COMMENTARY

Behavioral Science Research in the Cooperative Group Setting: the Southwest Oncology Group Experience

Carolyn Cook Gotay, Carol M. Moinpour, Sarah Moody-Thomas, Ellen R. Gritz, Kathy S. Albain, Edward DeAntoni, Lisa Hansen, Patricia A. Ganz

BACKGROUND

Cancer prevention, detection, treatment, and continuing care require individuals to behave in specified ways, whether abstaining from certain behaviors (e.g., sun exposure) or adopting others (e.g., following recommendations for state-of-the-art treatment). Thus, behavior is one of the keys to controlling cancer. Much progress in cancer control has stemmed from behavioral research and interventions. For example, reductions in tobacco use are largely responsible for lower rates of lung cancer (1), and increased use of mammography has led to decreases in breast cancer mortality (2). Moreover, a recent meta-analysis of psychosocial interventions in adult cancer patients (3) concluded that such interventions have a positive effect on emotional, physical, and social outcomes. According to Dr. Richard Klausner (4), Director of the National Cancer Institute (NCI), Bethesda, MD, “behavioral research is fundamental to the mission of [NCI] and the broader social goal of reducing cancer incidence, morbidity, and mortality.”

Clinical cooperative groups represent a rich potential resource to promote and support behavioral research in cancer. Each year, more than 20,000 new patients participate in cooperative group clinical trials, most of which test cancer therapies, that are conducted under the auspices of the NCI’s Division of Cancer Therapy and Diagnosis. In addition, most cooperative groups also sponsor behavioral research studies, although this emphasis is relatively new.

In this commentary, we illustrate the distinct contributions and challenges that behavioral studies pose within the cooperative group setting, drawing on our experiences over the past 10 years as members of the Southwest Oncology Group (SWOG).

BEHAVIORAL RESEARCH IN THE SWOG

Outcome Assessment Research

The first formalized behavioral science research activities in the SWOG focused on developing methods for outcome assessment: specifically, incorporating quality-of-life (QOL) end points within clinical trials of cancer therapy. The SWOG has provided an ideal environment for examining QOL outcomes in the context of cancer treatment for several reasons: QOL data can be collected at the same time and location that treatment is provided, QOL data can be obtained by the same personnel who collect treatment data, and most QOL data have been based on self-administered questionnaires for which administration does not greatly interfere with other clinic activities. QOL assessment within clinical trials also provides information of interest to oncologists. For example, QOL data may serve to characterize how the treatment affects the patient’s daily life, suggest ways in which treatment regimens may be modified to improve the patient’s well-being, and guide development of supportive interventions for patients undergoing treatment and after treatment has been completed (5–9).

SWOG behavioral scientists have made important contributions to this area of research through advocating the importance of QOL outcomes and their incorporation in clinical protocols and developing rigorous methodology for assessing so-called “soft end points,” such as QOL. Following an initial experience in which poor QOL questionnaire-submission rates forced the closure of one QOL companion study (10), specific SWOG policies for QOL studies have been developed (5) and revised. These policies provide guidance to SWOG investigators who are considering whether QOL end points are appropriate in a given trial and, if so, the design of the portions of the protocol that relate to QOL.

Table 1 provides a list of studies in the SWOG over the past 10-year period that include QOL end points (11–16). The results of these protocols have demonstrated how QOL data can enhance understanding of treatment effects. For example, one trial examined the effects of combined androgen-ablation treatment in patients with advanced prostate cancer. Patients were randomly assigned to receive either orchietomy plus an antiandrogen (flutamide) or orchietomy plus a placebo. Whereas the findings for survival and toxicity indicated no differences between the two arms (17), analysis of the QOL data revealed that patients who received combined androgen-ablation treatment had worse emotional functioning than patients who received orchietomy alone (13). This difference in psychological well-being was not totally explained by symptom status, as was originally hypothesized, and its origin deserves exploration in future research on the therapeutic effects and mechanisms of action of antiandrogens. This study, thus, demonstrates the importance of including comprehensive QOL assessment instead of relying solely on symptom measurement. Had the trial used only a measure of symptom status to assess differences in the QOL effects

