


The Innovator

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Critical Care Research at Baystate Health

Mark A. Tidswell, Associate Professor of Medicine, UMass Chan-Baystate

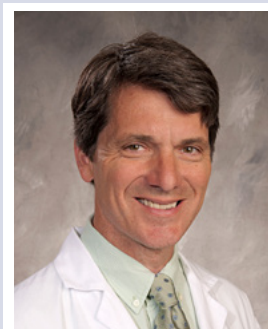
Over the past 50 years, the critical care research program became highly productive, nationally recognized, and financially viable, with over 300 publications and more than \$25 million in contracts. Academic and research productivity in the critical care division (now pulmonary and critical care) was long a priority. It started in 1973 with Dr. Daniel Teres, the first chief of a new medical-surgical ICU program. The National Center for Health Services funded him to develop a

severity of illness scoring system for ICU patients. Dr. Jay S. Steingrub joined Baystate in 1982 and became increasingly involved in running clinical trials. Dr. Thomas L. Higgins (Division Chief from 1995-2010) came from Cleveland Clinic, where he had already conducted clinical trials, created scoring systems for cardiac surgery outcomes, and authored numerous publications. Dr. Victor Pinto-Plata (Division Chief from 2015-2021) brought COPD studies from Brigham

and Women's Hospital to develop outpatient research.

Critical care research at Baystate received a boost in 1996 when Dr. Martin Broder (Department of Medicine Chairman) provided short-term support to Dr. Steingrub to bring on more clinical trials and establish a critical care clinical research program (CCRP). Dr. Steingrub hired a research assistant and a research coordinator and re-purposed a storage room for an office. The program also carried

out studies led by Dr. Higgins, Dr. William T. McGee, and surgeons Dr. Laurie Loiacono and Dr. Patrick Lee. The program achieved national attention when Dr. Steingrub co-authored a major sepsis study in the *New England Journal of Medicine*. As a result, colleagues at Vanderbilt University and UCSF encouraged us in 1999 to join the NHLBI ARDS network—10 university hospitals testing treatments for acute respiratory distress syndrome (ARDS), a



Mark A. Tidswell, MD

common ICU problem.

When I joined the division in 1999, I brought grant writing expertise from years of bench research at UCSF and the

(continued on page 2)

Growing Cardiovascular Clinical Research at Baystate Health



Andrew M. Goldsweig, MD, MS, FACC, FSCAI, FSVM, RPVI

Dr. Andrew M. Goldsweig Joins Baystate

Andrew M. Goldsweig, MD, MS, FACC, FSCAI,

FSVM, RPVI, joined the Baystate team in January 2023 as Director of the Cardiac Catheterization Laboratory and Director of Cardiovascular Clinical Research. He previously directed the Structural Heart Disease Program and Interventional Cardiology Clinical Research at the University of Nebraska Medical Center, where he also earned an MS degree in clinical research. After undergraduate studies at MIT and medical

school at NYU, he trained in cardiology and interventional cardiology at Yale and structural heart disease at Brown. His clinical work includes left atrial appendage occlusion (LAAO) to prevent stroke in atrial fibrillation without anticoagulation, septal defect and patent foramen ovale (PFO) closure, and valvular and coronary interventions. He is the chair of the Society for Cardiovascular Angiography and

Interventions (SCAI) Structural Heart Disease Council, an Associate Editor of the *Journal of SCAI (JSCAI)*, and an editorial board member for four other cardiology journals. He lives in West Hartford, CT, with his wife, Dr. Bracha Goldsweig, a Baystate pediatric endocrinologist, and their two children.

Cardiovascular Clinical Trials

Dr. Goldsweig is very excited to help grow

clinical trial infrastructure and productivity in the Baystate Heart & Vascular Center, working with research coordinator Christine Callahan, MS, RN, and Jay Gutta of the Baystate Clinical Trials Office. In cardiology, Dr. Ashequl Islam will lead Baystate enrollment in the EXPAND TAVR II trial of transcatheter aortic valve replacement (TAVR) for patients with moderate aortic stenosis. Dr. Goldsweig

(continued on page 3)

(continued from page 1)

Baystate clinical trial experience to create a successful application for the ARDS network. With this core funding, the CCRP became self-supporting. Participation in this NHLBI network also connected us to university researchers and more funded collaborations.

