ACC/AATS/AHA/ASE/EACTS/HVS/SCA/SCAI/SCCT/SCMR/STS 2017 Appropriate Use Criteria for the Treatment of Patients With Severe Aortic Stenosis

A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, European Association for Cardio-Thoracic Surgery, Heart Valve Society, Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons

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Abstract: The American College of Cardiology collaborated with the American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, European Association for Cardio-Thoracic Surgery, Heart Valve Society, Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons to develop and evaluate Appropriate Use Criteria (AUC) for the treatment of patients with severe aortic stenosis (AS). This is the first AUC to address the topic of AS and its treatment options, including surgical aortic valve replacement (SAVR) and transcatheter aortic valve replacement (TAVR).

A number of common patient scenarios experienced in daily practice were developed along with assumptions and definitions for those scenarios, which were all created using guidelines, clinical trial data, and expert opinion in the field of AS. The *2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (1)* and its 2017 focused update paper (2) were used as the primary guiding references in developing these indications. The writing group identified 95 clinical scenarios based on patient symptoms and clinical presentation, and up to 6 potential treatment options for those patients. A separate, independent rating panel was asked to score each indication from 1 to 9, with 1–3 categorized as "Rarely Appropriate," 4–6 as "May Be Appropriate," and 7–9 as "Appropriate." After considering factors such as symptom status, left ventricular (LV) function, surgical risk, and the presence of concomitant coronary or other valve disease, the rating panel determined that either SAVR or TAVR is Appropriate in most patients with symptomatic AS at intermediate or high surgical risk; however, situations commonly arise in clinical practice in which the indications for SAVR or TAVR are less clear, including situations in which 1 form of valve replacement would appear reasonable when the other is less so, as do other circumstances in which neither intervention is the suitable treatment option.

The purpose of this AUC is to provide guidance to clinicians in the care of patients with severe AS by identifying the reasonable treatment and intervention options available based on the myriad clinical scenarios with which patients present. This AUC document also serves as an educational and quality improvement tool to identify patterns of care and reduce the number of rarely appropriate interventions in clinical practice. (J Am Soc Echocardiogr 2018;31:117-47.)

Key Words: ACC Appropriate Use Criteria, balloon aortic valvuloplasty, severe aortic stenosis, surgical aortic valve replacement, transcatheter aortic valve replacement

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Abbreviations

AR = aortic regurgitation

AS = aortic stenosis

AUC = appropriate use criteria

AVA = aortic valve area

AVR = aortic valve replacement

BAV = balloon aortic valvuloplasty

BNP = b-type natriuretic peptide

CABG = coronary artery bypass grafting

CAD = coronary artery disease

LAD = left anterior descending

LV = left ventricular

LVEF = left ventricular ejection fraction

LVOT = left ventricular outflow tract

MELD = model for end-stage liver disease

MR = mitral regurgitation

MS = mitral stenosis

PBMV = percutaneous balloon mitral valvuloplasty

PCI = percutaneous coronary intervention

SAVR = surgical aortic valve replacement

STS-PROM score = Society of Thoracic Surgeons predicted risk of mortality score

TAVR = transcatheter aortic valve replacement

Vmax = peak aortic valve velocity

PREFACE

In an effort to address the rational use of tests and procedures in the delivery of high-quality cardiovascular care, the American College of Cardiology (ACC) and numerous partnering societies have undertaken a process to determine the appropriate use of treatment options for selected patient scenarios. Ever since the first Appropriate Use Criteria (AUC) were developed in 2005 as a response to the overutilization of cardiovascular imaging, numerous other cardiac subspecialty topics have been explored and translated into appropriate use ratings.

AUC publications reflect an ongoing effort by the ACC to critically and systematically create, review, and categorize clinical situations where tests and procedures are utilized by providers caring for patients with known or suspected cardiovascular diseases. Although not intended to be entirely comprehensive due to the wide diversity of clinical disease, the indications included in this document are meant to identify common patient scenarios encountered by the majority of practitioners. The AUC indications are often chosen based on gaps in Clinical Practice Guidelines and lack of evidence-based data, therefore relying on clinical practice experience and physician judgment to determine the final AUC ratings. The ultimate objective of AUC is to improve patient care and health outcomes in a cost-effective manner, but they are not intended to ignore ambiguity and nuance intrinsic to clinical decision-making. Local parameters, such as the availability or quality of equipment and personnel, may influence the selection of certain treatments or procedures; therefore, AUC should be considered complementary to sound clinical judgment and practice experience.

I am grateful to the writing group for the development of the severe aortic stenosis patient scenarios and overall framework of the document, and to the rating panel, an independent group of experts who thoughtfully scored the patient scenarios resulting in the final AUC ratings. A special thanks to Dr. Gregory Dehmer for serving as an expert moderator at the in-person rating panel meeting. We would also like to thank the AUC Task Force members who provided insight and guidance, and the ACC staff—Leah White and especially Lara Gold—for their skilled support in the creation and championing of this document.

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Chair, Aortic Stenosis Writing Group

1. INTRODUCTION

The management of patients with aortic stenosis (AS) has become a topic of considerable clinical interest. New diagnostic methods, from imaging to biomarkers, and the recognition of low-gradient AS have provided greater understanding of the condition but also created diagnostic challenges. Concurrently, there are new treatment options that create opportunities to try therapies other than the traditional aortic valve replacement (AVR). The development of transcatheter AVR (TAVR) technology has ushered in an exciting new era in the treatment of patients with symptomatic severe AS. TAVR provides treatment options in patients with advanced disease and extreme surgical risk in whom no effective definitive therapy was available previously. TAVR has also been shown to be a safe alternative to surgical AVR (SAVR) in patients in whom surgery is feasible but who are considered to be intermediate or high risk. However, selecting patients for TAVR or SAVR is a work in progress, as is the identification of symptomatic patients in whom AVR is futile because of advanced age and extensive comorbid conditions. The clinical availability of TAVR has also created challenges in patient selection, cost effectiveness, and the need to develop centers of excellence with dedicated multidisciplinary heart valve teams.

With the dissemination of TAVR to an expanding number of medical centers, the healthcare community needs to understand how best to incorporate this technology into clinical decision making with

regard to when to select TAVR compared with SAVR, when surgery is preferable, when balloon aortic valvuloplasty (BAV) is a reasonable diagnostic or treatment option, and when (at the 2 extremes of the healthiest patients and the most seriously ill patients) it is most reasonable to recommend no intervention at all. In an effort to respond to this need and to ensure effective referral for SAVR, TAVR, or conservative management with no intervention, this AUC project was initiated. The writing group recognizes that this field is evolving very rapidly, and hence this document will need to be updated in a timely manner in order to reflect advances in technology and clinical outcomes.

2. METHODS

To begin the AUC process, a writing group of multidisciplinary experts was formed to identify and categorize common clinical scenarios for patients with severe AS. This group of representatives from several cardiovascular subspecialty societies and ACC Councils consisted of anesthesiologists; cardiothoracic surgeons; and interventional, imaging, and general cardiologists. The goal of the writing group was to choose common patient scenarios experienced in clinical practice, and to categorize these scenarios on the basis of patient symptoms, anatomy, and comorbidities, among other factors. The writing group focused on identifying the most typical situations encountered in daily practice since it would be impossible to cover every possible patient presentation without making the list excessively long. Whenever possible during the writing process, the group members would map the indications to relevant guidelines, clinical trials, and other key references (see Guideline Mapping and References). Once the indications were formed, they were reviewed and critiqued by the parent AUC Task Force and numerous external reviewers representing a variety of cardiovascular subspecialty societies and ACC Councils. After the writing group incorporated this initial feedback, the indications were sent to an independent rating panel comprising additional experts specializing in severe aortic stenosis, along with a guideline and clinical trial mapping document for their reference (see Guideline Mapping and References).

The rating panelists were then tasked with scoring the clinical scenarios from 1 through 9, with 1–3 classified as "Rarely Appropriate care," 4–6 representing "May Be Appropriate care," and 7–9 classified as "Appropriate care." Rating panel members conducted this scoring via an electronic survey platform, and the median score from the 17 panelists was calculated for each scenario. Next, the panelists, several writing group representatives, and a moderator came together for an in-person rating panel meeting, where robust discussion of each indication ensued and feedback was given to the writing group representatives. The writing group then took this input and completed further vetting of the clinical scenarios, before sending the document back to the rating panel for an additional round of electronic scoring. When some of the scores came back in misalignment with guideline recommendations and other evidence, it became clear to the writing group that they needed to elaborate and provide further evidence to support the clinical scenarios they were presenting. Thus, this additional data was offered to the rating panelists and a final round of scoring commenced (see Final Deidentified AUC Scores). These multiple rounds of review and revision by independent groups ensured that numerous physician viewpoints were heard and considered.

A detailed description of the methods used for rating the clinical scenarios can be found in previous AUC methodology publications (3,4), along with a methodology update being published in 2017. Briefly, this process combines evidence-based medicine and practice experience, and engages a rating panel in a modified Delphi exercise. The composition of the rating panel is key; in order to prevent bias in the scoring, the majority of rating panelists chosen were generalists/nonproceduralists. Proceduralists such as surgeons and interventionalists, while offering important clinical and technical insights, might have a natural tendency to rate the indications within their specialty as more appropriate than might nonproceduralists. For the scoring, care was taken to provide the rating panel with objective, unbiased information, including guidelines and key references in the field (see Guideline Mapping and References). Other steps of the modified Delphi process are convening a formal writing group with diverse expertise in the treatment of severe AS, circulating the indications for external review before sending the indications to the rating panel, and establishing a moderator for facilitating panel interaction at the face-to-face meeting.

In rating the clinical scenarios, the rating panel was asked to assess whether the different treatment options for each indication should be categorized as Appropriate, May Be Appropriate, or Rarely Appropriate. It was emphasized that the treatment options should not be ranked in comparison with each other or based on physician preference but should instead be considered on their own merits and reasonableness for the given clinical scenario. When scoring the indications, the rating panel was given the following definition of appropriate use:

An Appropriate treatment is one in which the potential benefits, in terms of survival or health outcomes (symptoms, functional status, and/or quality of life) exceed the potential negative consequences of the treatment strategy.

The rating panel scored each indication as follows:

Median Score 7–9: *Appropriate care* for specific indication (treatment **is** generally acceptable and **is** a reasonable approach for the indication).

An appropriate option for management of patients in this population due to benefits generally outweighing risks; effective option for individual care plans although not always necessary depending on physician judgment and patient specific preferences (i.e., treatment is generally acceptable and is generally reasonable for the indication).

Median Score 4–6: *May Be Appropriate care* for specific indication (treatment **may** be generally acceptable and **may** be a reasonable approach for the indication). May Be Appropriate also implies that more research and/or patient information is needed to classify the indication definitively.

At times an appropriate option for management of patients in this population due to variable evidence or agreement regarding the benefits/risks ratio, potential benefit based on practice experience in the absence of evidence, and/or variability in the population; effectiveness for individual care must be determined by a patient's physician in consultation with the patient based on additional clinical variables and judgment along with patient preferences (i.e., treatment may be acceptable and may be reasonable for the indication).

Median Score 1–3: *Rarely Appropriate care* for specific indication (treatment **is not** generally acceptable and **is not** a reasonable approach for the indication).

Rarely an appropriate option for management of patients in this population due to the lack of a clear benefit/risk advantage; rarely an effective option for individual care plans; exceptions should have documentation of the clinical reasons for proceeding with this care option (i.e., treatment is not generally acceptable and is not generally reasonable for the indication).

The division of the numerical scores into 3 levels of appropriateness is somewhat arbitrary and the numeric designations should be

viewed as a continuum. It is important to note that there may be diversity in clinical opinion for particular clinical scenarios, such that scores in the intermediate level of appropriate use should be labeled "May Be Appropriate," as critical patient or research data may be lacking or discordant. This designation should serve as a prompt to carry out definitive research in this field whenever possible. It is anticipated that AUC reports will continue to be revised as further data are generated and information from implementation of the criteria is accumulated.

The scenarios included in this document are based on our current understanding of procedure outcomes plus the potential patient benefits compared with risks of the treatment strategies involved. Each patient should be treated individually on the basis of their own particular needs, so it is expected that all clinicians will occasionally care for patients with unique conditions that could result in a Rarely Appropriate treatment rating. When this occurs, clinicians should document the specific situation and patient characteristics, but it should not be used as a deterrent for treating the patient or denial of reimbursement. While a Rarely Appropriate designation should not prevent a procedure from being performed, an Appropriate designation is also not a requirement or "must do" for a given procedure. The AUC are offered to help guide patient care but should not be considered a substitute for sound clinical judgement and practice experience.

