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Should We Start a Structural Heart Program?

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Structural heart disease treatments include:

- Alcohol septal ablation to treat hypertrophic cardiomyopathy;
- Atrial septal defect (ASD) closure to repair a hole in the part of the heart that separates the atria;
- Patent foramen ovale (PFO) closure to repair a hole in the heart (a patent foramen ovale);
- Transcatheter aortic valve replacement (TAVR) to replace the aortic valve;
- Transcatheter mitral valve replacement (TMVR) to replace the mitral valve;
- Transcatheter pulmonary valve replacement (TPVR) to replace a failing prosthetic or donor pulmonary valve;
- Balloon valvuloplasty to open a narrowed heart valve and restore blood flow;
- Percutaneous left atrial appendage closure (LAAC) using a device that works as a plug to close the LAA, preventing blood clots from causing a stroke in people with atrial fibrillation.

Complex percutaneous structural heart interventions continue to grow and are providing options to patients who previously had limited options for the treatment of structural heart disease.

Disease Categories and Prevalence

Statistics show that over the last 30 years, deaths and disability from cardiovascular disease have been steadily rising across the globe. Two of the most prevalent cardiovascular diseases are heart valve disease and atrial fibrillation (AF).

Heart valve disease is a rapidly growing cause of cardiovascular morbidity and mortality. It affects about 2.5% of the population overall in the United States and includes valvular regurgitation or stenosis.[1] Mitral valve regurgitation is the most common valve disease in the United States, though aortic valve stenosis is also very common. More than 2 million people in the U.S. have a leaky heart valve.[1] One of the most common structural heart diseases is aortic stenosis (AS), with an estimated prevalence of 12% to 13% for AS overall and in those who are 75 years or older, the prevalence of severe AS is 2% to 4%.[2] Since the evolution of transcatheter aortic valve replacement (TAVR), patients who have met certain criteria with inoperable, high-surgical risk, intermediate-surgical risk, and low-surgical risk can undergo a nonsurgical, minimally invasive procedure whereby a prosthetic valve is deployed over the native aortic valve using vascular access via the femoral artery. Between 2012 and 2019, TAVR programs grew from 198 to 608 in number, a trend that is expected to continue.[2]

Atrial fibrillation (AF), the most common sustained cardiac arrhythmia, is increasing in incidence and prevalence worldwide, with U.S. prevalence ranging from approximately 1% to 2% of the general population, and a nonvalvular AF (NVAF) incidence of around 51.9%.[3] AF significantly increases the risk of ischemic stroke, and in patients with NVAF, the left atrial appendage has been determined to be the source of thrombus development in 91% to 99% of cases.[4] The left atrial appendage occlusion (LAAO) procedure has evolved over the years as a minimally invasive alternative to oral anticoagulation therapy for stroke prevention in patients with AF who are at high risk of bleeding.

In addition to heart valve disease and AF, about 1.4 million adults and 1 million children in the U.S. have a congenital heart condition. Congenital heart conditions are the most common type of birth defect in the U.S., affecting nearly 1% of births (about 40,000 babies) each year.[5]

Essential Structural Heart Program Components

With the advent of percutaneous valvular procedures and LAAO procedures, the cardiovascular industry has seen a significant increase in the volume of structural heart procedures to treat complex patients. To accommodate this influx, healthcare organizations should develop their procedural offerings and services into a formalized structural heart program. However, being in the position of starting a structural program is a challenging one and requires major institutional commitment and support, and the presence of key components (Figure 1). A solid structural heart program should include:

1. **A multidisciplinary team,** including interventional cardiologists, cardiothoracic surgeons, imaging specialists, nurses, and other healthcare professionals who collaborate to provide comprehensive care to patients with structural heart disease.
2. Access to **advanced imaging technologies** such as echocardiography, cardiac computed tomography (CT), and cardiac magnetic resonance imaging (MRI), to accurately diagnose and plan interventions for structural heart conditions.
3. **A well-equipped hybrid lab/operating room** with advanced equipment and technology that allows for complex, minimally invasive procedures requiring both surgical and catheter-based techniques to be performed in the same setting, such as LAA closure and transcatheter valve replacements or repairs.
4. **A dedicated clinic or program for post-procedure follow-up care,** including monitoring patients, managing complications, and optimizing long-term outcomes.

