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PERFORMANCE AND QUALITY MEASURES

2024 ACC/AHA Clinical Performance and Quality Measures for Adults With Valvular and Structural Heart Disease

A Report of the American Heart Association/American College of Cardiology Joint Committee on Performance Measures

Developed in Collaboration With the American Association for Thoracic Surgery and the Society for Cardiovascular Angiography and Interventions

Endorsed by the American Society of Echocardiography and the Heart Rhythm Society

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TABLE OF CONTENTS

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TOP 10 TAKE-HOME MESSAGES FOR ADULTS WITH VALVULAR AND STRUCTURAL HEART DISEASE

1. The current document includes a comprehensive list of 11 measures (5 performance measures and 6 quality measures) that can be clinically used in patients with valvular heart disease.
2. All 5 performance measures fulfill the attributes of performance measures (eg, high impact, targeting meaningful gaps in care, actionable, relatively low abstraction burden [in terms of cost, effort, and time], unlikely to have unintended consequences with their implementation), and are based on Class 1 clinical practice guideline recommendations.
3. The 5 performance measures listed are appropriate for public reporting or pay-for-performance programs.
4. The quality measures are not ready for public reporting or pay for performance but may be useful for clinicians and health care organizations for internal review and quality improvement. Quality measures may be upgraded in the future to a performance measure status after being assessed in real-world clinical practice, or can be completely retired in certain instances. For example, instances in which performance measures could be retired include very high levels of performance ("topping out") or new evidence showing marginal clinical impact or unforeseen adverse consequences, such as risk aversion.
5. All measures pertain to the outpatient setting except 1 quality measure that applies predominantly to the inpatient setting.
6. The measures are well defined and include definite exclusions (eg, hospice, palliative care, comfort care) and relative exceptions, which may be medical- or patient-related (eg, active bleeding, patient refusal).
7. Of the performance measures, 4 are related to proven therapies (1 is a medical treatment and 3 are surgical or catheter-based interventions), and 1 pertains to a diagnostic modality.
8. The 1 performance measure pertinent to medical treatment pertains to the prescription of a vitamin K antagonist (eg, warfarin) in patients with mechanical prosthetic valves, which has been proven to prevent valve thrombosis and thromboembolic events.
9. Three performance measures pertain to the implementation of an appropriate valve intervention in patients with the following: (1) severe symptomatic aortic valve stenosis; (2) chronic severe aortic regurgitation (symptomatic, or asymptomatic with left ventricular systolic dysfunction); and (3) chronic severe primary mitral regurgitation (symptomatic, or asymptomatic with left ventricular systolic dysfunction).
10. A notable quality measure is the objective documentation of risk while using a procedural risk score (eg, the web-based Society of Thoracic Surgeons Risk Calculator), and documentation of a multifaceted heart valve team discussion whenever a valvular procedure or surgical intervention is being considered.

PREAMBLE

The American Heart Association (AHA)/American College of Cardiology (ACC) performance measurement sets serve as vehicles to accelerate translation of scientific evidence into clinical practice. Measure sets developed by the AHA/ACC are intended to provide practitioners and institutions that deliver cardiovascular services with tools to measure the quality of care provided and identify opportunities for improvement.

Writing committees are instructed to consider the methodology of performance measure development[1,2] and to ensure that the measures developed are aligned with ACC/AHA clinical practice guidelines. The writing committees are also charged with constructing measures that maximally capture important aspects of care quality, including timeliness, safety, effectiveness, efficiency, equity, and patient-centeredness, while minimizing, when possible, the reporting burden imposed on hospitals, practices, and practitioners.

Potential challenges from measure implementation may lead to unintended consequences. The manner in which challenges are addressed is dependent on several factors, including the measure design, data collection method, performance attribution, baseline performance

rates, reporting methods, and incentives linked to these reports.

The AHA/ACC Joint Committee on Performance Measures (Joint Committee) distinguishes performance measures from quality measures. Performance measures are generally selected from the highest level of evidence, usually from Class 1 or 3 recommendations of clinical practice guidelines. They are commonly used for national quality improvement efforts, public reporting, and pay-for-performance programs. In contrast, quality measures may not have as much evidence base and generally comprise metrics that *may* be useful for local quality improvement but are not yet appropriate for public reporting or pay-for-performance programs. New measures are initially evaluated for potential inclusion as performance measures. In some cases, a measure is insufficiently supported by the clinical practice guidelines. In other instances, when the clinical practice guidelines support a measure, the writing committee may feel it is necessary to have the measure tested to identify the consequences of measure implementation. Quality measures then may be promoted to the status of performance measures as supporting evidence becomes available.

Biykem Bozkurt, MD, PhD, FACC, FAHA
Chair, AHA/ACC Joint Committee on Performance Measures

1. INTRODUCTION

In 2021, the Joint Committee convened the writing committee to begin the process of developing a performance measure set for valvular heart disease (VHD). The writing committee was charged with the task of developing new measures to evaluate the care of patients in accordance with the "2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease."[3]

This performance and quality measure set addresses care in the inpatient and outpatient settings. All Class 1 (strong) and 3 (no benefit or harmful, process to be avoided) guideline-recommended treatments or care processes were considered for inclusion as performance and quality measures. The current Class of Recommendation and Level of Evidence guideline classification scheme used by the ACC and AHA in their clinical practice guidelines is shown in **Table 1**. The value (benefit and cost) of a treatment or process of care was also considered. If high-quality, published, cost-effectiveness studies indicated that a Class 1 guideline recommendation for a treatment or process of care is considered a poor value by ACC/AHA standards, then it was not included as a performance measure.

The performance and quality measures for VHD included in the measure set are briefly summarized in **Table 2**, which provides information on the measure number, measure title, and care setting. The detailed measure specifications (Appendix A) provide not only the information included in **Table 2** but also provide more detailed information, including the measure description, numerator, denominator (including denominator exclusions and exceptions), rationale for the measure, guideline that supports the measure, measurement period, source of data, and attribution.

The writing committee developed a comprehensive VHD measure set of 11 measures that includes 5 performance measures and 6 quality measures as summarized in **Table 2** and Appendix A. The writing committee believes that implementation of this measure set by health care practitioners and facilities will improve care and outcomes and will help measure and compare health care among practitioners and facilities.

1.1. Scope of the Problem

VHD encompasses a large spectrum of diseases with variable pathophysiology, valve hemodynamics, clinical presentation, impact on cardiac structure and function, and outcomes. Common VHDs include—but are not limited to—aortic stenosis (AS), aortic regurgitation, mitral stenosis, mitral regurgitation (MR), tricuspid stenosis, tricuspid regurgitation, pulmonic stenosis, and pulmonic regurgitation. The realm of VHD expands to also include the management of prosthetic valve disease and issues related to anticoagulation therapies, as well as prevention and management considerations for infective endocarditis and rheumatic fever prophylaxis. Although rheumatic valve disease has an infectious etiology at its origin, it is a rare form of VHD in the United States, and most VHDs fall within the category of chronic noncommunicable diseases. In the age of delayed degenerative diseases, VHDs are highly prevalent and are expected to further increase in prevalence as the population ages, therefore representing a major cause of morbidity and death.

In a cohort of 2,500 subjects who were ≥65 years of age and identified from a primary care population, a community screening protocol by transthoracic echocardiography detected newly identified VHD in 51% of subjects.[4] The most common of those were mild lesions, namely aortic valve sclerosis and MR, which accounted for 56% of all newly identified VHDs. On the other hand, clinically significant VHD (eg, undiagnosed moderate or severe lesions) was identified in 6.4% of subjects.[4] Importantly, the likelihood of undiagnosed VHD was higher in the low socioeconomic groups, which increases the importance of accounting for social determinants of health when screening and diagnosing various patient populations for VHD. Based on the findings from their community screening project, the investigators estimated that the

TABLE 1 Applying American College of Cardiology/American Heart Association Class of Recommendation and Level of Evidence to Clinical Strategies, Interventions, Treatments, or Diagnostic Testing in Patient Care* (Updated May 2019)

CLASS (STRENGTH) OF RECOMMENDATION	Suggested phrases for writing recommendations:
CLASS 1 (STRONG) Benefit >>> Risk	• Is recommended • Is indicated/useful/effective/beneficial • Should be performed/administered/other • Comparative-Effectiveness Phrases†: – Treatment/strategy A is recommended/indicated in preference to treatment B – Treatment A should be chosen over treatment B
CLASS 2a (MODERATE) Benefit >> Risk	• Is reasonable • Can be useful/effective/beneficial • Comparative-Effectiveness Phrases†: – Treatment/strategy A is probably recommended/indicated in preference to treatment B – It is reasonable to choose treatment A over treatment B
CLASS 2b (WEAK) Benefit ≥ Risk	• May/might be reasonable • May/might be considered • Usefulness/effectiveness is unknown/unclear/uncertain or not well-established
CLASS 3: No Benefit (MODERATE) (Generally, LOE A or B use only) Benefit = Risk	• Is not recommended • Is not indicated/useful/effective/beneficial • Should not be performed/administered/other
Class 3: Harm (STRONG) Risk > Benefit	• Potentially harmful • Causes harm • Associated with excess morbidity/mortality • Should not be performed/administered/other

LEVEL (QUALITY) OF EVIDENCE‡	
LEVEL A	• High-quality evidence‡ from more than 1 RCT • Meta-analyses of high-quality RCTs • One or more RCTs corroborated by high-quality registry studies
LEVEL B-R (Randomized)	• Moderate-quality evidence‡ from 1 or more RCTs • Meta-analyses of moderate-quality RCTs
LEVEL B-NR (Nonrandomized)	• Moderate-quality evidence‡ from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies • Meta-analyses of such studies
LEVEL C-LD (Limited Data)	• Randomized or nonrandomized observational or registry studies with limitations of design or execution • Meta-analyses of such studies • Physiological or mechanistic studies in human subjects
LEVEL C-EO (Expert Opinion)	• Consensus of expert opinion based on clinical experience

COR and LOE are determined independently (any COR may be paired with any LOE).

A recommendation with LOE C does not imply that the recommendation is weak. Many important clinical questions addressed in guidelines do not lend themselves to clinical trials. Although RCTs are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

* The outcome or result of the intervention should be specified (an improved clinical outcome or increased diagnostic accuracy or incremental prognostic information).

† For comparative-effectiveness recommendations (COR 1 and 2a; LOE A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

‡ The method of assessing quality is evolving, including the application of standardized, widely-used, and preferably validated evidence grading tools; and for systematic reviews, the incorporation of an Evidence Review Committee.

