Inside:

WATCHMAN device: Better for AFib than anticoagulants? We lead the clinical trial

Philanthropy-funded cardiac research

Continuing education programs go virtual
When competitive water skier John Howell developed chronic atrial fibrillation in his 70s, he started a blood thinner regimen to treat and prevent blood clots and reduce the risk of stroke. But participating in sports can be dangerous for someone taking anticoagulants, which can cause excessive bleeding. One spill from his skis and Howell could bleed uncontrollably.

“You want a nice, efficient heart when you’re exercising,” he said. “Unfortunately, when you ski, you can take some dramatic crashes that can be life-threatening.”

After four or five years on the drug Eliquis, Howell, 80, wanted his AFib cured. Twice he tried cardioversion, a procedure that can restore normal heart rhythm by applying a controlled electric shock to the heart to break the pattern of abnormal electrical signals. After each time, however, his AFib returned.

Out of options, Howell’s cardiologist in Fredericksburg, Virginia, referred him to VCU Health Department of Cardiology chair Dr. Kenneth Ellenbogen, whom they were confident could help the retired dentist. Pauley Heart Center’s Atrial Fibrillation Program offers a full spectrum of innovative therapies and treatments and is focused on meeting the individual needs of each patient. Because Howell had a high risk of stroke, Ellenbogen recommended he receive a WATCHMAN implant, which he’d been successfully using for years. The parachute-shaped device is designed to keep harmful blood clots that form in the left atrial appendage from entering the blood stream and potentially causing a stroke.

The WATCHMAN is permanently placed at the opening of the left atrial appendage. The procedure requires an overnight stay in the hospital, and recovery takes about 24 hours.

“I was all for having it done,” Howell said. “I have the highest regard for Dr. Ellenbogen and felt like I was in really good hands.”

He had the procedure done without incident. “Then, I went about my life playing tennis and water skiing,” said Howell, a multi-time Eastern regional timed slalom champion.

Positive outcomes like Howell’s interested Ellenbogen in studying whether the newest version of the WATCHMAN device may one day be the preferred therapy for patients with non-vascular AFib who are at high risk of stroke. Ellenbogen is a co-chair of CHAMPION-AF, a global, head-to-head clinical trial of the WATCHMAN FLX device versus non-vitamin K antagonist oral anticoagulants (NOACs).

“This is a groundbreaking study that looks at a device that the doctors here have been implanting for a number of years successfully and looks at it as first-line therapy for preventing stroke in patients with atrial fibrillation,” Ellenbogen said. “That’s huge.”

WATCHMAN vs. NOAC
The CHAMPION-AF clinical trial compares NOACs like Eliquis with the WATCHMAN FLX, putting the best available drugs up against the best available left atrial appendage closure device.

“We’re studying different strategies for preventing stroke in patients with atrial fibrillation. And of course, the strategy most commonly used has been drug strategy,” Ellenbogen explains. “Blood thinners are great, but they make it harder for you to stop bleeding when you start bleeding. So, in patients who have atrial fibrillation, most
of their strokes come from what we call the left atrial appendage, which some surgeons call the appendix of the heart. Somebody came up with the idea of if we could close off the left atrial appendage, we might be able to prevent strokes for patients with atrial fibrillation. And they wouldn’t have to take blood thinners.”

In a number of pivotal studies, Ellenbogen said, it was found that patients who can’t take blood thinners but who received the WATCHMAN did well with an aspirin a day, or nothing.

The WATCHMAN device has now gone through several iterations, and the implantation procedure has been improved. “Maybe this type of device might be better than drugs for most people,” Ellenbogen said. “That’s the question our study is attempting to answer.”

**About the device**

The CHAMPION-AF trial will use the next-generation, FDA-approved WATCHMAN FLX device. Manufactured by Boston Scientific, WATCHMAN FLX is built on the WATCHMAN, the most studied and most implanted left atrial appendage closure device. More than 100,000 have been implanted worldwide, Ellenbogen said.

The trial includes about 150 sites globally and will enroll approximately 3,000 patients. Dr. Marty Leon, director of the Center for Interventional Vascular Therapy at New York Presbyterian/Columbia University Irving Medical Center, is a co-chair. Principal co-investigators are Dr. Shephal Doshi, cardiac electrophysiologist at Pacific Heart Institute, and Dr. Saibal Kar, interventional cardiologist at Los Robles Health System.

To be enrolled in the study, patients have to have at least a moderate risk of stroke from AFib. “We have a lot of patients who come to see us who don’t want to take blood thinners because they’re active, or they’ve had some bleeding,” Ellenbogen said. “This study gives them the opportunity to get a device implanted without having to have had a bleeding episode to get the device implanted. So, if you’re 70 years old and you have high blood pressure, you’re going to be on blood thinners the next 20 years of your life. But if you participate in this study, you have a 50% chance of having a device implanted. So, we can see which is better, the medicine or the drugs.”

After receiving the device, patients will be evaluated in three years. “We’ll be looking to see if this device is safe and effective compared to the drug,” Ellenbogen said.

**The big picture**

“This is probably one of the most important studies being done in the next five years in clinical cardiology. And Pauley is going be involved. I’m going to be involved as one of the two people who is going to steer the study to its conclusion. Whether it’s positive or negative, it’s going to possibly change the way we practice, possibly just reinforce the way we practice.”

That change could mean that any patient with AFib gets a WATCHMAN device implanted to prevent a stroke. The implant would be in place of drug therapy.

Perfect for active people like Howell, who have years of full lives ahead of them — trips to take, grandkids to raise and slalom course races yet to win.

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**What is AFib?**

If your heart beats too rapidly and irregularly, you may require treatment for atrial fibrillation, the most common abnormal heart rhythm. When the upper part of your heart (the atria) beats irregularly and too fast, this can cause your heart to quiver (“fibrillate”). As a result, your most important organ can’t get the oxygen and blood supply causing a stroke. About one in five people who have a stroke have existing clots from getting larger. They are prescribed for AFib patients because their irregular heartbeats can cause blood to collect in the heart and form a clot that can travel to the brain, cutting off the oxygen and blood supply causing a stroke. About one in five people who have a stroke have AFib. The more conventional anticoagulants are warfarin (Coumadin) and heparin. However, direct oral anticoagulants like Eliquis are a class of newer medications that have fewer drug interactions and do not require regular blood monitoring.

