Mission and Values

OUR MISSION
To develop and share knowledge that improves the care of patients around the world through innovative clinical research.

OUR VALUES

Integrity | Excellence | Respect | Innovation | Teamwork
Letter from the Interim Executive Director

“Inspiration to Impact” is the theme of this year’s DCRI annual report, spotlighting both our stories and our studies. Whether it’s building the infrastructure to conduct pediatric trials around the globe or utilizing new techniques to chart the progression of Alzheimer’s disease, each of these profiles began with a simple idea, a spark of inspiration.

When I joined the DCRI faculty as a health services researcher, the DCRI supported my inspiration—to improve population health. I experienced firsthand how the DCRI champions the journey from inspiration to impact, fostering creativity in our faculty and staff to achieve accelerated and improved outcomes for patients.

The stories featured in this year’s annual report reflect that remarkable quest from inspired ideas to better patient outcomes. They began under the leadership of Eric Peterson, during whose tenure the institute accelerated its academic productivity with more than 5,500 publications and nearly $1.5 billion in research funding.

This history inspires me to lead the DCRI as we navigate a rapidly evolving industry and develop a learning healthcare system at Duke. We will find new possibilities, chart new directions, and take informed risks. We will lead the next generation of clinical researchers and collaborate with partners to define our future. Most importantly, we will contribute to the health of patients here at Duke and around the world—remembering the reasons and inspirations behind the stories of those who come to work at the DCRI each day.

Lesley H. Curtis, PhD
Chair and Professor
Department of Population Health Sciences
Interim Executive Director, Duke Clinical Research Institute
Duke University School of Medicine
DCRI at a Glance

**Publications**

**FY18**
- 1,204 Publications
- 207 High-Impact Publications

**Study Phase**

- 1% Meetings/Seminars
- 19% Networks
- 15% Other
- 17% Phase I
- 23% Phase II
- 10% Phase III
- 4% Phase IV
- 11% Registry

**Study Population**

- 82% Pre/neonatal
- 10% Pediatric
- 2% Adolescent
- 1% Adult
- 2% Geriatric

**Study Size**

- 19% Small
- 10% Medium
- 30% Large
- 41% Mega

**Study Revenue Source**

- 45% Government
- 55% Industry
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INSPIRATION: A PASSION FOR IMPROVING PATIENT CARE
Reducing the disparities in health care

Among patients hospitalized with atrial fibrillation (AF), black and white individuals vary in demographics, prevalence of non-cardiovascular comorbidities, and prescription of oral anticoagulation.

“We have been very interested in understanding how AF affects different racial and ethnic populations and how management of AF differs as a function of race and ethnicity,” said the DCRI’s Kevin Thomas, MD. “We already know black populations have a significantly lower burden of AF relative to whites despite having a higher burden of traditional risk factors for developing AF, including hypertension, diabetes, heart failure, and kidney dysfunction.”

Thomas called the provocative phenomenon the “AF paradox,” because the group that has more risk factors for developing AF actually is half as likely to be diagnosed with it.

“Even though blacks are less likely to have AF, when they have it, they have worse outcomes relative to whites,” said Thomas. “They have more strokes, higher mortality, and are more likely to develop heart failure. So, despite the prevalence being less, the outcomes are worse.”

According to the National Institutes of Health, AF, the most common clinically significant cardiac arrhythmia, affects over 2.3 million people in the United States. AF is associated with an increased risk of stroke and heart failure and independently increases the risk of all-cause mortality.

DCRI researchers used data from 1 in 5 U.S. hospital discharges through the Premier Healthcare Database, a comprehensive electronic healthcare database with more than 700 contributing hospitals/healthcare systems. Data from 1,579,456 patients in 812 hospitals admitted between January 2011 and June 2015 with a primary or secondary diagnosis of AF were used.

According to Thomas, the genesis of this study was to evaluate the characteristics of patients hospitalized for AF and determine how many of those eligible were being treated with oral anticoagulants (OACs). The researchers wanted to understand how patients were treated and whether treatment differences explained why there may be overall higher rates of stroke associated with one racial population versus another.

The researchers found that blacks with AF were younger than whites, and though the prevalence of cardiovascular comorbidities was similar in the two groups, non-cardiovascular morbidities such as renal disease, pulmonary disease, and history of deep vein thrombosis/pulmonary embolism were higher in blacks. Black patients of various age groups, despite having more risk factors, were less likely to be treated with OACs as compared with white patients.

