Online Exclusive Article

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

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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.

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 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

have not been clearly described. This article presents the results of a survey involving CRNs from COG. The purpose of the survey was to characterize the role of CRNs in cooperative group clinical trials.

Clinical Research Nurses

Historically, among pediatric oncology cooperative groups, institutional clinical research associates (CRAs) have managed the data and regulatory aspects of clinical trials. In some institutions, a CRA will have a nursing background and this person is commonly referred to by a variety of titles, including a CRN. Existing literature describing the role of the CRA does not delineate between a non-nurse CRA and an RN/CRA (Devine, Nagel, Benson, & Krailo, 2005; Gwede, Johnson, & Trotti, 2000; Rico-Villademoros et al., 2004; Roche et al., 2002).

To formally define this new entity of combined CRA and nurse, two of the authors were asked by the chairperson of the COG Nursing Discipline to form a task force to examine the CRN role and devise a formal role description. A draft role description was completed to provide the framework for additional role characterization of the cohort of CRNs within COG. The authors of this article wrote the following text, which was reviewed by the COG Nursing Discipline chairperson.

> The RN/CRA utilizes evidence-based practice to coordinate and facilitate clinical research studies according to national or regulatory body professional standards and the nursing professional standards of his or her institution. The RN/CRA possesses a range of nursing skills including, but not limited to, collaboration with the primary healthcare team to develop individualized care plans for study participants, facilitation of in-service instruction for members of the healthcare team, demonstration of autonomy as well as the ability to collaborate within a multidisciplinary healthcare team to meet the needs of the patient and family, and promotion of research as an integral component of evidence-based practice and professional education developed through his or her nursing experience that can be applied to research. Working collaboratively with an interdisciplinary team, the RN/CRA undertakes the delivery of safe and ethical nursing care to address the needs of the research participants and/or their families. Integral to the RN/CRA role is the incorporation of knowledge of the nursing process into research.

Literature Review

Although several articles described the role and work activities of the CRN in the literature (Chadwick, 1992; Fishwick et al., 2002; Martin, 1994; Rice & Cheak, 2000; Ritchie & Tanasichuk, 1983; Stephens-Lloyd, 2004), few relate specifically to CRNs. Mueller and Mamo (2002), in a qualitative study, attempted to describe the benefits and drawbacks of the nurse clinical trial coordinator role by identifying career benefits and weaknesses of the role as well as the numerous job titles associated with the role. One limitation of this study is that qualitative studies are not designed to be generalizable, although the study does suggest that nurses contribute positively to clinical trial coordination in the form of their dedication to caring work coupled with their nursing-related knowledge and skills.

Ocker and Plank (2000) analyzed the existing roles of non-nurse research coordinators, oncology nurse clinicians, and oncology advanced practice nurses. Their sources included articles from a literature review, a variety of research nurse job descriptions, and a review of the Nurse Practice Act in the authors' home state (Wisconsin). The literature review identified three main roles of the oncology research nurse: educator, patient advocate, and protocol manager. Ten job descriptions were evaluated and found to mirror the findings of the literature search. The authors then asked research nurses from the oncology program to review the job descriptions, literature review, and Nurse Practice Act. Although this could be construed as member checking, the authors did not explain the number of nurses who participated in the review, what their backgrounds were, the length of time they had worked in oncology clinical trials, nor their expertise at analyzing and grouping themes. The conclusions of the study were that nursing education and expertise are vital to the success of the oncology research nurse role. The authors of this current article agree with the three identified roles; however, insufficient identification exists of nursing knowledge and skills brought to the oncology research nurse role.

Study

A descriptive design was used to reveal the roles of the oncology CRN. The characteristics of a descriptive study include data collection to allow the researcher to describe the variables of interest and relationships between variables (Engberg & Bliss, 2005).