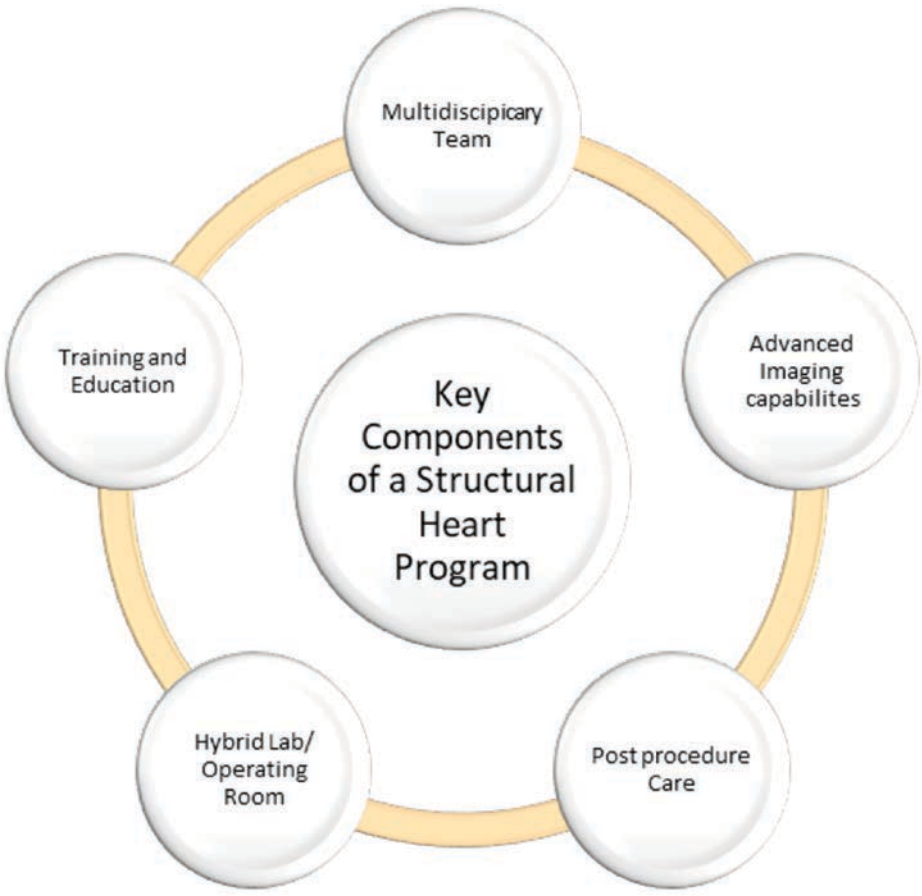

Figure 1. **Key components of a structural heart program.**

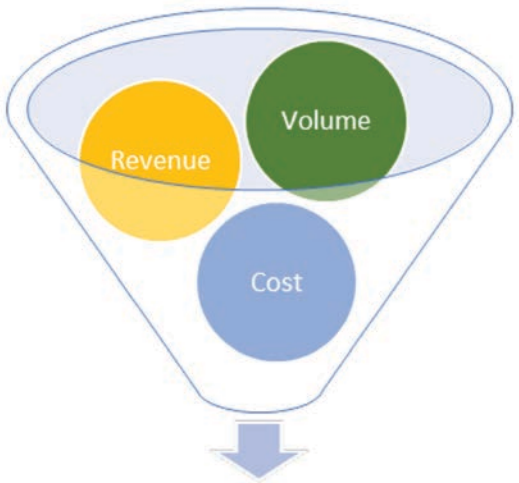

Figure 2. **Economics of a TAVR program.**

5. Ongoing **training and education** for staff members to ensure they are up to date on the latest advances in structural heart interventions and technologies.

With these key elements in place, hospitals can provide comprehensive and high-quality care for patients with structural heart disease.

It is also important to understand hospital margins based on revenue before adding new procedures and services. This includes price and volume against costs, which include materials, overhead, length of stay, labor, and complications. Price has the greatest effect on reducing margins, while increasing volume and controlling material costs, length of stay, and complications can have a positive impact and increase margins.