“The next phase of the study will be to take a deeper dive into understanding what might be driving these differences in OAC prescriptions,” said Thomas. “However, the bad news for all individuals with AF is that we found that, among eligible patients, only about 45 to 46 percent are prescribed OACs independent of race and ethnicity, which means more than half of eligible patients are not being prescribed blood thinners, which could reduce strokes and also be life-saving.”
Understanding serious public health issues

Despite reports in recent years suggesting childhood obesity could be reaching a plateau in some groups, the big picture on obesity rates for children aged 2 to 19 remains unfavorable.

Three decades of rising childhood obesity continued their upward trend in 2016, according to an analysis from the DCRI and other Duke Health researchers. The findings show 35.1 percent of children in the U.S. were overweight in 2016, a 4.7 percent increase compared with 2014.

“About four years ago, there was evidence of a decline in obesity in preschoolers,” said the DCRI’s Asheley Cockrell Skinner, PhD. “It appears any decline that may have been detected by looking at different snapshots in time or different datasets has reversed course. The long-term trend is clearly that obesity in children of all ages is increasing.”

The data are based on body mass index (BMI) data for children participating in the National Health and Nutrition Examination Survey (NHANES), a large database updated every two years. Researchers examined data back to 1999 that included 33,543 children.

The researchers identified notable spikes between 2014 and 2016 in obesity for preschool boys, which rose from 8.5 percent to 14.2 percent, and girls aged 16 to 19, whose rates of obesity jumped from 35.6 percent to 47.9 percent.

Boys and girls aged 16 to 19 had the highest rates of overweight and obesity of any age group in 2016, with 41.5 percent being considered overweight, defined by the Centers for Disease Control and Prevention (CDC) as having a BMI at or above the 85th percentile for age and sex. Of these 16-to-19-year-olds, 4.5 percent have Class 3 obesity, the highest of three obesity categories defined by the CDC.

Both Class 2 and Class 3 obesity are considered severe and are linked with greater risk of heart and metabolic health problems, such as high blood pressure and cholesterol.

“Despite some previous reports, the obesity epidemic has not abated,” said Sarah C. Armstrong, MD. “This evidence is important in keeping the spotlight shined on programs to support healthy changes. Obesity is one of the most serious health challenges facing children and is a predictor for many other health problems. When we see that leveling off, we can become complacent—we can’t afford to do that.”

Armstrong, a pediatrician, acknowledges the paper focuses on the problem of obesity rather than solutions and wants to encourage families with direct advice.

“Although the latest trends show that we haven’t figured out what works as a population, we do know individual changes can support families’ health,” Armstrong said. “We know families can avoid added sugar in beverages and food, get at least an hour of activity a day, and incorporate vegetables into every meal to improve their health. Even if your child is a picky eater and wants to eat the same vegetable every day, that is still a good choice.”
Expanding the definition of physical health

DCRI researchers have found that patients with chronic angina who are optimistic about their recovery appear to have better outcomes, a finding that adds to a growing body of evidence that a person’s state of mind can influence their physical health.

“Angina is a chronic pain condition, and it can severely impact a person’s quality of life,” said Alexander Fanaroff, MD, MHS. “People often stop doing things they enjoy—playing with grandkids, exercising—because they worry about the pain and fear they might have a heart attack.”

“There’s limited evidence that’s the case, but if there’s a way to manage these negative feelings so that people can continue doing things that make them happy, it would greatly improve the quality of their lives and, potentially, their physical health.”

Fanaroff and colleagues analyzed data from RIVER-PCI, a large, multicenter clinical trial conducted by the DCRI and Columbia University. In RIVER-PCI, patients with chronic angina were randomly assigned to receive a drug called ranolazine or placebo. Patients in both groups had previously undergone a percutaneous coronary intervention that had not fully opened their blocked blood vessels. The drug was being tested as a potential intervention to reduce the need for additional procedures or hospitalizations.

At enrollment in the trial, patients were asked how strongly they agreed with the phrase, “I am optimistic about my future and returning to a normal lifestyle.”

Of 2,389 patients in the trial, 33.2 percent strongly agreed with the optimism statement, 42.4 percent agreed, 19.1 percent were undecided, and 5.2 percent disagreed, indicating they were pessimistic. The researchers evaluated the unadjusted and risk-adjusted association between the patient’s optimism at enrollment and whether they needed another procedure or had to be hospitalized.

