Oncology Issues

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ISSN: 1046-3356 (Print) 2573-1777 (Online) Journal homepage: https://www.tandfonline.com/loi/uacc20

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To cite this article: Charles A. Coltman Jr. (1994) The Southwest Oncology Group, Oncology Issues, 9:4, 16-17, DOI: 10.1080/10463356.1994.11904481

To link to this article: https://doi.org/10.1080/10463356.1994.11904481

Published online: 18 Oct 2017.

The Southwest Oncology Group

by Charles A. Coltman, Jr., M.D.

The Southwest Oncology Group (SWOG) is one of several national groups that are supported by the National Cancer Institute (NCI) to conduct cancer clinical trials. It has evolved since 1956 into an adult multidisease, multimodality clinical research organization with a national network of 4,000 investigators. The name Southwest Oncology Group is misleading because the group's network of investigators extends from the East to the West Coast and from the Canadian border to the Gulf of Mexico. During 1993, 6,500 new patients were registered at more than 627 affiliated institutions in 44 states and the District of Columbia. Close interaction among all components of the group assures optimal performance by group members and rapid completion of scientifically sound and innovative cancer clinical trials.

Until 1976 membership in the Southwest Oncology Group and other major cooperative groups was restricted to physicians based at large universities or teaching institutions. This membership restriction severely limited the number of patients available for clinical trial research and deprived wide segments of patients from potentially beneficial or curative treatment. The restriction also guaranteed that the majority of community physicians remained unaware of the most current new cancer treatment methods available to their patients.

THE BIRTH OF CGOP

In response to a mandate by the NCI to modify this situation, the Southwest Oncology Group initiated the Cooperative Group Outreach Program (CGOP) in 1976. In committing its resources to establishing this broad outreach program, the Southwest Group identified a number of specific goals as being important to the success of the outreach program. These were to:

- enhance the recruitment of patients into cancer clinical trials from the group's affiliated hospital program
- initiate and supervise participation in cancer clinical trials in a wider segment of the community
- support community physicians and institute quality control in management of cancer patients in the community
- provide educational programs to expand and enhance the skills of the community physician
- involve the community physician in Southwest Oncology Group activities, emphasizing the importance of this link in overall cancer management.

Affiliates in the CGOP program are not directly funded through grant awards by the NCI; instead, the program includes direct supervision by major Southwest Oncology Group member institutions located within a close geographic area, ensuring close communication between the experienced participants and the new CGOP affiliates. The SWOG operations office provides the member institutions with nominal budgets to support the registration and quality control efforts for the individual affiliates. The CGOP affiliates are paid quarterly by the operations office on a per-case basis; this money is used to assist CGOP physicians with data management expenses and with travel to group meetings. The performance of CGOP affiliates, with regard to the quality and quantity of treated patients, directly affects the overall performance evaluation of the member institutions. The institutions have major incentives for a high level of involvement and commitment to the success of the CGOP program.

THE GROWTH OF CGOP

Since its inception, the CGOP program has experienced continued steady growth, both in membership and in participation in all group activities. The CGOP program has successfully enhanced the accrual of the Southwest Oncology Group, contributing a total of 5,764 patients from the years 1987 through 1992. Membership has grown from 467 investigators at 203 CGOP institutions in 1986 to 1,347 investigators at 309 institutions in 1993. All SWOG member institutions, with the exception of two, have active CGOP programs.

While SWOG leadership strives to increase accrual through the CGOP program, it also recognizes that the program's success hinges on the participation of community physicians in SWOG's scientific and educational programs. The integration of community physicians into Southwest Oncology Group research is apparent from physician membership in virtually all of the group's scientific committees. This involvement includes participation in the development and coordination of research trials and authorship of publications. Members of the CGOP program are encouraged to attend the semiannual group meetings where they have direct access to continuing education forums and detailed reviews of past, present, and future clinical trials.

Essential to the success of the CGOP program is the quality of data obtained from outreach physicians. Obviously, poor-quality data will result in ineligible and nonevaluable research subjects and negate the potential accrual contributions to be made by CGOP participants. Not only are the CGOP affiliates regularly audited under the group's quality assurance program, they are also strongly supported by the Southwest Oncology Group's extensive comprehensive educational programs, which concentrate on the importance of accurate data collection practices and protocol treatment that conform to the group standards for accuracy, completeness, and timeliness. These efforts are validated by group statistics from 1992–93 showing that CGOP affiliates of the Southwest Oncology Group accrued 936 patients, with overall patient eligibility of 90 percent and evaluability of 96 percent. The integration of community/private practice physicians has proven invaluable and, certainly, indicates the need for continued increased participation by this subset of clinicians. Furthermore, these data support the hypothesis that SWOG physicians and data management teams are without peer in the clinical trials arena.

