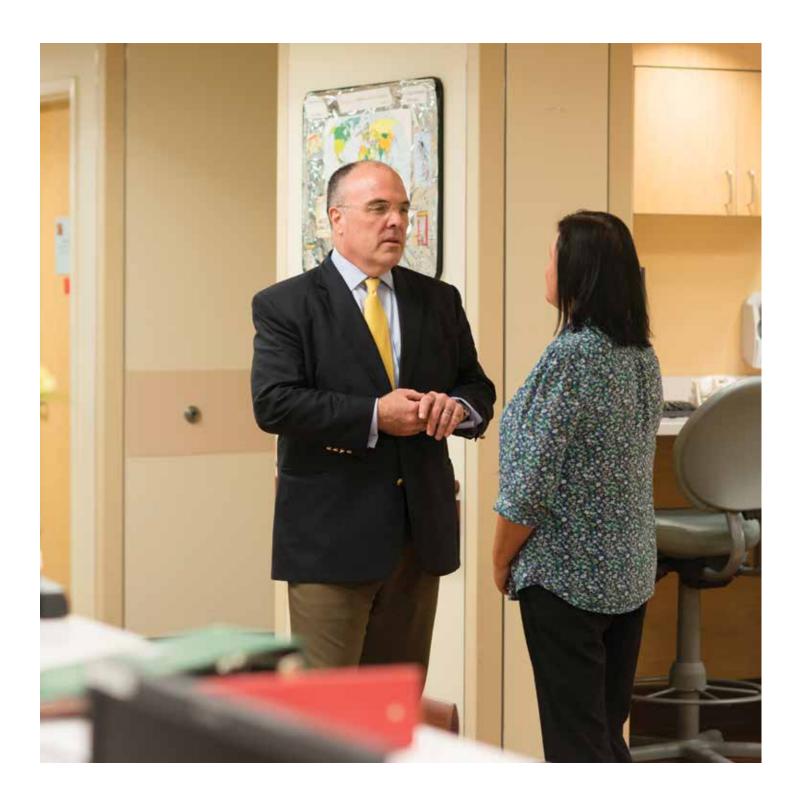
REVEALING





Changing What's Possible





MUSC Health is committed to innovation, discovery, and robust improvement, which is why this *Year in Review 2015* is titled "Revealing Tomorrow." In the following pages, you'll read about the many ways our clinicians and researchers pioneer new therapies and, with our industry partners, create new models for delivering health care to the people of South Carolina and beyond.

In 2015, MUSC Medical Center was again ranked by *U.S. News & World Report* as the number one hospital in South Carolina. Furthermore, two of our programs were again nationally ranked: Pediatric Cardiology and Heart Surgery as number 31 in the nation and Ear, Nose, and Throat as number 32. Five other adult specialties were ranked as high-performing.

September brought the long-awaited news that we had received the nation's ultimate credential for high-quality nursing: Magnet® Recognition from the American Nurses Credentialing Center. This recognition of quality patient care, nursing excellence, and innovation in professional nursing practice is held by only 7% of U.S. hospitals. What this means for our patients is that they are cared for in an environment that attracts top-rate providers and uses the most advanced nursing standards. Congratulations to the nursing teams whose years of preparation were responsible for this recognition. We stressed early on that Magnet® designation is about the entire team, so congratulations to the interprofessional team as well.

As always, improving community health beyond our walls is a priority, too, and in 2015 we expanded alliances of many kinds that will help us achieve our goals. With these partners, MUSC Health will move medicine forward to improve effectiveness and accessibility of care in groundbreaking ways.

Patrick J. Cawley, M.D., MHM, FACHE CEO, MUSC Health
Vice President for Health Affairs
Medical University of South Carolina

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Cover: Tomorrow's medicine will be much more personalized due to genomic sequencing and other research breakthroughs.

Left: Chief Executive Officer Patrick J. Cawley, M.D., MHM, FACHE, confers with a colleague.

MUSC Health is South Carolina's most nationally recognized health system and a leader in eHealth innovations. Each year more than a million patient encounters occur at its 779-bed medical center and more than 100 ambulatory sites. Leading services include MUSC Hollings Cancer Center, one of fewer than 70 National Cancer Institute-designated centers in the U.S., a nationally recognized children's hospital, and the state's only transplant center. Founded in 1824, the Medical University of South Carolina has risen to become a premier academic medical center at the forefront of the latest advances in medicine, with world-class scientists and clinicians.

MUSC Health

Discovering is the journey in our business of healing. Revealing new ways to defeat disease, improve value and safety for every patient, and transform health care delivery—these are the activities that drive innovation at the Medical University of South Carolina.

As MUSC Health advanced transformational discovery in 2015, the following milestones were achieved:

- The U.S. News & World Report 2015-16 Best Hospitals named MUSC Medical Center the number one hospital in South Carolina.
- The American Nurses Credentialing Center presented the MUSC Medical Center with Magnet Recognition®, a distinction held by only 7% of U.S. hospitals. This designation recognizes health care organizations for quality patient care, nursing excellence, and innovations in professional nursing practice. MUSC Health's nursing culture especially supports education, which includes life-long learning and the mentoring of colleagues and students.
- The future Children's Hospital and Women's Pavilion received a \$25 million pledge from Charleston businessman Shawn Jenkins, co-founder and CEO of the software company Benefitfocus. In May, the MUSC Board of Trustees approved the naming of the new facility to be the MUSC Shawn

Jenkins Children's Hospital. In addition, the state legislature approved \$25 million for the project. It is scheduled to break ground in 2016 and be completed in 2019. During planning, we sought input from patients' families on its design. This is one of the many ways MUSC Children's Hospital incorporates the principles of patient- and family-centered care into every aspect of clinical practice.

(MUHIC) was launched to create strategic and operational plans for promoting a culture of innovation throughout all clinical areas and coordinate with MUSC's innovation initiatives already established. MUHIC will coordinate and collaborate with people and programs throughout the enterprise to foster dynamic solutions for health care issues.

The MUSC Health Innovation Center

MUSC Health completed the second year of a five-year health insurance pilot for the South Carolina Public Employee Benefit Authority in which all MUSC employees were offered a new health insurance plan based on the patient-centered medical home. Initial data show that (1) preventive screenings are up among the MUSC Health plan participants, as compared to all other state employees who are on the standard state health plan, and (2) the

- historical growth rate of health care costs for members of the MUSC Health plan decreased by more than 40%.
- The South Carolina Telehealth Alliance (SCTA), a collaboration of stakeholders in telehealth that includes MUSC Health, Palmetto Health, and Greenville Health System as well as community hospitals, government agencies, and health care providers, advanced several objectives. As a result, the SCTA is closing the gap on health disparities throughout the state.
- To better coordinate patient care across the entire continuum—from birth to hospice— MUSC Health created and expanded collaborations with diverse partners in the health care industry, such as other hospitals, health systems, payors, senior living facilities, and urgent care providers. Aligned with these new partners, we are better able to share clinical information, standardize processes, reduce avoidable readmissions, and aggregate data for research, all of which improves outcomes.

Through innovative initiatives and partnerships, MUSC Health seeks to generate new knowledge and share best practices that will make a difference for all, in South Carolina and beyond.

As frontline providers of quality care, MUSC Health nurses are empowered to say what they feel is best for their patients. Their opinions are key to organizational decision-making.

Strong Solutions

Discovering new ways to strengthen patient safety and quality is an expectation of every member of the MUSC Health team. In 2015, infection control experts succeeded in reducing infection rates, clinicians built more evidence-based practices into Epic electronic medical records, and managers adopted a business-world methodology that leads to controlling costs. For many years, MUSC Health has been building a nursing culture that engages nurses and involves them in organizational decision-making. In 2015, the American Nurses Credentialing Center recognized that culture with Magnet® designation. A Gallup survey estimates that Magnet® hospitals experience 7.1% fewer safety-related incidents than the industry norm. Culture and commitment come together at MUSC Health for strong solutions, strong lives.

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Nurses Take Top Prize in Nursing Excellence



In September, MUSC Health received the ultimate credential for high-quality nursing care when the American Nurses Credentialing Center (ANCC) awarded the medical center with Magnet Recognition®, an acknowledgment of quality patient care, nursing excellence, and innovations

in professional nursing practice. This status is held by only 7% of U.S. hospitals. "Achieving this designation is about our continual process to improve patient care," says Marilyn Schaffner, Ph.D., RN, Chief Nursing Officer. "But it's also about recognizing the excellence that our nurses provide every day." The ANCC's review covered 69 standards within four domains: transformational leadership, structure empowerment, exemplary professional practice, and new knowledge innovations and improvements.

The Magnet reviewers cited the evidence of nurses' autonomy to make decisions about care. One example was a hospital-wide nurse-led project to reduce errors in medications administered from a second IV bag set up on an infusion system (pump). If a nurse is distracted while hanging the second bag, she or he may forget to unclamp it. A nursing team's analysis of this error revealed not only the system's lack of a hard stop or alarm to remind the nurse to unclamp, but nurses' inconsistent knowledge about best practice related to hanging the secondary bag at proper height and labeling secondary tubing. The nursing leadership team implemented training for hanging and labeling IV bags and asked the pump's manufacturer to redesign the system. The manufacturer is now working to include a hardstop warning feature in one of its software updates. Eventually, patients in other hospitals around the nation will benefit from this safety initiative driven by the nurses at MUSC Health.

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Dyed water in two IV bags was used during a training program to demonstrate that insufficient height of the second bag prevents infusion into the pump and patient.

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ICU Central Line-Associated Blood Stream Infections O bushes Rate Higher Than Expected Rate Lower Than Expected Hand Hygiene ICU Ventilator-Associated Pneumonia Infections

Infection Control Wins

MUSC Health operates on the principles of a High Reliability Organization: leadership engagement, robust process improvement, and a culture of safety. Infection control efforts—always a major focus in safety—battled the bugs in several new ways in 2015.

Reducing catheter-associated urinary tract infections (CAUTI)

MUSC Health had a huge win against one of health care's most persistent infections. "This year, we took CAUTI to the mat," says Danielle Scheurer, M.D., MSCR, SFHM, Chief Quality Officer. The goal was to beat the standardized infection ratio (SIR), the industry's primary measure, of 1.0. MUSC Health achieved an SIR of .94 in 2015 (down from 2.5 in 2014). The CAUTI prevention team tackled CAUTI from several angles:

- A single position was designated to address the infection rates. CAUTI Prevention Nurse Carol Balabushka, MSN, RN, led the "CAUTI ZERO" efforts.
- The team worked closely with clinical departments to ensure that Foley catheters were inserted only for appropriate indications. They created a best practice advisory within Epic to alert staff when an indwelling catheter had been in for 24 hours.

