

## Background

The Pain Impact Questionnaire (PIQ-6), is a patient reported outcome measure with 6 items, developed for monitoring the severity of pain and the impact of pain on the patient's health-related quality of life [1]. Chronic pain is defined by ICD-11 as pain persisting or recurring for longer than 3 months [2]. It is estimated that 22.5% of the adult Japanese population suffer from chronic pain [3]. However, the PIQ-6 has not been validated in Japanese patients.

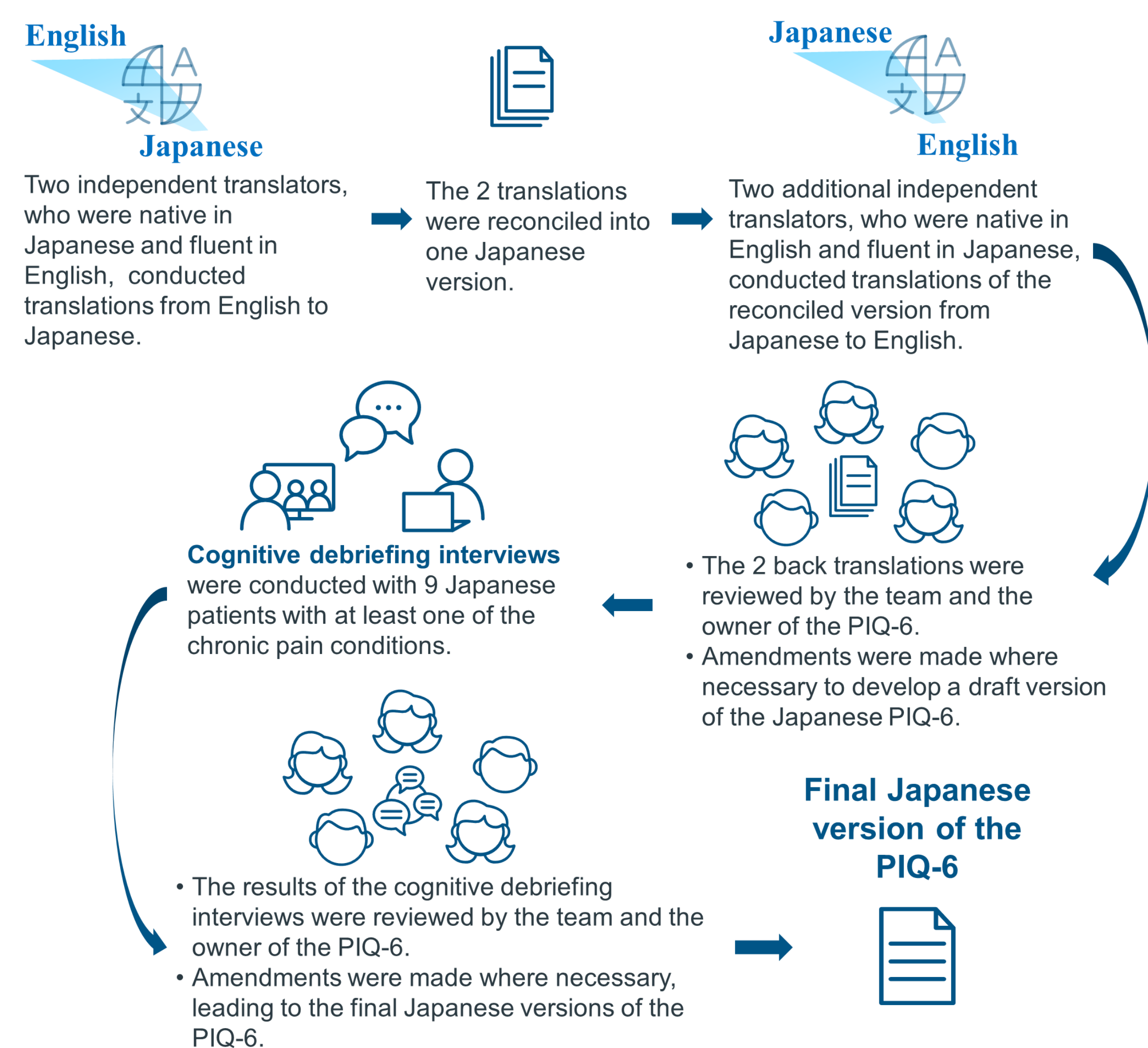
## Objective

- To develop the Japanese version of the PIQ-6 and psychometrically validate the measure for Japanese patients with chronic pain conditions.
- In this study, we will report the results from the initial phase of the study where we conducted the translation and cognitive debriefing interview for the development of the Japanese PIQ-6.

## Cognitive debriefing interview

- This study adhered to the translation and cultural adaptation guidelines established by the ISPOR task force in 2005[4]. The process is summarized in Figure 1.
- Participants suffering from chronic pain conditions, as specified in the 2021 Japanese guidelines for managing chronic pain, were recruited through a patient panel managed by Rakuten Insight, Inc. The relevant conditions included lower back pain, knee osteoarthritis, migraine, postherpetic neuralgia, trigeminal neuralgia, and rheumatism[5].
- The study was reviewed and approved by an independent ethics committee (SOUKEN Co., Ltd) in March 2025.

