Functional Integration of Nursing Research Into a Pediatric Oncology Cooperative Group: Finding Common Ground

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Purpose/Objectives: To provide a brief description of the historic role of nursing and nursing research in the culture of previous pediatric oncology cooperative groups and compare the research language used in cooperative groups with the language used in nursing research.

Data Sources: Published empirical, clinical, and methodologic reports.

Data Synthesis: The culture and language of nursing research differ from those of medical research and the pediatric oncology cooperative group, the Children's Oncology Group (COG). Different approaches exist to integrate nursing research priorities into the priorities of COG, including freestanding protocols, companion protocols, and research objectives included in therapeutic protocols.

Conclusions: Full integration of nursing research into COG is feasible but dependent on recognition of cultural and language differences among researchers. Integration will be demonstrated by the number of concepts and protocols contributed to or developed by active nurses in COG.

Implications for Nursing: Significant advances exist for nurses conducting research in COG. These research efforts are facilitated by a familiarity with the science language used by other disciplines in COG and an understanding of COG's research processes. Increased interdisciplinary scientific collaborations involving nurses in COG particularly benefit pediatric patients with cancer.

Key Points . . .

- Historically, nurses routinely did not assume independent or coinvestigator roles in oncology cooperative groups.
- Nurses generally have not been formally educated about oncology cooperative groups' research processes.
- A key aspect of fostering nursing research in oncology cooperative groups is understanding scientific discourse regarding clinical trials.

As the 21st century began, the four pediatric oncology cooperative clinical trial groups (the Children's Cancer Group, Pediatric Oncology Group, National Wilms Tumor Study Group, and Intergroup Rhabdomyosarcoma Study Group) merged to become the unified Children's Oncology Group (COG). During their preceding half-century of existence, the two principal legacy groups (the Children's Cancer Group and the Pediatric Oncology Group) had evolved distinct organizational cultures. In the context of this article, culture can be defined in its broadest sense as the "totality of socially transmitted behavior patterns, arts, beliefs, institutions, and all other products of human work and thought" and the "predominating attitudes and behaviors that characterize the functioning of a group or organization" (Dictionary.com, 2003a). The cultural attributes of the groups were reflected in a variety of ways, including meeting format, voluntary participation, communication

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styles, decision making, group policies and procedures, information flow, work pace, and power structures. In these two group cultures, efforts to initiate nursing research programs had limited success. However, nurses in these groups viewed the merger as an opportunity to critically evaluate past nursing research efforts and develop plans for a new approach that would facilitate nursing contributions to the new cooperative group. One factor identified as a contributor to past failures of nursing research efforts in cooperative groups was the difference between the language used in nursing research and cooperative groups. The purpose of this article is to provide a brief description of the historic role of nursing and nursing research within the culture of pediatric oncology cooperative groups and help translate the research language used in cooperative groups into the language used by nursing researchers. The historic perspective and translation of language are anticipated to increase interdisciplinary collaboration by allowing scientists from different disciplines to speak, or at least understand, the same research language.

Background

Nurses' Role in Cooperative Groups

Beginning in 1955, the National Cancer Institute has sponsored oncology clinical trials cooperative groups as a part of its efforts to generate and foster clinical trials. These groups commonly design and implement multisite clinical trials of new drug treatments, surgical or radiation interventions, or symptom management interventions (Works, 2000). Historically, nurses have contributed significantly to the successful implementation of adult and pediatric oncology cooperative group clinical trials. They have participated in protocol or disease committees in varying roles that include concept design, trial outcomes analysis and publication, and patient, family, and nurse education about treatment protocols and clinical trials (Klimaszewski et al., 2000). Nurses were responsible for the daily coordination of activities associated with clinical trials and administering the protocol-directed therapy through patient care (Aikin, 2000). As essential as these nursing functions were, they did not include principal responsibilities for generating research objectives or designing studies to address specific research questions or hypotheses.

