The NCCCP

*Enhancing Access,
Improving the Quality of Care,
and Expanding Research in the
Community Setting*

Disparities

CLINICAL TRIALS

Quality of Care

Survivorship and Palliative Care

Biospecimens

INFORMATION TECHNOLOGY

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NCCCP and the Association of Community Cancer Centers

by Christian Downs, JD, MHA

For over 30 years, the Association of Community Cancer Centers (ACCC) has been working to ensure patient and provider access to the best community-based cancer care. ACCC has done this by using advocacy on *behalf* of its membership and education *to* its membership.

Those of us in the provider community, then, were excited several years ago when the National Cancer Institute (NCI) launched the NCI Community Cancer Centers Program (NCCCP). The pilot program's purpose: to build a community-based research platform to support a wide range of basic, clinical, and population-based research on cancer prevention, screening, diagnosis, treatment, survivorship, and palliative care at community hospitals—contributing to enhanced quality of care for patients and advancing cancer research.

Believing that shared knowledge improves outcomes for patients and providers, ACCC has supported NCCCP-member cancer centers in their effort to communicate their findings. In fact, there are many examples of ACCC and NCCCP working together:

- There are currently 30 NCCCP sites; 27 are ACCC-member programs.
- NCCCP sites have contributed articles to ACCC's journal, *Oncology Issues*. For example, the Helen F. Graham Cancer Center at Christiana Care, Newark, Del., contributed an article in the Jan/Feb 2011 issue on "The Center for Translational Cancer Research."
- NCCCP sites have presented at ACCC meetings. At the ACCC 37th Annual Meeting, March 26, 2011, three NCCCP sites (The Cancer Institute, St. Joseph Medical Center, Towson, Md.; Helen and Harry Gray Cancer Center, Hartford Hospital, Hartford, Conn.; and the Cancer Program of Our Lady of the Lake and Mary Bird Perkins Cancer Center, Baton Rouge, La.) co-presented on "Multidisciplinary Care Conferences and Clinics in the Community Setting: A Paradigm for the Best Cancer Care."
- NCCCP sites have participated in ACCC educational programs. Geisinger Cancer Institute, Danville, Pa., was one of the programs that participated in ACCC's *Transitions Between Care Settings* educational project. Billings Clinic Cancer Center, Billings, Mont., participated in ACCC's *Cancer Care Patient Navigation: A Call to Action* educational project
- Three NCCCP sites received a 2011 ACCC Innovator Award. The Marsha & Jimmy Gibbs Regional Cancer Center at Spartanburg Regional Medical Center, Spartanburg, S.C., was recognized for its Cancer Survivorship Program. Mountain States Tumor Institute, St. Luke's Regional Medical Center, Boise, Idaho, was honored for its Pharmacist-run Oral Chemotherapy Program. The Nancy N. and J.C. Lewis Cancer & Research Pavilion at St. Joseph's/Candler, Savannah, Ga., was one of three programs honored for its Patient Navigation Program.

The document you are reading now is the next step in the evolution of the ACCC and NCCCP relationship. Taking the NCCCP White Papers—ranging in size from 19 to 170 pages—ACCC editorial staff worked with NCCCP sites and White Paper authors to develop practical, "how-to" articles that community cancer programs can use and put to work today. In 2011, these articles ran in a year-long series in *Oncology Issues*. And for the first time ever, these articles now appear in one monograph.

Given the changes that are taking place in community cancer care delivery, all providers should look to support the continuation of the NCCCP program. By working together, we can improve cancer care for patients and providers close to their homes and families.

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Improving Cancer Care *&* Expanding Research in Community Hospitals

Lessons from the National Cancer Institute Community Cancer Centers Program

by Maureen R. Johnson, PhD; Steven B. Clauser, PhD; Donna M. O'Brien, MHA; Joy M. Beveridge, MS; and Arnold D. Kaluzny, PhD

Approximately 85 percent of U.S. cancer patients are treated in their local communities.[1] To assure that patients have access to the latest knowledge and technology, the National Cancer Institute (NCI) has supported various initiatives to improve ways to expand research and deliver the latest scientific advances to patients in their communities, including:

- The Community Clinical Oncology Program (CCOP) and the Minority-Based Community Clinical Oncology Program (MB-CCOP), which were launched more than 20 years ago to increase clinical trials in the community[2]
- The Community Networks Program (CNP), which was launched in 2005 to support models to address cancer healthcare disparities[3]
- The Cancer Research Network (CRN), which focuses on the role that large managed-care systems play in community cancer care.[4]

To supplement these efforts, and to expand the focus and number of communities involved, NCI launched the Community Cancer Centers Program (NCCCP) in 2007 as a public-private partnership with community hospitals to explore the best methods to enhance access to care—especially for those with healthcare disparities—improve quality, and expand research within a community setting.[1] This article is an introduction to a series of articles which present the experience of the NCCCP sites in meeting the goals of the program.

Overview of the NCCCP

The NCCCP addresses the full cancer continuum, from prevention, screening, diagnosis, treatment, survivorship, and palliative care, through end-of-life care. The areas of focus include:

- Disparities
- Clinical trials
- Quality of care
- Survivorship and palliative care
- Biospecimens
- Information technology (IT).

The NCCCP created a network of hospital-based community cancer centers to serve as a research platform to support NCI goals and to facilitate the sharing of best practices. For the pilot network, 16 sites from across the country, representing urban, semi-rural, and rural settings were selected in 2007 to receive NCI funding (see Table 1, page 4). In 2010, the network expanded to 30 sites in 22 states (see Figure 1, page 72 and pages 84–85 for a full listing of NCCCP sites).

Goals for the NCCCP Pilot

The NCCCP established specific improvement goals in each of the defined focus areas. For example, to work toward reducing healthcare disparities, pilot sites must expand outreach to underserved populations and increase community partnership arrangements, primary care provider linkages, patient navigation programs, and screening resources.

For clinical trials, pilot sites must increase patient accruals, including accrual of under-represented and disadvantaged populations, and accrual to different types of trials. Pilot sites are developing programs to increase physician participation in clinical trials and to identify patient and physician barriers to participation. In an effort to better provide state-of-the-art cancer care in a community setting, pilot sites are also identifying the infrastructure

Table 1. NCCCP Pilot Sites Selected in 2007

1. Billings Clinic, Billings, MT (Billings Clinic Cancer Center)
2. Hartford Hospital, Hartford, CT (Helen & Harry Gray Cancer Center)
3. St. Joseph's / Candler, Savannah, GA (Nancy N. and J.C. Lewis Cancer & Research Pavilion)
4. Our Lady of the Lake Regional Medical Center, Baton Rouge, LA (Our Lady of the Lake Cancer Center and Mary Bird Perkins Cancer Center)
5. Sanford USD Medical Center, Sioux Falls, SD (Sanford Cancer Center)
6. Spartanburg Regional Hospital, Spartanburg, SC (Gibbs Regional Cancer Center)
7. St. Joseph Hospital, Orange, CA (St. Joseph Hospital Cancer Center)
8. Christiana Hospital, Newark, DE (Helen F. Graham Cancer Center at Christiana Care)
9. Ascension Health of St. Louis, MO, including these locations:
   - St. Vincent Indianapolis Hospital, Indianapolis, IN (St. Vincent Oncology Center)
   - Columbia St. Mary's, Milwaukee, WI (Columbia St. Mary's Cancer Center)
   - Brackenridge Hospital, Austin, TX (Shivers Center)
10. Catholic Health Initiatives of Denver, CO, including these locations:
    - Penrose-St. Francis Health Services, Colorado Springs, CO (Penrose Cancer Center)
    - St. Joseph Medical Center, Towson, MD (St. Joseph Cancer Institute)
    - A coordinated regional program in Nebraska sponsored by: Good Samaritan Hospital in Kearney (Good Samaritan Cancer Center); St. Elizabeth Regional Medical Center in Lincoln (St. Elizabeth Cancer Center); and St. Francis Medical Center in Grand Island (St. Francis Cancer Treatment Center)

necessary to conduct early phase clinical trials in community hospitals.

In the area of quality of care, pilot sites must increase their use of cancer disease-specific multidisciplinary care conferences or clinics (MDCs). Expanded use of evidence-based guidelines is required, along with participation in a network-based quality improvement project, expansion of genetic counseling and molecular testing programs, and adoption of cancer-center-specific medical staff conditions of participation.

Pilot sites are working to expand their survivorship, psychosocial, and palliative care activities, including implementing patient treatment summaries, incorporating survivorship care plans into their care model, 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 the collection of high-quality biospecimens to advance cancer research and quality of care.

Finally, pilot sites are exploring what is needed to adapt or adopt their existing IT infrastructures to utilize NCI's caBIG® tools to support cancer research.[6] Implementation of electronic health records (EHR) for the cancer center is another key area because it is widely recognized as an integral component for state-of-the-art cancer care and research.

The NCCCP Network: A Learning Collaborative

One of NCCCP's cornerstones was to create a network of community cancer centers to improve quality of care and support research through sharing of best practices and providing technical assistance to one another. Over the three years of the pilot program, pilot sites worked together on several initiatives to assess their programs, select areas for improvement, and measure progress.

Much of this work is posted on NCCCP's website: *http://ncccp.cancer.gov/About/Progress.htm*.

The 16 original NCCCP pilot sites, in conjunction with their NCI colleagues, have functioned as a learning collaborative to address the major challenges community hospitals face as they attempt to provide state-of-the-art cancer care and to expand research. While each of the pilot sites had to address many specific deliverables to receive funding, they were also required to develop network reports, or White Papers, on specific program deliverables to help NCI better understand how the pilot sites adapted the NCCCP model and how the program components were implemented in very diverse settings.

NCCCP White Papers

During the third year of the pilot, the 16 pilot sites worked together on seven major topics to produce the final White Papers. These reports were designed to address common barriers and strategies for success. Subcommittees, comprised of representatives from each of the pilot sites, focused on specific program initiatives and developed the White Paper content. The authorship and organization of each paper varied, depending on the participants involved. These White Papers represent the input and experience of all the NCCCP pilot sites and thus each of the Principal Investigators of the 16 pilot sites are acknowledged as contributors.

ACCC's monograph is a compilation of these White Papers, documenting the NCCCP sites' collective insights on topical issues relevant for community cancer centers. Below is a brief synopsis of each of the topical areas.

Reducing Cancer Healthcare Disparities (page 6). With a major focus on reducing healthcare disparities, 40 percent of program funding was dedicated to efforts to provide patients from underserved populations with the same access to quality cancer care and research studies as provided to other cancer patients with similar disease burdens. During the course of the NCCCP pilot, the 16 sites saw more than 27,000 new cancer cases per year and served diverse popu-

lations that included African American, Hispanic, Asian, and Native American peoples. Several sites served rural and frontier populations—historically challenging areas for patients to access the full cancer continuum of services. The pilot sites' efforts to reduce disparities, increase community outreach activities and screening events, and improve the coordination of cancer care for underserved populations through patient navigation services are discussed in three articles.

Clinical Trials (page 26). Increasing accrual to clinical trials is an important goal for the NCI. Making these trials available to more patients in the community setting, with a specific focus on underserved populations, is a high priority for the NCCCP. In these articles, pilot sites discuss several strategies that were employed to support this initiative.

Multidisciplinary Care (page 40). With the increasing complexity of cancer care and the fragmentation found in community settings, a multispecialty and multidisciplinary approach that brings together surgeons, medical oncologists, radiation oncologists, pathologists, and primary care physicians along with clinical research nurses, social workers, and other support staff is needed to develop and execute a comprehensive and holistic treatment plan tailored to the unique needs of each patient. Most community cancer centers depend upon private practice physicians to provide the medical care in their programs, which makes the organization and support for this approach to care challenging. NCCCP sites worked together to explore the best ways to implement this model of care.

Medical Staff Conditions of Participation (page 45). With most community cancer centers relying upon private practice physicians to provide the medical care and to support NCCCP programmatic goals, it is important to have strong alignment with these physicians. The NCCCP Conditions of Participation were developed to support the achievement of these goals.

Survivorship and Palliative Care (page 49). Patients are considered survivors from the time of their cancer diagnosis. With the NCCCP's focus on the cancer continuum from prevention and screening, through treatment to survivorship, palliative care, and end of life care, it has been a high priority to develop programs and tools to support cancer patients. One priority tool is a patient treatment summary that consolidates all relevant information on the cancer patient in one document that can be maintained by the patient and available to the primary care physician or another healthcare provider. With the fragmentation of cancer care and limited data sharing often without common electronic health records, it is challenging to develop these summaries. NCCCP sites have worked to develop and implement the patient treatment summary for their patients and the article will discuss the challenges and solutions that were employed to support this initiative.

Information Technology (page 61). The overarching IT goal was to expand information technology capabilities in the community cancer setting to meet the technology needs of the NCCCP and to support the program's objective to improve the continuity of care. The IT Subcommittee worked to implement electronic health records (EHRs) at each of the pilot sites, develop requirements for an oncology-specific EHR, and leverage available resources to meet the informatics needs of the pilot sites. The IT article discusses how the NCCCP network and pilot sites developed a technology vision and strategies to implement technology solutions, as well as the NCCCP's collaborations with ASCO and NCI's Center for Biomedical Informatics and Information Technology to address the specialized needs for an oncology EHR.

Biospecimens (page 71). Given changes in science and technology that are driving discoveries in the study of cancer and its treatment, an objective of the NCCCP pilot was to understand the capacity for community hospitals to collect high-quality biospecimens and thus bring research advances to the community setting and partner with NCI and its research mission. High-quality biospecimens are critical for molecular research, the foundation for developing molecularly targeted therapies. The NCCCP Biospecimen Initiatives article documents the experiences of the pilot sites as they worked to implement NCI Best Practices for Biospecimen Resources, increase their understanding of how to consent donors, and prepare for the collection, processing, annotation, and storage of specimens in local biorepositories and/or distribution to other laboratories or biorepositories.

One of the NCCCP pilot program goals was to understand the common challenges faced by community cancer centers and develop recommendations, based on the collective experiences of the network hospitals, for how to adapt the NCCCP program model in a range of community settings. The overview of the program model, the White Papers, and the resources on the website described in this monograph are intended to be available for use by community cancer centers as they strive to improve the quality of cancer care and the expansion of research opportunities for patients in their communities.❡

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Reducing Cancer Healthcare
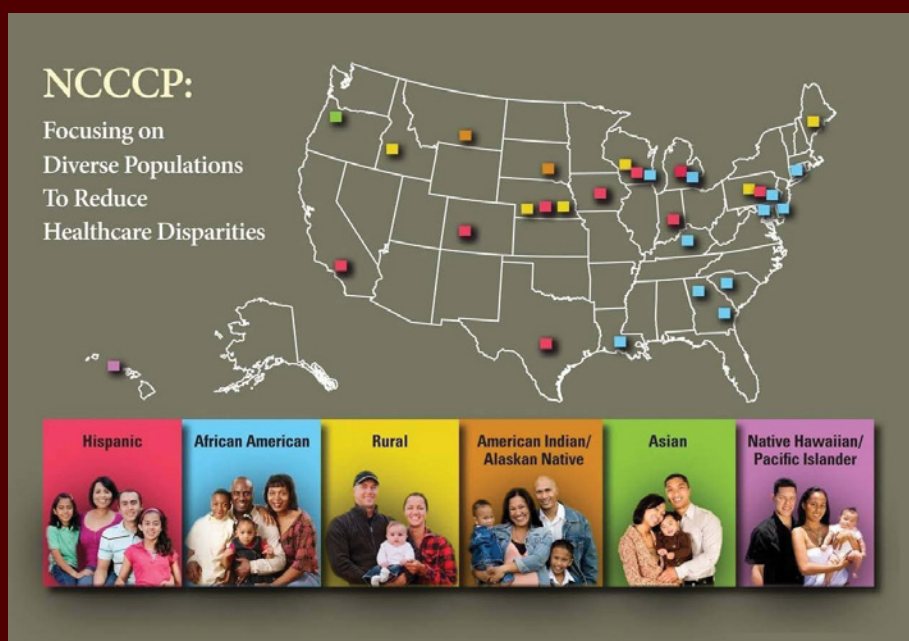
NCI launched the NCCCP pilot program in 2007 with 16 community hospitals. In 2010 NCI expanded the network and added 14 sites. Today, 30 NCCCP sites are working to reduce cancer healthcare disparities.

Disparities at NCCCP Sites

Defining Disparities and Targeting Efforts

The NCCCP placed a strong focus on reducing healthcare disparities and dedicated 40 percent of program funding to this effort. At the start of the pilot, the 16 sites were using different definitions of disparities. Specific definitions were needed to help understand how to define disparate populations in their communities. The Disparities Subcommittee decided to use the Minority Health and Health Disparities Research and Education Act of 2000 definition for disparities, i.e., populations with differences in "the overall rate of disease incidence, prevalence, morbidity, mortality or survival rates" as a basis.[1] The subcommittee further defined disparate populations to include not only racial and ethnic minorities, but also residents of rural areas, women, children, the elderly, persons with disabilities, the uninsured, the underinsured, and those who are socioeconomically disadvantaged. Each NCCCP site began to implement this definition to determine the priorities and focus for its own community.

Next, the subcommittee developed a Program Overview and Work Plan to provide NCCCP sites with specific direction about how to focus their disparities efforts for the remainder of the pilot. With input from all NCCCP subcommittees, a Disparities Dashboard (see pages 8–9) was developed. This tool included the program vision, a definition of disparities, metrics, and key pilot-wide disparities activities for each NCCCP focus pillar. The performance-based dashboard served as a management tool to improve the performance of NCCCP pilot sites in providing integrated cancer care and research to underserved populations, enabling sites to:

- Plan and manage an initiative to address cancer healthcare disparities
- Build skills
- Enhance the understanding of NCI to develop effective metrics to track cancer healthcare disparities efforts in community-based settings.

The complete listing of the disparities activities defined for each of the NCCCP program pillars are included in the Disparities Vision, Work Plan, and Dashboard, available online at: *http://ncccp.cancer.gov/files/NCCCP-Disparities-Dashboard-Combined.pdf*.

The NCCCP Experience

Each NCCCP site needed a champion—typically the site's representative to the Disparities Subcommittee—to translate the defined disparities work plan into action. Champions included physicians, dedicated outreach coordinators, cancer program administrators, and nurse navigators.

Outreach coordinators often worked with hospital committees to define the site's focused activities. Some NCCCP sites formed a disparities taskforce or committee (e.g., Hospital Health Equity Committee). Other sites looked to their Diversity Council or cancer coalition to identify gaps in care. Still others interacted with parish nurse programs and departments of mission and ministry. Determining the focus of disparities activities required input from a wide range of participants, including administration, cancer physicians, hospital or cancer data analysts, outreach team members, and patients. Input from community partners, such as public health departments, clinics, advocacy groups, other providers, and state cancer coalitions helped accurately define the necessary work.

Standardized data collection was a crucial component for the overall effort. The Disparities Subcommittee identified end-result activities and methods to measure success. For many activities, these definitions and data requirements were specific to a particular work activity at an NCCCP site. The 16 pilot sites used various means of gathering data, including electronic capture, running reports from diverse hospital computer programs, and manual data entry; therefore, it was not possible to define a project that all 16 sites could complete in the same way. The Disparities Subcommittee, however, could be used as a forum to define both critical and desired data elements for capture. The subcommittee worked to discover and address deficiencies in collecting race and ethnicity data according to Office of Management and Budget (OMB) guidelines.

The NCCCP sites identified staff responsible for gathering and compiling the disparities data. While manual data entry often fell to outreach coordinators and nurse navigators, overall project analysis involved additional personnel. Due to the time constraints and logistics of manual entry, many NCCCP sites began developing electronic data collection solutions, ranging from Excel spreadsheets to Access

NCCCP DISPARITIES VISION DASHBOARD

The NCI, through public/private partnerships with NCCCP pilot site community hospital-based cancer centers, will expand state-of-the-art cancer care continuum, from prevention and screening through treatment, follow-up and end of life care.

Definition of Disparities

Health Disparities:"Different public and private agencies have different definitions of a 'health disparity' for their own program-related purposes, however these definitions tend to have several commonalities. In general, health disparities are defined as significant differences between one population and another. The Minority Health and Health Disparities Research and Education Act of 2000, which authorizes several HHS programs, describes these disparities as differences in "the overall rate of disease incidence, prevalence, morbidity, mortality or survival rates." The Institute of Medicine publication,"Unequal Treatment"highlights inequities related to access and treatment as major factors in defining disparities.

NCCCP Disparities Dashboard	Overall Disparities Requirement: All patients screened and diagnosed with cancer		
	Clinical Trials	Biospecimens	Information Technology
Consolidated disparities metrics from pilot sites by area of focus (OMB categories to be used for race and ethnicity metrics unless otherwise noted)	• % change minority patient accrual to pilot CTSU trials • % change minority accrual for NCI Cooperative Group and CCOP trials • % change in capturing data on race and ethnicity (e.g., decrease in missing data)	• # pilot sites that set up systems for special handling of specimens and consents for specific populations (e.g., Native Americans)	• % of sites (those participating in caBIG®) submitting race /ethnicity data to caBIG®
Key Disparities Activities/Overall Disparities Pilot Projects	• Minority accrual working group to develop recommendations for implementation by sites. • Track progress on race and ethnicity reporting • Track progress on role of navigators in accrual of patients to CT	• Education session on specimen and consent issues for special populations to be held for Biospecimen and other Subcommittees	• Support to be provided for multiple pilot projects • Work with vendors as opportunities arise on standardization of race and ethnicity data fields

databases and incorporation of data from cancer registry systems. Working with IT resources provided system-wide impact at their locations.

All NCCCP sites were able to:

■ Develop a standard framework through the Disparities Work Plan and Dashboard
■ Agree to common definitions
■ Provide guidance, networking, and best practice sharing
■ Collect data through periodic site assessments to measure the success of this work.

Baseline, interim, and final assessments were conducted throughout the pilot period. Data tracking included the number of new community partnerships established, number of patients navigated, and number of community screenings and patients screened, as well as improvements in race and ethnicity measurements.

Comparing data across sites using these indicators was challenging, so the NCI and NCCCP sites worked together to develop a subset of data as metrics for each pillar on the Disparities Dashboard.

Lessons Learned

NCCCP sites persist with efforts to improve data collection and data collection tools. The program's work aimed at reducing cancer healthcare disparities is ongoing and constantly evolving. NCCCP sites agree that it is important to:

■ Understand and define disparate populations specific to each organization and community, while clearly identifying what makes the targeted group a disparate population.
■ Identify and target efforts narrowly enough with a specific subpopulation to be successful and to measure change over time. While NCCCP's initial plan was to look at all the disparate populations within a service area, the sites quickly realized the enormity of the work required to address all needs. Focusing on a particular subpopulation provides the chance to have a significant impact on eliminating healthcare disparities.
■ Educate all involved cancer team members, regardless of what type of activities their work involves, about the importance of reducing disparities in cancer healthcare.

and research to populations experiencing healthcare disparities (those with an excess burden from cancer) across the

For the NCCCP, we define the populations affected by health disparities to include racial and ethnic minorities, and other underserved populations: residents of rural areas, women, children, the elderly, persons with disabilities, the uninsured, underinsured and those who are socioeconomically disadvantaged.

by the pilot sites are offered treatment– policies in place with annual confirmation

Quality of Care	Survivorship	Disparities
• % pilot sites with improvement in completeness of race and ethnicity data for Commission on Cancer Quality of Care study (e.g., decrease in missing data)	• % of sites that have introduced tracking of race and ethnicity data in at least one of their Survivorship and Palliative Care programs	• % change # of overall patients screened • % change # of community partner organizations • % change # of screening events by disease • % change # patients navigated • % change in number of pilot sites collecting race/ethnicity data
• Specific projects may emerge based on data collection and findings from quality of care initiatives • Medical staff conditions of participation at pilot sites to include care of the uninsured	• Specific projects may emerge based on data collection and findings from Survivorship and Palliative Care initiatives	• Training modules/programs offered for race/ethnicity reporting • Track progress on voluntary breast screening tracking tool for populations experiencing healthcare disparities • Work with sites to track those never screened before, and those without a primary care physician

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■ Improve team members' understanding and knowledge of the best ways to make an impact on the defined disparate population.

This type of work requires continual and long-term efforts, and it is difficult to demonstrate measurable progress or change within a short time frame.

Major Challenges

The program's efforts to reduce cancer healthcare disparities presented a few common challenges for NCCCP pilot sites:

Understanding and defining the term "disparities." The immediate interpretation is often that the disparate population is a racial or ethnic minority; however, disparities may include rural populations and other groups that require specific definitions for tracking (i.e., what constitutes a rural patient for cancer care in a specific market?).

Time constraints. Ongoing subcommittee calls placed multiple demands on staff members to participate. Many NCCCP sites did not have the resources or enough time to accomplish all the work given ongoing clinical responsibilities. For example, increasing and nurturing effective partnerships in the rural and Native American communities proved time intensive and long in duration.

Data tracking and IT systems. Hardware changes across organization enterprises were necessary to enhance race and ethnicity data collection to meet OMB guidelines.

Limited resources. Additional resources to screen and treat disparate populations were not included as part of the NCCCP project. To avoid overwhelming NCCCP sites and scattering efforts, the Disparities Subcommittee agreed outreach roles and responsibilities should be clarified, with goals prioritized. And while hospital marketing and public relations support for disparities activities can improve success, these teams are often focused on a variety of hospital events and cannot provide adequate support to cancer center activities.

Barriers to Success

Although NCCCP sites faced several challenges while trying to reduce cancer healthcare disparities, six major recur-

Sustainable funding mechanisms are important for [disparities] long-term collaborations, and they help build the trust needed with different population groups.

ring themes surfaced. Creative strategies to overcome many of these obstacles emerged over time. Others, however, remain ongoing challenges.

Cultural issues. Chief among the cultural concerns were language barriers and trust issues. Reaching patients who spoke languages other than English presented challenges. Most often, NCCCP sites experienced a lack of bilingual staff or volunteers and translators available to assist with these patients. Educational materials had to be translated into the language of the non-English-speaking target population, which in most cases was Spanish. Another challenge: certain ethnic groups displayed a lack of trust in the medical system and its representatives. NCCCP sites spent more time and effort than anticipated to build a working rapport with African American, Hispanic, and Native American populations before disparities projects could be implemented. Faith-based community network models helped some NCCCP sites overcome these hurdles. Legal residency issues posed other problems, as services were often not available to patients who could not prove legal residency in the U.S.

Staffing. A few NCCCP sites lacked the key staff needed to conduct screening and education. Physician turnover and lack of nurses, patient navigators, and outreach staff contributed to this barrier. Instances of lack of buy-in and commitment from the host institution and physicians presented other challenges. Because these programs were often scheduled after normal working hours, it was sometimes difficult to convince qualified medical professionals to give up their valuable time off.

Training and development. Organization and time management issues ranged from deciding on which population to target to finding an appropriate time to hold training sessions for key staff. Often, NCCCP sites underestimated the time needed to develop and complete disparities projects and train staff.

Partnership difficulties. While NCCCP sites consistently acknowledged the many benefits of working with other organizations, these partnerships also created their own barriers to success. The most common challenge was the time necessary to establish trust with community members and community organizations, relationships that cannot be artificially rushed. Building relationships with several diverse communities at the same time could present additional challenges. At times, competing priorities within a partnering community or a faith-based organization created implementation problems for the projects. Not all community or public health organizations were able to deliver on the promises to support a project. Although participation in coalitions was a helpful strategy, large or complex coalitions might involve multiple agendas and deter focused action.

IT. Information technology barriers varied from site to site. It was sometimes difficult to collect accurate race and ethnicity data. Use of multiple databases that had no connectivity presented other challenges.

Funding deficiencies. A number of NCCCP sites had problems garnering consistent financial support for addressing cancer care disparities. At one site, patients who were diagnosed with cancer were supported by charity or community care within the hospital system, yet procedures had to be created to offer medication or equipment support from entities outside of the system. Financial assistance for treatment was an issue for undocumented patients who were often ineligible for governmental programs. Funding for specific outreach programs was frequently dependent on public or donor support that could be discontinued unexpectedly. Occasionally, state funding for existing initiatives was withdrawn, requiring program adaptation. Sustainable funding mechanisms are important for projects that require long-term collaborations, and they help build the trust needed to develop programs with different population groups.

The Importance of Improved Race and Ethnicity Data Collection

To ensure accurate reporting of information and accurate metrics to measure program effectiveness, NCCCP sites were expected to achieve compliance with OMB guidelines for use of race and ethnicity across multiple databases. These databases reside in many locations, including:

- Hospital financial systems
- Hospital inpatient and outpatient systems
- Cancer registries
- Hospital pathology systems
- Individual physician and practice office systems
- Community outreach activity logs.

For many healthcare organizations, the admission and/or registration process occurs via an automated software solution. This means that for most community cancer centers, changing data that is entered into the system is not simple. In addition, the cancer center is only one service line in an institution, and changes made in the cancer center can affect other parts of the organization.

To meet NCCCP goals for race and ethnicity data collection, sites secured buy-in from cancer services and hospital administration, admitting management and staff, IT teams, and patient support. An inclusive approach—identifying everyone affected by the project and involving all stakeholders early on—allowed NCCCP sites to define the project's scope, requirements, and planning phases.

NCCCP sites understood that accurate and standardized data would serve many purposes, including:

- Establishing common metrics and outcomes for tracking and reporting race categories and ethnicity

Table 1. OMB Categories for Race and Ethnicity Reporting

Race

- **American Indian or Alaska Native:** A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.
- **Asian:** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.
- **Black or African-American:** A person having origins in any of the black racial groups of Africa.

- **Native Hawaiian or other Pacific Islander:** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
- **White:** A person having origins in any of the original peoples of Europe, the Middle East, or Northern Africa. May include persons from Central or South America whose ancestors came from Europe.
- **More than one race:** A person whose ancestors are from different races (such as having one parent who is white and one who is black).
- **Other race.**

Ethnicity*

- **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central American, South American, or other Spanish culture or origin, regardless of race.
- **Non-Hispanic.**

*The Ethnicity categories should be asked as two separate questions: 1) Do you consider yourself to be Hispanic or Non-Hispanic? and 2) What racial category best describes you? Thus, two separate data fields are required for this information. Other categories for "more than one race" or "does not want to respond" can be included.

Source. Office of Management and Budget (OMB). Revisions to the standards for the classification of federal data on race and ethnicity. *Federal Register.* 1997;62(210):58781-58790.

- Reporting accurate demographics of patients treated
- Analyzing outcomes to identify gaps in care related to race and ethnicity
- Providing culturally and linguistically appropriate care to patients
- Providing cultural awareness programs to staff based on patients treated.

A key resource outlined for OMB guidelines is available online at: *http://www.whitehouse.gov/sites/default/files/omb/assets/information_and_regulatory_affairs/re_app-a-update.pdf.* The minimum categories for data on race and ethnicity for federal statistics, program administrative reporting, and civil rights compliance reporting are defined in Table 1, above.

Data collection approaches for reducing cancer healthcare disparities may involve modifications to existing processes. Consider incorporating information from the Health Research and Educational Trust (HRET) guidelines. The HRET Disparities Toolkit (*www.hretdisparities.org/*) is a web-based tool that provides information and resources for

systematically collecting race, ethnicity, and primary language data from patients. HRET also provides a training deck to assist with staff training during implementation of the new collection process.

The NCCCP Disparities Subcommittee suggested that baseline metrics be collected at project implementation and quarterly thereafter. NCCCP sites used the following outcome measures for reporting over the course of the pilot period:

- Percentage improvement in race and ethnicity tracking in specific hospital and cancer program databases.
- Percentage of sites using OMB categories for tracking in specific hospital and cancer program databases.

Implementation—Perspective from NCCCP Sites

Guiding principles to help implement race and ethnicity data collection include the following steps:

1. Review and standardize the definition and categories for race and ethnicity.

…each cancer center needs to address cancer disparities specific to its community.

NCCCP site Billings Clinic holds a ceremony to present pink shawls to women who complete a breast cancer education program focused on Native American health.

