



Heart Valve
Voice US



Re-imagining the Heart Valve Patient Journey

A Path to Improving Patient Experience
and Outcomes by 2030



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Forward

We all struggle with a healthcare system that is imperfect, if not, at times, completely broken. But for decades, **millions of people around the world with heart valve disease have been dealt a particularly bad hand.**

Not only have they and their families had to deal with burdens of the disease and its complications, but they have had to navigate a complex system that has let them down at almost every turn. The situation is particularly dire for many minority and underserved patient populations.

As a result, the likelihood of a patient getting properly treated is less than 35%.¹ Only 44% of people with clinically significant valve disease are diagnosed properly¹, and less than half of those people are ever treated.^{2,3}

For nearly fifty years, the only treatment option for most was open-heart surgery: frightening for patients and not without its own risks. Because of that, guidelines recommended that doctors only perform surgery if the risk of imminent death outweighed the risks of surgery. “Wait and watch” was a common prescription.

Unfortunately, “wait and watch” is still a common prescription. For example, patients with severe aortic stenosis

have a 50% risk of dying within two years,⁴⁻⁹ greater than many forms of cancer. But do we routinely tell people facing most other life-threatening conditions to “watch and wait?” In many cases, for heart valve patients “watchful waiting” is simply patient neglect.

Why are heart valve patients treated differently? Are the “new,” less-invasive treatments that have been available for almost 15 years any less safe or effective? Are alternatives more expensive? Are patients routinely apprised of all their treatment options? No, many new treatments are preferred by patients, safer, more effective and less costly for healthcare systems.

We think **the problem is how we approach the solution.** Past “solutions” have proposed incremental changes within a broken system.

That’s because we have become so attached to the routines of the past 50 years within the medical establishment that they still dictate how patients should be treated in the “modern” era.

Based on the demands we’ve heard from our patient community in recent years, **we’ve taken a completely different approach.** Instead of restricting our approach to incremental fixes, we are taking our direction from

*34% is a weighted average of mitral and aortic valve disease treatment rates, assuming approximate incidence rates of people between 65-75 years old (2.5% aortic, 6.5% mitral, based on Nkomo, 2005).



our patients and care partners. Instead of making iterative tweaks to how we think about the solution, we propose solutions that start from scratch: **we built a vision for a consumer-friendly approach** that maximizes efficiencies in getting people diagnosed quickly and treated safely, and have laid out action steps to bring us closer to that vision.

In this report we will:

- **Focus on the future** – define a vision for how heart valve patients should be treated.
- **Provide a resource for patients** to navigate the system today so they get closer to this new experience, now.
- **Lay out a plan** aimed at achieving that goal in the U.S. by 2030.

We base these recommendations on input from patients and patient-advocate stakeholders with extensive experience navigating the challenges

of the heart valve disease journey. We have consulted with leading clinicians. This input has provided the lens through which we have considered the thoughtful advice of the experts in our community. Our qualitative and quantitative approach involved interviews, workshops, surveys, and a review of the most recent science to develop the ideal, consumer-experience approach for improving the patient journey.

Please join us on this mission to envision and implement a future **where heart valve disease patients are provided a treatment experience that maximizes health, safety and care.**

John Lewis, Executive Director

Heart Valve Voice US



Executive Summary

Heart valve disease is a condition that should be treated seriously. It is:



Common



Deadly



Costly



Indiscriminate



Growing as the population ages



Treatable

Patients with heart valve disease unnecessarily suffer from significant fear, anxiety and confusion about whether to seek treatment and how to do it as a result of a poorly coordinated healthcare system.

The U.S. healthcare system needs to take urgent, immediate action because heart valve disease is:

- **Undiagnosed: only 44% of patients with clinically significant valve disease are diagnosed¹**
- **Undertreated: only 34% of patients diagnosed with clinically significant valve disease are treated^{2,3}**



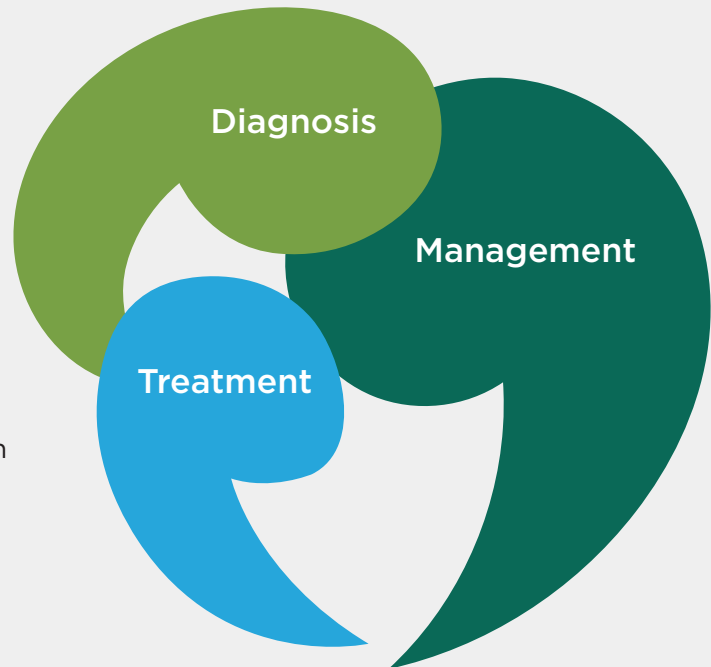
2030 Vision

- 90% of Heart Valve Disease patients will be properly diagnosed

- 95% of patients will be satisfied or extremely satisfied with their outcomes

- 90% of patients will be treated according to their priorities

- > Everyone who is at risk for heart valve disease is screened annually.
- > Positive diagnoses of clinically significant disease are immediately referred to “Heart Support Team” (no watching).
- > Patient chooses treatment using decision-making tools.
- > Multidisciplinary Heart Support Team is involved in ongoing follow-up and monitoring throughout patient’s life, from initial diagnosis, through treatment and beyond.



[†]34% is a weighted average of mitral and aortic valve disease treatment rates, assuming approximate incidence rates of people between 65-75 years old (2.5% aortic, 6.5% mitral, based on Nkomo, 2005).



