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EXPERT CONSENSUS SYSTEMS OF CARE DOCUMENT

2019 AATS/ACC/ASE/SCAI/STS expert consensus systems of care document: A proposal to optimize care for patients with valvular heart disease

A Joint Report of the American Association for Thoracic Surgery, American College of Cardiology, American Society of Echocardiography, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons

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PREAMBLE

This statement was commissioned as a Multisociety Expert Consensus Systems of Care Document by the American Association for Thoracic Surgery (AATS), American College of Cardiology (ACC), American Society of Echocardiography (ASE), Society for Cardiovascular Angiography and Interventions (SCAI), and Society of Thoracic Surgeons (STS). Expert Consensus Systems of Care Documents are intended to summarize the position of these partnering organizations on the availability, delivery, organization, and quality of cardiovascular care, with the intention of establishing appropriate benchmarks. These Systems of Care Documents are overseen by the ACC Task Force on Health Policy Statements and Systems of Care.

With the rapid evolution and dissemination of transcatheter technologies, as well as advances in surgical repair and valve replacement techniques, there is an imperative for the cardiovascular community to establish the provider, institutional, and systems-based standards for delivery of high-quality valvular heart disease (VHD) care. The AATS, ACC, ASE, SCAI, and STS have, therefore, joined together to provide expert consensus and, wherever feasible, evidence-based recommendations for systems of care related to VHD, in the spirit of ensuring access to quality outcomes. The writing group anticipates that future updates to this consensus statement will be necessary as newer imaging and treatment technologies become available and more data are generated regarding patient outcomes, cost, and cost-effectiveness.

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1 | INTRODUCTION

1.1 | Background

In the past decade, the evaluation and management of patients with VHD has changed dramatically. Advances in noninvasive imaging have enabled reliable, reproducible, and objective measurements of valve disease severity, along with an appreciation of any associated hemodynamic and structural consequences. There is enhanced

understanding of the natural history of VHD based upon longitudinal studies of large numbers of patients that have correlated outcomes with noninvasive measurements as well as with data obtained during exercise testing. Advances in surgical techniques, especially those associated with valve repair; improved operative results; and perioperative management strategies have contributed substantially to better patient outcomes. Transcatheter aortic valve replacement (TAVR) has revolutionized the treatment of patients with symptomatic, severe aortic stenosis (AS) and now provides a less-invasive treatment option for many eligible patients. Transcatheter repair of mitral regurgitation (MR) with an edge-to-edge clip device occupies a specific treatment niche currently, and more options for this valve lesion are anticipated in the near future. Transcatheter mitral valve replacement (TMVR) is the subject of intense investigation, and tricuspid valve interventions in high-surgical-risk patients are being developed. Collectively, these advances have led to an increasing number of treatment options, lower thresholds for and earlier timing of intervention, and the provision of less-invasive therapies to an older, sicker, and more frail population.[1,2] As the number and complexity of VHD treatment options have expanded, expert clinical judgment from an experienced multidisciplinary team (MDT) has assumed increasing importance.

The number of patients with significant VHD who could benefit from appropriate intervention increases as a function of age. The elderly are the fastest growing segment of the U.S. population. Estimates of the prevalence of moderate or severe aortic or mitral disease in U.S. patients over the age of 75 years approach 4% and 10%, respectively.[3] The prevalence of moderate or severe VHD in a large-scale community screening program of patients over age 65 years in the United Kingdom exceeded 11%, with a projected doubling before 2050.[4] The number of patients who will be eligible for TAVR is estimated to increase fourfold over the next 5 years.[5,6] Accordingly, implementation of optimal treatment strategies for patients with VHD will affect a sizable portion of the population.[7] Access to appropriate care is critical, but as the complexity and cost of diagnosis and treatment continues to increase, it will not be feasible for all institutions to provide the full complement of resources and clinical experts necessary to care for the full spectrum of patients with VHD, while also ensuring the highest-quality outcomes.

1.2 | Statement of the problem

Providing optimal care to patients with VHD is an increasingly complex process, starting with early recognition and diagnosis at the primary care/general cardiology level and including appropriate timing of referral for further evaluation and management, MDT assessment, shared decision-making, and long-term follow-up. In the past, intervention for VHD was often delayed until the onset of severe symptoms. It is now recognized that the longstanding effects of VHD can lead to irreversible changes in left ventricular (LV) function, repeated hospitalizations, patient morbidity (e.g., atrial fibrillation, heart failure, endocarditis), reduced quality of life (QOL), and premature mortality, which can often be prevented by earlier treatment. However, prior studies estimated that nearly 30–50% of patients with severe VHD who met guideline criteria for intervention were not appropriately recognized or referred,[8–11] even in highly resourced environments.[7,12]

There are an increasing number of treatment options available to patients with VHD; yet, not all patients are aware of or have access to the full spectrum of interventions. For most patients with severe primary MR, for example, it is well-recognized that mitral valve repair is superior to mitral valve replacement.[13–15] However, repair rates for primary MR vary significantly among individual surgeons and across institutions.[16–20] Although repair rates for primary MR have increased,[21–24] there remains concern that many patients with anatomy amenable to repair instead undergo valve replacement, with adverse downstream consequences related to LV dysfunction and the presence of valve prostheses. Similarly, some patients with symptomatic severe AS, as well as their providers, may not be aware that they would be eligible for TAVR due to the lack of a system of care that might enable them to access comprehensive MDT consultation with all treatment options being considered. Alternatively, TAVR may be inappropriately recommended when surgical aortic valve replacement (SAVR), sometimes in combination with aortic or coronary bypass surgery, would be a better option. Patients and referring providers may be unaware of specific physician competencies or experience, center volumes, structure, processes, or outcomes. Other less-invasive procedures for selected valve-related problems may be performed only at certain institutions, such as percutaneous closure of paravalvular leaks, alternative-access TAVR, and valve-in-valve procedures for degenerated surgical bioprostheses. Ideally, personnel and resource restrictions at one institution should not negate the opportunity for referral to another with a wider array of services and a more established MDT.

1.3 | Purpose of the document

The intent of this document is to propose a system of care for patients with VHD, the primary goal of which would be to optimize outcomes for all patients and ultimately improve the care of VHD at all centers. This approach is intended to increase the identification of patients with VHD and emphasize best practices as captured in the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease[2] and the 2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease.[25] It is also intended to promote the efficient utilization of resources, facilitate communication and continuity of care, and emphasize the need for transparency in reporting of and accountability for outcomes relative to national benchmarks. The standards proposed for the optimal structure and function of valve centers, as well as key processes of care, mirror those in a companion 2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Aortic Valve Replacement document. An interconnected system of providers and institutions may help strike the right balance between access and quality outcomes. The case for centers with the ability to offer more comprehensive care is logical, but it is critically important that patients and referring clinicians be made aware of the quality of care delivered in all centers. A major priority in optimizing VHD patient care is to identify and support centers with excellent outcomes and improve outcomes at centers where opportunities exist, not simply to promote those centers with good reputations or large procedural volumes.

A systems approach to the management of patients with VHD could help promote care among centers in a manner analogous to those adopted for the management of other medical and surgical disorders such as stroke and trauma,[26,27] thereby improving outcomes. On the basis of experience in other disciplines, this proposal includes the adoption of two tiers of valve centers, namely comprehensive (Level I) and primary (Level II) valve centers, the attributes of which should be defined by objective criteria (Figure 1). The intent is not to limit the number of centers per se but rather to set performance and quality goals for a valve center to meet benchmarks to be considered either comprehensive or primary in a manner that would be more objective than simple self-designation. The guiding principle in such a model would be to optimize the care of the individual patient by ensuring access to the right care in the right place at the right time, while promoting shared decision making (SDM) and respecting individual values and preferences. This principle can be applied to the clinician who must identify the presence of potentially important VHD, to the primary center providing local care for several conditions, and to the comprehensive center offering the full spectrum of services. Any such system of care should allow patients to be cared for at the appropriate level, promote seamless transitions between different levels of care when necessary, and place a premium on communication and shared learning. Patients with VHD should be informed of their treatment options, including those not routinely offered locally or through their health plan, and be given the opportunity to pursue alternatives according to their own expectations and preferences. The geographical, cultural, and financial barriers to establishing a system of care are recognized; yet the rational dissemination of complex care models founded on the principle of highest-quality outcomes that matter to patients remains an important goal.

1.4 | Elements of the model

Knowledge of VHD pathophysiology and natural history, the essentials of patient assessment, and the range of available treatment options is expected across all levels of providers. Current knowledge and performance gaps around recognition and treatment relate to the decline in physical examination skills and a lack of appreciation of the improvement in outcomes seen in patients previously deemed too ill or frail for intervention. It is the responsibility of professional societies and individual valve centers to provide education, support, and guidance for the appropriate management of VHD patients and to minimize any such gaps. Many sections of the 2014 AHA/ACC Guidelines for the Management of Patients with Valvular Heart Disease and its 2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease are a resource for the primary care physician/general cardiologist. In addition, there are several ongoing ACC efforts to provide concise and relevant tools for VHD patient diagnosis and treatment, including the Managing Aortic Stenosis and Emerging Mitral Regurgitation Clinical Care initiatives.

The proposed system of care would typically begin at the local level, with community providers and primary (Level II) valve centers communicating openly and collaborating with a comprehensive (Level I) center (Figure 1). Ideally, patient movement within such a system would be predicated on the desire to match the complexity of disease with the appropriate resources while placing a premium on maintaining relationships between patients and their longstanding healthcare providers.

For example, there are patients with primary MR who might benefit from referral to the highest level of VHD care. Patients with severe primary MR may have complex valve pathology that makes durable surgical repair technically challenging, such as anterior leaflet or bileaflet disease, Barlow's disease, or extensive annular or subvalvular calcification. The decision to operate on an asymptomatic patient with severe primary MR and preserved LV and systolic function is complex and hinges critically on the likelihood of a successful, durable repair in the hands of an experienced mitral surgeon working in collaboration with intraoperative echocardiographic imaging experts.[1,2,17] In addition, the successful management of atrial fibrillation at the time of mitral valve surgery may require comprehensive approaches to ablation that are not widely practiced.

