The full version of this article
may be viewed online at
DOI: [10.1200/JOP.2015.005736](https://doi.org/10.1200/JOP.2015.005736)

Impact of the National Cancer Institute Community Cancer Centers Program on Clinical Trial and Related Activities at a Community Cancer Center in Rural Nebraska

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Disclosures provided by the authors are available with this article at jop.ascopubs.org.

QUESTION ASKED: What is the impact of participating in the National Cancer Institute Community Cancer Centers Program (NCCCP) on the number of clinical trials available, number of patients enrolled in trials, and trial-related services provided to patients at a rural community-based cancer program?

SUMMARY ANSWER: Significant increases in the number and percentage of patients enrolled in clinical trials, in the number of available treatment and non-treatment (eg, prevention, biospecimen, cancer control) trials, in clinical trial staffing, and in the number of tissue samples collected and/or stored were observed during the 5-year period of NCCCP. Biospecimen trials helped promote standardization of collection and storage processes in our community cancer program. Employment and utilization of a genetic counselor, smoking cessation counselor, outreach project coordinator, and two nurse navigators enabled delivery of improved cancer care continuum services to our rural patient population.

METHODS: SFCTC clinical trial activities data from July 2002 to June 2007, the 5 years before participation in the NCCCP, and from July 2007 to June 2012, the 5 years during the program, were gathered and compared. Data capture included information on the number and percentage of patients on clinical trials, number and type of available clinical trials, percentage of underserved patients in clinical trials, clinical trial staffing, collection and storage of tissue samples, organizational infrastructure, linkage to NCI-designated cancer centers, and availability of new cancer care services. Percentages of patients in clinical trials were calculated as the ratio of the number of patients enrolled onto clinical trials over the number of analytic new patient cases of cancer through our tumor registry per year. Percentages of tissue samples collected and/or stored were similarly measured as the number of biospecimens collected over the number of analytic new patient cases of cancer per year. Statistical analyses were performed using chi-square and Wilcoxon tests.

ASSOCIATED CONTENT

DOI: [10.1200/JOP.2015.005736](https://doi.org/10.1200/JOP.2015.005736);
published online ahead of print at
jop.ascopubs.org on August 11, 2015.

BIAS, CONFOUNDING FACTOR(S), DRAWBACKS: Data 5 years prior to and 5 years during NCCCP were prospectively collected. Analysis of data was performed after the completion of NCCCP.

REAL-LIFE IMPLICATIONS: Improving access of all adult cancer patients to clinical trials in the communities where they live is crucial to provide the best cancer care. Participation in the NCCCP had a positive impact on our clinical trial and related activities, providing our rural Nebraska population with enhanced access to both clinical trials and cancer care services. Implementing programs and policies that facilitate the delivery of high-quality care in the community setting is feasible and greatly needed. The NCCCP had a positive impact by providing expanded spectrum of clinical trial types and programs to the population of patients in our cancer program service area. [JOP](#)

Table 1. Clinical Trial–Related Activities 5 Years Before and During NCCCP at SFCTC

Activity	5 Years Before NCCCP, July 2002 to June 2007	5 Years of NCCCP, July 2007 to June 2012	P	First Year of NCORP, July 2014 to June 2015
No. of dedicated clinical trial staffing (FTE)	2 (1.2)	5 (3.9)	.012	6 (5)
Total No. of accruals (range)	83 (9-35)	640 (51-230)		90
Overall participation rate in trials, % (range)	3.2 (2-7)	23 (9-41)	< .001	18
Average accrual No. per clinical trial	13.2	15.8	.5	1.61
No. of clinical trials by sponsor (range)				
Cooperative	46 (5-14)	130 (14-29)		43
Industry	3 (1-2)	48 (3-15)		5
Investigator initiated	5 (0-1)	33 (2-10)		8
Total	54 (6-17)	211 (19-54)		56
No. of clinical trials by type (range)				
Total treatment	40 (4-14)	138 (14-36)	.015	46
Average No. per year	8	28		NA
Total nontreatment	15 (0-10)	61 (3-33)	.009	10
Average No. per year	3	12		NA
Supportive care	0	10 (0-10)		
Prevention	0	3 (0-1)		0
Quality of life	4 (0-1)	8 (1-2)		0
Cancer care delivery	0	7 (1-2)		2
Biospecimen	10 (2-5)	33 (3-9)		1
Annual rate of increase in:				
No. of available trials	3.4	6.7	.36	NA
No. of accruals	3.1	36.9	.02	NA
Percentage of accruals	0.6	6.5	.03	NA

Abbreviations: FTE, full-time equivalent; NA, not applicable; NCCCP, National Cancer Institute Community Cancer Centers Program; NCORP, National Cancer Institute Community Oncology Research Program; SFCTC, Saint Francis Cancer Treatment Center.

