Portuguese adaptation and validation of a patient-reported experience measure for patients with rheumatoid arthritis: A protocol study

Daniela Oliveira, MD[a,b,c,*], Miguel Bernardes, PhD[a,c], Carlos Vaz, PhD[a,c], Lúcia Costa, MD[a], João Almeida Fonseca, PhD[b,d,e,f], Cristina Jácome, PhD[b,d]

Abstract

Background:
There is a growing attention to patient-reported experience measures in assessing the quality of care in patient-centered care models. A specific patient-reported experience measure for patients with rheumatoid arthritis (RA) has been developed in the United Kingdom—Commissioning for Quality in Rheumatoid Arthritis Patient-Reported Experience Measure. This patient-reported experience measure might be feasible to be used in Portugal, yet an adaptation and validation process is needed. Therefore, the aims of this study will be to translate and cross-culturally adapt the Portuguese version of the Commissioning for Quality in Rheumatoid Arthritis Patient-Reported Experience Measure, evaluate its content and face validity through a qualitative approach, and evaluate its psychometric properties through a clinical field testing.

Methods:
This study is based on a multimethod approach combining qualitative and quantitative approaches. This study will include patients with RA from a single rheumatology center. Three sequential phases are planned: Commissioning for Quality in Rheumatoid Arthritis Patient-Reported Experience Measure translation and cultural adaptation, Commissioning for Quality in Rheumatoid Arthritis Patient-Reported Experience Measure content and face validity assessed through 2 focus groups with at least 10 patients, and the Commissioning for Quality in Rheumatoid Arthritis Patient-Reported Experience Measure field testing through a cross-sectional study with 50 patients.

Conclusions:
By involving patients with RA in the validation and implementation of the Commissioning for Quality in Rheumatoid Arthritis Patient-Reported Experience Measure, we expect to demonstrate the usefulness of this specific patient-reported experience measure to improve health care provided to patients with RA.

Key Words: patient reported outcomes, qualitative research, rheumatoid arthritis, tool validation

Introduction

Rheumatoid arthritis (RA) is a major global public health challenge with increasing prevalence and incidence rates.[1–3] The increasing number of patients needing specialized care is imposing a major burden and significant health costs on healthcare systems.[1,3] The current challenge is to continue to guarantee access to specialized health care while maintaining its quality.

There is a growing attention to patients' experience in assessing quality of care in patient-centered care models. According to the World Health Organization, quality of health care should be safe, effective, timely, efficient, equitable, and people-centered.[4] Patient-centered care is associated with higher levels of treatment adherence and with decreased use of healthcare services and annual medical costs.[5,6] Specifically in patients with RA, patient-centered care has been associated with clinical safety, improved effectiveness, and experienced care.[7–9]

Patients' experience about the care received can be evaluated with patient-reported experience measures (PREM), which emphasizes the most significant aspects of health care for patient to identify areas of health care requiring improvement.[10] In the United Kingdom, a specific PREM for patients with RA has been developed by the Commissioning for Quality in Rheumatoid Arthritis Patient-Reported Experience Measure (CQRA-PREM). This PREM aims to evaluate patients' perspectives on care provided in rheumatology units of the National Health Service.[8] CQRA-PREM presents good construct validity and good internal consistency[8] and has been recently validated in Dutch.[9] This PREM might be feasible to routinely assess the experience of patients with RA in Portuguese clinical practice, yet an adaptation and validation process is first needed.

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Therefore, the main aims of this study will be to (1) translate and cross-culturally adapt the Portuguese version of CQRA-PREM, (2) evaluate its content and face validity through a qualitative approach, and (3) evaluate its psychometric properties through a clinical field testing.