2. Educate and train staff on cultural awareness issues and information collection for race and ethnicity data.
3. Assess the cancer center's process for tracking and data collection.
4. Avoid duplication of collection of race and ethnicity data.
5. Develop processes for tracking and data collection across the cancer program, including survivorship, quality, biospecimens, community outreach, and patient navigation.

Some community cancer centers may ask, "Given the complications of classifying and collecting accurate race and ethnicity data—should such data still be collected?" NCCCP pilot sites respond with a resounding "Yes." The concepts of race and ethnicity create differential social, political, economic, and health-related realities for all people. These realities include the structures, beliefs, and practices of healthcare, medicine, and economics that contribute to health disparities for minority populations.[2] Continued collection of race and ethnicity data can help illuminate the historical contexts of health disparities and their impact on current populations.

Recommendations and Conclusions

NCCCP efforts to reduce cancer healthcare disparities were the impetus for sites to: 1) review OMB categories and revise hospital registration processes, 2) establish patient navigation programs, and 3) expand outreach and screening activities. The NCCCP provided financial support for staff positions, such as outreach coordinators and nurse navigators, which may not have been funded otherwise. Quarterly reports from the NCCCP sites provided a comprehensive picture of the outcomes achieved over the three-year pilot, including an increased number of community partnerships for all sites.

For community cancer centers looking to reduce healthcare disparities, NCCCP sites offer these recommendations. First, understand that each cancer center needs to address cancer disparities specific to its community. Obtain input from organizational stakeholders, as well as community partners. Engage stakeholders who can offer financing solutions. Key community partners to consider are the agencies that generate the state's cancer control plan, the National Breast and Cervical Cancer Early Detection Program (NBCCEP), and the American Cancer Society.

Second, know that any disparities plan should include the population to be targeted, specific activities to address the disparities, and metrics to measure success. Before identifying a disparities project, community cancer centers should analyze and use available data to identify disparities that exist, review gaps in care delivery, and prioritize work.

To help reduce cancer healthcare disparities, community cancer centers should also:

- Identify a disparities coordinator and team that can positively communicate the issues and impact change within the cancer center.
- Learn about the local community, its resources, and key members to help reach disparate populations. Engage members of disparate populations on outreach teams when possible. Consider forming a community advisory committee to gain ongoing input from the community.
- Use the tools developed and posted on the NCCCP website (*http://ncccp.cancer.gov/about/reports-and-tools.htm*).
- Collaborate, when possible, with NCI-funded Community Networks Programs (CNPs) that focus on the targeted disparate populations.
- Learn from best practices that currently exist. Use existing education materials (evidence-based and tested). Be aware of health literacy concerns with patients.
- Keep stakeholders informed and communicate with them frequently. ▣

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How NCCCP Outreach Efforts Help Reduce Cancer Disparities

by Nora Katurakes, RN, MSN, OCN®; Deb Hood, MBA; Mitchell Berger, MD, MMM, CPE, FACP; Donna Costa, MA, MHS; Renea Duffin, MPA; Delisa Simon-Dawkins, BLS, MT

Efforts to reduce cancer healthcare disparities are challenging and require multidimensional strategies and solutions. These efforts should be tailored to the demographics of each community and to specific priorities. NCCCP sites identified community outreach and screening events as critical to successfully engaging disparate communities for reducing cancer disparities. To that end, NCCCP community outreach programs involved the intentional and bi-directional process of building relationships in the community to facilitate access to information, education, services, and support for addressing community health and healthcare needs.[1] Together, NCCCP sites worked to develop tools and resources designed to improve, expand, and demonstrate the impact of outreach efforts. They shared best practices and tools, including:

- Cultural awareness webinars to provide education on how disparate populations' healthcare beliefs may influence interactions with the healthcare team.

Outreach coordinator draws blood from a local resident during a free health screening event, part of Community Health Day activities at NCCCP site Christiana Care.

Table 1. NCCCP Disparities Community Outreach Template

Define target population and determine specific project activities:

- Review community data, surveys, or other local or state processes to determine a significant unmet need (e.g., Hispanic women at risk for breast cancer and African-American men at risk for prostate cancer).
- Consider targeting the defined populations with specific cancer outreach, screening, and follow-up efforts. (Note: for Native Americans, NCCCP sites recommend that only one tribe be the focus for such an effort.)

Determine partners and focus:

- Define the goal and purpose of the partnership. Consider other community groups (e.g., Federally Qualified Health Centers, faith-based organizations) or efforts that serve the target populations and develop partnerships and/or form advisory groups.

Define scope, objectives, goals, and expected outcomes:

- Identify the scope (e.g., track screening through resolution of abnormal finding; track screening through treatment; promotion of clinical trials, follow-up care, and survivorship) and determine effective and measurable strategies and targets. Consider the following:
  - ✔ What information can be tracked
  - ✔ Community input and/or experience from other providers and community groups
  - ✔ The need for culturally appropriate material
  - ✔ Possible consultation with NCI CNPs, advocacy resources, or other NCI programs as needed.

Develop metrics and proposed targets:

- Determine baseline and change metrics for the specific effort during the project time frame. The NCCCP breast screening tracking tool and the proposed colon cancer tool may offer useful templates.

Document barriers:

- Note strategies to overcome barriers specific to the project activity. Flag items for discussion with others on routine conference calls, initiate connections with other pilot sites, contact NCI as needed.

Evaluate:

- Assess effectiveness of the specific effort to make changes in interventions and to overcome barriers. Note ongoing barriers and share successes with other sites and NCI through quarterly reports, email updates, or agenda items for discussion on monthly calls.

- Case studies to share strategies for reaching underserved populations (see pages 17–18) and to help identify promising practices, as well as challenges, related to increasing enrollment in clinical trials.
- A template for community outreach to guide outreach program planning with an overview of important considerations for how to develop, implement, and evaluate focused community outreach efforts (Table 1, above).

Over the course of the NCCCP pilot, as sites planned and implemented new programs, they consolidated their collective experience into the Disparities White Paper. This article features content from the paper to offer guidance for other community cancer centers working toward the same goals.

Getting Started
To implement successful outreach projects, NCCCP sites found it helpful to first:

- Identify a specific targeted program (e.g., increase mammography for Hispanic women at risk for breast cancer)
- Establish clearly defined outcomes and metrics
- Ensure the collection of baseline data.

NCCCP sites recognized the importance of stakeholder engagement to project success. Key stakeholders included senior hospital administration, community health and outreach staff, nurse and patient navigators, registrars, and IT staff. A dedicated IT person helped NCCCP sites think about evaluation and data management to better analyze and track outreach data. For example, building an Access database helped incorporate important quality outcome measures into NCCCP outreach projects. The process of identifying outcome measures required input from nurse navigators and outreach staff.

It Takes a Village—Partnerships
NCCCP sites found that partnerships were critical to the success of outreach projects. The collaborative efforts among NCCCP sites provided guidance in the development and implementation of outreach projects. Partnerships and relationships with a variety of organizations—both large national organizations, such as the American Cancer Society (ACS) and community organizations—helped bring screening and education to large numbers of underserved populations through local events such as Cultural Heritage Festivals. In addition, partnering with academic organizations, such as the Community Networks Program through NCI's Center to Reduce Cancer Health Disparities (*http://crchd.cancer.gov/cnp/overview.html*), opened doors to other partnership and grant opportunities.

Partnerships with community-based organizations offered numerous benefits—both to NCCCP sites and to their communities. Area residents gained a greater appreciation for the cancer center's mission and its ability to serve disparate and vulnerable populations. For many NCCCP sites, working with carefully chosen community and faith-based groups helped establish key relationships that opened avenues to collaboration on additional grant proposals and expanded reach to more communities with trusted partners.

Another benefit to partnerships was the opportunity for NCCCP sites to add staff with specific skills, such as

To create an effective outreach program infrastructure at a community cancer center, NCCCP sites recommend:

- Establishing support from physicians and senior hospital administration
- Identifying internal (physician and administration champions) and external advocates to support outreach initiatives
- Developing a multidisciplinary disparities committee made up of individuals representing appropriate clinical specialties and operating areas, such as patient registration, social services, and quality management
- Conducting a needs assessment before beginning a project
- Hiring a dedicated outreach coordinator (1.0 FTE is recommended) who is familiar with the targeted population
- Considering whether a nurse or lay outreach worker is best for your efforts
- Implementing a policy for accepting charity care
- Working with hospital leadership to develop a plan to handle positive findings in the uninsured population
- Building community partnerships that offer resources and credibility to your program and build trust within the community
- Providing follow-up reports to the community partners
- Ensuring that outreach staff is representative of the target populations (e.g., Hispanic outreach community worker)
- Fostering community engagement through the use of volunteers to promote outreach initiatives and donations
- Researching grant opportunities to support and sustain your outreach program
- Implementing a plan to collect data, especially patient race and ethnicity data, in compliance with federal OMB guidelines
- Ensuring timely data entry to promptly follow up on screening results and to document all services and issues in the disparities program database for tracking and reporting purposes
- Identifying best practices and evidence-informed approaches to addressing cancer care disparities that are applicable to your community
- Creating a Disparities Dashboard to identify areas for intervention, such as common tumor sites (e.g., breast, prostate, colon)
- Utilizing the dashboard tool to assess barriers to care, evaluate success reaching program goals, and ultimately measure quality indicators.

Staff resources may consist of a full-time community outreach coordinator who also serves as the patient care coordinator, a community educator, dedicated IT personnel, and administrative assistants. To meet defined goals and objectives, other staff can support program activities as appropriate. Bilingual capabilities are important for certain positions.

After identifying appropriate staff resources, offer education to ensure that personnel are equipped with proper training to implement a successful outreach program. Useful training modules include topics such as cultural sensitivity, health literacy, and race and ethnicity tracking. The NCI's Cancer Control P.L.A.N.E.T. (*http://cancercontrolplanet.cancer.gov*) is a resource to help planners, program staff, and researchers to design, implement, and evaluate evidence-based cancer control programs.

language translation. For example, bilingual staff in one partner organization helped translate educational information about the dangers of smoking to an underserved Hispanic population. Collaboration with experienced African-American outreach liaison staff helped NCCCP sites gain insight into new communities.

How might other cancer centers create such partnerships in their own communities? Try inviting the organizations to become members of a Community Advisory Council. Identify and reach out to church members or informal leaders to increase awareness of cancer services. Keep faith-based and community partners informed about hospital programs through ongoing communication, such as newsletters, a monthly calendar of events, or email alerts.

Many NCCCP sites collaborated with existing coalitions to bring services to large numbers of people in underserved communities. This strategy often led to support from other public health entities and cultural groups. Community partnerships should be ongoing relationships in order to sustain outreach projects and goals.

For community cancer centers that want to implement or improve outreach efforts, NCCCP sites offer these key strategies:

- Engage your community in the initial design, development, and implementation of any outreach efforts.
- Conduct a needs assessment before planning a program. Ask key stakeholders: *What programs would be helpful to* our *community*?
- Take time to establish priorities and consider staffing capabilities.
- Incorporate your cancer team (nurses, patient navigators, and outreach staff) into activities. Include staff from your community partners.
- Stay flexible and adapt as necessary. Some organizations may experience funding cuts that reduce program staffing and disrupt the flow of projects.
- Identify dedicated IT personnel, data management, and evaluation requirements at the project's start to help analyze and track outreach data.
- Build a database that incorporates key outcome measures.

Coordinating Resources for the Uninsured

Developing systems that work collaboratively to provide direct care and financial support to the uninsured is often a challenge. In their efforts to reach out to the uninsured, NCCCP sites found three key strategies and offer these suggestions. First, establish a list of community resources

Barriers to Successful Outreach Efforts

For community cancer centers looking to implement outreach programs, NCCCP sites identified these possible barriers to success:

- Lack of a consistent point person for various community organizations
- Diverse communication pathways that may occur when working simultaneously with two or more cultures
- Inability to identify key leadership within the faith-based community
- Transportation and childcare challenges that must be met before attendees can participate in outreach programs
- Multiple databases with no electronic connectivity
- The ability to manage collected data (i.e., paper-based data)
- Language differences
- Preconceived notions and perceptions about the institution
- Difficulties related to identifying additional funding to continue programs once they are established
- The ability to gain trust from other organizations that have similar targets and intentions and to overcome skepticism from community members
- Weather-related challenges (for outdoor events)
- Time needed for staff training and development
- Unanticipated interruptions, such as change in community leadership or loss of key staff members during implementation.

and providers willing to deliver cancer services to the uninsured *before* starting a screening program. Second, agree on a plan with hospital leadership to handle positive findings in uninsured populations. Know your hospital's policy on charity care. Finally, ensure timely data entry. This strategy will allow expeditious follow-up of screening results and document services and issues in the disparities program database for effective tracking and reporting.

Establishing Metrics

Various forms exist to capture and track data for measuring outreach program effectiveness. During the initial design of any database, quality metrics stratified by race, ethnicity, and abnormal findings can assist in improving overall quality and promoting equity. Having patients self-report by completing registration forms, pre- and post-tests, or surveys is an efficient way to collect information. While integrated IT programs are preferable, a simple Excel spreadsheet can also be created and easily modified to record collected metrics information for various types of outreach programs.

As part of their outreach efforts, NCCCP sites adapted several different tracking systems. Most sites used multiple databases to track their data. Having one database or interconnected databases will ensure compliance and assist with quality improvement.

In addition to demonstrating the impact of outreach efforts on targeted populations, tracking metrics specific to the cancer center are important for performance measurement, administrative justification, and budget justification. NCCCP sites suggest these metrics for outreach education or screening programs:

- Race, ethnicity, sex, and age of participants
- Zip code (to determine if outside the service area, rural or urban)
- Insurance status
- Number and type of screening events
- Number of patients screened by disease site (e.g., breast, cervical, prostate)
- Number of previous cancers and their disease sites
- Number of patients completing a screening for the first time
- Abnormalities found
- Number of patients lost to follow-up after an abnormal screening and reason
- Staff and volunteer hours
- Fixed and variable direct costs per screening event
- Number of screenings completed per provider per hour
- How the participant heard about the event (e.g., email, word of mouth, media, physician).

Lessons Learned: The NCCCP Outreach Implementation Experience

The majority of NCCCP sites reported an overall positive experience implementing outreach projects. Benefits included:

- Increased awareness of the cancer center within the community
- More opportunities for collaboration with community organizations
- New opportunities to partner with public organizations (e.g., Health Department)
- Prospects for funding and donations
- Increased ability to identify and treat more patients whose cancer would have otherwise gone undetected
- Greater participation in screening events
- Improved credibility with diverse populations.

When NCCCP sites faced challenges to success, the primary obstacles were the lack of manpower and insufficient buy-in from private practice physicians. Outreach efforts to targeted populations require:

- Additional resources to maintain or enhance existing projects
- Dedicated outreach coordinators to locate, meet, and establish rapport with specific disparate populations
- Increased use of community needs data for planning
- The ability to provide ongoing outreach efforts for achieving long-term goals
- Internal support and cohesiveness among management and staff.

Communication barriers due to language, cultural beliefs or health literacy may influence whether minorities get high-quality healthcare. Identifying key members in the community who can help address these barriers is crucial to outreach efforts. A comprehensive outreach program should provide culturally sensitive and linguistically appropriate educational programs, including printed materials and hands-on training

At one NCCCP site, CHOE staff provided 225 public awareness and community-based screening programs reaching nearly 15,000 individuals annually. Success was achieved by planning programs that aligned with state and local initiatives, as well as careful review of evidence-based programs prior to initiating new programs.

The use of research-tested intervention programs (RTIPs) (http://rtips.cancer.gov/rtips) provided useful guidance. Through partnership with the NCI Cancer Information Service, CHOE used the "Using What Works" Program to assure that all staff had basic training for program planning, implementation, and evaluation. Through this program, staff learned about creating measurable goals and establishing a means to track success. Additionally, the NCCCP Disparities Community Outreach Template (Table 1, page 14) assisted with understanding how a program is developed, how it is implemented, and what steps are necessary to establish and attain measurable outcomes. All initiatives incorporated the best practices in patient navigation established by Dr. Harold Freeman.

From 2008 through 2009, this NCCCP site reached 2,254 individuals for breast, colon, prostate, and cervical cancer screenings. Of these, 1,288 persons were reached through a Combination Community Screening Program, which combines cholesterol, diabetes, and cancer risk assessment in an effort to draw in persons who may not come to a stand-alone cancer screening or who do not understand the need for screening. The program started in 2005; it continued with funding from the Avon Breast Foundation for Women, Susan G. Komen for the Cure-Philadelphia Affiliate, the state Delaware Cancer Consortium, and the NCCCP. Screening venues included community and faith-based events and state service centers. Implementation of the Combination Community Screening Program required a full-time program coordinator to manage daily operations, arrange events to assist with meeting goals, track outcomes for each event, and organize follow-up for individuals requiring further assistance. The coordinator also targeted high-risk zip codes in an effort to touch never-screened residents, the uninsured, or individuals needing assistance to understand risk factors and the importance of cancer screenings.

An important step in development of this program was the establishment of, and the process for, the use of accurate forms to collect patient information for tracking purposes. The forms included demographic and medical history information, as well as clinical testing results. Recent changes incorporated information on smoking history, revised the race and ethnicity data, and added information on whether or not the person needs assistance to complete cancer screenings.

With a strong infrastructure in place, the Combination Community Screening Program was easier to expand through the development of alternative strategies. For example, "Health Information on the Go," a program for blood pressure screenings, incorporates questions about cancer screening and allows individuals to provide information that is passed on to a patient navigator. The navigator can contact the patient for additional follow-up.

These statistics clearly demonstrate the program's success: Of the 1,288 who participated in the program, 588 (46 percent) were African Americans, 159 (13 percent) were Hispanic, and 320 were uninsured. There were 486 referrals for further assistance; 189 were referred for cancer screening assistance; 140 individuals were provided with further information on how to eliminate financial barriers; 74 percent actually completed screenings. Reviewing follow-up processes to encourage more screening completions remains challenging.

The major obstacles to this outreach effort included:

- Availability of staff during non-traditional working hours
- Additional bilingual staff required to focus on the Hispanic community
- Ensuring that the individuals served were not using the screening for second opinion or diagnostics
- Collecting data without an electronic data management system in place required manual tracking through spreadsheets and other databases
- Ensuring follow-up for individuals contacted by navigators and recommended for cancer screenings.

This program can be adapted and used by other community cancer centers as a strategy to serve hard-to-reach individuals, provide education, and deliver information. This type of setting is less threatening for some individuals than going to the doctor, and it allows screenings in a variety of community venues that provide easier access. ❡

(e.g., breast self-exam models), and offer convenient cancer screenings within the community. Create an approach for how to best serve disparate groups by attempting to identify "at risk" populations within your community. Consider other community groups or efforts that serve these populations and develop partnerships. Endorsements from local community and faith-based leaders may also increase access to disparate populations and secure additional resources, volunteers, or staffing. These collaborative strategies can enhance organizational credibility and trust, important factors to the success of the program.

Understanding the community's perception of the cancer center is also important. Communities want to know that the cancer center is there for the long run, not just for one program or project. For example, navigating patients with positive screenings helps to ensure that the underserved are brought into the healthcare delivery system for further diagnostic and treatment services. This process includes coordinating appointments with specific clinicians for consultation and procedures, offering referral to finan-

Using the NCCCP Disparities Community Outreach Template (Table 1, page 14), one NCCCP site designed an event to raise awareness in the minority community about the importance of being screened for cancer. Scheduled in conjunction with Minority Cancer Awareness Week, the event included screening for breast, skin, prostate, and colorectal cancers, as well as blood pressure and glucose screenings. Free food and children's activities, including a clown and face-painting, were also offered. This NCCCP site used grant resources to underwrite the program and to promote the event.

The outreach event required six months of advance planning. The help of more than 100 volunteers and generous donations from the community were crucial to the successful implementation of this screening program. Success factors included a team approach to preparations, adequate planning time, and the involvement of the local community.

Obstacles included the weather and the need for sufficient bilingual translators to assist at the event. An ideal addition would have been a bilingual physician or nurse practitioner.

Buy-in from the community included attendance by the city mayor, who also served as the event's Honorary Chairperson. Other cancer-related community-based organizations and health organizations were invited to participate in the health fair.

Through this one event, the NCCCP site is able to reach a large number of people and provide education for hundreds more. 🔖

cial assistance programs as appropriate, providing follow-up support, and serving as a patient advocate.

Remember to provide evaluation and follow-up information to community partners related to achievements of your joint efforts. Continue to foster these relationships, for example, by notifying community partners about events and screenings or by providing speakers for future community events. In an effort to build trust, it is important to consider community partnerships as long-term friendships that require nurturing. 🔖

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Community member meets with cancer program representative during a screening event held as part of National Minority Cancer Awareness Week at The Cancer Program of Our Lady of the Lake and Mary Bird Perkins (NCCCP site).

Additional contributors to this article are acknowledged on page 25.

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How the NCCCP is Using Patient Navigation to Help Reduce Cancer Disparities

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Patient navigation is a key focus of the NCCCP Disparities program pillar. This article is a brief account, from the NCCCP Disparities White Paper, of how the network sites developed and implemented patient navigation programs as part of efforts to reduce cancer healthcare disparities.

Navigation at NCCCP Sites

While navigation services vary widely based on patient needs and available resources, NCCCP navigation programs are consistent, offering:

- Patient education on disease and treatment
- Connection with local resources for financial or emotional support
- Facilitation of screening for abnormal findings and scheduling follow-up or staging appointments
- Quick referral to resolution
- Collaboration with the multidisciplinary and clinical trial teams
- Provision of a single contact for the patient to connect with, in some cases in a culturally sensitive environment, and obtain support.

NCCCP sites employed a variety of approaches to patient navigation, including:

- *Outreach navigation:* often to direct people from disparate populations into screening and through the abnormal result resolution process. The purpose of outreach navigation is to facilitate early detection to reduce disease mortality. The navigator helps ensure the population has access to screenings by collaborating with community partners to provide health fairs, community screening events, mobile mammography, and cancer awareness education programs. Outreach navigators act as a liaison with local resources.
- *Abnormal-to-disease navigation:* where navigators work with diagnostic areas of the hospital system (e.g., endoscopy, mammography, radiology) to help move patients from an abnormal finding to resolution for a cancer diagnosis. They provide patients with information and resources to help with finances and reduce barriers to resolving abnormal findings. Patients are assigned to another navigator for continuation of services.
- *Diagnosis-to-treatment navigation:* that has navigators assisting patients from an initial diagnosis through the completion of treatment.
- *Inpatient navigation:* to assist patients who are hospitalized due to the acute needs of a suspicious finding, new diagnosis, or the effects of treatment. The goal is to provide the patient with information to prevent future admission or inpatient stay and to get the patient on an effective treatment plan quickly.
- *Survivorship navigation:* to assist patients beyond treatment and through the course of late and long-term effects, follow-up appointments, and potential disease recurrence.

Establishing a Patient Navigation Program

At the launch of the NCCCP, there was considerable variation in the provision of navigation services among the sites. One site had no patient navigation services. Working in conjunction with the NCCCP, this community cancer center decided to focus initial navigation services on breast cancer due to the community's disease morbidity and size. Reaching out to physicians to introduce and explain the navigator's role in breast cancer patient care was paramount to establishing the program. Demonstrating that navigation bridges gaps in care from the time of diagnosis through treatment and survivorship was essential to the success of the early development of a navigation program. Furthermore, the navigator kept primary care physicians informed of their patients' care and provided smooth access through the healthcare system for patients and their families. The oncologists employed by this institution supported the addition of a nurse patient navigator.

Prior to NCCCP funding, another site expanded its program by adding a breast health specialist position,

At NCCCP site St. Joseph Hospital of Orange, Calif., a Pacific Islander patient navigator reviews a colorectal cancer educational flipchart culturally tailored for Native Hawaiian and Pacific Islanders.

yet few program services had been established. This site formed a Breast Health Group composed of key people from medical oncology and the surgeon's office, along with other interdisciplinary team members. A positive result of this action was that patients began to meet with the navigator at the time of diagnosis rather than after treatment. The navigator served as a central point of contact, a patient advocate, and a physician partner in patient education. The NCCCP site learned that less focus on the "ideal" navigation infrastructure and more focus on small changes that lead to improved process outcomes helped enhance its program.

Strengthening Patient Navigation Programs

For sites with well-established patient navigation programs, NCCCP participation helped expand outreach with focused disparities efforts. Leveraging the NCCCP, these sites enhanced services to meet the needs of underserved populations across multiple counties in both rural and urban communities.

For example, prior to joining the network, one site had launched a physician-led, multidisciplinary Breast Cancer Action Team. The model used breast navigation that began with an abnormal finding (BIRADS 4 or 5

screening mammogram) and continued to resolution of finding, through treatment, and into survivorship. One key outcome measure was the time from a positive screening mammogram to resolution. Through NCCCP participation and the program's concentrated work, the site expanded community outreach efforts and cancer screenings; this resulted in an increased volume of patients with BIRADS category 4 or 5 screening mammograms. The addition of a diagnostic nurse navigator proved essential to their goals and activities.

As part of its disparate population focus, the NCCCP is concerned with the needs and issues within rural patient populations. One NCCCP site specifically identified rural areas and American Indians as target populations. With NCCCP funding, this site hired a regional navigator to focus on challenges unique to the specific communities. To determine how best to use the navigation services, two elements were crucial: trust from the disparate population and knowledge about community education and screening programs already in practice. The regional navigator traveled throughout rural communities and area reservations to meet with key staff members at healthcare programs. One goal of these meetings was to identify existing supportive programs so that cancer patients could enroll

NCCCP-site volunteer and prostate screening participant.

in them in their home communities. This collaboration built trust and allowed for further program development. The regional navigator identified a significant lack of education and understanding about cancer prevention and early detection. Free educational programs, such as the Cancer 101 series available through NCI's Spirit of Eagles program, were used to stress the importance of screening. This site's experience highlighted the importance of conducting fact-finding and trust building endeavors *before* developing a program. Understanding the needs of the community and working collaboratively to meet those needs are essential to building a successful program.

At another NCCCP site, the Community Health Outreach and Education (CHOE) department provided public awareness and access to cancer-screenings for state residents and high-risk populations. This NCCCP site conducted an inventory of existing programs related to established community and state efforts, including a review of their importance, relevance, and outcomes in terms of increasing cancer screenings in disparate populations. The site determined that continued efforts to provide resources for this outreach program were important. Choosing to focus on the African-American community, the site decided to start with HPV vaccinations. Once partnerships were formed, the site

initiated a health fair event for OB/GYN adolescents. Part of the goal was to offer cervical cancer screenings to parents and/or guardians of the targeted girls. The site also placed a cancer screening navigation nurse onsite during clinic hours to meet with patients and improve screening completion rates. Indirectly, the NCCCP site found that most state residents were unfamiliar with resource materials or local programs.

Using Lay Navigators

While lay navigators are not clinically trained, they can provide some of the same services as their clinical counterparts. The focus of lay navigation tends to be on barriers to care and ways to address or mitigate those barriers for the patient. Often employed by either the hospital or the clinic, lay navigators may also be affiliated with an outside organization such as the American Cancer Society (ACS) or Community Networks Program (CNP). Use of culturally appropriate lay navigators for disparate populations is becoming more common in cancer care. Understanding cultural, geographic, or spiritual barriers to care is helpful for the lay navigator. The best approach is to pair a patient with a navigator of similar race or ethnic background. Program services provided by

NCCCP BREAST SCREENING

Patient Name	DEMOGRAPHICS				
		City	Zip	Day Phone	Ethnicity

	ABNORMAL FINDINGS				
	Breast Exam Result and Date	Screening Mammogram Result and Date	Diagnostic Mammogram Result and Date	Ultrasound Result and Date	MRI Result and Date

	DIAGNOSTIC INFORMATION				
	Date of Diagnosis/ Resolution	Diagnosis	Definitive Diagnosis by: (what test)	Biopsy Results	Stage of Diagnosis

	TREATMENT INFORMATION				
	High Risk Counseling Date	Genetic Test Results/Date	Clinical Trial Offered (Y/N)	Reasons not on Trial	Presented at Multi-Disciplinary Clinic/Conf prior to start of treatment?

		Chemotherapy			
	Date Started	Type of Chemo	Date Completed	Physician	Hormonal Therapy

	NAVIGATOR				
	Name	Date Connected with Patient	Navigation Started	Referrals to Other Services (List)	Barriers to Care

TRACKING TOOL – Version 2.0

	Race	Marital Status	Age Range	Insurance	Other	Activity that caused person to be screened (if any)

	Estrogen Status	Progesterone Status	HER2/NEU	Other		

	Time from definitive diagnosis to first appointment for treatment consult	Surgery Date	Type of Surgery	Surgeon/Physician		

Radiation Therapy					
Date Started	Type of Radiation	Date Completed	Physician		

Reasons for not completing testing/treatment					

Recommendations for Expanding or Developing Successful Navigation Programs

For community cancer centers looking to establish or expand patient navigations services, NCCCP sites offer these recommendations.

✔ Assess program readiness prior to implementing a patient navigation program. Use tools, such as ACCC's Patient Navigation Pre-assessment Tool (*http://www.accc-cancer.org/education/pdf/PNTOOLS2009/Pre-Assessment-Tool.pdf*) to evaluate program readiness and gather necessary information for project planning and development.

✔ Assess your program's current systems in relation to the needs of your community. Design the program so it fits with your organization's care delivery system. Clearly define the scope of the patient navigator's role. Establish how nurse navigation will interface with all disciplines and hospital support programs.

✔ Involve all key stakeholders. Engage cancer program administration and physicians *early on* in the process.

✔ Contact established successful navigation programs to learn from their experiences and challenges, and make use of existing forms and tools. Ask questions and adapt the information to meet the specific needs of your organization and patient population.

✔ Hire staff with experience in outreach and/or oncology. Consider hiring staff that is representative of the disparate community you are trying to serve.

✔ Ensure that all staff is aware of cultural issues specific to your community, including the special needs of local disparate populations.

✔ Educate all cancer program staff about your navigation program.

✔ Understand how patients access your healthcare delivery system and create mechanisms at those entry portals to refer patients to the navigator.

✔ Have the right programs and staffing in place to access care for your disparate patient populations. Community cancer centers need to help reduce barriers by using insurance counselors, financial counselors, and social service providers. Other barriers to consider include educational materials, language, cultural awareness, transportation, and trust.

✔ Use tracking and screening tools and patient satisfaction survey data to develop standards for your patient navigation program and services.

✔ Establish metrics to measure the program achievements and outcomes.

✔ Develop a disease-specific program (e.g., breast cancer navigation).

✔ Collaborate when possible. With proper collaboration, even data collection systems from different providers can work together to establish, focus, and meet project benchmarks.

the navigator include, but are not limited to:

■ Helping with insurance issues
■ Addressing barriers to care
■ Offering lodging arrangements for patients at no cost
■ Providing fuel cards to assist with transportation expenses
■ Purchasing a wig for patients who desire one yet cannot afford it
■ Providing general gift items (e.g., hats, scarves, lotion) to help cope with the symptoms of disease and side effects from treatment.

Evaluating Navigation Services and Establishing Quality Tracking Metrics

Most services offered by patient navigators are non-billable. Therefore, patient navigation is a service that must demonstrate efficiency to justify its use of resources. While the support navigators offer patients is certainly valuable, community cancer centers often struggle to provide a business case to show that navigation services can also indirectly generate revenue. NCCCP sites found navigator programs help to:

■ Reduce inpatient stays and ER visits
■ Increase downstream revenue for other services
■ Improve coordination of care
■ Increase the number of referrals to the cancer center
■ Reduce wait times from abnormal findings to diagnosis
■ Improve patient satisfaction surveys
■ Perform outreach in targeted areas of the community
■ Direct disparate populations through the continuum of cancer care.

Navigator programs must be able to track appointments and patient concerns, along with other information. To help track information on breast cancer patients, the NCCCP

and the benefits their services can provide patients.

developed the breast screening tracking tool (pages 22–23). Designed as a quality improvement tool, it can be used to track time from abnormal finding to diagnosis or resolution of abnormal finding, or to treatment. The tool is a complex spreadsheet divided into four main areas: Demographics, Screening and Diagnostics, Treatment, and Navigation. With the NCI goal of making clinical trials available to more patients in the community, the NCCCP incorporated a category on trial referral into the tool.

