BY VIORELA POP, PHD; LAVINIA DOBREA, RN, MS, OCN; SANDRA BROWN, MS; NOAH GONZALEZ; RACHELLE ALQUITELA, BS; RON BATI; MARTHA FRENCH, RN, MSN; SONIA LABEET; MELINDA LIMA, RN, BSN; VIRGINIA TRUJILLO CASTRO, RN, BSN(C); NANCY WALTER, RN, BS, OCN; SARAH M. BARRETT, BA; AARON SASSOON, MD; AND LAWRENCE D. WAGMAN, MD

A Model for Tissue Banking in the Community Setting

The Cancer Biospecimen Repository Program at St. Joseph Hospital—The Center for Cancer Prevention and Treatment

Molecular advances in cancer prevention, diagnosis, and treatment selection have led to the development of powerful analytical tools that have gained unprecedented momentum in patient care. Biospecimen repositories are key resources for the development of molecular analytics. In an era of personalized medicine, therapeutic advances based on molecular profiling of cancer as a genomic disease are superseding traditional metrics based on criteria related to disease site or general tumor and patient characteristics. Unfortunately, progress remains slow as less than 5 percent of adult oncology patients participate in clinical trials,[1] and the number of research studies available at community hospitals that diagnose and treat a large majority of patients may be limited.[2] That said, community cancer programs have a high need for rapid translation of research into evidence-based practice to benefit patients of all ages.[3,4] Importantly, banking of biological specimens can advance oncology research efforts by providing valuable resources from participants and promoting collaborative partnerships.

The Critical Need for Biorepositories

Biorepositories can provide large numbers of specimens accompanied by relevant clinical information to support molecular research for progress against cancer. Research on specimens already plays a key role in the identification of tumor markers, specific drug targets, and novel approaches for minimally invasive treatments. At the same time, more information is needed to ensure curative treatments for patients with cancer who vary not only in their diagnosis but in inherent characteristics like age, ethnicity, genetic variations, pre-existing health conditions, and other factors. While biobanking considerations are numerous and differ across disease types, biobanking remains a viable option for community hospitals. Important determinants for successful cancer biobanking include sustainable investments and proper resource allocations that support patient accrual and sample collection. A biobank must also have standardized protocols to ensure sample quality, and the ability to implement ethical, legal, financial, and policy parameters to efficiently use specimens in local and collaborative research.

> The specific aim of the repository is to collect biospecimens for use in research from patients undergoing intervention, biopsy, or surgery.

Often, biobanks result from needs in a specific medical field and can lead to relevant translational approaches. For example, the experience of established biorepositories, such as the Johns Hopkins Brady Urological Institute founded in 1994, has led to

novel development of diagnostic tests for prostate cancer.[5] Lung cancer research at the Department of Pulmonary and Critical Care, University of Toledo Medical Center in Toledo, Ohio, resulted in successful next-generation sequencing studies to identify variations in the human genome that affect cancer incidence, known as RNA polymorphisms.[6] The Canary Prostate Active Surveillance Study (PASS) involved several institutions in California, Texas, Missouri, and others with more than 900 men contributing data for genome-wide association studies to identify sequence-specific drug targets.[7] The Mayo Clinic biobank houses data from more than 50,000 patients with quality controls and samples for multiple disease processes, including several types of cancers, and researchers can access approximately 23,000 serum samples from 17,000 patients.[8]

Our comprehensive community cancer program at St. Joseph Hospital in Orange, Calif., has developed and actively maintained a cancer research program for nearly 30 years. We remain among the most active of Orange County community hospitals that participate in clinical trials, with a dedicated staff of full-time research professionals who review and implement new studies for our patients. In the past year alone, The Center for Cancer Prevention and Treatment at St. Joseph Hospital saw 1,565 new patient analytic cases, of which 391 (25 percent) consented for one of the 48 available clinical studies across several disease sites.

In this article, we describe the importance of the national biobanking effort and our ongoing success with the St. Joseph Hospital (SJO) Biospecimen Repository. The Biospecimen Repository received formal Institutional Review Board (IRB) approval in 2011, with ongoing participation in several data sharing projects.

A Brief History of the SJO Biospecimen Repository

The SJO Biospecimen Repository began as part of the combined efforts of medical personnel, staff members, and patient donors across several departments at The Center for Cancer Prevention and Treatment. In 2010, the local IRB reviewed and evaluated a written proposal submitted from our interdisciplinary team, which functions as a single institution resource for multiple types of cancer neoplasms. Protocol approval for patient consents and sample collection began on Feb. 1, 2011.

