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MULTISOCIETY EXPERT CONSENSUS SYSTEMS OF CARE DOCUMENT

2019 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Mitral Valve Intervention

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

Endorsed by the Heart Failure Society of America

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TABLE OF CONTENTS

PREAMBLE

Transcatheter repair and replacement procedures have become an integral feature of the management of appropriately selected patients with valvular heart disease (VHD), thereby enabling the delivery of less-invasive treatments across a broad spectrum of conditions previously correctable only with open-heart surgery. Demonstration of the feasibility, effectiveness, and safety of transcatheter valve therapies in randomized controlled trials and large prospective registries has generated tremendous interest in these treatments and led to their widespread dissemination. Whereas there are established criteria for training and board certification for the performance of adult cardiothoracic surgery and percutaneous coronary interventions, training standards for transcatheter structural valve interventions are still evolving. The purpose of this document is to update the operator and institutional recommendations and requirements for transcatheter mitral valve (MV) interventions (1). The document is similar in theme and intent to the "2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Aortic Valve Replacement" (2). It is recognized, however, that there are significant differences not only between aortic valve and MV pathologies, but also between the respective pathways for patient evaluation, treatment options, and interventional/surgical skillsets.

The emergence of transcatheter interventions for VHD has been facilitated by technological innovations, advances in multimodality imaging, improved patient selection, and standardized management pathways (3,4). A cohesive and highly functional multidisciplinary team (MDT) is the foundation of the enterprise, surrounding the informed patient with the services, navigational aids, and counseling necessary for a successful outcome. Given the clinical challenges posed by patients with VHD, the need for structural imaging expertise, the highly technical nature of transcatheter interventions, and the availability of alternative surgical treatment options, several considerations are important for operators and institutions planning to offer a comprehensive program of invasive

therapies. It is pertinent to view the recommendations and requirements that follow more from the perspective of the treatment or set of treatments that is most appropriate for an individual patient with MV disease than through a narrower lens that focuses on only a specific type of intervention.

The American Association for Thoracic Surgery (AATS), The American College of Cardiology (ACC), The Society for Cardiovascular Angiography and Interventions (SCAI), and The Society for Thoracic Surgeons (STS) have joined together to provide recommendations and requirements for operators and institutions to assess their potential for launching and/or maintaining a transcatheter MV intervention program. As of this writing, the edge-to-edge clip repair device (MitraClip, Abbott Vascular, Santa Clara, California) is the only U.S. Food and Drug Administration (FDA)-approved transcatheter mitral valve repair (TMVr) system for clinical use. Other transcatheter repair systems are anticipated, and it is further acknowledged that transcatheter mitral valve replacement (TMVR) systems are likely to be introduced into clinical practice in future years. AATS, ACC, SCAI, and STS believe that adherence to these recommendations will maximize the chances that these therapies will be successfully incorporated into management pathways for patients with MV disease in the United States. These recommendations attempt to balance the need to support optimal quality outcomes with the goal of facilitating access to such innovative therapies—an important paradigm for the development and implementation of future, less-invasive approaches to structural heart disease.

1. INTRODUCTION

1.1. Background

Moderate or severe mitral regurgitation (MR) is the most common valve lesion among adults, with prevalence increasing as a function of age (5,6). Surgical valve repair yields superior outcomes to replacement in patients with primary MR (7,8). The evidence base for the treatment of heart failure (HF) patients with secondary MR has recently evolved (9,10). Due to a combination of the anatomic and functional complexity of the MV and the wide spectrum of pathologies that can affect it, numerous surgical repair and replacement techniques for MR have been developed over the past several decades. Although surgery for secondary MR has been associated with improved functional outcomes and quality of life (QoL) in selected patients (11,12), operative intervention has not been shown to extend survival in these challenging patients. It follows that several innovative concepts for transcatheter MV therapy have been explored. Approaches to TMVr can be loosely categorized on the basis of the anatomic region targeted for repair (e.g., leaflet, annulus, chordae tendineae, left ventricle [LV]). Repair techniques that include combinations of these approaches have also been explored (13–15). TMVR platforms are in earlier stages of clinical development (16).

To date, the largest transcatheter clinical experience has been with leaflet repairs, specifically, percutaneous, edge-to-edge leaflet repair, in which the anterior and posterior leaflets of the MV are approximated to restore coaptation and create a double orifice valve. This approach is based on the surgical technique described by Alfieri et al. and has been used for a variety of pathological MR disease states (17,18). The edge-to-edge clip repair device was approved for use in the United States in 2013 for treatment of selected patients with primary MR, on the basis of the outcomes reported in the EVEREST (Endovascular Valve Edge-to-Edge REpair Study) trials and REALISM (Real World Expanded Multicenter Study of the MitraClip System) Registry (18–20). In March 2019, the indication for edge-to-edge clip repair was extended to symptomatic patients with moderate-to-severe or severe secondary MR (MR grade >III per American Society of Echocardiography criteria) with a left ventricular ejection fraction (LVEF) >20% and <50% and an LV end-systolic dimension <70 mm, whose symptoms and MR severity persist despite maximally tolerated guideline-directed management and therapy (GDMT) as determined by an MDT experienced in evaluating and treating HF and MV disease.

The FDA secondary MR indication for edge-to-edge clip repair integrates the results of the MITRA-FR (Multicentre Study of Percutaneous Mitral Valve Repair with the MitraClip® Device in Patients with Severe Secondary Mitral Regurgitation) and the COAPT (Cardiovascular Outcomes Assessment of the MitraClip® Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation) trials published in September 2018 (9,10). Conducted in France, MITRA-FR randomized 304 patients with HF and secondary MR to edge-to-edge clip repair plus medical therapy versus medical therapy alone and found no difference in the primary endpoint of all-cause death or unplanned hospitalizations for HF at 12 months (9). Conducted in the United States and Canada, COAPT similarly randomized 614 patients with HF and secondary MR to medical therapy plus edge-to-edge clip repair versus medical therapy alone (9). In contrast to the MITRA-FR trial, COAPT demonstrated a marked reduction in the primary efficacy endpoint of all hospitalizations for HF within 24 months (35.8% per patient-year in the device group compared with 67.9% per patient-year in the control group; hazard ratio: 0.53; 95% confidence interval: 0.40 to 0.70; $p < 0.001$). Furthermore, among COAPT patients, death from any cause within 24 months occurred in 29.1% in the device group compared with 46.1% in the control group (hazard ratio: 0.62; 95% confidence

interval: 0.46 to 0.82; p<0.001). The clinical benefits observed in COAPT but not in MITRA-FR relate to important differences between the trials in design, execution, endpoints, duration of follow-up, severity of MR, LV size (volume), rigor of HF therapy, procedural success rates, and durability of MR reduction. For example, compared with patients in the MITRA-FR trial, patients in the COAPT trial had more severe MR as assessed by higher mean effective regurgitant orifice areas and less remodeling as reflected in lower mean LV end-diastolic volumes. COAPT further required for inclusion the use of maximally tolerated GDMT as verified by an HF specialist. In contrast, HF medication use was more variable in MITRA-FR and allowed to change during follow-up. Finally, COAPT was conducted in comprehensive heart valve centers with prior edge-to-edge clip repair experience, resulting in lower rates of immediate and 1-year ≥3+ residual MR than those observed in MITRA-FR. These considerations may help guide MDT management decisions, patient selection, and recommendations for procedural benchmarks for transcatheter MV interventions directed at symptomatic HF and severe or moderately severe secondary MR.

To replicate the COAPT results in general practice for symptomatic HF patients with secondary MR, several steps will need to be completed (4,21). MR etiology (primary versus secondary versus mixed) and severity should be documented by an echocardiography expert knowledgeable and experienced in the integrative assessment of MR. GDMT should be determined and verified by a cardiologist who is experienced in caring for patients with HF and can supervise extended optimization of treatment, including the use of cardiac resynchronization therapy when indicated, in collaboration with an electrophysiologist. The transcatheter operator must be experienced and able to select patients for whom there is a high likelihood of a safe and durable repair with this technique. A cardiac surgeon expert in MV repair and replacement techniques should be available for patient consultation and surgical intervention when this approach is deemed preferable by the MDT, whose consensus recommendation should be communicated to the patient as part of a shared decision-making process.

