Target: Aortic Stenosis
WELCOME
Clyde W. Yancy, MD, MSc, FAHA

Clyde W. Yancy, MD, MSc is Chief of Cardiology at Northwestern University, Feinberg School of Medicine, and Associate Director of the Bluhm Cardiovascular Institute at Northwestern Memorial Hospital. He holds the Magerstadt Endowed Professor of Medicine Chair and Professor of Medical Social Sciences. He concurrently serves as Vice-Dean of Diversity & Inclusion, Northwestern University, Feinberg School of Medicine. He is an Honors graduate of Southern University (Baton Rouge, LA), Alpha Phi Omega honors graduate of Tulane University School of Medicine (MD) and Beta Sigma honors graduate of the University of Texas-Dallas School of Business and Management (MSc).

His research interests are in heart failure, clinical guideline generation, outcomes sciences and health care disparities. He is extensively published with well over 500 peer reviewed publications and has been named among the top 1% of cited scientific authors. He is Deputy Editor, JAMA Cardiology; Senior Section Editor (Heart Failure), Journal of the American College of Cardiology; and serves on the editorial boards for Circulation, Circulation Heart Failure, the American Heart Journal and JACC Heart Failure.

He has served the NIH, NHLBI, PCORI, FDA and AHRQ in a variety of service and leadership roles.

He is a Master of the American College of Cardiology, a Fellow of the American Heart Association, a Master of the American College of Physicians and a Fellow of the Heart Failure Society of America. He is the chair of the ACC/AHA Heart Failure Guideline Writing Committee, Chair of the ACC Heart Failure Clinical Pathway Writing Committee and Co-Chair of the Aortic Stenosis Science Advisory Group. He is a former President of the American Heart Association (2009-2010), as well as past recipient of the AHA National Physician of the Year and the Gold Heart award. He is the recipient of innumerable best doctor and best teacher awards and has held a number of Visiting Professorships at leading academic medical centers.

In 2016, he was elected to the National Academy of Medicine, one of the topmost tiers of recognition for physicians. In 2018, he was named a member of the Minority Subcommittee on Health in the Department of Health and Human Services.
J. Matthew Brennan, MD, MPH

Dr. Brennan is an Interventional Cardiologist at Duke University School of Medicine—specializing in the treatment of complex coronary artery disease and the clinical management of valvular heart disease. His research interests include shared decision making—particularly as it relates to coronary and valvular heart disease—and the use of statistical techniques and study design to provide non-biased estimates in comparative effectiveness analyses using large non-randomized, observational databases. Dr. Brennan has served as the Director of the Duke analysis center for the Transcatheter Valve Therapies (TVT) Registry and co-director of the analysis center for the Society of Thoracic Surgeons (STS) Database. He was the PI of a U01 grant from the US FDA for the use of Medicare data for comparative effectiveness research and a PCORI award for comparison of TAVR vs SAVR using STS and TVT Registry data. Dr. Brennan's research has most recently focused on defining the scale of undertreatment of Aortic Valve Stenosis in the United States and bringing awareness to the issue.
GAPS IN THE JOURNEY OF THE AORTIC STENOSIS PATIENT IMPACT AND IMPLICATIONS

J. Matthew Brennan, MD, MPH
Interventional Cardiology
Duke University School of Medicine
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DISCLOSURES

CONSULTING & STUDY DESIGN FOR:

- EDWARDS Lifesciences
- AtriCure
- CardioCare

Today’s slides were created in collaboration with the ELS team and Boston Consulting Group and reviewed by the AHA Scientific Oversight Committee.
OVERVIEW

1. Case for change in severe aortic stenosis
2. Barriers to appropriate management in the patient pathway
3. Looking forward to improving care
CASE FOR CHANGE
AORTIC STENOSIS: SIGNIFICANT BURDEN & RISK IN THE ELDERLY

Risk of sAS increases with age; ~1 in 15 individuals over 80 with severe AS (sAS)

Significant mortality risk if untreated once symptoms develop

Prevalence of significant aortic stenosis (%)¹

Within 2 years of symptom onset, 1 in 2 patients with Severe AS will die without Aortic Valve Replacement.