COR indicates Class of Recommendation; EO, expert opinion; LD, limited data; LOE, Level of Evidence; NR, nonrandomized; R, randomized; and RCT, randomized controlled trial.

prevalence of clinically significant VHD may double before 2050.[4] In another large nationwide registry analysis from Sweden, Andell et al[5] identified all patients in Swedish hospitals with a first diagnosis of VHD between 2003 and 2010. They reported a VHD incidence of 63.9 per 100,000 person-years, with AS, MR, and aortic regurgitation accounting for nearly 90% of all diagnoses.[5] Notably, 69% of new VHD lesions in this study were diagnosed in subjects ≥65 years of age.[5] In a meta-analysis by Osnabrugge et al,[6] inclusive of 7 reports and 9,723 subjects, the investigators reported a 12.4% pooled prevalence of AS in the elderly (>75 years of age), with a 3.4% pooled prevalence of severe AS. In another population-based study from a single academic center in Norway, Eveborn et al[7] prospectively performed—over a 14-year period—serial echocardiographic imaging studies to examine the prevalence and progression of degenerative AS. They found an increasing prevalence of AS with age: 1.3% in the 60- to 69-year age group versus 3.9% in the 70- to 79-year age group and 9.8% in the 80- to 89-year age group.[7] The investigators also found a nonlinear progression in mean transaortic valve pressure gradients, with substantial individual variability and an average annual increase of 3.2 mm Hg.[7]

Notably, outcomes associated with VHD have improved markedly over time due to significant advances in diagnostic measures and new therapeutic approaches. The former includes measures targeting at-risk patients and those with established VHD, in addition to harnessing the advances in multimodality imaging, whereas the latter is promulgated by enhanced surgical techniques and novel catheter-based interventions. Surgical valve replacement and repair have been long-standing mainstay treatment modalities for VHD. However, transcatheter-based therapies are rapidly evolving and have obtained progressively expanded clinical therapeutic indications over the past decade.[8-13] Surgical and transcatheter interventions are performed primarily in patients with severe symptomatic VHD, although evolving evidence supports its likely benefit in patients with severe asymptomatic VHD and even moderate VHD. Accurate diagnosis and periodic monitoring are critical to assess the need and timing of intervention, which may depend on a myriad of factors, such as the severity of the VHD, presence of symptoms, its impact on cardiac anatomy and function (eg, left ventricular dilation or dysfunction), as well as its effects on the pulmonary circulation (eg, pulmonary hypertension). To this effect, accurate diagnoses and classification of the severity of VHD lesions are important. The writing committee for the 2020 ACC/AHA VHD guideline[3] provided a classification of the VHD stages. These stages are progressive, and continuous clinical and imaging monitoring are required. The 4 stages include: stage A (at risk for the development of VHD), stage B (progressive VHD: asymptomatic with mild or moderate severity), stage C (severe asymptomatic VHD), and stage D (severe symptomatic VHD).[3]

To inform and update the practicing clinician about the essential elements in the diagnosis, classification, and management of patients with VHD (eg, patient education, periodic monitoring, medical therapy, and surgical and percutaneous interventions), the ACC and AHA often join efforts with other societies to construct clinical practice guidelines consisting of concrete and direct clinical recommendations. Several iterations of the VHD guidelines were published by the ACC and AHA over the years,[14,15] including the most recent "2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease."[3] To increase the clinical dissemination of the most recent clinical practice guidelines[3] and particularly to enhance the implementation of their evidence-based and high-impact recommendations, the ACC and AHA have rejoined efforts to construct a set of performance and quality measures for VHD and structural heart disease (SHD). These measures can be used to assess, measure, and compare care processes of patients with VHD across multiple providers and institutions.

1.2. Disclosure of Relationships With Industry and Other Entities

The Joint Committee makes every effort to avoid actual, potential, or perceived conflicts of interest that could arise as a result of relationships with industry or other entities (RWI). Information about the ACC/AHA policy on RWI can be found online. All members of the writing committee, as well as those selected to serve as peer reviewers of this document, were required to disclose all current relationships and those existing within the 12 months before the initiation of this writing effort. ACC/AHA policy also requires that the writing committee chair and at least 50% of the writing committee have no relevant RWI. Writing committee members are excluded from writing or voting on sections to which their specific RWI may apply.

Any writing committee member who develops new RWI during his or her tenure on the writing committee is required to notify staff in writing. These statements are reviewed periodically by the Joint Committee and by members of the writing committee. Author and peer reviewer RWI that are pertinent to the document are included in the appendixes: Appendix B for comprehensive writing committee RWI and Appendix C for comprehensive peer reviewer RWI. Disclosure information for the Joint Committee is also available online.

The work of the writing committee was supported exclusively by the ACC and the AHA without commercial support. The American Association for Thoracic Surgery and the Society for Cardiovascular Angiography and Interventions served as collaborators on this project. Members of the writing committee volunteered their time for this effort. Meetings of the writing committee were confidential and attended only by writing committee members and staff from the ACC and AHA.

2. METHODOLOGY

2.1. Literature Review

In developing the updated VHD measure set, the writing committee reviewed evidence-based clinical practice guidelines and scientific statements that would potentially impact the construct of the new measures. The clinical practice guidelines and scientific statements that most directly contributed to the development of these measures are shown in **Table 3**. Notably, the "2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease"[15] and its 2017 focused update[16] were not reviewed or considered, because they were completely replaced by the "2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease."[3] Recommendations from the "2020 AHA/ACC Guideline for the Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy"[17] were reviewed,

TABLE 2 2024 ACC/AHA Valvular Heart Disease Measures

Measure No.	Measure Title	Care Setting	Attribution	Measure Domain	COR/LOE
Performance Measures					
PM-1	VKA for Mechanical Heart Valves	Outpatient	Individual practitioner	Treatment	COR: 1, LOE: A
PM-2	AV Intervention for Severe Symptomatic AS	Outpatient	Individual practitioner	Treatment	COR: 1, LOE: A; COR: 1, LOE: B-NR; COR: 1, LOE: C-EO
PM-3	AV Surgery for Chronic Severe AR	Outpatient	Individual practitioner	Treatment	COR: 1, LOE: B-NR
PM-4	TTE for Asymptomatic Chronic Severe Primary MR	Inpatient, Outpatient	Individual practitioner	Monitoring	COR: 1, LOE: B-NR
PM-5	Mitral Valve Intervention for Chronic Severe Primary MR	Outpatient	Individual practitioner	Treatment	COR: 1, LOE: B-NR
Quality Measures					
QM-1	Documentation of Risk and Heart Team Discussion Before SAVR or TAVI	Inpatient	Facility, Individual practitioner	Patient Education and Monitoring	COR: 1, LOE: C-EO
QM-2	AVR for Asymptomatic AS With LV Systolic Dysfunction	Outpatient	Individual practitioner	Treatment	COR: 1, LOE: B-NR
QM-3	TAVI for Severe Symptomatic AS >80 Years of Age	Outpatient	Individual practitioner	Treatment	COR: 1, LOE: A; COR: 1, LOE: C-EO
QM-4	Post-AVR Echocardiogram	Outpatient	Individual practitioner	Monitoring	COR: 1, LOE: B-NR
QM-5	Adequate BP Control in AR Patients	Outpatient	Individual practitioner	Treatment	COR: 1, LOE: B-NR
QM-6	Treatment for Symptomatic Severe Rheumatic MS	Outpatient	Individual practitioner	Treatment	COR: 1, LOE: A; COR: 1, LOE: B-NR

ACC indicates American College of Cardiology; AHA, American Heart Association; AR, aortic regurgitation; AS, aortic stenosis; AV, aortic valve; AVR, aortic valve replacement; BP, blood pressure; COR, Class of Recommendation; LOE, Level of Evidence; LV, left ventricle/ventricular; MR, mitral regurgitation; MS, mitral stenosis; PM, performance measure; QM, quality measure; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation; TTE, transthoracic echocardiogram; and VKA, vitamin K antagonist.

but the consensus of the writing group was to exclude measures pertinent to the hypertrophic cardiomyopathy from this guideline, because they were too narrowly focused and outside the scope of the current document.

2.2. Definition and Selection of Measures

The writing committee considered a number of additional factors, which are listed in Table 4. The potential impact, appropriateness for public reporting and pay for performance, validity, reliability, and feasibility were considered. The writing committee examined available information on current gaps in care.

3. ACC/AHA VHD MEASURE SET

3.1. Discussion of VHD Measure Set

After reviewing the existing clinical practice guidelines and scientific statements (Table 3), the writing committee discussed which guideline recommendations could serve as the basis for new performance or quality measures. The writing committee reviewed the attributes of performance as well as the existing publicly available measure sets. In the following section is a description of the new measures that are created for both the inpatient and outpatient setting.

3.1.1. Retired Measures

The current measure set represents the first set of performance and quality measures for VHD and SHD that are created by the ACC and AHA in collaboration with other societies. Therefore, there are no previous measures to revise or retire.

3.1.2. Revised Measures

The current measure set represents the first set of performance and quality measures for VHD and SHD that are created by the ACC and AHA in collaboration with other societies. Therefore, there are no previous measures to revise or retire.

3.1.3. New Measures

After reviewing the "2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease"[3] and other societal position statements and documents (Table 3), the writing committee initially considered a preliminary set of 20 measures from definitive recommendations with proven clinical benefit (mostly Class 1 guideline recommendations), which were predominantly pertinent to the diagnostic, monitoring, and treatment domains. The initial comprehensive set included 9 performance measures: 2 were subsequently dropped, 2 were kept with edits or modifications, and 2 were downgraded to quality measures (because they were deemed to satisfy some but not all the attributes defined in Table 4). The final set included 5 performance measures and 6 quality measures, which were voted on after multiple rounds of anonymous voting and meticulous consideration of the attributes of performance measures. Of the initial

TABLE 3 Associated ACC/AHA Clinical Practice Guidelines and Other Clinical Guidance Documents

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease[3]
2020 AHA/ACC Guideline for the Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy[17]
2019 AATS/ACC/ASE/SCAI/STS Expert Consensus Systems of Care Document: A Proposal to Optimize Care for Patients With Valvular Heart Disease[18]
2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation[19]
2019 AHA/ACC Clinical Performance and Quality Measures for Adults With High Blood Pressure[20]
Guidelines for the Early Management of Patients With Acute Ischemic Stroke: 2019 Update to the 2018 Guidelines for the Early Management of Acute Ischemic Stroke[21]
2018 Guidelines for the Early Management of Patients With Acute Ischemic Stroke[22]
Surgery for Aortic Dilatation in Patients With Bicuspid Aortic Valves[23]
2015 American Heart Association/American Stroke Association Focused Update of the 2013 Guidelines for the Early Management of Patients With Acute Ischemic Stroke Regarding Endovascular Treatment[24]
2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation[25]
Guidelines for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack[26]
Percutaneous Device Closure of Patent Foramen Ovale for Secondary Stroke Prevention[27]

AATS indicates American Association for Thoracic Surgery; ACC, American College of Cardiology; AHA, American Heart Association; ASE, American Society of Echocardiography; HRS, Heart Rhythm Society; SCAI, Society for Cardiovascular Angiography and Interventions; and STS, Society of Thoracic Surgeons.

comprehensive set of 20 measures, 9 measures were excluded for various reasons. For example, some did not fit the attributes of a performance measure, or they were unlikely to be upgraded in the future from a quality measure. Others were considered outside the scope of the current document or are covered in other performance measure documents. For example, statin use in patients with mild and moderate AS has been shown to reduce ischemic atherosclerotic events by 20% but not aortic valve-related events.[30,31] This measure was deemed by the writing committee most suitable to be considered in a future atherosclerotic cardiovascular disease performance measure document. The measure related to anticoagulation for nonvalvular atrial fibrillation (AF) has been extensively covered in the performance measure document in patients with AF, with 2 dedicated measures related to anticoagulation prescription in the inpatient and outpatient settings.[32] In the rationales for the 2 performance measures in the aforementioned document, the writing committee explicitly stated that nonvalvular AF increases the risk of stroke 5 times while AF in the setting of mitral stenosis increases the risk of stroke 20 times over that of patients in sinus rhythm.[32] A separate measure pertinent for AF in the setting of mitral stenosis is likely to be topped out and of low impact, and therefore is not included in the current document. The measure on the use of early surgery for infective endocarditis was deemed to have a complex construct and to likely be too difficult to measure, especially given issues with ascertaining appropriateness of surgery and its timing in these complex patients.

The writing committee created a comprehensive list of 11 measures that can be clinically used in patients with VHD. This set includes 5 performance measures and 6 quality measures. **Table 5** includes a list of the measures with information on the care setting and a brief rationale. All of the measures pertain to the outpatient setting, except for 1 quality measure that applies predominantly to the inpatient setting.

