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Delineating the Role of a Cohort of Clinical Research Nurses in a Pediatric Cooperative Clinical Trials Group

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Childhood cancer has gone from an almost universally fatal disease prior to the 1960s to one that is curable in about 80% of patients (Bleyer, 2002). This remarkable achievement has come about through the effort of clinical investigators, laboratory scientists, and the cooperative clinical trials groups. With this success has come the realization that curing all childhood cancers is an achievable goal. The Children's Oncology Group (COG) is an international research organization that was formed in 1998 (Ruccione & Kelly, 2000) and is devoted to the development of new treatments and cures for the cancers of infants, children, adolescents, and young adults. The vision of COG is to eliminate the personal, familial, and societal burden of cancer in children and adolescents. To fulfill this vision, COG performs clinical and research trials to define optimal treatments for children and adolescents with cancer; conducts laboratory research that will translate into more effective treatments with reduced short- and long-term side effects; works to identify the causes of childhood cancer to develop strategies for prevention; conducts research to improve the quality of life for children and their families, including end-of-life care whenever necessary; and builds partnerships across the world (CureSearch, 2010).

The COG Nursing Discipline consists of more than 1,000 RNs who perform a variety of nursing roles, including inpatient and outpatient staff nurses, nurse managers, nurse practitioners, clinical nurse specialists, nurse educators, case managers, and clinical research nurses. Pediatric oncology nurses have the opportunity to contribute their knowledge and practical expertise by participating as members of research and scientific committees and strategic organization committees within COG. Nurses routinely contribute to the development, implementation, evaluation, and reporting of clinical research projects. In particular, nurses have the ability to identify, early in the protocol development process, issues that may lead to potential companion or nested

Purpose/Objectives: To describe the roles and responsibilities of the clinical research nurse (CRN).

Design: A descriptive design was used to reveal the roles of pediatric oncology CRNs.

Setting: The Children's Oncology Group (COG) password-protected Web site.

Sample: 85 nurses who performed clinical research associate work within COG.

Methods: The Clinical Trials Nursing Questionnaire was used to investigate the roles and responsibilities of CRNs.

Main Research Variables: Protocol assessment, protocol planning, subject recruitment, informed consent process, investigational product, implementation and evaluation, data management, and professional nursing role.

Findings: The study found that 55% of respondents ($n = 47$) were employed in a hospital setting, the majority (81%) had more than five years of oncology experience, and the average age of respondents was 45.56 years (range = 24–65 years). CRNs rated all role components as very important, with the consent process being of greatest importance. Eighty-nine percent reported experiencing autonomy and independence in the role.

Conclusions: Clinical specialization of RNs has increased significantly in the past several decades. Acknowledging that nurses are responsible for performing many different roles that are critical to the successful completion of clinical trials is crucial.

Implications for Nursing: Evaluation of this dual role is still in its infancy, but articulating the role of CRNs in the conduct and context of clinical research is an important first step.

nursing research studies. Well-informed nurses effectively translate critical protocol information not only to other nurses but to patients and families. Because nurses are involved longitudinally throughout all phases of illness, their involvement in clinical research assists with the provision of optimal care to children with cancer. However, the particular contributions of clinical research nurses (CRNs) in COG member institutions