

## Using a Community Cancer Treatment Trials Network for Cancer Prevention and Control Research: Challenges and Opportunities

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### Abstract

Using data collected as part of a larger evaluation of the National Cancer Institute-funded Community Clinical Oncology Program (CCOP), this paper examines the degree to which selected community, interorganizational, and structural characteristics associated with accrual to cancer treatment protocols share equal importance in accruing patients to cancer prevention and control research protocols. Analysis reveals that there are similarities in the factors that prove to be effective for accrual to both types of protocols; however, the two are not isomorphic. CCOP structure was an important predictor of treatment accrual but was not significant for cancer control accrual. Variables measuring the community health resources available to the CCOP were not significant for either treatment or cancer prevention and control research accrual when CCOP structure and interaction with participating research bases were considered. Only CCOP interaction with participating research bases was a significant predictor of both treatment and cancer prevention and control research accrual. The policy implications of these findings are discussed.

### Introduction

Within the world of clinical oncology, randomized clinical trials are highly regarded as the preferred approach to assessing available technology. Increasingly, this approach is part of a larger clinical trials network which may influence the ability to accrue patients to particular type trials. Unfortunately, a clinical network designed to evaluate one type of technology may not be equally effective in evaluating other types of technologies. As Ashby (1) described many years ago, "There is no such thing as a 'good organization' in any absolute sense. Always it is relative and an organization that is good in one context or under one set of criteria may be bad under another."

Perhaps this is best illustrated in community oncology where increasing emphasis is moving from cancer treatment to prevention and control (2). The development of cancer prevention and control trials represents a significant departure from previous activities which focused on research involving single patients being treated for cancer. Cancer prevention and control research are oriented to behavioral and chemoprevention activities involving populations and requiring access to healthy individuals. The purpose of this paper is to assess the degree to which selected environmental and organizational characteristics of a clinical trials network which demonstrated an ability to accrue patients to treatment protocols are equally important for assuring accrual to cancer prevention and control protocols.

### Cancer Prevention and Control within a Community Trials Network: The Community Clinical Oncology Program.

The implementation of cancer prevention and control research through an existing clinical trials program provides an opportunity to test whether a trials network proven effective to test cancer therapy would be equally effective in conducting large scale cancer prevention and control trials. Initiated in 1983, the CCOP<sup>2</sup> was designed to "bring the benefits of clinical research to cancer patients in their local communities" (3). Although this initial effort focused on treatment trials, in 1987 the NCI mandated that its CCOP establish a large-scale prevention and control effort involving community physicians as part of the NCI's clinical trials program (4).

The CCOP is a federally funded research alliance designed to increase community participation in NCI-approved clinical trials and involves three major components: the individual CCOPs, the designated research bases, and the NCI/DCPC. Each component has an important long-term complementary role to play in the overall mission of assuring availability of state-of-the-art cancer care in local communities (5).

At the community level, a CCOP is a working group of hospitals, physicians, and support staff that can range from as few as two physicians and staff affiliated with a single hospital and office to as many as 50 physicians and staff affiliated with many hospitals, health maintenance organizations, and offices within the community. Each CCOP is led by a clinician-principal investigator responsible for its performance. The primary function of the community CCOP is to accrue patients to cancer treatment and control protocols developed by the research bases and approved by the NCI.

Research bases, as the second component in the alliance, are NCI-funded cooperative research groups and core

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<sup>2</sup> The abbreviations used are: CCOP, Community Clinical Oncology Program; NCI, National Cancer Institute; DCPC, Division of Cancer Prevention and Control; ACOS, American College of Surgeons.

