

The Innovator

Baystate  Health



Spring 2019

Lung-MAP study explores alternative therapies for cancer treatment



John McCann, MD, Baystate Principal Investigator for the Eastern Cooperative Oncology Group (ECOG)

With cancer therapy advancing rapidly, having cancer trials at Baystate allows our standard of cancer care to stay state-of-the-art. There are nearly 30 active clinical trials for cancer at Baystate, which is part of an interconnected network of cancer researchers across our region, the country, and the world. Lung cancer, the most common type of advanced cancer, relies heavily on clinical trials help to discover more effective and less toxic treatments.

One of the latest lung cancer trials, the Lung-MAP study, is an innovative protocol to evaluate biomarker-driven therapies and immunotherapies in previously

treated non-small cell lung cancer. Like the name of the trial suggests, Lung-MAP evaluates a patient's cancer molecular profile and provides a "map" of the molecular changes that may be targets for new treatments. This trial offers an opportunity to investigate treatment regimens to determine a new standard of care. Lung-MAP is considered an "umbrella trial": an interconnected network of trials subdivided by medication/treatment type. Depending on which branch of lung cancer the patient falls under, a specific medication or combination of medications/therapies is prescribed. One of the treatment options under this umbrella is immunotherapy.

"Immunotherapy has been a great advance in cancer research, and it's very exciting," says John McCann, MD, Baystate Principal Investigator for the Eastern Cooperative Oncology Group (ECOG). "With certain types of lung cancer, we are able to skip chemo entirely and go straight to immunotherapy." Both chemotherapy and immunotherapy are administered intravenously. Chemotherapy targets and damages a cancer cell's ability to multiply, which can have adverse effects on normal cells and cause side effects. On the contrary,



The D'Amour Center for Cancer Care at 3350 Main Street in Springfield, MA, where this and many other cancer trials take place.

immunotherapy does not affect the cancer cell directly and has fewer side effects. Instead, it tells the body's own immune cells to identify the cancer cells as harmful and attack them, like if you had an infection. Molecular targeting is also a treatment option, using medications that target the molecular changes in cancer cells. Driver mutations control the activity of the cancer and drugs that attack the driver mutation can slow the multiplication of the cells. Since not all cancer cells are the same, "it is becoming mandatory to see what molecular/cellular profiles exist within the cancer cells," Dr. McCann says. "Molecular abnormalities can be targets for new types of treatment." The Lung-MAP trial allows

the research team to obtain a detailed molecular profile by sending a patient's pathology specimen out for analysis. If a molecular driver is identified, the patient may be able to receive a new investigation therapy at Baystate. This capability allows the patient to have cutting-edge treatment close to home.

"It's very rewarding for the patients as well as the investigators," adds Dr. McCann. "Through these clinical trials, patients get to have access to medications they wouldn't normally have access to."

For more information about the Lung-MAP study and other cancer trials, contact Katie Colbeck, CCRP at (413) 794-9875 or visit baystatehealth.org/patients/learn-about-clinical-trials.

Engaging Springfield students in research

With a grant from the National Institute of Environmental Health Sciences (NIEHS), Baystate investigator Sallie Schneider, PhD and her team will be able to bring hands-on research experience to students in Springfield's middle and high schools. As part of the National Institutes of Health (NIH), NIEHS supports a research grant at Baystate that studies how environmental exposures affect growth and development of breast cancer. One goal of the grant focuses on community involvement, aiming to promote education among local students. To that end, she is collaborating with Ron St. Armand, Director of Science in the Springfield Public School System (SPSS) and Peter Blain, BSEP, to devise a city-wide research project to study exposures to chemicals that act like estrogen during puberty and their effects on changes in the breast, as well as other organs. SPSS received a Massachusetts Life Science grant to purchase equipment, supplies and to develop a professional



Sallie Schneider, PhD

development course aimed at supporting this community initiative.

