# Recruiting Participants to Cancer Prevention Clinical Trials: Lessons From Successful Community Oncology Networks

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**Purpose/Objectives:** To describe the organizational designs and task environments of community oncology networks with high accrual rates to cancer prevention clinical trials.

**Design:** Replicated case study design; structural contingency theory. **Setting:** Local Community Clinical Oncology Programs (CCOPs) funded by the National Cancer Institute to test preventive and therapeutic interventions in community settings.

**Sample:** Primary sample: oncology professionals affiliated with four CCOPs ranking among the top 10 in earned cancer control accrual credits in fiscal years 1999–2003. Secondary sample: oncology professionals affiliated with three CCOPs ranking among the top 10 three to four times during the study period. A total of 63 people participated in the interviews.

**Methods:** Primary sample: on-site interviews with CCOP investigators, clinical research staff, and nononcology physicians. Secondary sample: telephone interviews with each CCOP's nurse administrator and at least one prevention research nurse.

Main Research Variables: Staffing patterns, organizational processes, recruitment strategies, and environmental characteristics.

**Findings:** All of the CCOPs employed dedicated prevention research staff. Recruitment through media publicity, mass mailings, or group information sessions worked best when prevention trials had flexible eligibility requirements and evaluated interventions with few health risks. Prevention trials evaluating agents with known toxicities in high-risk populations required more targeted recruitment through cancer screening programs, physician referral networks, and one-on-one discussions with protocol candidates.

**Conclusions:** High-performing CCOPs configured their structures, processes, and recruitment strategies to fit with accrual goals. They also benefited from stable and supportive task environments.

**Implications for Nursing:** Nurse-coordinated research networks have great potential to generate new knowledge about cancer prevention that can reduce cancer incidence and mortality significantly.

A gior advances in the molecular study of neoplasia, cancer risk assessments, and molecular-targeted drug development have established cancer prevention as an exceptionally promising area for scientific investigation and clinical practice (Lippman & Levin, 2005). Although expanded treatment options and improved medical management are helping patients with cancer live longer and better, interventions designed to prevent, arrest, or reverse the carcinogenesis process offer the greatest hope for reducing cancer incidence, morbidity, and mortality (Ford et al., 2003). Byers et al. (1999) estimated that, with accelerated efforts to develop and implement preventive interventions, the United States could achieve a 19% decline in cancer incidence rates by 2015 and a 29% decline below the 1990 levels in cancer

# Key Points . . .

- All of the high-performing Community Clinical Oncology Programs (CCOPs) have established clear criteria for deciding which cancer prevention protocols are most feasible for implementation in their communities.
- Many high-performing CCOPs have assigned RNs to prevention trials to gain flexibility in task assignments and to prepare for future molecular studies of cancer risk and targeted prevention that are likely to require nursing expertise.
- Most of the high-performing CCOPs have sought and received grants from local entities to help cover participant recruitment expenses.
- Varied recruitment strategies are needed to achieve and sustain high levels of prevention trial participation.

mortality rates. In absolute numbers, such interventions could prevent approximately 100,000 cases of cancer and 60,000 deaths from cancer each year.

The expanding scope of cancer prevention research has created opportunities for oncology nurses to lend their expertise to prevention clinical trials and to educate patients about evidence-based prevention strategies (Bailey, Bieniasz, Kmak, Brenner, & Ruffin, 2004; Jennings-Dozier & Mahon, 2000; Loescher, 2004; Oncology Nursing Society, 2001). Cancer centers and clinical cooperative groups increasingly are partnering with local networks of oncology professionals to assess the effectiveness of chemopreventive agents in reducing cancer risk and the diagnostic efficacy of new screening technologies (Hawk, Umar, & Viner, 2004; Lippman & Hong, 2002; Weiner, McKinney, & Carpenter, 2006). Community oncology networks already engaged in cancer treatment research

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have had to make significant adaptations to recruit healthy but high-risk individuals to cancer prevention clinical trials. This article describes the organizational designs and task environments of community oncology networks that have achieved and sustained high levels of prevention trial participation.