The rate of additional procedures and hospitalizations was higher in patients who expressed pessimism and in those who were undecided (35 percent and 32.8 percent), compared with the most optimistic patients (24.4 percent). This finding persisted after adjusting for how sick patients were when they enrolled; the most optimistic patients had a lower prevalence of prior heart attack, heart failure, diabetes, and chronic kidney disease and less severe angina to begin with than less optimistic patients.

“The first thing you always want to be cautious about, when interpreting non-randomized comparisons, is that the most optimistic patients had fewer other problems, and that colors everything,” Fanaroff said. “But even when adjusted for better health using statistical methods, we still found that more-optimistic patients were less likely to be hospitalized for angina or to need another revascularization procedure.”

Fanaroff said the findings suggest the need for additional prospective studies designed to specifically measure how optimism affects outcomes for patients with angina, but until then, both patients and clinicians could look for ways to bolster optimism as they navigate the disease.

“As a clinician, if you can identify patients who are less optimistic for whatever reason—whether because their disease has made them despair, or there are comorbidities—maybe there is a way to talk to them that could help,” Fanaroff said. “I hesitate to recommend any sort of intervention on the basis of these preliminary data, but as a human being, it doesn’t cost you or society anything to assure chronic angina patients that there are medications and procedures that are helpful, and that it’s possible to have a normal life.”
Providing insight into patient behavior

Doctors often cite the high price of a prescription drug as a reason they don’t prescribe it, while patients similarly say that cost is a main reason they stop taking a drug.

Removing this financial barrier might increase the use of evidence-based therapies, improve patient adherence to those medications, and potentially save lives. That theory was tested in a study of heart attack survivors led by the DCRI.

“This study provides insights into medication-taking behavior and tackling the adherence problem, a big problem in the U.S.,” said Eric Peterson, MD, MPH. “While financial issues are certainly part of the problem, a more complete answer will be needed to further improve adherence and related patient outcomes.”

The researchers enrolled 11,001 heart attack patients between June 2015 and June 2016 at hundreds of sites across the country in a study known as ARTEMIS. Doctors at participating hospitals provided usual care, but at roughly half the sites selected randomly, the cost of antiplatelet medications was offset by vouchers over the course of the study’s one-year span.

Payment vouchers eliminated price differences between an older generic therapy, clopidogrel, and a newer, more effective version of the therapy, ticagrelor. Doctors had full discretion on which of the two drugs to prescribe.

The study found that clinicians were indeed sensitive to their patients’ cost concerns. When patient co-pays were covered, doctors were approximately 30 percent more likely to prescribe the more effective drug.

When patients were asked about their medication use, 80 to 85 percent reported that they filled all their prescriptions continuously, but the study’s analysis of pharmacy fill data indicated that only 55 percent had been fully compliant.

Regardless of the measure of medication use, the study confirmed that more of the patients who got the payment vouchers adhered to their recommended drug regimens.

But those improvements did not appear to result in a reduced rate of death, heart attacks, or strokes compared with patients who got usual care.

“Our study confirms some of our thoughts on how drug prices affect doctors’ and patients’ behaviors,” said Tracy Wang, MD, MHS, MSc. “But we still have work to do to understand how we can both measure and improve treatment adherence to improve outcomes,” Wang said. “We should consider co-payment reductions as part of broader initiatives to improve medication use and clinical outcomes.”
Finding new approaches to serious diseases

The DCRI’s Laura Schanberg, MD, and the University of Washington’s Sarah Ringold, MD, working with a team of investigators from the Childhood Arthritis and Rheumatology Research Alliance (CARRA), have been approved for a $7 million funding award by the Patient-Centered Outcomes Research Institute (PCORI) to study treatments for juvenile idiopathic arthritis (JIA).

JIA affects as many as 300,000 children in the U.S.. The condition can cause pain, suffering, school and work absence, and diminished ability to engage in normal activities. In younger patients, arthritis can cause joint damage, deformities, and growth problems. Eye inflammation can cause permanent damage to the eyes, including blindness. Studies suggest that how JIA is treated early after diagnosis makes a difference in long-term outcomes, making it critical to test treatment effectiveness from early in the course of the disease.

The study will determine whether a six-month course of abatacept given soon after diagnosis of limited JIA (affecting four or fewer joints) will prevent the involvement of more joints, eye inflammation, or a need for stronger treatment. Abatacept is a biologic medication that acts specifically on a part of the immune system known to be involved in the development of arthritis.

“This will be the first time that a preventive approach to JIA has been tried.”