Best Practice Sharing

Connecting patient navigation across all NCCCP pillars was important to the Disparities Subcommittee. Further, communication between program pillars provided new opportunities for sharing best practices, pooling resources, and decreasing redundancy.

The Disparities Subcommittee found collaboration—both within individual hospital networks and among NCCCP sites—was essential to developing, implementing, and/or expanding patient navigation services. This collaboration helped to validate the importance of navigation and to foster new ideas and opportunities. Best practice discussion included assessment tools, cultural considerations that may reduce barriers to care, appropriate programs for target populations, community partnerships, tracking and screening tools, and performance improvement activities.

Conducting Patient Surveys

Navigator programs are demonstrating increased patient satisfaction with the patient navigator role.[1] NCCCP sites developed patient surveys to help evaluate their navigator programs against several core measures:

- Was the education offered by the navigator helpful?
- Was coordination of care timely?
- Did the support given by the navigator help reduce fears?
- How was the navigator's knowledge of disease and treatment options?
- Did the navigator share resources to help reduce barriers to care?

The NCCCP patient survey highlighted the reality that people are often unaware of navigators and the benefits their services can provide patients. Although many cancer centers offer patient navigation services, marketing campaigns do not spotlight them. Using information from the patient surveys, NCCCP sites began to direct navigation program marketing efforts, establish quality measure checks, understand patient educational needs, and streamline the referral process.

Successful Outcomes

Looking back, the patient navigation programs at all NCCCP sites experienced success during the program's pilot phase. Quality of care was improved and physician support increased. Many of the navigators:

- Joined nationally recognized organizations, including the Academy of Oncology Nurse Navigators and the National Coalition of Oncology Nurse Navigators
- Participated in activities to advance the standard of care for patients
- Shared the benefits of nurse navigation.

Comprehensive navigation programs with appropriate staffing can help meet the needs of targeted, underserved populations by conducting outreach activities and providing services that will reduce healthcare disparities and increase access to care for disparate populations. ❑

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Using an Online Tool to Understand and Improve Clinical Trial Accruals

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Unfortunately, only three percent of adults with cancer participate in clinical trials. In underserved urban and rural communities, the adult accrual rate is even lower. These groups include populations with disproportionately high cancer rates, so their absence from clinical trials is a significant factor in ongoing healthcare disparities.

To meet its goal of increasing clinical trial accrual—especially among minority or underserved populations—NCCCP formed a Clinical Trials Subcommittee in 2007. Its mission: to enhance NCCCP site access to clinical trials that provide cutting-edge advances and state-of-the-art care, and to help develop new preventatives, diagnostics, and treatments. Today, the Clinical Trials Subcommittee assists NCCCP sites as they continue to work to demonstrate:

- An increased capability to offer multiple types of Phase II and Phase III trials, and to develop protocols for appropriate referral of patients for Phase I trials to NCI-designated cancer centers or academic medical research institutes
- Improved accrual rates of under-represented and disadvantaged patients in all trials
- Enhanced participation in complex clinical trials including multi-modality (i.e., radiation therapy plus surgery) and translational research trials.

The NCCCP Clinical Trials Subcommittee also explored patient and physician barriers to clinical trial enrollment; the infrastructure necessary to perform Phase II and Phase III trials; and mechanisms to increase minority accrual. In addition to the Screening and Accrual Log discussed in this article, NCCCP developed other tools for the network sites, including a clinical trials portfolio, a minority matrix, and the RECIST criteria toolkit.

Screening and Accrual Log

A key step toward increasing clinical trial accrual was the development of the NCCCP web-based Clinical Trials Screening and Accrual Log (Trial Log). The log, designed for the 16 NCCCP pilot sites, allowed collection of real-time enrollment barriers, and created a foundation for developing strategies to overcome these barriers. The log is managed by the NCCCP Trial Log Working Group, enabling real-time, network-driven, trial-specific accrual data.

During the first year of the NCCCP pilot, representatives from all 16 sites worked on developing the Trial Log. The process included:

- Conducting a literature search
- Collecting existing tools used by clinical research programs
- Participating in weekly meetings to develop a comprehensive list of patient and physician accrual barriers, based on barriers most frequently cited in the literature
- Revising the barrier list based on NCCCP input, including webinars, presentations of best practices, and lectures from previous cooperative group conferences and American Society of Clinical Oncology (ASCO) meetings.

Two versions of the log were created. The first version (developed from August 2007 through January 2008) was launched in February 2008, and was used for four NCCCP clinical trials. After data analysis, a second iteration of the log was developed and implemented in March 2009. Nineteen trials were tracked on this log, and the number of trials tracked continues to grow as NCCCP network priorities change. (Version 2 of the Trial Log can be found on pages 30–31.)

Due to the extensive changes in the tool from version 1 to version 2, data collected in log versions 1 and 2 remain separate. For example, during development of version 2, the tool was revised to allow for real-time utility and enhanced functionality for data entry, monitoring, and analysis. The log was modified to add data-quality checks and to allow NCCCP sites to review data in real-time to address barriers and to share best practices. Reports were created that allow for evaluating screening versus actual accrual patterns by race, gender, ethnicity, and age. Using these reports, NCCCP sites can monitor the recruitment of under-represented populations, identify strategies, and implement plans to improve recruitment for specific populations. NCCCP Trial Log Working Group leadership also monitors the logs, reviewing data to monitor use, possible trends, and progress.

Screening event held at NCCCP site, The Cancer Program of Our Lady of the Lake and Mary Bird Perkins Cancer Center.

Key Stakeholder Buy-in

Among all NCCCP sites, the unanimous rationale for participating in the Trial Log project was a commitment to work to increase overall accrual to clinical trials and to reduce disparities in cancer care by making clinical trials more available to the underserved populations. Clinical research staff, support staff, information technology teams, principal investigators, data managers, nurse navigators, and management were all key stakeholders in the Trial Log project.

Information needed for the log came from various places, including private practice physicians, Community Clinical Oncology Programs (CCOPs), patient navigators, and research departments. Accordingly, at NCCCP sites where private practices were the main source of patient referral, practice physicians were also important stakeholders.

Key Success Elements

NCCCP sites found it critical to have someone at each site responsible for providing education about the Trial Log, its purpose, and how to maximize the log's value—both during implementation and on an ongoing basis. While each site had previously captured data regarding difficulties in recruiting underserved populations to clinical trials, this project presented an opportunity not only to analyze barriers to recruitment but also to evaluate different strategies to resolve identified issues. Key success elements included:

The creation of a robust analysis tool. This analysis required personnel, time to perform the literature review, and evaluation of key issues identified by the CCOP sites. NCCCP sites came to the program with a variety of experiences and skill sets. Eight of 16 sites had an existing tool for collecting data, but these tools varied from simple paper to sophisticated databases. Additionally, the amount of information collected was inconsistent and was in itself a barrier to understanding site accrual.

IT support. Information technology (IT) support was critical as it helped operationalize a tool to facilitate collection of data gathered on barriers and challenges and then provided a mechanism to easily analyze desired information and generate reports.

Identification of log owners. The more successful NCCCP sites identified "champions" or "leaders" for the Trial Log. These sites achieved greater participation in the development and implementation processes, and provided ongoing education to key staff members, as well as to all new staff members.

Standardization of trial screening definitions. During development of the Trial Log, NCCCP sites found that trial screening definitions varied from site to site. Standardization of these definitions was important to ensure the accuracy of the information entered into the Screening and Accrual Log. Screening definition examples include:
1. **CALGB 80405 (Colorectal)**: Unresectable locally advanced or metastatic colorectal adenocarcinoma with no prior chemotherapy.
2. **SWOG S0421 (Advanced Prostate CA)**: Hormone refractory metastatic prostate adenocarcinoma to bone and no prior chemotherapy.
3. **CALGB 90601 (Advanced Uroepithelial Neoplasm)**: Locally advanced or metastatic urinary tract transitional cell CA with no prior chemotherapy for metastatic disease.

Time commitment. This element was probably the most pivotal success factor. To make this process work, a significant amount of time was required in developing the Trial Log, assessing and re-assessing what the tool was measuring, refining the tool and the processes involved, and educating and reinforcing the value of the tool. The Trial Log provided insight that was not available through other identified tools.

Implementing the Trial Log

NCCCP sites had varying degrees of success implementing the Trial Log. While the stakeholders involved in implementation were similar to those involved in the development phase, sites found that adding members to the research team, such as clinical research assistants (CRAs), was helpful. The time commitment for the implementation phase was significant. Research staff at each site worked to include the Trial Log into their standard pro-

Through the Screening and Accrual Log, the NCCCP was able to better barriers for enrollment to clinical trials.

cesses. Although all NCCCP sites reported implementation of the Trial Log, actual use of the log varied from site to site. Evidence suggested that a few sites were using the log in real-time, while other sites were using a batching process or retrospective data entry.

Some sites that offered both cooperative group trials and pharmaceutical trials chose to adopt the Trial Log through a local replica Excel spreadsheet or Access database, which allowed for standardizing processes at those NCCCP sites. One NCCCP site created two different site-specific screening logs—one for radiation and one for medical oncology. Specific information was logged weekly, per the oncologist's schedule, on every new or returning consulted patient.

The tool has proven valuable, providing information that is used for internal reports, as well as information required on an ongoing basis for other NCCCP project reports. It also provides physicians with a pre-screening tool that lets them know they will be seeing a patient who is potentially eligible for a study.

Collaboration with other NCCCP sites and participation with NCCCP subcommittees was extremely helpful and important to the implementation process. Conference calls provided a forum to ask questions, share information, solve problems, and receive feedback. The conference calls were also an opportunity to discuss best practices. If a site could not participate in a subcommittee conference call, minutes from the call were reviewed and the site communicated with other NCCCP sites to share information regarding the addition or deletion of trials from the Trial Log. Obtaining and sharing information was key to success.

NCCCP sites found that continued education and reinforcement of processes and goals was essential for appropriate utilization of the Trial Log.

Challenges and Barriers

NCCCP sites identified three major challenges and barriers to successful implementation of the Trial Log. The most common challenge was the time required to complete the steps in the screening and enrollment processes, particularly during the log's initial implementation. NCCCP sites worked to develop strategies and streamline the process for using the log. Second, sites had to develop a process for incorporating the log into their daily workloads. Various staff challenges comprised the third major barrier. Specific challenges and barriers included:

- *Time.* Nine of the 16 sites reported time as a challenge and noted a duplication of processes with existing site-specific trial logs.
- *Log Versions.* The development of versions 1 and 2 of the log created modest confusion and data overlap that required clarification.
- *Demographic Data Capture.* It was sometimes diffi-

cult to capture required demographic data (i.e., race, ethnicity, rural); however, NCCCP sites were able to address this barrier by reporting data according to Federal guidelines.

- *Staff Turnover.* Change in staff increased the need for ongoing training about how to use the log.
- *Website Problems.* The Trial Log website occasionally experienced issues that required IT programming support.
- *Communication.* Communication with private practices or practices not located at the NCCCP site was difficult. For the expanded NCCCP network, a recommendation was made that each new site develop a site-specific screening tool that includes the data captured and term definitions used on the NCCCP Trial Log.
- *Infrastructure and IT Support.* The level of infrastructure and IT support required enhancement for successful utilization of the tool.

As the NCCCP expands, the ability to house and analyze the data is a challenge that must be met.

Lessons Learned

NCCCP sites found it critical to maintain good communication about the introduction and implementation of the Trial Log with all the key stakeholders—including the NCCCP project coordinator, the site's research manager, and research coordinators.

As with any new tool or project, metrics are needed to help validate the effort. The Trial Log incorporates the appropriate questions needed to collect the data for measurement purposes. By standardizing these questions, the data is useful in understanding which trials do not accrue. However, for reporting to be relevant, all fields must be completed. The use of the Trial Log data collection form improved the process because data could be collected prior to entering it on the website, making sure that all questions were answered before recording online. Additionally, use of the form enabled sites to document the subject's unique identifier in the event a data query was generated that required site clarification.

Implementation and use of the Trial Log allowed NCCCP sites to:

- Track, assess, and compare enrollment and barrier information by population at each site and develop new strategies for clinical trial accrual
- Identify trials required to meet the needs of individual communities served by the site
- Communicate among sites on possible ways to overcome barriers to accrual
- Increase physician input and accountability by discussing barriers to accrual

Site Specific Implementation Challenges and Barriers

- At a few of the sites, the limited number of open, NCCCP-endorsed studies reduced the ability to capture data as the ability to contribute screened patients was low.
- The frequent need to change passwords through NCI was another issue. For one NCCCP site, having both data managers and study coordinators access the log as users worked best, because the log asks for information on patients not participating in the trials, as well as those participating; this data must be entered by the study coordinators who originally received the referral. The biggest challenge for this site was staff remembering to enter patients into the log, which only pertains to a limited number of studies. Now, staff use a spreadsheet that lists all referrals. At the end of each month, that spreadsheet is reviewed against the Trial Log to make sure all qualified referrals have been entered into the screening log.
- Another NCCCP site was initially challenged in efforts to gain the support of the two research coordinators charged with using and maintaining the Trial Log. Providing education for staff on the value of the NCCCP project and having IT support in place increased buy-in for the project. The web-based training sessions were essential in learning how to access and use the log. With increased use, the log has become a routine step in screening and enrolling patients. Staff found the Trial Log's design straightforward and easy to use.
- One site faced obstacles trying to come to agreement on the criteria defining a "screened" patient. Once definitions were clarified, documented on the Trial Log, and the tool was further refined, entering screened patients on the log became more routine, and time commitment ceased to be an issue.
- To overcome language barriers, one site developed Spanish and Vietnamese short forms for consenting patients to clinical trials.

- Capture data and identify barriers in real-time
- Bring clinical trials to the forefront at their sites.

Through the Screening and Accrual Log, the NCCCP was able to better understand specific barriers for enrollment to clinical trials. For example, the log could reveal common findings among patients screened for a particular trial or it could provide data about when physicians did not participate in a specific trial and why. Also, the Trial Log helped provide a better understanding of characteristics of patients screened and accrued to a specific trial. Best practices were shared among NCCCP sites. In addition, there is now a better understanding of how much has been accomplished as a network to date, and strategies to meet future goals have been identified. Next steps with the Trial Log will be to periodically assess accrual rates across different trials for different populations pre- and post-intervention. ¶

NCCCP Clinical Trial Screening and Accrual Log, v2.0

Patient Identification Number: _____
(Record the patient ID for your records)

1. Date of patient screening (mm/dd/yy): _____

PATIENT DEMOGRAPHICS

2. Ethnicity (select only one): ☐ Hispanic or Latino　　☐ Non-Hispanic or Latino　　☐ Unknown

3. Race:　　　　☐ American Indian or Alaska Native　　☐ Native Hawaiian or Other Pacific Islander
　　　　　　　☐ Asian　　　　　　　　　　　　　　☐ Black or African American　　☐ Caucasian
　　　　　　　☐ More than One Race　　　　　　　☐ Not Reported, Patient Refused
　　　　　　　☐ Not Reported, Data Not Available　☐ Unknown, Patient Unsure of Race

4. Gender (select only one)　　☐ Male　　☐ Female

5. Age (ex. 43)

PROTOCOL SCREENING METHODS

6. Protocol for which the patient was screened (select only one):

　　☐ ECOG 11505 (Lung)　　　　　☐ ECOG E2804 (Renal Cell) Phase II　　☐ ECOG E2805 (Adjuvant Renal)
　　☐ ECOG E5202 (Adjuvant Colon)　☐ PACCT-1 (TAILORx)　　　　　　　☐ NCCTG N0147 (Adjuvant Colon)
　　☐ NSAPB B-42 (Breast)　　　　☐ NSABP C-10 (Colon) Phase III　　　☐ CALGB C80405 (Colorectal)
　　☐ CALGB 50303 (Lymphoma) Tissue Procurement

7. What method(s) were used to identify this patient for protocol screening (select all that apply):

　　☐ Chart review　　　　　　　　　☐ Tumor board　　　　　　　　　☐ Cancer/tumor registry
　　☐ Patient care rounds　　　　　　☐ MDC/disease site conference　　☐ Review of surgical schedule
　　☐ Review of clinic schedule　　　☐ Patient self referral　　　　　　☐ Physician referral (NCCCP investigator)
　　☐ Physician referral, within institution　☐ Physician referral, outside institution　☐ Patient navigator
　　☐ Response to advertisement　　　☐ Other: _____

8. Was the patient navigator used in identifying the patient for screening:　　☐ Yes　　☐ No

9. If the patient navigator was involved, indicate how they were involved (select all the apply):
　　☐ Navigator screened the patient　　　　　　　　☐ Navigator obtained consent for treatment
　　☐ Navigator referred patient to the research team

PROTOCOL SCREENING

10. Did the patient enroll in the protocol:　　☐ Yes　　☐ No

11. If the patient did not enroll in the protocol, indicate the reason (select only one):

　　☐ Patient did not meet trial eligibility criteria (skip to question 13)
　　☐ Patient was eligible but declined participation (skip to question 14)
　　☐ Patient was eligible but physician declined to offer participation (skip to question 15)
　　☐ Patient was eligible but started treatment prior to completion of screening (skip to question 12)

12. If the patient was not captured prior to starting treatment, indicate reason why (select only one):

- ☐ Urgency to initiate treatment
- ☐ Patient not referred to research team
- ☐ Recurring patient/Not new patient
- ☐ Insufficient medical records at time of screening
- ☐ Other: _____

13. If the patient did not meet trial eligibility criteria, indicate the reason why (select all that apply):

- ☐ Performance status
- ☐ Abnormal labs
- ☐ Abnormal organ function
- ☐ Prior therapy
- ☐ Time requirement from surgery or therapy
- ☐ Co-morbidities
- ☐ Insufficient or unavailable pathologic samples for study (include unclear margins)
- ☐ Does not meet genetic testing criteria
- ☐ Patient had progressive disease
- ☐ Other: _____

14. If the patient was eligible but the patient declined participation, indicate the patient-related reason why (select all the apply):

- ☐ No desire to participate in research
- ☐ Preference for standard treatment
- ☐ Patient preferred another trial
- ☐ Lack of awareness/education about trials
- ☐ Perceived side effects/toxicities too great
- ☐ Cultural/religious issues
- ☐ No insurance coverage
- ☐ Financial concerns/indirect costs (work, etc.)
- ☐ Social issues (housing, childcare)
- ☐ Mistrust of research
- ☐ Family member influenced against trial participation
- ☐ Language barrier/lack of access to interpreter
- ☐ Patient declined to be retested per protocol
- ☐ Refused to have re-biopsy or further tissue collection
- ☐ Insurance company refused to pay for additional testing
- ☐ Insurance company denied coverage
- ☐ Other: _____

15. If the patient was eligible but the physician declined to offer participation, indicate the physician-related reason why (select all the apply):

- ☐ Preferred to offer standard of care
- ☐ Preferred to offer a different trial
- ☐ Medical concerns (age, frailty of patient)
- ☐ Medical concerns (patient tolerating treatment, performance status)
- ☐ Concerns over patient non-compliance/lack of social support
- ☐ Lack of time for physician/research staff to offer patient the trial
- ☐ Lack of physician/research staff time/support to administer trial
- ☐ Lack of knowledge/awareness of the trial by MD/research staff
- ☐ Lack of adequate reimbursement
- ☐ Physician declined to have patient retested per protocol
- ☐ Insurance company refused to pay for additional testing
- ☐ Insurance company denied coverage
- ☐ Refused to have re-biopsy or further tissues collection
- ☐ Language barrier/lack of access to interpreter
- ☐ Other: _____

16. If there was a language barrier, indicate the language spoken (select only one):

☐ Spanish   ☐ French   ☐ Chinese   ☐ Vietnamese   ☐ Other:_____

Developing the NCCCP Trials Portfolio

by Stephen Grubbs, MD; Camille Servididio, RN, MPH;
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In 2007 the National Cancer Institute launched the Community Cancer Centers Program (NCCCP) as a public-private partnership with community hospitals to explore the best methods to enhance access to care—especially for those with healthcare disparities—improve quality, and expand research within a community setting.[1,2] That same year, NCCCP formed the Portfolio Working Group to assist in the development of the Clinical Trials Screening and Accrual Log (pages 30 and 31). Originally, this group was charged with selecting clinical trials to populate the Trial Log. The NCCCP Clinical Trials portfolio also provides each NCCCP site with a high visibility portfolio of selected trials to encourage enrollment. At the Clinical Trials Subcommittee's direction, it was determined that the portfolio should have the following three characteristics:

1. A finite number of clinical trials that did not contain the broad number of trials open for accrual at each NCCCP site. A finite number of open commonly used trials would allow analysis of site implementation and use of the Trial Log, refinement of the Trial Log tool, and discovery of network barriers to accrual.
2. Clinical trials of common diseases with high incidence to allow maximum participation by all NCCCP sites.
3. A variety of clinical trial types to achieve the NCCCP deliverables for a mix of clinical trial types.

Developing the Trials Portfolio

The Portfolio Working Group was composed of representatives from nine NCCCP sites and one NCI representative with a goal of recommending a 10-trial portfolio. Participants met monthly and included NCCCP site principal investigators, physician clinical investigators, clinical research nurses, and CRAs (clinical research assistants).

The Portfolio Working Group encountered several initial barriers that would potentially limit Trial Log participation by all NCCCP sites. The first challenge was identifying clinical trials in which all sites could participate, as

Physician from one NCCCP site discusses her patient's case.

well as receive trial funding. NCCCP sites are members of numerous NCI-sponsored Cooperative Groups and research bases, but have only one common membership, Clinical Trials Support Unit (CTSU). Therefore, to allow full network trial access, CTSU trials were preferentially chosen to populate the portfolio.

The second barrier the Portfolio Working Group faced related to competing clinical trials. The Clinical Trials Subcommittee recognized the need for site-specific trial priorities. In other words, not all sites would utilize all the portfolio trials. The Portfolio Working Group considered the potential of competing trials in building the portfolio.

Finally, trial type variety was initially limited by the CTSU, which was populated in great part by Phase III trials. Over the last three years, the CTSU expanded its variety of trials by adding Phase II and cancer control trials, which

Patient and doctor at one NCCCP site.

has allowed expanded variety in the NCCCP portfolio.

The Portfolio Working Group followed these guidelines:

- Seek to identify CTSU trials attractive for site participation and consistent with the defined NCCCP deliverables
- Review the trial's accrual goals and current status for time to completion
- Obtain Portfolio Working Group committee agreement to propose portfolio addition
- Present recommendations to Clinical Trials Subcommittee for portfolio addition approval
- Establish screened-patient definition
- Request that the Trial Log add trial to portfolio.

Implementation

The initial February 2008 Trial Log portfolio consisted of three Phase III CTSU accessible trials, including trials for adjuvant breast cancer, lung cancer, and metastatic colon cancer. The Portfolio Working Group expanded the list over the next 12 months, adding eight additional trials for colon and breast cancer and expanding disease types to lymphoma, chronic lymphocytic leukemia, and renal cancer. The trial types were diversified to include Phase II, Phase III, tissue procurement, and cancer control trials, meeting the NCCCP Clinical Trial deliverable for trial type variety. To date, five trials (breast, colon, prostate, and cancer control) have been removed from the portfolio upon accrual completion or early closure. By 2010, the portfolio consisted of 13 trials, including lymphoma, breast, colon, lung, kidney, bladder, head and neck cancers, and cancer control trials.

Outcomes and Evolution

The Portfolio Working Group encountered a new challenge when analysis of Trial Log data entry identified patients as "screened" who were clearly ineligible for the trial (i.e., women with metastatic breast cancer being screened for an early stage adjuvant trial). To meet this challenge, the Portfolio Working Group defined minimum patient characteristics for each portfolio trial in order for a patient to

be considered "screened." The Trial Log was also modified to require the definition for log entry.

In 2008 the Portfolio Working Group had a special network opportunity to promote the accrual to a Wake Forest Community Clinical Oncology Program (CCOP) Research Base cancer control trial. WFU 98308 had a unique limited 61-day accrual period in November and December 2008 and was available to the network via the CTSU. This double-blinded placebo controlled trial recruited patients with chronic lymphocytic leukemia using a medication to potentially reduce the incidence of acute respiratory illness during the winter of 2009. The Clinical Trials Subcommittee prepared the network for rapid site trial activation and accrual. WFU 98308 successfully reached its accrual target of 293. Eight NCCCP sites participated in the trial, screening 427 patients in 61 days and accounting for 22 percent (63 patients) of the trial accrual. The NCCCP network experience and subsequent Trial Log analysis were presented at the 2009 Oncology Nursing Society (ONS) Congress plenary session and as a poster at the 2009 Annual American Society of Clinical Oncology (ASCO) meeting.

In the past year, the Portfolio Working Group provided analysis of Trial Log data, in particular of slow-accruing trials. Outcomes of data analysis of the slow-accruing trials led to the identification of accrual barriers, potential network or site interventions, and recommendations to remove trials from the portfolio. For example, the ECOG E1505 non-small cell lung cancer adjuvant chemotherapy trial was observed to have slow accrual both nationally and by the NCCCP. The Portfolio Working Group proposed and the Clinical Trials Subcommittee hosted a special all-site webinar with the E1505 trial principal investigator to stimulate accrual among NCCCP investigators. NCCCP sites and clinical investigators were afforded the opportunity to directly interact with the trial principal investigator. Post-intervention accrual analysis is pending.

NCCCP Site Experiences

Seven sites reported that the NCCCP portfolio broadened their program's portfolio with trials in new disease types and varieties of trials. Other sites had already opened NCCCP portfolio trials before NCCCP portfolio designation. Seven sites also noted that the NCCCP portfolio trials became high-profile trials among their investigators and research staff, leading to enhanced accrual. Several sites expanded

The NCCCP portfolio has allowed individual sites to expand their trial portfolio mix to a greater variety of disease and trial types.

Success Stories

One NCCCP site had limited access to cancer control trials and enthusiastically participated in the WFU 98308 trial. The research team anticipated the national activation date of the trial, dedicated a full-time research nurse to this trial, prepared investigators with investigator approval and a physician "champion," and developed recruitment materials for immediate IRB approval at the time of trial activation. This site's team was highly successful in its accrual efforts achieving the leading accrual among all of the NCCCP membership. The research team found their accomplishment to be a significant "morale booster" for the entire research team and led to the NCCCP presentations at both ONS and ASCO.

Another NCCCP site leveraged its participation in the NCCCP portfolio to expand its Cooperative Group and local CCOP relationships. The site has opened Radiation Therapy Oncology Group (RTOG) trials and has successfully engaged its radiation oncologists as clinical trialists. The site's portfolio expansion has strengthened its relationship with its local CCOP, and the site reports that the high-profile NCCCP trials have increased clinical trial awareness in the community.

their Cooperative Group memberships to participate in portfolio trials. Multiple members noted that shared best practices about portfolio trial selection and activation assisted in building their site portfolios for NCCCP trials, as well as non-NCCCP trials.

NCCCP sites reported several barriers to full portfolio participation, including:

- Competing trials
- Site-specific populations not amenable to the trial
- Lack of access to trial participation
- Tissue procurement requirements
- Institutional Review Board-related issues.

Current Responsibilities

Today, the Portfolio Working Group is tasked with:

- Evaluating and recommending to the Clinical Trials Subcommittee addition or subtraction of portfolio clinical trials
- Working closely with the Trial Log Working Group to manage the NCCCP Trials Portfolio by monitoring real-time screening and accrual data
- Creating screening definitions for all portfolio trials
- Evaluating trial accrual barriers identified by the screening log and developing strategies to enhance accrual
- Monitoring NCCCP clinical trial deliverables and adjusting the portfolio
- Identifying special clinical trial niche projects for network participation.

The Clinical Trials Portfolio Working Group provides the NCCCP a multi-site and multidisciplinary membership to serve the needs of trial portfolio development. The NCCCP portfolio has allowed individual sites to expand their trial portfolio mix to a greater variety of disease and trial types. Still, barriers to full NCCCP portfolio participation remain, including variable access to clinical trials by all sites. The combination of Trial Log activity and the NCCCP Trials Portfolio has allowed the NCCCP network to present its activities at prominent national meetings. 📷

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Using a Minority Matrix and Patient Navigation to Improve Accrual to Clinical Trials

by Maria Gonzalez, BS; Mitchell Berger, MD, MMM, CPE, FACP; Donna Bryant, RN; Christie Ellison, RN, BSN, OCN®; Jay Harness, MD; Mark Krasna, MD; Rachel Oelmann, MBA; and Kathy Wilkinson, RN

The NCCCP Clinical Trials Subcommittee created an Underserved and Minority Accrual Working Group (UMWG). This group was tasked with:

- Documenting challenges to clinical trial accrual
- Collecting and disseminating accrual strategies developed at NCCCP sites
- Collectively focusing efforts in this area.

Minority Matrix Criteria

After conducting a SWOT (strengths, weaknesses, opportunities, threats) analysis, the UMWG developed an assessment tool, or matrix, to define the minority or underserved populations served by NCCCP sites, and also to collect baseline and ongoing information on each site's attributes. The goal: to develop partnerships among NCCCP sites in order to share challenges, look at best practices, and ultimately increase underserved and minority accrual to clinical trials.

NCCCP developed the matrix and used the tool to collect and document several cancer program attributes across site priority populations including: Caucasian, African American, American Indian/Alaskan Native, Asian, Hispanic, Native Hawaiian/Pacific Islander, Rural, and the Elderly. The attributes studied include:

- Information tracking systems
- Institution infrastructure
- Research infrastructure
- Minority navigator and personnel programs
- Clinical trial education
- Accrual barriers
- Strategies to improve trial accrual
- Internal resources, interpreters, and translation services ("ethnic resources")
- Community partnerships and patient advocates.

Today, NCCCP sites use the matrix to measure improvements in program development and to track and evaluate outcomes.

Key Stakeholder Buy-In

Considerable support from a variety of sources was important to the successful implementation of the Minority Matrix Project—ranging from administrative staff to clinical research staff. Generally, ultimate guidance for the deployment of this project fell to the cancer research managers and their support staff. To establish credibility for the matrix tool and to understand how best to implement the project within existing clinic or hospital processes, the clinical research professional provided a platform to educate the key stakeholders.

Nurse navigators and care coordinators at each NCCCP site were critical to the successful implementation of the project. For example, navigators provided feedback on the matrix tool that helped foster a sense of buy-in and ownership in the project's ultimate outcomes.

Support from community outreach coordinators, or similar positions, was also critical due to their intimate knowledge of disparate populations for regional service areas.

Finally, implementation of the Minority Matrix Project required buy-in and support from physicians and clinical and operational directors at each NCCCP site. For example, leadership had to allocate navigator and/or outreach coordinator time and resources for the project.

The Implementation Experience

Overall, NCCCP sites reported a positive experience with project implemention. Collaboration among NCCCP sites to share experiences and best practices was integral to implementation efforts. In addition, electronic collection of race and ethnicity data helped to identify target populations for this project.

NCCCP sites held multiple meetings between clinical research staff and team members that focused on disparate populations. The goal of these meetings was two-fold: 1) to identify how to best facilitate a cooperative approach to the Minority Matrix Project and 2) to ensure that all aspects of outreach to disparate populations and ultimately the patients' care were integrated into one model.

The project was unique to many NCCCP sites in that it was the first time their programs had implemented a project that specifically addressed barriers to clinical trial accrual for minority or underserved populations. Accordingly, NCCCP sites experienced a "cross-cutting" element to the project as both disparities coordinators and research staff collaborated on the development and implementation of the project.

Implementation barriers included:

- Competing priorities
- Data collection (without a system-wide electronic health record, data collection had to be done manually)
- Allocation of resources to devote to the project
- Scheduling challenges
- Available navigator capacity.

While these barriers were relatively minimal given the scope of the Minority Matrix Project, infrastructure-based elements, such as the presence of electronic health records, helped to better facilitate the process. Overall, NCCCP sites with dedicated clinical or cancer research staff reported fewer implementation barriers than those sites without such support. As stated previously, NCCCP network collaboration was vital to the project. NCCCP sites were able to:

- Share implementation barriers
- Work together to identify best practice solutions
- Create a forum for follow-up discussion.