# Background

The National Cancer Institute's (NCI's) Community Clinical Oncology Programs (CCOPs) support the nation's largest network for testing preventive and therapeutic interventions in community settings (NCI, 2004). The network program funds consortia of community hospitals, physicians, and clinical research nurses to enroll participants in clinical trials designed and monitored by cancer centers and clinical cooperative groups that NCI has designated as "CCOP research bases." Individual CCOP awardees use their grants to hire research staff, develop and maintain data management systems, travel to research base meetings, and procure study-related supplies and services. As of October 2005, 63 CCOPs distributed across 35 states, the District of Columbia, and Puerto Rico were participating in NCI-sponsored clinical trials.

During the initial funding cycle (1983–1986), CCOPs demonstrated their ability to accrue large numbers of patients to cancer treatment trials and to meet quality-control standards (Feigl et al., 1987). A second request for applications, issued in 1986, expanded the program's scope to include research on cancer prevention, early detection, and cancer control (e.g., symptom management, supportive care). The new program guidelines required CCOP research bases to design and conduct cancer prevention and control clinical trials and required CCOPs to meet annual accrual targets.

The cancer prevention and control research mandate presented major challenges for CCOPs and their research bases. At the research base level, few investigators had interest or expertise in designing cancer prevention clinical trials (Mc-Kinney, Warnecke, & Kaluzny, 2000). At the CCOP level, investigators reported limited time and resources to recruit cancer-free individuals to prevention trials (Kaluzny et al., 1993; Klabunde, Kaluzny, & Warnecke, 2000). For several years, only a few cancer prevention and control clinical trials were open for accrual. However, a series of large-scale chemoprevention trials activated from 1992-2001 compelled CCOPs to adopt new recruitment strategies. During a multiyear period of experimentation, a subset of CCOPs achieved and sustained notably higher levels of cancer prevention and control accruals than their counterparts. The current study examined the organizational adaptations, recruitment strategies, and environmental factors contributing to their exemplary accrual performance.

The structural contingency theory of organizational design provided a conceptual foundation for this research (Galbraith, 1973; Nadler & Tushman, 1982). The theory posits that an organization's ability to achieve and sustain a desired level of performance (i.e., organizational effectiveness) largely depends on the extent of internal congruence among organizational subsystems and external congruence among the organizational design and the demands and constraints of the task environment. Katz and Kahn's (1978) subsystem model of organizations was used to develop research questions and to assess the extent of fit among organizational components (see Table 1). Structural contingency theory does not suggest that organizational components must be configured in one particular way. However, based on the theory, the authors posited that high-performing CCOPs would exhibit a tight fit among subsystems as well as in their task environments.

# Methods

The authors conducted case studies of seven high-accruing CCOPs using a protocol approved by the institutional review board in the School of Public Health at the University of North Carolina at Chapel Hill. The study employed a replicated case study design with the individual CCOP serving as the unit of selection and the unit of analysis (Yin, 1994).

## **Study Sample**

To identify high-performing study sites, the authors ranked CCOPs by earned cancer control accrual credits for each fiscal year from 1999–2003. NCI program staff assign a credit value to each protocol approved for CCOP use. The credit values range from 0.1–1.5, depending on the intervention's complexity and data management requirements. Typically, a CCOP receives about \$2,000 per earned accrual credit. In addition to receiving a defined amount of credit for each new enrollment, CCOPs may receive follow-up credit if a protocol requires tests and/or examinations during a multiyear period. The study period was selected

## **Table 1. Organizational Subsystems**

Subsystem	Theoretical Definition	Key Research Question(s)
Production	Focuses on product- directed activities	How have high-accruing Com- munity Clinical Oncology Programs (CCOPs) staffed cancer prevention and control research initiatives and re- cruited participants to cancer prevention and control trials?
Maintenance	Reinforces the roles of organizational members through recruitment, socialization, rewarding, and sanctioning	What kinds of incentives, train- ing, and feedback have high- accruing CCOPs offered to encourage accruals to cancer prevention and control trials?
Supportive	Procures resources for production, exports fin- ished products, and es- tablishes legitimacy and favorable organizational relationships within the larger social environment	How have high-accruing CCOPs obtained a diversified "menu" of cancer prevention and con- trol protocols? How have they obtained external funding and physician referrals for cancer prevention and control trials?
Adaptive	Monitors relevant envi- ronmental changes and attempts to modify orga- nizational structure and processes to fit with ex- ternal changes; engages in strategic planning	How have high-accruing CCOPs modified their structures, processes, and strategies to maintain high cancer prevention and control accru- als under changing environ- mental conditions?
Managerial	Coordinates and directs all subsystems, re- solves conflicts, and coordinates external requirements with orga- nizational resources and needs	How do high-accruing CCOPs assess the appropriateness of cancer prevention and control protocols for implementa- tion and coordinate cancer prevention and control re- cruitment strategies?