In part, nurses did not assume routinely independent or collaborative research roles in oncology cooperative groups because curricula in nursing academic graduate programs gave insufficient attention to science in these cooperative groups. Research terminology, roles of studies' principal investigators and coinvestigators, and examples of group research were not studied routinely. Thus, nurses were not prepared formally to assume leadership roles in cooperative groups. Although graduate-level academic programs for nurses studying advanced practice oncology or research began to proliferate in the 1980s (Brown & Hinds, 1997; McGee, 1988), these programs were limited in number and did not contain content on oncology cooperative groups and clinical trials consistently (e.g., terminology and purposes of different clinical trials, strategies and ethics of monitoring clinical trial activities). In addition, some nurses entered nononcology graduate programs and were not exposed to curricular content on cooperative group clinical trials. Once employed, these nurses experienced serious difficulties finding time and mentorship to conduct independent or collaborative clinical research.

Formally prepared to function as independent or collaborative researchers, nurses with doctoral degrees primarily focused on patient survival and the "human experience" of patients, families, and healthcare providers during cancer treatment (Haberman, 2000). This research focus differed from the predominant "curative therapy approach" of cooperative groups' clinical trials. Although complementary to the curative approach, the human experience focus was considered by non-nurses to be of secondary importance and too complex to study in oncology cooperative clinical trials.

Nursing research and knowledge only recently have reached a point where conducting clinical trials on variables considered important to nursing care is possible. Many nurse researchers completed their doctoral programs with minimal to no exposure to the dominant designs of clinical trials that are sponsored by oncology cooperative groups and other aspects and processes of cooperative groups. Instead, nurse researchers were prepared formally in the language of social sciences and, to a lesser extent, basic sciences.

With this difference in research language and values, few nurse researchers committed themselves to establishing a research career in oncology cooperative group activities. Several nurse researchers found establishing relationships with a cooperative group difficult and left after a brief period (Ruccione & Kelly, 2000). Recently, oncology nurse leaders have urged adult and pediatric nurse researchers and advanced practice oncology nurses to work together in interdisciplinary research teams and use the research language used by other disciplines (Given, 2001). In addition, nurses in COG have planned to initiate greater efforts to contribute to cooperative groups and identify and facilitate the research priorities of the nursing discipline within cooperative groups (Fochtman & Hinds, 2000; Hinds & DeSwarte-Wallace, 2000; Ruccione & Kelly). These factors suggest that this is an opportune time to review the causes of the previously limited nursing contribution to pediatric oncology cooperative groups.

The Importance of Science and Research Language

Clinical, basic, and translational research are the core activities of cooperative groups. Research scientists share the culture of modern science. Because culture and language are inextricably linked, basic and clinical research scientists share a common language that has facilitated their communication in the new COG organizational culture. In the context of this article, language is defined in the inclusive sense of the "communication of thoughts and feelings through a system of arbitrary signals, such as voice sounds, gestures, or written symbols" through a system used by a nation, people, or other distinct community (Dictionary.com, 2003b). The nursing research culture and language (derived from social sciences) differ from that of medical research. A key aspect in fostering nursing research in COG is full integration of nurse scientists into the cooperative group, but differences in language and culture may influence the quality of collaboration between scientific disciplines.

Basic differences between nursing research and cooperative groups' language and values are listed in Table 1. Notable differences include nursing's emphasis on health, symptom management, and quality of care compared to the cooperative groups' emphasis on disease and treatment outcomes. An

Table 1. Examples of Language and Value Differences Between the Pediatric Oncology Cooperative Group and Nursing Research

