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Reducing Readmission Rates and Empowering Heart Failure Patients

Sanjeev K. Gulati, MD
Director, Advanced Heart Failure and Transplant Cardiology

AT CAROLINAS HEALTHCARE SYSTEM'S (CHS) SANGER HEART & VASCULAR INSTITUTE, we are committed to developing innovative processes that offer patients the very best care. Recent healthcare reform initiatives place a larger emphasis on readmission rates and other quality indicators, and the heart failure community has been directly affected.

Heart failure affects more than 5 million Americans or approximately 1 in 56 individuals. Of these, only half will survive over the next five years. The population of heart failure patients is expected to double over the next 30 years. Heart failure is the most common cardiovascular discharge diagnosis, medical discharge diagnosis and reason for inpatient readmission. Twenty to 24 percent of heart failure patients are readmitted within 30 days.

Sanger's team of heart failure specialists are at the forefront of the development of a chronic disease management program, designed to streamline guidelines based on heart-failure care and provide patients more efficient, unifying cardiovascular care.

REDUCING READMISSIONS

Heart Success is a CHS-wide initiative and phased plan developed to standardize and optimize the care of heart failure patients. Following a hospital discharge, the **Heart Success** program serves as a tool to transition the patient from the acute care setting, which is a high-risk transition point. The program is designed to:

- engage patients and their families to increase adherence to physician direction such as diet and medication
- reduce variations in care
- identify better ways to manage high-risk patients across the care continuum and improve outcomes

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HELP YOUR PATIENTS FIND OUR EXPERTS

Sanger Heart & Vascular Institute now has a dedicated referral line to help you find the right physician for your patients.

Call **877-999-SHVI (7484)** to speak with a representative who can assist you in finding a specialist or the nearest Sanger office location.

RECEIVE *THE SANGER REPORT* VIA E-MAIL

To receive *The Sanger Report* via email, visit **www.sangerheart.org** and fill out the short sign-up form located on our home page.

INSIDE ...

Sanger Heart & Vascular Institute

Care Delivery Innovations

INNOVATION IS A WORD WE HEAR FREQUENTLY IN THE MEDICAL COMMUNITY. MOST OFTEN, INNOVATION describes a new technology, the latest medical device or a leading-edge minimally invasive treatment. At Sanger Heart & Vascular Institute, we have a different definition of innovation: improving the way we deliver care to patients who have limited treatment options. This issue of *The Sanger Report* is a true reflection of the strides our experts have made to innovate care delivery for multiple subsets of patients with cardiovascular disease.

Congestive heart failure is a devastating disease, affecting more than 5 million Americans, and that number is expected to double in the next 30 years. Sanger has developed a comprehensive program to manage care for these complex patients and reduce hospital readmissions. **Sanjeev K. Gulati, MD,** Director of Advanced Heart Failure and Transplant Cardiology, details the improved outcomes we've had with the Heart Success program launched in January 2012.

Atrial fibrillation (AF) is also on the rise. **J. Warren Holshouser, MD,** Director of Cardiac Electrophysiology, reports on our advances in care for AF, including development of an integrated care model. Our future AF center will streamline care and offer patients multiple access points throughout the region.

Michael J. Rinaldi, MD, Director of Clinical Research, discusses our involvement in SYMPLICITY, a trial investigating a catheter-based procedure to treat hypertension. Already approved in Europe, this procedure could improve care for patients with the most drug-resistant forms of hypertension.

Through our partnership with the Heineman Foundation of Charlotte, Sanger physicians are establishing and strengthening cardiovascular care centers in Latin America and beyond. We look forward to assisting our partners in Belize with performing the country's first open heart surgery later this year.

As our healthcare system evolves, innovation will remain a constant driver to improve patient outcomes.

Sincerely,

Paul G. Colavita, MD, FACC
President
Sanger Heart & Vascular Institute

Clinical Trial Brings New Treatment for Hypertension

Michael J. Rinaldi, MD, FACC, FSCAI
Director of Clinical Research

AT CAROLINAS HEALTHCARE SYSTEM'S (CHS) SANGER HEART & VASCULAR INSTITUTE, we're committed to offering patients the most up-to-date care options. Our participation in national clinical trials helps us bring innovative techniques and therapies to those who may have limited treatment options. Sanger is one of 60 centers nationwide involved in a clinical research study, the **SYMPLICITY** trial, to test the safety and efficacy of a new investigational procedure that treats patients with uncontrollable hypertension—a group of patients who currently have limited treatment options.

