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Lessons Learned: Enhancing Nurse Contributions to Cancer Clinical Trials in SWOG

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Abstract

Objectives—To review nursing research contributions and future opportunities for nurses in cooperative oncology group research in SWOG (formerly Southwest Oncology Group).

Data Sources—Peer-reviewed journal articles, grant submissions, professional manuals, research policy reports, meeting minutes.

Conclusion—Nurses and nurse researchers have had active roles in SWOG research involving quality of life, symptom management, recruitment and adherence, and data quality. There are untapped opportunities for nurses and nurse researchers to make greater contributions to cooperative group research, particularly in cancer survivorship, health outcomes, and quality of life.

Implications for Nursing Practice—Nursing science and evidence-based practice will be enhanced by conducting nursing research in the multi-site cooperative group setting.

Keywords

Cooperative group; SWOG; nursing research; quality of life

SWOG, formerly Southwest Oncology Group, is one of the largest cancer clinical trials organization in the United States. SWOG is a National Cancer Institute (NCI) funded cancer cooperative group with over 500 institutional sites participating in therapeutic trials, as well as trials in cancer prevention and control. SWOG was established in 1956 as a pediatric oncology group and an adult cancer division was formed in 1958. In 1980, the pediatric division separated to form the Pediatric Oncology Group. Since 1980, SWOG has expanded its clinical trial repertoire to the conduct of trials in cancer prevention, symptom management, translational medicine, and health economics. Nurses have a long history of

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contributions to SWOG trials, particularly in the realm of quality of life (QOL) and symptom management research.

History

Nurses first became active as a group in SWOG in 1980 when the Nursing Subcommittee was established within the Cancer Control Committee. The focus of this fledgling group was to define the role of nurses in SWOG, improve the care provided for clinical trial patients, contribute to the design of symptom interventions and patient-reported outcomes (PRO) research, provide nursing education, and enhance communication among nurse members. These clinical trial nurse pioneers sought to broaden their contributions to the science and conduct of cooperative group trials and successfully petitioned the Board of Governors for full committee status. Thus, the Nurse Oncologist Committee was established in 1981. Research and protocol liaison subcommittees were formed to provide avenues for nursing contributions to clinical trial development. By 1987 the committee's membership had expanded to over 100 members.

Nurse-Generated Science in SWOG

In the mid-1980's, three nurse researchers joined the group as special members and submitted study proposals. The first SWOG trial led by a nurse researcher was SWOG 8807, "An investigation of the relationship between an integrated, system educational approach and breast self-examination (BSE) compliance."¹ June Strickland, RN, PhD, developed the phase III study that enrolled 2,451 participants from nine participating Community Clinical Oncology Programs (CCOPs). The study compared physician message with or without a breast self-examination (BSE) class, to physician message, BSE class and telephone reinforcement. All interventions increased BSE compliance over baseline but the combination of all three interventions led to the highest level of BSE compliance.

SWOG made its first foray into PRO research with S8313, an adjuvant breast cancer trial. Kathy Hayden, RN, BSN, was the first nurse QOL coordinator(see description below) in SWOG and the lead author on the QOL component of the study. Hayden and colleagues experienced daunting challenges, including poor questionnaire submission rates resulting in substantial missing data; this led to early closure of the QOL component of S8313. Hayden's 1993 article, Pitfalls in quality-of-life assessment: Lessons from a Southwest Oncology Group breast cancer clinical trial,² highlighted the challenges of collecting patient self-report data in the cooperative group setting. SWOG responded to these lessons learned by developing guidelines for collection of PRO data in SWOG trials.³ Initially, studies including a QOL outcome were designed as stand-alone companion trials to therapeutic trials. Enrollment on the QOL companion became a requirement for enrollment on the therapeutic trial. Nurses continued to serve as study coordinators and co-coordinators for these trials. They were actively involved in protocol development, assisting sites with questionnaire compliance, manuscript preparation, and authorship. Subsequently SWOG researchers learned that embedding the QOL measures and outcomes in the therapeutic protocol was a more efficient use of cooperative group resources. As a consequence, experienced SWOG nurses served as co-coordinators for the QOL component of the therapeutic protocol.