- Nurses were encouraged to use the Early
 Discontinuation Protocol that empowers
 them to remove a catheter when it is no
 longer indicated without a physician order.
- A new condom catheter was used in certain male patients, reducing the overall number of catheter insertions.
- A new Foley catheter tray with step-by-step instructions helped standardize insertion and management.

Improving high-level disinfection

To ensure effective disinfection of certain devices that enter the body, a task force assessed disinfection practices, launched customized processes for each device, and began laying the groundwork for a centralized service in the hospitals.

Other tactics to reduce hospitalacquired infections

- Risk assessment and process improvement in sterile processing departments
- Assessment of the ventilator-associated pneumonia prevention bundle to ensure best practice
- Trial of a new electronic hand hygiene monitoring system
- Trial of a UV light system to disinfect rooms at discharge, with an initial focus on rooms vacated by patients with highly contagious infectious diseases, such as Clostridium difficile
- Adoption throughout the inpatient units of the Emergency Department's protocol for identifying sepsis.

Surgery checklist improves safety

MUSC Health is one of the seven South Carolina hospitals that were the first in the state to self-certify as a Safe Surgery 2015 Hospital. Safe Surgery 2015 is a statewide effort that seeks to ensure the use of a surgical safety checklist in operating rooms (ORs). South Carolina was the first state to begin the self-certification program. Hospitals' applications to the South Carolina Hospital Association provided information that confirmed surgical teams' use of the checklist before anesthesia, before incision, and before the patient leaves the OR. A multidisciplinary committee reviewed applications. Hospitals that met the criteria were recognized at a conference in September.

Program Builds Cultural Awareness

The patient-provider relationship is very personal. If the patient runs into a language barrier or perceives bias, the relationship can suffer, which affects trust and adherence and ultimately outcome. As America undergoes significant demographic change, the importance of cultural diversity in health care systems cannot be overstated. Optimal public health depends on it. Anton Gunn, MSW, Executive Director of Community Health Innovation and Chief Diversity Officer, is responsible for nurturing a diverse and

diversity-aware workforce at MUSC Health. "To be a leader and innovator in health care, you have to understand the difference that 'different' makes," he says. "It's not about social justice or making us feel good. It's about being an excellent organization. We have to have excellence in care for every single person." Metrics will tell Gunn when MUSC Health has met this goal. "We have a lot of quality metrics that we track in the hospital's database. Length of stay, central line infections, readmission rates. We also record race.

Anton Gunn, MSW, is Executive Director of Community Health Innovation and Chief Diversity Officer.

gender, age, and other patient data. I'll know we are successful when MUSC Health has zero disparities in all patients for all quality metrics,"

Building upon MUSC's diversity and inclusion strategic plan that was in place before his January 2015 arrival, Gunn began the year by overseeing four teams (Pipeline and Recruitment, Communications and Community Relations, Engagement and Inclusion, and Education and Training) that were charged with implementing that strategic plan. As their work unfolded, Gunn oversaw the following initiatives:

Language access

An Epic report revealed that the top five languages spoken by patients are Spanish, Gullah, American Sign Language, Portuguese, and Mandarin. Gunn's office is currently assisting the Office of Interpretive Services to ensure that appropriate resources are delivered when and where patients and staff need them. There is a focus on increasing training opportunities for the Interpreter Services team, coordinating more interpreter services at MUSC Health's outreach clinics, and hiring more interpreters and translators to ensure 24/7 coverage in the hospitals.

LGBTQ health care equality

After completing a survey known as the Healthcare Quality Index (HEI) from the Human Rights Campaign Foundation, MUSC Health achieved 2015 and 2016 status as a Leader in LGBT Healthcare Equality. MUSC Health achieved this status by using best

practices that improve the experiences of Queer) patients, employees, and families. HEI is the national benchmark on corporate community. The HEI 2016 report will be released in March 2016.



Cultural competency for staff

Given immigration rates and Charleston's tourism scores. MUSC Health clinicians are practicing in a truly global environment, says Gunn. "One day, a physician can be talking to a person from West Ashley, but on the next, he could be talking to a patient from West Africa." So Gunn is working to give physicians and providers the best global medicine training and support to enable them to deliver cross-cultural care to all patients.

Gunn has made presentations in MUSC departmental meetings and floor units. He is also in the process of creating a clinician survey to assess cross-cultural competence. Training the MUSC Health team will eventually include everyone, including registration and facilities staff, as MUSC Health seeks to promote better health outcomes for all.



A Spanish interpreter (center) assists a patient with understanding the care his clinicians will provide.

Controlling Cost While Improving Quality

Throughout the health care industry, there is increased demand for providing value, which is determined by quality of care and cost control. MUSC Health is in the process of improving this value equation by enhancing the numerator (quality) and controlling the denominator (cost). The Center for Evidence-Based Practice and Value Institute (CEBP/VI) ensures the effective integration of these factors into clinical operations at the medical center.

Health outcomes

The CEBP/VI supports clinicians in providing high-quality care by developing evidencebased guidelines and orders sets, known as

MUSC Ideal Care Plans. In 2015, ten MUSC Ideal Care Plans were developed, resulting in the completion of nine evidence-based clinical guidelines and 13 order sets for use in Epic electronic medical records. Ideal Care Plans were developed for adult urinary tract infections, colorectal surgery site infections, pediatric Kawasaki disease, and status epilepticus, among others. The CEBP/VI staff also worked closely with nursing and clinical informatics managers to analyze best practice evidence for use in decision-making processes for nine topics, such as time restriction of laboratory orders, integration of IV infusion pumps, and establishment of a cardiac early warning system in the Children's Hospital.

Cost control

How much does it cost MUSC Health to deliver care for a patient who receives a mammogram or an organ transplant? A team of analysts led by Barton L. Sachs, M.D., MBA, Chief of Staff, Special Assistant to CEO, MUSC Health, has introduced a time-driven activity-based cost accounting methodology from the business world. Initial team members were Meredith Alger, MS, RD; J. Butler Stoudenmire, BS; Marcelo S. Guimaraes, M.D.; Scott Brady, BA; Kelly Howard, BHA, RT; John L. Waller, M.D.; and Brian Whitsitt, MHA. The methodology measures the actual cost of delivering care.

The process begins with the identification of a medical condition and patient population, obtains cost estimates for almost all required resources (personnel, space and equipment, consumables, etc.), and ends with a total cost for the continuum of care cycle.

The team's pilot project was launched in Vascular Interventional Radiology to discover the cost of port placement. The answer: \$1,556. In 2015, the methodology was completed for five more services or procedures. A complete description of this accounting process is available at MUSChealth.org/pn/yir-2015/tdabc.pdf. "The goal is not to make everything we do

profitable," explains Patrick J. Cawley, M.D., MHM. Chief Executive Officer, MUSC Health and Vice President for Health Affairs. MUSC. "In health care, as in every business, there are loss leaders you continue because they benefit the organization in other ways. The goal is improved knowledge. Knowing promotes innovation. Knowing eliminates unnecessary variation. Knowing provokes the team to re-examine basic processes and come up with new ways of doing things."

MUSC Health will now examine not only best clinical practice for, say, hip replacement, but also its cost to be able to base the whole picture-quality and cost-on evidence.

MUSC Health is one of ten academic hospitals selected in the summer of 2015 to participate in the University of Utah's "Becoming a Value- Driven Organization" Collaborative Training Program, funded by a grant from the Robert Wood Johnson Foundation. MUSC Health's project is focused on implementing an evidence-based protocol for the management of pediatric patients with appendicitis in an effort to reduce unnecessary imaging, length of stay, direct variable cost, the negative appendectomy rate, and readmissions.

Overview of an accounting process that measures the cost of delivering care

Identify medical condition and patient population

to examine

2.

Define scope of the "patient care cycle," including time period and services provided

3.

Develop process maps for each activity in care cycle; identify resources utilized in each step

4.

Obtain time estimates for each process step using electronic health record time stamps and observation

5.

Estimate cost of each resource 6.

Determine the practical capacity of each resource and calculate capacity cost rate (CCR)

7.

Multiply resource CCR by process time to compute total costs over care cycle

Innovation in the Clinic

Innovation reaching the clinic in 2015 thanks to MUSC Health clinician/researchers includes new drugs for heart failure and cystic fibrosis; new medical devices such as the first MRI-safe implantable cardioverter-defibrillator and a novel spinal surgery rod; and a diagnostic tool that will remove the ambiguity from lung cancer diagnosis. Clinical trials at MUSC Health are setting the standards for care nationwide and offering patients in the region access to revolutionary cancer treatments, including precision therapy and immunotherapy, as well as novel treatments for many other diseases, such as a thermosensitive gel for Menière's disease and a gene therapy for sickle cell disease. New centers are fostering a culture of innovation and helping translate that innovation into improved patient care.

MUSC Health cardiologist Dr. Michael
Zile was on the international executive
committee of a trial that led to the first
new heart failure drug in 20 years.

CLINICAL INNOVATION

CLINICAL INNOVATION REVEALING TOMORROW

Providing new options to heart failure patients

The summer of 2015 saw approval of the first new drug for heart failure (HF) in almost two decades. The angiotensin receptor-neprilysin inhibitor Entresto (Novartis Pharmaceuticals) was approved for HF with reduced ejection fraction (HFrEF) based on the results of the PARADIGM-HF trial (NCT01035255) published in the September 11, 2014 issue of the New England Journal of Medicine. MUSC Health cardiologist Michael R. Zile, M.D., who served on the international executive committee of the PARADIGM-HF trial, predicts that the new therapy "will replace ACEs and ARBs as the cornerstone of standard therapy for patients with HFrEF."

However, patients with HFrEF account for only about half of the three million heart failure cases in the U.S. each year. The other half are attributable to heart failure with preserved ejection fraction (HFpEF). In patients with HFrEF, the left ventricle does not fully contract, while in those with HFpEF, the ventricle does not fully relax. No agent has been shown to improve morbidity and mortality in patients with HFpEF.

That could be changing. Zile is on the international executive committee of the PARAGON-HF trial (NCT01920711), which will assess the efficacy of Entresto in patients with HFpEF, and MUSC Health is one of the sites enrolling patients into the trial. Results are expected in 2017. "PARAGON-HF will be the largest clinical trial in patients with HFpEF," says Zile. "We hope that Entresto will form the foundation for novel and effective treatment that reduces symptoms and increases survival in HFpEF."

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Illustration by Linda Nye

CLINICAL INNOVATION

Developing Next-Generation Medical Devices

A new generation of implantable cardioverter-defibrillators

MUSC Health cardiologist Michael R. Gold, M.D., Ph.D., has played a seminal role in introducing innovations in implantable cardioverter-defibrillator (ICD) technology into the clinic. Gold led the trials resulting in FDA approval of the first MRI-compatible ICD and the first entirely subcutaneous ICD (S-ICD), serving as worldwide principal investigator for the former and U.S. principal investigator for the latter.