Only half of patients with high blood pressure are adequately treated and a segment of this population can't be controlled despite adequate medical and dietary therapy and lifestyle modification. These patients are at increased risk of stroke and renal failure and treatment options have been very limited.

A MINIMALLY INVASIVE APPROACH

Interventional cardiologists are now testing a catheter-based procedure to disrupt nerves to the kidneys, called renal sympathetic nerves, using radiofrequency ablation. These nerves, which form a plexus around each renal artery, appear to be important to the regulation of blood pressure. Ablation may result in significant blood pressure reduction. The nerves are accessed through a standard renal angiogram with several treatment sites along each renal artery in a rotating manner.

In the randomized HTN-2 trial, 106 patients with resistant hypertension were treated with renal nerve ablation or sham placebo. This was a resistant population with systolic blood pressure ≥160 mm Hg, and on an average of five medications. Average systolic blood pressure reduction was a remarkable 32 mm Hg at six months follow-up, with no major complications or change in renal function. **(See Figure 1 on page 8.)** The preceding HTN-1 open-label study suggests blood pressure reduction is maintained beyond two years of follow-up.

While this therapy remains investigational in the United States, it's approved in Europe, where thousands of patients have been treated with this technology. The

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IS YOUR PATIENT A CANDIDATE?

Patients are eligible to participate if they:

- are between 18 and 85 years old
- have systolic blood pressure consistently ≥160 mm Hg (≥150 mm Hg for patients with type 2 diabetes)
- are taking three or more maximum-dose blood pressure medications, including a diuretic

J. Warren Holshouser, MD, FACC
Director, Cardiac Electrophysiology

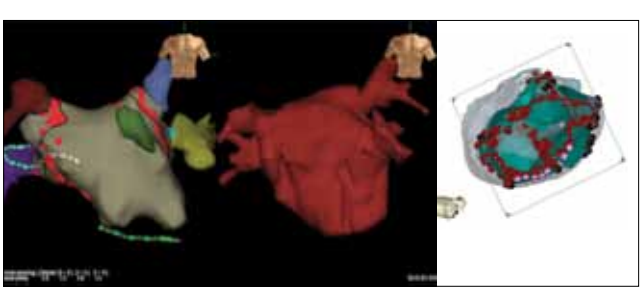
A New Age of Care for Atrial Fibrillation

ATRIAL FIBRILLATION (AF) IS THE MOST COMMON HEART RHYTHM DISORDER IN THE adult cardiology population. The number of patients with AF is expected to double from 2010 to 2050, translating into a tremendous challenge for our healthcare system and for our patients. Strategies to manage this ever-increasing population will be important for every practice and hospital system and is a priority for Sanger Heart & Vascular Institute and Carolinas HealthCare System (CHS). Whether we treat patients with ablation, new rhythm- or rate-control medications, anticoagulation or novel device therapies, AF promises to keep the medical community busy in the 21st century.

The cornerstone of AF care focuses on the management of stroke risk and the treatment of disabling symptoms. Historically, patients deemed at high risk for stroke have used vitamin-K antagonists such as warfarin to produce a 70 percent reduction in overall stroke risk. Risk factors for nonvalvular AF include **C**ongestive heart failure, **H**ypertension, **A**ge over 75, **D**iabetes, and **S**troke (**CHADS2** risk score).

The last quarter of 2010 saw the introduction of the first new oral anticoagulant for stroke prevention in AF in nearly half a century. With a second agent introduced in 2011, the options for anticoagulation in nonvalvular AF are burgeoning. Tailoring these options to our patients remains a challenge given the absence of an objective way to quantify the countering bleeding risk.

Treating a patient's disabling symptoms remains the most gratifying component to AF care. Consistent with the **AFFIRM** trial, using a rate-control or a rhythm-control strategy must be tailored to the individual, factoring in his or her underlying symptoms and clinical circumstances.



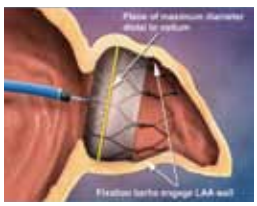
■ Pulmonary vein (PV) isolation map

CABANA Enrollment Center

Treatment of atrial fibrillation (AF) has focused on a tailored approach, including medical therapy or catheter ablation in symptomatic but drug-resistant patients. Sanger Heart & Vascular Institute is one of six southeastern enrollment centers for the NIH-sponsored **CABANA** trial, which compares medical therapy with ablation for AF with a primary endpoint of mortality.

