

## Increasing Minority Participation in Cancer Clinical Trials: The Minority-Based Community Clinical Oncology Program Experience

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### A B S T R A C T

#### Purpose

The National Cancer Institute's (NCI) Minority-Based Community Clinical Oncology Program (MBCCOP) seeks to enhance minority participation in cancer clinical trials by building clinical trials outreach and management capacity in healthcare institutions serving large numbers of minority cancer patients. This article examines temporal trends in MBCCOP accruals to cancer prevention and control (CP/C) and cancer treatment trials and the racial distribution of study participants, along with the major factors affecting minority enrollment.

#### Methods

We used NCI databases to analyze temporal trends in overall accruals and accruals by race. We analyzed transcripts from an NCI-sponsored meeting with MBCCOP principal investigators and data from a follow-up survey to identify factors affecting minority enrollment.

#### Results

Between 1992 and 2003, annual patient accruals to treatment trials increased 39% despite little change in the number of MBCCOP grantees. During this same period, annual participant accruals to CP/C trials more than doubled. Between 1995 and 2003, minorities comprised 51% to 67% of the MBCCOP patients accrued to cooperative group treatment trials compared with  $\leq 23\%$  of the patients accrued by other cooperative group members and affiliates. Major factors affecting minority enrollment include the availability of "clinically relevant" protocols, regulatory requirements, characteristics of the patient population, and the level of support from sponsoring institutions and community physicians.

#### Conclusion

MBCCOPs have demonstrated their ability to facilitate the participation of racial/ethnic minorities in clinical trials. However, the contributions that they could make to the design and conduct of minority-focused research studies merit further exploration.

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### INTRODUCTION

In September 1990, 3 years before the National Institutes of Health (NIH) Revitalization Act of 1993 mandated the inclusion of women and minorities in clinical research, the National Cancer Institute's Division of Cancer Prevention (NCI/DCP) launched a program to increase access to cancer clinical trials among racial and ethnic minorities. This Minority-Based Community Clinical

Oncology Program (MBCCOP) awards cooperative agreements to build clinical trials outreach and management capacity in healthcare institutions providing cancer care to patient populations that are at least 40% minority. (The following population groups qualify as minority: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and Hispanic or Latino. See Office of Management and Budget Standards for the

Classification of Federal Data on Race and Ethnicity at <http://www.whitehouse.gov/omb/fedreg/1997standards.html>.) MBCCOP grantees are part of a nationwide network of 63 Community Clinical Oncology Programs (CCOPs) that enroll patients onto cancer prevention and control (CP/C) and treatment trials through cancer centers and clinical cooperative groups that NCI/DCP has designated as CCOP research bases.<sup>1</sup>

A major MBCCOP goal is to reduce racial/ethnic disparities in cancer incidence, survival, and mortality rates by facilitating broader minority participation in state-of-the-art cancer treatment and CP/C research. Long before the "NIH roadmap" proposed partnerships between academic centers and community-based physicians to accelerate the pace of scientific discovery,<sup>2</sup> the MBCCOP provided financial support for these collaborations. Fiscal year (FY) 2003 accrual data illustrate the importance of the MBCCOP as a mechanism for enhancing minority participation in clinical trials. During that year, the 11 MBCCOP grantees comprised 18% of the CCOP grantees, but enrolled half of the minority study participants.

Between 1995 and 1997, the Eastern Cooperative Oncology Group and the National Medical Association convened a series of physician workshops to identify barriers to minority participation in cancer clinical trials and possible solutions.<sup>3,4</sup> Minority community physicians cited a lack of information about available clinical trials and distrust of the medical centers sponsoring the trials as their primary reasons for not recommending clinical trials to minority patients. MBCCOPs have sought to reduce these barriers through ongoing physician education and community outreach. Yet, their role in making cancer clinical trials more accessible to racial and ethnic minorities has received little attention in the medical literature.

