ADULT CORONARY ARTERY BYPASS GRAFT SURGERY IN THE COMMONWEALTH OF MASSACHUSETTS

January 1 – December 31, 2003

Mass-DAC

Department of Health Care Policy

Harvard Medical School

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MASSACHUSETTS CARDIAC SURGERY CENTERS 2003

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Boston Medical Center (BMC) 88 East Newton Street Boston, MA 02118	North Shore Medical Center - Salem Hospital 81 Highland Avenue Salem, MA 01970
Brigham & Women's Hospital (B&W) 75 Francis Street Boston, MA 02115	Southcoast Hospital Group - Charlton Memorial Hospital 363 Highland Avenue Fall River, MA 02720
Cape Cod Hospital 27 Park Street Hyannis, MA 02537	St. Vincent Hospital at Worcester Medical Center 20 Worcester Center Blvd. Worcester, MA 01608
Caritas St. Elizabeth's Medical Center 736 Cambridge Street Boston, MA 02315	Tufts-New England Medical Center (NEMC) 750 Washington Street Boston, MA 02111
Lahey Clinic 41 Mall Road Burlington, MA 01805	UMass Memorial Medical Center 55 Lake Avenue North Worcester, MA 01655

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1 - KEY FINDINGS

- In 2003, there were **7485** hospital admissions in which at least one cardiac surgery was performed in Massachusetts. More than half **(58.7**%) of the admissions were those in which an isolated coronary artery bypass graft (CABG) surgery was undertaken.
- There were **210 fewer** isolated CABG surgery admissions performed in Massachusetts in 2003, as compared to 2002.
- **Fourteen** hospitals performed at least one CABG operation in Massachusetts in 2003. Thirteen of the fourteen hospitals started performing cardiac surgery prior to 2003; one hospital, North Shore Medical Center - Salem Hospital, performed cardiac surgery for the first time in 2003.
- In the thirteen hospitals that performed cardiac surgery prior to 2003, the number of CABG surgeries ranged from **114** to **640** during 2003.
- The unadjusted mortality rate (defined as the number of patients dying within 30 days of surgery divided by the number of patients undergoing CABG surgery) in Massachusetts during 2003, was **2.25%**.
- There were 8996 isolated CABG surgery admissions during 2002 and 2003. The unadjusted mortality rate within 30 days of CABG surgery during 2002 and 2003 was **2.22%**.
- **One** hospital, UMass Memorial Medical Center, was identified as under-performing on the basis of 30-day mortality.

2 - INTRODUCTION

2.1 - What is in this Report?

This report describes procedures for calculating hospital-specific standardized 30-day mortality rates following isolated coronary artery bypass graft (**CABG**) surgery performed in Massachusetts hospitals in 2003. Surgeries performed in United States Government Hospitals (e.g., VA Boston Healthcare System – Jamaica Plain Campus) are not included in this report. Information pertains to patients who were 18 years of age or older at the time of their surgery.

Not all hospitals in Massachusetts are permitted to perform cardiac surgery. Hospitals wishing to establish a new cardiac surgery program must submit an application to the Determination of Need Program in the Massachusetts Department of Public Health. In 2003, there were fourteen cardiac surgery programs in Massachusetts: eleven established and three new programs. Of the three new programs, two programs (Southcoast Hospital Group – Charlton Memorial Hospital and Cape Cod Hospital) began performing cardiac surgery in 2002. North Shore Medical Center - Salem Hospital began performing cardiac surgery in 2003. All Massachusetts hospitals with cardiac surgery programs submitted data to Mass-DAC.

This document is the 2nd annual report describing hospital-specific standardized mortality rates following isolated CABG surgery in Massachusetts. It describes standardized mortality rates for the fourteen cardiac surgery programs in Massachusetts that performed at least one isolated CABG surgery between January 1, 2003 and December 31, 2003. Also contained in this report are hospital-specific mortality rates following isolated CABG surgery performed over the two year period between January 1, 2002 and December 31, 2003. This time frame represents the time period over which data collection began.

2.2 - What is Coronary Artery Bypass Graft Surgery?

For a heart to function properly, it needs an oxygen-rich blood supply. Coronary arteries send oxygen-rich blood to the heart. When the coronary arteries are healthy,

blood flows easily so that the heart muscle gets the oxygen it needs. Coronary artery disease begins when blood flow to the heart is reduced due to a build-up of plaque. Plaque may build up because of high cholesterol, high blood pressure, smoking, diabetes, genetic predisposition, or other factors. If the plaque build-up increases, the coronary arteries narrow and blood flow to the heart is reduced, often leading to angina (chest pain, arm pain, or jaw tightness that occurs with exertion, or in more serious cases, at rest). If blood flow is completely blocked by a sudden development of a clot within a coronary artery, this usually results in a heart attack or myocardial infarction, referred to as MI, which may irreversibly damage the heart muscle.

Coronary artery disease is usually treated by one of three methods (medication, coronary intervention, or cardiac surgery). The choice of treatment depends on the degree of blockage, patient symptoms, and the number of coronary arteries involved. Coronary artery bypass graft (CABG) surgery is a type of cardiac surgery that creates a new route or bypass around the blocked part of the artery, allowing the blood flow to reach the heart muscle again. During CABG surgery, the blocked coronary arteries are bypassed using some of the patient's own blood vessels. The internal mammary arteries are commonly used for the bypass; however, the saphenous vein in the leg or the radial artery in the arm can also be used. Surgical procedures in which CABG is the only major heart surgery performed are referred to as ***isolated CABG*** surgery.