Anticoagulants keep blood clots from forming in an artery, a vein or the heart, and may prevent existing clots from getting larger. They are prescribed for AFib patients because their irregular heartbeats can cause blood to collect in the heart and form a clot that can travel to the brain, cutting off the oxygen and blood supply causing a stroke. About one in five people who have a stroke have AFib. The more conventional anticoagulants are warfarin (Coumadin) and heparin. However, direct oral anticoagulants like Eliquis are a class of newer medications that have fewer drug interactions and do not require regular blood monitoring.

While for many people there is no apparent cause for AFib, it can be related to underlying conditions or risk factors, including previous heart attack, congestive heart failure, leaky valves, coronary artery disease or inflammation near the heart, high blood pressure or diabetes.
A head start
New undergraduate research programs provide career-level experiences

Alexis Hawbaker’s desk is covered in sticky notes. A student at William & Mary, she labels herself a naturally curious person who jots down every great question that comes to her. “They just come to me out of nowhere, so I write them down and stick them there,” she said, intending to circle back to them. This year, she brought a few of those questions to Pauley, including one that reads: “Could the link between nerves, the extracellular matrix and myofilaments contribute to cell degeneration?”

Hawbaker is a participant in a new undergraduate program designed to provide students with career-forming experiences in multidisciplinary research. A collaboration between Pauley and William & Mary, Research Experience in All-Around Cardiac Health (REACH) pairs students with sponsor faculty for a 10-week mentored research fellowship program funded through an institutional award by the American Heart Association, welcomes students from not just William & Mary, but any school, to experience research at VCU — one of just a handful of institutions nationwide to be selected to host. Despite COVID-19, both programs were able to stay on track in their first year, through a virtual research symposium.

Over the course of their experiences, students participating in the AHA-funded program are also required to submit narratives and annual updates to the association.

“It’s not only exposing the students to clinical research, but also professional development,” says Megan O’Hare, program manager. “We’re participating in the things that researchers do on a day-to-day basis in their lives, as well as educating our fellow classmates,” said Anuj Kotak, a third-year biomedical engineering and psychology student at VCU who participated in the inaugural program. “For those of us going into cardiology as physicians, or conducting research, these are skills that we’ll be using for the rest of our lives.”

For his research, Kotak was paired with Dr. Cory Trankle, instructor for the Department of Internal Medicine’s Division of Cardiology. “The work I did with Dr. Trankle — only one other hospital in the nation is working on that type of research, so I felt like this was an opportunity to participate in something that could have a lasting impact on the field,” he said. “That’s why I found this program so exciting … I thought that it would be impossible to do at the undergraduate level. It has solidified my plan to become a cardiologist.”

“It’s not only exposing the students to clinical research, but also professional development.”

Undergraduate students classified as juniors or seniors, applicants undergo initial interviews and submit project proposals to the director of Pauley, competing for funds — including a stipend plus cost of housing. Over the course of their experiences, participants undergo final interviews and submit project proposals to the director of Pauley, competing for funds — including a stipend plus cost of housing.

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The Innovation of the Heart Research Reception held last November and co-hosted by the American Heart Association and VCU Health brought together Pauley Heart Center researchers and the donors who make their research possible.

The annual networking event celebrated the cardiovascular research and partnerships between VCU Health Pauley Heart Center and the American Heart Association, and the resulting progress in the prevention and treatment of heart disease, stroke and related health issues.

Throughout the reception, AHA-funded researchers discussed their work, and its impact on the health of our community. Eleven participants from Pauley presented posters describing how AHA grants had enabled and advanced their research.

Drs. Lei Xi, Qun Chen, Arun Samidurai and Teja Devarakonda described their studies on novel approaches to attenuate injury following a heart attack, while Drs. Justin Canada, Anindita Das and Adolfo Mauro discussed their studies in the emerging field of cardio-oncology and how to protect the heart against the toxicity of cancer therapies. Dr. Justin Heizer presented his study on management of heart failure patients, and Drs. Aldo Bonaventura, Brian Mitchell and Alessandra Vecchie shared their research in the area of inflammation of the heart.

“The researchers who presented at the Innovation of the Heart reception represent only some of the excellent work taking place at Pauley Heart Center,” said event organizer Dr. Fadi Salloum, the Natalie N. and John R. Congdon Sr. Endowed Chair in the Pauley Heart Center and assistant chair for research in the Department of Internal Medicine.

Innovation of the Heart also included a formal research presentation on cardiac sarcoidosis by Dr. Jordana Kron, associate professor in the VCU School of Medicine and cardiologist at VCU Health Pauley Heart Center, and Dr. Jennifer Jordan, assistant professor in the VCU College of Engineering’s Department of Biomedical Engineering and director of the Cardiovascular MRI Core Lab at the Pauley Heart Center. Kron and Jordan are co-principal investigators on a study made possible by the AHA’s 2019 Collaborative Sciences Award, a three-year $750,000 award to investigate a new treatment for cardiac sarcoidosis, an inflammatory condition that can lead to heart failure. The first-of-its-kind study evaluates the efficacy and safety of using interleukin-1 blockade to treat patients who present with cardiac sarcoidosis. The AHA award builds on a $50,000 Pauley Pilot Research Grant that Kron received last spring. (Read more about Kron’s research on Page 12.)

“I was very excited to share the research I am involved in,” Kron said of her event participation. “It is important that the supporters of the AHA understand how much their support means to the researchers and, more importantly, to the patients who benefit from the science.”

Innovation of the Heart followed the American Heart Association/American Stroke Association Scientific Sessions, an annual conference devoted to the future of cardiovascular medicine and science and attracting researchers from around the globe. Every year Pauley Heart Center sends a group of professionals to this national event to share their research and engage with scientists and medical professionals.

In 2019, 25 researchers representing Pauley — the most in the center’s history — presented their work at the prestigious meeting held in Philadelphia. Research topics included cardio-oncology and heart attack-related heart failure.

For more information about this event, email Whitney Jones, AHA, at whitney.jones@heart.org.

AHA and VCU: By the numbers*

• 1971: Year the first American Heart Association grant was awarded to a researcher at the Medical College of Virginia, to study re-innervation of the cardiac transplant
• 2021: Year the AHA and VCU will celebrate 50 years of partnership

Total AHA funding to VCU and MCV for 271 research projects since 1971

$22,005,628

*As of January 2020
In fiscal year 2020, we achieved a fundraising record of $6.6 million, fueling innovation and advancements in clinical care at the VCU Health Pauley Heart Center.