A Course of Action for 2030

DIAGNOSIS For At-Risk Patients - Goal: Increase the percentage of patients diagnosed from 44% to 90%

Near-Term Solutions (1-5 Years)	Long-Term Solutions (5-8 years)
<ul style="list-style-type: none"> Secure echocardiograms on the list of preventative/screening services for Medicare and actively educate patients and providers to optimize usage Develop echocardiogram reports that would include follow-up recommendations based on guidelines Incentivize rapid adoption of new technologies replacing stethoscopes, as well as artificial intelligence and machine learning Expand American Heart Association’s “Target: Aortic Stenosis” campaign to other valve diseases Increase public education efforts, especially in Black, Hispanic and Rural communities Increase awareness of cardio-oncology among HCPs and patients 	<ul style="list-style-type: none"> Implement an annual screening program for at-risk people, e.g., all people >65; Start with the “Welcome to Medicare” checkup, expanding to annually, as appropriate Support with research showing cost/benefit Develop and implement “Pay for Quality” performance measures Develop and adopt new testing technologies based on blood, biomarkers, genomics, etc

MANAGEMENT For Patients Referred to Treatment - Goal: 95% of patients satisfied or extremely satisfied with their outcomes

Near-Term Solutions (1-5 Years)	Long-Term Solutions (5-8 years)
<ul style="list-style-type: none"> Create a suite of easily accessible resources to help patients manage their ongoing journey throughout their lives Include emotional/psychosocial support within the care continuum and within Heart Team 	<ul style="list-style-type: none"> Improve upon the suite of resources to include interactive tools to help patients navigate their journey Provide reimbursement for qualified peer-to-peer support services Involve patients on the heart valve team Support development of new drug therapies to slow or reverse valve disease Establish formal support structure for care partners



TREATMENT For Diagnosed Patients - Goal: Increase % of patients treated from 34% to 90%

Near-Term Solutions (1-5 Years)	Long-Term Solutions (5-8 years)
<ul style="list-style-type: none">• Develop patient-focused decision-making aids to help patients in assessing their treatment options• Develop an annual report of % of referred patients that are/are not treated (if not, why) to track progress against this goal• Continue and expand the American Heart Association’s “Target Aortic Stenosis” campaign	<ul style="list-style-type: none">• Develop an automated system to regularly alert healthcare providers and patients with reminders• Pay for quality of performance of appropriate referrals upon diagnosis• Adjust coverage and reimbursement decisions to accommodate for patient preferences for risk/benefits• Increase access by facilitating expanded catheterization lab capabilities• Establish easy system to match patients with specialists



The Problem

Heart valve disease is a debilitating condition, with a significant impact on quality of life.¹⁰⁻¹² It occurs when there are structural or functional abnormalities in one or more of the four valves located in the heart (see Box 1).¹³ The resulting disruption of proper blood flow between the chambers of the heart and other organs in the body can cause debilitating symptoms.¹⁰

IMPACT – Heart Valve Disease is:

COMMON, affecting approximately 3.4% of the U.S. population¹⁴, or as many as 11.6 million people.¹⁵ It tends to affect older Americans (one in 10)¹⁶, with mitral valve disease being almost twice as common as aortic valve disease.¹⁶

DEADLY. More than 25,000 Americans die each year.¹⁴ Once diagnosed, a valvular patient's survival is low: fewer than 50% of aortic stenosis patients survive more than two years after the onset of symptoms,⁴ and the average life expectancy of untreated older patients (i.e., those in Medicare) is 1.8 years.¹⁷

COSTLY. Total U.S. healthcare expenditures for heart valve disease in 2016 were \$23.4 billion.¹⁸

INDISCRIMINATE. While the disease is usually a progressive condition, disproportionately impacting older people, it generally affects demographic sub-populations equally, regardless of race, gender, or socioeconomic status, although there is some evidence suggesting that it affects Hispanics more than other groups.¹⁹

GROWING. As the U.S. population ages, the number of people with significant valvular disease is projected to more than double before 2050.¹

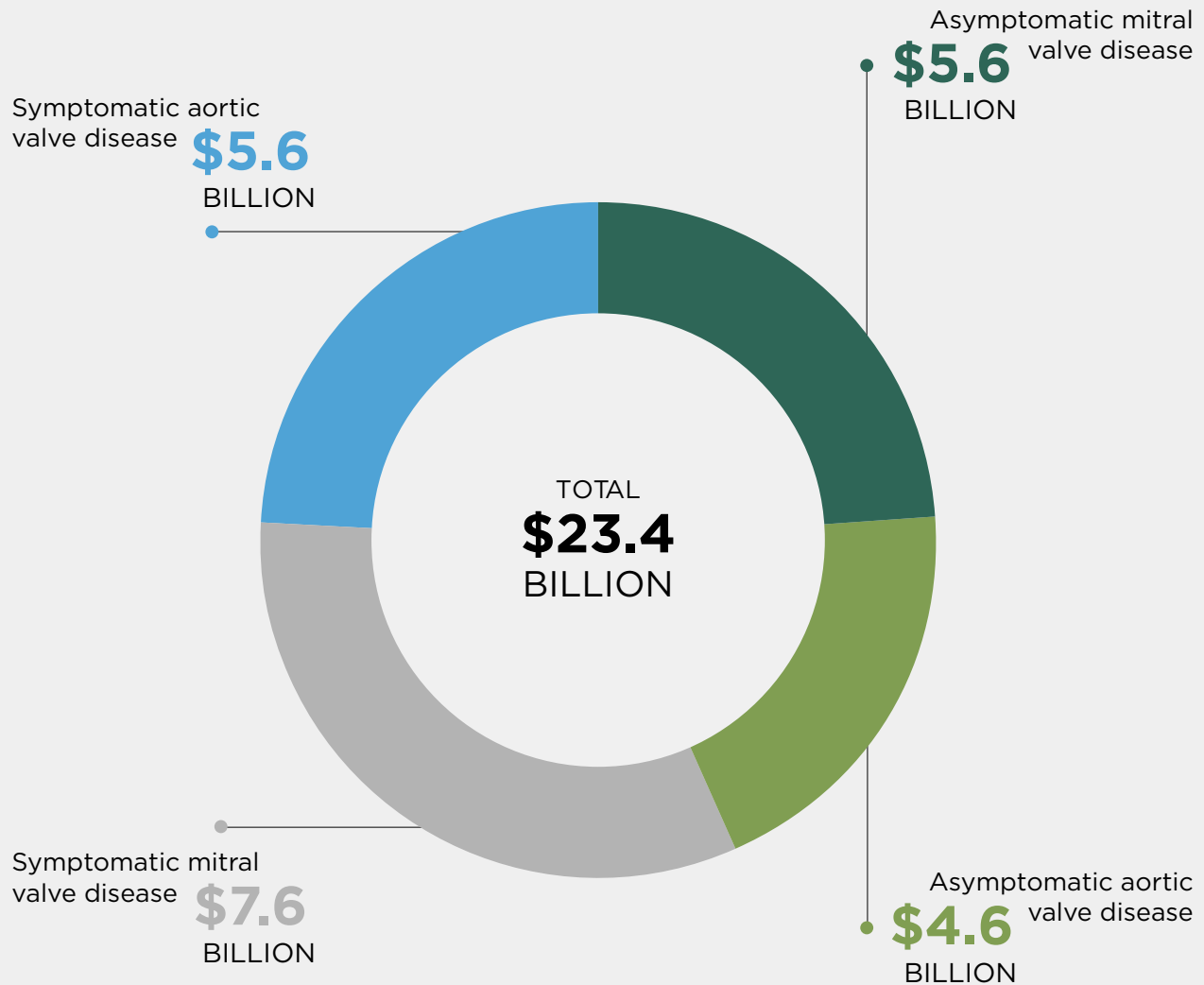
Waiting to treat is expensive and deadly