2.3 - Why Report on CABG Surgery?

CABG surgery accounts for the majority of cardiac surgery performed nationally and is costly. In 2003, isolated CABG surgery accounted for 58.7% of the more than 7400 cardiac surgery hospital admissions (**Table 2.1**) in Massachusetts. Only patients undergoing isolated CABG surgery were used to determine hospital mortality rates in this report. Patients who had valve surgery in addition to a CABG were not included in the report.

Table 2.1: Surgical Procedure Type Classification of Adult Cardiac Surgeries During January 1, 2003 – December 31, 2003, Commonwealth of Massachusetts.

Surgical Procedure Type	Number of All Cardiac Surgery Admissions	% of All Cardiac Surgery Admissions
Isolated CABG	**4393**	**58.7**
Mitral Valve Replacement (MVR)	123	1.6
Aortic Valve Replacement (AVR)	536	7.2
MVR + CABG	81	1.1
AVR + CABG	512	6.8
AVR + MVR	37	0.5
Other Cardiac Surgery	1705	22.8
Non-Cardiac (Thoracic) Procedures	98	1.3
All Cardiac Surgery Admissions	7485	100

2.4 - Who Receives CABG Surgery in Massachusetts?

Of patients undergoing isolated CABG surgery, 74% were males, more than half were aged 65 years or older, and the majority were white (**Table 2.2**). Patients who lived outside of Massachusetts at the time of their surgery comprised 7% of the 4393 isolated CABG surgery admissions.

Table 2.2: Age-Sex-Race distribution for all adult Isolated CABG Surgeries in MA hospitals during January 1, 2003 - December 31, 2003. Entries represent numbers of patients.

Age Group	Females					Males				
	White	African American	Hispanic	Other§	Total	White	African American	Hispanic	Other§	Total
18 – 44	21	2	3	2	28	60	2	5	10	77
45 – 54	71	6	7	2	86	342	12	26	26	406
55 – 64	211	6	15	17	249	879	13	38	29	959
65 – 74	352	15	16	20	403	925	14	23	47	1009
≥ 75	375	5	9	7	396	736	5	7	32	780
Total	1030	34	50	48	**1162**	2942	46	99	144	**3231**

2.5 - Why Report Hospital-Specific Mortality Rates?

Data collected on quality can be used to provide useful information to both patients and health care providers, stimulate additional research, and foster improvements in quality of care. This report uses 30-day mortality as a measure of hospital quality, defined as death occurring within 30 days of the date of the operation, regardless of cause. While it is not the only important endpoint, mortality was selected as the primary measure of hospital quality because it is serious and unambiguous.

2.6 - What is Mass-DAC?

Mass-DAC is a data analysis center responsible to the Massachusetts Department of Public Health for the collection, storage, and analysis of the cardiac data submitted by Massachusetts hospitals. Mass-DAC is located in the Department of Health Care Policy, Harvard Medical School in Boston (www.massdac.org). Mass-DAC is advised by several committees on an ongoing basis: the Massachusetts Cardiac Care Quality Advisory Commission, the Cardiac Advisory Board, and the Cardiac Surgery Data Adjudication Committee. In addition, both the National Society of Thoracic Surgeons and the Massachusetts Society of Thoracic Surgeons serve as resources.

2.7 - What Data are Used in the Report?

All Massachusetts hospitals that perform cardiac surgery are required by law to submit specific information to Mass-DAC. This report includes data submitted by hospitals in Massachusetts that performed isolated CABG surgery between January 1, 2003 and December 31, 2003. Key variables were rigorously verified by Mass-DAC. This process involved: (1) continuous data quality reports to data managers located at each hospital; (2) discussions with chiefs of every cardiac surgery department Massachusetts; (3) audits of selected chart information by an independent Cardiac Surgery Data Adjudication Committee, and by experienced and independent nurses contracted for record abstractions; (3) a review by an external Cardiac Advisory Board; and (4) linkages and cross-checks with state administrative databases. The same procedures were used to collect data for CABG surgery performed during calendar year 2002.

2.8 - Risk Adjustment for Assessing Hospital Mortality

Specific "risk" factors are known to contribute to heart disease. These risk factors include high cholesterol, smoking, high blood pressure, family history of heart disease, diabetes, age, gender, and general health status prior to the CABG operation. Such factors also have an impact on the risk of mortality following surgery. Sicker patients or patients with more health-related risks may be more likely to die following a CABG

operation than healthier patients. Moreover, patients who are sicker may be more likely to be treated at particular hospitals while patients who are healthier may be more likely to be treated at other hospitals. To compare hospitals fairly and not to penalize hospitals that treat sicker patients, it is therefore important to consider differences in patient health prior to surgery.

The statistical process of accounting for differences in patient sickness prior to their surgery is called ***risk adjustment***. This statistical process aims to "level the playing field" by considering health risks that patients have prior to surgery. The hospital specific 30-day mortality rates in this report have been adjusted in order to account for differences in patient health prior to surgery.

