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Overview: A Decade of Quality Community Research

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Clinical Research

In 1994 we are celebrating the tenth anniversary of the Community Clinical Oncology Program, a clear marker of the community's involvement in clinical trials. Now, a decade after the initiation of this landmark program we all recognize the high quality of the community's contribution to research. Individually, many community investigators have joined the leadership of the cooperative groups, working on key committees as authors and co-authors of papers, as study chairs, and as contributors in many other ways.

This series of articles examines the progress and present status of community involvement in clinical trials, from dramatic successes to barriers that impede increased participation and changes that are being made to ensure continued progress.

Overview: A Decade of Quality Community Research

by Albert B. Einstein, Jr., M.D.

In 1982 it was hard to imagine that oncologists in community hospitals would end up playing such an essential role in cancer research.
In those days, a few of us were fortunate enough to continue our involvement in academic research endeavors, even though we had left the "ivory towers" for private oncology practice. But many well-qualified clinical investigators felt disenfranchised, cut off from an integral part of their commitment to the patients they served and from their own commitment to continue the hunt for solutions to the problems they faced every day.

In the late 1970s, Edward L. Moorhead, Bill Dugan, Gale Katterhagen, and a handful of other individuals began to campaign under the ACCC banner to involve community physicians in clinical research. They lobbied the National Cancer Institute (NCI), Congress, and the National Cancer Advisory Board, but they faced formidable opposition. The NCI was skeptical, while many of the university-based cancer researchers expressed grave reservations.

The arguments against involving the community appeared cogent: lack of clinical research experience, lack of data management staff, and lack of experience with federal regulations and funding requirements. Yet several arguments for involving the community prevailed:

- The bulk of patients were seen in the community
- Many well-qualified clinical investigators had migrated to the community.
- Because the community was becoming more sophisticated, some types of patients were not being seen at university centers.
- The community had proven its ability to handle federal funds and requirements in two predecessor programs: the Clinical Oncology Program (COP) and the Community Hospital Oncology Program (CHOP).

Vincent DeVita, the NCI director, recognized the potential of involving community oncologists in cooperative clinical trials and launched two programs: the Cooperative Group Outreach Program (CGOP) and the Community Clinical Oncology Program (CCOP). Searching for rationale to fund these programs, DeVita suggested that the conduct of clinical trials was a mechanism for rapid dissemination of new information to community physicians. This technology transfer hypothesis allowed him to purloin $10 million from the Cancer Control Division's funding pot, at that time a separate funding line that was not to be used for conventional research purposes.

By the end of the past decade,

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in the Community

the CGOP and CCOP approach had turned the cancer research equation upside down—from 5 percent of all patients coming from the community in the early 1980s to more than 50 percent of all patients on clinical trials accrued from community investigators!

HURDLES TO COMMUNITY ACCEPTANCE

In between, a number of hurdles were overcome. First, there was the concern over the quality, timeliness, and completeness of community data. The National Surgical Adjuvant Breast and Bowel Project (NSABP), of course, was a trailblazer in the use of community investigators. NSABP planners recognized that the questions that needed to be answered about breast cancer would require huge numbers of patients available only by the development of a nationwide network of investigators, many at community institutions.

The North Central Cancer Treatment Group had pioneered the involvement of community hospitals and physicians in their trials and demanded a high standard of excellence in their data collection. On the other hand, the investigators in Southwest Oncology Group (SWOG), the Eastern Cooperative Oncology Group, and the Cancer and Acute Leukemia Group B were less experienced with community investigators and were wary. SWOG, for example, proactively segregated all of the CCOP participant data and measured each CCOP's performance against established quality standards.

Over time it became clear that most community investigators took great pride in their work and that the overwhelming majority of programs were tightly organized. Such well-organized programs translated into significant accruals, high quality, and timely submission of data. At one point, Charles A. Coltman, Jr., M.D., SWOG chairman, said he measured the performance of his own institution against the CCOP's and found it lacking. He said he expected his institution and all other university member institutions to live up to the high standards set by these community participants.

A second hurdle concerned cancer control. Peter Greenwald, M.D., the division's director, wanted cancer control to be a real part of the CCOP agenda. He insisted that the community and the cooperative groups begin the study of prevention and other control trials that would satisfy this requirement. For many years, there was a lack of any real trials that would allow the community to satisfy its obligation to participate in cancer control research initiatives. Indeed, the term "cancer control research" remained amorphous, and a number of studies were suggested, only to be disapproved as not "hitting the mark."

Yet, as Congress and the public became more insistent on a prevention focus, it became clear that the community was going to become the focal point for new research endeavors in this area. Access to asymptomatic individuals for potential prevention studies could only be accomplished through community providers. Eventually a number of scientifically strong research hypotheses were generated that led to significant prevention trials, such as the Breast Cancer Prevention and Prostate Cancer Prevention trials. The community was quick to understand that these prevention research efforts were entirely different from conventional research trials and altered their staffing configurations and methods of patient accrual to reflect these new studies.

Today, there is no question about the enormous impact and high quality of the community's contribution to both conventional and prevention research. The articles in this edition of *Oncology Issues* reflect this contribution.

As we look toward the future, however, the community's involvement in clinical research faces significant new obstacles. The uncertainty, and at times the denial, of reimbursement for patient care by managed care organizations threatens patient accrual in clinical trials. The public's confidence in the research establishment has been shaken by the revelation of fraudulent data. The increased safeguards and complexities required by federal funding agencies to detect and prevent the accumulation of this fraudulent data (as rare as this may be) deter both investigators and participants from becoming involved in clinical trials. The lack of funding and increased complexities of performing clinical research may unravel what many have worked so hard to build.

Without a doubt, the potential loss of the community's contribution to cancer clinical research through the vagaries of health care reform would be a major setback for today's clinical research agenda.