Methods

Research Design

Data collection: To date, one validated instrument is available to delineate the perceived role of the CRN in clinical trials, the Clinical Trials Nursing Questionnaire (CTNQ). The CTNQ measures the frequency and importance of clinical trials nursing activities (Ehrenberger & Lillington, 2004). The conceptual basis for the instrument development was the Nursing Role Effectiveness Model (Doran, Sidani, Keatings, &

Table 1. Sample Characteristics

Characteristic	$\bar{X}$	Range
Age (years)	45.6	24–65
Characteristic	**n**	**%**
Gender		
Female	80	95
Male	5	5
Education		
Diploma or associate degree in nursing	24	28
Bachelor's degree	40	47
Postgraduate education	20	24
No response	1	1
Years in nursing		
5 or less	4	5
5–10	6	7
10–20	30	35
More than 20	41	48
No response	4	5
Years of clinical research experience		
5 or less	32	38
5–10	29	34
10–20	19	22
More than 20	4	5
No response	1	1

N = 85

Doidge, 2002). This framework has been used previously to define nurses' roles in health care and relates these roles to specific patient and system outcomes. The CTNQ contains 12 sections and 154 items. The first eight sections examine the role components of the nurse where participants indicate the frequency and importance of each role. Frequency is indicated as 0 (never, not part of my role), 1 (once or twice), 2 (occasionally), 3 (repeatedly), and 4 (extremely frequently) and represents the frequency with which the respondent has performed the activity in the past year. Importance is indicated as 0 (not important), 1 (somewhat important), 2 (important), 3 (moderately important), and 4 (very important) and indicates the importance of the activity to the safe and effective practice of clinical trials nursing care. Section nine asks questions related to the nurses' perceptions and experiences of their clinical research role, and section 10 contains questions regarding professional characteristics. The final two sections contain questions related to each participant's employment organization and personal demographics. No open-ended questions are included.

Research ethics board approval was obtained from Hamilton Health Sciences and McMaster University. Approval also was obtained from the COG nursing steering committee and COG administration prior to commencing the study. With the assistance of a webmaster at COG, the CTNQ was converted from a pen-and-paper survey to a Web-based survey. The CTNQ was posted on the COG Web site and an invitation e-mail was sent to all nurses and all CRAs in May 2007 with instructions to complete the survey if they were both a nurse and CRA. Reminder e-mails were sent 14 and 21 days after the introductory e-mail. Eighty-five complete and 20 incomplete surveys were received. The COG office removed the names of respondents, and unique identifier numbers were inserted.

Data Analysis

Data analysis involved the use of descriptive and inferential statistics. Frequencies of scores, means, and ranges were calculated on single variables. The nonparametric procedure of the Kruskal-Wallis test was used to assess mean group differences of the data (Loiselle & Profetto-McGrath, 2004). Statistical difference was set at $p < 0.05$.

Results

Demographic Profile

Eighty-five respondents from across the United States and Canada completed the survey during the time it was posted on the COG Web site. Respondents from the United States were from the West (10), Midwest (9), Great Lakes (13), South Central (11), Southeast (17), North Central (10), and the Northeast (6) geographic regions. Participants from Canada were from British Columbia (1), Ontario (1), and Quebec (1). Six respondents did not indicate a location. The majority of respondents (81%) had more than five years of oncology experience and functioned in the role of lead CRA for COG at their institution (see Table 1).

Role Components

The frequency and importance of the CRN role are presented in Table 2.

Table 2. Means and Ranges of Subscales of Respondents for the Clinical Trials Nursing Questionnaire

	Frequency		Importance	
Subscale	$\bar{X}$	**Range**	$\bar{X}$	**Range**
Consent process	2.67	2.06–3.26	3.61	3.46–3.74
Data management	2.48	1.66–3.09	3.26	2.85–3.5
Implementation and evaluation of study components	2.61	1.7–3.24	3.55	2.99–3.83
Investigational product	1.63	0.87–2.39	3.34	2.72–3.76
Professional nursing role performance	2.29	1.41–3.01	3.47	3.19–3.68
Protocol assessment	1.46	0.37–2.39	3.11	1.95–3.76
Protocol planning	2.28	1.61–2.51	3.33	2.87–3.68
Subject recruitment	2.01	0.62–2.88	3.1	2.12–3.64