Methods

Study design

This study is based on a multimethod approach combining qualitative and quantitative approaches. Three sequential phases are planned (Fig. 1), according to the objectives described above:

Phase 1: CQRA-PREM translation and cultural adaptation
Phase 2: CQRA-PREM content and face validity
Phase 3: CQRA-PREM field testing to assess its psychometric properties

Phase 1: CQRA-PREM translation and cultural adaptation.
CQRA-PREM includes 7 domains for patient-centered care, namely (1) needs and preferences; (2) coordination of care and communication; (3) information, education, and self-care; (4) daily living and physical comfort; (5) emotional support; (6) family and friends; (7) access to care; and one question for evaluating the overall experience of the care provided. The questionnaire includes 23 questions, and answers are given on a 5-point Likert scale, ranging from "strongly disagree" to "strongly agree." Considering the categorical 5-point Likert scale as linear, each answer will be scored using relative frequencies and medians (interquartile ranges). The median time needed to complete the questionnaire will be calculated.[8]
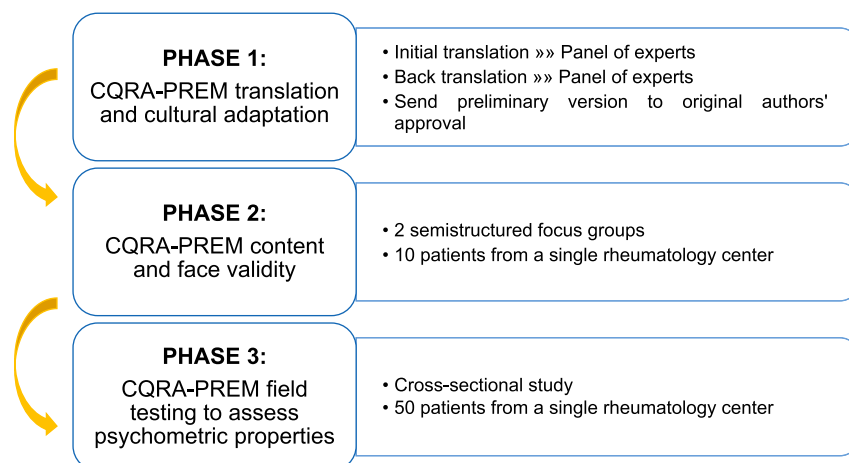
The translation and cultural adaptation of CQRA-PREM will be undertaken in accordance with the international recommendations, including initial translation, evaluation of this translation and cultural adaptation by a panel of experts, back translation, and finally testing in a sample of the study population.[11,12] The translation will be performed independently by 2 native Portuguese researchers fluent in English (one rheumatologist and one healthcare researcher). These translations will be assessed by a panel of 3 experts in rheumatology and in PROMs validation. The disagreements in the translation will be discussed by the panel in an online meeting. A synthesis of this discussion will produce one common version. Then, the Portuguese version of CQRA-PREM will be back-translated by one bilingual researcher with source language (English) and with no prior knowledge of the questionnaire. The back translation will be assessed and compared with the original by the panel of experts. In addition, a copy of the English consensus version will be sent to the original authors for approval. The preliminary Portuguese version of CQRA-PREM will be defined and used in Phase 2.

Phase 2: CQRA-PREM content and face validity.
Currently, content validity, that is, the face validity of an outcome measure, is based on a qualitative approach by a committee of experts. However, what may be considered as a good outcome by a healthcare professional or researcher may differ from what is imperative to the patient. The point of view from patients in all development stages of a health measure can improve the acceptability, relevance, and quality of this measure.[11] Therefore, in this study, face validity of the CQRA-PREM will be assessed by performing semistructured focus groups with patients with RA.

Patients will be recruited from a single Portuguese rheumatology center. A convenience sample of patients 18 years or older with RA followed up in the rheumatology consultation or day hospital in the last year will be recruited by telephone. In this phone call, patients will be informed about the aims of the study and invited to participate in a group interview. Trained physicians will perform the recruitment of participants including patients with different ages and years of disease and treatments (use/not, use of targeted synthetic or biologic disease-modifying antirheumatic drugs tsDMARDs or bDMARDs, respectively) in an attempt to assess different experiences and cover all domains of CQRA-PREM. Patients with psychiatric or cognitive disorders that may interfere with data collection, those physically or psychologically unable to communicate, and those unable to speak Portuguese will be excluded.

