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Support for the HVI is provided by Edwards Lifesciences.
ABOUT THE COLLABORATORS

Society of Cardiovascular and Angiography Interventions

The Society for Cardiovascular Angiography and Interventions (SCAI) promotes excellence in invasive and interventional cardiovascular medicine through education and representation, and the advancement of quality standards to enhance patient care. SCAI was established in 1976 under the guidance of Drs. F. Mason Sones and Melvin P. Judkins. These scientists, whose contribution permitted the development and implementation of invasive cardiology, foresaw the need for an organization which would service and advance the discipline further.

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THE HEART VALVE INITIATIVE

About the Heart Valve Initiative
The Heart Valve Initiative is a multi-year effort that began in 2017 when a variety of organizations came together to address gaps in existing heart valve disease care and the impact of these gaps on patient outcomes. Based on the results of subsequent literature reviews, landscape assessments, engagements with key stakeholders, and best practices research, the HVI was established in partnership with the Society of Cardiovascular and Angiography (SCAI), Avalere Health (“Avalere”), and other stakeholders providing guidance through key technical expert and advisory roles. The engagement was undertaken to advance the management and treatment of patients with heart valve disease. Support for the HVI is provided by Edwards Lifesciences.

History of the Heart Valve Initiative
The Initiative was sparked by results from an environmental scan conducted by SCAI and Avalere Health. The purpose of the scan was to define priority gap areas in identification and management of valve disease. Overall, the results of the scan showed that there is a lack of a standardized assessment and management of heart valve disease in cardiovascular care settings. This gap presents an opportunity to identify interventions to ensure standard and routine assessment of patients throughout their care journey and timely interventions as symptoms progress. As presented in Figure 1, the Initiative recognizes several gaps along the patient journey and offers potential solutions to address them in the primary care and cardiology care settings.

Figure 1

<table>
<thead>
<tr>
<th>Care Setting</th>
<th>CARDIOLOGIST</th>
<th>INTERVENTIONAL CARDIOLOGIST</th>
<th>PRIMARY CARE/CARDIOLOGIST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Journey</td>
<td>Routine Assessment of Symptom Progression</td>
<td>Selection of Treatment and Management</td>
<td>Access to Specialist for Further Examination</td>
</tr>
<tr>
<td>Gaps in Patient Journey</td>
<td>Poor Assessment of Symptoms</td>
<td>Lack of Patient Engagement</td>
<td>Geographic Limitations</td>
</tr>
<tr>
<td>Opportunities To Improve Patient Journey</td>
<td>Standardize Scheduling of Routine Exams</td>
<td>Engage in Shared Decision-Making with Patients To Select Timely Treatments</td>
<td>Develop stronger referral networks between cardiologists and interventional cardiologists in rural/urban regions</td>
</tr>
</tbody>
</table>

HVI GOAL: BETTER IDENTIFICATION, TREATMENT, AND MANAGEMENT OF PATIENTS WITH HEART VALVE DISEASE TO IMPROVE OUTCOMES AND REDUCE COMPLICATIONS
THE HEART VALVE INITIATIVE QUALITY MEASURES

Introduction to the HVI Quality Measures
Avalere and SCAI conducted a literature review and environmental scan which revealed existing gaps within heart valve disease care and opportunities to close through the implementation of quality measures. We assessed the clinical guidelines and guidance documents below to identify potential measure concepts. To ensure that identified measure concepts are meaningful to patients and providers, we sought feedback from the multi-stakeholder HVI Steering Committee, who prioritized measure concepts for further refinement. The HVI Technical Expert Panel (TEP) provided input on the measure specifications and selected two measures to under adequate testing for future adoption. The HVI Quality Measures were created to support the Initiative’s goal:
To support better identification, treatment, and management of patients with Heart Valve Disease to improve outcomes and reduce complications

HVI Quality Measures
The Quality Measures developed with input from the Steering Committee and TEP include:

- MEASURE #1: PATIENTS AT RISK FOR AORTIC STENOSIS THAT HAVE A TRANSTHORACIC ECHOCARDIOGRAM DOCUMENTED
- MEASURE #2: SURVEILLANCE IN MODERATE ASYMPTOMATIC AORTIC STENOSIS PATIENTS
- MEASURE #3: SURVEILLANCE IN SEVERE ASYMPTOMATIC AORTIC STENOSIS PATIENTS
- MEASURE #4: SHARED DECISION-MAKING ON TREATMENT OPTIONS

Figure 2

The following guidelines and guidance documents were reviewed to identify these measure concepts:

- 2017: AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease
- ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/SCCT/SCMR/STS 2017 Appropriate Use Criteria for Multimodality Imaging in Valvular Heart Disease
- ACC/AATS/AHA/ASE/EACTS/HVS/SCA/SCAI/SCCT/SCMR/STS 2017 Appropriate Use Criteria for the Treatment of Patients with Severe Aortic Stenosis
- 2014: AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease
- 2012: European Heart Journal Guidelines on the management of Valvular Heart Disease
- 2006: ACC/AHA/ASE Guidelines for the Management of Patients with Valvular Heart Disease
- 2003: ACC/AHA/ASE Guideline Update for Clinical Application of Echocardiography

As reflected in Figure 3, the measure development process entailed extensive review of the literature and refinement of the measures based on feedback from key stakeholders.
Request for Public Comment

To strengthen these measure specifications and ensure that the measures will impact patients’ care and support clinicians, HVI is seeking feedback on the measure concepts through a public comment period. The public comment process is essential to ensure that quality measures are developed transparently. It is an opportunity to collect balanced input from critical stakeholders on the measures under development and to provide critical feedback and suggestions from the widest array of interested parties that will inform the final measure. This comment period provides you with an opportunity to shape new quality measures that have not yet been finalized or put into use. We are seeking your input to ensure that these measures are useful and meaningful to patients, their families, and clinicians.

You can provide comments that reflect whether you are in favor of the measures, how you might use the measures, or how to change the measures to be more useful to patients and clinicians. All input is helpful to make the refine the measures so that they can be adopted in the future. At the end of the public comment period, all public comments will be reviewed, and measures edited as appropriate. You can comment on any aspect of the measures. Please submit your comments here by October 30, 2019.

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### Figure 3

**Request for Public Comment**

To strengthen these measure specifications and ensure that the measures will impact patients’ care and support clinicians, HVI is seeking feedback on the measure concepts through a public comment period. The public comment process is essential to ensure that quality measures are developed transparently. It is an opportunity to collect balanced input from critical stakeholders on the measures under development and to provide critical feedback and suggestions from the widest array of interested parties that will inform the final measure. This comment period provides you with an opportunity to shape new quality measures that have not yet been finalized or put into use. We are seeking your input to ensure that these measures are useful and meaningful to patients, their families, and clinicians.

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MEASURE #1: PATIENTS AT RISK FOR AORTIC STENOSIS THAT HAVE A TRANSTHORACIC ECHOCARDIOGRAM DOCUMENTED

Measure Type: Process

Description: Percentage of patients, 65 and older, who are at risk for aortic stenosis (AS) that have a transthoracic echocardiogram (TTE) documented in the medical record.

Denominator: All patients who have a heart murmur.

Denominator Exclusions: Documentation in the medical record of:

- Limited life expectancy
- Metastatic cancer

Numerator: Patients who have documented in the medical record that a current or prior TTE has been performed.

Rationale: Valvular AS is a progressive disease. As many as 50% of patients with severe AS report no symptoms at the time of diagnosis. (Pellika PA, 1990; Pellika PA 2005; Pai RG, 2005). Untreated symptomatic severe AS is associated with worse outcomes. (Varadarajan P, 2006; Dichtl W, 2008) In fact, as many as half of patients die within 1-2 years. (Varadarajan P, 2006; Dichtl W, 2008)

Individual variability exists with regards to the rate of hemodynamic change. Patients who are older, sicker, and those with leaflet calcification may experience progression more rapidly. (2014 Guideline) Given the progressive nature of the disease combined with the fact that patients may not recognize symptoms, there is inherent value in detecting patients who are at risk for aortic stenosis. According to the 2014 Vascular Heart Disease Guidelines “TTE is indicated when there is an unexplained systolic murmur, a single second heart sound, a history of a bicuspid aortic valve, or symptoms that might be due to AS.”

Echocardiographic imaging allows reliable identification of the number of valve leaflets along with qualitative assessment of valve motion and leaflet calcification. The use of TTE can assist the physician in determining the left ventricular (LV) response to pressure overload. A TTE allows diagnosis and evaluation of concurrent valve lesions, with mitral regurgitation being common in patients with AS.

Clinical Recommendation:

2017 ESC/EACTS Guidelines for the Management of Valvular Heart Disease

Echocardiography is the key diagnostic tool. It confirms presence of aortic stenosis; assesses the degree of valve calcification, LV function and wall thickness; detects the presence of other associated valve disease or aortic pathology and provides prognostic information.

TTE is indicated in patients with signs/symptoms of AS or a bicuspid aortic valve for accurate diagnosis of the cause of AS, hemodynamic severity, LV size, and systolic function, and for determining prognosis and timing of valve intervention. (Class I, Level of Evidence: B).

