

# Access to **All** Appropriate Treatments for **All** Heart Valve Disease Patients

*July 25, 2018 MEDCAC Meeting*



Donnette Smith  
Heart Valve Disease Policy Task  
Force Representative; President,  
The Mended Hearts; Valve Disease  
Patient  
Marilyn Serafini, Executive Director,  
Heart Valve Voice

# Disclosures

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- Donnette Smith has served as a:
  - Spokesperson for Gilead on a campaign for angina (Received honorarium)
  - Consultant to Edwards Lifesciences on SAVR and TAVR (Received honorarium)
  - Spokesperson for Amgen on access to care
  - Patient representative for ACC at valve roundtables
  - Patient representative for Novartis at Heart Failure Conference in Galway, Ireland
- Marilyn Serafini, as Executive Director of Heart Valve Voice, and other Members of the Task Force, receive support from Edwards Lifesciences, Abbott, and Medtronic, Inc. (major)



# Representing Patients

Donnette was born in Athens, Alabama, and moved to Huntsville, Alabama, after her marriage to Tom in October 1980. She began her career in 1966 with the George C. Marshall Space Flight Center, National Aeronautics and Space Administration, where she worked under the leadership of Dr. Werner von Braun and was a member of his Saturn V Rocket Team. She later transferred to the U.S. Army Missile Command as a Technical Writer where she continued until her retirement in 1999.



After her second heart surgery in 1994, Donnette became the founding President of Mended Hearts Huntsville Chapter 260, and has served as Chapter VP, Treasurer and Visiting Chairperson. On the National level, she served as Treasurer and Executive Vice President for two terms each. She is currently the President of Mended Hearts. She has also served as the Mended Hearts representative for projects such as the I Heart Flu Shots campaign, the Hearts in Harmony campaign with Dr. Bob Arnot, and Speak From The Heart program with Gilead Sciences. She has also served as the Patient's Voice for several writing groups with the American College of Cardiology.

Donnette and Tom's greatest joy is attending sports activities in which the grandchildren participate, which includes golf, tennis, football and basketball!



# Working on Behalf of Patients

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Marilyn Serafini is Executive Director of Heart Valve Voice US. Following her mom's successful aortic valve replacement, Marilyn became an advocate for heart valve patients in April of 2018. Before joining Heart Valve Voice-US, Ms. Serafini was president & co-CEO of the Alliance for Health Policy, a nonpartisan, not-for-profit organization dedicated to helping policymakers understand the foundations of health policy, the roots of the nation's health care issues, and the trade-offs posed by various proposals for change.



# Representing the Heart Valve Disease Policy Task Force

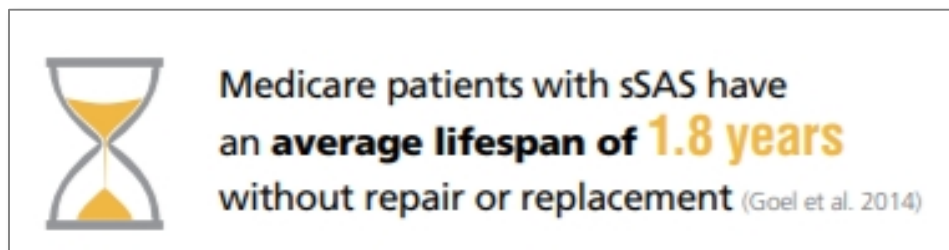
- The Heart Valve Disease Policy Task Force is a coalition of organizations advocating for policy solutions that improve access, research, and awareness on heart valve disease detection and treatment



# A Serious and Deadly Disease Impacting Millions



- If left untreated, heart valve disease can be fatal



For patients with sSAS without repair or replacement

(Otto 2000)



SAS = symptomatic aortic stenosis

sSAS = severe symptomatic aortic stenosis

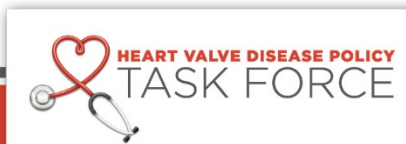
1 Alliance for Aging Research. 2018. *Silver Book Valve Disease Fact Sheet: Chronic Disease & Medical Innovation in an Aging Nation*. [www.silverbook.org](http://www.silverbook.org).

Bach et al. 2007. Prevalence, Referral Patterns, Testing, and Surgery in Aortic Valve Disease: Leaving women and elderly patients behind? *J Heart Valv Dis* 16(4):362-9.

Nkomo et al. 2006. Burden of Valvular Heart Diseases: A population-based study. *Lancet* 368(9540):1005-11.

