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A Needs Assessment of Oncology Nurses' Perceptions of National Cancer Institute–Supported Clinical Trial Networks

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Purpose/Objectives: To describe oncology nurses' understandings of the function and infrastructure of, current level of participation in, and the advantages and disadvantages to conducting research through cancer cooperative groups (CCGs).

Design: Descriptive.

Setting: Cross-sectional, Web-based needs assessment.

Sample: Doctorally prepared Oncology Nursing Society (ONS) members (n = 962), ONS Clinical Trial Nurses Special Interest Group members (n = 568), and a random sample of master's-prepared ONS members (n = 2,000) for a total of 3,530 ONS members.

Methods: A 28-item questionnaire was distributed via e-mail.

Main Research Variables: Familiarity with different cooperative groups, understanding about their functions and infrastructures, and perceived advantages and disadvantages of and barriers to conducting research through cooperative groups.

Findings: Fifty-four percent of respondents reported being very familiar with cooperative groups, and 19% reported having no knowledge about their functions and infrastructures. Attending meetings and enrolling patients were the most frequently cited activities. Limited funding and time, lack of opportunities, perception that CCGs are too political, and lack of receptivity for nursing research were identified as barriers to conducting research within cooperative groups.

Conclusions: ONS members' self-described roles correlated to their participation in CCGs. Of respondents who had the education and qualifications with which to lead clinical trials as principal investigators, few reported successful collaborations with conducting research through CCGs.

Implications for Nursing: Although respondents reported more advantages than disadvantages to conducting research through CCGs, they did not report a high level of involvement, such as taking the lead in conducting research. Respondents expressed interest in learning more about conducting research within cooperative groups.

Key Points . . .

- Oncology nurses generally are aware of cancer cooperative groups (CCGs) and most often reported attending meetings and enrolling patients in clinical trials as their activities.
- Most respondents expressed an interest in learning more about opportunities to conduct research in CCGs.
- Perceived barriers to conducting research in CCGs were limited funding and time, regulatory issues, and lack of receptivity for nursing research.

their studies across several sites. Equally as important, nurse scientists have collected and analyzed sufficient descriptive data that support the development of randomized clinical trials. In addition to providing a large and diverse study sample, multisite research brings the added value of increased interdisciplinary collaboration; yet, conducting this type of clinical research is an expensive endeavor.

The need to conduct multisite research is not a new phenomenon, nor is it unique to the nursing discipline. In 1955,

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Historically, nurse scientists have conducted their research at one site; however, with the National Institutes of Health (NIH, 2001) mandate to include culturally diverse samples and prepare findings that can be generalized to an increasingly diverse society, nurse scientists are seeking new approaches to expand the conduct of

the National Cancer Institute (NCI) established the Cancer Cooperative Group Program following congressional approval to increase support for chemotherapy studies for cancer. Currently, the Cancer Cooperative Group Program includes 12 cooperative groups, which place more than 22,000 new patients in cancer treatment clinical trials each year (NCI, 2006).

In 1983, recognizing the need to increase accrual beyond academic centers and that physicians trained at academic cancer centers were, in increasing numbers, entering community practices to care for the majority of patients with cancer in the country, NCI (n.d.) established the Community Clinical Oncology Program (CCOP).

In addition to increasing access to cancer treatment trials, the Cancer Cooperative Group Program expanded its research goals by supporting a network for cancer prevention, symptom management, and palliative care clinical trials. Since 1984, 172,000 patients have enrolled in cancer treatment, prevention, and symptom management clinical trials through the CCOP (NCI, n.d.).

Despite the presence of two national networks, less than 2% of adult patients with cancer are enrolled in NCI-sponsored clinical trials (Christian & Trimble, 2003). In 1997, NCI launched the Clinical Trials Support Unit with a primary goal to facilitate physician and patient access to NCI-sponsored clinical trials by permitting noncooperative group members to enroll patients (Cancer Trials Support Unit, n.d.). Table 1 compares the three networks.

Throughout the 50 years of the NCI Cancer Cooperative Group Program's existence, nurses have played a number of supporting roles in managing clinical trials, most notably in the areas of patient recruitment, accrual, and data management. Within the infrastructure of the cooperative groups, nurses have been disease committee liaisons, patient advocates, educators for nurses with less experience, and, to a much lesser degree, protocol chairs. Membership eligibility varies among the cooperative groups. In general, membership is conferred at the institutional level (e.g., academic medical center, hospital, group practice) and the overarching consideration is the potential to accrue patients to clinical trials. Individuals from a variety of disciplines, including nursing, can join cancer cooperative groups (CCGs) through an existing institutional member.