3. GENERAL ASSUMPTIONS

1. The comments and scenarios in this document are limited to patients with severe valvular AS and are not intended to be applied to those with mild or moderate disease.
2. Diagnostic tests and procedures are performed and interpreted by qualified individual(s) in a facility that complies with national standards for performing echocardiography, computed tomography (CT), coronary angiography, and invasive hemodynamic assessment, as well as interventions such as TAVR and SAVR, and other transcatheter and surgical procedures.
3. A qualified clinician has obtained a complete medical history and performed the physical examination such that the clinical status of the patient can be assumed to be valid as stated in the indication (e.g., an asymptomatic patient is truly asymptomatic for the condition as stated and sufficient questioning of the patient has been undertaken).
4. The indications are at times purposefully broad to cover an array of cardiovascular signs and symptoms and to account for the ordering physician's best judgment as to the presence of cardiovascular abnormalities. Clear documentation of the reason for ordering the test or procedure should be included in the medical record. Additionally, there are likely clinical scenarios that are not covered in this document.
5. For some clinical scenarios, more than 1 table may need to be consulted to determine the appropriateness of a specific intervention. For example, an applicable scenario in Table 2 may indicate that AVR (TAVR or SAVR) is Appropriate. An additional table, such as Table 3, which includes information on surgical risk and comorbidities, may need to be consulted to determine the appropriateness of TAVR or SAVR specifically.
6. Procedures are rated for their level of reasonableness specific to clinical scenarios, rather than a forced, rank-order comparison against other procedures. Determination of the range of modalities that may or may not be reasonable for specific indications is the goal of this document, rather than determining a single best procedure for each indication. As such, more than 1 procedure type or even all procedures may be considered Appropriate, May Be Appropriate, or Rarely Appropriate for a given clinical indication.
7. Cost is considered implicitly in the appropriate use determination. Clinical benefits should always be considered first and costs should be considered in relation to these benefits in order to better convey net value. For example, a procedure with moderate clinical efficacy should not be scored as more appropriate than a procedure with high clinical efficacy solely due to its lower cost. When scientific evidence exists to support clinical benefit, cost effectiveness should be considered for that indication.
8. The level of appropriate use does not consider issues of local availability or skill.
9. The category "May Be Appropriate" (M) is used when insufficient data are available for a definitive categorization or there is substantial disagreement regarding the reasonableness of that indication. The designation "May Be Appropriate" should not be used as grounds for denial of reimbursement.
10. It is assumed that these clinical decisions will be made in the context of a Heart Valve Team, comprising experts in cardiac surgery, interventional cardiology, cardiac imaging, anesthesiology, and geriatrics, as well as additional members as needed.
11. It is assumed that particularly complex transcatheter or surgical procedures or procedures performed on asymptomatic patients will be done at centers with the appropriate expertise to minimize the risk of complications and poor clinical outcomes.
12. Throughout this document, patients are defined as being at high, intermediate, or low surgical risk on the basis of the following criteria:
    - **High or Extreme Risk:** A patient is determined to be at high or extreme risk for SAVR by the Heart Team. High risk is indicated by a Society of Thoracic Surgeons predicted risk of mortality (STS-PROM) score of 30-day surgical mortality >8% with additional input from the Heart Team for anatomic or functional factors not reflected in the risk score that may make the patient high risk. Anatomic factors include porcelain aorta, hostile chest (e.g., prior chest radiation), and left internal mammary artery (LIMA) crossing the midline in a substernal location. Functional factors include frailty, advanced liver disease/high model for end-stage liver disease (MELD) score, oxygen-dependent chronic obstructive pulmonary disease (COPD), end-stage renal disease (ESRD), severe pulmonary hypertension with right ventricular dysfunction, and neurocognitive impairment. A predicted risk of death by 30 days after surgery of ≥15% is considered to be extreme risk.
    - **Intermediate Risk:** A patient is determined by the Heart Team to be at an intermediate risk for SAVR. Most commonly, intermediate-risk patients have an STS-PROM between 3% and 8%–10%. All additional factors included in high-risk patient evaluation can be considered by the Heart Team, which can render an otherwise low-risk patient to be intermediate risk.
    - **Low Risk:** Patients with an STS-PROM <3% and no other factors that would cause the Heart Team to determine the patient to be at significantly higher risk.

Table 1 Assumptions: Asymptomatic, High-Gradient, Severe AS

13. To mirror the structure of the guidelines, this table of scenarios is focused on Stages C1 and C2 (patients with high gradients) (1). It does not address issues of low flow or low gradient, which are addressed in a separate table.
14. High-gradient, severe AS is defined as peak aortic valve velocity (V_{max}) ≥4 m/sec or mean gradient ≥40 mmHg, usually accompanied by aortic valve area (AVA) ≤1.0 cm^2 (or indexed AVA ≤0.6 cm^2/m^2).
15. For treatment options, we listed "AVR" and did not differentiate between SAVR and TAVR because this distinction is a moving target and our approach parallels how the guidelines dealt with this issue. The first decision is *whether* to perform valve replacement and the subsequent decision is *how* to replace the valve.
16. Whether a patient is symptomatic from AS can be difficult to discern, particularly in an elderly, sedentary population that often has multiple comorbidities. It should be assumed that the clinician has taken a

thorough history and believes the patient to be asymptomatic from AS. When there is uncertainty about symptoms, the guidelines recommend an exercise stress test to clarify how the AS is affecting the patient and thereby guide management decisions. If it is not feasible for the patient to undergo an exercise stress test, then the clinician must rely on other clinical factors and echocardiographic features to make a management decision regarding the timing of potential AVR.

17. It can be difficult to distinguish normal exercise limitations from abnormal symptoms due to AS. As in the guidelines, an abnormal exercise stress test is characterized by exercise-induced angina, excessive dyspnea early in exercise, dizziness, or syncope, which are all consistent with symptoms of AS. Additionally, limited exercise capacity (below age and sex-specific predicted metabolic equivalent of task, or MET) or abnormal blood pressure response (e.g., hypotension or failure to increase blood pressure with exercise) are factors leading to an abnormal exercise stress test. An increase in the mean gradient with exercise $\geq$18 mmHg has also been associated with an increased event rate.

Table 2 Assumptions: Flow, Gradient, and Ejection Fraction

18. For this Table, BAV is only offered as a bridge to decision about whether to perform AVR and not as a palliative procedure.
19. Several criteria have been proposed and utilized to distinguish truly severe AS from pseudosevere AS. The recent guidelines define truly severe AS as an AVA $\leq$1.0 cm^2 and V_{max} >4 m/sec at any flow rate, but other criteria have been proposed. For these scenarios, assume that the clinician has applied these various criteria and accurately characterized the stenosis as truly severe AS or pseudosevere AS.
20. For treatment options, we listed "AVR" and did not differentiate between SAVR and TAVR because this distinction is a moving target and our approach parallels how the guidelines dealt with this issue. The first decision is *whether* to perform valve replacement and the subsequent decision is *how* to replace the valve.
21. Low flow is defined as a stroke volume index <35 ml/m^2.
22. Low gradient is defined as a mean gradient <40 mmHg (or V_{max} <4 m/sec).
23. Flow reserve on dobutamine echocardiogram is indicated by an increase in the stroke volume index by $\geq$20%.
24. For patients with a reduced ejection fraction (<50%), no information is provided regarding symptoms as the presence or absence of symptoms would likely not alter management decisions.
25. In some of the scenarios in this table, a distinction is made between patients with left ventricular ejection fraction [LVEF dysfunction (LVEF 20%–49%) and those with very severe LV dysfunction (LVEF <20%)]. While it is somewhat arbitrary to choose an LVEF cut-off of 20%, we believe it is useful to include some scenarios in which a patient has very severe LV dysfunction, and this cut-off was used in the TAVR trials as an exclusion criterion.
26. Pseudosevere AS can only be definitively diagnosed if there is flow reserve accompanied by an increase in AVA and no more than minimal change in the transvalvular gradient. This suggests a primary myocardial problem with more moderate valvular stenosis. The guidelines suggest that if the AVA with dobutamine is >1.0 cm^2 along with V_{max} <4 m/s, then the patient has pseudosevere AS, although other cut-offs have been proposed for this designation.
27. Determination of cut-off point(s) for a very calcified aortic valve consistent with severe AS is an active area of research. Although a definitive cut-off point has not yet been determined, it does appear clear that the cut-off points will differ depending on sex, with a higher cut-off point indicative of severe AS in males.
28. In patients with preserved LVEF, low-flow, low-gradient AS, some have utilized dobutamine to distinguish truly severe AS from pseudosevere AS. Although this is an option, caution is advised when performing this in patients with a hypertrophied ventricle and small chamber cavity. Alternatively, using computed tomography (CT) to assess valve calcification may help to make this distinction.

Table 3 Assumptions: Symptomatic Severe AS: High- or Extreme-Risk Patients

29. For this Table, BAV may be considered as either a palliative intervention or a bridge to decision about definitive therapy with AVR.
30. Some of these scenarios include a statement regarding anticipated life expectancy and whether it is more or less than 1 year. That 1-year cut-point was used to be consistent with the valve guidelines and the TAVR trials (5–10), which usually excluded patients with an anticipated life expectancy <1 year. To be clear, this is an anticipated life expectancy based on comorbidities and other factors not related to the AS—factors that would not be expected to be favorably altered by AVR.
31. "Frailty" is a geriatric syndrome defined as impaired resilience to stressors. There is no universal definition of frailty and many criteria have been proposed. The Fried criteria (11) are commonly used, with frailty defined as meeting 3 out of 5 criteria (slow gait speed, weak handgrip, exhaustion, physical inactivity, and shrinking). It is recognized that frailty falls along a spectrum. Some patients will have such severe frailty that valve replacement is exceedingly unlikely to yield clinical benefit. For these scenarios, however, assume that $\geq$1 objective definitions of frailty have been utilized to deem a patient "frail," that the patient is not "severely frail," and that this information should be considered when assessing patient-reported symptoms, procedural risk, and anticipated benefit after the various treatment options. This is an evolving concept and an active area of research.
32. Since there are no specific cut-offs established for B-type natriuretic peptide (BNP) and clinical risk/outcomes, BNP has been included with a qualitative description (normal versus elevated) that likely still provides useful information in these scenarios. It is recommended that BNP values be interpreted in light of the age, sex, and renal function of the patient.
33. In these scenarios, an STS-PROM >15% has been used as a surrogate marker for an extensive number of comorbidities.
34. For the scenarios on liver disease (cirrhosis), we used the model for end-stage liver disease (MELD) score, which is often used to describe the severity of liver disease. An alternative would be the Child-Pugh classification. Our intent is to provide examples of more mild cirrhosis versus more severe cirrhosis in these scenarios.
35. Particularly for scenarios in Table 3, whether a transfemoral approach is feasible may have implications for the appropriateness of TAVR. For some scenarios, transfemoral TAVR may be deemed appropriate, whereas alternative-access TAVR may be considered less or not appropriate. For the scenarios in this table, assume that TAVR can be performed by a transfemoral approach. Increasingly, with smaller sheath sizes, a significant majority of procedures will be performed via a transfemoral approach. If an alternative access approach is necessary, then the invasiveness of that approach, the expertise of the team, and patient factors should be taken into account when deciding whether to perform the procedure.

Table 4 Assumptions: Symptomatic, High-Gradient, Severe AS With Associated Coronary Artery Disease (CAD)

36. CAD is defined as a hemodynamically significant lesion (ischemia on functional testing) or angiographically severe ($\geq$70%) stenosis.

37. Noninvasive or invasive risk stratification as well as impact of anatomical complexity on type of revascularization have not been studied specifically for the AS population.
38. Decisions about the optimal revascularization strategy to accompany valve replacement can be complex and require a Heart Team decision with input from interventional cardiology and cardiac surgery.
39. These scenarios describe coronary lesions that have not already been revascularized by a patent graft.

Table 5 Assumptions: Severe Symptomatic AS and Other Valve or Ascending Aortic Pathology

40. In this table, some therapeutic options are not rated (box grayed out) because they are not relevant to the clinical scenario.
41. Although some of the therapeutic options offered for these scenarios are not yet approved by the FDA for those specific indications [e.g., placement of a MitraClip after TAVR for a patient with severe secondary mitral regurgitation (MR)], there are published data reporting on these approaches. Since these scenarios are faced by clinicians and non-FDA approved therapies have been performed and reported, we believe it is important to rate the appropriateness of these treatment options.
42. For the treatment options that involve 2 transcatheter therapies, it is assumed that they will occur sequentially and not during the same procedure. For example, for the TAVR plus MitraClip option, it is assumed that TAVR would be performed first and that there would be a reassessment of the severity of the MR before potentially proceeding with MitraClip placement at a later time.
43. The surgical risk in these scenarios is determined by the SAVR risk, as that is the risk that is relevant for FDA-approved uses of TAVR. In reality, however, the surgical risk for a double valve procedure, for example, is higher than that for SAVR alone.
44. BAV as a bridge to decision may mean a decision on a treatment strategy regarding which valves to intervene on or whether to pursue any definitive therapies. For example, in a patient with severe AS and severe secondary MR and high surgical risk, a BAV may provide some insight into whether the MR would improve with TAVR alone or whether a double valve procedure would be a preferable therapeutic intervention. The clinical response to a BAV (e.g., change in 6-minute walk distance or change in BNP) may also be helpful in determining whether a patient is likely to benefit from TAVR.
45. For the scenarios in which MitraClip is an option, assume that the MR is amenable to treatment with a clip and that there are no anatomical contraindications.