“These gifts allow us to test novel ideas and use that data to apply for national grants, recruit new faculty, educate the next generation of health care providers and ultimately provide the best cardiovascular care here in Virginia,” said Carrie Mills, Pauley’s lead development officer.

A $5 million gift from the Pauley Family Foundation, the majority of which went to clinical care, was announced in February. Other sizeable gifts included $600,000 from C. Kenneth Wright supporting research in electrophysiology and cardiac arrhythmias, and a $250,000 gift from an anonymous benefactor that was earmarked for cardio-oncology research.

“Gifts of every size make a huge impact, allowing our faculty, students and caregivers to improve cardiovascular care for all,” said Mills, noting that 147 donors contributed to the record-breaking year.

Many donors are people who have experienced Pauley’s excellent patient care, either as patients themselves, or through friends and family, said Margaret Ann Bollmeier, president of the MCV Foundation, which manages Pauley’s financial assets. “Contributors want to show their gratitude to the excellent physicians and support their research and future innovations for the benefit of future patients.”

“Dr. Hundley’s vision is exciting, and people want to be part of helping the Pauley Heart Center realize it.”

Mills said donors this fiscal year also included alumni, faculty and staff, community leaders and friends of Pauley Heart Center, who supported Pauley through planned, major and annual fund gifts. Those donations were also counted in VCU’s seven-year Make It Real capital campaign, which ended in June 2020.

Pauley’s fundraising success comes on the heels of another financial milestone. In 2019, Pauley received the most external funding in one fiscal year. Additionally, U.S. News & World Report just recognized VCU Medical Center as the No. 1 hospital in the Richmond metro area for the 10th year in a row in its 2020-21 “Best Hospitals” rankings. VCU Medical Center ranked No. 44 for cardiology and heart surgery out of more than 4,500 hospitals nationwide.

These recent, significant achievements reflect the leadership and direction of Dr. Greg Hundley, director of Pauley Heart Center since 2018. “The applied research and cutting-edge work at Pauley Heart Center attract donors who want to support innovations and positive outcomes,” Bollmeier said. “Dr. Hundley’s vision is exciting, and people want to be part of helping the Pauley Heart Center realize it.”

Created by Hundley in 2019, the Pauley Advisory Board has played a significant role in fundraising, Bollmeier added. “Founding advisory board chair Roger Boeve has recruited a highly respected, connected and diverse board that is reaching out to community members to share the Pauley Heart Center vision and solicit support for it.”

“We’re so grateful for the support of the community,” Mills said. “Their gifts allow us to provide the best care to patients.”

Pauley Heart Center staff celebrate a milestone year of philanthropy.

A record year for giving at Pauley! Gifts of every size make an impact on research, education and patient care.
VCU Health cardiology and heart surgery programs rank among top 50 in the nation.

U.S. News & World Report has recognized VCU Medical Center as the No. 1 hospital in the Richmond metro area for the 10th year in a row, according to its recently released 2020-21 “Best Hospitals” rankings. VCU Medical Center ranks as the No. 2 hospital in Virginia and among the top 50 in the country for cardiology, heart surgery and urology.

VCU Medical Center ranked No. 44 for cardiology and heart surgery out of more than 4,500 hospitals nationwide. The rankings are based on clinical data such as patient outcomes and a survey of physicians.

Specialty areas considered included transcatheter aortic valve replacement, aortic valve surgery, heart bypass surgery, abdominal aortic aneurysm repair and heart failure. “We’re excited that VCU Medical Center was rated ‘high performing’ in treating heart failure,” said Dr. Greg Hundley, Pauley’s director. “Our standing places us in elite company, while illustrating something we already know — that world-class care is right here in Richmond. We are treating some of our community’s most vulnerable, complex patients with compassionate, patient-centered care. For this reason, patients turn here when they need care the most.”

Transcatheter aortic valve replacement (TAVR) was introduced as part of the U.S. News & World Report’s ranking methodology this year, highlighting the important role it and other minimally invasive procedures play in helping Pauley’s patients return to their normal lives as quickly as possible. TAVR is an alternative to open-heart surgery for patients with symptomatic aortic stenosis. The procedure involves inserting a new heart valve through a catheter in the groin, advancing the valve upward to the heart and implanting it there.

For other advanced procedures, such as heart transplants, the patient survival rate is 96.4%, which exceeds the national average of 91.3%. Pauley is a national leader in device-based treatments for advanced heart failure and is a center of excellence for comprehensive sarcoidosis treatment.

Center of excellence

VCU Health’s extracorporeal life support program earns coveted Gold Level ELSO Award.

As one of the oldest programs and just the third of its type in the U.S., VCU Medical Center’s extracorporeal life support (ECLS) has long given “coding” patients a fighting chance. Since the late 1970s, the center has provided extracorporeal membrane oxygenation (ECMO) to individuals in the direst conditions.

Now, patients and their loved ones have even more assurances that they’re in the best possible hands, as July 1 the center received a prestigious Gold Level ELSO Award for Excellence in Life Support from the Extracorporeal Life Support Organization (ELSO).

ECMO is used for patients whose lungs cannot provide enough oxygen, including patients with COVID-19. For those patients, when all other therapies fail, ECMO offers a 50% chance at recovery.

The center’s ECMO services include five life-sustaining ECMO units, treating more than 40-60 patients per year. In 2019, the program’s survival rate for extracorporeal cardiopulmonary resuscitation was over 70%.

“I think it speaks to the public, to our providers, to our referrals and to the community that we have gone the extra mile to achieve those criteria to qualify us to be a center of excellence,” says Patricia Nicolato, D.O., associate professor in the Department of Surgery and Division of Cardiothoracic Surgery, and director of VCU Health’s ECLS program.

Designed to recognize and honor ECLS centers reaching the highest level of performance, innovation and quality, ELSO’s award program is based on the organization’s guidelines for new programs, training and education. The Centers of Excellence designation and awards for excellence signify leaders in ECLS. Recognized by U.S. News & World Report and Parents magazine as a criterion for top institutions, gold- and platinum-level awards recognize ECLS programs worldwide that distinguish themselves through processes, procedures and systems that promote excellence and exceptional, patient-centered care.

As a result, the award not only serves as further assurance to VCU Health’s patients and referring health systems, but also grants VCU Medical Center an additional point in the U.S. News & World Report ranking system and a leg up in other evaluations.

