It is our pleasure to share our second annual clinical report, which includes details of our continued growth and major developments in our programs and services. These developments range from entering Phase II trials of stem cell therapy for cardiac muscle regeneration to offering an innovative neuro protection system for carotid artery stenting.

At the Vanderbilt Heart and Vascular Institute a team of physician leaders provides the most comprehensive services in cardiology, cardiac surgery and vascular services in the region. Vanderbilt Heart is home to an exceptionally talented and experienced group of cardiovascular providers and staff. We provide our patients with the most advanced diagnostic tools, evidence-based therapies and opportunities to participate in innovative clinical trials.

The unique collaboration among our cardiologists and surgeons is paving the way for the future of heart care, which we believe lies in exciting developments in cardiovascular treatment and research as we strive to improve the lives of those in our community one heart at a time. This is where heart is headed.
More rapidly, perhaps, than in any other field of medicine, the treatment of heart disease has been transformed by extraordinary advances in basic and clinical science. Vanderbilt Heart provides an opportunity to bridge not only the two arms of science, but to improve the ways researchers and clinicians interact to increase the efficiency and quality of what we do. We have achieved a real partnership between the providers, whether they are physicians, nurse practitioners or nurses, and the researchers in the labs in a way that was not possible before. This partnership illustrates how hypotheses about disease that emerge from basic science discoveries can be tested in a clinical setting and, conversely, how clinical observations can lead to entirely new and unexpected hypotheses. With current and anticipated developments at the cellular and molecular level, including knowledge of the human genome, future opportunities for continuing these advances are enormous.
Volunteer Program
We implemented a Red Coat volunteer program that provides our patients with a point of contact upon their arrival at Vanderbilt. A volunteer ambassador escorts patients to clinic appointments and offers support to patients and their families.

Town Hall Meetings
Senior leadership implemented quarterly meetings

to update staff and faculty on progress made by the institute in further casting the vision for an elite heart program.

QUALITY
U.S. News & World Report ranked

Amy Major, Ph.D., assistant professor of Medicine and Pathology, received the Irvine H. Page Young Investigator Research Award in recognition of her leadership in cardiology research. Her work was highlighted during the 7th Annual Council on Arteriosclerosis, Thrombosis and Vascular Biology Conference.

O/E MORTALITY (UHC)
Vascular Surgery 0.69
Cardiology 0.72
Cardiac Surgery 0.31

Six Sigma
We have committed to training all clinical program managers in Six Sigma to enhance their quality improvement skills, and through our new Quality Council we will be able to prioritize projects and disseminate quality improvement initiatives throughout the organization.

Quality Improvement Curriculum
We incorporated a new quality improvement curriculum for all cardiology fellows in the 2007-08 academic year. This curriculum included a course in basic methods of health care quality improvement and participation of fellows, faculty, and staff in organized quality improvement teams.

Morbidity and Mortality Process
Our intense monthly process of reviewing all inpatient complications aims at continuously improving our process and systems.

SUMMARY OF FISCAL YEAR 2005 THROUGH 2007

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<th>Category</th>
<th>2005</th>
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<td>Total Cardiac Outpatient Exam Rooms</td>
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CLINICAL SERVICES

Cardiac Surgery
Interventional Cardiology
Arrhythmia and Electrophysiology
General Clinical Cardiology
Vascular Surgery
Cardiac Transplantation
Adult Congenital Heart Program
Heart Failure

CARDIAC SURGERY

The Cardiac Surgery Program, directed by John Byrne, M.D., provides comprehensive surgical services to adults with cardiovascular disease. The program is a nationally recognized pioneer in “hybrid” coronary artery revascularization, an innovative interventional approach that teams cardiac surgeons and interventional cardiologists.

In addition to pioneering this exciting “hybrid” approach to coronary artery disease, the program has nationally recognized surgical expertise in congenital and acquired valvular heart disease, heart failure, cardiac transplantation and left ventricular assist device implantation.

Highlights of 2007:
- University Health Consortium data documented that Vanderbilt is in the top 10 in CABG volume and outcomes (ranked No. 10) among UHC members.
- We performed 1006 major cardiac surgical operations in 2007. Using the risk model from the Society of Thoracic Surgeons national database, we achieved an observed to expected mortality ratio of 0.53. We also submitted our outcome data to University Healthsystem Consortium (UHC) Clinical Database, and by the UHC risk model our cardiac surgery observed to expected mortality ratio was 0.31

These results reflect the wonderful efforts of hundreds of our colleagues who, through effective teamwork, give superb care to our patients.

INTERVENTIONAL CARDIOLOGY

Vanderbilt Heart cardiac surgeons and interventional cardiologists continue their collaborative and innovative approaches for cardiovascular care. This collaboration has become a model for many U.S. and international institutes. We established training programs for cardiovascular physicians around the world. Embodying its commitment to innovation, excellence in patient care and continuous quality improvement, our Interventional Cardiology Program, led by David Zhao, M.D., achieved important milestones in 2007.

Highlights of 2007:
- Increase in clinical volume with excellent outcomes. UHC O/E ratio (observation/expected mortality) for elective coronary intervention is at nation’s best
- Performance of the first cardiac stem cell transplantation in Tennessee
- One of five centers funded by NIH for Cardiac Cell Therapy Research Network (CCTRN)
- Door-to-balloon time for acute ST elevation myocardial infarction within the top tier in the nation
- Trained 10 Chinese interventional cardiologists
- Expansion of cardiac cath lab recovery room with addition of seven short-stay beds
Interventional Trends

TOTAL CATH LAB PROCEDURES
BY FISCAL YEAR (not encounters)

TOTAL INTERVENTIONAL PROCEDURES
BY FISCAL YEAR

Cardiac Surgery Trends

UNITED STATES  2004–2007

VANDERBILT MEDICAL CENTER  2004–2007
Within hours of undergoing a cardiovascular procedure, Loretta Minor immediately reached up to touch her chest. She expected to feel a long, jagged scar — but there wasn’t one. Immediately she thought the doctors were unable to perform the stenting procedure she needed. She expected to feel a long, jagged scar — but there wasn’t one.