Of the various studies that have examined minority representation in NCI-sponsored clinical trials,<sup>5-11</sup> only one study has assessed the contributions of MBCCOPs. Between 1992 and 1993, Kaluzny et al evaluated the MBCCOP's early implementation phase.<sup>10,11</sup> Their study documented a 37% increase in treatment accruals and a 65% increase in CP/C accruals between the 1990 to 1991 and 1991 to 1992 fiscal years. Although racial and ethnic minorities comprised more than 70% of MBCCOP study participants, the MBCCOPs' ability to accrue minorities was highly dependent on the availability of clinically relevant protocols, the level of institutional support, and factors endemic to the communities they served. This article examines accrual trends and factors affecting minority enrollment since the 1992 to 1993 evaluation and discusses possibilities for future program development.

## METHODS

We used NCI/DCP databases to analyze temporal trends in MBCCOP accruals to treatment and CP/C trials and trends in the percentage of minority study participants. At a May 7, 2004, meet-

ing convened by the NCI/DCP, the principal investigators of 12 MBCCOPs and two CCOPs serving growing numbers of minorities described their individual programs, discussed collective issues and challenges, and suggested ways in which the NCI/DCP could advance community-based research on racial/ethnic disparities in cancer incidence and clinical outcomes. We analyzed transcripts from this meeting to identify current factors affecting minority enrollment. A July 2004 e-mail survey completed by all MBCCOP principal investigators provided additional descriptive information.

## RESULTS

### *MBCCOP Characteristics*

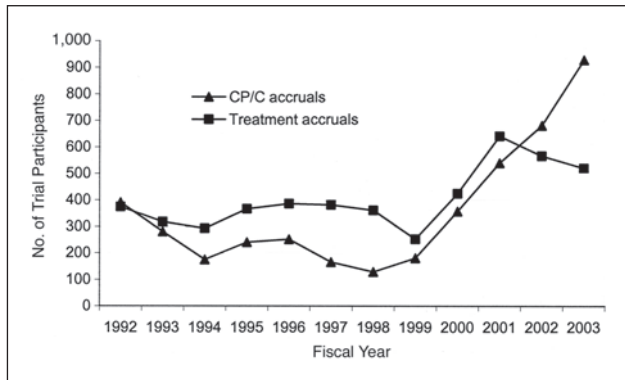
The 13 currently funded MBCCOPs are distributed across 10 states, the District of Columbia, and Puerto Rico. They include nine academic health centers (two historically black education institutions), a Veterans' Affairs (VA) Research Service hospital, a large county hospital, a community hospital, and a hospital-affiliated community cancer center. Five MBCCOPs have been continuously funded for more than 10 years.

MBCCOPs enroll patients onto clinical trials by forming working groups of hospitals, physicians, and clinical research staff. In addition to oncologists, the participating physicians may include surgeons, primary care physicians, and nononcology medical specialists. As of June 2004, the MBCCOP network included 49 hospitals and 510 physicians. Minority physicians accounted for 37% of all MBCCOP physicians. Within individual MBCCOPs, the number of component hospitals ranged from one to 10 (median, three), and the number of participating physicians ranged from 10 to 63 (median, 38). The number of minority physicians ranged from one to 60 (median, eight).

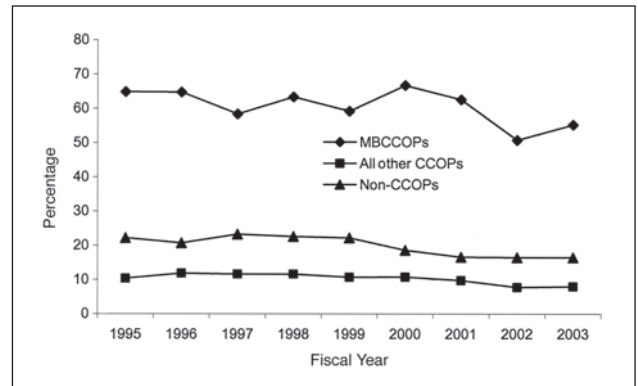
MBCCOPs affiliate with cancer center and cooperative group research bases to access research protocols and to enroll study participants. As of June 2004, the number of research base affiliations reported by individual MBCCOPs ranged from two to eight (median, four). Through these external affiliations or collaborations with investigators within their own institutions, MBCCOP investigators coauthored 46 scientific publications. Within individual MBCCOPs, the number of reported publications ranged from zero to 16 (median, two).

