TECHNICAL REPORT

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Coordinated Multi-Language Translation of A Validated Symptom Questionnaire for Carbohydrate Intolerances: A Practical Structured Procedure

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ABSTRACT

Background & Aims: Validated questionnaires help to minimize diagnostic bias, to standardize symptom assessment and to achieve comparability between studies and centers. In a recent European guideline the adult and the pediatric carbohydrate perception questionnaires (aCPQ and pCPQ), were recommended to be used for the diagnosis of carbohydrate intolerances in adult and pediatric patients. The implementation of this guideline into clinical practice makes availability of validated translations a necessity.

Methods: Clinical experts who recognized the need for these questionnaires to be available in their own language participated in the translation process. The tasks were assigned and a workflow following a predefined procedure based on recommendations of the Rome foundation was developed. The procedure had 5 phases: foundation, nomination, translation, revision, cognitive debriefing.

Results: Within eight months the aCPQ was translated into Bulgarian, French, Hungarian, Italian, Polish, Romanian, Russian and Slovenian language and the pCPQ into Dutch, French and Romanian. This expands the population which can be served with the aCPQ from 160 million to over 500 million Europeans. The reach of pCPQ expanded from 92 million to 193 million Europeans.

Conclusions: We report the development and implementation of a centrally organized process of translation of validated questionnaires, following a predefined procedure based on recommendations of the Rome foundation. This structured procedure may aid future efforts to standardize and harmonize the translation of validated questionnaires.

Key words: validation – questionnaire – translation – carbohydrates intolerance – aCPQ – pCPQ – Bulgarian – French – Hungarian – Italian – Polish – Romanian – Russian – Slovenian.

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Abbreviations: aCPQ: adult carbohydrate perception questionnaire; CT: counter translator; HO: head office; NL: national leader; pCPQ: pediatric carbohydrate perception questionnaire; T: forward translator.

INTRODUCTION

Validated assessment of symptoms is crucial for the diagnosis and the initiation of the therapy in many diseases and syndromes. Validated questionnaires help to minimize the diagnostic bias, to standardize the symptom assessment and to achieve the comparability between studies [1]. This is also relevant for the diagnosis of carbohydrate intolerances [2, 3] for which recently validated questionnaires for adult [2] and pediatric [4] patients have been published [the adult and the pediatric carbohydrate perception questionnaires (aCPQ, pCPQ)]. In a recent European guideline these questionnaires were recommended for the diagnosis of carbohydrate intolerances [5]. However, since these questionnaires were validated in German (aCPQ, pCPQ) and English (aCPQ), the implementation of the European guideline into clinical practice makes validated translations into various languages a necessity. In the past, local users who identified a need for a validated symptom questionnaire in their own language usually arranged translation and validation of published questionnaires. However, for the purpose of undelayed implementation of the recommendations of the guideline, the need for a fast and a coordinated translation of the aCPQ and pCPQ into a variety of languages was identified.

We report the development and implementation of a centrally organized process of translation, following a predefined procedure based on recommendations from the

Rome foundation. A structured description of the procedure is provided that can be adjusted to the translation of other validated questionnaires and the results of the implementation of this process are reported.

METHODS

The translation process was initiated by two of the authors (J.H., H.F.H.). The original versions of the questionnaires used for the translation process were in English (aCPQ) and German (pCPQ). Clinical experts who had participated in developing the European Guideline on hydrogen and methane breath tests and who recognized the need for questionnaires to be available in their own language were invited to participate in the process.

Structures and Roles

To define and assign responsibilities the following structures and roles were defined:

Head office (HO): Three authors (J.H., H.F.H., M.S.) developed, coordinated, managed, and supervised the process. The HO was responsible for the communications between institutions and for data processing. It contacted and nominated the national leaders and chaired the revision and modification of the translated questionnaires and approved the final version of the translated questionnaires.

National leaders (NL): Clinical experts for each country/language executed and monitored the national translation process. They named two forward-translators (T1, T2) and one counter-translator (CT), and were responsible for the revision and modification of the translated questionnaires. NL are listed as authors of this manuscript.

Translators 1 and 2 (T1, T2): The T1 and T2 had to be native speakers of the target language and fluent in English or German respectively. They translated the original questionnaire into the target language. The two forward-translators worked independently from each other.

Counter translator (CT): The CT had to be a highly experienced English or German speaker as well as fluent in the target language and was not involved in the forward translation process. The CT's translated the final forward translation back into the original language.

Translation Procedure

The flowchart diagram (Fig. 1) followed a published model (9) and illustrates the 5 phases of the procedure. The responsibility column assigns tasks with an "x" to the structures. The workflow column visualizes work steps (rectangles) and decision points (rhombus).

Phase 1: Foundation: Phase 1 comprises initiation of the process and the development of a standard procedure. Working structure, tasks for each role and the steps to be taken to achieve a validated translation were defined and a timetable for the process was developed that allowed flexibility.

