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Aurora Health Care
This fall, the world of cardiac transplantation and mechanical circulatory support will be turned upside down when the United Network for Organ Sharing (UNOS) will implement a new national donor heart allocation system.

With this new system, donor hearts will be offered out to a 500-mile radius for the highest recipient on the list instead of being restricted to a much smaller area.

The listing also will change based on the intensity of treatment. Rewards will be given for patients on temporary mechanical circulatory support devices, such as veno-arterial extracorporeal membrane oxygenation (ECMO). Traditionally, those patients transplanted directly from ECMO have done very poorly. The goal of the system was to get the donor hearts to the sickest patients.

While the goal of the new listing algorithm was to get the donor hearts to the sickest patients, it may instead lead to centers placing less-ill patients on ECMO in order to improve their status for transplantation. As noted in April's Journal of the American College of Cardiology, it appears that the new system will get the donor hearts to those patients who have had their treatment intensified by their physicians.

Our approach for 2018 at Aurora St. Luke's Medical Center is to "get the word out." We are attempting to talk to and communicate with all physicians and providers who care for heart failure patients throughout the Aurora system. It is important for all physicians caring for heart failure patients to understand what treatment options are available.

There is a sense that heart failure patients wish to stay in their local communities, but when patients develop advanced heart failure, they have less than a 50 percent chance of surviving one year. The American College of Cardiology and the American Heart Association have triggers for referring patients to a Center for Advanced Heart Failure Therapy. These triggers include a left-ventricular ejection fraction less than 25 percent; a left-ventricular end-diastolic dimension greater than 6.4 cm; worsening heart failure despite maximum medical therapy, including intolerance to beta-blockers; increasing use of diuretics; and intolerance to angiotensin-converting enzyme (ACE) inhibitors.

Also, it is recommended that the patient be referred if the patient has had two or more emergency room visits or admissions to the hospital for heart failure within a 12-month period of time.

Understand that we will evaluate patients up to the age of 70 for cardiac transplantation. We also evaluate patients up to the age of 80 for mechanical circulatory support (left ventricular assist device placement) as destination therapy. We also aim to evaluate patients and put them in a position for the optimal therapy at the appropriate time. We have all the options available through the Aurora St. Luke's Medical Center Advanced Heart Failure Therapies, Mechanical Circulatory Support Device and Cardiac Transplant programs.

As in many other centers, our ECMO program has seen tremendous growth in the past five years. Both veno-arterial for cardiogenic shock and venovenous for respiratory failure have seen a tenfold increase in the past five years. Our dedicated perfusionists are critical in providing this necessary service. Our outcomes with ECMO are above national benchmarks for survival.

On the mechanical circulatory support device front, we offer centrifugal pumps for short-term (bridge-to-transplantation) and long-term (destination therapy) use.

Aurora’s Advanced Heart Failure cardiologists (Drs. Vinay Thohan, Nasir Sulemanjee, T. Edward Hastings, Omar Cheema, Eric Roberts, and Asad Ghafoor) are providing outreach to see patients both at Aurora St. Luke’s and in their local communities. Dr. Dianne Zwicke continues to lead the world-class Aurora Pulmonary Hypertension Program. All of these cardiologists are involved in clinical and basic science research and education.
The cardiovascular surgeons and the advanced heart failure cardiologists are clinically supported by strong groups of clinical engineers, registered nurses, nurse practitioners, and physician assistants.

For information about Aurora’s Advanced Heart Failure and Transplant Fellowship Program, contact Serena Messer at 414-649-5841 or serena.messer@aurora.org.

Aurora St. Luke’s at Cutting Edge of Electrical Therapy for Heart Failure

A urora St. Luke’s Medical Center and Aurora Health Center in Lake Geneva are the only sites in Wisconsin to participate in an international heart failure clinical trial studying a new leadless pacemaker that uses ultrasound energy to regulate the heart beat. Sponsored by EBR Systems, Inc., the SOLVE CRT Study (Stimulation of the Left Ventricular Endocardium for Cardiac Resynchronization Therapy in Non-Responders and Previously Untreatable Patients, clinicaltrials.gov identifier NCT02922036) will be led locally by Imran Niazi, MD, who will serve as the principal investigator for the Aurora sites, and subinvestigator M. Eyman Mortada, MD.

