Translation and linguistic validation of 6 PROMIS Profile domains for adults in Korean

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Introduction

- **Capital City:** Seoul
- **Population:** 51.4 million (as of 2017)
- **Language:** Korean (Hangeul) - Phoenic

- 11th largest economy in the world.
- Fastest Internet connection speeds
- Longest years of tertiary education in the world
- 2nd most equal access to quality healthcare
- 3rd highest health adjusted life expectancy
Introduction

Living and culture in South Korea

• Housing: Mixed with traditional and modern architect (Ondol, Hanok).
• Food: Almost always accompanied by a big bowl of hot soup or stew, sticky rice and variety side dishes. Metal chopsticks & spoons are main silverwares.
• Family oriented. Socialized.
Introduction

PRO Division at Center for Clinical Epidemiology
Samsung Medical Center

Validation team
- Youngha Kim, MS
  PRO validation researcher
- Jung Hee Yoon, RN
  PRO validation researcher

e-PRO system development team
- Jinhwang Kim, MS
  Full Stack Developer
- Yeongrae Joi, MS
  GUI Designer
- Mangyeong Lee, MS
  UX/HCI researcher

Data analytics team
- Danbee Kang, PhD
  Research Professor
- Minwoong Kang, MS
  Bio-statistician
- Ji Hyun Lim, BS
  Bio-statistician

Faculty
- Dong-ryul Oh, MD, Ph.D
  Department of Radiation Oncology
- Jin Seok Ahn, MD, Ph.D
  Department of Hematology and Oncology
- Ki Sun Sung, MD, Ph.D
  Department of Orthopedic Surgery
- Hye Yun Park MD, Ph.D
  Department of Pulmonary and Critical Care Medicine
- Soo-Yong Shin, Ph.D
  Chief of the Center for Big Data Research
Introduction

Department of Hematology and Radiation oncology, Orthopedics, Psychiatry, Pulmonary, Gastroenterology, Endocrinology

Collaboration

Behavior Scientist

Clinical Epidemiologist

Korean FDA

System Developer and Security

SOUTH KOREA

UNITED STATES

美 NCI, Northwestern Univ.
01 Objectives
Objective

1. Validating PROMIS Profile Domains for adults in Korean and distribute in Korea

2. Increase awareness of PRO and PROMIS in Korea

3. Set up a system for PNC in Korea
Objective

- Patient-Reported Outcomes Measurement Information System (PROMIS) is valid, reliable and precise measurement system than previously PROMs that assess self-reported patient’s physical, mental, and social health.

- Specific purpose of the study was to translate and linguistically validate the 6 PROMIS profile domains for adults into Korean.
02
Methods
Methods

Table 1. Number of Korean translated PROMIS item banks for adult

<table>
<thead>
<tr>
<th>PROMIS Domain</th>
<th>Number of items in bank</th>
<th>Number of translated items in bank*</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROMIS Bank v1.0 - Fatigue</td>
<td>95</td>
<td>69</td>
</tr>
<tr>
<td>PROMIS Bank v1.0 - Sleep Disturbance</td>
<td>27</td>
<td>23</td>
</tr>
<tr>
<td>PROMIS Scale v1.0 - Pain Intensity 3a</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>PROMIS Bank v1.1 - Pain Interference</td>
<td>40</td>
<td>36</td>
</tr>
<tr>
<td>PROMIS Bank v1.2 - Physical Function</td>
<td>121</td>
<td>106</td>
</tr>
<tr>
<td>PROMIS Bank v2.0 - Ability to Participate in Social Roles and Activities</td>
<td>35</td>
<td>31</td>
</tr>
</tbody>
</table>

Total number of items 321 268

- Profiles already translated were excluded: depression & anxiety.
- Items (individual questions) available in Korean from short forms were excluded.
- Total of 6 PROMIS PROFILES and 268 items were chosen.
Methods

- **Forward Translation**: Each source item in English was translated into Korean by three independent professional translators who are bilingual in English and Korean.

- **Reconciliation**: A fourth independent bilingual translator selected one of the three forward translations and created either a hybrid version or a new version of the translated items.

- **Back Translation**: The reconciled version was back-translated by three native English-speaking translators.