As the Minority Matrix Project is an ongoing project, the extent of implementation at NCCCP sites is not yet fully measured. The degree of implementation is relative to the existing support, resources, and tools available at each NCCCP site. Some sites have launched the matrix tool and have begun accrual to their selected trials; other sites are still in the initial stages of implementation.

What Matrix Data Revealed
Using the matrix tool, NCCCP identified the following barriers to improving clinical trial accrual:

- Lack of physician engagement in the clinical trial process
- Mistrust of the healthcare system and the clinical trial process in underserved communities
- Lack of inclusion of certain rural populations and underserved groups who historically received care elsewhere
- Inadequate research and navigation staff to support the special needs of the underserved.

Minority Matrix data showed that patient navigators—because of the patient trust engendered through the navigators' facilitation of many aspects of patient care—could enhance patient education and accrual to clinical trials. NCCCP sites also found that navigators and research nurses had a positive effect on physician referral to clinical trials. How? Navigators are able to introduce cancer services to patients in the early phases of cancer diagnosis and treatment decision making, thus making it possible for patients to become educated about clinical trials at an earlier stage and ultimately become more open to clinical trials participation, even in the underserved populations.

The matrix allowed NCCCP sites with similar populations to network with each other to identify common barriers and develop tools to overcome common challenges.

Using the Matrix
NCCCP sites offer these recommendations for community cancer centers that want to use a matrix tool.

1. Plan at least one year from concept to complete implementation.
2. Identify resources required *prior to* starting the project.
3. Develop standardized definitions.
4. Understand the patient population(s).
5. Start small and expand. Pick one outreach site. Refine processes, then add other sites.
6. Dedicate appropriate resources, including administrative support.
7. Include all cancer center annual program reports, demographic data, and cancer statistical data about the populations served to establish good baseline information for the matrix.
8. Identify a staff person to maintain data and update frequently.
9. Update the matrix using a different color font in order to recognize changes in the evolving document.
10. Establish a process to track all activities.

Other Tools
In addition to the matrix, the UMWG developed two other tools: 1) a webinar series on cultural awareness and clinical trial education for patient navigators and research staff and 2) a patient navigation project.

Webinar. The webinar series was designed to improve understanding of culture related to healthcare beliefs that may impact provider interactions and clinical trial accrual. The series used lectures, interactive case studies, and an expert panel—including a trial patient—to discuss accrual strategies. Populations covered included Hispanics, African Americans, and Native Americans.

Patient navigation project. Matrix data revealed that patient navigators could improve clinical trial accrual of underserved populations. The patient navigation project was designed to help navigators: 1) educate patients about clinical trials, 2) advocate for clinical trial inclusion in treatment discussions, and 3) serve as liaisons between the patients and the research team.

Today, NCCCP sites tailor the project to their unique infrastructures and track the navigator and research staff activity for specific target populations and trials. The goal is to see improvement in the targeted underserved population in clinical trials education, patient advocacy, and streamline navigation and research processes.

Twelve of the 16 NCCCP sites are participating in the patient navigation project and tracking education, screening, and enrollment data. The UMWG continues to meet monthly with a primary focus to discuss real-time project issues; challenges, best practices, and project development ideas are shared.

The Minority Matrix will continue to be updated in tandem with the patient navigation project and hopefully continue to show opportunities for future NCCCP projects.

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Developing the RECIST Criteria Toolkit NCCCP sites use this tool to improve compliance

by Mitchell Berger, MD, MMM, CPE, FACP; Maria Gonzalez, BS; Robert Siegel, MD; Lucy Gansauer, RN, MSN; James Bearden, MD, FACP; Heather Benzel, RN, CCRP; Kandie Dempsey, MS, RN, OCN®; Tricia Griffin, MD; Mark Krasna, MD; and Kristen Gowen, RN

In 2009 the NCCCP Best Practices Working Group of the Clinical Trials Subcommittee was tasked with developing a RECIST (Response Evaluation Criteria in Solid Tumors) criteria toolkit.

RECIST is a set of criteria defined by an international committee to measure tumor response via CT, MRI, and X-ray using formalized rules for measurement of tumor target lesions. While compliance with RECIST criteria in itself does not increase accrual to multi-modality clinical trials, the use of standard techniques and tools to measure response to treatment on imaging lends greater power and credibility to the results obtained, especially in multi-modality treatment plans. One of the goals of the Clinical Trials Subcommittee was to enhance NCCCP site compliance with use of the RECIST criteria in the evaluation of imaging studies used to measure response to treatment of solid tumors. As part of this effort, educational materials and tools were provided to physicians and clinical trial professionals within the network. The resources were designed to simplify the process of measuring and comparing time imaged malignant lesions across studies. NCCCP sites were able to use the tools for education, adoption, and/or implementation as they deemed appropriate.

Historical Background

RECIST criteria were initially published in 2000 in the *Journal of the National Cancer Institute* and subsequently revised in January 2009 (RECIST 1.1) in the *European Journal of Cancer.* Though RECIST is largely known in terms of measurement guidelines, the RECIST criteria also address issues related to different imaging technologies such as PET, MRI, CT, with and without contrast, as well as lesions in bone or those with cavitation. While RECIST criteria are internationally accepted, they are not mandatory and are not an NCI standard. Salient features of the changes in the RECIST criteria include:

1. Decrease of maximum target lesions from 10 to 5 total and from 5 to 2 per organ.
2. Disease progression requires both a 20 percent increase in tumor size AND a 5 mm absolute increase.
3. Information has been added regarding the use of PET/CT scanning and other imaging in the detection of new lesions.
4. For the measurement of lymph nodes, the short axis is to be measured and the axis must be ≥ 15 mm to be considered measurable.

Toolkit Development

Many NCCCP sites collaborated in the development of the RECIST toolkit. Through monthly conference calls and the sharing of experiences within each institution's research community, the basic goals and needs for this program were assessed. Many institutions provided previously utilized measurement flowsheets, while others provided Power-Point presentations already in existence at their institutions. NCCCP sites with early success in integrating RECIST measurements consistently into their SOPs shared their experiences and best practices. In addition, a PowerPoint presentation provided an overview of RECIST specifics and a rationale that could be shared with radiology staff.

The RECIST toolkit provides templates for the reporting of data and source documentation for sponsor and cooperative group audits, and simplifies monitoring of disease for response. RECIST toolkit components are organized in two categories: NCCCP-generated documents and reference documents.

NCCCP-generated RECIST toolkit documents include:
- Introduction to the "Toolkit"
- Template guideline and a sample standard operating procedure (SOP)
- Summary and quick reference document
- Tumor measurement summary template
- Implementation matrix.

Reference documents in the RECIST toolkit include:
- Original *JNCI* article on RECIST from 2000.
- Updated *European Journal of Cancer* article from 2009
- PowerPoint presentation by Stephen S. Grubbs, MD, Christiana Care, Del. dated 2005. (This presentation does *not* reflect 2009 changes.)
- PowerPoint presentation by EORTC regarding the RECIST 1.1 changes.

Toolkit Implementation

As all NCCCP clinical sites have different constituencies, how each site approaches the process of optimizing the recording of necessary data is best left to the individual

institution. NCCCP sites offer these considerations to other community cancer centers looking to enhance compliance with RECIST criteria:

1. Have a designated radiologist or team of radiologists assigned to RECIST compliant readings. (Availability of picture archiving and communication system [PACS] technology is helpful.)
2. Use Grand Rounds and educational venues for this type of presentation to radiologists to emphasize importance of RECIST.
3. Use a summary of RECIST readings signed by a radiologist or PI (principal investigator) to facilitate source documentation.
4. Budget appropriately in industry trials to account for the additional RECIST workload. (This option is not available in Cooperative Group trials.)

Success in implementing the RECIST toolkit required the buy-in of radiologists and radiology technicians, medical and radiation oncologists, and the clinical research team. The NCCCP PI was essential to help drive the implementation process. NCCCP sites found two toolkit components most useful: 1) the tumor-size measurement flowsheet, which enhanced consistency of measurement from scan to scan, and 2) the quick-reference guide for physicians.

The implementation process created an opportunity to discuss and more fully appreciate the constraints on both the researchers and the radiologists. Many of the radiologists became aware of the specificity by which clinical trials determine improvement or progression, while the clinical research team became more aware of the manpower constraints within the radiology department that made it difficult for the radiologists to comply with requests. Some NCCCP sites created a process of identifying clinical trial patients on requisitions, which generally resulted in more attention to RECIST criteria in these highlighted patients. In addition, having an interdepartmental team seemed to help improve communication and process development across departments within an institution.

NCCCP sites continue to evaluate the overall experience in rolling out the RECIST toolkit. The project requires significant time investment to develop and implement the processes involved and to garner support from the stakeholders. Because this project increases the work and time involved for a radiologist to interpret a diagnostic study, ongoing reinforcement about the project's importance is key.

Barriers and Challenges

While many NCCCP sites are in the process of implementing and fine-tuning the process, other sites face a few predictable barriers. For example, implementation of the RECIST toolkit requires a change in workflow for secretaries, schedulers, physicians who need to identify clinical trial patients on requisitions, and—most importantly—for the radiologists who have not incorporated RECIST evaluation

Case Study

Concurrent with the NCCCP's decision to move forward with a RECIST education and implementation program, research staff at one NCCCP site were noting inconsistencies in measurement and tracking of reference lesions. A subsequent audit by a cooperative group confirmed the concerns raised by the research staff. Rather than "reinventing the wheel," this site was able to share and learn from other NCCCP site experiences with similar issues and the processes used to correct them.

The site works with a 30+ member radiology department located in various sites of service. The patients on research trials use multiple facilities to obtain radiographs, so a process was needed to disseminate this information to the radiologists staffing these locations. Having one radiologist do all the reviewing for RECIST was not feasible. However, researchers identified one radiologist who became their advocate and agreed to present the details of RECIST at the equivalent of radiology Grand Rounds. While this NCCCP site did not anticipate universal acceptance of the required changes, the site hoped to achieve sufficient "buy-in" to create a RECIST core group.

PACS availability allows this core group to review films performed in other locations without much difficulty. In addition, physicians have received a tumor measurement flowsheet created by the NCCCP for assistance in identifying what is measurable and to show the history of the lesions' measurements.

Secretaries and research physicians had to be trained to somehow identify a patient in a clinical trial to allow for "special handling" of each case.

Research staff now has a better appreciation of how these efforts affect radiology workflow and have been more aggressive in funding a radiology line item in studies in which there is a budget. In most other studies, the radiologists' efforts—the extra time and effort it takes to be in compliance with RECIST criteria—have largely been uncompensated.

in routine radiology practice. Many of the institutions deal with large hospital-based and/or private practice radiology groups with multiple offices, making it difficult to isolate a core group of radiologists to function as the RECIST "team." This barrier introduces an added level of institutional inconsistency that detracts from the goals of the project and accountability. However, with the digitization of films and PACS technology, identifying a designated group of radiologists for the research process can be improved.

NCCCP sites with multidisciplinary teams and integrated radiologists found it easier to have a consistent radiologist involved in the process to facilitate the successful implementation of RECIST within their department and/or program.

Metrics

One NCCCP site led the effort to create a matrix tool that network community cancer centers could use to quantify their RECIST implementation status and monitor progress quantitatively.

Fifteen of the 16 NCCCP sites implemented RECIST and were able to compare their performance on the assessment tool pre-intervention to post-intervention. Here's what the matrix data revealed:

- All participating sites saw an increase in average score from baseline of 8.9 to 13.
- Sites were able to make the most progress around the education and coordination measures, with an average score increase of 2.6 for all sites in those two areas.
- Ten sites demonstrated progress from baseline, revealing that many sites benefited from this best practice project.
- Four sites that did not have a process at baseline (scores of 1 in all categories) were able to make significant progress with scores, averaging a 10 point improvement increase.
- Four sites that scored above 6 (entry score) did not make any additional progress.
- One site scored 21 and was able to provide expertise and support in the development of this project.
- The site that demonstrated the greatest benefit from the project saw a 13 point score increase. Analysis of interventions performed at this site will hopefully help other sites fine tune their processes.
- While a score of 30 is best practice; the highest score among the NCCCP sites was 22. This finding clearly shows that this process is difficult, requiring coordination and commitment to accomplish the best practice outcome.

The data demonstrated the clear success of sharing best practices across NCCCP sites and of learning from a site that was performing at a significantly higher level. New users of the matrix and the sites that did not make significant progress along the matrix need to consider how best to implement the RECIST matrix into their clinical trial program.

Overall, participating sites viewed the process of developing and implementing the RECIST program as a positive experience. The development process was collaborative since all sites had dealt with this problem in one form or another. The conference calls provided an opportunity to discuss what each site had learned from prior interventions on this issue.

Although it is too early to assess the full extent of the RECIST toolkit success, it is evident that talking about the process created a level of dialogue between the involved disciplines that had not always existed previously and allowed for a better understanding of the logistical issues at each institution. The most often-cited recommendation from participating sites was to have a physician "champion" within the radiology group who could help spearhead the process rather than having the initiative appear to be something imposed by an outside entity. 🕮

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Expanding Multidisciplinary Care in Community Cancer Centers

An MDC assessment tool developed by the NCCCP

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In Brief

By 2009 "expansion of integrated multi-specialty cancer care through new or expanded approaches to improve coordination" was a program deliverable for all NCCCP sites. Accordingly, an NCCCP Quality of Care Subcommittee was established and tasked with identifying a means to evaluate and implement multidisciplinary cancer care (MDC) at each NCCCP site.

The end result was the creation of a MDC development assessment tool composed of seven key indicators—with five levels, ranging from "evolving MDC" to "achieving excellence"—to measure the level of MDC implementation at each site. NCCCP sites incorporated each of the key assessment areas into their programs; however, the levels for each area varied from site to site, depending on geographic factors and availability of resources. For example, an NCCCP site in an urban area may easily have a face-to-face MDC model, whereas a rural site may need to implement a virtual MDC model due to the distance between specialists and patients.

Three years into the MDC project, all NCCCP sites showed measured improvement in the level of multidisciplinary cancer care delivered at their community cancer centers. Sites agreed that the most important factor in the establishment of a MDC model is effective physician leadership throughout the process. A number of challenges to the implementation of MDC were identified, including limited support staff and insufficient amounts of time.

Community cancer centers may find this MDC assessment tool and the experience of the NCCCP sites helpful in their efforts to create and/or expand multidisciplinary care at their own centers.

Assessment Tool Development

A small working group was formed within the Quality of Care Subcommittee to establish a framework for a MDC model that allowed NCCCP sites to assess their current programs and/or further develop their capabilities to deliver comprehensive and integrated services. The working group agreed that a common definition of multidisciplinary cancer care includes:

■ Prospective and/or concurrent review of patient care
■ Multidisciplinary physician specialists
■ Development and review of treatment plans based on evidence-based guidelines
■ Efficient communication among physicians
■ Written treatment plans that are updated as necessary and reviewed with the MDC team.

Based on the collective experience of the working group members (patient caregivers and hospital administrators), seven key assessment areas of MDC were identified. In no particular hierarchy, these areas were:

1. Case planning
2. Physician engagement
3. Coordination of care
4. Infrastructure
5. Financial
6. Clinical trials
7. Medical records.

These assessment areas were put into a matrix, each with five levels of increasing accomplishment (e.g., from Level 1 – "evolving MDC" to Level 5 – "achieving excellence"). After the NCCCP Executive Subcommittee (comprised of the Principal Investigators at each site) approved the completed tool, it was provided to the NCCCP sites to evaluate their existing capacity to deliver multidisciplinary cancer care.

Now, community cancer centers across the country can use the MDC assessment tool to evaluate their programs and guide growth opportunities in the delivery of MDC. This tool can be found on pages 42 and 43.

During their efforts to improve and expand the delivery of multidisciplinary care at their own cancer centers, NCCCP sites utilized the assessment tool, applied several MDC models to develop their MDC infrastructure, and shared lessons learned.

MDC Models

NCCCP sites used the tool to assess how best to deliver MDC to meet patient needs, while taking into consider-

ation facility space, logistical realities, and the cancer center environment. The results showed multidisciplinary cancer care at each site was at different points along the assessment scale; the spectrum ranged from minimal collaboration to face-to-face multidisciplinary clinics. Some NCCCP sites were able to use the tool to assess their programs, yet were unable to advance to a higher level due to local contributing factors. Here are three of the MDC models used by the NCCCP sites:

Tumor Board. Several sites changed the format of their weekly retrospective disease-specific tumor boards from educational case presentations to evidence-based and guideline-driven prospective case reviews. In this restructured format, the MDC model presents a patient's case to the MDC team prior to the start of treatment. A treatment plan is developed and documented for future reference. A nurse navigator, present during the case review, coordinates the treatment plan and communicates it to the patient.

NCCCP sites found the most challenging issue to this MDC model was the time commitment needed from support staff to handle the bulk of the upfront work. Other challenges included:

- Obtaining physician buy-in
- Changing the physician mindset from the "status quo"
- Moving the tumor board lead from the pathologist to the disease-specific physician
- Providing resources or benefits to physicians to make MDC conference attendance possible.

Face-to-face MDC (aka MDC Clinic). In this model, all MDC team members meet with the cancer patient in one room to discuss treatment options. An important benefit of this model is that the patient is able to leave the MDC clinic with a completed treatment plan. The nurse navigator ensures that the patient understands the treatment plan and assists with the coordination of diagnostic tests, treatments, and follow-up visits.

Though multidisciplinary clinics are enhanced by having all team members available as needed rather than requiring patients to schedule more appointments at other locations, this model is often not feasible for many community cancer centers. Barriers to the implementation of this model include:

- Availability of adequate MDC clinic space
- Coordination of team member schedules to fit the clinic time
- Physician buy-in (clinic productivity and therefore revenue is decreased under this MDC model)
- Ability of support staff to assemble all necessary reports, test results, and imaging scans prior to the face-to-face MDC clinic meeting.

Virtual MDC. NCCCP sites that did not have the physical space to hold team meetings or that could not have face-to-face clinics due to distance between team members implemented virtual MDCs. In this model, members of the MDC team see the cancer patient at different times and places within a specified time frame. A treatment plan is developed, written, and sent to all team members, as well as the patient and primary care physician. A nurse navigator assists the patient through the process to ensure that all appointments are met and that all diagnostic and treatment information is communicated to the MDC team.

NCCCP sites found two major challenges to the virtual MDC model:

- How to identify the needs of MDC team members
- How to identify the gaps in communication and close those gaps to ensure timely and accurate communication of the treatment plan.

During the three-year pilot period, NCCCP sites initiated 27 new MDCs, increasing the total number from 47 to 83. At the end of the assessment period, 36 MDCs were functioning in the five most common disease-specific MDCs: breast, lung, colorectal/GI, prostate/GU, and head and neck. NCCCP sites that were able to implement particular disease-specific MDCs showed significant improvements in the level of MDC care as measured with metrics, such as the number of physicians participating and the percent of patients prospectively presented. Though three of the NCCCP sites did not have functioning MDCs at the end of the initial three-year pilot, these sites were able to demonstrate steps taken toward establishing multidisciplinary care delivery levels.

Based on the outcomes of the MDC evaluation and implementation efforts, NCCCP sites identified two key roles as crucial to successful MDC development: an effective physician leader and an experienced nurse navigator.

Physician Leader

NCCCP sites found that effective physician leadership was essential to influence movement to higher levels of MDC development and was a major component of successful implementation and maintenance of MDC in a community cancer center. An effective physician leader has a scope of authority and accountability to:

- Oversee the development and implementation of the MDC program
- Provide leadership for the vision and strategic plan for the MDC program
- Have report relationships and authority within the organization that enable the physician leader to be accountable for the MDC program
- Be an active participant in the MDC program, as appropriate.

To be most effective, NCCCP sites believe that the physician leader should be an active oncology clinician who is skilled at developing peer relationships. An effective physician leader will help ensure continued physician participation in MDC. Why? A physician who serves as a champion for MDC will engage private practitioners in a process that respects their schedules, yet allows for participation in MDC, either in person or virtually. Interest and involvement by physicians in the community, as well as cancer-center-employed physicians, offers many benefits, including:

- Wider participation by physicians overall
- Broader overall knowledge base
- Wider range of physician perspectives and greater consensus.

Nurse Navigator

The second influential factor for successful MDC development and implementation is the engagement of an experienced nurse navigator. The standard role of the navigator is to:

MDC Assessment Tool

Assessment Area	Evolving MDC (Level 1)	Developing MDC (Level 2)	MDC (Level 3)
Case Planning	Care planning is asynchronous with patient presenting to multiple physician offices without a shared medical record.	Care planning is asynchronous with patient presenting to multiple physician offices with a shared medical record.	Most care planning is asynchronous, but some patient care plans are discussed in multidisciplinary conferences, which occur on a weekly basis.
Physician Engagement	Diagnostic and treatment physician belong to multiple independent groups, with little interaction, and a representative from some groups is engaged with the cancer center.	Diagnostic and treatment physician belong to multiple independent groups, with little interaction, and at least one representative from each group is actively engaged with the cancer center.	The MDC has a physician agreement of participation, and physicians are actively engaged in developing treatment standards.
Coordination of Care	Patient care is episodic. Patient has to present to multiple locations on multiple days for treatment and or diagnostic modalities. Information is stored in multiple locations, and difficult to coalesce.	Patient care is episodic, but some treatment and diagnostic modalities are coordinated. Information is coordinated and is readily available to physicians and staff.	MDC has some dedicated diagnostic and treatment abilities to meet patient's care needs. Information is readily available to physician and staff.
Infrastructure	Limited physical infrastructure with limited information system support. Hospital, physician office model.	Limited physical infrastructure with integrated clinical and administrative information systems used by all.	Some dedicated physical facilities, which do not cover the full spectrum of care, with independent clinical and administrative information systems.
Financial	Billing is episodic, based on encounter with facility or physician. No facility fee is applied.	N/A	Physicians bill separately. Introduction of facility fee for MDC. Communication between MDC and physician offices.
Clinical Trials	Patient not reviewed for eligibility for clinical trials. No literature given to patient on clinical trials.	Some patients reviewed for eligibility. No formal process to review patients for clinical trials. Clinical trial literature given to patient.	2% of patients participating in clinical trials. There is a formal accrual and recruitment plan. Clinical trial literature given to all patients.
Medical Records	Paper chart plus some EMR with isolated pockets.	Mainly for documentation reasons only. Medical information is not integrated. Little to no sharing. Mixture of paper and electronic.	Mixture of paper and EMR. Starting to share labs, radiology, medical history, treatment plans, and medications.

Moving towards Excellence (Level 4)	Achieving Excellence (Level 5)
All patient care planning is done through a multidisciplinary conference, which occurs on at least a weekly basis.	All patient care planning is done through a multidisciplinary conference, which occurs while the patient encounters care.
Same as prior, with the addition of engagement in quality improvement initiatives and strategic direction.	Same as prior, with the addition of physicians have operational and financial authority for the MDC.
MDC is fully integrated with treatment and diagnostic modalities, and all information is available from a single source.	Same as prior, with the addition of ancillary services such as education, support groups, and wellness programs for patients and families.
Some dedicated physical facilities, which do not cover the full spectrum of care, with integrated clinical and administrative information systems.	Dedicated center with ability to provide full service to patients with integrated information systems.
N/A	Global bill for MDC billing, inclusive of facility fee.
4% of patients participating in clinical trials. There is a formal accrual and recruitment plan. Clinical trial literature given to all patients.	6% of patients participating in clinical trials. There is a formal accrual and recruitment plan. Clinical trial literature given to all patients.
75% of hospital system and physician offices is integrated electronically across the continuum.	Fully integrated electronic record across the continuum with access to information.

Case Planning _____

Physician Engagement _____

Coordination of Care _____

Infrastructure _____

Financial _____

Clinical_____

Trials _____

Medical Records _____

Total Score _____

Level 1—Evolving MDC Program

This level describes organizations that meet regulatory requirements and Association of Community Cancer Centers (ACCC) guidelines. There are a few performance improvement initiatives underway, and some centers of excellence. The leadership vision for quality is unclear. The organization lacks sufficient personnel and financial resources to administer a fundamental program that supports conducting MDC initiatives designed to attain improvements in patient care, quality, safety, and efficiency.

Level 2—Moving Towards MDC Program

Organizations at this level have some of the fundamental structures and processes for achieving MDC initiatives. The leadership vision for quality is under development. Some personnel and financial resources are available to support the organization attain some improvements in patient care, quality, safety, and efficiency, but they are insufficient for a comprehensive program.

Level 3—MDC Program

Organizations at this level have many of the fundamental structures and processes for running MDC initiatives. Leadership's vision for quality is known to many in the organization. Personnel and financial resources are available to support the organization in attaining a number of changes in the improvement of patient care quality, safety, and efficiency, and changes largely are driven by the cancer center staff.

Level 4—Moving Towards MDC Excellence

Organizations at this level have many significant structures and processes for deploying MDC initiatives. Personnel and financial resources are available to support the organization in attaining many important changes and improvements in patient care, quality, safety, and efficiency. Some staff outside the cancer center play lead roles in fostering initiatives.

Level 5—Achieving MDC Excellence

Organizations at this level have many best of class structures and processes deploying MDC initiatives. Personnel and financial resources are spread throughout the organization and available to support the attainment of many important, leading, and creative changes and improvements in patient care quality, safety, and efficiency. Many staff outside the cancer center play lead roles in fostering initiatives and achieving results. This level also provides organizations with stretch goals.

- Help guide the patient and family through the healthcare system
- Act as the central contact for patients and families
- Ensure that the patient and family understand the diagnosis and treatment plan
- Assist patients with scheduling tests and consultations.

An experienced nurse navigator can facilitate multidisciplinary care and provide open communication between all disciplines. A navigator has the process knowledge to coordinate patient schedules, will follow-up on care planning, and will communicate with the patient and the MDC team. When patients are not able to see all disciplines at the same time, on the same day, or at the same location, the navigator will help guide the patient through the process. Even community cancer centers that are able to offer face-to-face MDC find the support of a nurse navigator important in addressing the needs of the patients beyond the MDC.

Other Stakeholders
In addition to the physician leader and nurse navigator, NCCCP sites found that expansion of MDC at a cancer center involved other key stakeholders including:
- Cancer patients
- Hospital or cancer center leadership
- Cancer program director
- Medical and radiation oncologists
- Pathologists
- Surgeons (both oncologic and other specialists)
- Primary care physicians
- Cancer registrar and staff
- Research and clinical trials staff
- Medical geneticists
- Legal departments
- Hospital staff
- Social workers
- Dietitians
- Community outreach staff.

Barriers to MDC Implementation
NCCCP sites found that the most common barrier across all types of MDC models was the inability to schedule private practice physician time, resulting in a lack of physician engagement. The community oncology physician's schedule is complicated by decreasing revenues. Today, these physicians have to see more patients to receive the same compensation, and this scenario results in tight schedules that do not accommodate time for MDC participation. Other potential barriers to MDC implementation identified included:
- Contract issues that may prevent physician groups from seeing patients in the MDC model
- Single-physician specialty practices where it may be difficult for the physician to allot time away from patients
- The ability to identify and engage a physician leader for each disease site
- The availability of space for multidisciplinary clinics and limited support staff
- The amount of time required to address billing agreements, conditions of participation, credentialing of physicians to practice within the MDC, and the ability to identify the billing process and auditing responses from insurance companies
- Prior failed attempts to launch MDC that would neces-

sitate additional, time-consuming planning efforts and require physician dialogue to gain buy-in.

Recommendations and Conclusion
In the end, NCCCP sites gained many valuable insights through the process of developing the MDC assessment tool and expanding multidisciplinary care at their cancer centers. As a group, they offer a stepwise approach with the following recommendations to other community cancer centers interested in establishing or enhancing MDC:
- Recognize that effective physician leadership is essential for MDC success
- Gain support of hospital or cancer center leadership to acknowledge the benefits of the physician leader role
- Utilize a MDC model that will succeed (e.g., implement MDC for a disease site that has a high volume and a willing physician leader)
- Develop a process that makes it easy for private practice physicians to participate (e.g., provide specific benefits to participating physicians, such as offering CME credits or allowing access to specialized equipment and technology at the clinic)
- Accept the need for flexibility as no one model will be suitable for all services
- Be willing to adapt or make changes to the process *immediately* in order to use MDC team members' time wisely and efficiently
- Recognize the importance of available support staff to address patient needs—beyond clinical care—that could be barriers to completing care
- Engage an effective nurse navigator with knowledge of the process to coordinate patient schedules
- Understand that not every community cancer center is meant to reach a level five for all key elements in the MDC assessment tool to measure success.

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NCCCP Cancer Center Medical Staff
Conditions of Participation
Developing effective partnerships

by H.A. Zaren, MD, FACS

Community hospitals face major challenges as they attempt to involve community oncologists in meeting the goals of the National Cancer Institute (NCI) Community Cancer Centers Program (NCCCP). Most NCCCP sites rely upon private practice physicians to support their cancer programs. The NCCCP sites recognized that more active involvement with their cancer physicians was needed to improve the community cancer centers' abilities to offer state-of-the-art cancer care and to promote research. To help support this objective, NCCCP sites worked together to develop the NCCCP Cancer Center Medical Staff Conditions of Participation (COPs). The participating hospitals established an appropriate set of criteria, critical to meet the goals of the NCCCP as well as the programmatic goals of the cancer centers.

The "Recommended Conditions of Participation" can be found on pages 46 and 47 and are available on the NCCCP website at: *http://ncccp.cancer.gov/NCCCP-Conditions-of-Participation.pdf*. These recommendations represent goals to strive for, and each NCCCP site has been working over the three-year pilot to adopt some form of the "Recommended COPs" that will be achievable in their community setting using this document as a guide. The site-specific COP recommended by the NCCCP consists of criteria for:

■ Medical staff professional affiliations
■ Cancer expertise and continuing education
■ Research and clinical trials
■ Cancer practice commitments
■ Cancer program obligations.

How might community cancer centers benefit from implementing conditions of participation? The answer is simple—COP implementation will increase physician commitment to the organization and collaborative efforts between disciplines. Across the NCCCP sites, COPs include: 1) establishing cancer medical staff practice pattern standards for achieving quality of care and promoting research, 2) advancing physician involvement in the community cancer center, and 3) engaging physicians in multidisciplinary teams.

Committing to COPs requires an investment of time by the participating physicians, so it is important to underscore the benefits in terms of the physicians' professional needs and the needs of their patients. NCCCP sites tracked the amount of time physicians donated to activities that are included in the COPs so that all could quantify the value of this commitment for largely private practice physicians. At the various NCCCP sites some of the benefits included:

■ The ability to compare their clinical performance to national guidelines and to other physicians in the organization
■ The opportunity to *prospectively* present their patients to a multidisciplinary committee to help ensure optimal treatment plans
■ Enhanced branding with support from the cancer center through marketing efforts for participating physicians
■ Identification in hospital call centers as preferred providers
■ Navigation support for patients
■ Research nurse support
■ Support for attendance at national meetings.

COPs can be put in place with existing "hospital privileges" and not be mutually exclusive. NCCCP sites created "peer pressure" by recognizing and rewarding physicians who met requirements, thus achieving reasonable goals over time. In order to increase physician participation to meet these standards, NCCCP sites suggest that community cancer centers:

■ Increase clinical trial opportunities by supporting research
■ Encourage general discussion between disciplines
■ Clarify expectations for physicians and for hospital administration
■ Recognize distinction in clinical performance among physicians
■ Increase collaboration to support the cancer center's strategic plan
■ Attract high-quality physician recruits
■ Provide institutional and administrative support for physician activities
■ Incorporate National Comprehensive Cancer Network (NCCN) and other guidelines for care into routine practice.

Overall, NCCCP sites reported four elements that were critical to develop support for the COPs: 1) identifying key stakeholder buy-in, 2) developing the rationale for participation, 3) identifying required elements and success factors, and 4) incorporating best practices.