Table 6 Assumptions: Noncardiac Surgery

46. Severe/critical or critical AS—as per guideline for valvular heart disease.
47. Major surgery is defined according to ACC/AHA guidelines.
48. Urgent—needs to be accomplished in next 1–3 days.
49. Signs of cardiac decompensation include physical signs of congestive heart failure, higher filling pressures on cardiac catheterization or as estimated by echocardiography, elevated biomarkers, significant MR, pulmonary hypertension, and decreased ejection fraction.
50. Nonobstructive CAD can be determined by angiography, coronary CT, or recent noninvasive perfusion imaging.
51. Patients with significant CAD are managed according to coronary revascularization guidelines in addition to the above recommendation for AS.
52. If AVR is appropriate, the choice of SAVR versus TAVR should be based on patient risk and the urgency and type of upcoming noncardiac surgery.

Cardiac Risk Stratification for Noncardiac Surgical Procedures:

- High Risk (reported cardiac risk often >5%)
  - Emergent major operations, particularly in older patients
  - Aortic and other major vascular surgeries
  - Peripheral vascular surgery
  - Anticipated prolonged surgical procedures associated with large fluid shifts, blood loss, or both
- Intermediate Risk (reported cardiac risk generally >1% but <5%)
  - Carotid endarterectomy
  - Head and neck surgery
  - Intraperitoneal and intrathoracic surgery
  - Orthopedic surgery
  - Prostate surgery
- Low Risk (reported cardiac risk generally <1%)
  - Endoscopic procedures
  - Superficial procedures
  - Cataract surgery
  - Breast surgery

Table 7 Assumptions: Failing Aortic Valve Bioprosthesis

53. For the purposes of this document, aortic bioprosthesis failure is defined as severe dysfunction of the valve, either stenosis or regurgitation, causing clinical symptoms or evidence of LV dysfunction. There should be evidence of structural deterioration of the valve rather than prosthesis-patient mismatch or paravalvular regurgitation.
54. For small surgical valves undergoing a redo SAVR, it is assumed that an aortic root enlargement will be performed as clinically indicated.
55. In these scenarios, it is assumed that TAVR is a viable option and not contraindicated for safety reasons. Assume, for example, that TAVR would not be contraindicated because it might obstruct the coronary arteries due to the type of bioprosthesis already implanted. Nonetheless, in these cases, it is important to consider several factors (e.g., particulars of the already implanted bioprosthesis, risk of coronary obstruction) when weighing TAVR valve-in-valve versus redo SAVR, not just the residual gradient that may result.

4. DEFINITIONS

Aortic Regurgitation (AR): the backward flow of blood from the aorta into the left ventricle owing to imperfect functioning (incompetence) of the aortic semilunar valve.

Aortic Stenosis (AS): a congenital or acquired disorder of the aortic valve leading to abnormal narrowing of the orifice and increased impedance to the flow of blood out of the heart into the aorta.

Ascending Aortic Aneurysm: a pathologic process in the most proximal portion of the aorta within the thoracic cavity leading to dilation of the aortic wall, which has a propensity to expand, dissect, and rupture.

Balloon Aortic Valvuloplasty (BAV), also known as Valvotomy: inflation of a balloon positioned across a narrowed (stenotic) aortic valve in order to widen or enlarge the orifice.

Bioprosthetic Valve: a manufactured valve with leaflets made of biologic tissue (often porcine or bovine) that may be used to replace a malfunctioning heart valve.

B-type Natriuretic Peptide (BNP): a biomarker that is released from heart muscle in response to increased stretch and is useful in the diagnosis, estimation of severity, prognosis, and management of heart failure.

Cirrhosis: liver disease characterized pathologically by loss of the normal microscopic lobular architecture with fibrosis, nodular regeneration, and variable amounts of liver failure.

Coronary Artery Disease (CAD): impedance or blockage in ≥1 of the arteries supplying the heart, usually due to atherosclerosis.

Ejection Fraction (EF): the percentage of blood pumped or ejected from the ventricle with each contraction.

Extreme Surgical Risk: the point at which the risks of a surgical procedure to the patient exceed the expected clinical benefits.

Flow Acceleration: an increasing blood flow velocity across a narrowed orifice or vascular structure.

High Gradient Severe Aortic Stenosis: peak velocity ≥4 m/sec or mean gradient ≥40 mm Hg, usually accompanied by AVA ≤1.0 cm^2 (or indexed AVA ≤0.6 cm^2/m^2).

Left Anterior Descending (LAD) Artery: 1 of the primary epicardial coronary arteries supplying the anterior surface of the heart.

Left Ventricular Outflow Tract (LVOT): a virtual structure, composed of ventricular myocardium and the mitral valve, that allows for passage of blood as it leaves the left ventricle and passes through the aortic valve.

MitraClip: a catheter-based method of treatment to improve a leaking mitral valve that involves placement of a fabric-covered metallic clip device on the valve leaflets.

Mitral Annular Calcification: a common degenerative process involving the fibrous annulus of the mitral valve with progressive deposition of calcium within, along, and beneath the mitral valve annulus, occasionally leading to stenosis.

Mitral Regurgitation (MR): the backward flow of blood from the left ventricle into the left atrium due to imperfect functioning (incompetence) of the mitral valve. Primary mitral regurgitation is due predominantly to valvular pathology (e.g., leaflet prolapse), whereas secondary mitral regurgitation is due mainly to ventricular remodeling and annular dilatation, which cause restricted leaflet motion and/or malcoaptation.

Mitral Stenosis (MS): A pathologic narrowing of the mitral valve orifice that may be congenital or acquired.

Model for End-Stage Liver Disease (MELD): a scoring system for assessing severity of chronic liver disease that correlates with prognosis and mortality.

Percutaneous Balloon Mitral Valvuloplasty (PBMV): inflation of a balloon positioned across a narrowed (stenotic) mitral valve in order to widen or enlarge the orifice.

Porcelain Aorta: structural disease of the aortic wall defined by the extensive, circumferential calcification of the ascending thoracic aorta, detected by computed tomography (CT) or fluoroscopy.

Prosthesis-Patient Mismatch: occurs when the indexed effective orifice area (EOA) of a normally functioning prosthetic valve is too small in relation to patient body size.

Pulmonary Hypertension: increased pressure in the blood vessels within the lung.

Septal Hypertrophy: abnormal enlargement or thickening of the interventricular septum just beneath the aortic valve and adjacent to the mitral valve.

Septal Myectomy: surgical excision of a portion of abnormally thickened interventricular septum that is obstructing the flow of blood from the heart.

Surgical Aortic Valve Replacement (SAVR): a relatively common open cardiovascular surgical procedure whereby a diseased aortic valve is surgically removed and an artificial valve prosthesis is sutured in its place.

Surgical Risk:

High or Extreme Risk: A patient is determined to be at high or extreme risk for *SAVR* by the Heart Team. High risk is indicated by a Society of Thoracic Surgeons predicted risk of mortality (STS-PROM) score at 30 days of ≥8%, with additional input from the Heart Team for anatomic or functional factors not reflected in the risk score that may make the patient high risk. Examples of anatomic factors include porcelain aorta, hostile chest (e.g., prior chest radiation), and left internal mammary artery (LIMA) crossing the midline in a substernal location. Examples of functional factors include frailty, advanced liver disease (high MELD score), oxygen-dependent chronic obstructive pulmonary disease (COPD), end-stage renal disease (ESRD), severe pulmonary hypertension with right ventricular dysfunction, and neurocognitive impairment. A predicted risk of death by 30 days after surgery of ≥15% is considered to be extreme risk.

Intermediate Risk: A patient is determined by the Heart Team to be at an intermediate risk for SAVR. Most commonly, intermediate-risk patients have an STS-PROM between 3% and 10%. All additional factors included in high-risk patient evaluation can be considered by the Heart Team, who can determine an otherwise low-risk patient to be intermediate risk.

Low Risk: patients with an STS-PROM <3% and no other factors that would cause the Heart Team to significantly determine the patient to be at higher risk.

SYNTAX (Synergy between PCI with TAXUS drug-eluting stent and Cardiac Surgery) Score: a grading tool used to determine the complexity of CAD.

Transcatheter Aortic Valve Replacement (TAVR): a catheter-based technique to replace a diseased aortic valve, involving implantation of a valve bioprosthesis deployed within the native aortic valve.

Tricuspid Regurgitation (TR): the backward flow of blood from the right ventricle into the right atrium due to imperfect functioning (incompetence) of the tricuspid valve, which, in turn, is commonly due to stretching of the tricuspid valve annulus.

Valve-in-Valve: most commonly refers to a transcatheter valve placed in a previously implanted surgical bioprosthesis for structural valve deterioration. This term can also be used for a transcatheter valve placed inside a previously placed transcatheter valve that has undergone structural valve deterioration. A second transcatheter valve placed acutely inside a transcatheter valve for inadequate valve function of the first valve during the initial procedure should not be included in this definition but should be considered as multiple valves at initial implant.

5. TREATMENT OF PATIENTS WITH SEVERE AORTIC STENOSIS: APPROPRIATE USE CRITERIA (BY INDICATION)

The final ratings for the treatment of patients with severe aortic stenosis are listed by indication in Tables 1 to 7. The final score for each indication reflects the median score of the 17 rating panel members and has been labeled according to the categories of Appropriate/A (median score 7–9), May Be Appropriate/M (median score 4–6), or Rarely Appropriate/R (median score 1–3). In the tables, the final score for each indication is shown in parentheses next to the Appropriate Use Criteria rating of A, M, or R.

TABLE 1 Asymptomatic, High-Gradient, Severe AS

Indication		Appropriate Use Median Score (1-9)	
		No Intervention	AVR (TAVR or SAVR)
1.	■ LVEF ≥50% ■ V_{max} 4.0–4.9 m/sec ■ Negative exercise stress test ■ No predictors of symptom onset or of rapid progression (e.g., ΔV_{max} >0.3 m/s/y, severe valve calcification, elevated BNP, or excessive LV hypertrophy in the absence of hypertension) ■ High or intermediate surgical risk	A (7)	M (5)
2.	■ LVEF ≥50% ■ V_{max} 4.0–4.9 m/sec ■ Negative exercise stress test ■ No predictors of symptom onset or of rapid progression (e.g., ΔV_{max} >0.3 m/s/y, severe valve calcification, elevated BNP, or excessive LV hypertrophy in the absence of hypertension) ■ Low surgical risk	A (7)	M (5)
3.	■ LVEF ≥50% ■ V_{max} 4.0–4.9 m/sec ■ High-risk profession (e.g., airline pilot) or lifestyle (e.g., competitive athlete) or anticipated prolonged time away from close medical supervision ■ Low surgical risk	M (4)	A (7)
4.	■ LVEF ≥50% ■ V_{max} 4.0–4.9 m/sec ■ Negative exercise stress test ■ ≥1 predictor(s) of symptom onset or of rapid progression (e.g., ΔV_{max} >0.3 m/s/y, severe valve calcification, elevated BNP, or excessive LV hypertrophy in the absence of hypertension) ■ High or intermediate surgical risk	M (4)	A (7)
5.	■ LVEF ≥50% ■ V_{max} 4.0–4.9 m/sec ■ Negative exercise stress test ■ ≥1 predictor(s) of symptom onset or of rapid progression (e.g., ΔV_{max} >0.3 m/s/y, severe valve calcification, elevated BNP, or excessive LV hypertrophy in the absence of hypertension) ■ Low surgical risk	M (4)	A (8)
6.	■ LVEF ≥50% ■ V_{max} 4.0–4.9 m/sec ■ Abnormal exercise stress test ■ High or intermediate surgical risk	R (3)	A (8)
7.	■ LVEF ≥50% ■ V_{max} 4.0–4.9 m/sec ■ Abnormal exercise stress test ■ Low surgical risk	R (2)	A (8)
8.	■ LVEF ≥50% ■ Very severe AS (V_{max} ≥5 m/sec or mean gradient ≥60 mmHg) ■ High or intermediate surgical risk	M (4)	A (7)
9.	■ LVEF ≥50% ■ Very severe AS (V_{max} ≥5 m/sec or mean gradient ≥60 mmHg) ■ Low surgical risk	R (2)	A (8)
10.	■ LVEF <50% ■ V_{max} ≥4 m/sec or mean gradient ≥40 mmHg ■ High or intermediate surgical risk	R (2)	A (8)
11.	■ LVEF <50% ■ V_{max} ≥4 m/sec or mean gradient ≥40 mmHg ■ Low surgical risk	R (1)	A (9)
12.	■ Undergoing another cardiac surgery or ascending aortic surgery	R (1)	A (9)

A = Appropriate; AS = aortic stenosis; AVR = aortic valve replacement; BNP = b-type natriuretic peptide; LV = left ventricular/left ventricle; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate; SAVR = surgical aortic valve replacement; TAVR = transcatheter aortic valve replacement; Vmax = peak aortic valve velocity.

Table 1 Results and Discussion

This table is designed to highlight decision making in patients with asymptomatic severe aortic stenosis, which conforms to stages C1 and C2 in the ACC/AHA guidelines (1,2). The decision to be made is between aortic valve replacement (AVR) and no intervention, as the choices do not differentiate between TAVR versus SAVR since the type of AVR is influenced by variables not considered in this table. Balloon valvuloplasty was not offered as an option as it would rarely, if ever, be considered an option in the asymptomatic patient. The scenarios do not include those for the various forms of low-gradient severe aortic stenosis and, with the exception of the last scenario, are limited to decision making for patients who have unequivocally severe aortic stenosis.