The Importance of Economics: Revenue, Volume, and Cost

Revenue. Reimbursement, policies, and coverage by healthcare payers, such as Medicare and private insurers, play a crucial role in the economics of any structural heart program. Adequate reimbursement is essential for hospitals to adopt and sustain structural heart programs. Depending on payer type and geographic location, reimbursement rates can vary. Reimbursement structures influence the use of cardiovascular procedures, and geography alone results in differences in reimbursement.

Volume. Of course, volumes are important when calculating revenue for a program. Market analysis can be a valuable tool for predicting procedural volumes. Doing a market analysis can assist in analyzing demographic data and can help predict the prevalence of aortic disease in the hospital's primary and secondary service areas. Understanding the aging population or the increase in risk factors for valve disease can contribute to the demand for specific structural heart procedures. Likewise, it is important to understand the competitive landscape of who the providers are and the market share they are capturing. Economic conditions, including income levels and healthcare expenditure, can influence affordability and demand for medical procedures and need to be considered as a potential impact on volumes.

Cost. The chief drivers of costs include management of in-hospital complications, device price, labor, and length of stay (LOS), with device price as the majority of that cost. For example, the cost of prosthetic valves can be anywhere from $30 to $35K in comparison to surgical aortic valve replacement (SAVR) bioprosthetic valve costs around $5.5K or less. What has impacted the cost of the valves for TAVR procedures is the lack of manufacturers in the market that include valves manufactured by Edwards Lifesciences, Medtronic, and Boston Scientific. Until the FDA approves new manufacturers, there is minimal competition and little market pressure to reduce prices.

Since the first structural heart procedure was performed more than 15 years ago, many proceduralists have adopted a minimalist, percutaneous coronary intervention (PCI)-like approach. The main aspects of the minimalist approach include the performance of the procedure under conscious sedation, the use of percutaneous access, the use of left ventricle guidewire pacing instead of transvenous pacing, predilatation of the valve only on selected cases, no intensive care unit monitoring after the procedure, and even same-day or next-day discharge.[6] The minimalist approach is associated with a decrease in the total hospital stay and costs related to hospitalization. The reduction of post-procedure LOS presents considerable opportunities for all structural heart programs, regardless of procedural volumes, to curb costs and decrease the intensity of health resource utilization. Fortunately, the overall incidence of complications has decreased significantly as a result of an increase in experience treating these patients, use of cardiac CT as the main imaging modality for evaluation, significant technological advancements in the design of the prostheses, and decrease in the size of the sheaths.

Final Considerations

When starting a new program, administrators need to be aware of the current Centers for Medicare and Medicaid (CMS) regulations for the various structural heart procedures for new programs, as well as any state regulatory requirements. It is also imperative to keep in mind that societal recommendations call for the program to have a multidisciplinary team that includes an interventional cardiologist, cardiac surgeon, echocardiographic and radiographic image specialist, clinical cardiology valve expertise, heart failure specialist, cardiovascular anesthesiologist, nurse practitioner/physician assistant for pre, peri, and post-procedural care, valve coordinator/program navigator, institutionally supported data manager for the Society for Vascular Surgery Transvalvular Therapy (SVS TVT) registry, and hospital administration representative.[7]

Building a structural heart program is challenging and is fraught with many considerations, including the initial financial investment and resource allocation, staff training and education, and regulatory requirements. The endeavor will require the collaboration of the entire team, ongoing education, and a continuous commitment to providing the utmost in quality patient outcomes. How should a hospital evaluate if it is feasible to move forward with a structural heart program or even a TAVR program? In order to reach a "Go" or "No-Go" decision, many factors discussed above need to be determined. Implementing and offering structural heart procedures requires capital outlay, as modern technologies come with increased expense. New manufacturers entering the market will eventually assist in decreasing device costs and paired with hospital operational efficiencies, will help offset some of the overall costs. Still, the challenge for any organization will be to provide a supportive case that makes offering these revolutionary procedures financially feasible. ■

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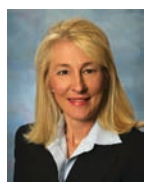

Corazon has assisted many hospitals in determining whether a structural heart program is a feasible proposition and has assisted hospitals with successful program implementation ensuring a comprehensive analysis that considers clinical, operational, financial, and regulatory aspects, ultimately optimizing the hospital's ability to provide advanced cardiac care. To learn more, visit www.corazoninc.com or call (412) 364-8200.

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