2 Clark et al. 2012. Five-Year Clinical and Economic Outcomes Among Patients with Managed Severe Aortic Stenosis. *Circ Cardiovas Qual Outcomes* 5(5):697-704.

3 Otto et al. 2000. Timing of Aortic Valve Surgery. *Heart* 84(2).



# Barriers to Better Health Outcomes

- Low disease awareness



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- Lack of symptoms/disregard of symptoms

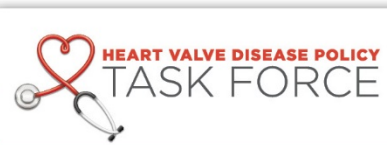


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HVD = heart valve disease

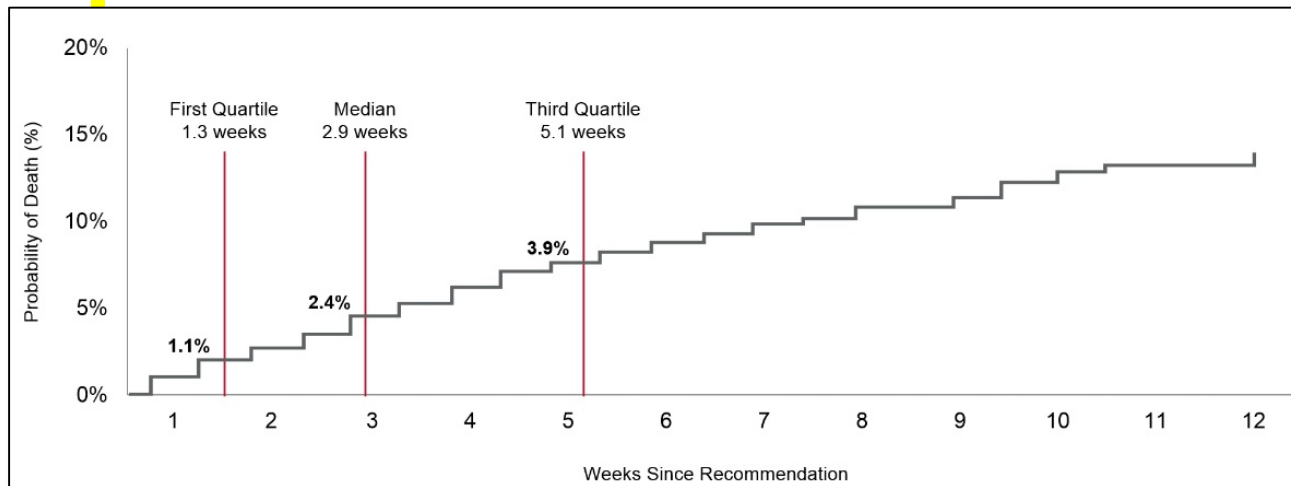
4 Belden Russonello Strategists, on behalf of the Alliance for Aging Research. 2016. *Report of Findings from National Survey Research on Public Awareness of Heart Valve Disease.*

5 Belden Russonello Strategists, on behalf of the Alliance for Aging Research. 2016. *Report of Findings from Opinion Research Among Heart Valve Disease Patients.*



# Probability of Death Increases with Wait Times

- “Watchful waiting” increases the risk of death
- Timeliness from diagnosis to intervention matters



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First 12 Weeks Since Recommendation: Cumulative Probability of Death without Intervention

6 Malaisrie et al. 2014. Mortality Awaiting Aortic Valve Replacement. *Ann Thorac Surg* 98.





# Undertreatment of Aortic Stenosis is Well Documented

- Limited access to appropriate treatment
  - Studies show that at least half of patients with severe aortic stenosis don't undergo aortic valve replacement<sup>7</sup>

7 Bach et al. 2009. Evaluation of Patients with Severe Symptomatic Aortic Stenosis Who Do Not Undergo Aortic Valve Replacement. *Circ Cardiovasc Qual Outcomes* 2:533-599.

Varadarajan et al. 2006. Clinical Profile and Natural History of 453 Nonsurgically Managed Patients with Severe Aortic Stenosis. *Ann Thorac Surg* 82(6):2111-5.  
Jan 2009. Unoperated Patients with Severe Symptomatic Aortic Stenosis. *Circ* 120(S18):S753.