Amplifying the role for stress testing addressed by the guidelines, the scenarios in this table underscore the importance of stress test performance in decision making (12–17). For definitions of an abnormal stress test, the reader is referred to assumption #17. However, it is recognized that stress testing in elderly patients may be challenging and stress test results may not be available for all patients. In such situations, the decision to intervene or manage the patient medically will be influenced predominantly by surgical risk and the presence of factors associated with possible symptom onset and/or rapid disease progression. The definitions of surgical risk are covered in the General Assumptions (#12).

In scenarios with an abnormal stress test, the scores reflect the fact that raters considered stress test positivity as a surrogate for symptomatic AS and intervention was considered Appropriate regardless of surgical risk. Similarly, reduced ejection fraction (<50%) was recognized as carrying a Class I recommendation for intervention regardless of surgical risk, and intervention was rated Appropriate with no role for stress testing to inform decision making. In these scenarios, medical management was considered to be Rarely Appropriate.

Where stress tests were normal, the scenarios listed additional factors that have been reported to be predictive of symptom onset and/or rapid progression but not of sudden death, and therefore do not carry Class I recommendations for intervention in the current guidelines. When none of these features were present, medical management was rated Appropriate. However, given the relentless progression of severe aortic stenosis (18,19), intervention was rated May Be Appropriate regardless of surgical risk even in the absence of such features.

Conversely, even with a normal stress test, in the presence of factors that are predictive of symptom onset and/or rapid progression but not of sudden death, raters considered intervention as Appropriate, particularly if the risk of surgery was low, with medical management as a May Be Appropriate alternative approach.

Recognizing that very severe aortic stenosis (defined as V_{max} ≥5 m/sec or mean gradient ≥60 mmHg) identifies a group of patients at increased risk for death and indication-driven AVR (20), raters considered intervention Appropriate, particularly when surgical risk was low, and medical management a May Be Appropriate alternative when surgical risk was higher.

The table also captures the notion that intervention is Appropriate (and failure to intervene, Rarely Appropriate) when the patient with severe aortic stenosis undergoes cardiac surgery for another indication. Finally, in settings in which syncope could be fatal for the patient and/or others and there might be limited access to medical care for surveillance of LV function and/or AVR, should symptoms develop, AVR was considered Appropriate in the low–surgical-risk patient and medical management as a May Be Appropriate alternative.

TABLE 2 Flow, Gradient, and Ejection Fraction

Indication		Appropriate Use Median Score (1–9)		
		No Intervention	BAV (as Bridge to Decision)	AVR (TAVR or SAVR)
Reduced Ejection Fraction (<50%)				
13.	■ AVA ≤1.0 cm^2 (or indexed AVA ≤0.6 cm^2/m^2) on resting echo ■ LVEF 20% to 49% ■ Low flow ■ Low gradient ■ Flow reserve on low-dose dobutamine echo ■ Truly severe AS ■ High or intermediate surgical risk	R (2)	R (3)	A (8)
14.	■ AVA ≤1.0 cm^2 (or indexed AVA ≤0.6 cm^2/m^2) on resting echo ■ LVEF 20% to 49% ■ Low flow ■ Low gradient ■ Flow reserve on low-dose dobutamine echo ■ Truly severe AS ■ Low surgical risk	R (1)	R (2)	A (9)
15.	■ AVA ≤1.0 cm^2 (or indexed AVA ≤0.6 cm^2/m^2) on resting echo ■ LVEF 20% to 49% ■ Low flow ■ Low gradient ■ Flow reserve on low-dose dobutamine echo ■ Pseudosevere AS	A (8)	R (2)	R (2)
16.	■ AVA ≤1.0 cm^2 (or indexed AVA ≤0.6 cm^2/m^2) on resting echo ■ LVEF 20% to 49% ■ Low flow ■ Low gradient ■ No flow reserve on low-dose dobutamine echo ■ Very calcified aortic valve on echo and/or CT, suggesting truly severe AS, or calculation of a projected valve area that remains severely reduced ■ High or intermediate surgical risk	M (4)	M (5)	A (7)
17.	■ AVA ≤1.0 cm^2 (or indexed AVA ≤0.6 cm^2/m^2) on resting echo ■ LVEF 20% to 49% ■ Low flow ■ Low gradient ■ No flow reserve on low-dose dobutamine echo ■ Minimal calcification on aortic valve on echo and/or CT ■ High or intermediate surgical risk	A (7)	R (3)	R (2)

Continued on the next page

TABLE 2 Continued

Indication		Appropriate Use Median Score (1–9)		
		No Intervention	BAV (as Bridge to Decision)	AVR (TAVR or SAVR)
18.	■ AVA ≤1.0 cm^2 (or indexed AVA ≤0.6 cm^2/m^2) ■ LVEF <20% ■ V_{max} ≥4 m/sec or mean gradient ≥40 mmHg on resting echo ■ High or intermediate surgical risk	R (3)	M (4)	A (7)
19.	■ AVA ≤1.0 cm^2 (or indexed AVA ≤0.6 cm^2/m^2) ■ LVEF <20% ■ Mean gradient <20 mmHg on resting echo ■ No flow reserve on low-dose dobutamine echo ■ High or intermediate surgical risk	A (7)	M (4)	R (3)
20.	■ AVA ≤1.0 cm^2 (or indexed AVA ≤0.6 cm^2/m^2) on resting echo ■ LVEF <20% ■ Low flow ■ Low gradient ■ Flow reserve on low-dose dobutamine echo ■ Truly severe AS ■ High or intermediate surgical risk	R (3)	M (5)	A (7)
21.	■ AVA ≤1.0 cm^2 (or indexed AVA ≤0.6 cm^2/m^2) on resting echo ■ LVEF <20% ■ Low flow ■ Low gradient ■ Flow reserve on low-dose dobutamine echo ■ Pseudosevere AS ■ High or intermediate surgical risk	A (7)	R (2)	R (2)
Preserved Ejection Fraction (≥50%)				
22.	■ AVA ≤1.0 cm^2 (or indexed AVA ≤0.6 cm^2/m^2) ■ V_{max} ≥4 m/sec or mean gradient ≥40 mmHg on resting echo ■ Symptomatic ■ High or intermediate surgical risk	R (1)	R (2)	A (9)
23.	■ AVA ≤1.0 cm^2 (or indexed AVA ≤0.6 cm^2/m^2) ■ V_{max} ≥4 m/sec or mean gradient ≥40 mmHg on resting echo ■ Symptomatic ■ Low surgical risk	R (1)	R (1)	A (9)
24.	■ AVA ≤1.0 cm^2 (and indexed AVA ≤0.6 cm^2/m^2) ■ Low flow ■ Low gradient ■ Symptomatic ■ Evidence of a severely calcified valve ■ Clinical, hemodynamic, and anatomic data support valve obstruction as the most likely cause of symptoms ■ High or intermediate surgical risk	R (2)	R (3)	A (8)
25.	■ AVA ≤1.0 cm^2 (and indexed AVA ≤0.6 cm^2/m^2) ■ Low flow ■ Low gradient ■ Symptomatic ■ Evidence of a severely calcified valve ■ Clinical, hemodynamic, and anatomic data support valve obstruction as the most likely cause of symptoms ■ Low surgical risk	R (1)	R (1)	A (9)
26.	■ AVA ≤1.0 cm^2 (and indexed AVA ≤0.6 cm^2/m^2) ■ Low flow ■ Low gradient ■ Evidence of a severely calcified valve ■ Asymptomatic ■ High or intermediate surgical risk	M (6)	R (3)	M (4)
27.	■ AVA ≤1.0 cm^2 (and indexed AVA ≤0.6 cm^2/m^2) ■ Low flow ■ Low gradient ■ Evidence of a severely calcified valve ■ Asymptomatic ■ Low surgical risk	M (6)	R (2)	M (4)
28.	■ AVA ≤1.0 cm^2 (and indexed AVA ≤0.6 cm^2/m^2) ■ Normal flow ■ Low gradient ■ Confirmation of internal consistency of the AVA, flow, and gradient measurements ■ Evidence of a severely calcified valve ■ Symptoms believed to be due to AS ■ High or intermediate surgical risk	R (3)	M (4)	A (7)
29.	■ AVA ≤1.0 cm^2 (and indexed AVA ≤0.6 cm^2/m^2) ■ Normal flow ■ Low gradient ■ Confirmation of internal consistency of the AVA, flow, and gradient measurements ■ Evidence of a severely calcified valve ■ Symptoms believed to be due to AS ■ Low surgical risk	R (3)	R (3)	A (7)

A = Appropriate; AS = aortic stenosis; AVA = aortic valve area; AVR = aortic valve replacement; BAV = balloon aortic valvuloplasty; CT = computed tomography; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate; SAVR = surgical aortic valve replacement; TAVR = transcatheter aortic valve replacement; Vmax = peak aortic valve velocity.

Table 2 Results and Discussion

Consistent with the approach taken in the prior table and in the ACC/AHA valve guidelines, Table 2 focuses on whether AVR is appropriate and does not specify how it should be performed (transcatheter or surgical approach). The rating assigned to each approach is based on information provided in other tables. BAV was offered as an option as a bridge to decision and not for palliative care purposes. The scenarios were constructed mindful of the staging set forth in the ACC/AHA guidelines but also include scenarios encountered clinically but not in the guidelines (e.g., normal-flow, low-gradient, severe AS). The cut-points used for ejection fraction, flow, and gradients are the same as those used in the guidelines and most publications. In clinical care, measurement errors can be made when assessing AS severity by echocardiography or other imaging modalities. For the purpose of these scenarios, raters were told to assume that the measurements were verified and accurate.

The panel rated BAV as Rarely Appropriate except in cases in which the patient was intermediate to high risk and the potential clinical benefit of AVR was uncertain; in those scenarios, BAV was rated May Be Appropriate (21). When pseudosevere AS was demonstrated or suspected, no intervention was rated Appropriate and aortic valve replacement was rated Rarely Appropriate. Generally, when the AS was confirmed to be severe and symptoms were present, AVR was rated Appropriate regardless of EF, flow, or gradient. The only exception was when AVR was rated Rarely Appropriate for patients with an LVEF <20%, mean gradient <20 mmHg, and no flow reserve, who were at intermediate or high surgical risk given the extremely poor prognosis of these patients regardless of AVR (22). However, most of the data on that subset of patients are from small cohorts and precede the widespread utilization of TAVR, so it is unknown whether TAVR may have less risk and more potential benefit in these patients. For the asymptomatic patient with paradoxical low-flow, low-gradient severe AS, both no intervention and AVR were rated May Be Appropriate regardless of surgical risk.

TABLE 3 Severe AS: High- or Extreme-Risk Patients

Indication	Appropriate Use Median Score (1-9)			
	No Intervention	BAV (as Bridge or Palliative Care)	TAVR	SAVR
Due to Multiple Comorbidities				
30. ■ Severe symptomatic AS ■ STS-PROM 8%–15% ■ Health status seems to be influenced more by comorbidities than by AS ■ Anticipated life expectancy >1 y	M (4)	M (5)	A (7)	M (4)
31. ■ Severe symptomatic AS ■ STS-PROM 8%–15% ■ Health status seems to be influenced more by AS than by comorbidities ■ Anticipated life expectancy >1 y	R (2)	M (4)	A (8)	M (5)
32. ■ Severe symptomatic AS ■ STS-PROM 8%–15% ■ Health status seems to be influenced more by comorbidities than by AS ■ Anticipated life expectancy <1 y	A (8)	M (5)	R (3)	R (1)
33. ■ Severe symptomatic AS ■ STS-PROM 8%–15% ■ Health status seems to be influenced more by AS than by comorbidities ■ Anticipated life expectancy <1 y	M (6)	M (5)	M (4)	R (2)
34. ■ Severe symptomatic AS ■ STS-PROM >15% ■ Health status seems to be influenced more by comorbidities than by AS ■ Anticipated life expectancy >1 y	M (6)	M (5)	M (6)	R (2)
35. ■ Severe symptomatic AS ■ STS-PROM >15% ■ Health status seems to be influenced more by AS than by comorbidities ■ Anticipated life expectancy >1 y	M (4)	M (5)	A (7)	R (3)
36. ■ Severe symptomatic AS ■ STS-PROM >15% ■ Health status seems to be influenced more by comorbidities than by AS ■ Anticipated life expectancy <1 y	A (8)	M (4)	R (3)	R (1)
37. ■ Severe symptomatic AS ■ STS-PROM >15% ■ Health status seems to be influenced more by AS than by comorbidities ■ Anticipated life expectancy <1 y	A (7)	M (5)	R (3)	R (1)