All 5 performance measures fulfill the attributes of performance measures as summarized in **Table 4**. All 5 performance measures are high-impact measures that target meaningful gaps in the quality of care and are based on Class 1 clinical practice guideline recommendations with a high level of evidence. They are also actionable, have a very low abstraction burden (in terms of cost, effort, and time), and pose no unintended consequences in their implementation. Of those, 4 are related to proven therapies (1 is a medical treatment and 3 are surgical or catheter-based interventions), and 1 pertains to a diagnostic modality (medical imaging test).

One medical treatment performance measure pertains to the prescription or treatment with a vitamin K antagonist (eg, warfarin) in patients with mechanical prosthetic valves, which has been proven to prevent valve thrombosis and thromboembolic events in these patients.[33-35] Appendix A provides a summary for the rationale and evidence for the measure as well as data on its construct. Direct oral anticoagulants are not adequately studied or proven as a thromboprophylaxis therapy for mechanical prosthetic valves.[36] Their use is therefore not recommended and does not count toward the implementation of this measure. On the other hand, like many performance and quality measures, many patients have reasons to be excluded or exempted from this measure. These exclusions include definite exclusions (such as being on hospice, palliative, or comfort care) and relative medical- or patient-related exclusions (such as active bleeding or patient refusal). This measure should be implemented in a shared decision-making process with the patient and the patient's health care team (eg, the cardiologist and the primary care professional). Therefore, the measure should

TABLE 4 American Heart Association/American College of Cardiology Joint Committee on Performance Measures: Attributes for Performance Measures[28]

1. **Evidence Based**	
High-impact area that is useful in improving patient outcomes	a) For structural measures, the structure should be closely linked to a meaningful process of care that in turn is linked to a meaningful patient outcome. b) For process measures, the scientific basis for the measure should be well established, and the process should be closely linked to a meaningful patient outcome. c) For outcome measures, the outcome should be clinically meaningful. If appropriate, performance measures based on outcomes should adjust for relevant clinical characteristics through the use of appropriate methodology and high-quality data sources.
2. **Measure Selection**	
Measure definition	a) The patient group to whom the measure applies (denominator) and the patient group for whom conformance is achieved (numerator) are clearly defined and clinically meaningful.
Measure exceptions and exclusions	b) Exceptions and exclusions are supported by evidence.
Reliability	c) The measure is reproducible across organizations and delivery settings.
Face validity	d) The measure appears to assess what it is intended to.
Content validity	e) The measure captures most meaningful aspects of care.
Construct validity	f) The measure correlates well with other measures of the same aspect of care.
3. **Measure Feasibility**	
Reasonable effort and cost	a) The data required for the measure can be obtained with reasonable effort and cost.
Reasonable time period	b) The data required for the measure can be obtained within the period allowed for data collection.
4. **Accountability**	
Actionable	a) Those held accountable can affect the care process or outcome.
Unintended consequences avoided	b) The likelihood of negative unintended consequences with the measure is low.

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be attributable to any of the health care professionals caring for the patient. The presence of a mechanical heart valve and the prescription or treatment with a vitamin K antagonist should be documented within and abstracted from the medical records (whether electronic health care records data, administrative data, clinical registries, or paper medical records). Different international normalized ratio target ranges apply to various patients. This is outlined in the "2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease,"[3] which is dependent on various factors such as type of valve, location of valve, comorbidities, and previous history of thromboembolic events. This performance measure does not, however, delve into the achieved international normalized ratio targets, to simplify the construct of the measure and make it easier to implement.

There are 3 performance measures pertaining to the implementation of an appropriate valve intervention in patients with 3 valvular conditions: (1) severe symptomatic AS; (2) chronic severe aortic regurgitation (symptomatic or asymptomatic with left ventricular systolic dysfunction); and (3) chronic severe primary MR (symptomatic or asymptomatic with left ventricular systolic dysfunction). Based on the available evidence, the valve intervention varies according to the valve location, pathology, and patient symptoms, and may include aortic valve surgery or transcatheter aortic valve implantation,[37-40] or mitral valve surgery or transcatheter edge-to-edge repair,[41,42] respectively. The tables in Appendix A include details on the construct of these measures, their rationale, as well as evidence pertinent to these disorders and their surgical or transcatheter treatments. In addition, there is clinical information providing descriptions of common symptoms, definitions of severity of the valve disorder, and the respective thresholds for left ventricular systolic dysfunction (eg, ejection fraction 55% and ≤60% for chronic severe aortic regurgitation and primary MR, respectively). To minimize the complexity of the valve intervention measures and ensure feasibility, the writing committee included left ventricular ejection fraction thresholds but not left ventricular dimensions (eg, left ventricular end-systolic diameter ≥40 mm for valve intervention in patients with chronic severe primary MR).[43] Given the complexity of the valve intervention decision-making in these patients, these measures are attributed to the primary cardiologist, as opposed to the primary care health care professional, who is likely to refer these patients to a specialist to determine—in shared decision-making with the patient—the merits of the intervention after discussing risks, benefits, alternatives, and patient values, as well as other preferences.

Last, 1 performance measure involves a diagnostic modality and performance of a transthoracic echocardiogram within the preceding 12 months among patients with established chronic severe primary MR. It is therefore applicable to the outpatient setting where a transthoracic

TABLE 5 New Measures*

Measure No.	Care Setting	Measure Title	Rationale for Creating New Measure	Rationale for Designating as a Quality Measure Versus a Performance Measure
PM-1	Outpatient	VKA for Mechanical Heart Valves	In patients with a mechanical valve prosthesis, there is high-level evidence that therapy with an oral VKA at an appropriate INR goal reduces the incidence of valve thrombosis, thromboembolic events, and associated morbidity.	High impact, easy to measure, satisfies the attributes of a PM.
PM-2	Outpatient	AV Intervention for Severe Symptomatic AS	Patients with severe symptomatic AS have a high risk of death if AV intervention is not performed, as high as 50% at 1 y. Both SAVR and TAVI are effective across the spectrum of surgical risk, with significant improvements in morbidity, death, and functional status.	High impact, easy to measure, satisfies the attributes of a PM.
PM-3	Outpatient	AV Surgery for Chronic Severe AR	Patients with chronic severe AR who either have LV dysfunction (EF <55%) or who develop symptoms, have a high risk of death, LV decompensation, and deterioration of functional status if AVR is not performed.	High impact, easy to measure, satisfies the attributes of a PM.
PM-4	Inpatient, Outpatient	TTE for Asymptomatic Chronic Severe Primary MR	Serial echocardiograms are essential to evaluate changes in LV function and structure in patients with asymptomatic chronic severe primary MR to guide management decisions.	Actionable, easy to measure, satisfies the attributes of a PM.
PM-5	Outpatient	Mitral Valve Intervention for Chronic Severe Primary MR	Patients with chronic severe primary MR who develop symptoms or LVEF <60% have a high risk of death, LV decompensation, and deterioration of functional status if mitral valve intervention is not performed.	High impact, easy to measure, satisfies the attributes of a PM.
QM-1	Inpatient	Documentation of Risk and Heart Team Discussion Before SAVR or TAVI	Clinically meaningful measure that incorporates risk assessment and shared decision-making with the patients before intervention.	QM because of moderate abstraction and lack of robust evidence regarding its impact.
QM-2	Outpatient	AVR for Asymptomatic AS With LV Systolic Dysfunction	Asymptomatic patients with severe AS who have LV systolic dysfunction (EF <50%) benefit from SAVR or TAVI in particular clinical settings (low LVEF, cardiothoracic surgery for another indication).	Complex construct and feasibility issues make it better fit for a QM.
QM-3	Outpatient	TAVI for Severe Symptomatic AS >80 Years of Age	TAVI is preferred to SAVR in most patients >80 y of age because of its safety profile and lower concern for valve durability in this age group.	May have unintended consequences if used as a PM (eg, some elderly patients may still be safe for SAVR), and as such QM is more appropriate.
QM-4	Outpatient	Post-AVR Echocardiogram	TTE after valve implantation or repair provides an assessment of the procedural results and serves as a baseline against which comparison can be made for any change.	Clinically meaningful measure but lacks strong evidence to support its impact.
QM-5	Outpatient	Adequate BP Control in AR Patients	Adequate BP control in asymptomatic patients with chronic AR may help prevent structural LV deterioration and mitigate the occurrence of HF symptoms.	Does not fit all attributes of a PM (measure feasibility).
QM-6	Outpatient	Treatment for Symptomatic Severe Rheumatic MS	Treatment of patients with severe symptomatic rheumatic MS with either PMBC or surgery has shown significant clinical benefits.	The measure definition is complex and may pose abstraction burden. Better fit for QM (low impact).

*The current measure set represents the first ACC/AHA VHD measure set; therefore, all the measures in the measure set are new and are included in the new measures table.

ACC indicates American College of Cardiology; AHA, American Heart Association; AR, aortic regurgitation; AS, aortic stenosis; AV, aortic valve; AVR, aortic valve replacement; BP, blood pressure; EF, ejection fraction; HF, heart failure; INR, international normalized ratio; LV, left ventricle/ventricular; LVEF, left ventricular ejection fraction; MR, mitral regurgitation; MS, mitral stenosis; PM, performance measure; PMBC, percutaneous mitral balloon commissurotomy; QM, quality measure; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation; TTE, transthoracic echocardiogram; VHD, valvular heart disease; and VKA, vitamin K antagonist.

echocardiogram is readily available and can be ordered by the cardiologist or other health care professional (thus, attribution to a wider segment of professionals). A transthoracic echocardiogram will ascertain the severity and mechanism of primary MR and assess the existence and progression of left ventricular dysfunction or dilation (eg, ejection fraction or dimension), which then helps dictate the intervention modality (eg, surgical repair, surgical replacement, or transcatheter edge-to-edge repair) and its timing, particularly in patients who are asymptomatic.

Six quality measures were selected, all of which were based on Class 1 clinical practice guideline recommendations. These quality measures fulfill some but not all the attributes of a performance measure. They have less clinical impact or might be lacking in other important characteristics (eg, feasibility, validity, or unintended consequences) and are therefore not suitable to measure performance among providers and institutions or for public reporting. However, they can be used for internal quality assessment and internal peer review processes. Many of these measures are added to clinical registries and may be upgraded in the future to a performance measure status after assessment in real-world practice or completely retired in certain instances (eg, topped out or emerging evidence showing marginal clinical impact). Thus, if additional evidence supports the importance of the proposed quality measures, they may be ultimately changed to performance measures. Of the 6 selected quality measures, 4 pertain to therapeutic strategies (medical, percutaneous, or surgical intervention), and the other 2 pertain to other domains (eg, patient education or monitoring). One notable quality measure involves the objective documentation of risk using a procedural risk score (eg, the web-based Society of Thoracic Surgeons Risk Calculator), and the documentation of a multidisciplinary heart valve team discussion whenever a valvular procedure or surgical intervention is being considered. Although documentation of a heart team discussion and risk stratification can be done before hospitalization, this is the only measure in this document pertinent to the inpatient setting, given that risk stratification is usually a dynamic process and best reassessed before the index procedure. Although there is a paucity of high-level evidence supporting the merits of a heart team approach, the writing committee agreed with the expert opinion expressed by the 2020 ACC/AHA VHD Guideline Writing Committee that a multifaceted heart team approach is important whenever a valvular procedure or surgical intervention is being considered, after accounting for patient-specific, procedure-specific, and institution- or operator-specific risks and benefits.

Overall, the measures are structured in a typical format in which the goal is to seek a higher performance score, ideally nearing 100%. Performance and quality measures are designed to help health care professionals reduce gaps in the quality of care that they provide to their patients. For more detailed information on each measure's construct, refer to the specifications in Appendix A.