because the two largest cancer prevention clinical trials, the Study of Tamoxifen and Raloxifene (STAR) and the Selenium and Vitamin E Cancer Prevention Trial (SELECT), were activated during or after 1999 (Lippman et al., 2005; Wickerham, 2003). The four CCOPs ranking among the top 10 for the entire study period comprised the primary sample. Three additional CCOPs ranking among the top 10 three to four times during the study period were selected as a secondary or "replication" sample for testing causally relevant "success factors" identified through on-site case studies of primary sample CCOPs. Table 2 presents descriptive data on the study sites.

## **Data Sources**

From March-May 2004, two-person research teams made two- to three-day site visits to each CCOP in the primary sample. With the help of each CCOP's administrator, the research teams scheduled 60- to 90-minute interviews with individuals whose roles in the CCOP or involvement with prevention trials made them especially knowledgeable about the CCOP's cancer prevention and control research activities. These key informants included CCOP leaders, other participating oncologists, the CCOP nurse administrator, research nurses and clinical research associates assigned to cancer prevention and control clinical trials, other CCOP staff (e.g., institutional review board specialists), and nononcology physicians who participated in cancer prevention and control clinical trials or referred numerous patients to the trials. The research teams used semistructured discussion guides, tailored to the interests and expertise of individual participants, to guide the interviews. All interview participants gave their written informed consent to participate in the study and to have their interviews tape recorded and transcribed verbatim.

After analyzing the site-visit data, the authors developed discussion guides for 60- to 90-minute telephone interviews

with the nurse administrator and at least one prevention research nurse in each of the secondary sample CCOPs. The interviews explored the organizational and environmental variables identified as possible "success factors" in the primary sample analysis. With each individual's written informed consent, the interviews also were tape recorded and transcribed verbatim.

Sixty-three key informants participated in on-site or telephone interviews (see Table 3). Additional information on each CCOP's structure, activities, and task environment was obtained from grant applications, annual progress reports, and U.S. census and health-related databases.

## **Analytic Methods**

Analysis proceeded in three phases: data coding, withincase analysis, and cross-case analysis. The authors used qualitative data analysis software (ATLAS.ti 4.2, ATLAS.ti Scientific Software Development GmbH, Berlin, Germany) to code the textual data derived from interviews and to provide a traceable record of data interpretation. Using a topical coding list, two authors coded the data and the other author reviewed the coding for accuracy and consistency. The authors then prepared a detailed within-case analysis for each primary sample CCOP, which was shared with the principal investigator and administrator to confirm factual accuracy.

For the cross-case analysis, the authors prepared a spreadsheet comparing the structures, processes, strategies, and environments of the seven CCOPs. Because the CCOPs were selected based on a shared outcome (i.e., high cancer prevention and control accruals), the analysis focused on cross-case commonalities rather than cross-case differences (Ragin, 1999a, 1999b). Different ways of configuring organizational subsystems to generate high accruals also were analyzed.

CCOP Sample Central Office Site		Service Area	Participating Healthcare Providers			
Primary						
Central Illinois	Decatur, IL	37 counties in central, southern, and northeast Illinois	Two component hospitals <sup>a</sup> , one affiliate hospital, and three oncology practices			
Southeast Cancer Control Consortium	Winston-Salem, NC	100 counties in North Carolina, South Carolina, southeast Georgia, eastern Tennessee, and southern Virginia	22 hospitals and 33 oncology practices			
Upstate Carolina	Spartanburg, SC	Six counties in northwest South Carolina and one county in southwest North Carolina	One component hospital, two affiliate hospitals, two affiliate surgical practices, and six oncol- ogy practices			
Wichita	Wichita, KS	51 counties in south-central Kansas (primary service area includes Wichita and 12 surround- ing counties)	Two component hospitals, 16 affiliate institutions, and three oncology practices			
Secondary						
Carle Cancer Center	Champaign-Urbana, IL	38 counties in east central Illinois and western Indiana plus Mexico City, Mexico	One large multispecialty clinic, two affiliate hos- pitals, one affiliate oncology practice, and the National Cancer Institute of Mexico			
Duluth	Duluth, MN	16 counties in northeastern Minnesota, northern Wisconsin, and northwestern Michigan	One health system encompassing two hospitals, one multispecialty clinic (including oncology), six satellite clinics, and 20 regional clinics			
Grand Rapids	Grand Rapids, MI	38 counties in western and central Michigan	Eight component hospitals, one affiliate hospital, and 13 oncology practices			

