



Carolinas HealthCare System
Sanger Heart & Vascular Institute



ADVANCED
HEART FAILURE AND TRANSPLANT
PROGRAM GUIDE

SANGER HEART & VASCULAR INSTITUTE



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Advanced Heart Failure and Transplant Program Guide

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what sets

Sanger Heart & Vascular Institute

apart

Key Program Differentiators

Sanger Heart & Vascular Institute's network throughout the Carolinas makes exceptional cardiac care accessible to those who need it. More than 100 physicians and more than 20 care locations comprise our network, with the heart transplant and mechanical circulatory support team doing its work at Carolinas HealthCare System's main hospital in Charlotte, North Carolina. As one of only a few in the region, the advanced heart failure program plays a critical role in the health of Carolina residents.

Award-Winning Partnerships

Sanger partners with Carolinas HealthCare System's Levine Children's Hospital, ranked a best children's hospital by *U.S. News & World Report* for excellence in pediatric heart surgery and cardiology for several consecutive years.

Convenient Location

Based in Charlotte, Sanger Heart & Vascular Institute is one of only a few cardiovascular centers in North Carolina with an adult heart transplant program. We are also the closest transplant center to most patients in South Carolina.

Quality Care

Sanger's team continually surpasses national and regional averages for length of stay and survival rates.



Charlotte Location Means Convenient Access to Care

 Top 30 Most Popular Domestic Cities for American Travelers¹

 Top 10 Speediest Major Airport²

 No. 2 Best Airport³

 Greenville, SC: 1.5 Hours

 Raleigh, NC: 2 Hours

 Charleston, SC: 3 Hours

 Wilmington, NC: 4 Hours

1 March 2014 Hotels.com, of 50 US cities

2 June 2013 *USA Today*, of commercial airports

3 April 2012 *Travel + Leisure*, of 22 major airports

Sanger Heart & Vascular Institute

history



History of Sanger Heart & Vascular Institute

In the 1950s, Paul Sanger and Francis Robicsek began Sanger Heart & Vascular Institute as a cardiothoracic and vascular surgery group. Since inception, we have fostered open-door, multidisciplinary collaboration with an evidence-based approach that provides quaternary-level care to patients. Built on a strong history of innovation, Sanger continues to evolve by bringing the latest science and capabilities to patients, and growing our medical staff by recruiting nationally and internationally recognized experts. Currently, there are more than 100 Sanger physicians and 20 care locations, including advanced heart failure, transplant, and mechanical circulatory support specialists on the advanced heart failure clinical and surgical team.

In 1986, the Heart Failure and Transplant Program was started under the direction of Alan Thomley, MD. Sanger has achieved a number of milestones over the past several decades, beginning with **Charlotte's first heart transplant** performed in January 1986. The **first pediatric heart transplant** was performed in February 1989, followed by the first neonate transplant in June of 1990.

In October 1995, our surgeons implanted the System's first left ventricular assist device (LVAD), giving patients with advanced heart failure a bridge to transplant. The Centers for Medicaid and Medicare Services later awarded Sanger a disease-specific certification to perform destination therapy in 2010. Combining both the bridge-to-transplant and destination procedures, our surgeons now perform more than **40 LVAD implantations annually**.

We continue to provide these lifesaving procedures, both full heart transplant and LVAD, to several dozen patients each year. To date, we have implanted more than **200 LVADs** and performed nearly **600 transplants**.



The implantation of the **first total artificial heart in North and South Carolina** in 2014 was another ground-breaking accomplishment for our program at Sanger. The new technology means patients with poor right ventricular function can now be supported with a bridge-to-transplant device, providing a lifesaving treatment until a long-term solution is available.

Sanger has demonstrated a continuous commitment to innovation, and as technological advances continue to drive change, the team looks forward to remaining on the front end of adopting these new technologies and procedures.

