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by Alan M. Keller, M.D., and Douglass C. Tormey, M.D., Ph.D.

In a Spring 1989 *Oncology Issues* article written by then Chairman of the Eastern Cooperative Oncology Group (ECOG) Paul P. Carbone, M.D., and Marvin Zelen, Ph.D., a prediction was made that in 1989, 3,000 patients would be accrued to ECOG studies from community programs. Reality far outpaced the prediction. In 1989 5,304 patients were registered from the community (CGOP and CCOP) through the ECOG statistical office.

Growth has been remarkable. In 1989 there was a group-wide follow-up of 7,026 patients. By the end of 1993 there were 16,873 patients in active follow-up, more than half of whom were in community settings.

Approximately four cases in follow-up are equivalent in work load to one new patient registration. That translates into 4,000 "new" accruals per year exclusively from the follow-up cases. The burden of these new registrations and follow-ups affects everyone in the organization. Yet despite the increased work load, the scientific quality has been maintained thanks to the vigilance of the nurses, data managers, and investigators. Presently less than 1 percent of 21,000 active and inactive cases is considered lost to follow-up. Additionally, at the time of the last monitoring in July 1993, only 0.1 percent of on-studies and only 5 percent of follow-ups were overdue. This success rate has been self-imposed and dates to 1978 when the ECOG leadership recognized that for its studies to be meaningful and applicable to the oncologic community, it must have excellent quality control and ask no less of itself than any credible bench researcher.

QUALITY CONTROL

Repercussions of current events may test the veracity of cooperative group clinical research. The quality control program of ECOG has proven that clinical research can be reliable and reproducible. ECOG's quality control program was strengthened 16 years ago when it was noted that all quality and integrity issues could not be detected from review of forms submitted to the statistical center. While a form's timeliness and quality could be centrally monitored, issues of eligibility, laboratory parameters, informed consent, adherence to protocol treatment, and evaluation of response required review of original source documents to accurately address quality. As an outgrowth of that effort, several quality control programs exist within ECOG, including the Audit Committee, the Toxicity and Response Committee, Radiation Quality Assurance, Surgical Quality Control, Bone Marrow Transplant Quality Control, and Pathology Quality Control.

Following written policies and procedures and working with the statistical office and operations office, the Audit Committee evaluates on-site all member and affiliate institutions in order to verify the accuracy of data submitted. In addition to reviewing original source documents, the audit team, made up of two experienced investigators and an experienced data manager or research nurse, examines ADR reporting, pharmacy drug logs, and IRB approvals.

Routine audits are performed on a three-year review. A broad representation of studies is audited to assess quality in adjuvant trials, advanced disease studies, and complex hematologic protocols. Audit reports are reviewed by the Audit Committee and the statistical center with recommendations to the group chair. Following new guidelines, these reports will be faxed to the National Cancer Institute (NCI) within 24 hours. Possible actions include: 1) reaudit in three years, 2) reaudit within a specified time period, 3) suspension pending correction of major deficiencies, or 4) termination in ECOG.

Four hundred and forty-seven audits were completed from January 1989 to June 1993, with 53 main institutions and 394 affiliates included. The community investigators, data managers, nurses, and pharmacists are intimately involved in the audit process as committee chairs, committee members, and on-site auditors.

Rather than a punitive role, the audit has served as an educational process where ideas are shared, weaknesses are corrected, and improvements are continually sought. While no group is immune to the unscrupulous investigator or over-zealous support staff, the audit process serves to keep any such influence at minimum levels, thus protecting patients and future trial participants while advancing the science.

ENCOURAGING COMMUNITY INVESTIGATOR LEADERSHIP

Since its founding in 1954, the Eastern Cooperative Oncology Group (ECOG) has grown to approximately 3,500 investigators, of whom more than 2,800 are located in community hospitals.

ECOG is responding to a changing health care environment and new regulatory issues by increasing involvement of all group participants. Leadership activities, new investigator involvement, educational sessions, and enhancing communications with electronic communications are important areas that will help ECOG adapt to a rapidly changing future.