Section: 3.2.1. Diagnosis and Follow-Up states “TTE is indicated when there is an unexplained systolic murmur, a single second heart sound, a history of a bicuspid aortic valve, or symptoms that might be due to AS.”

Data Source: EHR/Claims

Setting: Ambulatory

Reporting Period: Calendar Year

Copyright:

Citations:

MEASURE #2: SURVEILLANCE IN MODERATE ASYMPTOMATIC AORTIC
STENOSIS PATIENTS

Measure Type: Process

Description: Percentage of patients, 65 and older, with a diagnosis of moderate asymptomatic aortic stenosis (AS) who underwent surveillance to monitor for disease progression at least once in the past 24 months.

Denominator: All patients, 65 yrs and older, with a diagnosis of moderate asymptomatic AS.

Denominator Exclusions: Documentation in the medical record of:
- Limited life expectancy
- Metastatic cancer

Numerator: Patients that were seen at least once during the past 24 months as part of surveillance for disease progression.

*For purposes of this measure, surveillance for moderate asymptomatic AS includes updating the patient’s medical history and includes documentation of a TTE as part of surveillance.

Clinical Recommendations:


Periodic monitoring with TTE is recommended in asymptomatic patients with known VHD at intervals depending on valve lesion, severity, ventricular size, and ventricular function. (Class I, Level of Evidence: C)

Table 4 of the 2014 VHD guidelines also notes the frequency of echocardiograms in asymptomatic patients as every 12-24 months for V_{max} 3.0-3.9 m/s Stage B VHD patients.

AVR is reasonable for patients with moderate AS (stage B) (aortic velocity 3.0–3.9 m/s) who are undergoing other cardiac surgery (Class II, Level of Evidence: C)

Rationale: Valvular AS is a progressive disease. In the case of patient with severe AS the rate of progression to symptoms is high, and there is only a 30-50% chance of an event-free survival of two years. (2014 Guideline) For this reason, patients with asymptomatic AS require frequent monitoring for disease progression.

Table 8 of the VHD guidelines delineates the valve anatomy and hemodynamics, hemodynamic consequences and symptoms associated with Stage B (progressive AS):

<table>
<thead>
<tr>
<th>Stage</th>
<th>Definition</th>
<th>Valve Anatomy</th>
<th>Valves Hemodynamics</th>
<th>Hemodynamic Consequences</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>B</td>
<td>Progressive AS</td>
<td>Mild-to-moderate leaflet</td>
<td>Mild AS: Aortic V_{max} 2.0–2.9 m/s</td>
<td>Early LV diastolic dysfunction</td>
<td>None</td>
</tr>
<tr>
<td>Calcification of a bicuspid or trileaflet valve with some reduction in systolic motion or Rheumatic valve changes with commissural fusion</td>
<td>or mean $\Delta P &lt; 20$ mm Hg Moderate AS: Aortic Vmax 3.0–3.9 m/s or mean $\Delta P 20–39$ mm Hg</td>
<td>may be present Normal LVEF</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Once moderate AS is present (aortic velocity between 3.0 m per second and 3.9 m per second) the average rate of progression is an increase in velocity of 0.3 m per second per year, an increase in mean pressure gradient of 7 mm Hg per year and a decrease in valve area of 0.1 cm$^2$ per year. Progression of AS can be more rapid in older patients and in those with more severe leaflet calcification. Since it is not feasible to predict the exact rate of progression in an individual patient, regular clinical and echocardiographic follow-up is mandatory in all patients with asymptomatic mild-to-moderate AS (see Section 3.2.1.2. of the VHD Guidelines). For this reason, it is important to monitor these patients for disease progression from Stage B to Stage C AS.

**Data Source:** EHR, Claims, Medical Record

**Setting:** Ambulatory

**Reporting Period:** Calendar Year

**Copyright:**

**Citations:**

MEASURE #3: SURVEILLANCE IN SEVERE ASYMPTOMATIC AORTIC STENOSIS PATIENTS

Measure Type: Process

Description: Percentage of patients, 65 and older, with a diagnosis of severe asymptomatic aortic stenosis (AS) who underwent surveillance to monitor for disease progression at least once during the measurement year.

Denominator: All patients, 65 years and older, with a diagnosis of severe asymptomatic AS.

Denominator Exclusions: Documentation in the medical record of:
- Limited life expectancy
- Metastatic cancer

Numerator: Patients that were seen at least once during the measurement year as part of surveillance* for disease progression.

