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Nurse-Led Programs to Facilitate Enrollment to Children's Oncology Group Cancer Control Trials

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Abstract

The progress made over the past 50 years in disease-directed clinical trials has significantly increased cure rates for children and adolescents with cancer. The Children's Oncology Group (COG) is now conducting more studies that emphasize improving quality of life for young people with cancer. These types of clinical trials are classified as cancer control (CCL) studies by the National Cancer Institute and require different resources and approaches to facilitate adequate accrual and implementation at COG institutions. Several COG institutions that had previously experienced problems with low accruals to CCL trials have successfully implemented local nursing leadership for these types of studies. Successful models of nurses as institutional leaders and "champions" of CCL trials are described.

Keywords

nurses as leaders; cancer control clinical trials; pediatric oncology

Introduction

With contemporary treatments, over 80% of children with cancer are now expected to survive at least 5 years (Adamson, 2013; Ward, DeSantis, Robbins, Kohler, & Jemal, 2014).

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Much of this progress results from research conducted by pediatric oncology cooperative clinical trials groups across the world. The Children's Oncology Group (COG) is the largest of these cooperative groups and operates within the National Cancer Institute's National Clinical Trials Network (Adamson, 2013). The majority of children and adolescents diagnosed with cancer in the North America are treated at cancer centers and children's hospitals affiliated with COG (Shochat et al., 2001). Because the progress made over the past 50 years in disease-directed clinical trials has significantly increased cure rates for children and adolescents with cancer, COG is now conducting more studies that emphasize improving quality of life (QoL) for young people with cancer.

Within the COG, research focusing on QoL and similar aims is led by the Cancer Control and Supportive Care Committee (Sung et al., 2013), the Nursing Discipline (Landier, Leonard, & Ruccione, 2013), the Outcomes and Survivorship Committee (Armenian et al., 2013), and the Behavioral Science Committee (Noll et al., 2013). These QoL-focused studies are classified as cancer control (CCL) research within the cooperative group system, and are supported through funding from the National Cancer Institute's Division of Cancer Prevention, as well as by grant funding through the National Institutes of Health, charitable foundations, and similar sources. CCL research focuses on the prevention and detection of cancer and on increasing the quality of survival for people who develop cancer (Best, Hiatt, Cameron, Rimer, & Abrams, 2003). While prevention and early detection of cancer are a major focus in adult oncology, pediatric oncology CCL research is primarily focused on the reduction of treatment-related toxicities in children with cancer, and patient and family responses to cancer treatment. Broad areas deemed important by both pediatric oncology health care providers and by patients and parents include toxicities that impair QoL and those that increase risk for mortality. Priority research areas identified by the COG Cancer Control and Supportive Care Committee are as follows: (1) infection and inflammation, (2) neurological complications, (3) palliative care and symptom control, and (4) nutrition and antiemetic control (Sung et al., 2013).

Pediatric oncology nurses across North America, Australia, New Zealand, and parts of Europe currently provide care to children and adolescents enrolled on COG clinical trials at over 200 institutions. Pediatric oncology nurses are also involved in developing and conducting these clinical trials within the COG (Landier et al., 2013). The COG Nursing Discipline consists of over 2,000 registered nurses representing all COG sites; 47.4% of these nurses hold a master's or doctoral degree and 37.1% are advanced practice nurses (APNs) who practice as nurse practitioners or clinical nurse specialists (W. Landier, personal communication, 2010). Nurses are involved in COG research through participation on disease and discipline steering committees and individual protocol committees. Nurses also have an opportunity to assume leadership roles in the conduct of CCL research within COG and at their local institutions.

Challenges to enrollment on CCL trials have been previously identified (Vanhoff et al., 2013; see Table 1). Accrual to clinical trials is critical to ensure that new knowledge can be gained to improve outcomes for patients. Failure to successfully accrue sufficient numbers of patients to CCL trials can result in early study closure, resulting in wasted investment of financial and other resources and in lost opportunities to answer the critical clinical

questions addressed by the trials (Johnston et al., 2013) The roles of the physician, institution, and patient are cited as important factors in the successful conduct of clinical trials (Minasian & O'Mara, 2011); the importance of the clinical research associate (CRA) role in CCL trials has also been emphasized (Vanhoff et al., 2013). While the importance of nurses taking a leadership role in the conduct of certain clinical trials is recognized in adult medicine (Hersher, 2012) and adult oncology (Rosenzweig, Bender, & Brufsky, 2005), the importance of the nurse or APN in leading CCL research within pediatric oncology has not yet been specifically defined. However, the presence of a CCL "champion" (ie, a member of the pediatric oncology team with a strong interest in and commitment to CCL research) at each participating site has been identified as an important facilitator for improving accruals to COG CCL trials (Vanhoff et al., 2013). The CCL champion ensures that (1) CCL protocols are activated in a timely manner at local institutions; (2) systems are developed to identify and screen potential patients; (3) patients, families, and staff are educated about CCL research; and (4) the local institution is represented at COG or other appropriate CCL research meetings.