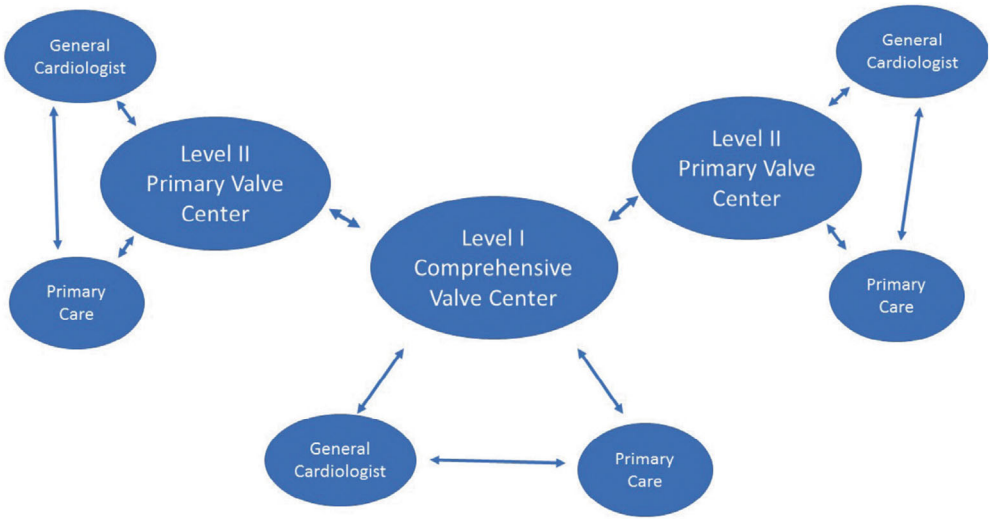

FIGURE 1 Relationships among primary care clinicians, general cardiologists, and valve centers

The management of patients with AS should also be considered in the context of the appropriate level of care within an organized system. Transfemoral TAVR has become available in over 580 sites in the United States, but there remain nearly as many centers that only offer SAVR. Hence, access to TAVR technology, when considered preferable to operative intervention, may require directed referral to a partner institution or center. Patients who are not candidates for transfemoral TAVR may benefit from alternate access techniques, which might not be available at all TAVR sites. It is well-documented that the results of SAVR vary across sites.[28,29] The optimal performance of aortic valve surgery in some patients may require additional operative techniques. Patient-prosthetic mismatch is not uncommon in small patients who may receive small valves, resulting in compromised long-term outcomes. The expertise to perform more-complicated operations, including aortic valve repair, valve-sparing root reconstruction, root enlargement, composite valve graft replacement, ascending aortic/hemi-arch replacement, and myectomy for subvalvular obstruction, is not widespread, underscoring the need for a system of care that facilitates triaging such patients to the appropriate level.

It is important that centers designated as having VHD expertise not only perform certain procedures, but also have MDTs capable of assessing and managing patients according to evidence-based guidelines while emphasizing SDM. The MDT and the valve center are responsible for maintaining performance standards and improving quality. Communication between centers and among referring providers is essential for fulfilling these responsibilities. Public reporting is a critical part of the continuous quality improvement process, and risk-adjusted results should be made available to referring physicians, patients, and families.

2 | METHODS

The ACC convened the Evolving Valve Management Strategies Roundtable in December 2016. The Roundtable was a multidisciplinary effort to facilitate the identification of gaps and challenges in the care of patients with VHD and a component of the ACC's Succeed in Managing Heart Disease Initiative. Multiple medical and surgical subspecialty stakeholders and advanced practice clinicians participated in the Roundtable. Also participating were representatives of government (i.e., premarket and postmarket divisions of the Food and Drug Administration, Centers for Medicare and Medicaid Services, and National Institutes of Health), industry, integrated health systems, and patient groups, as well as systems of care experts from other specialties (stroke). The discussions identified support for the goals of providing patients with VHD access to an integrated system of care delivery, ensuring rigorous quality assessment and improvement, and focusing on patient-centered outcomes. As a result of these discussions, a writing committee was formed to create a proposal outlining the structure, processes, and essential components of an integrated system of care for VHD patients.

The writing committee was composed of representatives from the AATS, ACC, ASE, SCAI, and STS. Existing organized and tiered systems of care for the treatment of several other acute disorders (trauma, stroke, S-T segment elevation myocardial infarction [STEMI]) and nonacute (bariatric surgery, cancer) were reviewed by the committee. A leading member of the Brain Attack Coalition had previously presented the elements of that system to the Roundtable. Where appropriate, the writing committee referred to multisocietal recommendations for operator and institutional procedural volumes, infrastructure, personnel, and reporting requirements. This document was built upon the 2014 AHA/ACC Guidelines for the Management of Patients with Valvular Heart Disease and its 2017 Focused Update, as well as other ACC documents, including the 2017 ACC Expert Consensus Decision Pathway for Transcatheter Aortic Valve Replacement, the 2017 ACC Expert Consensus Decision Pathway for Mitral Regurgitation, the ACC/AATS/AHA/ASE/EACTS/HVS/SCA/SCAI/SCCT/SCMR/STS 2017 Appropriate Use Criteria for the Treatment of Patients With Severe Aortic Stenosis, and the 2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Aortic Valve Replacement.[30–34]

The format was based on the Donabedian model, which incorporates: (a) structure; (b) process; and (c) outcomes. The financial and political implications of developing a system of care for VHD patients were discussed, taking into account the tension between: (a) patient access to highly impactful yet expensive technology; and (b) the need to ensure highest-quality outcomes while minimizing cost, risks, and any potential unintended consequences.

The work of the writing committee was supported exclusively by the without commercial support. Writing committee members volunteered their time to this effort. Conference calls of the writing committee were confidential and attended only by committee members and society staff. A formal peer review process was completed consistent with ACC policy and included expert reviewers nominated by the ACC (see Appendix C). A public comment period was also provided to obtain additional perspective. Following reconciliation of all comments, this document was approved for publication by the ACC Clinical Policy Approval Committee, the AATS Council, the ASE Board of Directors, the SCAI Board of Directors, and the STS Executive Committee of the Board of Directors.

3 | HISTORICAL PERSPECTIVE FROM OTHER PROGRAMS

Organized and tiered systems of care in other areas of medicine have been developed and embedded in the complex and large U.S. healthcare system. Often a key question is: what should constitute the designation of a center within a system as specialized and comprehensive? Examples of requirements for such a designation are available in multiple areas of medicine, both for acute problems (stroke, trauma, and myocardial infarction) and selected chronic disorders (bariatric surgery for obesity, adult congenital disease, pulmonary hypertension) (Table 1). Each system is different in terms of its intent and outcome; however, each is an organized and tiered system of care. These systems also differ with respect to accreditation and designation within a tiered structure. While this review focuses on specialized centers of care, there is no intent to diminish the important

TABLE 1 Comprehensive/advanced care centers in other areas of medicine

	Cancer	Trauma	Stroke	Bariatric surgery	STEMI
Year initiated	1960	1976	2001	2005	2006/2007
Sponsoring organization	National Institutes of Health	American College of Surgeons	Brain Attack Coalition	American Society of Bariatric Surgery American College of Surgeons	American College of Cardiology (D2B Alliance) American Heart Association (Mission: Lifeline)
Levels of care	Basic Laboratory Cancer Center Cancer Centers Comprehensive Cancer Center	Level I Level II Level III Level IV	Acute Stroke-Ready hospital Primary Stroke Center Comprehensive Stroke Center	Bariatric Surgery Center of Excellence	STEMI-referral hospital (non-PCI capable) STEMI-receiving hospital (PCI-capable)

D2B: Door to Balloon; PCI: percutaneous coronary intervention; STEMI: ST-segment elevation myocardial infarction.

role played by clinicians at the primary care level who are responsible for initial recognition and triage of patients with VHD.

The first U.S. Cancer Centers were established in 1960 by the National Institutes of Health, with the objective of addressing research and training.[35] Currently, there are 70 specialized cancer centers across 35 states. Motivated by the wide variability in the quality of care and the disparate outcomes of patients with traumatic injuries, the American College of Surgeons published a statement in 1976[36] describing three tiers of trauma centers with graded infrastructure, personnel requirements, and site visits by an accreditation body. They proposed a coordinated network of centers, in which seriously injured patients could be transferred to a regional center with the highest available density of expert trauma services. The development of this network of specialized trauma centers has been associated with improved patient outcomes in both urban and rural areas.[37,38]

Inspired by the successful outcomes achieved by the implementation of trauma centers, the Brain Attack Coalition proposed and implemented the establishment of multidisciplinary acute stroke centers. The Coalition has defined the components of Primary and Comprehensive Stroke Centers and of Acute Stroke-Ready Hospitals.[26,39,40] This initiative established the foundation for accreditation of stroke centers. Based on the Brain Attack Coalition recommendations, different organizations (the Joint Commission, Det Norske Veritas Germanischer Lloyd, and Health Care Facilities Accreditation Program) have developed certification programs to recognize hospitals possessing the required infrastructure and personnel to best treat patients with stroke.

Variability in surgical outcomes prompted the American Society of Bariatric Surgery and the American College of Surgeons to designate centers of excellence to standardize care and ensure high-quality management of morbidly obese patients undergoing weight reduction surgery.[41] Similar to stroke centers, bariatric surgery centers participate in an accreditation process that was introduced to ensure that quality metrics are met.

For patients with cardiovascular disease, the development of local networks to streamline and improve the treatment and outcomes of patients with acute STEMI spread widely in response to the recognition that reperfusion times were often inappropriately prolonged.[42] To ensure the provision of optimal care, networks for patients with chronic cardiovascular diseases have also been established. For example, in the United Kingdom's National Health Service, congenital heart disease care has been redirected; three tiers of care, ranging from local to specialist surgical centers, have been organized to provide different levels of care according to patient need.[43] In the United States, adult congenital heart disease centers (https://www.achaheart.org/provider-support/accreditation-program) as well as pulmonary hypertension centers (https://phassociation.org/phcarecenters/medical-professionals/center-criteria/) have been formally designated after meeting rigorous requirements upon external review. The European Society of Cardiology has issued a position paper on heart valve centers that mandates evaluation and care for all patients with VHD by dedicated physicians working in specialized environments.[44]

The aforementioned initiatives have had several effects, including: (a) increased access to high-quality care due to awareness of a system that designates centers as having met criteria (including quality metrics) for accreditation; (b) reduced mortality for trauma patients[45]; (c) decreased mortality and improved rates of timely tissue plasminogen activator (tPA) administration/mechanical reperfusion in appropriate patients with ischemic stroke[34,46]; (d) improved safety and reduced costs for patients undergoing bariatric surgery[47,48]; (e) improved guideline-directed therapy and outcomes in patients with STEMI[49]; and (f) recognition-based external accreditation using objective criteria and periodic reviews.