Nurse researcher Donna Berry, RN, PhD, FAAN was instrumental in advancing nursing contributions to SWOG studies. Dr. Berry was co-coordinator on three prostate cancer trials for the QOL portions of those trials. She served in a unique role on cancer prevention trial S9917, where she assisted in developing recruitment and retention strategies for participants with high-grade prostatic intraepithelial neoplasia.⁴ During the 1990s, Dr. Berry and Nurse Oncologist Committee chair, Jeanne Parzuchowski, RN, MS, recruited five nurse

researchers into SWOG. Several of these nurse researchers presented concepts to the group for consideration; however, none were approved for development. Challenges to moving nursing research forward during this era included feasibility of extending single-site nursing research to multiple sites, lack of cancer control funding for instrument development trials, limited cooperative group experience in behavioral science studies, and lack of funding for pilot studies involving non-drug intervention strategies.

The National Cancer Institute established several initiatives targeting minority populations in the late 1980s in response to cancer survival rates that were inferior to Caucasian counterparts.⁵ The new programmatic focus prompted changes in SWOG committees, membership, and proposed trials; consequently, SWOG leadership and the NCI were more receptive and supportive of pilot/feasibility studies. Pilot study S9418, employing Hispanic lay-health educators, was developed and conducted by Lisa Hansen, RN, MS, and colleagues to convey cancer screening information to Hispanic women in the San Antonio area. The study demonstrated that female cancer survivors could be trained to convey cancer screening information to their social contacts and that these contacts were prompted to obtain breast and cervical cancer screening.⁶

The Group had several disappointments when cancer control studies with nurse involvement were activated, but were not completed. Hansen was the nurse coordinator for an oral mucositis study testing L-glutamine in head and neck cancer patients undergoing radiation therapy (S9908). Unfortunately, this study was closed when the pharmaceutical company withdrew support for the use of their agent. An ambitious smoking cessation trial, S0002, was developed by Ellen Gritz, PhD, and nurse researcher, Linda Sarna, RN, PhD, FAAN. The trial faced insurmountable accrual difficulties, in part, because eligible patients were seen primarily by surgeons and SWOG did not have many members that were lung cancer surgeons. Patient recruitment strategies required the recruitment of surgical practices often at different physical locations from the participating SWOG institution. Despite three years of effort and enthusiastic support by the study team, the study was closed due to poor accrual.

Dr. Antoinette Wozniak and colleagues developed S0229, a randomized trial testing a pulmonary rehabilitation intervention in locally advanced lung cancer patients. Four years after activation, the trial was closed due to poor accrual. The pulmonary rehabilitation study required specialized personnel and clinic facilities that were not commonly available in SWOG institutions. These problems alerted researchers to the importance of evaluating required resources for conducting cancer control interventions. In addition, we realized the need for conducting pilot studies of these interventions to demonstrate feasibility within the multi-site setting before launching large-scale trials. An example of a successful pilot study that preceded a phase III trial was the peer-delivered telephone intervention for breast cancer patients. The pilot study was successfully completed with recognized nursing effort and helped refine the Phase III trial that was successfully completed, also with nursing contributions.⁷

Nurses as QOL Coordinators to Ensure Quality Control for PRO Data

Patient ratings of QOL and functional status garnered greater attention in the cancer clinical trials arena during the late 1990s and early 2000s. More validated questionnaires were available and systems were in place to electronically scan questionnaires into the statistical database. However, the problems of missing patient data continued to plague researchers and statisticians, particularly in advanced stage disease trials.⁸ Monitoring the completion of PRO questionnaires by patients and ensuring that these forms were submitted to the Data Operations Center represented new territory for clinical trial staff. Institutional staff required

training on the proper methods for administering questionnaires to avoid biasing the patient's answers. In the early 1990's the first Quality of Life Questionnaire Training Video was produced by Hayden and statistical center staff. The video and specific training on questionnaire completion was included on the Clinical Trial Training Course agenda that was held for new clinical research associates (CRAs) at the semi-annual group meetings. In addition, the video was distributed to all SWOG institutions in 1993. Education on proper questionnaire administration and submission entered the digital age in 2008 when a 20-minute online training module, Southwest Oncology Group Patient Reported Outcome Questionnaires, was launched on the SWOG website; this training program was also narrated by a nurse oncologist. Institutional staff must view the module before administering questionnaires to clinical trial participants.⁹