This summer, Dr. Schneider will begin educating Springfield high school science teachers in a professional development course to prepare them for the upcoming school year. She will help teachers to incorporate research into their current biology curriculum and develop

critical thinking ability. In the fall she will provide reagents so that each student can analyze a small aspect of the study. The goal will be to combine the analyses performed across the schools and classrooms to have a better perspective of changes that occur when exposed to chemicals during critical periods. Dr. Schneider hopes the students feel excited or empowered by contributing to a research study, but more importantly that they have a new understanding for how various chemicals in the environment can impact their health. The school has suggested four strategic priorities that will ensure that effective instruction occurs in every class and that there are shared expectations for all students. These priorities include:

- Coaching, developing and evaluating educators based on a clear vision of strong instruction
- Implementing a consistent, rigorous curriculum built on common standards with common

unit assessments

- Deploying data that is timely, accurate and accessible to make decisions for students, schools and the district
- Strengthening social, emotional and academic safety nets and supports for all students and families

"This is a fantastic collaboration between Baystate and the Springfield schools," says Dr. Schneider. "We are investing time to involve students in research in hopes that the real life experience will help them to get excited about science and increase awareness." It is Dr. Schneider's hope that AP students will eventually visit the Baystate Research labs to do simple stains of cells and learn more about hands-on biomedical research themselves.

"We are excited to see what will come out of this grant," she concludes. "It's a collaboration that our research department hasn't gotten to do before."



Select Recent Awards

EILEAN ATTWOOD, MD

Supportive Pregnancy Care, ObGyn/ March of Dimes

NORMAN DESCHAINE

2019 Ryan White, HIV/AIDS/Holyoke Health Center, Inc./HRSA; 2019 Connecticut River Valley Farmworker Health Program, Community Health Centers/MA League Community Health Centers/HRSA

ROSA FELDMAN

Baystate Noble Opioid Treatment and Prevention Program, MA Dept. of Public Health

ASHEQUL ISLAM, MD

Assessment of the CARILLON Mitral Contour System in Treating Functional Mitral Regurgitation Associated with Heart Failure The CARILLON Trial, Cardiology/ Cardiac Dimensions, Inc.

TARA LAGU, MD

Improving Access to Care for Patients with Lower Limb Mobility Impairment, HCQ/Baystate Health, Inc./RPAP

PETER LINDENAUER, MD

SHIFT-CARE Challenge Health Homes BMC, HCQ/ACO/Health Policy Commission

QUINN PACK, MD

Exercise Prescription in Cardiac Rehabilitation: A Pilot Randomized Controlled Trial, HCQ/RPAP/Baystate Health, Inc.

VICTOR PINTO-PLATA, MD

Study of Pulmonary Rehabilitation In Nintedanib Treated Patients with IPF:Improvements in Activity, Exercise Endurance Time, and QoL, Critical Care/ Boehringer Ingelheim Pharm

SALLIE SCHNEIDER, PHD

Studying EDC exposure on macrophage function and ER negative breast cancer progression, PVLSI/University of Wisconsin/Nat. Institutes of Health (NIH)

CHANDRIKA SRIDHARAMURTHY, MD

Collaborative Care for Kids (CATCH Grant), Pediatrics/American Academy of Pediatrics

JAY STEINGRUB, MD

VICTAS - Vitamin C, Thiamine and Steroids in Sepsis, Critical Care/Johns Hopkins University/Marcus Foundation; HostDx Sepsis in the Diagnosis and Prognosis of Emergency Department Patients with Acute Respiratory Infections: a Multicenter Pilot Study, Critical Care/ Inflammix, Inc.

MARK TIDSWELL, MD

Pilot study of non-invasive ventilatory support for acute hypoxemic respiratory failure: High flow nasal cannula vs. Helmet vs. Mask, Critical Care/Baystate Health, Inc./RPAP

New Faces of Research



Maria Valdez, BS
Research Assistant I
Clinical Trials Office



Kamal Faridi
Biostatistician
IHDPs



Vicky MacLeod, BA
Research Assistant I
Clinical Trials Office



Ali Griffin, BSN
Clinical Research
Regulatory Specialist
Clinical Trials Office



Paula Pelletier, MS, RN
Clinical Research
Nurse Coordinator
Clinical Trials Office

