

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 32). 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 34) 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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