“This will be the first time that a preventive approach to JIA has been tried,” Schanberg said. “If we are able to decrease the more severe forms of JIA and eye disease, it will substantially reduce the morbidity associated with the disease and change the standard of care of these patients. Another unique part of the study is embedding ethnographic assessment of participants in the trial, making it possible to learn about study participation as it is being experienced by patients.”

The study will use the infrastructure of the CARRA Registry, for which the DCRI serves as the data coordinating center. An outcomes team led by Kristin Siebenaler and Anne Dennos will work with network clinical operations to model a pragmatic trial executed in an ongoing registry. The proposal was developed under the auspices of PART-NERS, a PCORI-funded, patient-powered research network led by the DCRI’s Renee Leverty.
Examining how patients interact with the healthcare system

Patients with neck pain who are treated initially by a non-pharmacological care provider may be less likely to receive opioid treatment and advanced imaging, according to a study by DCRI researchers.

“We really wanted to look at pathways of care—where patients enter the healthcare system, and what does that look like in terms of downstream healthcare utilization and associated costs,” said Maggie Horn, DPT, MPH, PhD.

Neck pain is a widespread problem; approximately half of all people will have a serious episode of neck pain at some point in their lives. However, there is little agreement among care providers about where a patient should initially seek treatment for neck pain. Many recommendations for treating neck pain are extrapolated from recommendations for treating back pain, and it is unclear how these affect outcomes for neck pain patients.

Horn and her colleagues conducted a retrospective cohort study of 1,702 patients who consulted a primary care provider, physical therapist, chiropractor, or specialist for a new case of neck pain.

The most common initial provider type was a primary care provider (750 patients, 44.1 percent), followed by chiropractor (382, 22.4 percent), physical therapist (293, 17.2 percent), and specialist (277, 16.3 percent). Patients seeking care from a chiropractor or physical therapist had the lowest prevalence of chronic or generalized pain (2.4 percent and 19.8 percent, respectively), substance abuse (4.2 percent and 12.3 percent), depression (16.5 percent and 29.0 percent), anxiety (16.0 percent and 25.9 percent), and tobacco use (6.0 percent and 12.3 percent). In contrast, specialists had the highest prevalence of patients with any comorbidity, with the exception of low back pain, where chiropractors had the highest prevalence (76.4 percent).

The median duration of an episode of care in the sample was 42 days, with patients seeking care from a primary care provider having the shortest median episode of care (1 day), followed by physical therapist (51 days), specialist (91 days), and chiropractor (120 days). Very few patients (19, 1.1 percent) underwent surgery for their neck pain.

“Patients who initially received care from a chiropractor or physical therapist were less likely to receive opioid therapy within one year of their initial visit. Patients who first saw a chiropractor were also less likely to receive advanced imaging and injections. Initiating care with a specialist or physical therapist increased the odds of advanced imaging, but only initiating care with a specialist increased the odds of injections.

These findings, Horn said, suggest that initiating care with a non-pharmacological provider for neck pain may be one way to decrease opioid exposure.

“I think this is an opportunity to start a conversation about how we direct patients within the healthcare system,” she said. “We should be thinking more carefully about how we can use alternative providers for people with neck pain.”
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Patients seeking care from a chiropractor or physical therapist had the lowest prevalence of:

- Chronic or generalized pain (2.4% and 19.8%, respectively)
- Substance abuse (4.2% and 12.3%)
- Depression (16.5% and 29.0%)
- Anxiety (16.0% and 25.9%)
- Tobacco use (6.0% and 12.3%)
MY DCRI STORY:
FROM DIFFERENT PLACES, FOR DIFFERENT REASONS—A SHARED COMMITMENT
“I wanted to work somewhere where the patient was the priority and accessibility to knowledgeable staff and faculty were readily available, and where my years of experience were of value....The work we do at the DCRI is so much closer to the ‘medicine’ of it all. The proximity to patients and providers is key to developing better treatments and interventions, and I feel so much more a part of that here.”

Michelle Foltz, Project Leader
Amy Corneli  
Associate Professor in the Department of Population Health Sciences and General Internal Medicine

Previous experience has taught me that we must engage research participants and their communities in the design, implementation, and interpretation of clinical research. Our trials rely on participant behaviors, and with meaningful engagement, we can conduct trials with a greater likelihood of success.

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I have been embedded as a social scientist in several international clinical drug trials, responsible for conducting formative research to inform the clinical trial’s study design and study procedures prior to initiation; embedded behavioral research during the clinical trial to assess participant behaviors related to the trial’s endpoints and to monitor participants’ satisfaction with the trial; and exploratory descriptive research after closure of the clinical trial to explore the context of the study results and how to improve study procedures for subsequent clinical trials.