The edge-to-edge clip device is most often deployed by a single physician under the guidance of an interventional echocardiographer in a catheterization laboratory. This physician may be either an interventional cardiologist or a cardiothoracic surgeon. However, for some patients, the expertise of 2 physicians (e.g., 2 interventional cardiologists, or an interventional cardiologist and a cardiothoracic surgeon) could be required. Future applications of novel transcatheter MV repair and replacement systems are likely to require joint participation by the cardiothoracic surgeon and interventional cardiologist in many aspects of care such as: preoperative assessment, patient selection, and intraprocedural and postprocedural management and follow-up.

Several other TMVr systems focusing on leaflet modification (such as leaflet ablation and space occupation between leaflets), chordal manipulation, or annular reduction are either in clinical use or in various stages of development, whereas TMVR platforms for treatment of native MR not due to extensive annular calcification remain strictly investigational at this time (22–25). There is increasing experience with the use of transcatheter aortic valve replacement (TAVR) valves for treatment of highly symptomatic, prohibitive, or high-surgical-risk patients with degenerated bioprosthetic MVs (valve-in-valve) (8); patients with failed surgical MV repairs with annuloplasty rings (valve-in-ring); and patients with MR due to severe annular calcification (MAC) (valve-in-MAC) (14). This space is evolving rapidly (26), and it is anticipated that future iterations of these recommendations will address novel systems as they are introduced into clinical practice and tailored to specific patient populations. The foundational elements are likely to remain the same, however, as these procedures will certainly require similar preprocedural patient assessment, intraprocedural personnel and equipment, operator experience, and postprocedural care pathways.

The current landscape for transcatheter MV interventions also includes balloon commissurotomy for selected patients with mitral stenosis (7) and mitral paravalvular leak (PVL) closure with an occluder device. Although such procedures are important components of the total transcatheter MV interventional experience at any 1 center, this document will not include specific recommendations for these interventions.

1.2. Process

The characterization of quality using the Donabedian triad of structure, process, and outcomes measures is a reasonable framework for establishing quality of care for MR patients (27,28). The 2006 Institute of Medicine report Performance Measurement: Accelerating Improvement provides the context for translating the need for assessment of performance in health care into measures of quality (29). The measures are related to the key periods of patient evaluation, which include patient engagement and decision making, procedure performance, postprocedural care, and assessment of intermediate- and longer-term outcomes. This document incorporates several measures into proposed operator and site requirements for a transcatheter MV interventional program.

1.3. What Is New in the 2019 Operator and Institutional Requirements?

Outlined in the following text are important areas of emphasis within this updated document.

- The document focuses on the overarching goal of improving patient outcomes across all transcatheter MV sites and providing guidance regarding the use of data and analyses for program assessment. For example, sites whose risk-adjusted outcomes are worse than expected, relative to a national benchmark population, are expected to initiate robust performance improvement programs that are often informed by external review and facilitated by registry participation and certification programs (where available).
- The document is intended to be forward thinking, combining site process and outcome measures, which can be updated with new data that reflect evolving patient characteristics and novel transcatheter technologies. Many operator and institutional requirements are not expected to change substantially as they reflect basic infrastructure needs, fundamental clinical skills, experience, and MDT consensus decision making.
- The writing committee does not consider the recommendations in this document to exceed the capabilities of most centers, as currently structured or with reasonable modifications. Further, the recommendations are not intended to exclude existing or future centers for MV transcatheter intervention.
- Recommendations and proposed operator and institutional criteria for performance of transcatheter MV interventions have been updated in view of the clinical, registry, and trial experience gained since publication of the initial, multisocietal 2014 document (1). It is also acknowledged that standards for MV surgical programs are intimately related to the outcomes achieved with transcatheter interventions. The infrastructure and case volumes required to support an active MV surgical program constitute reasonable metrics by which to assess a site's capability to provide the anticipated spectrum of transcatheter interventions.
- This document recommends that sites incorporate methods and processes promoting patient- and family-centered care with informed shared decision-making (SDM). This recommendation goes beyond patient education and the traditional use of informed consent, which involves an explanation of generic risks and potential benefits of any intervention. It specifically includes an individualized approach utilizing patient-specific, data-driven risk assessment; clear explanation of treatment options; explanation of the rationale for the MDT's recommendations; and the incorporation of patient goals, preferences, and values into treatment decisions (30).

2. METHODS

Since transcatheter valve therapy is continuing to mature, the evidence upon which to base these recommendations is still evolving. Therefore, the standards are based on best practices, expert consensus, and trial and registry data when available. As the procedures evolve, technology changes, experience grows, and more data accumulate, there will be a need to update these recommendations periodically. Because there is a strong consensus that these new valve therapies are best performed using an MDT approach, these criteria may be best applied at the institutional level.

Partnering societies used the ACC's policy on relationships with industry to author this document (31). To avoid actual, potential, or perceived conflicts of interest that could arise as a result of industry relationships, all members of the writing committee, as well as peer reviewers of the document, were asked to disclose all current healthcare-related relationships, including those existing 12 months before initiation of the writing effort. A committee was formed to include a majority of members with no relevant relationships with industry (RWI) or other entities. Author and peer reviewer RWI pertinent to this document are disclosed in Appendixes 1 and 2, respectively. In addition, to ensure complete transparency, authors' comprehensive disclosure information (including RWI not pertinent to this document) is available as an online supplement to this document. The work of the writing committee was supported exclusively by the partnering societies without commercial support. Writing committee members volunteered their time for this effort. Conference calls of the writing committee were confidential and were attended only by committee members and relevant staff.

3. KNOWLEDGE BASE AND SKILLS

No one individual, group, or specialty possesses all of the necessary skills for optimal management of these complex patients (32). Therefore, it is essential that the cornerstone of a program to manage patients with MR is a formal, collaborative MDT with expertise in VHD, HF, electrophysiology, cardiac imaging, interventional cardiology, cardiac valve surgery, and cardiac anesthesia. MDT members should keep abreast of research advancing knowledge in this field, including the application of and outcomes with invasive therapies and perioperative care. The principal goal of these programs must be to provide the best possible patient-centered care (33).

The transcatheter edge-to-edge clip repair device has been commercially available since 2013, following FDA approval of its use for selected patients with primary MR. The pool of individuals trained in this procedure has

expanded significantly over time and may increase further in the wake of the March 2019 FDA approval of the use of the edge-to-edge clip device for treatment of selected patients with secondary MR. Clinical experience with the edge-to-edge clip device is reflected in The Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry (34,35). Approximately 18% of patients treated with the edge-to-edge clip device and reported to the STS/ACC TVT Registry have had secondary MR (35).

Echocardiography laboratory certification by the Intersocietal Accreditation Commission or a similar body that provides standards for consistent practice and quality is desirable. The MDT echocardiography expert should have the skills necessary to acquire and interpret transthoracic (TTE) and transesophageal echocardiographic (TEE) studies, including with the use of semiquantitative and quantitative measurements, as well as with 3-dimensional (3D) TEE assessment of MV anatomy and function. Echocardiographic guidance is critical to procedural success, and the interventional echocardiographer must be highly skilled. The implanting physician also must be able to interpret intraprocedural images. Expertise in the interpretation of cardiac computed tomography (CT) scans is needed to determine patient eligibility for transcatheter mitral valve-in-valve replacement using a TAVR device, as well as for assessment of valve-in-ring and valve-in-MAC candidates. Such expertise will also be needed for investigational TMVR systems that may move into clinical use in future years.

Minimum training for specific MV procedures and devices should follow FDA approval requirements. Proctoring and simulation play important roles in technical training and proficiency maintenance for newly introduced procedures (36–40).