### *Accrual Trends*

Figure 1 shows total MBCCOP accruals to NCI-sponsored cancer treatment and CP/C clinical trials by fiscal year. With the exception of FY 1992, annual CP/C accruals trailed treatment accruals throughout the 1990s. Between FY 1999 and FY 2001, the number of patients accrued to treatment trials more than doubled. This accrual pattern was similar to that of the larger CCOP network, reflecting the availability of large adjuvant trials and pediatric trials for the most common cancers. Annual accruals to CP/C trials



**Fig 1.** Minority-Based Community Clinical Oncology Program (MBCCOP) accrual trends, 1992-2003. In fiscal year (FY) 1992, 10 MBCCOPs received National Cancer Institute's Division of Cancer Prevention (NCI/DCP) funding. Over the next nine FYs, the number of MBCCOPs fluctuated between seven and ten. In FY 2002 and FY 2003, 11 MBCCOPs received NCI/DCP funding. CP/C, cancer prevention and control.



**Fig 2.** Minority percentage of patients accrued to cooperative group treatment trials by Minority-Based Community Clinical Oncology Programs (MBCCOPs), other Community Clinical Oncology Programs (CCOPs), and non-CCOP members/affiliates. Non-CCOP members of cooperative groups include academic medical centers, National Cancer Institute-designated cancer centers, and other large research institutions. Affiliates include community hospitals and oncology practices that affiliate with cooperative groups through "main member" institutions.

also increased between FY 1999 and FY 2001, primarily due to the activation of two major prevention trials: the Study of Tamoxifen and Raloxifene (STAR)<sup>12</sup> and the Selenium and Vitamin E Cancer Prevention Trial (SELECT).<sup>13</sup> By FY 2003, the number of participants accrued to CP/C trials was almost two times higher than the number accrued to treatment trials.

**Minority Representation in Clinical Trials**

After the March 1994 publication of NIH guidelines on the inclusion of women and minorities in clinical research, all NIH agencies began requiring more detailed reporting of the race/ethnicity of study participants. Between fiscal years 1995 and 2003, the CCOP network enrolled 7,073 minority patients on NCI-supported cancer treatment trials coordinated by cooperative groups. These patients accounted for 21% of minority enrollments. Although MBCCOPs comprised less than 20% of CCOP grantees, they contributed 33% of the CCOP network's minority accruals and 7% of the minority patients enrolled by all cooperative group members and affiliates.

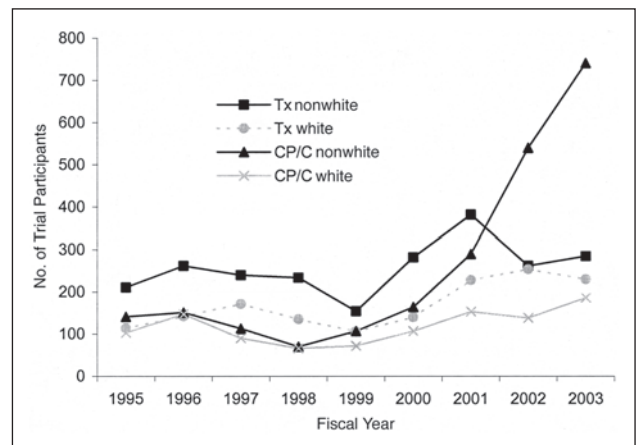
Figure 2 shows temporal trends in the percentage of minority patients accrued to cooperative group treatment trials by MBCCOPs, other CCOPs, and non-CCOP institutions (eg, academic medical centers, NCI-designated cancer centers). Between fiscal years 1995 and 2003, minorities comprised 51% to 67% of the patients accrued by MBCCOPs (median, 63%), compared with ≤ 12% of the patients accrued by other CCOPs and ≤ 23% of the patients accrued by non-CCOP institutions.

Figure 3 shows the number of nonwhite and white participants that MBCCOPs enrolled onto NCI-sponsored treatment and CP/C clinical trials by fiscal year. Between fiscal years 1995 and 1999, minorities comprised 51% to 60% of CP/C study participants. By FY 2003, the minority proportion of CP/C study participants had climbed to 80%.

Over the 9-year period, MBCCOPs contributed 44% of the 5,221 minority individuals that the CCOP network enrolled onto CP/C trials.