TREATMENT INDICATED FOR SEVERE AORTIC STENOSIS WITH EVIDENCE OF MYOCARDIAL DAMAGE

Surgical Valve Replacement (SAVR)

Transcatheter Aortic Valve Replacement (TAVI)

Survival after randomization to medical (standard) therapy or AVR (TAVI) in inoperable symptomatic sAS

- Hazard ratio, 0.55 (95% CI, 0.40–0.74)
- P<0.001

Source: Leon et al. 2010
TREATMENT BENEFITS EXTEND OUTSIDE SURVIVAL

Relative to medical management, AVR (TAVI) with significant benefit on QoL & economics

<table>
<thead>
<tr>
<th>Physical benefits</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical management $^1$</td>
<td>TAVI $^1$</td>
<td></td>
</tr>
<tr>
<td>KCCQ total symptoms (12 mos.)</td>
<td>59</td>
<td>75</td>
</tr>
<tr>
<td>KCCQ physical limitations</td>
<td>40</td>
<td>56</td>
</tr>
<tr>
<td>SF-12 physical</td>
<td>30</td>
<td>35</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mental benefits</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical management $^1$</td>
<td>TAVI $^1$</td>
<td></td>
</tr>
<tr>
<td>KCCQ quality of life (12 mos.)</td>
<td>48</td>
<td>76</td>
</tr>
<tr>
<td>KCCQ social limitations</td>
<td>50</td>
<td>65</td>
</tr>
<tr>
<td>SF-12 mental</td>
<td>47</td>
<td>53</td>
</tr>
</tbody>
</table>

Decreased post-op hospitalization costs $^2$

1 year follow up costs

- TAVR $\rightarrow$ $54K$
- Medical management $\rightarrow$ $29K$

+86%

Notes: Values represent survey data where 100 represents better outcomes and 0 represents worse outcomes.

Source: 1. Reynolds et al. (Circulation, 2011) 2. PARTNER 1B Trial (Circulation, 2012)
Less than 1 in 2 patients with known Severe AS receive treatment within a year after symptom development.

UNDER-TREATMENT IS EVEN GREATER FOR WOMEN & MINORITIES

Severe symptomatic AS$^{1,2}$

US Population Treatment Rate

<50%

<table>
<thead>
<tr>
<th>ssAS diagnosed incidence / 10k</th>
<th>Men</th>
<th>Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>ssAS diagnosed incidence / 10k</td>
<td>6.09</td>
<td>3.91</td>
</tr>
</tbody>
</table>

A woman is 36% less likely to be diagnosed than a man, and
A woman is 20% less likely to be treated than a man

<table>
<thead>
<tr>
<th>ssAS diagnosed incidence / 10k</th>
<th>Caucasian</th>
<th>Black</th>
</tr>
</thead>
<tbody>
<tr>
<td>ssAS diagnosed incidence / 10k</td>
<td>6.20</td>
<td>2.19</td>
</tr>
</tbody>
</table>

A black patient is 65% less likely to be diagnosed than a white patient
A black patient is 23% less likely to be treated than a white patient

BARRIERS TO APPROPRIATE MANAGEMENT & COVID
POTENTIAL CHALLENGES ACROSS THE PATIENT PATHWAY

**Awareness**

*Lack of recognition of the burden of sAS and its impact on patients from QoL to survival*

**Detection & diagnosis**

*Failure to refer an indicated patient to echo; challenges on echo review; missed follow up for less severe AS*

**Referral**

*Challenges in assessing symptomatic status, patient uncertainty in risk/benefit trade off*
Public Awareness Gaps
DESPITE INROADS IN TREATMENT, AWARENESS REMAINS LOW FOR AORTIC STENOSIS

Questions for EU patients over 60

Q: Which of the following health conditions concerns you most?

- Just 2% of respondents said that valvular heart disease is the condition that concerns them the most.

Q: Do you know what “aortic stenosis” is?

- Even in 2017, only 4% of respondents were aware and could correctly define aortic stenosis.

Source: Gaede et al. (Clinical Research in Cardiology, 2019)
Detection & Diagnosis Gaps
CHALLENGES IN AUSCULTATION IN DETECTING AORTIC STENOSIS

Limited accuracy identifying AS by exam, including among graduating medical trainees\(^1\)

Limited accuracy identifying Valvular Heart Disease by exam, including among practicing clinicians\(^2\)

Sources: 1. Mangione S. JAMA 1997, 2. Gardezi S. Heart 2018
AORTIC STENOSIS NOT INDOLENT WITH NEED FOR CAREFUL MONITORING TO CAPTURE PROGRESSION TO SIGNIFICANT DISEASE

Majority of patients progress from *sclerosis to severe AS* within 8 years\(^1\)