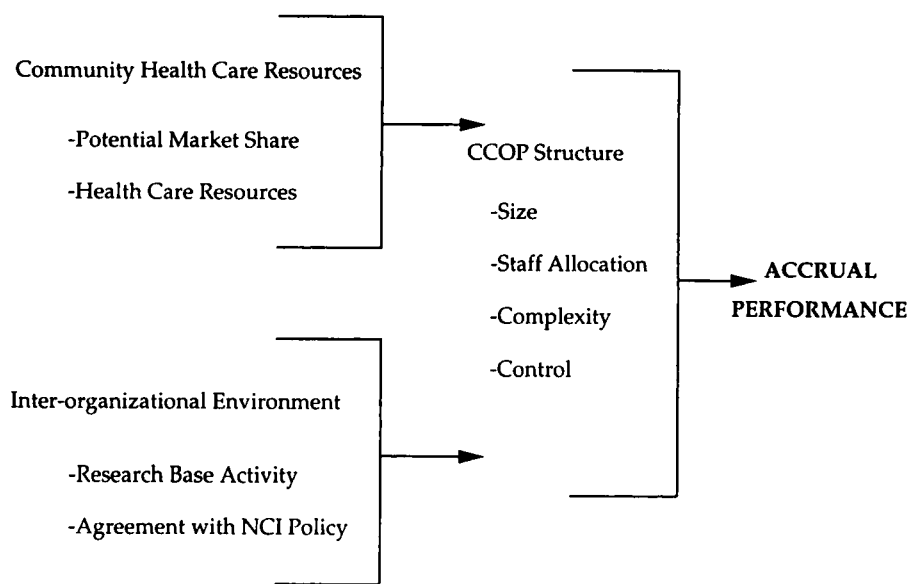


Fig. 1. CCOP community, interorganizational, and structure affecting performance.

grant-supported cancer centers. They are responsible for the design of clinical trial protocols, the collection and analyzing of study data, and monitoring of the data quality and patient accrual performance of the CCOPs. NCI management policy allowed each CCOP to be affiliated with up to five eligible research bases, only one of which could be a national multispecialty cooperative group.

The DCPC is a constituent part of the NCI, one of the institutes of the NIH. The division is responsible for overseeing the CCOPs through its Community Oncology and Rehabilitation Branch. The DCPC cooperates with the Division of Cancer Treatment in the protocol approval process, and with other committees and units of the institute that oversee the quality and accountability of patient care for NCI-approved studies.

Originally conceived as a vehicle to facilitate the diffusion of cancer treatment technology to local communities, in 1987 the program assumed a broader mandate, including: (a) to bring the advantages of cancer control research as well as treatment to individuals in their own communities by having practicing physicians and their patients participate in both clinical treatment and cancer control research protocols; (b) to increase the involvement of primary health care providers and other specialists such as surgeons, urologists, gynecologists, and primary care physicians; and (c) to reduce cancer mortality by accelerating the transfer of newly developed cancer prevention, detection, treatment, and continuing care technologies to widespread community application.

This expansion of the program into cancer control research trials represents a significant departure from previous activities which were focused on treatment research involving patients being treated for cancer. Cancer control research is defined as the reduction of cancer incidence, morbidity, and mortality through an orderly sequence from research on interventions and their impact in defined populations to the broad, systematic application of the research results and includes research on cancer prevention and early detection (6).

**Analytical Framework.** Three separate perspectives are critical to understanding the factors affecting accrual per-

formance: the structure of the CCOPs; the community within which it functions, and the interorganizational relationships among the components of the program in the NCI, research bases, and CCOPs. The structural perspective focuses on the configuration of the CCOP, predicting that high performance will occur where there is an appropriate fit between the nature of the task performed by the CCOP and the structural characteristics of the CCOP. The interorganizational environment focuses on activity among the various programmatic components: the NCI, participating research bases, and the local CCOPs. Finally, the character of the community in which the CCOP is located provides the necessary patients and resources for assuring performance. Fig. 1 presents a schematic outline of these major variable sets.

Previous analysis suggests that selected environmental and structural characteristics are important complementary factors influencing accrual to treatment protocols (7, 8). Specifically, when the resources of the community in which the CCOP is located are held constant, then the interorganizational factors (as measured by the number of CCOP nurses attending research base meetings), the structure of the CCOP (as measured by the number of components participating in the CCOP), and staff allocation (as measured by the total number of h/week worked by data managers in a CCOP) are major predictors of treatment accrual. Our objective is to determine whether these characteristics that are proven to be important in predicting treatment accrual are equally important to assuring cancer control research accrual.

### Materials and Methods

Data for this analysis is based on a larger evaluation of the CCOP Phase II, conducted by the Shep's Center for Health Services Research at the University of North Carolina, and its subcontractor, the Survey Research Laboratory of the University of Illinois, Chicago, under a contract from the NCI/DCPC (9). The data used here was gathered from CCOP grant applications, annual progress reports, and on-going monitoring efforts of patient accrual by the NCI on 50 CCOPs and 17 research bases. Our methodological approach assesses the relative contribution of selected community character-

istics within which the CCOP is located, the interorganizational relationships, and the structure of the CCOP itself characterizing the CCOP, NCI, and participating research bases relative to treatment and cancer control research accrual. Appendix A presents the means, SDs, and Pearson correlation coefficients for all independent and dependent variables.

