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Translation to Portuguese and cultural adaptation of Food Allergy Quality of Life Questionnaire - Parent Form (FAQLQ-PF)

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Summary

Food allergy is a health problem with significant negative impact in Quality of Life (QoL). We aimed to translate into Portuguese and culturally adapt to our population the Food Allergy Quality of Life Questionnaire - Parent Form (FAQLQ-PF). Cross-cultural translation was performed according to guidelines. Linguistic validation consisted in 3 steps: forward translation, backward translation and comprehensibility testing. A consensual version was obtained and tested in parents of food allergic children by cognitive debriefing. Twelve questionnaires were fulfilled, all completed in ≤ 15 min. No comments, doubts or suggestions were posed, except for 2 parents regarding a question about the number of food their children had to avoid. Two gave special positive feedback about the utility of FAQLQ-PF. Changes have been included after this pre-test in accordance to doubts and suggestions of participants, and the Portuguese version is now able to be used in clinics and research.

Introduction

Worldwide, a large number of health assessment tools have been produced and validated, providing more accuracy to individual and collective assessments of health status. Health-related QoL (HRQL) is defined by the World Health Organization (WHO) as: “the effects of an illness and its consequent therapies upon a patient as perceived by the patient” (1,2). This has been increasingly recognized as an important health assessment outcome measure, and there is currently a growing interest of the scientific and the health care communities in tools validated throughout the world and able to quantify this subjective outcome. HRQL

gives insight in the impact of disease from the patient’s perspective and therefore clinicians can assess HRQL to get insight into the specific problems of patients, and to follow-up over time the effect of a chosen management. The clinician could therefore discuss areas most affecting HRQL with the patient, and help them to manage the mentioned problems. HRQL can be measured with questionnaires, also called instruments or scales (3). These assessment measures, increasingly used, are most of the times formulated in English, targeted for its use only in the English-speaking population.

In order to use these health evaluation tools developed and applied in another language, translation and cross-cultural adapta-

tion of the proposed tool should be carried out, otherwise another measure should be developed (4). Translation and cultural adaptation of health questionnaires published in other cultures is important in the international setting, as they provide the use of the tool in clinical practice and in research, provide greater accuracy in measuring health aspects related to the population in question, comparison of results between different samples, as well as the cross-cultural studies. This entire process turns the application into a more reliable, understandable tool, and part of the cultural aspects of the specific population under investigation.

A critical aspect in the management of allergic diseases is their subjective impact (5). Available data show that, from the patients' perspective, allergy is more than just an annoying disease: when compared to healthy subjects, patients with asthma, rhinitis, chronic urticaria, atopic dermatitis and food allergy reported markedly reduced HRQL (6). Food allergy is sometimes a long-lasting disease and has significant negative impact in QoL of patients and their families (7). As there is no cure available, the only form of treatment is strict avoidance of foods causing allergic reactions and provision of emergency treatment (8), which may interfere with daily life (9). In addition, a chance of accidental exposure, which could lead to a severe allergic reaction, may in turn be a source of anxiety (10). Emerging treatments such as oral immunotherapy and anti-IgE therapy may alter QoL but valid and reliable instruments are needed to measure such changes (11). In this context, reliable and valid disease-specific questionnaires to measure HRQL in food allergy have become available recently (11-14). However, food allergy mostly affects children (8), and difficulties in assessing HRQL in children may arise because of age, lack of insight, cognitive limitations, differences in language ability and understanding and sensitivity to social threat, or normative pressures (15). Parents are usually intermediates and so, a food allergy-specific questionnaire allowing parents to report children's HRQL from the child's perspective was recently developed and validated (11). It has been translated into nine languages, but not yet into Portuguese.

Given the little availability of specific assessment tools designed for evaluating HRQL of food allergic patients in Portugal, and since children are the most frequently affected age-group, we aimed to translate the Food Allergy Quality of Life Questionnaire - Parent Form (FAQLQ-PF) into Portuguese and culturally adapt it to the Portuguese population.

Methods

Study design and Subjects

For this cross-sectional study, subjects were recruited from Allergy Departments of a private and a public hospital. Children aged 0-12 years-old, with confirmed immediate IgE-mediated food allergy, who were present at the hospitals for their scheduled

appointments accompanied by a parent, were randomly selected. Medical records and prior diagnostic tests were assessed by the investigators, to determine eligibility. The diagnosis of food allergy had been previously established based on international guidelines: a compatible clinical history in combination with the presence of positive skin prick tests, positive specific IgE and a positive (presence of objective symptoms and/or signs compatible with food allergy - either mucocutaneous, respiratory, abdominal manifestations, alone or combined) oral open food challenge or the occurrence of a recent reproducible reaction (8). In order to be eligible, food allergy had to still be active at the time of the study. Parents of selected eligible children were invited to participate.

Parents were asked to fulfill the questionnaire, and instructions were given by the investigators on how to proceed. Time needed to complete the questionnaire and the feedback provided by parents as well as questions raised during the process and suggestions for questionnaire comprehensibility were recorded by the investigator.