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TABLE 3 Continued

Indication	Appropriate Use Median Score (1-9)			
	No Intervention	BAV (as Bridge or Palliative Care)	TAVR	SAVR
With Frailty or Disability				
38. ■ Severe AS (V_{max} 4-4.9 m/s) ■ STS-PROM 8%-15% ■ Frail ■ No chest pain or syncope ■ Fatigue but no shortness of breath ■ Normal BNP	M (5)	M (4)	M (5)	R (3)
39. ■ Severe AS (V_{max} 4-4.9 m/s) ■ STS-PROM 8%-15% ■ Frail ■ No chest pain or syncope ■ Fatigue but no shortness of breath ■ BNP elevated	M (4)	M (4)	A (7)	M (4)
40. ■ Very severe AS (V_{max} ≥5 m/s) ■ STS-PROM 8%-15% ■ Frail ■ No chest pain or syncope ■ Fatigue but no shortness of breath ■ Normal BNP	M (4)	M (5)	A (7)	M (4)
41. ■ Very severe AS (V_{max} ≥5 m/s) ■ STS-PROM 8%-15% ■ Frail ■ No chest pain or syncope ■ Fatigue but no shortness of breath ■ BNP elevated	R (3)	M (5)	A (8)	M (4)
42. ■ Severe AS (V_{max} ≥4 m/s) ■ STS-PROM 8%-15% ■ Dependent in >3 activities of daily living (bathing, dressing, eating, ambulating, toileting, transferring) ■ Shortness of breath	M (5)	M (5)	M (5)	R (2)
43. ■ Severe AS (V_{max} ≥4 m/s) ■ STS-PROM 8%-15% ■ Dependent in >3 activities of daily living (bathing, dressing, eating, ambulating, toileting, transferring) ■ Fatigue but no shortness of breath	M (6)	M (4)	M (4)	R (2)
Due to Anatomy				
44. ■ Severe symptomatic AS ■ Porcelain aorta or hostile chest ■ Otherwise high or intermediate surgical risk due to comorbidities	R (2)	M (4)	A (8)	R (3)
45. ■ Severe symptomatic AS ■ Porcelain aorta or hostile chest ■ Otherwise low surgical risk due to comorbidities	R (1)	R (3)	A (8)	M (4)
Due to Specific Comorbidities				
46. ■ Severe AS ■ STS-PROM 8%-15% ■ Oxygen-dependent lung disease ■ Shortness of breath ■ BNP normal	M (5)	M (5)	A (7)	R (3)
47. ■ Severe AS ■ STS-PROM 8%-15% ■ Oxygen-dependent lung disease ■ Shortness of breath ■ BNP elevated	R (3)	M (5)	A (8)	M (4)
48. ■ Severe symptomatic AS ■ STS-PROM >15% ■ End-stage renal disease ■ Longstanding dialysis, not a renal transplant candidate ■ Multiple comorbidities	M (5)	M (4)	M (6)	R (2)
49. ■ Severe symptomatic AS ■ STS-PROM 8%-15% ■ End-stage renal disease ■ Short time on dialysis ■ Renal transplant candidate ■ Nondiabetic, nonhypertensive etiology	R (3)	R (3)	A (7)	A (7)
50. ■ Severe symptomatic AS ■ STS-PROM 8%-15% ■ Cirrhosis with MELD >14	M (5)	M (5)	A (7)	R (2)

Continued on the next page

TABLE 3 Continued

Indication	Appropriate Use Median Score (1-9)			
	No Intervention	BAV (as Bridge or Palliative Care)	TAVR	SAVR
51. ■ Severe symptomatic AS ■ STS-PROM 8%–15% ■ Cirrhosis with MELD <10	R (3)	M (4)	A (7)	M (5)
52. ■ Severe symptomatic AS ■ STS-PROM 8%–15% ■ Moderate to severe dementia (minimally oriented) ■ Symptoms described by family but not verbalized by the patient	A (8)	R (3)	R (2)	R (1)
53. ■ Severe symptomatic AS ■ STS-PROM 8%–15% ■ Malignancy ■ Life expectancy >1 year	M (5)	M (4)	A (7)	M (6)
54. ■ Severe symptomatic AS ■ STS-PROM 8%–15% ■ Malignancy ■ Life expectancy <1 y	A (7)	M (5)	R (2)	R (1)

A = Appropriate; AS = aortic stenosis; BAV = balloon aortic valvuloplasty; BNP = b-type natriuretic peptide; M = May Be Appropriate; MELD = model for end-stage liver disease; R = Rarely Appropriate; SAVR = surgical aortic valve replacement; STS-PROM = Society of Thoracic Surgeons predicted risk of mortality score; TAVR = transcatheter aortic valve replacement; Vmax = peak aortic valve velocity.

Table 3 Results and Discussion

This table is based on the *2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: A Report of The American College of Cardiology/American Heart Association Task Force on Practice Guidelines* (1) and the *2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines* (2). This table focuses on the appropriateness of either SAVR or TAVR for symptomatic patients with severe AS. The appropriateness of SAVR or TAVR is judged separately and independently of the other, and one is not prioritized over the other. BAV is also offered as either a bridge to decision or for palliative care. Severe AS is defined as a Vmax ≥4 m/s, and in scenarios 38–43, an additional descriptor of Vmax (4.0–4.9 m/s versus ≥5 m/s) is provided to determine the severity of AS. Raters were told to assume that the measurements were verified and accurate.

These scenarios are those encountered frequently in symptomatic patients who are considered to be at high or extreme risk of mortality with SAVR on the basis of STS-PROM scores. We define "high risk" as STS-PROM of 8%–15% and extreme risk as STS-PROM >15%. In some scenarios in this table, the cause of symptoms may be judged to be related more to comorbidities than to AS, or the cause of symptoms may be unclear. "Frail" is defined as dependent in >3 activities of daily living.

In scenarios addressing patients at high surgical risk, raters were influenced by whether symptoms were felt to be the result of the comorbid conditions versus AS and by the anticipated life expectancy imposed by the comorbidities. Thus, there was mostly an Appropriate rating for TAVR in patients with anticipated life expectancy >1 year, and mostly Rarely Appropriate for those with life expectancy <1 year. Raters considered both TAVR and SAVR to be Rarely Appropriate in patients at extreme risk and with anticipated life expectancy <1 year.

Scenarios 44–47 address patients with additional risks not captured in the STS-PROM—porcelain aorta or hostile chest, and oxygen-dependent lung disease. In these scenarios, TAVR was rated as generally Appropriate and SAVR was rated Rarely Appropriate" in those with porcelain aorta or oxygen-dependent lung disease in which symptoms of dyspnea were considered most likely related to the lung condition (BNP normal). Other scenarios (48–54) identify patients with different extremes of end-stage renal disease, in which both TAVR and SAVR were rated Appropriate for those who were renal transplant candidates with only a short time on dialysis; other scenarios identify patients with cirrhosis, in whom TAVR was considered Appropriate; and other scenarios identify patients with dementia (both TAVR and SAVR Rarely Appropriate if dementia was moderate to severe) or malignancy (both TAVR and SAVR Rarely Appropriate if anticipated life expectancy is <1 year).

These scenarios provide detail that might inform assessment of risk versus benefit of particular interventions and, in some cases, scenarios that might indicate patient risk to be higher than that determined by the STS-PROM alone. This may call into question the potential benefit of the procedure.

TABLE 4 Symptomatic, High-Gradient, Severe AS* With Associated CAD

Indication		Appropriate Use Median Score (1–9)				
		TAVR	TAVR + PCI	SAVR	SAVR + PCI	SAVR + CABG
55.	■ 1- or 2-vessel CAD, no proximal LAD involvement ■ High or intermediate surgical risk	A (7)	A (7)	M (4)	M (4)	A (7)
56.	■ 1- or 2-vessel CAD, no proximal LAD involvement ■ Low surgical risk	R (3)	R (3)	M (6)	M (5)	A (8)
57.	■ 1- or 2-vessel CAD, including proximal LAD ■ High or intermediate surgical risk	M (4)	A (7)	R (3)	M (4)	A (7)
58.	■ 1- or 2-vessel CAD, including proximal LAD ■ Low surgical risk	R (2)	R (3)	R (3)	R (3)	A (9)
59.	■ 3-vessel disease; SYNTAX <22 ■ High or intermediate surgical risk	M (4)	A (7)	R (3)	M (4)	A (7)
60.	■ 3-vessel disease; SYNTAX <22 ■ Low surgical risk	R (2)	R (3)	R (2)	M (4)	A (9)
61.	■ 3-vessel disease; SYNTAX ≥22 ■ High or intermediate surgical risk	R (3)	M (6)	R (3)	M (4)	A (7)
62.	■ 3-vessel disease; SYNTAX ≥22 ■ Low surgical risk	R (1)	R (2)	R (2)	R (3)	A (9)
63.	■ Left main; SYNTAX <33 ■ High or intermediate surgical risk	R (2)	A (7)	R (2)	R (3)	A (8)
64.	■ Left main; SYNTAX <33 ■ Low surgical risk	R (1)	R (2)	R (2)	R (3)	A (9)
65.	■ Left main; SYNTAX ≥33 ■ High or intermediate surgical risk	R (2)	M (6)	R (2)	R (3)	A (8)
66.	■ Left main; SYNTAX ≥33 ■ Low surgical risk	R (1)	R (2)	R (1)	R (2)	A (9)

*High-gradient, severe AS = V_{max} ≥4 m/sec or mean gradient ≥40 mmHg, usually accompanied by AVA ≤1.0 cm^2 (or indexed AVA ≤0.6 cm^2/m^2).

A = Appropriate; AS = aortic stenosis; AVA = aortic valve area; CABG = coronary artery bypass grafting; CAD = coronary artery disease; LAD = left anterior descending; M = May Be Appropriate; PCI = percutaneous coronary intervention; R = Rarely Appropriate; SAVR = surgical aortic valve replacement; SYNTAX = synergy between PCI with TAXUS drug-eluting stent and cardiac surgery; TAVR = transcatheter aortic valve replacement; Vmax = peak aortic valve velocity.

Table 4 Results and Discussion

Management of patients with severe symptomatic aortic stenosis with coexistent unrevascularized stable CAD is depicted in Table 4. CAD is frequently associated with AS and almost two-thirds of the patients undergoing TAVR have CAD (23); however, many patients have had prior successful revascularization without significantly jeopardized myocardium. The scenarios in this table describe patients on the basis of anatomical characterization of unrevascularized stable CAD using a SYNTAX score (24). Determination of stable CAD can be challenging because it is difficult to distinguish symptoms of CAD from those of severe aortic stenosis in some patients; however, this clinical judgement is left to evaluating physicians using clinical, laboratory, and angiographic data. A SYNTAX score was used for determining the appropriate mode of revascularization in stable CAD patients without aortic stenosis in the recently published *2016 Appropriate Use Criteria for Coronary Revascularization in Patients With Acute Coronary Syndromes* (25). The current table is organized using a SYNTAX score of 0–22 in patients with 3-vessel CAD to characterize anatomically less complex disease with similar outcomes after percutaneous or surgical revascularization. On the other hand, for patients with LM (left main) disease, the SYNTAX trial showed similar outcomes in patients with a SYNTAX score of 0–32; hence the cutoff of <33 was used in the table (26).

The rating panel scored TAVR and PCI as Appropriate or May Be Appropriate in patients with high or intermediate surgical risk and those with any anatomical variation of CAD. In these high- and intermediate-risk patients, if CAD is extensive (3-vessel or LM disease), the rating panel found TAVR alone to be Rarely Appropriate except in patients with a low SYNTAX score. SAVR and CABG were found to be Appropriate for all patients with CAD and aortic stenosis, whereas only SAVR without coronary revascularization was rated as Rarely Appropriate if there was significant CAD involving LAD, 3 vessels or LM coronary artery. The hybrid procedure with SAVR and percutaneous coronary revascularization was rated as May Be Appropriate in patients with a low SYNTAX score; however, in patients at low surgical risk with proximal LAD involvement, percutaneous revascularization was Rarely Appropriate when patients were undergoing SAVR. In some high– and intermediate–surgical-risk patients with an intermediate or high SYNTAX score, SAVR with percutaneous coronary revascularization was found to be May Be Appropriate depending on technical considerations.

Performing surgical coronary revascularization at the same time as SAVR for CAD with severe stenoses involving proximal arteries has been the standard of care when technically feasible. Hybrid procedures have been performed in some patients with a potential benefit of mini-incision SAVR and revascularization using stenting when appropriate (27); however, comparative data for hybrid versus a complete surgical approach are limited. Revascularization strategies before or with TAVR are also not studied in prospective studies. That being said, retrospective data suggest that procedural risk does not increase in patients with CAD if they have conservative medical treatment when undergoing TAVR. Some studies have suggested higher 1-year mortality after TAVR in patients with CAD than in those without CAD. PCI can be performed safely in patients with severe AS; however, those with depressed LVEF or a high STS-PROM score (>10%) have a 30-day mortality >10% after PCI (28). Expeditious treatment of AS is important when PCI is performed before TAVR. There is limited experience with TAVR followed by staged PCI and there are potential challenges, including inadequate guided catheter support and limited access to the coronary arteries depending on the types of TAVR valves. In summary, optimal management of CAD in patients with AS is a complex decision process requiring clinical, anatomical, and technical considerations that is best achieved with close collaboration between Heart Team members.