Affiliations of authors: C. C. Gotay, Cancer Research Center of Hawaii, University of Hawaii, Honolulu; C. M. Moinpour, Southwest Oncology Group Statistical Center, Seattle, WA; S. Moody-Thomas, Louisiana State University Health Sciences Center, Stanley S. Scott Cancer Center, New Orleans; E. R. Gritz, The University of Texas M. D. Anderson Cancer Center, Houston; K. S. Albain, Loyola University of Chicago, Stritch School of Medicine, Maywood, IL; E. DeAntoni, University of Colorado Health Sciences Center, Denver; L. Hansen, Columbia River Community Clinical Oncology Program, Portland, OR; P. A. Ganz, Jonsson Comprehensive Cancer Center, University of California, Los Angeles.

Correspondence to: Carolyn Cook Gotay, Ph.D., Cancer Research Center of Hawaii, University of Hawaii, 1236 Lualualei St., Honolulu, HI 96813 (e-mail: cgotay@crch.hawaii.edu).

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of the two treatments, the strong and provocative effect of antiandrogen treatment on psychological well-being would not have been detected.

### Intervention Research

SWOG behavioral research has extended beyond QOL outcome assessment into research on behavioral interventions in primary prevention (i.e., reducing cancer incidence), secondary prevention (i.e., detecting cancer earlier), and tertiary prevention (i.e., addressing the impacts of cancer management). Current and past behavioral intervention protocols are listed in Table 2 and will be briefly described below.

### Primary Prevention

**Lung cancer.** Cancer patients who continue to smoke during and after treatment, as many do, are at increased risk for negative outcomes, including developing additional primary cancers (18). More effective approaches to long-term smoking cessation in cancer patients are required, particularly for patients with lung cancer and other smoking-related cancers. Activation is pending for an SWOG protocol for patients with newly diagnosed stage I or II non-small-cell lung cancer. This trial builds on previous research that has established the effectiveness of a number of approaches, used alone and in combination, for smoking cessation, including self-help materials, physician or nurse advice, nicotine replacement (patch or gum) (19), and the antidepressant drug bupropion (20). In particular, attempts to change smoking behavior have been shown to be more successful if both the biologic and the behavioral aspects of tobacco addiction are addressed.

The two-arm SWOG study will, therefore, compare the effectiveness of a combined pharmacotherapy (active bupropion and nicotine patch) plus a behavioral intervention with that of

### Table 2. Behavioral studies conducted or pending in the Southwest Oncology Group (SWOG)*

<table>
<thead>
<tr>
<th>Study (reference No.)</th>
<th>Phase</th>
<th>Disease and site</th>
<th>Date</th>
<th>Accrual</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>SWOG-8807</td>
<td>III</td>
<td>Stage C prostate cancer</td>
<td>May 1989</td>
<td>December 1993</td>
<td>2235†</td>
<td>3200</td>
</tr>
<tr>
<td>SWOG-9418</td>
<td>Pilot</td>
<td>Breast, cervix</td>
<td>May 1994</td>
<td>January 1996</td>
<td>Promotoras 5</td>
<td>6</td>
</tr>
<tr>
<td>SWOG-9632</td>
<td>Pilot</td>
<td>Breast</td>
<td>June 1997</td>
<td>August 1998</td>
<td>Women contacted 123</td>
<td>141</td>
</tr>
<tr>
<td>SWOG-9832</td>
<td>III</td>
<td>Breast</td>
<td>July 1998</td>
<td>Still open</td>
<td>137</td>
<td>300</td>
</tr>
<tr>
<td>SWOG-0002</td>
<td>III</td>
<td>Lung</td>
<td>Not yet open</td>
<td></td>
<td>442</td>
<td></td>
</tr>
</tbody>
</table>

†Comparison study to therapeutic protocol.
‡Promotoras are lay health workers in the Hispanic community.
“placebo bupropion,” nicotine patch, and the behavioral intervention. The behavioral intervention includes physician and oncology nurse messages, tailored self-help materials, and reminder telephone calls conducted by an oncology nurse or clinical research associate. The cessation advice and materials incorporate two established aspects of effective health-promotion messages: 1) They are delivered by trusted, respected individuals; and 2) they build individual confidence to make behavior changes. Outcomes are assessed at randomization, at the end of 11 weeks of pharmacologic treatment, and 6 and 12 months later, and they include self-report of smoking status measured behaviorally and validated via cotinine levels in saliva, as well as QOL (including mood and symptoms). Survival, recurrence, and the incidence of second primary cancers will be tracked as exploratory outcomes.