The research project was approved by the Ethics Committee and carried out in accordance with the Declaration of Helsinki. A written consent was signed by all included subjects.

Translation and cross-cultural adaptation methods

The process of linguistic equivalence was initiated by contacting the authors of the original questionnaire in order to define their concepts and ask for authorization to use it in the present study. Cross-cultural translation was performed according to guidelines (16).

Forward translation (translate from source language, English, to the target language, Portuguese) was performed by two independent translators that had no previous knowledge of the questionnaire, originating versions 1 and 2 (V1 and V2). Both were native speakers in the target language and bilingual in the source language; two independent translations were obtained. Supported by an experienced specialist in food allergy diagnosis and treatment, a combined version (V3) was obtained between V1 and V2. Agreement was achieved through unanimity on a single reconciled version with all elements (translators and physician).

During forward translation, different interpretations were obtained from the translators work, and are presented in **table 1**. During all the questionnaire, the expression *child* was translated differently "criança" versus "filho"; as it is frequently filled in by parents the expression "filho" was chosen. In section C, similar translations were reached by the translators. In section D question P8b, the expression *reassurance* caused some doubts, and after translation "conforto" was considered the most appropriate. In section D question P10, there was differences in the translation of *stuffy nose, itchy in the ears, redness of the skin, light-headedness, inability to stand*, the following expressions were

reached after consensus and correspond respectively to “nariz entupido”, “comichão nas orelhas”, “vermelhão na pele”, “sensação de desmaio”, “não se suster de pé”.

V3 was backtranslated into English by other independent translator who was bilingual speaker and not acquainted with the questionnaire. Later, a comparison of the backtranslated version with the original English language questionnaire was performed by the expert research. Discrepancies were documented and analyzed by all elements participating in the cross

cultural translation procedure with regard to their applicability and cultural equivalence. The following inconsistencies were noticed between the original questionnaire and the back translated version:

- The items choices differed from the original version, however they had similar meanings, and therefore the translated options were kept.
- In question 4, the original expression “afraid to try unfamiliar foods” was different from the backtranslation “Afraid to

Table 1 - Different interpretations obtained from the translators work during forward translation and the final consensus choice.

Localization	Original expression	Options of the independent translators	Final choice
Instructions	<i>Scenarios</i>	“Situação” “Cenário”	Cenário
Section A			
question 1	<i>Food</i>	“Alimentação” “Comida”	Comida
question 3	<i>Dietary restriction</i>	“Restrições dietéticas” “Restrições alimentares”	Restrições alimentares
questions 6, 7 and 8	<i>Experience</i>	“Sente-se” “Experiência”	Experiência
Section B			
question 16	<i>New places</i>	“Sítios novos” “Locais diferentes”	Sítios novos
question 17	<i>Concerned that he/she must always be cautious about food</i>	“Preocupado por ter de estar sempre alerta quanto à comida” “Apreensiva(o) por ter sempre de ser cuidadosa(o) em relação à sua alimentação”	Apreensiva(o) por ter sempre de ser cuidadosa(o) em relação à sua alimentação
question 23	<i>More anxious in general</i>	“Geralmente é mais preocupada” “É mais ansioso”	É mais ansioso
Section D			
question P4	<i>Vegetables</i>	“Legumes” “Vegetais”	Legumes
question P8b	<i>Reassurance</i>		Conforto
question Q9	<i>Dietician</i>	“Dietista” “Nutricionista”	Dietista
questions P1, P2 of part 2	<i>treating himself</i>	“Se auto tratar eficazmente” “Se tratar a si próprio com eficácia”	Se tratar a si próprio com eficácia
part 3, question P1 and P3	<i>None at all</i>	“Nenhuma” “Nada”	Nada
part 3	<i>some</i>	“Moderadamente” “Mais ou menos”	Mais ou menos

try new foods”; since the meaning might not be exactly the same it was changed.

- In question 5 and 17, instead of *concerned*, the expression *apprehensive* was used in the backtranslation; despite the similarities, the expression could be doubtful in comprehensibility and it was changed (question 17).
- In section D, Part 1, “Your child’s food allergy” differed from the original version “My child’s food allergy”; translation was changed to adapt to the original version.
- In question Q10, the symptoms that differed were *tears, redness of the skin, light-headedness* and *inability to stand*, however the meanings were similar and the translated expressions were not changed.
- In part 3 there was a difference in the selected options of the questionnaire, namely in the translation of *none at all*, which was backtranslated to *nothing*; since the translation has the same meaning it was accepted.

The final backtranslated version was reached by consensus and then sent to the original authors for approval and their suggested changes were incorporated. After that, some terms had to be modified aiming at a better understanding by patients.

Then, the pre-final version (PFV) of the questionnaire was obtained and applied to parents of food-allergic children by cognitive debriefing. The possible difficulties related to the text and time required to fill it were investigated. The translation was again assessed according to the results, and an updated and modified final version (FV) of the questionnaire was obtained (*Annex 1*).