TABLE 5 Severe Symptomatic AS and Other Valve or Ascending Aortic Pathology

Indication	Appropriate Use Median Score (1-9)					
	BAV (as Bridge to Decision)	TAVR Alone	TAVR + PBMV	TAVR + MitraClip	SAVR Alone	SAVR + Other Valve or Ascending Aortic Surgery or Myectomy
Symptomatic AS and Mitral Valve Disease						
67. ■ Severe symptomatic AS ■ Severe primary MR ■ High surgical risk	M (4)	M (4)		M (6)	R (3)	A (7)
68. ■ Severe symptomatic AS ■ Severe primary MR ■ Intermediate surgical risk	R (2)	R (3)		R (3)	R (3)	A (8)
69. ■ Severe symptomatic AS ■ Severe primary MR ■ Low surgical risk	R (1)	R (1)		R (2)	R (2)	A (9)
70. ■ Severe symptomatic AS ■ Severe secondary MR ■ High surgical risk	M (4)	M (5)		M (5)	M (4)	A (7)
71. ■ Severe symptomatic AS ■ Severe secondary MR ■ Intermediate surgical risk	R (3)	M (4)		M (4)	R (3)	A (8)
72. ■ Severe symptomatic AS ■ Severe secondary MR ■ Low surgical risk	R (1)	R (1)		R (2)	R (3)	A (9)
73. ■ Severe symptomatic AS ■ Severe rheumatic MS (no absolute contraindications to MBV) ■ High surgical risk	M (4)	M (4)	A (7)		R (3)	A (7)
74. ■ Severe symptomatic AS ■ Severe calcific MS or severe rheumatic MS (with absolute contraindications to MBV) with extensive mitral annular calcification ■ High surgical risk	M (4)	M (5)	R (2)		R (3)	A (7)
Symptomatic AS and Tricuspid Valve Disease						
75. ■ Severe symptomatic AS ■ Severe secondary TR ■ Dilated right ventricle and/or tricuspid valve annulus ≥40mm ■ Minimal to no right ventricular dysfunction ■ Minimal pulmonary hypertension ■ Intermediate surgical risk	R (2)	M (5)			R (3)	A (8)
76. ■ Severe symptomatic AS ■ Severe secondary TR ■ Dilated right ventricle and/or tricuspid valve annulus ≥40mm ■ Moderate to severe right ventricular dysfunction ■ Minimal pulmonary hypertension ■ Intermediate surgical risk	R (2)	M (5)			R (3)	A (7)
77. ■ Severe symptomatic AS ■ Severe secondary TR ■ Dilated right ventricle and/or tricuspid valve annulus ≥40mm ■ Moderate to severe right ventricular dysfunction ■ Severe pulmonary hypertension ■ High surgical risk	M (4)	A (7)			R (2)	M (5)

Continued on the next page

TABLE 5 Continued

Indication	Appropriate Use Median Score (1-9)					
	BAV (as Bridge to Decision)	TAVR Alone	TAVR + PBMV	TAVR + MitraClip	SAVR Alone	SAVR + Other Valve or Ascending Aortic Surgery or Myectomy
Symptomatic AS, Bicuspid Aortic Valve, and Ascending Aorta						
78. ■ Severe symptomatic AS ■ Bicuspid aortic valve ■ High surgical risk ■ Ascending aorta <4.5cm	R (2)	M (5)			A (7)	M (5)
79. ■ Severe symptomatic AS ■ Bicuspid aortic valve ■ High surgical risk ■ Ascending aorta ≥4.5cm	R (2)	M (4)			R (3)	A (8)
80. ■ Severe symptomatic AS ■ Bicuspid aortic valve ■ Intermediate surgical risk ■ Ascending aorta <4.5cm	R (1)	R (3)			A (7)	M (5)
81. ■ Severe symptomatic AS ■ Bicuspid aortic valve ■ Intermediate surgical risk ■ Ascending aorta ≥4.5cm	R (1)	R (2)			R (3)	A (8)
82. ■ Severe symptomatic AS ■ Bicuspid aortic valve ■ Low surgical risk ■ Ascending aorta <4.5cm	R (1)	R (2)			A (8)	M (5)
83. ■ Severe symptomatic AS ■ Bicuspid aortic valve ■ Low surgical risk ■ Ascending aorta ≥4.5cm	R (1)	R (1)			R (2)	A (9)
Symptomatic AS, Basal Septal Hypertrophy, Flow Acceleration, and Narrowed LVOT						
84. ■ Symptomatic severe AS ■ Prominent basal septal hypertrophy with flow acceleration and narrowing in the LVOT ■ High or intermediate surgical risk	R (3)	M (6)			M (4)	A (7)
85. ■ Symptomatic severe AS ■ Prominent basal septal hypertrophy with flow acceleration and narrowing in the LVOT ■ Low surgical risk	R (1)	R (3)			M (4)	A (8)

A = Appropriate; AS = aortic stenosis; BAV = balloon aortic valvuloplasty; LVOT = left ventricular outflow tract; M = May Be Appropriate; MBV = mitral balloon valvuloplasty; MR = mitral regurgitation; MS = mitral stenosis; PBMV = percutaneous balloon mitral valvuloplasty; R = Rarely Appropriate; SAVR = surgical aortic valve replacement; TAVR = transcatheter aortic valve replacement; TR = tricuspid regurgitation.

Table 5 Results and Discussion

This table was constructed using common clinical scenarios of other valvular and structural heart conditions that are commonly encountered when treating patients with severe AS. Although it is impossible to exhaustively include all scenarios a clinician may encounter, the writing group has attempted to identify the most common ones that may present challenges to clinical decision making. The group was also cognizant of the fact that the risk profile of different patients presenting with the same concomitant valvular conditions may dictate different management. Therefore, we have listed 6 possible treatment options in this table, with not all options as viable alternatives for each clinical scenario.

The first 6 clinical scenarios address the management of severe MR at the same time as treatment of severe AS. The key to these scenarios is the need to differentiate primary from secondary MR since the latter may improve with correction of the AS, whereas the former will not. The scenarios have also been categorized according to whether patients are at low, intermediate, or high surgical risk, even though these are not always absolute determinations in individual patients. Scenarios 67–69 address concomitant primary MR, which would not be expected to improve with correction of the AS alone unless also treated by a concomitant or staged procedure. For the high-risk patient with concomitant severe symptomatic AS and severe primary MR (scenario 67), rating panelists scored TAVR alone as May Be Appropriate as there may be patients for whom double valve surgery is considered too high risk and mitral clip is not anatomically feasible but in whom the clinician believes that the dominant valve lesion is AS and TAVR alone will yield clinical benefit in the absence of any improvement in the MR.

Scenarios 70–72 address concomitant secondary MR in which isolated treatment of the aortic valve may be associated with different expectations. Depending on the degree of LV dysfunction, myocardial damage, mitral leaflet tethering, and annular dilatation, secondary MR can often improve with treatment of only the AS. Scenarios 73 and 74 address concomitant MS with either a rheumatic or calcific etiology, both of which are being encountered increasingly. It should be noted that BAV is quite likely to benefit patients with rheumatic MS but not those with calcific MS.

The management of severe AS with severe tricuspid regurgitation (TR) with or without right ventricular dysfunction and pulmonary hypertension is covered in clinical scenarios 75–77. Severe TR is a very poor prognostic sign in patients with AS and the outcome is dependent on the degree of

pulmonary hypertension and right ventricular dysfunction. The TR should be treated whenever possible, hence the panel ratings.

Scenarios 78–83 address the management of bicuspid aortic valve disease with or without an ascending aortic aneurysm. The writing group chose 4.5 cm as the threshold for an enlarged aorta on the basis of the most recent valve guidelines (29,30). It should be noted that experience with TAVR in bicuspid disease is relatively limited at present. It should also be taken into consideration that the management of an enlarged ascending aorta is determined by multiple factors, including the rate of enlargement, whether the aortic valve is bicuspid or tricuspid, and the patient's age and risk level.

The last 2 scenarios deal with the presence of septal hypertrophy and LVOT obstruction. It is crucial to determine whether the stenosis is valvular or subvalvular. If significant LVOT obstruction is present, it should also be treated since it will not improve and may indeed worsen after correction of the AS.

TABLE 6 Noncardiac Surgery

Indication	Appropriate Use Median Score (1–9)		
	No Intervention	BAV	AVR (TAVR or SAVR)
86. ■ Symptomatic severe/critical AS ■ Elective major surgery ■ Nonobstructive CAD	R (1)	M (4)	A (8)
87. ■ Symptomatic severe/critical AS ■ Urgent major surgery ■ Nonobstructive CAD	R (2)	M (6)	A (7)
88. ■ Asymptomatic severe/critical AS ■ Elective major surgery ■ Nonobstructive CAD ■ No signs of cardiac decompensation	M (4)	R (3)	A (7)
89. ■ Asymptomatic severe/critical AS ■ Urgent major surgery ■ Nonobstructive CAD ■ No signs of cardiac decompensation	M (5)	M (4)	M (5)

A = Appropriate; AS = aortic stenosis; AVR = aortic valve replacement; BAV = balloon aortic valvuloplasty; CAD = coronary artery disease; M = May Be Appropriate; R = Rarely Appropriate; SAVR = surgical aortic valve replacement; TAVR = transcatheter aortic valve replacement.

Table 6 Results and Discussion

This table's scenarios deal with the need for major noncardiac surgery in patients with hemodynamically severe/critical aortic stenosis. The rating panel addressed the appropriateness of intervention on the aortic valve to reduce the risk of major noncardiac surgery. The pivotal issues under consideration were a.) whether the major noncardiac surgery was elective or urgent and b.) whether the severe AS was symptomatic or asymptomatic.

In patients with *symptomatic* severe aortic stenosis, the rating panel felt that it would be Rarely Appropriate to choose *no* intervention on the AS prior to major urgent or elective surgery because of the marked increase in risk of perioperative morbidity or mortality. Balloon valvuloplasty with temporary reduction in the degree of stenosis was considered May Be Appropriate, with more definitive SAVR or TAVR rated Appropriate.

In patients with *asymptomatic* severe/critical AS needing elective major surgery, a more conservative approach such as no intervention was considered May Be Appropriate and AVR (TAVR or SAVR) was considered Appropriate by the rating panel. In scenario 88, in which the surgery was elective and the patient was asymptomatic, the rating panel felt that if an intervention were to be done, it would be more reasonable to do a definitive intervention such as TAVR or SAVR rather than BAV, which is a palliative procedure, and hence rated Rarely Appropriate.

For cases in which urgent major surgery is necessary in the asymptomatic patient with severe/critical AS, options for no intervention, temporizing BAV, or AVR (TAVR or SAVR) were all considered as May Be Appropriate by the rating panel, which recognized that other considerations might inform decision making in an individual patient.

TABLE 7 Failing Aortic Valve Bioprosthesis

Indication	Appropriate Use Median Score (1–9)		
	BAV	TAVR	SAVR
90. ■ Severe symptomatic AS or AR ■ Degenerative surgical bioprosthesis—size ≥23 mm ■ High surgical risk	R (1)	A (8)	A (7)
91. ■ Severe symptomatic AS or AR ■ Degenerative surgical bioprosthesis—size ≥23 mm ■ Intermediate surgical risk	R (1)	A (7)	A (8)
92. ■ Severe symptomatic AS or AR ■ Degenerative surgical bioprosthesis—size 21 mm ■ High surgical risk	R (1)	M (6)	A (7)
93. ■ Severe symptomatic AS or AR ■ Degenerative surgical bioprosthesis—size 21 mm ■ Intermediate surgical risk	R (1)	M (5)	A (8)
94. ■ Severe symptomatic AS or AR ■ Degenerative surgical bioprosthesis—size ≤19 mm ■ High surgical risk	R (1)	M (5)	A (7)
95. ■ Severe symptomatic AS or AR ■ Degenerative surgical bioprosthesis—size ≤19 mm ■ Intermediate surgical risk	R (1)	R (3)	A (8)

A = Appropriate; AR = aortic regurgitation; AS = aortic stenosis; BAV = balloon aortic valvuloplasty; M = May Be Appropriate; R = Rarely Appropriate; SAVR = surgical aortic valve replacement; TAVR = transcatheter aortic valve replacement.

Table 7 Results and Discussion

This table addresses the clinical situation of patients who are symptomatic owing to a failing aortic bioprosthesis (asymptomatic patients are not included). The mechanism of bioprosthetic failure may be stenosis, regurgitation, or a combination of both. In addition, one must be certain that valve stenosis, manifested as an increased transvalvular gradient, is due to valve dysfunction and not prosthesis-patient mismatch. Historically, surgery for a failing bioprosthesis has been the only treatment option; however, clinical results of valve-in-valve procedures have been

improving and have led to FDA approval for the 2 commercially available transcatheter valve technologies for patients at high or extremely high surgical risk. Additionally, these technologies may soon be approved for patients at intermediate surgical risk. Guidelines for the use of TAVR as a valve-in-valve treatment are evolving but have not yet been established.

Mortality is increased in patients when valve-in-valve procedures are carried out inside a small surgical bioprosthesis (≤21 mm), which may be due to higher residual transvalvular gradients (31). For this reason, TAVR in a bioprostheses of ≤19 mm is generally discouraged, particularly in cohorts other than high surgical risk. Despite the possibility of high residual gradient, one might consider TAVR in patients at high surgical risk in order to alleviate severe symptoms of regurgitation or stenosis. As implantation techniques have evolved, the placement of valves in a higher (more aortic) position has been associated with lower residual gradients, which could have implications for survival after valve-in-valve procedures (32,33).

