohol and other medications. We proposed changing or rewording the question because despite the fact that consuming alcohol is common, it is still considered socially unacceptable in the Arabic culture. The point was that including alcohol consumption as the main focus within an item in the questionnaire could raise some cultural sensitivity issues. It was not totally deleted, but the item was paraphrased such that alcohol consumption remained within an item that covered other dietary items and their potential interactions with medications.

In addition, discussion was held with the developers regarding the inclusion of a nongraduated VAS that was added at the end of the LMQ. The investigators of this study preferred to use a graded VAS with scores ranging from 0 to 10; this was to help in the interpretation of the findings resulting from using this tool, a suggestion that was approved by the developers.

The cognitive debriefing interviews were conducted to assess the comprehension and time burden of the questionnaire. The overall good level of comprehension of almost all the statements within the tool was predicted because the development of the LMQ was based on qualitative explorations of patients' perspectives on medication-related issues. The respondents' comments about the length of the questionnaire and the redundancy of some items could be explained by the fact that this tool was designed to identify almost all possible issues related to medicine intake. This is not unusual. In some studies, criticism of the original instrument occurred and changes that could affect its central construct were proposed as a result of testing the tool in different populations [16,18,19].

Most of the guidelines regarding translation and cultural adaptation of PRO instruments recommend that the back translation is carried out by a native speaker of the original language

who is also fluent in the target language. Finding a person with such characteristics in our setting was difficult. The back translation in our study was performed by a qualified bilingual translator whose mother language was Arabic, and who was familiar with the Western culture. Moreover, further research is needed to determine the psychometric properties of the produced Arabic version among Arabic-speaking populations before its use in research and clinical practice. Specifically, the construct validity and internal consistency reliability should be measured.

Conclusions

We believe that translating and culturally adapting the LMQ outside English-speaking countries will provide a valuable input and add to the work that is already being conducted elsewhere by the developers of the LMQ. Through a robust translation process, this work has also made available an Arabic version of the LMQ that is culturally equivalent to the original English tool.

Acknowledgment

REFERENCES

[1] Frazier SC. Health outcomes and polypharmacy in elderly individuals: an integrated literature review. J Gerontol Nurs 2005;31:4–11.
[2] Salisbury C, Johnson L, Purdy S, et al. Epidemiology and impact of multimorbidity in primary care: a retrospective cohort study. Br J Gen Pract 2011;61:e12–21.
[3] Fulton MM, Riley Allen E. Polypharmacy in the elderly: a literature review. J Am Acad Nurse Pract 2005;17:123–32.
[4] Rambhade S, Chakarborty A, Shrivastava A, et al. A survey on polypharmacy and use of inappropriate medications. Toxicol Int 2012;19:68.
[5] Moynihan R, Doust J, Henry D. Preventing overdiagnosis: how to stop harming the healthy. BMJ 2012;344:e3502.
[6] Krska J, Morecroft CW, Rowe PH, et al. Measuring the impact of long-term medicines use from the patient perspective. Int J Clin Pharm 2014;36:675–8.
[7] Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. Am J Hosp Pharm 1990;47:533–43.
[8] Krska J, Morecroft CW, Poole H, et al. Issues potentially affecting quality of life arising from long-term medicines use: a qualitative study. Int J Clin Pharm 2013;35:1161–9.
[9] Tran V-T, Montori VM, Eton DT, et al. Development and description of measurement properties of an instrument to assess treatment burden among patients with multiple chronic conditions. BMC Med 2012;10:68.
[10] Elliott RA, Marriott JL. Standardised assessment of patients' capacity to manage medications: a systematic review of published instruments. BMC Geriatr 2009;9:27.
[11] Carter SR, Bulanadi MG, Katusiime B, et al. Comprehensively measuring patients' subjective thoughts, feelings and experiences of living with medicines: Living with Medicines Questionnaire (LMQ). Int J Clin Pharm 2015;37:424–5.
[12] Wild D, Grove A, Martin M, et al. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. Value Health 2005;8: 94–104.
[13] Su C-T, Parham LD. Generating a valid questionnaire translation for cross-cultural use. Am J Occup Ther 2002;56:581–5.
[14] Sousa VD, Rojjanasrirat W. Translation, adaptation and validation of instruments or scales for use in cross-cultural health care research: a clear and user-friendly guideline. J Eval Clin Pract 2011;17:268–74.
[15] Rowe P, Krska J. Satisfaction with medicines: the views of elderly patients. Int J Pharm Pract 2008;16:A3.
[16] Santo RM, Ribeiro-Ferreira F, Alves MR, et al. Enhancing the cross-cultural adaptation and validation process: linguistic and psychometric testing of the Brazilian–Portuguese version of a self-report measure for dry eye. J Clin Epidemiol 2015;68:370–8.
[17] Beaton DE, Bombardier C, Guillemin F, et al. Guidelines for the process of cross-cultural adaptation of self-report measures. Spine 2000;25:3186–91.
[18] Tran V-T, Harrington M, Montori VM, et al. Adaptation and validation of the Treatment Burden Questionnaire (TBQ) in English using an internet platform. BMC Med 2014;12:109.
[19] Awaisu A, Samsudin S, Amir NA, et al. Measurement of nicotine withdrawal symptoms: linguistic validation of the Wisconsin Smoking Withdrawal Scale (WSWS) in Malay. BMC Med Res Methodol 2010;10:46.
[20] El Meidany YM, El Gaafary MM, Ahmed I. Cross-cultural adaptation and validation of an Arabic Health Assessment Questionnaire for use in rheumatoid arthritis patients. Joint Bone Spine 2003;70:195–202.