### Measuring CCOP Performance

A key indicator of individual CCOP performance is the ability to recruit and enroll patients on NCI-approved cancer treatment and cancer control research trials. Appendix B presents an illustrative list of treatment and cancer control protocols in use during the evaluation period. The exact number of protocols used by CCOPs was a function of CCOP adoption policies, activation, and close dates. However, during this period, CCOP had access to a total of 832 protocols, of which 722 were classified as treatment, 87 cancer control, and 23 both treatment and cancer control.

For each patient enrolled on a particular trial protocol, a weight or credit was assigned by the NCI. This credit weight was determined by the NCI/DCPC and Division of Cancer Treatment at the time a protocol was initially reviewed for approval. Accrual credit values were based on the complexity of the protocol and the level of resource intensity expected to be required of the CCOPs to accrue patients. Typically, treatment-related credits averaged 1.09 credits/patient enrolled, but ranged from 0.7 to 2.0 credits/patient. Cancer control research credits averaged only 0.2 credits/patient enrolled, but ranged from 0.1 to 1.0 credits/patient.

The measures of performance used in the following analysis are aggregations of all accrual credits earned/CCOP for patient enrollment on cancer treatment and control research protocols during the operational period of the CCOP Phase II program (June, 1987 through May, 1990). Aggregated accrual credit totals provide concise measures of overall program performance by the CCOP organizations.

Since the number of cancer control protocols available to the CCOPs varied over the study period, our analysis controlled for their availability. Data on cancer control protocol availability was gathered from CCOP annual reports and aggregated to create a measure consistent with our aggregate credit performance variable. The measure is an indicator of the number of cancer control protocols that each CCOP had available for their participation.

### Community Health Care Resources Environment

The local health care environment provides the patients, personnel, and facilities needed by the participating CCOPs. Specifically, accrual to protocols requires a population base sufficiently large to provide eligible patients for recruitment to protocols. The number of patients that the CCOP can expect to have access to, given the presence of alternative treatment sources, is their potential market share. Equally important is the recognition that state-of-the-art medicine cannot be practiced without an infrastructure that provides at least a minimal set of health care resources necessary to support the required activities of the CCOP. Indicators were developed for each of the following community factors.

**Potential Market Share.** The amount of the patient market potentially controlled by the CCOP is a multiplicative measure resulting from the overlap of the service area patient population and the extent to which the CCOP has penetrated

the local cancer care hospital facilities. The specific elements in the measure are the number of new cancer cases in the service area in 1986 multiplied by the proportion of short-term hospital beds in ACOS-accredited<sup>1</sup> service area hospitals that are formally affiliated with the CCOP (e.g., market penetration). ACOS accreditation was used to identify those community hospitals likely to be actively involved in cancer care. Data on ACOS hospital facilities was obtained from the American Hospital Association Guide (10). Three CCOPs were located in areas in which none of the community hospitals had ACOS accreditation and in these cases our indicator was based on the proportion of all short-term hospital beds in the service area which had a formal affiliation with the CCOP.

**Health Care Resources.** Our indicator of resources is an additive population and distribution-scaled index of population density, medical personnel (i.e., nurses), and medical facilities (i.e., medical schools and short-term general hospitals) in the service area. County level data on the index measures were taken from the Bureau of Health Professions Area Resource File and aggregated and/or averaged over the respective service areas.

### Interorganizational Environment

The relationship of the CCOP to the NCI and research bases provide a link to the larger research community. This linkage sets the rules, requirements, and expectations to which individual CCOPs must conform (11–13). Two indicators were developed.

**Research Base Activity.** The exchange between research bases and CCOPs goes beyond the flow of protocols and the accrual of patients. The exchange requires the involvement of personnel which, in the case of CCOPs, involves physicians, nurses, and data managers participating in ongoing activities at the research base, thus enhancing the mutual involvement with and commitment to the larger enterprise (7, 8). CCOPs may influence or be influenced by research base decisions or actions through participation in meetings, the chairing of scientific committees and/or protocols, and the co-authoring of publications by CCOP and research base personnel. The activity level of nurses was chosen as an indicator of CCOP-research base interaction because of the critical role nurses play in identifying potential enrollees and alerting physicians to appropriate available protocols.<sup>4</sup> CCOP-research base activity is measured by the total number of CCOP nurses attending one or more research base meetings in a given year. Data are taken from the CCOP annual reports.