Number of years from aortic valve thickening to severe aortic stenosis

For patients with *moderate disease*, ~50% will require an intervention in 5 years\(^2\)

AVR free survival in patients with moderate aortic stenosis

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\(^1\) Cosmi et al. 2002  \(^2\) Lancellotti et al. 2018.
COMPLEXITY IN ECHO TECHNIQUE AND INTERPRETATION CAN ALSO CONTRIBUTE TO MISSED SEVERE AORTIC STENOSIS

Thorough doppler evaluation critical to accurately determine the severity of AS¹

Variation in the number of severe AS patients diagnosed depending on echo criterion used

<table>
<thead>
<tr>
<th>Guidelines/Recommendations</th>
<th>Parameter</th>
<th>Patients with severe stenosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHA/ACC³</td>
<td>AVA &lt; 1.0 cm²</td>
<td>69%</td>
</tr>
<tr>
<td>ESC²</td>
<td>AVA/BSA &lt; 0.6 cm²</td>
<td>76%</td>
</tr>
<tr>
<td>Otto⁴</td>
<td>$V_{\text{max}} &gt; 4.0 \text{ m/s}$</td>
<td>45%</td>
</tr>
<tr>
<td>AHA/ACC³</td>
<td>$\Delta P_m &gt; 40 \text{ mmHg}$</td>
<td>40%</td>
</tr>
</tbody>
</table>

AVA, aortic valve area; BSA, body surface area; $V_{\text{max}}$, peak flow velocity; $\Delta P_m$, mean pressure gradient

¹ Thaden et al. 2015 ² Minners et al. 2008
EXERCISE STRESS TESTING UNDERUTILIZED, DESPITE COMPELLING EVIDENCE OF BENEFIT IN ASYMPTOMATIC PATIENTS

Despite literature showing formal stress tests find abnormal results in 40-70% of asymptomatic severe AS cases. Valvular Heart Disease II Survey show low rates of formal stress testing in severe AS.

**Share with abnormal stress**

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amato et al (treadmill)</td>
<td>66</td>
<td>67%</td>
</tr>
<tr>
<td>Lafitte et al (treadmill)</td>
<td>60</td>
<td>65%</td>
</tr>
<tr>
<td>Lancellotti et al (Exercise echo, bicycle)</td>
<td>69</td>
<td>38%</td>
</tr>
<tr>
<td>Marechaux et al (Exercise echo, bicycle)</td>
<td>50</td>
<td>48%</td>
</tr>
<tr>
<td>Lancellotti et al (Exercise echo, bicycle)</td>
<td>128</td>
<td>47%</td>
</tr>
</tbody>
</table>

**Share severe AS patients receiving stress testing**

<table>
<thead>
<tr>
<th>Stage</th>
<th>n</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHYA I</td>
<td>409</td>
<td>6.1%</td>
</tr>
<tr>
<td>All</td>
<td>2152</td>
<td>3.1%</td>
</tr>
</tbody>
</table>

Notes: Study n shown above each column. 1. Iung et al. 2019 2. Redfors et al. 2017
Referral & Treatment Gaps
60% OF UNTREATED SSAS PATIENTS ARE FOLLOWED IN CARDIOLOGY CLINICS

Furthest point of patient contact in the spectrum of ssAS care

Diagnosed untreated (by 'leakage point')

14% 32% 7% 47%

Note: Cardiologist category includes ICs with >5 PCIs, and GCs
Source: Optum data, BCG EHR analytics
PATIENT PREFERENCE, MISCLASSIFICATION, AND VIEW OF SYMPTOMS DRIVE REFERRAL GAPS

### Cited reasons for no AVR in patients with severe, symptomatic AS

<table>
<thead>
<tr>
<th>Reason</th>
<th>PCP visit only (n=53)</th>
<th>CV consultation, no AVR referral (n=214)</th>
<th>AVR referral (n=92)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient or family refusal, n (%)</td>
<td>7 (13.2)</td>
<td>130 (60.7)</td>
<td>59 (64.1)</td>
</tr>
<tr>
<td>AS incorrectly deemed not severe, n (%)</td>
<td>13 (24.5)</td>
<td>32 (15.0)</td>
<td>8 (8.7)</td>
</tr>
<tr>
<td>Symptoms not attributable to AS, n (%)</td>
<td>3 (5.7)</td>
<td>20 (9.3)</td>
<td>7 (7.6)</td>
</tr>
<tr>
<td>Mild or stable symptoms, n (%)</td>
<td>4 (7.5)</td>
<td>18 (8.4)</td>
<td>6 (6.5)</td>
</tr>
<tr>
<td>High risk, n (%)</td>
<td>0 (0)</td>
<td>13 (6.1)</td>
<td>2 (2.2)</td>
</tr>
<tr>
<td>Not documented, † n (%)</td>
<td>26 (49.1)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

Source: Tang 2018
1 IN 3 MEDICALLY MANAGED PATIENTS “CHOOSE” THIS STRATEGY, BUT ARE THEY ADEQUATELY INFORMED?