2.9 - How are Hospital Differences in Patient Outcomes Measured?

If there are differences in hospital quality, due to staff, experience, or other factors, then the risks of in-hospital mortality for two patients having exactly the same risk factors prior to cardiac surgery but who are treated in different hospitals will not be the same. The statistical model used to calculate mortality rates in this report - a ***hierarchical logistic regression*** model – models the difference between the risks of mortality for patients with the same risk factors who are treated at different hospitals. This is accomplished through the inclusion of a hospital -specific (random) effect that represents quality factors for each hospital. If there are no differences in the hospital-specific effects across the hospitals, then there is no evidence of quality differences.

3 - IDENTIFYING OUTLYING CARDIAC SURGERY PROGRAMS

The purpose of this report is to identify hospitals that have ***unusually*** high or **unusually** low mortality rates. Such hospitals are denoted "outlying" – however, the designation of outlying depends on how "unusual" unusual is. Two methods were used to identify outlying hospitals. The first method calculates a 95% interval estimate for each hospital's risk-standardized mortality rate. If the interval estimate does not contain the state unadjusted 30-day hospital mortality rate, the hospital is designated outlying.

However, because any one hospital could influence the estimates of the risk-standardized mortality rate for other hospitals, Mass-DAC also calculates the expected number of mortalities at each hospital using the experience of all **other** hospitals in Massachusetts. If the probability that the actual number of mortalities is different from the expected number of mortalities is small, then the hospital is classified as "outlying."

If the 95% interval estimate for a particular hospital excludes the state unadjusted 30-day hospital mortality rate **or** if the probability of the observed mortality based on mortality predicted from all other hospitals for a particular hospital is small, then Mass-DAC classified the hospital as outlying. It is important to note that the classification in this report is relative to all hospitals in Massachusetts performing CABG surgery.

3.1 - Standardized Mortality Incidence Rates (SMIR)

Mass-DAC calculated a standardized mortality incidence rate (SMIR) and a corresponding 95% "posterior" interval for each hospital. The SMIR is interpreted as the projected mortality rate at the hospital **today** if hospital quality remained the same as in 2003. Each hospital's SMIR should only be interpreted in the context of its posterior interval. If the 95% interval includes the unadjusted state rate, then the hospital's SMIR is no different from what was expected. If the interval excludes the state unadjusted rate, then the hospital's SMIR is "unusual" from what was expected. In this case, if the upper limit of the interval is lower than the unadjusted state rate, then fewer patients than expected died. Such a hospital would be categorized as an over-performing hospital. If the lower

limit of the interval is higher than the unadjusted rate, then more patients than expected died. Such a hospital would be classified as an under-performing hospital.

3.2 - Cross-Validated P-Values

Because data from all hospitals are used to estimate the expected number of deaths in any hospital, there is a risk that outlying hospitals may influence the estimates used to risk-adjust. One method to identify hospitals as outlying is through "cross-validation" – systematically drop each hospital from the data set and re-estimate the risk-adjusted model. Using the new model, the expected number of deaths at the dropped hospital is calculated. This expected number may be interpreted as the number of mortalities expected at the dropped hospital if the dropped hospital had the same level of quality as the remaining hospitals.

Mass-DAC compared the expected number to the actual number of deaths at the dropped hospital and calculated a "p-value." Because the p-value quantifies how **likely** the actual number of deaths would be if the dropped hospital had the same level of quality as all remaining cardiac surgery hospitals, small p-values (those ≤ 0.01) indicate that the dropped hospital is outlying. When the p-value is small and the actual number of deaths is larger than that predicted by the remaining hospitals, the dropped hospital is classified as under-performing; when the p-values is small and the actual number of deaths is smaller than predicted by its peers, then the hospital is classified as over-performing. Mass-DAC repeated this procedure, eliminating each cardiac surgery hospital.

3.3 - Sensitivity Analyses

Several sensitivity analyses were undertaken to determine whether conclusions would change when making reasonable changes to some of the underlying assumptions. These assumptions related to the amount of between-hospital variation in underlying quality of care. Mass-DAC varied assumption regarding the amount and type of between-hospital variation in quality of care, and re-estimated the SMIRs as well as the cross-validated p-values.

4 - HOSPITAL QUALITY FOLLOWING ISOLATED CABG SURGERY: 2003

Of the 4393 isolated CABG surgery admissions in 2003 in Massachusetts, 99 patients (2.25%) died within thirty days of the operation. **Table 4.1** lists the prevalence (%) of important risk factors and the relationship of each risk factor (controlling for all other risk factors) with 30-day mortality following surgery. For example, 73.6% of the 4393 CABG surgery admissions were for male patients. Odds ratios greater than 1 correspond to increased risk of mortality while those less than 1 correspond to decreased risk of mortality. The odds ratio of 0.43 for males indicates that males are 0.43 times as likely as females to die within 30 days of a CABG operation. In contrast, patients having cardiogenic shock prior to a CABG operation are 6.58 times more likely to die within 30 days than patients not having cardiogenic shock. Because age is measured in years, the table reports the average number of years over age 65 for the cohort.