 Table 2. Characteristics of Community Clinical Oncology Programs

<sup>a</sup> A component is a full consortium member of a CCOP. An affiliate is an institution that enrolls a minimum number of patients or participants in clinical trials but does not qualify for full consortium membership.

CCOP—Community Clinical Oncology Program

Table 3.	Distribution	of Interview	Participa	nts Across	Community	y Clinical	Oncology	Programs

	Primary Sample				Secondary Sample				
Participants	Central Illinois	Southeast Cancer Control Consortium	Upstate Carolina	Wichita	Carle	Duluth	Grand Rapids	Total	
Principal investigators or co–principal investigators	3	2	2	2	_	1	-	10	
Administrators	1	<b>2</b> <sup>a</sup>	1	1	1	1	1	8	
Research nurses or clinical research associates	8	3	8	6	2	2	1	30	
Other CCOP staff members	1	2	3	2	_	_	_	8	
Other CCOP oncologists	1	0	0	1	_	_	_	2	
Nononcology physicians	1	0	2	2	-	-	-	5	
Total	15	9	16	14	3	4	2	63	

<sup>a</sup> Includes CCOP assistant administrator

CCOP—Community Clinical Oncology Program

## Results

## Within-Case Analyses

From fiscal years 1999–2003, five of the seven CCOPs earned most of their cancer control accrual credits from two large chemoprevention trials. Based on five-year averages, STAR and SELECT accounted for 53%–86% of the cancer control credits that the five CCOPs earned from new enrollments. Three of those CCOPs earned more than 75% of their cancer control accrual credits from the two trials. As an alternative strategy, two CCOPs recruited participants to a more diversified portfolio of cancer prevention and control clinical trials. Based on five-year averages, STAR and SELECT accounted for 31% of one CCOP's earned cancer control accrual credits and 45% of the other CCOP's earned credits.

The following cases describe how two CCOPs configured their organizational subsystems to support concentrated versus diversified accrual strategies. Space does not permit a discussion of the other five CCOPs' organizational designs. However, most adopted some version of these models.

Upstate Carolina Community Clinical Oncology Program: The Upstate Carolina CCOP (UC-CCOP) hired its first prevention research nurse in 1992 to recruit participants to the Breast Cancer Prevention Trial (Fisher et al., 1998). Following the 1993 activation of the Prostate Cancer Prevention Trial (Thompson et al., 2003), UC-CCOP developed a massmailing recruitment system that made it one of the study's top four accruing sites. Using age- and gender-specific mailing lists purchased from a local marketing company, UC-CCOP sent study information to 4,000 men each month. Interested men attending group information sessions were scheduled for group eligibility screening sessions, where local clinicians performed the required digital rectal examinations, physical examinations, and prostate-specific antigen tests at no charge. The combination of mass mailings, group information sessions, and centralized free screening generated economies of scale and shortened the recruitment-to-enrollment cycle time to less than one month.

Since the 2001 activation of SELECT, UC-CCOP has used the same three-pronged approach to enroll more than 1,000 study participants and to become the second highest accruing study site. The local urologist serving as SELECT principal investigator and other community urologists routinely assist with participant recruitment and follow-up. The SELECT staff includes six full-time research nurses, two full-time data coordinators, and two part-time staff members who manage SELECT companion studies. By clustering appointments for randomization, the SELECT nurses are able to batch their six-month follow-up workloads. In addition to generating efficiencies, the practice fosters participant adherence by creating a "cohort effect" in which the men come to know and support one another.

UC-CCOP allocates part of its federal grant to support SELECT recruitment and retention activities. Funding from a local hospital foundation covers the initial prostate-specific antigen tests used to assess SELECT eligibility. The CCOP administrator monitors and evaluates the accrual performance of the prevention research staff, provides monthly updates on accrual progress, and convenes staff strategy sessions to encourage team problem solving.