Until this year, MRI had been contraindicated in patients with ICDs because the magnetic field could decrease the overall efficacy of the heart-pacing device or overheat the wires. In September, the FDA approved the Evera MRITM (Medtronic; Minneapolis, MN) as the first MRI-safe ICD on the basis of efficacy and safety results reported by Gold and colleagues in the June 23, 2015 issue of the Journal of the American College of Cardiology (JACC). When switched to "sleep mode," the device can still monitor the patient's heartbeat but is temporarily incapable of sending an electric shock to the heart. All 275 participants in the trial (NCT02117414) were implanted with the novel ICD; some then underwent full-body MRI. At 30-day follow-up, no loss in pacing or sensing ability was observed in devices exposed to MRI.

Gold also helped design—and MUSC Health participated in—early clinical studies that led to the 2012 approval of the subcutaneous ICD (S-ICD System®; Boston Scientific, Natick, MA), in which the leads are placed under the skin of the chest and are not connected to the heart or vasculature. The device's clinical promise was confirmed in an article by Gold and colleagues in the April 28, 2015 issue of

JACC, which reported good efficacy and a low complication rate at 22 months among 882 patients implanted with S-ICDs in previous clinical trials. Of the 111 events of ventricular fibrillation/tachyarrhythmia, 90% were terminated with one shock and 98% within five. The overall complication rate was 11.1%, with fewer complications seen as clinicians gained experience with the device.



MUSC Health cardiologist Dr. Michael Gold played a key role in introducing next-generation ICDs into the clinic.

Advancing neuroscience technologies

The MUSC Zucker Institute for Applied Neurosciences (ZIAN) is a technology accelerator that develops neuroscience technologies and moves them to commercialization. In 2015, ZIAN licensed its first medical device, Sinu-Lok™, a rod implant used in minimally invasive lumbar spinal fusion surgery. Spinal surgical device provider Amendia, Inc. (Marietta, GA) acquired the exclusive worldwide rights to manufacture and sell the device.

Sinu-Lok is an improvement over the standard rods surgeons have used in lumbar spinal fusion surgery. The standard bowed rod puts stress on the construct components, which can lead to a loosening of the construct after the surgery and other complications. Sinu-Lok has a sine wave (oscillating) shape that creates several concave locations in which the screws can seat when tightened. This patented shape also provides an extended range of axial connections between the screw-rod interface when the construct is tightened, creating divergence of the screw towers instead of the convergence caused by the standard rod.

Next in ZIAN's pipeline is the Blink Reflexometer™, a device that detects mild traumatic brain injury (concussion). Currently, there is no commercially available device that provides an objective way to detect a potential concussion on the athletic field, leaving clinicians and trainers with only subjective measures of altered behavior or cognitive function. The handheld Blink Reflexometer uses stimuli to trigger a blink and a high-speed camera to collect data on the body's response to these stimuli. The ZIAN research team collected baseline measurements from football players and other athletes in summer 2015 and tested the device throughout the fall season. It is expected to be commercially available by 2017.

ZIAN has eight additional active projects in the areas of cranial access for deep brain procedures, spine surgery, intraoperative neuromonitoring, glioblastoma treatments, and general surgical instruments.



The sine wave shape of Sinu-Lok™ (purple rod) creates concave sites in which spinal fusion screws can seat when tightened, which reduces complications.

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Redefining Stroke Care

New cerebrovascular therapies

The Division of Neuroendovascular Surgery has earned an international reputation for advancing intra-arterial therapies for ischemic stroke (caused by blood clots) and hemorrhagic stroke (caused by aneurysms and arteriovenous malformations). The team's research ranges from benchtop to pre-clinical studies and from first-in-human trials to pre- and post-market investigations. The team members are: Aguilla S. Turk, D.O., Professor and Director of the Division of Neuroendovascular Surgery; M. Imran Chaudry, M.B.B.S., Associate Professor; Kyle M. Fargen, M.D., MPH, Assistant Professor; Alejandro M. Spiotta, M.D., Associate Professor, and Raymond D. Turner, M.D., Professor and Co-Director of the Comprehensive Stroke & Cerebrovascular Center.

Furthermore, the group is the coordinating center for four international, multicenter trials addressing fundamental questions about current aneurysm and stroke treatment models of care.

Approaches

Among the division's numerous ongoing trials, the COMPASS Trial (A Comparison of Direct Aspiration vs Stent Retriever as a First Approach) holds significant potential to shape the field in terms of best practice for the removal of a blood clot in stroke. Turk is the co-principal investigator. In 2014, MUSC Health was the principal site of the precursor study (ADAPT FAST) that showed the efficacy of direct aspiration using a large-bore catheter as a first pass technique. This COMPASS Trial is the nation's first clinical trial comparison of

direct aspiration vs the use of a stent retriever as the first approach to thrombectomy.

In addition, Turk is the co-principal investigator of the POSITIVE Trial (Perfusion Imaging Selection of Ischemic Stroke Patients for Endovascular Therapy), which is studying endovascular therapy vs traditional medical therapy delivered six to 12 hours after onset of symptoms.

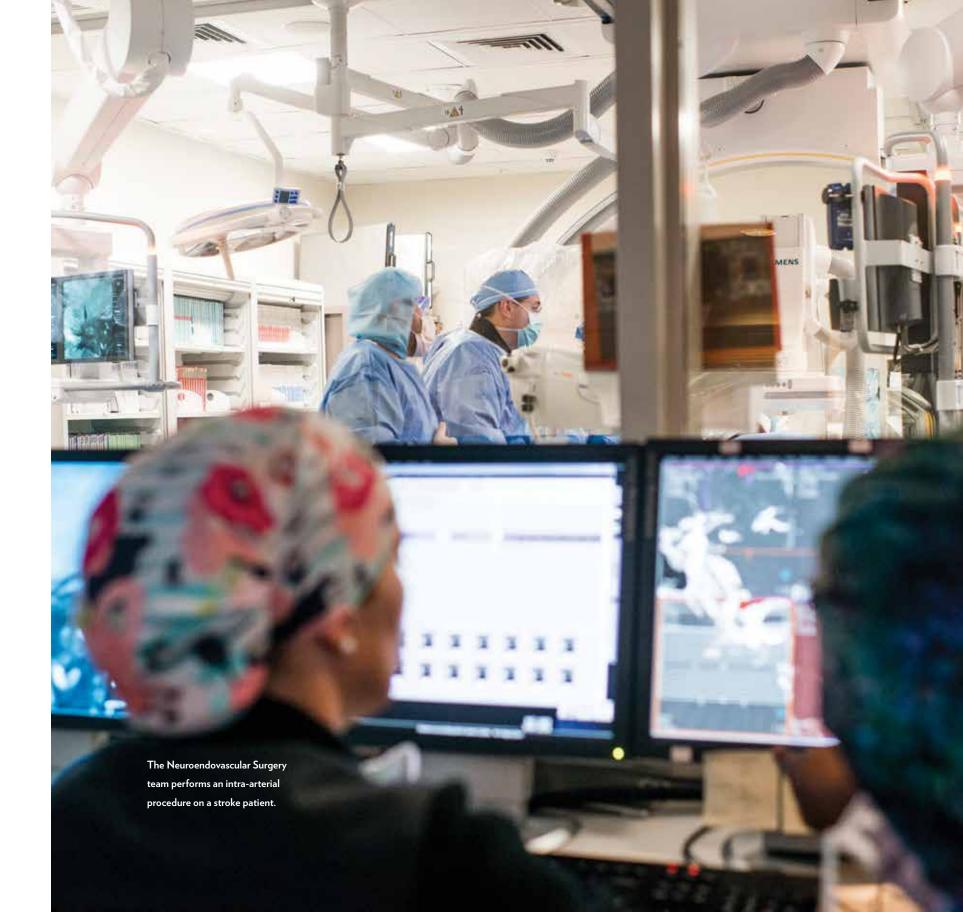
Devices

In terms of trialing next-generation devices for treating aneurysm and stroke, the year's highlights include:

- The ANSWER trial evaluated a reconstruction device, PulseRider™ (Pulsar Vascular, San Jose, CA), a T- or Y-shaped stent used to treat aneurysms arising at bifurcations. The first three U.S. cases were done by Spiotta, Turner, and Chaudry. They were able to achieve complete occlusion in otherwise difficult-to-treat aneurysms in all three cases. The team reported on these results in the January 5, 2015 Journal of Neurointerventional Surgery. Spiotta was the principal investigator.
- COAST is investigating a coil device that is novel in its softness and non-helical design.
 This device is designed to treat aneurysms smaller than 5 millimeters. Chaudry is the principal investigator.

Treating acute ischemic stroke: clot-removal devices now recommended

MUSC Health's Comprehensive Stroke & Cerebrovascular Center played a role in the revision of the American Heart Association (AHA) guidelines for treating certain stroke patients. The guidelines included the recommendation that stent retrieval devices be used to remove blood clots in large arteries for patients with acute ischemic stroke. Five landmark clinical trials provided the evidence that drove the revision. Christine A. Holmstedt, D.O., Co-Director of the Center, was a co-investigator in one of those trials, the ESCAPE trial (NCT01778335), which evaluated whether patients with acute ischemic stroke would benefit from rapid endovascular treatment using retrievable stents to remove the blood clot. The AHA noted that other mechanical thrombectomy devices may be used as judged by the physician. Holmstedt recommends that these procedures be done at a high-volume, comprehensive stroke center that has the personnel, experience, and imaging technology necessary for optimal outcomes.



Life-Changing Advances for Healthy Lungs

Lung cancer prevention, screening, and diagnosis

The five-year National Lung Screening Trial in which Hollings Cancer Center researchers James G. Ravenel, M.D. and Gerard A. Silvestri, M.D., MS were site lead investigators, provided evidence that is the basis for new best practices in screening for lung cancer. Silvestri and other experts reported the evidence for lung cancer screening and the nine components of an effective lung screening program to the Centers for Medicare and Medicaid Services (CMS) in 2014. This resulted in CMS approving coverage for lung cancer screening in its high-risk beneficiaries at accredited comprehensive programs.

As a result, Hollings, a National Cancer Institute-designated cancer center, is establishing a lung screening program under the direction of Nichole T. Tanner, M.D., MSCR, a pulmonologist trained in advanced diagnostics and interventional pulmonary procedures, and Benjamin Toll, Ph.D., a clinical psychologist who came to MUSC from Yale University and is one of the leading smoking cessation experts in the U.S. The CMS guidelines require that screening programs adhere to the nine components, which include a smoking cessation program, to qualify for reimbursement. Through the lung screening program and other ongoing research, Hollings continues to study how to best communicate the benefits and risks of screening in eligible patients, how to effectively incorporate smoking cessation efforts, and how to implement novel screening and diagnostic technologies.

