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THE SWOG EXPERIENCE WITH CCOPs

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I would like to present some information on the Southwest Oncology Group's approach to the NCI initiative concerning Community Clinical Oncology Programs. I will show that the CCOP physicians deliver high quality cancer care, that they have contributed to the scientific thrust of the Southwest Oncology Group, that the research data is of unequaled quality, and that the CCOPs are a completely integral part of the Southwest Oncology Group.

There are 23 member institutions in the Southwest Oncology Group. These are generally university medical centers. The Operations Office is in San Antonio and the Statistical Center is in Seattle. In addition, there are 18 CCOP institutions and 174 CGOP institutions. The Southwest Oncology Group involves 1,155 investigators at 216 institutions in 31 states, who accrue in excess of 4,000 new cancer patients to clinical trials yearly. One can clearly see that the Group is actually the non-Southwest Oncology Group.

Our initial approach was to develop a CCOP committee which included all 18 CCOP principal investigators. They identified two members who sat on the Southwest Oncology Group Board of Governors as full voting members.

We next established criteria for CCOP membership in the Southwest Oncology Group. They included the accrual of 50 patients to Southwest Oncology Group clinical trials. Secondly, that the Southwest Oncology Group quality control criteria were met, following a review of a minimum of 30 patient records. Thirdly, that they undergo a satisfactory quality assurance unit.

The quality control system was established because we were concerned about the quality of the data contributed to the Southwest Oncology Group data base by physicians who were relatively new to the clinical trials arena. The CCOPs provided eligibility checklists, prestudy forms and flow sheets for each cycle of treatment to the Southwest Oncology Group Operations Office. This was our choice because the Group Statistical Center was in transition from Houston to Seattle. Forms

Dr. Charles Coltman, Chairman of the Southwest Oncology Group, describes the performance of the CCOPs versus other group members.

were initially reviewed for correctness of the forms, completeness of forms, patient eligibility, the completeness of forms for each cycle of treatment, the correct dosage for each cycle, compliance with time limits, and completed off study forms. A computer generated letter identified the deficiencies with a deadline for resubmission of amended forms. This initial and second review is then used as a data base to determine the quality of the submitted data. A total of 1,689 patients with 7,031 cycles of treatment have been through the system.

Figure 1 shows the Southwest Oncology Group quality control items, the criteria, and the CCOP average. The criteria for correct forms is 100% correct and the criteria for compliance with time lines is 80% and all the other criteria are 90%.

FIGURE 1

Southwest Oncology Group CCOP Quality Control Criteria

	Criteria	CCOP Average
Correct Forms	100%	99.7%
Completed Prestudy Forms	90%	92.6%
Patient Eligibility	90%	98.0%
Complete Forms for Each Cycle	90%	87.9%
Correct Dosage for Each Cycle	90%	90.2%
Compliance with Time Lines	80%	82.8%
Complete Off Study Forms	90%	92.9%

In the column to the right is the CCOP average, with all averages exceeding the criteria save for complete forms with each cycle, shown on the fourth line, which is 2.1% below the 90% criterion. Ninty-eight percent of CCOP patients are eligible for study.

Figure 2 shows the prestudy form completeness at the time of initial and second review for three six month periods of time. It can be seen that the initial review is everywhere below the criterion line of 90%, and that at the time of second review, the completeness is everywhere above the criteria line indicating that with prompt review and early inquiry, we can retrieve large amounts of data.

Figure 3 in a similar fashion, shows the impact of second review on dose correctness.

Figure 4 shows the Southwest Oncology Group patient accrual by year and by institution type for the past 8 years. CCOP accrual began in 1983, 1,246 patients were accrued in 1985. It

can be seen that since 1983, the CCOPs have made an increasing contribution to case accrual. In 1985, 402 physicians in 18 CCOPs contributed 1,246 patients, an average of 69 patients per CCOP.

In addition to patient accrual, the CCOPs have made substantial administrative and scientific contributions to the Southwest Oncology Group (Figure 5). Six CCOP physicians are chair or vice chair of committees and 104 physicians participate in the various committees of the Southwest Oncology Group. One CCOP physician has coordinated a group study and 9 co-coordinate studies. One CCOP physician has been the senior author on a published manuscript and 16 have been contributing authors. Four CCOP physicians have been senior authors on published abstracts and 10 contributing authors.

