

short communication

Cross-cultural adaptation and face validity of the PREM-C9 version of the Patient Reported Experience Measure in patients with Chronic Obstructive Pulmonary Disease

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Abstract

Context. The 'Patient Reported Experience Measure in Chronic Obstructive Pulmonary Disease (PREM-C9)' is a scale developed and validated within the English healthcare context to better measure and understand the experience of patients with chronic obstructive pulmonary disease (COPD) and the care that they receive¹.

Objective. To cross-culturally adapt the PREM-C9 questionnaire into Catalan and Spanish.

Methods. The process to adapt the PREM-C9 questionnaire consisted of the following phases: production of a first consensus version in the target languages; Backtranslation; Cognitive debriefing; Face validity and Harmonisation. In the cognitive debriefing phase, the questionnaire was tested in a convenience sample of 10 patients with COPD (5 in Catalan and 5 in Spanish).

Results. Forward (FT) and back translation (BT) stages: Overall, the language used in the original version of the questionnaire did not cause substantial problems for translation into Catalan and Spanish. Face validity and cognitive debriefing: The content was considered relevant both by the health care professionals who participated in the assessment of face validity, and by the patients who participated in the cognitive interviews. However, some potentially relevant concepts were noted by patients and professionals as being lacking in the questionnaire. Harmonisation: It allowed the research team to pull together the best elements of the Catalan and Spanish versions and use them to optimise and align the wording in both.

Conclusions. By following a rigorous, multi-phase process of cultural adaptation, it was possible to produce versions in Catalan and Spanish of the PREMS-C9 questionnaire, which were acceptable to patients and health-care professionals.

Keywords: PREMs, Patient Reported Experience Measurements, COPD, Patient Experience, cross-cultural adaptation

Resum

Adaptació cultural i validesa de la versió PREM-C9 de la mesura reportada pel pacient en pacients amb malaltia pulmonar obstructiva crònica. L'experiència del pacient en la malaltia pulmonar obstructiva crònica (PREM-C9) és una escala desenvolupada i validada en el context sanitari anglès per a mesurar i comprendre millor l'experiència dels pacients amb EPOC i l'atenció que reben¹. **Objectiu.** Adaptar transculturalment el qüestionari PREM-C9 al català i al castellà. **Mètodes.** El procés d'adaptació del qüestionari PREM-C9 va constar de les següents fases: elaboració d'una primera versió consensuada en els idiomes de destí; traducció inversa; debriefing cognitiu, validesa aparent i harmonització. En la fase de debriefing cognitiu, el qüestionari es va provar en una mostra de conveniència de 10 pacients amb EPOC (5 en català i 5 en castellà). **Resultats.** Etapes de traducció cap endavant (FT) i traducció cap endarrere (BT): En general, l'idioma utilitzat en la versió original del qüestionari no va causar problemes substancials en la traducció al català i al castellà. Validesa i debriefing cognitiu: El contingut va ser, en general, considerat rellevant punt pels professionals sanitaris que van participar en l'avaluació de la validesa com pels pacients que van participar en les entrevistes cognitives. No obstant això, tant els pacients com els professionals van assenyalar que faltaven en el qüestionari alguns conceptes relacionats amb la rehabilitació, aprendre a respirar o bregar amb una exacerbació. Harmonització: Va permetre a l'equip de recerca identificar els millors elements de les versions en català i castellà i utilitzar-los per a optimitzar i alinear la redacció en ambdues. **Conclusions:** seguint un rigorós procés d'adaptació cultural, va ser possible produir versions en català i castellà del qüestionari PREMS-C9, que van resultar acceptables per als pacients i els professionals sanitaris.

Paraules clau: PREMs, Patient Reported Experience Measurements, EPOC, Experiencia de paciente, adaptació cultural

Resumen

Adaptación cultural y validez de la versión PREM-C9 de la medida reportada por el paciente en pacientes con enfermedad pulmonar obstructiva crónica. **Contexto:** la experiencia del paciente en la enfermedad pulmonar obstructiva crónica (PREM-C9) es una escala desarrollada y validada en el contexto sanitario inglés para medir y comprender mejor la experiencia de los pacientes con EPOC y la atención que reciben¹. **Objetivo:** adaptar transculturalmente el cuestionario PREM-C9 al catalán y al castellano. **Métodos:** el proceso de adaptación del cuestionario PREM-C9 constó de las siguientes fases: elaboración de una primera versión consensuada en los idiomas de destino; traducción inversa; debriefing cognitivo, validez aparente y armonización. En la fase de debriefing cognitivo, el cuestionario se probó en una muestra de conveniencia de 10 pacientes con EPOC (5 en catalán y 5 en castellano). **Resultados.** Etapas de traducción hacia adelante (FT) y traducción hacia atrás (BT): en general, el idioma utilizado en la versión original del cuestionario no causó problemas sustanciales en la traducción al catalán y al castellano. Validez y debriefing cognitivo: el contenido fue, en general, considerado relevante tanto por los profesionales sanitarios que participaron en la evaluación de la validez como por los pacientes que participaron en las entrevistas cognitivas. Sin embargo, tanto

