Carolinas HealthCare System
Levine Cancer Institute

UPDATES IN CANCER FOR CLINICIANS

WINTER 2015

System Opens Biospecimen Repository, Enhances Research Capabilities

Carol Farhangfar, PhD
Assistant Vice President of Tissue Procurement and Research

Carolinas HealthCare System has created a biospecimen repository (BSR) to collect and process blood, tissue, DNA and other samples from patients across the System, enhancing the capabilities of dedicated Carolinas HealthCare System investigators conducting clinical and translational research. The BSR will enable the evolution of Carolinas HealthCare System into a nationally recognized clinical service provider that can leverage tissues for molecular prognostication and application to personalized medicine. This "bedside-to-bench" approach will ultimately lead to a more personalized approach to treatment of cancer patients.

Biospecimens removed from patients during a procedure are processed and stored at the BSR for future analysis at the System's core or laboratory facilities or for use in collaboration with strategic partners. These biospecimens provide insight into the patient's disease and enable better care by yielding information on risk of disease, prognosis and likelihood of response to a certain treatment modality. The process for this collection is complex and varies for each disease site, sample type and facility location. An important goal for the Carolinas HealthCare System BSR is to integrate into current clinical processes seamlessly, minimizing the impact on the clinic staff while ensuring collection of high-quality samples.

The construction of the BSR facility, located at Carolinas Medical Center-Mint Hill, was completed this summer and includes numerous backups and security systems to ensure quality samples. Specimen freezers are equipped with triple-backup systems and are monitored 24/7 with multiple redundancies. A state-of-the-art information system, complete with sample barcoding and scanning, was developed to track biospecimen collection at every

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Message from the President of Levine Cancer Institute

Derek Raghavan, MD, PhD
President, Levine Cancer Institute

It is with pleasure that we present another edition of *Updates in Cancer for Clinicians*. Asim Amin, MD, and Stuart Burri, MD, have summarized research in two areas presented by Levine Cancer Institute staff at the recent Annual Scientific Meeting of the American Society of Clinical Oncology. I might also comment that our radiation oncologists, in collaboration with Southeast Radiation Oncology and our multidisciplinary oncology teams at the Institute presented data at the annual meeting of the American Society of Therapeutic Radiation Oncology, and we anticipate appearances at the Society of Surgical Oncology as well. Belinda Avalos, MD, and Jonathan Gerber, MD, have illustrated the exciting translational research that they are carrying out in leukemia.

It has been satisfying to see the synergies that have developed between our established long-term Institute staff members and the recruits from around the country – several of these presentations have represented a great deal of work by all of these investigators and clinicians. You will notice that we have recruited additional top talent from around the country. Antoinette Tan, MD, MHSc, (Rutgers/Robert Wood Johnson Cancer Institute) has joined us as division chief of Levine Cancer Institute at Carolinas Medical Center-Pineville, and as head of the Solid Tumor Oncology Breast Cancer Team–in collaboration with surgical leader Rich White, MD–Greg Pennock, MD, (MD Anderson Cancer Center) has experience in advanced melanoma and sarcoma and will be at Mallard Creek and Carolinas Medical Center-University; Laura McGirt, MD, (Vanderbilt University) a cancer dermatologist, will be in practice at the Institute's research and administrative headquarters in Charlotte; and Mary Ann Knovich, MD, (Wake Forest Cancer Center) will take a leadership role in the care of "benign" or non-cancer blood disorders. You will recall that Ify Osunkwo, MD, (Emory University) joined us to lead our adult patient sickle cell anemia program, and we have also recruited Obi Ogbata, MD, (University of Tennessee) and Hassan Ebrahim, MD, (E. Carolina University Medical School) to lead our operation at Levine Cancer Institute-Cleveland, and Ala'a Muslimani, MD, (trained at Wayne State Cancer Center) to start up our cancer team at Donayre Cancer Care Center, part of Columbus Regional Healthcare System, affiliated with Levine Cancer Institute.

While our major emphases include pathway-driven clinical practice, research and cost-effectiveness, we also prioritize quality of care. We have appointed Kim George, RN, MSN, a nationally known oncology nurse administrator, to oversee oncology nursing throughout our system, and Donna Feild, Pharm D, also with vast experience in oncology pharmacy, as the head of oncology pharmaceutics system-wide. This team will ensure that Institute sites meet all federal, state, and academic standards, and that our approach to oncology nursing and pharmacy is outstanding.

