Medico Oncology
2021; Volume 2, Issue 1, pages 1-9

http://medicosciencepress.org
https://doi.org/10.52701/monc.2020.v1i1.16

ARTICLE

TRANSLATION OF 15D QUESTIONNAIRE INTO ROMANIAN LANGUAGE TO STUDY QUALITY OF LIFE OF CANCER PATIENTS IN ROMANIA

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Abstract

The 15D is a self-administered 5 Likert survey for evaluation of health-related quality of life, which contains 15 questions. This research was aimed to translate the 15D questionnaire into Romanian to use for cancer patients and scientific community. The standard procedure of forward-backward translation was used in the translation procedure. The original questionnaire was given to two independent forward-translators (one English teacher and one experienced translator). The second step was the backward-translation with two English speakers who translated the first consensus version into English. The back translation was confronted with the original version. The third step was the pilot-test on 15 patients and 10 healthy people. The patients' obstacles in understanding and completing the questionnaires were reviewed and used to modify the questionnaires by the translation group. The final Romanian version of the 15D can be used for the next step of validation.

Keywords: *QoL, 15D questionnaire, translation, validation.*

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Published online: 25 May 2021

Introduction

In the last 30 years, several questionnaires have been developed for quantitative assessment of the physical, mental, and social aspects of health. Patient-reported outcomes (PROs) are standardized measures directly reported by the patient that characterize the patient's perception of the impact of disease and treatment on health and functioning. As defined by the US Food and Drug Administration (FDA), PRO is a tool based on a report that comes straight from the patient about its condition status without any amendment or interpretation of the patient's response made by a clinician or someone else(1).

Cancer and the side effects of cancer treatment are often associated with reduced quality of life (QoL) (2). Information about cancer patients' QoL in Romania is inadequate. The limited research on QoL in Romania is associated with the unavailability of validated questionnaires in Romanian versions. Therefore, the objective of this study was to translate and then to validate the

Romanian version of a QoL questionnaire. The questionnaires could be used to evaluate how much a cancer treatment could influence the patients' normal patterns in their usual activities. Furthermore, evaluating health outcomes between competing treatment alternatives are involved in comparative effectiveness studies and cost-utility analyses, which involve calculating incremental costs associated with incremental quality-adjusted life-years gained. Also, in pharmacoeconomic studies, the overall effect of an intervention on patient health-related quality of life is needed to be quantified.

Some questionnaires have been developed to assess QoL only for cancer patients: the European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire (EORTC QLQ-C30) has been used internationally in 'more than 3000 studies' as generic a questionnaire among cancer patients (3).

The 15D is a generic, standardized, self-administered measure of health-related quality of life (4) that can be used for all patients and their caregivers (Supplementary file_Questionnaire). It contains 15 questions with 5 response options each. 15D has high discriminatory power, being able to distinguish between individuals and groups in different health states cross-sectionally (5). The questionnaire is a health state descriptive system of 15 dimensions (6) (the abbreviations): mobility (move), vision (see), hearing (hear), breathing (breath), sleeping (sleep), eating (eat), speech (speech), excretion (excret), usual activities (uact), mental function (mental), discomfort and symptoms (disco), depression (depr), distress (distr), vitality (vital) and sexual activity (sex). The instrument is available in more than 30 languages for clinical evaluation and population studies (for example, Arabic, Bulgarian, Catalan, Chinese, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hebrew, Hungarian, Italian, Japanese, Norwegian, Polish, Portuguese, Russian, Serbian, Spanish).

The 5 Likert scale question rates the condition of an individual's health through 5 levels: from level 1 which represented the best possible health condition to the worst by level 5. The questionnaire completion time is brief and takes an average of 5-10 minutes. The 15D has been utilized for surveys of general and patient populations (7, 8) as a scale to compare different health conditions (9, 10), and to measure the physical and mental effects of health-related interventions (11, 12).

The objective of this study is to translate 15D questionnaire in Romanian language after standardised translation procedures to be used in clinical trials.

