

Cost-Effectiveness of Referring Patients to Centers of  
Excellence for Mitral Valve Surgery

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# **Cost-Effectiveness of Referring Patients to Centers of Excellence for Mitral Valve Surgery**

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## **ABSTRACT**

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### **BACKGROUND**

The 2014 American Heart Association/American College of Cardiology Valvular Heart Disease Guidelines state that mitral valve diseases should be repaired at a Center of Excellence (CoE).

We evaluate the cost-effectiveness of such referrals.

### **METHODS**

We estimate patients' life expectancy based on projected survival of patients after mitral valve surgery and develop a cost model to calculate short- and long-term benefits and costs to both patients and payers. Benefits include increased life expectancy and avoidance of medical complications for patients. Short-term costs include all upfront payments by patients and payers at the time of discharge. Long-term costs include all payments associated with the condition that prompted the surgical procedure incurred during the remainder of a patient's life. We assess cost-effectiveness of treating patients at CoEs vs non-CoEs according to patients' age and major comorbidities.

### **RESULTS**

Full implementation of the guidelines would result in 9% increase in the number of patients obtaining mitral valve repair instead of valve replacement, 2.2% to 4.8% reduction in mortality,

3.0% to 3.9% reduction in reoperation, 3.9% to 6.8% reduction in stroke, and an average gain of 1 to 4 months life expectancy, depending on patient's age and comorbidities. Choosing a CoE also results in financial savings to payers for younger and healthier patients (i.e., aged 50-70 with no comorbidities, and aged 50-60 with hypertension), due to avoidance of the costs of future complications. Overall societal benefits are positive for all age groups and all major comorbidities except patients over 80 with heart failure, renal disease or atrial fibrillation.

## **CONCLUSION**

Patients benefit from mitral valve surgery at a CoE under all situations. Payers may incur additional short-term costs when patients are referred to a CoE, but these are partially or fully offset by long-term savings. Redesigning co-pay structures and/or refining the set of patients who are referred to CoEs could better align the incentives of patients and payers and achieve a more desirable social outcome.

Mitral valve disease is the most common form of heart valve diseases in US, affecting 5% of the population and resulting in 500,000 hospital admissions per year.<sup>i</sup> Mitral valve repair and replacement are two different cardiac surgical operations to treat stenosis or regurgitation of the mitral valve. Existing literature indicates that mitral valve repair is superior to mitral valve replacement for degenerative mitral insufficiency because it offers better survival, fewer complications and lower costs.<sup>1,2,3,4</sup>

For purposes of our analysis, we define a Center of Excellence (CoE) as a medical center that performs more than 100 mitral valve procedures per year and is listed in the top 50 cardiac programs in the 2014 US News ranking.<sup>ii</sup> Despite the strong reputation of CoEs, our analysis of 3,397 patients with elective mitral valve diseases in New York from 2008-2012 shows that only 37% chose a CoE for mitral valve surgery. We estimate that the average risk-adjusted repair rate is 63% at a CoE and 54% at a non-CoE, which implies that 306 patients who could have had their mitral valve repaired instead received a less desirable valve replacement.

Recently, the 2014 American Heart Association/American College of Cardiology Valvular Heart Disease Guidelines called for referrals of patients to a CoE for a higher chance of repair.<sup>iii</sup> The main objective of this study is to estimate the incremental health gains as well as costs and benefits to payers of this type of referral strategy.

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<sup>i</sup> <http://heartvalvedisease.nm.org/mitral-valve-disease.html>

<sup>ii</sup> <http://health.usnews.com/best-hospitals/rankings/cardiology-and-heart-surgery?page=5>

<sup>iii</sup> Thoracic Surgery News, Nov 2014.

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## METHODS

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### HOSPITAL QUALITY AND PATIENT CHOICE

This study uses data from the New York State Inpatient Database, which includes 10 million discharges from all hospitals in New York State from 2008-2012. We identified discharges related to isolated mitral valve procedures through its clinical codes 35.12, 35.13 and 35.24 based on International Classification of Disease (9<sup>th</sup> revision) and focus on only elective cases. Patients were excluded if they were less than 30 years old, had coronary revascularization, congenital heart disease, excision of ventricular aneurysm, replacement of thoracic aorta, aortic fenestration procedure, closed heart valvuloplasty, heart transplant, or other valvular repair or replacement.<sup>5</sup> Patients were also excluded if they travelled from other states to New York or if they were Native (less than 1% of the sample). This resulted in 3,397 patients treated in 35 hospitals over the five year interval.

To measure the quality gap among hospitals, we used a probit model with procedure type (i.e., repair or replacement) as the dependent variable. Included in the probit model were independent variables of patients' demographics, insurance type and comorbidities. Because the literature suggests hospital volume is often a significant indicator of superior hospital quality,<sup>1,4,5,6</sup> we also included the volume of mitral valve procedures as an explanatory variable of hospital repair rate. Furthermore, since patients are not randomly assigned to hospitals, we cannot compare observed repair rates between hospitals. To correct for a potential selection bias if patients who are more likely to benefit from a high-volume hospital are also more likely to choose a high-volume hospital, we constructed a distance-based instrumental variable, which correlates with the probability of choosing a high-volume hospital but not with patient characteristics.<sup>7</sup>

To understand what factors affect patients' choices of hospitals, we used a probit model with the choice of a CoE vs a non-CoE as the dependent variable. The independent variables are patient demographics, payers, extra travel distance to the nearest CoE and a dummy indicating whether the patient has a local (i.e., within 5 miles) CoE.

