

IMPACT REPORT Fall 2020



 **MHIF**
PREVENTION
Nolan Family Center for
Cardiovascular Health

The Nolan Family Center for Cardiovascular Health: Accelerating World-Class Preventive Cardiovascular Research and Education

The Stuart Nolan Family, through their exceptional leadership gift of \$5 million made it possible for MHIF to create the Nolan Family Center for Cardiovascular Health, fulfilling MHIF's vision of addressing the adaptable root causes of heart disease.

"My personal connection to cardiovascular research started with the care and treatment I received more than 30 years ago at the Minneapolis Heart Institute®, which continues to allow me to live a full life," said Stuart Nolan, a long-time supporter of

MHIF. "My children have reached the age at which I had my first heart attack, raising the importance of understanding genetic and other risk factors that affect their heart health and underscore the importance of this work to my family. I have great faith in Dr. Miedema and his team of dedicated MHIF researchers who have shown a sincere commitment to furthering research to define the prevention and management of cardiovascular risks that affect many families."

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— Stuart Nolan

The work of the new Nolan Family Center for Cardiovascular Health is led by Dr. Michael Miedema and is happening at a time when wellness and overall health is as important as ever. This research will accelerate progress and innovation around how to prevent cardiovascular disease, which continues to be the number one cause of death for people around the world. This research will also address some of the challenges around health disparities by further defining and understanding risk factors, as well as identifying the best care pathways for addressing care in racial and ethnic minorities where heart disease outcomes are significantly worse than other populations.

"Our commitment to impactful, cardiovascular disease prevention research isn't new, but the inspiring gift from the Nolan family will propel our efforts to change the paradigm from heart disease to optimal health," said Michael Miedema, MD, MPH, director of the Nolan Family Center for Cardiovascular Health at MHIF and director of cardiovascular prevention at the Minneapolis Heart Institute®. (continued on next page)

Photo caption: Ryan and Courtney Dunlay, and Stuart Nolan



Creating a world without heart and vascular disease

Nolan Family Center Continued from front cover

"The research is all about determining who to treat and how to treat them, which gives our patients the best chance to avoid the tragic heart attack or the unwanted bypass surgery."

Dr. Miedema's leadership in the field of cardiovascular disease prevention includes serving on the executive review committee for the 2018 American College of Cardiology/American Heart Association (ACC/AHA) Cholesterol Guidelines and serving as a member of the 2019 ACC/AHA Committee for the Primary Prevention of Cardiovascular Disease. He also serves as an associate editor for the prevention section of ACC.org.

Over its 38-year history, MHIF has led groundbreaking research and education across a wide spectrum of prevention-related topics, including coronary artery calcium testing, blood pressure, cholesterol and statin use, nutrition and lifestyle behaviors, risk factors and screening for specific populations, premature heart disease and genetic disorders. New cutting-edge research planned for the Nolan Family Center for Cardiovascular Health will focus on risk prediction and optimal prevention therapies, including:

- Cardiovascular risk prediction studies related to coronary artery calcium and use of a novel polygenic risk score (an aggregate of risk defined by genetic markers)
- Trials of new lipid-lowering therapies to prevent cardiovascular disease
- A novel study to more accurately assess the rate of medication side effects
- Trials that incorporate lifestyle as an essential component of ideal cardiovascular health

"We are grateful to the Nolan family for a gift that drives the MHIF vision of creating a world without heart and vascular disease," said Kristine Fortman, MHIF CEO. "This significant gift will accelerate our impact in preventive cardiovascular research, including supporting the infrastructure for the research, staff and fellows to lead an accelerated pace of clinical studies."

"The Nolan family is creating a legacy in partnership with a respected research team, whose passion for discovery will advance our mission of achieving long and healthy lives for all without the burden of cardiovascular disease," said Scott Sharkey, MD, president and chief medical officer at MHIF. "At this moment in our history, an unprecedented pandemic has emphasized the importance of a healthy lifestyle; we are thankful to be able to drive this important research that will benefit our patients and their families now and for generations to come."



Ben Jaffray, Marna Fullerton, Shirley Bentdahl and Conley Brooks at the 2019 Founder's Event.