Wichita Community Clinical Oncology Program: Throughout the 1990s, the Wichita CCOP (WCCOP) cross trained research nurses to manage cancer treatment and cancer prevention and control clinical trials. The first two prevention research nurses, hired in 2000 and 2001, received partial salary support from the mid-Kansas affiliate of the Susan G. Komen Breast Cancer Foundation to recruit minority women to STAR. By the end of 2001, the prevention research staff included four nurses (three full-time equivalent [FTE] positions) and two data specialists.

Five research nurses (4.3 FTE) and three data specialists (2.5 FTE) currently manage a diversified portfolio of large and small prevention trials and early detection trials. Rather than having specific study assignments, the prevention research nurses recruit to all of the trials. They also have been trained to screen patient charts for symptom management trial eligibility so that WCCOP can continue to meet its cancer control accrual goals when major prevention trials close to accrual.

WCCOP's efforts to publicize cancer prevention trials in local media outlets have consistently generated a huge public response. The prevention research nurses have successfully used cross-trial marketing to enroll individuals on more than one cancer prevention and control clinical trial and to recruit the spouses and relatives of study participants. Through ongoing contacts with family physicians and internists,

WCCOP has developed a network of more than 175 primary care physicians who refer patients to prevention trials and perform protocol-required examinations and tests. Like her UC-CCOP counterpart, the WCCOP nurse manager monitors and evaluates accrual performance, provides monthly updates on accrual progress, and convenes staff strategy sessions to encourage team problem solving.

Summary: Figures 1 and 2 summarize the ways in which the two CCOPs have achieved internal congruence among organizational subsystems. UC-CCOP's production subsystem is designed to maximize recruitment to SELECT. To reinforce this strategy, UC-CCOP has a local urologist serving as SELECT principal investigator (managerial subsystem), annually allocates part of its federal grant for SELECT recruitment activities (supportive subsystem), publicly recognizes local physicians' contributions to SELECT (maintenance subsystem), and regularly monitors SELECT accruals to assess the need for adaptations (adaptive subsystem). As an alternative strategy, WCCOP recruits participants to a diversified portfolio of cancer prevention and control clinical trials (production subsystem). The strategy is reinforced by clear criteria for selecting protocols (managerial subsystem), regular visits to offices of physicians with high referral potential to discuss prevention and early detection trials for which their patients might qualify (supportive subsystem), public recognition of local physicians' contributions to prevention trials (maintenance subsystem), and the use of a symptom management checklist to systematically identify candidates for symptom management trials (adaptive subsystem).

## **Cross-Case Analysis**

Although the seven CCOPs have developed and linked subsystems in somewhat different ways, their organizational designs share many common elements. Figure 3 highlights the staffing arrangements, organizational processes, and recruitment strategies observed in all or most of the CCOPs. The organizational factors most frequently mentioned as contributing to high accrual performance are presented by subsystem.

**Production subsystem:** Interview participants described prevention trials as "very labor intensive," requiring numerous front-end activities to identify, recruit, and obtain consent from participants and ongoing contacts to keep participants adherent. Rather than depending on CCOP investigators or treatment research nurses to carve out time for those tasks, all seven CCOPs have assigned clinical research staff to work solely or primarily on prevention trials. A CCOP investigator



Figure 1. Organizational Configuration for Cancer Prevention and Control Research: Upstate Carolina Community Clinical Oncology Program



Figure 2. Organizational Configuration for Cancer Prevention and Control Research: Wichita Community Clinical Oncology Program

summarized the importance of dedicated prevention research staff as follows.

I don't think most oncologists have time to think about, "Well, we'd better put an article [about the prevention trial] in the newspaper today. We'd better remember to insert letters with mammogram notices so that we can recruit more women." You have to have dedicated research nurses or clinical research associates assigned to accrual. Otherwise, it just won't get done.

As of May 2004, the prevention staff proportion of total FTE adult research staff in the seven CCOPs ranged from 25%-56% (median = 47%). Five CCOPs reported having dedicated prevention research staff for more than 10 years.