4 | PROPOSED STRUCTURE FOR AN INTEGRATED MODEL OF CARE FOR PATIENTS WITH VHD

4.1 | Underlying principles

The development of an integrated model of care for patients with VHD is based on the concept of a graduated system in which the first tier has the critical function of recognition and consideration of referral. Subsequently, the patient is matched on the basis of disease complexity with the required center expertise, experience, and availability of resources. The following principles are emphasized:

- The primary goal is to improve the care of all patients with VHD.
- The first step is recognition and subsequent diagnosis of VHD, usually by a primary care physician, advanced practice provider, or general cardiologist.

- The second step often involves referral to a local general cardiologist who can further refine the diagnosis, initiate medical therapy as indicated, and identify those who can be managed for the time being without further intervention or who may need more specialized care such as surgery or transcatheter valve repair or replacement.
- Access to specialized care requires establishment of well-defined referral lines to centers having graduated levels of expertise and resources (Figure 1). Increasing disease complexity often requires higher-order, comprehensive care at a Level I center, whereas less complex disease can be managed at a Level II center.
- A Multidisciplinary Team (MDT) and an emphasis on patient shared decision-making are essential to the operations of both Level I and II valve centers.
- Full institutional support is required for provision of appropriate imaging and procedural resources, equity among the individual stakeholders of the MDT, care pathways that span the continuum, registry participation, and results reporting.
- Transparency, public reporting, mandatory participation in national registries, ongoing analysis of processes and outcomes, and a commitment to research are essential.
- Bidirectional communication and ongoing education of members of the MDT and the community of referring providers/centers are required to improve the quality of care in all settings.
- Processes of care should emphasize informed consent (information provided in various formats and languages), SDM, patient experiences, and individual choices.

4.2 | Role of the primary care clinician

By combining patient evaluations (history, physical examination, electrocardiogram, laboratory studies) with appropriate utilization of echocardiography,[50] primary care and practice-level clinicians play a vital gatekeeper role within a system of care for VHD. Approximately 70% of all echocardiograms performed in Medicare beneficiaries are ordered by a noncardiologist provider.[51] When significant VHD is suspected or confirmed, most patients should be referred to a local or regional cardiovascular specialist for further evaluation and management. The role of the primary care provider in recognizing VHD symptoms, initiating diagnostic testing, referring for specialized care, and establishing patient expectations cannot be overemphasized. It is also recognized that referral for specialized care may not be appropriate for certain patients. Therefore, defined pathways for patient referral that incorporate bidirectional communication between primary and subspecialty providers should be created. As the breadth of diagnostic approaches to VHD continues to expand (e.g., cardiac magnetic resonance, computed tomography [CT], 3-dimensional [3D] echocardiography, strain imaging), and as surgical and catheter-based treatment options continue to evolve, educational programs directed at the primary care provider assume increasing importance.[11]

Although electronic medical record systems have improved the communication of personal health information between primary and subspecialty care providers, the systematic integration of imaging data has generally not kept pace. A principal component of a well-designed system of care for VHD would be secure access to digital data of any diagnostic imaging procedure performed. This access would accelerate appropriate patient referrals, limit the need for repeat diagnostic procedures, and provide a platform to facilitate feedback on image quality. The roles of brief, simple, handheld echocardiographic scans during physical examinations (supported by machine learning algorithms to identify the potential need for a more detailed study) and alert notifications (e.g., suggesting referral to a specialist) on noninvasive imaging reports should also be considered.

4.3 | Comprehensive (level I) and primary (level II) valve centers

The proposed integrated model for a VHD system of care is shown in Figure 1. A Comprehensive (Level I) Valve Center should have the resources and capabilities to evaluate and perform all commercially approved interventional and surgical procedures. A Level I center should also have advanced imaging modalities (e.g., 3D echocardiography, cardiac magnetic resonance) that may not be available at a Level II center. A Primary (Level II) Valve Center should have, at a minimum, the expertise and resources to perform transfemoral TAVR and surgical procedures such as isolated SAVR. The ability to perform a durable mitral valve repair in patients with primary MR due to posterior leaflet pathology is desirable but not mandatory for a center to be defined as a Primary (Level II) Valve Center. If complex valve procedures are performed at the Primary (Level II) Valve Center, the same performance standards and expected outcomes as at a Comprehensive (Level I) Valve Center should be achieved. Patients can enter the system from multiple pathways. Each system of care should develop its own criteria for communication, feedback, and transfer. Level I and II Valve Centers should utilize the results of testing performed at referring practices and centers. Facilitation of long-term care of patients at the local level is of critical importance.

The following sections of the document provide recommendations for Level I and II Valve Center designations in relation to: (a) structure; (b) process; and (c) outcomes. "Structure" consists of institutional facilities and infrastructure, personnel, and types of procedures. "Process" comprises the requirements and function of the MDT, including its participation in registries, research, and education. Finally, "outcomes" consists of a combination of the number of procedures performed and procedural success, morbidity, mortality, and QOL after intervention.

5 | STRUCTURE

5.1 | Structural requirements of all advanced valve centers

Table 2 lists the recommended minimum procedural, institutional, and infrastructural requirements for the two levels of valve centers. Additional procedures may be performed at each center but are not required. Table 3 lists additional procedures that are not included in Table 2 but may be of benefit to selected subsets of patients with VHD. The major distinction between centers resides chiefly in the

TABLE 2 Structure of valve centers

Comprehensive (level I) valve center	Primary (level II) valve center
Interventional procedures[a]	
TAVR-transfemoral	TAVR-transfemoral
Percutaneous aortic valve balloon dilation	Percutaneous aortic valve balloon dilation
TAVR-alternative access, including transthoracic (transaortic, transapical) and extrathoracic (e.g., subclavian, carotid, caval) approaches	
Valve-in-valve procedures	
Transcatheter edge-to-edge mitral valve repair	
Paravalvular leak closure	
Percutaneous mitral balloon commissurotomy	
Surgical procedures[a]	
SAVR	SAVR
Valve-sparing aortic root procedures	
Aortic root procedures for aneurysmal disease	
Concomitant septal myectomy with AVR	
Root enlargement with AVR	
Mitral repair for primary MR	Mitral repair for posterior leaflet primary MR[b]
Mitral valve replacement[c]	Mitral valve replacement[c]
Multivalve operations	
Reoperative valve surgery	
Isolated or concomitant tricuspid valve repair or replacement	Concomitant tricuspid valve repair or replacement with mitral surgery
Imaging personnel	
Echocardiographer with expertise in valve disease and transcatheter and surgical interventions	Echocardiographer with expertise in valve disease and transcatheter and surgical interventions
Expertise in CT with application to valve assessment and procedural planning	Expertise in CT with application to valve assessment and procedural planning
Interventional echocardiographer to provide imaging guidance for transcatheter and intraoperative procedures[52]	
Expertise in cardiac MRI with application to assessment of VHD	
Criteria for imaging personnel	
A formalized role/position for a "valve echocardiographer" who performs both the preprocedural and postprocedural assessment of valve disease	A formalized role/position for a "valve echocardiographer" who performs both the preprocedural and postprocedural assessment of valve disease
A formalized role/position for the expert in CT who oversees the preprocedural assessment of patients with valve disease	A formalized role/position for the expert in CT who oversees the preprocedural assessment of patients with valve disease
A formalized role/position for an interventional echocardiographer	
Institutional facilities and infrastructure	
MDT (Table 3)	MDT (Table 3)
A formalized role/position for a dedicated valve coordinator who organizes care across the continuum and system of care	A formalized role/position for a dedicated valve coordinator who organizes care across the continuum and system of care
Cardiac anesthesia support	Cardiac anesthesia support
Palliative care team	Palliative care team
Vascular surgery support	Vascular surgery support
Neurology stroke team	Neurology stroke team
Consultative services with other cardiovascular subspecialties (see Section 5.2.4)	
Consultative services with other medical and surgical subspecialties (see Section 5.2.4)	
Echocardiography-3D TEE; comprehensive TTE for assessment of valve disease	Echocardiography-comprehensive TTE for assessment of valve disease
Cardiac CT	Cardiac CT
ICU	ICU
Temporary mechanical support (including percutaneous support devices such as intra-aortic balloon counterpulsation, temporary percutaneous ventricular assist device, or ECMO)	Temporary mechanical support (including percutaneous support devices such as intra-aortic balloon counterpulsation, temporary percutaneous ventricular assist device, or ECMO)
Left/right ventricular assist device capabilities (on-site or at an affiliated institution)	
Cardiac catheterization laboratory, hybrid catheterization laboratory, or hybrid OR laboratory[d]	Cardiac catheterization laboratory
PPM and ICD implantation	PPM and ICD implantation
Criteria for institutional facilities and infrastructure	
IAC echocardiography laboratory accreditation	IAC echocardiography laboratory accreditation
24/7 intensivist coverage for ICU	

AVR: aortic valve replacement; CT: computed tomography; ECMO: extracorporeal membrane oxygenation; IAC: Intersocietal Accreditation Commission; ICD: implantable cardioverter defibrillator; ICU: intensive care unit; MDT: multidisciplinary team; MR: mitral regurgitation; MRI: magnetic resonance imaging; OR: operating room; PPM: permanent pacemaker; SAVR: surgical aortic valve replacement; TAVR: transcatheter aortic valve replacement; TEE: transesophageal echocardiography; TTE: transthoracic echocardiography; VHD: valvular heart disease.

[a]A Primary (Level II) Center may provide additional procedures traditionally offered at a Comprehensive (Level I) Center as long as the criteria for competence and outcomes are met.

[b]If intraoperative imaging and surgical expertise exist.

[c]If mitral valve anatomy is not suitable for valve repair.

[d]Equipped with a fixed radiographic imaging system and flat-panel fluoroscopy, offering catheterization laboratory-quality imaging and hemodynamic capability.