Minimum requirements for transcatheter MV interventions include an understanding of basic radiation safety practices necessary for optimal imaging, operator and patient exposure protection, and knowledge of the use of x-ray contrast agents. Training in the interpretation of MV hemodynamics and the selective use of contrast injections will facilitate optimal catheterization laboratory and hybrid suite utilization. Catheter and wire skills, including knowledge of various techniques and the equipment available to access complex anatomy and negotiate vascular and anatomic structures, are required. Transseptal access to the MV is a prerequisite and fundamental skill, whereas surgical transapical access may be required for some TMVR systems when approved for clinical use. Wire and catheter skills are acquired during rotations through the catheterization laboratory in the course of general and interventional cardiology fellowships. Cardiac surgical trainees with an interest in transcatheter procedures learn these skills during dedicated catheterization laboratory rotations. Experience and skill with a variety of catheter-based interventional techniques is beneficial. These techniques include but are not limited to:

- Transseptal access
- Large vessel access and closure
- Coronary diagnostic procedures
- Percutaneous coronary interventions
- Peripheral vascular diagnostic and interventional procedures
- Balloon aortic, mitral, and pulmonic dilatation
- Stent implantation in right ventricular outflow tract and pulmonary arteries
- Intra-aortic balloon pump and other cardiac support device placement, including initiation of percutaneous cardiopulmonary bypass

Prior experience with TAVR is highly desirable as it reflects an understanding of the proper structure and process of an MDT. However, it should not be considered adequate experience for the performance of transcatheter MV interventions. The marked variability of MV morphology and pathology, as well as the variety of anatomic targets for transcatheter therapy, require different skillsets and experience for obtaining appropriate access and performing a successful procedure. Skillsets for 1 valve type do not necessarily translate to the other valve type, although there is a premium to be placed on cumulative transcatheter valve interventions.

These procedures may involve open or partially open surgical components. Therefore, operating theater standards for sterile technique are mandatory to ensure optimal patient outcomes. As 1 of the leaders of the team performing these procedures, the interventionalist must be able to enforce compliance with these standards, guided by the experience of the collaborating surgeon.

4. FACILITIES

The institution should have an active cardiac surgical program supported by at least 2 institutionally based cardiac surgeons experienced in the treatment of patients with VHD. This recommendation parallels that included in the "2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Aortic Valve Replacement" (2) and is predicated on concerns regarding both access and safety. Accordingly, 1 surgeon would be available for MDT participation as dictated by patient and procedural factors and the second surgeon would be available for coverage of the cardiac surgical service and emergency assistance. The institution should maintain a full range of diagnostic imaging and therapeutic facilities, including:

- A cardiac catheterization laboratory or hybrid operating room (OR)/catheterization laboratory equipped with a fixed radiographic imaging system with flat-panel fluoroscopy offering catheterization laboratory-quality imaging. A mobile C-arm imaging system in an operating room is not adequate.
  - The interventional/implantation suite must have a sterile environment with sufficient space to accommodate the equipment necessary for uncomplicated procedures (e.g., high-definition displays and monitors, O_2 analyzer, defibrillator/resuscitation cart, O_2 supply, suction, compressed air, CO-oximeter, activated clotting time analyzer), as well as any additional equipment that may be necessary in the event of complications. Space for anesthesia management and echocardiography is essential.
  - The interventional suite should stock a large variety of interchangeable equipment, including various access kits, endovascular sheaths, and introducers ranging from 4- to 26-F in various lengths; a wide range of guidewires for various purposes; cardiac diagnostic and interventional catheters; vascular closure devices; balloon dilatation catheters ranging from 2 to 30 mm in diameter and of various lengths and profiles; a full inventory of coronary and peripheral stents, including covered stents, occlusive vascular devices, snares, and other retrieval devices; drainage catheters; portable vascular access ultrasound; and various implantable device sizes with their delivery systems.
  - A specifically designed hybrid OR/interventional suite may be necessary for anticipated TMVR technologies. The "2012 ACCF/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update" outlined the specifications for a hybrid catheterization laboratory/OR (41).
  - Cardiopulmonary bypass (CPB) is rarely needed during the performance of currently approved transcatheter MV interventions (e.g., edge-to-edge clip device repair, balloon commissurotomy). However, procedure rooms that can accommodate the equipment needed for CPB will likely be necessary for future transcatheter MV interventions.
- Noninvasive imaging
  - An Intersocietal Accreditation Commission-accredited echocardiography laboratory, along with sonographers; Level 3-trained and National Board of Echocardiography certified echocardiographers; and cardiac anesthesiologists with training and experience in the acquisition and quantitative interpretation of TTE, TEE, and 3D TEE studies in patients with MV disease.
  - A vascular laboratory (noninvasive) with vascular specialists capable of performing and interpreting vascular studies is also essential.
  - Also needed is a CT laboratory with a multidetector CT scanner and technologists and specialists who can acquire and interpret cardiac CT studies, respectively.
  - A magnetic resonance imaging (MRI) laboratory with technologists and specialists who can acquire and interpret cardiac MRI studies in patients with VHD is desirable.
- Postprocedural recovery and intensive care facilities, with personnel trained and experienced in managing patients who have undergone transcatheter valve replacement and repair.

The need for outpatient facilities sufficient to allow high-quality preprocedural/postprocedural care and MDT consultation is self-evident. Appropriate office space for the medical, nursing, and technical personnel involved is also required, preferably in a central setting. Ancillary testing facilities (pulmonary function, echocardiography, vascular duplex scanning, clinical laboratory, CT) should be of high quality, ideally accredited by the appropriate certifying organization, and able to accommodate the patient load in a timely manner.

By their very nature, these complex procedures should only be undertaken in institutions that routinely perform surgical MV operations and participate in the STS Adult Cardiac Surgical Database with outcomes that equal or exceed those expected for their case mix relative to national benchmarks. Similarly, only institutions with interventional cardiology programs that have established programs in PCI, balloon valvuloplasty, TAVR, catheter closure of periprosthetic leaks, and deployment of septal closure devices, with outcomes that equal or exceed those established nationally for similar procedures, should offer transcatheter MV intervention.

Most importantly, there must be dedication on the part of the institution to provide these services and support, both financially and with no time constraints on the staff involved. The institutional commitment required for a successful program goes beyond the necessary space, personnel, and specialized facilities set forth in the previous text. The complex and time-consuming preprocedural patient triage process and the degree and intensity of postprocedural patient care after discharge are labor intensive for physicians, advanced practitioners (nurse practitioners, physician assistants), and nursing staff, as are informed consent and communication with patients, families, and referring providers. MDT decision-making conferences are invaluable. In addition to supporting the core nursing and technical support staff, arrangements between the institution and the physicians need to

be in place to cover physician efforts dedicated to nonreimbursable hours of clinical care and medical management of the program.

5. MULTIDISCIPLINARY TEAM

The MDT forms the core of the structural heart disease program, the defining principle for which is the optimization of patient outcomes. Transcatheter MV intervention programs can only be formed where joint cardiology and cardiac surgery collaboration has been established, along with partnerships extending across many other specialty areas, including anesthesiology, imaging, nursing, and social services. The MDT is supported through institutional resources and consists of the medical professionals necessary to deliver optimal patient-centered care. Composition of the MDT may continue to evolve in response to the introduction of novel MV technologies.

The MDT is typically led by medical (interventional cardiology) and surgical (cardiac surgery) codirectors. An MDT delivering full-service care to patients with MV disease should include individuals with the following knowledge, experience, and skillsets:

- Interventional cardiology with American Board of Internal Medicine (ABIM) board certification in the subspecialty;
- Cardiac surgery with American Board of Thoracic Surgery certification or equivalent;
- General cardiology with heart valve disease expertise and ABIM certification in cardiovascular diseases (general cardiology);
- HF, preferably with ABIM certification in advanced HF and cardiac transplant;
- Transthoracic and intraprocedural TEE (including 3D TEE) with advanced training per American Society of Echocardiography standards;
- Cardiac CT;
- Cardiac MRI, when available;
- Cardiac anesthesia;
- Physician assistants/nurse practitioners;
- Patient navigator/program coordinator;
- Data manager; and
- Hospital administration representative.