Materials and methods

Translations follow a forward-backward procedure, independently carried out by two native-speakers of the target language

– Romanian, and two English native, bilingual in the Romanian language. Discrepancies are mediated by a translational coordinator and solutions are reached by consensus. The last step was a pilot-testing of the translated questionnaire. A report was done after every step. An additional translator would be consulted if interim reports were not approved by the translational coordinator and it may be necessary to re-start the translation process.

Step 1: Forward translation procedure

The translation coordinator contacted two native speakers of the target language and fluent in English to do the forward translation of 15D. One of the two translators was unconnected with the health field. The two forward translations were carried out independently. The translation coordinator compared the two forward translations and checked them for any discrepancies. The disagreements between the two translations were commented with the translators until it was accepted by all parties into the provisional forward translation. Modifications were made in this draft to diminish discrepancies and to produce a single version in the Romanian language, which all participants agree on.

The items must be full of simplicity, clarity, and natural language because of the wide variety of respondents, some of whom may have a low level of education. Some of the difficulties observed by the translators should be noted in the report on the forward translation process to be checked in the pilot test.

The report on the forward translation process included not only problematic words, phrases or items, but also the points of disagreement and the solutions/consensus items. The outcome of this step was the first consensus version.

Step 2: Back translation procedure

Once the first consensus version has been agreed upon, the single forward translation was then back translated by two native speakers of English independently. Once the back translations are completed, the translation coordinator met with the back translators to discuss the process. The two English versions: the back translations and the original version were compared with ensure that there was no distinct meaning of the questions in the final questionnaire. The discrepancies were discussed and resolved until agreement within the translation group was reached. The translators were also asked to comment on their perceptions of the first consensus version of the questionnaire in the Romanian language.

The report on the back translation process included the differences between the original version and the back translations, or between the 2 back translations. The outcome of this step was the second consensus version.

Step 3: Pilot test

The second version of the 15D was pilot tested on 25 respondents who are native speakers of the Romanian language. Inclusion criteria for the pilot test were: cancer patients and healthy people; aged 18 years or older; ability to read and write standard Romanian; and willing to participate in the study, with a bias towards those in lower educational categories. The Romanian version of 15D was distributed to the patients before their chemotherapy treatment (n=15), and to the healthy people (n=10). The questionnaire was self-administered in the presence of the research team. The aim of pilot testing was to evaluate the clarity, understandability, and consistency of wording. Any misunderstandings that the patients had experienced with the questionnaire were registered by the researcher during the time the patients responded the questionnaire. Any items which responders' thought were inappropriate for any reason were recorded by the researcher. The patients' obstacles in understanding and completing the questionnaires were reviewed and used to modify the questionnaires by the translation group. The outcome of this step was the final consensus version. The time (minutes) required by each patient to complete the 15D questionnaire was also recorded.

Results

The translation followed the steps as in Figure 1. The nature and severity of translation problems vary greatly from missing punctuation marks and missing letters to incorrectly used expressions, but not in the way that could transform a questionnaire item into a meaningless expression.

Some of the translations were much more literar and we kept the translation that was more fluent and easier to understand. For example, the item 1.4 "I am able to walk indoors only with help from others." was translated in two ways: "Pot merge în afara casei doar cu ajutorul unei alte persoane." and "Pot să merg în interior numai cu ajutorul altora". We decided to combine the two translations with the literal form of the verb from the second translation: "Pot să merg în casă doar cu ajutorul unei alte persoane.".

We decided to combine the two translations for easier understanding in many translated items. The backward translation of 15D was compared with the original version and was found to be satisfactory.

Given this diversification, we propose a taxonomy of translation problems. Table 1 summarises problem types and typical examples that were encountered in the context of translations of 15D questionnaire.