TABLE 3 Additional possible catheter-based therapies at level I centers

Left atrial appendage closure
ASD or VSD closure
Alcohol septal ablation
Mitral valve replacement, mitral valve repair with techniques other than edge-to-edge clip system (currently investigational devices)
Tricuspid valve repair
Pulmonary balloon valvotomy or valve replacement

ASD: atrial septal defect; VSD, ventricular septal defect.

broader spectrum of services and higher density of expert personnel available at the Level I (Comprehensive) Center.

5.2 | Structural components of advanced valve centers

5.2.1 | Transcatheter treatments

Interventional cardiologists and cardiac surgeons at Comprehensive (Level I) and Primary (Level II) Valve Centers should have the expertise in catheter-based techniques necessary for evaluating and managing VHD. These include invasive hemodynamic assessment of VHD, coronary angiography and intervention, and peripheral vascular angiography and intervention. Additional expertise for the interventionalist at a Comprehensive (Level I) Valve Center includes atrial septal puncture and percutaneous closure of atrial septal defects. Proceduralists at all centers must be able to prevent, recognize, and treat complications and be skilled in coronary and peripheral vascular rescue and retrieval techniques (e.g., use of snares and forceps) for embolized devices; pericardiocentesis; and vascular access management, including use of covered endovascular stents. Collectively, these skills provide necessary support for catheter-based valve therapies. Beyond technical and procedural skills, the valve interventionalist must also develop expertise related to patient selection, including knowledge of the natural history of VHD, optimal timing for interventions, appropriate judgment about anticipated risks and benefits of an intervention, and the ability to determine the appropriate therapy for a specific pathology. These physicians should have the knowledge and skills to participate in SDM with patients and families.

The interventional procedural requirements for Comprehensive (Level I) and Primary (Level II) Valve Centers are outlined in Table 2. Proceduralists at both Comprehensive (Level I) and Primary (Level II) Valve Centers should be able to perform TAVR using a transfemoral approach and percutaneous balloon aortic valve dilation.

Comprehensive (Level I) Valve Centers should also have the personnel and facilities to perform alternative-access (nontransfemoral) site TAVR, including transthoracic and extrathoracic approaches. The additional expertise and procedural volumes at a Comprehensive (Level I) Valve Center would be expected to reduce the risk of complications related to nonfemoral access. Valve-in-valve procedures for degenerated aortic and mitral bioprosthetic valves should be available at a Comprehensive (Level I) Valve Center. Selected operators at a Comprehensive (Level I) Valve Center should be proficient in performing transcatheter mitral valve repair using the edge-to-edge technique, as well as percutaneous mitral balloon commissurotomy. Percutaneous closure of paravalvular leaks should be offered by the Comprehensive (Level I) Valve Center. Other procedures might be performed by the Comprehensive (Level I) Valve Center, such as left atrial appendage occlusion, complex septal defect closures, and alcohol septal ablation. Emerging therapies, including transcatheter mitral valve replacement, next-generation transcatheter mitral valve repairs, and tricuspid valve procedures, are not required but will likely be performed at a Comprehensive (Level I) Valve Center participating in ongoing investigational device studies. If a Primary (Level II) Center offers additional procedures that might traditionally be provided at a Comprehensive (Level I) Center, the same quality and outcome reporting requirements should be maintained.

5.2.2 | Cardiac surgical procedures

Both Comprehensive (Level I) and Primary (Level II) Valve Centers are expected to perform isolated SAVR with or without coronary artery bypass grafting. A Comprehensive (Level I) Valve Center should have the personnel and resources for performing more complex surgical procedures to treat other subsets of patients with VHD. The benefit of performing these procedures at Comprehensive (Level I) Centers extends beyond merely technical expertise and higher volumes. The composition of the MDT, as well as infrastructural and institutional resources, can be leveraged to optimize decision making and clinical care and to strengthen clinical training around complex VHD patients. Advanced surgical expertise is required to perform complex aortic root procedures, including composite valve root replacement and valve-sparing root repair. A Comprehensive (Level I) Center should also house the surgical skill and resources to treat patients with complicated infective endocarditis. In patients with AS who have concomitant septal hypertrophy, a myectomy at the time of SAVR is sometimes necessary to prevent dynamic outflow tract obstruction. Root enlargement to allow for larger-sized prosthetic valves should be available for patients with small annulus sizes. Successful repair of mitral valve disease, including durable repair not only for primary MR involving the posterior leaflet, but also for anterior leaflet prolapse, bileaflet prolapse, and Barlow's disease, should be offered at the Comprehensive (Level I) Valve Center. Repair of posterior leaflet prolapse might also be offered at a Primary (Level II) Valve Center depending on the level of surgical and imaging expertise and experience. Surgical mitral valve replacement should be available at both Level I and II centers. Annuloplasty repair of tricuspid regurgitation is often a straightforward addition to mitral repair in appropriate patients. The evaluation and surgical management (repair or replacement) of severe, secondary MR with regional or global LV systolic dysfunction, however, can be challenging and, for some patients, may be more appropriate at a Level I Center. Multivalve operations (other than simple annuloplasty tricuspid repair added to mitral valve surgery), reoperative valve surgery, operations for prosthetic valve endocarditis, and hybrid transcatheter/surgical procedures are likely better suited for a Comprehensive (Level I) Valve Center.

5.2.3 | Imaging

Consistent, high-quality imaging and interpretation are critical to evaluation, management, and procedural guidance for patients with VHD. Accurate echocardiographic assessment of the etiology and severity of VHD is often the pivotal first step in management. Valve centers

require an echocardiographer with expertise in valve disease, which includes an understanding of pitfalls in assessing valve lesion severity; quantification of lesion severity; evaluation of complex, multivalve disease; determination of anatomic suitability and procedural success for both catheter-based and surgical procedures; and identification of postprocedural complications.

Although echocardiography is the primary imaging modality for assessing VHD, cardiac and vascular CT has become an indispensable tool for appropriate planning of transcatheter interventions. Cardiac magnetic resonance imaging is increasingly used to assess regurgitant lesion severity and ventricular function. High-quality CT image acquisition, postprocessing, and 3D reconstruction are minimum requirements. Accurate measurements of intracardiac and vascular access route dimensions are critical.

As treatment options rapidly expand for VHD, a new specialty of interventional echocardiography is emerging.[52] Interventional echocardiographers blend a sophisticated knowledge of echocardiography with clinical expertise and can help guide management decisions at the point of intervention. They have become integral to the high performance of any MDT, especially at Comprehensive (Level I) Centers. The interventional echocardiographer is a critical participant in select valve cases (e.g., transcatheter mitral valve repair and repair of paravalvular leaks). Effectiveness in this role requires an individual who has regular involvement in these procedures and thus is familiar with the devices and procedural steps, is competent to provide interventionalists with imaging guidance for transcatheter procedures, understands how echocardiography can help avoid or identify procedural complications, recognizes the unique echocardiographic characteristics of transcatheter devices and delivery systems, is proficient with 3D imaging, and understands the treatment goals of transcatheter valve procedures.

Although it is important that advanced imaging expertise be readily available at Comprehensive (Level I) and Primary (Level II) Valve Centers, personnel representing these imaging areas may vary between centers. Both cardiologists and cardiac anesthesiologists should have the knowledge and skills to perform and interpret procedure-based transesophageal echocardiograms, particularly if they are board certified in echocardiography. Cardiovascular imaging specialists provide advanced CT services in most institutions.

5.2.4 | Personnel, institutional facilities, and infrastructure

Complications are best managed, and outcomes optimized, by the provision of appropriate facilities and the timely availability of relevant support teams. Compliance with this basic principle requires an institutional commitment similar in scope to other interdisciplinary cardiovascular service lines such as heart transplantation and mechanical circulatory support programs. All centers should have a formal MDT composed of personnel with expertise in managing patients with VHD, including a dedicated valve program coordinator (Table 4). There should be a dedicated educational and support system that can help patients navigate the SDM process with educational aides to explain their options. Both Level I and II Valve Centers should have medical/interventional and surgical codirectors who are committed and trained to provide care to patients with VHD, as well as adequate numbers of cardiologists, interventionalists, surgeons, imagers, and anesthesiologists with expertise in cardiac valve disease. For patients presenting with heart failure due to LV systolic dysfunction and secondary MR, a heart failure specialist should be part of the MDT. Depending on the size of the program and its participation in research, advanced practice providers, nurses, and research coordinators may also play an important role in the MDT and care of patients. Other members of the care team could include geriatricians, physical therapists, palliative care experts, and social workers. Additionally, Level I and II Valve Centers should have an intensive care unit (24/7 intensivist coverage for a Level I Center), cardiac anesthesia, vascular surgery, cardiac electrophysiology services for pacemaker implantation, and the ability to provide temporary mechanical support. The Comprehensive (Level I) Center should have access to emergent neurology consultations (particularly stroke services), subspecialty cardiac services (expertise in areas such as congenital heart disease, pulmonary hypertension, and advanced heart failure), and consultative medical and surgical services (e.g., renal, gastrointestinal, endocrine, pulmonary, infectious disease). To facilitate alternative-access (nontransfemoral) TAVR and emerging mitral and tricuspid transcatheter therapies, a Comprehensive (Level I) Center should have a hybrid procedure room with high-quality fluoroscopic imaging, surgical-quality lighting, hemodynamic monitoring, an adequate number of display monitors, and adequate space and equipment for numerous personnel, temporary mechanical support, cardiopulmonary bypass, and rescue procedures. Access to a ventricular assist device program is required for a Comprehensive (Level I) Center, as certain high-risk procedures may result in significant ventricular dysfunction and hemodynamic deterioration. Finally, a Comprehensive (Level I) Center is required to provide a defined mechanism for timely case discussion and image sharing with Primary (Level II) Centers, general cardiologists and primary care providers.

TABLE 4 The multidisciplinary team—minimum requirements

• Interventional cardiologist
• Cardiac surgeon
• Echocardiographic and radiographic image specialist[a]
• Clinical cardiology valve expertise[a]
• Heart failure specialist[b]
• Cardiovascular anesthesiologist
• Nurse practitioner/physician assistant for preprocedural and periprocedural care and MDT consults
• Valve coordinator/program navigator
• Institutionally supported data manager for STS/ACC TVT Registry
• Hospital administration representative as necessary

ACC: American College of Cardiology; MDT: multidisciplinary team; STS: Society of Thoracic Surgeons; TAVR: transcatheter aortic valve repair; TVT: transcatheter valve therapy.
[a]A single individual may provide both clinical and imaging expertise.
[b]For patients with heart failure due to LV systolic dysfunction and secondary MR.