The first stand-alone, nurse-led phase III randomized clinical trial was conducted through the Southwest Oncology

Group (Berry, Strickland, & Dawson, 1994). Investigators Strickland et al. (1997) compared three educational approaches for teaching breast self-examination in more than 2,200 healthy women in a limited institution trial from 1989–1993; however, 14 years later, nurse-led protocols remained an anomaly in cooperative groups. Ruccione, Hinds, Wallace, Kelly, and Children's Oncology Group Nursing Discipline (2005) wrote that one major contributor to this problem is a lack of preparation about CCGs in oncology master's and doctoral programs. Compounding the problem is the perceived lack of common language, research goals, and priorities by nurse scientists and cooperative groups.

Several important publications have highlighted nurses' roles in patient recruitment, data management, and patient care within the context of cancer clinical trials and cooperative groups (Ehrenberger & Lillington, 2004; Klimaszewski, 2000; Smith et al., 2006); however, data explaining the limited roles for nurse scientists within CCGs are sparse. Clinical research networks are beginning to emerge in other nursing specialties, such as cardiovascular and HIV/AIDS (Inventory and Evaluation of Clinical Research Networks, 2006).

The Oncology Nursing Society (ONS) endeavored to define multisite research and develop a multisite research strategic plan. In 2004, the ONS Multisite Research Work Group defined multisite research as "a study conducted by a consortium of two or more investigators using the same overall research plan in several different regional, national, or international sites. Data are pooled for analyses to accomplish the specific aims of the study and results are disseminated by the consortium of investigators" (ONS, 2004, p. 1). A three-year ONS Multisite Research Strategic Plan was approved by the ONS Board of Directors in 2005. The plan aimed to develop opportunities to engage oncology nurses in various settings and roles in the multisite research process and facilitate development and implementation of transdisciplinary professional partnership models for conducting multisite research. The specific goals focus on education (developing core competencies and a core curriculum for multisite research) and mentorship that will facilitate nurse participation in multisite research groups and networks, advocacy, and partnership. The latter goal will increase ONS's participation in national research initiatives and explore opportunities for ONS partnerships with existing multisite research groups and

Table 1. Comparison of National Cancer Institute–Supported Clinical Trial Networks

Network	Members	Types of Trials	Patients Enrolled in 2005
Cancer Cooperative Group Program	ACOSOG, ACRIN, CALGB, COG, ECOG, EORTC, GOG, NCCTG, NCIC, NSABP, RTOG, SWOG	Phases I–III disease treatment	22,000 adults and children
Community Clinical Oncology Program	63 physician practices in 30 states, District of Columbia, and Puerto Rico; eight cooperative groups; and six comprehensive cancer centers	Phases II–III prevention, disease treatment, and supportive care	5,321 ^a adults and children
Clinical Trials Support Unit	Qualified oncologists outside of the cooperative group program	Phase III disease treatment	7,036 adults

^a Number represents accrual to prevention and supportive care trials. Community Clinical Oncology Program accrual to disease treatment trials is included in Cancer Cooperative Group Program and Clinical Trials Support Unit numbers.

ACOSOG—American College of Surgeons Oncology Group; ACRIN—American College of Radiology Imaging Network; CALGB—Cancer and Leukemia Group B; COG—Children's Oncology Group; ECOG—Eastern Cooperative Oncology Group; EORTC—European Organisation for Research and Treatment of Cancer; GOG—Gynecologic Oncology Group; NCCTG—North Central Cancer Treatment Group; NCIC—National Cancer Institute of Canada, Clinical Trials Group; NSABP—National Surgical and Adjuvant Breast and Bowel Project; RTOG—Radiation Therapy Oncology Group; SWOG—Southwest Oncology Group

networks, such as the Cancer Cooperative Group Program, and promote data sharing and the use of common data elements and recommended clinical and research instruments. As the projects unfold, more information about opportunities for oncology nurses' participation in multisite research will be shared.

Given the perception of nurses' inadequate knowledge of and limited participation in CCGs, ONS conducted a needs assessment involving a subgroup of its membership to ascertain oncology nurses' understanding of the function and infrastructure of CCGs, the current level of participation in CCGs, and perceptions of advantages and disadvantages to conducting research through CCGs.

