

A New Hope to Heart Failure Treatment: Six Keys to Building a Quaternary Mitral and Tricuspid Center of Excellence

Early adopters of transcatheter mitral and tricuspid therapies share practical insights on creating a quaternary center of excellence.

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Hear failure is a worldwide health problem. Transcatheter mitral and tricuspid therapies have emerged to provide immediate symptomatic benefit to patients previously without options. For the past decade, treatment of heart failure has advanced with new medications, improvements in design of left ventricular assist devices, and intracardiac acute cardiogenic shock support devices. However, with development of transcatheter mitral and tricuspid interventional valves and devices, a paradigm shift has occurred, expanding patient access to definitive heart failure treatments. Structural interventional heart failure therapies now provide a new window of opportunity for heart failure treatment before a patient becomes “end stage.”

Advancement of promising transcatheter mitral and tricuspid therapies requires the development and nurturing of the multidisciplinary heart team (MDHT): a crew of medical experts working collaboratively to deliver expert team-based care in the treatment of these complex high-risk patients.¹ Unity and collaboration among multidisciplinary medical specialists form the building blocks for creating destination health systems with the infrastructure for a structural heart mitral and tricuspid center of excellence. These centers of excellence carry the unique medical, academic, and innovative infrastructure build required to formulate individualized patient-centric procedural and care management plans required for patients of high medical complexity.



Defining Purpose and Best Practices: Standardizing Delivery of Care, Identifying the Unmet Clinical Need

What defines a structural heart quaternary mitral and tricuspid center of excellence?

Commitment to building a mitral and tricuspid center of excellence requires patient access to all members of the medical team with subject expertise surrounding the different anatomic, pathophysiologic, and technical etiologies of valvular heart disease and heart failure. For us at Henry Ford, it meant a coalition of willing experts purposefully coming together from multiple disciplines (interventional cardiology, cardiothoracic surgery, interventional imaging, cardiac anesthesia, advanced heart failure, electrophysiology, advanced practice providers, and more) to deliver patient-centric care. At our institution, the MDHT meets weekly on Monday mornings for an aortic valve conference and Tuesday mornings for dedicated mitral and tricuspid valve conferences. Our MDHT convenes here to review each patient's case, medical history, serial imaging examinations, and clinical scenario to present a best practice recommendation for that patient's heart failure intervention. All medical team members provide their subject matter expertise in the care and presentation of each patient's illness; we confirm that we optimized the patient's heart failure medication regimens and clearly outlined their surgical versus transcatheter risk profile options, rehabilitation needs, and interventional imaging requirements.

What are some of the key barriers and challenges that early adopters of this center of excellence build face, and what are potential solutions to overcome these early adoption barriers?

At our institution, the time commitment required for attendance and participation in not one but two weekly MDHT conferences is outside of traditional relative value unit practice models for medical team reimbursement. Everyone participated because they believed in the concept

of the MDHT and the positive impact of team-based delivery of care. As our program grew under the leadership of Dr. William O'Neill over the past decade, our practice grew from one central hospital to expanded access to satellite campuses. As the conferences became more in-depth with increased patient volume, our health system recognized the value of the structural MDHT's decision-making and granted continuing medical education credits for every conference. This helped improve and increase engagement of all medical team members.

What should medical teams consider when in the initial phase of building a team for a structural heart quaternary center of excellence?

One of the most important aspects of initial programmatic phase building is identifying and solidifying the communication pathway for delivery of care. From the first day of our structural heart interventional fellows' training, we teach the importance of closed-loop communication pathways. If a referring physician sends a patient to our health system for quaternary care, they are entrusting the treatment of a patient they have formed a bond with into our health system's care. They've dedicated years of their clinical expertise and care to helping that patient and that patient's family/caregivers maintain their health. At our center of excellence, we make sure the patient's referring provider is provided written and verbal updates throughout their length of stay. If we discover the patients have more than one valvular heart disease or structural disease state, we communicate this back to the referring provider in real time to engage them in decision-making because we respect the doctor-patient privilege relationship that our referring providers have built with their patients. Our referring providers are part of our care team at Henry Ford Health, and the initial phase of building a team starts with valuing the importance of closed-loop communication in the delivery of each patient's care.