Sanger Heart & Vascular Institute Milestones

- 1986** First heart transplant performed
- 1989** First pediatric heart transplant performed
- 1995** First LVAD implanted
- 2010** Awarded a Disease Specific Certification to perform destination therapy
- 2012** Launched award-winning Heart Success Program
- 2013** Launched Virtual Heart Success Program
- 2014** First total artificial heart implanted

Heart Failure

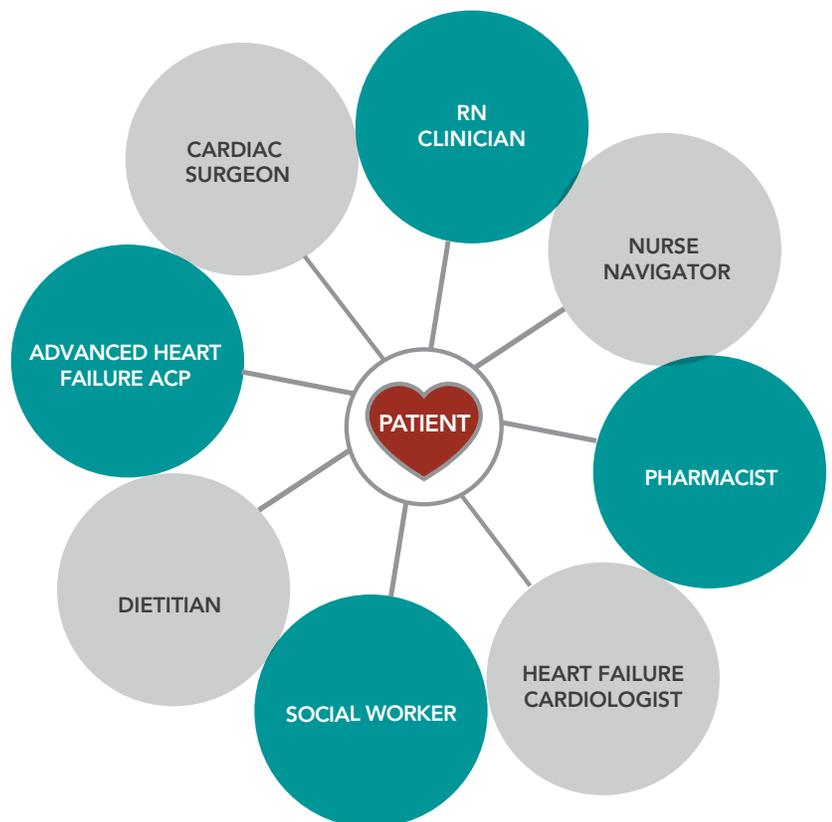
clinic

A Full Spectrum of Care

Led by a team of advanced heart failure experts, Sanger Heart & Vascular Institute's Heart Failure Clinic treats patients throughout all dimensions of disease. While early diagnosis and treatment are emphasized, patients referred at a later stage also receive the highest quality care to prevent further progression and improve quality of life.

The full spectrum of treatment options is available, including advanced medical therapies, mechanical circulatory support and cardiac transplant. The multidisciplinary treatment team meets regularly to ensure care is directed by the team's collective skill and expertise.

Our team partners with the patient's referring physician to keep them informed every step of the way, and to transition the patient back into that provider's care upon successful completion of treatment.





Specialized areas of care within the heart failure clinic allow Sanger to serve our region's patients who would otherwise have limited access to advanced care:

Advanced Heart Failure

For most heart failure patients, standard medical therapy and device therapy is sufficient to improve quality of life. For patients who do not respond to standard medical treatment, Sanger Heart & Vascular Institute has advanced therapies available. Primary care physicians and cardiologists can also refer patients into Sanger's long-term heart failure clinic for continued disease management. With advanced heart failure/transplant board-certified physicians, and a specially trained staff, we are regional leaders in the care for advanced heart failure.

Cardio-Oncology Patients

The cardio-oncology program treats oncology patients who have pre-existing cardiovascular conditions and patients who have developed congestive heart failure or cardiotoxicity as a result of their cancer treatment. The integrated approach, pairing Sanger experts with nationally renowned physicians from Levine Cancer Institute, ensures patients receive the best course of treatment.

Pulmonary Hypertension Patients

The complexity of pulmonary hypertension, along with its potential serious complications (including right heart failure), makes it important for patients with this condition to see a specialist. Providing the only pulmonary hypertension program in the region, the Sanger team is committed to improving care for the condition and utilizes a range of therapies, from oral medications to continuous intravenous infusions.