Prostate cancer prevention. The Prostate Cancer Prevention Trial (PCPT) is a randomized, double-blind, placebo-controlled study of the efficacy of finasteride in preventing prostate cancer, ascertained through a prostate biopsy at the end of the study (21,22). The trial enrolled nearly 25 000 men for a 3-month run-in period, during which all participants were given placebo to test adherence to the study drug. At the end of the run-in period, men who met basic trial requirements and had pill-taking adherence rates between 80% and 120% (n = 18 882) were randomly assigned to take a daily pill for 7 years. Currently, participants have four contacts with the PCPT staff each year: two visits to the clinic and two telephone calls. QOL (including symptoms) is assessed at study entry, at 6 months, and then yearly for 7 years. An additional measure of symptoms only is collected at randomization.

Behavioral science expertise has been crucial in developing strategies to enhance trial recruitment and adherence in this trial. For example, a single-institution pilot study tested the feasibility of an intensive intervention to enhance compliance with the prostate biopsy. The intervention included one-on-one and small-group sessions and printed materials about the biopsy procedure, in conjunction with a video that provided information about what to expect during a prostate biopsy. Measures of intention to have a prostate biopsy were obtained before and after exposure to the intervention; results are still being analyzed.

The pilot study also included a questionnaire to identify factors associated with intention. The content of the questionnaire was derived directly from previous behavioral research on factors that affect individuals’ likelihood of adhering to medical regimens (23). It included items to measure knowledge, social support, self-efficacy (e.g., the degree to which the individual believed that he would be able to handle the trial requirements), and the perceived benefit of the biopsy (e.g., in terms of answering the study question and providing definitive diagnostic information for the participant). The questionnaire findings will indicate whether these individual participant characteristics are associated with differential success of the pilot study intervention. This knowledge will guide the development of approaches for the full trial that are targeted to specific groups and/or tailored to individual characteristics to enhance adherence with the end-of-study prostate biopsy requirement.

Screening/Secondary Prevention

Breast self-examination. During the period from 1989 through 1993, the SWOG enrolled 2233 women (the majority from Community Clinical Oncology Programs [CCOPs]) in a trial that compared the impact of three interventions on the performance of breast self-examination (BSE). The interventions were based on several behavior-change models, including adoption theory (24) (e.g., raising awareness of the need to change behavior through a physician message), self-efficacy (i.e., confidence that one can successfully perform the target behavior, BSE), and behavioral reinforcement (e.g., personalized reminders to continue performing BSE).

Women were randomly assigned to one of three approaches to encourage BSE: 1) physician message about the value of BSE; 2) physician message plus participation in a class teaching BSE technique; or 3) physician message, participation in a BSE class, and reinforcement by regular reminders (telephone calls and postcards) to do BSE regularly. BSE compliance (i.e., self-report of performing BSE five or more times in a 6-month period) and accuracy (as determined by nurse ratings of five aspects of BSE performance [at intake and 6 months] or by responses to eight telephone interview questions [at 12 months]) were assessed at randomization and 6 months and 1 year later. The findings (25) indicated that compliance was statistically significantly higher (78%) for women in the most intensive intervention arm at 1 year as compared with women in the message-only and message-plus-training class arms (59% and 62%, respectively). In all three arms, compliance improved significantly from the time of randomization at both follow-up points. Moreover, comparison of the two less intensive arms showed that adding the training class to the physician message alone improved accuracy at both follow-up points.