“Previous studies have shown CRT to be an effective treatment for some patients with heart failure; however, as many as 30 percent of heart failure patients receiving conventional cardiac resynchronization therapy do not respond to the treatment,” Dr. Niazi explained.

The WiSE CRT System, a wireless, leadless, left ventricular endocardial stimulation system developed by EBR Systems, Inc. (Sunnyvale, Calif.), has the advantage of allowing direct endocardial left ventricular stimulation using leadless technology. Wireless transmission is achieved by using ultrasound energy that is converted to electrical energy by a receiver electrode. This electrode, about the size of a grain of rice, is directly implanted in the left ventricular endocardium nonsurgically using the retrograde aortic approach.

“Because of the small size and absence of a lead, long-term anticoagulation is not required and cardiologists can personalize treatment by customizing the location to pace the heart,” Dr. Niazi said.

Both physicians are cardiac electrophysiologists and Dr. Niazi heads the Electrical Therapy for Heart Failure Center. The cardiac electrophysiology department has among the largest experience in the nation in treating cardiac arrhythmias and heart failure with electrical devices and has participated in virtually all major trials in this field.

The SOLVE CRT study will use a revolutionary leadless left ventricular endocardial pacing technology to treat heart failure patients who have failed to respond to standard cardiac resynchronization treatment (CRT) or could not receive a standard CRT system for clinical reasons.
In July, Aurora Health Care Vascular Services began offering supervised cardiovascular rehabilitation in combination with medical therapy as the first-line treatment for patients with early-stage peripheral artery disease (PAD). A supervised exercise program has been identified as a best practice to improve functional capacity, decrease symptoms, and achieve risk-reduction benefits, explained Richard Carballo, MD, Medical Director, Aurora Vascular Services.

The PAD rehabilitation program is a Class 1A recommendation of the American College of Cardiology for patients with this disease, and the Society of Vascular Surgery also recommends supervised exercise therapy as the first-line treatment for claudication. Aurora’s PAD rehabilitation program will be offered in existing outpatient cardiac rehab locations at Aurora St. Luke’s, Sheboygan, Summit, Grafton, Burlington, West Allis, Kenosha, BayCare, Hartford, Marinette, Two Rivers, and West Bend.

PAD is atherosclerosis affecting the blood vessels and is common in patients with diabetes mellitus or a history of smoking, coronary artery disease, or stroke. A common early symptom is claudication—pain in the foot or leg after walking a short distance.

“Among patients with claudication, 60 to 70 percent of supervised therapy patients will see improvement in their walking distance,” Dr. Carballo said.

The Centers for Medicare & Medicaid Services recently began reimbursing hospitals and clinics for supervised exercise therapy for beneficiaries with intermittent claudication as a result of PAD.

Cardiologist Sharonne N. Hayes, MD, of Mayo Clinic Rochester presented “Heart Disease in Younger Women: Unique Risks, Prevention, & Treatment” during Grand Rounds at Aurora St. Luke’s Medical Center earlier this year.

Dr. Hayes is a professor of cardiovascular medicine, founder and director of the Women’s Heart Clinic, and director of Diversity & Inclusion at Mayo Clinic.

During her presentation, she reviewed the ways that cardiovascular conditions differently, predominantly, or uniquely affect younger women; the importance of sex and gender in prevention, diagnosis and management of heart disease; and emerging concepts in myocardial infarction in women.

The Grand Rounds discussion was broadcast on a live video conference, and a tape of the presentation was made available to Aurora caregivers who were unable to attend.
The advanced heart failure team at Aurora St. Luke’s Medical Center hit another milestone on May 8, 2018, implanting its 100th CardioMEMs™ remote monitoring device.