All research proposals and trials receive careful oversight to ensure patient safety and ethical study parameters from the St. Joseph local IRB, which is composed of physicians, statisticians, researchers, community advocates, and others for adequate protection of the rights of our human research participants. The Cancer Research Department is a major contributor to St. Joseph IRB activities. In the spring of 2017, the local IRB received a successful evaluation and obtained national accreditation by the Association for the Accreditation of Human Research Protection Programs.

Within The Center for Cancer Prevention and Treatment, the

After the patient has signed study informed consent, supplies are placed in the chart for draw at the time of IV placement in the pre-operative area.

Cancer Research Department brings together the varied interests of many departments that interact with our cancer patients, from those in primary care to disease site specialists in oncology, radiation, surgery, genetics, and pathology. Cancer research has been identified as a key priority for the hospital's 2015-2020 Innovating for a Healthier Community campaign (sjo.org/campaign) that pledges philanthropic support for accessibility to research studies and translational outcomes for cancer patients at St. Joseph.

Main Objectives of the SJO Biospecimen Repository

The specific aim of the repository is to collect biospecimens for use in research from patients undergoing intervention, biopsy, or surgery. Protocols are carefully followed to ensure sample quality and reliability for scientific analyses. Samples can be allocated to projects leading to the discovery of genomic and proteomic biomarkers related to tumor burden, therapeutic response, and treatment-related toxicities. In addition, the tissue can be used to test new treatment strategies in both benign and malignant conditions. Biospecimen procurement for research occurs within the clinical pathways of the institution as a routine daily procedure.

In our experience, patients give consent for their biospecimens to be used for research in the hope that the resulting knowledge might help other patients in future years. Our goal is to have every patient undergoing a cancer-related screening or treatment procedure provide informed consent to store his or her tissue for potential research purposes.

Currently, the SJO Biospecimen Repository has the flexibility to address all types of research projects by internal investigators and outside partners through an open-access policy that is available to researchers upon project review.

An Increased Need for Biospecimens

The need for specimens dedicated to cancer research is on the rise. A retrospective analysis evaluated more than 400 publications from investigators studying breast, lung, and ovarian disease processes. In the past decade, the average number of biospecimens used per study increased six-fold (<1,000 to greater than 6,000), and the average cohort size increased from approximately 50 to 200 cases.[9] In another study of more than 400 publications related to cancer research between 2010-2014 by Canadian investigators, 38 percent of studies used biospecimens obtained from either biorepositories (31 percent), hospitals (46 percent), or directly from patients (17 percent).[10]

The SJO Biospecimen Repository infrastructure and support system meets the need for readily available samples that can be routinely used for research. Especially important are analyses that identify key surface markers and immunogens needed for individualized medical treatment.

Ensuring the highest quality of samples is a high priority for the SJO Biospecimen Repository. Due to the need for high quality samples and the use of appropriate sampling procedures for every aspect of the collection and dissemination process, biorepository operations have become highly complex. As a result, the biorepository community is increasingly focused on standardization and harmonization of technical and operational practices.

> Information about biospecimens is most useful when linked to relevant clinical data. As such, relevant clinical details related to the specimen and patient are recorded in a secure database linked to the specimen code.

Approaching the Right Patients

All patients who undergo a surgical procedure as part of their cancer diagnosis or therapy are considered for participation in the SJO Biospecimen Repository. The Cancer Research Department has dedicated staff and a lab technician who manages daily referrals of patients from both hospital-employed and private practice multispecialty oncologic physicians affiliated with St. Joseph Hospital. Specimens are obtained during the planned intervention, surgical procedure, and/or at the discretion of the investigator. We have accrued a substantial collection of biospecimens obtained under highly standardized conditions that include benign, diseased, and/or normal tissue. Currently the SJO Biospecimen Repository has IRB approval for the acquisition of tissue, blood, bone marrow, and urine. This approval allows for the comprehensive collection of all samples from patients diagnosed with common cancers, rare cancers, and metastases, over lengthy periods of time (if required), enabling institutional support of several types of research projects.

The SJO Biospecimen Repository acquires biospecimen samples both prospectively and retrospectively, allowing collection of neoplastic and/or normal tissue and blood alongside corresponding pertinent clinical information. For prospective sample collection, patients are asked to sign an informed consent document at the time of the planned intervention, biopsy, or surgery. The consent form is approved by the IRB in different languages (English, Spanish, Vietnamese, Korean). Additional short-form consents help address the needs of patients who are fluent in other languages. When needed, the SJO Biospecimen Repository offers access to certified interpreters, a service that is provided for all

medical needs at our hospital and is also approved by the local IRB for use during consents to research. For acquisition of archived retrospective tissue samples, the SJO Biospecimen Repository stores samples from paraffin blocks/slides and tissue in formalin. For this patient population, the local IRB has granted a consent exemption as the tissue would otherwise be discarded, per College of American Pathologists and State of California Guidelines.

