Reforming the Community Research Program: From Community Clinical Oncology Program to the National Cancer Institute Community Oncology Research Program

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OVERVIEW

Community research has been an integral and influential component of the National Research Program since the late 1970s. Institutionalization of community research in the Community Clinical Oncology Program (CCOP) has resulted in successful collaborations, meaningful accrual, achievement of quality standards, and translation of research into clinical practice. Although the national clinical trial system is undergoing modernization and improvement, the success of the CCOP and minority-based CCOP in cancer treatment, prevention, and control research is being extended to include cancer care delivery research in the newly created National Cancer Institute (NCI) Community Oncology Research Program. This article briefly presents a historic perspective of community involvement in federally sponsored clinical trials and introduces the continued involvement in the newly created NCI program.

COMMUNITY CLINICAL ONCOLOGY PROGRAM

Perhaps the most important lesson learned from the institutionalization of community research within the CCOP system is that the community serves as a critical link to academic centers and research bases in translating research into practice. The integration of research in the community setting proved that successful collaboration with multiple stakeholders, including the NCI, cooperative groups, patient groups, academicians, scientists, and industry, can be achieved. By facilitating involvement of patients, while safeguarding the protection of human subjects, collecting high-quality data, engaging physician and research staff leadership in the development of trials, and subsequently translating the science into practice, the community has contributed to the entire spectrum of discovery, including basic science research, translational work, and clinical application.

Historically, the initial Request for Application for the CCOP was released in 1982 with the goal of selecting hospitals and medical practices willing to build a network for cancer prevention and cancer control trials. The NCI acknowledged that a key strategy for success would include funding the physicians specifically to establish the local infrastructure to meet specific needs and then facilitating the collaborations between the academic investigators to encourage community physicians to be active contributors in the research and to then communicate that research to their patients and their communities. In 1983, 62 CCOPs, most with previous experience in the CGOP, were selected and successfully accrued patients to treatment trials. As the CCOP evolved, the strategy expanded to include the accrual to cancer prevention and control studies, thus representing the full scope of cancer care in a community setting.

Throughout the years, the CCOP was successful with active accrual by the community and with meeting or exceeding the quality standards set by the cooperative groups. However, the populations served in the existing CCOP did not ade-
quately represent large minority groups, which resulted in the 1990 development of the Minority-based CCOPs (MB-CCOP), whose focus of activity was on the delivery of care to minority populations. The disparity was a result of the funded CCOPs’ geographic locations primarily in suburban areas with little minority population being served. The MB-CCOP was instrumental in providing resources to the physicians and sites that did care for underserved populations. In 2007, the NCI established the NCI Community Cancer Center Program (NCCCP) to complement the cancer care delivered at large, academic-based cancer centers by building a community-based research platform supporting basic, clinical, and population-based research on cancer prevention, screening, diagnosis, treatment, survivorship, and palliative care at community hospitals.7 As described in the NCCCP website, these cancer centers reach out to medically underserved members of their communities by offering free cancer screening events, cancer education programs, patient navigation services to improve care coordination, and formation of partnerships with local community organizations, such as churches and advocacy groups.8

From a performance standpoint, the NCI CCOP has a track record of contributing one-third of the NCI clinical treatment enrollment, nearly all of NCI cancer prevention and control accrual, and was integral to the successful development and completion of the major prevention trials (Fig. 1). CCOPs provided 31% of the 13,388 participants in the Breast Cancer Prevention Trial, 33% of the 19,747 participants in the Study of Tamoxifen and Raloxifene, and 29% of the 35,534 participants on the Selenium and Vitamin E Cancer Prevention Trial.9-11

The NCI attributes the CCOP performance and centrality to research to nearly 30 years of experience characterized by continuous self-evaluation, adaptation, and learning from other NCI practice-based research networks and quality enhancement efforts. Key components to developing and maintaining a successful community-based research program have been described. (Sidebar 1).4 Two cross-cutting themes appear to link the key principles proposed for the CCOPs’ strong performance: first, a culture of a team approach in building a research infrastructure and encouraging collaboration between academic and community investigators; and second, flexibility and discretion to design a system customized to manage local operations based on predictable funding.