Heart Success Program

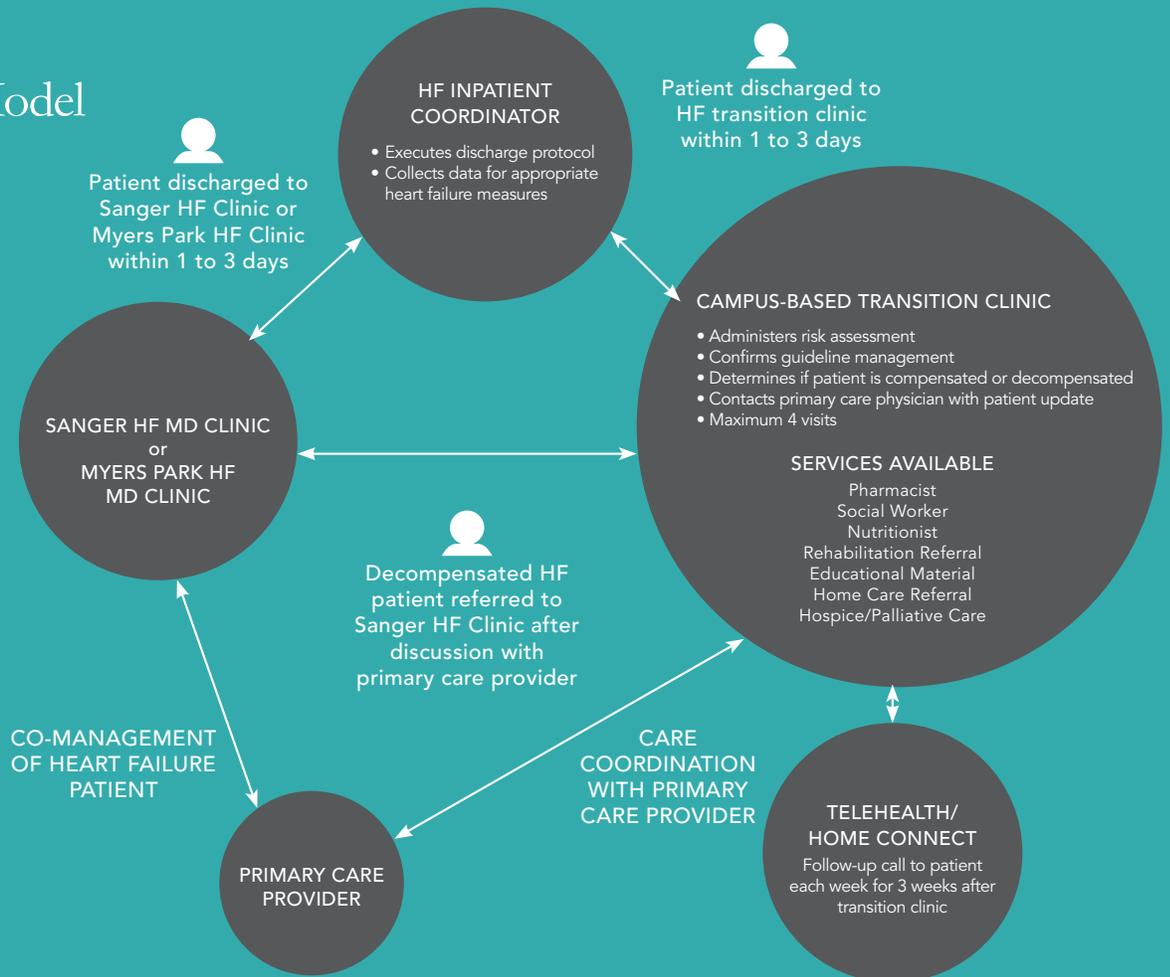
Heart failure is an increasingly common diagnosis, with the number of people affected growing consistently each year. These patients are at particular risk of hospitalization and readmission. Sanger's Heart Success Program is a unique, award-winning initiative designed to optimize care by empowering heart failure patients and their providers. This disease management program helps transition patients from the acute care setting, increases patient adherence by engaging patients and their families, and provides psychosocial follow-up through a monthly support group. In addition, Heart Success allows patients and families to connect and share their experiences, and gives Carolinas HealthCare System professionals an opportunity to educate patients.