The CCRP is recognized for its ability to recruit subjects, design trials, and high-profile author publications. It is unusual for a non-university hospital to have a research program that is so well organized and successful. Dr. Steingrub's leadership is a significant factor. Other key elements for success are identifying opportunities for collaboration, motivation, and expertise. Dr. Steingrub and Dr. Tidswell studied sepsis and ARDS. Dr. Higgins revised a mortality prediction model and defined ICU outcome measures. Dr.

McGee developed the concept of functional hemodynamics to direct fluid resuscitation in ICU patients. Dr. Patrick Mailloux's work on medications for the control of delirium led to a NEJM publication. Dr. Mary Jo Farmer brought studies of therapeutics for pulmonary hypertension. Lori-Ann Kozikowski, RN, joined the group in 2000 and was soon asked by the NHLBI to serve as lead clinical coordinator for the entire network. Many other Baystate staff, such as Gerald Korona PharmD, who ran the investigational pharmacy, contributed to our success. The CCRP gained funding again as an ARDS network site (2004-2012) and then as a NHLBI PETAL network funding (2012-2023; PETAL=Prevention and Early Treatment of Acute Lung injury). As a result, the research program supported itself for many years.

The pandemic surge in 2020

stopped all usual research, but COVID-19 research opportunities appeared. With our ARDS, sepsis, and clinical research expertise, we enrolled over a thousand patients in multiple COVID-19 studies. Our staff went the extra mile (and beyond!) to enroll in projects supported by NHLBI, NIAID, the Centers for Disease Control (CDC), and pharmaceutical companies. Our office is still busy with COVID trials even as we resume research in sepsis and ARDS. Current staff is Lesley DeSouza, who started with us in 1996; Scott Ouellette, who has collected thousands of samples from patients; Cynthia Kardos, RN, who brings many years of coordinator experience; Sarah Romain, RN, and PhD candidate, Denise Gallant, RN, Serena Estrada, and Rae Lynn DeFeo. During the pandemic, Dr. Steingrub expanded his role to work with CDC to monitor

respiratory viral pathogens. Dr. Tidswell consulted on several studies, including the ChAdOx SARS-COV-2 vaccine trial. Post-pandemic, we have many new projects, including an international network for the treatment of emerging respiratory diseases.

Small initial support from the Department of Medicine helped boost active critical care research into a nationally prominent, self-sustaining program. To get to where we are today, we established working relationships across the country, identified opportunities, and had the motivation and expertise to conduct multiple studies. As a result, we produced publications and financial contributions back to Baystate and can offer cutting-edge therapies to patients. Research also connects us to emerging treatments and ideas for better care delivery worldwide.

Epidemiology and Biostatistics Research Core (EBRC) Classroom

Alex Knee, Assistant Professor of Medicine, UMass Chan-Baystate, Program Manager, EBRC

Welcome to the first installment of the EBRC Classroom where we will briefly reflect on FAQs and hot topics in Epidemiology and Biostatistics. Since the most common question (and the first step of any research activity) is "How do I write a protocol?" we are going to focus on writing guidelines. Just like in medicine, following established guidelines is a great way to ensure that you are implementing best practices. Thankfully, many experts in the field have already come together to provide extensive guidance on what components should be included in a protocol. The most common writing guidelines are [STROBE](#) (for observational studies) and [CONSORT](#) (for RCTs), but there are actually 555 different writing guidelines available! Thinking of conducting a survey, check out [CHERRIES](#). Ready to start your QI project... check out [SQUIRE](#). The best source to access this guidance in a single place is the [Equator Network](#) where they have guidance on which guidance to use! In addition to these writing guidelines there is advice on

specific content such as reporting of [race and ethnicity](#) as well as [sex and gender equity](#). High quality journals will hold you to many of these standards, so be prepared!

Many guidelines offer a short article discussing the methodology for establishing the guidelines, along with a checklist. Since the EBRC views these checklists as guidance on best practice, you will see more of these as part of your ISRC reviews. If you want to delve into the nitty-gritty, several of the more popular guidelines also offer an "explanation and elaboration" manuscript. These are great resources to learn more about research methodology and they often provide information on best practices (beyond writing). They can also be useful references when responding to the ill-advised advice of a journal reviewer!