Elements of Culture: Language and Values	Nursing Research	Pediatric Oncology Cooperative Group
Domains of interest	**Foci**	**Foci**
	Health promotion	Cure and survival
	Disease prevention	Novel drug testing
	Health education	Supportive care
	Health restoration	Chemoprotectant
	Health maintenance	
	Outcomes	**Outcomes**
	Biophysical	Therapeutic efficacy
	• Temperature	• Complete response
	• Sleep	• Partial response
	• Wound healing	• Stable disease
	• Fatigue	• Progressive disease
	• Psychosocial	• Recurrence of disease
	• Mood	• Secondary disease
	• Social support	Toxicity
	• Coping	• Grades 1–4
	• Hope	Morbidity
	Behaviors and safety	• Disability
	• Adherence to treatment	• Complications
	• Health beliefs	Quality of life
	• Self-care skills	Survival
	Quality of life	• Event free
	Delivery of care	• Time to disease progression
	• Patient and family satisfaction with care	• Disease free
	• Models of care	
	• Staffing patterns	
Types of designs	Historical	Phase I–IV
	Qualitative	
	Descriptive	
	Correlational	
	Ex post facto	
	Quasi-experimental	
	Experimental	
	Methodologic	
Primary funding sources	National Institute of Nursing Research, National Institutes of Health (NIH)	Investigational drug branch
	National Cancer Institute, NIH	Community clinical oncology program
	American Cancer Society	Cancer control
	Oncology Nursing Society	Cooperative group outreach program
	Sigma Theta Tau International	Cancer therapy and evaluation program
		Pharmaceutical companies

Note. Based on information from Friedman et al., 1995; Gullatte & Otto, 2001; Haberman, 2000; Lester et al., 1997; McFadden, 1998; Mooney & Haberman, 1996.

important shared focus is quality of life for pediatric patients and their families. A significant difference in research designs is the presence of an intervention in all types of cooperative group studies compared to the descriptive, noninterventional studies that currently dominate in nursing. This difference is likely to decrease in the next few years because of the previously completed exploratory and descriptive research that will increase the amount of interventional research performed by nurses.

Research Language in Cooperative Groups

A clinical trial is a prospective research study of human participants that is designed to answer specific questions about biomedical or behavioral interventions. In the oncology cooperative group setting, the intervention usually involves testing the effectiveness of a new therapy, such as a drug, surgical, or radiation intervention. With the exception of phase I trials, primary interests include overall patient survival, disease-free survival, and intervention toxicity.

Clinical trial terminology is not used commonly in nursing research, and nursing studies lack parallel models for phase I–IV studies. Key characteristics of clinical trial phases are described in the following paragraphs (Ungerleider, Ellenberg, & Berg, 2001; Works, 2000), and parallels to clinical nursing studies are listed in Table 2.

A **phase I** clinical trial tests a new intervention for the first time in a small sample of individuals (e.g., 20–80 participants). No form of randomization is involved. In the language

Table 2. Translation of Cooperative Group Design Language Into Nursing Research Language

Clinical Trial	Characteristics	Parallel Nursing Study	Characteristics
Phase I	New intervention testing One-group design Small sample Dose escalation Dose-limiting toxicity	Intervention pilot test	New intervention testing One group, pre-experimental design Small sample, determining effect size
Phase II	Study intervention in larger groups determining new drug or treatment combination's effectiveness with a particular type of cancer Larger sample Determined efficacy (survival) Evaluated safety	Intervention study	Determining safe intervention delivery, timing, and dose Determining effect of intervention on dependent variables of interest Quasi-experimental design Randomizing intervention or standard care Basing sample size on intervention effect size
Phase III	Comparison of new intervention to standard treatment (disease-free survival) Large sample Randomization Monitor adverse effects (toxicity)	Multisite intervention study	Replicating study in larger sample Quasi-experimental design
Phase IV	Determine efficacy in different population Randomization	Extension and application to different populations	Determining intervention effects in different but relevant populations Quasi-experimental design Randomization Comparing intervention to standard care

of nursing research, a phase I clinical trial could involve pilot testing of an intervention in a small group of subjects. A one-group pre-experimental design could be used in which subjects serve as their own controls. The study may evaluate a dose range (e.g., identifying the most effective frequency or intensity of an exercise intervention for individuals with chronic illness) or determine treatment effectiveness (e.g., the dose or amount of intervention needed to achieve a small, medium, or large change in the dependent variables).

A **phase II** clinical trial determines efficacy and further evaluates the safety of the intervention. The study involves a larger group of subjects and does not require, but may include, randomization. Many nursing intervention studies could be classified as phase II clinical trials. The effect of the intervention is determined by the magnitude of change in the trials' dependent variables. The efficacy of the intervention usually is tested in a homogenous sample (e.g., children with acute lymphocytic leukemia [ALL]), and the sample size is based on a power analysis using the magnitude of the effect established in the phase I trial. The study design typically would be quasi-experimental. Although randomization is not a requirement in phase II studies, most nursing studies involve randomization in the new intervention or standard care group.