The COG CCL committee recently identified CCL responsible investigators (RIs) to serve in the role of CCL champion for each COG institution. As of September 2014, of the 101 CCL-enrolling institutions within COG, 18% have identified a nurse as the CCL RI, 11 (61%) of which are APNs (L. Sung, personal communication, 2014). Nurses have the potential to effectively champion CCL studies, thus providing institutional leadership for COG CCL research. Additionally, the APN is uniquely qualified to implement interventional CCL protocols at their institutions, since most of these studies examine interventions that are within the scope of APN practice (eg, symptom management). Nevertheless, there may be challenges in obtaining institutional support for extending the nurse and APN role to take responsibility for local site leadership of CCL trials. We describe and evaluate some successful models of nursing leadership of COG CCL studies to address the barriers previously reported.

Successful Models With Nurses as CCL Leaders

Several COG institutions have successfully implemented local nursing leadership of COG CCL studies. We report the experiences of the Ann & Robert H. Lurie Children's Hospital of Chicago (LCH), Mott Children's Hospital within the University of Michigan Health System (UMHS), The Hospital for Sick Children in Toronto (HSC), and the Children's National Health System (CNHS), Washington, D.C. Each of these institutions implemented nurse-led CCL models between 2010 and 2012. Prior to implementation of local nursing leadership for COG CCL studies, all of these institutions had previously experienced challenges with CCL study recruitment. One of the major factors contributing to low CCL trial enrollments was missed opportunities for recruitment due to failure to identify eligible patients during the study enrollment window. CCL studies were often overlooked by multiple health care team members, particularly in the midst of a new diagnosis. To address this issue, institutional nursing CCL leaders were empowered to facilitate CCL study enrollment. A consistent characteristic shared by these successful nursing-led CCL models is the presence of a CCL team with multidisciplinary leadership and membership. Each member of the team has a defined role with clear expectations, responsibilities, and

authority. Table 2 displays increased COG CCL study accrual at these institutions before and after implementation of the nurse-led CCL models.

APN-Led CCL Models

At LCH, UMHS, and HSC, an APN is identified as the lead or champion for each CCL study based on clinical role, professional expertise, and interest (eg, a neuro-oncology APN serves as the lead for studies specific to that population). Studies that involve more than 1 focus area (eg, both solid tumors and neuro-oncology) may have more than 1 APN lead. The lead APN identifies patients who meet eligibility criteria and then discusses the potentially eligible patients with the primary team. The CCL champion's familiarity with the patient population is intentional, in order to increase the timeliness of patient identification and understanding of the specific protocol requirements. The APN obtains informed consent/assent to CCL trials from patients and families when the interventions are within their scope of practice, which is commonly the case for supportive care trials. The APNs work with the medical, research, and nursing staff to oversee study conduct at their local sites, including data collection and study-related education.

Monthly research meetings specific to CCL studies are held at UMHS, HSC, and CNHS. During these meetings, currently open studies are reviewed, additional studies are prioritized for activation, and champions (leads) are assigned to each study. Enrollments are reviewed, but more important, missed opportunities for enrollments are discussed, obstacles identified, and solutions developed. These meetings build CCL study awareness across departments and specialties, as well as providing a venue for addressing general supportive care issues.

There are also unique aspects to each of the APN-led programs. At LCH, institutional support for continuing education or travel to a COG meeting was negotiated as an incentive for the APN taking on this new role. Studies that are nursing-related, such as ACCL1033, *A Comprehensive Approach to Medication Adherence in Pediatric ALL* (NCT01503632), are a particularly good fit for the APN-led CCL model at LCH. Additionally, partnering with a research nurse (a newly created role at LCH) is also effective, as both the APN and the research nurse each have distinct approaches to successfully identifying patients, but they work together to assure that all study requirements are completed.

At UMHS, the Stem Cell Transplant APN has been predominantly successful in enrolling patients on ACCL0934, *A Randomized Trial of Levofloxacin to Prevent Bacteremia in Children Being Treated for Acute Leukemia or Undergoing Hematopoietic Stem Cell Transplantation* (NCT01371656). One especially effective strategy at UMHS has been adding CCL study recruitment to the admission checklist. This serves to remind all team members involved with new patient admissions to discuss appropriate CCL studies with patients and families.

At HSC, the APN model of involvement in CCL studies is similar to those at LCH and UMHS, as the APNs in these programs mentored the APNs at HSC during the development phase. There are 2 dedicated CRAs on the CCL team who activate the studies, screen for eligible patients, and interact with primary physicians and APNs to enroll patients. The CRAs provide the APN with necessary training regarding all open studies, and they work

collaboratively with the APN group to facilitate identification, enrollment, and data collection for participating patients.