4. AREAS FOR FURTHER RESEARCH

All 11 measures included in the current set are actionable, feasible, and reliable process measures with established scientific evidence and proven clinical benefit. One may argue that outcomes (eg, death, stroke, myocardial infarction, or reintervention) represent the ultimate assessment of care. The writing committee elected not to include outcome measures in this initial set of VHD measures given the heterogeneity of the VHDs and patient populations, in addition to the lack of robust methodology for adequate adjustment for the case mix of patients (with a few exceptions). Use of outcome measures in the absence of robust adjustment models may render comparisons across institutions and providers meaningless and may create untoward and unintended consequences that would likely result in problems with implementation. Future research should focus on overcoming these barriers and validating meaningful outcomes for patients with VHD that can be reliably measured and reported.

The current document encompasses the first set of performance and quality measures pertinent to VHD and SHD released by the ACC and AHA in collaboration with other societies. These measures should be added to future clinical registries and examined for their performance in real-world clinical practice. Notably, the current set of measures is dynamic and subject to revisions and modifications based on the availability of new clinical evidence. Future research should therefore focus on implementing and examining the current measures and assessing their performance and utility in real-world practices. If a measure is found to be consistently topped out or performs poorly (eg, unintended consequences, not reliably reproducible in different clinical settings, or complex construct requiring laborious resources for abstraction), it can be dropped in the future. On the other hand, if a gap in a clinically meaningful quality measure is evident in contemporary practice and the measure is found to satisfy the attributes of a performance measure, it can be at some point elevated to a performance measure. The Society of Thoracic Surgery/ACC Transcatheter Valve Therapy Registry is a robust clinical registry created through a collaboration of the Society of Thoracic Surgery and the ACC. It monitors patient safety and real-world outcomes but only includes data on patients undergoing transcatheter valve replacement and repair procedures, and it is therefore not inclusive of patients with all stages of VHD or those with severe (stages C or D) VHD who did not undergo procedures. The AHA is in

the process of developing a disease-specific database pertinent to AS that can help examine aortic valve disease more comprehensively. Leveraging the resources of the AHA and ACC and other organizations, including their registries, is therefore critically important to examine the implementation and performance of these measures. Finally, new care processes and diagnostic and therapeutic strategies should continue to be examined and considered, especially with the emergence of new transcatheter therapies or new indications of existing transcatheter therapies in the fields of VHD and SHD.

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KEY WORDS ACC/AHA Performance Measures, performance measures, quality indicators, quality measures, structural heart disease, valvular heart disease

APPENDIX A. VHD MEASURE SET

Performance Measures for VHD

SHORT TITLE: PM-1: VKA for Mechanical Heart Valves (Outpatient Setting)

PM-1: Percentage of Patients With Mechanical Heart Valves Who Are Prescribed Anticoagulation With VKA (Outpatient Setting)

Measure Description: Percentage of patients age ≥18 y with any mechanical heart valve who are prescribed* a VKA

Numerator	Patients who are prescribed* a VKA
Denominator	Patients age ≥18 y with any mechanical heart valve or history of mechanical heart valve in the medical record
Denominator Exclusions	Hospice, palliative care, or comfort care only
Denominator Exceptions	Documentation of medical reason(s) for not prescribing a VKA (eg, major bleeding during the assessment period, patient on heparin because of pregnancy, or other medical reasons during the assessment period) Documentation of patient reason(s) for not being on VKA (eg, patient preference, patient lost to follow-up)
Measurement Period	12 mo
Sources of Data	EHR data Administrative data/claims Administrative data/claims expanded (multiple sources) Paper medical records
Attribution	Individual practitioner (eg, cardiologist, primary care physician)
Care Setting	Outpatient

Rationale

All patients with mechanical valves require lifelong anticoagulant therapy with a VKA.[33-36,44] In addition to the thrombogenicity of the intravascular prosthetic material, mechanical valves impose abnormal flow conditions, with zones of low flow within their components, as well as areas of high-shear stress, which can cause platelet activation that leads to valve thrombosis and embolic events. Therapy with an oral VKA at an INR goal appropriate for the comorbidity of the patient and the type and position of the mechanical valve prosthesis is required to decrease the incidence of thromboembolism and associated morbidity. Data show that anticoagulation with a VKA is protective against valve thrombosis (OR: 0.11 [95% CI: 0.07-0.2]) and thromboembolic events (OR: 0.21 [95% CI: 0.16-0.27]). It is preferable to specify a single INR target for each patient and to recognize that the acceptable range includes 0.5 INR units on each side of this target. A specific target is preferable because it reduces the likelihood of patients having INR values consistently near the upper or lower boundary of the range. Fluctuations in INR are associated with an increased incidence of complications in patients with prosthetic heart valves.[45,46]

Clinical Recommendation(s)

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease[3]
1. In patients with a mechanical prosthetic valve, anticoagulation with a VKA is recommended.[33-36,44] (Class 1, Level of Evidence: A)

*Prescribed may include prescriptions given to the patient for a VKA at most recent office visit, or documentation that the patient is already taking a VKA.

ACC indicates American College of Cardiology; AHA, American Heart Association; EHR, electronic health record; INR, international normalized ratio; OR, odds ratio; PM, performance measure; and VKA, vitamin K antagonist.

APPENDIX A. CONTINUED

SHORT TITLE: PM-2: **AV Intervention for Severe Symptomatic AS (Outpatient Setting)**

PM-2: Percentage of Patients With Severe Symptomatic AS Who Undergo AV Intervention Within 3 Months of Diagnosis (Outpatient Setting)

Measure Description: Percentage of patients age ≥18 y diagnosed with severe symptomatic AS who undergo either surgical AVR or TAVI within 3 mo of diagnosis

Numerator	Patients who undergo either surgical AVR or TAVI within 3 mo of diagnosis
Denominator	Patients age ≥18 y who are diagnosed with severe symptomatic AS who are eligible* for AV intervention
Denominator Exclusions	Hospice, palliative care, or comfort care only
Denominator Exceptions	Documentation of medical reason(s) for not undergoing surgical AVR or TAVI (eg, severe noncardiac organ dysfunction, frailty, expected minimal improvement in quality of life, contraindications) Documentation of patient reason(s) for not undergoing surgical AVR or TAVI (eg, patient preference)
Measurement Period	12 mo
Sources of Data	EHR data Administrative data/claims Administrative data/claims expanded (multiple sources) Paper medical record
Attribution	Individual practitioner (eg, cardiologist)
Care Setting	Outpatient

Rationale

Patients with severe symptomatic AS have a high risk of death if AV intervention (eg, SAVR or TAVI) is not performed, as high as 50% at 1 y. Both SAVR and TAVI have been shown to be effective across the spectrum of surgical risk, with significant improvements in morbidity, death, and functional status.

Symptoms of severe AS may include the following: exertional dyspnea, decreased exercise tolerance, HF symptoms, exertional angina, exertional syncope, or presyncope. Severe AS is usually defined by the following valve hemodynamics: AV Vmax ≥4 m/s, mean ΔP ≥40 mm Hg, or AVA typically ≤1.0 cm^2 (or AVAi ≤0.6 cm^2/m^2) but may be larger with mixed AS/AR. However, in the setting of low LVEF (<50%), these hemodynamic thresholds may not be achieved, at which time dobutamine stress echocardiography or other adjunctive diagnostic modalities may be needed to accurately confirm the diagnosis of severe AS.[3]

In symptomatic patients with severe high-gradient AS (Stage D1), ample evidence demonstrates the beneficial effects of AVR on survival, symptoms, and LV systolic function.[47-51] The most common initial symptom of AS is exertional dyspnea or decreased exercise tolerance. Clinical vigilance is needed to recognize these early symptoms and proceed promptly to AVR. More severe "classical" symptoms of AS, including HF, syncope, or angina, can be avoided by appropriate treatment at the onset of even mild symptoms. Outcomes after surgical or transcatheter AVR are excellent in patients who do not have a high procedural risk.[47,49,50,52]

Outcomes are poor with severe low-gradient AS but are still better with AVR than with medical therapy in those with a low LVEF, particularly when contractile reserve is present. The document "Echocardiographic Assessment of Valve Stenosis: EAE/ASE Recommendations for Clinical Practice" defines severe AS on dobutamine stress testing as a maximum velocity >4.0 m/s with a valve area ≤1.0 cm^2 at any point during the test protocol, with a maximum dobutamine dose of 20 mcg/kg/min.[53]

A subset of patients with severe AS present with symptoms and with a low velocity, low gradient, and low stroke volume index, despite a normal LVEF. Low-flow, low-gradient severe AS with preserved LVEF should be considered in patients with a severely calcified AV, an AV peak velocity <4.0 m/s (mean pressure gradient <40 mm Hg), and a valve area ≤1.0 cm^2 when stroke volume index is <35 mL/m^2. Typically, the LV is small, with thick walls, diastolic dysfunction, and a normal LVEF (≥50%).

The survival and symptom reduction benefit of TAVI is seen only in appropriately selected patients. Baseline clinical factors associated with a poor outcome after TAVI include advanced age, frailty, smoking or chronic obstructive pulmonary disease, pulmonary hypertension, liver disease, previous stroke, anemia, and other systemic conditions. The STS estimated surgical risk score provides a useful measure of the extent of patient comorbidities and may help identify which patients will benefit from TAVI. Patients with a mechanical impediment to SAVR, such as a porcelain aorta or previous chest radiation damage, may have better outcomes after TAVI than do patients who are frail or those with moderate to severe disease in >1 other organ system.[39,40,54] The likely benefits and risks of TAVI are considered in weighing the risk-benefit ratio of intervention in an individual patient. TAVI is not recommended in patients with 1) a life expectancy of <1 y even with a successful procedure; or 2) those with a chance of "survival with benefit" of <25% at 2 y.

Clinical Recommendation(s)

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease[3]

1. In adults with severe high-gradient AS (Stage D1) and symptoms of exertional dyspnea, HF, angina, syncope, or presyncope by history or on exercise testing, AVR is indicated.[39,40,54-58] (Class 1, Level of Evidence: A)
2. In symptomatic patients with low-flow, low-gradient severe AS with reduced LVEF (Stage D2), AVR is recommended.[37,59-65] (Class 1, Level of Evidence: B-NR)
3. In symptomatic patients with low-flow, low-gradient severe AS with normal LVEF (Stage D3), AVR is recommended if AS is the most likely cause of symptoms.[38,41,42] (Class 1, Level of Evidence: B-NR)
4. For symptomatic patients with severe AS for whom predicted post-TAVI or post-SAVR survival is <12 months or for whom minimal improvement in quality of life is expected, palliative care is recommended after shared decision-making, including discussion of patient preferences and values. (Class 1, Level of Evidence: C-EO)

*Eligible patients are those with severe AS (Vmax ≥4 m/s, mean ΔP ≥40 mm Hg, or AVA typically ≤1.0 cm^2 [or AVAi ≤0.6 cm^2/m^2]; however, in the settings of low LVEF [<50%] or low stroke volume, these hemodynamic thresholds may not be achieved, at which time dobutamine stress echocardiography or other adjunctive diagnostic modalities are needed) and accompanying symptoms (eg, exertional dyspnea, decreased exercise tolerance, HF symptoms, exertional angina, exertional syncope, or presyncope).

ACC indicates American College of Cardiology; AHA, American Heart Association; AR, aortic regurgitation; AS, aortic stenosis; ASE, American Society of Echocardiography; AV, aortic valve; AVA, aortic valve area; AVAi = indexed aortic valve area; AVR, aortic valve replacement; EAE, European Association of Echocardiography; EHR, electronic health record; HF, heart failure; LV, left ventricle (left ventricular); LVEF, left ventricular ejection fraction; PM, performance measure; SAVR, surgical aortic valve replacement; STS, Society of Thoracic Surgeons; TAVI, transcatheter aortic valve implantation; and Vmax, maximal velocity.