New anticoagulant agents have been shown to be non-inferior or even superior to warfarin for stroke prevention. There has also been a consistent signal for less intracranial bleeding—perhaps the most dreaded complication of oral anticoagulation. The newer agents have fewer drug and food interactions and don't require routine monitoring. Concerns over reversibility and cost remain.

Device therapy for stroke prevention using left atrial appendage (LAA) occlusion is also under investigation at Sanger. We're actively involved in the **PREVAIL** trial, comparing treatment with a LAA occlusion device to oral anticoagulation with warfarin to prevent strokes in patients with AF. Patients taking newer anticoagulation agents aren't candidates for this trial. Ideal patients are those using warfarin for AF.



■ Left atrial appendage occlusion device

As the incidence of AF increases, Sanger stands poised to continue its tradition of high-quality care. Collaboration between our partners and referring physicians remains the cornerstone of success in bringing new advances to patients.

Contact our Clinical Research Department at **704-355-4794** if you have a patient who may be a candidate for one of these clinical trials.

NEW MODEL OF AF CARE

CHS and Sanger have developed a center to manage patients who suffer from AF. Sanger's Atrial Fibrillation Center will offer state-of-the-art techniques and therapies. Our team of experts, including clinical cardiac electrophysiologists, cardiothoracic surgeons, a cardiac anesthesiologist and coagulation specialists, will manage patient care, focusing on the entire spectrum of AF, from initial evaluation with first-line therapies to more complex procedures, such as catheter-based or surgical ablation. Our goal is to provide comprehensive AF care that's personalized to the needs of our patients. ■

Reducing Readmission Rates and Empowering Heart Failure Patients

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- identify and deliver appropriate resources and tools for CHS providers to take care of complex patients
- identify and devise solutions for gaps in the continuum of care

In the first five months of operation, more than 175 patients were introduced to the **Heart Success** program by the inpatient nurse navigator. Without this program, these patients would have been discharged from the hospital without receiving any of the heart failure-specific resources designed to improve patients' quality of life and reduce their chance of readmission.

For patients who choose to enroll in the **Heart Success** program, the multidisciplinary team consults with each patient and empowers him or her with resources to self-manage his or her disease and return to the care of their primary care physician or cardiologist. The team includes:

- a dietitian
- a pharmacist
- a patient navigator
- a social worker
- a specially trained nurse practitioner and physician assistant
- home-care referrals
- rehabilitation referrals
- telehealth and remote diagnostics/monitoring

The **Heart Success** program is run by specially trained advanced care practitioners for patients who aren't enrolled in the long-term heart failure clinic, which manages patients with advanced heart failure throughout their disease process. In 2011, patient volume in the heart failure clinic increased 20 percent. Currently, 1,400 patients are being seen in the clinic. Heart transplantation and mechanical circulatory system support are also a part of the advanced heart failure clinic.

Aside from **Heart Success,** primary care physicians and cardiologists also have the ability to refer patients into the long-term heart failure clinic for continued disease management. The care model is similar to **Heart Success** and has specialized clinics for pre- and post-transplant patients, cardio-oncology for patients with cancer and congestive heart failure and pulmonary hypertension. ■

FAST FACTS

Sanger Heart & Vascular Institute has performed more than **488** heart transplants, with an adult one-year survival rate of **96 percent** and a pediatric one-year survival rate of **100 percent**.

The 30-day readmission rate for heart transplantation at Sanger is **5.88 percent,** with the expected readmission rate being **35.13 percent**. The average length of stay for patients is **11.11 days,** with the expected length of stay being **18.76 days**. Both of these parameters are better than expected.

REFER A PATIENT

For more information about our heart failure clinic or Heart Success, call **704-373-0212**.

Heart Failure Clinical Trials

IDENTIFY-HF: Diagnostic Device Risk Management of Atrial Fibrillation and Heart Failure

Of the 5 million patients in the United States with heart failure, about 50 percent experience diastolic heart failure, where the heart's ventricles become stiff and do not allow enough blood flow back to the heart, which causes a backup of blood in the lungs. And of that 50 percent, 20 percent have atrial fibrillation as well, which causes irregular impulses to the ventricles.

Sanger Heart & Vascular Institute is one of approximately 12 sites in the United States to look at 100 nondevice heart failure patients with diagnostics and monitoring in order to determine which patients are at the greatest risk of decompensation.