Honoring Founder and Friend Shirley Bentdahl

Shirley Bentdahl, longtime Founder and friend of MHIF passed away on August 21, fourteen months after a major stroke. Shirley, and her late husband Ray, have been key founders and leaders of MHIF since the early days of the Foundation. Ray served as Chairman of the Board from 1997 to 2000 and worked closely with many leading physicians and staff to build MHIF.

Along with their children Ann and Craig, the Bentdahls have been important partners in this work. Shirley served on the Founders Steering Committee since 2015 and helped to build a successful outreach effort by graciously hosting the Founder's receptions at her home in Scottsdale from 2016 to 2019. Shirley and Craig could be seen at most Founder's events and galas in the past several years.

Since 2012, Shirley and Craig have participated in the presentation of the Ray Bentdahl Distinguished Service Award, recognizing an individual's contributions to the Foundation as a leader, mentor, philanthropist, educator and researcher. Their daughter Ann is also former CEO of MHIF and former ANWF board member.

We are grateful for the Bentdahl family and their exceptional generosity, leadership and impact on this work and the lives of the patients we serve. We will miss Shirley, her grace and kindness.

Extraordinary Strides in Heart Valve Disease Research



The Valve Science Center team at MHIF continues to make extraordinary strides in its groundbreaking, industry-leading research on minimally invasive surgery and catheter-based valve repair and replacement.

Led by Dr. Paul Sorajja, Roger L. and Lynn C. Headrick Family Chair for Valve Science, the team is improving patient options and outcomes through groundbreaking research. Dr. Sorajja is currently the principal investigator on five international and national multi-center studies, elevating the scope and impact of the Valve Science Center. The Valve Science Center team's wide dissemination of research findings is making significant impacts on the lives of heart valve disease patients around the world.



Dr. Sorajja

Mitral Valve Research

Since conducting the very first transcatheter mitral valve replacement (TMVR) in the U.S. (seventh in the world) in April 2015, the Valve Science Center team continues as a world leader in transcatheter mitral valve research.

- In March 2019, MHIF published data from a global feasibility study, which is the largest experience to date, with transcatheter mitral valve replacement (TMVR) in the *Journal of the American College of Cardiology*. The study examined outcomes with expanded followup for the first 100 patients who underwent TMVR with the investigational Tendyne Mitral Valve System (manufactured by Abbott). Data showed the TMVR procedure was highly effective in relieving mitral regurgitation and improving symptoms, with an acceptable safety profile.
- The SUMMIT study is evaluating the safety and effectiveness of the Tendyne Mitral Valve System for the treatment of patients with symptomatic, moderate-to-severe or severe mitral regurgitation or for patients with symptoms due to severe mitral annular calcification. The trial provides the opportunity to evaluate the safety and clinical benefits of the new technology compared to current therapies, including patients who may not be eligible for traditional surgery.

Tricuspid Valve Research

More than 1.6 million patients in the U.S. today have tricuspid regurgitation (leaky tricuspid heart valve), which is a difficult-to-manage, age-related disease. The Valve Science Center team is at the forefront of new clinical research that is studying new minimally invasive treatment options for patients with the disease.

- In August 2019, researchers enrolled the first patient in the TRILUMINATE Pivotal clinical trial that Dr. Paul Sorajja is leading, which is the first pivotal Investigational Device Exemption (IDE) trial in the U.S. to evaluate a catheter-based, non-surgical treatment for patients with severe tricuspid regurgitation.
- In October 2019, Dr. Sorajja implanted the first 4TECH TriCinch™ System in the Midwest – the 23rd in the world – to treat tricuspid regurgitation. MHIF is one of seven centers in the U.S. conducting the device's Early Feasibility Study. The new minimally invasive treatment option is for symptomatic patients suffering from moderate to severe functional tricuspid regurgitation (FTR) who are at high risk for open heart surgery.

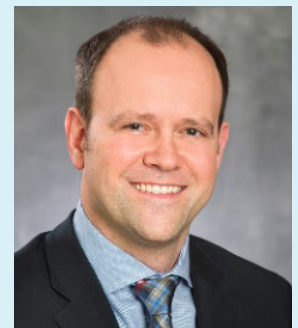
Aortic Valve Research

Aortic stenosis is one of the most common valve diseases and usually develops later in life. The Valve Science Center team continues groundbreaking research on aortic valve replacements with three devices under study in national clinical trials: EARLY TAVR, Acurate IDE, and Portico NG.