Measured against benchmarks for all 2020 Centers of Excellence, the ELSO awards recognize centers achieving qualifying scores on ELSO’s Excellence in Life Support Application — a multyear process of improvement.

VCU Health’s center is actively working toward the platinum-level award of achievement.
What is CARMAT?
A CARMAT, which is also the name of the company that makes it, is a total artificial heart. It replaces both lower pumping chambers of the heart. It’s very similar to the artificial heart we have right now, a device made by a company called SynCardia that’s pneumatically (air) powered. CARMAT’s pump is fully implantable and electrically driven.

What’s the goal of the trial?
A This is a trial to prove that the CARMAT total artificial heart can meet FDA standards for performance and safety.

Why is this trial significant?
A In the U.S., the total number of heart transplants done per year is approximately 3,000. The total number of patients per year who would benefit from a heart replacement is probably 50-60,000. No matter how hard we work to increase the number of donors available for heart transplantation, that gap is too broad. We need an off-the-shelf device that could be used for the variety of patients, different sizes, different ages, and produce good outcomes similar to a heart transplantation. I think in another five to 10 years, we will make multiple modifications of the CARMAT device to benefit a number of patients with advanced heart disease who could then have a pump put in and maintain a good quality of life. That’s what we want to get to.

How did VCU become a test site?
A VCU Health has a lot of experience with artificial hearts, and we have had some of the best outcomes in the world. CARMAT came to us because of our experience with artificial heart technology, patient management, patient selection and good outcomes.

For whom is the CARMAT heart designed?
A The CARMAT heart is meant for patients with advanced heart failure who require a heart transplant. So, while they’re waiting, if they get very sick, they could potentially go to the CARMAT artificial heart and then go towards the transplant. Once the pump is in, it will stabilize them. A drawback of the device is that it’s fairly big. It doesn’t fit everybody. So, the device would not fit a smaller woman.

How many patients will be included?
A The initial trial is seven patients nationally. We have a lot of patients who would benefit from the artificial heart technology, but because this is new technology, the trial is being restricted to the small group to allow us to study their outcomes carefully before we expand the use. Participants will be patients whom we evaluate for heart transplantation, and they may have severe biventricular failure. They are not going to be able to wait for a heart for many months, and potentially they would need to go to an LVAD device to take them to a heart transplant safely. We screen patients every day. We’re the largest heart transplant program in Virginia, and I think we’ll see a lot of patients being referred to us.

Describe the timeline.
A It’ll take probably two to three years to enroll enough patients. The goal for the trial is to get the patients that are on the device to transplantation or for survival up to six months.

Describe the team you’re working with. Who else in the health system is involved in CARMAT?
A We’ll have four surgeons trained, and two or three of us will scrub in together for the first implant surgery. There’s a whole ICU nursing team. There’s ICU critical care physicians who need to understand how to manage the patient postoperatively. There’s a whole group of cardiac anesthesiologists, physician’s assistants and fellows. The device coordinators manage the patients when they’re home. So, we’re looking at 40 to 50 people who need to really understand the intricacies of the device. For a trial like this, we would train for weeks before even conducting the first implant.

What does hosting this trial mean to Pauley?
A VCU Health is focused on innovation to benefit patients. We’re constantly looking at new ways to make it better for them. That can be done only by working together in large teams, in a complex system where we can partner with industry or other areas to create new knowledge and new technology. There are lots of things we need to learn as we go forward, but as an institution and as a heart center, to be able to be a part of a large trial like this, to help patients in the future, this trial is a very exciting step for us.

If someone thinks that they may be a good candidate, how do they enroll?
A If you think you may be a good candidate, speak with your cardiologist. We anticipate receiving referrals to our heart transplant and heart failure team from colleagues around the country.

To learn more about CARMAT, visit carmatsa.com.
George Williamson has a debilitating case of sciatica to thank for putting him into the skilled hands of VCU Health’s vascular surgery team. An MRI to determine the source of his persistent sciatic nerve pain revealed the presence of two abdominal aortic aneurysms the physicians in Pauley’s Aortic Program were uniquely equipped to treat.

Aortic aneurysms are abnormal bulges in the wall of the body’s main artery that grow slowly and have no symptoms. Left untreated, however, they can rupture and cause death. Williamson’s were in a spot that made a traditional repair impossible. His neurologist referred him to Pauley Heart Center, where Dr. Mark Levy monitored Williamson’s aneurysms for several years. When the time came for treatment, Dr. Robert Larson performed a six-hour surgery on the 80-year-old.

“Most hospitals are able to do the standard basic aneurysm repair, but Mr. Williamson had less fortunate anatomy,” said Larson. As with 5% of patients, Williamson’s aortic aneurysms were too close to the arteries that branch off to the kidneys for traditional endovascular aneurysm repair to work. Until recently, the only option these patients had were major abdominal surgery or no surgery at all.

Fenestrated endografts offer a number of benefits over open surgery, including shorter hospital stays, fewer complications and risks, and faster recovery times.

Open surgical repair wasn’t a possibility. “That’s a pretty huge operation,” Larson explained. “I’m not entirely sure that Mr. Williamson would have been able to come through that without major issues, given his age and his other medical problems.”

The retired investment banker was an excellent candidate, however, for fenestrated endovascular repair, or fenestrated EVAR. The minimally invasive surgical option uses a fenestrated graft, a custom-built device with holes called fenestrations that precisely fit the patient’s anatomy. The graft can cover the branch arteries of the aorta (in Williamson’s case, the kidney arteries) because the graft has corresponding holes positioned over the branch vessels that allow for blood to flow through the graft.

The graft is inserted into the femoral artery via an incision in the groin and guided through the blood vessel to the aneurysm. Once the fenestrated endograft is implanted inside the aneurysm, blood can flow through the diseased area without putting pressure on the weakened aortic wall. Fenestrated endografts offer a number of benefits over open surgery, including shorter hospital stays, fewer complications and risks, and faster recovery times.

“I read up on Dr. Larson,” Williamson said. “There are only a very few people who can do that operation. He saved my life.”

Larson has been performing the specialized surgery since Cook Medical LLC made this generation of the fenestrated graft available in 2012. “It’s revolutionized how we treat these types of aneurysms,” he said. “The technology that’s been developed is really exciting.”