6 | PROCESS

6.1 | Process requirements for advanced heart valve centers

The process and functional requirements for Comprehensive (Level I) and Primary (Level II) Valve Centers are outlined in Table 5.

TABLE 5 Processes for valve centers

Comprehensive (level I) valve centers	Primary (level II) valve centers
Documentation of formal referral and clinical pathways across the continuum of care	
Documentation of communication pathways among level I, level II, and practice-level providers	
Multidisciplinary team	
All patients are evaluated by the MDT	All patients are evaluated by the MDT
The MDT educates patients regarding treatment recommendations, treatment options, and the use of an SDM process that incorporates patient preferences	The MDT educates patients regarding treatment recommendations, treatment options, and the use of an SDM process that incorporates patient preferences
The MDT meets on a regular basis (preferably each week) to review cases, reach consensus management decisions, review outcomes, and assess quality	The MDT meets on a regular basis (preferably each week) to review cases, reach consensus management decisions, review outcomes, and assess quality
Criteria/metrics	
Documentation of attendance at MDT meetings and recording of the discussion and decision-making process for cases presented	Documentation of attendance at MDT meetings and recording of the discussion and decision-making process for cases presented
Documentation of an action plan to address performance and quality areas needing improvement	Documentation of an action plan to address performance and quality areas needing improvement
Regular morbidity and mortality meetings	Regular morbidity and mortality meetings
Registry participation	
Participation in the STS/ACC TVT registry or other accepted national registries	Participation in the STS/ACC TVT registry or other accepted national registries
Participation in the STS ACSD or other approved surgical database	Participation in the STS ACSD or other approved surgical database
Criteria/metrics	
TVT registry • 95% completion of 30-day vital status • Of those alive, 85% completion of KCCQ at 30 days • 90% completion of 1-year vital status • Of those alive, 75% completion of KCCQ at 1 year • Overall meets STS/ACC TVT Registry performance metrics for completeness and accuracy with ≥2 consecutive quarters of green rating/year	TVT registry • 95% completion of 30-day vital status • Of those alive, 85% completion of KCCQ at 30 days • 90% completion of 1-year vital status • Of those alive, 75% completion of KCCQ at 1 year • Overall meets STS/ACC TVT Registry performance metrics for completeness and accuracy with ≥2 consecutive quarters of green rating/year
National surgical database participation that meets state requirements	National surgical database participation that meets state requirements
Surgical performance that meets STS 2- or 3-star rating criteria	Surgical performance that meets STS 2- or 3- star rating criteria
Research	
Participation in pivotal RCTs comparing devices or device with surgery (optional)	
Publication of single-center or multicenter patient outcome studies (optional)	
Education and shared decision making	
Continuing education of MDT members	Continuing education of MDT members
Education of patients and the public	Education of patients and the public
Documentation of participation with patients in SDM using objective and validated resources and decision aids	Documentation of participation with patients in SDM using objective and validated resources and decision aids
Training	
Structural interventional fellowship year (optional)	
Cardiac surgery training in interventional structural heart skills and procedures (optional)	
Advanced training in echocardiography cardiac CT and CMR for the evaluation of VHD and guidance of valve procedures (optional)	

ACC: American College of Cardiology; ACSD: Adult Cardiac Surgery Database; CMR: cardiac magnetic resonance; CT: computed tomography; KCCQ: Kansas City Cardiomyopathy Questionnaire; MDT: multidisciplinary team; RCT: randomized controlled trial; SDM: shared decision making; STS: Society of Thoracic Surgeons; TVT: Transcatheter Valve Therapy; VHD, valvular heart disease.

6.2 | Process components for advanced heart valve centers

6.2.1 | Function of the MDT

The MDT plays a critical role in the collaborative evaluation, management, and treatment of patients with VHD. Each member of the team brings a perspective and expertise that is fundamental to optimizing patient outcomes. Although the size and specific make-up of MDT teams may differ between Comprehensive (Level I) and Primary (Level II) Valve Centers, these teams are foundational to all activities undertaken in any center.

The composition of the MDT is addressed in Section 5.2.4 and Table 4. The MDT should meet regularly (preferably each week) to review cases, verify the results of imaging and other pertinent studies, reach consensus on patient management decisions, review outcomes, and assess quality. The patient's individual needs and preferences should be discussed. Ideally, this approach leverages the combined experience and expertise of the group and leads to more standardized and evidence-based decision-making. For patients presenting with heart failure due to LV systolic dysfunction and secondary MR, a heart failure specialist is needed to ensure that optimal medical therapy has been instituted prior to consideration of interventional treatments. Other members of the MDT, such as collaborators from geriatric medicine, nephrology, and neurology, should be involved as needed. Beyond simply recommending, for example, that a patient would be best treated with SAVR or with TAVR, these MDT meetings should also provide a forum for detailed procedural planning. Input from different team members provides the best opportunity to prevent or

reduce complications. The MDT is also charged with reviewing performance metrics, outcomes, quality, and external reporting. Attendance should be taken at these regular meetings, and the discussion and management decisions for each patient should be documented. An important aspect of these meetings is to support the interaction with patients in SDM using validated resources and decision aids to reach a final decision regarding therapy.[53]

Members of the MDT also function together during the performance of both surgical and interventional procedures. Many of the approved and emerging treatments for VHD require skillsets that extend beyond the expertise of a single individual or type of training. The norm for these procedures should be the interactive participation of multiple team members (surgeon, interventionalist, echocardiographer, and cardiac anesthesiologist, as appropriate) to reduce complications and optimize outcomes.

The MDT also analyzes and compares institutional STS/ACC TVT Registry data against national benchmarks and develops an action plan to improve performance and outcomes if necessary. In addition, a regular mortality and morbidity conference should be held to review adverse outcomes, provide feedback in a safe environment, educate all team members, and serve as a springboard to quality improvement. Conference attendance should be documented. Continuing medical and nurse education credits should be provided, some of which can also qualify for risk management to satisfy various state licensing requirements. Data entrants are expected to participate in the ongoing activities of the STS/ACC TVT Registry and STS ACSD, to enable accurate and timely reporting. Extending MDT discussions beyond a single institution, while maintaining patient privacy and provider security, may foster more rapid dissemination of best practices.

6.2.2 | Registry participation

Valve centers, MDTs, and professional societies need to develop and implement a scientifically rigorous approach for performance measurement and quality assessment. A commitment to programmatic quality improvement is essential. Valve centers performing TAVR must demonstrate active participation in the STS/ACC TVT Registry, with submission to the registry of all cases that use Food and Drug Administration-approved valve technology, including any off-label uses. Data reported to the STS/ACC TVT Registry and compared against national benchmarks will facilitate maintenance of a safe, efficient, and effective valve program. This process will in turn help maintain uniformity, consistency, quality control, and a level playing field. All Comprehensive (Level I) and Primary (Level II) Valve Centers must demonstrate that data submissions meet STS/ACC TVT Registry performance metrics for completeness and accuracy, with at least two consecutive quarters of green rating/year. Information on QOL and survival out to 1 year will be important.

For surgical procedures, participation in either the STS ACSD or another approved national surgical registry that produces nationally benchmarked, risk-adjusted outcomes is essential. If there are requirements at the state level for participation in approved surgical registries, these should be met by all Comprehensive (Level I) and Primary (Level II) Valve Centers.

Data completeness is important for accurate reporting of outcomes and establishing national benchmarks. Both the STS Adult Cardiac Surgery Database and the STS/ACC Transcatheter Valve Therapy Registry hold participants to rigorous standards. Participants in the STS ACSD who do not meet data completeness thresholds are not included in the benchmark population for performance analysis and therefore will not be eligible to receive a composite score or participate in public reporting. Participation in a valve registry was a condition of reimbursement of the National Coverage Determination by the Center for Medicare and Medicaid Services. Extensive efforts have been used to ensure data completeness and accuracy. Completeness of any follow-up in the STS/ACC TVT registry is now 95%, with 89% of records having a 30-day follow-up completed and 68% having 1-year follow-up completed.[54] A key outcome for the STS/ACC TVT registry is patient-reported health status, which includes a QOL metric, the Kansas City Cardiomyopathy Questionnaire (KCCQ). Currently, 90% of baseline KCCQ scores are completed. The 30-day KCCQ score is 85% complete, with 1-year completeness being 73%. It will be important that 1-year mortality metrics and KCCQ scores be completed by all centers. It is expected that all heart valve centers will meet these two national registry data completeness standards.

6.2.3 | Research

Comprehensive (Level I) and Primary (Level II) Valve Centers should be leading investigative efforts to evaluate new technologies and improve clinical management of patients with VHD. Early feasibility and first-in-man studies will be appropriate for select Comprehensive (Level I) Valve Centers. Participation in pivotal device trials will be optional for both Comprehensive (Level I) and Primary (Level II) Valve Centers provided there is an adequate research infrastructure. There remain many important clinical questions that will not be answered by industry-sponsored trials but that may have a significant impact on the treatment of patients with VHD, which can be addressed by single-center or multicenter trials. Comprehensive (Level I) Valve Centers should seek to address many other questions, either by review of institutional data, analysis of existing literature, or national registry data inquiries. The role of MDT dynamics in outcomes and safety will need to be explored. Although efforts should be made to make the TVT and STS data forms as brief as possible, additional data fields could be helpful to address important research questions. Additionally, the TVT and STS registries should be leveraged to provide a framework for executing pragmatic randomized trials that would answer clinically important questions with improved efficiency, lower cost, and adequate power.

6.2.4 | Education

Members of the Comprehensive (Level I) and Primary (Level II) Valve Centers should provide ongoing education to clinicians at local, national, and international conferences. It is also important that the centers continue to educate their own MDT members and other professionals. There should be particular emphasis on the continued education and support of the valve program coordinator, advanced practice providers, and nurses. Comprehensive (Level I) Valve Centers should interface with Primary (Level II) Valve Centers to discuss best

practices, provide feedback on cases, and establish a shared understanding of when patients with VHD require referral for more complex care, as well as on-site coaching of the interventional team for technical skills. It is also important to educate patients and families to improve understanding, enable informed consent, and emphasize SDM. Further development and validation of SDM tools for patients with VHD is needed. Finally, education of the public about VHD may help improve early detection and optimize the timing of referral. Educational strategies should be tailored to local learners, with needs assessment-based curricula, repetition, and feedback. In addition to valve centers, education regarding VHD is the responsibility of all stake holders, including device companies, imaging companies, and professional societies.