With respect to advances in lung cancer diagnostics, Silvestri and colleagues reported in the May 17, 2015 issue of the New England Journal of Medicine their validation of a novel diagnostic test using a bronchial genomic classifier that measures the expression of 23 genes associated with lung cancer. The test reduces ambiguity in diagnosis, enabling physicians to better advise patients on next steps in their diagnostic odyssey. This classifier will be an increasingly important tool, as it is estimated that eight million Americans at high risk for lung cancer based on age and smoking history became eligible in February 2015 for annual screening through new private insurer and Medicare coverage requirements.



ORKAMBI, Flume testified to the drug's efficacy on behalf of the Cystic Fibrosis Foundation.

> "This drug is the next huge step toward the cure," Flume said. "It proves we can do it. Now, we just have to perfect it." In the 1,108 patients in the study, pulmonary exacerbations (worsening of respiratory symptoms) were reduced by 30% to 39% in the lumacaftor/ ivacaftor groups as compared with the placebo groups. The rate of events leading to hospitalization or the use of intravenous antibiotics was lower in the first group as well.

To build upon this success, Flume and MUSC colleagues will participate in more clinical trials studying other drugs and other drug combinations, as well as expanding the use of these drugs in other populations (patients with other gene mutations).

Dr. Patrick Flume, Professor of Medicine and Pediatrics in the Division of Pulmonary, Critical Care, Allergy, and Sleep Medicine (left), examines a CF patient with moderately severe lung dysfunction.

Preventing Pulmonary Embolism After Joint Replacement

In August, MUSC was awarded \$13.5 million by the Patient-Centered Outcomes Research Institute (PCORI) to conduct a 25-site trial enrolling 25,000 patients that will answer a long-standing clinical question: what is the best approach to anticoagulation after hip or knee replacement to prevent pulmonary embolism (PE)? Vincent Pellegrini, M.D., Chair of the Department of Orthopaedics, is the principal investigator for the trial.

In rare cases (1 in 1000), patients who undergo hip or knee replacement die as a result of PE. To prevent this, standard practice is to administer an anticoagulant for 35 days after surgery. Many new drugs touting higher efficacy at preventing clots have been approved in recent years, but these typically have a bleeding/ hematoma risk of 3% to 5%. Such bleeding episodes can lead to infection, delayed wound healing, reoperation, compromised function of the joint, and implant removal.

Whether the added protection against clots offered by these newer agents outweighs the risk of bleeding is unknown, because the cost of conducting a clinical trial enrolling enough patients to reach statistical significance has

been prohibitive. The PCORI funding mechanism was created to address just such gaps in the evidence that leave physicians and their patients without clear answers to clinical

The trial will randomize patients to one of three treatment arms—aspirin, warfarin, or rivaroxaban (Xarelto®; Bayer Aktiengesellschaft)—representing the full spectrum of currently available approaches, from the most conservative to the most aggressive. Its results should provide a definitive answer to whether the additional protection against clots provided by the new agents outweighs the risk of increased bleeding and will have immediate relevance to patient care.

MUSC Health will serve as the lead site, acting as the clinical coordinating center and hosting the central Institutional Review Board. Leslie (Les) A. Lenert, M.D., MS, SmartState Endowed Chair in Medical Bioinformatics, will sit on the central patient advisory board to assist in assessing patient preference and risk tolerance for use of anticoagulants after joint replacement.



A New Strategy for Vitamin D Supplementation in Infants

In the October 2015 issue of *Pediatrics*, two MUSC Children's Hospital faculty members—vitamin D researcher Bruce W. Hollis, Ph.D., and neonatologist Carol L. Wagner, M.D.—reported clinical trial findings definitively showing that sufficient vitamin D can be transmitted via breast milk to meet the needs of the exclusively breastfed infant, provided that the mother is adequately supplemented.

Breastfeeding is encouraged by the medical community in part because breast milk meets all nutritional needs of the child. with the glaring exception of vitamin D. Why such an essential vitamin would be missing from breast milk has always been puzzling. Many physicians erroneously believe that vitamin D simply cannot be transmitted via breast milk. To prevent deficiency in exclusively breastfed babies, the American Academy of Pediatrics recommends that they be supplemented with 400 IU/d of vitamin D_z , delivered via liquid drops. Unfortunately, the drops can be difficult to administer and not all mothers adhere to this directive, leaving some infants vulnerable to rickets or fractures.

The study results reported by Hollis and Wagner suggest that a more natural and effective way to supplement the child would be to adequately supplement the nursing mother. At the time the study was designed, the Institute of Medicine (IOM) recommended that adults, even nursing mothers, receive 400 IU/d of vitamin D_z ; the IOM has since increased the recommended dose to 600 IU/d. The study randomized mother/infant dyads to either 400 IU/d of vitamin D, each or 6,400 IU/d for the mother and none for the infant. The infants in both arms of the trial achieved vitamin D sufficiency, and no adverse effects were reported for mothers receiving the 6,400/IU day dose. The results suggest that adequate maternal supplementation -6,400 IU/d of vitamin D₂ vs. the current IOM recommendation of 600 IU/d—offers a safe and effective alternative to direct infant supplementation.

CLINICAL INNOVATION

Creating a Culture of Innovation

MUSC Health

Innovation

Center

MUSC Center for

Innovation and

Entrepreneurship

MUSC Health Innovation Center

Business as usual is no longer an option for health care. Innovation is an essential survival tool for medical institutions as models of care and reimbursement undergo rapid change. To thrive in this climate, they will need to constantly innovate and efficiently implement those innovations with the most promise for improving the quality and value of care.

South Carolina

Clinical &

Translational

Research Institute

Encouraging a culture of innovation and helping translate creative ideas into actual innovation in the clinic is the mission of the MUSC Health Innovation Center, one of only a handful of such centers nationwide.

It provides innovators a roadmap for moving their idea forward using existing resources on campus. The first stop is the MUSC Foundation for Research Development, which will

MUSC Foundation

for Research

Development

tected and will help find commercial partners for the development of MUSC innovations. Next is the MUSC Center for Innovation and Entrepreneurship, which will help innovators develop their concept into a tangible commodity, such as a prototype or a definitively & Translational Research Institute, housed at MUSC, then facilitates the translation of these

siloed," says center director Barton L. Sachs, at one of these points and not connected up development of their idea so that its potential to benefit patient care is promptly realized.

ensure that the intellectual property is promapped protocol. The South Carolina Clinical health care ideas into the clinic.

"Up to now, each of these resources was M.D., M.B.A. "People might have entered with the rest." The MUSC Health Center for Health Innovation ensures that innovators benefit from each resource at the right point in the

To tap into the creativity of the MUSC Health staff, the center will run quarterly theme-based campaigns to solicit innovative ideas. The first campaign, which was launched in November around the theme "Population Health Starts with Us," seeks ideas from faculty and staff on how to enhance their health and well-being.

Electronic Report Card for Trainees

Health care simulations allow providers to practice their clinical skills in a risk-free environment, but universal standards for skills assessment have been missing. Now, Healthcare Simulation South Carolina (HCSSC) is incorporating new software into its suite of manikin simulators to give trainees objective measures of their performance. "We asked, 'What did they learn? How long did it take? What's the learning curve?" says John Schaefer, III, MD, HCSSC Director and MUSC SmartState[™] Endowed Chair for Clinical Effectiveness and Patient Safety. "With this software, we can run a simulation and get that performance data."

Schaefer's team is located at the statewide HCSSC office at MUSC. The team builds and programs manikins to reproduce hundreds of patient scenarios, from inserting an IV to reviving a child who is not breathing. Since 2007, the number of simulations performed each year has grown from 5,000 at a few locations in South Carolina to 80,000 at 14 HCSSC Simulation Centers located within hospitals and technical colleges in North Carolina, South Carolina, and Alabama. In 2015, the new grading software was licensed for all simulators. This development is igniting interest in health care simulation from the Universities of Pittsburgh and Cincinnati and from medical associations in Europe. "The data we're able to collect now are similar to what flight simulators collect to train pilots," says Schaefer. "We didn't know how many times you needed to practice a technique to be proficient. Now we do. That's the power of data."



Healthcare Simulation South Carolina has developed software that evaluates trainees using manikins

MEDICAL UNIVERSITY OF SOUTH CAROLINA 23 22 REVEALING TOMORROW

Bringing Revolutionary Cancer Therapy to South Carolina Patients



Medical oncologist Dr. John Wrangle leads trials of novel precision and immune-based therapeutics.

In 2015, MUSC Hollings Cancer Center offered opportunities for cancer patients to enter trials of two of the most revolutionary approaches to cancer care: precision therapy and immunotherapy.

Precision therapy: the NCI-MATCH trial

In precision therapy, also known as targeted therapy, a biopsy specimen of a tumor is obtained and sequenced; if an actionable mutation is found, the patient receives an agent that is thought to target that mutation. Traditional clinical trials, designed to test the efficacy of a treatment in a large number of patients stratified by tumor site, have not proven the proper vehicle for testing precision therapies, which work only in patients whose tumors bear the targeted genetic signature.

The National Cancer Institute-Molecular Analysis for Therapy Choice (NCI-MATCH) trial offers a new clinical trial model that is more suited to testing precision therapies. It will leverage the resources of the NCI's National Clinical Trials Network (NCTN) to screen cancer patients nationwide for more than 60 mutations thought to be implicated in a number of cancers, particularly lung, colon, and breast cancer. Patients will be enrolled into

one of the 22 treatment arms based on the genetic signature of their tumor.

As an NCI-designated cancer center and a member of the NCTN, MUSC Hollings Cancer Center will be offering the NCI-MATCH trial to South Carolina cancer patients. John M. Wrangle, M.D., the principal investigator of the MUSC site of the trial, will be able to enroll patients into any of the trial's 22 arms. Wrangle is aiming for a turnaround time—the time it takes from tumor biopsy and genetic sequencing to a decision on enrollment into a treatment arm —of two weeks. Screening began in late 2015, and Wrangle expects the first patients to be enrolled in early 2016. For more information, contact MATCH coordinator Joni Harris at harrisj@musc.edu or 843-792-8876.

With a grant awarded in 2014 by the NCI Community Oncology Research Program (NCORP), MUSC Hollings Cancer Center partnered with community oncology practices to build their clinical trials infrastructure. As a result, South Carolina patients living in the vicinity of an NCORP partner site will be able to participate in the NCI-MATCH trial closer to home. For a full list of NCORP sites, visit http://ncorp.cancer.gov/findasite/.

