



Message from the Executive Director

One of my favorite aspects of an academic medical center is the constant infusion of new energy and ideas. This July, we welcomed new house staff to our hospital and new fellows to the DCRI fellowship program. We have 10 new DCRI fellows from a variety of specialties, including anesthesia, cardiology, infectious diseases, nephrology, pulmonary, and pediatric critical care.

I am also pleased to announce several new DCRI faculty hires David Carlson, Bradley Kolls, Neha Pagidipati, Sean Pokorney and Bryce Reeve.

We also welcomed back Rob Califf, but it is hard for me to call him a new hire. He is now the Vice Chancellor for Health Data Science at Duke Health as well as part of the senior management team for Verily Life Sciences, an Alphabet company. We are thrilled to have him back on campus and are excited to be a part of the data science transformations he will lead both at Duke and Verily.

The diverse clinical and research interests of the fellows and faculty highlight our commitment to novel research platforms and innovative clinical research that will improve the lives of patients around the world. We also highlight these interests in this edition of the DCRI Newsletter. We feature articles on the use of autologous CD34+ cells for the treatment of refractory angina, on a large study of childhood obesity as part of the American Heart Association's Strategically Focused Research Network for children, on the MURDOCK COPD Study, and on the exciting Project Baseline study.

It is an incredible time to be at Duke and the DCRI, and I want to thank you for your collaboration and ongoing support of our mission.



Eric D. Peterson, MD, MPH, FAHA, FACC

Executive Director,
Duke Clinical Research Institute
Professor of Medicine, Cardiology
Fred Cobb Distinguished Professor of Medicine

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SELECTED PUBLICATIONS, Pages 5–7

New DCRI faculty hires:



David Carlson, PhD (Department of Biostatistics and Bioinformatics and the Department of Civil and Environmental Engineering)



Bradley Jason Kolls, MD, PhD, MMCi (Neurology)



Neha Pagidipati, MD, MPH (Cardiology-Prevention)



Sean D. Pokorney, MD, MHS, MBA (Cardiology-Electrophysiology)



Bryce Reeve, PhD (Duke Center for Population Health Sciences)



FEATURE

Breathe Easy



The DCRI, Duke University's MURDOCK Study, and Boehringer Ingelheim Pharmaceuticals Inc. have launched a new collaborative research effort to closely follow 850 people living with chronic obstructive pulmonary disease (COPD). The study will measure changes to participants' health to better understand how COPD progresses within a community and follow participants for five years.

COPD is a term that includes chronic bronchitis and/or emphysema. This disease can make breathing harder

because less air flows in and out of the lungs. Chronic lower respiratory diseases, which include COPD, are the third-leading cause of death in the United States, and approximately 15 million Americans have been told by a healthcare provider that they have COPD.

Much of the understanding of current COPD management comes from randomized clinical trials that use strict inclusion criteria and regimented patient follow-up, which may not mirror real-world practices.

"By contrast, this observational study will create a diverse group of participants with COPD who will be followed for years, allowing us to better understand the impact and progression of COPD in a community," said Scott Palmer, MD, director for DCRI Respiratory Research and principal investigator for the MURDOCK COPD Study. "We hope this study will ultimately contribute to our understanding of how to provide better patient care and more effective treatment for patients in the community setting." [Read more here.](#)

Cholesterol Confusion

Dueling guidelines for the use of statins to prevent cardiovascular disease have fed confusion, but this much is now known: If all doctors followed advice from the U.S. Preventive Services Task Force, 9 million fewer adults would be taking the drug than if they adhered to the American College of Cardiology/American Heart Association recommendations.

An analysis by the DCRI also finds that most of those who would be dropped from the USPSTF guidelines are younger adults.

"Having multiple guidelines out there for cholesterol-lowering drugs can be confusing to physicians and patients," said the DCRI's Neha J. Pagidipati, MD, lead author of a study published April 18 in the *Journal of the American Medical Association*. "Until we get more definitive answers about the optimal approach, the best we can do is understand the pros and cons of each set of guidelines. Our study adds some of that context."

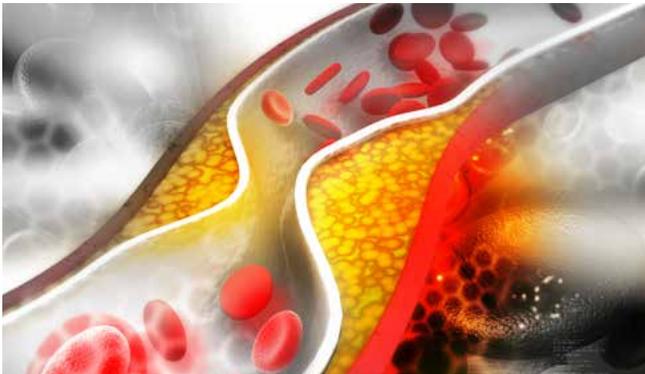
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FEATURE

Cholesterol Confusion (cont'd)



Pagidipati and colleagues — including senior author Michael J. Pencina, PhD, professor of biostatistics and bioinformatics at the DCRI — analyzed the most recent-available six-year data from the National Health

and Nutrition Examination Survey, a representative sample of U.S. residents that provides key health statistics over time.

