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TITLE PAGE

Title: Translation and cross-cultural adaptation of Nepali versions of the Patient-Reported Outcomes Measurement Information System (PROMIS®) Pain Intensity, Pain Interference, Pain Behavior, Depression, and Sleep Disturbance short forms in chronic musculoskeletal pain

Short title: Nepali PROMIS® short forms

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ABSTRACT

Purpose: The Patient-Reported Outcomes Information System (PROMIS®) measures have been translated into many languages and have been shown to have strong measurement properties across a wide range of clinical conditions. However, Nepali translations of the PROMIS short forms are not yet available. The aim of this study was to translate and cross-culturally adapt the PROMIS Pain Intensity, Pain Interference, Pain Behavior, Depression, and Sleep Disturbance short forms into Nepali.

Methods: We used the Functional Assessment of Chronic Illness Therapy (FACIT) translation methodology, which incorporated two forward translations, synthesis of the translations, a back translation, and three independent reviews, harmonization, cognitive debriefing, revisions, and proof reading. The translation and review teams were fluent in Nepali and English and represented five different countries and four continents. We evaluated the short forms for comprehensibility and relevance (two key aspects of the content validity of an instrument) conducting cognitive debriefing with six adults with chronic musculoskeletal pain, in compliance with recommendations by the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN). The final version was proofread by two native Nepali speakers before and three new proofreaders after cognitive debriefing.

Results: All five short forms were successfully translated and cross-culturally adapted into Nepali while maintaining equivalence to the source.

Conclusions: The translation and review team, along with a sample from the target population with chronic musculoskeletal pain and the proofreaders considered all five PROMIS short forms relevant and comprehensible. An important next step is to evaluate the measurement properties of these instruments.

Keywords

PROMIS®; chronic pain; pain assessment; outcome measurement; musculoskeletal pain; sleep

INTRODUCTION

Patient-centered care and high-quality clinical research rely on availability valid, reliable, and responsive patient-reported outcome measures (PROMs). A number of PROMs have been developed globally, especially in English, that assess various quality of life domains using a variety of development processes. However, these measures have not yet adequately been tested and used in developing and low-resourced countries, creating a barrier in high-quality patient care and health research.

The Patient-Reported Outcomes Information System (PROMIS[®]) is an initiative funded by the National Institutes of Health in the USA to develop item banks to assess various aspects of patient-reported health across different clinical conditions. The goal was to overcome the shortcomings of traditional PROMs, including poor comprehensibility, large measurement errors, difficulties with interpretation, and lack of comparability of scores across different PROMs [1, 2]. Additional advantages of the PROMIS measures include the use of Item Response Theory for instrument development, which enables reliable measurement with only a limited number of items via either computer-adaptive testing (CAT) or as fixed-length measures [1].

The fixed-length short-form versions of the PROMIS scales can be administered electronically or as hard copy questionnaires, and can be used in resource-limited settings that may not have easy access to the technology needed to administer CAT [3]. The fact that PROMIS measures are applicable across clinical conditions reduces the need to translate and validate many different condition-specific PROMs, saving resources. This can be particularly useful in developing countries where resources available for translating measures, including funding and trained translators are limited. PROMIS item-banks and short forms have been translated into many languages [4-7], more frequently in the western cultures, and have been shown to have strong measurement properties across a wide range of clinical conditions [8-11].

Domains such as pain intensity, pain interference, pain behavior, depression, and sleep quality [3, 4, 12, 13] are important to assess in chronic pain [14, 15], a leading cause of disability which results in a significant economic burden to society worldwide [16]. These domains are also important to assess in populations of individuals with other clinical conditions, including those with neurological disorders or psychological dysfunction. The availability of the PROMIS short forms for these five domains in Nepali would not only facilitate their clinical and research use in individuals speaking Nepali, but also allow for comparisons with individuals who speak other languages living in other countries. The translation of PROMIS measures into Nepali should follow recognized linguistic validation processes (e.g., [17-20]).