Williamson was in the hospital for four days, an average length of recovery for fenestrated EVAR. “If we had done the open procedure, he would have been here for at least two weeks, if not more, with several months of recovery and rehab,” Larson explained. “The most rewarding thing, from our point of view, is we can provide these types of therapies, and fix the problem and get people who were previously quite frail back to their normal routine as quickly as possible.”

Williamson, now 81, has made a full recovery since his 2019 surgery, which has enabled him to spend winters in Florida and continue his love of travel, volunteer work and philanthropy.

“I’m back to normal,” he said. “I think life is incredibly good.”
Despite pandemic, patient receives much-needed new heart

Raymond Hill needed a new heart — and fast. The Fredericksburg, Virginia, resident suffered from congestive heart failure, and in March 2020, his health was rapidly declining.

During a global pandemic, he needed a transplant. “I didn’t think I was going to get one, but I prayed on it,” he said.

Hill prayed from his ICU bed at VCU Medical Center, where staff provided lifesaving care to him and other patients at an unprecedented time. Days later, Hill was rushed into surgery to receive his new heart.

Dr. Benjamin Medalion, professor and chair for the Division of Cardiothoracic Surgery, performed the surgery. Medalion’s expertise includes heart and lung transplantation.

Hill was critically ill and declining fast. “Those patients cannot wait long,” Medalion said. “That’s why we decided to proceed, with extra precaution that we could apply in this era of COVID-19.”

Remarkably, Hill was one of the 14 heart transplant recipients at VCU Health from March to July of this year. All told, VCU transplanted a total of 186 organs during that time, which also included 59 livers, 112 kidneys and one pancreas.

Today, Hill, a doting grandfather, has a new heart. “It sounds like a drum, a beating drum,” he said. “I feel great.”

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“There’s no more satisfaction than knowing... when a transplant patient recovers, they’re back to normal activity and they can appreciate the new quality of life and new things they couldn’t do before,” Medalion said.

At home, Hill is adjusting to a new normal. And a new outlook on life, made possible by VCU Health. “Stay healthy, eat healthy and stay positive,” he said. “I got a new lease on life, so I got to take advantage of it.”

“View this online to hear Mr. Hill share his story.”

Pauley offers free CME and MOC programs via Zoom

As a part of our commitment to academic excellence, we offer weekly educational opportunities for learning. Each one-hour educational program allows attendees to interactively learn from rising, prominent and internationally recognized experts in the field of cardiology, some of whom are located in other countries.

Each conference features new and topical research. Conferences are free, and participants do not have to register ahead of time. Additionally, selected conferences allow attendees to earn continuing medical education (CME) credits, maintenance of certification (MOC) points or both.

Typically, physicians needing CME credits for their licensure and MOC for board certification must seek out these educational opportunities and pay for them out of pocket. But Pauley offers them for free to both internal and external participants. Pauley also offers continuing education credits to nurses, pharmacists, pharmacy technicians, psychologists, physician assistants, social workers and MRI technologists, noted Shannon Winston, Pauley’s new professional education program coordinator and event planner.

Among regional peer institutions, Pauley Heart Center has taken the lead in offering educational credits, Winston said, adding that these efforts support Pauley’s mission to provide comprehensive education and training to cardiology students and professionals, and will help further position Pauley as a leader in the field. “As we have

revamped the educational programming that Pauley offers, our attendance continues to grow,” Winston said. “We are eager to get the word out and encourage any interested parties to get involved.”

To sign up for emails about recurring or upcoming educational opportunities and events, or to learn more, email shannon.winston@vcuhealth.org. 
Search for COVID-19 therapies includes VCU Medical Center canakinumab clinical trial

Preliminary data from a clinical trial testing the safety and efficacy of the drug canakinumab in treating COVID-19 patients should be available this fall.

VCU Medical Center enrolled 51 patients into the trial to learn whether the drug is effective against a severe inflammatory overreaction called cytokine release syndrome that may occur in some patients with pneumonia due to COVID-19.

Canakinumab works to neutralize a protein, Interleukin-1β, in the body to suppress deregulated inflammation. It is FDA approved to treat a series of rare auto-inflammatory diseases and a type of juvenile arthritis.

“Interleukin-1β is an important cytokine that mediates fever and causes a cascade of inflammation in the body and is considered to be one of the key mediators in inflammatory response,” said Dr. Antonio Abbate, the James C. Roberts Esq. Professor of Cardiology in the Division of Cardiology and the study’s principal investigator.

Canakinumab was selected for the trial because of its strong cardiovascular safety profile, he noted.

The international study activated at VCU Health on April 29 and is sponsored by drug manufacturer Novartis.

In this phase 3, randomized, placebo-controlled trial, researchers enrolled volunteer COVID-19 patients who were experiencing severe COVID-19 pneumonia and who required oxygen but not a ventilator.

VCU Medical Center was involved in a previous study of canakinumab where it was shown to reduce recurrent cardiovascular events.

As VCU and hospitals worldwide work to combat the coronavirus from a number of angles, Abbate and Dr. Benjamin Van Tassell, professor in VCU’s School of Pharmacy and a co-investigator on the study, are also interested in impeding the symptoms’ progression from moderate to severe to fatal. And the inflammation, Van Tassell said, may be what’s actually fatal.

“It can kind of snowball on itself,” he said. “A little bit of inflammation can trigger more inflammation, which triggers more and more. And that seems to be the most dangerous part of a COVID-19 infection: when you enter into this hyper-inflammatory state.”

“We know that while the COVID-19 virus may be affecting people of all ages and diseases, it seems to be more severe in older patients and patients with comorbidities like heart disease, diabetes and obesity,” Abbate added. “These patients have chronic inflammatory state at baseline.”

Few studies have specifically looked at COVID-19’s effect on the heart, and none have looked at treatments for cardiac complications at this time, Abbate noted. For such a study to occur, patients would have had to have heart-related complications first and then enroll in a treatment study. But because individuals are being offered treatment studies when they present with COVID-19, there have been no studies looking specifically at patients who have cardiac complications. What we may expect is that some treatments may reduce the incidence (occurrence) of such complications.

The canakinumab study follows other drug treatment trials at VCU Medical Center, including two trials with an antiviral drug developed for Ebola, remdesivir, and another with a drug developed to treat rheumatoid arthritis, sarilumab. Abbate said the sarilumab did not show any clinical benefit in that specific trial; however, the full results have not been published. Results of several clinical trials for patients with severe COVID-19 symptoms, including a trial at VCU Medical Center, showed that remdesivir was effective in reducing the length and severity of COVID-19-related pneumonia. The FDA issued an emergency use authorization for remdesivir May 1 based on data from 180 clinical sites, including VCU Medical Center. Abbate points out that with over 1,000 clinical trials on COVID-19 ongoing worldwide, it will be important to stay updated on all the latest evidence in real time.