Additional participation may be required from specialists representing:

- Electrophysiology;
- Stroke neurology;
- Cardiac/cardiac surgical intensive care;
- Cardiac perfusionists;
- Vascular surgery;
- Renal medicine;
- Social work; and
- Palliative care.

The intraprocedural and postprocedural care provided by trained nurses and technicians familiar with transcatheter MV interventions is critical.

Sites planning to establish a new MV transcatheter interventional program should demonstrate experience with related surgical (e.g., repair, replacement) and transseptal access (e.g., patent foramen ovale closure, mitral paravalvular leak closure, left atrial appendage occlusion) procedures. For transcatheter MV procedures that can be performed by a single operator, it is important for the partnering (nonperforming) surgeon or interventional cardiologist to remain involved, as required in other aspects of patient selection and care. For example, in the case of edge-to-edge clip device repair performed by an interventional cardiologist, the surgeon can function as a patient advocate and/or as the referring physician, as well as a valued study collaborator in current and future device applications. The surgeon should be familiar with established standards of care for application of transcatheter MV therapies. Institutional support for nonclinically reimbursable time can help promote collaboration of this nature.

The MDT meets formally as a group on a regular (weekly) basis (aside from the usual "catheterization conference") to review all patients referred for transcatheter MV procedures, the outcomes of recent procedures, and patient follow-up.

5.1. Function of the MDT

The coordinated functioning of the MDT is essential to the processes of preprocedural patient selection, intraprocedural management, postprocedural care, postdischarge follow-up, and outcome reporting. Clear definitions of the roles and responsibilities of the various MDT specialists and effective communication are critical to a successful program with optimal patient outcomes.

The procedural success of transcatheter valve therapies begins with appropriate patient selection. Given the complexity of the decision-making process surrounding these procedures, all MDT members must provide objective input and clinical judgment from the outset. Whereas the "2014 SCAI/AATS/ACC/STS Operator and Institutional Requirements for Transcatheter Valve Repair and Replacement: Part II. Mitral Valve" document stipulated that every patient be evaluated by a cardiac surgeon and an interventional cardiologist, expectations for patient selection have changed as experience with these procedures has increased and indications have evolved. Specifically, patients with HF, reduced LVEF, and $\geq$ moderate secondary MR should first be evaluated and treated by an HF cardiologist who can then consider referral for MV intervention when clinically appropriate and after optimization of GDMT (including cardiac resynchronization

therapy when indicated). Not all such HF patients with secondary MR would need to be seen individually by a cardiac surgeon, for example, unless therapy other than transcatheter edge-to-edge clip device repair (e.g., CABG surgery, tricuspid surgery, surgical AF ablation) were felt to be potentially indicated after initial MDT review. Because surgical MV repair provides reduction of primary MR superior to edge-to-edge clip device repair, surgical consultation for these patients is critical to verify that operative risk is indeed high enough to warrant transcatheter intervention.

The patient selection process may be initiated at the regularly scheduled (weekly) conferences attended by all MDT members. Such conferences are analogous to transplant patient selection committee meetings and provide a venue in which patient-specific data and imaging are formally presented and discussed by the MDT. The respective expertise of each discipline represented among MDT members may then be integrated into a patient-specific recommendation. Each member of the MDT who formally evaluates the patient must record his/her opinion and enter it into the patient record.

Direct patient evaluation by cardiologists (including both interventional and valve/HF specialists) and cardiac surgeons can be accomplished jointly and, whenever possible, simultaneously in a venue such as a multidisciplinary heart valve clinic. Such clinics are convenient for patients and offer an opportunity for MDT members to jointly examine and evaluate complex cases.

Following the decision that a given patient is an appropriate candidate for transcatheter MV therapy, the procedure must then be carefully planned. All MDT members who will participate in the intervention (e.g., interventionalist, surgeon, echocardiographer, cardiac anesthesiologist, nurses, technicians) discuss the intended procedure, the individual steps of the planned procedure, the specific tools and equipment needed, the possible complications that may arise during the course of the procedure, and the contingency plans that will be implemented should the unexpected occur. Intraprocedural echocardiography is provided either by a cardiologist or anesthesiologist trained in interventional TEE and 3D TEE. Unexpected complications may arise, making immediate MDT support a necessity for problem solving and treatment. Communication and clear delineation of responsibilities are also critical.

Most patients recover routinely after edge-to-edge clip device therapy for severe MR. In isolated cases with hemodynamic or rhythm instability, postprocedural care should be provided in a cardiac intensive care setting. Algorithms for postprocedural care will evolve with innovations in transcatheter MV interventions and as a function of patient risk profile, access site (e.g., transapical versus transseptal), and institutional experience. A team approach to care is important and should include physicians skilled in critical care medicine when indicated by patient acuity. Subsequent in-hospital care should be provided on a telemetry unit staffed by nurses skilled in the assessment and care of the post-transcatheter intervention or cardiac surgical patient. Continued involvement of MDT members throughout recovery and hospitalization is mandatory. Emergence of a new problem (e.g., stroke) or an acute change in a pre-existing condition (e.g., renal dysfunction) will require assessment by a member of the extended MDT. Transition to home or a nonhome venue for the HF patient following transcatheter treatment of MR requires careful medication reconciliation at discharge, as well as attention to a host of additional issues, including cardiac rhythm management, antithrombotic therapy, blood pressure, renal function, nutrition, and plans for cardiac rehabilitation.

Postdischarge follow-up will assess device, echocardiographic, and clinical outcomes at specified timepoints, although any unanticipated change necessitates immediate access to the MDT. The extended services of a chronic HF management program for patients with LV dysfunction and secondary MR who have undergone intervention, for example, should not be interrupted. Registry reporting of patient outcomes, including QoL, should be required following FDA-approved transcatheter MV interventions.

6. SDM REQUIREMENTS

A major goal for any transcatheter MV program is for patients to participate meaningfully in their healthcare decisions. To this end, patients should: 1) be well-informed regarding all their treatment options and whether all options are available locally; 2) understand the risks and benefits presented using data on treatment options that are as patient-specific as possible; 3) articulate their treatment- and recovery-related goals; 4) express their preferences and values relative to their care; and 5) integrate these to make a final treatment choice. The Centers for Medicare and Medicaid Services (CMS) has actively promoted this SDM process to enhance beneficiary engagement and incentives in an SDM model: “The Centers for Medicare & Medicaid Services (CMS) identifies strengthening beneficiary engagement as one of the agency’s goals to help transform our health care system into one that delivers better care, smarter spending, healthier people, and puts individuals at the center. Specifically, the CMS Quality Strategy envisions health and care that is person-centered, provides incentives for the right outcomes, is sustainable, emphasizes coordinated care and SDM, and relies on transparency of quality and cost information” (42).

SDM regarding the choice of prosthetic heart valve was emphasized in the "2014 AHA/ACC Guidelines for the Management of Patients with Valvular Heart Disease": "The choice of type of prosthetic heart valve should be a shared decision-making process that accounts for the patient's values and preferences and includes discussion of the indications for and risks of anticoagulant therapy and the potential need for and risk associated with reintervention (COR I, LOE C-LD)" (8). Similar reasoning can be applied to the indications for and choice of intervention for severe MR, including surgical repair or replacement versus transcatheter intervention as applied on an individual patient basis.

The achievement of the goals of SDM can be challenging and time-consuming. As pointed out by CMS, "Practitioners have found it difficult to integrate SDM into their routine workflows for various reasons such as overworked physicians, insufficient practitioner training, inadequate clinical information systems, lack of consistent methods to measure that SDM is taking place, and uncertainty as to whether, or how, to promote change and invest in the time, tools, and training required to achieve meaningful SDM" (42). The focus should be on mutual goal setting within the context of clinical risks and benefits. Development of visual aids specific to the decision regarding MV intervention is encouraged.