Among medically managed patients, 31% chose ‘no treatment’ after referral¹...

...for these patients, 31%, felt unsure; and, 14% didn’t feel adequately prepared for the decision¹

<table>
<thead>
<tr>
<th>Reason</th>
<th>Proportion of Patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Considering TAVR elsewhere</td>
<td>1.4%</td>
</tr>
<tr>
<td>Symptoms not attributed to AS</td>
<td>1.4%</td>
</tr>
<tr>
<td>Acute MI within 30 days</td>
<td>2.8%</td>
</tr>
<tr>
<td>Concurrent acute illness</td>
<td>2.8%</td>
</tr>
<tr>
<td>Bicuspid AV</td>
<td>2.8%</td>
</tr>
<tr>
<td>Unknown</td>
<td>2.8%</td>
</tr>
<tr>
<td>Inadequate access for TAVR</td>
<td>8.5%</td>
</tr>
<tr>
<td>Evaluation ongoing</td>
<td>9.9%</td>
</tr>
<tr>
<td>Inoperable or anatomic...</td>
<td>11.3%</td>
</tr>
<tr>
<td>Unable to get commercial TAVR</td>
<td>14.1%</td>
</tr>
<tr>
<td>Bridging with BAV</td>
<td>15.5%</td>
</tr>
<tr>
<td>Medical Futility</td>
<td>19.7%</td>
</tr>
<tr>
<td>Patient preference</td>
<td>31.0%</td>
</tr>
</tbody>
</table>

Sources: ¹ Dharmarajan K. | PLOS ONE | https://doi.org/10.1371/journal.pone.0175926 April 21, 2017
Median odds ratio (MOR) expresses the likelihood of a different outcome (i.e. AVR) if a patient goes to another randomly selected provider. MOR of 1 indicates no difference in outcomes between providers; MOR of 1.5 indicates 50% chance of a different outcome if the patient goes to another randomly selected physician. Source: Optum EHR, n=30,642 patients. BCG analysis.

2.3x likelihood of different outcome (AVR or no AVR) if the patient had another managing cardiologist

- **Cardiologists ranked by treatment rates of AVR patients**
- **% of Class I indicated patients that are treated**
- **Top 25% of cardiologists by AVR rate**
- **Bottom 25% cardiologists by AVR rate**
- **Lots of referrals & treatments in top quartile of cardiologists**
- **Bottom quartile have very few referrals (some have no referrals)**

1. Brennan, TVT 2019
2. Median odds ratio (MOR) expresses the likelihood of a different outcome (i.e. AVR) if a patient goes to another randomly selected provider. MOR of 1 indicates no difference in outcomes between providers; MOR of 1.5 indicates 50% chance of a different outcome if the patient goes to another randomly selected physician. Source: Optum EHR, n=30,642 patients. BCG analysis.
Significant variation in cardiologist ssAS treatment rate with impact on outcomes

Cardiologists ranked by treatment rates of AVR patients

% of Class I indicated patients that are treated

Top 25% of cardiologists by AVR rate

22%

Increased risk of death for patients managed by cardiologists in the bottom quartile versus the top even when controlling for comorbidities

Bottom 25% cardiologists by AVR rate

1. Yes. 2. Median odds ratio (MOR) expresses the likelihood of a different outcome (i.e. AVR) if a patient goes to another randomly selected provider. MOR of 1 indicates no difference in outcomes between providers; MOR of 1.5 indicates 50% chance of a different outcome if the patient goes to another randomly selected physician. MOR can be directly compared to hazard ratios.
COVID-19: IMPACT OF A GLOBAL PANDEMIC ON SEVERE SYMPTOMATIC AORTIC STENOSIS

Source: https://coronavirus.jhu.edu/map.html, Accessed: 2/6/2021
COVID-19: IMPACT OF A GLOBAL PANDEMIC ON SEVERE SYMPTOMATIC AORTIC STENOSIS