6.2.5 | Training

Although the field continues to evolve rapidly, certain aspects have matured to the point where it is now time to implement more formalized training programs in VHD. Learning curves are to be anticipated, and procedure-based physicians who have been in practice since before the advent of transcatheter valve procedures will need to return to a structured training environment for proctoring. Such programs should include instruction on the technical and procedural aspects of intervention, as well as cognitive aspects related to patient evaluation and the timing of intervention. The Comprehensive (Level I) Centers have the responsibility to provide on-site support and education to the Primary (Level II) Centers. Expertise in VHD among cardiologists, surgeons, interventionalists, and imagers can be thought of as a subspecialty. By analogy, although heart failure can be cared for by internists and general cardiologists, advanced heart failure and transplant cardiologists are often needed to manage more complex cases requiring tiered medical and device therapies, mechanical circulatory support, or transplantation.

The rapidly changing nature of evaluation and treatment options for patients with VHD warrants specialized training and expertise. This reality has important implications for the training of cardiac surgeons, interventional cardiologists, imagers, and general cardiologists. There needs to be a new breed of VHD specialists who not only perform procedures, but also understand the underlying pathophysiology of VHD and are able to evaluate patients and determine optimal therapy. It is beyond the scope of this document to describe formal training pathways in VHD. Although not all Comprehensive (Level I) Valve Centers need to have formal fellowships in VHD, it is envisioned that most of these centers will provide such training.[55]

7 | PERFORMANCE METRICS

The delivery of high-quality care requires the ability to collect data regarding the number of all treated patients and their outcomes. Collection of such data serves as the foundation for assessment of practice and procedural patterns and promotion of improvements in process and outcomes. Comparison to external benchmarks has the additional merit of maintaining uniform standards across institutions.

The proposed metrics and reporting discussed herein are relevant to both Comprehensive (Level I) and Primary (Level II) Valve Centers. Such reporting will initially be performed by the individual valve centers. Reporting from regionalized systems of VHD care (Figure 1), including metrics regarding communication and transitions of care, would be an aspirational goal.

7.1 | Assessment of quality of care and development of performance metrics for VHD centers

The assessment of quality is fundamental to any system of VHD care. The collection of key patient-level data elements and the ability to adjust outcomes to account for the diversity of patient characteristics enable the transition from descriptive data to validated and objective performance metrics based on national benchmarks. Successfully assessing quality of care and performance for VHD centers requires a long-term and comprehensive approach to gathering the appropriate data on each patient; sharing it with an analytic center; and receiving standardized, objective, and actionable reports that include validated performance metrics benchmarked against the performance of other centers. The two established national registries collecting VHD-related data are focused, respectively, on surgical and transcatheter valve interventions; they represent important resources for the proposed system of VHD centers.

At the same time, there is a need to more broadly assess the quality of care in VHD patients in a way that is disease-based, comprehensive, and focused on more than simply procedures and operations. Because VHD is a chronic condition and the care of these patients extends over years, quality may be outstanding or poor at multiple time points. Timely detection of significant VHD, accurate assessment of disease severity, optimal timing of a valve procedure, and vigilant postprocedure surveillance and treatment, can all affect QOL in important ways beyond simply the technical success of the intervention. VHD has a more complex pathophysiology than just the valve; the care of VHD patients is often directed at changes in chamber size and function, thromboembolic complications, rhythm and conduction abnormalities, secondary manifestations of hepatic and renal dysfunction, and complex pulmonary and system vascular changes. These issues in comprehensively assessing quality of care are, in fact, daunting, but they need to be identified as important elements in optimizing outcomes.

The overall goals of reporting performance metrics are:

1. To provide patients and referring physicians with experience and results achieved at individual valve centers;
2. To promote the highest-quality standards for the care of patients with VHD; and
3. To establish a mechanism for every center to have a process for self-examination, and to improve continuously by using objective data that are benchmarked against national standards reported through professional society registries.

The committee recognizes that the ultimate metrics for quality standards are patient outcomes—both immediate and, ideally, long-term. However, it must be acknowledged that there are significant limitations to gathering data, performing analyses, and reporting results. Assessing in-hospital and short-term results of surgical

operations and transcatheter procedures provides a beginning, but long-term outcomes, including the patient's functional status and QOL after such treatments, are key to a learning healthcare system.

There are learning curves associated with all cardiac procedures, including TAVR.[56–58] Analysis of early STS/ACC TVT Registry data shows the cumulative TAVR volume–outcome relationship is strong during the learning curve, which is expected given that this is a procedure with potentially high risk in an elderly patient population.[59] In their analysis, Carroll et al.[59] noted that there was a steep slope for improved major outcomes in the first 100 cases. Thus, minimum operator requirements are outlined in the 2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Requirements for Transcatheter Aortic Valve Replacement.[26]

The committee acknowledges that outcomes will improve with experience. Volumes alone are not necessarily the best surrogate for quality, but a volume–outcome association does exist for many cardiac procedures.[60–66] Conversely, there are some procedures, such as transfemoral TAVR, that are becoming less complex and more routine with time and for which there may not be as strong a volume–outcome association. Therefore, volume recommendations must be incorporated carefully and selectively into any determination of which hospitals are designated as VHD centers. Volume thresholds are particularly challenging to determine with scientific rigor. Nevertheless, there is a need for standards because care efficiency and quality improve with the frequency of performance of major procedures and operations, just as experience leads to better results with most human endeavors. The primary motivation behind volume recommendations is not to exclude centers, but rather to serve as 1 metric in the identification of centers that are most capable of providing certain services. Patient-centered outcomes constitute the ultimate quality of care metrics and are more accurately demonstrated when volumes are sufficiently large to permit reliable statistical analysis.

The committee thus proposes that the heart valve centers be evaluated using both procedural volumes and available outcomes for each procedure. The thresholds for low-, moderate-, and high-volume centers should be based on the distribution of the number of procedures performed by valve centers throughout the country, combined with available data on the minimum number of procedures shown to be an inflection point for outcomes.

An example of the potential relationship between volume- and risk-adjusted outcomes is shown in Figure 2. An annual threshold volume might distinguish between low-, moderate-, and high-volume centers from an experiential (but not necessarily statistical) perspective and would not exclude any center from performing the procedure. The combination of volume and risk-adjusted outcome can help to define desirable levels of performance. In Figure 2, the upper-left quadrant represents higher-volume centers with optimal risk-adjusted outcomes, most likely demonstrating higher quality. The upper-right quadrant represents high-volume centers with less than optimal risk-adjusted outcomes, for which immediate action should be taken to identify and address problems leading to higher mortality. In both instances, our confidence in estimating acceptable or substandard risk-adjusted outcomes is greater with higher-volume programs because these programs' sample sizes are larger. However, it should

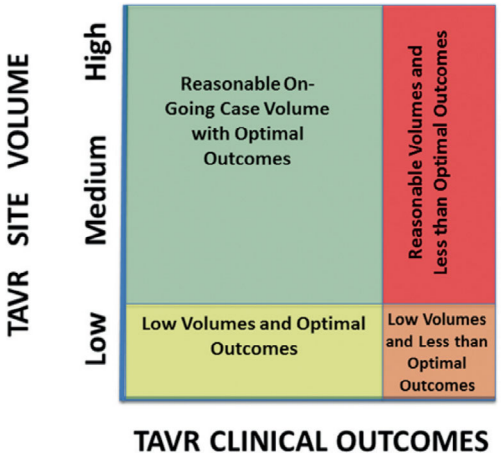

FIGURE 2 Categorization of sites based on TAVR volume and risk-adjusted mortality. This schematic categorizes TAVR programs by their case volumes and risk-adjusted clinical outcomes. Most programs have sufficient case volumes to achieve technical competence and acceptable results, although these volumes may not be sufficient to allow statistically valid quality assessments. A few programs may have adequate volumes to meet TAVR requirements and ensure statistically valid quality assessment but still appear to have suboptimal performance. These programs need to take immediate actions to improve their outcomes as it is likely they are underperforming. Some programs with lower volumes appear to have acceptable outcomes, but because of their small sample sizes, their outcome data are less statistically reliable. These programs must continue to assess their quality vigilantly. Finally, some programs have low volume and less than optimal outcomes. Although these outcomes are statistically less certain, action should be undertaken immediately to further assess and improve quality.[34] TAVR indicates transcatheter aortic valve replacement

be emphasized that the number of cases that might qualify as moderate to high volume on the basis of procedural experience is not necessarily the same as the sample size necessary to produce reliable estimates of quality, which may require accumulation of data over several years.

The lower left and right quadrant centers with lower volumes pose two problems: potentially inadequate volumes to achieve or maintain competence, and sample sizes that are too small to reliably estimate outcomes, as discussed in the following text. The lower-left quadrant centers should continue to assess their outcomes vigilantly, as their small sample sizes render their seemingly acceptable risk-adjusted outcome estimates less statistically reliable. The lower-right quadrant centers should undertake immediate corrective actions. Although there is greater uncertainty regarding the statistical reliability of their results, their low volumes, and suboptimal outcomes are worrisome.

For TAVR, serious adverse outcomes—including stroke, major bleeding, vascular complications, and mortality—were initially shown to decrease with increasing operator experience and volume.[59] As new technologies are introduced and less severely ill patients become eligible for the procedure, the threshold volumes suggested in this document may be periodically updated in response to ongoing analyses from national registries and center-specific experiences.

The writing committee acknowledges the difficulty in correctly assessing the performance of low-volume programs. The confidence intervals around a binary event such as death increase dramatically at lower volumes, producing a graph with a "funnel on its side" appearance, with the wide end at low volumes. Because of these wide confidence intervals, the results from a low-volume program (small sample size) have substantial statistical uncertainty. It is quite difficult to ascertain from this sample what the true underlying performance is of such a program. In contrast, the narrower confidence limits inherent with moderate- and high-volume programs (large sample size) mean that estimates of their true underlying performance are more reliable, enabling their observed performance to be more confidently compared with expectations for their case mix.