7. OUTCOME REQUIREMENTS

Outcome measures of quality and recommended performance monitoring metrics are outlined in **Tables 1 and 2**. **Table 1** includes outcome measures of quality for transcatheter MV procedures. These measures are proposed as appropriate starting points in this evolving space, in which risk adjustment tools are not yet available.

The principal outcome measure for surgical MV repair from the STS Adult Cardiac Surgery Database is a composite score that consists of: 1) risk-adjusted operative mortality (death occurring during the index hospitalization or following transfer to another acute care facility within 30 days, or death within 30 days of surgery); and 2) the risk-adjusted occurrence of any of the following 5 major complications—renal failure, stroke, cardiac reoperation, sternal infection/mediastinitis, or prolonged ventilation (43). This composite measure relates to the fundamental short-term goals of surgical procedures for MR, namely, survival with minimal perioperative complications. This measure enables differentiation of site performance, with the subsequent assignment of a star rating to each site, defined as lower than expected (1 star), as expected (2 stars), or higher than expected (3 stars). Presently, 1-year outcomes and QoL data are not available from the STS database.

Outcomes measures for transcatheter MV procedures should address similar goals of care for patients with MR. These procedures have thus far been directed at patients with HF and high or prohibitive surgical risk. There is a recognized need to track survival and assess objectively whether transcatheter MV intervention improves functional state and QoL compared with baseline. The STS/ACC TVT Registry has reported clinical outcomes (e.g., death, stroke, rehospitalization for HF) following transcatheter edge-to-edge clip device repair (35). Incorporation of patient-reported health status using the Kansas City Cardiomyopathy Questionnaire (KCCQ) is an additional feature (44). Changes in KCCQ from baseline to 1-year post-TAVR, for example, have been utilized to determine if surviving patients have derived functional benefit from the procedure (45,46). Application to transcatheter MV procedures would seem straightforward. Rehospitalization rate is an additional measure that can be considered to assess broad aspects of care, including patient selection, procedure performance, and postprocedural care. **Table 2** lists additional measures for future consideration.

Risk adjustment models for transcatheter MV procedural outcomes are under development. In a 2017 STS/ACC TVT Registry report of patients with MR treated with edge-to edge clip repair, factors associated with mortality or rehospitalization for HF after multivariate adjustment were increasing age, lower baseline LVEF, worse postprocedural MR, moderate or severe lung disease, dialysis, and severe tricuspid regurgitation (34). In the 2019 STS/ACC TVT Registry report of 12,334 edge-to-edge clip device repairs performed at 275 sites between November 2013 and September 2017, overall mortality was 2.1% (mean age 81 years, STS Predicted Risk of Mortality Score for MVR 8.3%), whereas the rates of any stroke, single leaflet detachment, and conversion to open surgery were <1% (35).

Data used to fulfill the requirements to maintain a safe, efficient, and effective MV intervention program can be generated from the STS/ACC TVT Registry and STS Adult Cardiac Surgery Database with linkage to the 1-year outcomes tracked by CMS. These requirements will maintain consistency and quality control for all sites. Individual site reports for transcatheter MV procedures are generated quarterly by the STS/ACC TVT registry. Each metric is accompanied by a national benchmark with a median value and interquartile range analyzed from the previous rolling 4 quarters of all site data submitted to the registry that pass a data quality check. These national benchmarks are presented graphically using box plots (see **Figure 1**). This method of individual site data presentation is a convenient first step for programs to assess their performance; however, the

TABLE 1 2019 Transcatheter MV Intervention Program Outcome and Performance Monitoring Metrics: Proposed Minimum Quality Standards

Preprocedural Process Metrics

- MDT assessment and consensus recommendation with documentation of:
  - Etiology and severity of MR
  - HF symptoms and NYHA class
  - Medical therapies for HF with secondary MR and optimization over ≥3 months by a general cardiologist or (preferably) an advanced HF subspecialist
  - EP specialist assessment of indications for and appropriate initiation of CRT for patients with HF and secondary MR
  - Surgical risk assessment for patients with primary MR and selected patients with secondary MR for whom procedures in addition to MR correction might be indicated (e.g., CABG, AF ablation, tricuspid repair)

Primary In-Hospital and 30-Day Outcome Metrics	Performance Requirement
In-hospital and 30-day all-cause mortality*	"As expected" or "better than expected" based on national benchmark data with 95% CIs
30-day stroke, TIA	Performance falls within 95% (outlier) and/or 90% (warning) boundaries on funnel plot
30-day major vascular complication	Performance falls within 95% (outlier) and/or 90% (warning) boundaries on funnel plot
30-day major bleeding	Performance falls within 95% (outlier) and/or 90% (warning) boundaries on funnel plot
30-day moderate-to-severe or severe MR	Performance falls within 95% (outlier) and/or 90% (warning) boundaries on funnel plot
30-day significant MS (mean gradient ≥8 mm Hg, valve area <1.5 cm^2)	
Primary 1-Year Outcome Metrics	Performance Monitoring Metrics (Under Development)
1-year all-cause mortality*	
Change in patient-reported health status (KCCQ) at 1-year vs. baseline	
1-year rehospitalization for HF	
1-year repeat MV intervention (transcatheter or surgical)	
1-year moderate-to-severe or severe MR	
1-year significant MS (mean gradient ≥8, valve area <1.5 cm^2)	

*Risk adjustment models under development.

AF, atrial fibrillation; CABG, coronary artery bypass grafting; CI, confidence interval; CRT, cardiac resynchronization therapy; EP, electrophysiology; HF, heart failure; KCCQ, Kansas City Cardiomyopathy Questionnaire; MDT, multidisciplinary team; MR, mitral regurgitation; MS, mitral stenosis; MV, mitral valve; NYHA, New York Heart Association; TIA, transient ischemic attack.

method has important limitations. Box and whisker plots only include a site's point estimate and do not provide a measure of the substantial statistical uncertainty associated with assessing small sample sizes. An alternative method to illustrate site performance is the funnel plot, as described by Spiegelhalter (47,48). This graphical approach has several advantages. It explicitly conveys the greater random fluctuation inherent in samples drawn from programs with low volumes and can be used with varying upper and lower control limits (e.g., 95% for outlier status, 90% for warning status). The STS Adult Cardiac Surgery Database reports for valve surgery are based on 3 years of data and advanced every 6 months.

Table 1 shows proposed outcome and performance monitoring metrics necessary for maintenance of an MV transcatheter interventional program, as well as other measures under development. These metrics were chosen by expert consensus opinion and based on cumulative experience to date with transcatheter MV interventions. Risk-adjusted mortality rates, composite measures, and patient-reported health status (including QoL, which is part of the KCCQ questionnaire) constitute future outcome metrics to be introduced into the maintenance requirements as the capabilities of the registry expand and statistical precision improves.