A group of seasoned SWOG nurses joined forces with SWOG psychologist and QOL expert, Carol Moinpour, PhD, to develop the role of the nurse QOL coordinator. The first Nurse QOL Training Session was offered at the Spring 2003 Group Meeting. Nurse QOL coordinators became part of the study development team and provided valuable assistance to institutions and the Data Operations Center by developing reminder systems and serving as a resource to institutions to help assure timely and accurate submission of QOL data. Nurse QOL coordinators have contributed to measurement of QOL and symptom measurement on multiple trials in SWOG cancer control and disease site committees.

The intensity of nurse-/CRA-generated reminder systems varied substantially across protocols until the task was integrated with the Expectation Report for other SWOG forms. The Expectation Report lists forms, image, and specimen submissions required at baseline, during the study, and during the off-study treatment follow-up period. When SWOG expectations for questionnaire submission became integrated with all forms expectations, the nurse QOL coordinator no longer had to develop and administer labor-intensive reminder systems; Yet sites continued to have multiple questions regarding PRO questionnaires and SWOG Data Operations staff saw the experienced nurse QOL coordinator as integral to quality control efforts for this type of data. Thus, the job description for a nurse QOL coordinator was updated in 2009 to emphasize the nurse's role as a clinical resource and protocol expert. SWOG now assigns nurses as co-study coordinators on symptom management and cancer prevention trials that include PROs. Roles include development of recruitment and retention strategies; conducting training sessions at group meetings for trials with unique clinical assessments or behavioral interventions; and working with sites to improve compliance with questionnaire submission. Nurses and CRAs have played this same role in a number of SWOG treatment trials with QOL outcomes. In this role, the nurse QOL coordinator or CRA also contributed to reporting the scientific results as authors on SWOG manuscripts (listed in Table 1).¹⁰⁻²⁶ Nursing input recognized by authorship on a large SWOG-coordinated prevention trial also occurred.²⁷⁻²⁹

Advancing Nursing Science in SWOG

SWOG nurse researchers and clinical trial nurses have made valuable contributions in the areas of quality of life and symptom management research for the past 30 years. Yet very few nurse-led trials have been conducted since the 1990's when a number of stand-alone QOL trials were developed in SWOG. Numerous attempts and proposals have been put forth to recruit experienced nurse researchers into the group. Barriers encountered by these researchers included lack of institutional support for travel to SWOG meetings, the lengthy and arduous process of protocol development and approval, and the difficulty in obtaining funding for non-therapeutic interventions and for the pilot studies required for these interventions. The types of research that some nurse researchers proposed for SWOG in the past, such as instrument testing and validation and qualitative research were not deemed

suitable for the cooperative group setting. More recently, drug-based symptom management trials have been enthusiastically supported, given the brisk accrual demonstrated from CCOP institutions.²⁶

Over the last decade, professional and government organizations have promulgated expansion of research in cancer survivorship, quality of life, and symptom management. This emphasis is evident in several recent publications, including the Institute of Medicine reports, *From Cancer Patient to Cancer Survivor: Lost in Transition*,³⁰ *A National Cancer Clinical Trials System for the 21st Century*,³¹ and *Implementing a National Cancer Clinical Trials System for the 21st Century*.³² SWOG was ahead of the curve when the leadership restructured Cancer Prevention and Control in 2008 and elevated the subcommittees, including Cancer Survivorship, Outcomes and Comparative Effectiveness, Prevention, and Symptom Control and Quality of Life, to full committee status. SWOG nurse liaisons have provided expertise to these study teams in determining trial feasibility, as well as helping develop recruitment strategies, symptom management interventions, and study implementation.