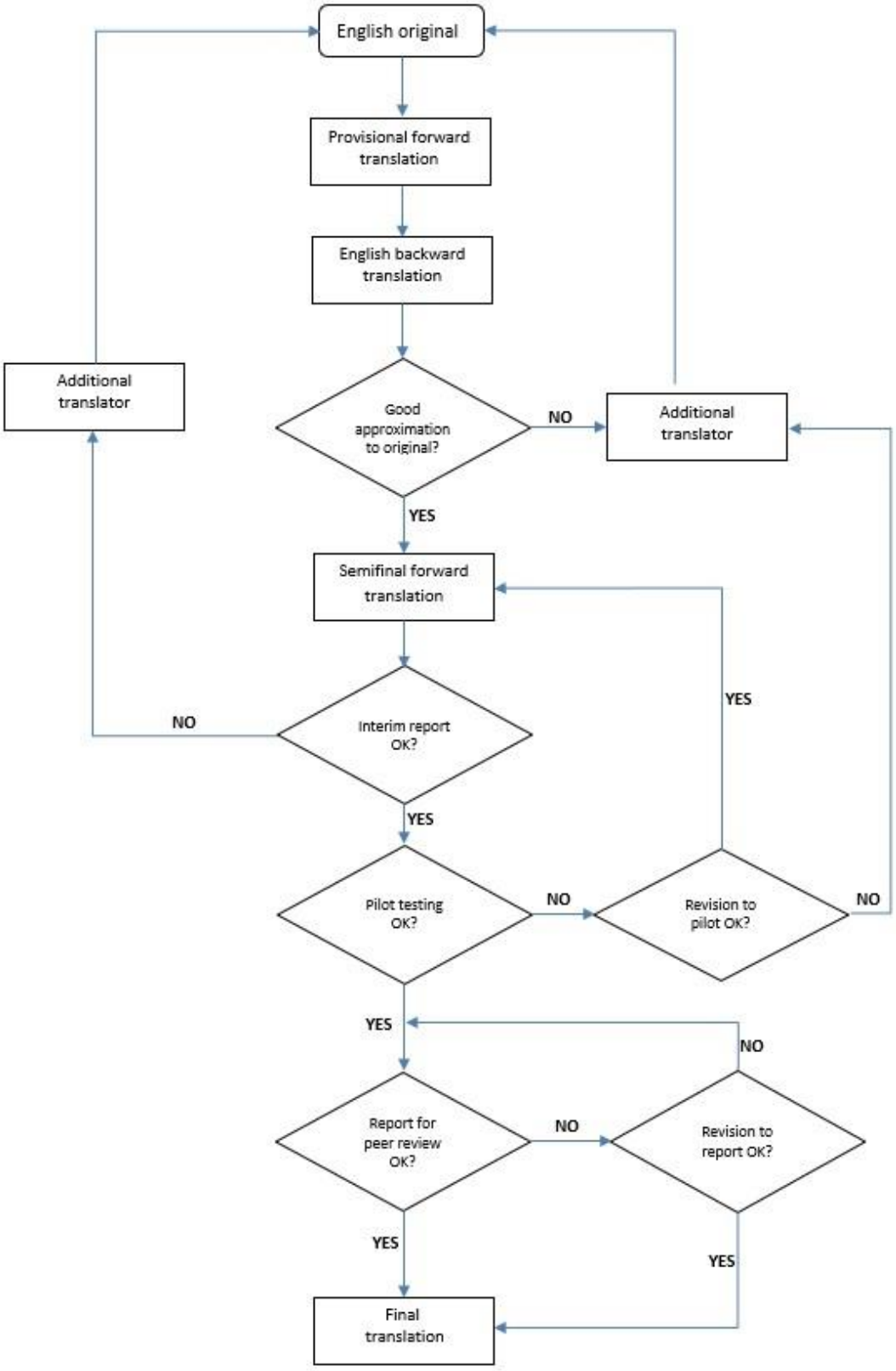

Figure 1 Translation algorithm

PROBLEM TYPE	DESCRIPTION OF THE PROBLEM	EXAMPLES
Semantic	Equivalence in the meaning of words/expressions	"Mă pot face înțeles/înțeleasă, dar vorbirea mea este cu deficiențe de vorbire (de exemplu: vorbire dezarticulată, șovăitoare, gângăvită)." and "Mă fac înțeles, dar discursul meu este de ex. disociat, ezitant, bâlbâit.". We kept the translation easier to understand even by patients with poor vocabulary: "Mă pot face înțeles/înțeleasă, dar vorbirea mea are unele deficiențe (de exemplu: vorbirea este dezarticulată, ezitantă, bâlbâită)."
Conceptual	Equivalence of the words? Does the item capture the speech function?	"Am unele dificultăți în vorbire, exemplu uneori mă bâlbâi sau încurc sensul cuvintele." and "Am dificultăți ușoare de vorbire , de ex. ocazional nu-mi găsesc cuvintele, mormăi sau schimb tonul." We kept some parts from the first translation, but the second one is more accurate and complete: "Am unele dificultăți în vorbire, de exemplu uneori nu-mi găsesc cuvintele, mă bâlbâi sau schimb sensul cuvintelor."
Consistency	Same expression	There are subtle differences that may cause problems for translators "Have you had. . .?" versus "Did you have . . .?". Both refer to past tense but the first refers to continuous episodes, the second to a single instance. Romanian language uses both past tenses.
Scaling	Do expressions capture intensity of symptoms, not frequency? Is the interval of the scale intact?	Item 4.1. had two different translations: "Pot avea dificultăți la respirație în timpul activităților solicitante sau a sportului, sau atunci când merg repede sau când urc pe un plan înclinat." and "Prezint scurtarea respirației în timpul muncilor fizice sau practicării sporturilor sau când mers pe jos în ritm alert pe un drum drept sau ușor înclinat." We kept the first part from first translator ("difficulty breathing") and the last part from the second translation, regarding "flat ground", to be easier to understand: "Pot avea dificultăți de respirație în timpul muncilor fizice sau a practicării sportului, sau atunci când merg repede sau când urc pe un drum înclinat."
Cultural diversity/ appropriateness	Has an issue a particular connotation in a given cultural context that is different from the original meaning?	Do not exist.

Table 1 Translation problems – taxonomy and examples

Discussion

The availability of high-quality translations will be of vital importance of the assessing QoL of the patients in Romania in the future. The goal of current management strategies for cancer is not only to improve survival but also to improve the overall QoL of patients. The importance of evaluating the patients' experiences during various stages of treatment is of overwhelming importance among health stakeholders.