“I just thought I had too much going on and they were not able to do the surgery,” said Minor. “But when I felt my shoulder I knew. I knew he was able to do everything he said he would.”

“Immediately she thought the doctors were unable to perform the stenting procedure she needed. They performed stenting of the left main coronary artery with cardio-pulmonary support. This required a small incision near her right shoulder, touch her chest. Within hours of undergoing a cardiovascular procedure, Loretta Minor immediately reached up to touch her chest. She expected to feel a long, jagged scar — but there wasn’t one. Immediately she thought the doctors were unable to perform the stenting procedure she needed. She expected to feel a long, jagged scar — but there wasn’t one.

“I just thought I had too much going on and they were not able to do the surgery,” said Minor. “But when I felt my shoulder I knew. I knew he was able to do everything he said he would.”

Ahmad admits that the long-term success of standard therapy is greater. But the risks to the patient must be carefully considered. Mark Robbins, M.D., is the interventionalist who collaborated with Ahmad on this case. They performed stenting of the left main coronary artery with cardio-pulmonary support. This required a small incision near her right clavicle while inserting the stent via a catheter through her groin up to her heart, negating the need for open heart surgery.

“For an appropriately selected group of patients who might not have other options because of co-morbid conditions, this provides them a way to address their coronary artery disease.”

It was the right solution for Minor, who spent three days at Vanderbilt. She arrived at the hospital by ambulance, unsure of her fate. “I was home for Thanksgiving,” she said. “I had no idea I would even be coming back home when I left.”

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Vanderbilt Heart is poised to become a national leader in treating structural heart disease with minimally invasive techniques. VHV physicians successfully closed a perivalvular leak in a patient with two mechanical valves — aortic and mitral. The patient had severe anemia, was emaciated, did not respond to therapy and was facing the possibility of a fourth open-heart surgery to repair the leak.

David Zhao, M.D., director of the Cardiac Catheterization Laboratory and Interventional Cardiology, collaborated with his colleagues in cardiac surgery and together they decided that the surgical risk was too great. Instead, Zhao proceeded with a percutaneous closure and successfully sealed the leak.

“Needless to say, the procedure was not easy and took a lot of effort from many people,” Zhao said. “This procedure has only been done in very few top centers in the world, and as far as we know has never been done with both mechanical aortic and mitral prostheses.”

The procedure, which took about two hours, was performed in the cath lab. The complexity of the cases that they can repair in the cath lab has reached new heights. “While we have done percutaneous work in vessels, we remain one of the few centers that can handle structural heart disease. This requires the physician to be highly experienced and able to adapt to any unique situation with precision,” Zhao said.

Zhao emphasized that a team approach ensured the success of the procedure. He developed a complication known as post-infant ventricular septal defect (VSD). Because of the myocardial infarction, part of the myocardium heart muscle sloughed off, creating a hole in her septum. “If we did not do anything to her, her mortality was almost 100 percent. Even with a surgical repair, which is the traditional way of doing things, the surgical mortality was 20-30 percent,” Zhao said.

Again, using a catheter and Amplatzer PVI muscular VSD closure device, Zhao, Joe Fredi, M.D., assistant clinical professor of Medicine, and their team repaired the hole. The patient was alert within a few hours and went home in a couple of days. “Success with these types of procedures crystallizes the excellent collaboration within Vanderbilt Heart and are the symbols of world class interventional programs,” Zhao said.

Vanderbilt Heart and Vascular Institute Report 2007 9
ARRHYTHMIA AND ELECTROPHYSIOLOGY

The Vanderbilt Arrhythmia Section is committed to utilizing modern technology to provide excellence in patient care, research and education in cardiac electrophysiology, serving as a center of excellence for the management of cardiac arrhythmias in the Southeast region.

The service includes:
• Dedicated state-of-the-art electrophysiology and device implantation laboratories
• Arrhythmia and Device Hospital Consultation Services
• Vanderbilt Heart Arrhythmia Clinic
• Vanderbilt Heart Center for Atrial Fibrillation
• Vanderbilt Heart Genetic Arrhythmia Clinic (as part of the Center for Inherited Heart Disease)
• ECG and Tilt Table laboratories

The Vanderbilt Heart Center for Atrial Fibrillation (VHCAF) provides a unique multidisciplinary team approach to treating patients with atrial fibrillation. These approaches include:
• Catheter-based ablation
• Full spectrum of surgical approaches (maze, modified-maze, mini-maze, minimally invasive epicardial approaches)
• Availability of new pacemaker technologies, screening for atrial fibrillation susceptibility genes
• Access to new anti-arrhythmic and non-anti-arrhythmic drugs
• Novel anti-coagulation therapies for atrial fibrillation

Our physicians performed more than 120 atrial fibrillation ablation procedures last year, 75 percent of these patients were atrial fibrillation-free during the 18-month follow-up. Innovative advances in 2007 included:
• The first hybrid (endocardial and epicardial) minimally invasive surgical approach for management of atrial fibrillation
• The Cardiac Resynchronization Program, which specializes in challenging or failed lead implants and offers left ventricular epicardial and endocardial approaches for failed biventricular implants. In the last 12 months, more than 75 laser lead extractions were performed with an exceptionally low incidence (<0.5%) of serious complications.

