Contemporary Clinical Trials 33 (2012) 46–54

Contents lists available at SciVerse ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

Sustainability and performance of the National Cancer Institute's Community Clinical Oncology Program

William R. Carpenter [a,b,c,*], Alice K. Fortune-Greeley [a], Leah L. Zullig [a], Shoou-Yih Lee [d], Bryan J. Weiner [a,b,c]

[a] Department of Health Policy and Management, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, Campus Box 7411, 1102A McGavran-Greenberg Hall, Chapel Hill, NC 27599, USA
[b] Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill, School of Medicine, CB# 7295, Chapel Hill, NC 27599, USA
[c] Cecil G. Sheps Center for Health Services Research, University of North Carolina at Chapel Hill, 725 Martin Luther King Jr. Blvd, CB# 7590, Chapel Hill, NC 27599, USA
[d] Department of Health Management and Policy, School of Public Health, University of Michigan, 1415 Washington Heights, Ann Arbor, MI 48109, USA

ARTICLE INFO

Article history:
Received 26 August 2011
Accepted 20 September 2011
Available online 2 October 2011

Keywords:
Clinical research
Practice-based research networks
Environment and public health
Cancer
Community Clinical Oncology Program

ABSTRACT

Introduction: The National Cancer Institute's (NCI) Community Clinical Oncology Program (CCOP) contributes one third of NCI treatment trial enrollment ("accrual") and most cancer prevention and control (CP/C) trial enrollment. Prior research indicated that the local clinical environment influenced CCOP accrual performance during the 1990s. As the NCI seeks to improve the operations of the clinical trials system following critical reports by the Institute of Medicine and the NCI Operational Efficiency Working Group, the current relevance of the local environmental context on accrual performance is unknown.
Materials and methods: This longitudinal quasi-experimental study used panel data on 45 CCOPs nationally for years 2000–2007. Multivariable models examine organizational, research network, and environmental factors associated with accrual to treatment trials, CP/C trials, and trials overall.
Results: For total trial accrual and treatment trial accrual, the number of active CCOP physicians and the number of trials were associated with CCOP performance. Factors differ for CP/C trials. CCOPs in areas with fewer medical school-affiliated hospitals had greater treatment trial accrual.
Conclusions: Findings suggest a shift in the relevance of the clinical environment since the 1990s, as well as changes in CCOP structure associated with accrual performance. Rather than a limited number of physicians being responsible for the preponderance of trial accrual, there is a trend toward accrual among a larger number of physicians each accruing relatively fewer patients to trial. Understanding this dynamic in the context of CCOP efficiency may inform and strengthen CCOP organization and physician practice.

1. Introduction

We stand on the edge of a new era in cancer clinical research. Rapid advances in proteomics and genomics are reshaping not only the practice of clinical cancer care, but also clinical research itself [1]. Simultaneously, there is a new imperative on improving the efficiency and productivity of the national cancer clinical trials system. The Institute of Medicine (IOM) and the National Cancer Institute's (NCI's) Operational Efficiency Working Group (OEWG) have recently issued stark reports advocating for substantial change in the cancer clinical trials system, which has reached "a state of crisis [2–4]." Cancer research leaders recently reiterated this urgency at the NCI-American Society of Clinical Oncology (ASCO) symposium, and specifically emphasized better understanding of the drivers of research efficiency and productivity [5].

* Corresponding author at: Health Policy and Management, Campus Box 7411, 1102A McGavran-Greenberg Hall, Chapel Hill, NC 27599, USA. Tel.: +1 919 966 6328; fax: +1 919 493 8681.
E-mail address: wrc4@email.unc.edu (W.R. Carpenter).

1551-7144/$ – see front matter © 2011 Elsevier Inc. All rights reserved.
doi:10.1016/j.cct.2011.09.007

To date, the NCI Cooperative groups that develop and manage NCI clinical trials have been a focal point of emphasis, and the IOM and OEWG reports have catalyzed their massive reorganization, consolidating from 9 groups to 4 with substantial corresponding system changes [6]. However, 30% of NCI treatment trial accrual and nearly all of its cancer prevention and control (CP/C) trial accrual (over 28,000 accruals in 2007) comes from the NCI Community Clinical Oncology Program (CCOP). The CCOP is tightly connected to the Cooperative groups; however, it is still independent of them, and while efforts to restructure the cooperative groups will affect CCOPs, research shows that organizational characteristics and local market conditions significantly influence CCOP productivity. For example, studies of CCOP performance in the 1990s demonstrated that managed care penetration and hospital competition were relevant factors affecting trial accrual, and that accrual to treatment trials and CP/C trials were differently affected by not only these factors, but also CCOP organizational characteristics [7–9] (Fig. 1).

