

# Oncology Clinical Trials Nursing: Developing Competencies for the Novice

Barbara Lubejko, RN, MS, Marjorie Good, RN, BSN, MPH, OCN®,  
Patricia Weiss, RN, MSN, OCN®, CCRP, Linda Schmieder, MSN, RN, CCRC,  
David Leos, RN, BSN, MBA, OCN®, and Penny Daugherty, RN, MS, OCN®

Oncology clinical trials are important in the improvement of outcomes for people with or at risk for cancer. Because of the complexity of oncology clinical trials and the needs of patients with cancer, nurses play a crucial and unique role in the trial setting. However, great variability exists in how the role of the nurse on a research team is defined and implemented. An Oncology Nursing Society project team set out to identify the core competencies required of a novice oncology clinical trials nurse (CTN) across diverse settings. This article describes the process used to develop core competencies for the novice CTN, presents the final core competencies, and offers examples of how those competencies might be used in practice.

**T**he Oncology Nursing Society (ONS) believes that oncology nurses are essential to the effective conduct of cancer treatment and prevention clinical trials. In particular, ONS has taken the position that the coordination of clinical trials (e.g., coordination of clinical sites, development of standardized treatment orders, symptom management, patient education and advocacy, facilitation of informed consent, assistance with participant accrual and retention) is accomplished best by RNs who have been educated and certified in oncology nursing (ONS, 2009).

However, the scope and practice of the oncology nurse who coordinates clinical trials has not been well defined. Nurses who are employed in clinical trial programs have a wide variety of job titles, practice in diverse settings, and come with inconsistent educational backgrounds. The lack of clear role definition and awareness of the specific contribution nurses can make to the research process has resulted in the clinical trials nurse (CTN) role being poorly understood.

The literature has just begun to delineate the knowledge and skills required for competent practice as a CTN. Most published

## At a Glance

- ✦ Wide variability in clinical trials nursing position titles, role implementation, and practice settings has hampered clear definition of core competencies.
- ✦ Core competencies were developed following a process of information collection, evaluation, and validation.
- ✦ Application of the competencies may lead to role clarity, standardization, and validation, which could increase professional satisfaction for oncology clinical trials nurses.

descriptions of the CTN role are anecdotal and based on individual experience. In 2000, a workgroup of the ONS CTN Special Interest Group (SIG) developed an instrument to help more formally evaluate the CTN role. The tool, the Clinical Trials Nursing Questionnaire (CTNQ), was found to be valid and reliable (Ehrenberger & Lillington, 2004) and measures the frequency with which specific activities are performed and their perceived importance.

Barbara Lubejko, RN, MS, is a project manager in the Education Department at the Oncology Nursing Society in Pittsburgh, PA; Marjorie Good, RN, BSN, MPH, OCN®, is a nurse consultant in the Community Oncology Prevention Trials Research Group in the Division of Cancer Prevention at the National Cancer Institute in Bethesda, MD; Patricia Weiss, RN, MSN, OCN®, CCRP, is a clinical analyst in Informational Technology in the Taussig Cancer Center at the Cleveland Clinic Foundation in Ohio; Linda Schmieder, MSN, RN, CCRC, is the director of Study Implementation in Clinical Research Services at Roswell Park Cancer Institute in Buffalo, NY; David Leos, RN, BSN, MBA, OCN®, is an oncology clinical educator at Memorial Hermann Southwest Hospital in Houston, TX; and Penny Daugherty, RN, MS, OCN®, is an oncology nurse navigator at Northside Hospital in Atlanta, GA. The authors take full responsibility for the content of the article. Project team members received an honorarium during the development of the clinical trials nurse competencies, but not for writing this article. The views expressed in this article are those of the authors and do not reflect the official policy or position of the Oncology Nursing Society. The content of this article has been reviewed by independent peer reviewers to ensure that it is balanced, objective, and free from commercial bias. No financial relationships relevant to the content of this article have been disclosed by the independent peer reviewers or editorial staff. (First submission July 2010. Revision submitted March 2011. Accepted for publication April 7, 2011.)

Digital Object Identifier: 10.1188/11.CJON.637-643