To help mitigate the statistical challenges of evaluating low-volume programs, a 3-year rolling data time frame is recommended to provide more observations and better assess true differences in outcomes. Consistent with standard profiling practice, the committee recommends identifying true quality outliers as having risk-adjusted performance that is statistically significantly different than expected for their case mix on the basis of the overall performance of the benchmark population of providers for similar patients. Statistical significance is usually determined by assessing whether the 95% confidence intervals around the provider's point estimate of risk-adjusted mortality include the overall average mortality, or whether the confidence intervals around their ratio of observed to expected mortality include unity (i.e., 1). Low-volume centers, particularly newer programs with less than 3 years of rolling data, need to be vigilant in their own internal assessments if "signals" or "trends" for poor quality are detected despite not reaching a 95% confidence level due to the challenge of accurate assessment of low-volume center quality. To provide larger sample sizes and greater statistical power, there could be a 3-year grace period for new or smaller sites to accumulate a sufficient number of cases before full accountability of outcomes is required. During the 3-year grace period, outcomes should be carefully monitored on a case-by-case basis, possibly including monitoring methods such as Cumulative Sum Control Charts and Variable Life Adjusted Display analyses, and worrisome trends in suboptimal outcomes should be addressed with action plans to enhance clinical performance. A minimum yearly volume of cases will be required to ensure programmatic efficiency and statistical relevance of outcomes.

The following section addresses the outcomes that should be reported on the basis of currently available metrics for TAVR, SAVR, and mitral valve repair. In the future, composite, multidimensional performance measures will further increase the effective number of endpoints for these procedures. This format will set the foundation for future procedures as they are evaluated and accepted into clinical practice.

7.1.1 | Transcatheter aortic valve replacement

The recommended outcome measures for TAVR need to address goals of care that may differ depending on age, life expectancy, and comorbidities. These goals may include improving QOL and functional status as well as reducing rates of rehospitalization and death over a 1- to 5-year time period. TAVR is now available for intermediate-surgical-risk patients and potentially soon for low-surgical-risk patients. The goals of care for these patients overlap somewhat with those for high-surgical-risk patients, but would also need to account for longer survival postprocedure. Clearly, there is a need to determine whether TAVR succeeds in improving functional state and QOL after hospital discharge or a 30-day time window and out to at least 1 year for all patients. These data can also be used to: (a) track the types of patients treated by the valve center; and (b) stratify outcomes according to these types.

Tables 6 and 7 include outcomes measures of quality for a TAVR program proposed in the 2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Requirements for Transcatheter Aortic Valve Replacement.[26] These proposed metrics are the beginning of an evolution in outcome assessment that can eventually approach the level of maturity, validation, and sophistication of SAVR. As outlined in Tables 6 and 7, any valve program with an outcome metric that falls into the bottom 10% for at least two consecutive quarters may have a quality issue that should prompt an immediate improvement effort. A primary goal is to promote the ability of all centers to achieve both adequate volumes and acceptable

TABLE 6 TAVR program performance minimum quality benchmarks

2018 criteria	
Primary outcome metrics	**Performance requirement**
In-hospital risk-adjusted all-cause mortality	• Based on 95% confidence intervals and national benchmark data, the program's performance is "as expected" or "better than expected"
30-day risk-adjusted all-cause mortality	• Based on 95% confidence intervals and national benchmark data, the program's performance is "as expected" or "better than expected"
30-day all-cause neurological events, including TIAs[b]	• Funnel plots using 95% (outlier) and/or 90% (warning) limits indicate that the program's performance falls within the selected boundaries[a]
30-day major vascular complications[b]	• Funnel plots using 95% (outlier) and/or 90% (warning) limits indicate that the program's performance falls within the selected boundaries[a]
30-day major bleeding[b]	• Funnel plots using 95% (outlier) and/or 90% (warning) limits indicate that the program's performance falls within the selected boundaries[a]
30-day moderate or severe AR[b]	• Funnel plots, using 95% (outlier) and/or 90% (warning) limits, indicate that the program's performance falls within the selected boundaries[a]
Primary outcome metrics in development	
1-year risk adjusted all-cause mortality	
Patient-reported health status (KCCQ) at 30 days and 1 year versus baseline	
30-day and 1-year risk-adjusted mortality and morbidity (composite index)	

AR: aortic regurgitation; KCCQ: Kansas City Cardiomyopathy Questionnaire; TIA: transient ischemic attack.
[a]As available for reporting.
[b]Presently only in-hospital and, shortly, 30-day mortality outcomes are risk adjusted. Therefore, other outcomes are not risk-adjusted and need to be interpreted in the context of a program's constellation of patients with their spectrum of characteristics that impact outcomes.
Adapted from Tommaso et al.[34]

TABLE 7 TAVR program performance criteria

TAVR quality requirements
To have optimal outcomes, a program will have: • Minimum quality requirement: STS/ACC TVT Registry-reported 30-day risk-adjusted all-cause TAVR mortality above the bottom 10% for metrics outlined in Table 6. Threshold for low- versus moderate- to high-volume centers • ≥50 cases/year or 100 cases over 2 years
SAVR quality requirements
To have optimal outcomes, a program will have: • ≥2 hospital-based cardiac surgeons who both spend ≥50% of their time at the hospital with the proposed TAVR program • A quality assessment/quality improvement program: 1. Active participation in the STS National Database to monitor outcomes 2. Quality metric: STS 2- or 3-star rating for isolated AVR and AVR + CABG in both reporting periods during the most recent reporting year Threshold for low- versus moderate- to high-volume centers • ≥30 SAVRs/prior year or 60 SAVRs over 2 years[a]

ACC: American College of Cardiology; AVR: aortic valve replacement; CABG: coronary artery bypass grafting; LVAD: left ventricular assist device; SAVR: surgical aortic valve replacement; STS: Society of Thoracic Surgeons; TAVR: transcatheter aortic valve replacement.
[a]For the purposes of this hospital volume requirement, SAVR is defined to include all SAVR (mechanical, bioprosthesis, homograft, autograft [Ross], composite valve graft, or root replacement) or aortic valve repair procedures, including concomitant valve resuspension for acute aortic dissection and valve-sparing aortic root replacement. Simple adjuvant aortic valve procedures (e.g., suturing closed regurgitant aortic valves in an LVAD patient, excising a papillary fibroelastoma or thrombus) are not included.
Adapted from Tommaso et al.[34]

outcomes (i.e., the upper-left quadrant in Figure 2). It is anticipated that most low-volume sites will steadily increase their number of procedures due to the approval of moderate-risk patients for TAVR, Food and Drug Administration approval of additional indications for TAVR usage, and ongoing aging of the U.S. population.

7.1.2 | Surgical mitral valve repair

Surgical mitral valve repair is a well-established procedure that mandates unique quality metric requirements. It has been shown that the short- and long-term results of mitral valve repair are superior to replacement in patients with severe primary MR. For patients with asymptomatic severe primary MR, surgical repair is reasonable provided a successful and durable repair rate >95% with an operative mortality <1% can be expected at a given center.[1,2] The treatment options for asymptomatic, severe primary MR should be considered by an MDT, with repair offered only if these high standards can be met.

Data from New York State suggest that higher total annual surgeon volume is associated with increased repair rates for primary MR, with an improved 1-year survival and steady decrease in reoperation risk when >25 total mitral operations are performed annually. In addition, mitral valve repair rates among surgeons with volumes of <25 mitral operations per year increase significantly if they operate at an institution in which another surgeon performs >50 mitral cases per year with mitral valve repair rates for primary MR >70%.[17] Using this observational study as a single example, an appropriate cut-off for low and high surgical volumes for mitral valve operation might be >25 per year per operator or >50 per year per institution.

TABLE 8 Mitral valve repair performance criteria—for primary degenerative MR[a]

To optimize outcomes, a mitral program will have: • Repair rate > 75% • 30-day operative mortality <1%
Threshold for moderate or high volume: • Annual case volume of 25 per surgeon or 50 per program

MR: mitral regurgitation.
[a]In the absence of calcification of the annulus or leaflet.

Current data from the Society of Thoracic Surgeons database[67] indicate a repair rate well below 95% for primary degenerative disease among 867 centers in North America, reporting more than 10 such cases over a 3-year period. Accordingly, on the basis of expert consensus and relevant data, it is proposed that a designated valve center should exceed that average and achieve a surgical mitral valve repair rate of greater than 75% for patients with primary degenerative MR in the absence of calcification of the leaflets or annulus (Table 8). In these patients, the 30-day operative mortality rate should be less than 1%. This quality metric applies to all valve centers that are performing mitral valve operations for primary MR. To achieve this metric, it is anticipated that some centers may limit surgical mitral valve repair to those pathologies that are most easily approached (e.g., isolated posterior leaflet prolapse or partial flail), whereas more experienced surgeons at a Comprehensive (Level I) Valve Center would be expected to undertake repair of more advanced pathologies, as reviewed previously. In addition, each valve center may choose to limit the scope of surgical practice for individual surgeons to ensure that repair rate thresholds are met or exceeded. Many would consider mitral valve repair to constitute a surgical subspecialty[68]; higher individual surgeon volumes are associated with higher repair rates, decreased reoperation risk, and improved survival.[17] Such data support the concept of preferential referral to an expert surgeon, who would more likely operate in a Level I valve center.

7.2 | Public reporting

The public has a right to know the outcomes and quality achieved at a valve center. The U.S. medical system is competitive, and marketing by hospitals and healthcare systems should not be confused with a rigorous approach to high-quality, objective, comprehensive, and valid measures of performance. Public distribution of data can be misleading in the absence of data quality controls, adequate risk adjustment, and national benchmarking of each hospital's results. Public reporting of risk-adjusted outcomes is an ethical responsibility, and one that is supported by professional societies. Public reporting of a performance measure relevant to a VHD center requires a major national effort that involves multiple years of work. In the cardiac surgical field, STS has been a leader; reviewing its experience is key to considering what a system of VHD centers will need to report in addition to SAVR outcomes.