APPENDIX A. CONTINUED

SHORT TITLE: PM-3: **AV Surgery for Chronic Severe AR (Outpatient Setting)**

PM-3: Percentage of Patients With Chronic Severe AR Who Are Eligible for AV Surgery and Undergo AV Surgery Within 3 Months of Diagnosis (Outpatient Setting)

Measure Description: Percentage of patients age ≥18 y diagnosed with chronic severe AR who are either symptomatic or asymptomatic with LV systolic dysfunction (LVEF ≤55%) who are eligible for AV surgery and who undergo AV surgery within 3 mo of diagnosis

Numerator	Patients who undergo AV surgery within 3 mo of diagnosis
Denominator	Patients age ≥18 y who are diagnosed with chronic severe AR who are eligible for AV surgery and are: (1) symptomatic or (2) asymptomatic with LV systolic dysfunction (LVEF ≤55%)
Denominator Exclusions	Hospice, palliative care, or comfort care only
Denominator Exceptions	Documentation of medical reason(s) for not undergoing AV surgery (eg, comorbidities making AVR extreme or prohibitive risk [such as severe pulmonary, renal, hepatic disease], contraindications) Documentation of patient reason(s) for not undergoing AV surgery (eg, patient preference)
Measurement Period	12 mo
Sources of Data	EHR data Administrative data/claims Administrative data/claims expanded (multiple sources) Paper medical records
Attribution	Individual practitioner (eg, cardiologist)
Care Setting	Outpatient

Rationale

Symptoms are an important indication for AVR in patients with chronic severe AR, and the most important aspect of the clinical evaluation is taking a careful, detailed history to elicit symptoms or diminution of exercise capacity. Patients with chronic severe AR who develop symptoms have a high risk of death if AVR is not performed,[66] and survival and functional status after AVR are related to the severity of preoperative symptoms, assessed either subjectively or objectively with exercise testing.[67-70] Even among symptomatic patients with a severe reduction in LVEF (<35%), AVR results in improved survival rate.[71-73]

In patients with isolated severe AR who have indications for SAVR and are candidates for surgery, TAVI should not be performed.[3]

LV systolic function is an important determinant of survival and functional status after AVR.[68,70,71,74-85] Outcomes are optimal when surgery is performed before LVEF decreases below 55%.[86-88] In asymptomatic patients with LV systolic dysfunction, postoperative outcomes are better if AVR is performed before onset of symptoms.[74]

Symptoms of chronic severe AR may include the following: exertional dyspnea, angina, or more severe HF symptoms. Imaging and/or angiographic criteria defining severe AR include: a Doppler jet width ≥65% of LVOT, a vena contracta >0.6 cm, holodiastolic flow reversal in the proximal abdominal aorta, regurgitant volume ≥60 mL/beat, regurgitant fraction ≥50% ERO ≥0.3 cm^2, angiography grade 3 to 4. In addition, diagnosis of chronic severe AR requires evidence of LV dilation.[3]

Clinical Recommendation(s)

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease[3]

1. In symptomatic patients with severe AR (Stage D), aortic valve surgery is indicated regardless of LV systolic function.[67-73] (Class 1, Level of Evidence: B-NR)
2. In asymptomatic patients with chronic severe AR and LV systolic dysfunction (LVEF ≤55%) (Stage C2), aortic valve surgery is indicated if no other cause for systolic dysfunction is identified.[68,71,78,79,81,89,90] (Class 1, Level of Evidence: B-NR)

ACC indicates American College of Cardiology; AHA, American Heart Association; AR, aortic regurgitation; AV, aortic valve; AVR, aortic valve replacement; EHR, electronic health record; ERO, effective regurgitant orifice; HF, heart failure; LV, left ventricle (left ventricular); LVEF, left ventricular ejection fraction; LVOT, left ventricular outflow tract; PM, performance measure; SAVR, surgical aortic valve replacement; and TAVI, transcatheter aortic valve implantation.

APPENDIX A. CONTINUED

SHORT TITLE: PM-4: **TTE for Asymptomatic Chronic Severe Primary MR (Inpatient and Outpatient Setting)**

PM-4: Percentage of Asymptomatic Patients With Chronic Severe Primary MR Who Received a TTE Within the Past 12 Months (Inpatient and Outpatient Setting)

Measure Description: Percentage of patients age ≥18 y with asymptomatic chronic severe primary MR who received a TTE within the past 12 mo	
Numerator	Patients who received a TTE within the past 12 mo
Denominator	Patients age ≥18 y with asymptomatic chronic severe primary MR (eg, mitral valve with prolapse)
Denominator Exclusions	Hospice, palliative care, or comfort care only
Denominator Exceptions	Documentation of medical reason(s) for not doing a TTE (eg, patient had an alternative imaging modality) Documentation of patient reason(s) for not doing a TTE (eg, patient preference, patient moved to another facility for care or lost to follow-up)
Measurement Period	12 mo
Sources of Data	EHR data Administrative data/claims Administrative data/claims expanded (multiple sources) Paper medical records
Attribution	Individual practitioner (eg, cardiologist, primary care physician)
Care Setting	Inpatient Outpatient

Rationale

TTE provides valuable information for surveillance of LV function (estimated by LVEF and LVESD) and PAP in asymptomatic patients with severe primary MR (Stage C1) if performed every 6 to 12 mo.[91-99] Chronic severe MR is tolerated poorly, reaching a trigger for surgery at an average rate of about 8%/y.[91,97] This progression varies from patient to patient, and because prognosis worsens if correction of MR is delayed beyond the onset of these triggers, referral to a Comprehensive Valve Center for early repair or careful surveillance is of value. Because echocardiographic measurements are variable, management decisions that rest on these measurements should be confirmed by repeat sequential TTE. In patients with milder chronic primary MR (Stages A and B), TTE is indicated periodically to evaluate for changes in MR severity, depending on valve anatomy and other considerations, because regurgitation may worsen over time. Because this process may develop slowly, MR can become severe and even lead to LV dysfunction in the absence of symptoms or clinical signs.[100,101]

Imaging and angiographic criteria defining chronic severe MR include the following: central jet MR >40% LA, holosystolic eccentric jet MR, vena contracta ≥0.7 cm, regurgitant volume ≥60 mL, regurgitant fraction ≥50%, ERO ≥0.40 cm^2, angiographic grade 3+ to 4+.[3]

Clinical Recommendation(s)

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease[3]

1. For asymptomatic patients with severe primary MR (Stages B and C1), TTE is indicated every 6 to 12 months for surveillance of LV function (estimated by LVEF, LVEDD, and LVESD) and assessment of pulmonary artery pressure.[91-101] (Class 1, Level of Evidence: B-NR)

ACC indicates American College of Cardiology; AHA, American Heart Association; EHR, electronic health record; ERO, effective regurgitant orifice; LA, left atrium (left atrial); LV, left ventricle (left ventricular); LVEDD, left ventricular end-diastolic dimension; LVEF, left ventricular ejection fraction; LVESD, left ventricular end-systolic dimension; MR, mitral regurgitation; PAP, pulmonary artery pressure; PM, performance measure; and TTE, transthoracic echocardiogram.

APPENDIX A. CONTINUED

SHORT TITLE: PM-5: **Mitral Valve Intervention for Chronic Severe Primary MR (Outpatient Setting)**

PM-5: Percentage of Patients with Chronic Severe Primary MR Who Undergo Mitral Valve Intervention Within 3 Months of Diagnosis (Outpatient Setting)

Measure Description: Percentage of patients age ≥18 y diagnosed with chronic severe primary MR who are either symptomatic (regardless of LV systolic function) or asymptomatic but have LVSD (LVEF ≤60%), and who are eligible for mitral valve intervention and undergo mitral valve intervention (mitral valve surgery or TEER) within 3 mo of diagnosis

Numerator	Patients who undergo mitral valve intervention (mitral valve surgery or TEER) within 3 mo of diagnosis
Denominator	Patients age ≥18 y who are diagnosed with chronic severe primary MR who are eligible for mitral valve intervention and are: (1) symptomatic, regardless of LV systolic function or (2) asymptomatic with LVSD (LVEF ≤60%)
Denominator Exclusions	Hospice, palliative care, or comfort care only
Denominator Exceptions	Documentation of medical reason(s) for not undergoing mitral valve intervention (eg, severe comorbidities, limited quality of life, poor functional status, prohibitive risk for mitral valve surgery and anatomy not amenable for TEER, contraindications) Documentation of patient reason(s) for not undergoing mitral valve intervention (eg, patient preference)
Measurement Period	12 mo
Sources of Data	EHR data Administrative data/claims (inpatient or outpatient claims) Administrative data/claims expanded (multiple sources) Paper medical record
Attribution	Individual practitioner (eg, cardiologist)
Care Setting	Outpatient

Rationale

Primary MR is a mechanical problem of the leaflet coaptation that only has a mechanical solution—that of mitral valve mechanical intervention. The onset of symptoms that results from severe MR worsens prognosis even when LV function appears to be normal,[102,103] and the negative prognosis extends even to mild symptoms.[102] Thus, the onset of symptoms is an indication for prompt mitral valve surgery.

The goal of therapy in MR is to correct it before the onset of LVSD and its subsequent adverse effect on patient outcomes. The ideal time for mitral valve surgery is when the patient's LV approaches but has not yet reached the parameters that indicate systolic dysfunction (LVEF ≤60% or LVESD ≥40 mm).[43,94,98,101,104,105] Because symptoms do not always coincide with LV dysfunction, imaging surveillance is used to plan surgery before severe dysfunction has occurred. If moderate LV dysfunction is already present, prognosis is worse after mitral valve operation.[43,101,104-107] Thus, further delay (although symptoms are absent) will lead to greater LV dysfunction and a still worse prognosis. Because the loading conditions in MR allow continued late ejection into a lower-impedance LA, a higher cutoff for "normal" LVEF is used in MR than in other types of heart disease. Although it is clearly inadvisable to allow patients' LV function to deteriorate beyond the benchmarks of an LVEF ≤60% or LVESD ≥40 mm, some recovery of LV function can still occur even if these thresholds have been crossed.[104,108]

Symptoms of chronic severe MR may include decreased exercise tolerance, exertional dyspnea, or more severe HF symptoms. Imaging and angiographic criteria defining chronic severe MR include the following: central jet MR >40% LA, holosystolic eccentric jet MR, vena contracta ≥0.7 cm, regurgitant volume ≥60 mL, regurgitant fraction ≥50%, ERO ≥0.40 cm^2, angiographic grade 3+ to 4+.[3]

Clinical Recommendation(s)

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease[3]

1. In symptomatic patients with severe primary MR (Stage D), mitral valve intervention is recommended irrespective of LV systolic function.[102,103] (Class 1, Level of Evidence: B-NR)
2. In asymptomatic patients with severe primary MR and LV systolic dysfunction (LVEF ≤60%, LVESD ≥40 mm) (Stage C2), mitral valve surgery is recommended.[43,94,98,100,101,104,106,107] (Class 1, Level of Evidence: B-NR)

ACC indicates American College of Cardiology; AHA, American Heart Association; EHR, electronic health record; ERO, effective regurgitant orifice; HF, heart failure; LA, left atrium (left atrial); LV, left ventricle (left ventricular); LVEF, left ventricular ejection fraction; LVESD, left ventricular end-systolic dimension; LVSD, left ventricular systolic dysfunction; MR, mitral regurgitation; PM, performance measure; and TEER, transcatheter edge-to-edge repair.