**Factors Affecting Minority Enrollment**

The 1992 to 1993 MBCCOP evaluation<sup>10</sup> identified five factors that influence MBCCOPs' ability to enroll minorities onto clinical trials: the availability of "clinically relevant" protocols, the level of institutional support, the quality of institutional review board (IRB) relationships, characteristics of the patient population, and the willingness of community physicians to enroll or refer minority patients onto clinical trials. In succeeding sections we compare findings from this early-phase evaluation with the accrual facilitators and barriers cited by MBCCOP principal



**Fig 3.** Minority-Based Community Clinical Oncology Program (MBCCOP) accruals to cancer treatment and cancer prevention and control clinical trials by race, 1995-2003. Tx, treatment; CP/C, cancer prevention and control.

investigators at the May 2004 meeting with NCI/DCP program staff.

*Protocol-related issues.* In the early 1990s, MBCCOP investigators identified two protocol-related barriers to minority enrollment; an inadequate number of treatment protocols for common cancers and patient ineligibility due to comorbidities. At the May 2004 meeting, MBCCOP leaders reported a critical shortage of treatment protocols for gallbladder cancer, liver cancer, renal cancer, and other cancer types that tend to be more prevalent in their communities. They expressed a strong desire to help cooperative group scientific committees design minority-focused treatment protocols and to assess the appropriateness of protocol eligibility criteria for minority populations.

*Institutional support.* The 1992 to 1993 MBCCOP evaluation characterized the healthcare environments of MBCCOPs as “fragmented and deteriorating.”<sup>10</sup> University-based MBCCOPs successfully weathered this decline in community resources by obtaining internal funding for program development. However, MBCCOPs dependent on community hospitals reported major difficulties building infrastructures for clinical trials’ outreach and data management.

At the May 2004 meeting, MBCCOP principal investigators reported waning institutional support for clinical research staff and protocol-required ancillary services. Several made comments such as the following: “The institution initially gave us a lot of funds for clinical research support, but as we’ve become more successful, they’re saying, ‘You don’t need our support anymore.’” Meeting participants attributed these cutbacks to the worsening financial health of urban-based hospitals, shifting institutional priorities, and administrators’ limited understanding of the value and requirements of community-based clinical research. The Gulf Coast MBCCOP experienced a major setback in 2001 when its institutional sponsor, the University of South Alabama (Mobile, AL), decided to end its association with the MBCCOP. After moving the MBCCOP cooperative agreement to a large community hospital (Mobile Infirmiry Medical Center, Mobile, AL), the CCOP principal investigator, Marcel Conrad, MD, and his research staff struggled to keep clinical trials on course amid major turnover among hospital-affiliated oncologists. In 2003, NCI/DCP awarded the prestigious Harry Hynes Award to Dr Conrad for successfully leading the Gulf Coast MBCCOP through this difficult transition.

As hospital contributions have declined, some MBCCOPs have partnered with local cancer centers to obtain staff and/or financial support. Almost all MBCCOP leaders reported increased reliance on pharmaceutical trials to help shore up research infrastructures. However, they noted that these trials do not provide a stable source of funding and may not fully reimburse costs if extensive follow-up is required. In some MBCCOPs, the higher per-

case reimbursement rates offered by pharmaceutical trials have made it more difficult to maintain oncologists’ commitment to NCI-sponsored trials.

*IRB relationships.* During the 1992 to 1993 MBCCOP evaluation, university-based MBCCOPs reported relatively few problems with the protection of human subjects reviews due to the presence of well-established IRBs in their institutions.<sup>10</sup> However, for MBCCOPs without university bases, the development and coordination of community hospital IRBs presented major challenges. Community IRB members’ lack of experience in reviewing clinical research protocols further complicated IRB relationships.

Although all of the MBCCOPs now work with established IRBs, meeting participants described the current IRB environment as “intolerable.” They expressed particular concern about the escalating volume of paperwork, which has burdened their clerical staff and prompted many IRBs to charge administrative fees. “We have to make hard choices about opening studies because the regulatory costs are so high,” said one physician. “If we don’t get the regulatory piece solved, this whole research enterprise is just going to fall apart.”