Before the focus groups, patients will answer a short questionnaire to report their age, sex, nationality, education, occupation, duration of pain/complaints, and duration of diagnosis. Two focus groups with at least 5 patients each will be conducted in a nondirective manner according to a semistructured discussion guide (Table 1). Taking into account the COVID-19 pandemic

PHASE 1: CQRA-PREM translation and cultural adaptation
- Initial translation »» Panel of experts
- Back translation »» Panel of experts
- Send preliminary version to original authors' approval

PHASE 2: CQRA-PREM content and face validity
- 2 semistructured focus groups
- 10 patients from a single rheumatology center

PHASE 3: CQRA-PREM field testing to assess psychometric properties
- Cross-sectional study
- 50 patients from a single rheumatology center

Figure 1. Three phases of the study protocol. CQRA-PREM = Commissioning for Quality in Rheumatoid Arthritis Patient-Reported Experience Measure.

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Table 1

Focus group semistructure guide

After presenting the questions of each of the 7 domains, participants were asked:
Do you have doubts about the interpretation of any question?
Any question seems confusing to you? Any words that are not clear?
Do you want to suggest improvements in any of the questions to make them easier to interpret?
Is there a question that you think does not apply or does not suit your case?
Do you think that something important is missing in this section and could be added?
After presenting the one question for evaluating the overall experience of the care provided, participants were asked:
Do you have doubts about the interpretation of this question?
Does it seem confusing to you? Any words that are not clear?
Do you want to suggest any improvements to make it easier to interpret?
Final remarks:
Are there any other particular subjects or themes that you think are relevant to be addressed in this questionnaire?
Is there any other topic you would like to add for a better understanding of your entire AR experience?
Do you have any final comments to make? Suggestions?

scenario, these interviews will be conducted using videoconference tools.

Phase 3: CQRA-PREM field testing to assess psychometric properties. To assess the CQRA-PREM psychometric properties, such as reliability and validity, we will collect data from at least 50 patients with RA recruited from a single Portuguese rheumatology center. Inclusion and exclusion criteria will be the same as stated for Phase 2.

Patients with RA will be consecutively included by a rheumatologist during a rheumatology consultation. In this presential appointment, the following data will be systematically collected: demographic characteristics, symptom and disease duration, treatment (use of tsDMARDs/bDMARDs or not), disease activity using a visual analog scale (VAS) by the patient and by the physician, physical function with Health Assessment Questionnaire,[12,13] overall health status with Medical Outcomes Study 36-Question Short Form,[13–17] EuroQol-5D,[17] C-reactive protein mg/dL (CRP), and erythrocyte sedimentation rate mm/hour (ESR).

Disease Activity Score for 28 joints (DAS28)[18] with erythrocyte sedimentation rate mm/hour (DAS28-ESR) or with C-reactive protein mg/dL (DAS28-CRP),[19] Clinical Disease Activity Index,[20] and Simplified Disease Activity Index[21] will be calculated to measure RA activity. DAS28 consists of the sum of number of tender and swollen joints (total of 28 joints) and disease activity reported in VAS and ESR (DAS28-ESR) or CRP (DAS28-CRP). The Clinical Disease Activity Index is a simple sum of DAS28 and VAS by the patient and by the physician.[20] The Simplified Disease Activity Index includes these 4 measures and CRP.[20] In addition, patients with RA will complete the Portuguese version of CQRA-PREM, and its completion time will be recorded. Figure 1 summarizes the 3 phases of the study.

Data analysis

To assess face validity, all focus group interviews will be transcribed and thematically analyzed (based on CQRA-PREM domains) by 2 independent researchers. Using NVivo v.12, qualitative data will be coded in emerging themes and subthemes, and finally, important aspects of care for patients will be summarized and interpreted.