Currently, approximately 65% of cardiac surgery programs in the United States report their outcomes publicly. There is evidence that those programs that do so have better outcomes than those that do not,[69] although the evidence regarding this association is variable. In addition, experience has shown that the process may have unintended

consequences, such as risk aversion.[70,71] The most commonly cited example of performance improvement is the New York State public reporting of cardiac surgery outcomes.[72–75] After the introduction of CABG report cards in New York State, risk-adjusted mortality declined by 41% between 1989 (4.17%) and 1992 (2.45%), with a corresponding reduction in the prevalence of high- and low-outlier hospitals. Between 1989 and 1992, New York Medicare patients experienced a 22% decline in CABG mortality rates versus a 9% decline nationwide. In 1992, New York State had the lowest Medicare CABG mortality rate in the nation. Finally, it is important that outcomes be risk-adjusted to help prevent risk avoidance and inappropriately restrictive case selection as causes of reduced mortality rates.[72]

STS online public reporting enables participants to voluntarily report and inform the public of their hospital's or program's heart surgery scores and star ratings. The STS began public reporting in 2010 and now publicly reports outcomes for isolated CABG, isolated AVR, and AVR plus CABG. The Society has imminent plans to report composite (risk-adjusted mortality, risk-adjusted morbidity) outcomes for mitral valve replacement, mitral valve repair, and mitral valve replacement or repair plus CABG. The publicly reported data are readily accessible through the STS website and Consumer Reports.

To make this reporting easily understandable to the public and general consumer, a 3-star rating system was constructed. This system was based on a multiprocedural, multidimensional composite measure designed to comprehensively evaluate the performance of a program or hospital on one of five common adult cardiac procedures (isolated CABG, isolated AVR, isolated mitral procedures, AVR + CABG, and mitral procedures + CABG).[29,67,76–78] A similar composite scoring for individual surgeon performance, based on these five procedures, is being implemented in 2019.[79] A 3-star rating indicates that the provider's performance is statistically significantly better than expected for their case mix with reference to the benchmark performance of all STS programs. A 1-star rating indicates performance worse than expected for the provider's case mix.

It is expected that both Comprehensive (Level I) and Primary (Level II) Valve Centers will report outcomes of both surgery and transcatheter valve interventions (when the latter are available). In addition to risk-adjusted outcomes, transparency is needed for all stakeholders (including patients and referring physicians) regarding procedural volumes, types of patients treated, and other metrics described in this document.

8 | OBSTACLES AND CHALLENGES TO A VHD SYSTEM OF CARE

The model proposed shares many features with other well-established systems, including integrated vertical healthcare delivery systems in which primary care is linked to tertiary/quaternary care and regional, disease-based systems, such as those championed by the National Brain Attack Coalition for acute stroke care. Both tiered and disease-based models of VHD care should help patients receive the level of care needed as a function of disease complexity. Nevertheless, there are several limitations to be recognized, including:

1. Access. The writing committee acknowledges that many patients may not be able or wish to travel to a remote center for VHD care for reasons related to age, frailty, geographic distance, separation from family, trust in their local caregivers, and the uncertainty created by placing their care in the hands of unfamiliar clinicians. There are additional barriers related to health plan coverage, restricted referral networks, lack of interoperability for both healthcare records and imaging, and perceptions of cultural bias. Many of these barriers have been addressed by large, vertically aligned healthcare systems in which cardiovascular specialists are employed and resources have already been consolidated to enhance efficiency. Referral out of network for other patients, however, may simply not be possible in part because of the economic environment that characterizes the current U.S. healthcare environment. In addition, some would argue that separation of patients from their local communities negates the possibility of achieving SDM. Patient preferences should always be respected, but an informed discussion of all treatment options available and the outcomes to be expected (as publicly reported), is an important prerequisite for successful SDM. Education, communication, and transparency can address some but not all of these issues. Cultural barriers to access involve more than simple geography and require interventions that are beyond the scope of this document. Whereas supporting a primary (Level II) valve center in a geographically remote/rural area is feasible on a selective basis, expanding the number of valve centers in metropolitan areas already populated by several programs is more difficult to rationalize.
2. Communication. The interoperability of electronic health records and digital imaging data needed to enable seamless patient movement within a VHD system of care is not available even within some vertically integrated health systems.
3. Cost. Comprehensive (Level I) Valve Centers will experience the higher costs associated with the management of more complex and higher-risk patients undergoing more expensive care with longer stays. Start-up and maintenance costs to establish and sustain the infrastructure required to provide comprehensive care for complex patients are substantial. Patients and families may incur higher costs related to travel or out-of-network care.
4. Professional and institutional skepticism. The writing committee also acknowledges that the simple construct of a tiered system of care may create the perception that this proposal would perpetuate the dominance of larger centers at the expense of smaller centers. The proposed concept of a system of care for VHD patients is not conceived to deny individuals and institutions the opportunity to provide services, nor should it be perceived to impede the ability of a committed center to achieve its strategic goals. Rather, it is intended to focus more on outcomes and not simply on procedural volumes, while providing a platform to guide best practices and promote quality improvement across all centers interested in the care of patients with VHD. Additionally, the proposal is not TAVR-specific but rather is meant to highlight the range of services, expertise, and experience required to care for patients across the spectrum of VHD. Health services research to assess the impact of a tiered system of care on patient outcomes, quality, and cost must be supported.

5. Knowledge and performance gaps. As discussed throughout this document, these persist despite the collective efforts of institutions, health systems, and professional societies. Enhanced collaboration and more targeted educational efforts are needed to reduce the observed variability in care and outcomes.

9 | SUMMARY AND NEXT STEPS

The increasing burden of VHD, coupled with the emergence of improved imaging techniques, better surgical outcomes, and transcatheter therapies, has stimulated discussions regarding optimal strategies for care delivery. The focus of this document is not to ask whether there are too many, too few, or just the right number of self-designated advanced valve centers, but rather to *initiate a discussion* regarding whether a regionalized, tiered system of care for patients with VHD that accounts for the differences in valve center expertise, experience, and resources constitutes a more rational delivery model than one left to expand continuously without direction. Admittedly, access to appropriate, high-quality care remains a concern and one that is not fully addressed here, although the role of the practice-level clinician in recognition and diagnosis is acknowledged. This proposal emphasizes performance and outcome standards for all providers and centers.

There are several next steps, beginning with broad educational programming. Strategies to shorten the learning curve associated with the performance of new interventions and incorporation of iterative changes in surgical techniques deserve emphasis. Centers can share best practices for efficient MDT functioning and SDM. Communication standards, particularly at transitions of care, can be formalized. The emergence of clinical registries has enhanced centers' ability to assess and compare quality. Setting performance standards both within and across centers is thus now feasible. The Joint Commission has instituted a Comprehensive Cardiac Advanced Certification Program for individual hospitals that includes VHD care.[80] External review, monitoring, and feedback at a system level, however, will be key processes going forward. These will require dedicated personnel and financing. There is a great deal of detailed work ahead to realize the goals of this proposal to the satisfaction of patients and the many other stakeholders involved.

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APPENDIX A: ABBREVIATIONS

ACC	American College of Cardiology
AATS	American Association for Thoracic Surgery
AS	Aortic stenosis
ASE	American Society of Echocardiography
AVR	Aortic valve replacement
CT	Computed tomography
KCCQ	Kansas City Cardiomyopathy Questionnaire
LV	Left ventricular
MDT	Multidisciplinary team
MR	Mitral regurgitation
SAVR	Surgical aortic valve replacement
SCAI	Society for Cardiovascular Angiography and Interventions
SDM	Shared decision making
STEMI	ST-segment elevation myocardial infarction
STS	Society of Thoracic Surgeons
STS ACSD	Society of Thoracic Surgeons Adult Cardiac Surgery Database
TAVR	Transcatheter aortic valve replacement
VHD	Valvular heart disease

APPENDIX B: AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—2018 AATS/ACC/ASE/SCAI/STS EXPERT CONSENSUS SYSTEMS OF CARE DOCUMENT: A PROPOSAL TO OPTIMIZE CARE FOR PATIENTS WITH VALVULAR HEART DISEASE

To avoid actual, potential, or perceived conflict of interest that may arise as a result of industry relationships or personal interests among the writing committee, all members of the writing committee, as well as peer reviewers of the document, are asked to disclose all current healthcare-related relationships, including those existing 12 months before initiation of the writing effort. The ACC Task Force on Clinical Expert Consensus Documents reviews these disclosures to determine which companies make products (on market or in development) that pertain to the document under development. Based on this information, a writing committee is formed to include a majority of members with no relevant relationships with industry (RWI), led by a chair with no relevant RWI. RWI is reviewed on all conference calls and updated as changes occur. Author RWI pertinent to this document is disclosed in the table below and peer reviewer RWI is disclosed in Appendix C. Additionally, to ensure complete transparency, authors' comprehensive disclosure information—including RWI not pertinent to this document—is available online. Disclosure information for the ACC Task Force on Clinical Expert Consensus Documents is also available online, as is the ACC disclosure policy for document development.

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APPENDIX B (Continued)

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Note. This table represents the relationships of committee members with industry and other entities that were determined to be relevant to this document. These relationships were reviewed and updated in conjunction with all meetings and/or conference calls of the writing committee during the document development process. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$5,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. According to the ACC, a person has a *relevant* relationship IF: (a) the *relationship or interest* relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the *document*; or (b) the *company/entity* (with whom the relationship exists) makes a drug, drug class, or device addressed in the *document* or makes a competing drug or device addressed in the *document*; or (c) the *person or a member of the person's household*, has a reasonable potential for financial, professional or other personal gain or loss as a result of the issues/content addressed in the *document*. DSMB: Data Safety Monitoring Board.
[a]No financial benefit.
[b]Significant relationship.

APPENDIX C: PEER REVIEWER INFORMATION—2018 AATS/ACC/ASE/SCAI/STS EXPERT CONSENSUS SYSTEMS OF CARE DOCUMENT: A PROPOSAL TO OPTIMIZE CARE FOR PATIENTS WITH VALVULAR HEART DISEASE

This table represents the individuals, organizations, and groups that peer reviewed this document. A list of corresponding comprehensive healthcare-related disclosures for each reviewer is available online.

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APPENDIX C (Continued)

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APPENDIX C (Continued)

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[a]AAMC: Association of American Medical Colleges; AATS: American Association for Thoracic Surgery; ABC: Association of Black Cardiologists; ACC: American College of Cardiology; ACP: American College of Physicians; AHA: American Heart Association; ASE: American Society of Echocardiography; ASNC: American Society of Nuclear Cardiology; SCA: Society of Cardiovascular Anesthesiologists; SCAI: Society for Cardiac Angiography and Interventions; SCCT: Society of Cardiovascular Computed Tomography; STS: Society of Thoracic Surgeons; TAVR: transcatheter aortic valve replacement.