Coordinating all aspects of care with the patient's primary care provider, the program utilizes a diverse group of caregivers, including advanced care practitioners, a dietitian, pharmacist, patient nurse navigator, social worker, and a specially trained nurse under the direction of board certified heart failure physicians. Heart Success also partners with telemedicine and home health for remote monitoring of patients. The program also strives to better manage complex heart failure patients, eliminate gaps in the care continuum and reduce variations in care.



Heart Success Model

HEART FAILURE (HF)



Jointly sponsored by the Heart Failure Clinic and Cardiac Rehabilitation, our free Heart Success Support Group offers support for congestive heart failure patients and their families. Topics of discussion include medication, stress management, nutrition and weight control, smoking cessation, diabetes and medical devices.

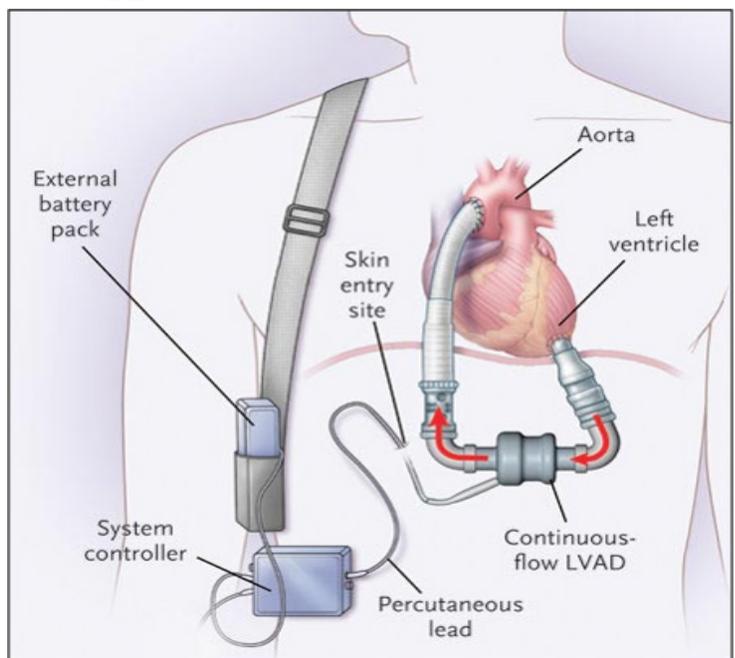
Raising

the bar

Groundbreaking Mechanical Circulatory Support

Sanger Heart & Vascular Institute implanted its first LVAD in 1995. Since then, we have become a regional leader in mechanical circulatory support, utilizing temporary or permanent LVADs for destination therapy in patients who are not candidates for heart transplant or as a bridge to cardiac transplant.

In 2010, Sanger was awarded a Disease Specific Certification by The Joint Commission to provide destination therapy for patients.



Components of the Continuous-Flow Left Ventricular Assist Device
Source: *New England Journal of Medicine*



Excellence in Transplant

The heart transplant program at Sanger Heart & Vascular Institute is supported by a team of nationally recognized experts devoted to excellence in care for patients across the region. The compassion and skill of these dedicated individuals have led to the program's ongoing success, evidenced by outcomes that far exceed the national average. Since its first heart transplant in 1986, the program's one-year and three-year patient survival rates have topped those of the nation. The program's average wait time for transplant is also significantly shorter than the national average.

The transplant team harnesses the strengths of critical support personnel, including transplant coordinators, dietitians, pharmacists and medical social workers. These professionals ensure the transplant patient and his or her family receive education and support throughout the process, from the initial appointment to lifelong follow-up after transplant.

The team meets weekly to discuss patients' care plans, enabling a multidisciplinary examination of each course of treatment for exceptional outcomes and quality of life for patients.

Total Artificial Heart

a closer look

Total Artificial Heart

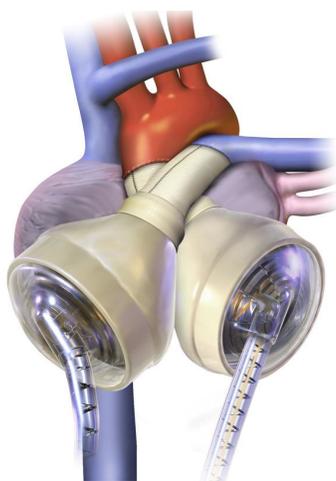
Sanger Heart & Vascular Institute has a long history of bringing advanced heart care to the Southeast, including the first heart transplant in Charlotte, NC. Sanger recently added to the list of breakthroughs by becoming the first in North and South Carolina to implant the total artificial heart.

