Preparing for Community Clinical Oncology Program Budget Cuts

Faced with the specter of budget cuts or flat funding, principal investigators from the National Cancer Institute's Community Clinical Oncology Program (NCI CCOP) worry that they will not be able to satisfy their accrual targets and data collection requirements for many of the nation's phase III clinical trials. The CCOP sites are charged with enrolling patients in prevention and treatment trials in the community setting.

In early 2007, NCI asked investigators to plan and prepare for a potential 10% budget reduction for fiscal year 2007. In May, Lori Minasian, MD, FACP, chief of the NCI's Community Oncology and Prevention Trials Research Group, which administers the CCOPs, told the *Journal of Oncology Practice* that it looks like the fiscal year budget for 2007 will be reduced by 5% to 8%, not 10% as originally proposed.

"The program has engaged and involved community oncologists in clinical trials research in order to help these physicians provide information about current treatment options to their patients," said Dr Minasian. "It seems a shame to reduce funding to a program that has demonstrated its value in providing evidence-based cancer information that patients and their physicians use on a day-to-day basis."

Since the program's inception, evaluations have shown that it has brought research into community areas far from academic centers. Additionally, physicians involved in the program have been early adopters of new evidence-based standards of care.

CCOPs have long been the engine for enhanced accrual to the nation's largest cancer clinical trials. Built on a vision put forward by NCI director Vincent DeVita, MD, in 1981, the NCI issued its first request for applications for CCOPs in 1983. Dr DeVita helped to shepherd development of a new clinical trial infrastructure, setting aside funding for broadening participation so that clinical research and state-of-the-art care could become available to patients who lived far from academic centers and to oncologists practicing in smaller sites. Under his direction, the concept proved feasible, and community oncologists demonstrated that they could significantly boost trial accrual. The initiative coincided with a growing contingent of oncologists leaving academic centers for smaller community-based practices. Now, 23 years later, the program has a solid foundation that has expedited clinical trial accrual.

The CCOP network consists of 50 CCOPs and 13 minority-based CCOPs across the United States, Canada, and Puerto Rico. According to the NCI, 3,675 physicians and 415 hospitals participate in the program (Fig 1).

National Surgical Breast and Bowel Project (NSABP) associate director Larry Wickerham, MD, said that CCOPs are crucial in launching and carrying out large longitudinal clinical trials. "Of the 50 CCOPs, almost all are participating in the NSABP. They

contribute one third of all patients enrolled. When you cut CCOPs, impacts on care are immediate."

Of the many clinical trials in which the CCOPs have played a fundamental role, the NSABP Cooperative Group's Breast Cancer Prevention Trial (BCPT) and Study of Tamoxifen and Raloxifene (STAR) trial stand out. The trials answered critically important breast cancer prevention questions.

In 1998, the BCPT (also known as P1) revealed that tamoxifen could lower the risk of invasive breast cancer in premenopausal and postmenopausal women by nearly 50%. Results from the NSABP's second breast cancer prevention trial, STAR (or P2) trial, presented in the spring of 2006, demonstrated that the osteoporosis drug raloxifene has the same efficacy as tamoxifen in preventing invasive breast cancer among women at elevated risk for breast cancer. The adverse effect profile differed, and principal investigators urged the oncology community to individualize treatment.

CCOPs also played a pivotal role in expediting enrollment and study completion for the Southwest Oncology Group (SWOG) Prostate Cancer Prevention Trial (PCPT). The trial found that men who took the drug finasteride reduced the risk of developing prostate cancer by 25% compared with controls. However, the results were tempered by the finding that men who developed prostate cancer while receiving the drug were more likely to develop high-grade prostate cancer. Thus far, finasteride remains the only drug available that prevents prostate cancer.

Although breast and prostate cancers are among the most high-profile cancers in the public eye, CCOPs have made it possible to study most cancers; for example, lung, colorectal, gastrointestinal, and ovarian cancers. Another major trial that was dependent on enrollment at CCOP sites was the Colorectal Adenoma Prevention Study (CAPS), which demonstrated that daily aspirin use reduced the risk of adenomas by 35% in patients with previous colorectal cancers.

Yet today, CCOP principal investigators agree that a significant challenge facing the program is that funding has not kept pace with inflation. "You are left with an unfunded mandate," noted Philip Kuebler, MD, PhD, who heads the Columbus, Ohio, CCOP. Dr Kuebler was referring to NCI's Challenge Goal 2015, a multifaceted group of objectives aimed at eliminating suffering and death due to cancer by the year 2015. "Trials for rare diseases are not being activated," he added. "Many head and neck trials have been eliminated." James Wade, III, MD, director of the Central Illinois CCOP (Decatur, Illinois), also expressed concern about the disbanding of some SWOG head and neck trials. . . . "The large randomized controlled trial is the way for us to get answers," he stressed. "From the outside in, it is confusing to us."

Other fiscal realities trouble CCOP investigators. "Studies are getting more complex," Dr Kuebler said. "Increasing data

Figure 1. National Cancer Institute's Community Clinical Oncology Program (CCOP) map.

requirements and documentation, demands for more specimens, coupled with inadequate reimbursement, are tough. It's harder to find good people with the salaries that we can provide. People are going to private industry."

Some physicians report that because funding has dried up, their practices have had to limit accrual. It is a thorny area without clear-cut solutions. Some trials investigators contend that they are blamed unfairly.

"The big problem is the doctor," said James N. Atkins, MD, chair of the Southeast Cancer Control Consortium CCOP in Winston-Salem, North Carolina. "Even though 70% of patients have a positive view of clinical trials, only 14% are told about them, and 3% go on them. The vast majority of doctors don't get patients on clinical trials." One potential strategy that Dr Atkins proposed is for two to three CCOPs to work together on recruitment.

Some CCOPs are taking another tack: they are trying to compensate for flat funding by participating in industry trials, which typically provide more research funding. "If you get \$1,500 to \$2,000 to put two people per year on a clinical trial, funds are totally inadequate," said Dr Atkins. "Data

managers cost anywhere from \$40,000 to \$80,000 per year." Dr Wade echoed this viewpoint. "You simply can't recruit and keep good staff," he said.

Many in the research community do not see how they can boost trial enrollment with the constraints imposed on them. "Our CCOP, like other CCOPs, is cutting back," said Dr Kuebler. "When you want more out of each patient to put on study, we are scrambling to fill the gap."

Keith Lanier, MD, head of the Columbia River Oncology Program in Portland, Oregon, called the situation "demoralizing." As he states, "Besides facing an ongoing struggle to keep staff, a number of trials have closed across the board." One matter that he raised particular concerns about was the lack of an adjuvant colorectal cancer trial.

Dr Wade likened diminishing funding to yanking the fuel out of steam engine. "In this case, the fuel is federal dollars. If they slow down, you get fewer studies and a longer time to get studies off the ground."

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