The Vanderbilt Heart Center for Atrial Fibrillation (VHCAF) provides a unique multidisciplinary team approach to treating patients with atrial fibrillation.

RESEARCH HIGHLIGHT
Vanderbilt investigators are enrolling patients in a double blind placebo controlled trial co-sponsored by the NIH and industry evaluating the efficacy of fish oil in reducing the recurrence of atrial fibrillation. We focus on pursuing knowledge and treatment at multiple levels: from a basic and molecular genetic understanding of atrial fibrillation, through clinical protocols and catheter ablation.

GENERAL CLINICAL CARDIOLOGY

The general clinical cardiology program under the direction of Keith Churchwell, M.D., continued to experience significant growth in volume in 2007.

Highlights include:
• Additional observation beds for the cardiac pre-procedural patients
• A resident independent service managed by our cardiac practitioners, which continues to grow steadily in volume and has been a great help in managing the significant increase in our general cardiology patient population
• The opening of a chest pain observation unit in the Emergency Department
• The addition of a full-time, board certified cardiologist in the Emergency Department, allowing for seamless communication and care of low-risk chest pain patients

The goals for 2008 include:
• Increasing bed capacity with additional space for observational patients in the cardiac catheterization lab
• Revising and updating clinical pathways for acute coronary syndrome in concert with the emergency medical department and interventional cardiovascular medicine
• Implementing a quality collaborative initiative to look at processes and projects throughout the general cardiovascular service to improve overall patient care, clinical efficiency, and significantly decrease the risk for adverse reactions in regards to patient care

CLINIC VISITS 2007

ischemic 9,937
interventional 5,879
arrhythmia/ep 4,711
vascular surgery 3,427
heart failure 3,177
cardiac surgery 1,517
prevention 839

DISCHARGES 2007

ischemic 1,363
interventional 1,200
arrhythmia/ep 558
vascular surgery 524
heart failure 520
The Division of Vascular Surgery continues to provide regional and national leadership in pursuit of less-invasive techniques for the comprehensive management of aortic aneurysms, carotid, and peripheral arterial occlusive disease.

New techniques added in 2007 to improve the safety and efficacy of thrombolytic therapy for both arterial and venous thrombosis include:
- Thrombolysis augmented by continuous low-frequency intravascular ultrasound, a procedure that shortens overall treatment time and dose of thrombolytic agent
- Minimally-invasive endovenous laser ablation of varicose veins and other therapeutic and cosmetic venous procedures.
- UHC O/E mortality was 0.69.

As the use of less invasive initial therapies for peripheral arterial diseases has increased, more referrals of patients who have failed these are being made to Vanderbilt Heart.

VASCULAR SURGERY

VASCULAR SURGERY RESEARCH HIGHLIGHTS
- Pivotal Study of the Aptus Endovascular AAA Repair System — currently enrolling
- RNA Expression Profiling from In Vivo Carotid Atherectomies (REPLICA): A carotid plaque observational study
- Use of TRC Autologous Bone Marrow Cells in Patients with Peripheral Arterial Disease to Treat Critical Limb Ischemia
- Embolic Protection with Reverse Flow (EMPIRE) Study of the Gore Neuro Protection System in Carotid Stenting of Subjects at High-Risk for Carotid Endarterectomy — currently enrolling
- Carotid Stenting for High Surgical-Risk Patients. Evaluating outcomes through collection of clinical evidence. (CHOICE)

SYSTEM REVERSES BLOOD FLOW TO EASE STENT SURGERY RISKS

Vanderbilt vascular surgeons are using a new technique for carotid artery stenting (CAS) that reverses blood flow to reduce the risk of stroke during the minimally invasive procedure.

Jeffery Dattilo, M.D., and Charles Ross, M.D., both assistant professors of Surgery, are the principal investigator and co-investigator, respectively, of the EMPiRE (Embolic Protection with Flow Reversal) clinical study, designed to test the safety and efficacy of the GORE Neuro Protection System.

The system has been used abroad with great success and is now being studied in selected centers in the United States. Vanderbilt Heart and Vascular Institute is one of 30 sites offering the procedure.

“About 30 percent of strokes are caused by atherosclerotic carotid artery disease. Correction of carotid blockage represents one of the ways to significantly reduce the risk of first-time and recurrent strokes,” Ross said.

To correct the blockage, Ross and Dattilo insert a sheath/balloon system from a patient’s femoral artery in the groin into his carotid artery in the neck. The system is then connected to the patient’s femoral vein. Within that connection is a filter. The carotid balloons are inflated, thus creating a natural reversal of flow from the carotid artery to the low-pressure venous system — away from the diseased internal carotid artery and the brain. The surgeons then treat the blockage with balloon angioplasty and stenting.

“With the reversal of flow in the artery, all of the debris or fragments broken loose can be safely filtered out of the system, instead of going toward the brain,” Dattilo said.

FISCAL VOLUMES 2007

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<td>Vascular lab procedures</td>
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<tr>
<td>Cases per Year</td>
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The Division of Vascular Surgery continues to provide regional and national leadership in pursuit of less-invasive techniques for the comprehensive management of aortic aneurysms, carotid, and peripheral arterial occlusive disease.

As the use of less invasive initial therapies for peripheral arterial diseases has increased, more referrals of patients who have failed these are being made to Vanderbilt Heart.
The axillary balloon pump is one of several examples of new and innovative procedures Vanderbilt Heart offers. New procedures such as this will help put Vanderbilt Heart at the forefront of cardiac care nationally.

