

HEART VALVE DISEASE: CONSENSUS STATEMENT

July 14, 2016

On July 14, 2016, Heart Valve Voice U.S. gathered key stakeholders together to discuss challenges people living with heart valve disease face in the U.S. and developed a consensus statement of how Heart Valve Voice U.S. and its partners can work together to address these challenges. The consensus statement will form the basis of Heart Valve Voice U.S.'s work to improve outcomes for people affected by heart valve disease by enhancing the diagnosis, treatment, and management of heart valve disease across the United States.

Heart Valve Voice U.K., with funding from Edwards Lifesciences, initiated Heart Valve Voice U.S. to improve the diagnosis, treatment, and outcomes for people living with heart valve disease in the U.S. Heart Valve Voice U.S. is inspired by Heart Valve Voice U.K., which has made a significant progress within a very short period of time for people living with heart valve disease in the U.K.

Currently, there is no nonprofit, patient advocacy organization focused exclusively on policy issues hindering the prevention, diagnosis, treatment, and management of heart valve disease in the U.S. Existing organizations offer invaluable support to people living with heart valve disease as a part of their missions. Heart Valve Voice U.S. will work collaboratively with these groups to maximize our collective impact and supplement those efforts by advocating for changes to enhance health outcomes for individuals affected by heart valve disease.

Research finds as many as one in three people in the U.S. with severe valve disease fail to receive proper diagnosis and treatment.¹ Heart Valve Voice U.S. will strive to improve the diagnosis, treatment, and management of heart valve disease by raising awareness of the disease, and its prevalence, severity, and under diagnosis and treatment. Heart Valve Voice U.S. brings together patients, patient organizations, allied nonprofits, medical experts, and researchers in the field of heart valve disease to educate and advocate for diagnosis so all those affected receive education, support, and the right treatment at the right time.

Facts on the Burden of Heart Valve Disease

Heart valve disease is a condition caused by wear, disease or damage to one or more of the heart's four valves that affects blood flow through the heart.

- More than 5 million people in the U.S. have heart valve disease. Many of them never experience symptoms.²
- Heart valve disease can affect any one or a combination of the four heart valves (aortic, mitral, pulmonary, and tricuspid). Diseases of the aortic and



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- mitral valves are most common.³ Heart valve disease may be present at birth or caused by infections, heart attacks, or heart disease or damage.
- Aortic stenosis, an aortic valve disease, affects up to 1.5 million people in the U.S.⁴
 - Although half a million Americans suffer from severe aortic stenosis, only half of those affected have symptoms.⁵
 - Without an aortic valve replacement, three out of four people with symptomatic, severe aortic stenosis will not survive three years.⁶
 - Yet, research shows severe aortic stenosis is undertreated.⁷
 - Although men and women suffer equally from heart valve disease, women are less likely to be diagnosed and have lower survival rates.⁸
 - Congenital heart defects, many affecting heart valves, are the most common types of birth defects in the U.S. Congenital heart defects are present in about 40,000 newborns each year.⁹
 - In older patients, the symptoms of heart valve disease may be dismissed as a “normal part of aging.”
 - Many people living with valve disease have other medical conditions that make treatment and recovery more difficult.
 - Joint clinical guidelines from the American Heart Association and American College of Cardiology recommend that people with severe, symptomatic valve disease be referred for evaluation of treatment options, including heart valve repair or replacement surgery.¹⁰ Yet, evidence shows that many are never referred for an evaluation.
 - With the aging of the U.S. population, the number of people with heart valve disease is expected to increase. The U.S. population over age 65 will more than double by 2060.¹¹
 - More than 1 in 8 people aged 75 and older have moderate to severe valve disease.¹²

We agree that there are many challenges at all stages of care that adversely affect the diagnosis and management of people with heart valve disease.

- Heart valve disease is under-diagnosed
 - Patients and family members unaware of symptoms
 - Clinicians not aware of symptoms, may dismiss symptoms, or are untrained in proper diagnosis
 - Women are less often diagnosed than men
- Those that are diagnosed are frequently not properly referred for treatment
 - Patients “lost” in referral patterns
 - Clinicians not aware of treatment alternatives

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- Medicare/insurance coverage/payment barriers limit patient access to treatment
- U.S. regulations can limit patient access to the latest treatments that are often available sooner to patients living outside the U.S.
- Underlying perceptions that some patients are too old or physically impaired to undergo heart surgery limit referrals contrary to clinical guidelines and patients' health.

The way forward to improving health outcomes for people with heart valve disease.

To improve health outcomes for people living with heart valve disease, we need to raise awareness of the prevalence and severity of heart valve disease in the U.S. and work to ensure timely detection so that all patients receive appropriate support and the right treatment at the right time for them.

Raising the profile of heart valve disease

Increasing awareness and understanding among the public of the risk factors, signs and symptoms of heart valve disease will help people at risk to seek advice for symptoms they might otherwise attribute to aging. Heart valve disease is treatable and can both extend life and enhance the quality of life for patients. Developing a call to action and collaborative effort to raise awareness and recognition of heart valve disease in the US, and mobilizing potential patients and their caregivers to seek appropriate care, are critical to enhancing outcomes associated with heart valve disease. Heart Valve Voice U.S. will seek to enhance collaboration between existing organizations that already generate awareness and provide support for patients, physicians and caretakers on heart valve disease symptoms and treatment options. As necessary, Heart Valve Voice U.S. will help identify and fill gaps where they exist, particularly in the area of educating policy makers about patient barriers to appropriate treatment of the disease.