It is gratifying to see that the Institute's reputation is growing. I recently was honored to moderate a session focused on science and society for the Echo Foundation at Charlotte's McGlohan Theater alongside two Nobel Laureates in Chemistry, Peter Agre, MD, (Johns Hopkins) and Martin Chalfie, MD, (Columbia University). In addition to a stimulating discussion on advances in scientific research, we also were able to host a think tank at Levine Cancer Institute, featuring Dr. Chalfie, and attended by many community business and scientific leaders. We believe that one of our roles at the Institute should be to interface with community leaders and, thus, stimulate scientific (and sociological) thinking in our community. To that end, we were also pleased to be key participants in a recent Chamber of Commerce meeting focused on "Charlotte – An Emerging National Destination Site in Health Care."

We are honored to be adding to the fabric of Charlotte society as a medical and cancer institution, a research center, and a community-minded team – right in line with the vision we established three years ago!

Sincerely,

We welcome your feedback at LevineCancerInstitute@CarolinasHealthCare.org and look forward to bringing you more news in the future!

The Hematologic Oncology Translational (HOT) Laboratory

Belinda Avalos, MD *(right)*
Vice Chair of the Department of Hematologic Oncology and Blood Disorders

Jonathon Gerber, MD *(left)*
Director of Leukemia Program

Levine Cancer Institute, part of Carolinas HealthCare System, is proud to announce the opening of the Hematologic Oncology Translational (HOT) Laboratory. Under the direction of Belinda R. Avalos, MD, and Jonathan M. Gerber, MD, the HOT Laboratory focuses on clinically relevant research in hematologic malignancies, particularly myeloid diseases, in order to develop better prognostic tools and more effective treatments for patients with these disorders. In addition, the laboratory is investigating the influence of age, race, and ethnicity on disease biology.

Dr. Avalos, the vice chair of the Institute's Department of Hematologic Malignancies and Blood Disorders and a former professor at The Ohio State University, brings vast experience in cell signaling pathways. Dr. Gerber, the director of the leukemia program at Levine Cancer Institute and a former assistant professor at The Johns Hopkins University School of Medicine, lends expertise in leukemia stem cell biology. Additionally, the laboratory is staffed by two senior scientists: Lawrence Druhan, PhD, an accomplished molecular biologist, and Sarah Baxter, PhD, an expert in proteomics. Their efforts are further supported by three skilled, full-time technicians: Andrea Price, Amanda Patterson and Jenna Sackenheim.

The laboratory team has state-of-the-art facilities at their disposal, with extensive capability for next-generation sequencing (whole genome, exome, transcriptome, and methylome), proteomic analyses, cytokine multiplex assays, cellular immunophenotyping, fluorescence activated cell sorting, cell culture, and microscopy.

Leukemia Stem Cells

Despite aggressive treatments that induce complete remission in the majority of patients with acute myelogenous leukemia (AML), most will relapse and die of their disease, a phenomenon that is true of many cancers. The high rate of disease recurrence suggests that current therapies kill the bulk of partially differentiated leukemic cells but are less effective at killing the key precursor cells responsible for disease initiation and relapse—the leukemia stem cells (LSCs). Recently, members of the HOT Laboratory developed a method to detect LSCs and distinguish them from normal hematopoietic stem cells. This assay has proven highly prognostic, with persistence of LSCs after therapy strongly correlating with subsequent relapse (even in those patients who achieved complete remission by all existing clinical standards).

The HOT Laboratory is one of only a handful in the world with expertise in isolating LSCs. Current research efforts are focused on further characterizing LSCs at the cellular and molecular levels through analysis of the LSC transcriptome and proteome, with the goal of identifying unique features of LSCs that can be translated into clinical biomarkers and novel therapies to target LSCs (but not the normal hematopoietic stem cells). Similar studies to identify and target the stem cell origin of other malignant hematologic disorders are also underway.

Signaling Pathways in Hematopoiesis and Leukemogenesis

Many cancers, including hematologic malignancies, are characterized by abnormalities in cell survival, proliferation, and differentiation. Knowledge regarding the signaling pathways and proteins that regulate these processes remains incomplete, and the HOT Laboratory team aims to leverage its expertise in cell signaling to better understand and target the LSCs (while sparing their normal counterparts). Members of the lab previously demonstrated important roles for numerous proteins in myeloid cell survival and differentiation. Mutations in such cell signaling pathways have been shown to play pivotal roles in leukemia, and novel targeted agents to address these aberrations are becoming an increasingly important part of the clinical armamentarium. However, better therapies are still desperately needed.