Much has changed since the 1990s. The clinical practice dynamic surrounding managed care is no longer what it was, and other factors have arisen and changed the clinical environment in which CCOPs operate. Among them, the Medicare Modernization Act of 2003 changed the reimbursement landscape substantially for cancer care, especially for chemotherapy, which is a dominant focus of investigation in NCI clinical trials [10,11]. These changes have spawned concerns regarding consequent changes in patient access and referral, which may also affect clinical trials participation [12]. As the nation engages in historic health care reform accompanied by substantial uncertainty [13,14], the current effect of the healthcare environment on NCI clinical trials is unknown.

This study reexamines the NCI CCOPs to inform and update our understanding of factors associated with trial enrollment and program sustainability. It employs a multilevel approach to examine factors associated with the CCOP, NCI research network, and local clinical care environment to understand factors associated with treatment trial accrual, CP/C trial accrual, and total trial accrual in the past 10 years. In doing so, this study addresses the calls from the IOM and NCI/ASCO to develop a better understanding of the drivers of clinical trial productivity and efficiency in the context of the clinical provider community in which cancer care is delivered.

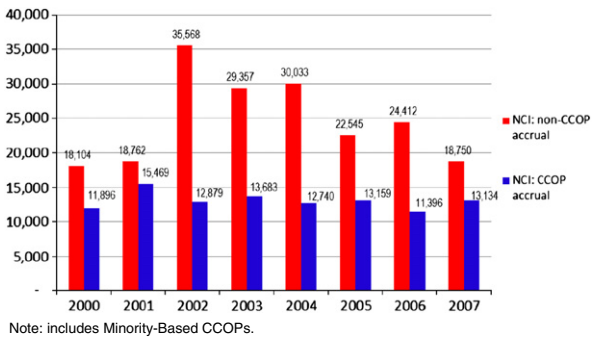

Fig. 1. Overall new accruals to NCI trials: NCI CCOP vs. NCI non-CCOP accrual, 2000–2007.

2. Materials and methods

2.1. The NCI CCOP Program

This study focuses on the NCI CCOP program, which has been described extensively elsewhere [1,15]. Briefly, the CCOP is a nationwide provider-based research network (PBRN) enabling community physicians to participate in NCI clinical research not only by enrolling patients in trials, but also by engaging them with academic researchers to contribute practice-based practical insight to collaboratively develop practical studies. The CCOP goals include not only enrolling patients onto trials, but also accelerating the use of evidence-based medicine in the community. Through first-hand participation in the clinical trials, community physicians practice the state-of-the-art science being investigated through the trial, and develop a sense of ownership and acceptance of study findings. This strengthens their likelihood of acting on the research findings and incorporating the evidence-based medicine into practice. Recent studies have validated this NCI goal, by showing that organizational participation in NCI clinical research is positively associated with adoption of state-of-the-art care [16–18] (Fig. 2).

2.2. Data and sample

This single-group, longitudinal quasi-experimental study used yearly panel data from 2000 to 2007 collected from CCOP progress reports and the NCI's *CCOP, MBCCOP, and Research Base Management System*. The unit of analysis was the CCOP. Because healthcare environmental data were measured at the metropolitan statistical area (MSA), we included all CCOPs that served at least one MSA and were active in the year 2000. This resulted in 45 CCOPs in the year 2000 decreasing to 41 CCOPs in 2007, for a total of 355 CCOP-year observations in the analytic sample.

Three dependent variables were separately examined as markers of CCOP performance: treatment trial accrual, CP/C trial accrual, and total trial accrual. Independent variables included CCOP characteristics, CCOP-Research Base (RB)[1] network characteristics, and environmental characteristics. Among CCOP characteristics, we examined the number of active and enrolling CCOP physicians, the number of CCOP components, the number of active institutional review boards (IRBs), and the number of CCOP or RB meetings attended by CCOP physicians or staff. A gini index was developed to enumerate each CCOP site's accrual as being concentrated among a few CCOP physicians, or more broadly and evenly distributed among multiple physicians. [19] This index was used to create a categorical variable indicating low, medium, and high physician accrual equity. The CCOP-RB network characteristics included the number of affiliated RBs and the number of treatment trials, CP/C trials, and total trials for which the CCOP had at least one accrual during the year.

To measure environmental characteristics, we used managed care penetration, hospital competition, and clinical trials competition. Using the InterStudy Competitive Edge Regional Market Analysis dataset, managed care penetration

[1] NCI Research Bases include the NCI Cooperative Groups and four other NCI affiliated organizations that develop and manage clinical trials conducted through the NCI research networks.