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Evaluation of Oncology Nurses' Knowledge, Practice Behaviors, and Confidence Specific to Chemotherapy Induced Peripheral Neuropathy

Rebecca Denise McAllister
University of South Florida

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Evaluation of Oncology Nurses’ Knowledge, Practice Behaviors, and Confidence 
Specific to Chemotherapy Induced Peripheral Neuropathy

by

R. Denise McAllister

A thesis submitted in partial fulfillment of the requirements for the degree of Masters of Science College of Nursing University of South Florida

Major Professor: Susan C. McMillan, Ph.D., A.R.N.P.
Cindy Tofthagen, Ph.D., A.R.N.P.
Janine Overcash, Ph.D., A.R.N.P.

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October 27, 2010

Keywords: Paresthesias, Neurotoxic, Nursing, Assessment, Skill

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Dedication

This is dedicated to my family. My husband and best friend Rodney, thank you for supporting my decision to attend graduate school and for encouraging me every day. I appreciate the sacrifices you have made in helping me realize my dream. To my son Stephen, thank you for your support, encouragement, and for your computer expertise. Because of you, I want to be the best, I can be. To my mother Betty, thank you for being my role model, instilling courage and strength, and for being my biggest fan. To Judi and Julie, thank you for encouraging me and for providing help when I needed it. To my brothers and sister Milton, Bobby, Ronnie, Jerry, and Betty Carol, thank you for being my cheerleaders and for showing patience and tolerance with my busy schedule. To my sister Rita, you inspire me everyday to advocate for those who cannot advocate for themselves.
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Evaluation of Oncology Nurses’ Knowledge, Practice Behaviors, and Confidence Specific to Chemotherapy Induced Peripheral Neuropathy

R. Denise McAllister

Abstract

Chemotherapy induced peripheral neuropathy (CIPN) remains one of the most serious and challenging symptoms oncology nurses encounter in caring for patients receiving neurotoxic chemotherapy. CIPN is under-addressed, under-reported, and symptoms are minimized by healthcare providers, which adversely affect patient quality of life, physical function, and emotional well-being. There is an absence of research examining nurses’ knowledge and practice behaviors related to CIPN. The purpose of this study was to explore oncology nurses knowledge, practice behaviors, confidence, and the relationship between education, experience, and knowledge specific to CIPN.

Data was collected at Oncology Nursing Society (ONS) Chapter meetings throughout central and south Florida. The sample consisted of 70 oncology nurses who provide direct care to patients with cancer. Participants completed the CIPN: Assessment of Oncology Nurses’ Knowledge and Practice–Revised questionnaire. Demographic data revealed the overall years of nursing experience mean to be 24.7 (SD=12.2), mean years of oncology experience to be 13.5 (SD=7.5), and mean age to be 50.3 years (SD=9.5). The participants varied in highest attained level of education with the majority having Bachelor of Science degrees (40.0%).
The results of this study revealed adequate nursing knowledge pertaining to CIPN 13.0 (SD=1.9) (81%). Fifty-percent of nurses reported always or frequently screening for CIPN. The majority of participants reported always or frequently; evaluating fine motor skills (68.6%), documenting findings (64.3%), assessing risk factors (55.7%), assessing motor function (52.9%), performing assessment prior to each neurotoxic chemotherapy infusion (58.6%), eliciting patient symptoms (65.7%), teaching strategies for adaptation (57.1%), and teaching safety precautions (74.3%). Nurses less frequently reported always or frequently assessing deep tendon reflexes (17.2%) and assessing muscle strength (35.7%). The majority reported confidence in sharp vs. dull sensation testing (62.8%), and manual muscle strength testing (52.9%), while the majority lacked confidence performing deep tendon reflex testing (71.5%), tuning fork vibration sensation testing (72.8%), and Romberg testing (72.8%). There was a significant relationship between highest educational level achieved and knowledge of CIPN (r=.252, p=.037).

This is one of two studies documenting oncology nurses’ knowledge, practice behaviors, and confidence specific to CIPN. Findings lay the foundation in documenting the need for providing oncology nurses with continued education, and the need to teach oncology nurses the skills necessary to confidently assess for CIPN and interpret the findings.
Chapter I: Introduction

The American Cancer Society (ACS) estimates 1,500,000 people are diagnosed with cancer annually with an estimated 11.1 million Americans living after a cancer diagnosis (ACS, 2009). Chemotherapy is an integral component of the cancer treatment paradigm that promotes cure, disease control, or palliation of symptoms. Chemotherapy-induced peripheral neuropathy (CIPN) is a serious clinical problem that affects those receiving: platinum based compounds; taxanes; plant alkaloids; biologics; antiangiogenesis agents; and proteasome inhibitors used for treatment of a variety of solid and hematologic malignancies (Visovsky, Collins, Abbott, Aschenbrenner, & Hart, 2007; Wilkes, 2007). Despite advances in therapies and side effect management, CIPN remains one of the most challenging symptoms oncology nurses encounter in caring for patients receiving neurotoxic chemotherapy (Wilkes, 2007).

Sensory signs and symptoms may include tingling, numbness, and burning in the hands and feet. Usually the symptoms are bilateral and are worse in the lower extremities. Symptoms may also include pain, and loss of vibratory, position, and temperature sense, touch, deep tendon reflexes, and two-point discrimination (Armstrong, Almadrones, & Gilbert, 2005). CIPN causes a disruption in work responsibilities and leisure activities with functional deficits based on location of paresthesias involving fingers, hands, arms, toes, feet, and legs (Bakitas, 2007). Functional effects of CIPN include but are not limited to; mobility and safety issues, weakness of extremities, inability to sense temperature changes, difficulty performing tasks that require hand and foot manipulation, and pain in
affected extremities (Bakitas, 2007; Toftthagten, 2010). Risk factors for CIPN include exposure to neurotoxic chemotherapy, concurrent use of neurotoxic medications, previous radiation to spinal fields causing pre-existing neuropathy, malignancies associated with pre-existing neuropathy such as multiple myeloma, co-morbid conditions such as diabetes mellitus, hypothyroidism, vitamin B deficiencies, human immunodeficiency virus, renal insufficiency, and alcoholism (Armstrong, et al., 2005; Wickham, 2006).

CIPN is under-addressed, under-reported, and minimized by oncology healthcare providers causing patients to suffer the ill effects of chemotherapy induced peripheral neuropathy and lack of management (Smith, Beck, & Cohen, 2008). The experience of CIPN negatively influences patient’s daily lives, adversely affecting quality of life (QOL) and physical function of patients with cancer who receive neurotoxic chemotherapy agents (Bakitas, 2007; Toftthagten, 2010). In addition to compromising patients’ QOL, treatment dose reductions, treatment discontinuation, or treatment postponement can occur due to the dose-limiting toxicity of CIPN (Kuroi et al., 2008; Visovsky, et al., 2007).

**Problem Statement**

There is an absence of research examining oncology nurses’ knowledge of pathophysiology of the peripheral nervous system, neurotoxic effects of chemotherapy, interventions used to manage CIPN, and the impact of CIPN to those receiving neurotoxic agents. Research is needed to examine nurse’s knowledge of this phenomenon because knowledge is pre-requisite to practice (Curley, 1998). Oncology nurse’s knowledge of CIPN needs to be assessed and any identified deficits need to be rectified
for the preservation of safety and improved QOL of oncology patients. The purpose of this study was to explore oncology nurses’ knowledge, practice behaviors, and confidence in assessing for CIPN.

Research Questions

The aim of this study was to answer the following research questions:

1. What is the level of knowledge among oncology nurses regarding CIPN?
2. What are oncology nurses’ self-reported practice behaviors in assessing for CIPN?
3. How confident are oncology nurses in assessing CIPN in their patients?
4. What is the relationship between oncology nurses experience, level of education, and knowledge specific to CIPN?

Definitions of Terms

For the purpose of this study, the following terms are defined:

*Peripheral nervous system*: the portion of the nervous system that is outside the brain and spinal cord, that transmits information between the central nervous system (e.g. the brain and spinal cord) and the rest of the body (Sweeney, 2002).

*Chemotherapy induced peripheral neuropathy*: neuromuscular systems due to damage to the peripheral nervous system, induced by neurotoxic chemotherapeutic agents (Visovsky, et al., 2007).

*Function*: ability to perform activities related to personal care and role responsibility (Barsevick, Much, & Sweeney, 2000).