Perceptions and Experiences in Clinical Research

Respondents reported feeling competent (94%) and satisfied (90%) with their role, although a majority (81%) reported experiencing stress related to their workload. Importantly, 43% reported stress related to role ambiguity, 85% felt they communicated effectively with prospective and current research subjects and their families, and 97% reported communicating effectively with the research team. About 75% of all respondents felt that they had the support of non-research nurses in this role, more than 90% experienced physician support of their role, and more than 70% experienced administrative support in their role. In addition, 89% experienced autonomy and independence in the CRN role.

Employing Organizations of Clinical Research Nurses

Fifty-five percent of respondents (n = 47) were employed in a hospital setting, whereas 33% (n = 26) were employed in an outpatient clinic setting. Of the remaining 12 respondents, two worked in a physician's office, four in a National Cancer Institute (NCI)-designated comprehensive cancer center, four in a school of medicine, one for the U.S. government, and one as "other not specified."

Associations of Role Components and Participant Characteristics

Table 3 presents the associations between role components and participant characteristics. The frequency with which participants performed protocol assessment was statistically significant (p = 0.02) when associated with the number of continuing education programs attended in the past year specific to clinical trials or clinical research. The same variable proved significant with respect to the frequency that participants engaged in subject recruitment (p = 0.002), obtaining informed consent (p = 0.026), data management (p = 0.017), and performance of the professional nursing role (p = 0.029). The variable of the highest degree completed in nursing was statistically significant only for the frequency of professional nursing role subscale (p = 0.047). Hours per week of nursing work showed a significant association with the importance placed on protocol planning (p = 0.016). The number of years in clinical research did not reveal any statistically significant results with any of the categories. An association was, however, seen in the variable number of years in nursing

Table 3. Associations Between Role Components and Demographic Characteristics

Component	Highest Nursing Degree	Work Hours Per Week in Nursing	Continuing Education Programs Attended[a]	Years in Clinical Research	Years in Nursing	Years in Oncology
Consent process						
Importance	0.958	0.648	0.227	0.883	0.975	0.698
Frequency	0.373	0.16	0.026*	0.547	0.881	0.642
Data management						
Importance	0.158	0.438	0.393	0.853	0.882	0.997
Frequency	0.33	0.052	0.017*	0.901	0.393	0.69
Implementation and evaluation of study components						
Importance	0.615	0.635	0.846	0.447	0.663	0.763
Frequency	0.503	0.159	0.365	0.88	0.941	0.935
Investigational product						
Importance	0.372	0.612	0.74	0.637	0.893	0.589
Frequency	0.235	0.446	0.242	0.129	0.036*	0.027*
Professional nursing role performance						
Importance	0.918	0.676	0.845	0.108	0.122	0.588
Frequency	0.047*	0.036*	0.029*	0.234	0.24	0.264
Protocol assessment						
Importance	0.342	0.42	0.122	0.742	0.478	0.232
Frequency	0.404	0.823	0.02*	0.339	0.062	0.037*
Protocol planning						
Importance	0.211	0.016*	0.537	0.69	0.421	0.169
Frequency	0.388	0.438	0.076	0.582	0.222	0.214
Subject recruitment						
Importance	0.765	0.278	0.686	0.888	0.694	0.034*
Frequency	0.749	0.776	0.002*	0.942	0.206	0.146

* $p < 0.05$

[a] In the previous year specific to clinical trials and research

and the frequency of investigational product (i.e., the frequency with which the RN/CRA handled the supervision of an investigational drug via ordering, storing, accounting, record keeping, or disposal) ($p = 0.036$). Finally, the greater the number of years working in oncology revealed that CRNs were more likely to undertake protocol assessment ($p = 0.037$) and place a higher level of importance on subject recruitment ($p = 0.034$) and frequency of investigational product ($p = 0.027$).