**Figure 1. Steps of translation and cultural adaptation**



## Results

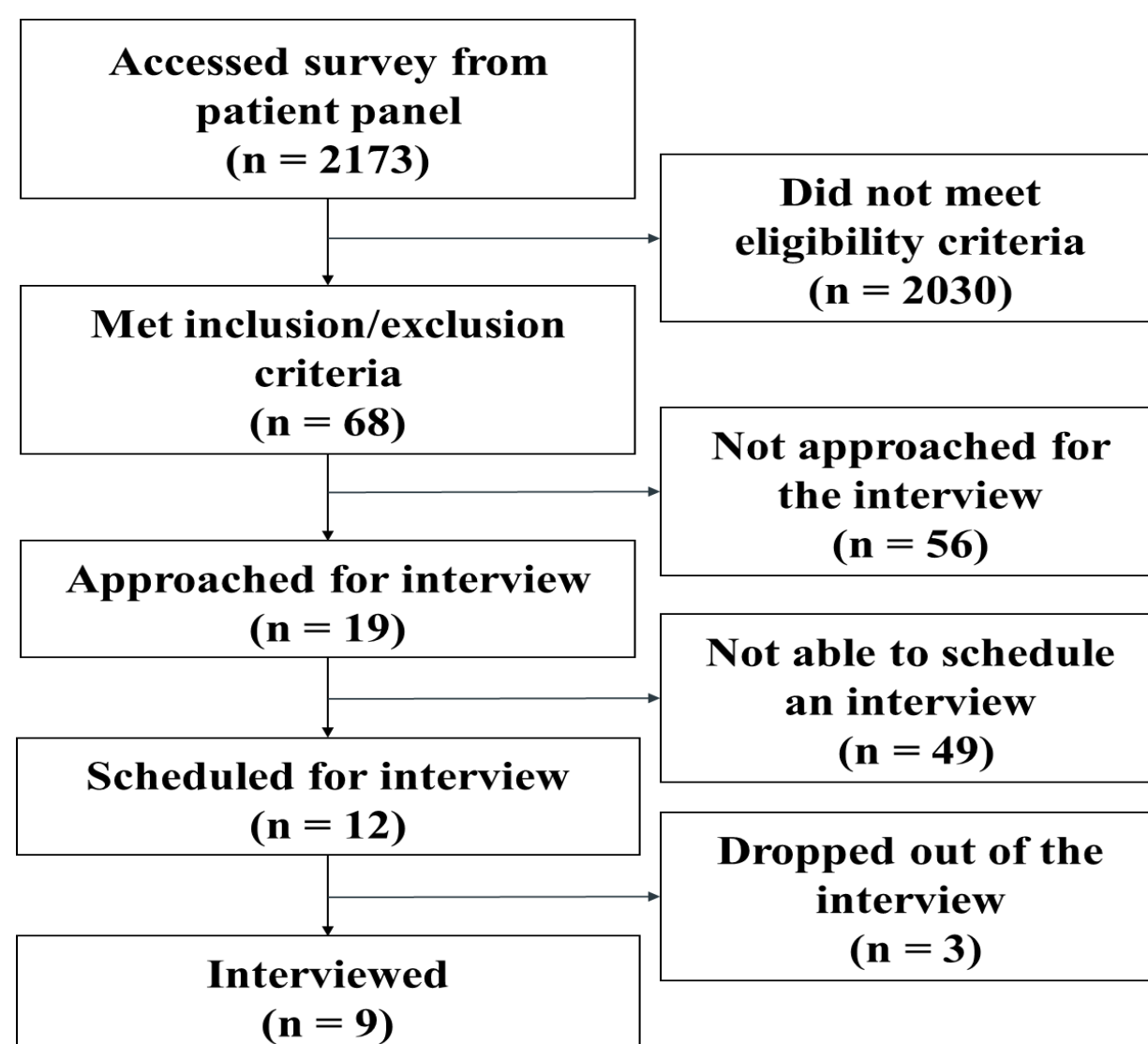
### Patients included

- Of the 2173 patients who accessed the survey, 68 patients met the eligibility criteria. A priority list was made based on sex, age, area of living and education level with an aim to recruit 12 patients and 9 patients with chronic pain conditions were interviewed (Figure 2).