Temporary guidance to triage intervention including AVR during COVID-19

- TAVI recommended for highly symptomatic AS patients
- TAVI or close monitoring recommended for minimally symptomatic AS patients

Recent prospective view highlighted higher rates of adverse events associated with deferred AVR

COMMON TREATMENT DELAYS COST LIVES\(^1\)

1 in 4 patients waited >5 weeks from referral to treatment

5-week delay translates to an 8% increase in mortality

<table>
<thead>
<tr>
<th>Weeks Since Recommendation</th>
<th>Total Percent of Patients that Underwent Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>20.4%</td>
</tr>
<tr>
<td>2</td>
<td>39.1%</td>
</tr>
<tr>
<td>3</td>
<td>53.8%</td>
</tr>
<tr>
<td>4</td>
<td>64.6%</td>
</tr>
<tr>
<td>5</td>
<td>73.8%</td>
</tr>
<tr>
<td>6</td>
<td>79.5%</td>
</tr>
<tr>
<td>7</td>
<td>83.5%</td>
</tr>
<tr>
<td>8</td>
<td>87.2%</td>
</tr>
<tr>
<td>9</td>
<td>88.6%</td>
</tr>
<tr>
<td>10</td>
<td>90.6%</td>
</tr>
</tbody>
</table>

LOOKING FORWARD TO IMPROVING CARE
TARGET: AORTIC STENOSIS

Structural Heart Disease Patient Care Pathway

1. **Awareness**
   - Delivery of targeted, credible education and resources to at-risk patient populations designed to drive health actions and behavior change.

2. **Detection**
   - Working within sites and expanding in ambulatory, focus on quality of education and analysis of gaps, assessment of patients missed, and why.

3. **Diagnosis**
   - Identify gaps between detection and appropriate diagnosis; identify barriers and changes in workflow that will improve diagnosis.

4. **Referral**
   - What is the process for referral, who is doing it, in what timeframe, identify gaps, identify best practices and scale them.

5. **Treatment**
   - Ultimately did patients receive the right treatment / guideline-directed therapy for their diagnosis.

6. **Monitoring**
   - Capabilities to capture patient reported outcomes like KCCQ via the digital Patient Support Network and Preferences Registry.
WHAT WOULD BE THE IMPACT OF BUILDING TO A GOLD STANDARD LEVEL OF CARE?

- With a proactive recognition of individuals at high-risk of sAS
- Objective criteria to indicate intervention timing and management protocols
- Greater society engagement and recognition
- Stronger public awareness and urgency to intervene
- At least 90% of patients receiving appropriate treatment

Potential for an additional **233,000** life years saved annually¹

Note: Life years saved (232,455) determined by multiplying the expected life year extension from a TAVI procedure (2.7 years) by the annual incidence of diagnosed untreated sAS patients (86,095).
Source: Analyses of Optum data
BECAUSE THEY’RE WORTH IT...

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Duke University School of Medicine
brenn009@duke.edu
Disclosures Dr. Yancy

Editor- JAMA Network
Special Government Employee- Department of Health and Human Services
Consultant- NHLBI, NIH, PCORI

Spousal employment, Abbott, Inc.
A vision of lowering cardiovascular mortality, specifically by “establishing and advancing a new standard of care in structural heart disease”

**How we will get there:**

- **Quality Systems Improvement:** Measure & recognize quality, deliver guideline-directed, optimal-care.
- **Public Health Awareness & Education:** Launch programs to increase patient awareness and engagement.
- **External Partnerships:** Amplify our reach with strategic organizational partnerships.
Our shared vision of ensuring all structural heart disease patients are identified and appropriately treated is no small undertaking.

With the support of Edwards Lifesciences and working with our clinical network on our patient-centered public outreach programs, we can better help the millions of Americans impacted by structural heart disease each year.

Nancy Brown, Chief Executive Officer, American Heart Association

We are excited to be collaborating with an organization who shares our passion for helping transform patients’ lives.

Together with the Association, we are confident we can have a positive impact on people living with structural heart disease.

The Association is uniquely positioned to lead this initiative given its representation of not only the scientific community, but also patients and the full spectrum of care providers, all aimed at helping people live longer, healthier lives.

Todd J. Brinton, M.D., F.A.C.C., Corporate Vice President of Advanced Technology and Chief Scientific Officer, Edwards Lifesciences
Aortic Stenosis Initiative Overview

To help healthcare providers identify and refine better/best practices that can be leveraged and scaled as part of an intensive continuous quality improvement for patients living with Aortic Stenosis.