Some of the metrics shown in Table 1 could also be used as warning signals for problematic performance. For example, worse than expected performance for risk-adjusted measures (when available) on 2 consecutive

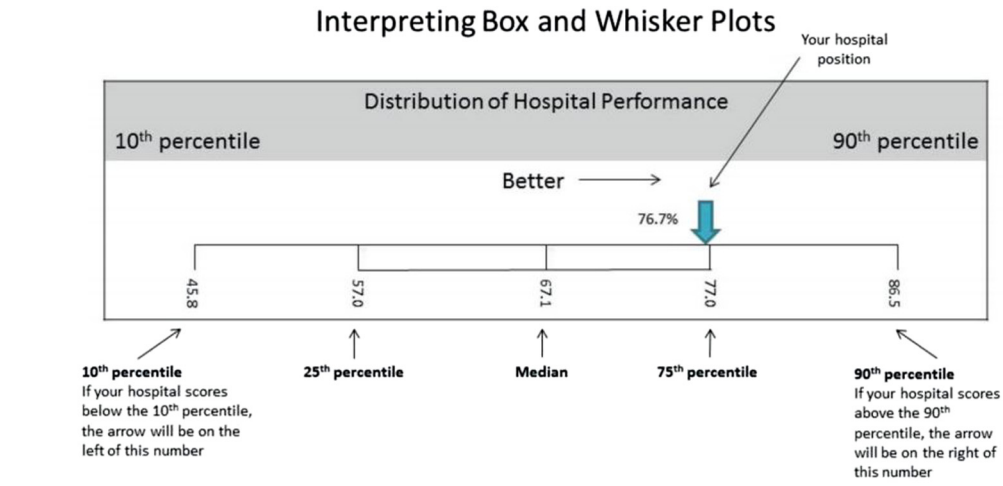
TABLE 2 2019 Transcatheter MV Intervention Program Performance Monitoring Metrics: Proposed Additional Metrics for Quality Assessment

Time Frame	Outcome Metric
In-hospital	Technical success rate*
	Conversion to open MV surgery
	Unplanned MCS
	Cardiac arrest
	Device embolization
	Single leaflet detachment
30-day	All-cause rehospitalization
	HF rehospitalization
1-year	All-cause rehospitalization
	Improvement in KCCQ ≥10 points above baseline

*Per MVARC criteria (50), for a technical success (measured at exit from the catheterization laboratory), all of the following must be present: I. Absence of procedural mortality; II. Successful access, delivery, and retrieval of the device delivery system; III. Successful deployment and correct positioning of the first intended device; and IV. Freedom from emergency surgery or reintervention related to the device or access procedure.

HF, heart failure; KCCQ, Kansas City Cardiomyopathy Questionnaire; MCS, mechanical circulatory support; MV, mitral valve; MVARC, Mitral Valve Academic Research Consortium.

FIGURE 1 **STS/ACC TVT Registry Example of a Quarterly Report to Sites Providing Site Performance in the Context of National Benchmark Statistics**



10th Percentile – 90% of hospitals achieved "better" scores than the 10th percentile. **25th Percentile or 1st Quartile** – 75% of hospitals achieved "better" scores than the 25th percentile. **50th Percentile or 2nd Quartile** – Middle of the distribution: half of the hospitals' data are above and half are below the median. **75th Percentile or 3rd Quartile** – 25% of hospitals achieved "better" scores than the 75th percentile. **90th Percentile** – 10% of hospitals achieved "better" scores than the 90th percentile. **Your hospital position** – "Your Hospital Position" is in relation to all other hospitals' data.

reports or falling outside the control limits on funnel plots for unadjusted measures should require immediate attention and internal quality control. The MV program should consider seeking external review of their performance, including patient selection, procedural success, and quality of care, in the context of the challenges inherent in caring for a patient population that is often elderly and burdened by HF and numerous additional comorbidities. There is broad agreement that excessive 1-year mortality and a low proportion of patients reporting functional improvement would constitute a warning for a program to reconsider its processes, case selection, and outcomes. Pertinent questions in this context would include:

1. Is the program performing transcatheter MV procedures in many patients who are unlikely to derive survival and/or functional benefit (similar to the cohort C patient considered for TAVR)?
2. Are there problems with substandard procedure performance and/or postprocedural care, including long-term HF management?

At the other extreme would be a program with a very low 1-year mortality and a higher than expected proportion of patients with improved QoL as reflected by changes in KCCQ scores. This scenario might raise other relevant questions. For example:

1. Is the program denying treatment to some high-risk patients who might benefit?
2. Does the program more often transfer more complex patients to another site (this may be appropriate in in some circumstances)?
3. Are patients undergoing transcatheter MV procedures at this institution in a lower-risk category than national benchmarks (49) and outside of current FDA indications for use?

Table 2 includes other proposed outcome metrics that can be monitored, evaluated, discussed, and compared with national STS/ACC TVT Registry-generated benchmarks to enhance the overall performance of a site program.

There are 2 important considerations in the use of Tables 1 and 2 for a site's quality assessment program. First, benchmarks should be continually updated through the STS/ACC TVT Registry to reflect the substantial improvements in transcatheter MV repair procedural success rates and clinical outcomes observed over the past 5 years. The quarterly report of the STS/ACC TVT Registry automatically updates these benchmarks on the basis of the last 4 quarters of reported data from sites meeting data quality standards. Second, the case mix for a MV program may change over time and may not be similar to the national average case mix of patients being treated at all centers. Risk adjustment models will help to assess a program's performance within the context of its patient mix.

8. NATIONAL REGISTRY REQUIREMENTS

FDA approval of a novel transcatheter valve repair or replacement system does not guarantee that the device will continue to demonstrate long-term efficacy that is comparable to other options, which are or will become available, or that its use will remain limited to the initially approved indication. Both postmarket surveillance organized through individual institutions or multicenter research groups and outcomes reported in multistakeholder registries are essential to track continued device safety and efficacy. Participation in device-specific registries can be challenging and requires institutional infrastructure and MDT resources that include experienced data managers with a background in cardiovascular disease, funding, office space, computer services, and a data coordinating/clinical research unit with rigorous attention to data precision and accuracy. Validated registry data are the foundational elements that allow objective assessment of the application of new devices to a more generalizable patient population. Centers that incorporate transcatheter MV interventions into their practice should participate in the STS/ACC TVT Registry and the STS Adult Cardiac Surgery Database. As discussed previously, these registries are evolving to include longer-term, risk-adjusted outcomes related to both survival and QoL. Data regarding the long-term (≥1 year) durability of MR reduction following either transcatheter or surgical intervention, as well as the need for MV reintervention, would be of additional interest.

Professional societies have a responsibility to promote long-term data monitoring and to provide collaborative oversight and guidance regarding the expectations for continued monitoring beyond the FDA approval phase of device development and implementation. Individual centers are responsible for critically evaluating their own program through local and regional quality improvement initiatives and for participating in registries to benchmark their performance against national standards.

A critical aspect of the integrity of post-procedural surveillance is the need for complete, accurate, and timely data submission from registry sites. Industry-sponsored research facilitates data acquisition and follow-up at the site level. Monitoring of investigative sites, the use of central core labs, and adjudication of endpoints are standard best practices in pivotal research studies. The STS/ACC TVT Registry relies on site-reported data without central echocardiographic core laboratory assessment or regular site monitoring. Nevertheless, there are several mechanisms in place to monitor data completeness and accuracy in the STS/ACC TVT Registry. These include site training and support by STS/ACC TVT Registry staff, data "cleaning" by data integrity checks utilizing range validation and other measures, auditing portions of site-level data, and adjudication of selected 30-day and 1-year outcomes. Collection of source documents and verification of prespecified key events can be added specifically for postapproval studies. The Duke Clinical Research Institute provides adjudication services for prespecified events and other operational support (51). Both the STS/ACC TVT Registry and STS Adult Cardiac Surgery Database use a third-party external audit mechanism to assess accuracy and completeness of data submission from sites. Site audits for the STS/ACC TVT Registry underwent a pilot evaluation in 2016. and regular audits started in 2017 using standards similar to those adopted by the STS Adult Cardiac Surgery Database. The STS/ACC TVT Registry has an extensive data quality initiative (52). Both national registries provide feedback to sites on the quality and completeness of their data submission. Importantly, the STS/ACC TVT Registry requires sites to submit data on 1-year outcomes, whereas the STS Adult Cardiac Surgery Database has thus far focused on 30-day outcomes.

