ASCO's Clinical Practice Committee

Challenges for Community-Based Clinical Trials

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By Therese M. Mulvey, MD

Recently at an impromptu meeting of community oncologists, discussions moved to the topic of clinical trials. In our nonrandomized and nonstatistically representative group, every member expressed concern over the viability of their community-based clinical trials program. One member of the group announced that his practice had discontinued all clinical trials, and another had discontinued

cooperative group trials and continued only industry trials. The barriers were legion, yet reimbursement was a universal theme. Each office had different levels of stress regarding payment for clinical trials. Funding a staff sufficient to safely and efficiently participate in cooperative group trials was the major issue.

It has been documented that less than 3% of cancer patients enroll onto a clinical trial. Barriers for patients have been well documented and include the perception of being in an "experiment" versus an "investigation," fear of loss of control, inconvenience, and concern about loss of insurance coverage or added costs. We have always had concerns about insurers not covering the routine costs associated with clinical trials, but recently we have heard more and more reports of insurance barriers. Reports are surfacing of insurance plans covering the cost of clinical trials, but not the cost of side effects of the treatments, further dissuading patient enrollment. Some low-cost insurance plans have a maximum of cancer care dollars that effectively do not cover any cancer care, much less the cost of a clinical trial. Not only can oncologists be financially dissuaded from opening clinical trials, patients may also have financial concerns about enrolling.

Design of clinical trials in the face of a declining workforce and fewer financial resources will require careful assessment of the cost to the patient enrolled and the feasibility and utility of conducting a trial in the community setting—where 80% of the patients receive their treatment. The senseless competition between sites of service for limited patients to enroll on a clinical trial must be honestly evaluated as the resources become more scarce. We as oncologists have a responsibility for ensuring fair and equitable distribution of resources if we are to make it together in the effort to sustain and improve clinical trials in the future. The efforts of ASCO, ASH, and other professional societies to preserve Medicare clinical trials coverage in October is to be celebrated. Yet,

Medicare Advantage patients continue to face a significant deterrent to trial enrollment, as do many working patients with self-insured health plans that choose not to cover clinical trials and are exempt from state laws requiring coverage. ASCO and others have also been working to address this issue, but the Centers for Medicare & Medicaid Services has refused to acknowledge the problem.

With declining reimbursement in general for oncology specialists, the investment in a clinical trials program will require physicians to carefully evaluate these scarce resources. The investment is considerable to do it right. Adequate staff, documentation concerns, and insurance verification all have real cost to a practice. Yet, who today in the course of their day did not call on the results of a clinical trial to guide decision making; it is this that drives the discussion. Every member of my nonstatistically significant social group agreed on this issue. The National Cancer Institute's (NCI) programs to support community-based research (Community Clinical Oncology Program and cooperative groups and the Clinical Trials Support Unit Independent Clinical Research Site programs) must be aware of what is happening around them to maximize resources and provide a wide range of trials to eligible patients in a community.

ASCO is committed to doing its part to support community-based researchers. The Society continues to recognize the efforts of these investigators through its Clinical Trials Participation Awards. For the fourth year, ASCO has also been helping practices learn successful tools at its Clinical Trials Workshop. ASCO also advocates in Congress for increased funding to the NCI. ASCO also supports local and regional innovation to address challenges with clinical trials by awarding State Affiliate Grants.

As we look forward to celebrating the 2008 Clinical Trials Participation Awardees at the Annual Meeting, we must learn from these exemplary sites what is working and what can be done to streamline the clinical trial system to maximize enrollment and opportunities to learn what works best. The practice of oncology is challenging every day. Clinical trials should not exacerbate the challenge to a point where the process is abandoned completely.

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