*Quality of life*: patients’ self-assessment of and satisfaction with their current level of functioning compared to what is perceived to be possible or ideal (Cella, & Tulsky, 1990).
Significance to Nursing

Symptom management and improving QOL are the primary focus of oncology nursing. CIPN is an unpleasant symptom that can potentially adversely affect the QOL, function, and safety of patients with cancer. Nurses can advocate on behalf of patients by understanding the distressing influence and long-term sequella CIPN can have on daily living. It is estimated ten to one-hundred percent of patients with cancer will develop CIPN depending on drugs, dosages, existing co-morbid conditions, and measurement tool utilized by the healthcare team (Bakitas, 2007). Nurses being in the forefront of oncology care are in the best position to identify neurotoxic agents, educate patients on early symptoms, assess for symptoms, and anticipate the care the patient will require with the intent to minimize or alleviate the burden of CIPN. Nurses have a great opportunity to evaluate their own knowledge of CIPN regarding assessment and intervention strategies relevant to clinical practice for the preservation of safety and improved QOL of the oncology patient. This study may shed light on oncology nurses’ level of knowledge, practice behaviors, confidence in neurological assessment pertaining to CIPN, and the relationship between knowledge of CIPN, and level of education, and nursing experience. The results of this study will be applied to the creation of a larger intervention study aimed at the management of CIPN. In addition, data generated from this study will help direct educational programs for oncology nurses.
Chapter II: Review of the Literature

This chapter outlines the review of literature. The theoretical framework is presented first, followed by pathophysiology, impact of CIPN on function and QOL, measurement tools, prevention and treatment strategies, and a summarization of the literature.

Theoretical Framework

The Synergy Model for Patient Care developed by the American Association for Critical Care Nursing provides the conceptual framework for this research. The premise of the Synergy Model for Patient Care, is when patient characteristics and nurses competencies match, optimal patient outcomes are achieved (Curley, 1998). The model identifies eight common characteristics displayed by patients when confronted with a health issue. These include resiliency, vulnerability, stability, complexity, resource availability, participating in care, participating in decision-making, and predictability. These characteristics aid the nurse in anticipating the needs of patients and providing optimal care based on the patient’s unique needs. The identified nursing characteristics include clinical judgment, advocacy-moral agency, caring practices, collaboration, systems thinking, response to dignity, clinical inquiry, and facilitator of learning (Arashin, 2010; Curley, 1998). The Synergy Model can be incorporated to guide clinical practice with CIPN as the primary focus. CIPN can place patients in a vulnerable state with possible compromise to treatment outcomes and can induce physiological or psychological stress. Nurses can identify a predictive path based on disease, risk factors,
selection of neurotoxic agents, and noting how patients are responding to neurotoxic chemotherapy. Oncology nurses can apply their clinical expertise, provide compassionate care, advocate on behalf of patients, and collaborate with interdisciplinary team members when approaching the care of patients with CIPN to minimize or alleviate the burden of CIPN.

Pathophysiology of CIPN

The nervous system is comprised of the central nervous system (CNS) and peripheral nervous system (PNS). The PNS consist of sensory, motor, and autonomic nerves. The sensory nerve fibers transmit impulses from the periphery to the CNS. The motor nerve fibers transmit impulses from the CNS to the muscles or organs. The large myelinated sensory nerves control vibration and position sense and unmyelinated small fiber sensory nerves control pain, perception of touch, and temperature. Motor nerves control voluntary movement, coordination, and maintain muscle tone. The autonomic peripheral nerves control blood pressure, intestinal motility, and involuntary muscles (Armstrong, et al., 2005; Wilkes, 2007).

The underlying pathophysiology rationale for developing CIPN has not been fully described, because of incomplete understanding. The pathogenesis may vary depending on the neurotoxic agent administered. Neurotoxic chemotherapeutic agents are thought to damage sensory axons, leading to degeneration and dying back of axons and myelin sheaths. Axons can regenerate, however, damage to cell bodies is often not reversible (Wickham, 2006).

Patients commonly speak of severe symptoms of CIPN causing interference with physical function including the inability to button clothing, write, drive, or walk (Bakitas,
Sensory signs and symptoms include numbness, tingling, burning, pain, ataxia, loss of deep tendon reflexes, and reduced sense of touch, vibration, and proprioception. Motor symptoms include weakness, gait disturbances, balance disturbances, and difficulty with fine motor skills. Autonomic symptoms include constipation, urinary retention, sexual dysfunction, and altered blood pressure (Bakitas, 2007; Visovsky, et al., 2007; Wilkes, 2007). These CIPN symptoms may be acute, mild or severe, transient, or prolonged (Postma, & Heimans, 2000).

Symptoms of CIPN are related to the affected nerve fibers. Sensory changes are usually noted first in the toes and feet, the fingers and hands second, followed by a proximal progression to the ankles and wrist in a stocking glove-manner (Wolf, Barton, Kottschade, Gothey, & Loprinzi, 2008). The distribution of symptoms is bilateral and symmetrical. Symptoms of CIPN can become progressively worse after discontinuing the neurotoxic agent. This phenomenon is known as coasting and occurs as result of receiving a cumulative amount of drug. The onset is usually a gradual progression; however, rapid onset can occur after receiving a neurotoxic agent (Wilkes, 2007).

Patients with pre-existing conditions, such as diabetes mellitus, alcohol related peripheral neuropathy, ischemic disease, vitamin deficiencies, renal insufficiency, prior exposure, or concurrent use of neurotoxic agents could be at increased risk for CIPN (Armstrong, et al., 2005; Wilkes, 2007).

Peripheral neuropathy may be reversible with dose modification or discontinuation, and in some cases; the damage is irreversible. The incidence and type of CIPN is dependant on the causative drug (Table 1) (Wilkes, 2007).
### Table 1

**CIPN: Causative Agent, Incidence, and Type**

<table>
<thead>
<tr>
<th>Agent</th>
<th>Incidence</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carboplatin</td>
<td>13%-42%</td>
<td>Sensory progressing to mixed sensori-motor</td>
</tr>
<tr>
<td>Cisplatin</td>
<td>57%-92%</td>
<td>Sensory progressing to mixed sensori-motor, autonomic</td>
</tr>
<tr>
<td>Oxaliplatin</td>
<td>13%-92%</td>
<td>Sensory, autonomic</td>
</tr>
<tr>
<td>Paclitaxel</td>
<td>59%-78%</td>
<td>Mixed sensori-motor</td>
</tr>
<tr>
<td>Docetaxol</td>
<td>20%-58%</td>
<td>Sensori-motor</td>
</tr>
<tr>
<td>Vincristine</td>
<td>57%</td>
<td>Mixed sensori-motor, autonomic</td>
</tr>
<tr>
<td>Vinorelbine</td>
<td>7%-31%</td>
<td>Motor and autonomic</td>
</tr>
<tr>
<td>Bortezomib</td>
<td>35%</td>
<td>Sensory, mixed sensori-motor</td>
</tr>
<tr>
<td>Thalidomide</td>
<td>22%-54%</td>
<td>Sensori-motor</td>
</tr>
</tbody>
</table>

*Note.* Adopted from Wilkes (2007).

**Impact on Function and QOL**

Symptoms of CIPN, other than numbness and tingling in the hands and feet have gained little attention in the literature. Bakitas (2007) purposely recruited 28 participants from a rural National Cancer Institute designated comprehensive cancer center to this qualitative study to better understand the impact of CIPN on daily living and function. The eligibility criteria included patients identified as having numbness, tingling, burning, shock-like, or painful sensations present bilaterally in feet or hands that was not present prior to initiation of chemotherapy, and found to be related to the initiation of chemotherapy. Demographics of participants included; mean age 59 years +/- 9.6 with an age range of 46-81 years, 71% female, median time since diagnosis was 34 months with range of 3-198 months, 50% had breast cancer, 21% had hematologic malignancies, 11% had ovarian cancer, 11% had colon cancer and 7% other malignancies. Primary data collection occurred through individual 25-90 minute interviews, which were audiotaped and transcribed into more than 700 pages of text. Data was analyzed using content analysis and constant comparison.
In this, qualitative study by Bakitas (2007), CIPN was best described as a constant drone that was distracting and unpleasant like that of background noise. Four themes that further defined the CIPN experience were becoming aware, learning new lyrics, functional, emotional, and social cacophony, and learning to live with CIPN. The awareness involved noticing symptoms, monitoring for changes, evaluating function, ignoring intense symptoms, and notifying the healthcare team of symptoms. Learning new lyrics symbolizes the difficulty patients had communicating the sensation of CIPN to the healthcare team so the symptoms could be understood. Role cacophony describes the interruption in activities of daily living, leisure, work, and role within the family. Some felt isolated when they could not participate in social activities. CIPN was also considered emotionally distressing. Learning to live with CIPN represents the trade-off for the benefit of treatment although the potential for irreversible nerve damage and permanent disability was of concern. Half of patients reported they had no recall of receiving education on CIPN. Patients reported healthcare providers assessed for CIPN, although rarely asked about the impact on daily living. Some received a change in chemotherapy or medications to control symptoms, while others ignored the symptoms and adjusted planned activities because of symptoms. The findings of this study contribute to the clarity of how those affected by CIPN live each day (Bakitas, 2007).

Tofthagen (2010) describes the effects of CIPN and neuropathic pain in the lives of 14 patients with cancer. The sample consisted of 8 men and 6 women, ranging in age from 42-84 years. The cancer diagnoses of the participants included breast (28%), lung (28%), colorectal (22%), multiple myeloma (14%), and cholangiocarcinoma (7%). Participants received neurotoxic chemotherapy regimens containing paclitaxel (28%),
oxaliplatin (28%), docetaxel (22%), thalidomide (14%), or vinorebine (7%) and must have received these agents within three years of data collection. Semistructured interviews were conducted, recorded, and transcribed. The interviews ranged 10-45 minutes in length, with participants being asked six questions related to CIPN symptoms; words to describe these symptoms; affect on daily life; interference with ability to function; what is most troubling about these symptoms; and participants were given opportunity to share any additional information about these symptoms.