Cancer screening in Hispanic women. In 1994, the SWOG implemented a pilot study to evaluate the feasibility of recruiting and training lay educators (“promotoras”) to increase cervical and breast cancer screenings among Hispanic women (Hansen L: unpublished data). Previous behavioral theory and research (26,27) had suggested that the involvement of Hispanic women who were already recognized as trusted and credible sources of information could increase the use of screening mammography and Pap smears in their communities. The pilot project was conducted through a minority-based community clinical oncology program (MBCCOP) in San Antonio, TX. Five Hispanic women, four of whom were breast cancer survivors, participated in a 12-week training course led by two bilingual health educators. The curriculum included information about risk factors, screening tests, and breast and cervical cancer treatment, as well as an overview of educational principles, community screening resources, and specific strategies to encourage screening in the community. The course incorporated didactic presentations, videotapes, and visits to community facilities. The promotoras then documented their efforts to encourage screening in female relatives and friends, and procedures to monitor subsequent screening behaviors were thus established. This project demonstrated the feasibility of recruiting and training lay health educators to deliver health education to special populations within the SWOG structure.

Tertiary Prevention

Enhancing well-being in women experiencing breast cancer recurrence. An ongoing SWOG study tests the hypothesis that participating in an intervention designed for breast cancer patients experiencing a first recurrence will enhance well-being (28). Three hundred breast cancer patients from SWOG institu-
tions are being entered in the study within 8 weeks after disease recurrence. The women are randomly assigned to either an intervention or a control group. In the intervention, which is carried out by Y-ME, a national breast cancer support and advocacy organization, breast cancer survivors—most of whom have themselves experienced a recurrence of their disease—provide information and peer support via telephone. Four to eight telephone calls are conducted over a 1-month period. Well-being end points are assessed at entry in the study and 3 and 6 months later through validated questionnaires measuring QOL and depression. A pilot phase of this protocol has been completed, with 30 patients enrolled from eight institutions. Eighty-six percent of the patients in the pilot phase found the intervention helpful, while 14% did not. Qualitative responses indicated the convenience of telephone support, and having an opportunity to talk to someone who had been through the same experience contributed to its success (28). This study is one of the few research projects anywhere to focus on improving well-being during cancer recurrence, and to our knowledge, it is among the first research partnerships between a cooperative group and a lay survivor organization.

CONDUCTING BEHAVIORAL RESEARCH IN A COOPERATIVE GROUP: BENEFITS AND CHALLENGES

There are both benefits and challenges associated with conducting behavioral research in a cooperative group such as the SWOG.

Benefits

Access to a Large and Varied Cancer Patient Population

SWOG’s nationwide accrual, further broadened through the mechanism of intergroup trials, makes available a group of patients and other potential participants for behavioral studies that far exceeds the numbers and diversity in any single institution. A total of 216 SWOG institutions contributed 4391 patients to therapeutic and nontherapeutic trials in 1998 (not counting the PCPT). Participating organizations included 23 CCOPs, 128 Community Group Oncology Programs, and 22 Urologic Clinical Oncology Programs. The CCOP participants included three MBCCOPs (organizations based in communities with large minority populations). SWOG-affiliated MBCCOPs provide access to African-Americans, Hispanics, Native Americans, and Asians and Pacific Islanders.

Thus, the patient population in SWOG trials includes registrations from community-based oncologists from many communities, not just patients seen at tertiary referral centers. The large numbers of SWOG participants enhance the likelihood of timely study completion, a particularly important consideration in rare diseases. Studies can be tailored to specific populations (e.g., specific disease sites, therapies, or demographics). Given the variety of organizations that belong to the group, there is also the potential to study institutional and organizational variations. Of course, the opportunities afforded by these patient and institutional resources are not limited to behavioral research.

Access to a Large and Varied Patient and Physician Base

Through cancer-control projects such as the PCPT, the SWOG has demonstrated that a cooperative group can go beyond its traditional patient and physician base. This is particularly important for prevention research, where behavioral change (and, thus, behavioral research) may be the focus of attention. The two largest cooperative group prevention trials to date, the PCPT and the Breast Cancer Prevention Trial (BCPT) conducted by the National Surgical Adjuvant Breast and Bowel Project (29,30), required enrollment of large numbers of healthy individuals at increased risk of cancer of the prostate (PCPT) or breast (BCPT). In both trials, initial concerns that the oncologists who enroll and treat most of the patients for cooperative group trials would have difficulty recruiting study subjects from a healthy population proved to be unfounded. In fact, the PCPT stimulated creative partnerships between SWOG institutions and organizations such as the Department of Veterans Affairs clinics and urology practices, enabling the achievement of the target sample size. The success of this effort provides evidence that behavioral research studies that require populations other than cancer patients are possible within an oncology cooperative group.