# Limited Access to Appropriate Treatment

- Providers don't always discuss TAVR, even with qualified patients
- Significant disparities exist for those that do get TAVR based on race, ethnicity, income, and where people live:
  - 94% of patients receiving TAVR are white<sup>8</sup>
  - In the US >90% of AVR surgeries are performed in hospitals that are urban, teaching hospitals<sup>9</sup>
  - 78% of patients served by these hospitals are in higher income zip codes<sup>10</sup>
  - Safety net hospitals—those public hospitals that are often providers of last resort—perform ~20% of AVRs<sup>11</sup>

8 Holmes et al. 2016. Annual Outcomes with Transcatheter Valve Therapy. *Ann Thor Surg* 101(2).

9 Analysis performed using HCUP Net Database for 2015 Hospital Discharges.

10 Ibid.

11 Ibid.



# Minority Disparities

- Minority and underserved patients receive far fewer treatments for heart valve disease (HVD) despite comparable surgical and transcatheter outcomes<sup>12</sup>
- African Americans (AA) experience risk factors for HVD at earlier ages
  - 42% of AA men and more than 45% of AA women aged 20+ have high blood pressure<sup>13</sup>
  - AA develop heart failure before the age of 50 at 20X the rate of whites<sup>14</sup>
  - 70% of AA men and 82% of AA women are overweight or obese<sup>15</sup>
  - AA are 1.7X more likely to have diabetes than whites and are more likely to develop serious complications<sup>16</sup>
- We need to fill research gaps to better understand why African Americans are underserved

12 Grover et al. 2017. 2016 Annual Report of The Society of Thoracic Surgeons/American College of Cardiology TVT Registry. *JACC* 69(10):1215-30.

13 American Heart Association. 2013. *African Americans & Cardiovascular Diseases*.

14 Bibbons-Domingo et al. 2009. Racial Differences in Incident Heart Failure Among Young Adults. *NEJM* 360.

15 American Heart Association 2016. *African Americans and CVD—2015 Statistical Fact Sheet*.

16 American Diabetes Association. Available at <http://www.diabetes.org/living-with-diabetes/treatment-and-care/high-risk-populations/treatment-african-americans.html>



# Mounting Evidence on TAVR Outcomes

- With original NCD, volume was used as a surrogate for outcomes to ensure quality in the absence of other evidence
- We now have a significant body of evidence on outcomes from TVT registry that proves its safety<sup>17</sup>
- TAVR is an important treatment option for inoperable, high-risk, and intermediate-risk patients that can:
  - Reduce the burden on the patient
  - Reduce hospital stays and recovery times
  - Produce better outcomes

17 Grover et al. 2017. 2016 Annual Report of The Society of Thoracic Surgeons/American College of Cardiology TVT Registry. *JACC* 69(10):1215-30.



## Mounting Evidence on TAVR Outcomes Cont.

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- Current NCD creates additional barriers to the less-invasive, and often patient-preferred treatment option
  - Using case volume as a surrogate for quality may inappropriately restrict access
- This also creates inequalities between patients—depending on which hospital a patient visits, their treatment can be vastly different



# Measuring Clinical Outcomes

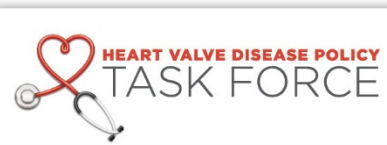
- Early studies showed that increased experience from higher volume facilities led to better outcomes in inoperable-risk and high-risk patients.
  - HOWEVER, more recent studies demonstrate that enhanced technology, widespread training, and group learning positively impacts outcomes independent of volume
- In general, recent studies show TAVR outcomes have been excellent in both high- AND low-volume facilities
- Quality metrics should include clinical outcomes
- We are concerned that any increase in volume criteria could close TAVR facilities and prevent opening of new ones—and the subsequent harm (i.e. increased mortality) outweighs any potential benefit



# Recommendations: All patients should have access to All appropriate treatments

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- 1) Volume is no longer a necessary surrogate for outcomes. There should be more emphasis on timely intervention and quality outcomes
- 2) The current 4 health outcomes measured (mortality, stroke, vascular complications, and bleeding) are medical, and there are other important outcomes that matter to patients, which should be included in the requirements. They include:
  - New onset of AFib
  - Quality of life
  - Mobility
  - Length of stay
  - Staying out of the hospital
  - Location of discharge
- 3) CMS should work with outside partners on survey research to determine patient preferences
- 4) Patients should have access to TVT registry data and meaningful information on hospital performance



# Questions and Thanks

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- Any questions?
- Many thanks!
  - You can reach me at [dlshsv@comcast.net](mailto:dlshsv@comcast.net) or 256-508-8438
  - You can reach the Heart Valve Disease Policy Task Force via Sue Peschin at [speschin@agingresearch.org](mailto:speschin@agingresearch.org)