**Agreement with NCI Policy.** The NCI is the third component in the CCOP trials network. Its primary function is to oversee the administration of the program and establish specific policies and guidelines for operation. Although there is considerable autonomy among the participating research

<sup>1</sup> The ACOS, through its Commission on Cancer, "approves" of organized cancer programs which stress the importance of multidisciplinary cancer conferences and accurate recording of diagnostic and treatment data in a cancer registry for evaluation. We chose to limit this measure to those hospitals with ACOS accreditation because it provided a means of identifying those community hospitals that actively promote their cancer care centers, thus better specifying the potential competitors to the CCOP.

<sup>4</sup> Physician involvement in research base activities also was tested in this model. It had a positive association with CCOP performance but was a slightly weaker predictor.

bases and CCOPs, NCI presents a set of expectations which directly affect the program through regulations, rules, and operating policy. The extent to which the attitudes and goals of CCOP personnel are in line with NCI's program goals may legitimize the activities of the CCOP and thereby facilitate its activities (14). Disagreement over program goals and/or management policy may interfere with the process of protocol accrual. Our indicator is an additive index of the level of agreement with general NCI program policy and administration. Data for this item comes from five related questions in the Key Informant Survey.

### CCOP Structure

Within the study of health service organizations, structure is considered to be an important component of professional behavior. It provides the basic mechanics for meeting goals and accomplishing tasks. Since our objective was to explain accrual performance, we focused on dimensions of CCOP structure that had the capacity to influence the accrual process. These dimensions of structure include size, staff allocation, complexity, and control.

Size has often been considered a dimension of structure (15, 16) but also is recognized as a surrogate for resource availability (17, 18). The availability of organizational resources facilitates accrual and thus is an important factor affecting accrual performance. Staff allocation refers to the ability of the CCOP to allocate resources to meet the specific task requirements involved in the accrual process. Accrual of patients to protocol generates a significant data burden for the group, requiring that personnel trained in this activity are available and committed to the accrual process. Our indicator of staff allocation is also an indirect measure of size, at least of the size of specialized staff dedicated to a particular organizational position.

Complexity and control are structural complements. Complexity provides a diversity required by the CCOP to maximize accrual performance. However, the benefits of complexity are best realized when matched by adequate levels of managerial control. Control provides the mechanism to integrate these resources, thereby maximizing accrual performance. Indicators for each of these structural characteristics are presented below.

**Organizational Size.** Size is often considered a major determinant of organizational structure and influences performance through "economies of scale." However, a close examination of literature on size (17–19) suggests that much of the impact of size may be spurious, and in fact, may not be a logical necessity related to various indicators of performance. CCOP size is measured by the number of hospital and group practice components formally participating in the CCOP.

**Staff Allocation.** The allocation of organizational personnel to specific tasks is an important component of program performance. Having sufficient personnel in appropriate staff positions should influence the ability of the organization to maximize accrual. Critical to CCOP performance is the utilization of data managers for clinical trial task activities. Data managers are responsible for interfacing with the research bases in the process of patient enrollment and for keeping accurate records of patient treatment required by the research base protocols. The measure of staff allocation used was an estimation of the total number of h/week worked by data managers in a CCOP.

**Organizational Complexity.** As part of a larger clinical trials network, CCOPs had the opportunity to affiliate with up to five eligible research bases, only one of which could be a national multispecialty cooperative group. Since each group has a different set of rules and expectations, the number of groups involved with each CCOP reflects the complexity that affects both the management of the CCOP and its ability to accrue patients. Our indicator of complexity is the number of research base affiliations a particular CCOP had early in the program.

**Managerial Control.** The greater the complexity of organizations, the greater the challenge to integrate these various components to achieve accrual performance. Within a consortium organization such as a CCOP, such integration usually occurs through the strong leadership of one individual or a small group of individuals. This type of leadership usually is accomplished by centralizing the power for policy making in that individual or group. Our measure of centralization refers to the degree of control top management exercises over the decisions and daily activities of the organization. This measure was constructed by subtracting the average perceived influence of hospital administrators, physicians, and staff personnel from the influence exercised by the principal investigator. This type of variable construction is consistent with Smith and Tannenbaum's "control graph" technique (20). The larger the magnitude of this difference, the greater the principal investigator's relative influence and, therefore, the greater the centralization of decision making within the CCOP. Information on the influence of CCOP participants on various organizational decisions came from items on the first Key Informant Survey.

## Results

**Treatment versus Cancer Control Research Accrual.** Figs. 2 and 3 present the aggregate treatment and cancer control credit accrual for each of the participating CCOPs. As seen in Fig. 2, aggregate treatment accrual ranged from 88.8 to 636.7 credits for the entire program period. The mean value for aggregate accrual to treatment protocols was 274.0 credits. The sum of treatment credits earned across the 50 CCOPs in the sample during this period was 13,700.6.