Some of you might be thinking, "I'm confused, guidelines like the CONSORT statement are for writing a final manuscript intended for publication, not a protocol." While this is sometimes true,

reviewing manuscript guidelines will help you focus on the essential protocol components. We recommend that you think about your protocol as the first draft of your manuscript! If you haven't written a well thought out protocol, your research project is more likely to run into critical issues and risk not getting published. However, if you cover all the important design components of a final manuscript in your protocol, you are much more likely to succeed. In addition, increased attention is being paid to research integrity and part of this is the agreement between what you say you are going to do (your protocol) and what you actually did (your manuscript). Journals are increasingly asking for the protocol to be submitted along with your final manuscript. The more these are in agreement, the easier the publication process can be. However, there is also specific guidance on protocol development. For example, the [SPIRIT statement](#) provides guidance on RCT protocols and is aligned with the CONSORT



statement which focuses on published manuscripts. If you want to take your research planning a step further, [pre-register](#) your protocol!

In closing, did you know that the EBRC has an [education page](#) on the HUB? We have assembled pre-recorded lectures and other resources for learning about clinical research. In fact, the EBRC provides all types of educational services from conducting formal seminars on research methods to participation in departmental journal clubs, or even a sidebar consultation on research methodology you would like to know more about. If you have any questions or topics would like us to write about, please reach out to us at biostatistics@baystatehealth.org. Otherwise, stay tuned for the next installment of the EBRC Classroom!

(continued from page 1)

will lead Baystate enrollment in the OCCLUFLEX trial of the Occlutech PFO Occluder, the first-ever head-to-head comparison of PFO closure devices. Dr. Amir Lotfi leads Baystate enrollment in two trials of the TherOx SuperSaturated Oxygen System, delivering oxygen-rich blood directly to the damaged heart muscle to promote recovery from heart attacks. In cardiac surgery, Dr. Siavash Saadat leads Baystate enrollment in the ROMA trial, comparing the use of veins vs. arteries as grafts in coronary bypass surgery. Dr. Matthew Kronick leads Baystate enrollment in the ADVANCE trial in vascular surgery, a head-to-head comparison of aortic aneurysm grafts from Medtronic and Gore. Dr. Goldsweig reports that several other major cardiovascular clinical trials are in startup, and he hopes to increase both the number of trials and enrollment rates.

Cardiovascular Outcomes Research

Many databases are available for retrospective cardiovascular outcomes research, and Dr. Goldsweig plans to foster this research

at Baystate. Such databases include:

- Governmental and private payer administrative claims
- The National Cardiovascular Data Registry (NCDR)
- Baystate data collected for NCDR.

Dr. Goldsweig serves on the steering committee of the NCDR LAAO Registry. SCAI and Medtronic also awarded him a grant to study cardiovascular outcomes among type I diabetics in the NCDR Diabetes Collaborative Registry in partnership with Baystate pediatric endocrinologist Dr. Bracha Goldsweig and Baystate Biostatistics Research Core Program Manager Alexander Knee. Dr. Goldsweig is especially enthusiastic about cultivating outcomes, research skills, and productivity among the 16 Department of Cardiovascular Medicine fellows.

Dr. Goldsweig is always eager to bring new research to Baystate and build collaborations with colleagues at Baystate, UMass, and around the world. Please get in touch with him at andrew.goldsweig@baystatehealth.org to discuss research collaboration.

Assessment of a Train-the-Trainer Model for a Parenting Intervention for Mothers in Recovery

Elizabeth Peacock-Chambers, MD, Assistant Professor of Pediatrics and Healthcare Delivery & Population Sciences at UMass Chan Medical School-Baystate and Amy LeClair, PhD, presented their study "Assessment of a Train-the-Trainer Model for a Parenting Intervention for Mothers in Recovery," during Tufts CTSI's 2nd Annual Dissemination of Research Results Open House on March 29th, 2023. The online event was an opportunity to learn about Tufts University and Baystate Health research. Study participants could also attend and learn about the study results in which they participated.

Drs. Peacock-Chambers and LeClair's research attempts to address the lack of support for parents with substance use problems. Parents with substance use disorders have unique needs that are often not addressed by current treatment systems. Those unique needs lead to increased risk, such as overdose, after the birth of a child compared to individuals who are not actively parenting or haven't had a recent birth of a child. At the same time, parenting can be a huge source of motivation for people to seek new treatment services. Still, there is a need for

(continued on page 4)

Research & Education Celebration 2023

Join us! June 12 - 16th, 2023

Research and Education Celebration returns virtually.

This event showcases the research activities and educational innovations of our clinicians to advance our patients' care and enhance our clinicians' knowledge and skills. The theme for this year is "Engaging Equity, Diversity, and Justice in Clinical Research, Education and Practice".