It is important to note that patients approached for participation with the SJO Biospecimen Repository are already scheduled for a procedure as part of their diagnostic and/or follow-up evaluation. Only after the collected sample has met the primary intended use for the patient, can any remaining portion of that sample be allocated for use in biospecimen research. Therefore, tissue procured for the SJO Biospecimen Repository is in excess of what is required for pathology evaluation and patient care.

A 2002 study described evidence based on feedback from donors and favorable consent rates, noting that many patients who desired and could benefit from biobank donations, were in fact not offered the opportunity.[11] However, the pre-operative approach and consent paradigm has received criticism as a barrier because of its design, which may actually limit the opportunities for patients to donate to larger biobanks.[12] While the pre-operative approach is common practice, it remains important to explore alternatives for consent and sample acquisition across a broader spectrum to maximize research participation.

In our experience overall, educated staff members and an optimal workflow can improve the ease of biospecimen donation. Patients agree to donate the excess samples for research, after diagnostic or other pathology criteria are met, and do not undergo a separate procedure or office visit only for the biospecimen program. Prior research studies vary in reporting actual screening and consent rates of patients who agree to participate in biospecimen research. For SJO Biospecimen Repository prospective samples where consent is required, the agreement to donate excess samples to research is approximately 90 percent of all those approached pre-surgery. While several measures are in place to ensure the ease of donation, barriers still exist and need to be identified and addressed to further improve knowledge and education about the importance of sample use in research.

Ensuring Sample Quality at Storage & Beyond

All biospecimens are collected and stored according to standardized techniques for subsequent use. Generally, samples include adult patients between the ages of 18 to 90 who receive surgery due to 'standard of care' procedure or perhaps a clinical trial or 'study driven' procedure. Once the initial sample is obtained, the on-site pathologist assesses adequacy of the tumor and normal tissue for diagnosis and biospecimen acquisition. With the availability of standardized lab reports, the SJO Biospecimen Repository can ensure that donors are disease-free, or have a pathologically confirmed or presumed diagnosis of neoplasia or other diseases. Specimens are provided a code and stored in appropriate media and temperature conditions as required for future access. For example, samples can be either formalin-fixed and paraffin-embedded, or undergo snap freezing with liquid nitrogen or dry ice/alcohol slurry.

Information about biospecimens is most useful when linked to relevant clinical data. As such, relevant clinical details related to the specimen and patient are recorded in a secure database linked to the specimen code. Data may include demographic characteristics and complete medical history, including cancer evaluation, diagnostic tests or imaging, treatment, trial participation (if any), and outcome. Data using specimens for scientific projects requires review and approval from members affiliated with the biospecimen program, and may be submitted for IRB approval as needed on a per-project basis. This process ensures confidentiality and adheres to best practice guidelines for protection of human subjects in research.

Lawrence Wagman, MD, executive medical director; program director, Wellness Program, at St. Joseph Hospital—The Center for Cancer Prevention and Treatment.