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Abstract

Purpose

Although 85% of patients with cancer are diagnosed and treated in the community setting, only 3% are enrolled onto clinical trials. Lack of adequate time, infrastructure, resources, incentives, and reimbursement adversely affect clinical trial participation. In July 2007, Saint Francis Cancer Treatment Center (SFCTC) in Grand Island, Nebraska, was selected as one of the initial 16 sites for the National Cancer Institute Community Cancer Centers Program (NCCCP).

Methods

Clinical trial and related activities data at SFCTC 5 years before and 5 years during the NCCCP were gathered and compared. Data included information on patients in clinical trials, number and type of trials, ratio of underserved patients, staffing, collection and storage of tissue samples, availability of new cancer services, and organizational infrastructure and linkage to National Cancer Institute–designated cancer centers.

Results

The number and percentage of patients enrolled onto clinical trials increased from 89 (3.2%) to 640 (23%; $P < .001$). All enrollees were rural Nebraskans, with 70% age > 65 years. Available treatment and nontreatment (eg, prevention, biospecimen, cancer control) trials increased from eight and three per year to 28 and 12 per year ($P = .012$), respectively. Staffing increased from 1.2 to 3.9 full-time equivalents ($P = .012$). A genetic counselor, smoking cessation counselor, and outreach project coordinator and two nurse navigators were hired. The number of tissue samples collected and/or stored increased from 26 (19%) to 320 (52%; $P < .001$).

Conclusion

NCCCP participation had a direct and positive impact on all activities, with enhanced access to expanded types of trials and cancer care services. Our data demonstrate the feasibility of successful implementation of an expanded spectrum of clinical trials and programs in a rural community.

ASSOCIATED CONTENT

DOI: [10.1200/JOP.2015.005736](https://doi.org/10.1200/JOP.2015.005736);
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INTRODUCTION

Cancer is a leading cause of death in the United States, accounting for more than half a million deaths annually, second only to heart disease.¹ The most reliable way of enabling effective new cancer treatments has been through carefully designed prospective clinical trials. Enrollment of sufficient numbers of participants onto these trials is vital to ensure adequate statistical power and generalizability. Currently, only 3% to 5% of all adult patients with newly diagnosed cancer are treated in clinical trials.²⁻⁴ Furthermore, representation of minorities and the elderly in clinical trials has been low.^{5,6} The low accrual rates of adults have a negative impact, often prolonging the clinical trial process and ultimately leading to either early closure of important studies or delayed completion and analysis of important results. This is in contrast to pediatric oncology, in which the standard of care is the enrollment of patients onto peer-reviewed cooperative group clinical trials, with an enrollment rate exceeding 60%.^{7,8}

Basic and clinical science research, which is crucial for the development of innovative approaches and strategies, have not always reached community-based patients with cancer.⁹⁻¹¹ Although cancer clinical trials provide the evidence base for new advances in oncology, poor enrollment threatens to slow the much needed progress in cancer care at a time when advances in science are promising new opportunities. Furthermore, enrollment in racial, ethnic, minority, elderly, adolescent, and young adult populations is not adequate to address aspects of care unique to these populations.¹²⁻¹⁴ Those who participate tend to be overwhelmingly white, urban, and age < 65 years and to belong to a higher socioeconomic status.¹⁵⁻¹⁹

To address some of these gaps, the National Cancer Institute (NCI) made communities research an integral and important component of the National Research Program in the late 1970s. First, the Cooperative Group Outreach Program was established, followed by the launch of the Community Clinical Oncology Program (CCOP) in 1983 and the Minority-Based Community Clinical Oncology Program in 1994.^{6,20-22} These programs accounted for one third of the NCI treatment clinical trial enrollments and nearly all of the NCI cancer prevention and control trial accruals, serving an integral role in the development and successful completion of these trials.²³⁻²⁶

In 2004, the NCI created the Clinical Trials Working Group²⁷ as a means of restructuring and improving the

administration of the NCI-sponsored clinical trials program in academic and community-based settings. In 2006, the NCI strategic plan was published, outlining the need to enhance research and its applications to improve care delivery throughout the cancer care continuum.²⁸ Optimum cancer care is best delivered as a continuum from prevention, screening, early detection, and diagnosis to treatment, surveillance, survivorship, palliative care, and end-of-life care; however, traditionally many of these services have not been readily available in the community setting.