Fig. 3 presents the distribution of aggregate cancer control credits for each of the participating CCOPs. Aggregate credit values ranged from 3.9 to 145.6 total cancer credits over the 3-year period. The mean value for aggregate cancer control credits was 41.2, with a sum total of 2058.4 across the 50 CCOPs in the sample.

Clearly, credits earned by treatment protocols exceeded those earned by cancer control protocols. In large part this is due to the imbalance in the credit-weight/patient assigned to the two types of protocols. Across all CCOPs in the sample the average credit-weight/patient in treatment protocols was 1.09, in cancer control protocols, 0.17.<sup>5</sup>

**Comparing Predictors.** Table 1 presents the simultaneous effects of community resources, interorganizational characteristics, and CCOP structure on treatment accrual. As seen, our indicator of interorganizational activity between the

<sup>5</sup> This number includes an averaging of the credit:patient ratio involved in cancer control protocols which had a credit ceiling, regardless of number of patients enrolled.

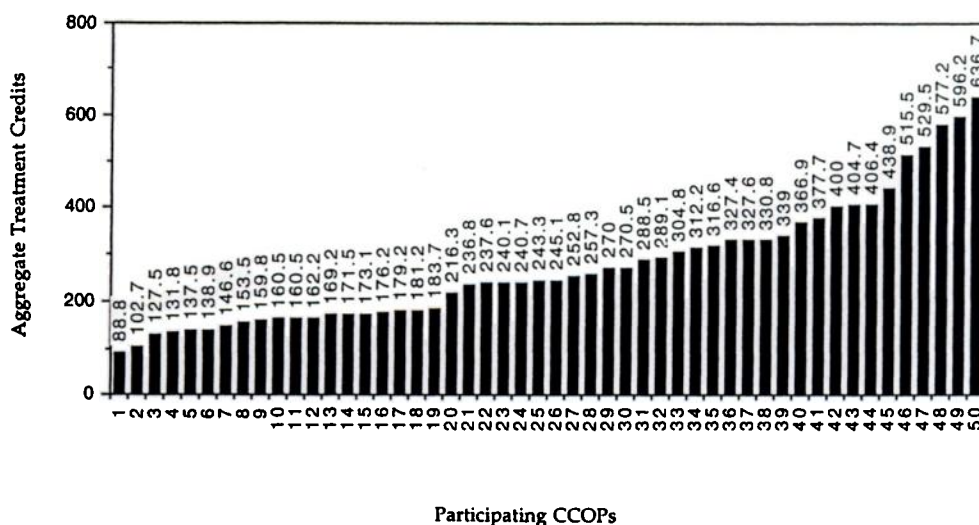


Fig. 2. Distribution of aggregated treatment totals by participating CCOP, summed across all program years (year 4 + 5 + 6).

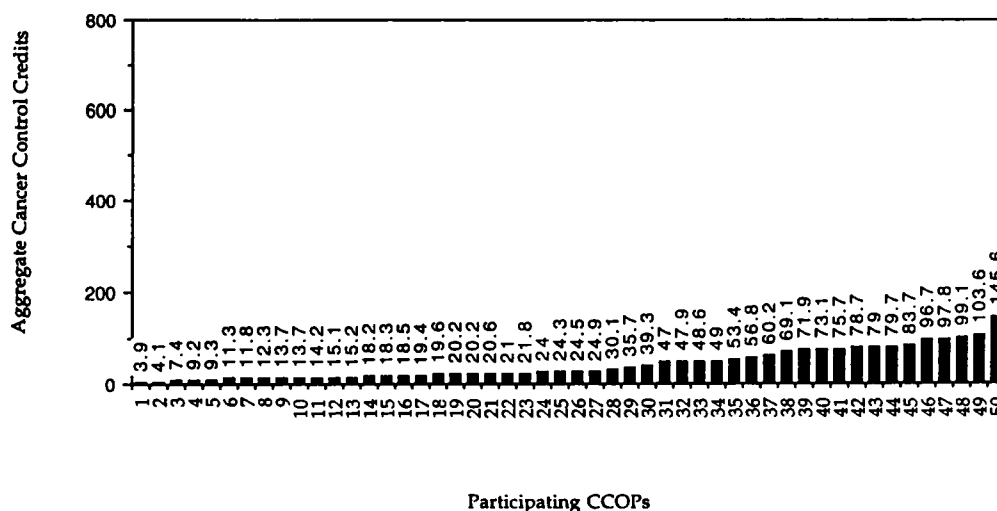


Fig. 3. Distribution of aggregated cancer control credit totals by participating CCOP, summed across all program years (year 4 + 5 + 6).