Results

There were no refusals to participate in the study. Twelve parents were recruited, 11 mothers and one father. All took ≤ 15 min to complete the PFV questionnaires. Demographic and food allergy characteristics of the children which parents were enrolled in the study sample are presented in **table 2**.

During the forward and backward translations, some questions were raised regarding the adequate expression for the grading scale. Furthermore grammatical and conceptual terms were discussed and corrected by consensus. One spelling error and two words lacking translation from the English version were identified. In the cognitive debriefing no comments, doubts or suggestions were done, except for 2 parents regarding a question about the number of food their children have to avoid. In this same question, 5 parents failed to correctly answer it. The sentence was reworded. All these changes were incorporated in the FV (*Annex 1*). Data related to the understanding of the FAQLQ-PF and changes performed in the final version in accordance to suggestions are presented in **table 3**. Two parents gave special positive feedback about the suitability and utility of FAQLQ-PF. Parents of 3 children (all aged < 3 years) considered

that parts of FAQLQ-PF were not adequate to their children, given their age.

Table 2 - Demographic and food allergy characteristics of the children which parents were enrolled in the pilot study sample.

Characteristics	n (%)
Age	
< 4 years	7
4 - 7 years	2
> 7 years	3
Symptoms of food allergy	
Anaphylaxis	9
Mucocutaneous involvement	3
Number of allergens	
Allergic to only 1 food allergen	7
Allergic to > 1 food allergen	5
Foods implicated in food allergy	
Milk	7
Egg	7
Tree nuts	1
Fish	1
Shrimp	1

Table 3 - Changes made after the cognitive debriefing process.

Original misunderstood terms / sentences	Pre-final version	Final version
General	<i>Gral</i>	Geral
Extremely	<i>Extremely</i>	Extremamente
Accidental	<i>Accidental</i>	Acidental
How many foods does your child have to avoid?	<i>Quantos alimentos diferentes o seu filho tem de evitar?</i>	A quantos alimentos diferentes o seu filho tem alergia?

Discussion

In the present study, a tool allowing parents to report children’s HRQL from the child’s perspective was translated and culturally adapted for use in Portuguese speaking population. The original version of FAQLQ-PF was primarily developed to as-

sess patients in English, and so it was necessary to translate and adapt to the social and cultural circumstances of our language. One factor that ensures the applicability of FAQLQ-PF in Portugal is the methodology used in the process of translation and cross-cultural adaptation of the questionnaire, which has been shown to preserve the sensitivity of the measure (17) as well as promoting an appropriate level of equivalence between the versions. It is known that the internal structure, semantics, and psychometric characteristics of a measure may change when it is translated to another language. This is more common if the process of cross-cultural equivalence is not correctly performed. Cross-cultural adaptation of a psychometric measure is a complex process that requires a translated version that is conceptually equivalent to the original version and culturally acceptable in the target country, but is important that all steps are rigorously performed. Technical and semantic equivalence should be sought between the source and target versions in order to avoid misinterpretation of data in the future.

Cross-cultural adaptation is relevant because, currently, there is no other HRQL measure for children with food allergy in Portugal. The decision to culturally adapt the FAQLQ-PF, rather than to develop a new measure, was based on the fact that the adaptation of a previously described and validated measure, which has been translated and validated to other languages, makes it possible to compare results across studies conducted in different countries. HRQL measurements may be used to measure the effects of interventions generally on patients' quality of life, and may also be used to compare the effect of different interventions on HRQL (18).

New interventions for food allergy treatment are under investigation, which represent alternative approaches and are already changing the paradigm of strict dietary avoidance for patients with food allergy (19). There is a need to reach a global picture of patient's perspective about these new strategies, so it is mandatory available tools to measure it. Desensitization protocols for food allergic patients have been successfully applied in Portugal and recently reported in literature (20-23), but given the lack of tools to measure the HRQL resulting from these treatments, such outcomes were not reported. This present study contributes to attain this gap.

Furthermore, a recent report identified the need for a more correct and extensive assessment of allergic patient-reported outcomes (PROs), both in clinical trials and in routine practice, to capture information unavailable from other sources, which is crucial for predicting health outcomes, for establishing health policy and for the optimal management of allergic diseases (5): the need to develop clinical trials in which PROs are the primary or co-primary outcome; and the necessity to assess patients' viewpoint with a rigorous methodological procedure (use of validated tools, correct administration of the questionnaires

and report of complete results). By providing a tool to measure PROs translated in Portuguese using rigorously methodological steps, our study goes towards the needs for allergic patients.

PROs recently gained great attention by regulatory bodies due to their importance in the overall treatment efficacy assessment (5,16,24). HRQL studies may be used by policy makers to improve the allocation of healthcare resources and, ultimately, combining HRQL data with epidemiologic data on prevalence may give insight into the societal impact of a disease (25), and therefore studies in this area help to provide the best possible care for allergic patients.

Conclusion

The Portuguese version of the FAQLQ-PF has been translated and culturally adapted for use in Portuguese speaking population. Changes have been included after the pre-test in accordance to doubts and suggestions of participants. The Portuguese version of the questionnaire can now be used both in clinical trials and in routine practice.

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