9. REQUIREMENTS FOR ESTABLISHING AND MAINTAINING A TRANSCATHETER MV INTERVENTION PROGRAM

Important issues to consider in the establishment of a transcatheter MV program are the size and spectrum of the clinical referral base needed to ensure an adequate number of patients to provide for the viability of the program. **Table 3** lists the requirements for transcatheter MV intervention programs. As noted, the current proposed case volumes for transcatheter MV repair pertain to the use of the edge-to-edge clip device for primary or secondary MR. Intervention for MR is a rapidly evolving field and recommended case volumes for transcatheter MV repair and replacement systems that may become available in the future may differ from those shown in the table. The case volumes reflect the writing committee's efforts to strike a balance across procedural quality, expected outcomes, and patient access. They are readily achievable for many sites and should not be considered exclusionary. Minimum case volume requirements reflect the process, infrastructure, and commitment needed for a successful program.

A search in the STS/ACC TVT Registry in July 2019 showed that 361 STS/ACC TVT Registry sites in the United States offer transcatheter MV repair with the edge-to-edge clip device (**Figure 2**). The 2019 STS/ACC TVT Registry report (35) showed that optimal procedural success

TABLE 3 2019 Transcatheter MV Intervention Site and Operator Requirements

MDT participants at transcatheter MV intervention sites should have the following minimum competencies:
- Documented expertise in valvular heart disease, HF, multimodality imaging, coronary and structural heart disease intervention, and cardiac surgery
  - A general cardiologist or valve expert knowledgeable and experienced in the assessment and treatment of patients with MR.
  - A dedicated HF cardiologist, preferably ABIM certified in AHF/Tx, knowledgeable and experienced with GDMT, indications for CRT and advanced mechanical support
  - A dedicated interventional echocardiographer with Level III training, knowledgeable and experienced in TTE, intraprocedural TEE, 3D TEE.
  - A dedicated cardiac CT imaging specialist*
  - Physicians and teams experienced in arterial and venous interventions involving coronary and peripheral circulations
  - Physicians and teams experienced in arrhythmia management, including pharmacological, ablative, and implantable device interventions
  - Expertise available in cardiac anesthesia, cardiac intensive care, and stroke neurology
  - Nurse, nurse practitioner, and/or physician assistant clinical expertise and patient care coordination.
- Participation in continuing education/lifelong learning activities.

Transcatheter MV intervention site program directors are responsible for accurate and transparent reporting, including the following QI/QA requirements:
- Site participation in the STS/ACC TVT Registry and STS Adult Cardiac Surgery Database
  - Registry submission of all transcatheter MV cases, including off-label and investigational device use
  - Regulatory documentation that data submissions meet metrics for completeness and accuracy
- MDT meetings (at least every quarter) with documentation of:
  - Review of site reports to national registries for transcatheter and surgical MR treatment
  - Assessment and plans for corrective action if site performance metrics fall below national benchmarks
  - Presentation of selective cases for M&M conferences
  - Documentation of incorporation of AUC (when available) into patient selection processes

For patients with MR meeting guideline criteria for intervention, there should be documentation of:
- MR etiology (primary vs. secondary [vs. mixed]) and severity assessed by an echocardiographer knowledgeable and experienced in the integrative assessment of MR
- MDT consensus and SDM for all patients:
  - MDT consensus decision regarding medical, surgical, or transcatheter therapy
  - MDT education of patient regarding treatment options
  - SDM process
- For patients with primary (or mixed) MR meeting guideline criteria for intervention, there should be documentation of:
  - Evaluation by a general cardiologist or valve expert with knowledge and experience in the care of patients with MR, as well as with MV repair and replacement
  - Evaluation by an interventional cardiologist
  - Evaluation by an MV surgeon with assessment of operative risk
- For patients with secondary MR meeting guideline criteria for intervention, there should be documentation of:
  - Evaluation by a general cardiologist, valve expert, or advanced HF cardiologist with knowledge and experience regarding MR, as well as MV repair and replacement. Evaluation should include HF status and optimization of GDMT (including CRT, when indicated) over ≥3 months. Clinical evaluation and verification of treatment response by an advanced HF expert is preferred whenever available.
  - Evaluation by an interventional cardiologist
  - Evaluation by a MV surgeon with assessment of operative risk when there is a potential need (as assessed by the MDT) for other surgical therapies (e.g., CABG, AF ablation, tricuspid valve repair)

To optimize outcomes at a new transcatheter MV intervention program, the interventional echocardiographer should document:
- Participation in 10 transseptal guidance procedures and 30 structural heart procedures (lifetime) (56)

To optimize outcomes at a new transcatheter MV intervention program, the interventionalist (cardiologist or surgeon) should document:
- 50 lifetime structural heart procedures
- Prior transcatheter MV repair experience (including while proctored) with participation in 20 transseptal interventions lifetime, including 10 as primary or coprimary operator†
- Board eligibility or certification in either interventional cardiology or cardiothoracic surgery
- Certification of device-specific training

To optimize outcomes at new transcatheter MV intervention programs, sites should have the following:
- A surgeon who has performed 20 MV surgeries in the previous year or 40 MV surgeries over the 2 previous 2 years, of which at least 50% should be repairs, and who is board eligible or certified by the ABTS or equivalent
- Minimum site MV surgical volume of 40 cases in the previous year or 80 cases over 2 years, of which at least 50% should be MV repairs
- STS star rating ≥2 for at least 2 consecutive performance reporting periods per year for both MVR and MVR plus CABG

To optimize outcomes at established transcatheter MV intervention programs, sites should document:
- ≥20 transcatheter MV interventions per year or ≥40 interventions over prior 2 years
- ≥20 MV surgeries per year or ≥40 surgeries over 2 years
- STS/ACC TVT Registry-reported 30-day all-cause mortality above the lowest decile
- Participation in the STS Adult Cardiac Surgery database
- STS star rating ≥2 for at least 2 consecutive performance reporting periods per year for both MVR and MVR plus CABG

The transcatheter MV intervention site should document the following resources and ongoing PCI experience:
- ≥300 cases per year.
- Participation in NCDR Cath/PCI or validated equivalent registry
- In-hospital risk-adjusted mortality rate above the lowest 25th percentile for the most recent 4 quarters

*A dedicated cardiac MR imaging specialist should be included as an MDT member, when available.
†As of this writing, transcatheter repair of MR is limited to the use of the edge-to-edge clip device. The recommended case volume numbers cited here for proceduralists and institutions may differ for other transcatheter repair and replacement systems introduced in the future.

ABIM, American Board of Internal Medicine; ABTS, American Board of Thoracic Surgery; ACC, American College of Cardiology; AF, atrial fibrillation; AHF/Tx, acute heart failure treatment; AUC, appropriate use criteria; CABG, coronary artery bypass grafting, CRT, cardiac resynchronization therapy; CT, computed tomography; GDMT, guideline-directed management and therapy; HF, heart failure; MDT, multidisciplinary team; M&M, morbidity and mortality; MR, mitral regurgitation; MV, mitral valve; MVR, mitral valve replacement, NCDR, National Cardiovascular Data Registry; PCI, percutaneous coronary intervention; QA, quality assurance; QI, quality improvement; SDM, shared decision making; STS, The Society of Thoracic Surgeons; TEE, transthoracic echocardiogram; TTE, transthoracic echocardiogram; TVT, transcatheter valve therapy.

FIGURE 2 Number of STS/ACC TVT Registry Sites Performing Transcatheter Mitral Valve Repair With the Edge-to-Edge Clip Device

*As of July 28, 2019.

increased across tertiles of case experience, whereas procedural time and procedural complications decreased. In a learning-curve analysis, visual inflection points for procedural time, procedural success, and procedural complications were evident after approximately 50 institutional cases, with continued improvements observed up to 200 cases. After multivariable adjustment, however, only procedural time after 50 cases remained significantly associated with institutional case experience, implying that better case selection may have contributed to the improved procedural and reduced complication rates noted with greater experience (53).