## **COST-BENEFIT MODEL**

To evaluate the impact of hospital choice we constructed a model to characterize short- and long-term costs to both patients and payers. Based on the steps and contingencies associated with mitral valve diseases (see Figure S1 in the Supplementary Appendix for a schematic), our model includes: (1) travel cost, (2) procedure cost, (3) cost of reoperation, (4) cost of stroke, (5) cost of bleeding, (6) cost of maintenance (i.e., warfarin for anticoagulation) for mechanical valve replacement, and (7) cost of Structural Valve Deterioration (SVD) for biological valve replacement. We estimated these costs for patients without comorbidities, which we refer to as “standard” patients, and for patients with common comorbidities, including heart failure, chronic lung disease diabetes, hypertension, and renal disease.<sup>4</sup>

Costs to patients associated with treatment in a given hospital were calculated as:

$$\begin{aligned} \text{Costs to Patients} = & \text{Cost of Operative Mortality} + \text{Cost of Long-term Survival} + \text{Cost of} \\ & \text{Reoperation} + \text{Cost of Stroke} + \text{Cost of Bleeding} + \text{Cost of Maintenance} + \text{Cost of SVD} + \\ & \text{Travel Cost} \end{aligned}$$

We evaluated each term in the patient cost function in terms of expected changes in Quality Adjusted Life Years (QALY) induced by the procedure. For example, Cost of Operative Mortality refers to expected loss of QALY caused by the possible outcome of operative death.

Similarly, costs to payers were calculated as:

*Costs to Payers = Procedure Cost + Cost of Reoperation + Cost of Stroke + Cost of Bleeding + Cost of Maintenance + Cost of SVD*

We evaluated each term in payer cost function by calculating the net present value of payments incurred using a 5% discount factor.<sup>iv</sup>

Finally, for both patients and payers, *the net benefit from a CoE* was calculated as the difference between the expected cost at a non-CoE hospital and that at a CoE.

## **MODEL ELEMENTS**

Because no single source or paper contains all the data required in our model, we drew from several sources in the medical literature to estimate the needed parameters. When necessary, we supplemented the literature review with estimates from existing datasets including Society of Thoracic Surgeons (STS) National Database and National Inpatient Sample Data. All costs and benefits were converted into 2014 US dollars. Table 1 summarizes the sources for each model element for patients of different ages, with and without comorbidities. Please refer to the Supplementary Appendix for details.

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<sup>iv</sup> [http://www.irs.gov/irb/2014-47\\_IRB/ar12.html](http://www.irs.gov/irb/2014-47_IRB/ar12.html)

**Table 1. Sources of Model Elements**

<b>Model Elements</b>	<b>Resources*</b>
Repair Rate	Daneshmand et al. 2010 <sup>2</sup> , Vassileva et al. 2013 <sup>4</sup>
Operative Mortality	STS Risk Calculator, NIS 2008-2012†
Long-term Survival	Ray et al. 2006 <sup>8</sup> , Daneshmand et al. 2010 <sup>2</sup> , Gelsomino et al. 2011 <sup>9</sup> , Daneshmand et al. 2009 <sup>10</sup>
Procedure-related Reoperation	Dumon et al. 2007 <sup>11</sup> , STS Risk Calculator
Stroke	Russo et al. 2008 <sup>12</sup> , National Institute of Neurological Disorders and Stroke
Bleeding	Keneko et al. 2014 <sup>13</sup> , Chikwe et al. 2011 <sup>14</sup> , Ailawadi et al. 2008 <sup>15</sup> , LaPar et al. 2010 <sup>3</sup>
Maintenance	<a href="http://health.costhelper.com/valve-replacement.html">http://health.costhelper.com/valve-replacement.html</a>
Structural Valve Deterioration	Bourguignon et al. 2014 <sup>16</sup>
Procedure Cost	Medicare Provider Utilization and Payment Data, NIS 2008-2012
Travel Cost	Paulsen et al. 2015 <sup>17</sup>

\*A detailed literature review is provided in the Supplementary Appendix.

†STS Risk Calculator incorporates the STS risk models that are designed to serve as statistical tools to account for the impact of patient risk factors on operative mortality and morbidity. National Inpatient Sample database is the largest U.S. database of inpatient hospitals that incorporates data from all payers.