CCOP and research base, *i.e.*, attendance of nurses at research base meetings, along with two structural characteristics of the CCOP, *i.e.*, organizational size (as measured by the number of components within a CCOP) and staff allocation (as measured by the number of hours/week worked by data managers), are important predictors of accrual controlling for characteristics of the community. Are these same factors equally important for predicting cancer control research accrual?

Table 2 presents the relationship of cancer control accrual to our indicators of the resources in the local community, interorganizational activity, and CCOP structure that were important to treatment accrual. As can be seen from the table, only our measures of interorganizational activity are important predictors of both treatment and cancer control research when controlling for all other factors. Spe-

cifically, our analysis reveals that, on the average, a CCOP which sent one additional nurse to research base meetings had an aggregated credit total cancer control of 3.56 credits higher than a CCOP which sent one fewer nurse to research base meetings. In addition, those CCOPs with high levels of agreement with NCI general program policy also, on average, had higher cancer control credits over the program period. Although nurse attendance at the research base meeting was important for both treatment and cancer control accord, attitudes toward NCI policy is important only for accrual to cancer control.

Variables measuring the community health care resources did not prove to be significant for either treatment or cancer control when interorganizational activity and structure also were considered. Equally important is the finding that CCOP structure, an important predictor of aggre-

Table 1 Predicting treatment credit performance with CCOP community, interorganizational, and structural characteristics

Characteristics	Aggregate treatment credit totals	
	b <sup>a</sup>	P
Intercept term	52.27	0.4815
Community health care resources		
Potential market share	-0.01	0.3400
Resource index	-3.22	1.2857
Interorganizational environment		
Research base activity	17.60	0.0001
Index of agreement with NCI policy	-2.46	0.5308
CCOP organizational structure		
Organizational size	11.99	0.0025
Staff allocation	1.08	0.0001
Organizational complexity	14.07	0.2386
Managerial control	40.16	0.0531
	Total model R <sup>2</sup> = 0.7786 <sup>b</sup>	
	Adjusted model R <sup>2</sup> = 0.7354	P = 0.0001

<sup>a</sup> b, unstandardized regression coefficients.

<sup>b</sup> R<sup>2</sup>, coefficient of determination.

Table 2 Predicting cancer control credit performance with CCOP community, interorganizational, and structural characteristics

Characteristics	Aggregate cancer control credit totals	
	b <sup>a</sup>	P
Intercept term	-45.34	0.1420
Community health care resources		
Potential market share	0.01	0.3335
Resource index	0.40	0.7486
Interorganizational environment		
Research base activity	3.56	0.0029
Index of agreement with NCI policy	3.43	0.0381
CCOP organizational structure		
Organizational size	-1.42	0.3577
Staff allocation	0.08	0.4600
Organizational complexity	4.25	0.3856
Managerial control	-2.00	0.8109
	Total model R <sup>2</sup> = 0.3912 <sup>b</sup>	
	Adjusted model R <sup>2</sup> = 0.2724	P = 0.0054

<sup>a</sup> b, unstandardized regression coefficients.

<sup>b</sup> R<sup>2</sup>, coefficient of determination.

gated treatment accrual, was not a significant predictor of aggregated cancer control research credits. Comparing factors affecting treatment and cancer control accrual thus suggests that aside from interactions with research bases, a different set of variables are critical predictors of cancer control accrual.

When considering the relative contribution of each of these variable sets, one needs to consider the percentage of variance explained. As seen in Table 1, the analysis is able to explain approximately 74% of the total variance in aggregate treatment accrual credits. Extending this same model to cancer control accrual reveals that the model explains only approximately 27% of the variance.

Table 3 presents the relationship of cancer control accrual to our indicators of community resources, interorganizational activity, and structure controlling for the number of cancer prevention and control protocols available to the CCOP. Protocol availability has a significant and positive effect on accrual, indicating that on the average, a CCOP having one additional protocol had an aggregate cancer

control credit total 1.62 higher than a CCOP that had one less protocol available. Moreover, the presence of protocol availability as a factor attenuated the contribution of agreement with NCI policy. Comparing the overall contribution of variables controlling for protocol availability revealed that protocol availability was able to increase the total variance explained in aggregated cancer control accrual from 27 to 40% of the variance. However, even with this improvement in the model specifications, the predictive power of the model is much less for cancer control than it is for treatment performance.