Figure 4.1 displays the SMIRs and corresponding 95% posterior intervals. The solid black vertical line in the figure is the unadjusted state 30-day mortality rate of 2.25%. Listed on the left-hand side of the figure are the total number of isolated CABG admissions and the expected 30-day mortality rates for each hospital. The expected mortality rate provides an overall assessment of case-mix severity at each hospital. Higher expected rates represent more severe case-mix. Listed on the right-hand side are the estimated SMIRs. All 95% probability intervals contain the unadjusted state rate of 2.25%.

Figure 4.2 presents the cross-validated p-values under a number of different assumptions regarding between-hospital variability in quality. The p-value for UMass Memorial Medical Center is 0.01. The cross-validation analysis indicated that the actual number of mortalities was statistically higher than the expected number of mortalities at UMass Memorial. This evidence suggests that, relative to all other cardiac surgery programs in Massachusetts, mortality following isolated CABG surgery at UMass Memorial Medical Center is higher than expected.

The 2003 data indicate one under-performing hospital. The 95% SMIR interval for UMass Memorial Medical Center just covers the unadjusted state rate of 2.25% and the cross-validated p-value indicates this cardiac surgery program is under-performing relative

to all other Massachusetts hospitals. These results remained unchanged relative to different modeling assumptions.

Table 4.1: Prevalences and Adjusted Odds Ratios of 30-Day Mortality Following Isolated CABG Surgery in Adults, Massachusetts: 2003. Based on 4393 surgeries with 99 deaths (2.25%). * Average age of patients undergoing isolated CABG surgery is 65 +1.7 = 66.7 years of age. ROC area ≈ 0.80. Intercept (95% PI) = -5.05 (-5.76, -4.35); Between-Hospital variance (95% PI) = 0.0939 (0.00111,0.483).

Risk Factor	Prevalence (%)	Odds Ratio	95% Posterior Interval (PI)
Mean Years over 65*	1.7	1.06	1.035, 1.087
Male	73.5	0.43	0.280, 0.680
Renal Failure	6.9	3.35	1.808, 5.566
Diabetes	38.1	1.21	0.763, 1.839
Hypertension	79.5	1.05	0.579, 1.843
PVD	17.4	1.34	0.784, 2.075
Prior CABG surgery	3.1	2.67	0.960, 5.488
Prior PTCA surgery	17.8	1.32	0.746, 2.145
Cardiogenic Shock	1.6	6.58	2.700, 13.87
Ejection Fraction (Ref = ≥ 40%)		1.00	--
< 30% or missing	12.6	1.13	0.549, 1.986
30 - 39	12.4	2.05	1.155, 3.285
MI (Ref = None)		1.00	--
< 6 hours	1.0	0.72	0.090, 2.404
7 – 24 hours	2.2	1.77	0.465, 4.514
1 – 7 days	23.0	1.16	0.630, 1.978
8 – 21 days	5.2	1.26	0.472, 2.608
> 21 days	18.9	1.01	0.498, 1.782
Status of CABG (Ref = Elective)		1.00	--
Urgent	65.8	0.74	0.430, 1.198
Emergent/Salvage	3.0	2.16	0.704, 4.958
Pre-Op Intra-Aortic Balloon Pump	11.7	1.71	0.892, 2.910

Figure 4.1. Ninety-Five Percent Posterior Intervals for Standardized Mortality Incidence Rates (SMIRs) Following Isolated CABG Surgery in Adults, Massachusetts, 2003. # of cases refers to the number of Isolated CABG surgery admissions; expected mortality rate is the percentage of cases expected to die given the case-mix of the patients in the hospital. The white vertical line in each box is the hospital's SMIR while the black vertical line denotes the unadjusted state 30-day mortality rate of 2.25%.