los pacientes como los profesionales señalaron que faltaban en el cuestionario algunos conceptos relacionados con la rehabilitación, aprender a respirar o lidiar con una exacerbación. Armonización: permitió al equipo de investigación identificar los mejores elementos de las versiones en catalán y castellano y utilizarlos para optimizar y alinear la redacción en ambas. **Conclusiones:** siguiendo un riguroso proceso de adaptación cultural, fue posible producir versiones en catalán y castellano del cuestionario PREMS-C9, que resultaron aceptables para los pacientes y los profesionales sanitarios.

Palabras clave: PREMs, Patient Reported Experience Measurements, MPOC, Experiència de pacient, adaptació cultural

Introduction

The 'Patient Reported Experience Measure in Chronic Obstructive Pulmonary Disease (PREM-C9)' is a scale developed and validated within the English health-care context to better measure and understand the experience of patients with chronic obstructive pulmonary disease (COPD) and the care that they receive¹. It consists of 9 items distributed in 3 subscales that measure the impact of COPD in the daily lives of patients, their opinion of the health care they receive, and their expectations about the care they will receive in case of an exacerbation of the disease.

There is no validated scale in Catalan or Spanish to evaluate the experience of patients with COPD and their COPD-specific health care. Having such a tool available can potentially contribute to the evaluation of the impact of the disease and to quality assessment of the care received in the context of the Catalan health care system. However, given that concepts relevant to patients and the organisation of health care can vary between countries, it is important to ensure a rigorous process of cross-cultural adaptation is used when planning to use a questionnaire like the PREM-C9 in another country and language.

Objective

To cross-culturally adapt the PREM-C9 questionnaire into Catalan and Spanish and to identify items which are potentially not relevant in that context as well as wording or other aspects of the scale which make it difficult to use for Catalan or Spanish-speaking patients.

Methods

Translation and cross-cultural adaptation of the PREM-C9 questionnaire into Spanish and Catalan was conducted according to *International Society for Pharmacoeconomic and Outcomes Research*² guidelines. The author of the original questionnaire¹ gave permission to adapt the PREM-C9 into Catalan and Spanish and the process consisted of the following phases:

Production of a first consensus version in the target languages.

Two translators who were native speakers of the target languages independently prepared a translated version of the questionnaire, two independent versions in Catalan and two independent versions in Spanish. Translators were requested to produce a version which was as faithful as possible to the original English version but which, as far as possible, used natural and understandable wording in the target language.

The two independent translations in each language were reviewed and compared by the research team until, following discussion, a consensus version was agreed upon for each. These were designated as the first consensus versions in Catalan and Spanish.

Backtranslation phase. In this phase, the first consensus Catalan and Spanish versions were each translated back into English by two native English speakers who were fluent in Catalan or Spanish. Therefore, a total of four native English-speakers participated in this process. The back-translations for each version were reviewed and compared, both with each other and with the original version. Any discrepancies between back-translated versions and/or with the original were identified and discussed by the research team, and modifications were made to Catalan or Spanish versions if considered necessary, to better transmit the meaning of the original. The result of this phase was designated the second consensus Catalan and Spanish versions.

Cognitive debriefing. In this phase, the second consensus version of the questionnaire was tested in a convenience sample of 10 patients with COPD (5 in Catalan and 5 in Spanish). There were 9 men and 1 woman and the average age was 68.8 years. The objective was to learn their opinion of the translated version and how they interpret each part of the questionnaire; the instructions, the response options, and the items or questions that make up the questionnaire. A further aim was to determine whether they had any difficulty understanding and responding to the questionnaire, and whether any further modifications to wording were needed.

Patients to be interviewed were identified by staff at the Hospital Clinic de Barcelona. After explaining the objectives of the study to patients and the implications of their participation, staff asked them for verbal consent to a) participate in the interviews, and b) provide their contact details so they could be contacted by the interviewer.

The interviews were conducted by phone or Skype due to the situation caused by COVID19. All interviews were conducted by an experienced interviewer who was bilingual in Catalan and Spanish. A topic guide was used for the study that included the following aspects:

- The patient's overall opinion of the questionnaire
- Whether content covered all relevant aspects of their experience of COPD and associated health care
- Ease of completion
- Comprehension and interpretation of each item

Face validity and harmonization were two additional aspects incorporated into

the project that are not always included in the standard process of cultural adaptation.