The purpose of the study is to validate a heart failure risk status algorithm in a diastolic heart failure population and to obtain pilot data regarding the potential of such a risk status score to help improve patient outcomes.

PATIENTS, AGES 18 OR OLDER, WITH THE FOLLOWING CAN BE INCLUDED IN THE IDENTIFY-HF STUDY:

- documented paroxysmal or persistent atrial fibrillation or strong suspicion of atrial fibrillation (i.e., palpitations)
- patient is indicated for or has an existing implantable cardiac monitor
- recent HF clinic/ER visit with IV diuretics or HF hospitalization (within prior 90 days)
- LVEF ≥ 40 percent by echo within previous six months (if myocardial infarction (MI) within past six months, echo must be performed within the last 30 days and also must be at least 30 days after MI)

Sanger Heart & Vascular Institute is involved in several national clinical trials that benefit patients with heart failure. We are currently enrolling patients in the following studies:

PATIENTS CANNOT PARTICIPATE IN THE IDENTIFY-HF STUDY IF HE OR SHE HAS THE FOLLOWING CONDITIONS:

- patient is pregnant
- patient has been participating in another study that may interfere with the **IDENTIFY-HF** protocol required procedures
- end-stage heart failure (Stage D or NYHA class IV)
- asymptomatic (Stage B or NYHA class I) heart failure
- severe aortic stenosis or insufficiency
- existing insertable cardiac monitor implanted for more than one year
- existing implantable pulse generator, implantable cardioverter defibrillator or cardiac resynchronization therapy device
- severe renal impairment (eGFR < 25 mL/min)
- permanent atrial fibrillation
- MI within prior 30 days

If you would like to refer a patient to this clinical trial, call **704-355-4794**.

LAPTOP-HF: Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy

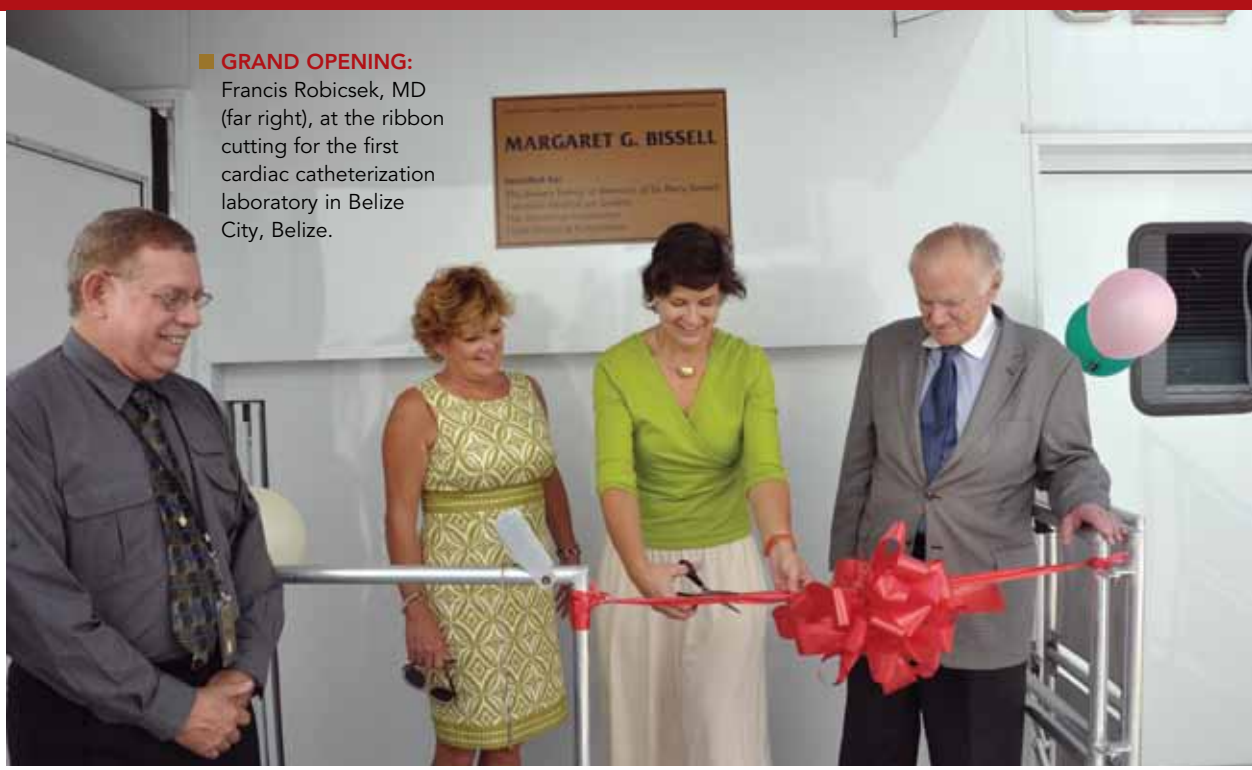
LAPTOP-HF is testing a new method of treatment for heart failure patients using left atrial pressure combined with physician direction and patient self-management to reduce heart failure-related hospitalizations. The trial is designed to adjust a patient's medications before he or she develops symptoms or requires hospitalization. This is done by measuring pressure in the heart from an implanted device similar to a pacemaker. Readings are then transferred to a handheld device that provides daily recommended medications and dosages and reminds patients to take their medications.