Participants reported a combination of sensory and motor symptoms associated with and without pain symptoms. The non-painful symptoms reported include numbness of fingers and toes (100%), loss of balance (57%), muscle weakness (57%), tingling (50%), generalized weakness (43%), lack of coordination (14%), short-term memory loss (14), trouble concentrating (14%), and loss of depth perception (7%). Almost 50% of patients reported near or actual injuries because of non-painful symptoms with 43% of participants reported being ambulatory prior to treatment who now require assistive devices to ambulate. Painful symptoms were reported including cold sensitivity (50%), pain (71%), burning (43%), muscle aches (36%), pins and needles (29%), soreness (22%), tremors (22%), jaw pain (14%), joint pain (14%), sharp pain (14%), shooting pain (14%), electric-like pain (7%), pressure (7%), stabbing pain (7%), and trampling pain (7%). Although patients had difficulty expressing or describing the painful sensation, the pain was located primarily in the upper and lower extremities. Neuropathic symptoms were described as interfering with usual activities such as activities of daily living (57%), walking (50%), picking up items (43%), driving (36%), hobbies (36%), relationships
(29%), household chores (22%), manual dexterity (22%), work (22%), writing (14%),
exercise (7%), sexual activity (7%), and sleep (7%).

The researcher reports patients had difficulty articulating symptoms of CIPN,
which is consistent with the literature. The participants have been coping with
neuropathic symptoms for up to three years and expressed their QOL had been adversely
affected. The interference with ability to perform activities is a source of great emotional
distress. This study supports the negative influences CIPN has on QOL, functional
capacity, and emotion well being.

Measurement Tools

CIPN was once considered a minor problem that would resolve over time and
seldom led to profound limitations (Smith, et al., 2008). This ideology has posed an
important challenge to neuropathy measurement in the oncology setting. Commonly used
grading scales, such as the National Cancer Institute Common Toxicity Criteria for
Adverse Events (NCI-CTCAE) (National Cancer Institute, 2003), Eastern Cooperative
Oncology Group (ECOG) (Oken, Creech, Tormey, Horton, Davis, McFadden, et al.
1982), World Health Organization (WHO) (Miller, Hoogstraten, Staquet, & Winkler,
1981), and Ajani (Ajani, Welch, Raber, Fields, & Krakoff, 1990) have different
definitions of grade and do not define terms (Wilkes, 2007). This allows for subjective
interpretation on behalf of healthcare providers leading to ambiguities when deciding
treatment modifications based on current grading tools.

An important study evaluating the inter-examiner and inter-test reliability
between widely used grading scales was conducted by Postma, Heimans, Muller,
the severity of CIPN in 37 patients with 148 observations according to WHO, ECOG, Ajani, and NCI-CTCAE criteria. The majority of participants were female with ovarian cancer who had previously received paclitaxel and cisplatin. The percentage of interobserver agreement on all grades of CIPN ranged from 46% to 84% (NCI-CTCAE 46%, Ajani 57%, ECOG 76%, and WHO 84%). A comparison of the different grading scales showed the interobserver agreement utilizing grades 0 to 4 was the lowest using the NCI-CTCAE grading scale at 45.9% while the agreement on severe (grade 3) neuropathy using the NCI-CTCAE was 42% with 58% disagreement. The interobserver agreement between the ECOG grade 3 CIPN was 40% and 0% for the WHO and Ajani criteria. This study demonstrates clinicians interpret the evaluation criteria and grading for CIPN differently. The authors stated the differences occur when accounting for the interpretation of patient symptoms related to interference with function. These widely accepted grading tools do not incorporate patient’s subjective experiences of daily living and functional impairment in the scale parameters. These tools are useful for identifying patients who are need of neurological examination, however do not reflect the extent and severity of CIPN (Postma, et al., 1998).

In an effort to quantify the symptoms and severity of CIPN, the Patient Neurotoxicity Questionnaire (PNQ) was developed by BioNumerik Pharmaceuticals with input from the Food and Drug Administration (FDA). It is a simple self-administered patient based questionnaire designed to delineate between interference and no interference in activities of daily living (ADL) resulting from CIPN (Hausheer, Schilsky, Bain, Berghorn, & Liberman, 2006). Shimozuma, Ohashi, Takechi, Morita, Ohsmi, Sunada, et al. (2004) evaluated the validity of this patient-based instrument with the
clinician-based instrument NCI-CTCAE and the Functional Assessment of Cancer Therapy-Taxane including neurotoxicity component (FACT/GOG-Ntx). The PNQ was utilized in a Phase III randomized trial comparing four treatment arms of different adjuvant taxane containing regimens in breast cancer patients in evaluating symptoms of neurotoxicity. CIPN symptoms were prospectively assessed in 300 patients at day thirty-eight following surgery and at baseline, cycle three, cycle five, and cycle seven of starting adjuvant therapy. The mean age was 51.7 years +/- 8.9, 55% had 1-3 positive nodes, 26.7% had 4-9 positive nodes, 18.3% had 10 or greater positive nodes. This study demonstrated that in a defined population of patients receiving neurotoxic chemotherapy, the PNQ is a reliable, sensitive, responsive instrument in the diagnosis and grading of CIPN with greater sensitivity than the FACT-Ntx and NCI-CTCAE. A lower incidence of severe forms of CIPN was reported by physicians based on the NCI-CTCAE as compared to the PNQ, thus demonstrating CIPN is under-reported by physicians. Kuroi et al. (2008) in a qualitative analysis evaluated the physicians’ perspectives regarding the utility and diagnostic value of the PNQ to assess CIPN. A questionnaire was sent to sixty-one physicians who participated in a Phase III randomized trial of adjuvant chemotherapy in breast cancer that used the PNQ to assess CIPN. Seventy-seven percent responded. The study concluded that neurosensory disturbances interfering with ADL are justification for treatment modifications. Based on the PNQ, moderate symptoms are justification for postponing treatment and severe symptoms should result in treatment discontinuation. Eighty-four percent reported the PNQ was helpful in the diagnosis and assessment of patients at risk for CIPN. The FDA has supported the use of the PNQ as a primary end
point in assessing the incidence and severity of CIPN in phase II and phase III trials in the United States (Hausheer, et al., 2006).

Oncology nurses’ assessment is critical to early identification. Assessment of neurological function on a routine basis, monitoring those at risk is crucial to successful intervention. Smith et al (2008) reports the Total Neuropathy Score (TNS) developed for neurologist has been described as the most comprehensive tool available and should be considered for use by oncology nurses in evaluating for CIPN. This scoring system (0-32 points) combines subjective sensory symptoms, subjective report of symptoms and amount of difficulty with daily activities, deep tendon reflex testing, manual muscle testing of muscles for the wrist and ankle, pin sensibility, quantitative vibration thresholds, and nerve conduction studies. This tool assesses neuropathy signs and symptoms and incorporates nerve conduction study results, but does not adequately assess painful neuropathy. The systematic review of seven studies describes the psychometric properties, clinical significance, and the utility of the TNS in assessing CIPN. This data synthesis concludes, this tool is too labor intensive for clinical practice, and inadequately assesses the pain component of neuropathy. This author also states, with basic physical assessment training and practice, nurses can become skilled at neuropathy assessment.

Binner (2010) developed the Chemotherapy-Induced Peripheral Neuropathy: Assessment of Oncology Nurses’ Knowledge and Practice, a questionnaire to determine the knowledge oncology nurses have specific to CIPN and to evaluate practice behaviors and CIPN assessment skills. The questionnaire contains 16 knowledge items, 16 practice items, and 9 demographic items related to skills, instructions, and perceptions. The test
was administered to 39 oncology nurses in 2 outpatient infusion clinics. Test results were evaluated for reliability.

This study indicated oncology nurses have adequate knowledge of CIPN with a mean knowledge score 12.6 (79%), out of a possible 16. All respondents indicated assessment of CIPN is essential to their role, 75% rated their CIPN assessment skills as fair to poor. Only 25% rated their assessment skills as good, and none rated their assessment skills as excellent. General physical assessment practices did not routinely include neurological physical assessment, 56.4% always or frequently perform baseline screening, 76.9 % always or frequently assess fine motor skills, 74.3% always or frequently document findings, 51.3% always or frequently assess risk factors, 76.9% always or frequently perform CIPN assessment prior to each infusion of a neurotoxic agent, 89.7% elicit symptoms of CIPN, 79.5% teach safety precautions. Oncology nurses reported never or occasionally performing deep tendon reflex testing (97.4%), muscle strength testing (77%), never or occasionally performing gross motor function testing (69.2%). The content validity index of this instrument was determined to be 0.95, and the internal consistency reliability was shown to be high, with a Cronbach’s alpha score of 0.84.

