The Cancer and Leukemia Group B Oncology Nursing Committee (1983-2006): A History of Passion, Commitment, Challenge, and Accomplishment

Ellen Lavoie Smith,1 Consuelo Skosey,2 Jane Armer,3 Deborah Berg,5 Constance Cirrincione,6 and Mary Henggeler4

Abstract

The Cancer and Leukemia Group B (CALGB) Oncology Nursing Committee (ONC) was initially established in 1983 as a working group with the specific aim of promoting protocol compliance through collaboration, communication, and education to enhance the scientific goals of the Group. Due to the efforts of its members, the committee gained full committee status. ONC members now serve as principal investigators and coinvestigators on research studies, continue to sponsor biannual educational sessions individually and in concert with other CALGB committees, and continue to develop tools to enlighten patients about their disease and the clinical trial process. The ONC, an administrative group of 12 members, provides leadership within CALGB. Although ONC members have always acted as liaisons to the disease and modality committees, three positions have recently been designated specifically for doctorally prepared nurse scientists. Since its inception, general nurse membership within the group has more than doubled to a total of more than 500 members.

The Cancer and Leukemia Group B (CALGB) Oncology Nursing Committee (ONC) has energized, instructed, and inspired oncology research nurses since its formation in 1983. Dr. Emil (Tom) Frei III was the Group Chairman at the time of the ONC’s inception followed by Dr. O. Ross McIntyre in 1990. These physician leaders recognized the value of professional networks for continuing education, development, and peer support and championed the establishment of the ONC. Dr. McIntyre was quoted as saying, "When the CALGB was in its infancy, everyone around the table was either a physician or a statistician. It was clear that many of the physician participants depended upon their personal secretary or their office nurse for doing a lot of the clinical information gathering, as well as other tasks related to CALGB. Bit by bit, these persons started to attend CALGB meetings."

The committee began with a focus to delineate nursing interventions that addressed the needs of the cancer patient on CALGB protocols and to promote educational programs that fostered the professional growth of the CALGB oncology nurse. After a time, scientific aspirations of CALGB nurse members began to emerge. Nurses sought to be viewed as more than clinical data managers and assistants. During this period, the Oncology Nursing Society came into being; its establishment led to further recognition and appreciation of oncology nursing within the CALGB.

Committee Structure

The current ONC committee is comprised of 12 members, including administrative officers, liaisons to the disease and modality committees, statisticians, and representatives from the CALGB Central Office. The administrative core consists of the Chair, the Vice-Chair, nurse researchers, and Educational and Administrative Coordinators. The composition of the administrative core has purposefully evolved over the years to strengthen the credibility and expertise of CALGB nurse members in preparation for nurse participation as principal and coinvestigators of CALGB-sponsored clinical studies. ONC members from main member and at-large institutions, affiliates, and community cancer oncology programs serve as liaisons to the disease and modality committees. They attend group and committee meetings and are involved in protocol design and review and other educational and research-related initiatives.

Current membership is comprised of more than 500 registered nurses involved in patient care and data management at each CALGB main member, at-large institution, affiliate, and community cancer oncology programs. Table 1 lists the leadership since the formal establishment of the ONC.

Specific Aims

The ONC in 1983 was a working group focusing on patient and nurse education. In 1991, the committee began to formally

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promote protocol compliance through collaboration, communication, and education. In 1993, the ONC continued to conduct educational programs and develop educational tools for cancer patients but expanded the committee’s goals to increase nursing activity in protocol initiation and development. The ONC leaders sought independent funding to support clinical research that would augment ongoing CALGB protocols. The ONC was successful in accomplishing these goals. The first scientific protocol to be chaired by a nurse and activated within the group was approved. During the years 1996 to 2000, the ONC continued to grow and evolve along with the field of oncology nursing. The ONC vision was to be an integral resource of CALGB and to make significant contributions to the group’s research agenda through the conduct of educational programs on topics relevant to CALGB trials and through the integration of nursing care elements into CALGB protocols. The current ONC leadership is focused on the goal of advancing nursing science that will affect patient care. Therefore, in addition to maintaining a commitment to the education of nurses, patients, and other health care professionals, the terms “nursing science” and “nursing research” have been incorporated into the committee’s formal mission. A new aim of the current ONC leaders is to advance oncology nursing science through the development of CALGB nursing studies in the areas of education, symptom management, and survivorship. Support for their initiatives has been gained through:

- Collegial and supportive actions of the Group Chairman Dr. Richard Schilsky,
- Articulation of a new research focus to CALGB leadership and CALGB members,
- Identification of barriers to the conduct of CALGB nursing research,
- Education of CALGB leadership and members regarding Advanced Practice Nurse qualifications to conduct scientific research,
- Design of a new paradigm that defines collaborative and mentoring relationships between the ONC and other CALGB and national research committees, and
- Building scientific credibility within the ONC through recruitment of nurse researchers.

### Table 1. ONC leadership from 1983 to the present

<table>
<thead>
<tr>
<th>Year</th>
<th>Chair</th>
<th>Vice-Chair</th>
</tr>
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<tbody>
<tr>
<td>1983-1991</td>
<td>Maryellen Maguire, R.N.</td>
<td>Mary Griffin, R.N.</td>
</tr>
<tr>
<td>1993-1996</td>
<td>Consuelo Skosey, R.N.</td>
<td>Deborah Berg, B.S.N., R.N.</td>
</tr>
<tr>
<td>1996-2000</td>
<td>Deborah Berg, B.S.N., R.N.</td>
<td>Ellen Lavoie Smith, R.N., MSN, AOCN</td>
</tr>
<tr>
<td>2006</td>
<td>Ellen Lavoie Smith, M.S.N., APRN-BC, AOCN</td>
<td>Mary Scott, M.S.N., APRN-BC, AOCN</td>
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### Summary of Progress

**1983 to 1991.** The activities of the committee during this period focused on drug administration, monitoring side effects related to therapy, providing patient and staff education, reporting toxicities, and submission of data. A major contribution to the Group was the development of a companion document to protocol CALGB 8534, which guided the safe administration of warfarin during protocol treatment for small cell lung cancer. Numerous educational sessions were sponsored by the ONC during this time with topics that included Organization of a Cooperative Group Nursing Committee, Nursing Care of the Patient Receiving Radiation Therapy, and Biological Approaches to Cancer Therapy (Immunotherapy). The committee produced a nursing-specific newsletter that was published by the CALGB Central Office, located at that time at the Dana-Farber Cancer Institute. This publication effort was expanded to meet the broader needs of the CALGB network and ultimately became known as the CAL-GaB, the CALGB newsletter. A dedicated column, addressing nursing issues related to clinical research, is a regular feature of the newsletter to this day.

The ONC developed the Data Audit Manual, a patient educational booklet on Biological Response Modifiers, which improved patient compliance in group-wide studies (publication and copyright), and a chemotherapy toxicity documentation tool.

**1993 to 1996.** The leadership of the ONC during this time period authored the first scientific research protocol written by a nurse, Consuelo Skosey. The study was conducted nationally throughout the Group. CALGB 9371 (A Weight Loss Program of Women with Breast Cancer: A CALGB Pilot Project) was approved and activated October 1993. This multicenter pilot trial evaluated the feasibility of conducting a weight loss intervention program in a cooperative group setting, compliance of women with breast cancer enrolled in the weight loss program, and the correlation between the expected beneficial weight loss and circulating levels of hormones and sex-hormone binding globulin. From October 1993 to 1998, 170 overweight women (+10% over ideal body weight) with stage I and II breast cancer consented to be enrolled in the Weight Watchers International weight loss program for 1 year after completion of adjuvant breast cancer therapy. Compliance was monitored at 4, 8, and 12 months of the (Weight Watchers International) program. The study closed in 1998, following the accrual of 150 evaluable subjects. Funding was obtained from Weight Watchers International for the hormone level analysis. An article for this study is currently in progress.