Methods

Instrument Development

A needs assessment questionnaire was developed by an ONS project team (see Figure 1). The 28-item questionnaire assessed nurses' familiarity with and understanding of the function and infrastructure of different cooperative groups, their perception of advantages and disadvantages of and barriers to conducting research through cooperative groups, and their demographic characteristics (e.g., education level, role, work setting). The format of the items in the questionnaire included forced choice, Likert scales, and open-ended comments. One forced-choice question was, "How familiar are you with the cooperative groups?" The participant could choose one of three responses: "I am aware that they exist," "I am very familiar with one or more of the cooperative groups," or "Not at all familiar." The needs assessment was developed using Zoomerang™ (Market Tools Inc., Mill Valley, CA), a software program that facilitates designing electronic surveys and analyzing results. A secure Web site was used for electronic responses, and a questionnaire identifying number ensured confidentiality. The questionnaire was pretested for face validity among a sample of nurses working in comprehensive cancer centers, community cancer centers, and schools of nursing. No reliability testing was conducted.

Study Population

Inclusion criterion was ONS members with valid e-mail addresses. The invited sample was derived from the ONS membership and consisted of doctorally prepared members ($n = 962$), Clinical Trial Nurses Special Interest Group members ($n = 568$), and a random sample of master's-prepared members ($n = 2,000$) for a total of 3,530 ONS members.

Procedure

The needs assessment was distributed in March 2005 via e-mail, and a reminder e-mail was sent two weeks later. The e-mail described the purpose of the needs assessment and

assured confidentiality. Informed consent was implied by an individual respondent's choice to complete and submit the questionnaire. No identifying information was included on the instrument.

Statistical Analysis

Descriptive statistics were used to identify the frequency, percentages, and cross tabulations for item responses based on the role of the respondent (i.e., administrator or manager, advanced practice nurse [i.e., clinical nurse specialist and nurse practitioner], educator, nurse scientist, research or protocol nurse, or clinical research associate or coordinator).

Results

Demographics

A total of 682 (19%) of the 3,530 members contacted completed the electronic needs assessment. Of the respondents, 62% were master's prepared, 16% had a doctorate degree, 15% had a bachelor's degree, and 7% had an associate's degree or a high school diploma. The respondents' primary roles were advanced practice nurse (36%), research or protocol nurse (26%), administrator or manager (17%), educator (13%), and nurse scientist (8%). The most commonly reported work settings were community cancer centers (26%), academic medical centers (22%), NCI comprehensive cancer centers (13%), and schools of nursing (12%).

Knowledge of Cooperative Groups

Fifty-four percent of the respondents reported being very familiar with cooperative groups, and 34% indicated they were aware of their existence. Research or protocol nurses (83%) were most familiar with CCGs followed by administrators or managers (53%), nurse scientists (47%), advanced practice nurses (nurse practitioners [44%], clinical nurse specialists [46%]), and nurse educators (28%). Participants who were familiar with CCGs also were knowledgeable about the various committee structures (e.g., disease site, cancer control, quality of life, discipline) and the multiple functions (e.g., prevent, cure, palliate) of CCGs. When asked about interest in learning more about opportunities to conduct research in CCGs, 65% answered affirmatively.

Level of Participation

Although the respondents were knowledgeable about many aspects of CCGs, 266 (39%) were not active or not members of one or more groups. Among participants who were active, most (>50%) were master's prepared. The most frequently reported activities in which respondents participated were attending meetings and enrolling patients. As expected, research and protocol nurses most frequently reported attending CCG meetings. About a third of the nurse scientists who reported active participation in CCGs had served on a committee, suggesting that once nurse scientists become involved in CCGs they may have more opportunities for participation. Nurse educators were the least likely to report participation at any level. Seventeen percent of respondents reported being aware of nurse-led studies conducted through CCGs, with the Children's Oncology Group most often cited as having a nurse as a lead investigator. In the questionnaire's open-ended comments, respondents could list other activities in which they participated, including liaison and leadership

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Figure 1. Oncology Nursing Society (ONS) Project Team Members

opportunities in various committees, regulatory and auditing activities, education and training, and patient care issues (e.g., developing protocol orders, providing direct patient care, following patients on study). The respondents' overall level of participation in CCGs is displayed in Table 2.