HEART PROCEDURE BUYS PRECIOUS TIME

The clock was ticking on Thomas Johnson’s ticker.

The 55-year-old patient from Clarksville, Tenn., had suffered multiple heart attacks that left his heart muscle severely damaged. A heart transplant was his only hope for survival and he had been on the waiting list for a year when he arrived at the Vanderbilt Heart and Vascular Institute on Oct. 29, 2007.

As he lay in bed in the Cardiovascular Intensive Care Unit (CVICU), he suffered continuous arrhythmia — nearly 100 episodes in a five-hour period. His surgeon, Steven Hoff, M.D., assistant professor of Cardiac Surgery, used a novel approach to buy his patient time while he awaited a heart transplant.

He placed an intra-aortic balloon pump in the axillary artery under Johnson’s collar-bone to help increase blood flow to Johnson’s heart and relieve the stress on it.

Balloon pumps are typically inserted through the groin via a catheter and pushed up through the artery to the heart.

The drawback to this approach is the patient has to lie flat on his back so as not to cause a kink in the line, which affects the blood flow.

“Being bedridden doesn’t make you a good transplant recipient, because the longer you’re in bed, the more debilitated you get, and the weaker you become,” Hoff said.

“If Mr. Johnson got a new heart, being immobile would complicate his recovery because his overall condition before the transplant would be worse.”

Also, Johnson has the most common blood type — O — which means he could have been waiting months or years for a heart transplant.

With the axillary balloon pump in place, Johnson was able to walk around the CVICU and even- tually worked up to eight laps a day. One month after arriving at Vanderbilt, he received the good news that a donor heart had been found.

He received the transplant on Nov. 30, his mother’s birthday. He recovered and went home later that week.

Johnson is the third Vanderbilt patient to receive the intra-aortic balloon pump in the axillary artery in the last few months.

“This technique is one of several examples of new and innovative procedures we’re now able to offer at Vanderbilt,” Hoff said.

“New procedures such as this will help put Vanderbilt Heart at the forefront of cardiac care nationally.”

Because Johnson was in the CVICU for a month, he and his family became well-acquainted with the doctors and nurses.

“I had Thanksgiving dinner in the hospital room with my family. I had four of my nurses who came in and ate with me. They are family now,” a grateful Johnson said.

CARDIAC TRANSPLANTATION

In 2007, the Cardiac Transplant team performed 16 heart transplants, including eight adult transplants and eight pediatric transplants. Most importantly, transplant outcomes remain at or better than expected. Our experienced team of surgeons, physicians, nurses and administrative staff are dedicated to combining the latest medical and technical advances in transplantation with timely, compassionate and personalized care.

Highlights of 2007:

• Recruitment and appointment of Steven J. Hoff, M.D., as the new surgical director for the Heart Transplant Program. Hoff brings his expertise and more than 12 years experience in cardiovascular surgery including ventricular assist device as a bridge to heart transplantation to the Vanderbilt Transplant Center.
• The Adult Heart Transplant Program has had a successful year in recruiting additional staff to strengthen our team to continue to ensure the highest quality patient care possible.
• Three experienced cardiac nurses, a new transplant social worker and data management specialist joined our team in 2007.
• The use of a diagnostic screening tool for the non-invasive assessment of rejection and adoption of novel approaches in transplant immunology have lessened recovery time and enhanced the quality of life for our patients.
• We’ve achieved low rejection rates and high patient satisfaction in our pediatric population with the use of non-steroidal immunosuppression and non-invasive rejection monitoring whenever possible.

CARDIOVASCULAR INTENSIVE CARE UNIT

Vanderbilt’s Cardiovascular Intensive Care Unit (CVICU) is designed to serve as an innovative center for specialized critical cardiovascular care. Reflecting Vanderbilt Heart’s close collaboration between cardiologists and cardiac surgeons, the 26-bed unit provides care for both critically ill, medically managed cardiac patients and post cardiac surgical patients.

Improvements to the CVICU in 2007 include:

• A focused emphasis on refining informatics tools to provide efficiency in the nursing workflow
• Creation of the CVICU Collaborative, which brings together nurses, physicians, informatics experts, respiratory therapists and other members of the team to achieve comprehensive solutions to provide the best care possible for the patient with heart disease.

Reflecting Vanderbilt Heart’s commitment to innovation, critical cardiovascular care pathways are updated annually and new pathways are developed for novel cardiovascular patient populations in order to standardize best practices. These pathways are a vital component of our cutting-edge “hybrid” approach to cardiovascular medical and surgical care.
CONCLUSIONS

Cardiologists from Vanderbilt Heart are teaming up with oncologists from the Vanderbilt-Ingram Cancer Center to understand why and how some cancer therapies cause heart failure and what can be done to prevent it.

INVESTIGATORS TRACK CHEMO’S IMPACT ON HEART FUNCTION

Vanderbilt-Ingram patient Reva Judy was in sound cardiovascular shape when, at 68, she began treatment with herceptin for Stage II breast cancer. Judy, who underwent chemotherapy and radiation prior to taking herceptin, said she knew there was a small percentage of people who had heart failure while on the drug.

“I took the risk,” she said.
She received four cycles of herceptin over two months. She began to experience breathing difficulty and was transported to Vanderbilt and placed in the care of Thomas DiSalvo, M.D., associate professor of Medicine and director of the Advanced Heart Failure Program. Judy’s cardiac function had dropped to 10 percent. It was 65 percent before she began taking herceptin.