- Most patients were male and had completed a university education (Table 1). The mean age was 57.7 years old. For those with multiple chronic pain conditions, the appropriateness of the PIQ-6 were confirmed for all the conditions.

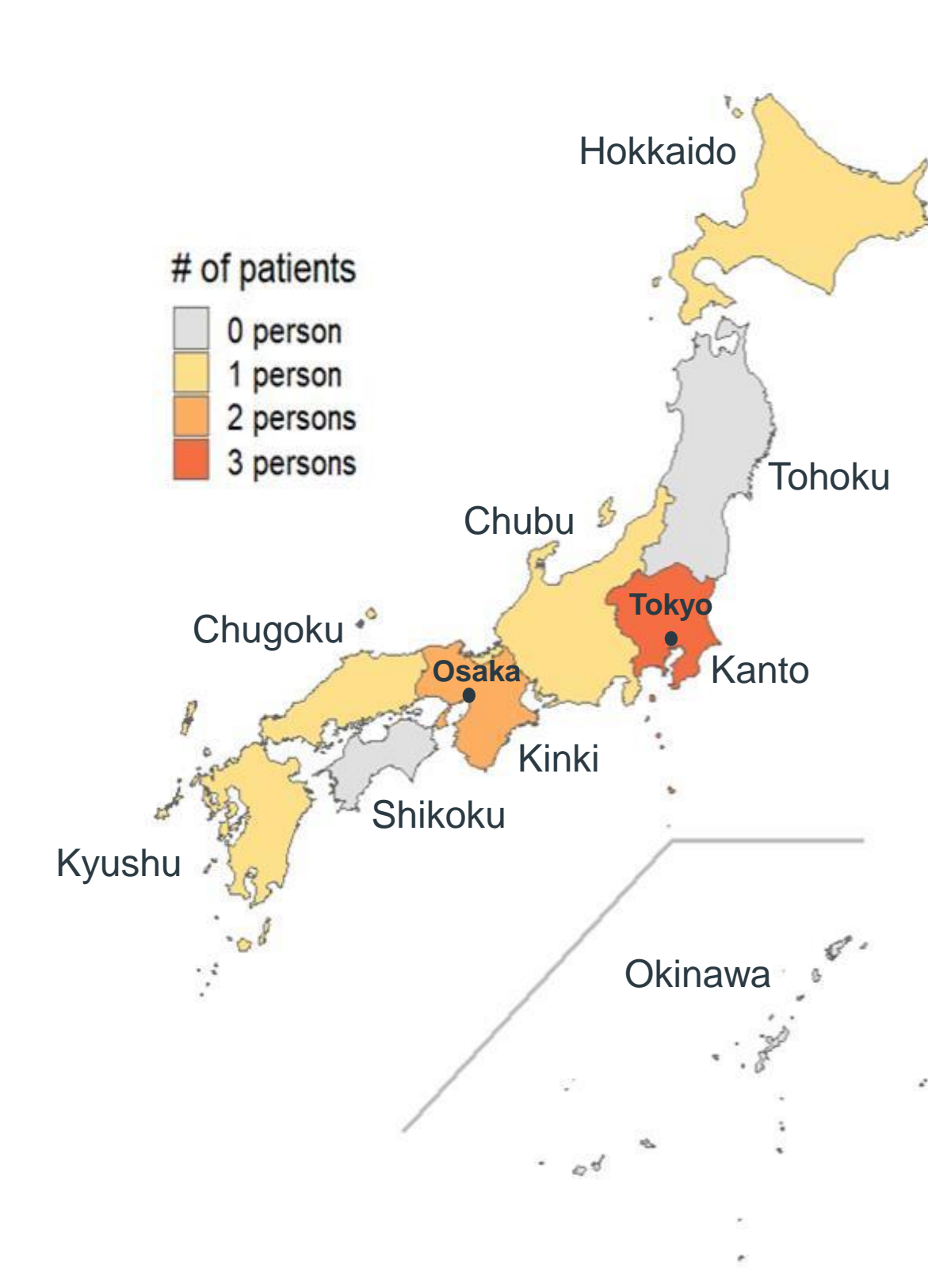
**Table 1. Demographic characteristics**