Nationally, nurse researchers have expanded the body of knowledge in pain management, fatigue, sexuality, fertility, family coping, long term sequelae of treatment, and other areas pertinent to survivorship.³³ Within SWOG there are untapped opportunities for advancing nursing involvement in cooperative group research. Nursing research and cancer care expertise will be particularly useful as the cooperative group CCOP system is integrated into the new NCI Community Oncology Research Program (NCORP).³⁴ NCORP will be emphasizing cancer care delivery research at the community level, but with trials conducted through multi-site institutions. Nursing care has always focused on patients' responses to disease and quality of life; this perspective will help SWOG design studies to evaluate cancer care delivery methods that are feasible in the community oncology setting. The Institute of Medicine report echoes the importance of the multidisciplinary team in addressing the crucial scientific questions of the 21st century. Nursing science provides opportunities for SWOG to enrich its interdisciplinary approach to clinical trials in the areas of cancer care delivery and patient-centered research. The SWOG committee structure, including the multidisciplinary committees, Symptom Control and Quality of Life and Cancer Survivorship, are led by nationally renowned researchers who value the expertise of their nurse members. The clinical trial development process has been streamlined by web-based development tools and specific timelines for internal review of concepts. Thus, the time is ripe to increase the contributions of nurses and nurse researchers to the scientific efforts of SWOG.

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TABLE 1

Published SWOG Clinical Trials with Nurse or Clinical Research Associate Authors *

Disease Site	Protocol	Trial Intervention	Nurse or CRA
Brain metastasis	S9021	Proxy ratings vs patient responses regarding effect of brain radiation on QOL	Schmidt SP ^{13†}
Breast cancer	S8313	QOL in two adjuvant chemotherapy regimens	Hayden KA ²
	S8807	Three interventions to increase breast-self exam compliance	Strickland CJ, Grevstad PK ¹
	S9248	Symptom distress in patients receiving paclitaxel for metastatic disease	Canfield VA ¹¹
	9831	Comparison of QOL in two adjuvant chemotherapy regimens	Grove Conrad ML ¹²
	S9832	Psychosocial distress and depression in women with recurrence receiving peer-delivered telephone counseling	Coleman DA ⁷
	S0316	Evaluating barriers to clinical trial participation	Williams PA ²⁴
	S0715	Comparison of neuropathy symptoms, fatigue, and functional status in patients receiving acetyl L-carnitine vs placebo to prevent taxane-induced peripheral neuropathy	Hansen LK ²⁶
Cancer Prevention & Control	S9217	Minority recruitment strategies in a phase III prostate cancer prevention trial	Parzuchowski J ²⁷
	S9217	Sexual function in men receiving finasteride vs. placebo for prostate cancer prevention	Langley C ²⁸
	S9217	Quality of life in men receiving finasteride vs. placebo for prostate cancer prevention	Johnson CR ²⁹
	S9418	Breast & cervical cancer screening after intervention provided by lay health educators	Hansen LK ⁶
	S9917	Recruitment strategies in a phase III prostate cancer prevention trial	Berry DL ⁴
Colorectal cancer	S9045	Quality of life in seven different chemotherapy schedules for advanced disease	Triplett JS ⁸
Lung	S9509	Comparison of health care costs and quality of life in two chemotherapy regimens for advanced disease	Grevstad PK ^{16,17,18}
Ovarian	S9324	Symptom distress and physical functioning in patients receiving chemotherapy for relapsed disease	Winakur GL ²⁰
Pancreas	S0205	Comparison of pain and emotional well-being in two chemotherapy regimens for advanced disease	Vaught NL ²³
Prostate Cancer	S8994	Comparison of QOL in patients receiving surgery vs. radiation therapy for local disease	Hayden KA ²²
	S9039	Comparison of QOL in two methods of androgen deprivation for advanced disease	Savage MJ ¹⁰
	S9235	Pain and symptoms in men receiving second line hormonal therapy	Coleman DA ¹⁵
	S9346	QOL and sexual functioning in two androgen deprivation treatments for advanced disease	Berry DL ²⁵
	S9916	Comparison of pain ratings and QOL in two chemotherapy regimens for advanced disease	Berry DL ^{19,21}
Multiple		Review of behavioral research in SWOG	Hansen LK ¹⁴

QOL: Quality of life.

* Current and completed yet unpublished trials with Nurse or CRA QOL coordinators are not included in table.

† Reference numbers identify publications with nursing authorship.