Discussion

The CTNQ has assisted with revealing the roles and responsibilities of CRNs within a large cooperative clinical research group. CRNs rated all role components as very important, which reveals two aspects. First, professional nursing role, consent process, and implementation and evaluation roles are considered crucial for CRNs to uphold because of the underpinning nursing expectations associated with ethical and professional nursing. Second, the CTNQ is able to adequately capture and measure important nurse-orientated input into clinical trials. The clinical importance of this finding is that the research team has access to the in-depth knowledge base and cognitive, critical thinking, and decision-making skills of the RN. This study clearly supports anecdotal observations already existing in the literature (Chadwick, 1992; Fishwick et al., 2002; Martin, 1994; Rice & Cheak, 2000; Ritchie & Tanasichuk, 1983; Stephens-Lloyd, 2004).

Similarly, and according to the Canadian Nurses Association (CNA), new roles and practice settings for RNs are being created and will continue to be created in the future to respond to the health needs of patients and to address opportunities in health service delivery (CNA, 2008). The CNA asserts that specialization is a focus in one field of nursing practice or health care that encompasses a level of knowledge and skill in a particular aspect of nursing greater than that acquired during basic nursing education (CNA, 2008). In the specialized role, RNs use their in-depth knowledge base and cognitive, critical thinking, and decision-making skills "to observe and monitor both obvious and elusive cues, to note minimally discernible patterns in the data, and to interpret and synthesize information" (CNA, 2002, p. 24). The consent process, implementation, and evaluation of all study components and data management had the highest frequency scores, which would account for the CRA and data management portion of the role. The clinical importance of this is that, again, the research team, including the research subject, has the advantage of an RN's in-depth knowledge base and cognitive, critical thinking, and decision-making skills.

Role title varied across respondents in this study. Twenty-six respondents had the words nurse and research in their title, 19 identified themselves with the word nurse only, 10 identified their title as clinical research/trial coordinator, and 7 as CRA. The remaining titles included data manager, clinical nurse specialist, research analyst, and RN/CRA (2). The variety of role titles was similar to that published in the existing literature. The lack of formalized role descriptions and regulatory systems may contribute to the wide variety of titles, and, clearly, this leads to confusion about what a CRN is primarily responsible for. Regardless of the specialty, the CRN title is applicable and warrants additional discussion in national and international jurisdictions. In addition, although the titles were varied, what was important for the respondents in this study was the value of attending continuing education programs which would assist in job performance. By attending continuing education programs, the CRN is able to liaise with others in similar situations and collaborate to inform and improve their practice.

The major limitation of this study was that the population of RN/CRAs in COG (i.e., the denominator) was unknown. At the time of this survey and data collection, registration within COG was permitted in one discipline only (either as a nurse or as a CRA). Nurses who perceived themselves to function predominantly as a CRA may not have completed the questionnaire. Clearly, this limitation warrants additional research with CRNs and CRAs to further delineate the scope of practice and roles of each. However, since the time of data collection, COG has recognized this limitation and allowed CRNs to register as a nurse and a CRA. This has enabled increased access to information and education in both groups. Future research also is warranted in other specialty areas which use CRN and CRA, as these roles are emerging and growing roles in health care internationally.

Conclusion

Clinical specialization of RNs has increased significantly during the past several decades, and many nurses perform diverse roles in conducting clinical trials. This study was the first step in acknowledging and defining the dual role (i.e., nurse and researcher) held by nurses in oncology. The authors were able to ascertain the functions, learning needs, and key challenges of the CRN who combine RN and CRA responsibilities within an international collaborative group. The establishment of a role identity will require support and collaboration from the nursing and CRA disciplines both within COG and more widely across the nursing profession. This study will help to support the decision to incorporate the needs, abilities, and interests of CRNs into COG. Nurses practicing as CRNs should describe their roles and make clear distinctions between themselves and other professional groups who function as CRAs but not

as nurses. Networking with other CRNs and publishing about the role will assist others in describing the role for themselves. Articulating the role of a CRN and recognizing the dual roles and perspectives of being a nurse and researcher are important steps.

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