A **phase III** clinical trial is designed to compare a new intervention with other standard or experimental interventions and obtain data on adverse events and intervention safety. Phase III clinical trials involve large groups of participants (several hundred to several thousand). Historically, the need for large sample sizes and the lack of appropriate infrastructures to effectively coordinate large multisite studies have caused difficulties for nurses conducting phase III clinical trials. Only a limited number of nursing intervention studies can be classified as phase III clinical trials because of sample size limitations and the inability to compare more than one experimental intervention. However, nurses can take advantage of COG to conduct phase III trials.

Phase IV clinical trials evaluate treatment effectiveness and safety in different populations. In nursing, this can involve testing an intervention that is effective for one sample population (e.g., children with ALL) in a different but appropriate population (e.g., children with brain tumors). Because control of all potentially confounding variables is difficult to achieve, study designs in phase IV nursing studies most likely are quasi-experimental.

Advantages of Nurse Participation in Oncology Cooperative Group Scientific Processes

Because cooperative groups serve as models for clinical trials throughout the world (Comis, 1998), significant advantages exist for nurses conducting research in pediatric cooperative groups. Likewise, significant advantages exist for cooperative groups when nursing research is conducted as a part of their efforts. A benefit for nurse researchers, as they increasingly become focused on developing and testing nursing interventions aimed at improving patient outcomes, is that oncology cooperative groups are structured uniquely to facilitate intervention trials and provide outcome data related to interventions. The semiannual meetings of cooperative groups' scientists provide opportunities for nurses to meet regularly and work on collaborative projects. These meetings alleviate the sense of isolation that some nurse researchers experience in their own institutions where colleagues may not be interested in similar

populations, concepts, designs, or measurement issues. The meetings also foster interactions with multidisciplinary researchers and often produce new scientific collaborations.

COG includes a well-organized and highly motivated group of nurse clinicians. These nurses are knowledgeable about research protocols, have a good sense of clinical trial design, and often are eager to be involved in nursing research at a variety of levels. Of particular importance, they are well versed in pediatric oncology cooperative groups' values and language and have established collegial relationships with group members from other disciplines. Nurse clinicians can guide nurse researchers' efforts skillfully, and both groups can become highly accomplished research collaborators.

COG offers opportunities for receiving feedback during the planning stages of a study, which allows feasibility and scientific merit. In COG, this feedback first may come from nurses attending the nursing research committee meetings or the disease committees (most often comprised of physician clinical investigators who develop therapeutic clinical trials meetings). In the early phases of study development, the nursing research committee can offer thoughtful critiques of research concepts in a supportive atmosphere and language familiar to nurses. This committee also is a place where possible design, methodology, and statistical questions can be addressed. In addition, the concepts' significance and adherence to COG research priorities can be discussed. Critique by other disciplines can be anticipated so that language and design issues can be addressed prior to presentations at the disease committees. COG has the resources (e.g., trial sites, personnel, participants, recruitment, data analysis, management capabilities) that support the implementation and evaluation of approved studies. As studies progress, COG meetings can be used to bring participants together to receive training in intervention, evaluation, or quality control.

The cooperative group structure, through multisite cooperation, allows global access to a large number of patients for recruitment into clinical trials. Often, this can increase rates of patient recruitment and has the potential to decrease the time and costs of conducting trials. Multicenter cooperation is very important to trial centers with small patient populations where only a limited number of trials may be open to accrual. Also, larger centers host multiple trials, and the same patients are eligible to consider enrolling in more than one therapeutic and nontherapeutic trial at the same time.

As nurses begin to consistently conduct their research in cooperative groups, protocol databases can become more reflective of nursing care outcomes. These databases then can be used to demonstrate progress in nursing science. In addition, the databases will allow simultaneous analysis of nursing and medical care outcomes.

