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# Achieving high cancer control trial enrollment in the community setting: An analysis of the Community Clinical Oncology Program

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ABSTRACT

Determining the factors that lead to successful enrollment of patients in cancer control clinical trials is essential as cancer patients are often burdened with side effects such as pain, nausea, and fatigue. One promising intervention for increasing enrollment in cancer control trials is the National Cancer Institute's Community Clinical Oncology Program (CCOP). In this article, we examined CCOP staffing, policies, and procedures associated with enrollment in control trials. Data were obtained from three sources: the online CCOP, MB-CCOP, and Research Base Management System, CCOP Annual Progress Reports, and a survey of CCOP Administrators conducted in 2011. We analyzed cancer control trial accrual in 2011 among 46 CCOPs using multivariate regression. Three factors were significant predictors of accrual. First, having a team of staff dedicated to enrolling patients in control and prevention trials, compared to having no dedicated staff, was associated on average with an additional 30 patients enrolled in control trials ($p<0.05$). Second, CCOPs that recognized physicians for enrolling a large number of patients compared to CCOPs that did not recognize high enrolling physicians enrolled on average an additional 25 patients in control trials ($p<0.05$). Lastly, the number of cancer control trials available was also associated with enrollment ($\beta=5.50$, $p<0.00$). Our results indicate that CCOPs looking to increase enrollment in control trials should consider dedicating a team of staff to enroll patients in these types of trials. In addition, CCOPs or other volunteer research systems looking to increase physician participation should consider recognizing high enrolling physicians.



## 1. Introduction

Despite evidence that clinical trials play a critical role in developing innovative treatments and in refining cancer prevention and control strategies, only 3–5% of adults with cancer in the United States participate in clinical trials [1]. One promising intervention for increasing participation in cancer clinical trials is the Community Clinical Oncology Program (CCOP). The CCOP network is a joint venture between the National Cancer Institute (NCI)'s Division of Cancer Prevention, which provides overall direction and funding, research bases, which design clinical trials, and community-based networks of providers (CCOPs), which assist with enrollment, data collection, and dissemination of study findings [2–8]. Although all three components of the network are critical to the success of the national program, the goal of this analysis is to identify the CCOP staffing, policies, and procedures associated with enrollment in NCI-sponsored cancer control trials. As defined by CCOP, *cancer control trials* test the effectiveness of symptom management, rehabilitation, and continuing care interventions to minimize cancer burden and improve quality of life [9].

*Abbreviations:* NCI, National Cancer Institute; CCOP, Community Clinical Oncology Program; MB-CCOP, Minority-based Community Clinical Oncology Program.

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Determining the factors that lead to successful enrollment of patients in cancer control trials is important for clinical care [10]. Among patients with advanced cancer, the majority experience moderate to severe pain, fatigue, anorexia, and/or nausea [11,12]. These side effects may persist even after active treatment ends. Efforts to improve side effects have not kept pace with efforts to develop innovative cancer treatments [13]. As the number of cancer survivors continues to grow, addressing the burden of cancer related side effects will continue to be important [13].

Understanding the factors that lead to successful enrollment of patients in control trials is also important for CCOP administrators. The landscape of available clinical trials is changing. In the past, CCOPs met a significant portion of NCI accrual expectations through large-scale cancer prevention trials [2]. For example, CCOPs overall provided approximately 30% of the enrollment in the Breast Cancer Prevention and the Selenium and Vitamin E Cancer Prevention trials [2]. As the number and scale of prevention trials decrease, there is an increasing need to meet accrual expectations through enrollment in cancer control clinical trials.

Prior research of cancer control trial accrual in the CCOP network has examined control and prevention trial enrollment together [3–6]. Quantitative analyses have focused on fixed organizational structural and environmental factors that contribute to enrollment [3,4]. CCOP administrators, however, are unable to modify these factors to increase enrollment in clinical trials. There have also been a number of case studies of successful CCOPs [5,6]. These studies tend to focus on prevention enrollment. Although some of the strategies also apply to control trials (e.g., dedicated research staff), others are not as relevant (e.g., mass media campaigns) [5].