NCCCP Recommendations for Cancer Center Medical Staff Conditions of Participation

Requirement	Suggested Metrics	Category	Criteria
1. Professional Affiliations	■ Active member of hospital medical staff	■ Required	■ Hospital to confirm
	■ Board eligible, certification, and re-certification as required	■ Required	■ Provide documentation
	■ Membership in oncologic societies, if available for specialty	■ Required	■ Provide documentation
	■ Leadership role and/or participation in local, state, and national community cancer activities	■ Strongly encouraged	■ Must participate in at least one yearly activity
2. Cancer Expertise and Continuing Education	■ Attendance at national and local oncology conferences (e.g., ASCO, ASTRO, AACR) with oncology CME credits	■ Strongly encouraged	■ 20 CME credits every 2 years in oncology-related topics from national and local conferences combined
	■ Dedicated commitment to a specific disease area and demonstration of an appropriate volume, which allows the physician to provide care for patients with good outcomes	■ Strongly encouraged	■ Completion of fellowship training in medical, surgical, or radiation oncology; or a general surgery, pulmonology, gynecology, pathology, imaging, or neurology practice focused in one or two disease sites
	■ Publications and presentations	■ Strongly encouraged	■ Hospital to track
3. Research and Clinical Trials	■ Participation in clinical trials and/or secondary or team credit for accrual coordination, referrals, or support for trials (surgeons, urologists, radiation oncologists)	■ Required	■ Must place, refer, and/or support patient on clinical trials (confirmation provided by cancer center clinical trials or research coordinator)
	■ Completion of the Human Participants Protection Education Research Teams online course (required by NIH to be an investigator for Cooperative Group or NCI studies)	■ Required	■ Provide documentation of education
	■ Involvement in national oncology research activities, such as ECOG, SWOG, RTOG, NSABP, and GOG	■ Strongly encouraged	■ Active participation and/or membership with at least one of these organizations

Buy-in from Key Stakeholders

When developing the COP, NCCCP sites identified a number of key stakeholders:

Physicians. Physician buy-in should include physicians employed by the cancer center; physician private practices, such as medical, radiation, and surgical oncology; contracted practices, such as pathology and radiology; and other participating physicians who serve a significant cancer patient population in the local community.

Medical staff leadership. Buy-in from the health system, hospital cancer center, and chief medical officer and/or medical director is mandatory.

Administration. Health system, hospital, and cancer center administrative leadership must also be on board. Practice administrators employed by physician private practices are also key.

Other stakeholders. The health system, hospital, and cancer center legal services must be involved in developing the COP. In addition, the Board of Directors and/or Board of Trustees of the health system, hospital, and cancer center must agree to support the COP.

Requirement	Suggested Metrics	Category	Criteria
4. Cancer Practice Commitments	Commit to a philosophy of cancer care that includes: ■ Discuss all appropriate treatment options with patients ■ Communication with primary care or referring physician throughout diagnosis and treatment, provide timely follow-up communication regarding patient recommendations, treatment status, and outcomes (e.g., within one week) ■ A willingness to provide timely verbal consults to cancer center and hospital physicians ■ A willingness to provide second opinions at request of patients or referring physicians (e.g., same day) ■ A commitment to the provision of timely patient return and coordination of follow-up care ■ Embraces multidisciplinary care, collaborating prospectively with other members of the patient's care team and involving the patient and family as a partner ■ Participation with navigators and care managers as available and when appropriate ■ Provide the treatment plan and summary as developed by the cancer center based on recommendations from the NCCCP program	■ All criteria listed will be part of acceptance of conditions of participation agreement obligations	
5. Cancer Program Obligations	■ Commitment to being a part of a strong oncology practice group committed to providing vision, oversight, and plans for growth and research support for the NCCCP program ■ Follow evidence-based guidelines, such as ASCO, NCCN, or similar guidelines offered at the cancer center ■ Provide data and clinical information to support cancer center patient care and performance improvement (PI) efforts, including sharing patient office practice data with cancer research office and/or registry as needed for quality data ■ Participate in multidisciplinary conferences, site-specific tumor boards, and/or specific tumor conferences as appropriate for the cancer center ■ Commitment to follow professional societies' (ASCO, NSGC, ASHG) recommendations on cancer genetics that include evaluation by appropriately trained professionals in genetic counseling, screening, and testing ■ Participate in at least one PI activity annually ■ Provide cancer registry with timely information ■ Conduct oncology educational sessions for staff and primary care physicians, as appropriate ■ Provide care for the uninsured and/or underserved per hospital-specific policy for the NCCCP program (e.g., agree to accept on a fair and proportional basis with other participating physicians, any patients referred through the cancer center) ■ Support screening efforts	■ All criteria listed will be part of acceptance of conditions of participation agreement obligations	■ Participate in at least 60% of local cancer center site-specific tumor conferences

Developing the COP

NCCCP sites identified the following key requirements for developing conditions of participation:

■ Support of key stakeholders
■ Development of a detailed marketing and educational plan targeted to physicians
■ Development of specific benefits of participation, such as marketing services for participating physicians
■ Support by administration to provide resources, such as patient navigation, social services, research nurses, and access to medical equipment
■ Provision of a venue for physicians to voice opinions
■ Progress reports on implementation.

Community cancer centers developing and implementing a COP must be willing to invest in personnel, information technology (IT), and quality of care initiatives. To be successful, NCCCP sites suggest that community cancer centers:

■ Provide resources and specific benefits for participation
■ Establish physician forums or subcommittees to discuss COP elements

NCCCP sites also reported a need to identify a "value" for physician time related to COP implementation.

- Acknowledge concerns for program success
- Involve the legal department to discuss legal concerns, such as Stark and appropriate marketing efforts
- Emphasize availability of professional development and continuing education
- Identify metrics to assess COP involvement.

NCCCP sites identified other factors leading to successful COP development, including 1) the need for private practitioners to support more coordinated care for cancer patients, 2) the branding of a cancer center connection by physician practices, 3) encouraging physician interest in clinical trials, and 4) engagement with private practice physicians by the NCCCP site principal investigator and/or cancer center medical director serving as a physician leader.

For some NCCCP sites, the legal issues related to COP development took up to 12 months. During this period, NCCCP sites reported a need for ongoing dialogue with *all* key stakeholders.

Implementing the COP

Overall, NCCCP sites found that successful implementation of the COP required four actions:

1. Availability of support staff throughout the implementation process
2. Reinforcement of the conditions of participation by integrating them into cancer center meetings and activities
3. Continued education and professional development throughout the implementation process
4. Participation of legal representatives from the hospital and private practice(s).

NCCCP sites experienced a variety of organizational, structural, and clinical barriers and challenges to COP implementation. For example, some NCCCP sites experienced structural barriers related to distance—not only the distance between private practices and the cancer center, but also distance within the local facilities.

NCCCP sites also reported a need to identify a "value" for physician time related to COP implementation. Private physicians must be willing and able to invest extra time and resources to fulfill initial COPs, and it is helpful if they understand the benefits that they can receive as a participating physician. Community cancer centers can help overcome physician resistance by facilitating meetings and open discussions among physicians.

Some NCCCP sites were able to add COPs to medical staff requirements in order to facilitate implementation. At the conclusion of the 3-year pilot period, 3 sites had completely implemented COPs, 11 sites were in the process of COP implementation, and 2 sites had not yet implemented COPs.

Lessons Learned

In the process of developing and adopting COPs, NCCCP sites faced many challenges, such as fear of the unknown with physician response and fear of a misunderstanding of institutional intent; these were overcome by open communication and education. Many NCCCP sites experienced challenges with their legal counsel's interpretation of the COPs and in tracking COP metrics. NCCCP sites added suggested metrics to the COPs to underscore the importance of tracking progress and compliance.

For community cancer centers looking to implement COPs, NCCCP sites offer these final recommendations:

- Develop a steering committee
- Designate a champion or leader, such as the cancer center medical director
- Ensure that financial support and time allocation of resources are available to implement the project
- Conduct onsite tours or teleconferences with programs with previous COP experience
- Develop an implementation plan and a way to monitor progress and have both approved by key stakeholders *prior to* COP development
- Consider introduction of the COP through existing boards and processes, such as the cancer committee
- Engage, as early as possible, the cancer center's legal department and participating physicians' legal counsel in COP development.

NCCCP sites found that their medical directors, physician leaders, and cancer committee leadership contributed significantly to successful COP implementation. For the organizations, the major benefits of COP implementation were two-fold. First, conditions of participation gave NCCCP sites the opportunity to gather a core of high-quality physicians. Second, NCCCP sites found that COP implementation utilized a more integrated partnership in support of patient care that improved care and increased physician and patient satisfaction.

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Survivorship & Palliative Care

A Comprehensive Approach to a Survivorship Care Plan

by Karyl Blaseg, RN, MSN, OCN®; Marilyn Kile, APRN, AOCN®; and Andrew Salner, MD, FACR

One of the NCCCP's goals is to enhance cancer survivorship and palliative care services. To meet this goal, the 16 pilot sites funded in 2007 were expected to:

■ Develop and deliver cancer treatment summaries and follow-up care plans to cancer survivors completing therapy
■ Expand existing, or create new, psychosocial and palliative care programs and services for patients and families.

At the start of the NCCCP program, a Survivorship and Palliative Care Subcommittee was formed with representatives from each of the original 16 NCCCP sites. This group worked collaboratively to help all NCCCP sites meet the expectations outlined above. The subcommittee's first project was two-fold: 1) to create a treatment summary template and 2) to explore approaches to deliver this treatment summary. The subcommittee also identified barriers to the implementation of a treatment summary and shared strategies and successful models adopted by the community cancer centers within the network.

Developing the NCCCP Treatment Summary and Care Plan Templates

The Survivorship and Palliative Care Subcommittee's development of the treatment summary template spanned 12 months and involved intense collaboration among the NCCCP pilot sites. To start the process, all NCCCP sites completed an initial questionnaire to help establish the goals and agendas for the subcommittee's discussions.

Survey results and subsequent discussions indicated that only a few NCCCP pilot sites were providing treatment summaries, and therefore, the subcommittee selected as its initial project the development of a NCCCP treatment summary template. The subcommittee's approach was to outline the process, develop the template, and then determine the method for distribution. The plan involved the generation of a detailed medical treatment summary for sharing with patients and their primary care provid-

ers. Subsequent to this effort, the subcommittee worked to develop a long-term survivor care plan, tailored to a given patient's treatment experience and related long-term consequences, and incorporating recommendations to promote healthy lifestyle choices.

As the subcommittee began outlining the process, a few NCCCP pilot sites shared drafts of their existing treatment summary documents. In addition, the subcommittee carried out a brief environmental scan to identify other entities that might have model forms available for consideration for use (e.g., major cancer centers, Lance Armstrong Foundation, Children's Oncology Group, and American Society of Clinical Oncology). Rather than developing a *de novo* template, the sites decided to systematically and sequentially evaluate the American Society of Clinical Oncology (ASCO) treatment summary and survivorship plan templates and then discuss suggested revisions. To start, the group chose to focus on documents related to breast cancer survivors, as this choice would allow all NCCCP sites to have input into the template. Once the general treatment summary template was developed, each NCCCP site would be able to revise, customize, or update to meet the diverse needs—based on geography and patient populations served—of their own organizations.

As the subcommittee adapted the ASCO treatment summary template, it paid particular attention to recommendations in the 2005 Institute of Medicine (IOM) report, "From Cancer Patient to Cancer Survivor: Lost in Transition," in an effort to identify areas that might benefit from enhancements.[1] For example, a key area missing from the ASCO template was information specific to psychosocial aspects of care: assessments completed, referrals made to support groups, symptom management, and other survivorship issues. Failure to address this aspect of patient care was itself the focus of a 2007 IOM report, "Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs" (*http://www.iom.edu/Reports/2007/Cancer-Care-for-the-Whole-Patient-Meeting-Psychosocial-Health-Needs.aspx*).

Over the course of several months, NCCCP sites suggested additional information that might be incorporated into the treatment summary template. They also discussed several concerns, including:

- The importance of developing a template as a summary (rather than re-creating the entire medical record)
- The need for the template to be user-friendly for both patients and primary care providers
- How data would be collected, how the document would be collated, and who would prepare and deliver the treatment summary document.

As part of the template development process, the subcommittee explored the feasibility of developing an e-version of the NCCCP treatment summary. An online tool, which would pull data from the various primary sources, was determined to likely be a multi-year project. In the interim, it was suggested that NCCCP sites using the treatment summary template develop a spreadsheet to identify where the primary data needed to populate the template were located. For example, key data elements come from a variety of places, such as the tumor registry, physician office records, freestanding infusion center datasets, or an existing electronic health record (EHR). To avoid errors, the subcommittee stressed that primary source data are preferable whenever possible. Information compiled in the spreadsheets could then serve as a first step in assisting informatics staff at each NCCCP site in exploring e-versions with NCI Information Technology (IT) leads.

Recognizing that a survivorship care plan includes both a treatment summary and a follow-up care plan, the subcommittee worked to modify ASCO's existing templates. Once the treatment summary template (pages 57–58) and survivorship care plan template (pages 59–60) were finalized, the subcommittee co-chairs asked ASCO to review their work. Overall, ASCO was impressed with the additions and in some cases modified its forms to address NCCCP-identified gaps. ASCO only requested that its copyright in the footer be removed and replaced with the following language: "Adopted from ASCO Breast Cancer Treatment Summary."

Next, NCCCP sites explored several models for successful implementation of the templates; some of these models included the development of survivorship programs and clinics to offer care and support to cancer survivors. Here is what they found.

Model 1—Treatment Summary Field Populated Through Cancer Registry

One NCCCP site populated the treatment summary field through its tumor registry. Initially, an Excel spreadsheet was created, and it was populated when registrars abstracted data for breast cancer patients. Manual completion of the treatment summary template took two to three hours per patient, so this NCCCP site looked at ways to complete the form electronically. After careful research and study by the site's Cancer Registry staff, a methodology was developed to automatically populate fields within the NCCCP Breast Treatment Summary by using the CNExT Registry software system.

A nurse practitioner-survivorship patient navigator from NCCCP site Hartford Hospital reviews a survivorship care plan with a patient.

Survivorship Care Plans 101

Multiple specialists, including surgeons, medical oncologists, radiation oncologists, nurses, and rehabilitation therapists, provide cancer care to patients. Because these specialists are typically located in separate sites and/or practices and often do not share a common patient health record,[1] various survivorship reports have made a strong case for creation of a treatment summary.[2-4] Developed by the cancer treatment team, this document would facilitate communication between the cancer treatment team and the patient, as well as the cancer treatment team and the patient's other healthcare providers, including primary care physicians and staff.[5]

The patient's treatment summary guides the development of a survivorship care plan. A care plan is a written record of the patient's cancer history, contains recommendations for follow-up care, and includes guidelines for surveillance testing for the detection of possible disease recurrence. The survivorship care plan also provides healthy behavior recommendations that are important to the post-treatment needs of cancer survivors.

Applying a comprehensive approach to a survivorship care plan, cancer care providers use the treatment summary to give patients detailed diagnostic and cancer-therapy-related information that previously had not been well or routinely provided. The treatment summary and follow-up care plan would also include:

- Information on short- and long-term effects of therapy
- Recommended monitoring for recurrence and adverse effects
- Referral information, as needed for persistent problems
- A review of and support for wellness strategies.

This approach has the potential to empower patients to resume control at a time when much control has been lost. In addition, the treatment summary communicates similar information to all allied providers, helping to ensure that each, including the patient's primary care provider, will be "on the same wavelength" in terms of plans for follow-up care. Having a clear summary treatment plan in place offers a number of other benefits, such as:

- Reducing the risk for inappropriate testing and duplication of services
- Promoting coordination of care by providing guidance on who is

doing what, when, and why
- Reducing the chance of providers failing to agree on needed follow-up care—a common situation that can lead to confusion, doubt, and concern on the part of the patient.

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Use of the follow-up letter function in the CNExT Registry system allowed available abstract fields to be electronically matched to corresponding NCCCP treatment summary fields. Unused abstract fields were reallocated and named to a new use to capture information not routinely abstracted by registrars. Cancer Registry staff did significant pre-implementation testing to ensure that all codes on the CNExT system assigned to the treatment summary form provided appropriate and meaningful numeric or text data. After testing was completed, Cancer Registry staff created and used abstract guidelines. These guidelines ensured that

staff would follow a standardized abstracting process so that the treatment form would be consistently completed.

At this NCCCP site, the Principal Investigator (PI), a breast surgeon, and the NCCCP nurse practitioner (NP) piloted utilization of the treatment summary. One copy of the treatment summary was given to the patient; a second copy was filed in the patient's chart. The PI and NP reviewed the treatment summary with their respective patients during the patients' next scheduled visit after treatment completion.

This site successfully mentored other NCCCP sites to implement the treatment summary form in the most

One NCCCP pilot site was awarded a Lance Armstrong Foundation community grant to develop a survivorship program that would use a patient navigator to coordinate specific survivorship care.

efficient manner possible, particularly those sites with the CNExT Registry system in place.

Model 2—Nurse Practitioner-Led Survivorship Program with Survivorship Software

One NCCCP pilot site was awarded a Lance Armstrong Foundation community grant to develop a survivorship program that would use a patient navigator to coordinate specific survivorship care. This program included the development of a treatment summary and care plan to be provided to and discussed with patients at a survivorship visit. After receiving the grant, the NCCCP site hired an NP to fill the survivorship patient navigator role. Using a nurse practitioner in this role provides patients with high-level, specialized survivorship care. In addition, the NP's services are billable, which creates a survivorship care model with the potential for self-sustainability and revenue generation.

Currently, the NCCCP site is piloting a breast cancer survivorship program where patients are seen four to six weeks after the completion of their primary cancer treatment. During this initial survivorship visit, patients are given a breast cancer treatment summary and care plan that outline all of the cancer treatments they have received and note potential side effects and late effects of their treatment. In addition, at this visit, the NP gives patients individualized education and counseling about their care plan, and provides information on support services, appropriate screenings, wellness, and lifestyle modifications to improve their overall health and well-being as they transition to survivorship.

The NP is a point of contact for breast cancer survivors and assists in coordinating the care they receive from their other healthcare providers. This model improves continuity of care and may help eliminate unnecessary provider visits. After the survivorship visit, the NP sends the treatment summary to all of the patient's healthcare providers to be integrated into the patient's medical records.

This NCCCP site also used the CNExT registry software to create its treatment summary. While this choice allowed the site to use existing resources to begin their survivorship program, the process is very time consuming and does not allow for a personalized approach to creating a care plan. Plans are under way to transition to an electronic, web-based survivorship package that will: 1) greatly decrease the time needed to create the treatment summary and 2) allow the NP to develop more personalized care plans for each patient using an extensive bank of published articles and educational information. Using this web-based survivorship tool, the goal is to expand the survivorship program more quickly to include additional cancer sites and patient populations.

This NCCCP site is using measures of patient quality of life and satisfaction with their survivorship care and experience to evaluate and improve the program and provide

a database that would permit future research on the impact of survivorship care on patients' subsequent health-related outcomes. Surveys measuring quality of life (FACT-B), fear of recurrence (Assessment of Survivor Concerns), and survivorship program satisfaction are filled out at the initial survivorship visit and six months post-visit. This information will be used to guide program development as staff seeks to expand the survivorship program to other types of cancer.

Staff also hopes to publish and disseminate the findings of their survivorship program evaluation, to expand the available resources on cancer survivorship, and to participate in the development of best practice models and guidelines for developing and providing cancer survivorship care in community cancer centers. Using new technology, such as the Cogent survivorship software, and seeking feedback from survivors through the program evaluation will help continually improve and expand the program to best meet the needs of the site's cancer survivors.

Model 3—Using the *Journey Forward Care Plan Builder*

At one NCCCP site, oncology providers, administrators, and staff embraced the IOM's assertion that a survivor's transition from treatment to follow-up and surveillance should be individualized and understandable. This site also involved cancer survivors, their families, patient advocates, primary care physicians, and insurance providers as key stakeholders in the effort to implement survivorship plans.

In 2009, the site conducted two pilot evaluations to determine the best mechanism for delivering treatment summaries and survivorship care plans.

The first pilot study used a manually dictated treatment summary. In this study, patients received their survivorship care plans during a follow-up appointment with either a survivorship NP or with their oncologist.

The second pilot used the *Journey Forward Survivorship Care Plan Builder*, a treatment summary and survivorship care plan builder for breast, colon, and other cancer types. A joint project between the National Coalition for Cancer Survivorship, the University of California Los Angeles Cancer Survivorship Center, Wellpoint, Inc., and Genentech Inc., the *Survivorship Care Plan Builder 2.0* is available as a download from *http://journeyforward.org/* or via CD. In this pilot, patients received individual survivorship summaries from their providers in a support group setting.

While both studies indicated that the survivorship plans were well received by patients, the NCCCP site ultimately opted to implement the *Journey Forward Survivorship Care Plan Builder*, along with a copy of the patient's pathology report. The *Journey Forward Survivorship Care Plan Builder* summary was deemed to be more patient friendly and easier to read.

The survivorship patient navigator typically meets with the patient and, if possible, his or her caregiver(s), within the last two scheduled treatments to educate patients about their personal treatment summaries.

The NCCCP site was under consideration by the collective developers of the *Journey Forward Survivorship Plan* as a possible 2010 beta site to incorporate this tool into the *Mosaiq* EMR system. Although ultimately not chosen as a test site, this NCCCP site requested, and the Journey Forward organization agreed to, the following:

- Maintain and update the *Journey Forward Survivorship Care Plan Builder* during 2010-2012 to adhere to ASCO guidelines, and resolve any software maintenance issues that arose
- Release the *Journey Forward Survivorship Care Plan Builder 2.0* version in the first quarter of 2010, with the updated version including a "generic" survivorship care plan template and other enhancements, such as expanded capacity for users to use local resources for patients and providers
- Continue to offer the *Journey Forward Survivorship Care Plan Builder* free of charge.

In addition, this NCCCP site created a Survivorship Matrix Assessment Tool with several categories and scaled, objective criteria to measure program maturity and growth over time. Matrix categories included policies and procedures specific to survivorship care, treatment summary utilization, coordination of the survivorship visit, and communication to primary care providers. Overall, this NCCCP site found the Survivorship Matrix Assessment Tool useful as it worked to establish its program model.

Model 4—Survivorship Patient Navigator Populating Pencil and Paper Treatment Summary

In July 2009, one NCCCP site hired a BSN/OCN with extensive experience in oncology care to serve as a 0.7 FTE dedicated survivorship patient navigator. The navigator was instrumental in developing individual patient survivorship cancer treatment summaries and follow-up care plans. With feedback from the cancer center's physicians, the NCCCP site adapted the ASCO Cancer Treatment Summary template to meet the perceived needs of its patients and primary care physicians. Alterations included simplifying the format and some of the information, with the goal of making the summary more reader friendly and applicable to any cancer diagnosis.

This site's medical and GYN oncology clinics are currently in the process of converting to an EHR; some documentation resides in the paper chart and other documentation in the EHR. As a result, the survivorship patient navigator populates the treatment summaries by hand. Depending on the complexity of the case, this process can take from as little as 10 minutes to one hour. Personal treatment summaries are provided to patients with a diagnosis of breast, prostate, head/neck, or lung cancer. In the near future, the site hopes to begin counseling patients who have completed treatment for GYN oncology diagnoses, colorectal cancer, and lymphoma.

Two methods are used to identify patients who are near completion of their planned therapies. For patients completing radiation therapy, the EHR designates them as a "finisher" in the daily master schedule. The survivorship patient navigator monitors the radiation therapy EHR master schedule almost daily to identify those patients who need personal treatment summaries developed. The second method of patient identification is through disease-specific patient navigators who help identify patients nearing the end of their chemotherapy treatments.

The survivorship patient navigator typically meets with the patient and, if possible, his or her caregiver(s), within the last two scheduled treatments to educate patients about their personal treatment summaries. Prior to the scheduled consultation, the survivorship navigator also works closely with the disease-specific navigators to obtain information about any specific needs that a patient may have so that these needs can be addressed during the consultation. If patients receive any treatment at an outside facility, the type of therapy and the provider's contact information are noted on the patient's personal treatment summary.

During the survivorship consultation, typically lasting 10-15 minutes, the survivorship patient navigator reviews the content of both the personal treatment summary and the survivorship care plan. A copy of the personal treatment summary and care plan is faxed or mailed to the patient's primary care provider and any other significant healthcare provider. An electronic copy is always saved for future reference or revisions if the patient should receive future treatment.

During the consultation, the survivorship patient navigator will make any referrals that are requested or identified as needed. The survivorship patient navigator will also follow up with patients as necessary through phone calls or by attending the patient's post-treatment appointments. Patients are encouraged to contact the survivorship patient navigator for any needs that may arise post-treatment. In this model, the survivorship patient navigator distributes treatment summaries and care plans to patients of specific diagnoses, though the navigator is also available to all patients of the cancer center through referrals or requests.

The Implementation Experience— Barriers, Strategies, and Resources

Many NCCCP sites struggled to implement a comprehensive survivorship care plan. Implementation barriers fell into one of four categories:
1. Time constraints

Given the challenges of collecting data
as radiation oncology, dedicated staff
information required to

Table 1. Barriers to Survivorship Treatment Summary and Care Plan Implementation

Barriers	Strategies to Oversome Barriers
Time Constraints ■ Time intensive to gather data and complete form ■ Time span between patient completing therapy and tumor registry abstracting data	■ Use tumor registry data to populate form ■ Purchase commercially available software product to electronically populate fields ■ Implement Rapid Quality Reporting System (RQRS) in tumor registry to provide more timely data abstraction
Information Technology ■ Manually populated forms versus documents automatically populated from EHR ■ Lack of shared EHR between cancer centers and private practice physician offices ■ Poor access to private practice medical records	■ Nurse navigators/nurse practitioners manually populate forms ■ Purchase software for shared EHR between cancer centers and private practice physician offices ■ Use existing processes for communicating and requesting information from private practice staff ■ Establish agreements for access to private practice medical records
Processes and Responsibilities ■ Who is appropriate to receive a treatment summary? ■ When additional treatment is received, how do updates get made to the summary?	■ Obtain feedback from multidisciplinary teams to identify survivor populations on which to focus for initial implementation ■ Establish survivorship clinics
Care Plan Recommendations ■ Lack of standards for adult cancer survivorship surveillance	■ Collaborate with multidisciplinary team members to establish follow-up surveillance recommendations based on ASCO, NCCN, and other professional guidelines

2. IT-related challenges
3. Processes and responsibilities
4. Care plan recommendations.

Table 1 (above) lists common barriers along with strategies that NCCCP sites used to overcome these barriers. General strategies suggested by the Survivorship and Palliative Care Subcommittee include providing education on best practices and establishing a workgroup to address barriers and identify successful strategies for implementation.

In addition, the Survivorship and Palliative Care Subcommittee identified the following key elements as necessary for successful implementation of treatment summaries and, ultimately, survivorship care planning or programs.

from private practice oncology offices, as well
is needed to collect the patient medical record
complete the treatment summary.

Administrative and Physician Support. Successful implementation of treatment summaries requires a physician *and* an administrative champion, as well as the general support of private practice physicians early in the planning phase. Identifying these champions is crucial to developing and sustaining quality cancer survivorship care. One major challenge is the ability to access private practice physician medical records to garner information for the treatment summary. A possible solution may be to develop a confidentiality agreement with private practice physicians so that tumor registrars, data analysts, and patient navigators from the hospital or community cancer center have access to pertinent files.

Information Technology and Cancer Registry. Ideally, EHR integration between hospital systems, as well as with private practice physician offices, will streamline implementation of survivorship plans. However, given the current lack of EHR integration with private practitioners, NCCCP sites focused on cancer registry databases to populate patient treatment summaries. Survivorship programs need to create an environment that promotes continued follow-up and support for long-term care. Key measures such as quality of life and tracking of latent side effects and second cancers are among some of the meaningful data to be compiled and tracked. In the absence of system-wide, compatible EHR systems, community cancer centers should use reliable sources currently in place to populate treatment summary forms with minimal duplication of effort. To this end, community cancer centers may need to survey many data sources, including the cancer registry, radiation and medical oncology records, and hospital surgical and pathology reports.

Establishing a registry or data repository for tracking patients is necessary to provide an ongoing means of evaluating the survivorship program, as well as patient outcomes. The cancer registry and any existing EHR systems are reasonable places to begin identifying data fields that are aligned with the NCCCP/ASCO-recommended treatment summaries and care plans. The survivorship program development team should include a representative from the cancer registry, as well as the IT department. These team members are essential to an overall understanding of where data are housed and how data might be exported into treatment summaries.

Staffing Resources. In addition to physician support and IT solutions, adequate staffing is necessary for successful implementation of treatment summaries. Given the challenges of collecting data from private practice oncology offices, as well as radiation oncology, dedicated staff is needed to collect the patient medical record information required to complete the treatment summary. For many community cancer centers this process is manual.

One solution may be to employ a nurse navigator to complete treatment summaries and distribute them to supporting physicians. The treatment nurse navigator, who already has an established relationship with the patient, could provide the treatment summary. Alternatively, a dedicated survivorship navigator, a registered nurse with oncology experience, could take on this role. The treatment nurse navigator would transition the patient to the survivorship navigator upon completion of acute treatment. A survivorship navigator may offer a number of benefits, including:

- Supporting and "navigating" patients during their transition from active treatment through recovery and beyond
- Improving patient satisfaction and health outcomes
- Establishing relationships with primary care physicians and facilitating communication between the oncologists and the primary care physicians
- Educating patients about the treatment summary and survivorship plan
- Ensuring that the psychosocial, financial, physical, and spiritual needs of patients continue to be met.

Nurse practitioners can provide clinical survivorship assessment, planning, intervention, and follow-up care for patients entering the survivorship phase. Survivorship clinics allow for the provision of comprehensive care plans using evidence-based and best practice guidelines. Since survivorship plans are necessary elements to empower patients to effectively manage the long-term and late effects of cancer and cancer treatment, a survivorship clinic with dedicated support staff may facilitate successful implementation of these tools.

Delivery of Survivorship Plans. Integration of the survivorship plan into the continuum of care process requires a multidisciplinary approach. Time must be established to allow for discussion between the dedicated survivorship staff and the patient to review the patient's survivorship plan and address any questions or concerns. In addition, patients should be encouraged to discuss aspects of the plan with other members of their medical team.

Patient Resources. Each step of the cancer care continuum requires education tailored to an individual patient's journey, taking into account issues of health literacy, language, and culture. Healthcare providers may be challenged in terms of accessing adequate communication tools and appropriate patient education resources.

Ideally, survivorship care planning should begin at the time of diagnosis, as recommended by the IOM[3], with the ultimate goal of empowering patients with knowledge and tools designed to increase their self-care behaviors and quality of life, to adhere to recommended care, and to

decrease anxiety and symptom severity. One solution is to provide patients with a survivorship organizer with tabs and file pockets to keep important information related to their diagnosis and treatment.

The Lance Armstrong Foundation currently provides such a tool (*http://www.store-laf.org/guidebook.html*). Each tab covers topics pertinent to the complete continuum of care for cancer patients. These survivorship organizers can be provided to newly diagnosed cancer patients and individualized patient education materials can be added throughout the continuum of care.

Survivor and Provider Satisfaction. When survivorship plans are implemented, satisfaction surveys (for survivors and providers) should be developed to evaluate these services on an ongoing basis. Feedback should be obtained from survivors, primary care physicians, and oncologists to determine how best to help survivors transition to recovery and to meet patients' post-treatment follow-up care needs.

To determine the success of treatment summary implementation and survivorship programs, patient satisfaction surveys that evaluate navigation and clinical program services should be developed and disseminated. Results of patient satisfaction surveys may lead to the development of quality improvement initiatives within the cancer center and, as a result, may improve patient outcomes.