## Discussion

The underlying hypothesis for analysis was that the CCOP organizational structure and its relationship to relevant environments, which had been proven effective for accruing patients to treatment protocols, would be equally effective for cancer control research. Our analysis suggests that although there are similarities, they are not identical. Instead,

Table 3 Comparing the effects of protocol availability on a model predicting cancer control credit performance using CCOP community, interorganizational, and structural characteristics

Characteristics	Aggregate cancer control credit totals	
	b <sup>a</sup>	P
Intercept term	-44.18	0.1140
Protocol availability		
Total cancer control protocols available	1.62	0.0026
Community health care resources		
Potential market share	0.00	0.3385
Resource index	0.38	0.7326
Interorganizational environment		
Research base activity	3.60	0.0010
Index of agreement with NCI policy	2.34	0.1231
CCOP organizational structure		
Organizational size	-1.17	0.4019
Staff allocation	0.07	0.4210
Organizational complexity	-1.32	0.7796
Managerial control	-3.08	0.6836
	Total model R <sup>2</sup> = 0.5158 <sup>b</sup>	
	Adjusted model R <sup>2</sup> = 0.4068	P = 0.0003

<sup>a</sup> b, unstandardized regression coefficients.

<sup>b</sup> R<sup>2</sup>, coefficient of determination.

it appears that cancer control research presents a different organizational challenge and that a different set of factors influence the cancer control accrual process. Specifically, cancer control research is, by definition, more oriented to prevention and behavioral interventions than to the direct treatment of cancer patients and represents a more "dynamic technology," that is, a technology that is not fully formed in terms of definition, scientific legitimacy, and implementation procedures (21, 22). As a dynamic technology, accrual may be influenced by ambiguity over what constitutes cancer prevention and control, *i.e.*, differing interpretations of the science required and the uncertainty involved in assessing population groups outside the usual medical setting. Thus, those who predict accrual to cancer prevention and control may need to consider the flow of information about cancer prevention and control, prevailing values, and larger environmental factors such as access to patients not normally seen by medical oncologists.

The fundamental structure and internal processes of the CCOP must therefore accommodate the dynamic character of cancer prevention and control research. Unlike accrual to treatment protocols, where the participating oncologists have ready access to patients that are potentially eligible for various protocols, oncologists may not have direct access to many of the subjects eligible for cancer prevention and control protocols. Thus, cancer prevention and control protocols are likely to be influenced by the linkage of primary care physicians within the community. Also, the multidimensional nature of cancer prevention and control requires special attention. Many prevention protocols involve behavioral intervention such as diet and smoking cessation requiring a different set of disciplinary skills therefore placing a premium on the ability of the CCOP to maintain communications among a diverse set of clinicians and other types of health care practitioners. This broadening of the clinical perspective has placed a premium on interdisciplinary activities involving various types of clinicians within the community and also on the set of organizational mechanisms that assure the integration of various perspectives within the CCOP itself. Unlike treatment activity which has been the primary focus of CCOP to date, successful accrual

to cancer control protocols requires considerable leadership on the part of the NCI, research bases, and participating CCOPs. Specifically, the NCI needs to provide a clear and sustained mandate for cancer control, the research bases need to develop appropriate protocols as well as perhaps provide technical assistance and a forum whereby CCOPs can exchange information and/or strategies for meeting the challenges of prevention and control, and the CCOP and particularly the principal investigator need to build and integrate the interdisciplinary staff required to implement community- and population-based cancer control protocols.

An additional avenue of exploration is to explicitly consider the attributes of cancer control research protocols as a factor affecting accrual (23). Cancer control research represents a multidimensional continuum involving protocols which may in fact be quite similar to treatment type protocols and others which are fundamentally different in terms of scope, population, and so forth. Further analysis is required to differentiate the accrual process for cancer control research protocols. It is quite likely that when cancer control protocols have similar characteristics to treatment protocols, the same factors which predict treatment accrual would in fact predict cancer control accrual. For example, the same factors which proved predictive of accrual to treatment protocols may be predictive of symptom control or chemoprevention protocols such as Tamoxifen or Finasteride but not prevention-behavioral type protocols. Cancer control research protocols which have a dissimilar set of characteristics from treatment may require a different organizational mechanism for facilitating accrual.

Randomized clinical trials for technology assessment require that consideration be given to the very nature and requirements of the technology being assessed. These characteristics need to be reflected in the organizational mechanism established to conduct the trial. Given the expanding technology, particularly in the area of cancer prevention and control, future analysis needs to prospectively assess those factors likely to effect accrual to cancer prevention and control protocols.