CardioMEMs (Abbott, Abbott Park, Ill.) technology measures pressure in the pulmonary artery and transmits information wirelessly to the physician, who can adjust the patient’s treatment plan as needed. The program is credited with reducing heart failure admissions by 50 percent since its inception in 2015. Aurora St. Luke’s was the first site in Wisconsin to implant the CardioMEMs device three years ago and today ranks among the top 10 hospitals in the nation in total implants and overall experience with remote monitoring.

The multidisciplinary team that supports the CardioMEMs program at Aurora St. Luke’s includes same-day surgery, catheterization laboratory, and advanced heart failure team members. Advanced heart failure and transplant cardiologist Omar Cheema, MD, performed the 100th procedure, and advanced heart failure and transplant cardiologist Nasir Sulemanjee, MD, leads the Aurora St. Luke’s CardioMEMs program.

Cardiovascular Disease Fellow-in-Training Daniel Harland, MD, was recognized by the American Society of Echocardiography (ASE) Education and Research Foundation as a Top 25 Investigator for the abstract he presented at the ASE annual scientific sessions in Nashville in June. Twenty-five early-career abstract presenters were selected for the honor based on the exceptional scientific merit of the research projects they presented. Dr. Harland and his co-investigators researched respirophasic variation in left ventricular outflow tract obstruction in patients with hypertrophic cardiomyopathy.

Aurora Health Care’s transcatheter aortic valve replacement (TAVR) team recently was recognized by Boston Scientific Corp. as the third highest enrollee in the REPRISE III clinical trial (NCT02202434), which studies the use of the LOTUS™ Transcatheter Aortic Valve System* and LOTUS Edge™ Aortic Valve System* in TAVR procedures. Aurora St. Luke’s Medical Center in Milwaukee enrolled 72 subjects in the REPRISE III study and ranked fifth out of 67 sites worldwide.

Interventional cardiologist Tanvir Bajwa, MD, was an author on the REPRISE III study’s endpoint manuscript, which was published earlier this year in JAMA. TAVR often is an option for patients with aortic valve stenosis who are not good candidates for open-heart surgery due to age or other medical conditions.

The team at Aurora St. Luke’s performs eight to 10 TAVR procedures per week and celebrated its 1,000th TAVR procedure in 2017.

The TAVR team is led by Daniel P. O’Hair, MD, a cardiothoracic surgeon and co-vice president of Aurora Heart and Vascular Services, and Dr. Bajwa, medical director for cardiac and peripheral intervention.

* Investigational Device. Limited by US law to investigational use only. Not available for sale.
Atrial fibrillation (AF) is the most common heart rhythm disorder, affecting more than 3 million people, and a leading cause of stroke. AF can affect quality of life and lead to serious complications, such as increased risk of stroke and heart failure, making it a major challenge to health and well-being. Treating AF can, at times, be complex.

At Aurora Health Care’s Center for Advanced Atrial Fibrillation Therapies, an experienced, multidisciplinary team of cardiologists, cardiac electrophysiologists, cardiovascular surgeons, nurses, and technicians use the most innovative technologies and evidence-based therapies to treat the most complex cases of AF. The center is based in the Aurora St. Luke’s Medical Center Physician Office Building in Milwaukee, with additional locations in Aurora Medical Center in Oshkosh, Aurora Medical Center in Summit, Aurora Medical Center in Grafton, Aurora BayCare Medical Center, and Aurora Medical Center in Kenosha.

**Procedures and treatments offered include:**
- Medications to treat AF and prevent complications
- Catheter-based or surgical ablation
- Hybrid ablation (a combination of surgical and catheter based ablation that does not require opening the chest); this coordinated approach is used in patients who have had failed prior ablation procedures or are in AF all the time
- Placement of pacemakers and other cardiac monitoring and therapeutic devices
- Implantation of left atrial appendage occlusion devices for reduction of stroke risk

**Hybrid Ablation**

St. Luke’s Medical Center at Aurora Health Care was the first center to provide this integrated approach, in which a surgeon and an electrophysiologist work together in the same setting. More than 200 such procedures have been performed at Aurora St. Luke’s in the last five years.