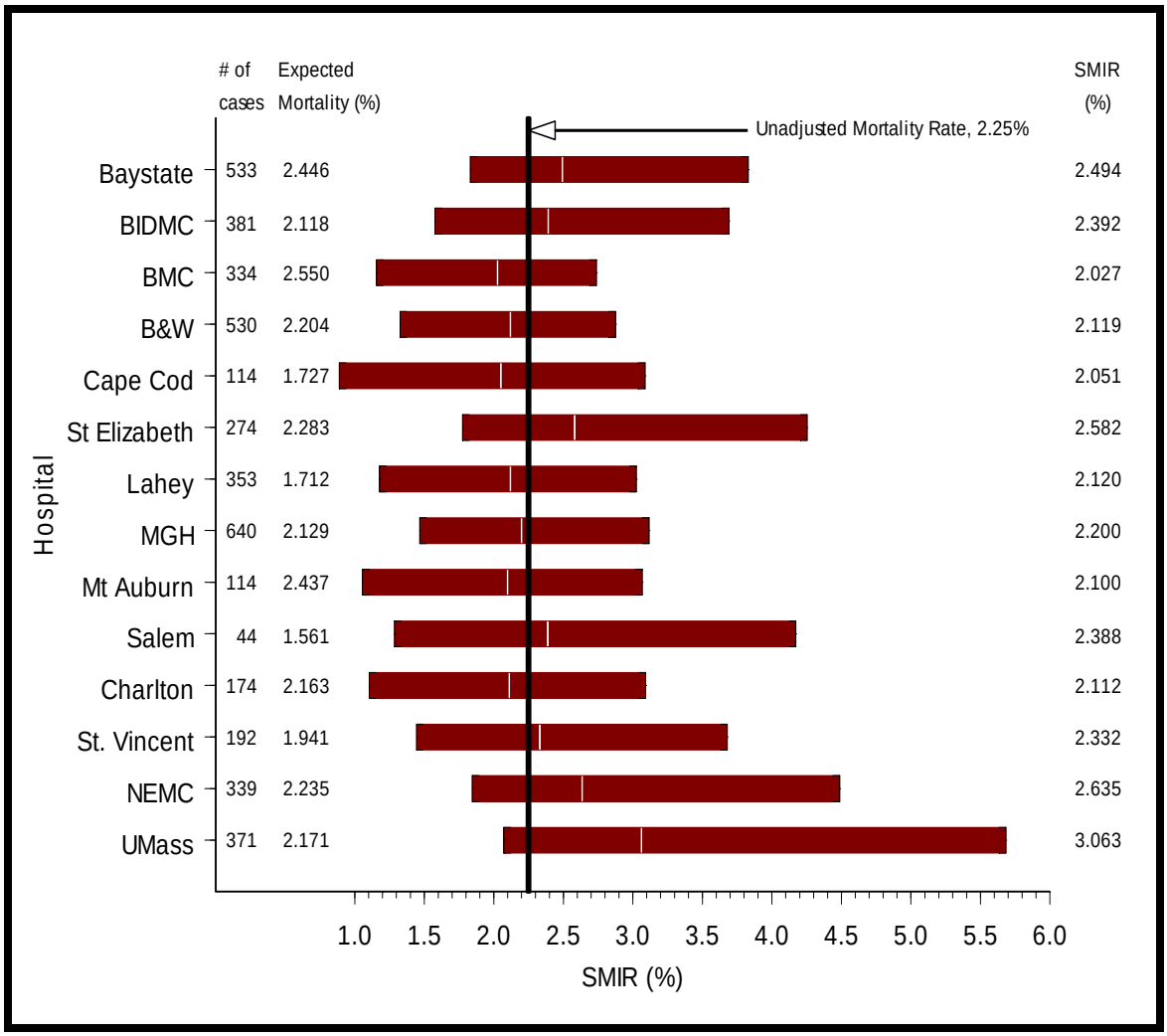
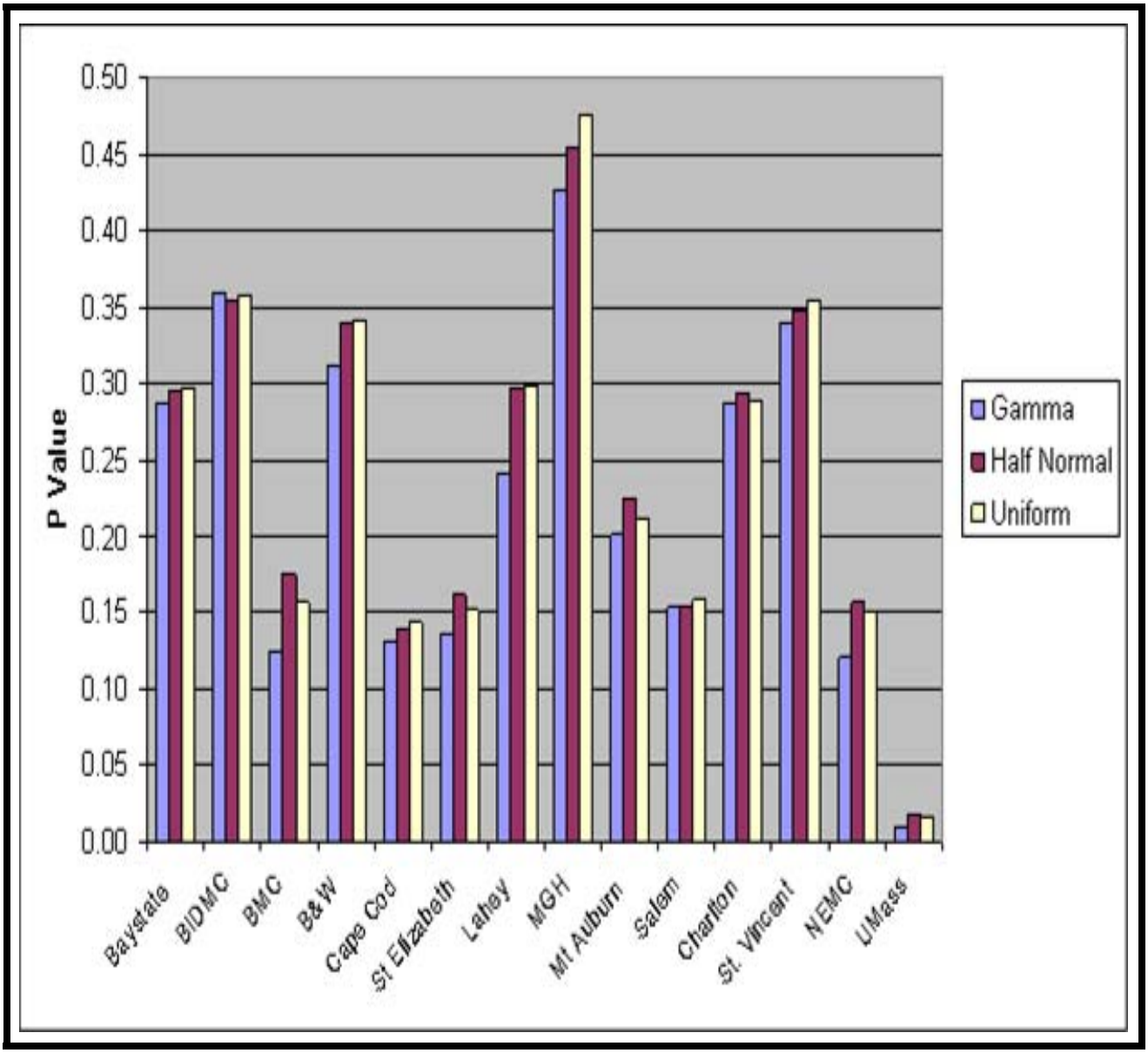