Optimizing immune checkpoint blockade for lung cancer

The advent of immune checkpoint blockade has changed the landscape of cancer care. Immune checkpoint blockade "takes the brakes off" the immune system, enabling T cells that have been lulled into indolence by the tumor microenvironment to recognize and kill nearby tumor cells. Remarkable and durable responses have been achieved in a subset of cancer patients with immune checkpoint blockade alone, but extending those benefits to a larger proportion of cancer patients will likely require novel combination regimens. In late 2015, MUSC Hollings Cancer Center began enrolling patients with non-small cell lung cancer (NSCLC) into a first-in-human, investigator-initiated phase 1b/2 trial of a combination regimen including the PD-1 inhibitor nivolumab and an investigational drug—IL-15 complexes known as ALT-803 (Altor Bioscience; Miramar, FL).

Medical oncologist John M. Wrangle, M.D., and cancer immunologist Mark P. Rubinstein Ph.D. collaborated to design the trial, drawing on Rubinstein's preclinical work with IL-15 complexes and Wrangle's clinical expertise in cancer immunology. The PD-1 inhibitor removes the brakes from the immune system

while the IL-15 complexes apply the gas, enhancing the T cell response and potentially stimulating other immune cells such as natural killer cells to attack the tumor.

The initial rationale for this clinical study stems from work done by Rubinstein as a postdoctoral fellow at the Scripps Research Institute. In 2006, Rubinstein co-discovered that complexing IL-15 to its soluble receptor makes it 100-fold more biologically active. This finding was of particular importance because, in 2008, IL-15 was ranked by the National Cancer Institute Immunotherapy Agent Workshop as the most promising immunotherapy agent for cancer, edging out even PD-1 inhibitors. For these reasons, Wrangle and Rubinstein saw tremendous potential in pairing one of the most promising of the approved immune checkpoint inhibitors, a PD-1 inhibitor, with IL-15 complexes.

The trial will first establish a safe dose for the IL-15 complexes in the context of nivolumab and then test the combination therapy in 40 NSCLC patients who are nivolumab naïve and 40 who have not benefited from previous nivolumab therapy. For more information, contact thoracic nurse navigator Claudia Miller, R.N., at millercl@musc.edu.



Trial of novel immunotherapeutic for NSCLC stems from research by immunologist Dr. Mark Rubinstein.

Groundbreaking Clinical Trials

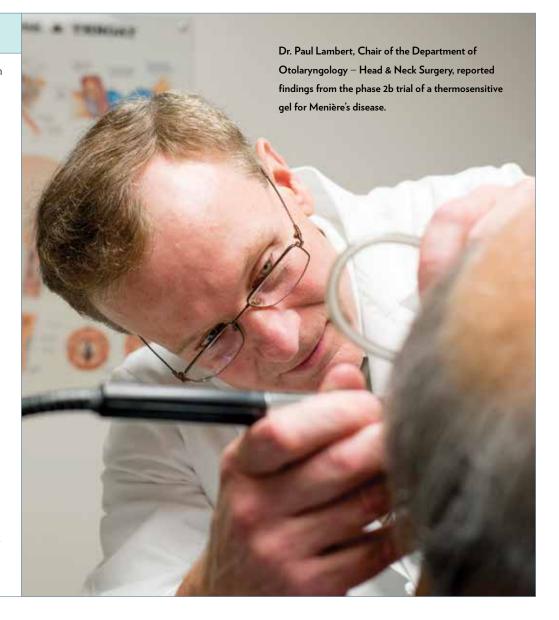
Menière's disease

An investigational treatment for Menière's disease has shown safety and efficacy in phase 1b and 2b trials (NCT01084525, NCT01412177) led by Paul R. Lambert, M.D., Chair of the Department of Otolaryngology – Head & Neck Surgery. Lambert reported the findings of the phase 2b trial this fall at the annual meeting of the American Academy of Otolaryngology and the 7th International Symposium on Menière's disease and Inner Ear Disorders in Rome, Italy.

In Menière's disease, fluid builds up in the inner ear, causing severe vertigo, hearing loss, and tinnitus that dramatically compromise quality of life.

The phase 2b trial showed that patients who were injected behind the ear drum with a steroid-containing thermosensitive gel (OTO-104, Otonomy; San Diego, CA) experienced significantly fewer and less severe Menière's attacks than those who received a placebo injection. The thermosensitive gel is liquid at room temperature but turns into a gel when exposed to body heat. Thus, unlike liquid solutions of steroids, which are non-detectable within 24 hours, the gel remains in place for weeks and can provide sustained relief without the need for frequent reinjection.

A phase 3 trial of the thermosenstive gel will open in early 2016. For more information, contact Shaun A. Nguyen, M.D. at nguyensh@musc.edu.



Sickle cell disease

Hematologist Julie Kanter, M.D., is the principal MUSC investigator for a phase 1 clinical trial (NCT02140554) of a new gene therapy for serious sickle cell disease (SCD) that she believes could be the next step toward a curative treatment. Currently, the only cure for a child with SCD is a hematopoietic stem cell (HSC) bone marrow transplant (HSCT) from an HLAmatched donor, but less than 10% of affected patients have such a donor. Gene therapy adopts a different approach: the patient's own HSCs are harvested from the bone marrow, transduced with a lentivirus carrying a functional copy of the human betaglobin gene with anti-sickling properties (the LentiGlobin BB305 Drug Product; bluebird bio, Inc.), and then reinfused into the chemotherapy-treated patient. These "genetically corrected" HSCs are designed to serve as a self-renewing source of healthy red blood cells, and so a single instance of gene therapy could potentially cure the disease or drastically lessen its severity. For more information, contact Dr. Kanter at 843-876-8483 or kanter@musc.edu.

Carotid stenosis

CREST-2 is a study for people who have asymptomatic narrowing of their carotid artery. The study consists of two parallel trials—one trial will compare carotid stenting plus intensive management vs intensive medical management alone, and the other trial will compare endarterectomy (surgery) plus intensive management vs intensive medical management alone. All study participants will receive intensive medical management to help control their risk factors for stroke.

MUSC Health stroke faculty Tanya N. Turan, M.D., and Marc I. Chimowitz, MBChB, are

members of the executive committee and run

the medical management core that oversees

medical management in the trial at all 120

participating sites in the U.S. and Canada.

participation in the Stroke Trials Network.

MUSC Health is also a study site as part of its

Intrahepatic cholangiocarcinoma

Radiation oncologist S. Lewis Cooper, M.D., is leading a phase 1 trial of a novel combination regimen for patients with unresectable intrahepatic cholangiocarcinoma (ICC) that pairs current first-line chemotherapy gemcitabine/cisplatin (gem/cis) with a liver-directed therapy, transarterial embolization with Yttrium 90 (TARE Y90). The Y90 resin microspheres are infused into the arterial system of the liver, which provides the blood supply to the tumor more than the healthy liver. The microspheres lodge in the microvasculature around the tumor and attack it via radiation and by blocking its blood supply. Cooper is hoping that combining gem/cis and TARE Y90, each of which extends survival about a year, will buy more time for patients with ICC. The primary goal of the phase 1 trial will be to determine a safe dose for the two therapies used in combination. For more information, contact Y90 study coordinator Sarah Annand at annands@musc.edu.

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New Care Delivery Models

The Challenge

Health care resources in South Carolina are concentrated in its metropolitan areas, limiting access for many of its rural residents and threatening to divide its population into health care "haves and have nots." The state's burden of chronic diseases, such as stroke, diabetes, and heart disease, is high, with increased complication and mortality rates among rural minority populations. Too often, patients with limited access to care have relied on emergency departments as a last resort, receiving care too late and at a high price tag for the state. South Carolina is responding with an ambitious telehealth initiative that will begin to erase health care inequities by delivering high-quality, affordable care, including preventive care, to all its residents.



The Solution—Making Connections

It has been a year of making connections for the South Carolina Telehealth Alliance (SCTA), a statewide collaboration of competing academic medical centers, community hospitals, and providers committed to improving access to affordable, quality care via telehealth for all of South Carolina's residents, including those in remote rural areas.

In 2015, the SCTA expanded the reach of telehealth in the state by investing in infrastructure—connecting more of the state's hospitals and equipping more community hospitals to provide telehealth services in their own region.

This integrated network of hospitals facilitates better coordination of care and best use of the state's health care resources, enabling patients to be treated as close to home as possible at a facility providing the level of care they require. As a result of this strategy, more than 96% of the state's population is now within an hour's drive of time-sensitive acute stroke care, compared with only 56% before telehealth.

Telehealth also connects rural practices to critically needed specialist services. For instance, the number of sites receiving multispecialty consultations such as mental health and nutritional counseling through the Virtual Tele Consultation program grew by 212% in 2015.

And telehealth is challenging our assumptions about where care is provided, taking care to those who need it in nontraditional settings such as schools, nursing homes, and prisons. For example, children in rural, predominantly African American Williamsburg County, who have historically received half the number of wellness visits as children in the rest of the state, now have access to care via telehealth at every public school in the county.



Special instruments, such as this digital otoscope, enable a student in a rural school to be examined by a physician at a distant site.

The telehealth infrastructure being built by the SCTA will enable rapid statewide rollout of new programs intended to improve the health of South Carolinians, such as preventive care initiatives to address the state's high burden of chronic disease.

Ultimately, however, the connections made possible by the SCTA are not merely a matter of broadband and bandwidth. The SCTA is fostering human connections—stronger collegiality among the state's specialists. a closer working relationship between specialists and primary care providers, and, above all, a greater understanding of and responsiveness to the needs of patients, regardless of their zip code.



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Stronger Together

A collaborative spirit and an enhanced telehealth infrastructure are enabling hospitals throughout South Carolina to cooperate in unprecedented ways to provide coordinated, convenient, and cost-effective patient care to all of South Carolina's residents.

Telestroke

When the MUSC Health telestroke program was founded in 2008, South Carolina was considered the buckle of the stroke belt. with stroke-related death rates much higher than the national average, particularly along the impoverished I-95 corridor. Today, more than 96% of the state's population is within a 60-minute drive of time-sensitive acute stroke care as a result of telestroke initiatives.

MUSC Health's Comprehensive Stroke Center, directed by Christine Holmstedt, D.O., is one of the highest-volume thrombectomy programs in the nation and serves as a telestroke hub for the South Carolina Telehealth Alliance, providing comprehensive stroke services for 19 partner sites. It has performed 7,000 telestroke consults and improved partner sites' average door-to-needle time—the time from the patient's arrival at the hospital until the administration of tissue plasminogen activator—from 99 to 67 minutes, with 20

minutes as the fastest time. In 2015, subhubs were developed at Regional Medical Center in Orangeburg (see story at right) and McLeod Health in Florence to admit patients who have received thrombolytic therapy at smaller hospitals in their region and require monitoring but do not need the comprehensive services (i.e., thrombectomy) available at MUSC Health. Better matching of patient needs and hospital resources maximizes the efficiency of care delivery and enables more patients

to be treated near their own communities. In addition to being a major player in building a statewide telestroke infrastructure, the program is working to improve stroke care in its own back yard. In 2015, it began to develop a "comprehensive stroke community" in the Charleston tricounty region that will serve as a national model for collaborative stroke care

Dr. Christine Holmstedt is the Director of the Comprehensive Stroke Center.