Five MBCCOPs reported that their IRBs participate in the NCI’s Central institutional review board (CIRB) pilot project.<sup>14</sup> As part of this project, a multidisciplinary CIRB reviews all phase III multicenter cancer treatment protocols. Once a protocol has received CIRB approval, local IRBs can designate one or more members to conduct a “facilitated review” in lieu of a full board meeting. If there are no local concerns, the CIRB performs all continuing reviews, amendment reviews, and reviews of serious adverse events. Meeting participants agreed that CIRB reviews have the potential to educate local IRBs about cancer clinical trials and to reduce regulatory workloads. However, they noted that many IRBs are continuing to conduct full-board reviews of all CIRB-approved protocols due to concerns about legal liability and/or members’ unwillingness to relinquish local control.

*Characteristics of the patient population.* The 1992 to 1993 MBCCOP evaluation identified patient-specific variables that, when present, limit the participation of minorities in clinical trials.<sup>10</sup> These variables included social structural factors (eg, limited education, language barriers), attitudes and beliefs (eg, fear and mistrust of the healthcare system and clinical research), and resource constraints (eg, economic pressures, lack of transportation). Health insurance status was not associated with study participation, largely due to the ability of university-based MBCCOPs to cover protocol-required procedures with internal resources.

In May 2004, MBCCOP leaders reported that high rates of in-migration have increased the racial/ethnic heterogeneity of their communities and widened gaps in education, income, and health-related beliefs. Although MBCCOPs still enroll patients onto clinical trials regardless of health

insurance status, declining institutional support has made it more difficult to procure protocol-related drugs and ancillary services for uninsured patients. To accommodate the growing ethnic diversity of their communities, many MBCCOPs have hired bilingual and trilingual staff.

*Community-physician involvement.* The 1992 to 1993 MBCCOP evaluation found that physicians practicing in MBCCOP communities often were reluctant to enroll or refer patients to clinical trials.<sup>10</sup> Interviewees attributed the low levels of community physician involvement to heavy patient loads, inadequate staff support for protocol-related activities, the lack of financial compensation, a general distrust of “academic medicine,” and doubts about the ability of lower-income minorities to participate in clinical trials. Few MBCCOPs reported success recruiting minority physicians, although some were developing promotional and educational materials to increase awareness of clinical trials among physicians practicing in minority communities.

At the May 2004 meeting and in a follow-up survey, MBCCOP leaders described the extent to which community physicians were supporting MBCCOP activities. Seven of the 13 principal investigators said oncologists in their institutions have a “strong commitment” to clinical research. Three MBCCOP leaders described oncologists’ participation as “good” or “operating on a plateau,” and three said oncologists’ participation was “improving.” Those reporting lower levels of participation said oncologists often are under too much pressure or are too busy to think about research protocols. Some MBCCOPs have successfully addressed this problem by using oncology fellows as “frontline screeners” for protocol eligibility or by assigning research nurses to assist with patient enrollment at oncology clinics.

With the exception of the investigators in the San Juan MBCCOP, where 100% of the investigators are minority physicians, most MBCCOPs are still striving to increase minority physicians’ participation. MBCCOPs have developed more proactive measures to recruit minority physicians. For example, a large county hospital with an MBCCOP has established a fellowship in breast oncology for minority female physicians. An MBCCOP affiliated with a historically minority medical school has invited physician alumni in surrounding communities to participate in collaborative research. Two additional MBCCOPs have partnered with minority oncologists in community practices to recruit minority physicians.

MBCCOP principal investigators described local primary care physicians and nononcology medical specialists as “overstretched,” with inadequate time and staff support to participate in clinical research or even to refer patients to cancer prevention and early detection trials. Declining reimbursement rates for patient care have discouraged even the most committed community physicians from enrolling patients onto clinical trials. One principal investigator explained,

“There’s a real disincentive for the doctors that have been loyal to us to put patients on clinical trials when they’re trying to push more and more patients into their day.”

### **MBCCOP Experiences With CP/C Research**

CP/C research includes *prevention studies*, which evaluate new methods of detecting cancer risk and preventing primary and secondary cancers, and *cancer control studies*, which evaluate symptom management, rehabilitation, and continuing care interventions designed to minimize the burden of cancer and improve quality of life. During the initial MBCCOP years, very few CP/C protocols were open for accrual. Following the activation of the Breast Cancer Prevention Trial in April 1992 and the Prostate Cancer Prevention Trial in October 1993, this situation began to change.<sup>15,16</sup> However, due to the challenges of developing community physician referral networks, MBCCOP accruals to CP/C trials did not show significant gains until 2000 (Fig 1).