Figure 4.2: Cross-Validated P-Values: Surgeries Performed in 2003. P-values for each of the 14 cardiac surgery programs are listed on the y-axis; the x-axis identifies each hospital. Results are presented under a variety of assumptions for fitting the hierarchical regression model.



5 - HOSPITAL QUALITY FOLLOWING ISOLATED CABG SURGERY: 2002 - 2003

Between January 1, 2002 and December 31, 2003, there were 8996 isolated CABG surgery admissions. Of these admissions, 200 patients (2.22%) died within thirty days of the operation. **Table 5.1** lists the prevalence (%) of important risk factors and the relationship of each risk factor (controlling for all other risk factors) with 30-day mortality following surgery.

Figure 5.1 displays the SMIRs and corresponding 95% posterior intervals for the combined 2002 and 2003 data. The solid black vertical line in the figure is the unadjusted state 30-day mortality rate of 2.22% for the combined years. All 95% probability intervals contain the unadjusted state rate for each hospital. However, the lower limit of the 95% interval for UMass Memorial Medical Center is equal to the state unadjusted rate of 2.22.

Table 5.2 lists the cross-validated p-values. The p-value for UMass Memorial Medical Center is very small (0.0004). The cross-validation analysis indicated the actual number of mortalities was statistically higher than the expected number of mortalities at UMass. The between-hospital variation is reduced by almost 75% when UMass Memorial Medical Center is eliminated.

On the basis of 30-day mortality following isolated CABG surgery using the combined 2002 and 2003 data there is evidence that UMass Memorial Medical Center is an underperforming program relative to all cardiac surgery hospitals in Massachusetts.

Technical details can be found in **Technical Details on Adult Coronary Artery Bypass Graft Surgery in the Commonwealth of Massachusetts: January 1 - December 31, 2003**

Table 5.1: Prevalences and Adjusted Odds Ratios of 30-Day Mortality Following Isolated CABG Surgery in Adults in Massachusetts: 2002 - 2003. Based on 8996 surgeries with 200 deaths (2.22%). * Average age of patients undergoing isolated CABG surgery is 65 + 1.69 = 66.69 years of age. ROC area ≈ 0.811. Intercept (95% PI) = -5.70 (-6.30, -5.06); Between-Hospital Variance (95% PI) = 0.0835 (0.00159, 0.356).

Risk Factor	Prevalence (%)	Odds Ratio	95% Posterior Interval (PI)
Mean Years over 65*	1.60	1.05	1.036, 1.070
Male	74.03	0.52	0.389, 0.722
Renal Failure	7.13	2.69	1.784, 3.874
Diabetes	38.03	1.14	0.836, 1.510
Hypertension	78.20	1.57	0.985, 2.408
PVD	17.71	1.50	1.047, 2.068
Prior CABG surgery	3.47	3.99	2.293, 6.234
Prior PTCA surgery	18.20	1.08	0.720, 1.538
Cardiogenic Shock	1.93	3.91	2.078, 6.720
Ejection Fraction (Ref = ≥ 40%)			
< 30% or missing	12.72	1.26	0.798, 1.858
30 - 39	12.05	1.62	1.066, 2.328
MI (Ref = None)			
< 6 hours	0.90	3.11	1.094, 6.796
7 – 24 hours	2.00	2.46	1.059, 4.693
1 – 7 days	21.79	1.10	0.704, 1.625
8 – 21 days	5.46	1.33	0.686, 2.238
> 21 days	19.39	1.22	0.763, 1.819
Status of CABG (Ref = Elective)			
Urgent	63.85	1.25	0.831, 1.866
Emergent/Salvage	3.48	1.94	0.854, 3.677
Pre-Op Intra-Aortic Balloon Pump	10.47	2.12	1.362, 3.161

Figure 5.1: Ninety-Five Percent Posterior Intervals for Standardized Mortality Incidence Rates (SMIRs) Following Isolated CABG Surgery in Adults, Massachusetts: 2002 - 2003. # of cases refers to the number of Isolated CABG surgery admissions; expected mortality rate is the percentage of cases expected to die given the case-mix of the patients in the hospital. The white vertical line in each box is the hospital's SMIR while the black vertical line denotes the unadjusted state 30-day mortality rate for the combined years.