APPENDIX A. CONTINUED

Quality Measures for VHD

SHORT TITLE: QM-1: **Documentation of Risk and Heart Team Discussion Before SAVR or TAVI (Inpatient Setting)**

QM-1: Percentage of Patients Who Have Documentation of Risk Score(s) and Heart Valve Team Discussion Before SAVR or TAVI (Inpatient Setting)

Measure Description: Percentage of patients age ≥18 y who have documentation of objective risk score(s) and heart valve team discussion before SAVR or TAVI

Numerator	Patients who have preprocedural documentation of: (1) an objective procedural risk score (eg, STS risk scores) and (2) a heart valve team discussion
Denominator	Patients age ≥18 y who underwent SAVR or TAVI
Denominator Exclusions	None
Denominator Exceptions	Documentation of medical reason(s) for not having risk score(s) or heart valve team discussion (eg, cardiogenic shock or acute aortic dissection requiring emergent procedure)
Measurement Period	During hospitalization or admission for index procedure (SAVR or TAVI)
Sources of Data	EHR data Administrative data/claims (inpatient or outpatient claims) Administrative data/claims expanded (multiple sources) Paper medical records
Attribution	Facility Individual practitioner (eg, cardiologist, cardiac surgeon)
Care Setting	Inpatient

Rationale

The decision to intervene, as well as the type of procedure recommended, is based on an assessment of patient-specific, procedure-specific, and institution- or operator-specific short-term risks and long-term benefits. Surgical mortality rate and major morbidity risks can be calculated with a web-based tool derived from the STS Adult Cardiac Surgery database for 6 specific procedures (http://riskcalc.sts.org/stswebriskcalc/calculate). TAVI-specific risk prediction tools are also available (http://tools.acc.org/TAVRRisk/#!/content/evaluate/).[109-114] Frailty assessment for at-risk patients is routine.[115-119] Patients toward the higher end of the risk spectrum, for whom intervention would be futile or associated with a high likelihood of a poor outcome, should be identified.[54,120-125] Risk prediction tools for transcatheter mitral valve repair are comparatively less robust.[13,121,122] The relationship between operator or institutional case volume and outcomes has been explored for surgical[126] and transcatheter[127-129] AVR, surgical mitral valve repair and replacement,[130-138] and transcatheter mitral valve repair.[139] The potential to return to activities of daily living after an intervention must be considered.

The MDT is an established feature of heart valve programs[140] and has been formally endorsed by the ACC, the ASE, the SCAI, the AATS, and the STS.[18] Key members of the MDT include cardiologists with subspecialty expertise in the clinical evaluation of patients with VHD, as well as specialists in advanced cardiovascular imaging. For the evaluation of the patient with secondary MR and TR, a specialist in HF is included. Interventional cardiologists with training and expertise in VHD and surgeons experienced in the treatment of VHD anchor the MDT. Other team members include cardiovascular nurses, cardiovascular anesthesiologists, and intensivists involved in periprocedural care. Finally, the engagement of the primary clinical cardiologist and patient is of critical importance. The MDT facilitates presentation of all appropriate options for medical, interventional, and surgical treatment to the patient in a balanced manner, using tools and techniques for shared decision-making in which patient preferences are considered.

Clinical Recommendation(s)

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease[3]

1. For patients with VHD for whom intervention is contemplated, individual risks should be calculated for specific surgical and/or transcatheter procedures, using online tools when available, and discussed before the procedure as a part of a shared decision-making process. (Class 1, Level of Evidence: C-EO)
2. Patients with severe VHD should be evaluated by a Multidisciplinary Heart Valve Team (MDT) when intervention is considered. (Class 1, Level of Evidence: C-EO)

AATS indicates American Association for Thoracic Surgery; ACC, American College of Cardiology; AHA, American Heart Association; ASE, American Society of Echocardiography; AVR, aortic valve replacement; EHR, electronic health record; HF, heart failure; MDT, multidisciplinary heart valve team; MR, mitral regurgitation; QM, quality measure; SAVR, surgical aortic valve replacement; SCAI, Society for Cardiovascular Angiography and Interventions; STS, Society of Thoracic Surgeons; TAVI, transcatheter aortic valve implantation; TR, tricuspid regurgitation; and VHD, valvular heart disease.

APPENDIX A. CONTINUED

SHORT TITLE: QM-2: AVR for Asymptomatic AS With LV Systolic Dysfunction (Outpatient Setting)

QM-2: Percentage of Asymptomatic Patients With Severe AS Who Are Eligible for AVR (LVEF <50%) and Who Undergo AVR Within 3 Months of Diagnosis (Outpatient Setting)

Measure Description: Percentage of patients age ≥18 y diagnosed with severe AS who are asymptomatic and eligible for AVR (LVEF <50%) who undergo AVR (SAVR or TAVI) within 3 mo of diagnosis

Numerator	Patients who undergo AVR (SAVR or TAVI) within 3 mo of diagnosis
Denominator	Patients age ≥18 y who are diagnosed with severe AS who are asymptomatic and are eligible for AVR (LVEF <50%)
Denominator Exclusions	Hospice, palliative care, or comfort care only
Denominator Exceptions	Documentation of medical reason(s) for not undergoing AVR (eg, severe comorbidities, limited quality of life, poor functional status, contraindications) Documentation of patient reason(s) for not undergoing AVR (eg, patient preference)
Measurement Period	12 mo
Sources of Data	EHR data Administrative data/claims Administrative data/claims expanded (multiple sources) Paper medical record
Attribution	Individual practitioner (eg, cardiologist)
Care Setting	Outpatient

Rationale

In asymptomatic patients with severe AS and normal LV systolic function, the survival rate during the asymptomatic phase is similar to that of age-matched controls, with a low risk of sudden death (<1%/y) when patients are followed prospectively and when patients promptly report symptom onset. However, in patients with low LVEF and severe AS, survival is better in those who undergo AVR than in those treated medically. The depressed LVEF in many patients is caused by excessive afterload (afterload mismatch), and LV function improves after AVR in such patients. If LV dysfunction is not caused by afterload mismatch, survival is still improved, likely because of the reduced afterload with AVR, but improvement in LV function and resolution of symptoms might not be complete after AVR.[60,62,65,141-147]

Prospective clinical studies demonstrate that disease progression occurs in nearly all patients with severe asymptomatic AS. Symptom onset within 2 to 5 y is likely when AV peak velocity is ≥4.0 m/s or mean pressure gradient is ≥40 mm Hg. The additive risk of AVR at the time of other cardiac surgery is less than the risk of reoperation within 5 y.[148-155]

Severe AS is usually defined by the following valve hemodynamics: AV Vmax ≥4 m/s, mean ΔP ≥40 mm Hg, or AVA typically ≤1.0 cm^2 (or AVAi ≤0.6 cm^2/m^2) but may be larger with mixed AS and AR. However, in the setting of low LVEF (<50%), these hemodynamic thresholds may not be achieved, at which time dobutamine stress echocardiography or other adjunctive diagnostic modalities may be needed to accurately confirm the diagnosis of severe AS.[3]

Clinical Recommendation(s)

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease[3]

1. In asymptomatic patients with severe AS and an LVEF <50% (Stage C2), AVR is indicated.[156-159] (Class 1, Level of Evidence: B-NR)

ACC indicates American College of Cardiology; AHA, American Heart Association; AR, aortic regurgitation; AS, aortic stenosis; AV, aortic valve; AVA, aortic valve area; AVAi = indexed aortic valve area; AVR, aortic valve replacement; EHR, electronic health record; LV, left ventricle (left ventricular); LVEF, left ventricular ejection fraction; QM, quality measure; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation; and Vmax, maximal velocity.

APPENDIX A. CONTINUED

SHORT TITLE: QM-3: TAVI for Severe Symptomatic AS >80 Years of Age (Outpatient Setting)

QM-3: Percentage of Patients With Severe Symptomatic AS >80 Years of Age Who Undergo TAVI Within 3 Months of Diagnosis (Outpatient Setting)

Measure Description: Percentage of patients age >80 y diagnosed with severe symptomatic AS who are eligible for AV intervention and who undergo TAVI within 3 mo of diagnosis

Numerator	Patients who undergo TAVI within 3 mo of diagnosis
Denominator	Patients >80 y who are diagnosed with severe symptomatic AS and are eligible for AV intervention
Denominator Exclusions	Hospice, palliative care, or comfort care only
Denominator Exceptions	Documentation of medical reason(s) for not undergoing TAVI (eg, anatomic contraindications to transfemoral TAVI, severe comorbidities, frailty, poor quality of life expected) Documentation of patient reason(s) for not undergoing TAVI (eg, patient preference)
Measurement Period	12 mo
Sources of Data	EHR data Administrative data/claims Administrative data/claims expanded (multiple sources) Paper medical records
Attribution	Individual practitioner (eg, cardiologist, cardiac surgeon)
Care Setting	Outpatient

Rationale

TAVI is a safe and effective procedure for treatment of severe symptomatic AS in all adults regardless of estimated surgical risk. The mortality rate for transfemoral TAVI is lower than that for SAVR (HR: 0.88 [95% CI: 0.78-0.99]) in a meta-analysis of RCTs. TAVI also is associated with a lower risk of stroke (HR: 0.81 [95% CI: 0.68-0.98]; $P = 0.028$), major bleeding, and AF, as well as a shorter hospital length of stay, less pain, and more rapid return to normal activities.[160] Compared with SAVR, TAVI results in higher rates of vascular complications, paravalvular regurgitation, permanent pacemaker implantation, and valve intervention, but most patients will consider that the advantages of TAVI outweigh these disadvantages. TAVI valves are durable to at least 5 y, and the limited data on TAVI durability are of less concern to most patients >80 y of age because the valve durability is likely to be longer than the patient's life expectancy.[161] If significant valve deterioration does occur, a second TAVI within the first prosthesis (called a valve-in-valve TAVI) is likely to be possible. When a transfemoral approach is not possible, other factors, such as alternative vascular access, comorbid cardiac and noncardiac conditions, expected functional status and survival after AVR, and patient values and preferences must be considered. The specific choice of a balloon-expandable valve or self-expanding valve depends on patient anatomy and other considerations.[162-167]

The survival and symptom reduction benefit of TAVI is seen only in appropriately selected patients. Baseline clinical factors associated with a poor outcome after TAVI include advanced age, frailty, smoking or chronic obstructive pulmonary disease, pulmonary hypertension, liver disease, previous stroke, anemia, and other systemic conditions. The STS estimated surgical risk score provides a useful measure of the extent of patient comorbidities and may help identify which patients will benefit from TAVI. Patients with a mechanical impediment to SAVR, such as a porcelain aorta or previous chest radiation damage, may have better outcomes after TAVI than do frail patients or those with moderate to severe disease in >1 other organ system.[39,40,54] The likely benefits and risks of TAVI are considered in weighing the risk-benefit ratio of intervention in an individual patient. TAVI is not recommended in patients with 1) a life expectancy of <1 y even with a successful procedure; or 2) those with a chance of "survival with benefit" of <25% at 2 y.

Clinical Recommendation(s)

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease[3]

1. For symptomatic patients with severe AS who are >80 y of age or for younger patients with a life expectancy <10 y and no anatomic contraindication to transfemoral TAVI, transfemoral TAVI is recommended in preference to SAVR.[9,10,168-173] (Class 1, Level of Evidence: A)
2. For symptomatic patients with severe AS for whom predicted post-TAVI or post-SAVR survival is <12 mo or for whom minimal improvement in quality of life is expected, palliative care is recommended after shared decision-making, including discussion of patient preferences and values. (Class 1, Level of Evidence: C-EO)

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; AS, aortic stenosis; AV, aortic valve; AVR, aortic valve replacement; EHR, electronic health record; HR, hazard ratio; QM, quality measure; RCT, randomized controlled trial; SAVR, surgical aortic valve replacement; STS, Society of Thoracic Surgeons; and TAVI, transcatheter aortic valve implantation.