Figure 1. Participation in the SJO Biobank

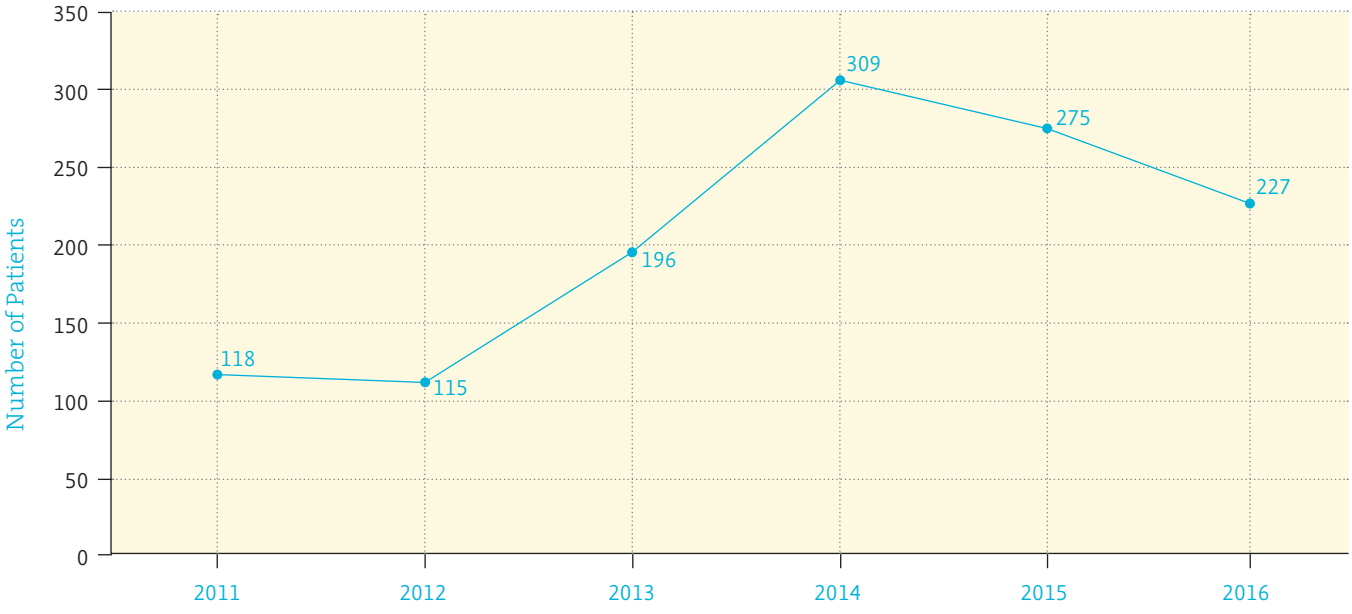

Figure 2. Age Distribution of Participants in the SJO Biobank

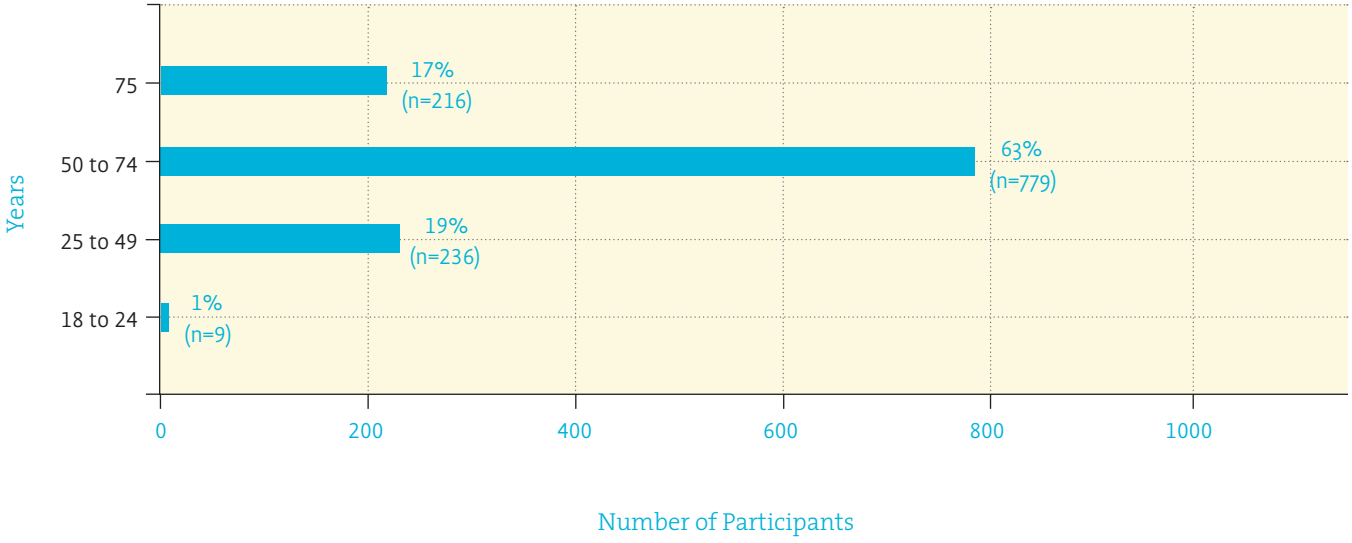

Table 1. SJO Biobank Patient Demographics		
	TOTAL (n)	PERCENTAGE
ETHNICITY		
Hispanic or Latino	118	9.5%
Not Hispanic or Latino	365	29.4%
Unknown (not reported)	757	61.1%
Total Participants	1,240	100.0%
RACE		
White	354	28.5%
Asian	46	3.7%
Black or African-American	7	0.6%
Native Hawaiian or Other Pacific Islander	6	0.5%
American Indian or Alaskan Native	3	0.2%
More Than One Race	3	0.2%
Unknown (not reported)	821	66.3%
Total Participants	1,240	100.0%

Highlights of the SJO Biospecimen Repository Samples

The Center for Cancer Prevention and Treatment sees approximately 1,500 to 2,000 cancer cases per year, with about a quarter of those individuals agreeing to participate in a research study. For example, in the year 2014 there were 1,830 cases accessioned by the cancer registry, from which 1,565 analytical cases (over 85 percent of accessioned cases) were diagnosed and/or treated at St. Joseph Hospital. In 2015 alone, approximately 25 percent of patients from analytical cases consented to one of the 48 available clinical studies across several disease sites.