This committee was successful in procuring financial support to subsidize educational programs at group meetings and to support travel for nurses from smaller institutions with limited resources. The ONC developed insightful educational programs for each CALGB meeting of such high caliber that other modality committee chairs asked to participate as cosponsors. First Lady Hillary Rodham Clinton was invited by the ONC to present her health care plan. Although unable to attend the meeting, Mrs. Clinton wrote an inspirational letter that was read to the group. Travel support for nurses to attend meetings and the success of the ONC educational programs generated camaraderie that strengthened the resolve of CALGB nurse members to realize even more collaborative projects.
To spotlight individuals knowledgeable in the chemical composition and administration of protocol drug(s), the ONC initiated a practice with the Pharmacy Committee to list a research nurse and pharmacist on each treatment protocol. The nurse served as a resource for drug administration issues.

The emergence of protocols involving genetic testing provided an opportunity to collaborate with the chair of the Cancer Control and Health Outcomes Committee and the correlative science leaders within the disease committees to define the role of research nurses in genetic counseling. A workshop and training session were developed to educate physicians, nurses, and others involved in the consent process on the effect of genetic discoveries and their attendant social and ethical issues. The ONC sponsored a special session at the 1995 Fall Group Meeting on Genetics for the Health Care Professional. The program was video taped for future reference and was funded by discretionary funds from the ONC.

ONC members developed a booklet describing Pulmonary Exercise Testing and Myelodysplastic Syndrome. These tools were valuable in aiding patients' understanding of the disease process and the purpose of specific laboratory tests.

1996 to 2000. The ONC's focus on education continued via the biannual educational programs and CAL-GaB articles written by ONC members. The educational programs included topics germane to current issues of the time, such as genetic implications in cancer, legislative and liability issues, implications of monoclonal antibody use, multidrug resistance, barriers and proposed solutions to clinical trials from the minority patient perspective, and disease-specific and symptom management updates.

Integrating nursing care and science into disease- and modality-generated studies was a priority of the committee and significant advances occurred. ONC liaisons provided nursing perspective and expertise during new study proposals and through formal protocol review, which resulted in important modifications in eligibility, treatment plan, dose modifications, correlative science specimen collection, and informed consent. ONC members also participated in decisions regarding study-specific data collection, thereby minimizing the collection of unnecessary data.

Collaborations with several other CALGB committees came to pass. In conjunction with the Pharmacy Committee, the ONC developed standardized sections on drug information and nursing implications to be included in protocol documents. Nurses worked with the Data Audit Committee to standardize the auditing process and were instrumental in improving compliance regarding submission of correlative science samples. ONC members served as advisors to study chairs and actively contributed to many group activities. Increasing patient advocate involvement within CALGB presented an opportunity for the ONC to develop an educational program to address advocate-specific needs. Through cross-committee collaborations, the ONC fostered relationships with seasoned CALGB scientists to mentor nurse investigators. The lymphedema assessment project emerged as a result of ONC collaboration with the Breast Committee; this assessment has become an integral question regarding survivorship in follow-up studies.

2000 to present. The ONC continues its strong commitment to clinical cancer research, as evidenced through its promotion of nursing research, and health care education for patients and medical professionals. This administration undertook a project to encourage collaboration with clinical nurse experts and nurse researchers in cooperative groups by pioneering the organization of the first “Cooperative Group Nursing Research Summit” held in Washington, DC on June 13, 2002. This nationwide initiative, led by Ellen Lavoie Smith, M.S., ARNP, AOCN and Susan Bauer-Wu, D.N.Sc., R.N., involved nurse leaders representing the National Cancer Institute, the National Institute of Nursing Research, the Komen Foundation, the American Cancer Society, and the Oncology Nursing Society. In addition, nine cooperative research groups were represented. This first step was essential to build working relationships between clinical nurse experts knowledgeable of cooperative group systems and nurse researchers who desire an affiliation with cooperative groups to conduct nursing research. The following objectives were identified:

- To understand the nursing research structure and culture of other cooperative groups;
- To investigate funding opportunities for cooperative group nursing research;
- To establish a collaborative, national network through which nursing studies can be conducted;
- To increase national awareness of nursing research opportunities within cooperative group settings; and
- To develop strategies to integrate nursing research into cooperative group research agendas.