Steven George  
Director of Musculoskeletal Research

It was a unique leadership opportunity for me to build a research team at the DCRI around a new therapeutic area.

I am very interested in changing the ways people are treated for their musculoskeletal pain conditions by applying more personalized approaches that account for the individual variation in reports of pain. This interest is motivated by my personal experiences as a clinician and practicing physical therapist, as well as the desire to improve the ability to predict who will respond favorably to available treatment options for nonpharmacological pain management.

“I am very interested in changing the ways people are treated for their musculoskeletal pain conditions by applying more personalized approaches that account for the individual variation in reports of pain.”

Debbie Hendrick  
Clinical Trials Coordinator

I came to work at the DCRI at a time in my life when I had a lot of questions related to my mom’s sudden death, and I was having a very difficult time moving on from that event. I was fortunate enough to get hired into Duke at the DCRI. My first assignment was with a cardiology study. I began to understand so much from working on the STICH study, and it really helped me to put my soul at rest regarding my mom’s death. I had gained so much knowledge and understanding of what truly happened to her.

“I began to understand so much from working on the STICH study, and it really helped me to put my soul at rest regarding my mom’s death.”

When I was hired into Duke, I started out as a project leader assistant, and I moved up to a clinical trials assistant from there. Today, I am a clinical trials coordinator for the Environmental influences on Child Health Outcomes (ECHO) Program, which is supported by the National Institutes of Health (NIH). Its mission is to enhance the health of children for generations to come. I am completely honored to work on such a great and noteworthy project.
Alpha Esser  
*Technical Trainer*

I was completely new to clinical research, and I was genuinely interested in knowing more about it. The DCRI’s mission really solidified my desire to work here, as in the past I had worked in industries where missions were more money-driven instead of research- and sharing-driven.

“I love the fact that our mission involves sharing information that improves patient care.”

I love the fact that our mission involves sharing information that improves patient care. Watching family and friends struggle with various illnesses and health issues, I am so excited to be working at a place that aids in those struggles and provides information that is changing lives for the better.

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Lynn Perkins  
*Assistant Director of Project Management in Clinical Events Classification-Safety Surveillance*

Most of us have family members with heart disease. My dad suffers from peripheral artery disease (PAD), so I was very interested in seeing the results of the EUCLID trial after the study database was locked last year. Unfortunately for patients with PAD, the study intervention wasn’t beneficial, but it was still exciting to advance knowledge about what works and what doesn’t in the treatment of patients with PAD. We can now move on to the next study.

I love working in Clinical Events Classification because we determine if suspected events occurring all over the world truly meet the standardized event definitions in the protocols.

“Most of us have family members with heart disease. My dad suffers from peripheral artery disease (PAD).”

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Guillaume Marquis-Gravel  
*DCRI Fellow*

As a research fellow from Canada, I chose to train here because it constitutes the academic institution providing probably the best opportunities around the world to be involved in innovative and large-scale pragmatic clinical trials in the cardiovascular field, integrating digital health technologies, learning health systems, and other innovative methods.

“I chose to train here because it constitutes the academic institution providing probably the best opportunities around the world to be involved in innovative and large-scale pragmatic clinical trials in the cardiovascular field.”
IMPACT: CHANGING CLINICAL PRACTICE THROUGH INNOVATIVE RESEARCH
Refining pediatric clinical trials around the world

The DCRI and its strategic partners have been awarded a grant from the U.S. Food and Drug Administration (FDA) to innovate and provide support to streamline pediatric clinical trials. This award will support efficient pediatric clinical trials by developing scientific and operational infrastructure, fostering collaborative networks, sharing knowledge, and engaging stakeholders.

“Although we’ve made a lot of progress in recent years, pediatric trials are still hard to complete successfully. There are perennial challenges—enrolling patients, finding access to supporting infrastructure, navigating a complex regulatory environment—that affect everyone working to advance pediatric research, but they can be especially challenging for research sites that don’t have access to resources or experience,” said Daniel Benjamin, Jr., MD, MPH, PhD, the award’s co-principal investigator.

Although the Pediatric Research Equity Act (PREA) and the Best Pharmaceuticals for Children Act (BPCA) were both implemented to encourage research sponsors to conduct more pediatric clinical trials, many drugs used in children lack sufficient information to guide their safe and effective dosing. Further, 42 percent of pediatric trials done under BPCA have not successfully supported pediatric indications.