Advantages and Disadvantages of Conducting Research in Cooperative Cancer Groups

The most frequently cited advantages and disadvantages of conducting research through CCGs are delineated in Figure 2. The results were fairly consistent across different professional roles; however, nurse scientists and doctorally prepared educators were likely to identify another advantage (opportunities to publish) and disadvantage (the kind of research I do is not valued). A considerable proportion of the sample responded that they did not have an opinion regarding disadvantages (31%) and advantages (13%) of conducting research through CCGs. Open-ended comments about disadvantages (n = 47) underscored the perceived barriers that make cooperative group research by nurses challenging (e.g., limited funding and time, lack of opportunities, regulatory issues, too political, lack of receptivity for nursing research).

Discussion and Nursing Implications

The 19% response rate for the needs assessment is comparable to other ONS needs assessments targeted to specific groups regarding a topic of potential interest; however, the response rate is higher than rates of ONS surveys targeted to the general membership (5%–10%). Nevertheless, findings should be interpreted with some caution because generalizability may be limited as a result of potential selection bias. Nurses who responded may have been more likely to be interested in or have involvement with CCGs. The findings are applicable only to the ONS membership and do not inform the larger population of nurse scientists from other clinical specialties.

The needs assessment of ONS members resulted in a respondent sample in which nearly half reported being involved and familiar with CCGs. The reported level of understanding of the function and infrastructure of CCGs indicates moderate familiarity, with the exception of 86 educators who reported the lowest level of familiarity and understanding. The group of educators included master's-prepared and doctorally prepared

Table 2. Nurses' Participation in Cancer Cooperative Groups

Type of Participation ^a	n ^b	%
Enrolled patients	307	45
Attended meetings	284	42
Served on a committee	98	14
Served as a principal investigator (PI) or co-PI	32	5
Not active	266	39

^a One hundred and seventeen respondents provided additional data via open-ended comments, of which 66 were sorted into five meaningful categories of activities: leadership (committee chair, study coordinator); direct care to patients on study; auditor, institutional review board, or regulatory; education or training; liaison (protocol, committee).

^b Respondents could select more than one option.

- Advantages (N = 662)**
- Assistance with data collection, management, and analysis (64%)
 - Access to patient populations (61%)
 - Access to data sets (58%)
 - Learning findings firsthand from completed studies (57%)
 - Opportunities for transdisciplinary research (55%)

- Disadvantages (N = 620)**
- No financial support to travel to cooperative group meetings (33%)
 - No salary support to participate in cooperative group activities (33%)
 - Do not understand how to shepherd a study through (21%)
 - Takes too long to initiate and complete a study (21%)
 - Participation not recognized for promotion (16%)

Figure 2. Top Five Advantages and Disadvantages of Conducting Research in Cancer Cooperative Groups

nurses. Nurse scientists have postulated that nurse educators and scientists may lack knowledge about or involvement in CCGs primarily because of nurse researchers' need to use research language that is common to the academic and clinical cancer centers in which they work (Given, 2001) or the difficulty in launching nursing studies in the Children's Oncology Group related to the paucity of nurse scientists in the group (Ruccione et al., 2005).

The type of participation in CCGs by ONS members clearly is linked to their self-described roles. Research nurses dominated the activities involved with enrolling patients into trials. Not surprisingly, only 32 respondents (5%) overall reported serving as investigators on a cooperative group trial. Nine percent of the doctorally prepared respondents and 5% of the master's-prepared respondents reported principal investigator or coinvestigator activity. The most often cited CCG for which ONS nurses served as investigators was the Children's Oncology Group, certainly reflecting the focused efforts led by Hinds and DeSwarte Wallace (2005) since 2000 to establish a new culture of collaboration among scientific disciplines in the group. Finally, even though the respondents perceived greater opportunities and advantages than disadvantages to conducting research through CCGs, among respondents who have the education and qualifications with which to lead trials as investigators, few reported successful collaborations with conducting research through CCGs.

The main recommendation resulting from the findings is to initiate educational programs directed at increasing nurses' understanding of the function and infrastructure of CCGs and opportunities to participate in the research activities of CCGs. The majority of respondents preferred a session at a national ONS-sponsored meeting or a Web-based tutorial. An educational session highlighting research opportunities in cooperative groups was provided at the 2006 ONS Annual Congress and at the 2007 Ninth National Conference on Cancer Nursing Research. An additional training program funded by the ONS Foundation was held in October 2006 to provide an educational opportunity about CCGs and the process involved in developing and submitting concept proposals for review and implementation by CCGs.