The constitution and bylaws of the Southwest Oncology Group, Article III, Section I, Part A, indicates that member institutions are hospitals, medical centers, community clinical oncology programs, or research institutes. To date 15 of 18 CCOPs have achieved the membership criteria and currently are full members of the Southwest Oncology Group with each principal investigator occupying a seat on the Board of Governors.

Section II of the same article of the bylaws indicates what this membership involves. Members are scientists who participate in the scientific and/or administrative conduct of group studies at any member institutions. All members, including the physicians at 15 of our 18 CCOPs, have the privileges of participating in protocol design and coordination, registration and treatment of patients on group protocols, receipt of drugs allocated to the group to conduct protocols, and election or appointment to any position and/or committee in the group.

In conclusion, the CCOP physicians deliver high quality cancer care through clinical therapeutic research to patients in the community. Secondly, CCOP physicians have contributed to the scientific thrust to the Southwest Oncology Group. Thirdly, the quality of the Southwest Oncology Group CCOP research effort is unequaled in the clinical trials arena. The CCOPs are a completely integral part of the Southwest Oncology Group with all the rights and privileges pertaining thereto.

FIGURE 2
Impact of Second Review on Prestudy Completeness
CCOPs

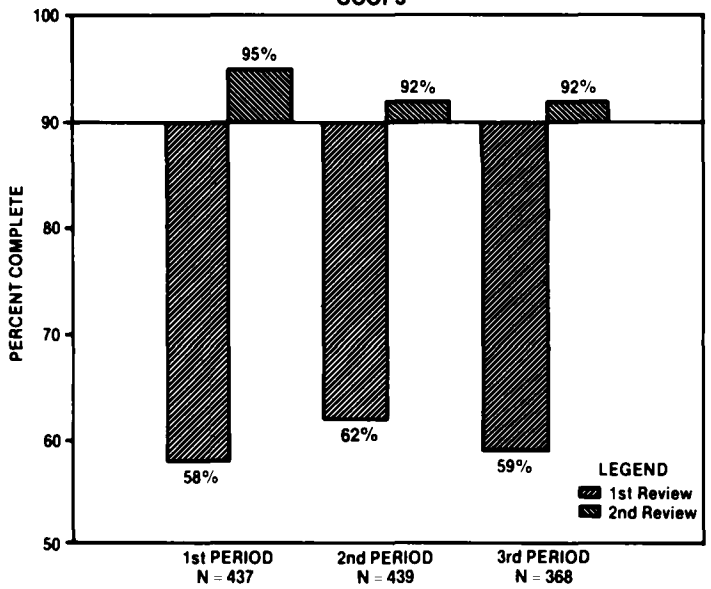

FIGURE 3
Impact of Second Review on Dose Correctness
CCOPs

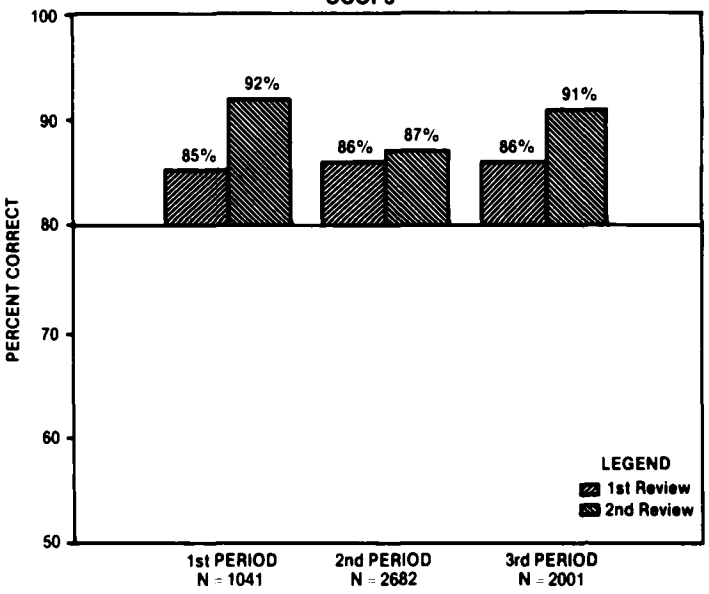

FIGURE 4
Patient Accrual by Year by Institution Type

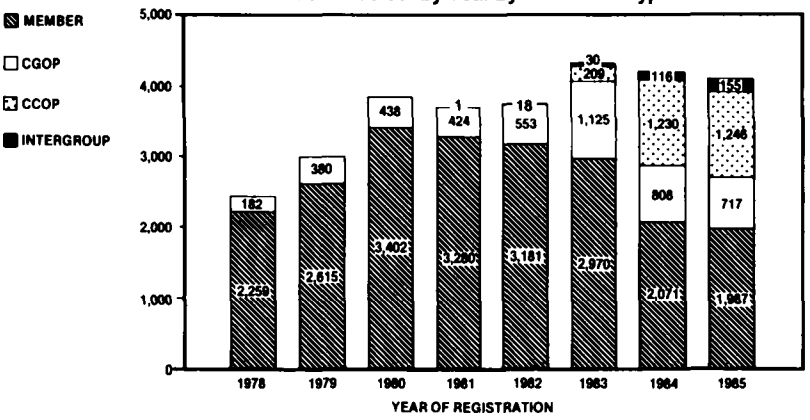

FIGURE 5

Southwest Oncology Group CCOP Scientific Contributions

Committee Chair/Vice Chair	**6**
Committee Membership	**104**
Study Coordinator	**1**
Study Co-Coordinator	**9**
Published Manuscripts:	
Senior Author	**1**
Contributing Author	**16**
Published Abstracts:	
Senior Author	**4**
Contributing Author	**10**

In conclusion, the Southwest Oncology Group is proud of its role in bringing this NCI initiative to its fullest partnership in the cancer clinical trials community. With respect to the Southwest Oncology Group — QUALITY IS JOB ONE.

QUESTION: How do the CCOPs compare to the main number of the institutions oncology quality assurance receiving specialist?