Education

We need to coordinate and improve efforts to educate both primary care providers and specialists on detecting heart valve disease and making appropriate referrals for evaluation in accordance accepted clinical guidelines. Timely diagnosis and appropriate treatment and management are essential to improving outcomes for people with heart valve disease. Equally important, we need to inform and empower people living with and at risk of developing heart valve disease and their

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caregivers to understand the symptoms and seek timely diagnosis and treatment. Often symptoms are attributed to the natural aging process, when in fact the person has treatable valve disease.

Utilize existing infrastructure and networks

Timely and appropriate treatment of heart valve disease is critical for patients to enjoy a longer, healthier life. We will work to ensure data resources are used to greater effect to support physicians and patients in making the best decision for each individual patient about the diagnosis, referral and treatment of heart valve disease. Effective referrals between primary and specialist care, as well as inpatient to outpatient care are also essential. Providing credible, independent and realistic support materials and advice is also crucial to engaging and empowering patients and their caregivers. Patient support is also critical. Many organizations offer significant support services for patients. Heart Valve Voice U.S. will work to link patients and family caregivers with these organizations for support.

Innovation and Access

The prevalence of heart valve disease is expected to grow with the aging of the U.S. population. Innovation is needed to improve outcomes for people living with heart valve disease and those at risk for developing it. Innovation in prevention, detection, treatment, and management benefit no one, however, when people who could benefit do not have affordable access to recommended care.

Heart Valve Voice U.S. Tentative Plan

Heart Valve Voice U.S. Heart Valve Voice U.S. efforts will operate as a 501(c)(3) charitable organization funded by charitable donations from individuals and charitable and for-profit organizations, including supporting corporate sponsors.

Topics may include:

- Providing actual heart valve patients and their caregivers a voice in supporting greater awareness and advocating for better outcomes for themselves and other people with heart valve disease.
- Raising awareness of the obstacles to better outcomes, including
 - Under-diagnosis (overall and in specific populations);
 - Under-treatment (lack of awareness/adherence to clinical guidelines); and

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- Failure to refer when called for in guidelines – identifying, raising awareness, and advocating for solutions.
- Effectively campaigning for the timely detection, improved recognition and optimal treatment of heart valve disease in accordance with accepted clinical guidelines across the U.S.
- Advancing the evidence base on the burden of heart valve disease in the U.S., including the economic losses from avoidable disability and premature death.
- Enhancing access to innovative diagnosis, treatment, and management options for people with or at risk of developing heart valve disease.

¹ Bach DC, Siao, D, Girard, SE, et al. Evaluation of patients with severe symptomatic aortic stenosis who do not undergo aortic valve replacement: the potential role of subjectively overestimated operative risk. *Circ Cardiovasc Qual Outcomes* 2009; 2(6):533-39.

² American Heart Association, New guidelines help doctors assess severity of heart valve disease. Available online at <http://news.heart.org/new-guidelines-help-doctors-assess-severity-of-heart-valve-disease/>. Accessed April 6, 2016.

³ Nishimura, RA, et al. 2014 AHA/ACC Guideline for Management of Patients with Valvular Heart Disease 2014. Available online at <https://circ.ahajournals.org/content/early/2014/02/27/CIR.000000000000031.full.pdf>. Accessed April 6, 2016.

⁴ University of Iowa Health Care, Facts & Figures: U.S. Aortic Stenosis Disease Prevalence & Treatment Statistics. Available online at http://www.uihealthcare.org/uploadedFiles/UIHealthcare/Content/Clinics/Heart_Surgery/factsfigures.pdf. Accessed April 6, 2016.

⁵ University of Iowa Health Care, Facts & Figures: U.S. Aortic Stenosis Disease Prevalence & Treatment Statistics. Available online at http://www.uihealthcare.org/uploadedFiles/UIHealthcare/Content/Clinics/Heart_Surgery/factsfigures.pdf. Accessed April 6, 2016.

⁶ Carabello, BA. A Fatal Disease with But a Single Cure. *J Am Coll Cardiol Interv.* 2008; 1(2):127-28.

⁷ See, e.g., Osnabrugge, RJL, Mylotte, D, Head SJ, et al. Aortic Stenosis in the Elderly: Disease Prevalence and Number of Candidates for Transcatheter Aortic Valve Replacement: A Meta-Analysis and Modeling Study. *J Am Cardiol* 2013; 62(11): 1002-12.

⁸ Nkomo VT, Gardin JM, Skelton TN, et al. Burden of valvular heart diseases: a population-based study. *Lancet* 2006; 368:1005-11.

⁹ CDC, Congenital Heart Defects (CHDs), <http://www.cdc.gov/ncbddd/heartdefects/data.html>.

¹⁰ Nishimura, RA, et al. 2014 AHA/ACC Guideline for Management of Patients with Valvular Heart Disease 2014. Available online at <https://circ.ahajournals.org/content/early/2014/02/27/CIR.000000000000031.full.pdf>. Accessed April 6, 2016.

¹¹ U.S. Administration on Aging. Aging Statistics. Available online at http://www.aoa.acl.gov/aging_statistics/index.aspx. Accessed April 6, 2016.

¹² Nkomo VT, Gardin JM, Skelton TN, et al. Burden of valvular heart diseases: a population-based study. *Lancet* 2006; 368:1005-11.