The handheld device, known as a patient advisor module (PAM), allows patients to record how they are feeling. Information from the implanted device downloads onto the PAM and periodically transmits to the physician's office over a telephone line. The physician can then use a computer to check the patient's heart performance and provide the medication and doses the patient should be taking. That information is then sent back to the PAM with further medical instructions.

PATIENTS MUST MEET THE FOLLOWING CRITERIA TO BE INCLUDED IN THIS TRIAL:

- ischemic or nonischemic cardiomyopathy for at least six months
- NYHA Class III symptoms at baseline
- receiving maximal tolerated stable medical therapy per ACC/AHA guidelines
- minimum of one prior HF hospital admission within the last 12 months

If you would like to refer a patient for enrollment in the **LAPTOP-HF** trial, call **704-355-4794**.



GRAND OPENING: Francis Robicsek, MD (far right), at the ribbon cutting for the first cardiac catheterization laboratory in Belize City, Belize.

Transforming Cardiac Care, One Nation at a Time

SANGER HEART & VASCULAR INSTITUTE IS PART OF A UNIQUE project to promote sustainable healthcare in third-world countries. Our team, along with the International Medical Outreach (IMO) Program, a partnership between Carolinas HealthCare System and the Heineman Foundation of Charlotte, established an international medical communication portal with the Guatemalan Institute of Cardiology and Cardiac Surgery (UNICAR).

This international portal is the first of its kind for the public hospital system in Guatemala and represents a major advancement in the quality of cardiac care in Central America.

COMMUNICATION: Geoffrey A. Rose, MD, with Sanger Heart & Vascular Institute, demonstrates the communication portal, showing a cardiac echocardiogram being performed in real time by UNICAR cardiologist Luis Arango, MD, in Belize.

REAL-TIME ACCESS

The portal enables UNICAR cardiologists to consult with Sanger cardiologists in real time on complex cardiac cases. Sanger cardiologists can then recommend diagnostic studies and propose treatment plans for conditions, 24 hours a day, seven days a week. It also allows cardiologists, surgeons, advanced care practitioners and nurses from both countries to participate in medical conferences and other educational opportunities not readily available in Guatemala.

Under the direction of Francis Robicsek, MD, Chairman Emeritus of Sanger Heart & Vascular Institute's Department of Thoracic and Cardiovascular Surgery, the IMO Program has established ongoing relationships among cardiologists, surgeons and technicians worldwide. Sanger and UNICAR have a long-standing history of cooperation dating back to the 1970s, when the Guatemalan Heart Program was established by Sanger cardiac surgeons and Guatemalan physicians trained at Carolinas Medical Center's (CMC's) main campus in Charlotte.

For decades, Sanger and the IMO Program have worked together to establish sustainable healthcare and medical programs in Guatemala and throughout Central America. These initiatives are made possible by

donated equipment and supplies, as well as by medical education and training.

INTERNATIONAL CARE

Sanger physicians train international medical personnel who travel to Charlotte to learn about echocardiography, catheterizations and surgery. After days, weeks or months of training, the personnel return to their native countries ready to practice cardiac care. Sanger also sends physicians and technicians to Central America to train medical personnel in their own healthcare facilities, with their own patients.

Last year, Sanger cardiologists traveled to Belize City, Belize, where the IMO Program donated the country's first-ever cardiac catheterization laboratory. This laboratory modernized cardiac care in Belize by 30 years and has so far treated hundreds of patients who otherwise would be unable to receive treatment.

A hospital in Escuintla, Guatemala, opened its first echocardiography laboratory, staffed by a Guatemalan echosonographer who received her training at CMC in 2011.