- **FACIT translation methodology was taken.**
• **Expert Review:** Reviewed by the 10 experts who were native speakers of Korean and fluent in English working in the field of health professionals (6 clinicians, 2 nurses, and 2 behavioral scientists)

• **Pre-finalization:** Determined the pre-final translation of the items by reviewing all of the previous translation steps

• **Harmonization and Quality assurance:** Performed by the PROMIS translation director addresses consistency and conceptual equivalence
• **Cognitive interview (n = 61, Round 1; n = 6, Round 2):** Participants assigned in at least 6 participants per item and were debriefed by the interviewers.

• **Qualitative data analysis:** Items that met the a priori threshold of ≥20% of respondents with comprehension difficulties were considered for rephrasing.

• **Translation finalized:** Final quality review was performed by the PROMIS translation director.
03 Results
Results

- A total of 67 outpatients participated in the cognitive interviews (61 participants in Round 1 and 6 participants in Round 2).

- Mean age was 57.1 years
- 55.2% were males & 71.6% were married
- **Intentional sampling for low literacy group** - 38.8% of participants were less than middle school graduates or more than 65 years.

- Most respondents understood the items and were able to interpret for Korean version of PROMIS profile domains.
Results – Cognitive Interview Round 1

- 54 items (20.1%) were found to be difficult for understand among at least 20% of respondents.
- Of 54 items, 29 items were not revise due to no alternative words or wording.
  - Some words/wordings were from existing translation items
- 25 items were slightly revised after consultation with the PROMIS translation director.

<table>
<thead>
<tr>
<th>PROMIS Domain</th>
<th>Number of items with difficulty in Round 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROMIS Bank v1.2 - Physical Function</td>
<td>26 (24.5%)</td>
</tr>
<tr>
<td>PROMIS Bank v1.0 - Fatigue</td>
<td>16 (23.1%)</td>
</tr>
<tr>
<td>PROMIS Bank v2.0 - Ability to Participate in Social Roles and Activities</td>
<td>5 (16.1%)</td>
</tr>
<tr>
<td>PROMIS Bank v1.1 - Pain Interference</td>
<td>4 (11.1%)</td>
</tr>
<tr>
<td>PROMIS Bank v1.0 - Sleep Disturbance</td>
<td>3 (13.0%)</td>
</tr>
<tr>
<td>PROMIS Scale v1.0 - Pain Intensity 3a</td>
<td>0</td>
</tr>
</tbody>
</table>
## Issue 1-1. Difference in living/housing environment

<table>
<thead>
<tr>
<th>Domain</th>
<th>Source item (English)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical function</td>
<td>Are you able to yard work like raking leaves, weeding, or pushing a lawn mower?</td>
</tr>
</tbody>
</table>

**Uncomprehending or difficult reasons**

- “I have not done yard work. The apartment building I live in has no garden.”

![US](image1.jpg) ![Korea](image2.jpg)
## Results

### Issue 1-2. Difference in housing/life style environment

<table>
<thead>
<tr>
<th>Domain</th>
<th>Source item (English)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical function</td>
<td>Are you able to carry a laundry basket up a flight of stairs?</td>
</tr>
<tr>
<td>Uncomprehending or difficult reasons</td>
<td>“I don’t have experience. I hang out the laundry on the apartment balcony.”</td>
</tr>
</tbody>
</table>

US

Korea
## Issue 1-3. Difference in eating culture

### Physical function

<table>
<thead>
<tr>
<th>Domain</th>
<th>Source item (English)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical function</td>
<td>Are you able to <strong>cut your food using eating utensils?</strong></td>
</tr>
</tbody>
</table>

### Uncomprehending or difficult reasons

- Korean use chopsticks instead of forks or knife, and do not cut food using eating utensils.