The HOT Laboratory's research is conducted in close collaboration with clinical investigators at Levine Cancer Institute, helping to solve clinical mysteries and ensuring rapid clinical translation of any significant findings. To support this mission, the laboratory is actively banking patient samples for future research. At present, the HOT Laboratory is also critically involved in importing the LSC research assay into the clinical laboratory, so that it can be utilized in upcoming clinical trials for AML. The HOT Laboratory is also establishing collaborations with

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Recent Data From ASCO 2014

Asim Amin, MD, PhD *(left)*
Director of Immunotherapy

Stuart Burri, MD, PhD *(right)*
Director of Radiation Oncology Research

The 50th Annual Meeting of the American Society of Clinical Oncology was held in Chicago, from May 30 through June 3, 2014. The meeting was well-attended, with more than 34,000 participants from all over the world. While advances in all disciplines were presented, the emergence of immuno-oncology appeared to be a recurrent theme in most therapeutic areas. Carolinas HealthCare System's Levine Cancer Institute physicians were involved with several immuno-oncology studies, and the results are briefly summarized below.

- The combination of PD-1 and CTLA-4 inhibition (nivolumab plus ipilimumab) in advanced melanoma showed an impressive 2-year overall survival of 80 percent, as reported by Sznol et al.[1] Ribas et al[2] showed an overall response of 40 percent in 411 patients with advanced melanoma who were treated with PD-inhibition alone (pembrolizumab); 62 percent of the patients were alive at 18 months.
- A Phase II study of PD-1 inhibition with nivolumab monotherapy in patients with pretreated advanced renal cell carcinoma (RCC) presented by Motzer et al[3] showed a 20 percent overall response. A Phase I study of nivolumab in combination with sunitinib or pazopanib presented by Amin et al[4] showed an overall response of 52 percent and 45 percent, respectively. While the incidences of renal and hepatic adverse events were noted to be higher than observed for single agents, none of the patients treated with the combination of nivolumab and sunitinib showed an increase in tumor burden from baseline.[4] A Phase I study of the combination of PD-1 and CTLA-4 inhibition (nivolumab 3mg/kg plus ipilimumab 1mg/kg) in patients with advanced RCC reported by Hammers et al[5] showed an overall response in 43 percent of the patients. This combination and dose is now being evaluated in a Phase III trial.
- An exploratory Phase I study based on PD-1 and CTLA-4 inhibition for solid tumors (including triple negative breast cancer, pancreatic cancer, gastric cancer, and small cell lung cancer) was presented by Callahan et al[6] as a trial-in-progress. Antonia et al[7] shared the interim results from a Phase I study with the combination of PD-1 and CTLA-4 inhibition in non-small cell lung cancer (NSCLC). Gettinger et al[8] and Hamanishi et al[9] presented data for PD-1 inhibition in NSCLC and ovarian cancer, respectively.

Continuing on the theme of immunotherapy, Amin et al[10] presented the long-term survival data from a Phase II study of the combination of AGS-003 (an autologous dendritic cell–based immunotherapy) and sunitinib in unfavorable-risk patients with advanced RCC that showed median overall survival of 30.2 months; 33 percent of the patients survived for at least 4.5 years, and 24 percent of the patients survived for more than 5 years. This combination is currently being evaluated in a Phase III study.

Stuart Burri, MD, PhD, and co-investigators from the Levine Cancer Institute neuro-oncology section[11] presented data from a retrospective analysis that showed a doubling of overall survival (15.9 months versus 7.9 months; p=.108) in patients with unresectable glioblastoma that were treated with initial standard radiation therapy and temozolomide plus bevacizumab compared to those treated with standard therapy.

The potentially practice-changing studies discussed at the plenary session included data that showed exemestane and ovarian suppression to be more effective than tamoxifen and ovarian suppression for premenopausal, hormone receptor-positive women with early stage breast cancer,[12] and that the addition of docetaxel to initial hormone therapy in high-risk, hormone-sensitive prostate cancer patients improves survival over androgen deprivation therapy alone.[13]

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step of the collection and storage processes. The BSR development team has worked with leaders and team members from across Carolinas HealthCare System (eg, Office of Clinical and Translational Research, Lab Services, and Information Systems) to develop tools for consistency and ease, including creation of umbrella protocols for all disease sites to use, electronic order forms to ensure proper blood collection for the BSR at the same point in time as routine lab work, and continuing education modules to enable clinic staff to consent patients for biospecimen collection.