**KEY POINTS**

- Community research has been an integral and important component of the National Research Program for more than 40 years and has served as a critical link in translating research into practice.
- The Community Clinical Oncology Program (CCOP) has been very successful with actively accruing patients, meeting quality standards, and providing leadership.
- A key strategy for community research success was based on funding physicians specifically and facilitating collaborations with academic investigators.
- Four key principles for the CCOP success have been defined and should serve as a guide as cancer clinical research evolves.
- A goal in changing the program is to maintain the key principles, while expanding research to better understand the current influences of a changing health care system.

**SIDEBAR. Key Principles to Community Clinical Oncology Program Success**

1. Building the infrastructure
2. Funding to empower local physicians
3. Collaboration between academics and community investigators strengthens research and practice
4. Flexibility in operations and organizations
In addition to these intrinsic keys for success, Carpenter et al examined the influence of the clinical provider community in which care was delivered on clinical trial productivity. Based on a longitudinal quasi-experimental study using panel data on 45 CCOPs nationally from 2000 to 2007, the authors determined that compared with the 1990s, the relevance of clinical environment had shifted. In the 1990s, managed care penetration was positively associated with accrual in areas of low to moderate penetration and negatively in the areas of high penetration, whereas greater hospital competition was associated with a decline in trial enrollment. However, this most recent study suggested that health maintenance organization (HMO) penetration and hospital competition were not substantial influences to accrual activity and concluded that CCOPs were able to adapt to the disruptive changes in health care financing in the 1980s and 1990s. These findings, coupled with the proven success of the CCOPs, highlights the importance of flexibility combined with an unwavering commitment of the community physician and staff to research and to improving the care of patients as the underpinnings for continued success in community research programs.

NATIONAL CANCER INSTITUTE COMMUNITY ONCOLOGY RESEARCH PROGRAM

We are living in an unprecedented time of cancer care discovery and progress with the growing momentum of science and technologic progress. Advances in genomics and proteomics have now identified opportunities for differing agents and approaches specific for genotypes expressed in limited subsets of the population. This personalization of medical intervention will require research population heterogeneity, an increase in number of trials, and an increase in prospective research participants. The current reinvigoration of the National Clinical Trials System is addressing the need for the system to evolve to optimally leverage these advances.

In 2013, the NCI Board of Scientific Advisors approved the creation of the NCORP, which expands on the success of the CCOP and MB-CCOP network, while integrating elements of the NCCC. The consolidation of the NCI community programs into the NCORP will achieve the dual goals of improving efficiency and expanding the scope of research to include cancer care delivery and health services research. This builds on the four key principles to strengthen the infrastructure and collaboration, while maintaining flexibility and expanding the research agenda to cover emerging issues in the delivery of cancer care. The components of NCORP will include Research Bases, Community Sites, and Minority/Underserved Sites (Fig. 2).

From a national perspective, how this country assesses health care quality, delivers medical services, and conducts the research that informs quality of care and clinical outcomes is shifting.

The wide-ranging consequences of a changing health care system—including the Affordable Care Act, the establishment of Accountable Care Organizations, and changes to practice environments—on cancer care delivery are unknown. To better understand these dynamics, the NCI definition of cancer care delivery research “examines how social

**FIG 2.** NCORP organizational structure.

Abbreviation: NCORP, National Cancer Institute Community Oncology Research Program.
current modernization of NCI support of community-based cancer research is a commitment to preserve and enhance research in the community. In this author’s opinion, this complements the modernization of the National Clinical Trial Network and enhances the overarching goals of research—to enhance the quality of our patients’ lives by improving patient outcomes and reducing disparities in care.

As community research moves forward, the guiding principles of the past success of the CCOP network, coupled with the wisdom, vision, and dedication of community researchers, will be invaluable in enabling community research to stay ahead of the curve. Community research experiences in cancer care delivery research will be critical to defining and better understanding health care system influences, thereby offering opportunities for practical solutions.

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References