*For purposes of this measure, surveillance for severe asymptomatic AS includes updating patient’s medical history, documenting that asymptomatic severe AS (stage C) has not progressed to symptomatic severe AS (stage D)†, and may include documentation of a TTE.

†Symptoms that asymptomatic AS has progressed to symptomatic AS include the following:

Mild Symptoms:
- Exertional dyspnea or decreased exercise tolerance
- Exertional angina
- Exertional syncope or presyncope

Classic Symptoms:
- Heart failure
- Angina
- Syncope or presyncope

Clinical Recommendations:


Periodic monitoring with TTE is recommended in asymptomatic patients with known VHD at intervals depending on valve lesion, severity, ventricular size, and ventricular function. (Class I, Level of Evidence: C)

Table 4 of the 2014 VHD guidelines also notes the frequency of echocardiograms in asymptomatic patients with VHD and normal left ventricular function as every 6-12 months for \( V_{\text{max}} \geq 4 \) m/s for Stage C VHD patients.

AVR is reasonable for asymptomatic patients with very severe AS (stage C1) with (139,140):
- Decreased systolic opening of a calcified valve;
- An aortic velocity 5.0 m per second or greater or mean pressure gradient 60 mm Hg or higher; and
c. A low surgical risk.  
(Class II, Level of Evidence: B)

2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease

Surgical AR is recommended for symptomatic patients with severe AS (Stage D) and asymptomatic patients with severe AS (Stage C) who meet an indication for AVR when surgical risk is low or intermediate. (Class I, Level of Evidence B-NR)

Surgical AVR or TAVR is recommended for symptomatic patients with severe AS (Stage D) and high risk for surgical AVR, depending on patient specific procedural risks, values, and preferences. (Class I, Level of Evidence A)

TAVR is recommended for symptomatic patients with severe AS (Stage D) and a prohibitive risk for surgical AVR who have a predicted post-TAVR survival greater than 12 months (58–61). (Class I, Level of Evidence A)

Rationale: Valvular AS is a progressive disease. In the case of patient with severe AS the rate of progression to symptoms is high, and there is only a 30-50% chance of an event-free survival of two years. (2014 Guideline) For this reason, patients with asymptomatic AS require frequent monitoring for disease progression. The timing for periodic clinical evaluation for patients with severe asymptomatic AS depends on comorbidities and patient specific factors.

Table 8 of the 2014 VHD guidelines delineates the valve anatomy and hemodynamics, hemodynamic consequences and symptoms associated with Stage C as represented below:

<table>
<thead>
<tr>
<th>Stage</th>
<th>Definition</th>
<th>Valve Anatomy</th>
<th>Valve Hemodynamics</th>
<th>Hemodynamic Consequences</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td>Asymptomatic severe AS</td>
<td>• Severe leaflet calcification or congenital stenosis with severely reduced leaflet opening</td>
<td>• Aortic Vmax ≥ 4 m/s or mean ΔP ≥ 40 mm Hg ≤ AVA typically is ≤ 1.0 cm² (or AVAi ≤ 0.6 cm²/m²) • Very severe AS is an aortic Vmax ≥ 5 m/s or mean DP ≥ 60 mm Hg</td>
<td>• LV diastolic dysfunction • Mild LV hypertrophy • Normal LVEF</td>
<td>None: Exercise testing is reasonable to confirm symptom status</td>
</tr>
<tr>
<td>C2</td>
<td>Asymptomatic severe AS with LV dysfunction</td>
<td>• Severe leaflet calcification or congenital stenosis</td>
<td>• Aortic Vmax ≥ 4 m/s or mean ΔP ≥ 40 mm Hg • AVA typically ≤ 1.0</td>
<td>• LVEF &lt; 50%</td>
<td>None</td>
</tr>
</tbody>
</table>
The 2014 VHD guidelines states that for patients with asymptomatic AS that have normal LV systolic function should undergo routine follow up at intervals of 6 months to 12 months. (2014 Guideline) This timing component is contingent on no change in signs or symptoms and if the aortic velocity is ≥ 4.0 m per second (Stage C). (2014 Guideline)

Once even mild symptoms caused by severe AS are present, outcomes are extremely poor unless outflow obstruction is relieved. Typical initial symptoms are dyspnea on exertion or decreased exercise tolerance. The classical symptoms of syncope, angina, and HF are late manifestations of disease and are most often seen in patients in whom early symptom onset was not recognized and intervention was inappropriately delayed. In patients with severe, symptomatic, and calcific AS, the only effective treatment is aortic valve replacement (AVR), which can result in improved survival rates, reduced symptoms, and improved exercise capacity. In the absence of serious comorbid conditions that limit life expectancy or quality of life, AVR is indicated in virtually all symptomatic patients with severe AS and should be performed promptly after onset of symptoms.