MBCCOP investigators participating in the 1992 to 1993 evaluation<sup>10</sup> identified four barriers to CP/C accrual: (1) a shortage of suitable CP/C protocols; (2) resource limitations; (3) the lack of local expertise on prevention trial recruitment; and (4) low accrual credit assignments for CP/C protocols. NCI/DCP assigns a credit value to each therapeutic and CP/C protocol approved for CCOP use. Credit values range from 0.1 to 1.5, depending upon the intervention’s complexity, data management requirements, and follow-up period. In June 2003, NCI/DCP increased the accrual credit assignment for all CP/C protocols to 1.0 to more fully cover study costs. With only one prevention trial (the Breast Cancer Prevention Trial) open for accrual, few MBCCOPs had developed the partnerships with community organizations or consumer liaison boards proposed in their grant applications.

As of May 2004, 51 CP/C protocols were open for MBCCOP participation. MBCCOP leaders reported existing or planned partnerships with Native American tribal leaders; Indian Health Service facilities; and community organizations, such as local health departments, American Cancer Society chapters, cancer care alliances, and National Black Leadership Initiative on Cancer coalitions. Five MBCCOPs had community advisory boards in place or underway.

*MBCCOP contributions to major cancer prevention trials.* Table 1 lists the contributions of the CCOP network and the MBCCOP subgroup to STAR and SELECT. Between July 1999 and June 2004, MBCCOPs enrolled almost 500 women onto STAR, 43% of whom were minorities. SELECT enrollments between July 2001 and June 2004 were more than three times higher ( $n = 1,662$ ), with minorities comprising 82% of the MBCCOP enrollees.

*STAR.* More than 400 centers across the United States, Puerto Rico, and Canada participate in STAR. As of

**Table 1.** CCOP and MBCCOP Accruals to STAR and SELECT

	STAR*		SELECT†	
	No.	%	No.	%
CCOP accruals of accruals from all study sites	6,286	33	10,444	29
MBCCOP accruals of total CCOP accruals	495	8	1,662	16
No. of minority women completing breast cancer risk assessments—CCOPs	18,769	3	NA	—
No. of minority women completing breast cancer risk assessments—MBCCOPs	3,728	6	NA	—
CCOP minority accruals of total minority accruals from all sites	485	39	2,463	31
MBCCOP minority accruals of total CCOP minority accruals	215	44	1,368	56

Abbreviations: CCOP, Community Clinical Oncology Program; MBCCOP, Minority-Based Community Clinical Oncology Program; STAR, Study of Tamoxifen and Raloxifene; SELECT, Selenium and Vitamin E Cancer Prevention Trial; NA, not applicable.

\*Cumulative totals July 1999 to June 30, 2004.

†Cumulative totals July 2001 to June 25, 2004.

June 30, 2004, the 1,243 minority women participating in STAR comprised 6.5% of the total enrollment ( $n = 19,024$ ). The MBCCOPs contributed 44% of the CCOP network's minority enrollments and 17% of the minority participants enrolled by all STAR study sites.

To recruit minority women for STAR, MBCCOPs placed advertisements in minority-targeted media outlets, made presentations at minority churches, distributed fliers at minority health fairs, and partnered with local mammography centers and high-risk breast clinics to offer STAR information and breast cancer risk assessment forms to their patients. Although these outreach activities encouraged 3,728 minority women to complete risk assessment forms, only 6% of these women entered the study. MBCCOP representatives cited several factors that limited their ability to enroll minority women. These factors included the lack of validation of the Gail Model for minority women; the lower overall incidence of breast cancer among minority women; the scant Surveillance, Epidemiology, and End Results (SEER) registry data on breast cancer incidence rates among minority subpopulations, such as Native Americans and non-Mexican Hispanics; and the lack of age- and race-specific rates for blood clots and other baseline adverse events.<sup>17-19</sup> Also, because STAR was limited to postmenopausal women, the MBCCOPs were unable to enroll premenopausal African American women despite the higher incidence of breast cancer in this population subgroup.<sup>20</sup>

**SELECT.** Like STAR, the SELECT trial has more than 400 study sites in the United States, Puerto Rico, and Canada. As of June 25, 2004, the 7,986 minority men enrolled by these centers comprised 22% of the total enrollment ( $n = 35,534$ ). MBCCOPs contributed 56% of the CCOP network's minority enrollments and 17% of the minority participants enrolled by all SELECT study sites.