Appendix A Means, SDs, and correlation matrix for all independent and dependent variables (n = 50)

	Mean (SD)	1	2	3	4	5	6	7	8	9	10	11
Health care resources												
1. Market share of potential patients in the CCOP service area	1525.7 (953.9)	1										
2. Index of health services resources in the CCOP service area	10.4 (3.5)	-0.03	1									
Health policy environment												
3. No. of CCOP nurses participating in research base activities	4.54 (4.2)	0.34	0.20	1								
4. Index of CCOP agreement with NCI program policy	13.6 (2.7)	-0.15	-0.11	0.02	1							
CCOP structure												
5. No. of hospital and group practice components	4.2 (3.5)	0.62	0.17	0.3	-0.11	1						
6. Total no. of data manager h/week	77.1 (44.0)	0.09	-0.03	0.19	0.21	0.20	1					
7. Total no. of research base affiliations/CCOP	3.2 (0.9)	-0.01	0.10	0.21	0.07	-0.02	0.31	1				
8. Index of centralized decision making in the PI	1.3 (0.5)	-0.05	0.08	0.25	0.26	-0.04	0.02	-0.01	1			
Access to cancer control protocols												
9. Total No. of CC protocols available to a CCOP	20.3 (8.1)	-0.04	<0.01	0.08	0.26	-0.08	0.16	0.40	0.10	1		
10. Aggregated treatment credits	274 (133.1)	0.32	0.1	0.73	0.07	0.48	0.54	0.31	0.27	0.24	1	
11. Aggregated cancer control credits	41.2 (33.0)	0.18	0.08	0.51	0.3	0.08	0.26	0.27	0.16	0.40	0.52	1

Appendix B Illustrative cancer control and treatment protocols available during study period

## Cancer control protocols

## CALGB-8561

Retrospective assessment of psychosocial sequelae in long-term survivors of advanced Hodgkin's disease.

## ECOG-C0387

Hematuria home screening using urinary dipsticks in men age 50 and over. An ECOG Pilot Study.

## ECCC-C880008

Brief physician-delivered quit smoking strategies for community clinical oncology settings.

## MDA-C880005

Randomized phase III cancer control protocol to assess compliance with protocol-directed breast screening vs. conventional advice in the early detection of familial breast cancer.

## MDA-C880009

Pilot study to test the feasibility of performing a chemoprevention trial of  $\alpha$ -tocopherol in oral leukoplakia in community clinical oncology programs (CCOPs).

## MINN-C880006

Smoking cessation protocol for primary care physicians' offices.

## NCCTG-844651

Hemoquant detection of colorectal neoplasia.

## NCCTG-868451

Controlled evaluations of sustained release oral morphine for the relief of cancer pain.

## SWOG-8711

A study of reproductive function in patients with testicular cancer.

## URCC-C870005

Managing chemotherapy side effects.

## Cancer treatment protocols

## CALGB-8513

Phase III trial of intensive treatment for adult acute lymphocytic leukemia: a comparison of combination chemotherapy plus alternating mitoxantrone and daunorubicin vs. combination chemotherapy plus daunorubicin.

## ECOG-1180

Evaluation of adjuvant therapy and biological parameters in node-negative operable female breast cancer.

## ECOG-4186

Combined modality therapy for breast carcinoma, phase III.

## NCCTG-874652

Evaluation of a somatostatin analogue in the therapy of advanced colorectal cancer: a phase III study.

## NCCTG-872451

Phase III study in the treatment of extensive non-small cell lung cancer: a controlled evaluation of a new approach to combined etoposide and cisplatin therapy.



## Appendix B (cont'd)

NSABP-B17	Clinical trial to evaluate natural history and treatment of patients with noninvasive intraductal carcinoma and lobular <i>in situ</i> registry.
NSABP-B20	Clinical trial to compare tamoxifen with sequential methotrexate, 5-fluorouracil and TAM, or CMF and TAM in patients with primary breast cancer, negative axillary nodes, and estrogen receptor-positive tumors.
POG-8104	Comprehensive care of the child with neuroblastoma: stage- and age-oriented study.
RTOG-8107	Radiotherapy with and without chemotherapy for malignant pleural mesothelioma localized to one hemithorax, phase III intergroup mesothelioma study I.
SWOG-8294	Evaluation of adjuvant therapy and biological parameters in node-negative operable female breast cancer.

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