To assess face validity, the translated versions of the questionnaire were reviewed by a convenience sample of several health professionals working with COPD patients within the Catalan health care system. Face validity refers to whether, on the surface, a questionnaire appears to measure what it is intended to measure: does it appear to cover all relevant questions, and does it use appropriate language. In the present study, health professionals were asked about the relevance of content overall, whether they considered any important aspect to be missing, bearing in mind the objective of the questionnaire, and whether the patients they see on a daily basis would have trouble answering the questionnaire. In addition to these general questions, professionals were also asked for their views on specific aspects of the questionnaire, such as the most appropriate way to refer to an exacerbation of COPD so that patients could better understand it.

Harmonisation

Finally, in a last review by members of the research team, the Catalan and Spanish versions of the questionnaire were compared in order to 'harmonize' them as much as possible. This was considered important as both language versions could be used in the same study, making it necessary to pool data obtained with them. Each part of the questionnaire was reviewed and changes were introduced as necessary to ensure that the terminology used and way items were formulated was as similar as possible.

Results

Forward (FT) and back translation (BT) stages

Overall, the language used in the original version of the questionnaire did not cause substantial problems for translation into Catalan and Spanish. However, a number of changes were felt necessary and were introduced either at the FT or BT stages.

The use of direct translations of some of the original English words lead to unnatural-sounding language in Catalan and Spanish, via the introduction of terms that would not naturally be employed by native Catalan or Spanish speakers. In other cases, direct translations were avoided because they could lead to ambiguous or possibly misleading interpretations of the concepts included in the PREMS-C9 (table 1).

Face validity and cognitive debriefing

The content was, overall, considered relevant both by the health care professionals who participated in the assessment of face validity, and by the patients who participated in the cognitive interviews. However, some potentially relevant concepts relating to rehabilitation, learning to breathe, or dealing with an exacerbation were noted both by patients and professionals as being lacking in the questionnaire.

On the part of the professionals, further aspects they considered to be missing were questions about therapeutic compliance, and questions about “aspects that are of great concern to patients”, such as oxygen therapy, weight of devices, exercise and physical activity, social relationships, treatments, and the amount of medication to take.

Examples of problematic wording highlighted	
'frustrated'	Although a direct translation exists (e.g. frustrat, in Catalan), it is not a word that is widely used, perhaps especially among the older population. Different options were discussed (and in some cases included for further testing during cognitive debriefing) and the direct translation was not used in any of the items in the final translated versions. In item 1 ('I am frustrated and unhappy by the limitations to my lifestyle caused by COPD'), 'frustrated' was replaced in Catalan by 'decebut' and in Spanish by 'decepcionado' (disappointed), an option which was proposed by patients. In item 6 ('I am frustrated by my lack of information about my condition'), 'frustrated' was replaced by 'worried', as that seemed to be the closest natural-sounding alternative.
'lifestyle'	It was felt that the direct translation ('estil de vida', in Catalan) might sound a little odd in this context as it could be associated with, for example, leading a 'luxurious lifestyle'. The alternative proposed during FT was 'la meva vida diaria' (my daily life), and on testing with patients was found to be generally preferred.
'I feel'	This is used to introduce a number of items in the English version but is not such a widely used construction in Catalan or Spanish, where it would be more natural just to go straight to the gist of the sentence. E.g. Instead of saying 'I feel that I do not have any support from others like my family/friends/carers', it would be more usual to simply say 'I do not have any support from others like my family/friends/carers'. However, to retain as much fidelity as possible with the original and to make the translation as natural as possible, 'I feel..' was replaced with 'I have the feeling that...' in a number of items, as that sounds somewhat more natural in the target language.
In item 9, ('I am not worried about the care I will get from health professionals when I get a 'flare-up'),	A direct translation was avoided as it can also transmit the idea of 'I do not care about the care I will get ...'. The alternative used was 'I am confident in the care I will get from health professionals...', which was felt to be less ambiguous.
'I am happy to talk about the future' (item 4)	Was interpreted as meaning that the patient would have no problem in talking about the future (as might be the case for some patients) rather than that talking about the future would literally make the patient happy, and different phrasings for this option were tested in the cognitive interviews.

Table 1: Examples of problematic wording highlighted in the forward and back translation stages, and solutions applied.

The professionals consulted also considered that 'the questions are relevant as well as short and simple, which should allow the questionnaire to be applied in usual care'. With respect to whether they thought patients would find the instrument simple to respond to, they suggested that, while the questionnaire is accessible in general, some patients may have difficulties understanding and answering some of the questions, especially those of advanced age and/or with lower levels of education.