The scenarios in Table 7 differ depending on surgical bioprosthesis size (≤19 mm, 21 mm, and ≥23 mm) and surgical risk (intermediate or high). The panel rated BAV as Rarely Appropriate in all of these scenarios because of the potential to shear off a leaflet in a way that would cause severe aortic regurgitation. In all scenarios, redo surgery to replace the surgical bioprosthesis was rated as Appropriate. For patients with a surgical prosthesis ≥23 mm, a TAVR valve-in-valve procedure was rated Appropriate for those at intermediate or high surgical risk. In patients with a 21-mm surgical bioprosthesis, TAVR was rated May Be Appropriate for both intermediate- and high-risk patients, and therefore could be considered an alternative to surgery. In the presence of surgical bioprosthesis ≤19 mm, TAVR was rated May Be Appropriate if the surgical risk was intermediate but Rarely Appropriate if the surgical risk was high.

6. DISCUSSION

This AUC effort was initiated to determine the reasonableness of different treatment options for severe AS, including SAVR, TAVR, BAV, and conservative management with no intervention. The scenarios were developed by experts in the field representing multiple subspecialty societies and ACC Councils, critiqued by numerous external reviewers and stakeholders, and scored by a separate, independent group of experts to arrive at the final AUC ratings. This multisocietal effort contributes important findings to the study of severe AS, which is a constantly changing field owing to the development of new technologies, medications, devices, and treatment options.

Although the development of these AUC incorporated evidence where available, it is important to note that AUC often address gaps in clinical practice guidelines and are therefore a blend of evidence-based medicine and clinical judgement. The scenarios chosen for this document were meant to cover common clinical situations encountered in everyday practice and should not be seen as encompassing all possible patient presentations that a clinician may face. Although the AUC ratings listed in this report provide guidance for when specific treatment options should be considered in patient populations, the role of clinical judgement and practice experience in determining the best options for individual patients should not be undermined.

Trends and Themes in Scoring

The scenarios in this document are grouped according to important branch points in clinical decision making in patients with AS. These include the presence or absence of symptoms, uncertainty in distinguishing between severe and pseudosevere stenosis, LV systolic function that is preserved versus impaired versus profoundly impaired without contractile reserve, the presence of concomitant coronary artery or other valvular disease, and the need for noncardiac surgery. Cutoffs for LV dysfunction and the severity of AS are consistent with those used in the guidelines for valvular heart disease. Section 3 of this document provides important details regarding the general assumptions used in defining the scenarios. The indications presented in this report were finalized after incorporating suggestions by the external reviewers and rating panel members. After the rating panel completed several rounds of rating, the median score from the 17 panelists for each scenario became the final AUC rating. The final scores reflect the evidence base at the time of the rating, with the recognition that catheter-based intervention for structural heart disease, and aortic stenosis in particular, is a rapidly evolving field.

The initial tables identify scenarios in which the overarching decision is definitive intervention versus more conservative management; these scenarios consider valve replacement (TAVR and SAVR) as 1 choice, with the understanding that in a given patient, other factors such as surgical risk would inform the choice of TAVR or SAVR. In scenarios in which the patient has reduced ejection fraction, intervention is generally considered Appropriate, with the decision for TAVR or SAVR based predominantly on surgical risk, the only exceptions being situations in which stress test results suggest that the stenosis is pseudosevere rather than severe or in which LV systolic function is profoundly impaired without contractile reserve. In these patients, medical management is considered Appropriate. In the asymptomatic patient, a positive stress test effectively identifies the patient as symptomatic, with intervention again considered Appropriate regardless of surgical risk. In asymptomatic patients with findings suggesting likelihood of symptom onset but not sudden death, intervention is rated Appropriate, whereas medical management is considered May be Appropriate.

In symptomatic patients, intervention is generally considered Appropriate, although scenarios in which expected survival is less than one year and overall health status is influenced more by comorbidities than aortic stenosis, a less aggressive option (medical management) is considered Appropriate. TAVR rather than SAVR is considered an Appropriate intervention in patients with frailty, since these factors can pose increased surgical risk that are not captured in STS-PROM risk scoring (porcelain aorta or hostile chest), and/or significant comorbidities, including lung or liver disease, malignancy, and dementia. These scenarios are presented at the extremes of comorbidity as black and white examples; unfortunately, in real practice, patients usually present in shades of gray. Multiple scenarios address the concepts of medical futility, including patients with life expectancy <1 year or those with moderate to severe dementia. In these scenarios, medical management is considered Appropriate, with palliative balloon valvuloplasty rated as May Be Appropriate.

Scenarios of patients with concomitant coronary artery or other valvular disease introduce options for additional surgical or catheter-based interventions for these conditions. Scenarios involving coexistent CAD use the SYNTAX score as a tool to define the complexity of disease and are consistent with the current AUC for stable CAD (25). For each scenario, SAVR and CABG are considered Appropriate, with catheter-based approaches considered Appropriate or May Be Appropriate for patients with intermediate or high surgical risk and less complex coronary disease. Similarly, surgery is considered Appropriate or May Be Appropriate for all scenarios describing both severe symptomatic AS and concomitant disease of the aorta or other heart valves. Catheter-based intervention is considered Appropriate only in patients with severe AS and rheumatic MS (as balloon mitral valvuloplasty is an established

treatment option) or in those with coexisting advanced right heart failure, severe functional tricuspid regurgitation (TR), and high surgical risk.

Scenarios were also developed to include patients with severe AS who must undergo major noncardiac surgery. In symptomatic patients or those undergoing elective noncardiac surgery, AVR (either TAVR or SAVR) is considered Appropriate. In contrast, AVR, balloon aortic valvuloplasty, and no intervention are considered May Be Appropriate in patients who are asymptomatic, those who are well-compensated, or those free of coronary disease undergoing urgent noncardiac surgery.

The final group of scenarios describes patients with failing bioprostheses. Balloon aortic valvuloplasty is considered Rarely Appropriate for these patients, and TAVR or SAVR are considered Appropriate depending on surgical risk and anatomical considerations, including coronary anatomy and size of the surgical prosthesis. For very small surgical prosthesis (≤19 mm), SAVR is preferred in patients with low or intermediate surgical risk because higher residual gradients are likely after a valve-in-valve TAVR procedure.

Given the complexity of the clinical presentations of patients with aortic stenosis, some overlap of these AUC scenarios is expected. Several indications share similar findings, signs, or symptoms but differ as to the nature and severity of the primary clinical driver. Thus, the scenarios were developed by the writing group and scored by the rating panel on the basis of the primary presentation. For example, decisions are determined by clinical interpretation that symptoms are due to comorbidities more than AS or that symptoms are caused by AS more than comorbidities. There needs to be flexibility in interpreting the nuances of many of these scenarios, just as there needs to be sound clinical judgment in making treatment decisions given the increasing complexity of patients with AS.

Use of AUC to Improve Care

The AUC can be applied in a number of important ways. As a clinical tool, the AUC assist providers in evaluating possible therapies under consideration and can help better inform patients about their treatment options. As an administrative tool, the AUC provide a way to compare practice patterns among physicians in order to identify areas for improvement and better resource allocation. Likewise, the AUC can be utilized by clinicians themselves as an educational tool to reduce their Rarely Appropriate cases and help guide decision making.

It should be stressed that this AUC is a guidance document, and therefore each patient with severe AS should be treated individually. An Appropriate rating should not be misinterpreted as a recommendation to perform a given procedure in every patient who meets the criteria listed. Rather, it should be seen as an option that would be reasonable to perform if the patient could gain potential benefit from the treatment. Similarly, a Rarely Appropriate rating should not be misinterpreted as one in which a procedure is prohibited. Individual patient circumstances do exist in which certain Rarely Appropriate treatments are reasonable to perform. Instead of limiting treatment in these situations, the category of Rarely Appropriate should focus on identifying patterns of care in which individual physicians may have higher rates of Rarely Appropriate cases than do their peers. That being said, the classifications of May Be Appropriate and Rarely Appropriate should not be considered as the basis for denying insurance coverage or reimbursement for the procedure, as physician decision making is required to determine what is best for each patient. Rather, the AUC may be used by administrators, regulators, and payers to ensure quality patient care, better clinical outcomes, and the efficient allocation of limited financial resources.

7. CONCLUSION

This AUC report serves as a helpful guide to physicians, patients, and policy makers regarding the rational use of treatment options available for severe AS. It can be used to inform decision making, improve the quality of patient care, and provide the foundation for educational initiatives to determine the impact of these AUC on clinician practice patterns. Some of these severe AS scenarios, particularly those rated May Be Appropriate and Rarely Appropriate, may require additional research and further evaluation to determine the best treatment options for individual patients. It is important to reiterate that an AUC score of Rarely Appropriate should not prohibit a treatment or procedure from being provided to the patient, and an Appropriate AUC score should not mandate that a procedure be performed or treatment offered. As advances in technology and evidence-based medicine occur rapidly, and future studies of implementation of these criteria for severe AS are conducted, we expect further areas of exploration and elaboration to be identified.

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APPENDIX A. RELATIONSHIPS WITH INDUSTRY (RWI) AND OTHER ENTITIES

Appropriate Use Criteria for the Treatment of Patients with Severe Aortic Stenosis: Members of the Writing Group, Rating Panel, External Reviewers, and AUC Task Force—Relationships with Industry and Other Entities (Relevant)

The ACC and the AUC Task Force continue to focus considerable attention on avoiding real or perceived relationships with industry (RWI) and other entities that might affect the rating of a test/procedure. The ACC maintains a database that tracks all relevant relationships for ACC members and persons who participate in ACC activities, including the development of AUC. A table of relevant disclosures by the writing group, rating panel, external reviewers, and AUC Task Force can be found below. In addition, to ensure complete transparency, a full list of disclosure information—including relationships not pertinent to this document—is available in the Online Appendix.

A more specific RWI policy applies to the Writing Group and Rating Panel of AUC documents:

- Writing Group: AUC Writing Groups must be chaired by a person with no relevant RWI. Although Writing Group members play an important role in the development of the final published document for a given set of AUC, they do not have any role in the AUC rating process and therefore have limited impact on how the documents will guide clinical care. Accordingly, RWI restrictions are not applied to Writing Group members, other than the Chair.
- Rating Panel: To avoid the potential for bias in the actual indication rating, fewer than 50% of Rating Panel members may have relevant RWI. AUC documents utilize a modified Delphi consensus method as outlined in the RAND Appropriateness Criteria Method paper and the ACC AUC Methodology paper. This method utilizes a two-step process: Delphi Method Step 1) writing committee members develop a list of typical clinical scenarios/indications; Delphi Method Step 2) technical panel members review and rate the individual clinical scenarios. The RAND Delphi method allows for the contribution of a wide range of viewpoints while minimizing and controlling bias through an independent rating panel, a review of score dispersion, use of the median rating to determine final recommendations, and a highly structured process for determining recommendations. As such, all rating panel members, even those with RWI, are allowed to rate as part of the technical panel modified Delphi process.

APPENDIX A (*Continued*)

Participant	Employment	Representing	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
				Writing Group				
Robert O. Bonow	Northwestern University Feinberg School of Medicine, Center for Cardiovascular Innovation—Director and Professor of Cardiology	ACC (Chair)	None	None	None	■ Harvard Clinical Research Institute (DSMB)	■ Gilead Sciences	None
Alan S. Brown	Advocate Lutheran General Hospital, Division of Cardiology—Director; Loyola Stritch School of Medicine—Clinical Associate Professor	ACC	■ Regeneron*	None	None	None	None	None
Linda D. Gillam	Morristown Medical Center, Department of Cardiovascular Medicine—Chair	ACC AUC Task Force liaison	None	None	None	■ Bracco† ■ Edwards Lifesciences† ■ Medtronic†	■ Abbott Vascular‡ ■ Bracco‡	None
Samir R. Kapadia	Cleveland Clinic Foundation, Cardiac Catheterization Laboratories—Director and Professor of Medicine	ACC	None	None	None	■ Claret Medical – Sentinel trial (Co-PI)†	■ Abbott Laboratories (Steering Committee)† ■ Boston Scientific (Steering Committee)† ■ Edwards Lifesciences (Steering Committee)† ■ St. Jude Medical (Steering Committee)† ■ Abbott Laboratories‡ ■ Claret Medical‡ ■ Direct Flow Medical, Inc.‡ ■ Edwards Lifesciences‡ ■ St. Jude Medical‡	None

(*Continued*)

Appendix A (*Continued*)

Participant	Employment	Representing	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Clifford J. Kavinsky	Rush University Medical Center, Rush Center for Adult Structural Heart Disease—Director	SCAI	None	None	None	None	■ Abbott Laboratories‡ ■ Edwards Lifesciences‡	None
Brian R. Lindman	Vanderbilt University Medical Center, Structural Heart and Valve Center—Medical Director	ACC Geriatric Cardiology Section Leadership Council	■ Roche Diagnostics	None	None	■ Edwards Lifesciences* ■ Roche Diagnostics*	■ Barnes-Jewish Hospital Foundation*	None
Michael J. Mack	Baylor Scott & White Health, Cardiovascular Governance Council—Chair	STS	None	None	None	■ Abbott Vascular† ■ Edwards Lifesciences – PARTNER 3 (Co-PI)† ■ Medtronic†	None	None
Vinod H. Thourani	Emory Hospital Midtown, Structural Heart & Valve Center—Co-Director and Chief of Cardiothoracic Surgery; Emory University School of Medicine—Professor of Surgery and Medicine	ACC Surgeons' Section Leadership Council	■ Edwards Lifesciences ■ St. Jude Medical	None	None	■ Abbott Medical ■ Boston Scientific† ■ Edwards Lifesciences† ■ Medtronic†	None	None
				Rating Panel				
Thomas M. Beaver	Shands Hospital at University of Florida, Department of Surgery—Professor and Chief of Cardiothoracic Surgery	STS	None	None	None	None	None	None
Steven M. Bradley	Minneapolis Heart Institute, Center for Healthcare Delivery Innovation—Associate Director	AHA	■ Heart Journal*	None	None	■ U.S. Department of Veterans Affairs HSR&D†	None	None
Blase A. Carabello	East Carolina University, Division of Cardiology—Chief	ACC	None	None	None	■ Edwards Lifesciences (DSMB)†	None	None