The data below provide information from all samples obtained for the SJO Biospecimen Repository during a period of approximately six years from the time of IRB approval on Feb.1, 2011, through Dec. 31, 2016. Prior to this time frame, archived tissue exists, likely in the form of formalin-fixed and paraffin-embedded blocks that were routinely stored according to hospital policy for approximately ten years after completion of standard-of-care procedures. Archived tissue may be accessed for special research projects upon request and project approval. Importantly, all data presented below reflect only the sample distribution accrued specifically to the SJO Biospecimen Repository between 2011 and 2016, after the completion of any standard-of-care sample procedures related to the patient's intervention, biopsy, surgery, or pathological analyses.

The annual number of patients who consented to the SJO Biospecimen Repository each year from the start of the study in 2011 through the end of 2016 is shown in Figure 1, page 41. There is a rapid spike in patient participation in the first few years, likely due to increased recruitment efforts and knowledge about the program among physicians, staff members, and patients. There is nearly a three-fold increase in the number of consents between 2011 (n=118 patients) to 2014 (n=309 patients). Although the number of consents since 2014 has decreased, this likely represents a stabilization of the annual rate of participation over time. Overall, 1,240 unique patients consented to the SJO Biospecimen Repository during the time frame of approximately six years.

Biospecimen Patient Demographics

The SJO Biospecimen Repository acquired samples from 1,240 unique patients who were considered as potential contributors for biospecimen donation. The following are a few general characteristics of these patients. There is a disparity according to gender, with a greater number of female patients (70 percent, n=867) versus male patients (30 percent, n=373) overall. In other studies and reports, the gender gap is somewhat smaller with about 60 percent females.[6,13] Our data distribution by age is shown in Figure 2, page 41, with approximately two-thirds of patients in the range of ages 50 to 74 (63 percent), with adequate representation of patients under age 50 (20 percent), and several patients aged 75 years and up (17 percent). Interestingly, the age distribution of patients contributing to our biorepository closely matches the Mayo Clinic Biobank, which has a total of 50,000 patients. The Mayo program subjects are approximately 22 percent under age 50, about 60 percent between ages 50 to 74, and about 18 percent age 75 and up.[8]

Race and ethnicity data from the SJO Biospecimen Repository is shown in Table 1, left. While there is a fair amount of representation of minority populations, including Asian, Hispanic or Latino, and African-American individuals, it is important to note, however, that a large component of these data are currently unreported to the biospecimen program. There is an ongoing process underway to obtain ethnicity information from other existing hospital record systems.

Pictured Front Row (L to R) Martha French, RN, MSN, clinical research nurse; Viorela Pop, PhD, clinical research associate; Lavinia Dobrea, RN, MS, OCN, manager, Oncology Research & Biospecimen Program; Rachelle Alquitela, BS, clinical research associate; Virginia Trujillo Castro, RN, BSN(c), clinical research nurse. Back Row (L to R) Sonia LaBeet, executive assistant; Noah Gonzalez, biospecimen technician; Ron Bati, clinical research associate; Melinda Lima, RN, BSN, clinical research nurse.

Sample diversity remains an important factor in biospecimen research. For example, patients with a cancer diagnosis may require additional educational materials to make informed decisions about research participation and financial implications. In a recent analysis of 110 surveys from cancer research subjects, about 90 percent of participants reported being Caucasian with low representation of minority groups.[14] In the same study, more than 50 percent reported limited risk/benefit assessment of trial participation, which correlated with sociodemographic factors like increased age and lower education level.[14] When requesting biospecimen donations, a survey of more than 400 individuals identified the importance of addressing cultural factors. In a community setting during educational outreach programs to ethnic minority groups, Asian participants were more likely to agree to the donation of blood for hepatitis and liver cancer research.[13] The SJO Biospecimen Repository continues to collect a variety of information about patients that may assist in the advances of personalized treatment and therapeutic efficacy.