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## RESULTS

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### HOSPITAL CHOICE

Among the 3,397 patients in our analysis, 1,269 (37.4%) chose a CoE (see Table 2). This percentage varied significantly with patients' distance to a nearest CoE, suggesting distance was an important factor affecting how patients chose hospitals. Among the 867 patients who had a CoE within 5 miles from their nearest hospital, 68% chose a CoE. Among those who did not have a CoE within 5 miles from their nearest hospital, only 27% chose a CoE. The mean ages of patients who chose non-CoEs and CoEs are almost the same (65.2 vs 64.6, p-value of 0.073). However, compared with CoEs, non-CoEs treated a higher percentage of patients in their 70s (28.7% vs 24.8%, p-value of 0.007) and a higher percentage of patients with insurance type Medicare (51.8% vs 48.5%, p-value of 0.029) and Medicaid (7.8% vs 6.3%, p-value of 0.052). There was no significant difference between CoEs and non-CoEs in terms of patients' gender and race.

**Table 2. Characteristics of Patients Treated at CoEs and non-CoEs\***

Variable	Non-CoE	CoE†	P-Value
<b>Age (mean)</b>	65.2	64.6	0.073
Below 50	11.5% (245)‡	14.2% (180)	0.989
50-60	20.3% (432)	19.1% (242)	0.192
60-70	27.1% (576)	27.9% (354)	0.700
70-80	28.7% (611)	24.8% (315)	0.007
Above 80	9.7% (210)	11.8% (150)	0.963
<b>Gender</b>			

Female	36.5% (776)	35.2% (447)	0.233
Male	42.8% (910)	45.9% (583)	0.965
Unknown	20.8% (442)	18.8% (239)	0.086
<b>Race</b>			
White	78.3% (1666)	64.5% (819)	0
Black	7.7% (164)	7.2% (91)	0.283
Hispanic	4.7% (99)	7.2% (92)	0.999
Asian	2.3% (50)	2.0% (25)	0.233
Other Race	7.0% (149)	19.1% (242)	1.000
<b>Insurance</b>			
Medicare	51.8% (1103)	48.5% (615)	0.029
Medicaid	7.8% (166)	6.3% (80)	0.052
Private	37.4% (795)	44.3% (562)	1.000
Self-Payer	0.4% (9)	0.7% (9)	0.867
Other	2.6% (56)	0.2% (5)	0
<b>Extra Distance to CoE</b>			
Less than 5 miles	13.2% (280)	47.0% (596)	1.000
More than 5 miles	86.8% (1848)	53.0% (673)	0
<b>Total Number</b>	<b>62.6% (2,128)</b>	<b>37.4%(1,269)</b>	

\*This summary is based on New York State Inpatient Database 2008-2012. Non-elective cases were excluded. Patients were excluded if they were less than 30 years old, had coronary revascularization, congenital heart disease, excision of ventricular aneurysm, replacement of thoracic aorta, aortic fenestration procedure, closed heart valvuloplasty, heart transplant, or other valvular repair or replacement.<sup>5</sup> Patients were also excluded if they travelled from other states to New York or they were Native.

†This study includes 35 NY hospitals, out of which 5 had volume of more than 100 mitral valve procedures per year and was listed in the top 50 cardiac program in the 2014 US News ranking. These five hospitals are called CoEs in this study.

‡Percentage of patients in each age group and number of cases (in bracket).

Table 3 (left) summarizes the estimation results of the patient choice model and shows how patient characteristics, payer, travel distance and proximity to a CoE affected the likelihood of choosing a CoE. We see that compared with white patients, patients of other races were less likely to choose a CoE. Compared with patients with private insurance coverage, those with Medicare and Medicaid were also less likely to choose a CoE. The probability of choosing a CoE decreased as the extra travel distance to the nearest CoE increases. Whether a patient had a local CoE significantly affected his/her likelihood of choosing a CoE. But we did not find age, gender and major comorbidities to play a significant role in affecting patients' choice of a CoE.

<b>Table 3. Impact of Patient Characteristics, Comorbidities, Payer and Distance</b>					
<b>Category</b>	<b>Variables</b>	<b>On Choice of A CoE<sup>†</sup></b>		<b>On MV Repair Rate<sup>††</sup></b>	
		<b>Coeff.</b>	<b>S.E.</b>	<b>Coeff.</b>	<b>S.E.</b>
Demographics	age	-0.003	0.003	-0.019 ***	0.003
	female	-0.029	0.061	-0.249 ***	0.050
	unknown gender	0.085	0.075	-0.198 ***	0.060
	black	-0.526 ***	0.097	-0.245 ***	0.087
	hispanic	-0.257 **	0.106	-0.296 ***	0.100
	asian	-0.789 ***	0.159	-0.444 ***	0.153
	others	0.486 ***	0.087	0.043	0.075
Payer	Medicare	-0.165 **	0.078	-0.156 **	0.064
	Medicaid	-0.35 ***	0.110	-0.272 ***	0.093
	Self	-0.082	0.355	-0.612 **	0.303
	Other	-0.821 **	0.378	0.074	0.174
Comorbidities	heart failure	0.364	0.326	-0.080	0.268

	lung disease	-0.074	0.074	-0.188 ***	0.060
	diabetes	-0.106	0.079	-0.127 **	0.064
	hypertension	-0.008	0.057	0.052	0.047
	renal disease	0.077	0.095	-0.216 ***	0.077
Proximity	extra dist. to a CoE	-0.015 ***	0.001		
	CoE in 5 miles	0.241 ***	0.062		
Mitral Volume				0.003 ***	0.001
	Constant	0.677 ***	0.183	1.533 ***	0.156

\*\*\* p<0.01, \*\* p<0.05, \* p<0.1

†A probit model was used for the analysis of patient choice of a CoE vs. a non-CoE. The dependent variable is whether a patient chose a CoE. Independent variables are patient demographics, insurance type, comorbidities, distance and proximity to a CoE. The baseline group has the following characteristics: male, white, private insurance, no comorbidities, and no CoE in local.