Heart Valve Disease Prevalence and Treatment Disparities

In a breakthrough study started in early 2019, MHIF is conducting new research in New Ulm, Minn., to understand the prevalence of undiagnosed heart valve disease among older adults. The study is offering free screenings for eligible adults age 65 and older in that community to help them determine if they might already have heart valve disease and not be aware of it.

MHIF's investigation is the first prospective population heart valve disease screening study in the U.S. and the second worldwide. Findings will help inform future screening and outreach efforts and create a lasting impact on how heart valve disease is diagnosed and treated. Dr. Mario Gössl, director of transcatheter research and education and co-chair for the MHIF Valve Science Center, is leading the study.



Dr. Gössl

Dr. Gössl also continues the TVINCITIES Disparity Study to better understand racial and ethnic disparities in the treatment of valve disease in order to help improve access to life-saving therapies like transcatheter aortic valve replacement (TAVR). Researchers are seeking to determine the impact of referral biases and patient factors on disparities in care for those requiring surgical or transcatheter therapies.

Prolific Pace of Publications

Since the Valve Science Center was formally established in 2016, efforts to disseminate research findings have grown exponentially. The team has published more than 200 articles and given thousands of presentations around the world. In 2019, the team had its best year ever with more than 70 publications.

MHIF Highlights on TPT

Twin Cities Public Television (TPT) began airing a brief two-minute segment highlighting valve disease as a public health crisis. The video tells the story of Dan Beranek, a former MHIF board member, who was surprised to learn he had heart valve disease when he participated in MHIF's valve disease study being conducted in New Ulm by Dr. Mario Gössl. The video also features Dr. Gössl and MHIF CEO Kristine Fortman discussing valve disease and how research has led to less-invasive treatments. You can also see the video on the Valve Science Center website – mplsheart.org/valve-science-center



On the Pulse – Valve Disease – November 23

A special On the Pulse webinar is scheduled for Monday, November 23 at noon featuring leaders from the Valve Science Center to talk about innovations and advances in heart valve disease treatment.

Please visit our website for updates and to find video recordings of the previous sessions - mplsheart.org/on-the-pulse-series

WELCOMING NEW TEAM MEMBERS

Dr. Vinnie Bapat

Vinayak (Vinnie) Bapat, MD, joined the Valve Science Center team in June, bringing his extensive expertise as a cardiothoracic surgeon and innovator in treatment of heart valve disease. He also serves as Chief of Cardiothoracic Surgery at Minneapolis Heart Institute®. Most recently, Dr. Bapat was a professor of cardiothoracic surgery at Columbia University Medical Center in New York.



Dr. Bapat

Dr. Bapat previously served as professor of cardiothoracic surgery at Guys and St. Thomas' Hospital, London and continues to hold that position as visiting professor. In addition to his clinical accomplishments, Dr. Bapat has been a collaborator among his peers in the world of transcatheter valves through the creation of two apps that are downloadable on mobile devices – Valve-in-Valve (VIV) Mitral and VIV Aortic. New transcatheter valve systems are the latest, minimally invasive technologies that have changed the way heart valve disease is treated. The apps provide imaging and clinical information, such as dimensions and characteristics of the various valve repair technologies and have been downloaded in 132 countries. Through these apps, physicians access data and clinical insights to determine the technology options based on their individual patient needs, including guidance and insights on the implant procedure.

Dr. Maurice Enriquez-Sarano

Maurice Enriquez-Sarano, MD, FACC, FAHA, FESC joined the Valve Science Center team in January as a senior research scientist. Dr. Sarano is a world-renowned expert in valvular heart disease and mitral regurgitation with a lifetime of accomplishments, impacting the practice of care and innovation globally. A long-standing advocate for early intervention, Dr. Sarano has positively impacted the lives of thousands of patients and families throughout the world.