“I knew there was a small chance this could happen, but I never dreamed it would happen to me,” she said.

Her oncologist stopped herceptin therapy, and with the help of heart medication Judy’s heart function has almost returned to normal. She has not had a recurrence of cancer.

How the heart repairs itself has been the focus of Douglas Sawyer’s basic science research program for the last decade.

“From the time your heart is about 10 years old, the muscle cells in it have to last the rest of your life. The heart cells have to maintain and repair themselves,” said Sawyer, M.D., Ph.D., associate professor of Medicine, and director of the Cardiology Fellowship Program. “Herceptin appears to interrupt those normal reparative mechanisms and allow for damage to take place. So in this case it’s not because the cancer therapy is causing damage, but because it interrupts the normal maintenance system.

“It’s like if you stopped changing the oil in your car, as opposed to putting something bad in your car.”

Sawyer and his colleagues will begin clinical trials soon to look for early markers of cardiac dysfunction in breast cancer patients receiving anthracyclines, the mainstay of treatment for a broad range of malignancies including breast cancer, leukemia, lymphoma and sarcoma.

They will also study patients receiving anthracyclines in combination with herceptin.

The researchers will be using MRI to detect early changes in cardiac function and will be looking for decreased heart rate variability as a possible indicator of chemotherapy cardiac toxicity.

“We hope to identify patients who are at increased risk of developing congestive heart failure and develop a treatment plan that gives them the best chance of breast cancer survival with the least risk of cardiotoxicity,” said oncologist Julie Means-Powell, M.D. “Wouldn’t that be nice if patients didn’t have to deal with breast cancer and congestive heart failure?”

ADULT CONGENITAL HEART PROGRAM

Vanderbilt Heart and the Division of Pediatric Cardiology are renowned centers of excellence for medical and surgical management of all forms of heart disease. This expertise in both childhood and adult cardiology enables us to offer a comprehensive adult congenital heart program and lead the field in care, research and education. We are staffed by a highly specialized team of adult cardiovascular specialists, pediatric cardiologists, electrophysiologists, cardiothoracic surgeons, nurses and administrative support. All of these team members are focused on the unique needs of adults with congenital heart disease.

Due to medical and surgical advances over the last 50 years, more than 85 percent of people born with congenital heart disease can expect to reach an adult age. As adults, these people have special problems that require care from health care providers with special expertise in congenital heart disease. The Vanderbilt Adult Congenital Heart Program is dedicated to providing the expert care necessary for these adults to have the highest quality of life.

HEART FAILURE

The Heart Failure program experienced substantial growth in patient volume in 2007. In addition to comprehensive inpatient and outpatient services, the program supports several clinical studies of stem cell therapies, novel pharmacological agents, heart failure care delivery systems and exercise training.

Highlights of 2007:
• The Heart Failure Longitudinal Disease Management program grew in enrollment and staffing.
• The Inherited Heart Disease Clinic opened and is a joint venture between faculty in the Heart Failure, Electrophysiology and Pediatric Cardiology. The Clinic provides systematic evaluation including genetic testing for patients with a familial heart disease.

The Heart Failure Program 2008 plans include:
• Development of distinct lines of service that involve multidisciplinary teams, including a Cardio-Oncology Clinic, a Hypertrophic Cardiomyopathy clinic and a dedicated inpatient facility for care of patients with heart failure
• Expansion of clinical research and trial offerings for Vanderbilt Heart’s patients
Vanderbilt Heart has more than 70 faculty members dedicated to understanding, preventing and treating cardiovascular disease. Our scientists participate in 60-70 ongoing studies and receive more than $8 million in extramural research funding.

In 2007 Vanderbilt Heart researchers were the first in Tennessee to perform a novel therapy that uses bone marrow stem cells to stimulate regeneration of the heart muscle after a heart attack.

Vanderbilt is one of three medical centers in the country providing this new treatment modality as part of a multi-center, randomized study funded by Amorcyte, a privately funded cell-therapy company studying stem cells for the treatment of cardiovascular disease. Vanderbilt’s participation in this Phase I, industry-supported study highlights its role as a key player in stem cell regeneration in this country.

Vanderbilt is a member of the Cardiac Cell Therapy Research Network, sponsored by the National Heart, Lung and Blood Institute (NHLBI). The grant awards Vanderbilt approximately $1 million a year for five years to participate in stem cell studies along with Texas Heart, University of Minnesota, University of Florida and Cleveland Clinic.

The NHLBI is funding Vanderbilt's Specialized Center of Clinically Oriented Research (SCCOR) program in Hemostatic and Thrombotic Diseases with nearly $3.2 million annually for five years to study why patients with diabetes and insulin resistance have a tendency to develop blood clots.

**SELECTED RESEARCH**

- The Effects of Valsartan on the Proteomic Signature of Obesity Randomized, Controlled, Phase II, Double-Blind Trial of Intramyocardial Injection of Autologous Bone Marrow Mononuclear Cells under Electromechanical Guidance for Patients with Chronic Ischemic Heart Disease and Left Ventricular Dysfunction – FOCUS (Cardiovascular Cell Therapy Research Network – CCTRN)

- A Phase II, Randomized, Controlled, Double-Blind Pilot Trial Evaluating the Safety and Effect of Administration of Bone Marrow Mononuclear Cells Two to Three Weeks Following Acute Myocardial Infarction - LATE TIME (Cardiovascular Cell Therapy Research Network – CCTRN)

- Defining Strategies for Improving Endothelial and Fibrinolytic Dysfunction in Obesity (SCCOR Project 1, Aim 4A)