“Despite how vital it is for children’s health, proper dosing information is still sorely lacking for many important therapies used in children and infants,” said Michael Cohen-Wolkowiez, MD, PhD, the award’s other co-principal investigator.

The creation of this award reflects consensus findings from a multi-stakeholder group that included regulators, industry, academia, patient advocacy groups, disease networks, and parents. The group noted that no single set of stakeholders can address these problems in isolation; instead, trial support involving all stakeholders could better ensure successful pediatric trials, especially those being conducted in patients with rare diseases.

The award will leverage and extend the extensive infrastructure, networks, and experience already in place via the Pediatric Trials Network, whose administrative coordinating center is located at the DCRI.

“This award will provide a key opportunity to address inefficiencies and for conducting more effective pediatric clinical trials, which will help inform the decisions parents and healthcare providers make when caring for our youngest patients,” Cohen-Wolkowiez said.

“Despite how vital it is for children’s health, proper dosing information is still sorely lacking for many important therapies used in children and infants.”
Developing innovative tools for clinicians and researchers

The progression to Alzheimer’s disease (AD) can be more accurately predicted in patients by incorporating longitudinal profiles of multiple clinical and neuroimaging markers in addition to the baseline information, say researchers.

A recent study shows how novel statistical models could improve the prediction of progression-free survival in patients with mild cognitive impairment (MCI) using multiple markers, all of which can be easily collected in a clinical setting.

“We have a burgeoning prevalence of AD because of the increasing number of people aged 65 and older in the U.S.,” said Sheng Luo, PhD. “Given that the number of new cases of Alzheimer’s and other dementias is projected to soar and the lack of modifying treatments for the disease, the question that we wanted to ask was how do we characterize the progression of AD for early detection and intervention in patients with MCI,” he said.

Alzheimer’s—a general term for memory loss and other cognitive abilities severe enough to restrict daily life—is the most common form of dementia, accounting for 60 to 80 percent of dementia cases. In 2017, an estimated 5.5 million Americans were living with AD and dementia, a number that is expected to grow. Many patients with MCI will go on to develop AD.

Using data from the Alzheimer’s Disease Neuroimaging Initiative (ADNI) study, Luo and his team assessed the combined prognostic value of longitudinal neurocognitive tests measured over time during a patient’s regular visits, as well as neuroimaging, genetics, and cerebrospinal fluid (CSF) markers, in determining the risk of AD conversion among individuals with MCI. According to the researchers, the ADNI data were very well-suited for the tasks because of the study’s large sample size, long follow-up period, wide breadth of cognitive markers and biomarkers, and prospective design.

To develop their prognostic model, the researchers used the weighted combination of historical information of five neurocognitive longitudinal markers that are routinely collected in observational studies. The comprehensive validity analysis provided solid evidence of the usefulness of the model for predicting AD progression.

“The main contribution of the study is that it can be used not only as a valuable prognostic tool, but can also prove helpful to the research community at large where they can use this particular tool in their current datasets,” said Luo. “Also, for clinical trials, this prognostic tool can be helpful in identifying subjects likely to develop AD in the timeframe of the trial,” he said.

According to Luo, their method can also be applicable to many other neurodegenerative disorders with similar disease and data structures and multiple longitudinal variables such as Parkinson’s disease, Huntington’s disease, and amyotrophic lateral sclerosis (ALS, also known as Lou Gehrig’s disease).

“If you apply this particular methodology to other studies of different diseases, you can derive similar prognostic tools with slight modifications,” he said.
Improving outcomes for surgical patients

New comprehensive guidelines highlight how perioperative nutritional interventions can improve surgical outcomes and reduce infectious morbidity and mortality in surgical patients.

“Having major surgery is like running a marathon because of the stress it puts upon the human body, and no one would ever imagine running a marathon without eating or drinking the night before or the morning of, but we ask our patients to do that all the time,” said Paul Wischmeyer, MD, director of perioperative research at the DCRI. “Patients who are fed early after surgery have significantly less mortality than patients who are not. Still, in the U.S., patients are not only commonly starved before surgery, they are starved after surgery, sometimes for days. We have to change this.”

According to Wischmeyer, lead author of the guidelines, 1 in 3 people who come into a hospital in the U.S. are malnourished, only 1 in 10 of those malnourished patients are ever diagnosed, and lastly, only 1 in 10 of those diagnosed receive any meaningful nutritional therapy. Collectively, only 1 in 100 patients with real malnutrition are being meaningfully treated for it.