Prevention and Treatment Strategies

Visovsky and colleagues (2007) constructed an evidenced based review of interventions aimed at the prevention and treatment of CIPN. The Oncology Nursing Society published this systematic review as a guide for oncology nursing practice. This analysis highlights a review of pharmacologic intervention studies utilizing amifostine, vitamin E, calcium and magnesium, nortriptyline, carbamazpine, acetyl-L-carnine,
glutamine, glutathione, alpha lipoic acid, and human leukemia factor for the prevention or reduction in CIPN. There is not enough evidence that meets the scientific rigor required to suggest any pharmacologic interventions for clinical practice. Non-pharmacologic interventions such as acupuncture, assistive devices, pulsed infrared light therapy, transcutaneous nerve stimulation, capsaicin ointment, and spinal cord stimulation do not have established effectiveness in the prevention or treatment of CIPN. The studies evaluating the above non-pharmacologic interventions have limited or complete absence of data in the oncology population.

**Summary**

Chemotherapy induced peripheral neuropathy (CIPN) is an untoward side effect that can potentially adversely affect the quality of life of patients with cancer who receive neurotoxic chemotherapeutic agents. Oncology nurses face many challenges in providing comprehensive care to patients receiving cancer therapies that can result in CIPN. The literature supports a lack of a standard comprehensive, reliable, valid measurement tool that captures early symptoms of CIPN. Kuroi et al. (2008) reports the current tools do not consider the patients’ verbal reporting of symptoms of PN. The inability for patients to adequately articulate the symptoms of PN can be problematic for oncology practitioners in understanding the symptoms and the impact long term. The National Cancer Institute Common Toxicity Criteria for Adverse Events (CTCAE), World Health Organization (WHO), and Eastern Cooperative Oncology Group (ECOG) have different definitions of grade and do not define terms, which allows for subjective interpretation leading to ambiguities when deciding upon treatment modifications.
Visovsky et al. (2007) through the ONS Putting Evidence Into Practice (PEP) initiative provides a comprehensive review of the literature with no identified large, randomized, double-blind clinical trials showing pharmacologic and non-pharmacologic efficacy in the prevention and treatment of CIPN.

Smith and colleagues (2008) reviewed the literature evaluating the usefulness of the Total Neuropathy Score (TNS) as an instrument designed to quantify CIPN that nurses may incorporate into clinical practice. It was determined this comprehensive tool assessing both subjective and objective aspects of peripheral nerve function lacked validity, adequate neuropathic pain assessment, and would require nurses to have basic knowledge of physical neurological assessment. Binner (2010) developed the first tool to explore oncology nurses’ knowledge and practice behaviors specific to CIPN. This study concluded oncology nurses have adequate knowledge related to CIPN, CIPN assessment skills were rated as fair to poor by 75%, and assessment practices to not routinely include neurological physical assessment. This instrument was found to be valid and reliable with a Cronbach’s alpha score =0.84. This study is the only one to evaluate oncology nurses knowledge and practice behaviors.

Bakitas (2007) evaluated 28 study participants in an attempt to clarify the CIPN symptom experience and the influence on everyday living. The metaphor of background noise was used to describe the constant drone of living with CIPN. Tofthagen (2010) purposely evaluated 14 oncology patients in a descriptive analysis examining the effects of CIPN and neuropathic pain. The participants described sensory and motor symptoms, with and without pain. The negative effects of CIPN on the physical and emotional wellbeing of patients with cancer are clearly described.
Chemotherapy induced peripheral neuropathy is a significant dose-limiting toxicity that adversely affects the lives of cancer patients. This symptom has been under-reported, minimized by oncology practitioners, and inaccurately described as a minor problem. There are many gaps in the knowledge of standardized nursing assessment, interventions, and patient education in the literature. Oncology nurses need to be aware of the current state of the literature, and become knowledgeable of the distressing influence CIPN has on daily living. Nurses can advocate for patients by understanding the pathophysiology of CIPN, identifying risk factors, educating patients on early symptoms, collaborating with the healthcare team, and by anticipating the care the patient will require. This knowledge and empowerment may minimize, or alleviate the burden of CIPN. Nurses have great opportunity to evaluate their own gaps in knowledge of CIPN for the preservation of safety and improved quality of life of the oncology patient.
Chapter III: Methods

This chapter outlines the research methods. Specifically the sample and setting, instrument, validity and reliability, consent process, and procedure for data collection and data synthesis are presented here. This project was a prospective, cross-sectional, descriptive study exploring oncology nurses’ knowledge, practice behaviors, and confidence in assessing CIPN.

Sample

This study was conducted at four Florida Oncology Nursing Society Chapter meetings located on the west and east coast and central Florida. The sample consisted of oncology nurses who are Oncology Nursing Society members and are chapter attendees. Study inclusion criteria supported participation from registered nurses who are currently providing or have in the past provided direct care to medical oncology-hematology patients and who can read, write, and speak English. Nurses whose oncology career has been outside of a medical oncology setting (i.e. critical care, surgical- oncology) were excluded.

Instrumentation

Chemotherapy-Induced Peripheral Neuropathy: Assessment of Oncology Nurses’ Knowledge and Practice-Revised.

The Chemotherapy-Induced Peripheral Neuropathy (CIPN): Assessment of Oncology Nurses’ Knowledge and Practice-Revised instrument assesses the knowledge, practice behaviors and confidence oncology nurses have specific to CIPN (Appendix A)
(Binner, 2010). This instrument was selected because it is the only available tool evaluating nurses’ knowledge, practice behaviors, and confidence pertaining to CIPN. This questionnaire contains sixteen knowledge items, sixteen practice items, five confidence items, and nine-item demographic survey questions specific to skills, instruction, and perceptions. The CIPN knowledge questions score can range from 0-16 based on number of correct answers. Unanswered questions are counted as incorrect. Practice domain questions are each rated to indicate frequency of practice behaviors on a scale of 0-3 (Never, occasionally, frequently, and always). The self-rated confidence questions are rated to indicate level of confidence in performing neurological physical assessment skills on a scale of 0-3 (Not at all confident, somewhat confident, confident, and very confident). These are not summed however, are reported as percentages (Binner, 2010).

Validity and Reliability

To assess Content validity the Assessment of Oncology Nurses’ Knowledge and Practice-Revised instrument was evaluated by a panel of experts including two medical oncologist and three PhD prepared nurses who have published on CIPN. The instrument content-validity index was 0.95. Internal consistency reliability was evaluated using Cronbach’s alpha. The alpha coefficient for the entire instrument was 0.84 (Binner, 2010).

Procedures

First, written permission to use the selected instrument was obtained from the author of the Chemotherapy-Induced Peripheral Neuropathy: Assessment of Oncology Nurses’ Knowledge and Practice-Revised instrument (Appendix B). Written permission
was then obtained from the Presidents of four Oncology Nursing Society (ONS) Chapters in Florida for the purpose of collecting data at their chapter meetings (Appendices C, D, E, & F). The Institutional Review Board (IRB) at the University of South Florida (USF) granted exempt status, so this study would be exempt from the process of signed consent (Appendix G). After study approval by the USF IRB, the CIPN: Assessment of Oncology Nurses’ Knowledge and Practice-Revised questionnaire was administered to a group of oncology nurses at the beginning of the Oncology Nursing Society (ONS) Chapter meeting held on the west coast, followed by an east coast chapter meeting, then a chapter meeting held in central Florida, with data collection ending at a meeting held on the west coast of Florida. The purpose of the study, study requirements, confidentiality, and voluntary participation were explained. Nurses were informed that by completing the questionnaire informed consent would be implied. All questions were answered to participants’ satisfaction. All data was kept anonymous and confidential. An assumption is that all oncology nurses have access to the literature regarding CIPN.

**Data Analysis**

Descriptive statistics were utilized to analyze the demographic data including frequencies and percentages, means, and standard deviations. Relationships between variables were assessed using the Pearson correlation coefficient. Data was analyzed using SPSS software version 16.0 to answer the research questions: Means and Standard deviations were utilized to answer research question one. Research questions two and three were addressed using frequencies and percentages. Pearson correlations were utilized to answer research question four.
Chapter IV: Results, Discussion, and Conclusions

This chapter outlines the findings of this cross-sectional, descriptive study. The results, discussion, conclusions, and recommendations for future research are presented.

Results

Demographic Data

The sample consisted of 70 oncology nurses, which included 69 females with demographic data missing on one participate. The age range of the participants was from 26 to 68 years. The overall nursing experience, ranged from 1 to 47 years with experience specific to oncology nursing, ranging from 6 months to 32 years (Table 2).

Table 2

<table>
<thead>
<tr>
<th>Demographic Variable</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>50.2</td>
<td>9.5</td>
</tr>
<tr>
<td>Years in Nursing</td>
<td>24.7</td>
<td>12.2</td>
</tr>
<tr>
<td>Years in Oncology</td>
<td>13.5</td>
<td>7.4</td>
</tr>
</tbody>
</table>

*Note.* Demographics (n=70, missing data on 1 participant).