- The Effects of Pentoxifylline on PAI-1 Levels in an Obese Population (SCCOR Project 1, Aim 4B)

- Transplantation in Myocardial Infarction Evaluation Protocol A Phase II, Randomized, Controlled, Double-Blind Trial Evaluating the Effect of Timing on the Administration of Bone Marrow Mononuclear Cells (BMMNCs) versus Placebo in Patients with Acute Myocardial Infarction – TIME (Cardiovascular Cell Therapy Research Network – CCTRN)
Coronary Stent System for the Treatment of De Novo Coronary Artery Lesions in Small Vessels

Characterization of Brachial Arterial T-PA Release, Vasodilator Function, and Vascular Compliance and Correlation with Fibrinolytic Balance, Oxidative Stress, and Inflammation Measures in Heart Transplant Recipients (SCCOR Project 1, Aim 3C)

The intracoronary tissue-type plasminogen activator (t-PA) release predicts major adverse cardiac events in patients with non-critical coronary artery disease (SCCOR Project 1, Aim 3A)

The Effects of Night-Time Versus Morning Administration of Eplerenone on the Diurnal Variation of Plasminogen

The Effects of Angiotensin, The Vascular Endothelium, and Fibrinolysis: The Effects of PAI-1

“PARTNERS HF” - Multi-Site Program to Access and Review Trending Information and Evaluate Correlation to Symptoms in Patients with Heart Failure (Medtronic, Inc)

Heart Failure (Scios, Inc.) Protocol A093 ASCEND HF

Elevated Serum HDL in Four Generations of a Nashville Family

Transcatheter Closure of a Patent Foramen Ovale Using the AMPLATZER PFO Occluder System

Clopidogrel optimal loading dose usage to reduce recurrent EveNTs/ optimal antiplatelet medication

The Effects of Ramipril on the Proteomic Signature of Obesity (SCCOR Project 1, Aim 2A)

Transcriptional Regulation on Human Monocyte Function

Coronary Artery Disease (Car DioDx, Inc.) PREDICT

Identification of Gene Expression Patterns in Circulating Cells that Predict the Presence of Coronary Artery Disease (CardioDx, Inc.) PREDICT

VUMC DEBUTS NOVEL STEM CELL HEART THERAPY

John Plummer, 63, underwent the stem cell regeneration therapy about one week after experiencing a heart attack.

“There are no guarantees,” said Plummer. “It was the prospect of improvement — any improvement — that made it worth it. There are certain risks, but the prospect of the study proving to be valuable to others as well, all of those considerations made it seem like something I ought to do. I look at it this way. This is an improvement you would give almost anything to make. There is nothing more important than your general health.”

Plummer, an English professor for 36 years at Vanderbilt University, is not the first patient tested for eligibility into the trial. More than 100 patients have been screened, but did not meet the criteria for study participation — impaired heart function after an acute heart attack.

“Currently, there is no way to replace or renew damaged heart tissue, but recent progress in regenerative medicine using stem cell therapy is showing promise in healing these “broken” hearts.”

If we treat a patient rapidly, some may not have any damage at all,” said David Zhao, M.D., director of the Cardiac Cath Lab. “But for those who, despite all efforts, suffer damage to the heart muscle, we are studying the effects of this treatment in repairing the heart muscle.

“We are hoping that this is just the beginning of the journey and eventually we will be able to provide this unique therapy as part of our treatment protocol to patients with a damaged heart.”

Vanderbilt’s participation in these industry-supported studies highlights its role as a key player in stem cell regeneration in this country. For years, Europe has been the site for much of the heart-related, stem cell-based therapies. Fewer than five centers in the country are doing this kind of cell-based therapy,” said Zhao.

“Coupled with the fact that we are one of five programs funded by the National Institutes of Health for cell-based therapies definitely brings Vanderbilt to the next level. We are playing a leading role in cell therapy.”

Patients enrolled in the Amorcyte trial, like Plummer, will be seen regularly for up to five years. Within three to six months, investigators expect to see some improvement in heart function.

“We’ve had this dogma in the cardiovascular world that we have a limited number of cells in our heart, and if we lose them, that’s it,” said Doug Vaughan, M.D., principal investigator and former director of the Division of Cardiovascular Medicine.

“The idea that we might be able to regenerate or repopulate the heart with cells that can actually improve heart function is tremendously exciting. It’s a whole new way of treating patients. It’s something that’s never been feasible before, let alone conceivable.” —Douglas Vaughan, M.D.
QUALITY INITIATIVES

Vanderbilt Heart has continued to develop and expand quality improvement efforts throughout the organization. Through improvements in processes in care and clinical data management there has been remarkable overall performance in observed to expected (O/E) hospital mortality for major clinical programs. There was continued strong performance in general cardiology, heart failure, and arrhythmia O/E, which were all under 0.7. For 773 patients hospitalized for uncomplicated percutaneous coronary interventions in 2007 we had zero mortality.