“Major surgery and gastrointestinal surgery are perhaps the most urgent to address, because 2 out of every 3 people are malnourished at the time of surgery, with very few being screened,” said Wischmeyer. “This is unfortunate, because malnourished patients are three times more likely to develop complications and are five times more likely to die after surgery.”

The Perioperative Quality Initiative, in collaboration with the American Society for Enhanced Recovery, brought together a group of international experts—surgeons, anesthesiologists, and dieticians—with the goal of providing consensus statements and recommendations on surgical nutrition screening and therapy.

The published guidelines propose a clearly defined plan of action before and after surgery. The researchers have developed and proposed the perioperative nutrition screen (PONS) score, which determines nutrition risk based on a patient’s body mass index, recent changes in weight, reported recent decrease in dietary intake, and preoperative albumin level, which is a predictor of postoperative morbidity and mortality.

“The PONS can be administered quickly, in less than 5 minutes, by nursing staff in surgical or preoperative clinics, and its results can be instantly uploaded into a patient’s electronic medical record, automatically triggering a nutritional consult and intervention,” said Wischmeyer.

According to Wischmeyer, there are well-studied high-protein supplements that everyone should drink before surgery to considerably improve surgical outcomes and boost and restore the body’s immune response that is turned off soon after surgery. The researchers also recommend a high-protein diet via oral nutritional supplements (ONS) or a dietician-recommended nutritional regimen both pre- and postoperatively for all patients, with a focus on those who are determined to be at nutritional risk before major surgery.

The goal, according to Wischmeyer, is to have all surgical patients in the U.S. undergo screening prior to surgery in clinics that specialize in nutritional issues, challenges, and treatments.

“No patient should ever have elective surgery without being screened for malnutrition, and no malnourished patient should ever have elective surgery without their malnutrition being treated first,” said Wischmeyer.
Creating guidelines for serious health conditions

The American College of Cardiology (ACC), along with the American Heart Association (AHA) and the Heart Rhythm Society, has released new guidelines for the treatment of patients with ventricular arrhythmias and the prevention of sudden cardiac death.

Ventricular arrhythmias are abnormal heartbeats occurring in the heart’s lower chambers, or ventricles. This condition can lead to cardiac arrest, which in turn can result in sudden cardiac death if the abnormal rhythm is not quickly stopped to restore a normal rhythm.

“Sudden cardiac arrest and sudden cardiac death are major public health problems, accounting for approximately half of all cardiovascular deaths, with at least 25 percent being the first manifestation of cardiac disease,” said the DCRI’s Sana M. Al-Khatib, MD, MHS, chair of the writing committee. “The risks of ventricular arrhythmias and sudden cardiac death vary in specific populations with different underlying cardiac conditions, and with specific family history and genetic variants, and this variation has important implications for studying and applying therapies.”

These new guidelines, which replace the 2006 ACC/AHA/European Society of Cardiology (ESC) Guidelines for the Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death, are intended to guide management of adults who have ventricular arrhythmias or who are at risk for sudden cardiac death, including diseases and syndromes associated with a risk of sudden cardiac death from ventricular arrhythmias. Some recommendations from the earlier guidelines have been updated as warranted by new evidence or a better understanding of existing evidence.

These guidelines include indications for implantable cardioverter defibrillators (ICDs) for the treatment of ventricular arrhythmias and prevention of sudden cardiac death. The guidelines also provide recommendations on the use of ICDs in patients with left ventricular assist devices, use of subcutaneous ICDs, the role of catheter ablation of ventricular arrhythmias, and recommendations on genetic counseling and genetic testing to help inform clinical practice. These guidelines are the first to include value statements, specifically on the strength of evidence surrounding ICDs and cost-effectiveness.

The writing committee stressed the importance of shared decision-making between patients and clinicians. “Treatment decisions should not be based only on the best available evidence, but also on the patients’ health goals, preferences, and values,” Al-Khatib said.
Piloting new health interventions

A pilot study testing the effects of a home-based telephone-supported physical activity program for chronic low back pain provides a foundation for a larger trial to study the effectiveness of these interventions in older veterans.

“The prevalence of chronic pain in the American veteran population is very high, and among those who have chronic pain, musculoskeletal pain such as chronic back pain is very common,” said Adam Goode, DPT, PhD. “Considering that in the general population, about 50 percent of all older adults have chronic low back pain and up to 60 percent of all veterans complain of chronic pain, the condition is extremely common and understudied.”

