The Content Validity of a Chemotherapy-Induced Peripheral Neuropathy Patient-Reported Outcome Measure

Ellen M. Lavoie Smith, PhD, ANP-BC, AOCN®; Rylie Haupt, BSN, RN; James P. Kelly IV, BS, Deborah Lee, MSN, RN, FNP, ACNP-BC, Grace Kanzawa-Lee, BSN, RN, Robert Knoerl, PhD, RN, Celia Bridges, BA, BSN, RN, Paola Alberti, MD, Nusara Prasertsri, PhD, RN, and Clare Donohoe

Smith is an associate professor and PhD program director in the School of Nursing at the University of Michigan in Ann Arbor; Haupt is an RN in the surgical intensive care unit at Saint Joseph Mercy Health System in Ann Arbor; Kelly is a medical student in the College of Osteopathic Medicine at Michigan State University in East Lansing; Lee is a clinical instructor and Kanzawa-Lee is a graduate student and research assistant, both in the School of Nursing at the University of Michigan; Knoerl is a postdoctoral research fellow in the Phyllis F. Cantor Center for Research in Nursing and Patient Care Services at the Dana-Farber Cancer Institute in Boston, MA; Bridges is a clinical research project manager in the School of Nursing at the University of Michigan; Alberti is a neurologist at the University of Milano-Bicocca in Monza, Italy; Prasertsri is a nursing instructor at the Boromrajonani College of Nursing Sanasathitphrasong in Thailand; and Donohoe is a nursing student in the School of Nursing at the University of Michigan.

This research was funded by a grant (RO3 CA186183-02) from the National Cancer Institute of the National Institutes of Health.

Smith, Haupt, Bridges, and Alberti contributed to the conceptualization and design. Smith, Haupt, Kelly, Lee, Kanzawa-Lee, Bridges, Alberti, and Prasertsri completed the data collection. Haupt and Alberti provided statistical support. Smith, Haupt, Kelly, Lee, Kanzawa-Lee, Knoerl, Bridges, Alberti, and Donohoe provided the analysis and contributed to the manuscript preparation.

Smith can be reached at ellenl@med.umich.edu, with copy to ONFEditor@ons.org.

Submitted July 2016. Accepted for publication March 6, 2017.

Keywords: chemotherapy-induced peripheral neuropathy (CIPN); EORTC QLQ-CIPN20; cognitive interviewing; measurement; validity

ONF, 44(5), 580–588.

doi: 10.1188/17.ONF.580-588

Purpose/Objectives: To test the content validity of a 16-item version of the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire–Chemotherapy-Induced Peripheral Neuropathy (QLQ-CIPN20).

Research Approach: Cross-sectional, prospective, qualitative design.

Setting: Six outpatient oncology clinics within the University of Michigan Health System’s comprehensive cancer center in Ann Arbor.

Participants: 25 adults with multiple myeloma or breast, gynecologic, gastrointestinal, or head and neck malignancies experiencing peripheral neuropathy caused by neurotoxic chemotherapy.

Methodologic Approach: Cognitive interviewing methodology was used to evaluate the content validity of a 16-item version of the QLQ-CIPN20 instrument.

Findings: Minor changes were made to three questions to enhance readability. Twelve questions were revised to define unfamiliar terminology, clarify the location of neuropathy, and emphasize important aspects. One question was deleted because of clinical and conceptual redundancy with other items, as well as concerns regarding generalizability and social desirability.

Interpretation: Cognitive interviewing methodology revealed inconsistencies between patients’ understanding and researchers’ intent, along with points that required clarification to avoid misunderstanding.

Implications for Nursing: Patients’ interpretations of the instrument’s items were inconsistent with the intended meanings of the questions. One item was dropped and others were revised, resulting in greater consistency in how patients, clinicians, and researchers interpreted the items’ meanings and improving the instrument’s content validity. Following additional revision and psychometric testing, the QLQ-CIPN20 could evolve into a gold-standard CIPN patient-reported outcome measure.

About 64% of individuals develop chemotherapy-induced peripheral neuropathy (CIPN) following treatment with neurotoxic chemotherapeutic agents, such as taxanes, platinums, and vinca alkaloids (Seretny et al., 2014). CIPN is mainly a sensory, length-dependent neuropathy affecting sensory, motor, and autonomic peripheral nerves and is most commonly characterized by numbness, tingling, and neuropathic pain in the extremities. Symmetrical neuropathic pain; altered touch, temperature, and vibration sensibility; and diminished proprioception are characteristics of sensory CIPN, whereas motor CIPN is characterized by weakness and muscle atrophy. Diminished deep tendon reflexes indicate sensory and motor CIPN. Autonomic CIPN symptoms are less common and include constipation, orthostatic hypotension,