Biospecimen Sample Types

From the 1,240 unique patient donors, there have been patients who have the ability to donate from multiple anatomical sites and sometimes donate samples on more than one occasion. Therefore, these donors have resulted in a log of 1,364 possible unique sample collections and a total of 2,508 total samples collected as described in Table 2, below. The 2,508 total samples consist of three main category types, namely 38.7 percent blood samples (n=971), 32.5 percent tumor samples (n=814), and 28.8 percent normal samples (n=723). In many instances,

Table 2. SJO Biobank Sample Types

	TOTAL (n)	PERCENTAGE
SAMPLE TYPE		
Blood	971	38.7%
Tumor Tissue	814	32.5%
Normal Tissue	723	28.8%
Grand Total Samples	2,508	100.0%
CORRESPONDING SAMPLE COLLECTIONS (blood, tumor tissue, normal tissue)		
All three sample types available	537	39.3%
Only two sample types available	250	18.3%
Blood and tumor tissue only	70	
Blood and normal tissue only	10	
Tumor and normal tissue only	170	
Only one sample type available	397	29.1%
Blood only	354	
Tumor tissue only	37	
Normal tissue only	6	
No sample donation for research available	180	13.2%
Grand Total Collections	1,364	100.0%

Table 3. SJO Biobank Sample Availability

	TOTAL (n)	PERCENTAGE
BLOOD SAMPLES		
With additional tumor and/or normal tissue	617	63.5%
With both tumor and normal tissue	573	
With tumor tissue only	70	
WIth normal tissue only	10	
Without any additional samples available	354	36.5%
Total Blood Samples	971	100.0%
TUMOR TISSUE SAMPLES		
With additional normal tissue and/or blood	777	95.5%
With both normal tissue and blood	537	
With normal tissue only	170	
With blood only	70	
Without any additional samples available	37	4.5%
Total Tumor Tissue Samples	814	100.0%
NORMAL TISSUE SAMPLES		
With additional tumor tissue and/or blood	717	99.2%
With both tumor tissue and blood	537	
WIth tumor tissue only	170	
With blood only	10	
Without any additional samples available	6	0.8%
Total Normal Tissue Samples	723	100.0%

patients may contribute one or more sample types, depending on their cancer specification, willingness to donate, and/or tissue availability after standard-of-care procedures. As such, of the 1,364 unique sample collections available, 39.4 percent have all three sample types available for analysis, while 18.3 percent have two sample types, and 29.1 percent have only one sample type available. On occasion, logistical reasons related to patient care (e.g., insufficient sample or cancelled procedure) result in a lack of sample acquisition for the SJO Biospecimen Repository. However, such instances of missed sample collections comprise only 13.2 percent of the total sample collections consented but not acquired. Given the relatively few years of active biobanking and limitations acquiring samples using the pre-operative approach and consent paradigm, our results indicate that research participation is attainable and productive in a community setting.

Table 4. SJO Biobank Tissue Samples by Disease Site				
DISEASE SITE	BLOOD SAMPLE	TUMOR TISSUE	NORMAL TISSUE	GRAND TOTAL (n, %)
Breast	221	182	184	587 (23.4%)
Colorectal	84	85	84	253 (10.1%)
Endocrine	9	10	7	26 (1.0%)
Gastric	16	12	11	39 (1.6%)
Genitourinary	34	29	27	90 (3.6%)
Gynecologic	96	90	75	261 (10.4%)
Head and Neck	87	63	54	204 (8.1%)
Hepatobiliary	148	109	101	358 (14.3%)
Lymph Node	24	21	11	56 (2.2%)
Neuro-oncology	29	37	7	73 (2.9%)
Other	43	50	39	132 (5.3%)
Skin	4	6	6	16 (0.6%)
Thoracic	176	120	117	413 (16.5%)
Total Samples	971	814	723	2,508 (100.0%)

Samples & Their Corresponding Specimens

The data in Table 3, page 45, further evaluates the availability of individual sample types and corresponding specimens from the same collection time point. When assessing the blood samples alone, more than two-thirds (63.5 percent, 617 of 971 total) have additional normal and/or tumor tissue available alongside the blood sample. Almost all normal samples (99.2 percent, 717 of 723 total) have corresponding analytes from either a tumor site or blood sample. Most importantly, 95.5 percent (777 of 814 total) of all tumor tissue samples have either corresponding normal tissue and/or blood available for evaluation alongside the tumor specimen. Only a small 4.5 percent of tumor specimens lack corresponding samples for evaluation. This data exemplifies our ability to provide multiple sample types for each case that reaches the SJO Biospecimen Repository, therefore increasing possible research advances for individual patients.