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![US](image_us.png)  ![Korea](image_korea.png)

US  Korea
## Issue 1-4. Difference in living/eating environment

<table>
<thead>
<tr>
<th>Domain</th>
<th>Source item (English)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical function</td>
<td>Are you able to open a can with a hand can opener?</td>
</tr>
</tbody>
</table>

**Uncomprehending or difficult reasons**

- Participants understood that a tuna tin can opened using with a pull tab, which is popularly used built-in device in Korea, rather than using a hand can opener.
# Issue 2. Need additional description or examples

<table>
<thead>
<tr>
<th>Domain</th>
<th>Source item (English)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical function</td>
<td>Are you able to carry a <strong>heavy object</strong> (over 10 pounds/5 kg)?</td>
</tr>
<tr>
<td></td>
<td>Are you able to run or jog for <strong>two miles</strong> (3km)?</td>
</tr>
</tbody>
</table>

**Uncomprehending or difficult reasons**

- Participants had difficulty thinking “a heavy object (over 10 pounds/5 kg)” or “two miles (3km)”. They wanted suitable examples.
- Korean are more used to numbers of bus stops or blocks when thinking about distances in everyday life, but the length of a bus stop or a block vary widely depending on the area the patient lives in.
## Issue 2. Need additional description or examples

<table>
<thead>
<tr>
<th>Domain</th>
<th>Source item (English)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain interference</td>
<td>How difficult was it for you to take in <strong>new information</strong> because of pain?</td>
</tr>
</tbody>
</table>

### Uncomprehending or difficult reasons

- 4 out of 7 Participants did not understand what was meant “new information”. What kind of the information do I take?

![Image of characters from the show Friends with the caption: That is brand new information!]

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**Results**

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Issue 3. Ambiguous meaning of wording

<table>
<thead>
<tr>
<th>Domain</th>
<th>Source item (English)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical function</td>
<td>Are you able to walk up and down two steps? Are you able to climb up five steps?</td>
</tr>
</tbody>
</table>

**Uncomprehending or difficult reasons**

- 6 out of 7 participants understood to climb the two steps *at a time*. They said it is easy to walk up and down two steps at a time.
- 3 out of 7 participants were confused whether “five steps” is “step by step” or “five steps at a time”.
Issue 4. Use of unfamiliar words

<table>
<thead>
<tr>
<th>Domain</th>
<th>Source item (English)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ability to participate in social roles and</td>
<td>I have to limit <strong>social activities</strong> at home.</td>
</tr>
<tr>
<td>activities</td>
<td></td>
</tr>
</tbody>
</table>

**Uncomprehending or difficult reasons**

- 5 out of 7 participants did not understand what was meant “social activities at home”. In Korea, social activities mean activities that involving interaction with people outside the home, especially company, rather than at home.
### Issue 6. Words rarely used/spoken in Korean

<table>
<thead>
<tr>
<th>Domain</th>
<th>Source item (English)</th>
</tr>
</thead>
</table>
| Fatigue  | How often did your fatigue make it difficult to organize your thoughts when doing **things** at home?  
          | To what degree did your fatigue make it difficult to start **anything** new?             |

**Uncomprehending or difficult reasons**

- **It was difficult to express** it as “doing things” or “anything” in Korean. To use it, we need words to the objects. There is no way on Korean to say “doing things”, so we have to say “work”.

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**Results**

**Domain Source item (English)**

Fatigue: How often did your fatigue make it difficult to organize your thoughts when doing **things** at home? To what degree did your fatigue make it difficult to start **anything** new?

Uncomprehending or difficult reasons:

- **It was difficult to express** it as “doing things” or “anything” in Korean. To use it, we need words to the objects. There is no way on Korean to say “doing things”, so we have to say “work”.
Issue 5. Similar but different words depending on levels and degrees – cannot distinguish

<table>
<thead>
<tr>
<th>Domain</th>
<th>Source item (English)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatigue</td>
<td></td>
</tr>
</tbody>
</table>

**Uncomprehending or difficult reasons**

- The items in fatigue item bank measure different levels and degrees of fatigue using a variety of adjectives (sluggish, run-down, physically drained, exhausted, bushed, totally drained, wiped out, and extreme exhaustion).

- *It was difficult to distinguish* between them and sort out the different Korean words to describe the level of fatigue.
Conclusions
Conclusions

- Some difficulties were found in the translation of some items, but for most items eventually an equivalent translation was obtained.

- The Korean version of the PROMIS profile domains has been linguistically validated in Korean adults.

- Further studies related to the validity and reliability of the Korean version of PROMIS profile domains can now be initiated.
This research was supported by a grant (18182MFDS407) from Ministry of Food and Drug Safety in 2018.
감사합니다

(Gam-Sa-Hop-Ni-Da)

Thank you