Phase 2: Nomination: The HO contacted clinical experts to serve as NL for each language. For each language one or two NL were selected. The NLs nominated T1 and T2 and CT. Names and contact information of the nominees were sent to the HO to confirm the selection.

Phase 3: Translation: A written instruction was sent to the NL including a detailed description of the translation process, the original validated questionnaire (English or German version) and a proposed deadline for the first tasks. T1 and T2 translated the original questionnaire into the target language. T1 and T2 then compared their translations and identified differences. A reconciliation process together with NL and HO was conducted to combine the two versions into one final forward translation in the target language. The CT then translated this version back into English or German.

Phase 4: Revision: The NL and HO compared the original questionnaire and the counter translated version with emphasis on the similarity of language (literal translation) and comparability of interpretation (cultural adaptation). Discrepancies were identified and dealt with accordingly. In case the HO and NL judged a revision necessary, the questionnaire was rephrased to resolve differences. Once the translation met the required criteria, i.e. similarity and comparability a prefinal version of the questionnaire in the target language was approved.

Phase 5: Cognitive debriefing: The prefinal target language questionnaire was tested with 5 patients, who were handed a form to assess whether they perceived the questionnaire easy to understand, and unambiguous and clear on a 5-point Likert-Scale (face validity). The answers "yes" and "mostly yes" were defined as acceptance criteria. All other answers led to revision. The patients were also asked whether they would rephrase the questionnaire and had the opportunity to add suggestions. In the case of the pCPQ the form could be answered by the patients or the care givers. Based on the patients' feedback and the expertise of the HO and NL it was decided whether modification of the questionnaire was needed. If deemed necessary modifications were made by HO and NL. After the HO had checked the accuracy of the translation process, the final version of the target language questionnaire was approved.

RESULTS

Clinicians representing 12 languages or countries announced their interest in translating the aCPQ and seven announced they would translate the pCPQ by signing a conflict of interest statement. Within a period of eight months eight language groups completed the translation process for the aCPQ and three groups completed translation of the pCPQ. The translation started in July 2021 and was completed in March 2022. By this time validated translations of the aCPQ (original versions in German and English) were available in Bulgarian, French, Hungarian, Italian, Polish, Romanian, Russian and Slovenian and translations for the pCPQ (original version in German) were available for Dutch, French and Romanian. After phase 4, revision of the target language questionnaire was necessary in 7 of 10 translations before a prefinal version of the questionnaire was accepted. After phase 5, modification according to patient's suggestions was necessary in one of ten prefinal translations before the final version of the translated questionnaire was accepted.