The total artificial heart replaces both ventricles and the four native valves. It is connected to an external pneumatic driver through tubes that run through the abdomen.

Approved by the FDA as a bridge-to-transplant device, the total artificial heart was used by the Sanger team to support critical cardiac function in a 49-year-old man with advanced heart failure while he waited for his donor heart.

The total artificial heart procedure is still relatively uncommon worldwide but provides critical support for a subset of patients awaiting transplant who cannot receive an LVAD because they have poor right ventricular function.

“This is a critical development for heart failure patients in our region,” says Sanjeev Gulati, MD, medical director of heart failure and transplant services at Sanger. “Until recently, these patients had few options available, unless they had the ability to travel outside of the region for care – a process that can be very difficult due to the severity of, and complications associated with, heart failure.”



Artificial Heart Rendering

The eight-hour surgery was performed on January 13, 2014, at Carolinas Medical Center, and was conducted by Eric Skipper, MD, FACS, medical director of adult cardiovascular surgery at Sanger. The patient has since undergone successful heart transplantation.

The patient's care team considers the first total artificial heart procedure to be a complete success, as both the short-term and long-term goals were accomplished. The short-term goal was to restore normal cardiac output, enabling organ recovery. The long-term goal was to reach transplantation and allow survival far beyond that point. The team anticipates the procedure will help many more people have a second chance at a lifesaving heart transplant.



Donor Program

LifeShare

LifeShare

The Sanger transplant program combines nationally renowned surgeons, leading-edge technologies, an exceptional supporting care team and a network of resources throughout Carolinas HealthCare System. One critical factor remains to ensure success: availability of donor organs. LifeShare of the Carolinas, a not-for-profit organ procurement organization, provides donation and procurement services to Carolinas HealthCare System.

LifeShare serves as the link between patients in need of a transplant and the donors who make that possible. The organization works closely with the United Network for Organ Sharing, which maintains the national transplant database and enforces strict guidelines regarding organ allocation.

LifeShare's hospital development specialists work with facilities across western North Carolina to identify potential donors and assist throughout the donation process.

Through this collaboration, Sanger is able to perform more than 20 heart transplants annually. The commitment and collaboration of these two teams has led to waiting times that are significantly shorter than the national average.

LifeShare is a federally designated member of the Organ Procurement and Transplant Network. It is accredited by the Association of Organ Procurement Organizations, the Eye Bank Association of America, and the Centers for Medicare & Medicaid Services.



Since 1986, when we performed our first heart transplant, Sanger Heart & Vascular Institute has consistently surpassed national averages for one-year and three-year transplant survival rates, with shorter wait times than the region and nation.



The advanced heart failure team at Carolinas HealthCare System's Sanger Heart & Vascular Institute encompasses the full spectrum of care, bringing together physicians, clinicians, researchers, pharmacists, social workers, dietitians and specialized nurses to provide patients with comprehensive treatment of the highest quality.

Leading the team are three renowned Carolinas HealthCare System physicians: Sanjeev K. Gulati, MD, FACC; Theodore A. Frank, MD, FACC; and Eric R. Skipper, MD, FACS, who work alongside other board-certified physicians specializing in the care of heart failure patients.

Dr. Gulati is the medical director of heart failure and transplant services. He helps VAD patients undergoing both bridge-to-transplant and destination therapy. He completed fellowships in cardiology and heart failure and transplant at Johns Hopkins Hospital and is board certified in cardiology as well as advanced heart failure and transplantation. Dr. Gulati's additional clinical interests include echocardiography, cardiac catheterization and heart failure device technology.

Dr. Frank is the director of cardiac transplantation. He completed fellowships in cardiac transplant at the University of Pennsylvania and in cardiology at Yale-New Haven Hospital and is board certified in cardiology, advanced heart failure and transplant. In addition to his work with advanced heart failure, transplant and pulmonary hypertension, he also has clinical interests in exercise physiology and cardio-oncology.