The practicing oncologist can benefit greatly from the work that was performed in translating 15D scale, by applying the instrument to the selection of treatment modalities based on both treatment efficacy and the patient's wishes. In the future, QoL research in Romania will continue to be integrated into the practice of oncology.

In the pilot study, the cancer patients could complete the questionnaire in a longer time than the healthy subjects. This could be due to the severity of the diseases which made the patients need more time to focus on completing the questionnaires. The patients' cognitive function in understanding the questionnaires could be affected by multiple and severe symptoms in cancer (13). Nevertheless, all the patients in pilot testing must be able to fill in the questionnaire by themselves. The interpretation of this scale in a broad spectrum of cancer patients must be careful and might need to be validated when applying it to other types of cancer. This phenomenon may concur significantly to poor explanatory assessments. Ideally, the questionnaires should be given 72 h before the administration of the chemotherapy (14). However, the system in this hospital could not trace the patients 2–3 days before administration of chemotherapy. As a result, the questionnaires were given only a few hours before chemotherapy. Patients' memory and concentration levels a few hours before chemotherapy could be affected by patients' psychological distress.

The role of quality-of-life assessment in cancer care can be considered using 15D Romanian version due to the following outcomes, such as:

- to compare two standard therapies having similar survival outcomes;
- to identify the negative effects of the therapy when survival time is long;
- to find out whether a new therapy is preferable to standard therapy (cost-effectiveness analysis) in reimbursement decision;
- to determine whether a therapeutic regimen is better than supportive care only, when survival time is short. It is important to identify the needs for the supportive care and to determine negative effects of the adjuvant therapy;
- to target the problems and to facilitate the communication in clinical practice.

https://doi.org/10.52701/monc.2020.v1i1.16

Conclusions

The final Romanian version of the 15D can be used for the next step of validation.

Acknowledgements

We would like to acknowledge Harri Sintonen for helpful comments during the preparation of this manuscript. Harri Sintonen is the developer of the 15D and obtains royalties from its electronic versions.

Conflict of interest

The authors declare no conflict of interest.

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