



Translating Scientific Advances into the Community Setting

The National Cancer Institute Community Cancer Centers Program pilot

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Cancer death rates have been dropping over the last decade, and the most current *Annual Report to the Nation on the Status of Cancer* provides further evidence of progress made. For the first time, the report documented both a decline in cancer incidence for men and women, as well as a decline in death rates.¹ However, cancer is and will continue to be a challenge to the medical community both in the United States where by 2030, the U.S. Census Bureau estimates 19 percent of the population will be over age 65,² as well as worldwide, where the World Health Organization estimates that cancer will overtake heart disease as the world's leading cause of death by 2010.³

Despite these challenges, scientific advances are bringing individualized cancer care to a new level. Research on unique genetic changes and the subsequent modifications in biological pathways that lead to cancer is creating novel therapies that are highly specific, often with reduced toxic side effects. As a result of these advances, the delivery of cancer care is also changing.

Increasingly, with leading-edge technology and well-trained medical specialists more widely accessible, this more complex level of care—including advanced cancer treatment and access to clinical trials—can now be provided by hospitals in community settings.

The National Cancer Institute Community Cancer Centers Program

As new knowledge and technologies accelerate, the National Cancer Institute (NCI) recognizes the need to understand how to deliver the latest scientific advances to patients in their communities, where approximately 85 percent of U.S. cancer patients are treated. In response, NCI developed a pilot program, the NCI Community Cancer Centers Program (NCCCP), which is exploring the best methods to enable the provision of state-of-the-art, multi-specialty care and early-phase clinical trials in community-based locations.

The program is studying how to adopt and expand components of optimum cancer care and research into community settings. In this program, “optimum cancer care” is defined as programs that:⁴

- Place a strong focus on healthcare disparities
- Offer clinical trials
- Use electronic health records
- Collect high quality biospecimens
- Use evidenced-based care that is coordinated across disease site-specific multidisciplinary teams
- Include survivorship programs in the care model

- Attempt to connect or partner with national research efforts such as the NCI's cancer Bioinformatics Grid (caBIG®).

The NCCCP pilot addresses the full cancer care continuum—from prevention, screening, diagnosis, treatment, survivorship, through end-of-life care. The areas of focus are identified in Figure 1. An innovative feature of the pilot is the requirement to integrate work on healthcare disparities, quality of care, and information technology (IT) throughout the NCCCP pilot focus areas and the full cancer care continuum.

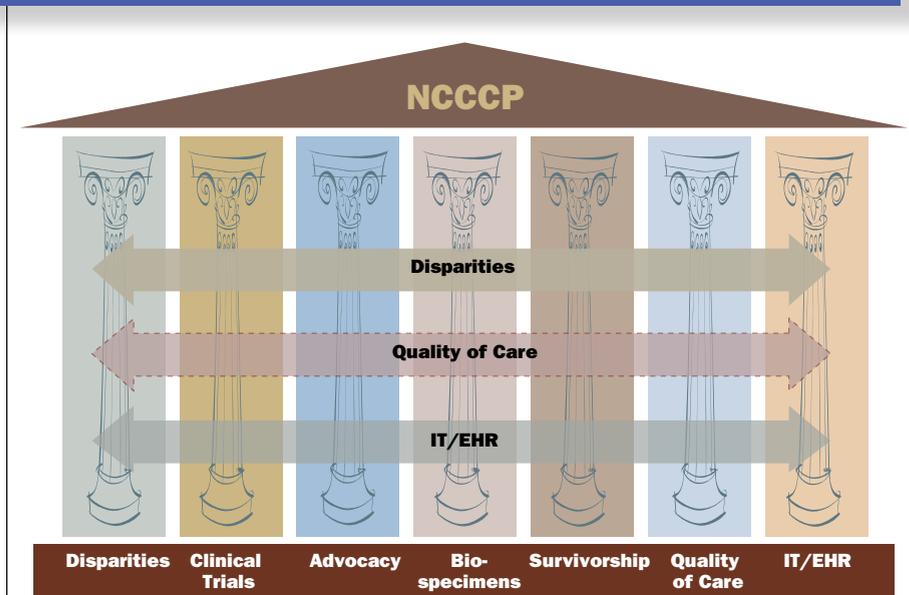
As a template for state-of-the-art community-based cancer care, some of the pilot site eligibility requirements included hospital-based programs with at least 1,000 new cancer cases per year, and medical, surgical, and radiation oncology all offered in the cancer center, providing a multidisciplinary approach to cancer care. Hospitals selected to participate in the pilot also needed to demonstrate provision of services necessary to care for cancer patients in their communities such as: 1) screening, navigation, survivorship, and palliative care services; 2) the ability to offer clinical trials, with a minimum of 25 patients accrued per year; 3) the potential to collect high quality biospecimens; and 4) plans to implement electronic health records. Commission on Cancer accreditation and College of American Pathologists accreditation or Joint Commission laboratory accreditation was also required. Finally, community outreach and reducing healthcare disparities are important components of the program; each site has to have a policy in place that all patients who are screened with an abnormal finding and/or diagnosed with cancer are offered treatment.