"CAMERA SHY":
Jennifer Blanquart
Clinical Research
Coordinator I
Baystate Regional
Cancer Program

Camron Clark
Clinical Research
Coordinator I
Baystate Regional
Cancer Program

Infectious diseases clinical research with Dr. Daniel Skiest

The field of Infectious Diseases (ID) is one of several subspecialties of Internal Medicine. It differs from other fields in Internal Medicine, such as cardiology, pulmonary, nephrology etc., which primarily focus on a single organ system. Since microbes (including bacteria, viruses, fungi, parasites) can affect a single organ (for example pneumonia) or the entire body (systemic infection), such as bacterial sepsis or HIV, ID doctors need to be have knowledge of the whole body. They interact with nearly all medical specialties and a treat a wide spectrum of patients.

Since new types of infections are continuously being discovered, ID doctors need to constantly stay up to date. In only the last few years, numerous infections have been either discovered or have affected new populations or new clinical manifestations. West Nile virus, SARS, bird flu, Middle East Respiratory Syndrome (MERS), Zika virus, Chikungunya fever, are only a few of these. The clinical manifestations and treatment of newly discovered infections, as well as the ability of most bacteria and viruses to develop resistance to medications, creates a continuous need for both laboratory and clinical researchers. New treatments



Daniel Skiest, MD, FACP, FIDSA

need to be evaluated in several phases of clinical trials and often require the inclusion of several thousand patients prior to approval for the general public.

"It seems that every time we are about to catch up, the microbes seem to get ahead," says Dr. Daniel Skiest, Director of ID Clinical Research and the Adult HIV/AIDS Program at Baystate Health and Vice Chair for Academic Affairs in the Department of Medicine. "Research will always be an important aspect of ID."

Dr. Skiest gained experience in HIV clinical trials as a faculty member of University of Texas Southwestern Medical Center.

"Our HIV clinic cared for 3,500 patients and we were able to enroll many patients in novel and ultimately lifesaving treatments for HIV in the mid to late 1990s and the early 2000s," he says. Shortly after being recruited to Baystate in 2005, Dr. Skiest started the ID trials unit. To date, Dr. Skiest and his team have enrolled over 300 individuals in clinical studies, mostly in HIV, but also influenza, pneumonia and hepatitis C.

One trial in progress, the REPRIEVE trial, has recruited 7,500 participants from over 100 sites across the globe. Thirty of these participants are enrolled at Baystate. REPRIEVE is the largest study ever involving HIV-infected individuals and is sponsored by the NIH (National Institutes of Health). This study will evaluate whether the use of a statin medication will prevent vascular events (heart attacks, strokes) in patients with HIV between 40-75 years old and without known heart disease. The study is important since individuals living with HIV are 50-100% more likely to develop heart disease than people without HIV.

Another ongoing study, The Respiratory Virus Hospitalization Study (FLU 003), an international observational study, aims to better characterize the

manifestations and complications of influenza. It includes adults hospitalized with influenza and other flu-like illness. Since it began eight years ago Baystate has enrolled over 130 individuals. Participants must be 18 years or older and have been admitted to the hospital for influenza or a targeted non-influenza viral respiratory infection.

Other ongoing studies are a study of novel 2 drug regimen for treatment of HIV (GEMINI), a study of novel 3 drug combination treatment for HIV (Gilead-1489) and the Cooperative Re-Engagement Controlled Trial (CoRECT, sponsored by the CDC), which seeks to improve outcomes for HIV-infected individuals who are not in care.

The research team includes Dr. Armando Paez, Dr. Durane Walker, and Caroline Hinojosa (regulatory specialist), Mary Lee Bertrand, RN (study coordinator), Victoria Cobb (study coordinator), and Maribella Gonzalez (research assistant). They are located at 3300 Main Street, which is also the location of the main ID clinic.

"It's exciting and gratifying to be able to play a role in bringing new treatments to our patients," concludes Dr. Skiest.

For questions and more information about these and other ID trials, call (413) 794-5376.