Characteristics		Chronic pain patients (N = 9)	
		n (%)	Mean (SD)
Sex	Male	6 (66.7)	
	Female	3 (33.3)	
Age	Years	-	57.7 (18.6)
	High school graduate	2 (22.2)	-
	College graduate	2 (22.2)	-
Educational level	University graduate	5 (55.6)	-
Diseases with chronic pain	Lower back pain	3 (33.3)	-
	Knee osteoarthritis	1 (11.1)	-
	Migraine	2 (22.2)	-
	Postherpetic neuralgia	3 (33.3)	-
	Trigeminal neuralgia	2 (22.2)	-
	Rheumatism	4 (44.4)	-

**Figure 2. Patient flow diagram**



**Figure 3. Areas of residence**



**Table 2. Results from the cognitive debriefing interview**

Section	Comment from interview	Modification
Overall	Unsure of which pain to answer about when one has multiple pain conditions	No change
	Suggest to reduce the choices in each question	No change
	Suggest to add definitions or quantify the choices in each question	Changed the instruction
	Suggest to change wording of "past 4 weeks"	No change
Instructions	Suggest to shorten the instruction	No change
Q1: Severity of pain	Uncomfortable in the wording used for the choice "Moderate"	No change
Q2: Influence of pain on work	No specific comments	-
Q3: Influence of pain on enjoyment of life	Suggest to add definition of enjoyment of life	Changed wording
Q4: Influence of pain on simple tasks	Suggest to add " , " to make the question easier to read	No change
	Suggest to add definition of simple tasks	Added wording
Q5: Influence of pain on leisure activities	Confusion on the interpretation of the question	Changed wording
	Unable to understand the difference between Q3, Q5	No change (changed Q3 for clarification)
Q6: Influence of pain on emotion	Suggest to add more detailed definition of leisure activities	No change
	Suggest to add wording to clarify that it is the emotion due to pain	Added wording
	Suggest to delete the word "frequency"	No change
	Suggest to change wording related to emotion	No change
	Feel people may be frustrated from the question itself	No change