These data reflect an early experience with the use of this repair system in an older, largely high/prohibitive surgical-risk patient cohort, the vast majority (86%) of whom had primary MR, and thus may not reflect the experience in HF patients with reduced EF and secondary MR. Outcome differences between the MITRA-FR and COAPT trial cohorts may derive in part from the higher rates of procedural success and sustained MR reduction achieved in the latter study (9,10), which in turn implies that skill and experience matter (53). The median number of cases per site in the STS-ACC TVT Registry report was 30; 83 of 275 sites contributed to the highest-volume tertile. Very few sites performed >150 cases. Individual operator case volume and performance data are not available from the registry at this time.

The surgical program case volumes in **Table 3** were obtained by querying the STS Adult Cardiac Surgery Database, reviewing the published experiences from other data sources (54), and soliciting expert surgical opinion. An analysis of data from the STS Adult Cardiac Surgery Database on access to mitral valve repair or replacement (MVRR) surgery in the United States by hospital referral region (HRR), as defined by the Dartmouth Atlas, has indicated that the proportion of the population living within an HRR with a center performing ≥25 surgical MVRRs is 92.0%, whereas 81.7% of the population lives within an HRR with a center performing >40 surgical MVRRs per year (55). Centers performing ≥40 surgical MVRRs per year of which ≥20 are MV repairs, are in the same HRR as 78.7% of the population. Outcome data as a function of center surgical MVRR case volume above or below thresholds of 25 or 40 annual

cases, however, are not available from the STS Adult Cardiac Surgery Database at this time. Data from New York State suggest that higher total annual surgeon volume is associated with increased repair rates for primary MR (the preferred strategy), with an improved 1-year survival and decreased reoperation risk when >25 total MV operations are performed annually (54). In addition, repair rates among surgeons with case volumes <25 MV operations per year increase significantly if they operate at an institution in which another surgeon performs >50 MV cases per year with repair rates for primary MR >70% (54).

The proposed requirements are constructed to: 1) ensure patient safety and promote quality; 2) demonstrate that there is a commitment on the part of the institution to the structural heart disease program; and 3) use existing volume as a surrogate for an established MV program to ensure adequate experience for the maintenance of a sustainable MV intervention program. Defining minimum operator and institutional requirements for these therapies is an important first step to ensuring their optimal implementation. Several of the MDT and proceduralist competencies listed in **Table 3** parallel those included in the "2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Aortic Valve Replacement" (2), although many are specific to MV intervention.

10. COMPLIANCE WITH DOCUMENT RECOMMENDATIONS

Compliance with these professional society recommendations is voluntary but expected to achieve and sustain optimal care for patients with MV disease who are considered for transcatheter or surgical intervention. The scrutiny rightfully applied to transcatheter interventions has also led to a re-examination of expectations regarding surgical MVRR. Patients with MR should have access to all appropriate treatment options. Professional societies have an obligation to promote best practices, as reflected in the proposed requirements and quality metrics listed in **Tables 1 to 3**, and to provide support to programs and operators who fail to meet consensus performance standards.

For transcatheter MV intervention, the CMS National Coverage Determination (NCD) is currently based on compliance with the institutional and operator requirements listed in the "2014 SCAI/AATS/ACC/STS Operator and Institutional Requirements for Transcatheter Valve Repair and Replacement. Part II. Mitral Valve." Compliance with the NCD allows coverage and payment from Medicare.

The Writing Committee endorses the recommendations included in the "2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Aortic Valve Replacement," regarding both registry and professional society actions to facilitate best practices. As applied to transcatheter MV intervention programs, these would comprise annual reports from the STS/ACC TVT Registry and the STS Adult Cardiac Surgery Database containing the following summary statistics:

- Number of all active transcatheter MV intervention programs and frequency distribution of yearly site volume. The report should identify the number and percentage of active transcatheter MV intervention programs whose yearly volume falls below the minimum requirements outlined in this document.
- Number of all active surgical MV programs and frequency distribution of yearly site volume. The report should identify the number and percentage of active MV surgical programs whose yearly volume falls below the minimum requirement for a complementary transcatheter MV intervention program.
- Number of active transcatheter MV intervention programs that meet and fail to meet the data quality and completeness requirements of the STS/ACC TVT Registry.
- Number of active surgical MV programs that meet and fail to meet the data quality and completeness requirement of the STS Adult Cardiac Surgery Database.
- Number of transcatheter MV intervention programs that meet and fail to meet the outcomes standards outlined in **Table 1**.
- Number of surgical MV programs that achieve each category of star rating for MV surgery.

Sites that fail to meet volume, quality of care, and compliance for reporting performance metrics as outlined in this document should receive notice from the relevant national registry informing them of this finding. The issues surrounding site certification and ongoing program accreditation are beyond the scope of this document.

11. CONCLUSIONS

Transcatheter interventions for patients with severe MR are expected to increase sharply in the years ahead. The prior 2014 multisociety document (1) was published just 1 year after FDA approval of the edge-to-edge clip device for treatment of prohibitive surgical risk patients with severe primary MR and thus could not provide much granularity. The interim experience with the edge-to-

edge clip device for MV repair as reported to the STS/ACC TVT Registry (34,35) and described in landmark RCTs (9,10) allows for greater clarity regarding standard setting for this specific intervention. Additional perspectives on surgical MVRR have been gained from registry analyses (54,57) and RCTs (11,58). Newer transcatheter systems for the treatment of severe MR are anticipated, and it is expected that the proposed requirements herein will need to evolve with further advances in equipment, techniques, and patient selection. Nevertheless, the guiding principles and foundational elements included in this and companion multisociety documents (2,4) constitute an enduring commitment to optimizing patient outcomes.

PRESIDENT AND STAFF

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KEY WORDS **Expert Consensus Systems of Care Document, heart failure, mitral valve, outcome measures, registry, transcatheter mitral valve repair, transcatheter mitral valve replacement**

APPENDIX 1. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT): 2019 AATS/ACC/SCAI/STS EXPERT CONSENSUS SYSTEMS OF CARE DOCUMENT: OPERATOR AND INSTITUTIONAL RECOMMENDATIONS AND REQUIREMENTS FOR TRANSCATHETER MITRAL VALVE INTERVENTION

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APPENDIX 1. CONTINUED

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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;* 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*.

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‡Relationship with this company is limited to enrolling patients in clinical trials. This disclosure was entered under the Clinical Trial Enroller category in the ACC's disclosure system. To appear in this category, the author acknowledges that there is no direct or institutional relationship with the trial sponsor as defined in the ACC/AHA Disclosure Policy for Writing Committees.

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AATS, American Association for Thoracic Surgery; ACC, American College of Cardiology; AHA, American Heart Association; SCAI, Society for Cardiovascular Angiography and Interventions; and STS, The Society for Thoracic Surgeons.

APPENDIX 2. PEER REVIEWER INFORMATION—2019 AATS/ACC/SCAI/STS EXPERT CONSENSUS SYSTEMS OF CARE DOCUMENT: OPERATOR AND INSTITUTIONAL RECOMMENDATIONS AND REQUIREMENTS FOR TRANSCATHETER MITRAL VALVE INTERVENTION

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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ACC, American College of Cardiology.

APPENDIX 3. ABBREVIATIONS

ACC	American College of Cardiology
AATS	American Association for Thoracic Surgery
COAPT	Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation
CMS	Center for Medicare and Medicaid Services
FDA	Food and Drug Administration
GDMT	guideline-directed management and therapy
HF	heart failure
KCCQ	Kansas City Cardiomyopathy Questionnaire
MDT	multidisciplinary team
MITRA-FR	Multicentre Study of Percutaneous Mitral Valve Repair with the MitraClip Device in Patients with Severe Secondary Mitral Regurgitation
MR	mitral regurgitation
MV	mitral valve
MVRR	mitral valve repair or replacement
QoL	quality of life
SCAI	Society for Cardiovascular Angiography and Interventions
SDM	shared decision making
STS	The Society of Thoracic Surgeons
TAVR	transcatheter aortic valve replacement
TEE	transesophageal echocardiographic
TMVR	transcatheter mitral valve replacement
TMVr	transcatheter mitral valve repair
TVT	transcatheter valve therapies
VHD	valvular heart disease