A commitment to quality stroke care at Regional Medical Center in Orangeburg

The Regional Medical Center (RMC), a 286bed, acute-care hospital and Primary Stroke Center in Orangeburg, SC, is dedicated to providing quality stroke care for its patients. Currently serving about 250 stroke patients per year, RMC's Emergency Department has established stroke pathways that quickly quide the patient through radiological studies and clinical evaluations.

RMC partnered with MUSC Health for telestroke in February 2015, which brought further dramatic gains in key stroke metrics. The number of patients who received thrombolytic therapy more than doubled (from 10 in 2014 to 24 in 2015), and the percentage of those who received it within 60 minutes of arriving at the hospital, as

quidelines suggest, increased from 20% in 2014 to 54% in 2015.

RMC Stroke Program Coordinator Sherry Davis, BSN, SCRN, believes that educational in-services provided by MUSC Health physicians helped drive home why it is so important to act quickly when it comes to stroke. Davis and her colleagues were especially struck to learn that two million neurons die every minute that thrombolytic therapy is delayed. Davis has seen firsthand how much of a difference early intervention makes. "We have had several patients this year walk out of our doors with no symptoms after receiving stroke treatment here," said Davis.

RMC has also partnered with MUSC Health's Teleneurology and Tele-EEG services to help cover its neurology needs and hopes to expand the program in the future.

Brad Holmes, MSN, RN (right) and April Wolfe, BSN, RN (left) of the Regional Medical Center in Orangeburg, SC. Holmes is the Emergency Department Nurse Director.



Stronger Together (continued from previous page)

Pediatric Emergent and Critical Care

For a child in crisis, rapid evaluation and intervention by pediatric critical care subspecialists can change the trajectory of care. Providing access to that subspecialty care is the mission of the Pediatric Emergent and Critical Care telemedicine program, led by MUSC Children's Hospital pediatric intensivist S. David McSwain, M.D., MPH. Since its launch in 2014, the program has conducted more than 50 teleconsultations at four sites—Conway Medical Center, Tidelands Georgetown Memorial Hospital, Tidelands Waccamaw Community Hospital, and Beaufort Memorial Hospital.

David Haseltine, M.D., of Tidelands Health still vividly remembers the case of an asthmatic child in respiratory distress. "With the rapid bedside guidance provided by Dr. McSwain, we were able to stabilize the patient and improve his breathing to the point that he could be transferred to MUSC without needing intubation," says Haseltine. "Without the aid of telehealth and guick intervention, only a few years ago this same scenario would have resulted in respiratory failure, intubation for transport, and a several day ICU stay for weaning off the ventilator.'

Indeed, data from the pilot phase of the project showed that teleconsultations reduced unnecessary PICU admissions and transfers, including five air transfers, providing a tremendous cost savings without sacrificing quality of care (see Table).

McSwain is also the principal investigator for a \$1 million Duke Endowment grant awarded to MUSC Health in 2015 to help develop the South Carolina Children's Hospital Collaborative Telehealth Network. The goal is to create an integrated telehealth network that will enable each of the state's children's hospitals to provide similar teleconsultation services in its own referral region. This network will enable new pediatric telehealth programs to be scaled up efficiently to benefit children throughout South Carolina.

TABLE. MUSC Pediatric Emergent and Critical Care Teleconsultations

Teleconsultation Outcome	Percentage of patients	
Affected triage decision	43%	
Resulted in transfer to a lower- acuity setting	40%	
Prevented transfer	11%	
Averted air transport	12%	
Non-critical care transport	15%	

PICU Admission Rate (telephone): 70% PICU Admission Rate (Telehealth): 51%

ICU Innovations and Tele-ICU

ICU Innovations is an outreach effort led by MUSC Health Tele-ICU Director Dee Ford, M.D., which offers ICUs at MUSC Health partner hospitals quarterly on-site case-based interprofessional team education, collaborative protocol development and implementation, and ad hoc discussions with MUSC Health's interprofessional team for unique dilemmas. So far, six seminars have been conducted at two hospitals, and 51 continuing education/ continuing medical education credits have been awarded. Physician champions working with the ICU Innovations team are also eligible to receive maintenance of certification credit through MUSC Health.

In 2013, MUSC Health partnered with St. Louis-based Advanced ICU Care, the nation's largest tele-ICU provider, to create a new model of ICU care in South Carolina. The MUSC Health Tele-ICU operations center opened in January 2016 and, in partnership with Advanced ICU Care, is delivering comprehensive, around-the-clock ICU patient monitoring provided by board-certified intensivists, nurse practitioners, and critical care registered nurses to two community hospitals, with two more to come on board by the summer of 2016.



Motivating Lifestyle Change Through Telenutrition

Since the founding in 2012 of MUSC Health's Virtual TeleConsultation (VTC) program by Samir M. Fakhry, M.D., Chief of the Division of General Surgery, the demand for nutritional counseling has been palpable. It was the first service provided by the VTC and remains one of the most popular, with almost 600 teleconsultations in 2015.

The demand is not surprising in a state where two of three adults are overweight or obese and where obesity-related diseases take a heavy toll. With obesity rates of 32.1% for the overall population and 42.7% for African Americans, South Carolina has the fourth highest prevalence of diabetes in the nation and the third highest for African Americans. Two of five adults in South Carolina have high blood pressure, and stroke and heart disease are the two leading causes of death.

The simple solution for lessening this disease burden is lifestyle modification, but motivating behavior change within the time constraints of a typical office visit has proven difficult. To alter life-long dietary habits, patients need more guidance, reinforcement, and follow-up. Telenutrition removes the onus from the physician by providing virtual access to a registered dietitian every four to six weeks who provides patients the tools they need to make healthy changes to their diet. Amanda

Peterson, RDN, LD, counsels and educates patients on lifestyle modifications, such as interpreting food labels, controlling portion sizes, and being mindful of their eating habits and behaviors. Additionally, she works with them to tailor healthy meal plans to their personal and cultural food preferences.

For patients, the service can be transformational. Just ask Sallie Middleton, a 67-year-old African American woman with diabetes, who was referred to the program by the Medical Center of Santee because her blood sugars were dangerously high. Middleton was motivated to change; she had seen a cousin lose her battle with diabetes, lapsing into a coma before dying. "My sugar was going to give me a stroke or a heart attack or cause me to go into a coma and I don't want that," says Middleton. "I want to live."

Middleton lost 15 pounds the first month and 40 pounds by month four and is now exercising regularly, walking three miles morning and evening. "I have so much energy now and my sugar is awesome," says Middleton. She laughs as she remembers her son calling her one night after 11 pm to find her dusting the furniture and walls because she had so much energy. She convinced him to follow her new diet as well and he lost 12 pounds in the first two weeks. Now she's

working on her sister and the members of her congregation. As patients such as Sallie Middleton share their experiences and success stories, telenutrition could be a catalyst for transforming communities.

"I thank God for that program," says Middleton. She is also grateful to Dr. Monnie Singleton, who had the vision to offer VTC telenutrition services at both of his practices, the Singleton Health Clinic in Orangeburg and the Medical Center of Santee. "Telehealth is the wave of the future," says Singleton, "and I like to ride the crest of the wave and be an early end-user."

To make the case that telehealth-delivered nutritional counseling has a crucial role to play in obesity management, the MUSC Center for Telehealth is offering free telenutrition services to partnering practices and will share data from this pilot study with the Centers of Medicare & Medicaid Services. In 2015, Medicaid began reimbursing for in-person obesity management, covering six physician and six dietitian visits annually for patients with a body mass index greater than 30, but does not currently cover telenutrition.

For more information on VTC telenutrition services, contact program coordinator Laura Langston at langstl@musc.edu.







Changing Young Lives

Nurse practitioner Kelli Garber, MSN, APRN, PPCNP-BC, vividly remembers her first telehealth patient from Williamsburg County—a young girl with asthma who had begun to sit out recess, fearing a bout of wheezing, and who was always sleepy in class. Further investigation revealed that the girl's physician had moved away and her medications were running out. Once Garber prescribed the needed medications, the girl's condition began to improve, and she now sleeps through the night and plays at recess. "You have changed her life," the girl's grandmother told Garber. "We didn't know she could be this healthy."

Many parents in impoverished, predominantly African American Williamsburg County work minimum-wage jobs in Myrtle Beach, boarding a bus each day for the commute to work. Taking a sick child to the physician requires a day off work, which most parents cannot afford. There is no guarantee that a provider will be available given the shortage of primary care physicians in this rural county. Poor health translates to chronic absenteeism and a higher dropout rate. The vicious cycle repeats for another generation—poverty prevents proper health care, and poor health hampers students from graduating and breaking free of poverty.

Disrupting that cycle by empowering school nurses is the mission of the MUSC Center for Telehealth's school-based telehealth program.

"The school nurse knows all the families, the children, the needs," says Garber. "Access to a provider through telehealth enables them to provide that next level of care. Without that access, they can recommend but barriers may keep families from following through."

"We need to put the care where the child is and that's the school," says Lynn Floyd, BSN, RN, CRRN, who was hired in 2015 as a telepresenter for the program after working more than 15 years as a school nurse in Williamsburg County. "I have witnessed that it helps kids get back to school quicker."

The school-based telehealth program was begun four years ago as a pilot study by MUSC Children's Hospital pediatrician James T. McElligott, M.D., now Medical Director for Telehealth. Today, with the school district's support, the program is in every school in Williamsburg County. Over the next 3 years, the program plans to expand to more schools in Sumter and Bamberg Counties and to add more schools along the I-95 corridor and potentially other sites across the state. The program places special emphasis on the care of asthma and trauma-related mental health issues, both of which have been implicated in poor graduation rates.

Before telehealth, if a child with asthma experienced an exacerbation at school, the nurse had little choice but to send him or

her home or to an emergency department. Garber and Floyd are developing a new asthma initiative to offer nurses more choices. Enrolled students will be given any needed prescriptions for controller and rescue medications. When they experience an episode of asthma, the school nurse or telepresenter will administer the medication and they can go back to class. For children or parents requiring more training on asthma management, Anita B. Shuler, RRT, AE-C, and Aimee Tripp Tiller, RN, A-EC, of MUSC Children's Hospital will offer educational sessions.