There is a lot still unknown about COVID-19 and its symptoms. “It’s clear that at different stages of the disease, you’re trying to prevent different complications,” he said.

Abbate is also the medical director of the Clinical Research Unit at VCU Health and an associate director at the C. Kenneth and Dianne Wright Center for Clinical and Translational Research, which oversees clinical trials at VCU with the help of a National Institutes of Health award. The Clinical Research Unit is a unique, dedicated space at VCU Health used for clinical trials, and its committed staff of nurses has been heavily involved in COVID-19 trials.

“With all of the moving pieces in the COVID-19 pandemic, it has really helped to be at a place like VCU that has the experience, the infrastructure, the personnel and the will to do this kind of trial,” Van Tassell said.
Investigating a new method to treat sarcoidosis

A disease that has no cause or cure, sarcoidosis affects people of all ages throughout the world. Once considered a rare disease, the inflammatory condition now affects about 40 in every 100,000 African Americans in the U.S. and about five in every 100,000 Caucasians. It occurs in all races and in men and women but is most common among African American females ages 20 to 40.

The disease most commonly affects the lungs but can involve almost any organ system, including the skin, eyes, joints and heart. Cardiac involvement, which occurs in up to 25% of patients with sarcoidosis in other organs, can lead to life-threatening heart rhythm problems and heart failure.

“The field of cardiac sarcoidosis, and sarcoidosis in general, really needs new mechanistically driven therapies,” said Jordana Kron, M.D., an associate professor in the VCU School of Medicine and a cardiologist at Pauley.

In 2019, Kron was awarded a $50,000 Pauley Pilot Research Grant to investigate a new treatment protocol for cardiac sarcoidosis. The 15-month philanthropic grant is being used to evaluate the efficacy and safety of using an interleukin-1 blockade to treat patients who present with cardiac sarcoidosis. The study is the first of its kind to explore the new treatment paradigm.

“A new, safe and effective treatment could be life-altering for patients with cardiac sarcoidosis. It may also open the door for new therapies for cardiac sarcoidosis and other inflammatory heart diseases in the future,” said Kron, a translational science scholar at the VCU C. Kenneth and Dianne Wright Center for Clinical and Translational Research.

Interleukin-1 is a protein whose presence indicates inflammation in the body. Kron’s research aims to evaluate if using medication to block the protein will help treat cardiac sarcoidosis.

“Corticosteroids are the most commonly used treatment for sarcoidosis, but there is little data showing their efficacy, and they have significant side effects,” Kron said. “Interleukin-1 is the prototypical cytokine that plays a role in most inflammatory processes. Blockade of the protein has been shown to be effective in many types of heart disease.”

While cardiac sarcoidosis is the focus of Kron’s research, she is optimistic that, if shown to be effective, the blockade could be used to treat other forms of heart disease.

“A new, safe and effective treatment could be life-altering for patients with cardiac sarcoidosis.”

VCU has led clinical and translational research of cardiac sarcoidosis for nearly a decade, and VCU Health is home to the Multidisciplinary Sarcoidosis Clinic, the only center of its kind in Virginia. At the clinic, patients are able to meet with specialists in pulmonology, cardiology, electrophysiology and rheumatology.

In December 2019, VCU was recognized as a Sarcoidosis Center of Excellence. This two-year designation provides formal recognition of our team’s commitment to meet the needs of sarcoidosis patients and efforts to keep abreast of the ongoing advances and findings in the space.

Kron, who was awarded an endowment fund through the Wright Center to further support her research, is joined in the study by co-principal investigator Jennifer Jordan, Ph.D., an assistant professor in the VCU College of Engineering Department of Biomedical Engineering and director of the Cardiovascular MRI Core Lab at Pauley.

Jordan’s research focuses on translational and clinical cardiovascular MRI techniques and cardiac magnetic resonance tissue characterization in patients who have received chemotherapy for breast cancer. For this study, she is using her expertise in cardiac magnetic resonance to help assess inflammation in cardiac sarcoidosis and evaluate responses to treatment.

The Pauley Pilot Grant enabled Kron to successfully apply for and receive external funding. A $275,000 R21 grant from the NIH will be used to explore the feasibility and safety of interleukin-1 blockade as a novel therapeutic agent to treat clinically active cardiac sarcoidosis. A $750,000 AHA Collaborative Sciences Award will support her research, is joined in the study by co-principal investigator Jennifer Jordan, Ph.D., an assistant professor in the VCU College of Engineering Department of Biomedical Engineering and director of the Cardiovascular MRI Core Lab at Pauley.

Kron also received a Johnson Center grant to participate in a trial looking at steroids versus steroids plus methotrexate, and another Wright Center grant to look at optimizing cardiac MRI in cardiac sarcoidosis patients with defibrillators.
Advancing the understanding of aging hearts

Recent advances in clinical treatment have dramatically improved outcomes for adult patients suffering an acute myocardial infarction, or heart attack. However, the outcome for elderly patients remains disappointing.

Ongoing research by Dr. Qun Chen, associate professor in the Division of Cardiology, and Dr. Edward Lesniewsky, professor in the Division of Cardiology, focusing on aging hearts may lead to new ways of addressing cardiac injury in the aging population. Elderly patients have a higher mortality rate during heart attack compared to young and adult patients, even with the current highly successful use of emergency coronary intervention with stents to open the blocked artery during a heart attack.

In their study, the researchers hypothesized that pre-existing and age-related mitochondrial defects are a key factor increasing susceptibility to cardiac injury in aged hearts. Mitochondria are organelles found in the cells of every complex organism and produce about 90% of the chemical energy that cells need to survive.

“We propose that the restoration of mitochondrial function in aged hearts in the baseline state is critical to improve outcomes in the aged heart,” said Chen, principal investigator. Specifically, the researchers are paying close attention to the relationship between inflammation and microvascular disease, then we can create therapies to target inflammation, restore microvascular blood flow, and hopefully improve their exercise tolerance and quality of life,” she said. The results from this study will inform future research.