The statistical analysis will include appropriate descriptive analysis. Average (standard deviation) or median (interquartile range) for continuous variables (depending on the distribution) and frequencies for categorical variables will be used. Based on the COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) checklist, reliability (internal consistency), construct validity (hypothesis testing and divergent validity), and interpretability of the CQRA-PREM will be examined.[22] Internal consistency will be evaluated with the Cronbach alpha coefficient. To evaluate hypothesis testing, the PREM domains will be analyzed by subgroups (eg, different years of disease and patients with or without bDMARDs or tsDMARDs), with a hypothesis that these patients will have different experiences with provided care. Divergent validity will be evaluated with Spearman rank or Pearson correlation coefficients depending on the sample distribution. Interpretability of the CQRA-PREM will be evaluated by testing floor and ceiling effects of different domains. The quantitative analysis will be performed using IBM SPSS Statistics version 25.0 for Windows (IBM Corporation Software Group, New York, NY). The statistical significance will be set at $P < .05$.

Ethics and dissemination of results

This study was approved by the ethical committee of University Hospital Center of São João/Faculty of Medicine of Porto (FMUP) (approval by the ethics committee on December 18, 2020). The Guideline for Good Clinical Practice of the International Conference on Harmonization and the ethical principles of the Declaration of Helsinki was followed.[23] Data collected will only be used for research purposes in accordance with the Portuguese Data Protection Law (Law No. 58/2019, of August 8, 2019) and the General Data Protection Regulation. The reporting of the study will follow the consolidated criteria for reporting qualitative research (COREQ)[24] and the standards for reporting qualitative research.[25]

All patients will be informed of the study details and will sign an informed consent and that they may withdraw at any time without having to give a reason. The principal investigator will be the only researcher to have access to these documents. After the participant signs the informed consent, the confidentiality and anonymity of the data (including during the transcription of the interviews) will be kept by assigning an alphanumeric code to each participant to protect their identity. All collected data will be kept in a secure and restricted access area at the Faculty of Medicine of University of Porto (FMUP), only accessible to the principal investigator. After the complete transcription of the interviews, the interviews recordings will be deleted. The original database will be protected by password, only known by the principal investigator. The remaining researchers will have access to a pseudoanonymized database.

The findings of this study will be disseminated to healthcare professionals and scientists in the field through publication in peer-reviewed national and international journals and conference presentations. Contacts with patient associations during conference will also be sought.

Discussion

This study aims to adapt and validate a PREM for Portuguese patients with RA, possibly contributing to optimize patient-centered care in national rheumatology healthcare centers. To the

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best of our knowledge, no PREM is currently available with this purpose in Portugal.

A PREM is a measurement tool to assess the person centeredness of care delivery. Understanding the quotidian and healthcare experience of Portuguese patients with RA and the impact of this disease on patient's quality of life will bring a new contribution to enhance the evidence base in this area, with a relevant potential to improve the management of patients with RA. The development of a PREM seems to be a cost-effective strategy with impact on a large number of patients, easily disseminated in several clinical contexts. By involving patients with RA in the development, validation, and implementation process of this PREM, we expected that this study will improve health care provided to patients with RA and possibly their health outcomes.

It is crucial to acknowledge the limitations of this study design. CQRA-PREM psychometric properties such as internal consistency, construct validity, and interpretability will be assessed. However, in its short time frame, we will be unable to determine other relevant properties such as test–retest reliability and responsiveness or even recruit patients from different rheumatology centers. We believe that this study can constitute an important first step to future larger, multicentric, and powered studies on patients' experience aggregating rheumatology centers of different geographical areas of Portugal. Moreover, the researchers intend, after the implementation of all phases of the study, to include CQRA-PREM in the Rheumatic Diseases Portuguese Register (reuma.pt), thus contributing for its widespread implementation in daily clinical practice in Portugal. This national register, developed by the Portuguese Society of Rheumatology, aims to register all patients with rheumatological conditions, ensuring the monitoring of the effectiveness and safety of treatments and the standardization of health care.

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Conflicts of interest

The authors declare no conflicts of interest.

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