The NCI Community Cancer Centers Program (NCCCP) was launched in 2007 as a pilot to support these broader initiatives, with an emphasis on reducing cancer health care disparities across the cancer continuum. Both the NCI strategic plan and the NCCCP emphasized the need to enhance access to high-quality care and advance cancer research in the communities where most patients receive their care.^{27,28} Along with two other community hospitals in Nebraska, our community-based center—Saint Francis Cancer Treatment Center (SFCTC)—in Grand Island, Nebraska, was selected as one of the initial 16 pilot sites and successfully competed for continuation in the program beyond the pilot. In this article, we present and compare our clinical trial- and cancer care-related data from the 5 years before and 5 years during the NCCCP period at SFCTC.

Part of Catholic Health Initiatives (CHI) of Denver, Colorado, Saint Francis Medical Center is a 200-bed community hospital in central Nebraska. As a regional referral center, it offers a variety of specialty services, including a cancer treatment center. The Saint Francis Cancer Program serves > 600 new patients with cancer per year, with > 21,000 clinical visits. The primary service area is home to 40,595 women and 40,381 men in four counties. The tertiary market area stretches from South Dakota to Kansas and west into the Nebraska panhandle. The majority of the Saint Francis service area is rural; > 20% of the Hall County population, where SFCTC is located, is Hispanic, and 80% of the Hispanic households in the county have an annual income < \$25,000.

SFCTC started as a satellite clinic of the University of Nebraska in 1989. With the hiring of a medical oncologist in 1995, it became a community hospital-based cancer program. Initial approval by American College of Surgeons Commission on Cancer in 1996 has been maintained with commendations over the past 18 years and complemented with two Outstanding Achievement Awards in 2010 and 2013 surveys. The Saint Francis Cancer Program started

participating in the American Society of Clinical Oncology Quality Oncology Practice Initiative (QOPI) in 2010 and became a QOPI-certified practice in 2012. SFCTC has maintained its academic affiliation with University of Nebraska. To create collaboration and partnership with NCI programs, our community-based cancer program applied and became an affiliate of Eppley Cancer Center, an NCI-designated cancer program in Omaha, Nebraska, just before its participation in the NCCCP in 2007.

METHODS

SFCTC clinical trial activities data from July 2002 to June 2007, the 5 years before participation in the NCCCP, and from July 2007 to June 2012, the 5 years during the program, were gathered and compared. Data capture included the number and percentage of patients in clinical trials, number and type of available clinical trials, percentage of underserved patients in clinical trials, clinical trial staffing, collection and storage of tissue samples, organizational infrastructure, linkage to NCI-designated cancer centers, and availability of new cancer care services. Percentages of patients in clinical trials were calculated as the ratio of the number of patients enrolled onto clinical trials over the number of analytic new patient cases of cancer through our tumor registry per year. Percentages of tissue samples collected and/or stored were similarly measured as the number of biospecimens collected over the number of analytic new patient cases of cancer per year. Biospecimen trials helped promote standardization of collection and storage processes at our site. Statistical analyses were performed using χ^2 and Wilcoxon tests.

RESULTS

Before NCCCP participation, there were only two dedicated research staff members, one clinical research nurse, and one clinical research associate at SFCTC. With NCCCP funding, this increased to five staff members, comprising two clinical research nurses and three clinical research associates. This translates into an overall clinical trial staffing increase from an average of 1.2 full-time equivalents (FTEs) in the 5 years before the NCCCP to 3.9 FTEs during the 5 years of the NCCCP (Wilcoxon $P = .012$; Table 1).

Total number of accruals during each 5-year period increased from 83 (range, nine to 35 per year) to 640 (range, 51 to 230 per year). The pre-NCCCP clinical trial enrollment rate increased from 2% to 7% per year to 9% to 41% per year during the NCCCP, with an overall clinical trial participation

rate increase from 3.2% in the 5-year period before the NCCCP to 23% during the 5 year-period of the NCCCP ($\chi^2 P < .001$). Average accrual per clinical trial was 13.2 before the NCCCP and 15.8 during the 5-year period of the NCCCP (Wilcoxon $P = .5$; Table 1).

Clinical trial mix by sponsor type increased three- to four-fold in all categories during the NCCCP funding period and included NCI Cooperative Group-, industry-, and investigator-initiated trials. There was an increase in the number of both treatment and nontreatment (ie, prevention, supportive care, quality of life, and biospecimen) trials. Treatment clinical trials increased from an average of eight to 28 per year (Wilcoxon $P = .015$), and nontreatment clinical trials increased from an average three to 12 per year (Wilcoxon $P = .009$). The total number of available clinical trials before the NCCCP increased from six to 17 per year to 19 to 54 per year (Table 1). Patient accruals to these trials also increased proportionately, with an increase in all types of clinical trial accruals during the NCCCP period (Figure 1). Accrual details based on type of trial are shown in Figure 2.