Exploring links between inflammation and HFpEF

People live with and die of heart failure every day — as many as half with preserved left ventricular ejection fraction (HFpEF). Conventional treatments for heart failure with reduced ejection fraction remain less effective for individuals with HFpEF.

This suggests that there is a missing link in the mechanism and understanding pathophysiology of HFpEF. A new study seeks to explore the role of inflammation and microvascular disease in pathogenesis of HFpEF using a novel cardiac MRI quantitative myocardial perfusion mapping.

Possibly due to comorbidities like diabetes and obesity, data shows that HFpEF patients have higher inflammation in their blood streams. Dr. Roshanak Markley, assistant professor of medicine in internal medicine and radiology at VCU Health, believes that’s no coincidence. A new 18-month study led by Markley uses a novel perfusion technique and MRI to explore possible links between inflammation, microvascular disease and HFpEF.

According to Markley, previous research using phase contrast cinemagnetic resonance imaging (cMRI) of coronary sinus blood flow during stress shows that coronary flow reserve is significantly lower in patients with HFpEF. Her new study, “Inflammation and Microvascular Dysfunction in Patients with Heart Failure with Preserved Ejection Fraction: Exploration of a Potential Missing Link Using Cardiac MRI,” examines the relationship between inflammation and microvascular disease using a novel cMRI perfusion technique that can quantify myocardial blood flow and create an automated pixel-wise perfusion map of the heart to diagnose microvascular disease.

“If we can find a link and identify these high-risk patients with inflammation and microvascular disease, then we can create therapies to target inflammation, restore microvascular blood flow, and hopefully improve their exercise tolerance and quality of life,” she said.

The hypothesis of Markley’s study suggests that inflammation induces coronary microvascular disease (CMD), leading to impairment of diastolic function and exercise capacity. Markley explores the strength of correlation between CMD, diastolic impairment and inflammatory biomarkers. Recruited from referrals across VCU Health, the study includes 20 men and women but aims to key in on a prevalence for HFpEF among females. By administering adenosine and increasing blood flow in the heart, the researchers image the perfusion in the heart using a novel sequence that can calculate the myocardial blood flow and create a perfusion map for more accurate assessment of blood flow. Subjects will also undergo an echocardiogram to assess for impairment in diastolic function and laboratory assessment of inflammation in the blood.
Dr. Bethany Denlinger joined the health system faculty in 1995 and is an associate professor of internal medicine/cardiology. She is board certified in internal medicine, cardiology and echocardiography. In addition to serving as cardiology staff physician at McGuire Veterans Administration Medical Center, Denlinger is medical director of the echocardiography lab and cardiac rehab at VCU Health Community Memorial Hospital in South Hill, Virginia. VCU Health CMH provides health services for the south-central region of Virginia and northern North Carolina.

Why did you pick the field of cardiology?
I was always interested in the medical field, but I didn’t decide on cardiology until I was a second-year medicine resident. I had some difficult call nights during my rotations and saw exciting things. I was busy, but I knew at the same time, I really loved cardiology.

What about your work brings the most satisfaction, and why?
I like the problem-solving part of taking care of patients. Some have typical complaints of chest pain, but sometimes not. Women have atypical symptoms of heart disease and can be more difficult to diagnose. I have patients that I’ve known for a long time. I’m satisfied with the big picture of taking care of them and their community. I’ve been here 25 years, and now I’m taking care of generations of families and friends.

What about your work do you find most challenging, and why?
Medical problems/presentations are not the same for everyone, and people don’t always follow the rules. Whenever you start thinking you’ve seen it all, a patient presents with a new set of symptoms, and you learn more.

How did your relationship with Community Memorial Hospital in South Hill start?
When I was a third-year cardiology fellow, Dr. George Vetrovec told me about an opportunity to work in South Hill doing outreach for three days a week. At that time, “outreach medicine” was unheard of. I was trying to decide between academics and private practice. I thought working in South Hill would be something I would do for a year or two until I figured out what I wanted to do. After all these years, I’m still here.

What motivates you to make the hour-plus drive to South Hill three times a week?
I like the variety of working in South Hill, McGuire VA and VCU Medical Center. I’ve gone through a lot of cars in 25 years. The drive gives me time to separate work from home. I vary my time listening to medical lectures, books, the news or just jamming.

“Thought working in South Hill would be something I would do for a year or two... After all these years, I’m still here.”

What’s a typical day like for you in South Hill? Describe your duties.
I do consults and stress tests and read echocardiograms and Holter monitors in the morning. In the afternoon, I have a busy clinic.

When you’re not working in South Hill, how do you spend those other weekdays?
The other two days a week I work in the echo lab at McGuire VA Hospital, reading echos, doing transeophageal echos, stress echos and teaching cardiology fellows.

What would people find surprising about your work, and why?
I think primary prevention is the hardest part of all of cardiology. We are successful in putting stents in people having heart attacks, but getting people to eat healthy and exercise is very difficult. It sounds easy, but it’s important to do the basics: eat vegetables and fruit, exercise daily, quit smoking, know your blood pressure and take your prescribed meds every day.

How do the needs of cardiology patients in rural South Hill compare to VCU Medical Center? To the VA?
I grew up in a rural area, so I really enjoy the patients in South Hill. You must sort out which patients in South Hill can be managed in South Hill and which need to go up the road for a higher level of care, such as major complex surgery. Overall, the cardiology needs in all three areas are similar, but access to advanced technology is easier at VCU Medical Center.

Describe a patient encounter that made you say, “Here’s why I keep doing this. Here’s why my work matters.”
I really like my patients. I don’t have one example, but I’m inspired when patients show a lot of resilience during their illnesses. The coronavirus pandemic has made life even more difficult. Sometimes I think I learn more from my patients than they learn from me.

What do you enjoy doing in your free time?
My husband is a pulmonologist, and we have two grown children. Sam lives in Charlotte, N.C., working as a technology consultant. Ellie is a senior at Virginia Tech. I run in my free time. I have run 19 marathons, although No. 20 will be different. I’m trying to focus on the journey, not the destination. Running is 50% physical and 50% mental. I enjoy getting out there, pounding the pavement and clearing my mind.
Lorenzo Azzalini, M.D., Ph.D., M.Sc.

With an international background and exposure to medical training across four countries and two continents, Dr. Lorenzo Azzalini brings various and unique approaches to treatment of complex heart conditions.

“I like to think of myself as an eclectic professional who can choose from a vast array of possible options to provide each patient with a tailored solution to their heart problem,” said Azzalini, who has spent his career mastering the art and science of interventional, minimally invasive cardiology treatments.