One of the preliminary but important prerequisites of validity of PROMs is content validity [21]. It comprises comprehensibility, relevance, and comprehensiveness [21]. While all three aspects of content validity are integral during the development process of PROMs, evaluation of comprehensibility and relevance to the local context are the primary goals of the cross-cultural validation process. However, these are rarely assessed or are assessed inadequately in many translation studies. Without the assessment of comprehensibility and relevance in the target language and culture, the subsequent testing of measurement properties of the translated measure can be compromised.

Given these considerations, here we aimed to (1) translate five PROMIS short form measures assessing pain intensity, pain interference, pain behavior, depression, and sleep disturbance into Nepali using PROMIS recommended translation guidelines [17], (2) cross-culturally adapt them into Nepali, and (3) evaluate the comprehensibility and relevance of the items to the Nepali context using an in-depth cognitive debriefing approach. We hypothesized that this methodology would yield culturally adapted Nepali versions that are comprehensible and relevant across a wide range of medical conditions.

METHODS

We translated and culturally adapted five PROMIS short forms into Nepali. Each instrument had 3 to 8 items; thus, a total of 32 total items were translated. The names and respective number of items in the translated short forms are listed in **Table 1**. Detailed descriptions of the instruments are provided below. Before translating these instruments into Nepali, a formal agreement was signed between the lead author (SS) and the PROMIS Health Organization (PHO), as an official permission to translate these instruments into Nepali. The Institutional Review Committee of Kathmandu University School of Medical Sciences, Dhulikhel, Nepal reviewed and approved by the study protocol.

[Insert Table 1 about here]

PROMIS measures

All PROMIS measures, including the five PROMIS static forms translated here, are scored on the T-score metric (i.e., with a score of 50 representing the mean and 10 the standard deviation of a reference population (often a US general population sample)) [22, 23]. In addition, for all PROMIS measures, a higher score reflects more of the domain that is assessed (e.g., more pain intensity, more anxiety, more sleep disturbance, for the Pain Intensity, Anxiety, and Sleep Disturbance scales, respectively) [24].

Pain Intensity version 1.0 short form 3a

The Pain Intensity short form 3a includes three items assessing three pain intensity domains: (1) worst pain in the past week, (2) average pain in the past week, and (3) current pain [25, 26]. The responses to the items use a five-point Likert scale ranging from 1 to 5 where 1 = *Had no pain*, 2 = *Mild*, 3 = *Moderate*, 4 = *Severe*, and 5 = *Very severe*. As noted previously, higher scores indicate greater pain intensity [26, 27].

Pain Interference version 1.0 short form 6b

The 6-item PROMIS Pain Interference short form 6b assesses the self-reported consequences of pain on social, cognitive, physical, and recreational activities [25, 26, 28]. Respondents are asked to rate the interference of pain in each activity listed using a 1 to 5 scale, where 1 = *Not at all*, 2 = *A little bit*, 3 = *Somewhat*, 4 = *Quite a bit*, and 5 = *Very much* [26]. Higher scores indicate greater pain interference [28].

Pain Behavior version 1.0 short form 7a

The 7-item PROMIS Pain Behavior short form 7a assesses the perceived frequency of different pain behaviors [25, 29, 30]. Respondents indicate the frequency of each of the seven pain behaviors listed in the past seven days using response options ranging from 1 to 6, where 1 = *Had no pain*, 2 = *Never*, 3 = *Rarely*, 4 = *Somewhat*, 5 = *Often*, and 6 = *Always* [25, 26]. Higher scores indicate greater frequency of pain behaviors [30].

Depression version 1.0 short form 8b

The 8-item PROMIS Depression short form 8b assesses depressive symptoms [25, 31]. Respondents are asked to rate the frequency with which they experienced each depressive symptom in the past seven days using a five-point scale with 1 = *Never*, 2 = *Rarely*, 3 = *Somewhat*, 4 = *Often*, and 5 = *Always* [25, 26]. Higher scores indicate greater frequency of depressive symptoms [31].