††A probit model was used for the analysis of MV repair rate. The dependent variable is whether a patient received mitral valve repair. Independent variables are patient demographics, insurance type, comorbidities, and hospitals' mitral volume. The baseline group has the following characteristics: male, white, private insurance, and no comorbidities. Distance is used as an instrument for mitral volume to correct for the potential selection bias that patients who choose high-volume hospitals are also those who are more likely to benefit from high-volume hospitals.

## REPAIR RATE

The likelihood of receiving a repair was influenced by both hospital and patient characteristics. From Table 3 (right), we see that hospitals with high mitral volume had significantly higher repair rates. Consequently, after correcting for potential selection bias, our analysis shows that visiting a CoE (which is high volume by definition) instead of a non-CoE resulted in an average increase in the probability of mitral valve repair by around 9%. However, several patient characteristics, including old age, and comorbidities of chronic lung disease, diabetes, and renal failure, directly reduced the chance of mitral valve repair. Other patient characteristics, such as female gender and non-white race, as well as having Medicare, Medicaid or self-pay coverage,

reduced the likelihood of receiving a mitral valve repair indirectly by reducing the probability of choosing a CoE.

## LIFE EXPECTANCY

Our model estimates that the average life expectancy a patient gained from going to a CoE instead of a non-CoE ranged from 1-4 months depending on patients' age and comorbidities (Table 4, top). Generally speaking, patients in their 70s benefited the most. However, existence of comorbidities reduced the benefits from a CoE for all age groups. The relationship between patients' age and benefits is not linear, because younger patients were more likely to receive a mechanical valve replacement, which is both more durable and more hazardous (with respect to stroke risk) than a biological valve.

We converted life expectancy into monetary value using the formula  $1000k \times \text{age}^{-0.66}$ .<sup>18</sup> For patients with mitral valve replacement, this number was further discounted by yearly mortality rates associated with biological or mechanical valve replacement. The results are summarized in Table 4 (middle). These show that patients' benefit ranges from \$471 (for patients in their 80s with heart failure) to \$7,978 (for patients in their 70s with no comorbidities).

<b>Table 4. Savings to Patients and Payers*</b>				
	<b>Age Group</b>			
<b>Comorbidities</b>	50	60	70	80
<b>Patient Life Expectancy (mo)**</b>				
Standard	2.95	3.17	3.70	2.91
Hypertension	2.88	3.02	3.34	2.50
Heart Failure	2.04	2.38	2.00	1.41

Diabetes	2.30	2.39	2.67	1.94
Renal Disease	2.31	2.16	2.50	1.43
Atrial Fibrillation	2.12	2.08	2.17	1.54
Chronic Lung	2.24	2.36	2.66	1.97
<b>Patient Monetary Savings†</b>				
Standard	\$6,022	\$6,633	\$7,978	\$5,256
Hypertension	\$6,234	\$6,274	\$6,882	\$3,973
Heart Failure	\$3,235	\$4,044	\$2,575	\$471
Diabetes	\$3,873	\$4,034	\$4,600	\$2,195
Renal Disease	\$4,070	\$3,379	\$3,219	\$776
Atrial Fibrillation	\$3,470	\$3,148	\$3,096	\$878
Chronic Lung	\$3,563	\$3,856	\$4,481	\$2,280
<b>Payer Monetary Savings‡</b>				
Standard	\$411	\$49	(\$942)	(\$1,632)
Hypertension	\$325	(\$37)	(\$1,014)	(\$1,729)
Heart Failure	(\$65)	(\$254)	(\$1,057)	(\$1,578)
Diabetes	(\$510)	(\$768)	(\$1,563)	(\$2,087)
Renal Disease	(\$515)	(\$782)	(\$1,561)	(\$2,031)
Atrial Fibrillation	(\$272)	(\$461)	(\$1,282)	(\$1,789)
Chronic Lung	(\$517)	(\$784)	(\$1,563)	(\$2,031)

\*All results are based on our findings that average repair rate of CoEs is 9% higher than that of non-CoEs. Related risk factors include operative mortality, long-term survival, reoperation, stroke, bleeding, maintenance (for mechanical valve) and structural valve deterioration (for biological valve).

\*\*Increase in life expectancy refers to the difference between life expectancy at CoEs and that at non-CoEs. Green color indicates that patients achieve positive increase in life expectancy.

†Conversion of life expectancy to monetary value is based on the formula  $1000k \times \text{age}^{-0.66}$ .<sup>18</sup> Green color indicates that patients achieve positive savings.

‡ Cost to payers refers to the difference between cost at CoEs and that at non-CoEs. We estimate that mitral valve repair costs \$46,000 and mitral valve replacement costs \$53,000 at non-CoE hospitals and both costs are \$4,000 higher at CoEs.