Inside Pauley’s advanced Cardiac Catheterization Laboratory, Azzalini performs interventional treatment for more advanced forms of coronary artery disease, including chronic total occlusions — complete blockages — and severely calcified coronary arteries. These are conditions that, under more conventional techniques, are rarely successful.

“My passion is to provide an interventional treatment option to patients with advanced forms of coronary disease where surgery would not be an option,” said Azzalini, associate professor of medicine at the VCU School of Medicine and Pauley’s director of complex coronary interventions.

Besides being busy in the cath lab and outpatient clinic, Azzalini is also very active in research, with over 140 peer-reviewed publications and several multicenter collaborations in the field of chronic total occlusion intervention, complex PCI, acute kidney injury and mechanical circulatory support. Moreover, Azzalini has a key role training interventional cardiology fellows in the subspecialty of complex coronary interventions.

He was brought to VCU Health with the goal of growing the health system’s Complex Coronary Interventions program, aimed at patients with chronic total occlusions, those requiring mechanical circulatory support, and individuals with advanced chronic kidney disease or severely calcified coronary arteries. Before joining VCU Health, Azzalini served as co-director of the Chronic Total Occlusion program at San Raffaele Hospital in Milan, Italy.

“I have always been amazed by the complexity of how the human body works,” he said.

Wendy Bottinor, M.D., M.S.C.I.

In the rapidly emerging field of cardio-oncology, Dr. Wendy Bottinor strives to be a leader. She makes sure a patient’s heart is healthy for cancer treatment and helps minimize cardiovascular problems both during and after cancer care. She and other cardio-oncology specialists do this, in part, by improving our understanding of the cardiovascular toxicities of novel anti-cancer agents.

During medical training, her interest in the highly specialized field was sparked when she met patients with cancer who required heart treatment. “I realized early on that there was a lot of overlap between cancer and cardiovascular disease, and it’s an area with a lot of room for discovery,” she said.

With so many unanswered questions surrounding cardio-oncology, she is helping VCU Health and the VCU School of Medicine take the lead on finding answers by building up the program at the academic medical center.

“Both our clinical and research work will ultimately give patients with cancer and survivors the best heart care possible,” said Bottinor, who has completed a formal fellowship in cardio-oncology and is an assistant professor of internal medicine and cardiology.

In 2020, Bottinor returned to the site of her medical school and residency. “The opportunity to return to Richmond and work with mentors and collaborators who helped me become the physician I am today is very exciting. I am proud of the education and training that I received at VCU and am looking forward to contributing to this great organization to develop a patient-centered, interdisciplinary program in cardio-oncology,” she said.

Frank Raucci, M.D., Ph.D.

There aren’t many doctors who do what Dr. Frank Raucci does. As a pediatric cardiologist with Children’s Hospital of Richmond at VCU, diagnosing and treating heart conditions in kids is his specialty. Yet beyond the bedside, he spends much of his time “at the bench” in laboratories, researching ways to improve the care he and other doctors like him provide.

“Unlike our peers who treat adults, in pediatrics, we have relatively few physician-scientists who participate in research, and I’ve dedicated many years of training to fill that role,” said Raucci, who joins other physician-scientists at CHoR. “Cardiac care in children has traditionally been understudied from a scientific standpoint, so I felt like I could make an impact on patients not only through care, but by helping understand the underlying mechanisms of heart disease in children. I take the questions we get at the bedside to the research bench — and back into the hospital to improve care for kids.”

In addition to his research, Raucci provides inpatient cardiac care at CHoR. He has subspecialty training in pediatric cardiac CT, MRI and echocardiography imaging techniques for diagnosing and treating both congenital and acquired heart disease in kids.

He also works with CHoR’s neurology team. Neuromuscular cardiology is Raucci’s primary area of focus, and the specialty has a number of promising genetic therapies and treatments in development. “Over the next decade, we will have a better understanding of the genetic and molecular mechanisms of congenital and acquired heart disease in children, which should help us develop new therapies that provide improved quality of life,” he said.
Letter from the director

Treating all patients with dignity and respect is an unwavering commitment of our health system. Yet, there have been times throughout our history when we have fallen short of this commitment and damaged the trust communities place in us.

We recently ratified a diversity, equity and inclusion statement that will guide the future of our institution. As part of it, we vowed to fearlessly accept criticism and continuously learn from our mistakes with transparency and humility. Our history can teach us valuable lessons to make VCU Health and the communities we serve better places.

As this issue of The Beat was going to press, a new book titled, “The Organ Thieves: The Shocking Story of the First Heart Transplant in the Segregated South,” was published that explores our institution’s first heart transplant along with issues of racism and health care in the South. The book gives us a new opportunity to reflect and learn from the circumstances of the first heart transplant at VCU Medical Center (formerly known as MCV).

Every day we strive to make the communities we serve healthier, and our expert clinicians and researchers seek solutions to our most pressing health problems. Within these pages we share updates on the latest clinical trials being conducted at VCU Medical Center in response to the COVID-19 pandemic. Dr. Antonio Abbate and his team have been working tirelessly — literally around the clock — to contribute meaningful data in the international quest for safe and effective drug therapies against the virus. Preliminary data from a clinical trial testing the drug canakinumab in treating COVID-19 patients should be available this fall.

We’re also on the forefront of research into atrial fibrillation, a common abnormal heart rhythm. Untreated, AFib can increase the risk of stroke. In our cover story, you’ll read about a clinical trial spearheaded by Dr. Kenneth Ellenbogen to determine if the WATCHMAN FLX is as effective as anticoagulants in preventing strokes in patients with AFib. The parachute-like device has already made a significant positive difference in the life of an active 80-year-old patient you’ll meet here.

You’ll also meet our newest providers, whose expertise allows us to further expand our clinical services. We’re excited to introduce Pauley’s director of complex coronary interventions, Dr. Lorenzo Azzalini; cardio-oncology specialist Dr. Wendy Bottinor; and pediatric cardiologist Dr. Frank Raucci. Welcome! You might hear from them, or our other expert faculty, in our expanded educational offerings that are free and online for our colleagues around the globe.

As we wind down a year of unique challenges, we see opportunities to lead and grow. Please join me in celebrating the important work we’re doing, and supporting the important work yet to come.

Sincerely yours,
Dr. Greg Hundley