For every year that patients wait to get treated, costs rise significantly: for example, the total cost per patient for medically managed, severe aortic stenosis almost doubles from \$34,194 to \$63,844 between year one after diagnosis and year five.²⁰ Survival drops an average of 17% each year treatment is delayed.^{20,21}



Economic Burden

TOTAL COST OF HEART VALVE DISEASE IN THE U.S.



1 - GRAPHIC SOURCE: The Silver Book: Valve Disease. Alliance for Aging Research. Accessed October 6, 2022. <https://www.agingresearch.org/document/the-silver-book-valve-disease/>



Treatment - Heart Valve Disease is:

UNDIAGNOSED. More than 56% of people with clinically significant heart valve disease are undiagnosed.¹ That number is projected to increase to 67% before 2050.¹

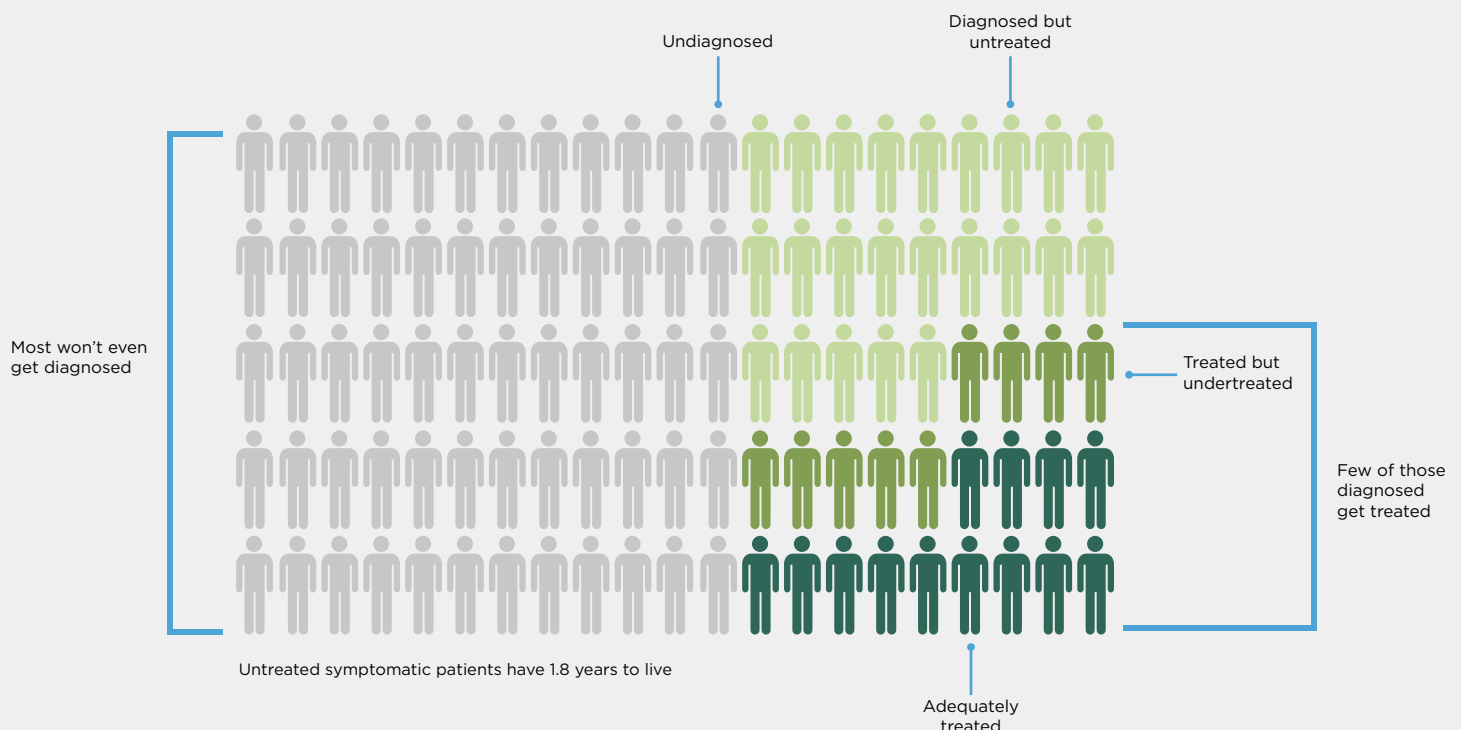
TREATABLE. There are excellent treatment options currently available to repair or replace faulty heart valves through surgical or minimally invasive procedures. Many more innovative treatments are in development. New mitral valve treatments significantly reduce risk of re-hospitalization and death (approximately 50% and 37%, respectively).²⁰ On average, aortic valve replacements reduce the risk of death by 27%.²

UNDERTREATED. Only a small minority of diagnosed patients undergo treatment (29% of mitral valve disease³, 48% of aortic valve disease²)

UNDERTREATED MORE IN WOMEN. Women with aortic stenosis are less likely (37% vs 63%) to be treated than men in the U.S., despite equal prevalence.^{21,22}

UNDERDIAGNOSED MORE IN MINORITIES. Asian and Black patients are 51-68% less likely to be diagnosed than White patients.¹⁹⁻²²

All of these people need to be treated





What is Heart Valve Disease

Heart valve disease results from damage to the valves of the heart.

