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Are Cooperative Groups Dinosaurs?

by Carl G. Kardinal, M.D.

Cooperative groups have played a major role in my early clinical research training and continuing education. A comradery among group members has generated life-long professional affiliations as well as friendships.

When I first became a cooperative group member more than 20 years ago, cooperative groups were the vanguard of clinical research. They were asking and answering critical clinical questions. Funding was abundant and new agents were readily available for testing.

In 1974 when I became the principal investigator on a cooperative group grant for the Ellis Fischel State Cancer Hospital (Columbia, Mo.), we were funded at approximately $1,000 per case accrued. This seemed adequate, and the primary institution was willing to pick up any differences in cost so it could retain an NCI designation as a CCOP or a cooperative group member. In 1995 we are still funded at a rate of $1,000 per case accrued, but unfortunately not in 1974 dollars. And the funding is per treatment case—often considerably less per cancer control case accrued.

Enter managed care—mergers and downsizing, budget restrictions, gatekeepers, capitation for oncology care, restricted access, and discounted fees. Primary institutions are no longer able or willing to absorb the differences between NCI funding and the real costs of clinical research. An NCI designation alone is no longer enough. How will the extra data managers required for chemoprevention trials be funded? How can we get investigators to cooperative group meetings when travel funding is so limited?

Today NCI funding is at best flat and at worst decreasing. With local institutional funding being withdrawn, none of us may be able to continue cooperative group participation—at least to the level of a few years ago. With severe funding restrictions, cooperative groups face near extinction.

Several other factors contribute to this problem, including unfunded mandates and control of new agents by the pharmaceutical industry. Unfunded mandates, which are intended to ensure certain ethical standards of behavior, drain the already meager research dollars that must be diverted to fund them. Unfortunately fraud will happen despite these well intentioned but superficial trappings. Audits, ethics training, and the signing of conflict of interest statements do not necessarily ensure that anyone, including investigators, will act ethically. What are the ethical issues in mandating that a "Dear Participant" letter warning of endometrial cancer risk be sent to a patient with metastatic malignant melanoma who may have been randomized to receive tamoxifen plus chemotherapy?

Currently, new agents are being controlled by the pharmaceutical industry, which has been willing to pay the true costs generated by clinical trials. Funding has been three to ten times the NCI level, and investigators have been diverting their cases from cooperative group protocols to competing pharmaceutical studies. As a result, pharmaceutical trials are being completed rapidly, while many cooperative group trials are languishing. Cooperative group trials are becoming confirmatory and often less innovative. Consequently, by the time protocols are activated, the questions being raised are often of less interest.

Is there any hope for the cooperative groups? I sincerely hope so, since they have been the bread and butter of cancer clinical trials. What can the cooperative groups do to help assure their survival? Some of the answers seem obvious: Seek alternative sources of funding, form alliances with the pharmaceutical industry, streamline the process of protocol generation, and ask innovative scientific questions.

To encourage wider participation in cooperative group meetings, costs need to be decreased, perhaps by conducting meetings over weekends and downsizing and shortening the meetings themselves.

What can the NCI do to help assure the survival of the cooperative groups? Here again some of the answers are obvious: funding, funding, funding! Short of that, eliminate unfunded mandates and the hysteria associated with repeated "Dear Participant" letters, and in turn restore dignity and respect to the cooperative groups.

The Western Cancer Study Group, the Central Oncology Group, the Southeastern Cancer Study Group, the Piedmont Oncology Association, and the Mid-Atlantic Group have all died. NSABP is out of the ICU, but still in the hospital. ECOG is moving its operations office for the second time in two years, and at a minimum is receiving outpatient care. In the current climate none of the groups are truly healthy, and within each group turbulence exists. NCI is in a state of flux with the departure of Broder, Chabner, and others. At the moment the outlook for the cooperative groups appears bleak, but not hopeless.

The groups need a strong national spokesperson. They need the support of the public, the Congress, and most of all the support of the individual investigators. The groups have always had and will continue to have ACCC support. If all subsets will work together, the cooperative groups will once again assume their dominant role in clinical cancer research.