Finally, cooperative groups offer opportunities to increase nursing research endeavors' visibility. Nursing research must be visible to have a role in establishing research priorities (Rieger, 2002). In the COG disease committees or scientific committees (i.e., those that focus on cancer control, supportive care, or end-of-life care), opportunities exist for nurses to discuss, collaborate, and improve their science in interaction with other scientists from a variety of backgrounds. In doing so, these nurses can assist others in refining their research questions and methods and contribute more directly to the scientific mission of pediatric oncology cooperative groups.

Nursing's Contribution to the Science of Cooperative Groups

Nursing research in COG may take the form of freestanding or companion protocols, the latter focusing on nursing care research objectives and linked to a disease-specific protocol or trial. Alternatively, the objectives may be sponsored by nursing but incorporated into a therapeutic protocol. In any of these approaches, the study protocols may be open for participant enrollment in a limited number or to all COG institutions. Studies that are limited in the number of institutions involved have the advantage of recruiting nurses who can dedicate some of their time to the studies and actively enroll patients. Small studies with manageable numbers of researchers make dispensing information about study logistics easier. Groupwide approaches allow study findings to be generalized across geographic and patient diversities.

Freestanding nursing protocols are highly visible and provide recognition of nurse productivity in cooperative groups. Nurse researchers also may secure extramural funding more easily for independent protocols rather than for research objectives integrated in treatment-related protocols. Finally, freestanding protocols can provide a forum for pilot testing nursing research studies that may be integrated into treatment-related, groupwide studies at later dates.

An advantage of companion protocol approaches is that the patient population and design data points are shared between two clinical trials, thus giving greater enrollment efficiency and opportunity to interpret the data from the trials in the context of one another. An example of the harmony of a companion protocol approach is in a current nursing protocol that is examining the differences in sleep efficiency, duration, fatigue, dexamethasone pharmacokinetics, and pharmacogenetics in children and adolescents being treated for ALL before and during dexamethasone pulses (grant RO1 NR07610). This protocol is linked to three frontline therapeutic protocols whose overall objectives are to improve the cure rate of children with non-B cell ALL. The same patient population would participate in the therapeutic and companion protocols. Data collection times for nursing protocols match those for the therapeutic protocols so that patients do not need to return to the care setting for additional nursing data collection, and the outcomes from the nursing and medical protocols can be used to help interpret the other protocols' findings.

Nursing objectives, inserted in disease-specific research protocols, provide a systematic approach to examining supportive care, symptom management, quality of life, self-care skills, and other patient or family responses to cancer and its treatment while allowing data to be compared with treatment outcomes. All patients enrolled in disease-specific protocols also will participate in nursing objectives. Mechanisms available in cooperative groups to facilitate patient enrollment and monitoring then become available for nursing objectives.

Efforts to incorporate nursing objectives in disease-specific protocols are enhanced greatly if they occur during the protocols' development stages and not after protocols are open for recruitment. Nurses who are active members on disease committees of cooperative groups are in a key position to know when new protocols are being developed and the primary design features of new protocols. Furthermore, at times, treatment-related protocols are amended or temporarily closed.

Freestanding nursing research protocols associated with such protocols could remain open for recruitment, whereas nursing objectives nested within an existing non-nursing protocol would depend on recruitment to the primary study.

Conclusion

The nature of cooperative group science is changing, which makes this an ideal time for nurses to become more actively involved. Comis (1998) identified several general goals of cooperative groups that are not yet fully realized.

- Build on the scientific breadth of members.
- Integrate health outcomes and economic measures in protocol activities.
- Identify the most appropriate therapies to consider for reimbursement.
- Establish a framework that builds on the strengths of each member.
- Enhance international cooperation in clinical trials.

These goals are remarkably similar to the vision of COG, which is to incorporate the talents of all members to facilitate its scientific aims. One factor that will assist nurses' ability to integrate and contribute to cooperative groups is being able to speak the same research language that dominates COG. In addition, non-nurse members of the cooperative groups must be familiar with these language differences to assist in translating nurses' research ideas that are highly relevant to cooperative groups.

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