Heart valves have tissue leaflets, which open and close with each heartbeat to control the direction and flow of blood through the heart (see Figure 1).²⁶ When the leaflets or associated structures become damaged or the valve opening becomes compromised, blood flow is restricted or the valve becomes leaky. This causes strain on the heart as it attempts to compensate.²⁶

Causes of heart valve disease are mostly related to degenerative change due to aging.²⁷ Other risk factors are common to cardiovascular diseases in general and include obesity, high cholesterol and high blood pressure. The presence of other conditions, particularly congenital heart disease, coronary heart disease, cardiomyopathy, endocarditis infection or rheumatic fever, also contributes to heart valve disease.²⁶

Additionally, exposure to radiation treatment to the mediastinum is associated with a risk of radiation-induced heart valve damage characterized by valve fibrosis and calcification, with a latent interval of 10-20 years between radiation exposure and development of clinically significant heart valve disease.²⁸ There are several types of heart valve disease. These are defined based on which of the four heart valves is damaged or malfunctioning and whether it is a case of stenosis, which is a narrowing of the valve space, or regurgitation, which occurs because of improper closure of the leaflets and results in blood leaking backwards into the heart chamber.²⁶ The most common ($\approx 75\%$) forms of heart valve disease affect the mitral and aortic valves,^{1,29} but recent data suggest that tricuspid valve disease is also on the rise.³⁰

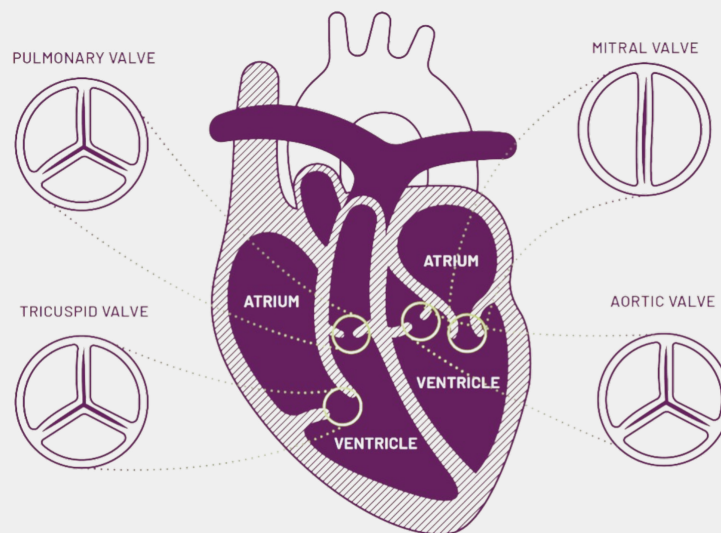


Figure 2 (Source: Global Heart Hub)



Prioritizing the Patient Perspective

Heart valve disease is a complex and life-threatening condition. As a result, **doctors and other healthcare providers have been at the forefront in leading past efforts to address challenges** with patient access, care, and treatment. Treatment guidelines are written by large committees of leading doctors.³¹ Even recommendations for improvement coming from the patient community tend to rely heavily on input and guidance from clinicians.^{32,33} As we write this report, Heart Valve Voice US is consulting with a panel of expert clinicians to leverage their expertise, and ensure our recommendations are responsible in light of the potential impact on people's lives.

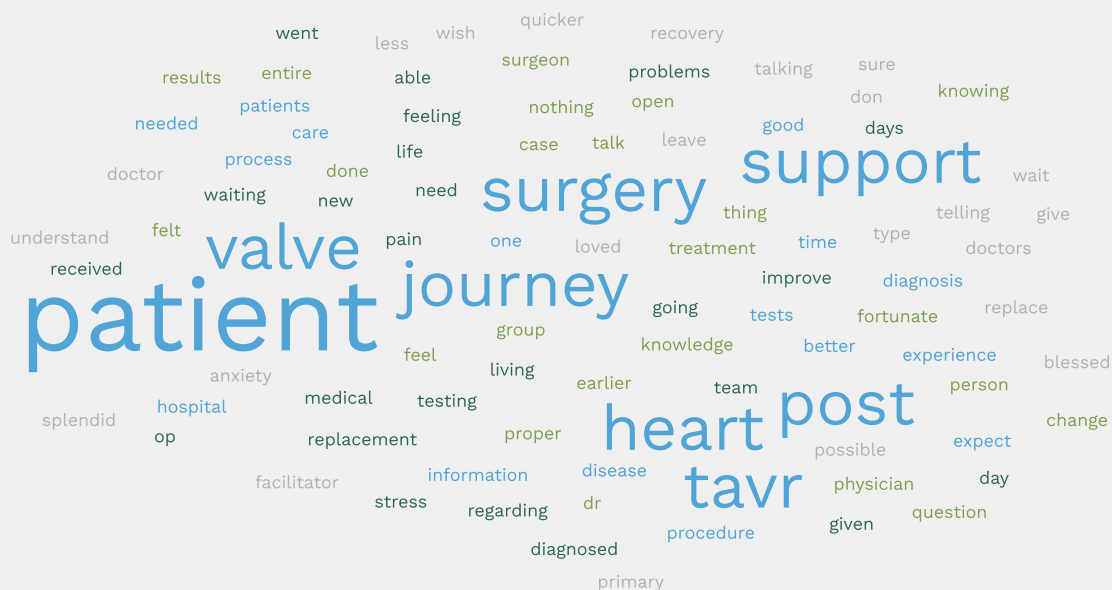
While it is appropriate and necessary to engage expert opinion and input in advancing solutions to the problems outlined in this paper, it is our view that a key reason for lack of sustained progress lies in **how we approach the solution**. Past “solutions” have been proposed by physicians without the significant engagement of patients and caregivers. Our approach is to start with the patient perspective and build our solutions from there, layering in the input of other stakeholders in the heart valve disease ecosystem.