In this article, we examine modifiable CCOP staffing, operational policies, and procedures to determine their effect on enrollment in cancer control trials. We believe our results are relevant beyond CCOPs to other clinical research programs conducted within community settings. Our findings are particularly applicable for volunteer research programs hoping to encourage physician participation in clinical research.

## 2. Materials and methods

### 2.1. Study setting and population

The study population is the NCI CCOP network. As of November 2012, 47 CCOPs and 17 Minority-based CCOPs (MB-CCOPs) operated in 35 states and Puerto Rico. MB-CCOPs primarily focus on enrolling minority patients into NCI-sponsored clinical trials. MB-CCOPs also tend to be located primarily at academic medical centers or universities, whereas university hospitals may be part of some CCOPs, they cannot be the lead organization. Therefore, MB-CCOPs also tend to be located in more urban areas than participating CCOPs, which focus on enrolling patients in a local or community setting. We had to exclude MB-CCOPs from this analysis, as T-tests and Chi $X^2$ tests demonstrated that they are systematically different than the CCOPs. For example, CCOPs on average enrolled over 108 patients to cancer control trials while MB-CCOPs only enrolled 37 patients. In addition, the number of available cancer control trials was on average 21 trials for CCOPs, but only 10 trials on average for MB-CCOPs. Both differences were statistically significant. Thus, we did not feel comfortable combining both CCOPs and MB-CCOPs in a single analysis.

The specific sample for this study includes 46 CCOPs, as an additional CCOP joined the program after the data was collected. In total, the CCOP network includes over 450 hospitals and physician practices, with the average CCOP composed of about 10 hospitals or practice sites. CCOPs also include over 2000 physicians, with the average CCOP composed of 48 physicians.

### 2.2. Study design and data sources

The study used a cross-sectional design with the CCOP as the unit of analysis. We obtained data from three sources. The online CCOP, MB-CCOP, and Research Base Management System, maintained by NCI Division of Cancer Prevention, provided data on CCOPs' 2011 menu of NCI-sponsored cancer control trials and CCOPs' 2011 patient enrollment into those trials. Second, the progress reports that CCOPs submit annually to NCI provided data on the CCOP's cancer patient volume. The progress reports covered the nine-month period from June 2010 through February 2011. Finally, a survey of CCOP Administrators conducted in the fall of 2011, provided data on the total number of CCOP staff (including CCOP-funded and non-CCOP funded staffs) in 2011, cancer control and prevention dedicated staff in 2011, and whether the CCOP recognizes physicians for enrolling patients and/or expects physicians to enroll a certain number of patients per year. The goal of the survey was to learn more about how the CCOPs are organized and how they operate. The survey specifically addressed CCOP organizational structure, sponsored educational trainings, physician resources and support for screening, consenting, and enrolling patients, as well as CCOP staffing procedures. The survey was designed and administrated with the support of NCI Division of Cancer Prevention officials. Although the time periods covered by the three data sources do not overlap perfectly, the CCOP features examined in this study exhibit only small fluctuations from year to year.

### 2.3. Measures

The study's outcome was patient enrollment (i.e., accrual) in NCI-sponsored *cancer control trials* in 2011. We did not include accrual into cancer prevention trials. Given that the goal of this article was to determine CCOP staffing, organizational policies, and procedures that influence cancer control trial enrollment, we selected two sets of factors that we felt CCOP administrators could modify and would influence future planning and CCOP operations.

The first factor characterizes the CCOP's staffing arrangement and included two measures: (1) *Number of CCOP research staff in 2011*, defined as the number of non-physician personnel supported by CCOP research grants and the number of staff who worked on NCI CCOP trials that were not supported by CCOP funds (e.g., whose salaries were covered by participating hospitals); and (2) *Number of CCOP research staff dedicated to control and prevention trials* who focused on enrollment in NCI-sponsored cancer control and prevention trials in 2011. We were unable to distinguish cancer control dedicated staffs from those who focused on prevention. Given that the average enrollment in cancer prevention trials was only nine patients