Available Disease Sites

The data in Table 4, above, organizes all 2,508 available samples according to the type of sample and its corresponding disease site. Of all samples, the largest category is breast tissue that comprises nearly a quarter (23.4 percent) of the total samples existing in the biobank. Following breast tissue, the most abundant sample category is thoracic (16.5 percent), which is mostly composed of the lung site. Hepatobiliary (14.3 percent) samples include all liver, pancreas, and gall bladder disease sites, followed by gynecologic (10.4 percent), colorectal (10.1 percent), head and neck (8.1 percent), neuro-oncology (2.9 percent), and genitourinary (3.6 percent) cancer types. Each of the additional cancers such as endocrine, gastric, lymph node, and skin comprise less than 2 percent each of the total samples available in the biobank. The "Other" category (5.3 percent) includes any cancers in other areas such as the abdomen, pelvis, bone, or skeletal regions. The wide variety of samples available in the biobank reveals our ability to obtain a diverse set of disease sites for research purposes.

Collaborative Endeavors

Ultimately, biospecimen repositories contribute to the overall knowledge base to advance valuable insight into precision cancer care. By providing essential biologic samples, as well as comprehensive demographic and diagnostic records, the SJO Biospecimen Repository allows investigators to have access to the necessary tools for the pursuit of specific research projects. Often, successful cooperation with outside partners can benefit the larger goals in cancer research. For example, the SJO Biospecimen Repository contributed hundreds of archived tissue samples, which were collected prior to the start of the SJO Biospecimen Repository in 2011, to assist the research analyses of a third-party collaborator. In a recent study, investigators utilized the SJO Biospecimen Repository to optimize a next-generation sequencing tumor assay and showed that concurrent analysis of tumor and germline DNA improved testing accuracy and interpretation.[15]

Future Considerations

While challenges remain, they are surmountable and every sample counts and can make a difference. Next-generation science and innovative policies can be leveraged to make the best treatments available to patients. A single institution biorepository can have a consistent and effective contribution to translational science. In a pediatric tumor bank, the authors note that excellence in simple biobanking practices adequately meet the needs of major efforts with genomics that can enable the advancements expected for translational research.[4] As another group of researchers elegantly stated, "For donors, it often means having the opportunity to contribute their biospecimen and health data to drive research that can address their specific disease. For biobanks, it means access to potential donors to seek their consent to accrue biospecimens. For research users, it means finding and obtaining the right biospecimens within biobanks and navigating regulatory and oversight processes.[12]

A cancer biospecimen repository should continue to meet recommendations as outlined by the Blue Ribbon Panel in their September 2016 report to the National Cancer Advisory Board (cancerresearchideas.cancer.gov/#CancerResearchIdeasArchive). Common themes in the report included:

- Prevention and early detection
- Involvement in clinical trials
- Data sharing among centers
- Pediatric cancers
- Tumor evolution
- Standardization of biospecimens collection and processing
- Enhanced communication between the donors and biobanks
- Public engagement around biobanking.

The SJO Biospecimen Repository continues to align with these recommendations and refine processes to ensure goals are met. There is a need for quick improvement on the research front of personalized medicine. This is especially true for understanding the benefits of minimally-invasive biopsies (e.g., liquid or aspiration biopsies), the meaning of genetic differences between sample types and genetic changes over time, and the improved correlations between imaging and pathology findings of the same tissue. One example of using multiple modalities was in breast cancer patients. In a prospective analysis comparing data from core-needle biopsy identification of ductal carcinoma in situ alongside specific pre-operative features, researchers proposed an algorithm to assist in a better evaluation of risk factors during staging, diagnosis, surgery, and additional treatment planning.[16] The evolution of metastatic disease also remains a high priority, and there is a need to further explore the biological and environmental reasons for the occurrence of metastases in some tissues, while other sites are spared. For example, by collecting metastatic and non-metastatic tumor samples, liquid and normal samples, biospecimen repositories can provide resources that will generate data and knowledge for discovery. It also remains important to continue advances in the discovery of precise driver mutations, treatment targets, prognostic factors, and protective factors to improve curative therapies in oncology.

As years pass and samples accrue, it's important to prepare for changes in operational logistics and implement procedures related to biobank legacy planning.[17] The operational phases following continued sample collection, immediate and long-term use, collaborative distribution, and project completion will necessitate best practices for transfer and/or destruction of materials as samples become unusable.