## Results (continued)

### Results from the cognitive debriefing interviews

- Modifications were prioritized for comments received from three or more patients. Comments from fewer patients were also considered if they improved the accuracy of the question. Table 2 documents the comments from the interview and the corresponding modifications.
- Multiple patients suggested giving specific examples of the tasks and activities of interest within each question and quantifying the choices (such as "once a week" and "twice a day"). However, these changes were not implemented, as they could restrict the type of impact captured in the measure and contradict with the purpose of the measure to capture the severity and impact of pain as perceived subjectively by the patients. Instead, wordings used were adjusted to clarify this nature of the measure. Patients also had difficulty understanding the concept of "enjoyment of life".

## Discussion

- In this initial phase of the study, a culturally adapted Japanese version of the PIQ-6 was developed through cognitive debriefing interviews with chronic pain patients. This Japanese version of the PIQ-6 will enable stakeholders such as healthcare professionals to better understand the severity and impact of pain in Japanese patients with chronic pain conditions.
- In the Portuguese cultural adaptation, no problematic questions or concepts were identified [6]. Conversely, in our study patients preferred specifying the tasks and activities within each question and quantifying the choices. Additionally, patients struggled to understand the concept of "enjoyment of life". This could be due to the cultural difference in Japan, reflecting the careful and conservative nature of Japanese people. This results indicated the importance of cultural adaptation when developing a measure.
- One limitation of this phase is the dropout of 3 patients, which may have affected the overall results. However, 9 patients were successfully interviewed, exceeding the guideline's suggested sample size. Additionally, the interviewed patients included individuals with all target diseases, both sexes, ages ranging from 20s-70s, living in various areas of Japan, and with different education levels. Another limitation is the absence of interviews with patients from the Tohoku and Shikoku area, where different dialects could be spoken, potentially affecting the study's comprehensiveness.
- In the subsequent phase of the study, the psychometric properties of the culturally adapted Japanese version of the PIQ-6 will be assessed using a larger sample of Japanese patients with chronic pain conditions.

## Conflict of interest

- This work was fully funded by IQVIA Solutions Japan G.K. All authors are employees of IQVIA Solutions Japan G.K., who are the funders and is the Japanese branch of IQVIA which owns the original PIQ-6. The study was fully conducted by the funder.

## Reference

- World Health Organization. International Classification of Diseases Eleventh Revision (ICD-11). Geneva: World Health Organization. 2022. [Cited 04.16.2025] Available from <https://icd.who.int/browse/2025-01/mms/en#1581976053>
- Yabuki S, Ushida T, Takeshita K et al. A Nationwide Survey of Chronic Pain Sufferers in Japan. Rinsho Seikei Geka. 2012;47(2):127-134.
- Becker J, Schwartz C, Saris-Baglama RN et al. Using Item Response Theory (IRT) for Developing and Evaluating the Pain Impact Questionnaire (PIQ-6"). Pain Medicine. 2007;8(suppl\_3):129-S144.
- Wild D, Grove A, Martin M et al. Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. Value Health. 2005;8(2):94-104.
- The Committee for Clinical Practice Guideline for the Management of Chronic Pain. Clinical Practice Guidelines for the Management of Chronic Pain. Tokyo: Publication Department, Shinko Trading Co. Ltd [Cited 04.16.2025] Available from [https://www.jhsnet.net/pdf/totsu\\_guideline\\_jp.pdf](https://www.jhsnet.net/pdf/totsu_guideline_jp.pdf)
- Cavalheiro, L.M, Gil, J.A, Gonçalves, R.S, et al. Measuring the pain impact in adults with a chronic pain condition: adaptation and validation of the Pain Impact Questionnaire (PIQ-6) to the Portuguese culture. Pain medicine. 2011;12(10):1538-1543.