RNs have primary responsibility for prevention trial recruitment and screening in five of the seven CCOPs. Some of those CCOPs have successfully reassigned treatment research nurses to prevention trials, whereas others have hired nurses with backgrounds in medicine or surgery, diagnostic testing, health and wellness education, or cancer screening. Although support staff members typically help with data management and participant follow-up, the administrators of those CCOPs said that nurses' knowledge of medications and patient care allows them to coordinate a wider range of clinical trials, field questions from study participants, and perform protocol-required examinations and tests. The two CCOPs in which nurses comprise less than half of the prevention staff have hired clinical research associates with backgrounds in medical or scientific fields. By all accounts, the research associates have performed very well. However, the CCOP administrators acknowledged that nursing experience makes reassigning prevention staff to symptom management trials easier when large prevention trials close to accrual.

All seven CCOPs employ multiple strategies to recruit prevention trial participants. Typically, prevention trials are launched with a "media blitz" that involves local newspapers, hospital newsletters, television news shows, and health-related radio talk shows. Most of the CCOPs have set up dedicated telephone lines to respond to public inquiries. Callers who seem to be eligible are invited to participate in individual conferences or group information sessions.

By cultivating good connections with local health reporters, some CCOPs have been able to publicize prevention trials without paying for advertisements. Others have worked with hospital marketing departments to develop and place advertisements in local media outlets. A STAR coordinator at one of the Southeast Cancer Control Consortium sites commented, "Placement makes all the difference in the world. The ad has to be on page 2–3 of the [health or food] section. If you go further back in the section, you don't get a response."

Following initial media publicity, CCOPs employ more targeted recruitment strategies. Interview participants described partnerships with local cancer screening programs as one of the best ways to reach consumers who are concerned about preventive health care. For example, WCCOP recruited most

#### **Production Subsystem**

- · Assign dedicated research staff to prevention trials.
- · Nurses comprise the majority of prevention research staff.
- Creatively use media for prevention trial recruitment.
- · Target consumers with higher levels of concern about cancer and health.
- Employ multiple recruitment strategies.

#### Maintenance Subsystem

- · Recognize high-accruing physicians and research staff.
- Encourage friendly competition for participant accruals.
- · Provide training and ongoing mentoring for new prevention staff.
- Cross train prevention staff to manage several clinical trials.
- · Regularly update physicians and research staff on accrual progress.

#### Supportive Subsystem

- Join Community Clinical Oncology Program research bases with strong cancer prevention and control research programs.
- Seek external funding to help support trial recruitment costs.
- Target local physicians with high referral potential for academic detailing.
  Urge patients to see their own physicians for protocol-required examinations
- Orge patients to see their own physicians for protocol-required examinations and tests.
- At least one component hospital is a major cancer referral center.

#### Adaptive Subsystem

- Monitor accruals and adjust staffing and strategies as needed.
- Adapt forms and processes to minimize impact of the Health Insurance Portability and Accountability Act.
- Conduct some industry-sponsored trials to help subsidize staffing costs.
- Engage in futuristic planning.

#### **Managerial Subsystem**

- Maintain strong administrative leadership.
- Establish clear criteria for deciding which protocols to open.
- Allocate staff resources to the "most doable" clinical trials.
- Hold strategy meetings to encourage team problem solving.

## Figure 3. Organizational Factors Contributing to High Cancer Prevention and Control Accrual Performance

of its SELECT participants from annual citywide prostate cancer clinics. The Grand Rapids CCOP partnered with a prevention-focused healthcare system to offer STAR breast cancer risk assessment forms to all patients at a mammography center. Women completing the risk assessment forms gave written permission for the CCOP to share the results with their primary care physicians. Those determined to be at high risk for breast cancer were invited to attend STAR informational sessions, and their physicians were added to the list of medical offices targeted for special STAR presentations.

Interview participants noted that successful recruitment strategies are not necessarily transferable across prevention trials and may lose their effectiveness over time. For example, UC-CCOP successfully used targeted mass mailings followed by large group information sessions to recruit men to two prostate cancer prevention trials. However, when they held large group sessions to explain breast cancer prevention trials, they found that women wanted one-on-one discussions with research nurses. Prevention research staff at the Central Illinois CCOP described group information sessions as a "very good strategy for launching prevention trials. But when the numbers kept dwindling, we had to come up with other recruitment methods that wouldn't require so much time and advertising."

Maintenance subsystem: All of the CCOP administrators said that they regularly update physician investigators and research staff on accrual progress. Three CCOPs circulate written reports of each investigator's accruals to encourage "friendly competition." Two CCOPs recognize high-accruing investigators and staff at group meetings. Three CCOPs consider accrual performance in staff evaluations but do not use performance as a basis for determining salary increases.