During the hybrid procedure, a cardiothoracic surgeon ablates abnormal areas on the exterior of the heart while an electrophysiologist uses intracardiac catheters to map and ablate abnormal atrial tissue from inside the heart, blocking the electrical pathways that cause the irregular heart rhythm. Electrophysiological testing using multipolar catheters is performed to confirm that the erratic signals have been eliminated.

Compared to traditional treatment in patients with failed prior ablation and those in persistent AF, hybrid treatment has shown:
- Greater success in eliminating AF
- Better long-term results; up to 75 percent of people remain AF-free one year later
- Improved quality of life after the procedure
- Lower average cost per person at five years, versus catheter ablation or medical management alone

Candidates for hybrid ablation include people with long-standing AF, people with a heart chamber too large for standard ablation, people who have had an unsuccessful catheter ablation procedure, and people whose AF has not responded satisfactorily to medication or other treatments.

**Prevention of stroke**

During AF, the atria are unable to efficiently pump blood. This can result in sluggish blood flow in the heart, particularly in the left atrial appendage, increasing the risk that a clot will form, break loose, and possibly block blood flow in the brain or other organs.

“Atrial fibrillation increases the risk of stroke by five times,” explained electrophysiologist Jasbir Sra, MD, director of electrophysiology at Aurora Health Care. “And when stroke does occur, a person with AF tends to have a worse

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prognosis than those without AF. Appropriate treatment can reduce risk of stroke and lead to better outcomes.”

To mitigate this risk, patients with AF may be placed on a blood thinner. Aurora Health Care offers an Anticoagulation Clinic to help these patients monitor their blood’s clotting ability and medication levels.

For patients unable to take these medications due to allergies or bleeding issues, a left atrial appendage closure device may be considered. These devices are placed in the left atrial appendage, a small pouch within the wall of the left atrium in which blood sometimes pools. By blocking this appendage from the remainder of the atrium, clots formed there are unable to enter the blood stream, reducing the risk of stroke in patients with AF.

Aurora has been at the forefront of using these devices, having taken part in clinical trials for the Watchman™ (Boston Scientific, Minneapolis), which is now U.S. Food and Drug Administration-approved. Physician-investigators currently are participating in the AMPLATZER Amulet LAA Oclcluder Trial (Amulet IDE) (clinicaltrials.gov identifier: NCT02879448). This clinical trial is studying the effectiveness and safety of the AMPLATZER™ Amulet™ (Abbott, Abbott Park, Ill.).

In the U.S., the Amulet™ is an investigational device limited by federal law to investigational use.

Other AF rhythm-control treatments

Oftentimes, AF can be well controlled with medication, either taken alone or in combination with another therapy, such as ablation.

During standard catheter-based cardiac ablation, a doctor threads thin, flexible wires called catheters through blood vessels into the heart. Radiofrequency heat or cryoablation (extreme cold) are used to ablate the abnormal tissue that causes arrhythmia.

All AF ablations performed at Aurora Health Care include isolation of the pulmonary veins, which play an important role in this common arrhythmia.

Pulmonary vein isolation ablation has a very high success rate for patients who have paroxysmal AF (AF that comes and goes). Afterward, many people remain AF-free with improvement in symptoms and quality of life.

Several thousand such procedures have been done since 1999, when the first procedure was performed by Dr. Sra.

Device placement

Aurora cardiac electrophysiologists offer skilled placement of various medical devices that regulate the heartbeat, including permanent placement of and long-term follow-up for pacemakers, biventricular pacemakers and implantable cardioverter defibrillators.

Innovations in AF management

Aurora cardiac electrophysiologists and other staff members work closely with academia and industry to lead investigations into innovative approaches to identify patients at risk of AF and its complications, as well as to improve treatment and reduce the burden of this common arrhythmia on health care utilization.