The researchers estimated that, if fully implemented, the USPSTF recommendations would result in a 15.8 percent rise in the use of statins among U.S. adults aged 40 through 75 with no prior cardiovascular disease. Those newly recommended for statins would be in addition to the 21.5 percent of U.S. adults already taking the lipid-lowering therapy. [Read more here.](#)

Back to Basics

The DCRI is teaming up with Verily Life Sciences and Stanford Medicine to conduct a longitudinal study that will collect broad phenotypic health data from approximately 10,000 participants, who will each be followed over the course of at least four years. The study is the first initiative of Project Baseline, a broader effort designed to develop a well-defined reference, or “baseline,” of health as well as a rich data platform that may be used to better understand the transition from health to disease and identify additional risk factors for disease.

Each site will gather deep datasets on participants through repeat clinical visits; daily use of a wrist-worn investigational device and other sensors; and regular participation in interactive surveys and polls by using a smartphone, computer or call center. Data collected will include clinical, imaging, self-reported, physical, environmental, behavioral, sensor, molecular, genetic, and other health-related measurements.

One of the focus areas of the Project Baseline study is participant involvement, which includes development of a participant committee and the option to receive certain health data and test results, participate in conference calls with members of the study team and evaluate new tools and technologies.

“Through the Project Baseline study, we are aiming to engineer a true twenty-first century approach to health — in a preventive and personalized way,” said Adrian F. Hernandez, MD, MHS, professor of medicine at Duke and member of the DCRI. “Instead of having the annual physical exam that has not changed in decades, we’re hoping to develop new platforms that will discover changes in health as they happen in meaningful and actionable ways. To do this successfully, we will partner with participants to learn and deliver the best approaches for every aspect of the study.” [Read more here.](#)





FEATURE

Getting a Handle on Heartache

An analysis of data from the entire development program consisting of three trials assessing the feasibility of using a stem cell therapy to treat patients with the most severe cases of angina, refractory angina (RA), showed a statistically significant improvement in exercise time as well as a reduction in mortality.

One of the warning signs of coronary artery disease is angina, or chest pain, which occurs when the heart muscle does not receive enough blood. Unlike angina pectoris or “stable angina,” which can often be treated with medication, RA can be incapacitating, impacting quality of life. In the most severe cases, those with class III or IV angina, treatment options are exhausted, and patients remain severely debilitated. Unfortunately, one of the untoward consequences of the improved survival of patients with chronic ischemic heart disease is more patients with refractory angina.

A meta-analysis of three trials that each showed promising results looked at injecting RA patients with autologous CD34+ cells — which have been shown to increase blood flow — and the therapy’s effect on mortality and total exercise time (TET), an important predictor of long-term mortality.



“The goal of this meta-analysis was to combine patient level data from three very similar trials to try understand what it would tell us,” said lead investigator Tom Povsic, MD, FSCAI, associate professor at the DCRI. “Therapies for these patients are direly needed,” said Povsic, “and results from our meta-analysis are very compelling.”

[Read more here.](#)

Food for Thought

Duke Health and DCRI researchers will launch four projects this summer to better understand and treat the health impacts of childhood obesity.

The projects include clinical and population health research on the most effective treatments for childhood obesity and basic science research on differences in gut bacteria among children who are overweight compared to those in a healthy weight range, and how those differences might influence

their risk of obesity and response to treatment.

Duke will conduct the studies as part of the American Heart Association’s Strategically Focused Research Network (SFRN) for children, which will provide \$3.7 million over the next four years for the research. The DCRI’s Jennifer Li, MD, chief of the Division of Pediatric Cardiology at Duke University School of Medicine, will lead the work.

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FEATURE

Food for Thought (cont'd)

“Unfortunately, up to a third of children are obese or overweight,” said Li, who is also a professor of medicine and of pediatrics. “This is a generation of kids who might not do as well as their parents because they face a future

risk of heart attacks, diabetes and stroke. This grant can help us figure out the best interventions, including those that might work on a larger scale in communities across the country.” [Read more here.](#)



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Duke Clinical Research Institute

Room 0311 Terrace Level
2400 Pratt Street
Durham, NC 27705
Reception Desk: 919.668.8700
DCRI-info@dm.duke.edu

Learn more: Visit DCRI.org

Editor: Mark Slagle
Designer: Wally Lamb
Faculty Advisor: Adam DeVore