THE PHYSICIAN'S ROLE

SWOG believes that continued participation by community physicians is also integral to the rapid completion of key trials and that it is important to develop new, successful cancer treatment methods that

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can be readily transferred to the community setting. Because of the complex nature of these trials, it is important that community physicians be capable of providing identical treatment programs that duplicate previous successes. Obviously, cancer treatments that cannot be administered by community physicians greatly reduce the number of future patients that can be cured and compromise cooperative groups' efforts to increase cancer survival.

The Southwest Oncology Group CGOP participants are fully involved in all new group scientific initiatives. Outreach investigators have been included in group trials using investigational new agents and in basic science studies requiring contributions of specimens. These ancillary biologic trials include several leukemia biology studies (French-American-British Classification System for Leukemia, cytogenetics, flow cytometry, and proto-oncogene expression); flow cytometry in genitourinary cancer, breast cancer, head and neck cancer, sarcoma, and lymphoma; and pharmacokinetics studies in gynecological cancer, as well as lymphoma and myeloma immunophenotyping. Cancer control studies (i.e., quality of life studies in brain, breast, and genitourinary cancer patients, smoking cessation in bladder cancer patients, and evaluation of reproductive function in testicular cancer patients) are also open to CGOP investigators. Contributions are provided by the CGOP affiliates to rapidly address and answer these complex and important research questions.

The CGOP membership has assumed an active role in the group's largest cancer prevention study, the Prostate Cancer Prevention Trial, launched nationwide in October 1993. This study is the first large-scale prevention trial for prostate cancer and will enroll 18,000 men age 55 and older in a seven-year double-blind study to test whether taking the drug finasteride will prevent prostate cancer. The Southwest Oncology Group is coordinating this intergroup study, which includes participation by the Eastern Cooperative Oncology Group, the Cancer and Acute Leukemia Group B, Community Clinical Oncology Program affiliates, and NCI-supported cancer centers. Twenty-three of the participating 227 sites are CGOP affiliates; as of March 16, 1994, they have been responsible for enrollment of 991 of the 10,296 men accrued to the study.

Although significant strides have already been made toward the integration of community practitioners in cooperative group research, there still lies potential for even greater participation in successful cancer research. The future success of outreach programs is contingent on the commitment of the National Cancer Institute, each cooperative group, and the community physicians themselves. Problems in the community setting must be identified and the solutions implemented if we are to guarantee major reductions in the national cancer mortality rate.

The National Surgical Adjuvant Breast and Bowel Project

by Bernard Fisher, M.D., Arthur P. DeCillis, M.D., D.L. Wickerham, M.D., and Walter M. Cronin, M.P.H.

The National Surgical Adjuvant Breast and Bowel Project (NSABP) is a multidisciplinary cooperative group that conducts clinical trials in breast and colorectal cancer. Since its inception in 1958, the NSABP, under the leadership of Dr. Bernard Fisher, has played an important role in improving the treatment and management of these cancers.

In an earlier article in *Oncology Issues* (Vol. 4, 1989) Dr. Fisher and Mr. Cronin stated the belief that clinical trials can flourish only if community-based physicians are involved and invested in this research. In the early 1970s, the NSABP took the initiative to increase the participation of community-based oncologists in clinical studies. This effort provided the model for the National Cancer Institute's establishment of the Cooperative Group Outreach Program (CGOP) and the Community Clinical Oncology Program (CCOP). The results of these efforts are apparent. Since 1988, community-based institutions have entered more patients on NSABP studies than university or NCI-designated cancer centers (Table 1). Today, the majority of NSABP institutions are not affiliated with university-based medical centers. Community-based physicians participating in our studies are primary contributors to the improvement of breast and colorectal cancer treatment. This is very appropriate since clinical oncologists are also primary consumers of the results of clinical studies and, according to clinical research findings, make scientifically justified therapeutic decisions. Hence, we are committed to expanding the involvement of community-based investigators and including their diverse patient populations in NSABP clinical trials.

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CHANGING THE PARADIGMS

The NSABP has always been committed to conducting clinical research that changes the paradigms of cancer management. Under Dr. Fisher's direction, the NSABP's past trials in breast cancer have resulted in the change of standard surgical treatment from mastectomy to lumpectomy, the shifting of chemotherapy to the adjuvant setting, and the widespread use of tamoxifen in postmenopausal women, particularly those with high estrogen-receptor values.

Recently, the NSABP demonstrated the importance of radiation therapy to lumpectomy in patients with noninvasive ductal carcinoma. We have implemented and completed breast cancer trials evaluating the impact of preoperative chemotherapy, as well as the value of administering intensified and increasing amounts of chemotherapy with colony-stimulating factor support. Our studies have tested the impact of 5-FU modulation on colon cancer outcome.

The NSABP has continued to expand the scope of the hypotheses to be tested in breast and colorectal cancer studies. In 1992 we began the Breast Cancer Prevention Trial to test whether long-term tamoxifen therapy is effective in preventing the occurrence of and mortality due to invasive breast cancer. With the goal