Chronic low back pain is a persistent pain in the lower back region that lasts for at least three months. It represents the second-leading cause of disability worldwide and is a major economic problem, resulting in approximately $100 to $200 billion per year in costs for the U.S.. The prevalence of chronic low back pain in adults has increased more than 100 percent in the last decade and continues to increase dramatically in the aging population in the country, affecting both men and women in all ethnic groups with a significant impact on functional capacity and occupational activities.

Conducted in the Durham Veterans Affairs Health Care System and funded by the Veterans Health Administration, one of the largest integrated healthcare systems in the U.S., the pilot study demonstrated that home-based telephone-supported physical activity interventions are feasible, acceptable, and safe for older veterans.

“To improve physical function among older adults was our primary outcome,” said Goode. “Improving function is very important for the population with chronic low back pain, for low back pain in older adults leads to functional decline, which is associated with many deleterious effects such as changes in cognitive function and mortality.”

According to the study, despite current guidelines indicating that individuals with chronic low back pain should participate in regular exercise, fewer than 40 percent of veterans with chronic pain, including chronic low back pain, use exercise to treat their pain.

“As far as back pain in general is concerned, there are not a lot of interventions that have a large impact on improving outcomes,” said Goode. “One simple intervention is exercise or physical therapy that can considerably improve physical function among older adults and can be successfully delivered in the home setting.”
Providing new incentives for drug adherence

For children with type 1 diabetes, daily monitoring of blood glucose levels is vital because glucose-level awareness dictates the rest of their diabetes care, such as insulin dose adjustments, eating behaviors, and physical activity. However, studies have shown that overall diabetic glycemic control often deteriorates during adolescence, leading to increased risks of costly and potentially life-threatening complications.

Using small financial incentives and accessible monitoring tools such as wireless glucometers and apps may motivate young people to play a more active role in the management of their condition. The results of a randomized controlled trial, led by researchers at the DCRI and the Perelman School of Medicine at the University of Pennsylvania, show that participants in the intervention group, who received a financial incentive, were nearly three times more likely to achieve daily glucose monitoring goals.

Behavioral economic interventions using financial incentives have been successfully used to increase adherence to chronic disease management regimens in adult populations but have not yet been widely tested in younger populations. The authors say the study shows that the strategy may be an effective way to reach a population that has historically been considered difficult to engage.

“Young people are often financially dependent on others, such as their parents, making financial incentives an attractive option for encouraging them to become more engaged in their own health as they move into adulthood,” said Charlene Wong, MD.

“Our results showed that offering a small monthly financial incentive significantly improved daily glucose monitoring and suggest similar financial incentives could also be an effective way to improve management of other chronic health conditions in youth, such as medication adherence in those who have received transplants or have asthma.”

During the three-month intervention period, participants in the incentive arm received $60 in a virtual account at the beginning of each month, from which $2 was deducted for every day that check goals were not achieved. During the three-month follow-up period, incentives were discontinued. All participants received daily monitoring feedback letting them know whether they had reached their daily goals and, if applicable, the remaining balance in their account.

Results of the study showed that, in the financial incentive group, participants achieved check goals roughly 50 percent of the time, compared with 18.9 percent of the time for participants in the control group. Adherence to glucose monitoring goals decreased in both groups during the follow-up period (15.3 percent in the intervention group and 8.7 percent in the control group). Despite a significant increase in daily monitoring, changes in blood glucose levels did not differ significantly between the groups during either the intervention or follow-up periods.
between the ages 14 and 20 with poorly controlled type 1 diabetes

Incentive arm participants received $60 in a virtual account at the beginning of each month. $2 was deducted for every day that check goals were not achieved.

RESULTS

The financial incentive group achieved check goals roughly 50% of the time.

The control group achieved check goals roughly 18.9% of the time.

Adherence to glucose monitoring goals decreased in both groups during the follow-up period (15.3% in the intervention group and 8.7% in the control group).
New Faculty

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Hwanhee Hong, PhD  
Department of Biostatistics  
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Michael (Luke) James, MD  
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Kishan S. Parikh, MD  
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Medicine – Cardiology

Kathleen Welsh-Bohmer, PhD  
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Department of Psychology  
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Christina M. Wyatt, MD  
Department of  
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DCRI Fellows

SECOND-YEAR FELLOWS

Daniel Edmonston, MD  
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Nathan Waldron, MD, MHS

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FIRST-YEAR FELLOWS

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Oliver Jawitz, MD  
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Anna Hung, PhD  
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