Emphasis on Quality Control

The SWOG has established a system for data analysis and collection that includes careful attention to quality control. Behavioral research conducted within the SWOG can build on expertise in study design and implementation, including development of forms, tracking and reminder systems, and training modules.

Organizational Infrastructure

Cooperative groups provide an opportunity for behavioral scientists to develop protocols with multidisciplinary input from oncologists (from disciplines of medical oncology, radiation oncology, gynecologic oncology, surgical oncology, and pathology), nurses, basic scientists, epidemiologists, statisticians, and patient advocates. Most behavioral research in the SWOG has been generated by three committees: 1) the Behavioral and Health Outcomes Subcommittee of the Cancer Control Research Committee, 2) the Committee on Women and Special Populations, and 3) the Nurse Oncologist Committee. These committees, in conjunction with the 13 committees that focus on specific cancer sites, allow cross-fertilization of ideas in a “think-tank” environment that provides immediate interdisciplinary feedback and efficient development of ideas. Thus, the cooperative group offers considerable potential for developing translational research to integrate behavioral and biologic parameters.

In addition, the SWOG holds national meetings twice a year that are attended by a substantial proportion of the membership. These meetings provide a forum to publicize studies, to answer questions, to obtain feedback from investigators across the country about how a protocol is proceeding, and to conduct specialized training sessions. The structure of the SWOG, like that of many other cooperative groups, also includes certified data managers and clinical research associates in all member organizations. These individuals have considerable experience in recruitment and accrual, data collection and entry, and medical records abstraction, providing a cadre of research staff who is available for behavioral as well as clinical research.
Challenges

Quality-Control Mechanisms Geared Toward Clinical Outcomes

In many clinical sites, the quality-control mechanisms that are used routinely in the day-to-day conduct of treatment trials are not always appropriate or sufficient for a behavioral intervention or measure. For example, although QOL questionnaires are becoming more routine as a data-collection mechanism, the newness of this approach requires additional attention to ensuring that questionnaire data are collected in a timely fashion. In addition, statisticians with expertise in analytic techniques specific to behavioral research are rarely found in the cooperative-group setting. To address these challenges, behavioral scientists in the SWOG have undertaken a number of training activities, including educating the Statistical Center staff who monitor data quality about how to answer questions from investigators, nurses, and clinical research associates at SWOG institutions and determine when data forms need improvement.

Institutional staff also need ongoing training about outcome assessment in general and in the specific context of research issues that may not surface in therapeutic research. For example, unlike chart data documenting treatment information, QOL data need to be collected according to schedule because they cannot be retrieved at a later date. Ensuring that QOL data are collected as specified required new strategies for tracking data, monitoring institutions, and reminding data managers in advance when QOL data-collection points were approaching. The SWOG has ensured that quality-control procedures are specified precisely in the protocol and institutionalized at the statistical center. These procedures are necessary to communicate that data forms for behavioral science research are regarded as being just as important as those for treatment clinical trials.

In the SWOG, we are fortunate to have access to statisticians who are interested in learning more about the statistical issues presented by QOL and other behavioral research. For example, even state-of-the-art quality-control procedures cannot prevent the missing data problems that are associated with advanced-stage disease. Methodologic research is needed to develop appropriate analytic techniques for datasets with severe missing data problems (31,32). Such research issues are of great theoretical interest to statisticians.

Behavioral Science Not the Major Focus Within Cooperative Groups

Behavioral and social scientists are a distinct minority in oncology cooperative groups. There have been occasions within the SWOG institutions when behavioral scientists have enthusiastically supported behavioral interventions, but these interventions either failed to proceed to full protocol development or were opened as protocols but failed to accrue their target sample size. Such failures can occur when clinicians in the disease committees do not endorse the interventions proposed by the behavioral scientists. The clinicians may feel that the ideas demand heavy resources, involve skills not present among institutional staff, are not feasible in the context of treatment delivery, or do not pose what seem to be interesting or useful questions.