What Patients Tell Us

Based on surveys, interviews and patient preference studies,³² we've heard the following:

- A “Watch and Wait” prescription for heart valve disease patients creates immense confusion and anxiety for patients and their caregivers. They don't know how to react and frequently struggle with what to do next. They are often not provided details on follow up actions or timetables for treatment.
- Addressing patient fear of the unknown and anxiety are patients' highest priority
- There is universal desire for more information and better communication about HVD (including about what to expect post-treatment for rehab and long-term management of the condition)
- Patients have a strong interest in “having a voice” in their care decision-making and being an active part of the care team (accessible and meaningful shared decision-making tools and resources are urgently needed)
- Patients want a strong emotional and psychological support system (including peer to peer connections in the HVD community), especially in the period post-diagnosis and pre-treatment/procedure
- In retrospect, while earlier/more timely diagnosis is important to all, it is not necessarily the case that patients and caregivers would want to have earlier treatment. This underscores the need for risk/benefit-derived decision-making tools.





- Patients believe it is important to address disparities in care, especially implicit bias in the healthcare system and ensuring person-centered care where individuals’ values and perspectives are considered.
- Many patients are willing to tolerate substantial increases in risks (including increased risk of hospitalization, death or stroke) in exchange for other priorities, including fast, independent recovery.
- Beyond the strong need for information and support tools, a common theme among these patient perspectives is that they feel anxious, overwhelmed, and confused.

“Heart disease is a lifetime diagnosis, and we are never really quite cured. We have to have a mentality of a constant state of awareness and a lifetime plan.”

Mark Ridder
AHA Heart Valve Patient Ambassador

“Just plain fear” ***“No one to talk to”***

- “What to do if physician does not listen”***
- “Lack of access to appropriate mental health support post intervention”***
- “Finding a heart specialist to talk to locally”***
- “Separating symptoms from the effects of aging”***
- “Not being told by the Doctor that there are other options besides open heart surgery”***
- “The patient selection process seemed more difficult than necessary”***
- “Not enough time with doctors for explanation and concerns that we have”***

Verbatim statements from September 2022 online survey of HVD patients



Patients/Caregivers Prioritize Need for Education & Support

“Just plain fear”



Awareness

- Lack of patient awareness of the disease and its symptoms
- Lack of info on what to ask doctors about their condition
- No/little access to a patient with disease experience
- Lack of info about treatment options

“I had to insist and fight for a TAVR procedure rather than an open heart procedure”



Clinicians

- Lack of physician awareness of what to look for or recognizing symptoms
- Lack of effective detection/diagnosis of the disease
- Lack of timely referral to specialist

“Lack of access to appropriate mental health support post intervention”



Health System

- Access to care/proximity to doctors
- Insurance coverage
- Too many tests

Relative importance chart based on responses to question: “Please select the top three biggest challenges for patients in the heart valve disease treatment journey” - HVV online survey 157 HVD patients & caregivers, September 2022



What Clinicians Say

We consulted some of the country's leading heart valve disease clinical experts in the development of this report, and in many respects, their perspectives are aligned with those of patients:

- Patients need better resources to know what to expect - we need to develop a “map” that can help guide patients through their journey
- What do they need to know and do at what time points?
- The “ideal” patient journey “map” should be more nuanced - instead of doing one from pre-diagnosis through follow up, break it up into population segments and timing of encounter with the healthcare system (e.g., one journey for an individual with a heart murmur but normal structural heart exam, one journey for an individual with early, pre-symptomatic AS, one for an individual with moderate to advanced AS etc.)
- Improve shared decision-making tools so patients understand their options and what to expect if “watchful waiting” is proposed. Patients need to understand the risks and benefits of moving forward with a procedure. Provide

clearer communication tools for providers to consider how patients feel about recommendations to watch and wait (e.g., the idea of having to get sicker before treatment can occur).

- Include emotional/psychosocial support within the care continuum.

In other regards, the experts are more cautious about how to approach the problem than patients and caregivers.

- Experts appreciate the desire to lay out a vision of a different paradigm, but also caution against “getting out over our skis” in advancing something that is unattainable given current evidence, technology, and healthcare system infrastructure. Might be better to focus on advancing a more discrete, attainable goal (e.g., aim to provide better care to those already diagnosed with advanced AS). For those with certain risk factors or early AS, experts propose improving tracking and monitoring, including incorporating more direction in Echo reports (e.g., follow colonoscopy or mammogram model where the report clearly states when a follow up exam should be done). Use emerging software platforms to



embed these follow up triggers in EMRs so primary care and general cardiology providers have a clear roadmap.

- Experts are not convinced that there is (or could be) sufficient evidence to justify calling for Echo screening for all 65+ individuals (e.g., through Welcome to Medicare or some other mechanism). They would prefer an approach that adds Echo to list of potential tests to be done in Welcome to Medicare when warranted by the initial exam. Likely best to focus on an enriched sub-population (using advanced technologies and tools) among 65+ individuals (including those with other risk factors or symptoms that might be associated with moderate to severe AS).

- An overreliance on use of traditional stethoscope as a diagnostic tool when more advanced, more accurate technologies are becoming available, including those that incorporate artificial intelligence that minimizes variability in diagnosis.
- There is a concern among some experts about the quality and consistency of Echo exams and reports. Clear guidelines and quality improvement measures/metrics are needed.

“Watchful waiting is patient neglect”

Heart Valve Disease Clinician



A Tale of Two Heart Valves

DOROTHY'S EXPERIENCE (2022)

A fictional account of a typical heart valve disease patient experience, derived from hundreds of true stories.

At 65 years old, Dorothy began feeling more tired than usual. Over the course of several months, she found herself breathing heavily when climbing her stairs to bed each evening.

She mentioned it to her doctor, who replied, “well, it’s not like you’re a spring chicken anymore, Dorothy. Maybe you should take it easy.”

TIME TO TREAT: 20 months
COST: \$234,460
HOSPITALIZATIONS: 3
LENGTH OF HOSPITAL/POST-ACUTE CARE: 6.5 months
OUTCOME: 3.5-year survival

[FOR DETAILS SEE APPENDIX]

But Dorothy’s experience got worse over the next six months, to the point where she couldn’t keep up in her daily walks with her neighbor. Her daughter, Keisha, suggested she see another doctor, but Dorothy didn’t want to offend her general practitioner, who she had seen and trusted for years.

Keisha insisted, and helped Dorothy schedule an appointment with a cardiologist. After listening to her heart with a stethoscope, the cardiologist couldn’t hear anything wrong, but suggested Dorothy get an EKG.

After eight months of different tests, Dorothy’s energy levels were at an all-time low and she was having a hard time breathing. Doctors had prescribed blood thinners and “water pills” (diuretics) to deal with some increased fluid in her lungs. She had visited the hospital twice out of fear and concern about her health.