Key Recommendations

NCCCP sites have learned several important lessons with regard to the development and implementation of comprehensive survivorship plans. One general recommendation is the significance of understanding survivorship issues from the perspectives of both survivors and their healthcare providers; another is to become familiar with available resources, reports, articles, and literature from national agencies focused on cancer survivorship. Other key recommendations for cancer centers include:

- Know the capabilities of the cancer center's EHR software and use the best data available to construct summaries, recognizing that—as yet—there is no single place where all of the relevant data resides.
- Engage key stakeholders to move survivorship from a concept to a reality.
- Focus not only on the patient's physical needs but also on psychosocial needs in survivorship follow-up care.
- Tailor recommendations and referrals provided in the survivorship plans to the specific needs of each survivor.
- Ensure that treatment summaries have a multidisciplinary approach.
- Recognize that not all patients are transitioned back to primary care providers for their follow-up care.
- Personalize survivorship programs to meet institu-

tional needs (i.e., EHRs, data availability, staff availability). There are many ways to get this done. Reshaping some existing data strings and sharing practices between hospitals and physician offices may help reduce apparent barriers.

- Personalize the treatment summary to meet the needs of the cancer center's patient population and program, as long as essential elements are included.
- Use existing databases and resources in the public domain to reduce cost and staff time.
- Ask existing programs for help and advice; they likely have gone through the learning curve and would be happy to share what works.

Development of the treatment summary and care plan tools was a labor-intensive but gratifying collaborative process that involved a great deal of dedication at each NCCCP site. The Survivorship and Palliative Care Subcommittee members actively champion the premise that a survivorship care plan is not only important to the patient but is also an instrumental tool that can be used by healthcare providers—including primary care and other nononcology specialty care providers—to positively affect the health and well-being of survivors for years to come. While having the resources and systems in place to ensure the delivery of treatment summaries and care plans can be very challenging, the benefits and the rewards to the survivors and other care providers are enduring. ❧

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Breast Cancer Adjuvant Treatment Plan and Summary

The Treatment Plan and Summary provide a brief record of major aspects of breast cancer adjuvant treatment. This is not a complete patient history or comprehensive record of intended therapies.

Patient name: _____ Patient ID: _____ Race: _____

Patient DOB: (___/___/___/) Age at diagnosis: _____ Patient phone: _____

Support contact name: _____ Relationship: _____ Support contact phone: _____

BACKGROUND INFORMATION

Family history: ☐ None ☐ 2nd degree relative ☐ 1st degree relative ☐ Multiple relatives | BRCA 1/2: ☐ Pos ☐ Neg

Previous breast cancer: ☐ Yes (___/___/___/) Type: ☐ No   Breast Atypia: ☐ Yes (___/___/___/) ☐ No

Definitive breast surgery: Date:(___/___/___/)Type: ☐ Lumpectomy ☐ Mastectomy ☐ Mastectomy/immediate recon

lymph nodes removed: _____ # lymph notes positive: _____ Biopsy date: (___/___/___/)

Axillary dissection: ☐ Yes (___/___/___/) ☐ No   Sentinel node biopsy: ☐ Yes (___/___/___/) ☐ No

Notable surgical findings/comments: _____ Surgical margin clear: ☐ Yes ☐ No

Tumor type: ☐ Infiltrating ductal ☐ Infiltrating lobular ☐ DCIS ☐ Other: _____ Tumor size: _____

T stage: ☐ Tis ☐ T1 ☐ T2 ☐ T3 ☐ T4a ☐ T4b ☐ T4c ☐ T4d   N stage: ☐ N0 ☐ N1 ☐ N2 ☐ N3   M Stage: ☐ M0 ☐ M1

Pathologic stage: ☐ 0 ☐ I ☐ II ☐ III ☐ IV Oncotype DX recurrence score: _____ Breast: ☐ Right ☐ Left ☐ Bilateral

ER status: ☐ Positive ☐ Negative   PR status: ☐ Positive ☐ Negative   HER2 status: ☐ Positive ☐ Negative

Major comorbid conditions: _____ HRt use: ☐ Yes ☐ No ☐ oophorectomy ☐ Hysterectomy

Echocardiogram or MUGA result prior to chemotherapy (if obtained): EF= %   Onset of Menses: (___/___/___/)

Onset of menopause: ☐ Yes (___/___/___/) ☐ No   Smoking History: ☐ No ☐ Yes/Current ☐ Yes/Past Years: ____

ADJUVANT TREATMENT PLAN | ADJUVANT TREATMENT SUMMARY

White sections to be completed prior to chemotherapy administration, shaded sections following chemotherapy

Height: _____ in/cm Pre-treatment weight: _____ lb/kg | Post-treatment weight: _____ lb/kg

Pre-treatment BSA: _____ Date last menstrual period:(___/___/___/) | Date last menstrual period: (___/___/___/)

Name of regimen: _____

Start date: (___/___/___/) | End Date: (___/___/___/)

Treatment on clinical trial: ☐ Yes ☐ No   Name of clinical trial(s): _____

Chemotherapy Drug Name	Route	Dose	Schedule	Dose reduction needed	Number of cycles administered
				☐ Yes _____% ☐ No	
				☐ Yes _____% ☐ No	
				☐ Yes _____% ☐ No	
				☐ Yes _____% ☐ No	

Side effects experienced:

☐ Hair loss ☐ Nausea/Vomiting

☐ Neuropathy ☐ Low blood count

☐ Fatigue ☐ Menopause symptoms

☐ Cardiac symptoms ☐ Cognitive

☐ Other: _____

Allergic events: _____

Anthracycline administered: ☐ Doxorubicin _____mg/m2

☐ Epirubicin _____mg/m2

Serious toxicities during treatment (list all): _____

Hospitalization for toxicity during treatment: ☐ Yes ☐ No

Neurotoxicity that impairs activities of daily living: ☐ Yes ☐ No

Reason for stopping adjuvant treatment: _____

Adopted from American Society of Clinical Oncology Breast Cancer Treatment Summary
Important caution: this is a *summary* document whose purpose is to review the *highlights* of the breast cancer chemotherapy treatment plan for this patient. This does not replace information available in the medical record, a complete medical history provided by the patient, examination and diagnostic information, or educational materials that describe strategies for coping with breast cancer and adjuvant chemotherapy in detail. Both medical science and an individual's health care needs change, and therefore this document is current only as of the date of preparation. This summary document does not prescribe or recommend any particular medical treatment or care for breast cancer or any other disease and does not substitute for the independent medical judgment of the treating professional.
Version 2.0

Breast Cancer Adjuvant Treatment Plan and Summary

The Treatment Plan and Summary provide a brief record of major aspects of breast cancer adjuvant treatment. This is not a complete patient history or comprehensive record of intended therapies.

ADJUVANT TREATMENT PLAN	ADJUVANT TREATMENT SUMMARY

ENDOCRINE THERAPY

☐ None ☐ Tamoxifen ☐ Aromatase inhibitor ☐ Other

Medication:

Duration:

Date endocrine therapy started (or to start) (___/___/___/)

TRASTUZUMAB (HERCEPTIN) THERAPY

Trastuzumab (Herceptin) planned: ☐ Yes ☐ No

Planned or completed dates of trastuzumab therapy:

Start date (___/___/___/) End date (___/___/___/)

Trastuzumab (Herceptin) prescribed: ☐ Yes ☐ No

Pre-trastuzumab ejection fraction: %(___/___/___/)

Most recent ejection fraction: %(___/___/___/)

Radiation Therapy Summary

Location	Beam Arrangement	Area	Mode	Tumor Dose Total	Dates of Rx From	To	# of Visits	Elapsed Days
		☐ Local (breast)						
		☐ Regional (nodes)						
		Partial Brst RXT: ☐ Yes ☐ No						

Lymphedema: ☐ Yes ☐ No Date: (___/___/___/)   Breast Reconstruction: ☐ Yes ☐ No Date: (___/___/___/)

ONCOLOGY TEAM MEMBER CONTACTS	SURVIVORSHIP CARE PROVIDER CONTACTS
Provider:	Provider:
Name:	Name:
Contact Info:	Contact Info:
Provider:	Provider:
Name:	Name:
Contact Info:	Contact Info:
Provider:	Provider:
Name:	Name:
Contact Info:	Contact Info:
Provider:	Provider:
Name:	Name:
Contact Info:	Contact Info:

Supportive and Survivorship Services

Survivorship Clinic Appointment Made: ☐ Yes ☐ No Date: (___/___/___/)   Provider Name   Phone Number

Nutrition Services			
Genetic Services	☐ Yes ☐ No Date: (___/___/___/))		
Social Work/Psychology	☐ Yes ☐ No Date: (___/___/___/)		
Rehabilitation Services	☐ Yes ☐ No Date: (___/___/___/)		
Other Support Service(s)	☐ Yes ☐ No Date: (___/___/___/)		

Living Will: ☐ Yes ☐ No   Advanced Directive: ☐ Yes ☐ No

Complementary Services (e.g. Yoga, Tai Chi):

Survivorship Educational Materials Provided:

Adopted from American Society of Clinical Oncology Breast Cancer Treatment Summary
Important caution: this is a *summary* document whose purpose is to review the *highlights* of the breast cancer chemotherapy treatment plan for this patient. This does not replace information available in the medical record, a complete medical history provided by the patient, examination and diagnostic information, or educational materials that describe strategies for coping with breast cancer and adjuvant chemotherapy in detail. Both medical science and an individual's health care needs change, and therefore this document is current only as of the date of preparation. This summary document does not prescribe or recommend any particular medical treatment or care for breast cancer or any other disease and does not substitute for the independent medical judgment of the treating professional.
Version 2.0

Patient Name:

FOLLOW-UP CARE TEST	RECOMMENDATION	PROVIDER TO CONTACT
Medical history and physical (H&P) examination (see below)	Visit your doctor every three to six months for the first three years after the first treatment, every six to 12 months for years four and five, and every year thereafter.	
Post-treatment mammography (see below)	Schedule a mammogram one year after your first mammogram that led to diagnosis, but no earlier than six months after radiation therapy. Obtain a mammogram every six to 12 months thereafter based on the guidance of your physician.	
Breast self-examination	Perform a breast self-examination every month. This procedure is not a substitute for a mammogram.	
Pelvic examination	Continue to visit a gynecologist regularly (at least annually). If you use tamoxifen, you have a greater risk for developing endometrial cancer (cancer of the lining of the uterus). Women taking tamoxifen should report any vaginal bleeding to their doctor.	
Coordination of care	About a year after diagnosis, you may continue to visit your oncologist or transfer your care to a primary care doctor. Women receiving hormone therapy should talk with their oncologist about how often to schedule follow-up visits for re-evaluation of their treatment.	
Genetic counseling referral	Tell your doctor if there is a history of cancer in your family. The following risk factors may indicate that breast cancer could run in the family: • Ashkenazi Jewish heritage • Personal or family history of ovarian cancer • Any first-degree relative (mother, sister, daughter) diagnosed with breast cancer before age 50 • Two or more first-degree or second-degree relatives (grandparent, aunt, uncle) diagnosed with breast cancer • Personal or family history of breast cancer in both breasts • History of breast cancer in a male relative	

YEARLY BREAST CANCER FOLLOW-UP & MANAGEMENT SCHEDULE

Visit Frequency for H&P	Years 1-3:	3 months	6 months	(circle one)
	Years 4-5:	6 months	12 months	(circle one)
Visit Frequency for Mammography:		6 months	12 months	(circle one)

VISIT FREQUENCY	HISTORY AND PHYSICAL	MAMMOGRAPHY
3rd Month (if applicable)		
6th Month (if applicable)		
9th Month (if applicable)		
12th Month (if applicable)		

Notes:

• Risk: You should continue to follow-up with your physician because the risk of breast cancer continues for more than 15 years after remission.

• Symptoms of Recurrence: Report these symptoms to your doctor: new lumps, bone pain, chest pain, shortness of breath or difficulty breathing, abdominal pain, or persistent headaches.

• Not Recommended: The following tests are not recommended for routine breast cancer follow-up: breast MRI, FDG-PET scans, complete blood cell counts, automated chemistry studies, chest x-rays, bone scans, liver ultrasound, and tumor markers (CA 15-3, A 27.29, CEA). Talk with your doctor about reliable testing options.

Late Effect	Population at Risk	Risk	Interventions
Cancer recurrence	All women with a history of breast cancer	Varies by stage and tumor characteristics	Mammography, physical examination
Second primary cancer	All women with a history of breast cancer	Varies by treatment, age, and genetic predisposition (women with BRCA[a] mutations are at higher risk)	Mammography, pelvic examination, general physical examination, patient education
Psychosocial distress and depression	All women with a history of breast cancer	Approximately 30 percent experience distress at some point; distress declines over time	• Assessment for distress/depression • Some psychosocial interventions are effective in reducing distress/depression
Arm lymphedema	Women who had axillary dissection and/or radiation therapy	Across treatments and time since treatment, approximately 12 to 25 percent of women develop lymphedema	Massage and exercise (manual lymphatic drainage), use of elastic compression garments, complex decongestive therapy
Premature menopause and related infertility and osteoporosis	• Women who received adjuvant chemotherapy (e.g., alkylating agents such as cyclophosphamide) • Women with BRCA mutations who elect oophorectomy	Risk depends on the chemotherapy regimen, the cumulative dose, and patient age (see details below)	• New reproductive technologies for infertility • Diagnostic and preventive strategies for osteoporosis • Assessment of sexual function
Symptoms of estrogen deprivation (e.g., hot flashes, sweats, vaginal discharge)	Women taking endocrine therapy	More than half report symptoms, although mild in most cases	Promising non-hormone treatments include antidepressants, dietary changes, and exercise
Weight management	Women who had adjuvant chemotherapy and experience menopause	Roughly half report weight gain of 6 to 11 pounds; one-fifth report weight gain of 22 to 44 pounds	Diet/exercise interventions "Heart Healthy" lifestyle behaviors
Cardiovascular disease	• Women receiving specific therapies (e.g., anthracycline chemotherapy, trastuzumab [Herceptin]) • Premenopausal women with ovarian failure following chemotherapy	• Congestive heart failure develops in 0.5 to 1 percent of women • Increased risk of atherosclerosis	• Symptomatic women should have a symptom-directed cardiac work-up; routine screening of cardiac function is not recommended • Preventative strategies for heart disease
Fatigue	Women with breast cancer	Reported in one-third of survivors 1 to 5 years after diagnosis. Prevalence similar to that seen in women in the general population of same age. A subgroup of survivors has more severe and persistent fatigue.	Exercise programs appear promising
Cognitive changes	Women who received adjuvant chemotherapy	Estimates vary, but up to one-third of women report cognitive changes. New evidence suggests onset may precede chemotherapy treatment.	Evidence lacking
Risk to family members	All survivors	An estimated 5 to 10 percent of women with breast cancer have a hereditary form of the disease. Likelihood increases to 20 percent in women with multiple factors	Genetic counseling
Sexuality (decrease in libido and dryness)	Women who had adjuvant chemotherapy or HRT	Predicting the risk of infertility to each individual is often impossible. Risk is dependent on the drug(s) used, dosage received, duration of use, and the individual's age at the time of administration.	• Assessment of sexual function • Referrals to appropriate care providers
Spirituality	All women with a history of breast cancer	Some survivors have reported that the cancer experience has led them to re-examine their spiritual beliefs and contributed to changes in their life and relationships. Surviving cancer is more like a spiritual journey that teaches how to change your life and your relationships.	• Referrals to spiritual care advisors

[a]BRCA genes (e.g., BRCA1 and BRCA2) are genes that normally help to suppress cell growth. A person who inherits an altered version of the BRCA genes has a higher risk of getting breast, ovarian, or prostate cancer.
[b]Possible Late Effects Among Breast Cancer Survivors (IOM. 2006. From Cancer Patient to Cancer Survivor: Lost in Transition. Hewitt, M, Greenfield S, Stovall E, eds. Washington DC: National Academies Press pgs. 82-83)
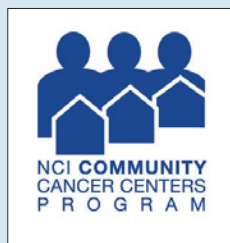
TECHNOLOGY EXPANSION
in Support of Community Cancer Care

The NCCCP IT experience

by Beverly Albury, BS; Nancy Harris, MPA-HSA; and Joshua Mann

The experiences of the NCCCP's pilot Information Technology Subcommittee remain timely in light of emerging science where translational research and personalized medicine are increasingly the nexus of clinical care standards. To support this highly integrated care model, community cancer centers must combine and unify data and data collection systems in ways that enhance patient-centered portfolios and enable advanced analytics. This integration requires the expansion of data sharing capabilities, especially given the reality that patients receive care from many different providers in many different settings, using disparate data collection systems.
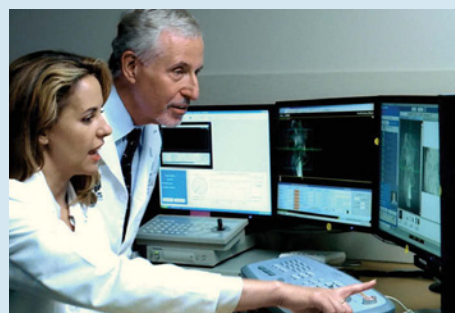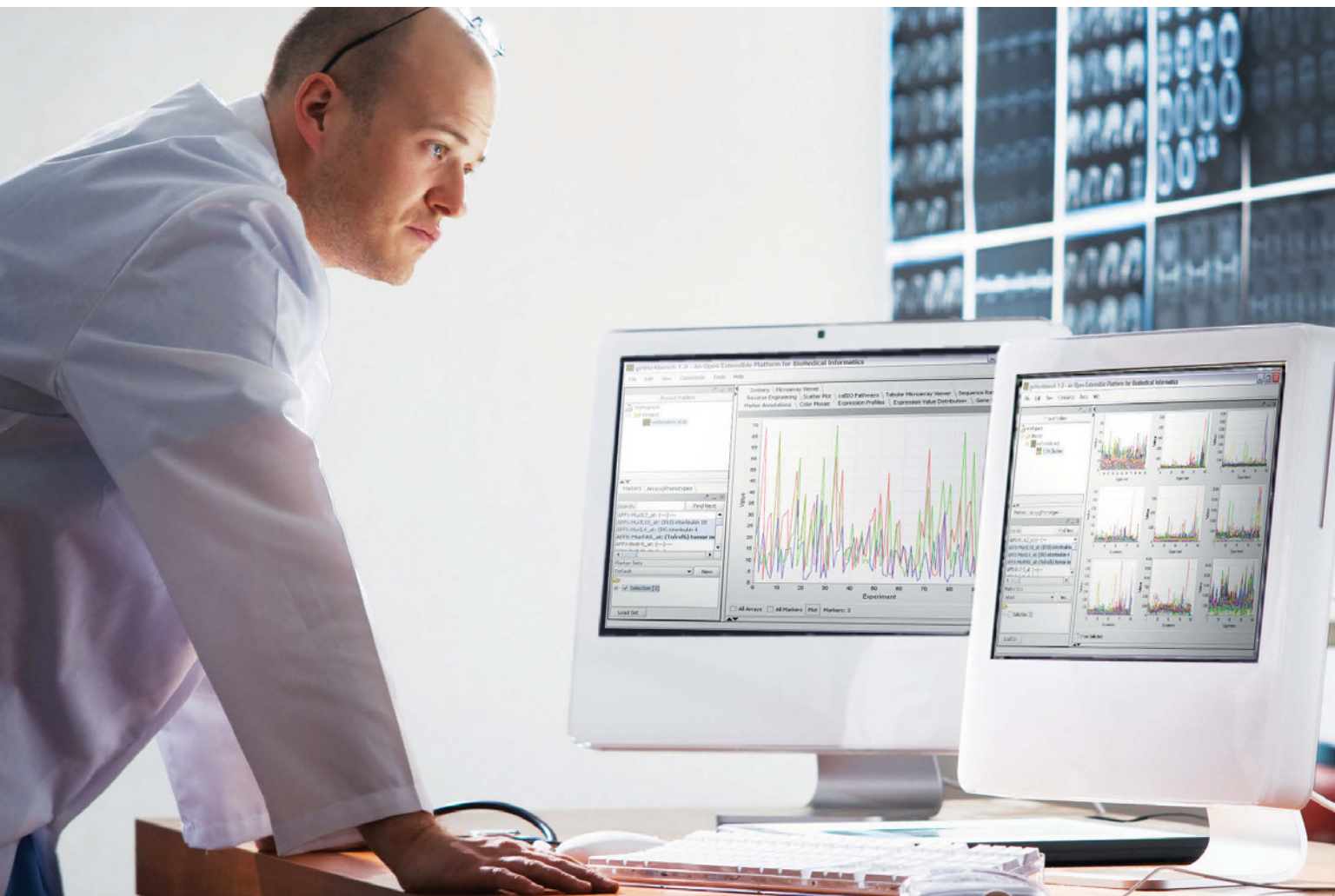
Patients diagnosed with cancer want access to the latest treatments with the ability to stay in their own communities where their support systems are well established. With the acquisition of innovative technology and well-trained medical specialists, community hospitals now provide a sophisticated level of care, including new cancer treatments and access to clinical trials. However, the advancement in care options has led to fragmented cancer care in many communities. Patients may have surgery in one location and then go to a clinic for radiation therapy. They might go to yet another facility or stay at home to receive chemotherapy. Today's community cancer centers seek system integration to provide continuity of care and outcome measurements—tools that will help practitioners improve patient care.

NCCCP programmatic efforts have focused on ensuring that patients—especially those from underserved populations—have greater access to advanced care. Part of this access is contingent on the successful deployment of information technology. Sharing the experiences of the NCCCP pilot sites, in both technology expansion and implementation planning, may help the IT departments of other community cancer centers move to a more integrated and expanded technology offering.

Technology Support for Program Goals

The NCCCP pilot was designed to build a community-based research platform to support a wide range of basic, clinical, and population-based research on cancer prevention, screening, diagnosis, treatment, survivorship, and palliative care at community hospitals. Recognizing that research- and outcomes-driven activities stem from data

sharing, and hoping to improve continuity of care, NCCCP considered IT a critical and crosscutting component of the core program pillars.

The program established subcommittees to support the work of the NCCCP pillars; each NCCCP organization provided at least one representative to the IT Subcommittee. This group studied the technology needs and methods of expansion required for a community-based cancer center to enable state-of-the-art cancer care and research while supporting the overall technology needs of the NCCCP. Each site was responsible for having an electronic health record (EHR) and an electronic tumor registry system in place by the end of the three-year pilot period. As part of the NCCCP pilot, sites looked at how the NCI cancer Biomedical Informatics Grid (caBIG®) and related tools might be leveraged.

What is caBIG®?

Overseen by the NCI Center for Biomedical Informatics and Information Technology (CBIIT), the mission of caBIG (*https://caBIG.nci.nih.gov*) is to develop a collaborative network that accelerates the discovery of new approaches for the detection, diagnosis, treatment, and prevention of cancer, ultimately improving patient outcomes. To achieve this mission, caBIG seeks to bring the oncology technology community together with the scientific, clinical, and patient communities.

The caBIG initiative operates through an open development, standards-based information network. Anyone can participate in caBIG and there is no cost to join. The caBIG community includes academic cancer centers, NCI-supported research endeavors, and a variety of federal, academic, not-for-profit, vendor, and industry organizations. caBIG provides research- and outcomes-driven activities stemming from data sharing that can have a significant impact on the patient. Through its work with the NCCCP pilot sites, NCI studied how the resources available through caBIG could benefit the technology expansion needs of community-based cancer centers.

Technology Vision and Strategy

NCCCP pilot sites developed a technology vision and a business strategy to support their respective cancer centers, providers, patients, and the communities they served. The process involved:

- Establishing mission statements
- Documenting organizational governance for the technology needs of the cancer center
- Developing workflows and policies for supporting the business units that comprise the cancer center
- Mapping technology expansion needs to user needs
- Working to establish short- and long-range plans for meeting those technology needs.

At the time of the NCCCP pilot launch, a few sites were already in the process of putting an IT strategy in place. Other sites had the development of an IT strategy on their priority list, but had yet to begin. For these sites, the first step was establishing the cancer center's IT vision, grounded in the reality that community cancer centers often lack sufficient funding to adopt IT tools.

Developing this vision required a great deal of collaboration with department leadership and end users. Through networking and sharing experiences, resources, and tools, NCCCP pilot sites were quickly able to create action plans for improved services. Having IT staff attend as monthly participants in each of the cancer center's departmental staff meetings helped improve operational objectives. Because business needs are often discussed during these meetings, IT staff were able to clearly understand user needs early enough in the process to influence decisions based on the technology department's policies and experience.

Supporting a full stable of disparate and sometimes duplicative systems was a key frustration common to all NCCCP pilot sites. By inventorying systems with mapping to user communities and support needs, many sites were able to reduce or eliminate duplicative services and processes. NCCCP sites also looked at integration strategies to support mutual cross-department needs, such as access to laboratory data, radiology data, and demographics.

This process fostered relationship building and trust between the cancer center departments and IT staff. Departments began to realize that, by working with IT, their needs were more likely to be met, whether through better technology deployment or through a synergistic approach to leadership and budgeting to justify technology spending. Over the pilot period, informatics needs within NCCCP sites were better defined and became more visible, which, in turn, resulted in better funding for technology acquisition. For a few sites, these efforts led to an FTE in the cancer center to support oncology technology and data integration needs.

Baseline Assessment and Goal Planning

After establishing a technology vision and documenting short- and long-range informatics strategies, NCCCP sites reviewed how caBIG tools might meet or supplement their cancer centers' business strategies and how they might implement the tools. Sites also evaluated vendor solutions that might be a better fit for the community cancer setting.

The process began with a baseline assessment of the pilot sites' existing capabilities, in terms of technology platforms, security, infrastructure, operations, and business needs (see Table 1, page 64). CBIIT developed a web-based tool for

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Table 1. Conducting an IT Infrastructure Self Assessment

For community cancer centers looking to improve their IT infrastructure, NCCCP sites suggest conducting a self-assessment first. Questions might include:

INFRASTRUCTURE READINESS

- Does an IT support infrastructure (i.e., help desk) exist?
- Is there an existing infrastructure for providing training to end users in applications?
- Are there formal means for exchange of data between the clinical (hospital) and research data activities?
- Is the computer network bandwidth sufficient for demanding applications (e.g., imaging or gene expression)?
- Are there institutional standards for data and network security?
- Are there institutionally-supported mechanisms for providing outside secure access to servers?
- Are key research and clinical informatics capabilities largely outsourced or insourced?
- Does staff have access to an internet-accessible workstation as part of their work?
- How many locations does the institution have?
- Does the institution make use of mobile computing?
- Does the institution provide wireless computer access?
- What type of security is provided and/or required for wireless access at the institution?
- Does the institution have a central software version and revision control and management process?

INSTITUTIONAL READINESS

- Does the institution host and/or participate in any Cooperative Groups? If so, which ones?
- Does participation in the Cooperative Groups involve data sharing?
- Does the institutional leadership support informatics initiatives?
- What is the size of the cancer community served (i.e., number of cancer treatment beds, cancer inpatient and outpatient visits)?
- Is the institution's current documentation of standards and processes for data collection complete and up to date?
- Does the institution proactively manage processes for continuous improvement and share lessons learned?
- Does the organization have and actively use two-way communications for the purpose of facilitating interactions between IT/informatics staff and their served community, and does it encourage feedback from the prospective user community?
- What are the major communication audience segments within the organization?

- Which have been the most impactful communications vehicles for the cost?
- Is the institution currently sharing data within the organization?
- Is the institution currently sharing data outside the organization?

ORGANIZATIONAL CAPABILITY

- What server operating systems are used?
- What desktop operating systems are used?
- What database systems are supported by the organization?
- Does the institution have supported web browsers? If so, which ones?
- How many total supported users are there at the institution?
- Is there a clinical informatics group that supports the organization?
- Does the institution have internal software development capabilities?
- Is there a standard clinical workstation supported by the organization?
- How many clinical PIs are there (i.e., total number of clinical labs)?
- Do all clinical researchers (i.e., PIs, nurses, physicians) have access to the clinical workstation(s)?

FUNCTIONALITIES SUPPORTING CLINICAL TRIALS OR LIFE SCIENCES RESEARCH

- Is there a standard clinical data management capability for the institution?
- Does the institution have a central clinical trials participant repository?
- Is there an automated function to input laboratory data into clinical data management systems?
- Does the institution have a patient study calendar system?
- Does the institution have software tools for adverse event management and reporting?
- Does the institution manage gene expression data?
- Does the institution manage *in vivo* imaging data?
- Does the institution have a central tissue bank and an accessible associated database?
- Does the institution manage and integrate translational medicine data?

Electronic Tumor Registry

Having an electronic tumor registry that exchanges data electronically was an NCCCP pilot requirement that all sites had in place early in year one of the pilot. This allowed the sites to collaborate with the American College of Surgeons Commission on Cancer (CoC) to beta test a new software solution, Rapid Quality Reporting System (RQRS). This system facilitates data collection in a more real-time manner. Through participation in the RQRS effort, the 16 NCCCP pilot sites are developing processes and workflows that will improve how tumor registry data will be captured in the future. They are also gaining access to valuable, real-time data which helps drive NCCCP quality improvement activities.

the collection of these data. Once NCCCP sites submitted their baseline assessments, caBIG program support and CBIIT leadership reviewed the data and provided each site with a Capabilities Analysis Report. The report included an objective weighting, reflecting the site's readiness to deploy technology in accordance with the site's technology vision and strategies. After reviewing these reports, NCCCP sites participated in a phone conference with caBIG program support and NCCCP IT leadership to ask questions and further define intentions. Program support staff updated the Capability Analysis Reports to reflect additional information requested by the NCCCP sites.

The next step included learning more about the resources available to NCCCP sites through NCI's caBIG program and evaluating whether these resources would meet their cancer center's needs. This task was difficult, as maneuvering through the caBIG environment was complex. However, caBIG support staff and CBIIT leadership provided tool demonstrations and individualized support to help NCCCP sites understand how caBIG tools and resources might meet their users' needs.

Once a site had a good understanding of its technology needs and whether caBIG tools and resources could support them, the site completed a detailed Technology Goals Planning document to record its technology expansion plans. NCCCP IT leadership developed a template to standardize the information provided by NCCCP sites, requiring sites to compare the business needs of the cancer center and its departments with the tools available through caBIG or through the vendor community. NCCCP sites

compared these potential solutions with their Capabilities Analysis Report to identify where they should make changes to their capabilities to implement a technology solution. The process allowed each site to systematically address technology vision and strategy requirements with available technology solutions to determine which solutions might best meet their identified business needs. Each site detailed implementation plans for the technology selections and conducted an analysis of the level of effort and cost required for potential technology selections. The final Technology Goals Planning document required cancer center executive leadership sign-off from each organization so that the NCCCP understood each site's level of commitment to these plans and vice versa.

Key Stakeholders
To help establish what IT tools and systems would meet an organization's needs, NCCCP IT leadership and caBIG support staff created a series of presentations and materials designed to help sites compare and evaluate caBIG tools with those of the vendor community. The key stakeholder audiences were:
- *Leadership and decision-makers*. This group needed information on the overall benefit to the organization, users, and patients. They were interested in cost, time to completion, staff-time requirements, efficiencies gained, and return on investment.
- *End users*. These stakeholders were pressed for time, as they were busy with clinical duties and patient care. Information for this group often needed to be delivered in 10 minutes or less. End users were more interested in how the tools met their needs, saved time, impacted workflow, improved support, and in how they would be trained.
- *IT*. This group required materials that discussed the practicalities, such as hardware needs, platforms, security, documentation, time to implement, training, certification, support needs, and costs.

With the three stakeholder groups in mind, caBIG support staff and NCCCP IT leadership provided sites with:
- Tool-specific overview slide decks with notes fully fleshed out so that each site's IT lead could use these more general materials to engage any audience
- Detailed slide decks targeted to specific stakeholder group information needs
- Recorded video demonstrations of caBIG tools showing a typical user experience, available at the viewer's convenience
- One-on-one teleconferences with each of the site's stakeholder groups, tailored to fit their unique needs and scoped to the specific audience.

NCCCP IT leadership developed a template to standardize the information provided by NCCCP sites, requiring sites to compare the business needs of the cancer center and its departments with the tools available through caBIG or through the vendor community.

Over time, caBIG determined that these types of materials were also in high demand from many other groups outside of the NCCCP. This finding led to the development of caBIG Knowledge Centers, NCI-funded organizations that provide expertise and support for caBIG domains and applications.