Dr. Sarano

A native of Tunisia, with a medical degree and post-graduate engagements with the University of Paris VI among other institutions, Dr. Sarano first came to Minnesota at the Mayo Clinic in 1991. He was the founding director of the Valvular Heart Disease Clinic and built an incredible legacy. He and is the author of more than 350 original manuscripts in peer-reviewed literature and book chapters. Over his remarkable career, Dr. Sarano has served as an educator and mentor of countless physicians.

Perspectives on COVID-19 and Ongoing Cardiovascular Research

A conversation with Dr. Scott Sharkey, chief medical officer, MHIF

The MHIF mission is as relevant today as it was 38 years ago. How is this evident in what is going on currently through the research you are doing?

Dr. Sharkey: The mission of research and education – as a method to identify and solve problems – is no different now than it has been in the past. Despite the powerful emotional stress this pandemic has placed on all of us, science and research provide us a way forward. Once the research is accomplished, we must share this knowledge with our professional colleagues across the globe to spawn further dialogue and provide benefit for patients everywhere. During these months of uncertainty, we must maintain our focus on this mission.

Now that we're six months in, how would you characterize things as they are today related to cardiovascular research during the pandemic?

Dr. Sharkey: There are a number of things that have made research much more difficult right now. In March, the governor of Minnesota issued a proclamation to stop elective procedures at all hospitals in the state so they would have capacity to deal with an onslaught of COVID-19 patients. With that, almost all of our research was put on pause.

Unfortunately, this created anxiety and uncertainty for patients regarding the safety of health care settings. Patients feared hospitals would fill with COVID-19 patients, exposing others to the risk of infection. Fortunately, this has not happened. The systems put in place have provided patients and hospital staff with remarkable safety, despite the contagious nature of this virus. Over time, the ban on elective procedures has eased and our research has recovered substantially.

Other considerations include research restrictions implemented by some of our industry partners involving their new drugs or technologies.

At MHIF, we have taken extraordinary measures to protect the health of our staff and patients, resulting in some limitations in the number of individuals working in our building at any one time. Consequently, our patients and staff have the confidence that participating in research will not expose them to unnecessary infection risks.

What would you want patients to know about the cardiovascular research that is ongoing?

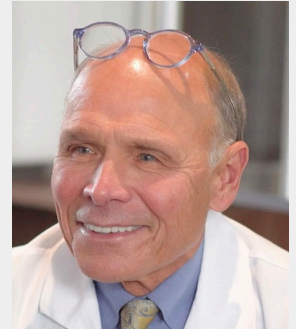
Dr. Sharkey: We're back at it and making up for lost time! We have a backlog of patients that are waiting and we have a number of new studies that are being proposed for enrollment so it's important for patients to know they

have access to consider research studies when they are discussing their treatment options with their physician. We also have a number of studies that are directly related to the pandemic.

What research are you doing that is directly COVID-19 related?

Dr. Sharkey: A remarkable number of new treatments directed at treating or preventing COVID-19 have emerged. As a physician, I see multiple approaches to dealing with this virus and MHIF is participating in most of these exciting studies.

- 1) Antiviral drugs (eg. Remdesivir) that kill or stop the virus from replicating.
- 2) Inflammation "calming" drugs (eg. mavrilmumab). Evidence to date suggests an over-reaction from the body's immune system in severe COVID-19 infections.
- 3) Antibodies directed against COVID-19 obtained from the convalescent plasma of previously infected patients or lab manufactured antibodies (eg. Regeneron).
- 4) A vaccine for COVID-19, which is an ongoing effort around the world.
- 5) Treatment of COVID-19 related complications (e.g., formation of harmful blood clots) with anti-coagulation drugs.



Dr. Sharkey

Keep your body, mind and heart healthy during coronavirus (COVID-19)

As the coronavirus pandemic has progressed, the Minneapolis Heart Institute Foundation® (MHIF) is continually monitoring the situation and taking all necessary precautions to always keep our patients, employees and partners healthy and safe. During this difficult time, we stress the importance of taking precautions and taking good care of yourselves and your loved ones. Our hearts go out to those affected by COVID-19 and we are extremely grateful to our physicians, nurses, other care team members and everyone in our greater health care community for their commitment to caring for patients. For more information, please visit mplsheart.org/coronavirus.