Then a friend of hers suggested she see his doctor and ask about a possible heart valve problem. After waiting two months to get an appointment, Dorothy was finally seen by another cardiologist who ordered an echocardiogram, a scan of Dorothy’s heart. This test revealed she was suffering from severe aortic stenosis and moderate mitral valve regurgitation that may have caused her to have an enlarged heart. Dorothy’s new doctor speculated that this condition had been developing over several years.

Dorothy was immediately referred to open-heart surgery where her aortic valve was replaced, and her mitral valve repaired. After a couple of weeks in the hospital intensive care unit and another few weeks in recovery, Dorothy was discharged to a cardiac rehabilitation facility where she struggled for six months to recover.

A year later, Dorothy was feeling better, and was once again able to walk with her friend around the block. But one day, her daughter Keisha discovered Dorothy had passed away in her sleep after a heart attack.



A Tale of Two Heart Valves

JUAN'S EXPERIENCE (2032)

A fictional account of a future state, based on the vision articulated in this report.

At 58 years old, Juan was entering the last few years of his career at the state university, where he taught undergraduate physics. As a condition of his annual physical and the “know your numbers” campaign run by his employer and health insurance company, Juan’s general practitioner used a portable heart scanning device to determine if Juan had any heart issues.

The device indicated that Juan may have a structural heart defect and provided Juan and his doctor with a link to a site that could allow them to evaluate their options.

TIME TO TREAT: 4 DAYS

COST: \$72,991

HOSPITALIZATIONS: 1

LENGTH OF HOSPITAL/POST-ACUTE

CARE: 1 DAY

OUTCOME: 23.2-year survival

[FOR DETAILS SEE APPENDIX]

Juan went home that evening, filled out the form with the help of his wife and son, and woke up the next morning with a call from his doctor’s office to tell him that based on Juan’s current condition, his personal preferences, and his options, Juan was an immediate candidate for a heart valve repair.

Juan was offered the names and phone numbers of other people like him who opted for various treatments. Juan spoke to several of them, and after another conversation with his doctor, decided to pursue the treatment option that seemed right for him.

Within a week, Juan went in for his procedure, which was conducted at the hospital, but allowed him to return home that evening.

Juan went on to live a normal, healthy life: he retired from teaching seven years later and spent the next 20+ years with family and friends, occasionally volunteering as a peer reviewer for the American Journal of Physics.



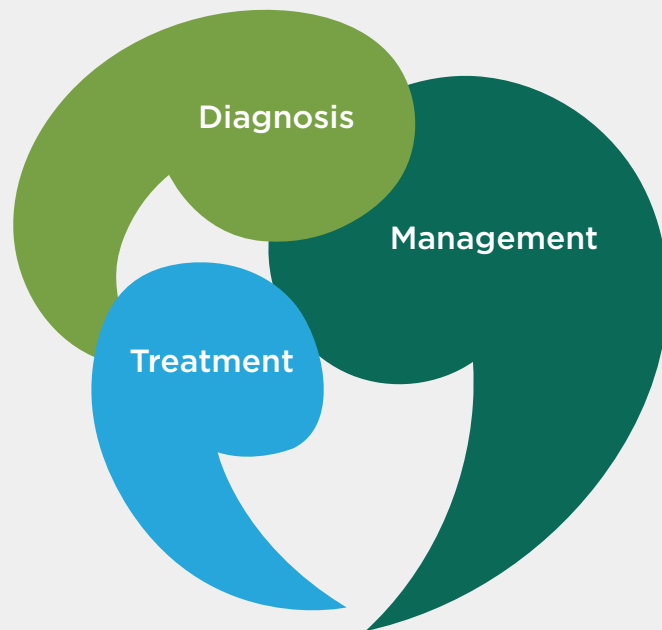
A Vision for the Future

THE IDEAL APPROACH TO MANAGING HEART VALVE DISEASE PATIENTS

In 2030:

- > Everyone who is a candidate for heart valve disease is screened each year with new technologies through community-based outreach that immediately diagnose HVD.
- > Positive diagnoses of clinically significant disease are immediately referred to "Heart Support Team."
- > Patient chooses treatment, in consultation with heart team, using decision-making tools that match their preferences with appropriate treatment options.
- > Multidisciplinary Heart Support Team* is involved in ongoing follow-up and monitoring from diagnosis, through treatment and throughout patient's life.

*The Multidisciplinary Heart Team will be expanded to include "Support" as a key, to address the non-clinical needs of the patient and their families.



Once patients have been diagnosed, they remain in a state of vigilant and regular management of their disease through the rest of their lives. Depending on the severity of their disease, they may get treated multiple times with different kinds of treatments. Or they could live a long, high quality life without any further intervention.



A Map to Help Guide Patients in Their Journey

Patients are clear that they need new, better tools to help them navigate their journey. This report is focused on providing the healthcare system with recommendations on how to improve that journey, but one of those recommendations includes developing new, patient-friendly tools. One advocate suggested a “Google Maps” for patients. In the development of this report, Heart Valve Voice US has identified as many as two dozen different checklists and tools to help patients ask the right questions and understand what to expect. Many of these tools are available on the Heart Valve Voice US’s Resources web page (<https://www.heartvalvevoice-us.org/resourcesforyourjourney/>). A top priority for Heart Valve Voice US and the patient community is to update and consolidate these resources into one location or app that can be shared and referenced by all relevant stakeholders, including hospitals, doctors, and other patient organizations.

An “ideal” patient resource would be:

- Customizable variables matching the individual’s unique situation (disease type, stage or severity of disease).
- Clear language using lay terms, accessible to people from wide range of backgrounds, cultures, literacy levels and languages.
- Easy-to-understand resources to explain the disease, treatment

options and what to expect.

- Step-by-step guides and timelines to help patients understand what decisions they will have to make and when.
- Links to decision-making tools that can help patients identify and share their goals and preferences with their doctors.
- Short, specific and relevant lists of questions to ask their doctors to ensure their diagnosis and treatment follow appropriate guidelines.
- Ability to integrate with existing tools on any platform, including options for accessibility.
 - This could include development of an SMS-text system for people without access to smart phones or computers.
 - Alternatively, for patients without access to cell phone technology, a system that involves automated phone calls to patients, who could use voice menus to connect with additional resources.
 - Options for those who are visually or hearing impaired.