Sleep Disturbance version 1.0 short form 8b

The 8-item PROMIS Sleep Disturbance short form 8b assesses self-reported perceptions of sleep quality, sleep depth, and sleep satisfaction [26, 32]. This short form asks respondents to indicate their level of sleep quality in the past seven days using three different response scales with five options each, ranging from 1 to 5. The response options for the first four items are 1 = *Not at all*, 2 = *A little bit*, 3 = *Somewhat*, 4 = *Quite a bit*, and 5 = *Very much*. The response options for the next three items are 1 = *Never*, 2 = *Rarely*, 3 = *Sometimes*, 4 = *Often*, and 5 = *Always*. The last item on the Sleep Disturbance short form 8b is rated using

response options 1 = *Very poor*, 2 = *Poor*, 3 = *Fair*, 4 = *Good*, and 5 = *Very good*. Higher scores indicate greater sleep disturbance [32].

Translation process

Careful translation of the instructions, items and response options of the five PROMIS short forms were performed using the Functional Assessment of Chronic Illness Therapy (FACIT) translation methodology [17, 20] recommended by the PHO.

The aims of the translation were to (1) retain the semantic or linguistic equivalence (i.e. the meaning of the translated Nepali items is the same as the English versions), (2) cultural appropriateness or relevance (if the items are relevant to Nepali culture), and (3) assess if the Nepali items measure the same construct as the English language versions. To achieve universality of translation, the translators represented from five countries with large Nepali populations including Nepal, the United States, United Kingdom, Australia, and New Zealand. All translators and reviewers were fluent in the source (English) and target (Nepali) languages. All the members involved in the translation processes considered the item definitions (i.e., a description of the concept assessed by each item, plus definitions of each item's key words), provided by the PHO, when translating and finalizing all items. The translation process involved standard PROMIS recommended methodology summarized in Figure 1 and described below.

Forward translation. In the first step, two native Nepali speaking translators (with prior experience of translating contents and scales from English to Nepali) independently translated the five PROMIS short forms from English into Nepali. Both translators were living in Nepal at the time of translation.

Reconciliation. An independent native Nepali translator (a Nepali Social Anthropologist based at a University in the UK) then reconciled the two forward translations into a single Nepali version. In the process, the translator either retained the better of the two translations or made necessary changes in the previously available translation to optimize the translations, or created a new translation when the forward translations were considered suboptimal.

Back-translation. A native English-speaking translator (an academic from Australia who has spent several years in Nepal and speaks Nepali fluently) with a great deal of experience in translating PROMs - back-translated the reconciled versions into English. The back translator was blind to the original English version of the scales.

Translation project manager's review. The translation project manager (TPM), the lead author of the paper (SS), performed a thorough review of all translations. The TPM also has a great deal of experience translating, cross-culturally validating PROMs from English into Nepali [33-40]. The TPM noted the consistencies and discrepancies in the translations and added notes or comments for the reviewers (see below) and the PROMIS instrument developer representative to consider.

Three independent reviews. Three additional bilingual (native Nepali speaking) reviewers living in three different countries (Nepal, Australia, and the USA) reviewed all the translation steps independently. These three reviewers did not participate in any of the previous steps. Each reviewer identified their preferred translation for each item, added any additional comments or concerns regarding the translations, and made a written recommendation for the final translation. In some cases, the reviewers suggested a new translation.

Pre-finalization review. The TPM reviewed all the translations and comments from all the translators and reviewers again and made any additional comments or notes. The language coordinator (LC) who is a bilingual Native Nepali speaker living and working in New Zealand as a General Practitioner for 20 years finally reviewed the translation history and made recommendations for the final Nepali versions of the PROMIS short forms. The LC also back translated the provisional versions of all five scales, which the TPM sent to the PHO representative in charge of reviewing all translations.

Quality review and harmonization across languages. The PHO representative then reviewed the full documentation of the translation, evaluated the back-translations by comparing them to the English source, and responded to comments and concerns of the TPM, back

translator, reviewers, and the LC. The PHO representative then made recommendations to improve the translations or formulated questions for the translation team to consider.

Finalization. The LC, with some assistance from the TPM, finalized the Nepali translation of the PROMIS short forms by incorporating feedback from the PHO representative and keeping all items consistent with their item definitions. The LC then created a final back-translation version, which the TPM sent to the PHO representative again for a final review and approval. All steps of the translation process were recorded in one document and coordinated by the TPM.