Michael A. de Arellano, Ph.D., Professor in the Department of Psychiatry and Behavioral Sciences, is directing the efforts to establish telemental health programs at selected schools and to adapt evidence-based protocols for the management of mental health in pediatric populations to a telehealth format. Regan Stewart, Ph.D., oversees the provision of services, with the support of Garber and school-based telehealth program manager Elana Wells, MPH. Telehealth is being used both to triage patients in need of mental health services and to conduct therapy. The telemental health program will be rolled out at D.P. Cooper Charter School in 2016. For more information, contact school-based telehealth program manager Elana Wells at navon@musc.edu.

Managing Chronic Disease With Mobile Health Technology

The ubiquitous smartphone promises to be a gateway to improved care for patients with chronic diseases. The Technology Applications Center for Healthful Lifestyles (TACHL) in the MUSC Health College of Nursing, led by Frank A. Treiber, Ph.D., Director, and Kenneth Ruggiero, Ph.D., Associate Director, is committed to developing patient-friendly mobile health (mHealth) technology that seamlessly connects patients and health care providers using apps, body sensors, remote monitoring devices, and the electronic health record. It is collaborating on over 30 funded mHealth projects addressing the prevention and management of the leading chronic diseases in South Carolina.

TACHL designs or optimizes apps that remind patients to take medications or check key health measures such as blood pressure, give immediate audio and visual feedback, and promote patient engagement by providing personalized motivational and social reinforcement. Health care providers receive reports summarizing medication intake and vital sign functioning, enabling them to make nimble adjustments to treatment plans. Most importantly, patients guide how these apps are constructed, so that they are more likely to make them a part of their everyday activities. For example, in collaboration with pediatrician

Ronald J. Teufel, M.D., and with funding from the South Carolina Clinical and Translational Research Institute, Treiber and TACHL Senior Systems Architect Sachin K. Patel, MS, developed the Smart Phone Asthma Monitoring System (SAMS) to ensure better follow-up care for children hospitalized with severe asthma. The app, which was developed with guidance from youth with asthma and their parents, syncs to Bluetooth-enabled controller and rescue inhalers and transmits

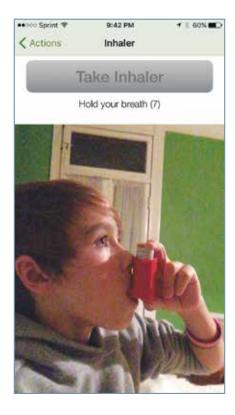
summarized usage data to providers. It also guides children how to use the inhaler properly, even recording a brief video so that MUSC Children's Hospital pediatric respiratory therapists such as Anita B. Shuler, RRT, AE-C, can evaluate their technique. Children answer a series of questions daily about their symptoms and the circumstances surrounding inhaler use. An interface is being developed to provide parents treatment recommendations based on their child's data profile.



Remote monitoring devices enable better tracking of patients' vital signs and medication intake at home.

The app is now being tested in a feasibility trial with patients in Charleston and Columbia. With funding from the Center for Telehealth, Shuler and other pediatric respiratory therapists will begin piloting one-month telehealth follow-up visits with these children in early 2016, basing treatment recommendations on reports generated using app-collected data.

The Smart Phone Asthma Monitoring System enables better follow-up care for children with asthma.



The Digital House Call

MUSC Health employees and insured family members 18 years and older will be able to schedule e-visits through MyChart, the patient portal for Epic, in early 2016. E-visits enable patients to obtain rapid care for mild conditions such as the flu, red eye, and rashes from the comfort of their own homes or offices for a flat fee of \$25. The visits are fully integrated into patients' electronic health records.

For asynchronous e-visits, which can be submitted 24/7, the patient logs onto MyChart and fills out a questionnaire about his or her condition, even appending a photograph (e.g., of a rash) if pertinent. The information from the questionnaire is sent to a provider, who indicates if the condition can be treated using the service or if the patient needs to be seen in-person. If an e-visit is deemed appropriate, a provider will respond within 4 hours (if the request is submitted 7 am to 7 pm) with treatment recommendations, guidelines for home care, and any needed prescriptions. Requests submitted after 7 pm will be answered the following day.

"E-visits are an incredibly high-level triage mechanism," says Edward C. O'Bryan, M.D., lead physician for the e-visit program. "They will have a ripple effect where people with mild conditions can be seen more rapidly, conserving more in-person slots for those with complex conditions."

Coming later in 2016, patients will be able to schedule a virtual visit with their provider through Epic MyChart. These real-time, face-to-face video visits offer unprecedented convenience for both patients and physicians. Because patients can be "seen" from anywhere, they need not miss hours from work to keep a medical appointment. Physicians can also increase their productivity by filling empty slots in their schedule with video visits.

TRANSLATING DISCOVERY Illustration of drug compound courtesy of Dr. Yuri Peterson of the South Carolina Center for Therapeutic Discovery and Development.

Translating Discovery

Tomorrow's clinical innovations will spring from today's research only if models of discovery evolve to promote translation. The South Carolina Clinical & Translational Research Institute, which received a \$23.7 million follow-on grant in 2015 from the NIH's Clinical and Translational Science Award program, provides research teams with the infrastructure to move innovation into the clinic. Better collaboration between basic scientists and clinicians will also be needed if research is to yield clinically meaningful answers, and multi-institutional collaborations will provide the required diversity of expertise and scope of resources. New models of funding, including industry/academia partnerships and entrepreneurial ventures, are also necessary. This strategy has worked well for MUSC, which garnered \$247 million in research funding in fiscal year 2015, representing a 12% increase in overall funding and a 32% increase in corporate funding since last year.

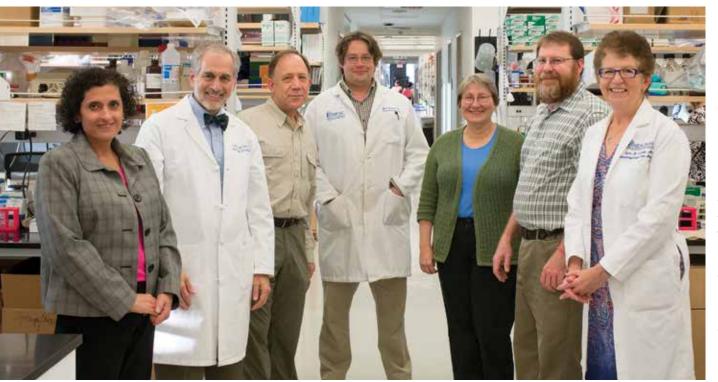
Illustration of drug compound courtesy of Dr. Yuri Peterson of the South Carolina Center for Therapeutic Discovery and Development.

A New Model of Drug Discovery Attracts Industry Partnership

Drug discovery is at an impasse: nine of ten investigational compounds fail to show efficacy in clinical trials. Karen Lackey, who successfully led industry drug discovery efforts for 25 years before joining MUSC Health as Director of the South Carolina Center for Therapeutic Discovery and Development, is on a mission to change that.

She believes the synergy created by industry/academia partnerships is the answer. Industry offers state-of-the-art platform technologies and extensive experience with the drug development process. Academic researchers offer a deeper understanding of clinical pathology and biological mechanisms that industry will need if it is to do a better job of choosing only the most promising of drug development candidates to take forward into clinical trials.

In May 2015, MUSC Health entered into just such a collaboration with Bristol-Myers Squibb (BMS), the goal of which is to identify biomarkers and possible drug targets for fibrotic disease. BMS is funding basic and translational scientists and clinicians at MUSC specializing in three fibrotic diseases: scleroderma, idiopathic pulmonary fibrosis (IPF), and diabetic kidney disease (DKD). MUSC investigators will work closely with BMS teams specializing in fibrosis, biomarkers, and immunology. Funded investigators include Michael G. Janech, Ph.D., of the Division of Nephrology; Carol Feghali-Bostwick, Ph.D., and Stanley Hoffman, Ph.D., of the Division of Rheumatology & Immunology, who offer innovative models of fibrotic disease; and MUSC Health rheumatologists Richard M. Silver, M.D., and James C. Oates, M.D., pulmonologist Lynn M. Schnapp, M.D., and endocrinologist Maria F. Lopes-Virella, M.D., Ph.D., who will collect samples and analyze data from patients with scleroderma, IPF, and DKD, respectively, to identify new therapeutic targets.



Left to right: Dr. Carol Feghali-Bostwick, SmartStateTM and Kitty Trask Holt Endowed Chair in the Division of Rheumatology & Immunology; Dr. Richard Silver, Director, Division of Rheumatology & Immunology; Dr. Stanley Hoffman, Professor, Division of Rheumatology & Immunology; Dr. Yuri Peterson and Dr. Deirdre Luttrell of the South Carolina Center for Therapeutic Discovery and Development: Dr. Michael Janech, Associate Professor. Division of Nephrology; and Dr. Lynn Schnapp, Director, Division of Pulmonary and Critical Care

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Clinician/Researcher Collaborations

Precision immunotherapy gets small

A physician/scientist team is designing nanoparticles that smuggle therapies directly to a trouble spot without knocking the rest of the body off balance. In 2015, transplant surgeon Satish N. Nadig, M.D., Ph.D.; bioengineer Ann-Marie Broome, PhD, MBA; and immunologist Carl Atkinson, Ph.D.,

invented several technologies that are covered by multiple pending patent applications. Their company, ToleRaM Nanotech, LLC, obtained exclusive rights to some of these technologies from MUSC Foundation for Research Development.

The idea started with organ transplant patients. Immunosuppressant drugs suppress

a recipient's entire immune system, causing unintended side effects such as infections and even cancer. The nanocarrier developed by ToleRaM delivers the immunosuppressant rapamycin directly to the vasculature of the donor organ, releasing it only when it is taken up by the cells lining the blood vessels, limiting side effects. ToleRaM's frontline product is a nanoparticle additive to the standard



Transplant surgeon Dr. Satish Nadig (right)



Bioengineer Dr. Ann-Marie Broome (left)

University of Wisconsin solution used to preserve donor organs during transport, which further protects the organ against the stresses of transplant. The additive suppresses the immune response only at sites where the blood vessels of a donor organ are joined to those of the recipient. The group is also designing a liposome delivery system for treating chronic lung disease and a nanoparticle that can deliver therapeutic agents to surgically inaccessible tumors.

This year, the team received pilot funding from the South Carolina Research Authority Launch Program to advance its proof-ofconcept using preclinical models. The team has also reached the exclusive second round for the prestigious Harrington Scholar-Innovator Award, which provides a five-year investment in clinician scientists who wish to fully develop the business and scientific components of their work.

"The partnership we've fostered is true team science," says Nadiq. "We're utilizing concepts in bioengineering and basic immunology and applying that to patients."

A "smart" wound dressing

Chronic wounds, such as pressure ulcers or diabetic foot/venous leg ulcers, affect three to six million Americans and cost the nation an estimated \$25 billion annually.