Register today.

Registration is now open. To register as an attendee please visit baystatehealth.vfairs.com or [click here to fill out the registration form.](#)

Submit a Poster.

We welcome any posters of projects presented at a national or regional conference in 2021-2023 or posters that have been accepted for presentation in 2023 (but not yet presented). Posters by residents or fellows that have been presented in Baystate forums to satisfy scholarship requirements are also acceptable. To submit a poster, [please fill out the poster submission form.](#)

Please note the deadline to submit a poster is May 22nd.

Meet the Keynote Speaker, Arvin Garg, MD, MPH.

Arvin Garg, MD, MPH, is a Professor of Pediatrics and Vice Chair of Health Equity at UMass Chan Medical School and UMass Memorial Children's Medical Center. Dr. Garg is also an Associate Editor for the Journal of Developmental and Behavioral Pediatrics.

Dr. Garg received his BA in Behavioral Biology from Johns Hopkins University, MPH from Boston University School of Public Health, and his medical doctorate from Boston University School of Medicine. After completing his clinical residency in pediatrics at the University of Connecticut, he



Arvin Garg, MD, MPH

worked for two years in private practice in Pennsylvania. He subsequently completed a post-doctoral General Academic Pediatric fellowship at Johns Hopkins University School of Medicine.

Dr. Garg's first faculty position was at the Floating Hospital for Children at Tufts Medical Center. Before joining UMass, Dr. Garg was at Boston Medical Center and Boston University School of Medicine for ten years. Dr. Garg has been recognized for his clinical teaching with awards from Tufts University School of Medicine, Boston University School of Medicine, and the Boston Combined Residency Program.

Dr. Garg's research addresses adverse social determinants of health (SDoH) within the delivery of pediatric care, particularly for low-income families, and has been cited in professional guidelines. During his fellowship, Dr. Garg's SDoH trial received both The Francis F. Schwentker Award Winner for Excellence in Research by House Staff and Fellows in the Department of Pediatrics at Johns Hopkins School of Medicine and The Society of Pediatric Research Fellow Clinical Research Award. Since 2009, Dr. Garg has been continuously funded by the NIH and has received extramural funding from private foundations. He currently holds two R01 awards and has published over 70 publications.

(continued from page 3)

evidence-based support to exist and to be accessible, and there is also a challenge in getting those supports to scale at a population or community level.

"One evidence-based practice we have been studying is Mothering from the Inside Out (MIO). MIO is a parenting support program focused on addressing the lack of support for parents with substance use disorders," says Dr. Peacock-Chambers. The program is delivered individually in 12 counseling sessions by a substance use disorder treatment counselor or mental health clinician. The goal is to help parents begin a process where they can start to manage the strong emotions that come up in their role as a parent.

To address the scalability problem, the team needed to change the training model to increase the number of clinicians who could be trained and reach more parents in recovery. Instead of simply providing individual trainings, the MIO team developed a new train-the-trainer model to build a cadre of trainers that can go on to teach the mental health clinicians, who then can work directly with parents. "There's also a feedback loop here where people who have been trained as mental health clinicians to deliver Mother from the Inside Out can feed back and become trainers themselves," says Dr. Peacock-Chambers.

To develop the train-the-trainer model in the MIO approach, Drs. Peacock-Chambers, LeClair and their research team reviewed the previous research on the effectiveness of train-the-trainer models, studied different programs for parents with substance use disorders and other parenting interventions, and the scalability of parenting interventions. They used that information to develop a curriculum where the expert trainers could teach the new trainers how to train the next generation of providers in MIO. "We also have an advisory group that consisted of a perinatal



Elizabeth Peacock-Chambers, MD

nurse that oversees a peer program for pregnant moms in recovery, a substance use counselor previously trained in MIO, a recovery support specialist working in a peer program, and mom-in-recovery who wasn't working in the field," says Dr. LeClair.

The new trainers that participated in the study reported that the train-the-trainer model created a safe space to slow down, reflect, and grow for themselves but also requested more time for preparation and reflection. The clinicians, the new group of providers being trained, felt the primary strength of the process was the ability to slow down and reflect but did recommend more interactive activities during the didactic portions and requested an explicit discussion on systemic racism and cultural differences. Finally, the parents said they became more comfortable in their parenting roles, 2 participants reported a decrease in substance cravings, and no participants reported an increase in cravings.