Research Nurse–Led CCL Model

Another model of nurse leadership of CCL research is in place at CNHS in Washington, D.C. A full-time research nurse coordinator role was created to manage and coordinate all of the CCL clinical trials, including COG, industry, multiinstitution and institution-initiated studies. The goal of this autonomous position is to facilitate the activation, recruitment, and effective management of CCL clinical trials. To accomplish this, the nurse meets regularly with each oncology subdivision to educate staff about new studies and to identify and recruit patients, as well as to elicit feedback regarding the appropriateness of opening new studies (determined by potential enrollment and anticipated study burden on families and providers). Once eligible patients are enrolled on CCL trials, the nurse communicates with study participants at home, in clinic, and during inpatient hospitalizations to assist with data collection. The position is supported by funding received by the institution for per case reimbursement, as well as through grant support. As part of laying the groundwork for the position, multiple CCL trials were opened, which helped justify the need for the position. Successful enrollment strategies used by the CCL nurse leader at CNHS include the following:

- Identifying interested advocates within each team
- Presenting relevant studies repeatedly at team meetings
- Following up with the primary clinician regarding patient eligibility
- Being available for consent conferences and being willing to consent (after training and within boundaries of license; ie, nondrug studies)
- Taking responsibility to identify, obtain, or follow up on data points
- Prioritizing when to approach families about studies

Conclusions

Engaging nurses as leaders in CCL research is an effective strategy to improve enrollment on CCL clinical trials. Nurses and APNs who have participated in the nurse champion model of CCL clinical trials to date report a positive experience. They have indicated that they are more involved and informed regarding the CCL studies, particularly with regard to the consenting process, as most of the models provide training for nurses involved in obtaining informed consent.

Participating in CCL research provides benefits to patients and families, the nurse, and the institution. Families are often interested in these types of studies. As an example, with the growing interest in fertility preservation, a recently opened study aiming to improve understanding of fertility rates of patients treated for lymphoma has been met with enthusiasm by staff, patients, and families. Having formal supportive care committees within the local institutions devoted to CCL research enhances the institutional cancer research

programs. Finally, the institutions receive some financial support for each COG CCL enrollment to help defray costs related to conducting the study.

Even after implementation of these nurse-led CCL models, some barriers to enrollment on CCL studies remain, and include a lack of availability of CCL champions to provide 24 hour-/7-day-per-week coverage and the limited time period that is often allocated to enroll patients on many of the CCL studies. Additionally, as more CCL studies are activated and more patients are enrolled, the amount of data collection at the sites increases; therefore, the workload for CRAs also increases accordingly. Since therapeutic (ie, disease treatment) studies remain a higher priority at COG institutions, CRA time is primarily directed to support these studies. Another challenge noted by sites with APN-led models is the amount of time required for the role, as most of the APNs already have a full-time role with other responsibilities. Despite these challenges, after implementation of nurse-led CCL models at several COG institutions, enrollments onto COG CCL trials improved. However, some sites had difficulty sustaining these enrollments over time; potential solutions for addressing this issue include use of the per-case reimbursement (and/or additional compensation, if available) to support the staff time and effort required to sustain this work, as well as implementation of audits and feedback systems to identify and ameliorate barriers to enrolling patients onto CCL trials. Ultimately, even with highly motivated nurses and APNs as leads of CCL trials, it is clear these trials cannot be implemented and managed by the nurses alone. The importance of recognizing the multidisciplinary team effort required to successfully accomplish this crucial work cannot be overemphasized.

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Table 1

Barriers to Institutional Cancer Control Accrual.[a]

Staff
Lack of
Leadership of CCL trials within the institution
Clear delineation of multidisciplinary team member responsibilities
Adequate staffing to manage increased workload
Commitment of multidisciplinary team toward increasing CCL enrollments
Availability of CCL knowledgeable staff 24 hours/7 days per week
Logistics
Failure to
Open CCL trials in timely manner
Adequately identify eligible patients in time to meet enrollment criteria
Interests and priorities
Lack of
Institutional prioritization
Patient/family interest in CCL trials
Resources
Lack of
Funding to defray institutional costs needed to carry out CCL trials

Abbreviation: CCL, cancer control.

[a]Based in part on data from Vanhoff et al., 2013.

Table 2

Enrollments to COG CCL Trials at Institutions With Nurse-Led CCL Programs Before and After Program Implementation.[a]

	No. of CCL Trial Enrollments Per Year					
Institution	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
A	1	1	13	17	34	15
B	0	0	1	2	13	6
C	2	2	3	25	14	18
D	0	0	1	15	17	24

Abbreviations: COG, Children's Oncology Group; CCL, cancer control.

[a]Data from Children's Oncology Group Statistics and Data Center (Institutional Report Cards), used with permission.