

# Linguistic validation of the Korean version of the U.S. National Cancer Institute's Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)

Juhee Cho<sup>1,2</sup>, Junghee Yoon<sup>1,2</sup>, Youngha Kim<sup>1</sup>, Dongryul Oh<sup>3</sup>, Jinseok Ahn<sup>4</sup>, Seok Jin Nam<sup>5</sup>, Sandra A. Mitchell<sup>6</sup>

<sup>1</sup>Center for Clinical Epidemiology, Samsung Medical Center, <sup>2</sup> Department of Digital Health, SAIHST, Sungkyunkwan University, <sup>3</sup> Department of Radiology, Samsung Medical Center, <sup>4</sup> Division of Hematology and Oncology, Department of Medicine, Samsung Medical Center, <sup>5</sup> Department of Surgery, Samsung Medical Center, <sup>6</sup> Division of Cancer Control and Population Sciences, National Cancer Institute

## Background / Objectives

The U.S. National Cancer Institute's PRO-CTCAE is a patient-reported outcome measure to capture symptomatic toxicity in cancer clinical trials. For more information about PRO-CTCAE visit: <https://healthcaredelivery.cancer.gov/pro-ctcae/>

The aim of this study was to translate and linguistically validate a Korean language version of PRO-CTCAE.

## Methods

124 items in the PRO-CTCAE item library were translated from English into Korean using multiple forward and back translations.

We enrolled 120 cancer patients stratified by gender, age, and education at a university-based cancer center in Seoul, Korea.

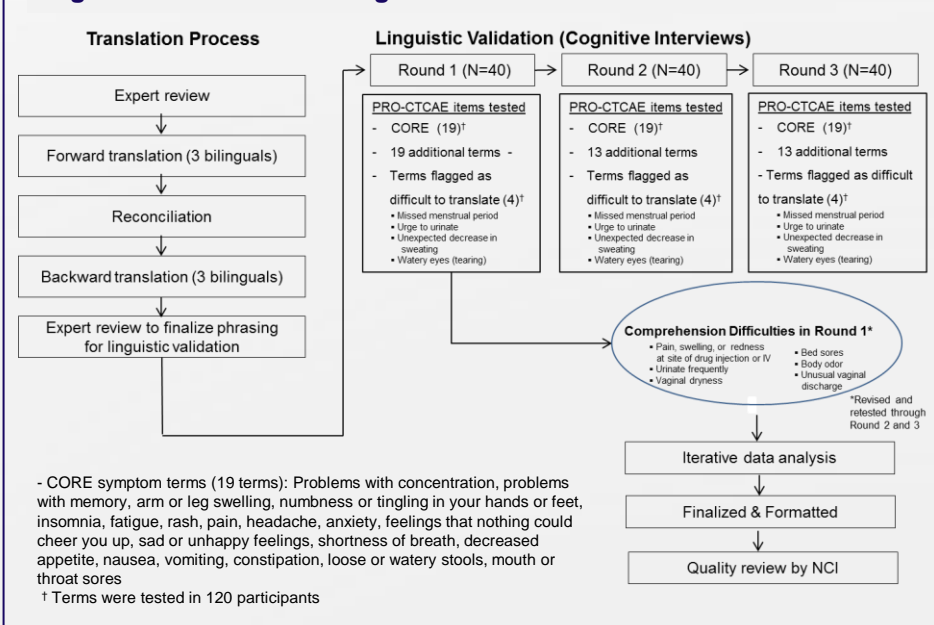
We conducted 3 rounds of cognitive interviews, with 40 patients participating in each round.

Each participant completed approximately 50 PRO-CTCAE items and participated in a cognitive debriefing interview.

The interviews were analyzed at the item level to evaluate the comprehensibility, acceptability, and ease of response.

Items for which  $\geq 20\%$  of patients experienced comprehension difficulties were rephrased and retested in subsequent rounds.

Figure 1. Procedure on linguistic translation and validation



## Results

A majority of PRO-CTCAE items were well comprehended by Korean speakers in Round 1.

Three items that presented difficulties in  $\geq 50\%$  of participants were revised/retested with all participants in Round 2. Four items presented difficulties in  $\geq 20\%$  were revised.

In Round 2, only 1 item presented difficulties in  $\geq 20\%$  and was revised/retested.