Aurora Health Care also sponsors, in cooperation with Heart Rhythm Society, the annual AF, VT, VF Summit in Chicago, Ill., a state-of-the-art forum on atrial fibrillation, ventricular tachycardia, and ventricular fibrillation. Top investigators and physicians in the field present recent developments in ablation, imaging and device technologies, and therapies, as well as results of the latest basic and clinical research. The 2018 AF, VT, VF Summit will be held Nov. 30 and Dec. 1 at the Sofitel Chicago. For information, contact Laurel Landis at laurel.landis@aurora.org.

To contact the Aurora Center for Advanced Atrial Fibrillation Therapies, call (414) 646-8989.
Aurora Health Care scientists and clinicians continue to make advances in cardiovascular research, thanks in part to funding awarded by Aurora Research Institute, which recently provided more than $170,000 in internal grants. Awards were allocated in three categories.

**The Sullivan Cardiac Research Award for Residents and Fellows** provides up to $30,000 per award to early-career physicians with an innovative cardiovascular research proposal.

Interventional cardiologist Tanvir Bajwa, MD, offers mentorship to all winners of the award, which is available through the generosity of Tim Sullivan, a member of the Aurora Health Care Board of Directors, and his wife, Vivian Sullivan. In 2014, the Sullivans donated $1 million to support cardiovascular research via Aurora's fellowship programs.

This year's recipients to date:

- **Heart Failure and Transplant Fellow** Owais Malick, MD, received $24,050 for his project, “Impact of simultaneous exercise testing and measures of central hemodynamics on the clinical outcomes of patients supported with CF-LVADs.” Dr. Malick is studying the mechanisms of exercise intolerance in patients with left ventricular assist devices (LVADs). Although LVADs improve quality of life for many end-stage heart failure patients, many others continue with impaired exercise capacity, the exact cause of which remains unknown.

- **Cardiovascular Disease Fellow** Thomas Wilson, MD, received $30,000 for his project, “Chewed versus integral pill of ticagrelor in all patients undergoing primary percutaneous coronary intervention—a platelet reactivity and patient outcomes study.” Patients with coronary artery disease often require stents to open narrowed or blocked arteries. To prevent fatal stent-related complications, patients take antiplatelet medications like ticagrelor. The study will examine whether ticagrelor is absorbed faster when it is chewed rather than swallowed whole. If chewing these medications results in more rapid inhibition of platelet activation, patients may have fewer stent-related complications and freedom from repeat procedures.

**The Cardiovascular Surgery Research Award** is given to laboratory and clinical investigators to fund patient-centered research of cardiovascular diseases.

Recipients are:

- **Vinay Thohan, MD**, received $12,000 for his project, “Implications of aorta calcification by routine CT (computed tomography) scan and its implications on stroke after continuous-flow left ventricular assist devices (CF-LVAD).”
- **Farhan Rizvi, PhD**, received $39,700 for his project, “Molecular dissection and signature of human atrial and ventricular fibroblasts.”
- **Renuka Jain, MD**, received $45,800 for her project, “Aortic wall stress in bicuspid aortic valves—correlation with surgical outcomes.”

**The Cardiac Research Award** was given to **Vinay Mehta, MD**, for his study, “Does catheter ablation in patients with cardiomyopathy and atrial fibrillation/atrial flutter lead to decreased mortality and hospital readmission?” Dr. Mehta was awarded $22,100 for his research.

The study will use a Medicaid national dataset to compare outcomes between treatment options for patients who were hospitalized for heart failure and treated for atrial fibrillation or atrial flutter. There are multiple treatment options for atrial arrhythmia and this study may help determine which treatments result in the best outcomes. The results will be used to shape future research to identify and validate best practices in the treatment of patients presenting with systolic heart failure and atrial arrhythmia.

Funding for the Cardiovascular Surgery Research Award and Cardiac Research Award is available thanks to the generosity of donors to the Aurora Health Care Foundation.

A scientific review committee comprising researchers and clinicians evaluates proposals based on overall impact of the proposed study, its significance, innovation and approach, and the investigators involved in the research.

To learn more about Aurora Research Institute's intramural cardiology awards, contact the Sponsored Programs Office at spo@aurora.org.
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