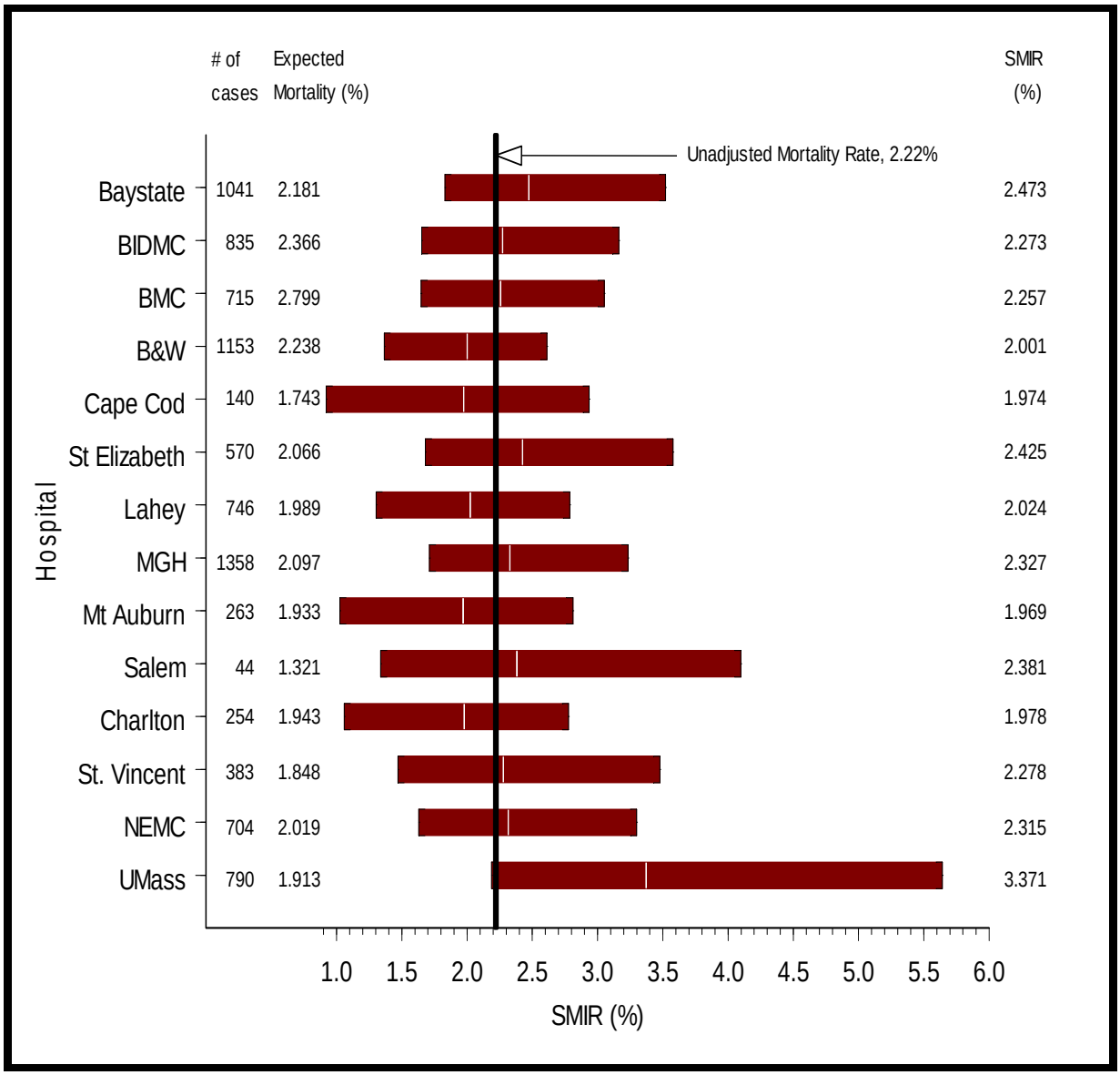


Table 5.2: Cross-Validated P-Values: Surgeries Performed in 2003. P-values for each of the 14 cardiac surgery programs.

Hospital	P Value
Beth Israel Deaconess Medical Center	0.48
Boston Medical Center	0.49
Brigham and Women's Hospital	0.22
Baystate Medical Center	0.27
Cape Cod Hospital	0.09
Caritas St. Elizabeth's Medical Center	0.26
Lahey Clinic	0.21
Massachusetts General Hospital	0.34
Mount Auburn Hospital	0.13
St. Vincent Hospital	0.44
Tufts-New England Medical Center	0.38
Salem Hospital	0.12
Southcoast - Charlton Hospital	0.14
UMass Memorial Medical Center	0.0004

6 - IMPORTANT DEFINITIONS

Aortic Valve Repair: Surgical repair of the aortic valve of the heart. The aortic valve is responsible for facilitating the flow of blood into the aorta.

Aortic Valve Replacement: A surgical procedure involving replacement of the aortic valve of the heart.

Cardiac Catheterization: A procedure that determines the extent and the location of the coronary artery obstruction or blockage.

Cardiac Surgery (as defined by the Massachusetts legislature for the Massachusetts Cardiac Study): Surgery on the heart and the thoracic great vessels. Examples of cardiac surgery include coronary artery bypass grafts, heart valve repair or replacement, heart transplantation, surgery of the thoracic aorta, repair of congenital heart defects, and minimally invasive heart surgery.