After reviewing more than 40 caBIG applications, NCCCP pilot sites identified the following tools as the most useful for community-based cancer centers:

- Clinical trials management systems, either as a suite of applications or in some cases a select few applications (e.g., Patient Study Calendar, Cancer Adverse Event Reporting, Patient Registry)
- Cancer tissue management tools
- Imaging archive and annotation tools
- Cancer array data collection and analysis tools.

Many NCCCP sites also identified commercial-off-the-shelf solutions that could increase integration and add functionality to existing platforms at their organizations.

Implementation and Deployment Planning

Planning for implementation of the technology solutions took most of the pilot's second year. NCCCP sites used the Technology Goal Planning document as the starting point for creating a Technology Implementation Plan, a detailed document that defined how the site would mobilize to deploy technology. The Technology Implementation Plan included:

- Costs, such as hardware, software, materials and labor
- Operational organization components (e.g., workflow committees, SOP updates, legal reviews)
- Pre- and post-implementation project measurements
- Risk identification and mitigation strategies
- Implementation milestones with associated timelines.

NCCCP sites provided data-sharing plans and specified any necessary steps for legal agreements to use the technology or share the data to meet end users' needs. This process often required working with the organization's Institutional Review Board (IRB).

NCCCP sites were not contractually obligated to adopt or adapt any technology solutions in the course of the pilot program, though they were required to identify and document plans for technology expansion deployment. NCI was particularly interested in how the community setting would be able to adopt caBIG tools, principles, and practices. While these open source tools are free, they may entail costs; hardware or software is often required to enable the solution and sometimes licenses must be secured. Implementation of certain tools may require contractor services if the technical skill sets are not readily

available in the cancer center. However, caBIG tools can be adopted at a cost substantially lower than commercial sector solutions.

NCCCP sites that pursued commercial off-the-shelf solutions identified a number of barriers to caBIG tool adoption, including:

- caBIG tools do not come with a 7-day-a-week, 24-hour-a-day, multi-tiered support service with the option of onsite support and training
- caBIG tools, while open source, still entail significant costs and sometimes require new software, licensure, servers, and security parameters to deploy
- caBIG tools are built in an interoperable, standards-based manner; however, the cost of custom interfaces for integration is expensive and can sometimes be a limiting factor
- Upfront costs associated with local installations are difficult for smaller community cancers to afford and require them to limit their initial investments.

CBIIT and caBIG program support took note of these issues. CBIIT worked closely with NCCCP sites to understand their unique implementation needs; where possible, they helped to develop strategies that would make adoption of caBIG tools easier. In some cases, NCCCP sites helped caBIG improve installation instructions, documentation, and training materials, thus helping to improve the resources available to other community-based cancer centers.

On the other side of the equation, some NCCCP pilot sites found caBIG tools did meet their needs. Those pilot sites that chose to adopt caBIG tools identified the following benefits:

- Open source solutions mean no to low acquisition costs
- caBIG tools are built to be interoperable and thus help to integrate systems
- caGrid allows access to a grid without the cost of development and maintenance
- Data sharing is a core principle of caBIG, so its tools and policies can be leveraged with little to no modification needed for state and local laws.

Accordingly, a number of pilot sites adopted caBIG tools within the pilot period. For example, Christiana Care adopted caTissue and NCI Biomedical Imaging Archive (NBIA); Our Lady of the Lake adopted NBIA; and St. Joseph Hospital adopted C3D, a cancer clinical trials data management system. Several other pilot sites planned to adopt caBIG tools, but as the economy slowed the timelines stretched, stalling technology progress in most healthcare organizations nationally. At the conclusion of the pilot period, several other caBIG tools were under consider-

Table 2. Clinical Oncology Requirements for an EHR

For community cancer centers looking to implement an oncology-specific EHR, NCCCP and ASCO have identified these core requirements. For a full list go to: www.asco.org.

DEMOGRAPHICS

Patient Demographics
- Name, DOB, MRN
- Contact information
- Race and ethnicity
- Language preference

Treating Physicians and Primary Physicians
- Name
- Subspecialty
- Address
- Phone and fax numbers

DIAGNOSIS

Primary Cancer Diagnosis
- ICD9, ICD10, or more clinically relevant system

Pathology
- Site
- Histology and pathology
- Biomarkers (ER, HER2, c-Kit, etc.)
- Molecular markers (bcr+, etc.)
- Chromosomal markers

Primary Staging
- AJCC for relevant diagnoses
- Tumor registry staging information for non-AJCC diagnoses

Metastatic Sites (if applicable)

Pathologic Features of Metastatic Site
- (e.g., transformed lymphoma or ER negative breast cancer)

List of Co-morbid Conditions
- Should be organ-based choices

PRIOR TREATMENTS

Prior Cancer Surgery
- Type and date

Prior Chemotherapy and Biotherapy Regimens
- Table format with regimen, dates, best response, reason for discontinuation

Prior Radiation Therapy
- Site and date

CURRENT PLAN

Intent Goals of Therapy
- Adjuvant
- Neoadjuvant
- Advanced/Palliative

Performance Status
- (including Karnofsky, etc.)

Sites of Disease Monitored
- Add choices of adjuvant (n/a), measurable, evaluable
- List of indicator lesion sites

Human Body Graphic
- Front and back for recording disease

Chemotherapy or Biotherapy Regimen Planned

Clinical Trial Protocol Number

Height, Weight, Body Surface Area, and Starting Doses

Duration of Treatment and Number of Planned Cycles

Radiation Therapy Planned

Surgery Planned

Pain Assessment

Major Toxicities Experienced

Hospitalizations Required for Toxicity

Disease Status at Completion of Treatment

Palliative Care and Hospice Plan

Ability to Make an Electronic or Print Copy of Treatment Plan
- Include treating physician and contact information (perhaps as a header or at the signature line)

Table 3. Oncology-Specific EHR Functionality

For community cancer centers looking to implement an oncology-specific EHR, NCCCP sites and ASCO have identified these core functions. For a full list go to: *www.asco.org*.

CHEMOTHERAPY AND DRUG MANAGEMENT

- Ability to order electronically.
- Ability to interface with pharmacy system.
- Ability to interface with electronic medication administration record.
- Ability to choose from predetermined regimen order sets of standard regimens or study protocols (configurable by institution).
- Electronic link to protocol from the order.
- Ability to have dates fill in automatically for multi-day and multi-week therapy.
- Ability to reorder from prior cycle.
- Ability to modify orders and doses.
- Document treatment parameters on order.
- Ability to sign off electronically on each cycle.
- Ability to verify orders electronically by nursing and pharmacy after MD/NP signs.
- Ability to use previous height/weight or apply new height/weight.
- Chemotherapy order sets, including NCCN guidelines and order sets, internal order sets, and access to a library of standards-based regimens and standards-based protocols.

BILLING CHARGE CAPTURE AND INVENTORY CONTROL

- Ability to interface with existing billing management system and inventory control system.
- Ability to track drug supply chain of events (inventory received, source, dose dispensed, lot number, dose discarded and why, waste record, expiration record and notification, and spill record and documentation). NOTE: These pharmacy functionalities could be handled outside of the EHR by the pharmacy management system.
- Ability to track the course of the drug (pharmaceutical company, clinical trial, vendor). NOTE: These pharmacy functionalities could be handled outside of the EHR by the pharmacy management system.
- Chemotherapy coding (J-codes) and reimbursement management should be part of a pharmacy system.

- Oncology specific procedure codes and drug administration billing codes (time dependent) for a comprehensive record of charges.
- Mechanism for insurance pre-authorization. Ability to electronically submit notification to billing office and billing system OR generate a report that can be taken to billing (configurable based in organizations needs).
- Billing office alert for all drugs and treatments to approve or authorize.
- Access to approved drug compendia.

CALENDAR AND SCHEDULER

- Alerts and pop-ups to remind caregiver of scheduled treatments, etc.
- Ability to schedule regimens/full course of care to include: physician visits; education and training; lab and radiology; infusion and injections.
- Ability to update calendar easily and push dates accordingly.
- Chemotherapy chair scheduling.
- Ability to print off calendar of treatments, lab and radiology appointments, and physician appointments to give to patient.
- Regimen-specific calendar that can be printed off for patient that includes the drugs being given and taken; lab, radiology, and physician appointments; side effects, etc.
- Calendar for patient that records the day oral medications should be taken and time interval with space to record actual time taken and any side effects experienced. Either a printable calendar that can then be scanned into the patient record when complete or through a patient portal, so patients are able to provide information electronically to their own record.

Implications for the Wider Oncology Community

Information Technology, now a critical component of care, comes at a cost—in dollars, people, and time. IT is particularly challenging for community cancer centers, where IT departments are small and resources are limited. Often, technology solutions at community cancer centers comprise a stable of disparate systems. Many of the domains within a community cancer center continue business operations in a paper-based system. Although the cost of technology is high, without the infrastructure, platforms, equipment, and security parameters in place to enable the new solutions necessary to drive cancer care forward, progress is even further hampered. And cost is not the only hurdle. The challenges involved in implementing new technologies and solutions can be as big or bigger a barrier. In short, the situation can seem overwhelming.

As part of the NCCCP pilot, the IT Subcommittee was required to write a White Paper that would discuss the pilot sites' experiences assessing the need for technology expansion to meet the business needs of a community cancer center. During the pilot, NCCCP sites reviewed NCI cancer Biomedical Informatics Grid (caBIG®) tools and resources. Where caBIG software and support solutions were identified as appropriate for technology expansion, the pilot sites evaluated how they might operationalize to support these deployments within a community-based setting. However, the subcommittee did not solely focus on caBIG because the pilot sites wanted to look at the global technology needs required to support community-based cancer centers.

The main objectives for the IT White Paper were to:

- Provide a roadmap for future NCCCP sites to leverage these recommendations and lessons learned from the pilot effort for their own technology implementation processes
- Share information with non-NCCCP community cancer centers and provide recommendations for the evaluation and implementation of technology expansion solutions based on the experiences of the 16 NCCCP pilot sites.

For community-based cancer centers looking to expand technology portfolios and implement information technology products based on business needs, NCCCP pilot sites offer the following key recommendations:

- Actively engage senior leadership in the entire process. Key steps include: determine if a real need for tool adoption exists, analyze the business need, understand the tool selection evaluation criteria, and communicate to end users the value of the tool.
- Gain senior level sponsorship and clearly define the need for additional IT resources (whether on a contractual basis or an FTE). Often community cancer centers do not have sufficient IT technology resources in place to adequately support a large-scale IT implementation. To overcome this challenge, senior level support is essential to obtain and maintain the appropriate level of funding.
- Have a strong governance model. This step is critical to effective IT implementation. Specifically, have robust policies, principles, and procedures in place to manage any potential risks or issues that may arise. This step can make the difference between success and failure of implementation.
- Rigorously define the business requirements *before* choosing a vendor. This helps focus the evaluation process on the real needs of the organization rather than on vendor-induced needs. It can also be an effective way to prevent vendor up-selling.
- Understand the functionality of the tools being evaluated. This recommendation may seem obvious, but decisions may be affected by other factors, such as the quality of the presentation, rather than the actual usability of the tool.
- Ensure a sufficient level of support (comparable to that of commercial vendors) can either be provided or acquired when adopting caBIG IT products (e.g., caTissue and NBIA).
- Train end users prior to the go-live date for the implementation of all technology tools to minimize any potential business disruption. Consider identifying "Super Users" (end users specially trained by the vendor) to train and support other end users.

While IT implementation is likely, at times, to be a challenging process, the benefits include the potential to improve the quality of patient care and, in particular, improve care for underserved communities across the country.

ation for future adoption by some of the pilot sites, including: caArray, Patient Study Calendar, caAERS, CTODS, caXchange, and C3PR.

Adopting an EHR

At the time of the NCCCP pilot launch, most sites either already had an EHR solution in place and were expanding deployment, or had selected a vendor and were planning for implementation. NCCCP sites that did not have an EHR at the organizational level worked to study requirements, conduct vendor evaluations, make a selection, and deploy that solution. By the end of the pilot's second year, all sites had EHRs in place at the organizational level.

NCCCP pilot sites recognized that EHRs did not include all of the fields required to support the highly specialized and unique domain of oncology. Therefore, a number of sites began to engage CBIIT and NCCCP IT leadership in gap analysis activities that required a detailed review of the specific needs of the oncology provider. After concluding that no vendor solutions met all the complex needs of the oncology domain, the pilot sites asked CBIIT and NCCCP IT leadership to help address the lack of suitable commercial products to fit their requirements. At the same time, the American Society of Clinical Oncology (ASCO) was handling a similar request from its membership. ASCO put together a work group to study the lack of oncology-supportive EHRs and published initial findings. The ASCO work group developed a two-page summary of the specialized needs in an oncology EHR. In October 2007 ASCO hosted a conference, bringing together oncology providers and vendors to discuss how the vendor community might meet the needs of the oncology community.

CBIIT approached ASCO about working collaboratively with NCCCP sites to address this mutually identified gap in vendor support, and the organizations established a number of work groups that developed a robust set of requirements for an oncology EHR. The effort produced the Clinical Oncology Requirements for an EHR (CORE) document, published in October 2009 at ASCO's bi-annual EHR conference. ASCO brought private practice clinical oncologists to the table, NCCCP pilot sites provided a host of domain engagement, and CBIIT brought clinical and standards experts. Although this project was not an NCCCP contract deliverable, sites volunteered many hours to help produce the CORE document. They participated in frequent, lengthy telephone conferences and document reviews, as well as collaborative efforts within their organizations to ensure inclusion of all appropriate domains. The CORE document includes high-level and user-specific oncology EHR functional requirements. Table 2 (page 67) and Table 3 (page 68) high-light key elements from the requirements document.

Around the same time that the CORE document was being developed, the federal government began encouraging practitioners to use electronic solutions for information exchange. Starting in 2011, practitioners can take advantage of incentives for "meaningful use" of Health Information Technology (HIT). These incentives provide practitioners higher Medicare or Medicaid funding for "meaningful use" of certified EHRs. Legislation includes a 2015 deadline requiring all physicians to implement EHRs and begin sharing data in "meaningful" ways or face reimbursement adjustments. These legislative mandates and incentives have created a new urgency in terms of EHR adoption, implementation, and meaningful use.

Going Forward

The work to expand information technology in NCCCP pilot sites was a transformative experience. As the sites' IT departments forged more collaborative relationships with the cancer center departments they served, pivotal changes occurred that improved understanding of processes and technology needs. Unifying IT departments with the other hospital domains allowed stronger business alignment and higher visibility for technology needs in the organizations' financial lines. With personalized treatment portfolios on the horizon and the need to improve technology access to better coordinate and deliver care, having a sound technology platform with a robust stable of business support technology in place is essential. Sharing the NCCCP IT Subcommittee's experience with the broader oncology community may benefit other community cancer centers as they evaluate and expand their own technology platforms. ∎

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NCCCP Biospecimen Initiatives
Bringing Research Advances to the Community Setting

by Mitchell Berger, MD, MMM, CPE, FACP; Jeff Christinson, PA, MHS, ASCP; Lucy Gansauer, RN, MSN, OCN®;
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NCI **COMMUNITY CANCER CENTERS PROGRAM**

Given changes in science and technology that are driving discoveries in the study of cancer and its treatment, an objective of the NCCCP pilot was to understand the capacity for community hospitals to collect high-quality biospecimens and thus bring research advances to the community setting and partner with NCI and its research mission. High-quality biospecimens are critical for molecular research, the foundation for developing molecularly targeted therapies. NCCCP's efforts involved understanding how to prepare NCCCP sites for consenting donors, collecting, processing, annotating, and storing specimens in biorepositories and/or distributing them to other laboratories or biorepositories. The experiences of the pilot sites were detailed in the NCCCP Biospecimens Subcommittee White Paper; highlights from the paper follow.

NCI began a due diligence process in 2002 to formally develop standardized resources for biospecimen research. The recommendations for standardizing biorepository protocols were released in 2003 via publication of the National Biospecimen Network Blueprint and Case Studies of Existing Human Tissue Repositories. In 2007 NCI created its NCI Best Practices for Biospecimen Resources (*NCI Best Practices*), which promoted state-of-the-art guiding principles to optimize biospecimens for cancer research. The document contained guidelines for informed consent, biospecimen collection, annotation, storage, and distribution. It also included guidelines for data gathering and recommendations for dealing with ethical and legal issues arising from biospecimen care and research. Based on comments from the biospecimen resource community, as well as more current and scientifically accurate recommendations, NCI revised the document in 2010. The document is available online at: *http://biospecimens.cancer.gov/practices/2011bp.asp*.

In 2007 the pilot sites reviewed the *NCI Best Practices* to determine the necessary requirements for their community hospitals to implement NCI objectives for research biorepositories. The NCCCP Biospecimens Subcommittee set the following goals:

- Complete the Biospecimens Gap and Fill Assessment Tool
- Address biospecimen formalin-fixation best practices (see page 73)
- Address disparities initiatives through a Special Request Biospecimen Disposal Standard Operating Procedure (see page 77)
- Establish a medium for external speakers to provide best practices to participating NCCCP sites
- Work with NCCCP sites on their local biorepository initiatives and document the various approaches.

Biospecimen Program Assessment
At the start of the NCCCP pilot, each site was responsible for evaluating and documenting the current state of its biospecimen program. To help in this effort, the Biospecimens Subcommittee created a Gap and Fill Assessment Tool (GAFAT). The sites used this tool to identify both current gaps in their biospecimen programs and solutions (or "fills") to those gaps. Based on the *NCI Best Practices*, the GAFAT served as a guide for tissue handling from all patient tumor resections for both clinical care and research purposes. Pilot sites initially completed the GAFAT in June 2008 and then updated it for final completion in fall 2009. The assumptions were: 1) to include all cancer resections for patient care and research and 2) that sites had access to unlimited resources (i.e., personnel and funds). The GAFAT addressed many competencies, including:

- Biospecimen consenting, annotating, collecting, processing, storing, and distributing
- Quality assurance and quality control
- Biosafety
- Principles of responsible custodianship
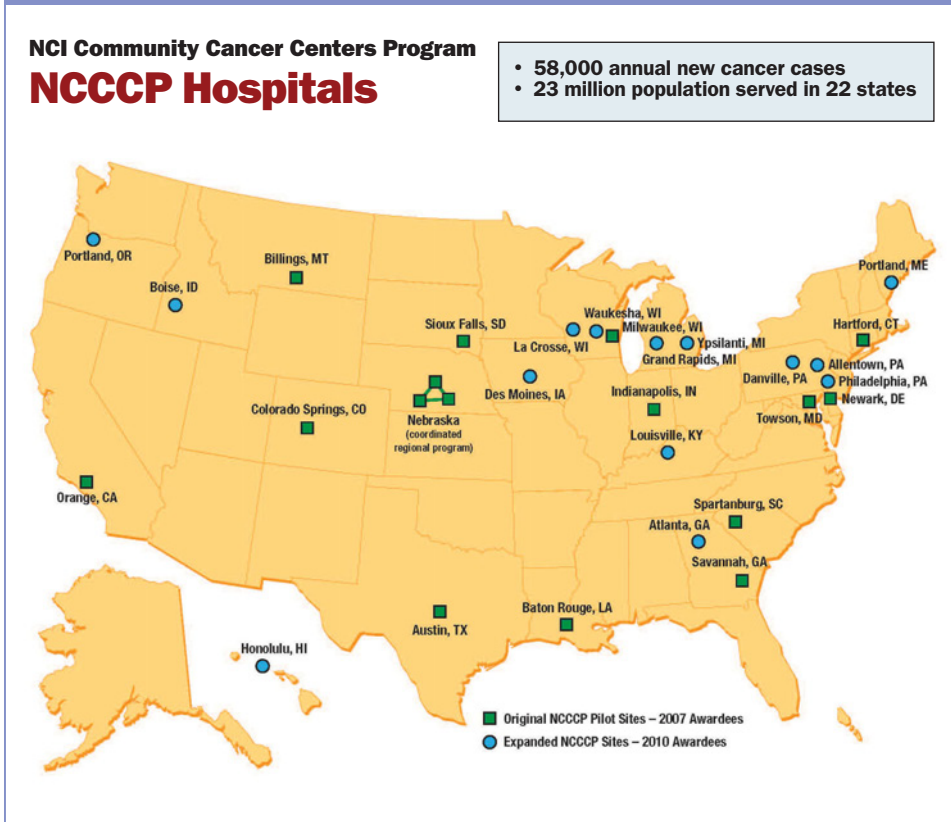- Privacy protection
- Intellectual property.

The GAFAT used by the pilot sites had three tiers, with each tier divided into the following two portions for sequential use:

- Scope, Applicability, Implementation, Technical, and

Figure 1. NCCCP 2010 Network

NCI Community Cancer Centers Program
NCCCP Hospitals

- 58,000 annual new cancer cases
- 23 million population served in 22 states

Portland, OR
Billings, MT
Boise, ID
Portland, ME
Sioux Falls, SD
Waukesha, WI
Milwaukee, WI
Hartford, CT
La Crosse, WI
Ypsilanti, MI
Grand Rapids, MI
Allentown, PA
Danville, PA
Philadelphia, PA
Des Moines, IA
Indianapolis, IN
Newark, DE
Colorado Springs, CO
Towson, MD
Nebraska
(coordinated
regional program)
Louisville, KY
Orange, CA
Spartanburg, SC
Atlanta, GA
Savannah, GA
Honolulu, HI
Baton Rouge, LA
Austin, TX

■ Original NCCCP Pilot Sites – 2007 Awardees
● Expanded NCCCP Sites – 2010 Awardees

Operational Best Practices
■ Ethical, Legal, and Policy Best Practices.

Completion of the GAFAT tool was an NCCCP deliverable, but more importantly, this process added value to sites through the evaluation of their capabilities for proper handling of biospecimens. The GAFAT also helped to show sites' capacity to support and participate in clinical trials that include a tissue collection component. Several sites voluntarily used a Biospecimen Percentage Implementation Tool (BPIT), an Excel spreadsheet, to track the progress of "fills" implementation on a quarterly basis.

Key Stakeholders

Support and engagement of key stakeholders was essential to successful implementation and use of the GAFAT. Assessment, development, and implementation of a biospecimen plan encouraged collaboration between oncology research professionals, information technology, and pathology departments for subsequent implementation of best practices in handling of biospecimens. At the NCCCP pilot sites, many individuals from the pathology laboratories provided insight for and collaborated on the development of

the GAFAT, including pathologists, pathology assistants, tissue bank staff (if existing biorepository), histotechnologists, and medical technologists. Ethicists and members of the legal department also participated by ensuring that solutions to fill the GAFAT complied with all ethical and legal standards.

Even with stakeholder buy-in and support, the GAFAT document was laborious and required extensive education about its use, utility, and data requirements. NCCCP sites reported that the tool was cumbersome and time consuming in the early phase of implementation. This challenge was eventually resolved through further education, site-pairing, and process mentoring.

Strong collaboration among the network sites and NCCCP leadership was critical to enabling individual sites to meet program objectives. Site-pairing (i.e., matching sites with more biorepository experience to sites with less experience) afforded opportunities for best practice sharing. In addition, the ongoing presence of a "site champion" for this project helped guide the development and implementation process for the GAFAT. These combined efforts, along with ongoing education, were critical components to the successful implementation and use of the GAFAT. Once in place, the tools provided an accurate measure of sites' baseline and progress, and helped guide the future direction of NCCCP biospecimen initiatives.

Updating the Tools

Information learned during NCCCP's three-year pilot period and updates made to the *NCI Best Practices* in 2010 led to modifications of the GAFAT-BPIT. The Biospecimens Subcommittee developed a simplified version with formulas that streamlined use and improved quantitative analysis. When the NCCCP network expanded from 16 to 30 sites in 2010, the revised tool was approved for use and its completion became a baseline deliverable for all 30 sites. The GAFAT-BPIT is now being used as a quarterly report tool to follow the overall progress of NCCCP sites. 📖

NCCCP Site Participation in the Formalin Fixation Project

Adequate tissue fixation is essential not only for preserving cellular morphology and diagnosing cancer, it is also critical for the accurate identification of protein profiles and molecular nucleic acid signatures used to personalize prognosis, prediction, and therapy for patients with cancer. Very little standardization of tissue fixation exists among pathology laboratories in the United States and elsewhere. Although non-formalin fixatives have been used in diagnostic pathology, 10% phosphate-buffered formalin without "proprietary additives" remains the "gold standard" for tissue fixation and diagnostic immunohistochemical (IHC) testing.[1] Studies have also shown that development of RNA-based assays from formalin-fixed, paraffin-embedded tissue is feasible; however, greater attention to tissue handling and processing is essential to improve the quality of biospecimens.[2]

In 2007 the American Society of Clinical Oncology (ASCO) and the College of American Pathologists (CAP) published recommendations for HER2/neu testing in breast cancer.[3] This pivotal paper recommended that breast tissue be fixed in formalin for at least 6 hours and no longer than 48 hours. More recently, ASCO and CAP published the complementary Estrogen Receptor/Progesterone Receptor Guideline that updated the total time in formalin to between 6 and 72 hours.[4]

In January 2009 the NCCCP Biospecimens Subcommittee initiated discussions on best practices for the collection, fixation, and processing of biospecimens for IHC and molecular testing. Participation in the formalin fixation project was voluntary. Although not an NCCCP subcontract deliverable, sites agreed to collect this information to establish a baseline for community hospitals' capabilities to follow *NCI Best Practices.* The intent was to establish protocols that would allow pathology laboratories to provide "high-quality" biospecimens for histologic diagnosis, molecular research, and construction of targeted therapies for patients with cancer.

The 2007 ASCO/CAP HER2 guideline and a working draft of the ASCO/CAP ER-PgR guideline served as the foundation for developing and implementing NCCCP's formalin-fixation best practices for the collection and preservation of tissue biospecimens.[4]

Development and Implementation of Formalin Fixation Best Practices

The Biospecimens Subcommittee provided a forum for sharing ideas and strategies for the implementation of the best practices based on the experiences of the participating NCCCP sites, and then allowed for benchmarking progress among the sites. Stakeholders included pathologists, laboratory staff, and pathologist assistants. It was essential to develop cooperation with a wide range of hospital departments and clinicians, including surgeons, medical oncologists, radiation oncologists, interventional radiologists, anesthesiologists, and others. The rationale for NCCCP site participation was that the development of infrastructure at local sites could support the collection of high-quality biospecimens for enhanced patient care.

Formalin fixation time is calculated from the time the biopsied or dissected (from resection) specimen is placed in formalin until the time it is removed from formalin, including the time in formalin during processing. A 6 to 72 hour formalin fixation time was mandated. This required the following:

1. The cooperation of the pathology department and the nursing/OR staff
2. Education on terminology
3. Revision of the pathology specimen requisitions.

A change in tissue preparation workflow (e.g., specimen cut-off times and weekend coverage) was necessary to ensure appropriate fixation times.

To develop the process at NCCCP sites, standard data elements were included in pathology reports, such as "Formalin fixation time is 6 to 72 hours" or "Total time in formalin is _____." The data to calculate total time in formalin include date and time specimen is placed in formalin and date and time specimen is removed from formalin. The first datum point (date and time placed in formalin) is provided by the clinician and/or OR staff or, in some instances, the pathology department if the specimens are received fresh. The second datum point (date and time removed from formalin) is determined by the pathology department. The actual times could be maintained on the specimen requisition or on the report, but were not required on the final reports.

Implementation at some NCCCP sites required a new mindset regarding turnaround times of surgical specimens to accommodate for appropriate fixation times. A few sites had to make weekend staffing changes. The ASCO/CAP guidelines for reporting predictive markers in breast carcinoma were used to educate staff about requirements that made these changes necessary. Several of the sites added templates for reporting the fixation times on the pathology reports to laboratory information systems; other sites developed programs for fixation monitoring. Sites trained pathologists and histology staff on placement of tissue in the appropriate processors with specific programmed times in formalin.

Success was monitored by the reporting of "formalin fixation time" on the pathology report—another requirement of the more recent ASCO/CAP guidelines. This requirement was instituted predominantly for breast carci-

noma cases, with some NCCCP sites planning to include fixation times on all pathology reports.

Pathology assistants monitored requisitions for the appropriate data elements. Histology managers worked closely with the OR staff leadership to ensure success. When documentation was not present, communication by phone or email between the pathology and histology staff and the OR staff ensured timely feedback and correction of any deficiencies.

While implementation of changes to ensure 6 to 72 hour total time in formalin became part of the normal work flow at NCCCP sites, barriers to the process included:

- Lack of understanding of the critical nature of the process by OR staff and OR technicians
- Competing priorities, such as specimens delivered fresh for intraoperative consultation or frozen section
- Tissue processors that may require different start times for standardization of time in formalin
- Commercial anatomic laboratory information systems (LIS) in the community currently do not have searchable fields for formalin fixation times and are not easily customizable for this feature; therefore, additional work was needed for the pathology assistants to dictate times and for the transcriptionists to type the data.

NCCCP sites provided educational tools to support the implementation of standard fixation times. For example, the Biospecimens Subcommittee offered presentations on the scientific significance of fixation time, focusing attention on the molecular process of fixation. The subcommittee also audited NCCCP sites for adherence to best practice fixation times by requesting percentages of specimens fixed within the 6 to 72 hour time interval as a deliverable. Data from early in the process and during implementation allowed sites to benchmark with other community hospitals.

Implementation of the 6 to 72 hour "formalin fixation time" requirement varied greatly among NCCCP sites. Several pilot sites started with policy and procedure development while other sites already had policies in place.

Costs to incorporate these process changes were not measured at any of the NCCCP sites. Associated costs may include education time of staff, reprinting requisitions, staff time to document data elements, and time for pathology assistants to dictate information. A potential cost is modifications to the LIS that would help with time calculations and provide automated recording of data on reports and audits. Implementation of LIS changes may help decrease the staffing costs to provide these data, especially if defined fixation times are required on all specimen types.

Staff place vials in a cryotray.

Lessons Learned and Recommendations

While many pathology laboratories have adopted the ASCO/CAP recommendations for formalin fixation of breast specimens, it is important to note that these are not "mandates." Although the ASCO/CAP recommendation for a minimum of 6 hours of formalin fixation was based on a study by Goldstein and colleagues[5] that looked at estrogen receptor staining in invasive breast carcinoma, an earlier study examining the effect of prolonged formalin fixation on breast biomarkers found that HER2/neu was stable for up to 20 days and ER/PR staining for up to 57 days.[6] Therefore, individual laboratories are free to use alternative fixation guidelines as long as they validate their protocols against the recom-

mended guidelines. In addition, while the NCCCP focused largely on formalin fixation times, delay to fixation (cold ischemia time) may have a negative impact on the identification of biomarkers. The recent ASCO/CAP ER-PgR guideline recommends that the delay to formalin fixation not exceed one hour and that biospecimens not be stored overnight at 4° C prior to fixation.[7]

Participating NCCCP sites conducted formalin fixation studies in 2009 and 2010. Study results indicated that laboratories in 2009 were able to calculate formalin fixation times in the majority of breast specimens, and 2010 data suggested that formalin fixation documentation was improved on all case types.

Many factors led to success among the different NCCCP sites challenged with maintaining and recording formalin fixation times. Communication, cooperation, and collaboration among multiple service areas, based on the knowledge that there is good scientific rationale for changing practice, proved important. Sites had to determine how to efficiently accomplish the goal of implementation within the context of limited resources (see "Steps to Implement Formalin Fixation Times at an NCCCP Site" at right).

The Biospecimens Subcommittee recommended ongoing educational events for the NCCCP network sites. With increased emphasis on formalin fixation studies, the goal for continued education is to break barriers to practice changes, improve tissue handling procedures, and implement changes in the community hospital setting that will advance molecular research to support genomically informed medicine. 🔲

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[3]Wolff AC, Hammond ME, Schwartz JN, et al. American Society of Clinical Oncology/College of American Pathologists Guideline Recommendations for human epidermal growth factor receptor 2

Fixation Time Documentation

Diagnostic pathology laboratories are tasked to keep track of the exact time that a breast biospecimen has been fixed in formalin and the 2010 ASCO/CAP ER-PgR guideline requires that this information be included in the surgical pathology report.