Cancer clinical trial networks have had a long history of solely physician and statistician leadership; however, the paradigm is changing. The NIH recognized the need to facilitate transdisciplinary research by developing the NIH Roadmap, which is a framework for identifying the most

compelling opportunities in three areas: new pathways to discovery, research teams of the future, and reengineering the clinical research enterprise (Office of Portfolio Analysis and Strategic Initiatives, 2006). Since 2001, the NIH Roadmap has articulated the need to change the current paradigm of just one or two scientific disciplines studying health and disease to one of the teams of multiple disciplines working in concert to improve the nation's health (Office of Portfolio Analysis and

Strategic Initiatives). Since the release of the NIH Roadmap, several initiatives have been issued with the goal of exploring new ways for creating new multisite networks that may offer opportunities for greater nursing involvement in the national research agenda.

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References

- Berry, D.L., Strickland, C.J., & Dawson, M.A. (1994, March). Southwest Oncology Group offers multisite research opportunities for nursing. *Oncology Nursing Society Advanced Nursing Research Special Interest Group Newsletter*, 5(1), 3.
- Cancer Trials Support Unit. (n.d.). Frequently asked questions. Retrieved January 19, 2006, from <http://www.ctsu.org/faq.asp>
- Christian, M.C., & Trimble, E.L. (2003). Increasing participation of physicians and patients from underrepresented racial and ethnic groups in National Cancer Institute-sponsored clinical trials. *Cancer Epidemiology Biomarkers and Prevention*, 12(3, Suppl.), 277s–283s.
- Ehrenberger, H.E., & Lillington, L. (2004). Development of a measure to delineate the clinical trials nursing role [Online Exclusive]. *Oncology Nursing Forum*, 31, E64–E68. Retrieved January 19, 2007, from <http://www.ons.org/publications/journals/ONF/Volume31/Issue3/pdf/517.pdf>
- Given, B. (2001). Into the millennium: Open the door and let the future in for cancer nursing research. *Oncology Nursing Forum*, 28, 647–654.
- Hinds, P.S., & DeSwarte Wallace, J. (2005). Pediatric oncology nursing research in the Children's Oncology Group: The second generation. *Seminars in Oncology Nursing*, 21, 77–78.
- Inventory and Evaluation of Clinical Research Networks. (2006). Inventory of clinical research. Retrieved January 22, 2007, from <https://www.clinicalresearchnetworks.org>
- Klimaszewski, A. (Ed.). (2000). *Manual for clinical trials nursing*. Pittsburgh, PA: Oncology Nursing Society.
- National Cancer Institute. (n.d.). Community clinical oncology program celebrates 20 years of research. Retrieved January 19, 2007, from <http://www.cancer.gov/prevention/ccop20th/history.html>
- National Cancer Institute. (2006). NCI's clinical trials cooperative group program. Retrieved January 19, 2007, from <http://www.cancer.gov/cancertopics/factsheet/NCI/clinical-trials-cooperative-group>
- National Institutes of Health. (2001). NIH policy and guidelines on the inclusion of women and minorities as subjects in clinical research—Amended October 2001. Retrieved January 19, 2007, from http://grants2.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm
- Office of Portfolio Analysis and Strategic Initiatives. (2006). Interdisciplinary research. Retrieved January 22, 2007, from <http://nihroadmap.nih.gov/interdisciplinary/>
- Oncology Nursing Society. (2004). *ONS role in multisite research* [Panel report]. Pittsburgh, PA: Author.
- Ruccione, K.S., Hinds, P.S., Wallace, J.D., Kelly, K.P., & Children's Oncology Group Nursing Discipline. (2005). Creating a novel structure for nursing research in a cooperative clinical trials group: The Children's Oncology Group experience. *Seminars in Oncology Nursing*, 21, 79–88.
- Smith, E.L., Skosey, C., Armer, J., Berg, D., Cirrincione, C., & Henggeler, M. (2006). The cancer and leukemia group B oncology nursing committee (1983–2006): A history of passion, commitment, challenge, and accomplishment. *Clinical Cancer Research*, 12(11, Pt. 2), 3638s–3641s.
- Strickland, C.J., Feigl, P., Upchurch, C., King, D.K., Pierce, H.I., Grevstad, P.K., et al. (1997). Improving breast self-examination compliance: A Southwest Oncology Group randomized trial of three interventions. *Preventive Medicine*, 26, 320–332.