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Green color indicates that payers achieve positive savings, and red color indicates negative savings more than \$500, and yellow color indicates negative savings that are less than \$500.

## **COSTS TO THE PAYERS**

Costs to payers depend on a patient's age and comorbidities (Table 6, bottom). Estimating these costs by using the sources in Table 1 and our statistical estimates of the increased likelihood of receiving a repair from a CoE, indicates that payers obtain positive savings through treatment at a CoE for patients in their 50s and 60s with no comorbidities, or patients in their 50s with hypertension. For the oldest age group (over 80) with comorbidities, payers incur additional costs ranging from \$1,578 (heart failure) to \$2,087 (diabetes).

## **SOCIETAL BENEFIT**

We calculate societal benefits by adding the net savings to patients and payers (See Table S1 in the Supplementary Appendix). Societal benefits are positive for almost all age groups and comorbidities. These positive savings are due to significant benefits to patients and relatively small costs to payers. The societal benefit is negative only for patients in their 80s with heart failure, renal disease or atrial fibrillation.

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## **DISCUSSION**

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Mitral valve repair is superior to mitral valve replacement for all age groups and all comorbidities. Based on inpatient discharge data from New York State 2008-2012, our study suggests that CoEs have significantly higher repair rates than non-CoEs and the average quality

gap is around 9%. However, around two-thirds of patients in the New York cohort failed to choose a CoE, and therefore some of these missed the opportunity to receive the more favorable mitral valve repair. This study shows that distance and payer type are two important factors affecting patients' choice of a CoE.

Our model predicts that referral of mitral patients to a CoE as outlined in the 2014 American Heart Association/American College of Cardiology Valvular Heart Disease Guidelines would benefit patients of all age groups and all comorbidities. However, the net savings vary widely for different age groups and different co-morbidities, ranging from \$471 to \$7,978.

There are situations in which payers achieve positive savings as well. For example, patients with no co-morbidities in their 50s or 60s and patients with hypertension in their 50s result in sufficient long-term reductions in costs of complications to offset the higher short-term procedure cost at a CoE. For these patients, the economic incentives of patients and payers align (Table 4). Presumably, better dissemination of information about the clinical and economic benefits of mitral valve at a CoE would result in more of these patients going to a CoE.

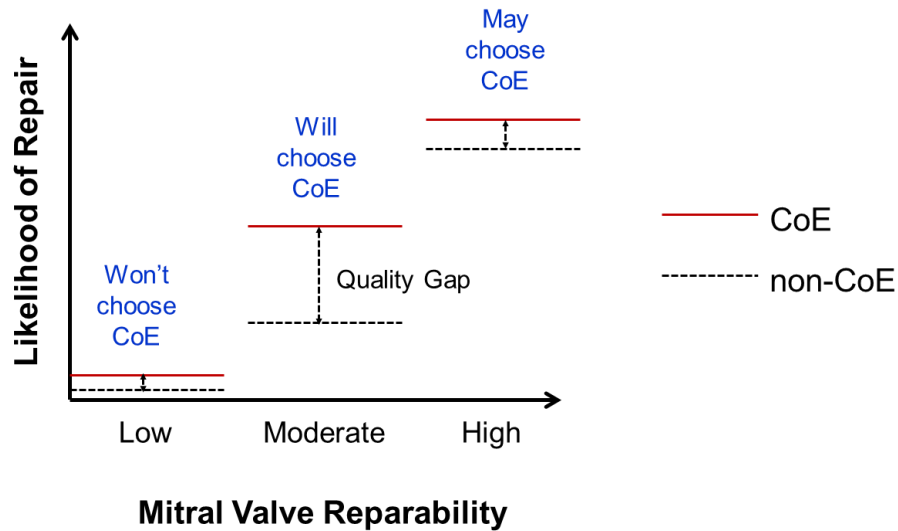
Economic incentives also align for patients over 80 with heart failure, renal disease or atrial fibrillation. In these cases, neither patients nor payers benefit from going to a CoE (Table 4). Our analysis of the New York State Inpatient Database shows that around 75% of patients in this category do not travel beyond their locality to go to a CoE, which is probably appropriate for these patients.

For the other categories of patients, net benefits are clearly positive for patients, but mildly negative for payers. A possible option for aligning incentives would be for payers to adjust the co-pay structure so that patients share more of the additional costs at a CoE.



We should note, however, that referring all patients to CoEs, as recommended by the Valvular Heart Disease Guidelines, could create capacity problems and longer waits for treatment at the CoEs. Furthermore, encouraging all patients to go to CoEs may retard the establishment and maintenance of proficiency of other hospitals.