NCCCP Complements Other NCI Programs

The NCCCP pilot is creating a network of hospital-based community cancer centers to serve as a research platform to support NCI goals and to facilitate sharing best practices. Through the pilot, NCCCP sites interact with and complement many NCI initiatives, including the Community Clinical Oncology Program (CCOP) and the NCI-designated Cancer Centers Program.

A unique feature of the NCCCP pilot is the creation of infrastructure to incorporate knowledge gained from other NCI programs into translational research opportunities in the community. Half of the NCCCP pilot sites are also CCOP sites, and all sites are expanding their linkages with the NCI-designated Cancer Centers. Several sites have linkages with the NCI Community Network Program sites, and most are working with the Cancer Information

Figure 1. NCCCP's Core Components



Service Partnership Program.

This interaction with other NCI programs creates mutual benefit. NCCCP pilot sites gain by having access to clinical trials and the latest scientific advances for their patients. The research community gains a networked research infrastructure that helps improve access to patients for clinical trials, access to clinical data for analysis, and access to biospecimens.

NCCCP Pilot Sites

Ten organizations were selected for funding from across the county: six are community hospitals in both urban and semi-rural areas; two are rural hospitals that include Native American populations; and two are national health systems that were included to study how these organizations disseminate information and practices of the program to developmental sites that were not required to meet the baseline criteria at the time of award. Therefore, although 10 organizations are funded, 16 community hospitals are participating in the pilot (see Figure 2, page 27).

The pilot sites provide a strong study group with approximately 27,000 new cancer cases per year. These sites were chosen to represent a diverse range of programs that differ in program maturity and size, geographic and community settings, market characteristics, and medical staff arrangements. Each site has unique strengths and areas for improvement based on the NCCCP pilot areas of focus. All are sharing their expertise and best practices to create a strong network of sites.

NCI's investment is approximately \$500,000 per site per year, for a total commitment of \$15 million over the three-year pilot period. Due to the strong focus on addressing healthcare disparities, NCI requires that the sites must use 40 percent of their NCI dollars to address disparities. This program is a strong public-private partnership; the sites pledged to co-invest \$47 million (a 3-to-1 match for every NCI dollar) and their co-investment is being measured throughout the pilot.

NCCCP Pilot Goals

Specific improvement goals were set in each pilot area of focus during the three-year pilot. In the area of reducing healthcare disparities, for example, pilot sites must increase outreach to disparate populations, community partnership arrangements, primary care provider linkages, patient navigation programs, and screening resources. During the first two years, pilot sites already have made progress to reach the underserved, including:

■ Partnering with primary care providers to improve screening

■ Strengthening linkages with oncologists to coordinate care

■ Expanding survivorship and palliative care activities

■ Promoting research.

For clinical trials, pilot sites must increase patient accruals, including accrual of under-represented and disadvantaged populations, and accrual to different types of trials. Accordingly, pilot sites are developing programs to increase physician participation in clinical trials and to identify patient and physician barriers to participation. To better provide state-of-the-art cancer care in a community setting, pilot sites are identifying the infrastructure necessary to conduct early phase clinical trials in community hospitals.

Implementation of EHRs for the cancer center is another key area. Pilot sites are exploring what is needed to adapt or adopt their existing IT infrastructures to utilize NCI's caBIG® tools that are used to support cancer research.

In the area of quality of care, pilot sites must increase their use of multidisciplinary, disease-site-specific care committees and clinics. Other requirements: 1) expanded use of evidence-based guidelines, along with participation

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in a network-based quality improvement project; 2) expansion of genetic counseling and molecular testing programs on site or through referrals; and 3) adoption of cancer-center specific medical staff conditions of participation.

Pilot sites are also working to expand their survivorship, psychosocial, and palliative care activities, including implementing patient treatment summaries, incorporating survivorship care plans into care models, increasing staff training in survivorship and palliative care, and increasing referrals to hospice.

To help build a community-based bioinformatics research infrastructure, pilot sites are identifying the requirements, policies, and procedures needed to implement the NCI's Best Practices for Biospecimen Resources.⁵ This activity will identify what is necessary to enable community hospitals to participate in collecting high quality biospecimens to advance cancer research and patient care.