ANSWER: We're in the process of activating a group-wide quality control program so there's not a direct answer to the question. This is because our new Statistical Center has been evolving over the past year or so. In order to address the anxiety associated with the CCOP quality control program, because of the fact that they were concerned that the rest of the group wasn't participating in such a stringent quality control, I took the initiative of putting all of the data from the University of Texas Health Science Center of San Antonio through the same quality control system. Actually, I have slides which I refuse to show you that clearly and unambiguously demonstrate that the CCOP quality is everywhere better than the University of Texas Health Science Center of San Antonio, although there has been radical improvement with our data management since we have been exposing them to this harassment. But I can tell you, that the CCOP data set is really extraordinary and I have protocol coordinators in the group who are totally thrilled with the data coming from CCOPs compared to the rest of the Group institutions. In addition, while I don't have a slide to demonstrate this, we have not yet had time or long enough experience with CCOPs in our clinical trials, to generate longitudinal data, but we have looked at our CGOP physicians, the community physicians in the cancer control program -- the outreach program. With respect to at least two disease committees that we've examined, that is acute leukemia and multiple myeloma, we have discovered that the CGOP outcomes, as measured by complete response rate and overall survival, are everywhere better than the rest of the Southwest Oncology Group. One might say, well that's because the CGOP physicians get the healthy acute leukemia and myelomas and the university hospitals get the poor risk ones. But these data have been looked at by logistic regression equations and Cox regression models and the differences in outcome cannot be explained by potentially important pretreatment prognostic factors. In trying to hypothesize about how this outcome might be better, we can say that, it's not related to dose, it's not related to quality of data, and it's not related to potentially important prognostic factors. My only conclusion is that the CGOP physicians are directly caring for their patients, whereas many institutions in the university system have trainees involved as intermediaries in the care of patient. A highly trained CGOP Medical Oncologist or Hematologist must clearly do a better job than a first year fellow in Medical Oncology. ■