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.

The 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 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.

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