MUSC Health surgeon Stephen A. Fann, M.D., who specializes in treating patients with chronic, exudative wounds, saw firsthand that the wound gels commonly used to treat them provide some pain relief but do not adequately protect against bacterial infection. He asked bioengineer Michael J. Yost, Ph.D., Director of General Surgery Research, for a "smart" wound dressing that would allow fluid to drain from the wound but prevent external moisture and contaminants from reaching it.

With colleagues Veronica Rodriguez-Rivera, Ph.D., and J. Matthew Rhett, Ph.D., Yost devised a multi-layered wound care system that was inspired by the ancient Egyptians. Egyptian wound dressings comprised three layers: a bottom layer of cotton lint serving as a scaffold for tissue regeneration, a middle

layer of honey acting as an antibacterial agent, and an outer layer of grease for waterproofing. Yost and his team also built three layers into their wound closure system: a layer of reaction spun collagen impregnated with an antiinflammatory peptide to act as a substrate; a layer of biofabricated microvascular tissue to ensure an adequate blood supply to the regenerating tissue; and a cellulose membrane to wick fluid from the wound but to prevent entry of contaminants. The external surface of the membrane is sputtercoated with silver, making it at once hydrophobic and antibacterial. The dressing does not need to be removed or changed as it is semipermanent and biodegradable.

The team has created a company—Synovidah, LLC—to further develop and commercialize the novel wound dressing system. MUSC Health breast cancer surgeon Nancy DeMore, M.D., and College of Nursing professor Teresa J. Kelechi, Ph.D., who has long experience with wound care, serve on the advisory board of the company.

Multi-institutional Collaborations

Trans-Atlantic partnership finds genetic origins of a common cardiac disease

Faculty in the Department of Regenerative Medicine and Cell Biology at MUSC have formed a trans-Atlantic partnership with the French Leducq Foundation and Harvard/ Massachusetts General Hospital to investigate the origins of mitral valve prolapse (MVP), a degenerative cardiac disease affecting 1 in 40 people. Healthy heart valves function as oneway doors for blood flow. In MVP, the mitral valve fails to close properly and blood can flow in reverse. About half of people with MVP



Dr. Russell (Chip) Norris is a co-senior author on two Nature articles that identify a genetic origin for mitral valve prolapse. Photograph courtesy of Sarah Pack.

have symptoms and harbor increased risks of stroke, heart failure and sudden cardiac death.

In their 2015 articles, published in the August 10 issue of Nature and the August 24 issue of Nature Genetics, the members of the MUSC/ trans-Atlantic partnership identify heritable genetic errors during cardiac development that progress as affected individuals age. The team studied families with inherited MVP and a group of more than 10,000 individuals with non-inherited MVP and discovered genetic variations in genes that contribute to malformed mitral valves. In a broadcast interview with South Carolina Public Radio on November 23, MUSC researcher Russell A. (Chip) Norris, Ph.D., co-senior author on the studies, said the results helped identify "druggable" pathways that can now be targeted with pharmaceutical therapy in experimental models. The group hopes these therapies for MVP will soon generate clinical trials.

"We have found a genetic and biological reason for one of the most common diseases affecting the human population," says Norris. "This is a critical initial step as we transform this discovery into new remedial therapies to treat the disease."



World-class team collaborates to develop a new class of cancer therapeutics

Precision therapies target specific mutations to knock out pathways involved in cancer development. Cancer is devious, however, and can develop resistance to these therapies by using redundant pathways. Zihai Li, M.D., Ph.D., Chair of the Department of Microbiology and Immunology, has shown that the heat shock protein grp94 is a master regulator of many oncogenic pathways, making it an attractive drug target. A grp94 inhibitor could block multiple cancer-associated pathways at once, reducing the likelihood of resistance.

In September 2015, MUSC Hollings Cancer Center and its partners Memorial Sloan Kettering and the University at Buffalo were awarded a five-year \$6.8 million program project grant from the National Institutes of Health to elucidate the underlying biology and structure of the heat shock protein grp94 and to develop grp94 inhibitors for clinical trial. The award will fund three projects and two cores to accelerate the development of grp94-based cancer therapeutics.

Li is the national principal investigator for the grant, will head up its administrative core, and will lead a project to use genetic, biochemical, and immunological tools to elucidate the mechanisms by which grp94 promotes cancer and to assess the therapeutic potential of grp94 inhibitors against triple-negative breast cancer.

Gabriela Chiosis, Ph.D., of Memorial Sloan Kettering, whose laboratory has previously developed successful inhibitors against other heat shock proteins, will head the Medicinal Chemistry core and develop identified grp94-inhibiting compounds into pharmacologically viable agents for clinical trial. Structural biologist Daniel T. Gewirt, Ph.D. of the University at Buffalo will map the atomic structure of grp94 so that new inhibitors can be identified and engineered for better selectivity and binding capacity.

TRANSLATING DISCOVERY



Dr. Marvella Ford, Associate Director for Cancer Disparities at MUSC Hollings Cancer Center (left), and Bobbie Blake (right), who completed the MUSC research program.

Teaching a Love of Research and Innovation

A potential cancer cure begins at home

South Carolina has some of the highest cancer health disparities in the nation, according to Marvella E. Ford, Ph.D., Associate Director for Cancer Disparities at MUSC Hollings Cancer Center. In 2015, Ford received new support from the National Cancer Institute to fund an educational approach to the crisis: a \$1.2 million, five-year grant that connects youth in the most affected communities with leading cancer researchers at MUSC. "Our students are growing up in communities being decimated by these disparities," says Ford. "They really want to learn the tools to improve the health of their communities."

For 14 weeks each summer (beginning summer 2016), 21 student fellows from South Carolina's Historically Black Colleges and Universities— Claflin University, Voorhees College, and South Carolina State University—will be paired with cancer researchers at MUSC. Fellows will be immersed in full-time cancer disparities research, i.e., biology and epidemiology lectures and hands-on laboratory training in

basic cancer research methods. The funding establishes MUSC's first semester-long cancer health equity research curriculum and expands a program started at Hollings in 2007 by Ford and colleagues to diversify the state's population of biomedical and biobehavioral scientists.

Ford believes that training a diverse group of South Carolina students in cancer research will improve the state's ability to fight cancer. "The students in our program are excited to work at MUSC with some of the greatest cancer researchers in the country," says Ford. "We're issuing them a message of hope."



Malik Leach (left) and Kadeidre Gaymon (right) worked with research oncologist Dr. David Turner (center) in 2015.

MUSC Start-Ups That Are Changing Care

Newrizon Bio

Early rounds of chemotherapy and radiotherapy are effective at shrinking triplenegative breast cancers, but therapy resistance and tumor recurrence are common. A tiny population of cells in a tumor, called cancer stem cells (CSCs), are resistant to chemotherapy and radiation, according to Gavin Y. Wang, M.D., Ph.D., founder of Newrizon Biotechnologies, LLC, and Assistant Professor in the Department of Pathology and Laboratory Medicine. CSCs can self-regenerate, perpetuating therapyresistant tumor regrowth and metastasis.

"Through drug screens, we have identified small molecule compounds that successfully deplete the CSC population in triple-negative breast cancers," says Wang. "We're using preclinical models to test these compounds alone or with chemotherapy or radiotherapy to remove the root of the disease."

In 2015, Newrizon entered into an option agreement with MUSC Foundation for Research Development for the pending PCT patent application for the compounds



and is improving the chemical properties of those compounds to boost efficacy. The company is working to attract grants and venture capital for future clinical trials.

Dr. Gavin Wang, founder of Newrizon Biotechnologies, LLC



MUSC professors John E. Baatz, Ph.D., and Demetri D. Spyropoulos, Ph.D., have developed a special cryopreservation solution (SolnIX) and technique based on negative pressure expansion that allows tissue to be frozen without being damaged by ice crystal formation. When thawed, the stabilized tissue appears virtually identical to fresh tissue. They cofounded Cryogenix, LLC, to commercialize the technology, which they licensed from MUSC.

Their technique could be a real boon to biorepositories. Currently, the methods used to preserve specimens determine the analyses that can be run on them, forcing biorepositories to predict demand and leaving them to absorb the excess costs when they miscalculate. In contrast, tissues preserved using SolnIX and associated technologies can be analyzed using any (even unanticipated novel) methods, removing the quesswork for biorepositories and enabling them to provide samples in a more costeffective manner.

In 2015, Cryogenix received an SCBIO Quick Start Grant and partnered with the Integrated Biobank of Luxembourg to perform large-scale testing of the technique.

Teleconsent



A new teleconsent capability developed by Brandon Welch, Ph.D., MUSC Director of Telehealth Research and Innovation, could improve clinical trial recruitment by enabling patients to conveniently provide their informed consent using telecommunication. The provider and patient can read and discuss the consent form together in real time using audio and video, and the patient can virtually sign by providing a free-drawn signature or photo signature. Teleconsent is free for MUSC clinicians and researchers, does not require any special downloads or plugins, and follows the same federal standards for patient privacy that bind hospitals. In 2015, MUSC licensed the teleconsent technology to Doxy.me, a telemedicine company cofounded by Welch.

"Teleconsent doesn't replace the in-person consent process" says Welch. "It just augments it. And that's a way to increase recruitment numbers."

MitoHealth

Mitochondria, popularly known as the "power plants" of cells, are also acute sensors of the stressors responsible for organ injury. MUSC Foundation for Research Development has granted MitoHealth. Inc., an exclusive license to an assay of ATP-synthase beta, a new biomarker of kidney mitochondrial function. The biomarker could reveal early renal injury that others do not, according to MitoHealth. Inc., co-founders Rick Schnellmann, Ph.D., and Craig Beeson, Ph.D., both professors in the MUSC Department of Drug Discovery and Biomedical Sciences. In the May 2015 issue of Toxicological Sciences, they reported that damaged kidney mitochondria release a form of ATP synthase beta that is specifically detected in urine. A test for it could alert clinicians to changes in kidney function in patients with acute kidney injury caused by surgery or drug treatment MitoHealth plans to have a sensitive test ready for commercial development by 2016.



Patient-Guided Health Solutions (PGHS), cofounded by Sachin K. Patel, M.S., and Frank A. Treiber, Ph.D. of MUSC Health's Colleges of Nursing and Medicine, is using mobile health technology to engage patients in their own care. PGHS solicits guidance from patients about how to design smartphone software and hardware devices that will be easy to use and will encourage adherence to their treatment plans.

Based on degree of adherence, patients receive tailored motivational messages related to their current goals. In 2015, for example, PGHS had patients redesign a "smart" pill bottle cap, which tracks when the bottle is opened or closed, to send personalized photos or motivational messages. These messages often involve family, faith, and friends. "Grandparents like receiving photos of their grandchildren," says Treiber, "along with a quick message such as 'Keep taking your pills, grandpa, so we can go catch more fish!""

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PROGRESSNOTES

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