NCCCP's Collaborative Network

One of the cornerstones of the NCCCP pilot is to create a network of community cancer centers to improve quality of care and support research through sharing best practices and providing technical assistance to one another. The pilot sites have worked together to develop several NCCCP tools to assess their programs, select areas for improvement, and measure progress. Tools include the Multidisciplinary Care (MDC) Assessment Tool that enables sites to define their MDC model based on the extent of program integration in case planning, physician engagement, coordination of care, infrastructure needs, and financial considerations.

The Cancer Medical Staff Conditions of Participation is another tool to support pilot sites by recommending the requirements for physician experience and performance in community cancer centers. Core elements of these requirements include: 1) participation in clinical trials and in quality of care initiatives, 2) acceptance of uninsured patients, and 3) board certification.

A third tool, the Clinical Trials Accrual Tracking Log, tracks demographics, protocol screening methods, and enrollment details including reasons for not participating. Table 1 on page 28 briefly describes these and other tools, including the Breast Screening Tracking Tool, the Breast Treatment Summary Tool, the Breast Cancer Survivorship Care Plan, a uniform Chemotherapy Consent Form, a Genetic Counseling Assessment Tool, and the Gap and Fill Assessment Tool for Biospecimen Collection.

The NCCCP Network developed a cross-cutting disparities vision and work plan that integrates disparities activities across the NCCCP pilot focus areas, as well as a Template for Community Outreach that provides an overview on how to plan, implement, and evaluate focused community outreach efforts to target specific cancer healthcare

disparities. All tools are located on the NCCCP website (<http://ncccp.cancer.gov/About/Progress.htm>) for review and use by other community cancer centers.⁶

The NCCCP Network also forged new and innovative collaborations with national medical specialty organizations. For example, the pilot sites are working with the American College of Surgeons' Commission on Cancer to assess quality of care improvements against standard quality indicators. NCI is working with the American Society of Clinical Oncology (ASCO) to develop oncology-specific EHRs that will be tested at the NCCCP pilot sites. This initiative will ensure that the needs of community hospitals are considered in the planning and development of EHRs. Physicians from select NCCCP pilot sites participate in ASCO's Quality Oncology Practice Initiative (QOPI), which supports quality improvement projects for community, office-based oncology and hematology practices. These examples demonstrate the commitment of the pilot sites to work together as a network to enhance their ability to provide high-quality cancer care.

The NCCCP Network is also enhancing the cancer research infrastructure. Pilot sites are adopting optimal processes for formalin-fixation, the first necessary step for high-quality biospecimens, and some are participating in The Cancer Genome Atlas (TCGA) project and other biospecimen initiatives at academic research institutions, including NCI-designated Cancer Centers. Several caBIG[®] bioinformatics tools are being implemented in the areas of clinical trials, tissue collection, and imaging. Some pilot sites have already initiated EHR implementation; other pilot sites have reported increased accruals to clinical trials. These early accomplishments demonstrate that community cancer centers are willing and capable of actively contributing to cancer research.

NCCCP Challenges

Some early challenges were identified during the first year of pilot site operations. In the area of disparities, for example, pilot sites were not consistently tracking race and ethnicity in all program activities of the cancer centers and no pilot sites were consistently using Office of Management and Budget (OMB) reporting categories. To address this problem, pilot sites were directed to the tool kit provided by the Hospital Research and Educational Trust (HRET) and training was provided (<http://www.bretdisparities.org/>).

In the area of community outreach, pilot sites often have a number of activities underway without a focused approach to address a specific disparities problem in their community. To improve performance in this area, pilot sites developed The Template for Community Outreach Tool (see Table 1).

Another major challenge for the pilot programs is

Figure 2. NCCCP Pilot Sites

Legend

1. Billings Clinic, Billings Clinic Cancer Center, Billings, Montana
2. Hartford Hospital, Helen & Harry Gray Cancer Center, Hartford, Connecticut
3. St. Joseph's/Candler, the Nancy N. and J.C. Lewis Cancer Center & Research Pavilion, Savannah, Georgia
4. Our Lady of the Lake Regional Medical Center, Our Lady of the Lake Cancer Center and Mary Bird Perkins Cancer Center, Baton Rouge, Louisiana
5. Sanford USD Medical Center, Sanford Cancer Center, Sioux Falls, South Dakota
6. Spartanburg Regional Hospital, Gibbs Regional Cancer Center, Spartanburg, South Carolina
7. St. Joseph Hospital, St. Joseph Hospital Cancer Center, Orange, California
8. Christiana Hospital, Helen F. Graham Cancer Center at Christiana Care, Newark, Delaware
9. Ascension Health of St. Louis, Missouri, operates sites at: a) St. Vincent Indianapolis Hospital, St. Vincent Oncology Center, Indianapolis, Indiana; b) Columbia St. Mary's, Columbia St. Mary's Cancer Center, Milwaukee, Wisconsin; and c) Brackenridge Hospital, Shivers Cancer Center, Austin, Texas