Creating the Business Plan

What kind of support is required to champion a structural heart quaternary center of excellence?

At Henry Ford Health, we were fortunate to have Dr. William O'Neill build our Center for Structural Heart Disease. He is our physician champion. Under his mentorship, our team works alongside our hospital leadership to improve our patients' access to innovative, novel clinical trials and therapies. One of the most important phrases he

has engrained into our team's practice is "Patients first." As our physician leader, he unifies the team and demonstrates through his strategic vision, work ethic, and innovative mindset the goals our team needs to attain to deliver high-caliber care. For programs looking to follow this pathway, you need a motivated leader who is invested in the team's growth and recognition and puts others before themselves; this is the type of physician champion required to motivate a team to believe and share in the vision to do more to make a positive impact in patient's lives.

Medical teams also need to engage their hospital's leadership early in the process of creating a center of excellence. At Henry Ford Health, our hospital administration supports innovation. Henry Ford Health has a century's worth of history in providing innovative care, from pioneering robotic prostatectomies with the da Vinci system (Intuitive Surgical) under Dr. Mani Menon to the launching of the Henry Ford Innovations Institute, which focuses on training medical teams to take a product from concept to rapid adoption. Our chief executive leadership team, heart and vascular service line medical director, and research administration are supportive of our vision in spearheading innovation to improve quality of care.

As a clinical team member, what administrative value proposition does one need to consider when proposing hospital investment and buy-in for the creation of a quaternary center of excellence?

The goal is to create an infrastructure that will allow the identification of all patients with heart failure and valvular heart disease so that no patient is left behind. Empowering medical teams in our health system and our referring providers with the knowledge and access to technological infrastructure to identify, follow, and monitor these patients with progressive heart failure forms the basis of our center of excellence.

For example, we work closely at our institution with information technology (IT) leaders, database infrastructure leaders, and administrators to help improve team-based clinical workflows. Our ability to create a lean IT model for delivery of cardiovascular care (ie, Epic order entry and medical chart alerts) not only improved our colleagues' charting workflow but was an administrative investment that improved hospital tracking of cardiovascular quality metrics of care. These IT workflows resulted in an increase in penetration of delivery of care and physician and medical team engagement.



Building the Team: Guidance and Governance

What individual training expertise is required to demonstrate the skill required to be designated as a quaternary center of excellence for transcatheter mitral and tricuspid interventions?

This is a challenging question. Transcatheter mitral and tricuspid interventions are still in their infancy. There are no formal societal physician training documents. Henry Ford Health has been an early adopter of transcatheter mitral and tricuspid interventions, with unique expertise in these complex patient anatomies.

There is a significant early operator learning curve for transcatheter mitral and tricuspid interventions.² In our institution's experience, it takes approximately 50 mitral transcatheter edge-to-edge repair (TEER) procedures for an implanter and interventional imaging physician to overcome the early operator learning curve involved with learning the transcatheter device, delivery system, and imaging protocols for mitral procedures. We recommend that sites looking to start mitral and tricuspid TEER programs first invest in building a robust mitral TEER programmatic base. It may be worthwhile to even partner with an experienced center to help accelerate the learning curve. For new sites, we recommend performing 50 primary operator-led mitral TEER procedures with a dedicated interventional imaging physician before learning and performing tricuspid interventions. In an established, highly experienced team of interventional implanters and imaging physicians, it takes an additional 25 transcatheter tricuspid procedures (approximately) after obtaining expertise in mitral TEER procedures to start overcoming the learning curve of navigating the right heart anatomy; the right heart anatomy is complex and not yet fully understood by device and industry engineers or clinical teams.

What are the imaging requirements for building a transcatheter mitral and tricuspid center of excellence?

Much of the required imaging revolves around having access to imaging technology and physician time. The core imaging modalities actively involved in pre-, intra-, and postprocedural imaging include transthoracic echocardiography, transesophageal echocardiography (TEE), and cardiac CTA (CCTA).

Preprocedural imaging requires access to reproducible scanning protocols dedicated to the detection of valvular heart disease, quantification of degree of valvular heart disease, and ability to review serial imaging studies on one imaging platform to provide a timeline-based clinical assessment. At our institution, we actively engage in sonographer and physician education related to valvular heart disease and new device technologies. With every new clinical trial, we perform outreach to referring medical teams and hold conferences within our heart and vascular institute service

line to disseminate the scientific publications, trial, and training materials necessary to onboard these modern technologies.