- Increased awareness of the signs and symptoms of aortic stenosis among at risk populations.
- Increased percentage of aortic stenosis patients who are identified and diagnosed.
- Improved clinical pathways and processes to impact patient outcomes.
- Increased compliance with established guidelines for the appropriate follow-up of structural heart disease patients at discharge and beyond.
Indications for aortic valve replacement and TAVI (surgical or transcatheter)

- Severe high-gradient AS with symptoms (class 1 recommendation, level A evidence)
- Asymptomatic patients with severe AS and LVEF < 50 (class 1 recommendation, level B-NR evidence)
- Severe AS when undergoing other cardiac surgery (class 1 recommendation, level B-NR evidence)
- Asymptomatic severe AS and low surgical risk (class 2a recommendation, level B-R evidence)
- Symptomatic with low-flow/low-gradient severe AS (class 1 recommendation, level B-NR evidence)
- Moderate AS and undergoing other cardiac surgery (class 2b recommendation, level C-EO evidence)
- TAVI is preferred among symptomatic patients of any age with high or prohibitive surgical risk, if predicted survival after intervention is >12 months with an acceptable quality of life (class 1 recommendation, level A evidence)
Participating Pilot Sites

- Providence St Vincent Medical Center
  Portland, OR

- University of Utah
  Salt Lake City, UT

- Stanford Hospital
  Stanford, CA

- Ronald Reagan UCLA Medical Center
  Los Angeles, CA

- Colorado Heart and Vascular/St. Anthony Hospital
  Lakewood, CO

- Northwestern Memorial Hospital
  Chicago, IL

- University of Kansas
  Kansas City, MO

- Cleveland Clinic Main Campus
  Cleveland, OH

- Geisinger Medical Center
  Danville, PA

- Doylestown Hospital
  Doylestown, PA

- Deborah Heart and Lung Center
  Browns Mills, NJ

- Thomas Jefferson University Hospital
  Philadelphia, PA

- Penn Medicine
  Philadelphia, PA

- Baylor Scott & White Heart and Vascular Hospital
  Dallas, TX

- Vanderbilt University Medical Center
  Nashville, TN

- WellStar Kennestone Hospital
  Marietta, GA

- University of Utah
  Salt Lake City, UT

- Stanford Hospital
  Stanford, CA

- Ronald Reagan UCLA Medical Center
  Los Angeles, CA

- Colorado Heart and Vascular/St. Anthony Hospital
  Lakewood, CO

- Northwestern Memorial Hospital
  Chicago, IL

- University of Kansas
  Kansas City, MO

- Cleveland Clinic Main Campus
  Cleveland, OH

- Geisinger Medical Center
  Danville, PA

- Doylestown Hospital
  Doylestown, PA

- Deborah Heart and Lung Center
  Browns Mills, NJ

- Thomas Jefferson University Hospital
  Philadelphia, PA

- Penn Medicine
  Philadelphia, PA

- Baylor Scott & White Heart and Vascular Hospital
  Dallas, TX

- Vanderbilt University Medical Center
  Nashville, TN

- WellStar Kennestone Hospital
  Marietta, GA
Measure Development and Integration

- Measures scoped with clinical stakeholders and key volunteer input
- Structural heart disease measures created
- Develop measure change documents
- Stakeholder training
- Initiative site training
- Pilot measures in 15 sites in the U.S.
Establish and advance a new standard of care for patients with aortic stenosis

Structural Heart Disease Patient Care Pathway

**Awareness**
- Delivery of targeted, credible education and resources to at-risk patient populations designed to drive health actions and behavior change

**Detection**
- Working within sites and expanding in ambulatory, focus on quality of education and analysis of gaps, assessment of patients missed, and why

**Diagnosis**
- Identify gaps between detection and appropriate diagnosis; identify barriers and changes in workflow that will improve diagnosis

**Referral**
- What is the process for referral, who is doing it, in what timeframe, identify gaps, identify best practices and scale them

**Treatment**
- Ultimately did patients receive the right treatment/guideline-directed therapy for their diagnosis

**Monitoring**
- Capabilities to capture patient reported outcomes like KCCQ via the digital Patient Support Network and Preferences Registry
## Pilot Measures to Improve the Patient Care Pathway