There are also considerations regarding databases for local tracking and for collaborations. As translational genomic research becomes an international collaborative effort, biobanking networks have become more common.[5,12,18] One network sharing model uses a computer-based Text Information Extraction System (TIES) across several cancer centers. It allows management of biospecimen data and resources at the institutional level, and facilitates collaborations within regulatory guidelines among member institutions.[18] Computerized systems can also help track information effectively and easily, as exemplified by the iPhone interface for project management.[5]

St. Joseph Hospital is actively participating in collaborations that engage the community. With continued vigilance over all aspects of the SJO Biospecimen Repository, the biorepository remains a key step to the advancement of scientific progress and beneficial outcomes for patients and families. OI

Viorela Pop, PhD, is clinical research associate; Lavinia Dobrea, RN, MS, OCN, is manager, Oncology Research & Biospecimen

Program; Sandra Brown, MS, is manager, Cancer Genetics Program; Noah Gonzalez is biospecimen technician; Rachelle Alquitela, BS, is clinical research associate; Ron Bati is clinical research associate; Martha French, RN, MSN, is clinical research nurse; Sonia LaBeet is executive assistant, Administration & Cancer Research; Melinda Lima, RN, BSN, is clinical research nurse; Virginia Trujillo Castro, RN, BSN(c), is clinical research nurse; Nancy Walter, RN, BS, OCN, is clinical nurse; Sarah M. Barrett, BA, is manager, Pathology Operations; Aaron Sassoon, MD, is pathologist; and Lawrence D. Wagman, MD, is executive medical director; program director, Wellness Program, at St. Joseph Hospital–The Center for Cancer Prevention and Treatment, Orange, Calif.

References

1. Kehl KL, et al. Discussion about clinical trials among patients with lung and colorectal cancer. *J Natl Cancer Institute*. 2014;13:106(10).

2. Institute of Medicine (US) Forum on Drug Discovery, Development, and Translation. Transforming Clinical Research in the United States: Challenges and Opportunities: Workshop Summary. Washington (DC): National Academies Press (US); 2010. Chapter 3, Challenges in Clinical Research. Available online at : ncbi.nlm.nih.gov/books/NBK50888. Last accessed June 5, 2018.

3. Minasian LM, et al. Translating Research into Evidence-Based Practice: The National Cancer Institute Community Clinical Oncology Program. *Cancer.* 2010 October 1;116(19):4440–4449.

4. Zhou L, Catchpoole D. Spanning the genomics era: the vital role of a single institution biorepository for childhood cancer research over a decade. *Transl Pediatr.* 2015 Apr;4(2):93-106.

5. Chalfin HJ, et al. Role of biobanking in urology: a review. *BJU Int.* 2016;118(6):864-868.

6. Crawford EL, et al. Lung cancer risk test trial: study design, participant baseline characteristics, bronchoscopy safety, and establishment of a biospecimen repository. *BMC Pulmonary Medicine* 2016;16:16.

7. Newcomb LF, et al. Outcomes of active surveillance for the management of clinically localized prostate cancer in the prospective, multi-institutional Canary PASS cohort. *J Urol*. 2016;195(2):313-320.

8. Mayo Clinic. Mayo Clinic Biobank: Overview. Available online at: bioservices.mayoclinic.com/biobanks. Last accessed May 22, 2017.

9. Braun L, et al. Individual investigator profiles of biospecimen use in cancer research. *Biopreserv Biobank*. 2014;12(3):192-198.

10. Castillo-Pelayo T, et al. The importance of biobanking in cancer research. *Biopreserv Biobank*. 2015;13(3):172-177.

11. Malone T, et al. High rate of consent to bank biologic samples for future research: the Eastern Cooperative Oncology Group experience. *J Natl Cancer Inst*. 2002;94:769-771.

12. Watson PH, et al. Evolutionary concepts in biobanking–the BC BioLibrary. *J Trans Med*. 2009;7:95.

13. Gao W, et al. Culturally appropriate education intervention on biospecimen research participation among Chinese Americans. *Cancer Epidemiol Biomarkers Prev*. 2014;23(3):383–391.

14. Ulrich CM, et al. Cancer clinical trial participants' assessment of risk and benefit. *AJOB Empir Bioeth*. 2016;7(1):8-16.

15. Gray PN, et al. TumorNext: A comprehensive tumor profiling assay that incorporates high resolution copy number analysis and germline status to improve testing accuracy. *Oncotarget*. 2016;7(42):68206-68228.

16. Kurniawan ED, et al. Risk factors for invasive breast cancer when core needle biopsy shows ductal carcinoma in situ. *Arch Surg*. 2010;145(11):1098-1104.

17. Matzke LA, et al. Fundamental considerations for biobank legacy planning. *Biopreserv Biobank*. 2016;14(2):99-106.

18. Jacobson RS, et al. .A federated network for translational cancer research using clinical data and biospecimens. *Cancer Res*. 2015;75(24):5194-5201.