Milind Y. Desai	Cleveland Clinic Foundation, Heart and Vascular Institute—Professor of Medicine	ACC	None	None	None	None	None	None
Isaac George	New York Presbyterian Hospital/Columbia University Medical Center, Division of Cardiothoracic Surgery—Assistant Professor of Surgery and Medicine	ACC Surgeons' Section Leadership Council	■ Bolton Medical ■ Edwards Lifesciences ■ Medtronic	None	None	■ Direct Flow Medical (PI)† ■ Tendyne Medical (DSMB)	None	None
Philip Green	Columbia University Medical Center—Assistant Professor of Medicine	ACC Geriatric Cardiology Section Leadership Council	None	None	None	None	None	■ Plaintiff, complication of cardiac catheterization, 2016
David R. Holmes, Jr.	Mayo Clinic—Consultant	ACC Interventional Section Leadership Council	None	None	None	None	■ Technology licensed to Boston Scientific from Mayo Clinic†	None
Douglas Johnston	Cleveland Clinic Foundation, Department of Thoracic and Cardiovascular Surgery, Aortic Valve Center—Surgical Director	AATS	■ Edwards Lifesciences ■ St. Jude Medical*	None	■ JACE Medical	None	None	None
Jonathon Leipsic	University of British Columbia—Associate Professor of Radiology and Cardiovascular Medicine	SCCT	■ Edwards Lifesciences* ■ Neovasc† ■ Valcare Medical†	■ General Electric Healthcare	None	■ Heartflow, Inc.*	None	None
Stephanie L. Mick	Cleveland Clinic, Heart and Vascular Institute, Department of Thoracic and Cardiovascular Surgery—Surgical Director	ACC	■ Medtronic	None	None	None	■ Abbott Laboratories‡ ■ Direct Flow Medical‡ ■ Edwards Lifesciences‡ ■ St. Jude Medical‡	None

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Appendix A (*Continued*)

Participant	Employment	Representing	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Jonathan J. Passeri	Massachusetts General Hospital, Corrigan Minehan Heart Center, Heart Valve Program—Medical Director; and Interventional Echocardiography—Director	ACC	■ Medtronic	None	None	None	None	■ Defendant, endocarditis/ aortic regurgitation, 2014
Robert N. Piana	Vanderbilt University Medical Center, Division of Cardiovascular Medicine—Professor of Medicine	ACC	■ Axio Research ■ HCRI ■ W.L. Gore & Associates, Inc.	None	None	■ Terumo Medical (DSMB)	■ Doris Duke Charitable Foundation‡ ■ Duke Clinical Research Institute‡ ■ St. Jude Medical‡	None
Nathaniel Reichek	St. Francis Hospital, Cardiac Imaging Program—Director; State University of New York at Stony Brook—Professor of Medicine	SCMR	None	None	■ AbbVie*	None	■ Johnson & Johnson*	None
Carlos E. Ruiz	Hackensack University Medical Center, Structural and Congenital Heart Center—Director; Seton Hall Hackensack Meridian School of Medicine—Professor of Cardiology in Pediatrics and Medicine	HVS	■ Cardiac Implants, LLC† ■ Sorin ■ Valtech	None	■ Entourage* ■ MitrAssist*	■ Philips Healthcare* ■ St. Jude Medical*	■ BioInspire* ■ St. Jude Medical‡	None
Cynthia C. Taub	Albert Einstein College of Medicine—Professor of Medicine	ACC	None	None	None	None	None	None

James D. Thomas	Northwestern Memorial Hospital, Bluhm Cardiovascular Institute, Center for Heart Valve Disease—Director	ASE	■ Abbott Laboratories* ■ Edwards Lifesciences* ■ General Electric Healthcare*	None	None	None	None	■ Defendant, inappropriate referral for surgery, 2015*
Zoltan G. Turi	Hackensack University Medical Center, Structural and Congenital Heart Center—Co-Director, and Cardiac Catheterization Lab—Co-Director; Seton Hall Hackensack Meridian School of Medicine—Professor	SCAI	None	None	None	■ Mitralign (DSMB)*	■ Medtronic† ■ St. Jude Medical†	None
			Reviewers					
Michael A. Borger	Leipzig Heart Center—Director of Cardiac Surgery	HVS	■ Edwards Lifesciences ■ Medtronic ■ St. Jude Medical	None	None	■ Edwards Lifesciences† ■ NeoChord†	■ Edwards Lifesciences‡ ■ Medtronic‡	None
Joao L. Cavalcante	University of Pittsburgh, Division of Cardiology—Assistant Professor of Medicine	ACC	None	None	None	■ Medtronic*	None	None
Mehmet Cilingiroglu	Arkansas Heart Hospital—Professor of Medicine	SCAI	None	None	None	None	None	None
John A. Dodson	New York University School of Medicine, Leon H. Charney Division of Cardiology—Assistant Professor of Medicine and Population Health	ACC Geriatric Cardiology Section Leadership Council	■ Novartis Pharmaceuticals*	None	None	None	None	None
Maurice Enriquez-Sarano	Mayo Clinic—Professor of Medicine	HVS	None	None	None	■ Edwards Lifesciences†	None	None
Dominik Fleischmann	Stanford University School of Medicine—Professor of Radiology	SCCT	None	None	■ iSchema View, Inc.	■ General Electric Healthcare* ■ Siemens Medical Solutions†	None	None

(*Continued*)

Appendix A (*Continued*)

Participant	Employment	Representing	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Jeffrey G. Gaca	Duke University Hospital, Division of Cardiac Surgery—Heart Surgeon	STS	None	None	None	None	None	None
Christopher A. Glover	University of Ottawa Heart Institute, Cardiac Catheterization Laboratory—Director; and Department of Medicine—Associate Professor	AHA	None	None	None	None	None	None
Rebecca T. Hahn	Columbia University Medical Center, Structural Heart and Valve Center—Director of Interventional Echocardiography and Professor of Medicine	ACC	■ Edwards Lifesciences	■ Abbott Vascular ■ Boston Scientific ■ General Electric Healthcare	None	■ Mitralign, Inc.†	■ Edwards Lifesciences†	None
Kishore J. Harjai	Geisinger Wyoming Valley Medical Center and Hospital—Interventional Cardiologist	SCAI	■ Boston Scientific	None	■ aucmonkey.com	None	■ Boston Scientific ■ Janssen Pharmaceuticals‡	None
Stuart J. Head	Erasmus University Medical Center, Department of Cardiothoracic Surgery—Surgeon	EACTS	None	None	None	None	■ Medtronic Cardiovascular‡	None
Susheel K. Kodali	New York Presbyterian Hospital and Columbia University Medical Center, Structural Heart and Valve Center—Co-Director; Interventional Cardiology Fellowship Program—Director; Columbia University Medical Center—Assistant Professor in Medicine	ACC Interventional Section Leadership Council	■ Claret Medical ■ Edwards Lifesciences ■ Meril Lifesciences	None	None	None	■ Thubrikar Aortic Valve, Inc. (Scientific Advisory Board)† ■ VS Medtech, Inc. (Scientific Advisory Board)†	None

Ashok Krishnaswami	Kaiser Permanente San Jose Medical Center—Cardiologist	ACC Geriatric Cardiology Section Leadership Council	None	None	None	None	None	None
Hersh S. Maniar	Barnes Jewish Hospital and Washington University School of Medicine in St. Louis, Division of Cardiothoracic Surgery—Associate Professor of Surgery	AATS	None	None	None	None	■ Boston Scientific‡ ■ Direct Flow Medical‡ ■ Edwards Lifesciences‡ ■ St. Jude Medical‡	None
Randolph P. Martin	Piedmont Heart Institute, Cardiovascular Imaging—Medical Director; and Chief of Valvular and Structural Heart Disease	ACC	None	■ Abbott Vascular ■ Edwards Lifesciences ■ Medtronic*	None	None	None	None
Hani K. Najm	Cleveland Clinic Foundation, Department of Thoracic and Cardiovascular Surgery, Pediatric and Congenital Heart Surgery—Chair	ACC Surgeons' Section Leadership Council	None	None	None	None	None	None
Alina Nicoara	Duke University School of Medicine—Anesthesiologist and Associate Professor of Anesthesiology	SCA	None	None	None	None	None	None
Jae K. Oh	Mayo Clinic, Division of Cardiology, Echocardiography (Echo) Core Lab—Director	ASE	None	None	None	None	■ Echo Core Lab for Medtronic Core Valve*	None
Philippe Pibarot	Laval University, Department of Medicine—Professor; Quebec Heart and Lung Institute, Canada Research in Valvular Heart Diseases—Chair	ASE	None	None	None	■ Phoenix Cardiac* ■ Edwards Lifesciences* ■ Medtronic* ■ Canadian Institutes of Health Research*	None	None

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Appendix A (*Continued*)

Participant	Employment	Representing	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Michael H. Picard	Massachusetts General Hospital, Department of Cardiology—Director of Clinical Echocardiography	ASE	None	None	None	None	None	None
Pasala S. Ravichandran	Oregon Health and Science University Hospital and Legacy Medical Group—Cardiothoracic Surgeon	ACC Surgeons' Section Leadership Council	None	None	None	None	None	None
Matthias Siepe	University Heart Centre Freiburg, Bad Krozingen, Department of Cardiovascular Surgery—Professor	EACTS	None	None	None	None	None	None
Nikolaos I. Skubas	Weill Cornell Medical College—Professor of Anesthesiology; Director, Cardiac Anesthesia	SCA	None	None	None	None	■ Anesthesiology (Journal)† ■ Anesthesia & Analgesia (Editor)	None
Rakesh M. Suri	Cleveland Clinic Abu Dhabi, Thoracic and Cardiovascular Surgery—Chair and Chief of Staff	HVS	None	None	None	■ Sorin (PI)†	■ Sorin†	None
Elaine Tseng	University of California San Francisco Medical Center, Division of Adult Cardiothoracic Surgery—Associate Professor of Surgery	HVS	None	None	None	■ University of California*	■ American Heart Association† ■ Journal of Heart Valve Disease† ■ Society of Thoracic Surgeons†	None
Daniel Wendt	West German Heart Center, Department of Thoracic and Cardiovascular Surgery—Surgeon	EACTS	None	None	None	None	None	None

Brian K. Whisenant	Intermountain Health Care—Medical Director	ACC Interventional Section Leadership Council	■ Abbott Laboratories* ■ Boston Scientific* ■ Johnson & Johnson*	■ Edwards Lifesciences*	■ Coherex Medical*	None	■ Abbott Laboratories‡ ■ Direct Flow Medical‡ ■ Edwards Lifesciences‡ ■ Medtronic‡	None
Joshua M. Zimmerman	University of Utah Health, Department of Anesthesiology—Associate Professor; Medical Director of Preoperative Clinic	SCA	None	None	None	None	None	None

Appropriate Use Criteria Task Force

RWI and disclosure statements for members of the ACC Task Force on Appropriate Use Criteria can be found here: http://www.acc.org/guidelines/about-guidelines-and-clinical-documents/guidelines-and-documents-task-forces

This table represents *relevant* relationships of participants with industry and other entities that were reported at the time this document was under development. The table does not necessarily reflect relationships with industry at the time of publication. A person has a *relevant* relationship IF: the relationship or interest relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the document; the company/entity (with whom the relationship exists) makes a drug, drug class, or device addressed in the document, or makes a competing drug or device addressed in the document; or the person or a member of the person's household, has a reasonable potential for financial, professional, or other personal gain or loss as a result of the issues/content addressed in the document.

A person is deemed to have a *significant* interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$5,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships in this table with no symbol are considered *modest* (less than significant under the preceding definition). Relationships that exist with *no financial benefit* are also included for the purpose of transparency. Please refer to http://www.acc.org/guidelines/about-guidelines-and-clinical-documents/relationships-with-industry-policy for definitions of disclosure categories or additional information about the ACC Disclosure Policy for Writing Committees.

AATS = American Association for Thoracic Surgery; ACC = American College of Cardiology; AHA = American Heart Association; ASE = American Society of Echocardiography; AUC = Appropriate Use Criteria; DSMB = Data Safety Monitoring Board; EACTS = European Association for Cardio-Thoracic Surgery; HCRI = Harvard Clinical Research Institute; HSR&D = Health Services Research & Development; HVS = Heart Valve Society; PI = Principal Investigator; SCA = Society of Cardiovascular Anesthesiologists; SCAI = Society for Cardiovascular Angiography and Interventions; SCCT = Society of Cardiovascular Computed Tomography; SCMR = Society for Cardiovascular Magnetic Resonance; STS = Society of Thoracic Surgeons.

*Significant relationship.

†No financial benefit.

‡Clinical trial enroller.