For most MBCCOPs, the placement of advertisements in minority-targeted media outlets proved to be an effective recruitment strategy. However, the MBCCOPs experienced varying levels of success recruiting minorities through churches, health fairs, and prostate cancer screening pro-

grams. One of the most innovative strategies involved a group of veteran volunteers organized by the Westside Division of the VA Chicago Healthcare System. This "VA Strike Force" aggressively recruited African American men to SELECT, making the University of Illinois MBCCOP the fifth-highest contributor to SELECT and the number one contributor of African American men in the nation. In San Juan, Puerto Rico, the MBCCOP helped a primary care solo practice become one of the nation's top ten accruing sites by mentoring the physician's staff on regulatory requirements and data management procedures.

## DISCUSSION

MBCCOPs have demonstrated their ability to facilitate the participation of racial/ethnic minorities and other underserved populations in clinical trials. Over the past decade, more than 5,500 minority cancer patients have enrolled in NCI-sponsored clinical trials through the MBCCOP network. By developing partnerships with local physicians, healthcare organizations, and cancer advocacy groups, MBCCOPs have significantly increased the visibility and accessibility of cancer prevention and treatment trials in minority communities. Despite these accomplishments, MBCCOPs have not yet reached their full potential. Increased funding would enable them to expand minority outreach activities, procure protocol-related drugs and ancillary services for uninsured patients, and provide mentoring and staff support to minority physicians interested in serving as investigators. MBCCOPs also could serve as pilot sites for evaluating the effectiveness of clinical trials recruitment strategies with diverse minority populations.

The MBCCOPs' success in broadening access to cancer treatment and CP/C trials raises the question of how best to expand the network. Over the past 5 years, NCI/DCP program directors have witnessed a significant increase in applications for MBCCOP funding. However, many applicants lack the data management systems, regulatory

support, quality assurance programs, and other infrastructure components needed to successfully compete for the awards. One way to enlarge the pool of qualified applicants would be to fund existing MBCCOPs to mentor potential new sites on methods of strengthening their research capabilities.

Finally, the contributions that MBCCOPs could make to the design and conduct of minority-focused research studies merit further exploration. By collecting tissues from minority patients, MBCCOPs could investigate possible biologic explanations for racial/ethnic disparities in clinical outcomes. They also are well positioned to study emerging issues in minority populations, such as increasing incidence rates in certain cancer types that are not yet reflected in national databases.

Our discussions with MBCCOP leaders suggest that the NCI, in partnership with other federal agencies, could help MBCCOPs build effective research collaborations to reduce racial/ethnic disparities in cancer incidence and clinical outcomes by (1) arranging for MBCCOP principal investigators to meet with the cooperative group chairs and the chairs of disease-specific and minority research committees to identify a core group of research questions for protocol development; (2) supporting the development of research concepts and protocols that address questions that are relevant to minority populations; (3) providing financial support for MBCCOP investigators to design and conduct minority-focused clinical trials; (4) forming an MBCCOP Web site and support network to facilitate communication among investigators; and (5) facilitating the dissemination of minority-focused, evidence-based interventions across the entire CCOP network.

MBCCOP leaders have expressed a desire to develop a coordinated research network capable of defining and studying issues important to minority populations. Achieving this goal will require a recommitment of institutional support, the ongoing participation of committed clinician investigators, and additional dialogue with CCOP research bases on ways of promoting integrated research initiatives.

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**Authors' Disclosures of Potential Conflicts of Interest**

Although all authors have completed the disclosure declaration, the following authors or their immediate family members have indicated a financial interest. No conflict exists for drugs or devices used in a study if they are not being evaluated as part of the investigation. For a detailed description of the disclosure categories, or for more information about ASCO's conflict of interest policy, please refer to the Author Disclosure Declaration and the Disclosures of Potential Conflicts of Interest section in Information for Contributors.