Such experiences reveal the need for behavioral scientists to work closely with physicians to understand current and innovative therapies in a given disease, as well as the constraints posed by particular treatments on potential behavioral interventions. The importance of interdisciplinary or transdisciplinary (33) collaboration at an early stage of the study design cannot be overemphasized. In addition, behavioral scientists have expended substantial effort at educating the SWOG membership about the distinct contributions of their field and their potential applications in cancer clinical trial research. There are ample opportunities at the semiannual SWOG meetings to present workshops and to participate in educational sessions.

Competing Priorities of Institutional Staff

The settings in which SWOG members typically work pose limitations on the kinds of behavioral research that can be carried out. SWOG clinics are busy, and their staff primarily treat patients and only secondarily conduct research. In addition, although research staff are experienced at conducting treatment clinical trials, they may have little or no experience in conducting behavioral research and may lack the specialized personnel to conduct behavioral interventions. In addition, behavioral research requires stringent quality-control procedures (12,30,34,35) that come at a high cost, particularly in terms of staff time (35). In the context of competing priorities, institutions may decide not to activate or promote behavioral studies.

Behavioral scientists in the SWOG have begun to understand how to integrate behavioral research in SWOG institutions and address competing priorities by recognizing that getting any study, particularly a behavioral study, up and running in a cooperative group takes much longer than implementing a study in a single institution. For example, addressing the different concerns of Institutional Review Boards (IRBs) around the country, as study coordinators are called on to do, requires considerable time and patience. However, now that some initial behavioral studies have made it through the IRB process, the approval process for future trials should be less cumbersome. In addition, extra resources (e.g., outside funding) may be required for training, recruitment of additional personnel, or centralized conduct of an intervention or data collection. For example, external funding was obtained for the behavioral intervention trial for women with breast cancer recurrence to support the telephone activities of the peer counselors at a central location, because individuals with these skills were unlikely to be available at individual institutions. For behavioral research to be sustained in cooperative groups, therefore, additional targeted funding—through federal grants, pharmaceutical company support, or other means—for infrastructure development and maintenance is necessary, as is support for methodologic research and pilot studies. Based on the authors’ experiences in the SWOG over the past decade, the methodologic strengths of conducting behavioral research in the cooperative group setting and the unique contributions such studies can make are likely to be viewed positively in the review process.

Conclusions

Over the past decade, the SWOG has supported, initiated, and completed pioneering efforts in behavioral research related to QOL assessment and the full scope of cancer prevention and control. The first behavioral intervention—a telephone counseling program for recurrent breast cancer patients—is currently ongoing, while an intervention to increase BSE directed at

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healthy women was successfully completed. Behavioral scientists and clinicians as well have learned valuable lessons about how to work in a cooperative group over this period that provide a foundation for future behavioral research in the context of cancer. The multidisciplinary behavioral projects in progress at the SWOG have received peer-reviewed national funding, reflecting the high level of scientific rigor that can be maintained in the group setting. However, the availability of funding is an ever-present constraint on the development of behavioral research.

The recommendations of an NCI Working Group on Behavioral Research in Cancer Prevention and Control were published recently (1, 36, 37), and a new strategy for cancer control research from NCI’s Division of Cancer Control and Population Sciences (DCCPS) has been outlined (38). These recommendations all explicitly identify social and behavioral sciences as the basic science for cancer control research. DCCPS has recently initiated a number of targeted research opportunities in cancer control research that could be appropriately based in cooperative groups (e.g., PA-CA-99-163, “Exploratory Grants for Behavioral Research in Cancer Control”; RFA-CA-99-014, “Basic Biobehavioral Research on Cancer-related Behaviors”). Moreover, a January 2000 workshop cosponsored by DCCPS and the NCI Division of Cancer Prevention focused on expanding the participation of behavioral scientists within the CCOP.

All of these recent developments, as well as the changing health care system, offer exciting opportunities for cancer prevention and control research (37, 38). Partnerships among behavioral scientists, cooperative groups, and the NCI have the potential to provide benefits to all and, ultimately, to reduce the burden of cancer for both the individual and the larger community (39).

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NOTES

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