The participants varied in educational levels with both nursing education and highest education degree achieved examined (Table 3). In the nursing education category 59 (74.3%) of the 70 participants had undergraduate degrees (Diploma, Associate of Science, or Bachelors of Science) while 10 (14.3%) had Masters of Science (9) or Doctoral (1) degrees. The highest education level achieved category was higher in Masters of Science (2.8%) and Doctoral degrees (1.5%) compared to nursing education.
level category. Most were currently employed as registered nurses (85.7%) with a small subgroup (8.6%) employed as nurse practitioners. Among the participating oncology nurses, 65.7% held oncology certification.

Table 3

<table>
<thead>
<tr>
<th>Demographic Variable</th>
<th>Response</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic Nursing Education Level</td>
<td>Diploma</td>
<td>9</td>
<td>12.9</td>
</tr>
<tr>
<td></td>
<td>Associate</td>
<td>21</td>
<td>30.0</td>
</tr>
<tr>
<td></td>
<td>Bachelors</td>
<td>29</td>
<td>41.4</td>
</tr>
<tr>
<td></td>
<td>Masters</td>
<td>9</td>
<td>12.9</td>
</tr>
<tr>
<td></td>
<td>Doctorate</td>
<td>1</td>
<td>1.4</td>
</tr>
<tr>
<td>Highest Attained Education Level</td>
<td>Diploma</td>
<td>7</td>
<td>10.0</td>
</tr>
<tr>
<td></td>
<td>Associate</td>
<td>21</td>
<td>30.0</td>
</tr>
<tr>
<td></td>
<td>Bachelors</td>
<td>28</td>
<td>40.0</td>
</tr>
<tr>
<td></td>
<td>Masters</td>
<td>11</td>
<td>15.7</td>
</tr>
<tr>
<td></td>
<td>Doctorate</td>
<td>2</td>
<td>2.9</td>
</tr>
<tr>
<td>Current Position</td>
<td>RN</td>
<td>60</td>
<td>85.7</td>
</tr>
<tr>
<td></td>
<td>CNS</td>
<td>1</td>
<td>1.4</td>
</tr>
<tr>
<td></td>
<td>NP</td>
<td>6</td>
<td>8.6</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>2</td>
<td>2.9</td>
</tr>
<tr>
<td>Oncology Nursing Certification</td>
<td>No</td>
<td>23</td>
<td>32.9</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>46</td>
<td>65.7</td>
</tr>
<tr>
<td>Certification Type</td>
<td>None</td>
<td>23</td>
<td>35.7</td>
</tr>
<tr>
<td></td>
<td>OCN</td>
<td>40</td>
<td>57.1</td>
</tr>
<tr>
<td></td>
<td>AOCNP</td>
<td>3</td>
<td>4.3</td>
</tr>
<tr>
<td></td>
<td>OCCNS</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>3</td>
<td>1.4</td>
</tr>
</tbody>
</table>

Note. (n=69). *RN=Registered Nurse. CNS=Clinical Nurse Specialist. NP=Nurse Practitioner. OCN=Oncology Certified Nurse. AOCNP=Advanced Oncology Certified Nurse. OCCNS=Oncology Certified Clinical Nurse Specialist.
CIPN Knowledge

The participant’s level of knowledge in non-pharmacologic management, pharmacologic agents, neuropathy terminology, assessment principals, and symptomatology specific to CIPN was assessed. The mean CIPN knowledge score was 13.0 (SD=1.9) (81%) of 16.0 (Table 4).

Table 4

<table>
<thead>
<tr>
<th>Variable</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>CIPN Knowledge</td>
<td>8.0</td>
<td>16.0</td>
<td>13.0</td>
<td>1.9</td>
</tr>
</tbody>
</table>

Practice Behaviors

Participants practice behaviors were assessed by self-reported evaluation of screening patterns, assessment skills, documentation, and patient teaching related to CIPN (Table 5). Screening for peripheral neuropathy prior to initiating the first dose of neurotoxic chemotherapy was always or frequently performed by 35, (50.0%) of participating oncology nurses. Evaluating patient’s fine motor skills was always or frequently done by 48 (68.6%) oncology nurses surveyed. Documentation of CIPN assessment findings was always or frequently documented by 45 (64.3%) nurses caring for this population of patients. Only 12 (17.2%) oncology nurses reported always or frequently assessing deep tendon reflexes. Muscle strength was always or frequently measured by only 25 (35.7%) oncology nurses. An assessment of other risk factors associated with peripheral neuropathy was always or frequently assessed among 39 (55.7%) oncology nurses. Fine motor function such as evaluating gait, was always or frequently inspected by 37 (52.9%) oncology nurses surveyed. Of those surveyed, 41 (58.6%) always, frequently incorporate CIPN assessment prior to each infusion of a
neurotoxic agent. Eliciting symptoms of CIPN from patients was always or frequently done by 47 (65.7%) oncology nurses. Teaching patient strategies for adapting to CIPN functional impairment was always or frequently taught by 40 (57.1%) of oncology nurses. Educating patients regarding safety precautions used to avoid injury, among those suffering from CIPN was always or frequently instilled by 52 (74.3%) oncology nurses who care for those affected by CIPN.

Level of Confidence

The level of self-confidence among the participants (n=70) in performing a neurological physical examination by assessing deep tendon reflexes, tuning fork vibration sensation, sharp vs. dull sensation, Romberg test, and manual muscle strength testing was evaluated (Table 6). The majority 50 (71.5%) of nurses reported a lack of confidence in assessing deep tendon reflexes, a lack of confidence in using a tuning fork to assess vibration sensation 51 (72.8%) and a lack of confidence in performing Romberg testing 51 (72.8%). Most, 62.8% reported being confident in performing the sharp vs. dull sensation assessment skill, and a reported 37 (52.9%) oncology nurses reported confidence in assessing manual muscle strength.
<table>
<thead>
<tr>
<th>Self-Reported Practice Behavior</th>
<th>Response</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screen for baseline peripheral neuropathy</td>
<td>Never</td>
<td>8</td>
<td>11.4</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>27</td>
<td>38.6</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>23</td>
<td>32.9</td>
</tr>
<tr>
<td></td>
<td>Always</td>
<td>12</td>
<td>17.1</td>
</tr>
<tr>
<td>Assess fine motor skills</td>
<td>Never</td>
<td>10</td>
<td>14.3</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>12</td>
<td>17.1</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>37</td>
<td>52.9</td>
</tr>
<tr>
<td></td>
<td>Always</td>
<td>11</td>
<td>15.7</td>
</tr>
<tr>
<td>Document CIPN assessment data</td>
<td>Never</td>
<td>7</td>
<td>10.0</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>18</td>
<td>25.7</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>30</td>
<td>42.9</td>
</tr>
<tr>
<td></td>
<td>Always</td>
<td>15</td>
<td>21.4</td>
</tr>
<tr>
<td>Assess deep tendon reflexes</td>
<td>Never</td>
<td>38</td>
<td>54.3</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>20</td>
<td>28.6</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>9</td>
<td>12.9</td>
</tr>
<tr>
<td></td>
<td>Always</td>
<td>3</td>
<td>4.3</td>
</tr>
<tr>
<td>Assess muscle strength</td>
<td>Never</td>
<td>17</td>
<td>24.3</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>28</td>
<td>40.0</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>20</td>
<td>28.6</td>
</tr>
<tr>
<td></td>
<td>Always</td>
<td>5</td>
<td>7.1</td>
</tr>
<tr>
<td>Assess for other risk factors associated with peripheral neuropathy</td>
<td>Never</td>
<td>5</td>
<td>7.1</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>26</td>
<td>37.1</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>25</td>
<td>35.7</td>
</tr>
<tr>
<td></td>
<td>Always</td>
<td>14</td>
<td>20.0</td>
</tr>
<tr>
<td>Assess motor function skills (e.g., gait)</td>
<td>Never</td>
<td>7</td>
<td>10.0</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>26</td>
<td>37.1</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>27</td>
<td>38.6</td>
</tr>
<tr>
<td></td>
<td>Always</td>
<td>10</td>
<td>14.3</td>
</tr>
<tr>
<td>Perform CIPN assessment prior to each neurotoxic chemotherapy infusion</td>
<td>Never</td>
<td>13</td>
<td>18.6</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>16</td>
<td>22.9</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>25</td>
<td>35.7</td>
</tr>
<tr>
<td></td>
<td>Always</td>
<td>16</td>
<td>22.9</td>
</tr>
<tr>
<td>Elicit symptoms related to CIPN</td>
<td>Never</td>
<td>6</td>
<td>8.6</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>18</td>
<td>25.7</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>36</td>
<td>51.4</td>
</tr>
<tr>
<td></td>
<td>Always</td>
<td>10</td>
<td>14.3</td>
</tr>
<tr>
<td>Teach patient strategies for adapting to CIPN functional impairment</td>
<td>Never</td>
<td>10</td>
<td>14.3</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>20</td>
<td>28.6</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>35</td>
<td>50.0</td>
</tr>
<tr>
<td></td>
<td>Always</td>
<td>5</td>
<td>7.1</td>
</tr>
<tr>
<td>Teach safety precautions used to prevent injuries associated with CIPN (e.g., falls)</td>
<td>Never</td>
<td>8</td>
<td>11.4</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>10</td>
<td>14.3</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>35</td>
<td>50.0</td>
</tr>
<tr>
<td></td>
<td>Always</td>
<td>17</td>
<td>24.3</td>
</tr>
</tbody>
</table>
Table 6