Organizational research suggests that even the high-performing CCOPs could boost accruals by clarifying accrual expectations for investigators and staff and providing appropriate incentives and recognition (Henry & Strickland, 1994; Locke & Latham, 1990). Interview participants suggested greater use of incentives, such as plaques, certificates of appreciation, recognition in local newspapers, and funding for professional development. They also recommended more formal training for new prevention research staff.

**Supportive subsystem:** Each CCOP determines the number and types of research bases with which it will affiliate to access clinical research protocols. One of the selected research bases must be a national multispecialty cooperative group. Typically, a CCOP affiliates with five to six additional research bases.

Four national multispecialty cooperative groups, four specialty cooperative groups, and six cancer centers currently serve as CCOP research bases. Two of the research bases, the North Central Cancer Treatment Group and the University of Rochester Cancer Center, have highly productive cancer prevention and control research programs. Six of the highperforming CCOPs have enlarged their protocol portfolios by affiliating with one or both of those research bases.

Since 1992, six of the CCOPs have sought and received grants from participating hospitals, philanthropic groups, and hospital foundations to help cover the salaries of prevention research staff, participant recruitment expenses, or unreimbursed study-related examinations and tests. At all study sites, hospital marketing departments have helped with media publicity and the development of study marketing materials.

Because cancer prevention trials target cancer-free individuals seldom seen by oncologists, CCOPs have actively sought referrals from the larger medical community. Prevention research staff members in three of the CCOPs routinely visit physicians' offices to introduce new protocols and remind them of trials still open for enrollment. To make the most efficient use of staff time, those CCOPs typically target physicians with high referral potential, such as large, primary care group practices and physicians whose patients have expressed interest in prevention trials. To alleviate physicians' concerns about losing the patients they refer to prevention trials (Paskett, Katz, DeGraffinreid, & Tatum, 2003), six of the CCOPs encourage study participants to see their own physicians for protocol-required procedures.

Adaptive subsystem: All of the study sites have made significant adaptations to support cancer prevention and control research activities. Several environmental characteristics have helped them build strong research programs. First, six of the CCOPs serve predominantly rural areas. Although their largest hospitals and oncology practices are located in metropolitan areas, heavy regional demand for oncology services tends to moderate interprovider competition. Rural areas also have smaller and less differentiated healthcare service networks that make it easier for CCOPs to partner with primary care physicians, cancer screening

programs, and cancer advocacy groups to recruit prevention trial participants.

Second, all of the CCOPs serve areas with low to moderate managed-care penetration. In 2001, health maintenance organization enrollees accounted for 15% or fewer of metropolitan statistical area residents in six of the CCOPs and 25% of metropolitan statistical area residents in the seventh CCOP, as compared to a U.S. average of 32% (Aventis Pharmaceuticals, Inc., 2004). Research (Carpenter, Weiner, Kaluzny, Domino, & Lee, 2006) suggests that high managed-care penetration negatively affects clinical trials enrollment by limiting the uncommitted resources that institutions can devote to clinical research and by altering referral relationships.

Third, interview participants reported a high level of community interest in cancer prevention research. For example, a Central Illinois CCOP oncologist stated, "People in this area have a tremendous sense of community—volunteerism, participation, and a sense of doing something for the next person. So it's really the people here that make prevention research work." Other interview participants cited the willingness of local health reporters to publicize prevention trials and grants from local philanthropic groups as evidence of strong community interest and support.

Managerial subsystem: All seven CCOPs have established clear criteria for deciding which cancer prevention and control protocols are most feasible for implementation in their communities. Their principal investigators rely on seasoned nurse administrators to manage clinical research activities. As of May 2004, the tenure of the administrators of those CCOPs ranged from 5-18 years (X = 10.5 years). Five CCOPs have located all or most of their prevention research staff at the CCOP central office, allowing the administrator or a designated program coordinator to set accrual goals and quality standards, facilitate team learning and problem solving, and oversee participant recruitment activities. In the two CCOPs with decentralized staffing (Central Illinois CCOP and Southeast Cancer Control Consortium), the component and affiliate sites set their own accrual targets, determine which cancer prevention and control protocols to activate, and develop participant recruitment strategies. However, the CCOP administrators coordinate these activities through frequent mailings, conference calls, on-site visits, and training and continuing education programs.