Formatting, typesetting, and proofreading. The TPM performed the final typesetting and formatting to match the PROMIS format of questionnaires. Proofreading was performed by three independent new reviewers for clarity and comprehensibility of the questionnaires. The questionnaires were then ready for cognitive debriefing.

Cognitive debriefing

Cognitive debriefing was performed with six adult participants (three men and three women) presenting with chronic musculoskeletal pain in Dhulikhel Hospital, Kathmandu University Hospital, located in Dhulikhel, Nepal. Five to eight participants from the target population is usually considered adequate for cognitive debriefing [20]. They had a mean age 44 years (SD 17; range, 23 to 70 years). Three participants had education of either 5th grade or less, 1 with some high school degree, 1 with some technical degree, and 1 with a college degree. All study participants provided written informed consents before participating in the pretesting. All cognitive debriefing interviews were conducted in April 2017.

The primary aim of the cognitive debriefing was to evaluate the comprehensibility of the instructions, items, and response options as per the recommendations of PROMIS [22] and the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) [21, 41]. Two study authors SS and SM conducted all interviews together using the semi-structured PROMIS interview guide provided by the PHO. SS has several years of experience

conducting patient interviews for cognitive debriefing for several PROMs (e.g., [36-40]). SS trained SM to conduct cognitive debriefing. The interviewer assisting in the interview process noted all comments and suggestions from the study participants, audio recording of the interviews were not performed.

For comprehensibility, all the participants were asked what the items meant to them, and the interviewer confirmed if the patients' understanding of each item was correct (based on what the items meant in English) after completion of each measure. Some of the questions included in the cognitive debriefing interviews included, "*Were there any items in the questionnaire which were difficult to understand? If yes, which items were difficult to understand and why they were difficult? Could you suggest a better way to phrase these items?..... Explain in your own words the meaning of the item.*"

The secondary aim of the cognitive debriefing was to assess the relevance and cultural appropriateness of the items and response options. The participants were asked "*were there any items or responses on the questionnaire which were not relevant or were unsuitable or offensive to you?*"

The same two study authors collated and reviewed the comments and responses from all the participants. After cognitive debriefing, review of the comments, and revision of the scales, two new native Nepali speakers proofread the questionnaires for comprehensibility, readability, and accuracy of grammar after testing on a participant with chronic musculoskeletal pain.

RESULTS

Translations

The instructions for all the measures were relatively simple, therefore easy to translate. As the instructions in all five measures were similar, they were kept consistent across measures. Similarly, the response options also overlapped in a few measures (example, pain

interference and sleep disturbance) and were also kept consistent between the different measures. The LC made a total of 11 changes on the reconciled version and the response options after comments, questions and suggestions from the reviewers and the TPM.

Similarly, the LC made changes in 50% of the items (16 of 32 total items in 5 measures) after comments, questions, and suggestions from the reviewers and TPM. A further 11 additional changes were made after comments and feedback from the PHO representative. Additionally, two changes were made as a result of the cognitive debriefing. Detailed changes for each measure are described below and the final, linguistically validated Nepali questionnaires can be obtained from <http://www.healthmeasures.net>.

Key challenges of translation included the unavailability of a literal translation into Nepali for some words, or the fact that the literal Nepali translation was difficult for some participants to comprehend. For example, “*grimace*” and “*thrashed*” in the Pain Behavior short form and “*running errands*” in Pain Interference short form could not be translated into Nepali to reflect their exact meaning. Therefore, the translations of these items were expanded to match the closest meaning, using suggestions for alternative translations provided in the item definitions. In order to convey the intended meaning, examples of “*running errands*” (i.e., paying water and electricity bills) were provided in parenthesis. Paying water and electricity bills in Nepal require individuals to go to the physical offices to pay these bills, which is comparable to running errands in the western countries. A similar process was used when a literal translation was available but the word or phrase was considered by the translation team to be poorly understood across ethnic groups or people with low educational backgrounds, such as for example, “*ausat dukha*” for “average pain” in Pain Intensity short form. Solution to this with final translation, along with previous examples, are presented in Table 2.