Depending on patient preference, these tools can be delivered in traditional format, be internet-based, or mobile apps. Care partners would also have access and custom support services available.



A New Roadmap

A truly patient-centered system will take time and resources to develop. In the meantime, Heart Valve Voice US has identified this “Minimally Operable Decision-Tree” made of questions patients should ask themselves and their doctors to ensure they get diagnosed and on the road to treatment:

1. Have you experienced an increase in any of these symptoms over the last two months?

- Fatigue
- Pain, tightness, or pressure in the chest
- Lightheadedness or dizziness
- Shortness of breath
- Fainting

If yes, ask your doctor:

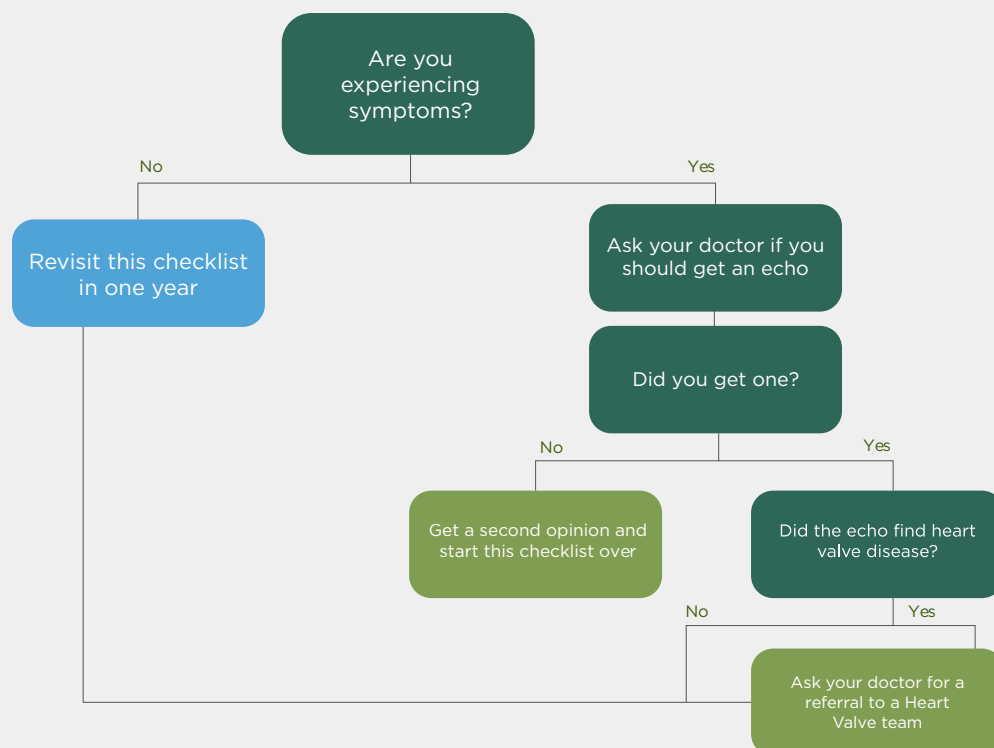
2. “Given that I am symptomatic for heart valve disease, will you refer me for an echocardiogram reviewed by a heart valve specialist?”

If you are diagnosed with heart valve disease by a heart valve specialist, ask your doctor:

3. “Are you a member of a certified Heart Team?”

4. “If not, will you refer me to an interventional cardiologist or heart surgeon who is a member of such a team?”

If your doctor is not aware of what a heart team is or of any other physicians associated with a heart team, find a new doctor.





A Course of Action: Recommendations

DIAGNOSIS For At-Risk Patients

Goal: Increase the percentage of patients diagnosed from 44% to 90% by 2030

Problem: only 44% of patients with clinically significant valve disease are diagnosed¹ BECAUSE:

- Anyone could have HVD but not everyone is screened for it
- Existing diagnostic tools fail to provide clinicians actionable information/direction
- Lack of patient and physician awareness of symptoms and disease reduces opportunity to trigger physicians detection efforts
- We lack simple, inexpensive systems to proactively find sick patients
- Health care reimbursement systems fail to reward care coordination
- Lack of consistent quality of current diagnostic tools
- Listening to a patient's heartbeat with a stethoscope (auscultation) is ineffective in detecting HVD (ranging from 67% to 83% effective⁴⁵)
- Lack of evidence to convince healthcare systems of needed change

Near-Term Solutions (1-5 Years)

- Secure echocardiograms on the list of preventative/screening services for Medicare
- Develop echocardiogram reports that would include follow-up recommendations based on guidelines.
 - Use emerging software platforms to embed these follow up triggers in EMRs so primary care and general cardiology providers have a prompt for referral (shown to improve referrals by 25%⁴⁶)
 - Include triggers to notify patients directly for 1, 2, 3-year follow-up for more mild cases, as appropriate
- Incentivize rapid adoption of new technologies replacing stethoscopes, as well as artificial intelligence and machine learning diagnostic tests to justify increased population screening, staged by age cohort Expand American Heart Association's "Target: Aortic Stenosis" campaign to other valve diseases
- Annual updates to OxVALVE study in US to track progress on goal

Long-Term Solutions (5-8 years)

- Implement an annual screening program for at-risk people, e.g., all people >65; Start with the "Welcome to Medicare" checkup, expanding to annually, as appropriate
- Develop and implement "Pay for Quality" performance measures
 - Develop and implement cheaper, more reliable, and easy-to-use diagnostic systems³⁵
 - Pay physicians to perform annual HVD exams
 - Make HVD training a regular practice in CME courses
 - Develop a quality measure to pay for performance of diagnosis
 - Reimburse physicians for "finding" patients
 - Develop clear guidelines and quality improvement measures/metrics
- Develop and adopt new testing tools based on blood, biomarkers, genomics, etc.