The BSR is already accepting specimens from 13 sites from Concord, NC, to Charleston, SC, under the BSR umbrella protocols and is supporting pharmaceutical trials and novel Carolinas HealthCare System's Levine Cancer Institute investigator-initiated studies with correlative samples for translational research related to the trial treatment. This collection is a team effort that has been enabled with cooperation and support from the lab, clinic, pathology, radiology, surgery staff and physicians. While recent new hires present the unique opportunity to further this effort, significant credit is due to the investigators at Carolinas HealthCare System who forged ahead creating disease-site repositories prior to an institution-wide effort, and especially to Jeffrey Kneisl, MD, who helped pave the way, setting the culture for obtaining fresh specimens during surgery. Collection of specimens on the scale planned for the Carolinas HealthCare System BSR has not been done previously in the community-based setting and is in perfect alignment with Carolinas HealthCare System's mission and Levine Cancer Institute's goal to bring the same high level of care and research to all System facilities.

The Hematologic Oncology Translational (HOT) Laboratory

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physicians at Carolinas HealthCare System's Levine Children's Hospital, focusing on pediatric leukemia and hematopoietic stem cell transplantation.

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New Physicians at Levine Cancer Institute

Carolinas HealthCare System's Levine Cancer Institute continues to grow, and nine new physicians have joined our team.

Manisha Bhutani, MD *Medical Oncology*

Dr. Bhutani has done extensive clinical research on multiple myeloma. Dr. Bhutani did her postdoctoral fellowship at MD Anderson Cancer Center and completed her fellowship in medical oncology at the National Institutes of Health. Her translational research and clinical interests include novel therapeutics, imaging, and immunologic manipulation in smoldering myeloma, multiple myeloma and other plasma cell disorders.

Hassan M. Ebrahim, MD *Medical Oncology*

Dr. Ebrahim's clinical interests include breast, gastrointestinal and gynecological cancers, and blood disorders. He completed his fellowship in hematology and medical oncology at Howard University and came to Levine Cancer Institute from East Carolina University, Brody School of Medicine, where he was an attending physician. His previous research has included work in breast cancer and lymphomas.

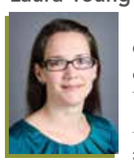
Mary Ann Knovich, MD *Director of Bleeding Disorders, Department of Hematologic Oncology and Blood Disorders*

Dr. Knovich is a board-certified hematologist who focuses on non-malignant and consultative hematology. She specializes in the care of patients with bleeding and coagulation disorders, particularly hemophilia and von Willebrand disease, thrombosis, and platelet disorders, such as thrombotic thrombocytopenic purpura. She came to Levine Cancer Institute from Wake Forest School of Medicine, where she was the medical director of the Comprehensive Hemophilia Diagnostic & Treatment Center and the adult sickle cell program for many years.

Brinda Koya, MD *Medical Oncology*

Dr. Koya's clinical interests include lung, breast and gastrointestinal cancers, as well as chronic leukemias. Prior to joining Levine Cancer Institute, she was a fellow in hematology and oncology at Kansas University Medical Center. She is an associate member of the American College of Physicians, American Society of Hematology and American Society of Clinical Oncology.

Laura Young McGirt, MD *Director of Dermatologic Oncology*

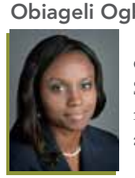


Dr. McGirt earned her medical degree at Duke University School of Medicine and completed her dermatology residency and a fellowship in immunology research at The Johns Hopkins University School of Medicine. Prior to joining the Institute, Dr. McGirt worked as an assistant professor of dermatology at Vanderbilt University School of Medicine. Dr. McGirt is a member of Alpha Omega Alpha, the American Academy of Dermatology, the United States Cutaneous Lymphoma Consortium, the Dermatology Foundation and the Society for Investigative Dermatology. Her clinical and research interests include cutaneous oncology (with a special focus on cutaneous lymphoma), as well as cutaneous reactions to chemotherapy and cutaneous graft-versus-host disease.

Ala'a Muslimani, MD *Medical Oncology*

Dr. Muslimani completed his fellowship in hematology and oncology at the Oakland University Beaumont Medical School in Royal Oak, MI, and came to Levine Cancer Institute from the Billings Clinic in Billings, Montana. Dr. Muslimani is a member of the American College of Physicians, the American Association of Clinical Oncology and the American Society of Hematology.

Obiageli Ogbata, MD *Medical Oncology*



Dr. Ogbata's clinical interests in genitourinary malignancies and breast, head, and neck cancers. She came to Levine Cancer Institute from the University of Tennessee, where she completed her fellowship. She is the recipient of a National Merit Award from the American Society of Clinical Oncology for her research in lung cancer and is a member of the International Association for the Study of Lung Cancer, among other organizations.