**Structural Heart Disease Patient Care Pathway**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Referral</th>
<th>Treatment</th>
<th>Monitoring / QoL Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Percentage of moderate aortic stenosis patients receiving a follow-up echocardiogram during the measurement period (index echo) that is within 24 months of prior echocardiogram.</td>
<td>• Percentage of patients diagnosed with severe aortic stenosis during the measurement period who were evaluated by the Multidisciplinary Heart Valve Team within 14 days of initial diagnosis</td>
<td>• Percentage of patients who receive definitive treatment (SAVR, TAVI or Palliative Care) within 30 days of initial evaluation by the Multidisciplinary Heart Valve Team</td>
<td>• Percentage of patients who completed a Kansas City Cardiomyopathy Questionnaire (KCCQ-12) prior to and within 30 days after TAVI</td>
</tr>
<tr>
<td>• Percentage of echocardiogram reports performed within a health system with aortic velocity $\geq 4$ m/s that include the severity of aortic stenosis and a clinical recommendation for further evaluation/referral of patients</td>
<td></td>
<td></td>
<td>• Percentage of patients who completed a Kansas City Cardiomyopathy Questionnaire (KCCQ-12) prior to and within 90 days after SAVR</td>
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<td>• Percentage of patients with low flow, low gradient severe aortic stenosis who receive a dobutamine stress test during the measurement period</td>
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<td>• Percent of patients who had improvement of at least 10 points in their KCCQ-12 score or had a total KCCQ-12 score of $\geq 60$ at 30 days after TAVI</td>
</tr>
<tr>
<td>• Percentage of patients with asymptomatic severe aortic stenosis who receive either an exercise stress test or an assessment of activity tolerance to confirm symptom status within 6 months of diagnosis</td>
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1. **Environmental Scan**: Reviewed relevant guidelines and other literature related to key processes of care for patients with Aortic Stenosis.

2. **Measure Concept Development**: Proposed potential measure concepts based on literature review and initial input from SAG and industry partners.

3. **Measure Selection**: In collaboration with the SAG, selected measure concepts for further development and specification based on level of supporting evidence, importance and feasibility.

4. **Measure Development**: With guidance from the SAG, identified target population (denominator), exclusions and exceptions and patients to include in numerator for each measure and method of reporting (e.g., rate or distribution).

5. **Approval**: Final review and approval by the full SAG.

6. **Specification**: Identified required data elements and created detailed measure logic for implementation in the AHA GWTG - CORE registry.

7. **Elaboration and Implementation**: Worked with IT vendor to ensure that programming and implementation are consistent with the intent of the measures.

8. **Post-Pilot Refinement**: Based on feedback from the sites, findings related to availability of data and an understanding of site workflow, we will add, refine or retire measures, as needed.
Aortic Stenosis Science Advisory Group Members

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Director of Cardiac Catheterization Lab
Assistant Professor, Harvard Medical School Cardiovascular Medicine
A Focus on Quality

<table>
<thead>
<tr>
<th>Get With The Guidelines - Stroke</th>
<th>Get With The Guidelines - Heart Failure</th>
<th>Get With The Guidelines - Resuscitation</th>
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<tbody>
<tr>
<td>Get With The Guidelines - AFib</td>
<td>Get With The Guidelines - Coronary Artery Disease</td>
<td>Hospital Certification</td>
</tr>
<tr>
<td>Mission: Lifeline</td>
<td>Target: Heart Failure</td>
<td>Target: Stroke</td>
</tr>
</tbody>
</table>
Leveraging the Get With The Guidelines-CORE environment, we rapidly created and deployed a new stand-alone data collection tool specifically for Aortic Stenosis.

**Get With The Guidelines - CORE**

- Rapid deployment of data elements and measures.
- CORE environment is standard platform that can be quickly customized.
- Allows for pilot environment, still under data use agreements, to enter patient data.

**Aortic Stenosis Tool Pilot**

- Patient form: one-time entry for each patient
- Event form: added to patient for each event or visit
- 68 data elements
- Reports for all measures, and specialized reports to monitor progress throughout year.
- Robust reporting, both for the hospital and comparison against the aggregate.
Learning Collaborative Model

- Spread best practices nationally through education, model sharing, developed tools and resources, and abstracts
- Identify consensus best practices among collaborative hospitals, bridging gaps within the patient journey to treatment
- Engage all hospitals in learning collaborative model to share practices (barriers and achievements) to identify opportunities for improvement along the journey
- Analysis of individual hospital patient journey from identification, diagnostics, treatment and referral process
Partnering pilot hospitals are testing:

- Data entry and data migration into a new tool
- Reporting capabilities
- Third party vendor applications
- Pilot measures and delivering feedback