A key comment from several patients was that the current response system was difficult to use and might be problematic for other patients. It was not a system they were used to, and several considered the scale to be 'back to front',

if they considered that the positive statement in each item should be given the highest score, of '5', and the negative statement, reflecting the highest level of problems or concerns, should be rated as '0'. Some patients also thought it would be easier to respond to a scale numbered 0 to 10. This was considered an important finding of this project and it is recommended that further testing, perhaps in a pilot study in a larger number of patients, be carried out to determine to what extent the current response format can be used as it is. Such findings can also highlight potential problems when the questionnaire is applied in field work.

Professionals and patients also made several comments which led to changes in the wording of the second consensus version. For example, patients noted that the idea of being able to 'control' one's illness (item 3) was unrealistic, as it suggested they could somehow switch their illness on or off, or reduce the severity of the symptoms. However, they did not suggest any suitable alternatives. After discussions in the research team, it was decided to use Catalan and Spanish wording which would rather suggest the idea of being able to cope with one's illness.

According to several patients, it also did not make sense to refer to GPs as the primary point of contact or care provider, as in the original version. The patients interviewed generally considered that it was much more usual for them to deal directly with a specialist, but not with a GP. For that reason, the Catalan and Spanish versions do not refer to GPs specifically, but to 'doctors'. This highlights the need for this type of rigorous adaptation procedure, as it flags up items which may not be appropriate across all health care systems.

Harmonisation

This was a very useful stage because it allowed the research team to pull together the best elements of the Catalan and Spanish versions and use them to optimise and align the wording in both. For example, suggestions from the Spanish-speaking patients were sometimes used to re-word the Catalan version, and vice versa. It was possible to achieve closely harmonised versions of the questionnaire in Catalan and Spanish which should facilitate the comparison and/or pooling of data when the two language versions are used in the same study.

Conclusions

By following a rigorous, multi-phase process of cultural adaptation, it was possible to produce versions in Catalan and Spanish of the PREMS-C9 questionnaire, which were acceptable to patients and health-care professionals. These new language versions of the PREMS-C9 take into account that some aspects of care for patients with COPD may differ between the Catalan setting and the English setting in which the questionnaire was originally produced. The Catalan and Spanish language versions require further psychometric and feasibility testing in larger samples to ensure that they will produce valid and reliable results in our setting, especially given the comments from patients about the response system used.

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Annex 1. COPD Patient Experience Healthcare Questionnaire

This questionnaire is designed to help us learn more about your experience of living with Chronic Obstructive Pulmonary Disease (COPD) and the care that you receive in relation to this condition.

Please read the questions carefully and ask if you do not understand anything. For each question please add a cross to one box that best matches your experience.

Name: _____ Date: _____

EXAMPLE:

	LOW SCORE							HIGH SCORE
0.	I am very happy	0	1	2	3	4	5	I am very sad

My everyday life with COPD - These questions relate to your everyday life with COPD

	LOW SCORE							HIGH SCORE
1.	I have accepted the limitations to my lifestyle caused by COPD	0	1	2	3	4	5	I am frustrated and unhappy by the limitations to my lifestyle caused by COPD
2.	I feel that I have good support from others like my family/friends/carers	0	1	2	3	4	5	I feel that I do not have any support from others like my family/friends/carers
3.	I feel that I am in control of my condition	0	1	2	3	4	5	I feel that I do not have any control over my condition
4.	I am happy to talk about the future	0	1	2	3	4	5	Talking about the future makes me feel depressed

Usual care in COPD - These questions relate to the everyday usual care given of your COPD

	LOW SCORE							HIGH SCORE
5.	I am confident that my GP will listen to my point of view	0	1	2	3	4	5	I am concerned that my GP will not listen to my point of view
6.	I have enough information about my condition	0	1	2	3	4	5	I am frustrated by my lack of information about my condition
7.	I understand how my COPD treatments work	0	1	2	3	4	5	I am confused about how my COPD treatments work

COPD Exacerbation (Flare up) - These questions relate to a flare-up of your COPD

	LOW SCORE							HIGH SCORE
8.	I am confident that in a 'flare up' I have quick access to treatment like a rescue pack or access to my GP/nurse	0	1	2	3	4	5	I am worried that in a 'flare up' I do not have quick access to treatment like a rescue pack or access to my GP/nurse
9.	I am not worried about the care I will get from health professionals when I get a 'flare-up'	0	1	2	3	4	5	I am worried about the care I will get from health professionals when I get a 'flare-up'

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