Matching Gift Opportunity

MHIF is pleased to share that a generous, anonymous donor has decided to make a lasting impact on innovative research research and care for children in need of specialized surgeries in Africa.

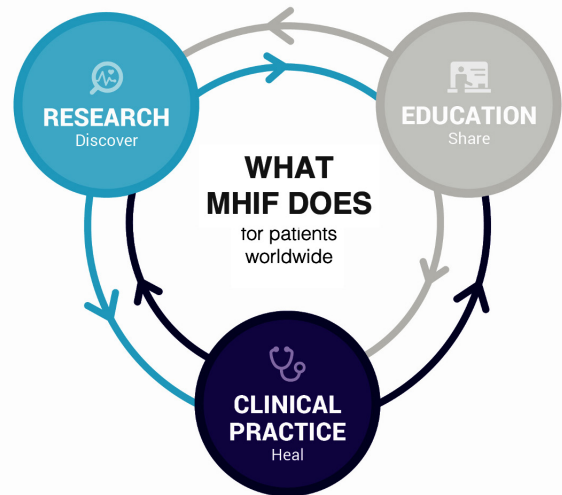
The opportunity to raise an additional \$60,000 for the Innovation Fund (areas like electrophysiology and heart failure), \$60,000 for coronary artery disease research and an additional \$120,000 for the Global Outreach program! You can see more and help meet those challenges with your generous gift.

- To support research in electrophysiology and heart failure, visit mplsheart.org/INNOmatching
- To support coronary artery disease research, visit mplsheart.org/CADmatching
- To support global outreach efforts, visit mplsheart.org/global-outreach

Here are some highlights about these areas:

Innovation

- Using new methods to map the sources of atrial fibrillation that are not available anywhere else in the world, MHIF researchers have increased the success rate for treating atrial fibrillation from 65 percent to 90 percent.
- Leading multiple studies that help predict the formation of ablation lesions and improve the consistency of complex ablation procedures to treat irregular heart rhythms.
- Exploring the use of intravenous iron to help exercise capacity.
- Developing new catheter-based treatments for valve disease, which often accompanies heart failure.
- Studying exciting possibilities for using new diabetes medications to improve heart failure outcomes – perhaps even for patients who don't have diabetes.
- Researching new "Heart-in-a-Box" technology that keeps donated hearts beating to extend the length of time they are viable for transplant.
- Leading a prospective registry started in 2009 to collect disease-specific data from patients seen in GAC in order to increase our understanding of the natural history and clinical presentation of multiple cardiac genetic arrhythmic conditions.
- Participating in a retrospective study of patients who had cardiac implantable electronic devices (CIEDs), in collaboration with Dr. Robert Hauser. We will compare longevity and reliability of CIEDs between 4 manufacturers.



Coronary artery disease

- Improving outcomes for patients with chronic total occlusions (vessels that are completely blocked for more than three months) through research on innovative percutaneous techniques (performed through a needle stick through the leg or arm) to clear complex blockages.
- Researching novel ways to prevent or delay the progression of intermediate saphenous vein grafts lesions (blockages of bypass graphs that don't require stenting). They frequently worsen and can be challenging to treat.
- REBIRTH Trial: A >3000 patient clinical study to study the safest method to access heart blood vessels for patients undergoing cardiac catheterization. We seek to expand this registry to a multicenter trial.
- Expansion of the PROGRESS family of global registries:
 - a. Bifurcations Registry: To study blockages that occur at the branching point (bifurcation) of the heart vessels, and procedures to treat them. These blockages are complex to access and treat and the registry aims to be a global repository of procedures to determine strategies that provide best outcomes to the patients.
 - b. Complications Registry: To study complications related to cardiac cath and stenting procedures and improve patient outcomes.

Global Outreach

MHIF's Center for Global Outreach seeks to improve care and prevent rheumatic heart disease globally for children and young adults. This program is the continued work of Dr. Vib Kshetry who provides treatment at no cost for children and young adults with critical cardiac surgical needs through annual surgical mission trips. Global Outreach also supports prevention, intervention, research and provider training with partners in Ethiopia and Tanzania.