An alternative approach, based on the process set up at an NCCCP-hospital-affiliated laboratory, is recommended for those laboratories that find it difficult to document the exact time of fixation: Once minimum and maximum fixation time guidelines were established by the individual laboratory, a policy was established that ensured all breast biospecimens satisfied the fixation requirements. For example, if a laboratory follows the 2007 ASCO/CAP "6 hour" minimum fixation recommendation, then the combined time of "pre-tissue processor" and "tissue processor" formalin fixation must add up to 6 hours. Therefore, it is necessary for the surgeon, interventional radiologist, and pathology staff to document the FCT (time biospecimen is placed in formalin) on the pathology requisition for all breast biospecimens. Knowing the FCT and when the tissue processor is started, a decision would be made as to whether the biospecimen is set-up that day or held until the next day for processing. Continual surveillance of FCT compliance should occur and feedback be given to those individuals not documenting the FCT for their patient's biospecimen.

While achieving the fixation time goal was a challenge for NCCCP sites with limited resources, all sites felt their accomplishments far outweighed the challenges. Most sites gained compliance with the ASCO/CAP guidelines and expanded the process from breast tissue to all or most tissue types with the knowledge that patients benefit from optimally processed tissue. It has been suggested that as implementation of the *NCI Best Practices* continues to grow, documented FCT may be necessary for other types of cancer that require immunohistochemical and/or molecular studies for diagnosis, prognosis, or research.

Other obstacles were encountered primarily when NCCCP sites had to change long-established processes. Workflow in the histology labs needed adjustment to accommodate for the minimum 6 hour and maximum 72 hour specimen fixation times. Simple changes included training staff to calculate fixation times. A web-based calculator was identified for use. The tool is available online at: *http://www.timeanddate.com/date/timeduration.html*). 🔲

Steps to Implement Formalin Fixation Times at an NCCCP Site

✔ Meet with hospital committee (Cancer Care Committee) to initiate working group.

✔ Educate working group on significance of initiative.

✔ Revise requisition and ordering process to include date/time of removal of specimen(s) on all cases and date/time formalin added.

✔ Educate OR staff and other hospital areas that submit biopsies to include time of removal and time formalin added.

✔ Educate pathology assistants and pathologist to document time formalin added on cases sent fresh or for frozen sections.

✔ Use training tools/signs in OR and outpatient surgery areas and radiology.

✔ Determine time out of formalin on all processors in histology department. Develop a chart based on what time tissue is placed in formalin will allow for appropriate time in fixation (6 to 72 hours). Load processors appropriately.

✔ Develop canned text to be placed on all reports to indicate fixation time. Example: Pre-analytic factors: Time in 10% phosphate-buffered formalin is between 6 and 72 hours. Pre-analytic factors: Time in 10% phosphate-buffered formalin is greater than 72 hours (74 hours, 10 minutes).

✔ Train histology staff to calculate the time with aid of online time and date duration calculators and to indicate which canned text to use.

✔ Train transcriptions to enter canned text codes from times/codes as documented by histology staff.

✔ Monitor process. Identify locations not providing times appropriately for further education. Surgeons/OR may need to be educated to not leave specimens in OR without formalin until case finished.

✔ Develop methods to calculate overall formalin fixation rates.

✔ Work with anatomic pathology laboratory information systems to allow for time entries, calculations, and automated documentation.

In the future, hopefully, nationally recognized LIS companies will automatically include solutions to include time to decrease the manual calculations, coding, and transcription.

PHOTOGRAPH/ISTOCKPHOTO

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Developing a Special Request Biospecimen Disposal SOP

A core goal of the NCCCP is to reduce cancer healthcare disparities. An early step in the process is to understand the diverse populations that are cared for, beginning with the study of biospecimens collected for cancer research. Personal, religious, and cultural beliefs can affect an individual's decisions regarding biospecimen disposal or return; therefore, it is important to have policies for the handling of biospecimens that are congruent with the religious and cultural beliefs of the populations served.

Disposal SOP Development and Implementation

The NCCCP Biospecimens Subcommittee developed the NCCCP Special Request Biospecimen Disposal SOP in an attempt to responsibly handle requests related to biospecimens collected from individuals of different cultural backgrounds and ethnicities. The model was based on the protocol at Billings Clinic and the College of American Pathologists (CAP) Guidelines. The generic SOP template was designed to be respectful of the communities served by the NCCCP with the intent of ensuring a mutual understanding of processes for biospecimen handling between pathology custodians and patients who have cultural and/or religious beliefs about human tissue. The subcommittee created the template to help NCCCP sites: 1) encourage and assure patients who might otherwise limit their participation and 2) foster patients' trust that their wishes will be honored.

Development of the disposal SOP template involved many participants from various NCCCP sites, particularly in the research and biospecimen fields. Stakeholders in the Disparities, Clinical Trials, and Biospecimens Subcommittees were engaged, and site-specific ethics and legal staff were critical to defining issues relevant to such a protocol and ensuring that it could be effectively implemented at NCCCP sites. Tissue procurement staff was also engaged in the process, which allowed for a thorough discussion of the options available to accommodate various religious and cultural beliefs. In addition, pathologists and others involved in tissue processing were consulted to ensure that tissue could be safely returned after processing without causing any increase in risk of cancer (because of the formalin) or becoming biohazardous if someone then chose to dispose of the tissue in an unapproved manner.

The Special Request Biospecimen Disposal Protocol SOP template includes:

1. A Biospecimen Disposal Standard Operating Model Protocol for Special Requests Outside the Scope of Routine Biospecimen Disposal Policy (page 79).
2. A Model Biospecimen Special Disposal Request Form (page 80).
3. A Model Biospecimen Special Disposal Release Form (page 80).

During the protocol development and implementation process, the NCCCP pilot sites shared best practices and


Biospecimen tissue collection during a surgical procedure at St. Joseph Hospital of Orange.

created a process that was "friendly" to the community hospital setting. While special requests for biospecimen disposal may not arise often in some areas of the country, NCCCP sites needed to be prepared to address the issue. The Biospecimens Subcommittee circulated the SOP to NCCCP sites to gather comments and suggestions from those that serve diverse cultures, as well as to ensure buy-in for future site adoption. Very early involvement of the pathologists and medical and surgical sub-specialists involved with tissue procurement was helpful to successful implementation of the SOP.

The research team discusses biospecimen collection processes with the surgical team at St. Joseph Hospital of Orange.
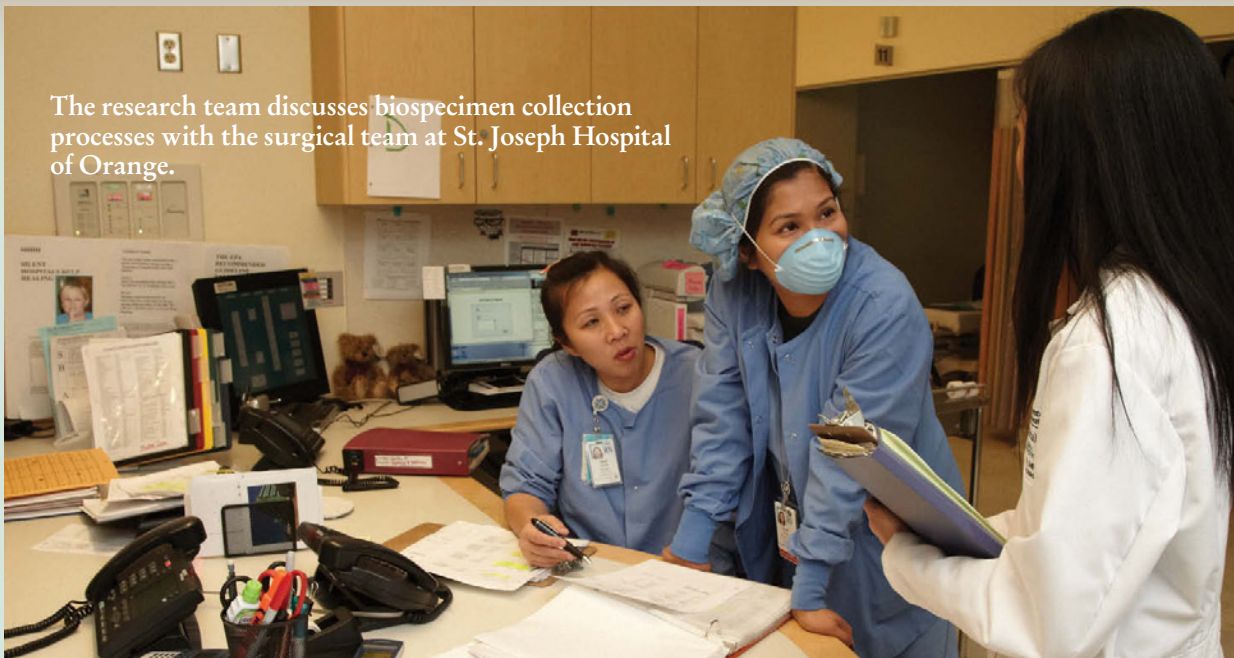
Lessons Learned

NCCCP sites reported the following challenges to the Special Request Biospecimen Disposal SOP:

- Competing priorities that prevented project completion
- State and local laws that required release of biospecimens through a mortuary
- Low frequency of special requests.

By the end of the NCCCP pilot's third year, only a few sites had implemented the protocol—largely because of competing priorities within their institutions and NCCCP network responsibilities. The continued adoption and implementation of the NCCCP Special Request Biospecimen Disposal SOP is a work in progress. The 2007 pilot sites, and the new sites added to the network in 2010, are increasing the use of policies that incorporate cultural considerations related to the donation of biospecimens.

When developing a similar biospecimen disposal SOP, NCCCP sites suggest that community cancer centers be very mindful of the different cultures they serve. Protocols need to be culturally appropriate and sensitive to the needs of *all* patients.

Case Example—NCCCP Site Billings Clinic

Billings Clinic Laboratory Services at Billings Clinic in Montana has had a biospecimens disposal policy in place since the 1990s. Given the community's significant American Indian population—approximately 6 percent of the regional population—the policy was designed with cultural awareness in mind. Seven reservations are in the Billings Clinic Cancer Center service area. Cancer rates for local American Indians are significantly higher than those for the non-Native American Indians and the survival rates are lower for most cancer types.

Part of the American Indian spiritual belief is to be buried as a whole, creating the need for special disposal requests for tissue or body part collections. Obstacles may be encountered, for example, if there is not notification of the patient's special request before or at the time of surgery, or the laboratory is not aware of the patient's request and the specimen may be disposed of. Communication between the patient, the surgery team, and the pathology department is vital; all three play a critical role in policy adherence. Another unique challenge is that the special request for biospecimen disposal is a paper-based process and, under Montana law, funeral homes are not always directly involved and there is the potential for a communication breakdown.

The Billings Clinic disposal policy was designed for quality patient care and service to ensure respect for the wishes of all patients served at the Clinic. Billings Clinic recognized the importance of developing a policy that was culturally appropriate for the facility's American Indian population. Overall, implementing a disposal policy at Billings Clinic improved cultural awareness for hospital and cancer program staff. Patients, surgeons, surgery staff, pathologists, and pathology staff were all instrumental in the successful implementation of this policy. The Billings Clinic disposal policy served as the starting template for NCCCP sites during the creation of the Special Request Biospecimen Disposal SOP.

Biospecimen Disposal Standard Operating Model Protocol for Special Requests Outside the Scope of Routine Biospecimen Disposal Policy

DRAFT Version 1.3   11.2.09

Purpose:

This model protocol defines a model for the release, at the patient's, or patient's legal representative's request, of any patient biospecimen** that is not subject to local, state, or federal regulations, e.g., bullets, pacemakers, implants, especially in regard to religious, cultural, or other requests. The biospecimen(s) will be released after the pathology evaluation has been completed. *Some of these biospecimens may be bio-hazardous and potentially infectious necessitating decontamination when appropriate and explanation of potential risks to the recipient.*

The facility may wish to include a procedure for re-acquiring the biospecimen if future studies are desirable, e.g., paraffin block. See the College of American Pathologists viewpoint concerning the issue of pathologist legal risk when no diagnostic tissue remains in a paraffin block that is submitted to another laboratory at the patient's request, but is then requested for additional studies by the patient or their physician.

All, portions, or none of this model procedure may be incorporated into the pathology department's policies and procedures at the discretion of the pathology medical director and facility risk management department. This model procedure should not supersede current federal, state, local, or facility regulations.

** Biospecimen is defined as any fluid, cells, tissue, substance, or material removed from the patient for pathology evaluation (clinical and anatomic pathology biospecimens) as well as remnant biospecimen (the biospecimen that is not used during the complete pathology evaluation) and derivative products such as: paraffin blocks, stained and unstained tissue on glass slides, nucleic acids or other derived chemical substances, and digital images.

Procedure:

1. The patient or patient's legal representative must submit a signed request to the pathology department for the release of the specified biospecimen(s). The request form can be filled out before or after collection of the biospecimen and returned to the pathology department with the biospecimen requisition if completed before collection or separately if completed after collection. The Biospecimen Special Disposal Request Form is available from the pathology department (see model form, page 80).

NOTE: As current policy, pathology departments may not release potentially infectious or bio-hazardous biospecimens (e.g., gallbladder stones, gangrenous limb amputations, blood/body fluids, tissue in formalin) to patients, but may release them to legal counsel or mortuaries with appropriate warning and documentation, or to patients after appropriate decontamination (e.g., gallstones that have been rinsed in water and alcohol). Patient viewing and/or provision of photographs of the biospecimen(s) is also used in some pathology departments, thus avoiding release of the biospecimen(s). The potential legal risk for the pathologist if a person becomes infected or injured from a received biospecimen needs to be determined for each facility based on local, state, and federal regulations and precedents.

2. Notification to save the biospecimen is made in writing on the biospecimen requisition form by the collecting or submitting provider if before collection, e.g., physician, nurse, physician assistant, or by the patient or patient's legal representative if after collection and before routine disposal per pathology department policy. The pathology department will hold the requested biospecimen(s) for the patient or patient's legal representative until the appropriate release form has been completed. The patient or patient's legal representative will be notified by phone and by certified letter when the requested biospecimen(s) has completed the final pathology evaluation. A copy of the certified letter and its receipt will be attached to the request form along with a copy of the original biospecimen requisition, all being filed in a confidential and physically secure area. The information and process must be compliant with HIPAA regulations.

3. The biospecimen(s) will be packaged to prevent leakage in case of breakage of a liquid or "in formalin" biospecimen and the package clearly labeled BIO-HAZARDOUS. The patient or patient's representative will complete the release form (see page 80): date of pick up, patient's printed name and signature, full contact information of the person picking up the biospecimen such as the current address and phone number, and a witness' printed name and signature that the specimen was received by the stated patient or patient's legal representative (identification must be reviewed) and that biospecimen custodianship has been transferred from the institution to the patient or patient's legal representative.

Frequently Asked Questions:

_____
_____
_____
_____
_____

Brief synopsis of pertinent policy points:

_____
_____
_____
_____
_____

Model Biospecimen Special Disposal Request Form
Ver 1.0 9/28/09

Patient's name (printed): _____
Date of biospecimen collection: _____
Biospecimen pathology acquisition number: _____
Biospecimen type to be released: (e.g., blood, tissue, paraffin block, glass slides)
_____

I, (the patient or legal representative), request the release of the above identified biospecimen to me or my legal representative:
Name (printed): _____
Current address (printed): _____
_____
_____
Current telephone number (include area code): _____

I, (the patient or legal representative), understand that the biospecimen I am requesting *may be bio-hazardous and potentially infectious*.
I hereby waive and release (facility name) and its employees and agents from any and all liabilities related to the transfer, handling, and disposition of this biospecimen once it has been released to me or my legal representative.

_____
Printed name of patient or legal representative   Date
_____
Signature of patient or legal representative   Date

If signed by a legal representative, what is your relationship to the patient? _____

RETAIN A COPY IN THE PATIENT'S FILE AND WITH THE BIOSPECIMEN RESULT REPORT
IN THE PATHOLOGY DEPARTMENT.
NCCCP/BS Disposal Project/Model Biospecimen Release Form Ver 1.0 9.28.09

Model Biospecimen Special Disposal Release Form
Ver 1.0 9/28/09

Patient's name (printed): _____
Date of release: _____
Biospecimen pathology acquisition number: _____
Biospecimen type to be released: (e.g., blood, tissue, paraffin block, glass slides)
_____
(Facility name) will release the above identified biospecimen to the following patient or legal representative:
Name (printed): _____
Current address (printed): _____
_____
_____
Current telephone number (include area code): _____

I, (the patient or legal representative), understand that this biospecimen I am receiving *may be bio-hazardous and potentially infectious*. I understand that (facility name) is willing to dispose of the biospecimen, but at my request, has agreed to release the biospecimen to me or my legal representative.

I hereby waive and release (facility name) and its employees and agents from any and all liabilities related to the transfer, handling, and disposition of this biospecimen once it has been released to me or my legal representative.

_____
Printed name of patient or legal representative   Date
_____
Signature of patient or legal representative   Date

If signed by a legal representative, what is your relationship to the patient? _____
_____
(Name of facility) Representative/Witness (printed and signature)   Date

RETAIN A COPY IN THE PATIENT'S FILE AND WITH THE BIOSPECIMEN RESULT REPORT
IN THE PATHOLOGY DEPARTMENT.
NCCCP/BS Disposal Project/Model Biospecimen Release Form Ver 1.0 9.28.09

Biospecimen Collection for Molecular Research

One of the goals of the NCCCP pilot was to explore the potential of community hospitals to collect high-quality biospecimens in support of molecular research. It is through the collection of high-quality biospecimens that researchers will be better able to define tumors by genomic and proteomic analyses and develop targeted therapies that are more effective and have fewer toxicities.

Each NCCCP site was encouraged to participate in the collection of biospecimens for molecular research, yet participation was not a requirement. The only subcontract deliverable was the Gap and Fill Assessment Tool (GAFAT), which was used by each site as an indicator of the starting point for each site; the GAFAT measured individual progress and followed the overall progress in building this capacity within the NCCCP network. While each site had its own unique situations and experiences, they were all tasked with assessing their biospecimen collection and storage capacity based on *NCI Best Practices.* The creation of a network of sites that could follow these standards would theoretically create a large source of high-quality biospecimens that were collected, processed, stored, annotated, retrieved, and disseminated in a standardized manner. Adherence to *NCI Best Practices* ensures consistency and harmonization for all resources.

Program Objective and Development

The NCCCP pilot sites evaluated their biospecimen programs and implementation of *NCI Best Practices* using the GAFAT (see page 71). The objective: to improve the quality of biospecimens and/or the biospecimen repository at each NCCCP site.

The consent process is discussed with a Native American patient at Billings Clinic, Montana

Implementation and development of biospecimen collection processes and repositories varied across the NCCCP pilot sites. Three sites (Christiana Hospital, CHI-Penrose, and CHI-St. Joseph/Towson) were selected via a competitive process to participate in The Cancer Genome Atlas (TCGA) after their second year in the NCCCP program. TCGA leadership specifically targeted the NCCCP community hospitals as potential tissue collection sites given their experience in the NCCCP network, noting their attention to the *NCI Best Practices* and their understanding of cancer research's need for high-quality biospecimens. Involvement in the NCCCP prepared the pilot sites for the next stage in the development of their collection processes and repositories. The benefits of TCGA participation included opportunities for the sites to upgrade their tissue procurement databases to caTissue, caBIG®'s biobanking management system, and to strengthen their translational cancer research tissue procurement processes.

Four of the NCCCP pilot sites (Ascension Health–St. Vincent Indianapolis Hospital, Hartford Hospital, Our Lady of the Lake Regional Medical Center, and St. Joseph Hospital/Candler) became associated with Moffitt Total Cancer Care™, which provided staff and financial support to collect high-quality biospecimens; thereby, creating and enhancing development of the sites' biospecimen repositories.

Two sites (St. Joseph Hospital of Orange and Billings Clinic) proceeded with self-initiated, site-specific endeavors, aided by external expertise and mentorship provided by mature NCCCP sites, such as Christiana Care and the CHI (Catholic Health Initiatives) sites. The networking and shared best practices among sites exemplified the power of the NCCCP network and the potential for standardizing processes within the community setting. Funding for the biospecimen repository at St. Joseph Hospital of Orange was secured through fundraising efforts by the institution, bolstered by a $100,000 donation from a local family affected by cancer.

One of the major factors of biospecimen repository success among the pilot sites was the cooperation of surgeons, medical oncologists, pathologists, laboratory staff, research staff, and administration. Cooperation and buy-in from these key stakeholders were essential for the promotion and support of the biospecimen repository within a cancer center and throughout the hospital. Ongoing education at weekly tumor boards also served as a vehicle for identification of patients eligible for tissue procurement.

Educational Opportunities

Presentations by external experts to members of the NCCCP Biospecimens Subcommittee served as valuable educational tools to enhance the biorepository programs at NCCCP sites. Given the spectrum of practice and knowledge among participating institutions, as well as the different backgrounds of individual participants (e.g., pathologists, technologists, and administrators), these discussions helped disseminate information and knowledge to ensure that all network sites had a fundamental grasp of important issues related to the biospecimen repository program.

Speakers covered a broad range of topics, including proper specimen handling and procedures to ensure valid diagnostic testing, the science behind those procedures, as well as more basic research discussions. The role of the NCCCP network was critical to the success of these programs. Without the NCI contacts and the cooperation of the participating institutions, the presentations would not have occurred. Members of the Biospecimens Subcommittee helped to stimulate the presentations by asking questions and guiding discussions to improve audience understanding of the topics. These educational efforts offered potential guidance for NCCCP sites as they developed practices and implemented processes at their respective institutions.

The best presentations were both informative and provided validation for current practices in a particular institution, or offered an outside expert's guidance and rationale to garner institutional support for implementation of a desired best practice. When the NCCCP pilot expansion occurred in 2010, the Biospecimens Subcommittee agreed to solicit feedback from the pilot sites to identify beneficial presentation topics for the new NCCCP sites. The subcommittee also relied on NCI leadership to suggest presentation subjects that would help inform the community cancer centers about early research in progress. The main barrier to success for these educational opportunities was ensuring participation of the appropriate staff. At times, pathologists were unable to participate due to clinical responsibilities, and lack of participation by others (e.g., administrators) led to a lost opportunity to educate and garner institutional support for a change. This obstacle was handled differently by each site. The Biospecimens Subcommittee learned that it was helpful to provide advance information about the presentation topic so that sites could identify the target audience and adjust schedules; they also made presentation material available on the NCCCP's intranet.

Program Challenges

As the pilot sites worked to develop and implement a biospecimen repository program, they reported challenges related to:

- Achieving full cooperation of the pathology department in terms of understanding the scope of the NCCCP program

- Funding and staffing for program support
- IT support from within the cancer center and NCI.

Many NCCCP sites identified pathology support and participation as a necessity, which had to be addressed at the outset of the program. While a few sites reported that funding for program support created challenges, several sites were funded by philanthropic efforts, grants, or outside sources such as TCGA and Moffitt. IT support is an integral part of the biospecimen process, and software applications such as the various caBIG tools (e.g., caTissue) can be costly and difficult to apply to a community-based program without a competent IT staff.

Other challenges included:
- IT infrastructure, implementation, and training
- Standardization of data collection
- Communication—at all levels of hospital organization
- Patient consent—legal, acquisition of consent, patient education
- IRB approval in a timely manner
- Changes required to existing procedures and practices
- Time commitment for participation in the NCCCP.

Program Outcomes

NCCCP sites were recognized locally and nationally for developing biospecimen programs; participation in a network supporting genomic research was an important factor in program progress. The biospecimen programs at several sites allowed patients to participate in clinical trials; led to expanded translational research and participation in programs such as TCGA; and helped increase accuracy and transparency in tracking of lab metrics and sharing of critical data.

Implementation of the formalin fixation best practices for breast specimens (see page 73) was the major accomplishment listed by all NCCCP sites. By 2010 at least one pilot site had implemented formalin fixation best practices for all cancer cases. Sites implementing these processes are prepared to meet the new ASCO/CAP guidelines.[1,2]

The sites identified general benefits of developing and implementing a biospecimen repository, including:
- Access to shared knowledge and experience
- Enhanced program performance due to adoption of the *NCI Best Practices*
- Access to experts and other resources
- Promotion of compliance with formalin fixation guidelines
- New perspectives and increased understanding of biospecimens from an individual and patient perspective to a national and scientific community perspective.

The three-year NCCCP pilot presented educational and networking opportunities and created major changes across NCCCP sites. While several sites entered the early stages of developing and implementing a biospecimen repository, others were able to develop working and contributing biospecimen repositories. Now, all NCCCP sites are using the 2010 *NCI Best Practices* as applicable to their institutions, including processes for consenting, annotating, collecting, processing, storing, and disseminating tissue. These protocols are being used for molecular research and are either already, or will be shortly, used for patient care.

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References

[1]Wolff AC, Hammond ME, Schwartz JN, et al. American Society of Clinical Oncology/College of American Pathologists Guideline Recommendations for human epidermal growth factor receptor 2 testing in breast cancer. *Arch Pathol Lab Med. 2007*;131:18-43.
[2]Hammond MEH, Hayes DF, Dowsett M, Allred DC, Hagerty KL, et al. American Society of Clinical Oncology—College of American Pathologists Guideline Recommendations for Immunohistochemical Testing of Estrogen and Progesterone Receptors in Breast Cancer. *J Clin Oncol.* 2010;June 1;28(16):2784-95.

This monograph represents the work and experiences of the community cancer centers involved in the NCCCP pilot. Lessons learned from the pilot program were beneficial to the sites that joined the expanded network in 2010. With contributions from hundreds of individuals at all of the NCCCP sites, guidance from NCI program advisors, and strategic partnerships with ASCO, the Commission on Cancer, ACCC, and several NCI-designated Cancer Centers, the NCCCP is working to bring the latest scientific advances and evidence-based care within easy reach of cancer patients across the United States. The NCCCP community hospitals represent a cross-section of the U.S. population and health care systems—and place a major focus on reducing cancer healthcare disparities and ensuring patients from underserved populations have access to quality cancer care and research studies. The hospitals, their locations, and their cancer centers are listed below.

California
St. Joseph Hospital
St. Joseph Hospital Cancer Center
1100 West Stewart Drive
Orange, Calif. 92868
714.633.9111
www.sjo.org

Colorado
Penrose – St. Francis Health Services
(Member of Catholic Health initiatives)
Penrose Cancer Center
2222 N. Nevada Avenue
Colorado Springs, Colo. 80907
719.776.5000
www.penrosestfrancis.org

Connecticut
Hartford Hospital
Helen and Harry Gray Cancer Center
80 Seymour Street
Hartford, Conn. 06102
860.545.5000
www.harthosp.org

Delaware
Christiana Hospital
Helen F. Graham Cancer Center
4755 Ogletown-Stanton Road
Newark, DE 19718
302.733.1000
www.christianacare.org

Georgia
Northside Hospital
Northside Hospital Cancer Care Program
1000 Johnson Ferry Road NE
Atlanta, Ga. 30342
404.851.8000
www.northside.com

St. Joseph's/Candler Hospital
Nancy N. and J. C. Lewis Cancer
and Research Pavilion
5353 Reynolds Street
Savannah, Ga. 31405
912.819.4100
www.stjosephs-candler.org

Hawaii
The Queen's Medical Center
The Queen's Cancer Center
1301 Punchbowl Street
Honolulu, Hawaii 96813
808.538.9011
www.queensmedicalcenter.net

Idaho
St. Luke's Regional Medical Center
Mountain State Tumor Institute
190 E. Bannock Street
Boise, Idaho 83712
208.381.9000
www.stlukesonline.org/boise

Indiana
St. Vincent Indianapolis Hospital
(Member of Ascension Health)
St. Vincent Oncology Center
2001 West 86th Street
Indianapolis, Ind. 46260
317.338.2345
www.stvincent.org/ourlocations/hospitals/Indianapolis

Iowa
Mercy Medical Center
Mercy Cancer Center
1111 6th Avenue
Des Moines, Iowa 50314
515.247.3121
www.mercydesmoines.org

Kentucky
Norton Suburban Hospital
Norton Cancer Institute
4001 Dutchmans Lane
Louisville, Ky. 40207
502.893.1000
www.nortonhealthcare.com/nortonsuburbanhospital

Louisiana
Our Lady of the Lake Regional Medical Center
Our Lady of the Lake Cancer Center
and Mary Bird Perkins Cancer Center
5000 Hennessy Blvd.
Baton Rouge, La. 70808
225.765.6565
www.ololrmc.com

Maine
Maine Medical Center
Maine Medical Center Cancer Institute
22 Bramhall Street
Portland, Maine 04102
207.662.0111
www.mmc.org

Maryland
St. Joseph Medical Center
(Member of Catholic Health Initiatives)
St. Joseph Cancer Institute
7601 Osler Drive
Towson, Md. 21204
410.337.1000
www.sjmcmd.org

Michigan
St. Joseph Mercy Hospital
St. Joseph Mercy Cancer Care Center
5301 McAuley Drive
Ypsilanti, Mich. 48197
734.712.3456
www.stjoeshealth.org/aboutsjmaa

Saint Mary's Health Care
The Lacks Cancer Center
200 Jefferson Street, SE
Grand Rapids, Mich. 49503
616.685.5000
www.smmmc.org

Montana
Billings Clinic
Billings Clinic Cancer Center
2800 Tenth Avenue North
Billings, Mont. 59107
406.238.2500
www.billingsclinic.com

Nebraska
St. Francis Medical Center
(Member of Catholic Health initiatives)
St. Francis Cancer Treatment Center
2620 West Faidley Avenue
Grand Island, Nebr. 68803
800.353.4896
www.saintfrancisgi.org

Good Samaritan Hospital
(Member of Catholic Health Initiatives)
Good Samaritan Cancer Center
10 E 31st Street
Kearney, NE 68847
308.865.7100
www.gshs.org

St. Elizabeth Regional Medical Center
(Member of Catholic Health initiatives)
St. Elizabeth Cancer Center
555 South 70th Street
Lincoln, Nebr. 68510
402.219.8000
www.saintelizabethonline.com

Oregon
Providence Portland Medical Center
Providence Cancer Center
4805 NE Glisan Street
Portland, Ore. 97213
503.215.1111
www.providence.org/oregon/facilities/hospitals/providence_
portland

Pennsylvania
Lehigh Valley Hospital
John and Dorothy Morgan Cancer Center
Cedar Crest & I-78
P.O. Box 689
Allentown, Pa. 18105-1556
888.584.2273
www.lvhn.org/lvh/locations/cedar_crest

Geisinger Medical Center
Geisinger Medical Center Cancer Institute
100 North Academy Avenue
Danville, Pa. 17822
570.271.6211
www.geisinger.org/locations/gmc

Albert Einstein Medical Center
Einstein Cancer Center and
Einstein Center One
5501 Old York Road
Philadelphia, Pa. 19141
215.456.7890
www.einstein.edu/facilities/aemc

South Carolina
Spartanburg Regional Hospital
Gibbs Regional Cancer Center
101 East Wood Street
Spartanburg, S.C. 29303
864.560.6000
www.spartanburgregional.com

South Dakota
Sanford USD Medical Center
Sanford Cancer Center
1305 West 18th Street
Sioux Falls, S.Dak. 57117
605.333.1000
www.sanfordhealth.org

Texas
University Medical Center Brackenridge
Seton Family of Hospitals
(Member of Ascension Health)
Shivers Center
601 East 15th Street
Austin, Tex. 78701
512.324.7000
www.seton.net

Wisconsin
Gundersen Lutheran Medical Center
Gundersen Lutheran Center for Cancer & Blood Disorders
1900 South Avenue
La Crosse, Wisc. 54601
800.362.9567
www.gundluth.org/laCrosse

Columbia St. Mary's Hospital
(Member of Ascension Health)
Columbia St. Mary's Cancer Center
2323 N. Lake Drive
Milwaukee, Wisc. 53211
414.291.1000
www.columbia-stmarys.org

Waukesha Memorial Hospital
ProHealth Care Regional Cancer Center
725 American Avenue
Waukesha, Wisc. 53188
800.326.2011
www.prohealthcare.org/locations/locations-v2-detail/?id=1119