Finally, patients benefit differently from a CoE depending on case complexity, which suggests that an even better option for aligning the incentives of patients and payers would be to develop ways to better predict which patients are most likely to benefit from the sophistication and experience of a CoE. For instance, it may be possible for a cardiologist or surgeon to analyze the preoperative echocardiogram to estimate of the reparability of the patient's mitral valve. For the sake of argument, suppose that these estimates are classified into low, moderate and high and that outcome data for hospitals are stratified according to these classifications. Then, as illustrated in Figure 1, the gap between CoEs and non-CoEs is likely to be small for the low category (some patients will get their mitral valve repaired regardless of visiting a CoE or not) and for the high category (some patients with unreparable mitral valve will get a replacement regardless of visiting a CoE or not). Hence, neither patients in these categories nor their payers will have strong incentive to choose a CoE. But for the moderate reparability category, the gap between CoEs and non-CoEs may be sufficiently large that the long-term cost savings from avoiding medical complications outweighs the short-term cost premium at CoEs. Hence, patients and payers alike will have incentive to choose a CoE.



**Figure 1. Mitral Valve Reparability & Quality Gap between CoEs and Non-CoEs**

How large a gap is required for the moderate reparability category to align payer incentives with those of the patient? Using the same approach described earlier, we find a 15% gap aligns incentives for almost everyone (see Table S2 in the Supplementary Appendix). Hence, if sufficiently accurate prediction of the quality gaps is possible based on preoperative (echocardiogram) data, then simply sharing these data with patients and allowing them to choose a hospital according to their self-interest will result in the best outcome for patients and payers.

In conclusion, our results suggest that both patients and society as a whole can benefit from referring mitral patients to CoEs. Under current conditions, such referral generally implies increased costs to payers, but these costs are outweighed by substantial gains by the patients. However, by properly designing the co-pay structure or by identifying the group of patients that benefit most from a CoE, payers can be given economic incentives to guide mitral valve patients to the right hospitals, leading to an increase in healthcare quality and reduction in medical costs.

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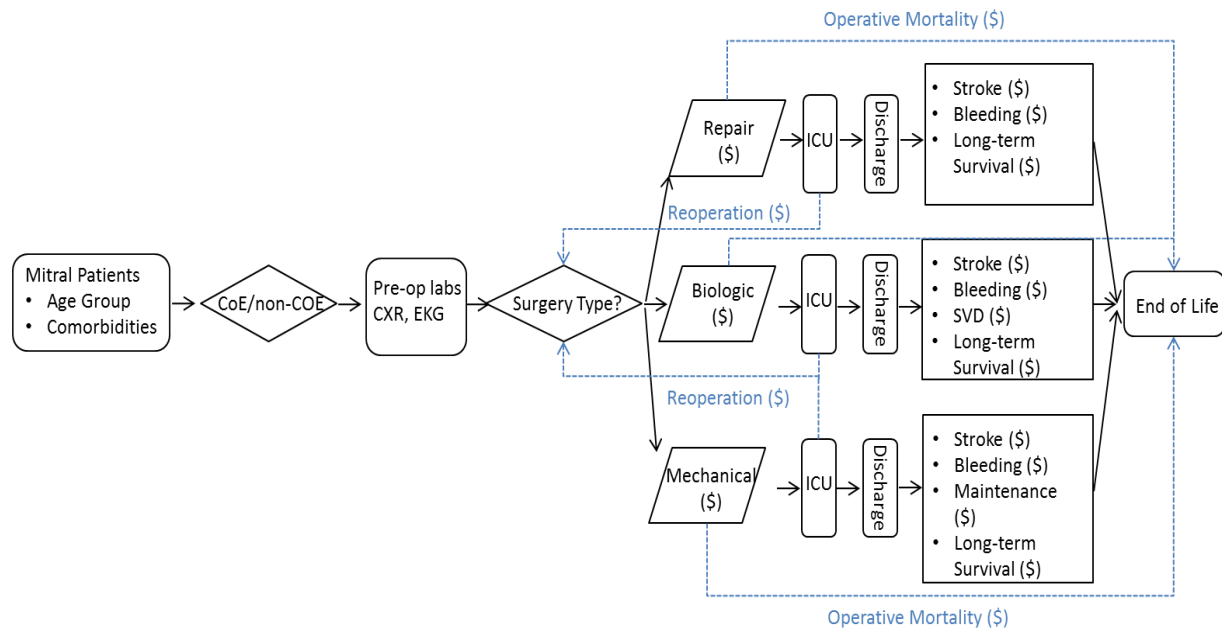
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## Supplementary Appendix



**Figure S1: Related Events and Decision Process for Patients with Mitral Valve Diseases**

### MODEL ELEMENTS

There is no single source or paper that provides all the data required in our model. Therefore, we drew from several sources in the medical literature to estimate the various parameters. When necessary, we supplemented the literature review by estimates from existing datasets including Society of Thoracic Surgeons (STS) National Database and National Inpatient Sample Data. All costs and benefits have been converted into 2014 US dollars.