*Frequency and Percent of Confidence in Performing Neurological Physical Assessment Skills*

<table>
<thead>
<tr>
<th>Assessment Skill</th>
<th>Confidence Level Response</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deep tendon reflexes</td>
<td>Not at all Confident</td>
<td>23</td>
<td>32.9</td>
</tr>
<tr>
<td></td>
<td>Somewhat Confident</td>
<td>27</td>
<td>38.6</td>
</tr>
<tr>
<td></td>
<td>Confident</td>
<td>17</td>
<td>24.3</td>
</tr>
<tr>
<td></td>
<td>Very Confident</td>
<td>3</td>
<td>4.3</td>
</tr>
<tr>
<td>Tuning fork vibration sensation</td>
<td>Not at all Confident</td>
<td>29</td>
<td>41.4</td>
</tr>
<tr>
<td></td>
<td>Somewhat Confident</td>
<td>22</td>
<td>31.4</td>
</tr>
<tr>
<td></td>
<td>Confident</td>
<td>15</td>
<td>21.4</td>
</tr>
<tr>
<td></td>
<td>Very Confident</td>
<td>4</td>
<td>5.7</td>
</tr>
<tr>
<td>Sharp vs. dull sensation</td>
<td>Not at all Confident</td>
<td>9</td>
<td>12.9</td>
</tr>
<tr>
<td></td>
<td>Somewhat Confident</td>
<td>17</td>
<td>24.3</td>
</tr>
<tr>
<td></td>
<td>Confident</td>
<td>32</td>
<td>45.7</td>
</tr>
<tr>
<td></td>
<td>Very Confident</td>
<td>12</td>
<td>17.1</td>
</tr>
<tr>
<td>Romberg test</td>
<td>Not at all Confident</td>
<td>36</td>
<td>51.4</td>
</tr>
<tr>
<td></td>
<td>Somewhat Confident</td>
<td>15</td>
<td>21.4</td>
</tr>
<tr>
<td></td>
<td>Confident</td>
<td>13</td>
<td>18.6</td>
</tr>
<tr>
<td></td>
<td>Very Confident</td>
<td>6</td>
<td>8.6</td>
</tr>
<tr>
<td>Manual muscle strength testing</td>
<td>Not at all Confident</td>
<td>11</td>
<td>15.7</td>
</tr>
<tr>
<td></td>
<td>Somewhat Confident</td>
<td>22</td>
<td>31.4</td>
</tr>
<tr>
<td></td>
<td>Confident</td>
<td>24</td>
<td>34.3</td>
</tr>
<tr>
<td></td>
<td>Very Confident</td>
<td>13</td>
<td>18.6</td>
</tr>
</tbody>
</table>

*Previous Education and Experience*

The participants’ previous education and experience obtained from demographic data was correlated with their knowledge pertaining to CIPN (n=69). Utilizing Pearson Correlation there was no significant relationship between generic nursing education level attained and knowledge of CIPN ($r=.233$, $p=.054$). There was however, a significant relationship between the highest education level achieved and CIPN knowledge.
Neither the number of years of experience in nursing nor the number of years of experience specific to oncology nursing were correlated with knowledge of CIPN.

Discussion

This study was initiated in recognition of the profound, negative effect CIPN has on the daily living of patients with varied cancer diagnoses and the lack of a standard approach among oncology nurses in addressing the care of patients who receive neurotoxic agents. This study may validate the existence of gaps in oncology nursing knowledge, practice behaviors and confidence pertaining to CIPN. These deficits, unless corrected, negatively influence patient outcomes, physical function, and enjoyment of life in those who are diagnosed with CIPN.

Demographic Data

Oncology registered nurses from ONS Chapter meetings across Florida participated in this prospective, cross-sectional descriptive study exploring oncology nurses’ knowledge, practice behaviors, and confidence in assessing CIPN. The participants consisted of registered nurses, nurse practitioners, a clinical nurse specialist, and nursing educators with the majority having undergraduate degrees. The sample was reflective of diverse oncology practice settings including inpatient hospital nurses, outpatient clinic nurses, and outpatient infusion nurses. The years of nursing experience and the years devoted specifically to oncology demonstrates participants are very experienced clinically and were very experienced in the care of the oncology patient. Most participants held oncology certification. A limitation of this prospective study is the relatively small sample size considering the number of eligible ONS members. Data were
not collected from a single site, but from several ONS chapters in different geographical regions throughout Florida. This makes the results from this study more generalizable. However, further study is needed in other states. Another study limitation was the potential for social desirability bias, whereby the participants may reply in a manner that is viewed as most favorable or correct. Further, nurses who choose to attend ONS meetings may be systematically different from other nurses who do not attend.

**CIPN Knowledge**

The mean CIPN knowledge score indicated adequate knowledge in the areas of non-pharmacologic management, pharmacologic agents, neuropathy terminology, assessment principals, and symptomatology specific to CIPN. Although the knowledge score is adequate, the scores range from 50%-100% (n=70) (Table 4). The initial cross-sectional exploratory study piloting this questionnaire obtained similar results with a mean knowledge score 12.6 (79%) (1.7) indicating adequate nursing knowledge (Binner, 2010).

With the wide range in overall knowledge scores, this indicates there is a need for on-going education regarding the non-pharmacologic management, pharmacologic agents, neuropathy terminology, assessment principals, and symptomatology specific to CIPN among new oncology nurses and experienced oncology nurses alike. Education through continuing education programs, oncology nursing specific educational forums, college courses, and pharmaceutical industry initiated educational endeavors are necessary in providing oncology nurses’ with the knowledge necessary to care to patients receiving neurotoxic chemotherapeutic agents.
**Practice Behaviors**

The practice behaviors subscales address screening, assessment skills, documentation, and teaching specific to CIPN (Table 5). Screening incorporates an assessment of baseline peripheral neuropathy symptoms prior to initiating the first dose of chemotherapy, assessment of other risk factors associated with peripheral neuropathy, and nursing assessment prior to each infusion of a neurotoxic agent. While the majority of the participants perform screening assessments prior to the first dose of chemotherapy, a significant number do not (Table 5). This data is consistent with the data reported by Binner (2010).

Some conditions and co-morbidities can make patients more prone to developing the complication of CIPN. Cancer, autoimmune disorders, nutritional deficiencies, kidney disorders, vascular and metabolic disorders, infectious diseases, and hereditary disease can cause baseline peripheral neuropathy (Wickham, 2006). It is essential in oncology nursing practice to assess for risk factors to determine who may need closer monitoring for CIPN during treatment. Baseline neurological assessment and assessment prior to each dose of neurotoxic chemotherapy allows the nurse and healthcare team to recognize changes in peripheral neuropathy once therapy has begun.

Assessment of CIPN incorporates fine motor skills, assessment of deep tendon reflexes, muscle strength, motor function skills, and eliciting symptoms related to CIPN. An assessment of motor, sensory, and autonomic function must be performed before, during, and after the completion of chemotherapy. An assessment specific to CIPN should include history, deep tendon reflexes, muscle strength, motor function, and an assessment of autonomic function (Armstrong, et al., 2005). Evaluating fine motor skills
by observing patients’ ability to grasp small objects or manipulate buttons on clothing can identify functional problems associated with CIPN (Armstrong, et al., 2005). Deep tendon reflex testing of the upper and lower extremities can provide information on the integrity of the peripheral nervous system with decreased reflexes indicate peripheral nervous system dysfunction. Muscle strength testing, noting weakness, and symmetry can provide information on the presence of motor fiber involvement by CIPN (Bickley, & Szilagyi, 2009). Assessing motor function by observing gait for unsteadiness, shuffling, wide base steps, or pain with ambulation may indicate CIPN (Armstrong, et al., 2005). Asking patients about the presence of CIPN may be as important as performing neurological testing (Rambaud, et al., 2001).

The majority of oncology nurses reported incorporating assessment of fine motor and, gross motor function skills, and eliciting symptoms of CIPN routinely into practice while deep tendon reflex and muscle strength assessments are integrated with much less frequency. The ability to assess fine motor skills, elicit symptoms of CIPN, and motor function assessment may occur with greater frequency because of limited time required to assess for CIPN utilizing these assessment measures. This may also suggest greater confidence in interpreting the outcome of these functions with accuracy. Despite the increased frequency compared to other assessment skills, there remains a significant portion of nurses who do not incorporate these simple, although important, neurological assessments in their daily care of patients at risk for CIPN. Another consideration is oncology nurses may not be asking the proper questions to elicit symptoms related to CIPN. Muscle strength assessment and deep tendon reflex evaluation occurs with less frequency. This may indicate that these functions require a higher level of physical
assessment skill and may be perceived as the responsibility of the physician or nurse practitioner. These assessment skills also require time to perform, suggesting oncology nurses may not be working in an environment conducive to performing these skills on a routine basis due to time constraints.