The PHO representative provided comments and input for five out of 7 items (71%) from the Pain Behavior short form and 3 of 6 items (50%) from the Pain Interference short form. The

Sleep Disturbance short form required major changes in a total of 3 of 8 items (37%) with an additional two items (25%) requiring input from the PHO representative.

[Insert Table 2 about here]

Results of cognitive debriefing

The instructions, items, and responses were all identified as relevant, and none were thought to be offensive by the cognitive debriefing participants. In general, younger and educated patients completed questionnaires with less assistance (e.g., reading the items for the participants) than older and less educated patients. All participants evaluated the instructions as easily comprehensible. The cognitive debriefing participants thought that most of the items and responses were easy to understand and offered the following suggestions for improving them.

Pain interference. Two participants suggested changes to response 1 from “*hudai hoina*” to “*patakkai/ kahile purayena*” (both mean “not at all” in English). The suggestion was considered and the response option was changed to the latter i.e. “*patakkai purayena*” but aligned grammatically with the items. One 23 year old male patient could not differentiate between items PAININ3 (“*How much did pain interfere with your enjoyment of life?*”) and PAININ10 (“*How much did pain interfere with your enjoyment of recreational activities?*”) of the Pain Interference short form, and recommended that only one of these be retained. The participant said, “*The same activities — games and sports — are my recreational activities and are things that give enjoyment.*” However, no changes were made in these two items and both items were retained, because other participants were able to complete these items without a problem. Participants are free to score both these items with a single activity in mind, for example, games, sports or music.

Depression. Two participants found it difficult to differentiate the meanings of the Nepali translations of “sad” and “unhappy” in two items EDDEP17 (“*I felt sad*”) and EDDEP36 (“*I felt unhappy*”). Participants knew that both of these words relate to negative emotional experiences, but could not distinguish between them. However, the items were retained as translated

because the translated versions conveyed the true meaning of the words and were understood by the remaining participants who were tested.

Two participants could not fully understand the meaning of “*byartha*” (English, “worthless”) in item EDDEP04 (“*I felt worthless*”) of the Depression short form. Both patients suggested that addition of a synonym could help improve comprehensibility. The remaining participants indicated that they understood “*byartha*”. The final version was updated by adding “*kaam nalagne*” (English, “*useless*”) in parenthesis as per participants’ suggestion.

Sleep disturbance. Two participants required assistance to be able to understand the response options when they were reversed, e.g., item 2 (SLEEP115, “*I was satisfied with my sleep*”) and item 3 (SLEEP116, “*My sleep was refreshing*”). Remaining four participants understood the items without needing any assistance. No change in the translated version was made at this stage to keep the response options consistent with the original English translations.

DISCUSSION

The study aimed to translate and cross-culturally adapt five PROMIS short forms assessing pain intensity, pain interference, pain behavior, sleep disturbance and depression into Nepali, the national language of Nepal. These PROMIS measures were all thought to be comprehensible and easy to complete by the translation team and study participants from the target population. The fact that the translation and review team involved persons from multiple countries (i.e., Nepal, Australia, the United States, United Kingdom, and New Zealand) supports the potential universality of the translation.

Although we had good agreement between the translators and reviewers for most of the items, some challenges in the translation of some of the items emerged. For example, during cognitive debriefing two participants were unable to differentiate between two items of the Depression short form (i.e., with the translation of “unhappy” and “sad” having similar meaning for these participants). Another challenge relates to the participants’ expression of difficulty with the reverse scored items of the Sleep Disturbance short form. The change from one type of

response to another confused some of the participants. Similarly, another instrument with reverse coded items, the Life Orientation Test – Revised (LOT-R) [42], has been translated into Nepali and found to be poorly interpreted reflected by poor internal consistency in a large sample. We have had good success in translation of PROMs to produce reliable and valid instruments in Nepali in the past for the PROMs which do not have reverse coded response options [33-40]. Simplifying PROMs for target populations with low-levels of literacy, such as Nepali, is very important because the participants' ability to interpret the meaning of the items and responses is dependent on educational level of the individual [35, 43]. With many individuals in Nepal living in low socioeconomic conditions [44], further testing of the Nepali translation of the Sleep Disturbance short form is recommended.