Below we discuss our estimates and sources of each model element for patients of different ages, with and without comorbidities. We consider common comorbidities including heart failure, chronic lung disease, diabetes, hypertension, and renal disease (Vassileva et al. 2013).<sup>1</sup>

**Repair Rate:** Our estimate of the impact of age on repair rate is based on Daneshmand et al. (2010), who studied 2,064 patients that underwent mitral surgeries from 1986 to 2006, and found that the probability of using a biological (over mechanical) valve is 20% for patients between 50 and 60, 36% for patients between 60 and 70, 71% for patients between 70 and 80 and 89% for patients above 80.<sup>2</sup> Impact of comorbidities on repair rate is estimated based on Vassileva et al. (2013), who studied 47,279 fee-for-service beneficiaries > 65 (from Medicare database) that underwent primary isolated mitral valve surgeries from 2000 to 2009, and found that the odds ratio is 1.23 for hypertension, 0.8 for diabetes, 0.78 for heart failure, 0.78 for chronic obstructive pulmonary disease and 0.8 for renal disease.<sup>1</sup>

**Operative Mortality:** Our estimate of operative mortality is based on the STS Risk Calculator, which incorporates the STS risk models that are designed to serve as statistical tools to account for the impact of patient risk factors on operative mortality and morbidity.<sup>i</sup> As the STS Risk Calculator does not provide separate results for biological and mechanical replacements, we used the National Inpatient Sample 2008-2012 to calculate them retrospectively. For patients aged 50-60, 60-70, 70-80 and over 80, we estimate operative mortality to be 0.24%, 0.44%, 0.79% and 1.61% for mitral valve repair, 0.37%, 0.36%, 1.03% and 2.91% for mechanical valve replacement, and 0.87%, 1.57%, 1.66% and 2.48% for biological valve replacement.

**Long-term Survival:** We estimated long-term survival of patients with mitral valve repair based on the US Social Security database, assuming that mitral valve repair restores patients' normal life expectancy (Ray et al. 2006).<sup>3</sup> Long-term survival associated with mitral valve replacement is estimated based on Deneshmand et al. (2010), who found that yearly mortality rate associated with biological valve replacement is 1.8 times that associated with mitral valve repair and yearly

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<sup>i</sup> For more details, please see <http://riskcalc.sts.org/stswebriskcalc/#/>.

mortality rate associated with mechanical valve replacement is 1.3 times that associated with mitral valve repair.<sup>2</sup>

We estimated the impact of comorbidities on long-term survival by using the studies of Daneshmand et al. (2010), Gelsomino et al. (2011), Daneshmand et al. (2009).<sup>2,4,5</sup> The hazard ratio is 2.3 for atrial fibrillation, 1.3 for Chronic Obstructive Pulmonary Disease (COPD), 1.2 for diabetes, 2.1 for heart failure, 2.48 for renal disease, and 1.37 for hypertension.

**Procedure-related Reoperation:** We estimated the likelihood of procedure-related reoperation from the results of Dumont et al. (2007), who studied 188 patients that underwent reoperation for recurrent mitral regurgitation at the Cleveland Clinic from Jan 1980 to Jan 2005, and reported that around 90% of procedure-related reoperations occur in the first year.<sup>6</sup> For simplicity, we assumed all procedure-related reoperations occur in the first year. We estimated the impact of comorbidities on procedure-related reoperation by using the STS Risk Calculator. For patients aged 50-60, 60-70, 70-80 and over 80, we estimate procedure-related reoperation rate to be 4.38%, 5.21%, 6.19% and 7.41% for mitral valve repair, and 6.12%, 7.53%, 9.23% and 11.38% for mitral valve replacement.

**Stroke:** We estimated stroke rates based on Russo et al. (2008), who studied 1,344 patients that underwent mitral surgery at the Mayo Clinic from Jan 1980 to Dec 1995, and reported that (1) annual stroke rate is 1.15% for mitral valve repair, 2.7% for mechanical replacement and 1.65% for biological replacement; (2) 5-yr ischemic stroke rate is 6.1% for mitral valve repair, 16.1% for mechanical replacement and 8% for biological replacement; and (3) 10-yr ischemic stroke rate is 9.9% for mitral valve repair, 23.3% for mechanical replacement and 12.2% for biological replacement.<sup>7</sup> From their results, we calculated the ratio of stroke rates for biological



replacement vs repair to be  $1.65\%/1.15\%=1.4$ , and the ratio for mechanical vs biological replacement to be  $2.7\%/1.65\%=1.6$ .

The impact of comorbidities on stroke was estimated based on National Institute of Neurological Disorders and Stroke.<sup>ii</sup> We estimated the age-adjusted hazard ratio to be 1.3 for diabetes and 2.5 for both heart failure and atrial fibrillation.

**Bleeding:** We estimated the rate of bleeding from Keneko et al. (2014), who studied a total of 768 patients with age <65 that underwent mitral valve surgeries from Jan 1991 to Jun 2012, and reported that there is no significant difference in the frequency of bleeding events between mechanical and biological valve replacements for patients younger than 65.<sup>8</sup> Chikwe et al. (2011), Ailawadi et al. (2008) and LaPar et al. (2010) reported that there is no significant difference in bleeding events between mitral valve repair and replacement.<sup>9,10,11</sup> Based on Keneko et al. (2014), we estimated freedom from major bleeding (same for mitral valve repair and replacement) at 5, 10, and 15 years to be 87.2%, 79.2%, and 71.2% respectively.<sup>8</sup> We were unable to find literature studying impact of comorbidities on bleeding and therefore used the same rates regardless of comorbidity.