Binner (2010) found assessment of deep tendon reflexes, assessment of muscle strength, and assessment of motor function skills were incorporated into oncology nursing practice with much less frequency than assessment of fine motor skills and eliciting of CIPN symptoms. This difference between the two studies in frequency of assessing motor function skills may be related to a larger sample size, the diversity in clinical settings, and the influence of advance practice nurses included in the sample of the present study.

Oncology nurses were asked to evaluate the frequency of documenting CIPN assessment data with the majority reportedly documenting assessment findings. A limitation of this study is elements of documentation pertaining to CIPN assessment and practice behaviors in oncology nursing practice are not included in this study. Further study is needed. The data supports that oncology nurses do not routinely incorporate screening, physical neurological assessment, or teaching related to adaptation and safety into practice. This suggests critical elements specific to CIPN are missing from the medical record. This creates a lack of continuity in patient care with an inability to follow improvement or progression of symptoms between treatment cycles. Binner (2010) reported consistent data.

Teaching was assessed by evaluating the frequency of occurrence in educating patients on strategies for adapting to the functional impairment induced by CIPN and the
frequency of educating patients on safety precautions used to prevent injuries associated with CIPN. The majority of oncology nurses self-reported teaching patient strategies for adapting to CIPN functional impairment and educating patients regarding safety precautions used to avoid injury associated with CIPN. Binner (2010) obtained differing outcomes, the majority of oncology nurses reported never or occasionally teaching strategies for adaptation, while the majority always or frequently taught safety precautions.

A significant number of oncology patients are not given strategies by their oncology nurse to adapt to the functional impairment. This may suggest oncology nurses feel helpless when functional deficits become evident. Safety precautions were not consistently addressed by approximately one-forth of the participants. This may reflect oncology nurses are unaware of how patients are forced to live or function at home with CIPN. There may also be a knowledge deficit on behalf of oncology nurses regarding the functional effects of CIPN by affected body location.

Tofthagen (2010) suggests a multidisciplinary approach to CIPN. Open dialogue regarding the patients’ symptoms and performance status with the physician can ensure proper decisions are made regarding continued treatment utilizing the causative agent. Occupational therapy and physical therapy can have a vital role in assisting with maintaining functional capacity and evaluating safety needs. Identifying potential safety hazards in the home may help patients avoid injuries. Oncology nurses can provide anticipatory guidance in preparing patients for possible changes in physical, social, or emotional function.
Level of Confidence

The level of self-confidence among the participants in performing a neurological physical examination by assessing deep tendon reflexes, tuning fork vibration sensation, sharp vs. dull sensation, Romberg test, and manual muscle strength testing was assessed (Table 6). The majority of participants reported greater confidence in performing sharp vs. dull sensation and manual muscle strength testing while having less confidence in assessing deep tendon reflexes, tuning fork vibration sensation testing, and Romberg testing. Sharp vs. dull sensation testing and manual muscle strength testing require only simple assessment tools for performing these functions. The lack of confidence in assessing deep tendon reflexes, tuning fork vibration and Romberg testing may indicate these skills requires a higher level of assessment knowledge in performing and there may be a knowledge deficit in interpreting the findings. Perhaps oncology nurses were never educated in performing these skills. These neurological assessment skills may be perceived as the responsibility of the physician or nurse practitioner. Binner (2010) did not report the level of confidence and perhaps this is an area for future exploration.

Previous Education and Experience

A significant, but weak relationship was identified between the highest educational level attained and CIPN knowledge, while no significant relationship was identified between nursing experience and knowledge of CIPN. The participants varied in their highest attained educational level; while most had Bachelor of Science degrees there were more Masters of Science and Doctoral degrees compared to basic nursing education. This relationship finding may represent a positive difference in higher education with specialized knowledge and oncology nurses’ ability to translate what is
learned into the clinical setting. Binner did not report on this relationship and may be an area of future exploration.

**Conclusions**

This is one of a few studies to document oncology nurses’ practice behaviors, and confidence, in addition to knowledge, and the relationship between education, experience, and knowledge of oncology nurses pertaining to CIPN. This study documents the current state of oncology nurses’ practice. The results support the need for enhancing the neurological assessment skills of oncology nurses. An efficient approach to CIPN assessment is needed to address the time constraints of the outpatient setting and the skillfulness required by oncology nurses in assessing for CIPN. The roles and responsibilities of assessing for CIPN should be delineated among oncology practices to overcome the ambiguity that currently exist among oncology nurses until evidence based CIPN assessment practice guidelines are developed. This study lays the foundation for future research and should serve as a stimulus for future studies.

**Recommendations for Future Research**

Oncology nurses desiring to capture a true reflection of assessment skills, practice behaviors, and patient outcomes related to CIPN have tremendous opportunity to contribute to the literature. A questionnaire examining the roles, responsibilities, perceptions, and barriers for healthcare providers in assessing and managing CIPN would provide further insight. Another area of exploration is a retrospective review of the medical record examining healthcare provider’s documentations of patients receiving neurotoxic agents. This would provide information into the assessment, and management of CIPN on behalf of nurses and physicians. Elements of patient descriptions of CIPN
could also be captured. This form of research would enable data collection and outcome measurement in a setting where no attempt is made to affect the outcome. Additional studies are needed to examine how patients live each day with CIPN, bringing attention and urgency to improving on our current practice and to the development of prevention and treatment strategies. Another area to explore where limited knowledge exists is the relationship between CIPN, interpersonal relationships, and sexual function. The piloting of a comprehensive CIPN patient assessment tool that is conducive to use in the current clinical environment is needed. Intervention studies are also needed to provide guidance on the prevention, and management of CIPN, and for the preservation of patient safety.
References


Binner, M. (2010, March). Chemotherapy-induced peripheral neuropathy: Assessment of oncology nurses’ knowledge and practice. Poster session presented at the 16th Annual International Conference on Cancer Nursing (ICCN), Atlanta, GA.


Appendices
Appendix A

CIPN: Assessment of Oncology Nurses’ Knowledge and Practice-Revised

Multiple choices: Please check the best response.

1. Nonpharmacologic strategies to consider in the management of symptoms associated with CIPN include all of the following except:
   - O Use of assistive devices (e.g., cane, orthotic brace, splint
   - O Use of heating pad
   - O Transcutaneous nerve stimulations (TENS)
   - O Acupuncture

2. Chemotherapy agents commonly associated with CIPN include:
   - O Paclitaxel, Vincristine, and Doxorubicin
   - O Paclitaxel, Cisplatin, and Gemcitabine
   - O Cisplatin, Gemcitabine, and Doxorubicin
   - O Paclitaxel, Cisplatin, and Vincristine

3. An unpleasant, abnormal sensation is called:
   - O Dystonia
   - O Ataxia
   - O Dysesthesia
   - O Hyperreflexia

4. All of the following are part of the assessment of patients suspected of having CIPN except:
   - O A test for impaired sense of balance
   - O A test for deep tendon reflexes
   - O Auscultation of lung sounds
   - O Auscultation of bowel sounds

5. A critical element in the clinical assessment of patients with CIPN is to:
   - O Monitor vital signs during neurotoxic chemotherapy infusions
   - O Determine the level of functional impairment involving ADLs
   - O Evaluate patient’s orientation to time, place, and person
   - O None of the above

6. The essential first step in assessing CIPN is:
   - O Sensory motor evaluation
   - O Motor system evaluation
   - O Patient interview
   - O Autonomic system physical assessment
### True/False: Check the correct response

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>True</th>
<th>False</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>Orthostatic hypotension may indicate autonomic CIPN.</td>
<td></td>
<td></td>
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<tr>
<td>8</td>
<td>Chemotherapeutic agents causing CIPN may affect position and vibration sense.</td>
<td></td>
<td></td>
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<tr>
<td>9</td>
<td>Impaired proprioception may be a symptom of CIPN.</td>
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<tr>
<td>10</td>
<td>The peripheral nervous system includes autonomic nerves.</td>
<td></td>
<td></td>
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<tr>
<td>11</td>
<td>Sensory symptoms of CIPN typically progress in a proximal to distal pattern.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>The stocking-glove distribution of sensory symptoms of CIPN refers to the paresthesias in the hands and feet.</td>
<td></td>
<td></td>
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<tr>
<td>13</td>
<td>Toxicity scales used to grade CIPN are very precise.</td>
<td></td>
<td></td>
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<tr>
<td>14</td>
<td>Patients readily report symptoms of peripheral neuropathy.</td>
<td></td>
<td></td>
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<tr>
<td>15</td>
<td>Oncology patients with diabetes or alcoholism are at greater risk for developing CIPN.</td>
<td></td>
<td></td>
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<tr>
<td>16</td>
<td>Assessment of neuropathic pain requires a separate and unique approach compared to assessment of nociceptive (tissue) pain.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### How often do you do each of the following in your nursing practice? Check one for each question.