Our greatest challenge to further improving O/E mortality in interventional cardiology has been patients transferred to Vanderbilt for primary percutaneous intervention after out of hospital cardiac arrest due to acute myocardial infarction (MI). These patients often later succumb to anoxic brain injury due to the initial out of hospital arrest, despite prompt successful cardiac revascularization in the catheterization lab. To address this challenge, we have:

- Instituted a therapeutic hypothermia protocol in the CVICU for patients admitted after cardiac arrest to reduce neurologic injury and improve clinical outcomes.
- Improved the speed and efficiency of care for patients transferred from other hospitals to Vanderbilt by developing the Acute MI Network Program as a resource for patients and referring hospitals in the region.
- We have continued solid performance in Joint Commission core measures for patients admitted to hospital cardiac arrest due to acute myocardial infarction (MI). These patients often later succumb to anoxic brain injury due to the initial out of hospital arrest, despite prompt successful cardiac revascularization in the catheterization lab. To address this challenge, we have:
- Designed and implemented in collaboration with the Vanderbilt Department of Bioinformatics a new electronic discharge order process within the Vanderbilt computer provider order entry system, Wizorder. This system automatically prompts physicians to review and document all relevant congestive heart failure and acute MI care measures in interventions prior to discharge, ensuring that each patient receives all of the appropriate medications and discharge instructions.
- Developed a dynamic team summary tool listing all active diagnoses for hospital patients to identify those with a working diagnosis of CHF. This in turn populates a real time CHF dashboard for case managers to ensure core measures are completed for all CHF patients during the hospitalization.

The multidisciplinary Chest Pain Center team continues to evaluate and optimize our performance for door-to-balloon time for patients presenting with acute MI.

- Our median door-to-balloon time was 68 minutes in 2007, with the majority of patients meeting the door-to-balloon time goal of under 90 minutes.
- We have implemented data analysis using subinterval goal times for each step in the process from patient presentation in the emergency department through catheter balloon inflation, and we use statistical process control charting to identify
Vanderbilt Heart had zero mortality for 773 patients hospitalized for uncomplicated percutaneous coronary interventions in 2007.
In 2007/08, Vanderbilt Heart will graduate its first fellow trained in Heart Failure Electrophysiological Device implantation and management and its first level 3 cardiovascular MRI fellow.

CME/PHYSICIAN EDUCATION

Vanderbilt Heart promotes accessibility, communication, continuing educational opportunities, and clinical collaboration for referring physicians and hospitals in Middle Tennessee. The Divisions of Cardiovascular Medicine and Continuing Medical Education sponsored Cardiology 2007, a two-day symposium with more than 200 attendees. Cardiac Surgery held its first biannual conference in 2007, the Valve Symposium, with about 55 attendees.

The Vanderbilt Heart and Vascular Network and Vanderbilt’s Physician Liaison service have organized monthly educational seminars by Vanderbilt physicians at multiple medical centers in the region, fostering opportunities for clinical collaboration. Efforts are under way to provide even greater access to the educational offerings at Vanderbilt Heart via inter-hospital streaming video transmission of the major teaching conferences.

Cardiovascular Medicine has six weekly CME conferences, and the Department of Cardiac Surgery has two. In 2008 we plan to globally Webcast four Cardiovascular Medicine CME conferences and one Cardiac Surgery CME conference.

FELLOWSHIP PROGRAM

The Division of Cardiovascular Medicine Fellowship Training Program, under the direction of Douglas Sawyer, M.D., Ph.D., and Julie Damp, M.D., is currently training 32 clinical fellows. Fellows in our program received competitive awards and grants from the American Heart Association, the American College of Cardiology, and the Leadership Council for Improving Cardiovascular Care sponsored by Schering Plough. Fellows are involved in multiple research projects, diversifying our division’s activity, including studies in molecular pharmacology, stem cell biology, advanced cardiovascular imaging of atherosclerosis and ischemia, as well as preventive health research at the Centers for Disease Control and Prevention in Atlanta.

We continue to attract a stellar group of clinical trainees from many of the best internal medicine training programs in the country who will begin their training in July 2008. This year we received approximately 500 applicants for eight fellowship training positions that begin in 2009.

NURSE RESIDENCY PROGRAM

Twelve new Cardiovascular Nurse Residents launched their careers at Vanderbilt Heart after completing a seven-week training program for new graduate nurses. During their training residents rotated through the various cardiovascular units and received intensive didactic and skill training in cardiovascular nursing. At the end of the training, they were matched with their job preference with input from trainers and staff on the skills and talents of each graduate.

The residency is now the only way for a graduate nurse to be employed in cardiovascular services. It is a highly desired program which has made acceptance into the program very competitive. By attracting the best graduates from across the country, the residency and Vanderbilt Heart provide an opportunity and a place for nurses to build a lifelong career. This year saw the third class of the residents to complete the program. We will offer two resident programs per year in an effort to ensure the best nurses are helping manage the growth and demand for quality care at Vanderbilt Heart.
NUCLEAR CARDIOLOGY

Under the direction of Marvin Kronenberg, M.D., and Keith Churchwell, M.D., the Vanderbilt Heart Nuclear Cardiology program has expanded to using three gamma cameras, with the associated increments in nursing and technical staff. The laboratory has continued the practice of routine single isotope studies, reducing the amount of radiation exposure to patients. A Rubidium-PET imaging program runs in collaboration with our colleagues in the Department of Radiology and Radiological Sciences, providing high quality perfusion imaging, which is especially useful for heavy patients, or for those who also require a near-simultaneous myocardial viability study.

This year has seen an expansion of nuclear cardiology research, with projects in several areas:

- The role of inflammation (judged by fluorodeoxyglucose uptake on PET scans) in the expansion of abdominal aortic aneurysms
- Evaluation and reduction of energy starvation in patients with dilated cardiomyopathies (using PET and cardiac MRI)
- The role of attenuation correction in more accurately identifying ischemia and infarction on standard SPECT images
- Evaluation of the usefulness of CT coronary angiography compared to standard nuclear stress imaging in patients with suspected coronary artery disease

CARDIAC MRI

The Cardiac MRI program, led by Mark Lawson, M.D., oversees the training of five cardiac fellows and partners with the Department of Radiology to perform magnetic resonance angiography studies. Vanderbilt’s is the only dedicated in-hospital Cardiac MRI in Tennessee. This quality care provides optimal telecommunications of cardiac structure and function.