Intraprocedural imaging is led by interventional imaging physicians performing TEE. Successful transcatheter mitral and tricuspid centers of excellence have invested in protecting the time of dedicated interventional imaging physicians for the pre-, intra-, and postprocedural management of patient imaging diagnostic care.

At Henry Ford, 60% to 70% percent of patients with mitral and/or tricuspid valve disease have concomitant atrial fibrillation. Most structural heart/valvular clinical trials now require pre- and postprocedural CCTA as part of their trial protocol, which calls for investment in CCT scanners with gantry speeds able to acquire images at irregular heart rates ranging from 40 to 130 bpm, encompassing the clinical scenario commonly associated with atrial fibrillation patients in valvular heart failure.



Promoting Communities of Practice

How can the MDHT overcome the technology adoption curve?

There are multiple stages to technology adoption. Innovators and early adopters typically encompass the scientific phase of clinical trial design and performance. Well-designed clinical trials are vital to the scientific advancement of cardiovascular medicine, but few patients and clinicians may be aware of or have access to the different clinical trials for mitral and tricuspid valve disease.

At Henry Ford's Center for Structural Heart Disease, we believe in the science of clinical trials. Active participation and involvement in clinical trials allow our patients access to new, potentially lifesaving technologic devices they otherwise would not have access to outside a trial. When we evaluate clinical trial opportunities for our patients, we look for clinical trials and devices that would serve an unmet need for our patient population, and this allows us to have multiple different anatomic solutions for varying pathophysiologic states of valvular heart disease.

Clinical trials contribute enormously to scientific and academic advancement. Once clinical trials are fully conducted, they progress to scientific peer review and publication of patient outcomes. Our structural heart team actively leads at the local, national, and international level to help teach the scientific findings of these clinical trials. Together, our scientific collaboration across local and global centers of excellence helps advance everyone's medical understand-

ing. This level of academic and scientific engagement helps move the cardiovascular field forward in the technology adoption curve.



Measuring Performance

How do you maintain growth and quality?

For structural heart, the national Society of Thoracic Surgeons/American College of Cardiology TVT registry was created as a national database to monitor procedural outcomes of transcatheter replacement and repair. Participation in this program provides local structural heart teams access to how their program is performing compared to national benchmarks and enables implementation of national standard of care quality metrics at local programmatic levels. At Henry Ford, our team actively contributes to the scientific data build and questions within the TVT registry based on our clinical experience to help advance the field of transcatheter heart valve procedures. Additionally, internal morbidity and mortality conferences are an additional vital component to help recognize potential areas of improvement in the day-to-day care of these complex patients.



Establishing Expertise

Moving forward: How do you establish subject matter expertise?

Subject matter expertise is required to maintain a consistent level of care across a health system and is formulated through medical team members' specific skills, clinical and academic expertise, and experience relevant to the growth of the program and organization. At Henry Ford, our team of key opinion leaders actively works at the national and international level helping to formulate scientific clinical trials, scientific training documents, and societal educational conferences to advance the field of transcatheter mitral and tricuspid interventions.

For many looking to start a mitral tricuspid program, attaining the academic recognition of "expert" is a significant time commitment external to clinical responsibilities. We would recommend that early and mid-career physician teams start with one subject matter of interest, obtain expertise in that, and collaborate with colleagues to publish

on your single-center experience before trying to become an expert on multiple areas of interest. Maintaining the qualification of expertise requires the ability to have introspective growth, and being open to constantly learning.

CONCLUSION

Looking back, what would you tell yourselves?

It will not be easy, but it will be meaningful. Building a structural heart quaternary mitral and tricuspid center of excellence is about saving one life at a time; there will be patients you can't save who presented too late and were too sick. It will require a team effort every step of the way.

As an early adopter to transcatheter mitral and tricuspid therapies, we know that advancement of a health system delivery of care requires up-front investment in patient- and medical team-based education on the availability of new therapies in the prevention of heart failure. The patients are all around us—the unmet clinical need is there. Team-based collaboration and institutional leadership support is critical for success of quaternary centers of excellence in health systems. ■

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