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Never</th>
<th>Occasionally</th>
<th>Frequently</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>17</td>
<td>How often do you screen patients for baseline presence of peripheral neuropathy prior to initiating the first dose of chemotherapy?</td>
<td></td>
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<tr>
<td>18</td>
<td>How often do you assess patient’s ability to perform fine motor skills (e.g., button clothes, use of zippers) if they are receiving neurotoxic chemotherapeutic agents?</td>
<td></td>
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<tr>
<td>19</td>
<td>How often do you document CIPN assessment data if the patient is receiving chemotherapy associated with CIPN?</td>
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<td></td>
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<tr>
<td>20</td>
<td>How often do you assess deep tendon reflexes on patients receiving neurotoxic chemotherapy?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>How often do you assess muscle strength in patients receiving neurotoxic chemotherapy?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
22. How often do you assess patients for the presence of other risk factors associated with peripheral neuropathy?
   - O Never
   - O Occasionally
   - O Frequently
   - O Always

23. How often do you perform objective motor function assessment skills (e.g., muscle strength, gait assessment)?
   - O Never
   - O Occasionally
   - O Frequently
   - O Always

24. How often do you perform nursing assessment of CIPN prior to each infusion of neurotoxic chemotherapy?
   - O Never
   - O Occasionally
   - O Frequently
   - O Always

25. How often do you attempt to elicit patient symptoms related to chemotherapy-induced peripheral neuropathy?
   - O Never
   - O Occasionally
   - O Frequently
   - O Always

26. How often do you teach patients strategies for adapting to functional impairments secondary to CIPN?
   - O Never
   - O Occasionally
   - O Frequently
   - O Always

27. How often do you educate patients about safety precautions used to avoid injuries associated with CIPN (e.g., thermal injury, falls)?
   - O Never
   - O Occasionally
   - O Frequently
   - O Always

28. Check your level of confidence in performing each of the following physical assessment skills:
   a. Deep tendon reflexes
      - O Not at all Confident
      - O Somewhat Confident
      - O Confident
      - O Very Confident
   b. Tuning fork vibration sensation
      - O Not at all Confident
      - O Somewhat Confident
      - O Confident
      - O Very Confident
   c. Sharp vs. dull sensation
      - O Not at all Confident
      - O Somewhat Confident
      - O Confident
      - O Very Confident
   d. Romberg test
      - O Not at all Confident
      - O Somewhat Confident
      - O Confident
      - O Very Confident
   e. Manual muscle strength testing
      - O Not at all Confident
      - O Somewhat Confident
      - O Confident
      - O Very Confident

29. Is CIPN a significant problem for your patients receiving neurotoxic chemotherapy agents?
    - O Yes
    - O No

30. Have you ever had instruction in assessment of CIPN?
    - O Yes
    - O No
31. Have you had instruction in physical assessment of CIPN in performing the following technique?
   a. Cranial nerves assessment  O Yes  O No
   b. Deep tendon reflexes       O Yes  O No
   c. Muscle strength           O Yes  O No
   d. Orthostatic blood pressure O Yes  O No
   e. Romberg test              O Yes  O No
   f. Temperature sensation     O Yes  O No
   g. Dull/sharp sensation      O Yes  O No
   h. Vibration sensation       O Yes  O No

32. Have you had instruction in:
   a. Pharmacology management of CIPN?  O Yes  O No
   b. Non-pharmacologic management of CIPN? O Yes  O No

33. Do you believe assessment of CIPN is essential in your role as an oncology nurse?
   O Yes  O No

34. How would you rate the adequacy of your skill in assessing CIPN? (Check one)
   O Poor  O Fair  O Good  O Excellent

35. Are patients routinely assessed for CIPN in your setting?
   O Yes  O No

36. If CIPN assessment is not routinely performed state reason. __________________________

Demographics

37. Gender  O M  O F

38. Age _________

39. Years in Nursing _______

40. Years in oncology nursing ________

41. Generic Nursing Education (check highest level attained)
    O Diploma
    O Associate
    O Bachelors
    O Masters
    O Doctorate

42. Education (check highest level attained)
    O Diploma
    O Associate
    O Bachelors
    O Masters
    O Doctorate
43. In your current position, are you a: (check one)
   O RN   O CNS   O NP   O Other (please indicate) _____________

44. Do you have Oncology Nursing Certification?
   O Yes   O No

45. If yes, please indicate which certification(s) you hold:
   O OCN   O AOCNP   O OCCNS   O Other (please indicate) _____________

Additional Comments:
________________________________________________________________________________
________________________________________________________________________________
________________________________________________________________________________
_______________________________________________________________________________

Thank You For Your Participation

Chemotherapy-Induced Peripheral Neuropathy (CIPN):
Assessment of Oncology Nurses’ Knowledge and Practice-Revised
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Appendix B

Letter of Approval: Instrument Author

April 13, 2010

Denise McAllister
13405 Godins Lane
Dover, Fl. 33527

Greetings Denise:

Enclosed you will find the CIPN questionnaire and the answer key. Items 1-16 are the knowledge domain and the practice domain is items 17-28c. Cronbach’s alpha was run on these items for tool reliability. Numbers 29-45 are demographics, instruction history, opinion or perceptions. These were not included in Cronbach’s alpha analysis.

This letter constitutes my permission for Denise McAllister to make copies of Chemotherapy-induced Peripheral Neuropathy (CIPN): Assessment of Oncology Nurses’ Knowledge and Practice-Revised© questionnaire and use for her graduate research work.

Good luck with your research, keep me posted, and contact me if I can be of further help.

Sincerely,

Madelaine Binner, DNP, CRNP-BC
Medical Oncology Nurse Practitioner
Appendix C

Letter of Approval: Peace River ONS Chapter

August 18, 2010

Peace River Oncology Nursing Society
Port Charlotte, Florida

R. Denise McAllister
13405 Godins Lane
Dover, Florida 33527

Dear Denise,
This letter is to serve as authorization; on behalf of the Peace River Oncology Nursing Society, granting you permission to collect data on oncology nurses knowledge of chemotherapy induced peripheral neuropathy during our local chapter meeting.

Best wishes to you in your graduate studies and contributions to oncology nursing.

Sincerely yours,

Tammy Bennett
Peace River Oncology Nursing Society
Chapter President
Appendix D

Letter of Approval: Palm Beach Area ONS Chapter

August 23, 2010

Palm Beach Area Oncology Nursing Society
Palm Beach, Florida 33773

R. Denise McAllister
13405 Godins Lane
Dover, Florida 33527

Dear Denise,
This letter is to serve as authorization; on behalf of the Palm Beach Area Oncology Nursing Society, granting you permission to collect data on oncology nurses knowledge of chemotherapy induced peripheral neuropathy during our local chapter meeting.

Best wishes to you in your graduate studies and contributions to oncology nursing.

Sincerely yours,

Joanne Abinanti RN, BSN, OCN
Chapter President
Palm Beach Area Oncology Nursing Society
Appendix E

Letter of Approval: Central Florida ONS Chapter

August 23, 2010

Central Florida Oncology Nursing Society
Orlando, Florida

R. Denise McAllister
13405 Godins Lane
Dover, Florida 33527

Dear Denise,

This letter is to serve as authorization; on behalf of the Central Florida Oncology Nursing Society, granting you permission to collect data on oncology nurses knowledge of chemotherapy induced peripheral neuropathy during our local chapter meeting.

Best wishes to you in your graduate studies and contributions to oncology nursing.

Sincerely yours,

Anne McCumber, RN, MS
Central Florida Oncology Nursing Society
Chapter President
August 4, 2010

Pinellas County Oncology Nursing Society
PO Box 10032
St. Petersburg, Florida 33773

R. Denise McAllister
13405 Godins Lane
Dover, Florida 33527

Dear Denise,
This letter is to serve as authorization; on behalf of the Pinellas County Oncology Nursing Society, granting you permission to collect data on oncology nurses knowledge of chemotherapy induced peripheral neuropathy during our local chapter meeting.

Best wishes to you in your graduate studies and contributions to oncology nursing.

Sincerely yours,

Rita King
PCONS Chapter President
Appendix G

Letter of Approval: USF IRB

09/30/2010

Rebecca McAllister,
College of Nursing
13405 Godins Lane

RE: Expedited Approval for Initial Review
IRB#: Pro00002159
Title: Evaluation of Oncology Nurses' Knowledge, Practice Behaviors, and Confidence Specific to Chemotherapy Induced Peripheral Neuropathy

Dear Rebecca McAllister,

On 9/29/2010 the Institutional Review Board (IRB) reviewed and APPROVED the above referenced protocol. Please note that your approval for this study will expire on 9/29/2011.

Approved Items:
Protocol Document(s):
Thesis:IRB 9/7/2010 12:14 AM 0.01

It was the determination of the IRB that your study qualified for expedited review which includes activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories outlined below. The IRB may review research through the expedited review procedure authorized by 45CFR46.110 and 21 CFR 56.110. The research proposed in this study is categorized under the following expedited review category:

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Your study qualifies for a waiver of the requirements for the documentation of informed consent as outlined in the federal regulations at 45CFR46.116 (d) which states that an IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of
informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that (1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB. Any changes to the approved research must be submitted to the IRB for review and approval by an amendment.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,

Krista Kutash, Ph.D., Chairperson
USF Institutional Review Board

Cc: Olivia Hart, USF IRB Staff