Dr. Skipper is the medical director of adult cardiovascular surgery. He completed his fellowship in cardiovascular and thoracic surgery at East Carolina University, where his research interests included transplant, left ventricular assist device (LVAD) and mitral valve repair. He is board certified in surgery and thoracic surgery. His other interests include structural heart surgery, minimally invasive valve surgery and transcatheter aortic valve replacement (TAVR).

Dr. Mishkin specializes in advanced heart failure and transplant cardiology. He completed fellowships in cardiology and in heart failure and transplant at the University of Florida. Dr. Mishkin's additional interests include mechanical circulatory support, inherited cardiomyopathies, pulmonary hypertension and cardio-oncology.

experts

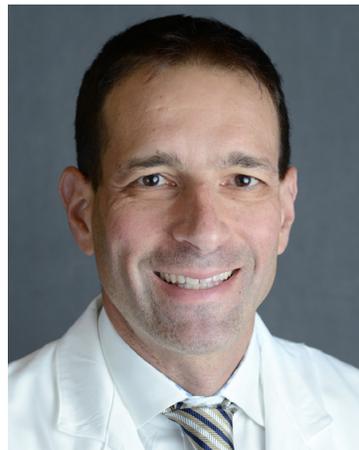
in advanced heart failure

meet our leaders



Sanjeev K. Gulati, MD, FACC

Medical Director, Heart Failure
and Transplant Services



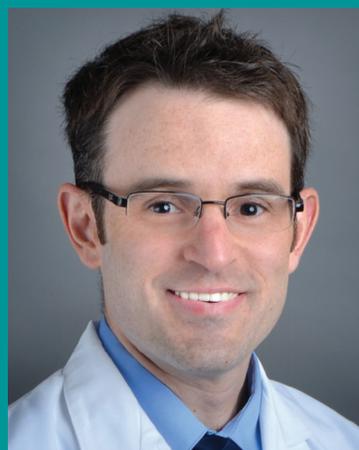
Theodore A. Frank, MD, FACC

Director, Cardiac Transplantation



Eric R. Skipper, MD, FACS

Medical Director, Adult Cardiovascular
Surgery



Joseph D. Mishkin, MD

Advanced Heart Failure and Transplant
Cardiology



Referral Criteria

Patients who are referred for consideration for transplant or mechanical circulatory support must meet the following criteria:

1. Systolic heart failure with refractory symptoms (Class 3b/4) despite optimal medical and device therapy (OMT)
2. Intolerant to HF medications or having to withdraw medications
3. One or more heart failure hospitalizations in six months
4. If on OMT and patient has:
 - a. Hyponatremia < 132 mmol/l
 - b. Hypotension SBP < 90 mmHg
 - c. Azotemia Bun > 40 (excluding dehydration) worsening renal function (thought to be secondary to HF)
5. Recurrent ICD shock or refractory VT
6. Escalating diuretic requirement
7. Age 18-75 years old with no obvious life-limiting co-morbidities

Before receiving an LVAD or being placed on the waiting list for transplant, these patients undergo a comprehensive evaluation. Both a cardiologist and transplant surgeon perform a physical assessment, including a right heart catheterization, echocardiogram, chest X-ray, abdominal ultrasound, pulmonary function test and mixed venous oxygenation consumption study. A social worker meets with each patient to assess psychosocial readiness, and a transplant coordinator provides education and counseling. A financial coordinator provides each patient with information about resources and helps develop a financial plan for post-transplant care.



Patients with diabetes and ischemic cardiomyopathy must undergo further testing, including a 24-hour urine test, a kidney evaluation and an eye exam. All patients must ensure that regular office visits and screenings have been updated in the past 12 months (mammogram, pap smear, PSA, colonoscopy and dental evaluation).

After the heart transplant evaluation is complete, the multidisciplinary transplant team reviews each evaluation to determine the optimal recommendation for each patient. Patients who are appropriate transplant candidates are placed on the United Network for Organ Sharing (UNOS) national waiting list.

To remain on the waiting list, patients must complete:

- ✓ An office visit with a heart transplant specialist every three months (or as needed)
- ✓ Lab work every three months (or as needed)
- ✓ An annual mammogram and gynecologic exam
- ✓ An annual prostate exam
- ✓ A right-heart catheterization every six months

To refer your patient or consult with a specialist,
call 704-355-8816.

supplemental

Program Information