**Maintenance:** We estimated costs of warfarin and associated risk event to be \$1,500/yr (paid by payers).<sup>iii</sup> We also assumed that age and co-morbidities do not affect maintenance cost.

**Structural Valve Deterioration (SVD):** We estimated SVD rate based on Bourguignon et al. (2014), who studied 450 patients that underwent Carpentier-Edwards PERIMOUNT pericardial mitral bioprostheses from 1984 to 2011, and reported that the actuarial freedom from structural valve deterioration (SVD) at 20 years is 23.7%.<sup>12</sup>

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<sup>ii</sup> [http://www.ninds.nih.gov/disorders/stroke/preventing\\_stroke.htm](http://www.ninds.nih.gov/disorders/stroke/preventing_stroke.htm)

<sup>iii</sup> <http://health.costhelper.com/valve-replacement.html>

**Procedure Cost:** We estimated that mitral valve repair costs \$46,000 and mitral valve replacement costs \$53,000 at local non-CoEs, and the costs are \$4,000 higher at CoEs, based on the Medicare Provider Utilization and Payment Data<sup>iv</sup> and National Inpatient Sample 2008-2012.

**Travel Cost:** We estimated travel cost to be \$2,000 (paid by patient) in addition to loss of life years based on a patient survey conducted by the University of Michigan Cardiovascular Center (Paulsen, et al. 2015).<sup>13</sup>

**Table S1: Societal Benefits from a CoE\***

Comorbidity	Age Group			
	50	60	70	80
Standard	\$ 6,433	\$ 6,682	\$ 7,036	\$ 3,624
Hypertension	\$ 6,559	\$ 6,237	\$ 5,868	\$ 2,244
Heart Failure	\$ 3,169	\$ 3,789	\$ 1,518	\$ (1,107)
Diabetes	\$ 3,363	\$ 3,266	\$ 3,036	\$ 109
Renal Disease	\$ 3,555	\$ 2,597	\$ 1,657	\$ (1,255)
Atrial Fibrillation	\$ 3,198	\$ 2,686	\$ 1,815	\$ (912)
Chronic Lung	\$ 3,046	\$ 3,072	\$ 2,918	\$ 249

\* Societal benefit is the sum of patient benefits and payer benefits.

† Green color indicates that payers achieve positive savings, red color indicates negative savings.

<sup>iv</sup> <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Inpatient.html>

**Table S2: Savings to Payers when Quality Gap Is 15%\***

Comorbidity	Age Group			
	50	60	70	80
Standard	\$ 3,491	\$ 2,873	\$ 1,229	\$ (8)
Hypertension	\$ 3,348	\$ 2,729	\$ 1,109	\$ (169)
Heart Failure	\$ 2,733	\$ 2,399	\$ 1,072	\$ 92
Diabetes	\$ 1,989	\$ 1,540	\$ 225	\$ (756)
Renal Disease	\$ 1,981	\$ 1,517	\$ 228	\$ (663)
Atrial Fibrillation	\$ 2,388	\$ 2,052	\$ 696	\$ (260)
Chronic Lung	\$ 1,981	\$ 1,516	\$ 229	\$ (662)

\* Cost to payers refers to the difference between cost at CoEs and that at non-CoEs. The results are based on the scenario when quality gap is 15%, i.e. repair rate at a CoE is 15% higher than a non-CoE. Related costs include those for procedure, reoperation, stroke, bleeding, maintenance (for mechanical valve) and structural valve deterioration (for biological valve). We estimate that mitral valve repair costs \$46,000 and mitral valve replacement costs \$53,000 at non-CoE hospitals and both costs are \$4,000 higher at CoEs.

† Green color indicates that payers achieve positive savings, red color indicates negative savings more than \$500, and yellow color indicates negative savings that are less than \$500.

**Table S3: Savings to Payers when Quality Gap Is 20%\***

Comorbidity	Age Group			
	50	60	70	80
Standard	\$ 6,058	\$ 5,226	\$ 3,039	\$ 1,346
Hypertension	\$ 5,867	\$ 5,034	\$ 2,878	\$ 1,130
Heart Failure	\$ 5,066	\$ 4,609	\$ 2,847	\$ 1,485
Diabetes	\$ 4,072	\$ 3,463	\$ 1,715	\$ 353
Renal Disease	\$ 4,061	\$ 3,433	\$ 1,720	\$ 477
Atrial Fibrillation	\$ 4,604	\$ 4,147	\$ 2,344	\$ 1,015
Chronic Lung	\$ 4,062	\$ 3,433	\$ 1,722	\$ 478

\* Cost to payers refers to the difference between cost at CoEs and that at non-CoEs. The results are based on the scenario when quality gap is 20%, i.e. repair rate at a CoE is 20% higher than a non-CoE. Related costs include those for procedure, reoperation, stroke, bleeding, maintenance (for mechanical valve) and structural valve deterioration (for biological valve). We estimate that mitral valve repair costs \$46,000 and mitral valve replacement costs \$53,000 at non-CoE hospitals and both costs are \$4,000 higher at CoEs.

† Green color indicates that payers achieve positive savings.

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