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Gregory Pennock, MD *Medical Oncology*

Dr. Pennock joined Levine Cancer Institute in May 2014. He previously served as the section leader for melanoma and sarcoma oncology at UF Health Cancer Center at Orlando Health. Additionally, he was medical director in the Office of Clinical Trials. At the Institute, he will continue to focus on the care of patients with advanced melanoma and sarcoma. He is a graduate of the University of Texas Medical Branch and completed hematology/oncology training at the University of Pittsburgh School of Medicine.

Antoinette R. Tan, MD, MHSc *Chief of Breast Medical Oncology, Chief of Medical Oncology-Pineville, Co-Director, Phase I Program*

Dr. Tan most recently served as director of Phase I and investigational therapeutics and as an associate professor of medicine at Rutgers Cancer Institute of New Jersey. Her research is focused on the development of novel therapeutics for breast cancer. She has extensive experience in the conduct of early phase clinical trials and breast cancer studies. She was a 2012 recipient of the National Cancer Institute Cancer Clinical Investigator Team Leadership Award. Dr. Tan has also served on several American Society of Clinical Oncology (ASCO) committees, including as chair of the ASCO Cancer Education Committee from 2012-2013.

Dr. Tan earned her medical degree from Robert Wood Johnson Medical School. She completed an internal medicine residency at North Shore University Hospital-New York University School of Medicine. She completed her fellowship in medical oncology at the National Cancer Institute. She also obtained a master of health sciences degree from Duke University School of Medicine.

Expansion of Pharmacy Care

Donna Feild, RPh, MBA
Director of Pharmacy

By June of 2015, Carolinas HealthCare System's Levine Cancer Institute plans to add additional staff to its care teams at all locations. Pharmacists will be available to perform a variety of duties, including provision of drug information, patient counseling, and dose and product checking. They will also be managing drug protocols and developing order sets that will be used in the upcoming computerized physician order entry implementation. Pharmacists will routinely screen patients' drug profiles to check for potential drug interactions. Pharmacy technicians will be available to order drugs, mix intravenous drugs, help with patient assistance programs, help manage inventory, and help manage drug shortages.

In this same timeframe, Levine Cancer Institute facilities that deliver infusion services will be undergoing renovations. In order to make each site meet the requirements of both the U.S. Pharmacopeial Convention (USP) 797, as well as the upcoming USP 800 regulations, Carolinas HealthCare System has created three prototypes of cleanroom environments. These prototypes are sized according to the volume of infusions that are compounded. Two of the prototypes are designed with both negative and positive pressure buffer cleanrooms, an anteroom, and a work area. The third prototype, designed for lower volume sites, places a glove box in the anteroom to eliminate the need for a positive pressure buffer room. All three prototypes will help to ensure the overall quality and sterility of all compounded medications and, equally important, will keep Institute staff safe from exposure to hazardous agents.

One of the most exciting aspects of this project is the standardization of pharmacy work space and processes. Pharmacy technicians will be able to move between Levine Cancer Institute sites, as the need arises, with little variation in the setup of the physical space or workflow. All doses will be double-checked by two pharmacists, a process enabled by the use of virtual technology and audiovisual technology. Much like the clinical treatment pathways that have been developed to help ensure consistent, quality patient care across Institute facilities, compounding procedures will be standardized at all Levine Cancer Institute facilities. The Institute is leading the way in meeting new USP standards and providing excellent pharmaceutical care–right where our patients live.

Levine Cancer Institute Wins Top Performance Award for Clinical Research

Carolinas HealthCare System's Levine Cancer Institute recently received a Top Performance award by Forte Research Systems for the organization's excellence in clinical research. The award was given to three sites that demonstrated exceptional research operations as measured through Forte's Research Resonance Network (RRN). Members of RRN report metrics and benchmark these against anonymized data provided by other RRN organizations.

To determine the award winners, Forte combined metrics across all categories–including IRB Cycle Time, PRMC Cycle Time, and Open-to-Accrual-to-First-Patient-In Cycle Time–and scored each facility by comparing its percentile rankings to similar organizations. The two other Top Performance winners were Indiana University Simon Cancer Center and Iowa University Holden Comprehensive Cancer Center. A Most Improved award was given to Karmanos Cancer Institute.

According to Levine Cancer Institute's Assistant Vice President of Clinical Trials, Mark King, the Top Performance award is particularly exciting given the vast Institute network. "Because our unique approach to decentralizing cancer care requires us to implement trials across multiple locations and across a large region, to be recognized for our efficient clinical research operations is a special accomplishment," he said. "Our ability to rapidly review, implement, benchmark and adjust our processes is particularly valuable in our clinical trial initiation process, which is among the swiftest in the nation and helps us deliver care of the highest quality."

Recent Data From ASCO 2014

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