APPENDIX A. CONTINUED

SHORT TITLE: QM-4: Post-AVR Echocardiogram (Outpatient Setting)

QM-4: Percentage of Patients Who Have TTE Within 3 Months After TAVI or SAVR (Outpatient Setting)

Measure Description: Percentage of patients age ≥18 y who have TTE within 3 mo after TAVI or SAVR

Numerator	Patients who have TTE within 3 mo after their procedure or surgery
Denominator	Patients ≥18 y who underwent TAVI or SAVR
Denominator Exclusions	Hospice, palliative care, or comfort care only Patients who die or are lost to follow-up within 3 mo after procedure
Denominator Exceptions	Documentation of patient reason(s) for not doing a TTE (eg, patient preference)
Measurement Period	12 mo
Sources of Data	EHR data Administrative data/claims (inpatient or outpatient claims) Administrative data/claims expanded (multiple sources) Paper medical record
Attribution	Individual practitioner (eg, cardiologist, cardiac surgeon)
Care Setting	Outpatient

Rationale

TTE after valve implantation or repair provides an assessment of the procedural results and serves as a baseline against which comparison can be made for any change. TTE provides accurate measurements of transvalvular velocities and pressure gradients, as well as detection and quantitation of transvalvular and paravalvular leak.[174-177] Normal transvalvular velocities and gradients vary across different types and sizes of prosthetic valves but are also affected by patient-specific factors, including body size and cardiac output. The postoperative study, recorded when the patient is asymptomatic and hemodynamically stable, provides Doppler flow data for a specific valve in an individual patient. In addition, TTE provides assessment of other valve disease(s), pulmonary artery pressure, atrial size, LV and RV size and function, and pericardial disease.

TTE is the primary imaging modality for postoperative assessment of prosthetic valve or repaired native valve function. Additional imaging, such as TEE, cardiac CT, or fluoroscopy, may be required when valve dysfunction is suspected and in the context of the clinical presentation.[3]

Clinical Recommendation(s)

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease[3]

1. In patients with a surgical or transcatheter prosthetic valve and in patients who have had valve repair, an initial postprocedural TTE study is recommended for evaluation of valve hemodynamics and ventricular function.[174-177] (Class 1, Level of Evidence: B-NR)

ACC indicates American College of Cardiology; AHA, American Heart Association; AVR, aortic valve replacement; CT, computed tomography; EHR, electronic health record; LV, left ventricle (left ventricular); QM, quality measure; RV, right ventricle (right ventricular); SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation; TEE, transesophageal echocardiography (echocardiogram); and TTE, transthoracic echocardiogram.

APPENDIX A. CONTINUED

SHORT TITLE: QM-5: Adequate BP Control in AR Patients (Outpatient Setting)

QM-5: Percentage of Patients With Chronic AR and Hypertension Whose Blood Pressure Is Optimally Treated (Outpatient Setting)

Measure Description: Percentage of patients age ≥18 y diagnosed with chronic AR (Stages B and C) and hypertension (SBP >140 mm Hg) whose blood pressure is optimally treated

Numerator	Patients with optimal BP treatment*
Denominator	Patients age ≥18 y who are diagnosed with chronic AR (Stages B and C) and hypertension (SBP >140 mm Hg)
Denominator Exclusions	Hospice, palliative care, or comfort care only
Denominator Exceptions	Documentation of medical reason(s) for not doing optimal BP treatment (eg, contraindications to lower BP such as stroke patients, patient intolerance) Documentation of patient reason(s) for not doing optimal BP treatment (eg, patient preference)
Measurement Period	12 mo
Sources of Data	EHR data Administrative data/claims (outpatient claims) Administrative data/claims expanded (multiple sources) Paper medical record
Attribution	Individual practitioner (eg, cardiologist, primary care physician)
Care Setting	Outpatient

Rationale

There is no evidence that vasodilating drugs reduce severity of AR or alter the disease course in patients with significant AR in the absence of systemic hypertension.[3]
Recommendations for GDMT for hypertension and HF apply to patients with chronic asymptomatic AR as for the general population.
Severe AR is associated with a wide pulse pressure, such that systolic blood pressure is higher than in patients without AR even when systemic vascular resistance is normal. Transaortic stroke volume increases further with medications that lower heart rate, such as beta-blockers, which may result in a paradoxical apparent increase in blood pressure. Vasodilating drugs, such as ACE inhibitors or ARBs, do not affect heart rate and thus may reduce systolic blood pressure without a substantial reduction in diastolic blood pressure in patients with chronic AR.[178-183]
In symptomatic patients who are candidates for surgery, medical therapy is not a substitute for AVR. However, medical therapy is helpful for alleviating symptoms in patients who are considered to be at very high surgical risk because of concomitant comorbid medical conditions.[178,184]

Clinical Recommendation(s)

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease[3]

1. In asymptomatic patients with chronic AR (Stages B and C), treatment of hypertension (systolic blood pressure >140 mm Hg) is recommended.[179,182,185] (Class 1, Level of Evidence: B-NR)

*Adequate treatment of BP in patients with chronic progressive (stage B) or severe AR (stage C) is for a target systolic BP <140 mm Hg.

ACC indicates American College of Cardiology; ACE, angiotensin-converting enzyme; AHA, American Heart Association; AR, aortic regurgitation; ARB, angiotensin receptor blocker; AVR, aortic valve replacement; BP, blood pressure; EHR, electronic health record; GDMT, guideline-directed management and therapy; HF, heart failure; QM, quality measure; and SBP, systolic blood pressure.

APPENDIX A. CONTINUED

SHORT TITLE: QM-6: Treatment for Symptomatic Severe Rheumatic MS (Outpatient Setting)

QM-6: Percentage of Patients With Symptomatic Severe Rheumatic MS Who Undergo PMBC or Mitral Valve Surgery Within 3 Months of Diagnosis (Outpatient Setting)

Measure Description: Percentage of patients age ≥18 y diagnosed with symptomatic severe rheumatic MS (mitral valve area ≤1.5 cm^2, Stage D) who undergo PMBC or mitral valve surgery within 3 mo of diagnosis	
Numerator	Patients who undergo PMBC or mitral valve surgery within 3 mo of diagnosis
Denominator	Patients age ≥18 y who are diagnosed with symptomatic severe rheumatic MS (mitral valve area ≤1.5 cm^2, Stage D) and are eligible for PMBC or mitral valve surgery
Denominator Exclusions	Hospice, palliative care, or comfort care only
Denominator Exceptions	Documentation of medical reason(s) for not undergoing PMBC or mitral valve surgery (eg, major contraindication to or prohibitive risk for procedure or surgery) Documentation of patient reason(s) for not undergoing PMBC or mitral valve surgery (eg, patient preference)
Measurement Period	12 mo
Sources of Data	EHR data Administrative data/claims (inpatient or outpatient claims) Administrative data/claims expanded (multiple sources) Paper medical records
Attribution	Individual practitioner (eg, cardiologist)
Care Setting	Outpatient

Rationale

The optimal treatment of patients with rheumatic MS is either PMBC or surgery.[3]
Mitral valve replacement is an option for treatment only if there is no other option and the patient has severe limiting symptoms.
Randomized trials have established the safety and efficacy of PMBC as compared with surgical closed or open commissurotomy in patients with a favorable valve morphology with less than 2+ MR in the absence of LA thrombus.[186-191] PMBC is performed by advancing ≥1 balloon catheter across the mitral valve and inflating it, thereby splitting the commissures. Favorable valve morphology consists of mobile and relatively thin valve leaflets, which are free of calcium, in the absence of significant subvalvular fusion.[53,192-194] An anatomic mitral morphology score can be used to determine suitability for PMBC and to evaluate the appearance of the commissures and degree of calcification.[195-197] Clinical factors, such as age, NYHA functional class, and presence or absence of AF, are also predictive of outcome. Older patients with lower gradients (<10 mm Hg) will not have as good an outcome as patients with higher gradients, probably because of other concomitant problems that cause symptoms, such as LV diastolic dysfunction and LA noncompliance, measured by net atrial-ventricular compliance.[198-202] PMBC should be performed only by experienced operators, with immediate availability of surgical backup for potential complications. Long-term follow-up has shown 70% to 80% of patients with an initial good result after PMBC to be free of recurrent symptoms at 10 y, and 30% to 40% are free of recurrent symptoms at 20 y.[188,196,203-207]
Mitral valve surgery is an established therapy for rheumatic MS, with the preferred approach being commissurotomy (either closed, where the valve is opened blindly through the LA or LV, or open, which allows more extensive surgery under direct visualization) when anatomy is favorable.[208-213] However, in the presence of severe valvular thickening and subvalvular fibrosis with leaflet tethering, mitral valve replacement may be the best option. In addition to those who have suboptimal valve anatomy (or failed PMBC), patients with moderate or severe TR may also have a better outcome with a surgical approach that includes tricuspid valve repair.[214] Patients undergoing mitral valve surgery at centers with a high level of expertise may have better long-term outcomes than those undergoing PMBC.[188,207] Because the natural history of rheumatic MS is one of slow progression over decades, surgery should be delayed until the patient has severe limiting symptoms (NYHA functional class III or IV), particularly if mitral valve repair is contemplated.

Clinical Recommendation(s)

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease[3]

1. In symptomatic patients (NYHA functional class II, III, or IV) with severe rheumatic MS (mitral valve area ≤1.5 cm^2, Stage D) and favorable valve morphology with less than moderate (2+) MR* in the absence of LA thrombus, PMBC is recommended if it can be performed at a Comprehensive Valve Center.[186-191,196,203-207] (Class 1, Level of Evidence: A)
2. In severely symptomatic patients (NYHA class III or IV) with severe rheumatic MS (mitral valve area ≤1.5 cm^2, Stage D) who 1) are not candidates for PMBC; 2) have failed a previous PMBC; 3) require other cardiac procedures; or 4) do not have access to PMBC, mitral valve surgery (repair, commissurotomy, or valve replacement) is indicated.[188,207,215] (Class 1, Level of Evidence: B-NR)

*2+ on a 0 to 4+ scale according to Sellers' criteria or less than moderate by Doppler echocardiography.[216]

ACC indicates American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; EHR, electronic health record; LA, left atrium (left atrial); LV, left ventricle/ventricular; MR, mitral regurgitation; MS, mitral stenosis; NYHA, New York Heart Association; PMBC, percutaneous mitral balloon commissurotomy; QM, quality measure; and TR, tricuspid regurgitation.