## Discussion

Since the 1990s, cancer prevention has evolved to become an important component of oncology science and practice. By partnering with networks of community oncology professionals, cancer centers and cooperative groups have been able to expedite participant recruitment to prevention trials and increase the external validity of study findings. Communities have benefited from educational programs on cancer prevention, an expanded array of cancer screening technologies, and increased access to interventions that may reduce the risk of developing cancer.

Consistent with the principles of organizational design, the high-performing CCOPs in the present study have adopted staffing patterns, organizational processes, and recruitment strategies that are coherent with their cancer prevention and control accrual goals and task environments (Galbraith, 1977). All of the study sites have assigned dedicated clinical research staff to recruit participants to prevention trials, screen and register study participants, coordinate interventions, and maintain ongoing contacts to keep study participants adherent. Most have placed RNs in such positions to gain flexibility in task assignments and to prepare for future molecular studies of cancer risk and targeted prevention that are likely to require nursing expertise.

The case studies revealed numerous examples of organizational processes that support cancer prevention and control research. All seven CCOPs have established clear protocol selection criteria, and most have obtained local funding for prevention trial recruitment and other study-related expenses. Most sites convene staff strategy sessions or cross-site conference calls to promote team learning and problem solving. All have modified study forms and, in some cases, established business agreements to meet requirements of the Health Insurance Portability and Accountability Act without sacrificing recruitment opportunities.

The CCOPs have implemented varied strategies to achieve and sustain high levels of prevention trial participation. Recruitment methods, such as general media publicity, mass mailings, and group information sessions appear to be most effective when prevention trials have flexible eligibility requirements and evaluate interventions with relatively few health risks. Prevention trials evaluating agents with known toxicities in high-risk populations typically require more targeted recruitment through partnerships with local cancer screening programs, the development of physician referral networks, and one-on-one discussions with protocol candidates.

Although the present study employed multiple strategies to minimize threats to validity (e.g., assigning several investigators to collect, analyze, and interpret data; inviting the study sites to review draft case reports; using varied data sources), possible threats to interpretive and internal validity should be kept in mind when evaluating research findings. Because the research was conducted with a small sample of CCOPs, the generalizability of study findings to settings beyond the study population cannot be determined. Future research should investigate whether the organizational and environmental success factors identified in this exploratory study are associated with high cancer prevention and control accrual performance in a larger sample of community oncology networks.

# Implications for Nursing

In October 2000, a supplement to the Oncology Nursing Forum (Vol. 27; 9, Suppl.) referred to cancer prevention as "oncology nursing's next frontier." Since that time, major advances in molecular oncology have blurred the distinction between cancer therapy and cancer prevention (Lippman & Hong, 2002). Technologic advances, such as noninvasive imaging and molecular diagnostics, are helping oncology professionals identify high-risk individuals who could benefit from preventive interventions (Lippman & Levin, 2005). Agents that have proven to be effective in treating advanced cancer are being tested in adjuvant settings and then modified for use as preventive agents. Because oncology nurses are familiar with many of the drugs and technologies being tested, they are well positioned to educate patients and their families about prevention trials, help study candidates clarify their reasons for participation, and serve as study coordinators

(Barrett, 2002). Many oncology nurses in academic medical centers, cancer centers, and community-based settings already are making major contributions to cancer prevention research. For nurses wishing to integrate preventive oncology research into their practice settings, the present study highlights key organizational design and environmental characteristics contributing to high levels of prevention trial participation.

The present study also raises questions specific to nursing research. For example, the CCOPs in which nurses comprised all or most of the prevention research staff reported less staff turnover. If this finding holds true for a larger sample, what might be the explanatory factors? What are optimal caseloads for research nurses when prevention trials require frequent follow-up over multiyear periods? What types of nurse training and incentives are associated with higher accrual performance?

# Conclusion

Community oncology networks have made significant adaptations to participate in emerging areas of cancer prevention research. The high-performing CCOPs examined in the present study have configured their structures, organizational processes, and recruitment strategies to fit with cancer prevention and control accrual goals. They also have benefited from relatively stable and supportive task environments that have made instituting organizational changes easier. Their experiences highlight the potential of nurse-coordinated research networks to generate new knowledge about cancer prevention and early detection that can significantly reduce cancer incidence, morbidity, and mortality.

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