Notable Recent Published Papers

Contact Baystate's Health Science Library for more information at libraryinfo.bhs.org/home

Andrews CM, Abraham AJ, Grogan CM, Westlake MA, Pollack HA, **Friedmann PD**. Impact of Medicaid Restrictions on Availability of Buprenorphine in Addiction Treatment Programs. *Am J Public Health*. 2019 Mar;109(3):434-436.

Keteyian SJ, Ehrman JK, Fuller B, **Pack QR**. Exercise Testing and Exercise Rehabilitation for Patients With Atrial Fibrillation. *J Cardiopulm Rehabil Prev*. 2019 Mar;39(2):65-72.

Coute RA, Nathanson BH, Panchal AR, Kurz MC, Haas NL, McNally B, Neumar RW, **Mader TJ**. Disability-Adjusted Life Years Following Adult Out-of-Hospital Cardiac Arrest in the United States. *Circ Cardiovasc Qual Outcomes*. 2019 Mar;12(3):e004677

Adamidis A, **Cantas-Orsdemir S**, **Tsirka A**, **Abbott MA**, **Visintainer P**, **Tonyushkina K**. Apparent Mineralocorticoid Excess in the Pediatric Population: Report of a Novel Pathogenic Variant of the 11 β -HSD2 Gene and Systematic Review of the Literature. *Pediatr Endocrinol Rev*. 2019 Mar;16(3):335-358.

Lagu T, Norton CM, Russo LM, **Priya A**, **Goff SL**, **Lindenaue PK**. Reporting of Patient Experience Data on Health Systems' Websites and Commercial Physician-Rating Websites: Mixed-Methods Analysis. *J Med Internet Res*. 2019 Mar 27;21(3):e12007.

Singh R, Douglass LM, O'Shea TM, Stafstrom CE, Allred EN, Engelke S, **Shah B**, Leviton A, Hereen TC, Kuban

KCK; **ELGAN Study Group**. Antecedents of epilepsy and seizures among children born at extremely low gestational age. *J Perinatol*. 2019 Mar 27.

Attaar A, Luketich JD, Schuchert MJ, Winger DG, Sarkaria IS, **Nason KS**. Prolonged Air Leak After Pulmonary Resection Increases Risk of Noncardiac Complications, Readmission, and Delayed Hospital Discharge: A Propensity Score-adjusted Analysis. *Ann Surg*. 2019 Feb 15.

Soares WE 3rd, **Wilson D**, Gordon MS, Lee JD, Nunes EV, O'Brien CP, Shroff M, **Friedmann PD**. Incidence of future arrests in adults involved in the criminal justice system with opioid use disorder receiving extended release naltrexone compared to treatment as

usual. *Drug Alcohol Depend*. 2019 Jan 1;194:482-486.

Pack QR, **Priya A**, **Lagu T**, **Pekow PS**, Berry R, Atreya AR, Ades PA, **Lindenaue PK**. Cardiac Rehabilitation Utilization During an Acute Cardiac Hospitalization: A NATIONAL SAMPLE. *J Cardiopulm Rehabil Prev*. 2019 Jan;39(1):19-26.

Walkey AJ, Shieh MS, Pekow P, Lagu T, Lindenaue PK. Changing heart failure coding practices and hospital risk-standardized mortality rates. *J Card Fail*. 2019 Jan 7.

Soares WE 3rd, Price LL, Prast B, Tarbox E, **Mader TJ**, **Blanchard R**. Accuracy Screening for ST Elevation Myocardial Infarction in a Task-switching Simulation. *West J Emerg Med*. 2019 Jan;20(1):177-184.

Aloia TA, Jackson T, Ghaferi A, Dort J, Schwarz E, **Romanelli J**. Developing minimally invasive procedure quality metrics: one step at a time. *Surg Endosc*. 2019 Jan 22.

Sharma SK, Bolduan RW, Patel MR, Martinsen BJ, Azemi T, **Giugliano G**, Resar JR, Mehran R, Cohen DJ, Popma JJ, Waksman R. Impact of calcification on percutaneous coronary intervention: MACE-Trial 1-year results. *Catheter Cardiovasc Interv*. 2019 Jan 25.