APPENDIX B. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (COMPREHENSIVE)—2024 ACC/AHA CLINICAL PERFORMANCE AND QUALITY MEASURES FOR VALVULAR AND STRUCTURAL HEART DISEASE

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Hani Jneid, *Chair, JCCDS Liaison, SCAI Representative*	University of Texas Medical Branch—John Sealy Distinguished Centennial Chair in Cardiology; Professor & Chief, Division of Cardiology; Medical Director, Cardiovascular Service Line	None	None	None	None	None	None
Joanna Chikwe, *Vice Chair*	Cedars-Sinai Medical Center—The Irina and George Schaeffer Distinguished Chair in Cardiac Surgery; Professor and Chairman, Department of Cardiac Surgery Smidt Heart Institute	None	None	None	None	Not relevant: ■ Cedars-Sinai Medical Center* ■ Edwards Lifesciences†	None
Suzanne V. Arnold	Saint Luke's Mid America Heart Institute—Clinical Scholar and Cardiologist; University of Missouri-Kansas City—Associate Professor Department of Medicine	None	None	None	None	Not relevant: ■ *Heart* Journal	None
Robert O. Bonow, *2020 ACC/AHA VHD Guideline Liaison*	Northwestern Memorial Hospital—Goldberg Distinguished Professor of Cardiology Northwestern University Feinberg School of Medicine	None	None	None	None	Not relevant: ■ *JAMA** ■ NHLBI	None
Steven M. Bradley	Minneapolis Heart Institute—General Cardiologist	Not relevant: ■ *JAMA**	None	None	None	Not relevant: ■ ACC‡ ■ AHA‡ ■ CardioHealth Alliance‡ ■ *JAMA** ■ Medtronic†	None
Edward P. Chen	Duke University Medical Center—Professor of Surgery and Chief, Division of Cardiovascular and Thoracic Surgery, Section of Surgical Disciplines	None	None	None	Not relevant: ■ NHLBI, CTSN Working Group‡ Relevant: ■ Bolton Medical‡	Not relevant: ■ Allergan† ■ Artivion† ■ Bolton Medical† ■ Edwards Lifesciences† ■ Medtronic Cardiovascular† ■ Medtronic Endovascular† ■ NHLBI/Icahn School of Medicine at Mount Sinai† ■ NIH/Duke University† ■ NIH/NHLBI/Emory University† ■ On-X Life Technologies† ■ Quark Pharmaceuticals† ■ *The Journal of Thoracic and Cardiovascular Surgery*‡ ■ W.L. Gore and Associates†	None

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APPENDIX B. CONTINUED

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Rebecca L. Diekemper§	AHA/ACC—Science and Health Advisor, Performance Measures	None	None	None	None	Not relevant: ■ AHA/ACC salaried employee	None
Setri Fugar	Medical College of Wisconsin—Interventional Cardiology Fellow	None	None	None	None	None	None
Douglas R. Johnston, *AATS Representative*	Northwestern Medicine Feinberg School of Medicine—Chief of Cardiac Surgery, Department of Surgery; Professor of Surgery (Cardiac Surgery)	Not relevant: ■ Gore‡ Relevant: ■ Abbott ■ Edwards Lifesciences* ■ LivaNova ■ Terumo Aortic (Bolton Medical)	None	Not relevant: ■ JACE Medical	Relevant: ■ Artivion‡ ■ Medtronic‡	Not relevant: ■ Beyond Limits, Inc.* ■ HD Medical* Relevant: ■ Artivion* ■ Edwards Lifesciences* ■ LivaNova	None
Dharam J. Kumbhani	University of Texas Southwestern Medical Center—Associate Professor of Medicine; William Clements University Hospital—Section Chief, Interventional Cardiology Cath Lab Director	Not relevant: ■ ACC*	None	None	None	Not relevant: ■ *Circulation*, Associate Editor*	None

APPENDIX B. CONTINUED

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Roxana Mehran	Icahn School of Medicine at Mount Sinai—Mount Sinai Professor in Cardiovascular Clinical Research and Outcomes; Director, Interventional Cardiovascular Research and Clinical Trials	Not relevant: ■ Cine-Med Research Institute ■ Idorsia Pharmaceuticals Ltd‡ ■ Ionis Pharma ■ *JAMA** ■ Novo Nordisk ■ Penumbra* ■ Protembis* ■ SCAI ■ Vectura* Relevant: ■ Bayer ■ Boston Scientific ■ Janssen Pharmaceuticals ■ Novartis	None	Not relevant: ■ Applied Therapeutics* ■ Controlrad* ■ Elixir Medical ■ Stel Relevant: ■ Boston Scientific* ■ Claret Medical, Inc.*	Not relevant: ■ Abiomed* ■ Alleviant Medical ■ Amgen ■ AM-Pharma ■ Arena* ■ AtriCure ■ Baim Institute for Clinical Research* ■ Beth Israel Deaconess Medical Center* ■ Biosensors* ■ Biotronik ■ Bristol-Myers Squibb* ■ Cardiovascular Research Foundation‡ ■ CellAegis* ■ CeloNova BioSciences ■ Cerecor* ■ Chiesi* ■ Concept Medical* ■ Cytosorbents* ■ Daiichi Sankyo* ■ DSI Medical Services, Inc.* ■ Duke University* ■ Element Science ■ Faraday Pharmaceuticals ■ Humacyte ■ Idorsia Pharmaceuticals ■ Insel Gruppe AG* ■ Janssen Pharmaceutical* ■ Magenta ■ Mediasphere ■ Medintelligence ■ Phasebio ■ Pi-Cardia ■ RenalPro ■ RM Global ■ Shockwave ■ Vivasure ■ WebMD* ■ Zoll Relevant: ■ Abbott* ■ AstraZeneca* ■ Bayer* ■ Boston Scientific* ■ CardiaWave* ■ CSL Behring* ■ Medtronic* ■ Novartis* ■ OrbusNeich* ■ Philips*	Not relevant: ■ AMA* ■ ACC ■ Applied Therapeutics* ■ Cardiovascular Research Foundation‡ ■ Elixir Medical ■ Stel ■ WebMD* Relevant: ■ Boston Scientific*	None

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APPENDIX B. CONTINUED

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Arunima Misra	Michael E DeBakey VA Medical Center Cardiology Section—Associate Professor, Baylor College of Medicine; Houston VA Medical Center—Director of the Echo Laboratory	None	None	None	None	None	None
Manesh R. Patel, *JCPM Liaison*	Duke University School of Medicine—Richard S. Stack Distinguished Professor; Chief, Division of Cardiology; Co-Director Duke Heart Center, Duke Clinical Research Institute	Not relevant: ■ Duke CME ■ Medscape* Relevant: ■ Amgen ■ Bayer* ■ Janssen Pharmaceuticals*	None	None	Not relevant: ■ Medtronic† ■ NHLBI* ■ Novartis* ■ PCORI Relevant: ■ Heartflow* ■ Johnson and Johnson*	Relevant: ■ Amgen*	None
Ranya N. Sweis	Division of Cardiology, Department of Medicine Northwestern University Feinberg School of Medicine—Associate Professor of Medicine, Interventional Cardiology; Clinical Practice Director, Outpatient Cardiology Practice	Relevant: ■ Merck	Relevant: ■ Edwards Lifesciences*	None	None	None	None
Molly Szerlip	Baylor Scott & White The Heart Hospital-Plano—Interventional Cardiology, Medical Director of Percutaneous Valve Program; Program Director of the Structural Heart Fellowship Program	Relevant: ■ Abbott ■ Edwards Lifesciences* ■ Medtronic	Not relevant: ■ Abiomed‡ Relevant: ■ Boston Scientific ■ Edwards Lifesciences‡	None	Relevant: ■ Abbott ■ Bayer ■ Boston Scientific ■ Conformal ■ Edwards Lifesciences ■ Medtronic	Not relevant: ■ Abbott† ■ Bayer† ■ Conformal† ■ Edwards Lifesciences† ■ Medtronic† ■ Shockwave Medical Relevant: ■ Heartflow	None

APPENDIX B. CONTINUED

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Poonam Velagapudi‖	University of Nebraska Medical Center—Chair, Early Career Section of the American College of Cardiology; Co-Chair, SCAI Education Committee; Assistant Professor of Medicine; Associate Program Director, Cardiovascular Medicine Fellowship; Director, Digital Innovation & Social Media Strategy, Division of Cardiology	None	Not relevant: ■ Abiomed Relevant: ■ Opsens Medical	None	None	Not relevant: ■ Abiomed ■ Chiesi Relevant: ■ Boston Scientific ■ Medtronic	None

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*Significant relationship.

†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 (ACCF or AHA/ACC) Disclosure Policy for Writing Committees.

‡No financial benefit.

§Rebecca Diekemper is an AHA/ACC joint staff member and acts as the Science and Health Advisor for the "2024 ACC/AHA Clinical Performance and Quality Measures for Adults With Valvular and Structural Heart Disease." No relevant relationships to report. Nonvoting author on measures and not included/counted in the RWI balance for this committee.

‖During a quarterly review of writing committee member disclosures in August 2021, Dr. Velagapudi reported receiving a speaker's fee from Opsens Medical for a presentation on physiology-related late breaking trials. When the disclosure was reviewed using specific ACC/AHA criteria, it was considered to represent a relevant relationship with industry. Given the current policy that at least 51% of the writing committee must be free of relevant RWI, the decision was made to remove Dr. Velagapudi from the writing committee. The only measure that was drafted by Dr. Velagapudi was previously removed from the measure set, and she did not participate in any further discussions or review of the manuscript.

AATS indicates American Association for Thoracic Surgery; ACC, American College of Cardiology; AHA, American Heart Association; AMA, American Medical Association; CME, continuing medical education; CTSN, Cardiothoracic Surgical Trials Network; *JAMA*, *Journal of the American Medical Association*; JCCDS, Joint Committee on Clinical Data Standards; JCPM, Joint Committee on Performance Measures; NHLBI, National Heart, Lung, and Blood Institute; NIH, National Institutes of Health; PCORI, Patient-Centered Outcomes Research Institute; SCAI, Society for Cardiovascular Angiography and Intervention; VA, U.S. Department of Veterans Affairs; and VHD, valvular heart disease.

APPENDIX C. REVIEWER RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (COMPREHENSIVE)—2024 ACC/AHA CLINICAL PERFORMANCE AND QUALITY MEASURES FOR VALVULAR AND STRUCTURAL HEART DISEASE

Reviewer	Representation	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Leonard N. Girardi	AATS Official Reviewer	Weill Cornell Medicine	None	None	None	None	None	None
Saurabh Gupta	ACC Official Reviewer	St. Charles Health System	■ Edwards Lifesciences* ■ Medtronic*	None	None	None	None	None
Saibal Kar	SCAI Official Reviewer	HCA Healthcare	■ Abbott Vascular* ■ Boston Scientific* ■ Gore* ■ Medtronic* ■ V-Wave*	None	■ Valcare†	None	None	None
Shahar Lavi	ACC Official Reviewer	London Health Sciences Centre	None	None	None	None	None	None
Clauden Louis	AHA Official Reviewer	BayCare Medical System	None	None	None	None	None	None
Puja Parikh	AHA Official Reviewer	Stony Brook University Renaissance School of Medicine	■ Medtronic	None	None	■ Abbott† ■ Boehringer Ingelheim† ■ Edwards Lifesciences†	None	None
Marcella Calfon Press	ACC/AHA Content Reviewer	UCLA Health	■ Abbott	None	None	None	■ Cardiac Dimensions‡ ■ Edwards Lifesciences‡	None
Marc Ruel	ACC/AHA Content Reviewer	University of Ottawa Heart Institute	■ Edwards Lifesciences ■ Medtronic ■ Xylocor	None	None	■ Artivion† ■ Medtronic†	■ AbbVie/Allergan‡ ■ Artivion‡ ■ AstraZeneca‡ ■ Medtronic‡ ■ PhaseBio‡	None
Jason H. Wasfy	ACC Official Reviewer	Harvard Medical School and Massachusetts General Hospital	■ ICER* ■ Pfizer	None	None	■ AHA* ■ NFLPA* ■ NIH*	■ AHA* ■ Massachusetts General Physicians Organization*	■ Plaintiff, quality measurement, 2022*
Jonathan Weinsaft	AHA Official Reviewer	Weill Cornell Medicine	■ Annapurna Therapeutics* ■ Bitterroot Bio ■ Lexeo Therapeutics*	■ General Electric	None	None	■ Lantheus Pharmaceutical‡ ■ Memorial Sloan Kettering Cancer Center* ■ Weill Cornell Medicine*	■ Defendant, Cardiac imaging, 2022

APPENDIX C. CONTINUED

Reviewer	Representation	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Marlene Williams	AHA/ACC JCPM Lead Reviewer	Johns Hopkins Bayview Medical Center	■ Haemonetics*	■ NACE	None	None	None	None

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*Significant (>$5,000) relationship.

†No financial relationship.

‡This disclosure was entered under the Clinical Trial Enroller category in the ACC's disclosure system.

AATS indicates American Association for Thoracic Surgery; ACC, American College of Cardiology; AHA, American Heart Association; HCA, Hospital Corporation of America; ICER, Institute for Clinical and Economic Review; JCPM, Joint Committee on Performance Measures; NACE, National Association for Continuing Education; NFLPA, National Football League Players Association; NIH, National Institutes of Health; SCAI, Society for Cardiovascular Angiography and Interventions; and UCLA, University of California, Los Angeles.