To understand the significance of this unique gathering, it is important to recognize historical barriers that influenced how nursing research was conducted in the past. Unlike medical research, most nursing research has been conducted at single institutions, using small, minimally diverse patient populations, thus limiting generalizability of results to the broader population. With the ability to conduct research in a more diverse patient population as part of a national cooperative group, nurses can facilitate scientifically credible nursing research that may result in improved patient care. As a result of this initiative, two additional summits have been sponsored by other cooperative groups. Summit participants from the National Institute of Nursing Research, The Children's Oncology Group, the Oncology Nursing Society, and others have recently conducted a large nationwide survey of oncology nurses and nurse scientists. The purpose of the survey is to assess attitudes and beliefs regarding the conduct of cooperative group nursing research. Survey results are pending. This survey is an outcome of the CALGB-sponsored summit, the results of which will guide future efforts to weave nursing research into cooperative group research agendas.

To further advance nursing research within CALGB, three ONC positions have been created for doctorally prepared nurse researchers. These researchers are responsible for building a portfolio of studies and for mentoring other CALGB nurses interested in conducting nursing research. This initiative has resulted in the following studies (Table 2) with ONC members serving as principal or coinvestigators.

Restricted funding by the National Cancer Institute and limited resources necessitated the implementation of a priority system for CALGB study development and activation. Although the above studies have been approved by the Executive Committee, they have not yet been activated. The following
Table 2. CALGB studies with nurse investigators

<table>
<thead>
<tr>
<th>Disease type</th>
<th>Concept/protocol</th>
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<tbody>
<tr>
<td>Prostate cancer</td>
<td>CALGB 170201 (Utilizing Escitalopram or Megestrol Acetate for the Management of Hot Flashes in Men Undergoing Hormonal Manipulation for Treatment of Prostate Cancer), Nurse Principal Investigator</td>
</tr>
<tr>
<td>Neuropathic pain from chemotherapy-induced peripheral neuropathy</td>
<td>CALGB 170601 (A Phase III Trial of Oral Duloxetine for Treatment of Painful Chemotherapy-Induced Peripheral Neuropathy), Nurse Principal Investigator</td>
</tr>
<tr>
<td>Breast cancer-expressive writing</td>
<td>CALGB 170301 (Expressive Writing Intervention for Breast Cancer Patients with Treatment-Induced Menopause: A Pilot Study), Nurse Principal Investigator</td>
</tr>
<tr>
<td>Breast cancer: lymphedema</td>
<td>CALGB 70305 (Lymphedema Prevention following Axillary Node Dissection in Patients with Breast Cancer), Nurse Coinvestigator</td>
</tr>
<tr>
<td>Narcotic-induced constipation</td>
<td>CALGB 70205 (A Phase II Trial of Methylaltrexone for the Treatment of Narcotic-Induced Constipation), Nurse Coinvestigator</td>
</tr>
<tr>
<td>Breast cancer-peripheral neuropathy survivorship study</td>
<td>CALGB 70301 (The Impact of Chemotherapy-Induced Peripheral Neuropathy on the Quality of Life of Breast Cancer), Nurse Coinvestigator (Study Amendment)</td>
</tr>
</tbody>
</table>

OC liaisons continue to provide critical review of data forms and draft protocols; their recommendations continue to guide and support CALGB investigators. ONC members are currently working to develop an oral chemotherapy safety component to be included as a standard section in all protocols using oral agents. ONC members continue to contribute to the formal and informal education of healthcare professionals through educational programs and articles in the CAL-GaB newsletter. Additionally, the ONC provides patient-focused education by developing study-specific educational brochures for CALGB 39804 (Pulmonary Metastatectomy) and CALGB 9781 (Trimodality Therapy versus Surgery Alone for Esophageal Cancer).

**Conclusion**

The challenges that investigators conducting clinical cancer research will also be challenges for oncology nurses. These challenges will require new approaches to nursing research, education, and patient management. The ONC provides nurses with a source of professional identity, useful research education, and a context for evaluating information. The CALGB ONC is proud to have taken the first step towards stimulating national interest in support of nursing research in a cooperative group setting. In the years to come, CALGB nurses will continue to build a framework to support and foster the advancement of nursing science and serve as an example of the outstanding scholarly achievements nurses bring to the field of clinical oncology research.
Clinical Cancer Research

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