"One thing we try to look for in this qualitative work is figuring out what's driving the change. We identified a relationship between the experts and the trainer with a parallel process between the trainer and the clinician, slowing down to reflect and creating a safe space. Those elements are an important part of the train-the-trainer curriculum. It's interesting because that's the same process we hope to create between the parents and a child," concludes Dr. Peacock-Chambers.

Notable recent published papers

Deshpande A, Klompas M, Guo N, Imrey PB, Pallotta AM, Higgins T, Haessler S, Zilberberg MD, Lindenauer PK, Rothberg MB. Intravenous to Oral Antibiotic Switch Therapy among Patients Hospitalized with Community-Acquired Pneumonia. *Clin Infect Dis*. 2023 Apr 3;ciad196. doi: 10.1093/cid/ciad196. Epub ahead of print.

Ismayl M, Abbasi MA, Al-Abcha A, El-Am E, Walters RW, Goldsweig AM, Alkhouli M, Guerrero M, Anavekar NS. Racial and Ethnic Disparities in the Use and Outcomes of Transcatheter Mitral Valve Replacement: Analysis From the National Inpatient Sample Database. *J Am Heart Assoc*. 2023 Apr 4;12(7):e028999. doi: 10.1161/JAHA.122.028999. Epub 2023 Mar 28.

Grady K, Vital C, Crisafi C. Use of Complementary Pain Management Strategies in Postoperative Cardiac Surgical Patients. *J Nurs Care Qual*. 2023 Apr 7. doi: 10.1097/NCQ.0000000000000712. Epub ahead of print.

Shinde A, Mohapatra S, Schlaug G. Identifying the engagement of a brain network during a targeted tDCS-fMRI experiment using a machine learning approach. *PLoS Comput Biol*. 2023 Apr 12;19(4):e1011012. doi: 10.1371/journal.pcbi.1011012. Epub ahead of print.

Friedmann PD, Dunn D, Michener P, Bernson D, Stopka TJ, Pivovarova E,

Ferguson WJ, Rottapel R, Hoskinson R Jr, Wilson D, Evans EA. COVID-19 impact on opioid overdose after jail release in Massachusetts. *Drug Alcohol Depend Rep*. 2023 Mar;6:100141. doi: 10.1016/j.dadr.2023.100141. Epub 2023 Feb 27.

DeBerry J, Rali P, McDaniel M, Kabrhel C, Rosovsky R, Melamed R, Friedman O, Elwing JM, Balasubramanian V, Sahay S, Bossone E, Farmer MJS, Klein AJP, Hamm ME, Ross CB, Rivera-Lebron BN. Barriers and facilitators to interhospital transfer of acute pulmonary embolism: An inductive qualitative analysis. *Front Med (Lausanne)*. 2023 Mar 1;10:1080342. doi: 10.3389/fmed.2023.1080342.

Oluwayiose OA, Houle E, Whitcomb BW, Suvorov A, Rahil T, Sites CK, Krawetz SA, Visconti PE, Pilsner JR. Urinary phthalate metabolites and small non-coding RNAs from seminal plasma extracellular vesicles among men undergoing infertility treatment. *Environ Pollut*. 2023 Mar 30;121529. doi: 10.1016/j.envpol.2023.121529. Epub ahead of print.

Wagner M, Gomez-Garibello C, Seymour N, Okrainec A, Vassiliou M. An argument-based validation study of the fundamentals of laparoscopic surgery (FLS) program. *Surg Endosc*. 2023 Mar 30. doi: 10.1007/s00464-023-10020-1. Epub ahead of print.

OnCore Clinical Trials Management System Updates

The Office of Research is excited to share the finalized OnCore Study Criteria to be used when vetting which new studies should go into OnCore. The document can be [found here](#) and is meant to serve as a guide study teams in the process.

The D'Amour Center for Cancer Care has completed its User Acceptance Testing for OnCore! With training and testing complete, the DCCC is now working with SPA and BOS, our external support, to migrate all qualifying studies.

Our partners with Point B will

wrap up their engagement with us and the CTMS project at the end of May. We are so thankful for their efforts and collaboration in launching OnCore. While the work continues, we are grateful for all the crucial work we were able to accomplish with their partnership.

A key component of OnCore is our invoicing capabilities. For those who handle invoicing in OnCore, please review our documentation outlining the new process and your role in successfully executing it. The documents can be [found here](#).

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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 Matthew Hamel at matthew.hamel@baystatehealth.org to submit yours.