NCCCP Biospecimen Initiatives

Bringing Research Advances to the Community Setting

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The National Cancer Institute Community Cancer Centers Program (NCCCP) was launched in 2007 as a three-year pilot, forming a public-private partnership with 16 community hospitals to explore the best methods to enhance access to care, reduce healthcare disparities, improve quality of care, and expand research within the community setting.[1] At the conclusion of the pilot period, the network sites collaborated to produce White Paper reports to document their experience addressing program deliverables in specific focus areas. *Oncology Issues* introduced a series about the NCCCP White Papers in the January/February 2011 edition.[2] This issue features content from the Biospecimens Subcommittee White Paper.

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/2010bp.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 34)
- Address disparities initiatives through a Special Request Biospecimen Disposal Standard Operating Procedure (see page 38)
- 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

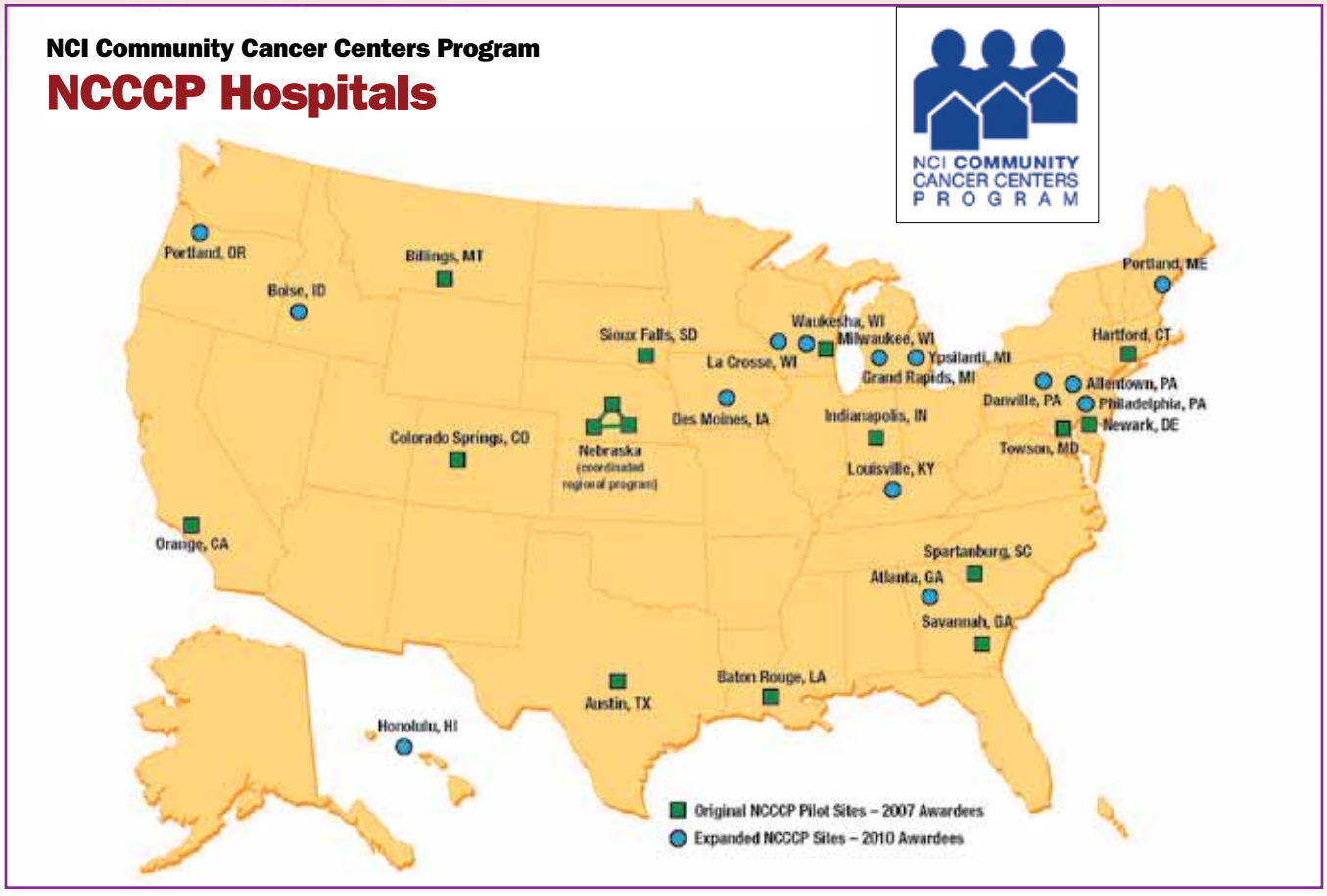
At the start of the NCCCP pilot, each site was responsible for evaluating and documenting the current state of its biospecimen program. To help in this effort, the Biospecimens Subcommittee created a Gap and Fill Assessment Tool (GAFAT). The sites used this tool to identify both current gaps in their 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 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.

References

[1]Johnson M, Clauser S, Beveridge J, O'Brien D. Translating scientific advances into the community setting. *Oncol Issues.* 2009;24(3):24-28.
[2]Johnson M, Clauser S, O'Brien D, Beveridge J, Kaluzny A. Improving cancer care and expanding research in community hospitals. *Oncol Issues.* 2011;26(1):26-28.

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