Traditionally, ECOG has been guided by academic institutions. While the group's success suggests that this practice has served it well, leadership development in the community is needed to ensure a viable group in the future. To this end, ECOG has been in the process of developing leadership opportunities for community investigators. Currently, the Community Cancer Committee (CCC) is open to all community investigators. The chair and co-chair of the committee are elected from the membership, each rotating between a CGOP and CCOP member. The chair is also a voting member of the ECOG Executive Committee.

CCC's role is to deal with administrative and financial issues related to the community programs. With approval of CCC's chair and members, the community leadership has developed a mechanism for increased community scientific involvement. A community co-chair position was established in each of the modality-oriented committees as well as in the disease-oriented committees. Appropriate new

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group-wide Phase III studies will have a co-chair from the community. Because 60 percent of accrual comes from community participation, the co-chairs of these committees and studies play a critical role in 1) ensuring that the studies are carried out in the community and are applicable to the patient and 2) keeping data points to a necessary minimum. A new position, the Associate Chair for Community Programs, will help coordinate and guide community activities.

NEW INVESTIGATOR INVOLVEMENT

New talent brings added assets. The involvement of new members in ECOG activities, however, has not been as efficient or as organized as it should have been. With a more activist Community Cancer Committee, plans are underway at ECOG for a more "user-friendly" introduction. This type of orientation to the working mechanisms of ECOG has been very successful in the data management area. A similar need exists for new community and academic investigators who come into the group.

A formal orientation program is being developed for ECOG's fall meeting. Senior investigators, senior operations office personnel, and representatives from the statistical center will outline administrative structure, flow of protocol development, record keeping, data retrieval responsibilities, audits, Institutional Review Boards, and the criteria and responsibilities of committee membership, including chair and co-chair activities. A larger group-wide emphasis is to be placed on ethics and scientific misconduct, conflict of interest problems, and cost effectiveness in clinical cancer research.

PATIENT ACCRUAL

Accrual from the community institutions dropped slightly from 1989 to 1993. While CCOP accrual as a percentage of total ECOG accrual remained constant at 17 to 18 percent, the CGOP accrual to therapeutic studies dropped from 39 percent in 1989 to 25 percent in 1993. The CCC and the Community Executive Committee are taking steps to increase eligible patients registered on clinical trials. In addition, by having a community physician serve as a co-chair of major Phase III trials, these important protocols will have an advocate from the large community base.

A career development pathway for community members, including a mentoring program and placing community physicians in co-chair positions in the modality and disease-oriented committees, is designed to increase community involvement and accrual.

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THE FUTURE OF COMMUNITY CLINICAL RESEARCH

Cooperative groups and intergroup mechanisms have allowed oncologists even in the smallest communities access to important studies. Patients benefit by having access, doctors benefit by having state-of-the-art therapies available, institutions benefit by keeping patients in the community, and science benefits by increasing accrual, thereby decreasing the timeline for study completion. However, the future of these smaller participants is in jeopardy.

We are all well aware that the NCI, under pressure from Congress, will be mandating more regulatory oversight. The fear for community research is that small groups with low accrual could be dropped from their university member institution affiliation. Will the member institution, which is already underfunded, be able to audit the CGOP at a more intense level? In this era of scant resources, is this the best way to spend valuable research dollars? If research funds are diverted to the regulatory process, we will need to reduce the number of community affiliates and contract the number of active studies. Accrual will drop, timelines for new knowledge will be extended, research will slow, and many good ideas will be on paper only.

Clinical research is already being affected by the rapidly changing health care environment. In this era of reform, health practice, prevention, early detection, follow-up, screening, molecular genetics, lab correlates, and prognostic information will all carry increased importance. As an ongoing part of its cancer control and correlative laboratory activities, ECOG has identified individuals with expertise in each of these areas and is developing a cost-analysis working group.

Although each of us will have to deal with the coming constraints affecting all clinical research, the Eastern Cooperative Oncology Group considers increased involvement by community physicians a high priority.

Health care reform, regulatory issues, funding, and headlines that call into question the veracity of clinical research are wake-up calls for the field. In order to make a positive response, all our forces must be marshalled, especially those in community programs where the transfer of basic research and clinical investigation will apply to the greatest population of patients. Responding in a proactive way and using an experienced and dedicated network of investigators, we can build on a firm knowledge base and continue our commitment to clinical research.