This year, the IMO Program will continue efforts to improve healthcare worldwide and participate in a milestone for cardiac health in Belize, supporting surgeons in Belize to perform the country's first open heart surgery. Two patients will be selected to receive this lifesaving surgery at Karl Heusner Memorial Hospital. ■

A Long and Productive Partnership

The International Medical Outreach Program is a partnership between Carolinas HealthCare System and the Heineman Foundation of Charlotte. Contrary to other local and national philanthropic organizations, where administrative and fundraising activities may consume 50 to 80 percent of collected funds, 100 percent of every donation received is spent on the designated project.

Guatemalan Institute of Cardiology and Cardiac Surgery: In the 1970s, the IMO Program helped establish UNICAR, which today is the largest cardiac surgery institute in Central America and performs more than 700 heart surgeries every year.

Cardiac Catheterization Laboratory Donations: Throughout the years, the program has donated equipment for cardiac catheterization labs in Central America, including Guatemala, Nicaragua, Belize and Honduras. The catheterization labs have provided vital cardiac services in both urban and rural areas.

Heart Surgery Training: By training international cardiologists and surgeons, Francis Robicsek, MD, and Sanger Heart & Vascular Institute physician volunteers have helped bring cardiac surgery to Central America. In 2007, Costa Rican physicians trained by the IMO Program performed the country's first successful heart transplant. Later this year, the program will help with Belize's first open heart surgery.

Echocardiograph Technician Training: The IMO Program works closely with hospitals throughout Guatemala, and soon in Belize, to train echocardiograph technicians. The hospitals send technicians to train at Carolinas HealthCare System's main campus in Charlotte.

■ **LIFESAVING CARE:** Sanger physician John C. Cedarholm, MD (right), performs a cardiac procedure.

■ **SUPPORT AND FRIENDSHIP:** Adrienne White and Ana Mariela Marroquin Garcia (right) by an echosonography laboratory in a hospital in Escuintla, Guatemala.

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Clinical Trial Brings New Treatment for Hypertension

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FIGURE 1

SYMPLICITY HTN-2 Trial:
Catheter-based procedure to disrupt nerves to the kidney

current enrolling **SYMPLICITY** trial will provide critical data for submission to the U.S. Food and Drug Administration for approval, should preliminary clinical trial results be confirmed. More than 500 patients will be enrolled. Sanger is the only center in the region to have been selected to participate in this exciting study.

According to the American Heart Association, hypertension is a major health burden strongly associated with stroke, heart attack and kidney failure. It's a leading attributable cause of mortality globally, causing approximately 7.5 million deaths each year.

If you would like to refer a patient for enrollment in the **SYMPLICITY** trial, call **704-355-4794**. ■

New Location

CMC-CARDIAC REHABILITATION opened its second location at Carolinas Medical Center-Pineville and is now accepting referrals. **For more information or to refer a patient, call 704-667-6010.**

LOCAL NEWS

▶ **Andrew Binder, MD,** joins Sanger Heart & Vascular Institute in September. Dr. Binder is an **adult cardiologist** who will see patients at our Shelby office.

▶ **Christopher W. Boyes, MD,** joins Sanger Heart & Vascular Institute in August. Dr. Boyes is a **vascular surgeon**.

▶ **David M. Drossner, MD,** joins Sanger Heart & Vascular Institute in August. Dr. Drossner is a **pediatric cardiologist** who will see patients at our Hickory pediatric cardiology office.

▶ **Santosh R. Rao, MD,** joins Sanger Heart & Vascular Institute in August. Dr. Rao is an **adult cardiologist** who will see patients at our Concord office.

▶ **Liam P. Ryan, MD,** joins Sanger Heart & Vascular Institute in August. Dr. Ryan is a **cardiovascular surgeon** specializing in complex aortic repairs.

▶ **Rohit Mehta, MD,** was named to the *Charlotte Business Journal's* **"40 Under 40"** list released spring 2012.

▶ **Charles R. Bridges, MD, Sc.D.,** chair of the Thoracic and Cardiovascular Surgery Department, and a team of researchers at Carolinas HealthCare System were recently awarded **The Excellence in Research Award, given by the American Society of Gene and Cell Therapy**. The award highlights a surgical technique developed by Dr. Bridges that successfully administers therapeutic DNA sequences in heart failure patients to reverse the disease—something that hasn't been successful with other research teams in the past. The award is only given to six PhD or junior researchers out of approximately 1,000 submitted abstracts.