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

Ellen M. Lavole 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

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,