Partnering pilot hospitals will be developing:

- Best practices impacting the Aortic Stenosis patient journey
- Tools and education that will be shared nationally
Patient Engagement

- Patient/Provider toolkit
- Online/download patient education tools
- Webinar/podcast series content
- Owned, earned, paid social media
- Dedicated forum within Support Network
- Patient stories on Support Network
- Initiative promotion on AHA owned email channels
Who We’re Talking To

Target Audience
Diagnosed and Undiagnosed AS patients 65+ experiencing symptoms and their loved ones

Insights:
• Age-related aortic stenosis usually begins after age 60
• Patients may not fully recognize disease progression and risks
• Abnormal heart murmurs may be missed, or doctors may fail to associate the symptoms with the disease
Find out more about managing aortic stenosis:

**Newly Diagnosed**
If you were recently diagnosed with aortic stenosis, you probably have questions. Find out about symptoms, risk factors and treatments.

Learn more about AS ➔

**Track Your Symptoms**
It's important to track your symptom progression to determine if it is getting better or worse. You may not experience noticeable symptoms until the narrowed valve greatly reduces blood flow.

Download the AS symptom tracker ➔

**Treatment Options**
AS can be treated and managing it appropriately can reduce the negative impact on your quality of life. If you notice a decline in routine physical activities or significant fatigue, it's worth a visit to your health care professional.

Learn about the AS care team ➔
Scheduling surgery, COVID-19 risks and more: What heart valve patients need to know

DALLAS, May 4, 2020 — An estimated five million patients in the United States live with heart valve disease, and many have had upcoming valve repair surgery rescheduled due to the COVID-19 pandemic. The American Heart Association, along with its North American cardiovascular societies, recently issued a framework for safely resuming cardiovascular treatment, such as heart valve surgery during the COVID-19 pandemic. People with heart valve disease live with symptoms that include shortness of breath, chest tightness and fatigue daily and must be especially cautious to avoid contracting COVID-19 due to the increased risk for complications.

"The most important thing for people with heart valve disease is to stay healthy and stay as active as possible," said Suzanne Arnoldi, cardiologist, St. Luke’s Health System, Kansas City, Missouri, and chair of the American Heart Association’s, the nation’s leading voluntary health organization dedicated to a world of longer, healthier lives. "Generally, heart valve patients whose condition can wait a few months are continuing to have the procedures done, whereas it may be safer for patients with less urgent valve problems to wait until things settle out a bit at the hospitals."

For those who have an upcoming procedure, Arnoldi advises patients to also maintain good nutrition and physical activity and follow public health guidelines for COVID-19 prevention: "The healthier you are going into the surgery, the quicker the recovery, which means fewer complications and shorter length of stay at the hospital and faster recovery after returning home," she said.

Arnoldi also advises people with heart valve disease to be diligent when it comes to social distancing and coronavirus prevention. "While COVID-19 could attack anyone, people with underlying medical conditions are at greater risk of developing serious illness from COVID-19. This is likely the bigger concern - not that COVID-19 makes the heart valve disease worse, but that the valve disease may make COVID-19 harder to battle," she said.

Learn more about heart valve disease and how to manage symptoms at home at heart.org/heartvalves.

Get the latest American Heart Association information and recommendation on COVID-19 here.

COVID-19 and AS Response

Dr. Arnold & AHA collaborate to address AS patient concerns during COVID-19

OBJECTIVE
Develop content for aortic stenosis patients, addressing concerns related to their condition and how it’s impacted by COVID-19

AHA YouTube channel: youtube.com/watch?v=Wxyoi1shxU
Amplify **Target: Aortic Stenosis** through communities or health care outreach efforts with partner organizations

**Impact**
- Increase patient and provider conversation about follow-up care
- Decrease time to diagnosis
- Improve self-management with AS patients

**Strategic Alliance Objectives**
- Increase instance of follow-up care & timely treatment
- Decrease disparities of care
- Improve knowledge for appropriately referring an AS patient

**Alliance organizations we’ve established a relationship with for year 1:**
- American Heart Association
- Association of Black Cardiologists, Inc.
- Alliance for Aging Research
- Preventive Cardiovascular Nurses Association
FREE WEBINAR
Key Messages for Clinicians in the
2020 AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease

Visit learn.heart.org
Webinar Date and Details Coming Soon!

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Co-director, Hypertrophic Cardiomyopathy Program
Questions – Please use Q/A section