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**REFERENCES**

1. Moulton G: Community Clinical Oncology Program celebrates 20 years of trials and a few tribulations. *J Natl Cancer Inst* 95:1822-1824, 2003
2. National Institutes of Health Office of the Director: Overview of the NIH roadmap. <http://nihroadmap.nih.gov/overview.asp>
3. McCaskill-Stevens W, Pinto H, Marcus AC, et al: Recruiting minority cancer patients into

cancer clinical trials: A pilot project involving the Eastern Cooperative Oncology Group and the National Medical Association. *J Clin Oncol* 17:1029-1039, 1999

4. Pinto HA, McCaskill-Stevens W, Wolfe P, et al: Physician perspectives on increasing minorities in cancer clinical trials: An Eastern Cooperative Oncology Group (ECOG) initiative. *Ann Epidemiol* 10:S78-S84, 2000
5. Chamberlain RM, Winter KA, Yijayakumar S, et al: Sociodemographic analysis of patients in

radiation therapy oncology group clinical trials. *Int J Radiat Oncol Biol Phys* 40:9-15, 1998

6. Murthy VH, Krumholz HM, Gross CP: Participation in cancer clinical trials: Race-, sex-, and age-based disparities. *JAMA* 291:2720-2726, 2004
7. Sateren WB, Trimble EL, Abrams J, et al: How sociodemographics, presence of oncology specialists, and hospital cancer programs affect accrual to cancer treatment trials. *J Clin Oncol* 20:2109-2117, 2002

8. Simon MS, Du W, Flaherty L, et al: Factors associated with breast cancer clinical trials participation and enrollment at a large academic medical center. *J Clin Oncol* 22:2046-2052, 2004
9. Tejeda HA, Green SB, Trimble EL, et al: Representation of African-Americans, Hispanics, and whites in National Cancer Institute cancer treatment trials. *J Natl Cancer Inst* 88:812-816, 1996
10. Kaluzny A, Brawley O, Garson-Angert D, et al: Assuring access to state-of-the-art care for U.S. minority populations: The first 2 years of the Minority-Based Community Clinical Oncology Program. *J Natl Cancer Inst* 85:1945-1950, 1993
11. Garson-Angert DV: Barriers to the Implementation of Minority-Based Clinical Trials: A Case Study of the Complexity of Joint Action [unpublished doctoral dissertation]. Chapel Hill, NC, University of North Carolina, 1997
12. Wickerham DL: Tamoxifen's impact as a preventive agent in clinical practice and an update on the STAR trial. *Recent Results Cancer Res* 163:87-95, 2003
13. Lippman SM, Goodman PJ, Klein EA, et al: Designing the Selenium and Vitamin E cancer prevention trial. *J Natl Cancer Inst* 97:94-102, 2005
14. National Institutes of Health: The Central Institutional Review Board initiative. [http://www.ncicirb.org/CIIRB\\_Project.asp](http://www.ncicirb.org/CIIRB_Project.asp)
15. Fisher B, Costantino JP, Wickerham DL, et al: Tamoxifen for prevention of breast cancer: Report of the National Surgical Adjuvant Breast and Bowel Project P-1 study. *J Natl Cancer Inst* 90:1371-1388, 1998
16. Thompson IM, Goodman PJ, Tangen CM, et al: The influence of finasteride on the development of prostate cancer. *N Engl J Med* 349:215-224, 2003
17. Adams-Campbell L, Makambi K, Palmer J, et al: The Gail Model as a Diagnostic Indicator in African-American Women: Truth or Consequence. *Proc Am Soc Clin Oncol* 22:101s, 2004 (suppl, abstr 1017)
18. Gail MH, Costantino JP, Bryant J, et al: Weighing the risks and benefits of tamoxifen treatment for preventing breast cancer. *J Natl Cancer Inst* 91:1829-1846, 1999
19. Miller BA, Kolonel LN, Bernstein L, et al (eds): *Racial/Ethnic Patterns of Cancer in the United States, 1988-1992*. Bethesda, MD, National Cancer Institute, NIH publication 96-4104, 1996
20. Newman LA: Breast cancer in African-American women. *Oncologist* 10:1-14, 2005