The annual rate of increase in the number of available clinical trials during the 5 years before and the 5-year period of the NCCCP was 3.4 versus 6.7 per year (Wilcoxon $P = .36$), the annual rate of increase in the number of patients accrued was 3.1 versus 36.9 patients per year (Wilcoxon $P = .02$), and the annual rate of increase of patients accrued was 0.6% versus 6.5% per year ($\chi^2 P = .03$; Table 1).

DISCUSSION

Progress in cancer therapy has historically come through advancement of initial empiric observations in phase I to II/III trials, with inclusion of a larger number of patients to demonstrate a statistically significant and clinically meaningful effect.²⁹ Clinical research has traditionally been available through NCI-designated cancer centers and programs. SFCTC was providing access to NCI Cooperative Group trials and investigator-initiated clinical trials starting as early as 1996 through its affiliation with University of Nebraska Medical Center. However, this effort was rather limited in scope and ability. Along with the NCCCP came strong support for staff and funding for research, not only through the NCCCP but also through cofunding support from our lead institution CHI as part of the NCCCP requirement for site coinvestment. One of the deliverables in the NCCCP program emphasizes creation of strong collaboration and partnerships between community hospitals, NCI programs, and NCI-designated

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cancer centers. This led our cancer program to strengthen its affiliation with the NCI-designated Eppley Cancer Institute in Omaha, Nebraska, which had been established just before the beginning of the NCCCP. Participation in the NCCCP helped solidify this relationship and enabled SFCTC to increase its participation in a variety of investigator-initiated, treatment, and nontreatment (eg, biospecimen, prevention, quality of life) trials.

Throughout our participation in the NCCCP, we observed significant improvements in every aspect of clinical trial activities. The availability of NCCCP funding and cofunding from CHI provided the much-needed impetus to support significant progress in our clinical research endeavor. This included increased staffing in our clinical trials office, with the addition of nurse navigators, genetic counselors, and a community outreach project coordinator. Our program has

retained all of these positions to date. Some of the funding provided by our lead institution was used to increase patient and physician awareness of clinical trials and related activities in the community through our marketing department.

Before the NCCCP, our cancer program data on clinical trial–related activities were already being captured. Collection of data during the NCCCP made it possible to compare and analyze the impact of this program. Not only were our overall clinical trial–related activities data significantly improved, but annual rates of increase in the number of available clinical trials as well as the number and percentage of accruals were all significantly higher during the 5-year NCCCP period, indicating that the increase was more likely a result of participation in the NCCCP rather than the expected existing rate of increase over the prior 5-year period (Table 1).

A number of factors may have played a role in the significant benefit that our program gained from NCCCP participation:

- First, SFCTC had an established infrastructure and interest in conducting clinical trials before the start of the NCCCP. This paved the way for robust adoption and use of resources that came with the NCCCP. Adding more clinical trial research nurses, clinical trial research associates, nurse navigators, genetic counselors, and a community outreach project coordinator, along with the establishment of linkage to an NCI-designated cancer center, expanded our existing ability to conduct a greater number and wider variety of clinical trials.
- Second, several investigator-initiated studies, such as the Breast Cancer Collaborative Registry (BCCR) with Eppler Cancer Center, lung cancer chemotherapy patient-centered outcomes research with University of Nebraska Medical Center, and phase I trials with investigators from academia and industry evaluating oral tyrosine kinase inhibitors, became available to our patient population. Investigator-initiated trial activity has been an exciting development in our NCCCP experience. Partnering with NCI-designated Eppler Cancer Center provided the infrastructure for access to a variety of treatment trials and nontreatment (eg, biospecimen registries, prevention, quality of life) studies. Increased availability of resources (eg, more staffing) coupled with networking opportunities through affiliation with NCI-designated Eppler Cancer Center set the stage for a successful community-academic partnership. One of these initiatives was (and still is) the BCCR, with the objective of developing and maintaining multicenter comprehensive data and a biospecimen bank. The BCCR provides core support services to its research group members and collaborators from different institutions for multidisciplinary research. SFCTC has been one of the collaborating institutions since 2007.
- Third, increased community outreach activities with the addition of an outreach coordinator enabled more efficient primary care physician and patient awareness about clinical trials and related activities. Educational programs for patients, establishment of multidisciplinary cancer conferences for physicians, and availability of nurse navigators attending patients' primary care, surgery, radiology, and radiation oncology appointments created an unprecedented awareness about clinical trials

FIG 1. Treatment, nontreatment, and total clinical trial accruals.

among all stakeholders involved in the care of patients with cancer. This resulted in increased clinical trial screening, increased clinical trial referrals, increased accruals, and more effective follow-up and reporting.