<ul style="list-style-type: none">• Increase public education efforts, especially in Black, Hispanic and Rural communities<ul style="list-style-type: none">◦ Provide patient organizations resources to execute credible, cost-effective public education campaigns◦ Secure public funding to support public education campaigns◦ Increase awareness of cardio-oncology among HCPs and patients	<ul style="list-style-type: none">• Perform healthcare economics studies to determine:<ul style="list-style-type: none">◦ Cost/benefit analysis of population-based screening◦ Ideal price/payment for diagnostic tests to justify increased population screening, staged by age cohort
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Considerations

- Healthcare professional experts appreciate the desire to lay out a vision of a different paradigm, but also caution against “getting out over our skis” in advancing something that is unattainable given current evidence, technology, and healthcare system infrastructure. This suggests that it might be better to focus on advancing more discrete, attainable goals (e.g., aim to provide better care to those with advanced AS).
- Healthcare professional experts are not convinced that there is (or could be) sufficient evidence to justify calling for echocardiogram screening for all 65+ individuals (e.g., through Welcome to Medicare or some other mechanism). They

would prefer an approach that adds echocardiogram to list of potential tests to be done in Welcome to Medicare when warranted by the initial exam. They recommend that it would be best to focus on an “enriched” sub-population (using advancing technologies and tools) among 65+ individuals (including those with other risk factors or symptoms that might be associated with moderate to severe AS).



MANAGEMENT For Patients Referred to Treatment

Goal: By 2030, 95% of patients satisfied or extremely satisfied with the outcomes of their treatment

Problem: patients and their families confronted with an HVD diagnosis suffer from intense fear, anxiety, and unsatisfactory treatment experience, BECAUSE:

- Patients are frequently not part of the decision-making process
- Patients generally don't know what to expect or what to ask their doctors about their condition
- Many physicians don't communicate effectively with their patients

- Patients often don't have people to talk to who would understand what they are going through
- Patients frequently experience depression and anxiety peri- and post-treatment; they lack mental health/emotional support, especially at time of diagnosis and pre-procedure
- There is a wide range of experiences
- Patients report barriers to streamlined care management over the lifespan of their condition due to the complexity of decision-making^{48,49}

Near-Term Solutions (1-5 Years)

- Create a suite of easily accessible resources to help patients manage their ongoing journey throughout their lives
 - Establish system to match patients with others who have been successfully treated
 - Develop easy-to-use, online shared decision-making tools that patients can complete on their own, then use to have an informed discussion with their physicians
 - Create an annually updated, online checklist of questions to ask doctors after a patient has been diagnosed with heart valve disease
 - Develop discussion guides to help clinicians better seek what patients' priorities are
 - Provide clearer communication tools for providers to consider how patients feel about recommendations to watch and wait (e.g., having to get sicker before treatment can occur)
 - Develop "Find a doctor/hospital" tool (with quality metrics)
- Include emotional/psychosocial support within the care continuum

Long-Term Solutions (5-8 years)

- Improve upon the suite of resources to include interactive tools to help patients navigate their journey
 - Develop disease & treatment-specific "patient journey" companion tools (online, apps, or other medium) to help guide patients through the process
 - Provide patients with access to systems and reminders to follow-up on their care
- Provide financial reimbursement for qualified peer- to-peer support services
- Involve patients on the heart valve team
- Support development of new drug therapies to slow or reverse valve disease
- Develop metrics to measure patient satisfaction
- Establish formal structure for care partners



TREATMENT For Diagnosed Patients

Goal: Goal: Increase % of patients treated from 34% to 90% by 2030

Problem: only 34% of patients diagnosed with clinically significant valve disease are treated^{2,3} BECAUSE:

- Most patients lack understanding of the dangers of HVD
- Patients often inaccurately or inconsistently track their symptom progression
- Many physicians lack of understanding of the dangers of HVD:
- While general cardiologists believe they have explained the condition sufficiently to patients, most patients don't fully understand their disease
- There is no standardized assessment and management approach for heart valve disease in cardiovascular care settings⁵⁰
- Early stages of disease may not require immediate action, but there is a lack of follow-up due to poorly coordinated systems
- Evidence to convince healthcare systems of needed changes is lacking
- Patients may not have access to high quality clinicians or facilities

Near-Term Solutions (1-5 Years)

- Develop patient-focused decision-making aids to help patients in assessing their treatment options
 - Develop “best of” online treatment options guide, implement campaign to centralize those resources
 - Develop an online risk/benefit decision-making tool
 - Develop discussion guides that can help physicians talk to patients about the risks/benefits of treatment options
- Develop an annual report of % of referred patients that are/are treated (if not, why) to track progress against this goal
- Continue and expand the American Heart Association’s “Target Aortic Stenosis” campaign

Long-Term Solutions (5-8 years)

- Develop an automated system to regularly alert healthcare providers and patients with reminders to complete ongoing monitoring/diagnostics
- Pay physicians for quality of performance of appropriate referrals upon diagnosis
 - Develop quality measure to track delays in diagnostic testing and treatment
 - Reward (or punish) physicians who order diagnostic tests that are/are not followed-up
 - Develop a centralized registry of echocardiograms to help monitor disease progress and treatment rates
- Adjust coverage and reimbursement decisions to accommodate for patient preferences for risk/benefits
- Increase access by facilitating expanded catheterization lab capabilities
- Establish easy system to match patients with Heart Team or HVD specialists

³34% is a weighted average of mitral and aortic valve disease treatment rates, assuming approximate incidence rates of people between 65-75 years old (2.5% aortic, 6.5% mitral, based on Nkomo, 2005).



Appendix: Analysis of Dorothy & Juan’s hypothetical stories

Parameter	Cost Adjusted to 2022	Source	Parameter	Cost Adjusted to 2022	Source
GP Appointment	\$150.00	est	Pre-op appt (2)	\$300.00	est
EKG	Not available				
10 months of med mgmt	\$37,091.05	35			
2 hospitalizations	\$31,791.58	36			
Cardiologist appt	\$250.00	est			
Echo	\$475.58	37	Portable echo		
Procedure & Admission Cost (NOTE 1)	\$100,955.48	43	Procedure & Admission Cost (NOTE 2)	\$ 72,215.14	43
IC stay (a few weeks)	\$52,419.42	39			
Cadiace rehab (6 mos.)	\$11,327.12	40			
Misc. testing (8 mos.)	Not available				
Cost of heart attack death	Not available				
Dorothy’s costs:	\$234,460.13		Juan’s costs:	\$ 72,990.62	
Dorothy’s outcome:	3.5 years		Juan’s outcome:	23.21	
5 year mortality rate following SAVR in high risk patient	62.400%	41	1 year prob of death following low-risk TAVR	0.995%	44
66 year old female life expectancy	19.89	42	58 year old male life expectancy	23.21	42
NOTE 1: High-Risk SAVR (risk from Log Euro score) - median LOS = 11 days (hospital stay)			NOTE 2: Low-Risk SAVR (risk from Log Euro score) - median LOS = 2 days		



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