After Round 3, no items presented difficulties in  $\geq 20\%$  of participants, and while 4 items presented difficulties for  $< 20\%$ , the 4 items were

Table 1. Symptom terms presenting comprehension difficulties across 3 rounds of interviewing

| Proportions with of difficulties in Round 1   | Round 1 (N=40)                         |                                    | Round 2 (N=40)                         |                                    | Round 3 (N=40)                         |                                    |
|---|--|------------------------------------|--|------------------------------------|--|------------------------------------|
|   | Number of participants interviewed (N) | Participants with difficulty N (%) | Number of participants interviewed (N) | Participants with difficulty N (%) | Number of participants interviewed (N) | Participants with difficulty N (%) |
| <b><math>\geq 20\%</math> Participants with comprehension difficulties</b>                            |  |                                    |  |                                    |  |                                    |
| Vaginal dryness   | 5                                      | 3 (60.0)                           | 18                                     | 1 (5.6)                            | 21                                     | 0                                  |
| Urinate frequently  | 9                                      | 5 (55.5)                           | 40                                     | 0                                  | 40                                     | 0                                  |
| Nothing would cheer you up  | 40                                     | 21 (52.5)                          | 40                                     | 2 (5.0)                            | 40                                     | 7 (17.5)                           |
| Pain, swelling, redness at a site of drug injection or IV   | 9                                      | 3 (33.3)                           | 40                                     | 0                                  | 40                                     | 0                                  |
| Wheezing (Whistling noise in the chest with breathing)  | 11                                     | 3 (27.3)                           | 10                                     | 0                                  | 9                                      | 1 (11.1)                           |
| Pain  | 40                                     | 9 (22.5)                           | 40                                     | 0                                  | 40                                     | 0                                  |
| Difficulty swallowing   | 9                                      | 2 (22.2)                           | 10                                     | 0                                  | 11                                     | 0                                  |
| Flashing lights in front of your eyes   | 10                                     | 2 (20.0)                           | 11                                     | 0                                  | 10                                     | 0                                  |
| <b><math>\geq 10\%</math> and <math>&lt; 20\%</math> Participants with comprehension difficulties</b> |  |                                    |  |                                    |  |                                    |
| Watery eyes (Tearing)   | 40                                     | 7 (17.5)                           | 40                                     | 5 (12.5)                           | 40                                     | 6 (15.0)                           |
| Missed expected menstrual period  | 21                                     | 3 (14.3)                           | 18                                     | 0                                  | 21                                     | 0                                  |
| Mouth and throat sores  | 40                                     | 5 (12.5)                           | 40                                     | 0                                  | 40                                     | 0                                  |
| Unexpected decrease in sweating   | 40                                     | 4 (10.0)                           | 40                                     | 1 (2.5)                            | 40                                     | 0                                  |
| Loss of control of urine (Leakage)  | 9                                      | 0                                  | 10                                     | 2 (20.0)                           | 11                                     | 0                                  |
| <b>Recommendation for further testing</b>   |  |                                    |  |                                    |  |                                    |
| Bed sores   | 9                                      | 1 (11.1)                           | 40                                     | 5 (12.5)                           | 40                                     | 6 (15.0)                           |
| Unusual vaginal discharge   | 5                                      | 0                                  | 18                                     | 1 (5.6)                            | 21                                     | 1 (4.8)                            |
| Body odor   | 9                                      | 1 (11.1)                           | 40                                     | 0                                  | 40                                     | 0                                  |

Table 2. Key cognitive interview findings

| Key Cognitive Interview Findings in Round 1                                 | Degree of Difficulties in Round 1     | Symptoms  |
|---|---------------------------------------|---|
| Difficulty understanding the meaning of specific words, phrases or concepts | $\geq 20\%$ difficulties              | Vaginal dryness<br>Wheezing (Whistling noise in the chest with breathing)<br>Flashing lights in front of your eyes        |
|   | $\geq 10\%$ and $< 20\%$ difficulties | Unexpected decrease in sweating<br>Bed sores<br>Unusual vaginal discharge   |
|   | Recommended for further testing       |   |
| Difficulty understanding the meaning of the question                        | $\geq 20\%$ difficulties              | Urinate frequently<br>Nothing would cheer you up<br>Pain  |
|   | $\geq 20\%$ difficulties              | Pain, swelling, redness at a site of drug injection or IV<br>Difficulty swallowing  |
| Different participants understood the question differently                  | $\geq 10\%$ but $< 20\%$ difficulties | Watery eyes (Tearing)<br>Missed expected menstrual period<br>Mouth and throat sores<br>Loss of control of urine (Leakage) |
|   | Recommended for further testing       | Body odor   |
|   |                                       |   |
|   |                                       |   |

## Conclusions

PRO-CTCAE-Korean has been linguistically validated for use in Korean speaking populations, and demonstrates generally high levels of comprehension, acceptability, and ease of response.

Quantitative evaluation of the measurement properties of PRO-CTCAE-Korean is warranted.

Any questions?  
Juhee Cho, Ph.D  
jcho@skku.edu