Surveillance can help identify when a patient with severe asymptomatic AS may be eligible for AVR surgical or transcatheter before the symptoms have progressed to a to the point where an appropriate intervention has been delayed. The choice of proceeding with surgical AVR versus TAVR is based on multiple factors, including the surgical risk, patient frailty, comorbid conditions, and patient preferences and values (3). Concomitant severe coronary artery disease may also affect the optimal intervention because severe multivessel coronary disease may best be served by surgical AVR and coronary artery bypass graft surgery (CABG). Outcomes after surgical AVR are excellent in patients who do not have a high procedural risk (O’Brien SM et al, 2009; Freeman RV et al, 2005; Kvidal P, 2000; Murphy ES et al, 1981; Schwarz F, 1982).

Data Source: EHR, Claims, Medical Record

Setting: Ambulatory

Reporting Period: Calendar Year

Copyright:

Citations:


MEASURE #4: SHARED DECISION-MAKING ON TREATMENT OPTIONS

Measure Type: Process

Description: Percentage of patients, age 65 years and older, with a diagnosis of severe aortic stenosis (AS) with whom a physician reviewed the range of treatment options that are appropriate and demonstrated a shared decision-making approach with the patient.

Denominator: Patients, age 65 and older, with a diagnosis of severe AS.

Denominator Exclusions: Documentation in the medical record of:
- Limited life expectancy
- Metastatic cancer

Numerator: Patients who engaged in shared decision making* with the physician on the treatment options that are available (i.e., transcatheter or surgical aortic valve replacement OR symptom management).

* Shared decision making may include the use of tools that include components such as:

- How comorbidities and other factors may impact surgical risk
- For patients with intermediate or high surgical risk this could include reviewing:
  - The benefits and risk associated aortic valve replacement (AVR)
  - Valve type options (if patient is electing surgical or transcatheter AVR)
  - Hospital stay time
  - Recovery time
- For patients with prohibitive surgical risk/inoperable this could include reviewing:
  - The benefits and risk associated TAVR compared to symptom management only
  - Hospital stay time (if electing TAVR)
  - Recovery time (if electing TAVR)
  - Hospice/palliative care (if electing symptom management through medications only)

Rationale: The management of patients relies on a shared decision making process that includes a detailed understanding of the risk and benefits of deploying different treatment strategies. Through the shared decision-making process physician or clinicians should discuss issues such as life expectancy, anticipated improvement in symptoms, and end of life planning. (2017 ACC Pathway) The decision to intervene and ultimately the type of intervention that occurs should be based on an individual risk–benefit analysis. The physician and patient must weigh the risk of the procedure and intermediate-term mortality against the benefits of the procedure. (2014 Guideline) There is value in eliciting patient values and preferences and describing risks and benefits to further shared decision-making.

The choice of proceeding with SAVR versus TAVR is based on multiple factors, including the surgical risk, patient frailty, comorbid conditions, and patient preferences and values (2017 ACC Pathway). When the choice of SAVR or TAVR is being made in an individual patient at intermediate surgical risk, other factors, such as vascular access, comorbid cardiac and noncardiac conditions that affect risk of either approach, expected functional status and survival after AVR, and patient values and preferences, must be considered. The choice of mechanical or bioprosthetic SAVR versus a TAVR is an important consideration and is influenced by durability considerations, because durability of transcatheter valves beyond 3 and 4 years has yet to be determined (Foroutan F et al, 2016).
In some patients with severe symptomatic AS, TAVR is not appropriate if the expected benefit from TAVR is less than the expected risk. For these patients’ palliative care may be the best option in terms of both quality and length of life. In those patients who meet the criteria for TAVR, discussion with the patient and family should again review the likelihood of symptom relief or improved survival, discuss possible complications and the expected recovery process, and ensure that patient goals and expectations are aligned with the possible procedural outcomes. (2017 Pathway) In the case of patients between the ages of 50 to 70, the choice of mechanical versus bioprosthetic valve replacement is a shared decision-making process that must account for the trade-offs between durability (and the need for reintervention), bleeding, and thromboembolism. (2017 Guideline)

**Clinical Recommendation:**

2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease

The choice of type of prosthetic heart valve should be a shared decision-making process that accounts for the patient’s values and preferences and includes discussion of the indications for and risks of anticoagulant therapy and the potential need for and risk associated with reintervention. (Class I, Level of Evidence C-LD).

**Data Source:** EHR, Claims, Medical Record

**Setting:** Ambulatory

**Reporting Period:** Calendar Year

**Copyright:**

**Citations:**