- Fourth, having a hospital-based or -employed program with academic affiliation might have made it easier for

FIG 2. Clinical trial accruals based on trial type. CCDR, cancer care delivery research; QOL, quality of life.

the physician and nonphysician staff to focus, share, and implement the goals of the NCCCP efficiently and to dedicate most of their time to this effort. Additionally, establishment of the CHI National Oncology Service Line facilitated the CHI NCCCP sites to work more collaboratively, making it possible to clearly define our program goals.

- Fifth, we had the opportunity to actively participate in collaborative learning at the national level by regularly participating in the network of NCCCP hospitals, sharing information on lessons learned, best practices, and tools developed in the network for benchmarking. NCCCP Webinars and in-person annual meetings complemented these efforts, providing further direction on creating a better culture of research in our individual settings.³⁰
- Last but not least, a dedicated local team with a pre-existing passion for and experience in clinical trials at our cancer center provided the most essential ingredient for a successful outcome, suggesting that local or institutional factors likely play an important role in how a site can most optimally use these types of resources.

Completion of the NCCCP coincided with substantial changes in the NCI clinical trials network system. Spurred by the recommendations of the Institute of Medicine 2010 report, the NCI Cooperative Group Program was consolidated into four adult groups under the National Clinical Trials Network. The centralized functions of the National Clinical Trials Network also include a centralized institutional review board, cancer trials support unit, imaging and radiation oncology core group, and common data management system that is hosted centrally. Our cancer program felt the impact of these changes starting in July 2012, with a temporary decline in the number of available cooperative group clinical trials and subsequent patient enrollment. Decreased funding for clinical trials staffing prevented hiring of new personnel. However, we were able to maintain our existing personnel through our institutional support.

The guiding principles of our success in the NCCCP, coupled with the wisdom, vision, dedication, and experience of our research staff, motivated and enabled us to apply and be accepted into the newly established NCI Community Oncology Research Program. To date, our clinical trial staffing, number of available clinical trials, and rate of participation continue to remain at levels comparable to those during our

experience in the NCCCP (Table 1). Our cancer program has been able to successfully implement and maintain an expanded spectrum of cancer care services in the post-NCCCP era. Among these are nurse navigation, genetic counseling, and prevention and screening activities, which have now become natural and indispensable parts of our cancer service lines. The current NCI Community Oncology Research Program supports easier access to all NCI National Clinical Trials Network trials, centralized institutional review board, common data management system, and development of cancer care delivery trials to provide even greater opportunities in promoting the highest-quality, cutting-edge cancer research and cancer care service delivery in the community where our patients live.

In conclusion, clinical trial participation offers patients with cancer access to innovative therapeutic approaches, with the potential for improving their outcomes. In the last decade, our enhanced understanding of cancer biology, genomics, and immunology has marked a new era of more sophisticated and less toxic cancer treatments. Clinical trials involving novel targeted therapies will require the inclusion of a broader patient population so that patients with rare driver mutations, pathways, and targets can all be captured. The time is now to improve access to clinical trials for all adult patients with cancer who wish to receive advanced care in the communities in which they live. Only with more vigorous clinical trial enrollment will the science and promise of discovering precision and targeted treatments be more rapidly realized.

Participation in the NCCCP had a positive impact on our clinical trial-related activities, providing rural Nebraskans with enhanced access to both clinical trials and cancer care services. Continued programs and policies that facilitate the delivery of high-quality care in these environments must be a priority. Our data demonstrate the feasibility of implementing an expanded spectrum of clinical trial types and programs in a rural community setting. **JOP**

Acknowledgment

We thank Eileen Dimond, RN, MS, for her invaluable input and guidance in the preparation of this article and for her support during the National Cancer Institute Community Cancer Centers Program.

Authors' Disclosures of Potential Conflicts of Interest

Disclosures provided by the authors are available with this article at jop.ascopubs.org.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST**Impact of the National Cancer Institute Community Cancer Centers Program on Clinical Trial and Related Activities at a Community Cancer Center in Rural Nebraska**

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No relationship to disclose

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No relationship to disclose

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