10. Catholic Health Initiatives of Denver, Colorado operates sites at: a) Penrose-St. Francis Health Services, Penrose Cancer Center, Colorado Springs, Colorado; b) St. Joseph Medical Center, St. Joseph Cancer Institute, Towson, Maryland; and c) a coordinated regional program in Nebraska sponsored by Good Samaritan Hospital, Good Samaritan Cancer Center Kearney, Nebraska; St. Elizabeth Regional Medical Center, St. Elizabeth Cancer Center, Lincoln, Nebraska; and St. Francis Medical Center, St. Francis Cancer Treatment Center, Grand Island, Nebraska.

accomplishing goals where cancer specialists operate in private, office-based practices. Issues include:

- Access to patient data
- IT linkages
- Coordination of care
- Promotion of clinical trials
- Legal implications (Stark and anti-kickback laws)
- Alignment of program and physician goals
- Physician time for NCCCP program activities.

Strategies to address these issues are being explored and shared across the NCCCP network. As tools and approaches are developed and being tested, they will be posted to the NCCCP public website.

NCCCP Evaluation

The multifaceted focus areas that NCCCP pilot sites are engaged in are embedded in a complex organizational setting and local environment. This local environment includes the cancer program within the community hospital, and encompasses many different medical staff organizations, from private practice to hospital-employed physicians. NCI has contracted with RTI International, Inc., to conduct a multi-level independent evaluation of the NCCCP project that assesses the program model and overall performance within this complex organizational and community structure. In addition, the NCI is studying the local, state, and national influences on the community cancer center programs, including effects

from national and state health policy environments and the effect of other hospitals in the pilot sites' local markets.

The independent program evaluation includes case studies of the pilot sites that are designed to: 1) understand the implementation of the pilot program, 2) assess change, and 3) determine successful structures and processes.

Economic studies are also being conducted and include a micro-cost study, a business case study, and a program sustainability study.

In addition, patient surveys are being conducted to assess the patient's experience with the program, including the patient's perspective regarding physician communication and coordination of care, as well as access to clinical trials and survivorship care. Focus groups eliciting patients' experience with the various program components are planned for the third year of the pilot program.

Looking to the Future

The NCCCP pilot is evaluating a comprehensive model for cancer care and research in community settings and determining whether a national network of diverse community cancer centers can support research and enhance the quality of care experienced by individuals at risk or diagnosed with cancer. Through sharing of best practices, the NCCCP program hopes to identify: 1) effective methods to increase accrual of patients into clinical trials, 2) approaches to reduce healthcare disparities, and 3) quality of care activities to help increase adherence to evidence-based practice guide-

Table 1. Pilot Tools being Tested by NCCCP Pilot Sites

Tool	Purpose
Clinical Trials Accrual Tracking Log	Tracks demographics, protocol screening methods, and enrollment details including reasons for not participating. Initial evaluation suggests that this tool has helped increase accrual rates.
Breast Screening Tracking Tool	Being tested as an effective mechanism for monitoring the lag time between initial screening, diagnosis and care, and recruitment for clinical trials, particularly for the underserved.
The Breast Treatment Summary Tool	Built upon ASCO's treatment summary forms and includes Institute of Medicine recommendations. It includes detailed information on treatments received and healthcare provider information.
The Breast Cancer Survivorship Care Plan	Includes surveillance guidelines, as well as a list of risk factors for potential long-term and late effects of therapy, and approaches to monitor and address these possible problems.
The Multidisciplinary Care Assessment Tool	Defines a multidisciplinary model for cancer care in the community setting, including integrated efforts in case planning, physician engagement, coordination of care, infrastructure, and financial considerations.
Chemotherapy Consent Form	This uniform template is easily modified for individual institutional use.
The Genetic Counseling Assessment Tool	Defines the minimal genetic counseling service requirements to guide improvements.
The Physicians Conditions of Participation	Recommends requirements for experience and performance, and includes volume of patients treated, participation in clinical trials and in quality of care initiatives, acceptance of uninsured patients, and board certification.
Biospecimen Assessment Tools	Assess and report progress on what is needed to implement the NCI's Best Practices for Biospecimen Resources.
Template for Community Outreach	Provides guidance to pilot sites on how to focus their disparities.

lines. Mechanisms to achieve a multidisciplinary model of cancer care and the benefits of that model will inform ways to improve service delivery in diverse community settings. To further support the cancer research enterprise, NCI will better understand how NCI's biorepository guidelines, caBIG[®] tools, and EHRs can be implemented in a community hospital-based cancer program. The NCI will use all of this information to assess the NCCCP pilot model on an ongoing basis and take the lessons learned to inform the future program. 

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