Vaidya R, **Wilson D**, **Paris Y**, **Madore L**, **Singh R**. Use of acetaminophen for patent ductus arteriosus treatment: a single center experience. *J Matern Fetal Neonatal Med*. 2019 Jan 28:1-7.

Common Rule implements first changes since 1991

The Common Rule is a framework for federally funded research studies in the United States that ensures ethical standards and protects human participants in clinical research. As of January 20, 2019, the Common Rule implemented new changes for the first time since its inception. This long-overdue change is much-needed, considering the scientific and technologic advancements since the early 1990s. Any project already approved under previous rule prior to January 2019 will remain as such.

Changes to the Common Rule as of January 2019 include:

- Revised, comprehensive consent forms

- Fewer details required annually for smaller, less-risky studies
- Any multi-site studies will be housed under a single IRB (January 2020)

Although the Common Rule changes are finally implemented, direction is still needed.

“How we go about handling the changes in Common Rule will be tricky,” explains Jennifer Pacheco, Director of Healthcare Research Compliance and Chief Research Compliance Officer at Baystate Health. “There is no federal guidance or ‘rule book’ yet and that is the biggest challenge. Until we are issued the federal guidelines document, we are unsure if our interpretation will be the same as other

institutions.” Since there is more documentation and precision in the new rule, it doesn’t reduce the administrative burden as hoped. Fortunately, the Common Rule will continue to change, with a new minimum revision period of every four years. This will introduce more frequent opportunities for growth and development of the rules already in place.

“This means that our research community needs to be open to change from time to time,” adds Pacheco. Overall, Pacheco supports the majority of the changes. She suggests keeping an ear open for various educational series presented by the Baystate IRB/HRPP



Jennifer Pacheco, MPH, CIM, CIP

throughout the year. If you’d like to learn more about the IRB/HRPP, visit baystatehealth.org/education-research/research-for-researchers.

Holiday celebration held in January

The Office of Research held their annual holiday gathering at the Munich Haus in Chicopee on January 24, 2019.



(L-R) Vida Rastegar, Aixa Perez-Carabello, Adele Miller, Judith Pride, RN, MSHS, CCRP, CCRP, CIP, Katherine Colbeck, CCRP, Laura Sorci, and Bella Gonzalez



(L-R) Alexander Knee, Randall Hoskinson Jr., Nicholas Jabbour, MD, Peter Friedmann, MD, MPH, DFASAM, FACP, Sue Decelle, Marc Labrie, Susan Garrow-Sloan, RN, CCRP



(L-R) Catherine McDougal, CCRP, CIP, Roxanne Labonte, Alexa Lopez, Marcia Winseck, Rebecca Greene, CPIA, Paul Visintainer, PhD, Joe Jerry, PhD

Research & Education Celebration

May 15, 2019 • 8 AM - 6 PM • Chestnut Conference Center

WORKSHOPS:

- Visualizing Complexity In Medical Training & Care
- Research Mentorship For Faculty: A Panel Discussion
- One Scholarly Approach, Many Educational Innovations
- Qualitative Data Analysis 101
- Generating Rigorous Qualitative Insights
- Strategies For Writing Up Your Educational Innovations: A Workshop To Get You Started
- Research On The Cheap
- Building Sustainability In Times Of Uncertainty
- How To Be An Efficient Site Investigator

POSTER VIEWING/SESSION • AWARD CEREMONY



FEATURED PRESENTER:

Kori LaDonna, PhD

Department of Innovation in Medical Education, University of Ottawa

For more information/full schedule call 413-794-3391 or visit baystatehealth.org/REC

The Innovator travels to Orlando



Carolanne Lovewell, RLATG, CPIA, Director of the Baystate Research Facility and Pioneer Valley Life Sciences Institute, takes a break to read the last issue of *The Innovator* with Minnie Mouse during a recent trip to Walt Disney World.

The **Innovator** Baystate Health

We are interested in ensuring that Baystate employees and patients (and their families) are aware of the important research that goes on at Baystate and how it contributes to better patient care. *The Innovator* welcomes feedback and story ideas. Contact Allison Litera at allison.litera@baystatehealth.org to submit yours.