Strengths and limitations

The current study has several strengths. First, we adopted standard best practice translation guidelines using translators and reviewers representing multiple countries consistent with the FACIT guidelines, as recommended by PROMIS [17]. One advantage of the FACIT guidelines is that it emphasizes the universal translation approach. This helps the translations to be more generalizable for use in individuals speaking the target language in multiple countries [17, 45]. The FACIT methodology also ensures that each member of the review team *independently* reviews the translations. These independent reviews of the translations is expected to prevent peer pressure on the reviewers to decide on final translations prematurely [17, 45]. Based on the robustness of the translation and review processes, we are confident that these measures are comprehensible and useful in multiple countries where Nepali is spoken. However, in hindsight, we realized that paying water and electricity bills by going to physical offices (Pain Interference Scale item PAININ14) is not common in developed countries, although it is a common practice in Nepali-speaking developing countries. Revision of this item to include an example of a household chore that is more universal should be considered in the

future, in order to facilitate comparability of scores in samples from developed and developing countries.

An additional strength of this study is that we adopted standard recommended methods for the assessment of comprehensibility and relevance of the PROMIS measures' items [17, 21], using the comprehensive guide and template developed and provided by the PHO. As a result, several critical points were identified related to comprehensibility of the instruments which were then addressed, ensuring the comprehensibility and cultural appropriateness of the five PROMIS short forms.

Important next steps are to evaluate measurement equivalence of the scales' items (e.g., by conducting differential item functioning analyses) and the scales' measurement properties in order better understand the usefulness of the translated Nepali PROMIS instruments [46]. The translation and cross-cultural adaptation processes described here, while representing best practices, do not guarantee that the resulting scales are necessarily reliable, valid, and responsive.

CONCLUSIONS

The Nepali translations of five PROMIS short form instruments (assessing pain intensity, pain interference, pain behavior, depression, and sleep disturbance) were successfully translated and cross-culturally adapted into Nepali. The resulting measures were viewed as comprehensible and relevant by the translation and review teams along with six Nepali adults with chronic musculoskeletal pain and a total of five proofreaders. However, the reverse-scored sleep disturbance short form items were difficult to comprehend for some participants, and Pain Interference item PAININ14 may be improved in order to improve the universality of the measures. In addition, future research is needed to evaluate the measurement properties of these five Nepali PROMIS short forms.

DECLARATIONS

Ethics approval and consent to participate

Ethics approval was obtained from the Institutional Review Committee of Kathmandu University School of Medical Sciences, Dhulikhel, Nepal. All study participants provided written informed consent to participate in the study.

Consent for publication

Not applicable

Competing interests

All authors declare no competing interests

Data availability

Not applicable

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Authors' contributions

- SS Conception, coordination of all translations as the Translation Project Manager, data acquisition, data analysis and interpretation, writing first manuscript draft, revising manuscript, final approval of the manuscript.
- HC Conception of the study, review of the translations and assured high quality of translations on behalf of PROMIS Health Organisation, review of the manuscript, final approval of the manuscript.
- AP Translation of the instruments, interpretation, review of the manuscript, final approval of the manuscript.
- CBT Interpretation, review of the manuscript, final approval of the manuscript.
- JHA Interpretation, review of the manuscript, final approval of the manuscript.

- RM Review of the translations, interpretation, review of the manuscript, final approval of the manuscript.
- SS Review of the translations, interpretation, review of the manuscript, final approval of the manuscript.
- JS Reconciliation of all translations, interpretation, review of the manuscript, final approval of the manuscript.
- SM Data acquisition, interpretation, review of the manuscript, final approval of the manuscript.
- DR Back translation, interpretation, review of the manuscript, final approval of the manuscript.
- MPJ Conception of the study, review of the translations, interpretation of the results, review of the manuscript, final approval of the manuscript.

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TABLE CAPTIONS

Table 1. Five PROMIS short forms translated into Nepali

Table 2. Some examples of key issues in translation and solutions

FIGURE CAPTION

Figure 1. Translation process using FACIT methodology

Note: LC, Language coordinator; TPM, Translation project manager.