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Lori Minasian

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Open Letter to Community Clinical Oncology Programs

by Lori Minasian, M.D.

There is no question that today's effective cancer treatments are the result of yesterday's clinical trials. Despite the impact that the evolving health care delivery system has had on participation in clinical trials, the need for an effective and streamlined clinical trials program has never been greater. At the same time, however, CCOPs, as major contributors to cancer clinical trials, have expressed concern about their ability to maintain their organizational arrangements, which have been successful and made them so valuable to the clinical trials program.

The National Cancer Institute (NCI) has initiated several projects intended to address CCOP investigator concerns and thereby strengthen and improve the national cancer clinical trials program. These projects include an informatics initiative, the informed consent initiative, and a national cost analysis.

Informatics. The Cancer Therapy and Evaluation Program (CTEP) has launched an informatics effort aimed at making the collection and submission of patient data more efficient. This year CTEP will require that the cooperative groups submit their data in an electronic format. CTEP is working with the biostatisticians of the cooperative groups to develop common data elements for all disease sites that will permit development of standard data forms for each disease site across the groups. In addition, a system for web-based patient registration and randomization is being discussed.

Informed consent. Two years ago the NCI formed an informed consent working group, comprised of medical, legal, ethical, communication, and consumer experts as well as representatives from the NCI, the Food and Drug Administration, and the Office for Protection from Research Risks. This group addressed the concern that the informed consent document has become overly complex and lengthy, and does not adequately educate potential research participants about the proposed study. The group's deliberations have resulted in recommendations for simplification and a template for the development of informed consent documents that will:

- permit better understanding of the proposed research by the potential participant
- aid investigators in writing "user friendly" documents
- assist institutional review boards (IRBs) in their review of these documents.

The NCI will initiate dissemination and promotion of these new guidelines this summer.

Cost analysis. Community oncologists have expressed tremendous concern that third-party payers are refusing to pay for clinical trials. To deny patients coverage for their participation in Phase III cancer clinical trials appears counterproductive, given that one arm of these studies is almost always standard treatment and that third-party payers want "evidence-based medicine." Medicare and other third-party payers have been very concerned about the perceived additional costs for putting patients on these studies. Yet, little real data exist on the costs of clinical trials. The White House Office of Science and Technology and the NCI have commissioned the Rand Corporation to conduct an analysis of the additional margin of cost incurred when a patient participates in a Phase III cancer clinical trial as opposed to receiving standard treatment. Additionally, the NCI is negotiating with Medicare to develop a two-year pilot project that will ensure payment for patient costs when Medicare patients participate in NCI-sponsored clinical trials. This pilot will also include a cost analysis. Overall, it is hoped that these two projects will demonstrate minimal additional costs, if any, and thereby eliminate the reluctance of third-party payers to cover the patient care costs for individuals enrolled in clinical trials.

The NCI Clinical Trials Implementation Committee has spent seven months in careful deliberation of the strengths and weaknesses of the current cancer clinical trials program. Several CCOP principal investigators were asked to provide their input. The committee plans to present its findings to the NCI Board of Scientific Advisors in September. The committee has discussed the above projects as well as other important factors such as open access to clinical trials from all the cooperative groups, the impediments created by local IRBs, the difficulties in having new ideas brought forth, and the underfunding of all aspects of the current clinical trials program.

There is a tremendous opportunity to make substantive and welcome changes to the current system. There is genuine interest on the part of the NCI, the cooperative groups, and other players to constructively discuss and collaboratively develop a strengthened national clinical trials program that will be more open, accessible, and flexible.

Lori Minasian, M.D., is program director and chief of Community Oncology and Rehabilitation Branch, Division of Cancer Prevention at the National Cancer Institute.