Using a dedicated cardiology magnet to look for artery blockages, Lawson and his colleagues can perform a heart and whole body angiogram in 45 minutes.

The image quality for most angiograms is comparable to CT. Because MRI is non-invasive and doesn’t require the use of X-rays, patients can have several scans over time to track the progress of their disease.

As stronger magnets are developed, MRI will achieve better spatial and temporal resolution. Combined with the rapid development of new contrast agents, these advances may lead to the development of coronary MR angiograms, and provide an alternative to CT angiography.

MR technology has several other applications to cardiovascular medicine as well — monitoring bone marrow-derived stem cells used in cardiac regenerative therapy is one example. MR eventually may be used to screen high-risk patients for pre-symptomatic signs of cardiovascular disease. With the improved spatial resolution of stronger magnets, atherosclerotic changes in the wall of the artery can be detected before blockage forms.

ECHOCARDIOGRAPHY

The Vanderbilt Echo Laboratory was the first in Tennessee to be accredited by ICAEL, and accreditation was granted for a second time in 2007. Active initiatives in quality assurance continue, according to ICAEL guidelines. This program includes periodic peer review of study performance and interpretation. Ongoing updating of echo equipment continues, maintaining state-of-the-art imaging capabilities. Increasingly, the lab and its staff are involved in monitoring catheter-based cardiac interventions, and also in assessing LV dyssynchrony before and after biventricular pacing.
The Vanderbilt Cardiovascular MRI Laboratory has been granted accreditation in the areas of Cardiovascular Imaging by the Intersocietal Commission for the Accreditation of Magnetic Resonance Laboratories (ICAMRL). The Nuclear Cardiology Laboratory has also been accredited this year by the Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories (ICANL).
PHYSICIAN REFERRALS AND TRANSFERS

We encourage open discussion and feedback on the appointment and referral process. To enhance our accessibility, we have implemented a dedicated 24/7 Access Program staffed by experienced cardiovascular nurses to handle expedient transfer of a patient or arranging urgent access to Vanderbilt’s cardiologists or cardiac surgeons. To make a patient referral or to coordinate an inpatient hospitalization or transfer:

(615)343-9188 or (866)886-2478 Fax: (615)343-6559

OUTREACH/NETWORK LOCATIONS

Tennessee
Nashville
Vanderbilt Heart
1215 21st Ave. South
Medical Center East
South Tower, 5th Floor
Nashville, TN 37232

Byrdstown
Vanderbilt Heart Byrdstown
Byrdstown Medical Center
8401 Hwy 111
Byrdstown, TN 38549

Celina
Vanderbilt Heart Celina
Cumberland River Hospital
104 Old Jefferson St.
Box 427
Celina, TN 38551

Columbia
Vanderbilt Heart Columbia
1220 Trotwood Ave Ste 401
Columbia, TN 38401

Crossville
Vanderbilt Heart Crossville
Physician’s Associates
1645 South Main Street
Suite 101
Crossville, TN 38555

Vanderbilt Heart Crossville
Crossville Medical Group
100 Lantana Road
Suite 202
Crossville, TN 38557

Franklin
Vanderbilt Heart Franklin
2105 Edward Curl Lane
Franklin, TN 37067

Lawrenceburg
Vanderbilt Heart
Lawrenceburg
South Terrace Medical Building
1611 Locust Avenue
Lawrenceburg, TN 38464

Lebanon
Vanderbilt Heart Lebanon
1420 W. Baddour Pkwy
Suite 240
Lebanon, TN 37087

Shelbyville
Vanderbilt Heart
Shelbyville
341 Union St., Suite 201
Shelbyville, TN 37160

Sparta
Vanderbilt Heart Sparta
207 E Bockman Way
Sparta, TN 38583

Winchester
Vanderbilt Heart
Winchester
1397 South College Street
Bldg 2 Suite 1
Winchester, TN 37398

Kentucky
Franklin, KY
Vanderbilt Heart Franklin, KY
Patterson Medical Clinic
1020 South Main Street
Franklin, KY 42134

Powderly, KY
Vanderbilt Heart Powderly
MC Community Health
1010 Medical Center Dr.
Powderly, KY 42387

STEMI Network sites
The Medical Center of Franklin, (Franklin, KY)
Three Rivers Hospital (Waverly, TN)
Bedford County Hospital
(Shelbyville, TN)
VA (Nashville, TN)
Hillside Hospital
(Pulaski, TN)
Medical Center of Manchester
(Manchester, TN)
Blandfield Army Community Hospital
(FT. Campbell, KY)
Vanderbilt Emergency Services
OUR COMMITMENT

We are committed to reaching the highest possible excellence in clinical care, continually improving the quality of care delivered, leading the forefront of medical innovations for cardiovascular disease and being easily accessible to meet the needs of patients and referring clinicians.

ABOUT THE PHOTOGRAPHS

The aerial photographs by David Maisel are from his larger body of work titled The Lake Project. The terrain is located in Owens Valley, California. From the air, the landscape emerges as a dynamic biological structure; even in its depleted state, the river and its tributaries adhere to the desert floor like nerve endings, veins or arteries; the mottled red river bank suggests magnified cellular patterns, a coagulated pool of blood, an inferno; a colony of invasive marks presumably created by potash mining are clustered like boils on the desert floor.

To see additional images, visit www.davidmaisel.com.