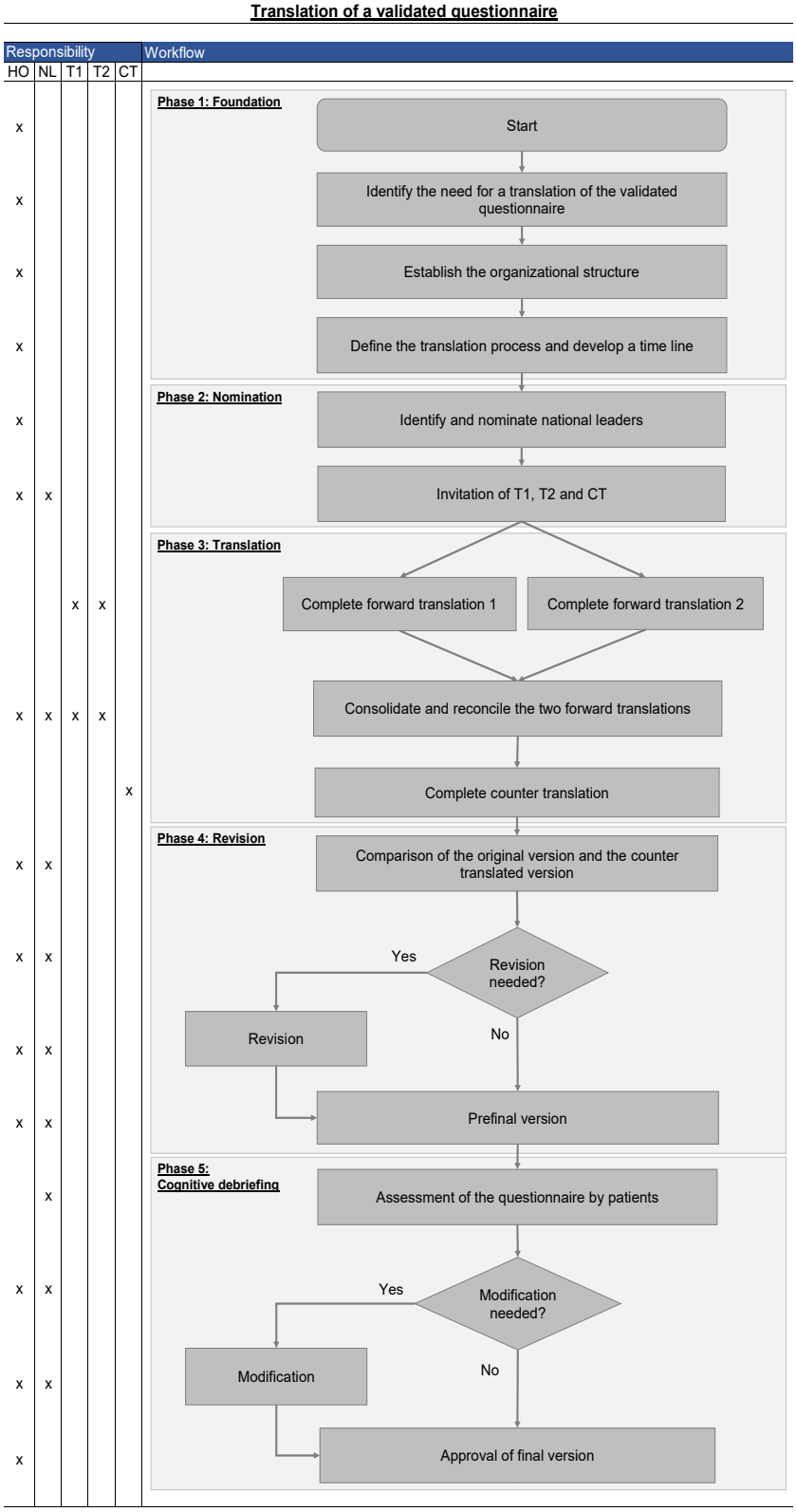

Fig. 1. Flowchart diagram of the coordinated translation procedure. The *responsibility column* assigns tasks with an "x" to the structures. The *workflow column* visualizes work steps (rectangles) and decision points (rhombus).

DISCUSSION

Validated questionnaires are valuable tools for the management of various clinical conditions and situations [1]. In general, their development results from a need for a validated, objective, and reproducible instrument for the measurement of symptoms and conditions. In many cases the need is identified for the purpose of clinical studies; however,

many of these questionnaires are used later in clinical routine [10, 11].

Recently two validated questionnaires for the diagnosis of carbohydrate-induced gastrointestinal symptoms in pediatric and adult patients have been published (aCPQ, pCPQ) [2, 4]. They allow for standardized and unbiased assessment of symptom severity after ingestion of a test carbohydrate in the course of carbohydrate breath tests and therefore allow a valid diagnosis of carbohydrate intolerance [5]. To make these questionnaires available for their use in different languages they needed to be translated in order to allow the quick implementation of the recommendations of the European guideline to use validated symptom questionnaires for the diagnosis of carbohydrate intolerances [2]. We considered it important to develop and conduct a translation process that would result in translations that did not need an additional validation process. To achieve this, a process based on guidelines published by the Rome Foundation [6-8], was developed.

Of the nineteen country/language groups that had signaled their interest to participate, 10 groups proceeded to nominate translators and counter-translators. Phase 3 was originally estimated to take 4 weeks but needed to be extended. After completing phase 4, the majority of translated questionnaires (7 of 11) required further revision by the NL and HO. Each prefinal version was tested with five patients to assure face validity. Only one of the eleven prefinal versions required further modification before the final target language questionnaire was approved.

The completed translations extend the reach of the aCPQ from its original German and English version to eight additional languages. This extends the population which can be served with the aCPQ from an approximate European population of 160 million to over 500 million people. The pCPQ was translated into Dutch, French and Romanian, expanding the size of the European population that can be served from 92 million people to 193 million people [12]. Within these populations the aCPQ can be used for adults, whereas the pCPQ can be used for children and adolescents up to 18 years of age.

We are confident, that the outlined structured translation procedure can serve as a blueprint for future initiatives.

CONCLUSIONS

We report the development and implementation of a centrally organized process of translation of validated questionnaires, following a predefined procedure based on recommendations of the Rome foundation. This structured procedure may aid future efforts to standardize and harmonize the translation of validated questionnaires.

Conflicts of interest: None to declare.

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Authors' contribution: J.H. and H.F.H. developed the translation process. J.H., H.F.H. and M.S. led the head office, collated the information, and produced the first draft of the manuscript. G.B., O.B., M.B., D.B., D.D., B.H., L.L., A.M., F.M., R.N., V.N. and B.T. served as national leaders for the translation processes and discussed and revised the draft and approved the final version of the manuscript.

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Supplementary material: To access the translated questionnaires visit the online version of the *J Gastrointestin Liver Dis* at http://dx.doi.org/10.15403/jgld-4463.

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