Cardiovascular Disease: Includes diseases of the heart or vessels that supply the body and the heart muscle with blood and oxygen.

Coronary Artery Disease: A disease affecting the coronary arteries in which the flow of oxygen containing blood to the heart muscle is partially or completely blocked, resulting in angina or a heart attack.

Coronary Artery Bypass Graft [CABG] Surgery: An operation in which the blocked coronary vessels are bypassed with the patient's own vessels to improve flow to the heart muscle. Coronary vessels are those vessels that supply the heart muscle with blood and oxygen.

Cross-Validation: Model validation is performed to ascertain whether predicted values from a statistical model are likely to accurately predict responses on future subjects or on

subjects not used to develop the analytical model. Cross-validation involves dropping a set of observations from the analytical process and the outcomes for the dropped set are predicted. This process is repeated many times in order to characterize the accuracy of the predictions.

Mitral Valve Repair: Surgical repair of the mitral valve of the heart. The mitral valve is responsible for facilitating the flow of blood from the left atrium into the left ventricle.

Mitral Valve Replacement: A surgical procedure which involves the replacement of the mitral valve of the heart.

Percutaneous Coronary Intervention: A non-surgical procedure designed to open and maintain the patency of obstructed coronary vessels. This treatment is an invasive procedure performed in the cardiac catheterization lab (e.g., outside of an operating room) by an interventional cardiologist in which a balloon, stent, or other device is delivered to the affected vessel to open and maintain its patency.

Risk Factors: Factors that contribute to an individual's risk of coronary artery disease or of death. These factors are classified as those that can be modified or changed by an individual, and those that cannot be changed. Examples of risk factors that cannot be modified include age, gender, family history of coronary artery disease, and ethnicity. Risk factors that can be controlled include diet, cholesterol levels, obesity, smoking, hypertension, inactive lifestyle, stress, and diabetes.

Standardized Mortality Incidence Rate (SMIR): The ratio of projected deaths (the number of deaths adjusted for the number of cases treated at the hospital and the hospital case mix) to expected deaths (the expected number of deaths calculated on the basis of the mortality experience of all cardiac surgery programs) multiplied by the state unadjusted rate. SMIRs are interpreted in terms of their corresponding probability intervals. If the probability interval includes the state rate, then the SMIR is no different from what was expected. If the interval excludes the state rate, then the SMIR is "significantly different" from what was expected. In this case, if the upper limit of the interval is lower than the

state rate, then fewer patients than expected died; if the lower limit of the 95% interval is higher than the state rate, then more patients than expected died.

7 - ADVISORY COMMITTEES

Mass-DAC gratefully acknowledges the support from members of several Advisory Committees who have donated their time to improve the quality of cardiac care in the Commonwealth of Massachusetts. Mass-DAC is also indebted to: Marc Ciriello, B.A. and Patricia L. Miller, B.S., for editorial comments and editing, and to the Massachusetts Cardiac Surgery Data Managers for their data collection efforts – their attention to detail has contributed enormously to this initiative.

Massachusetts Cardiac Care Quality Advisory Commission develops standards and criteria to be used by the Department of Public Health and Mass-DAC for the purpose of collecting, monitoring, and validating patient-specific outcome data from all hospitals in the Commonwealth of Massachusetts performing cardiac surgery or PCIs.

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APPENDIX:

STS DATA COLLECTION TOOL - VERSION 2.41

The Society of Thoracic Surgeons
Adult Cardiac Surgery Database
Data Collection Form

Version 2.41

A. Administrative

Participant ID: |___|___|___|___|___| Cost Link Field: |_____| Optional STS Trial Link Number: |___|___|___|___|___| Optional

B. Demographics

Patient Medical Record Number: _____ not harvested

Last Name: _____ First: _____ MI: ____ not harvested

Date of Birth: __ __/__ __/__ __ __ __ optional harvest Age: _____ system calculation

Gender: (Male) (Female)

Race: (Caucasian) (Black) (Hispanic) (Asian) (Native American) (Other)

Social Security (or National ID) Number: _____ not harvested

ZIP or Postal Code: _____ optional harvest

Referring Cardiologist's Name: _____ not harvested Referring Physician's Name: _____ not harvested

C. Hospitalization

Hospital Name: _____ controlled list Primary Payor: _____ not harvested

Date of Admission: __ __/__ __/__ __ __ __ Date of Surgery: __ __/__ __/__ __ __ __ Date of Discharge: __ __/__ __/__ __ __ __

Same Day Elective Admission: No Yes

Initial ICU Hours:_____ Readmn to ICU: No Yes → if yes, Additional ICU Hours _____ Total Hours in ICU:_____ calculated

D. Pre-Operative Risk Factors

Weight: _____ (kg) Height: _____ (cm)

Smoker: No Yes → if yes, Current Smoker: No Yes

Family History of CAD: No Yes

Diabetes: No Yes → if yes, select one: Diabetes Control: (None) (Diet) (Oral) (Insulin)

Hypercholesterolemia: No Yes

Last Creatinine Preop: _____

Renal Failure: No Yes → if yes, Dialysis: No Yes

Hypertension: No Yes

Cerebrovascular Accident: No Yes → if yes, When: (Recent <= 2 weeks) (Remote > 2 weeks)

Infectious Endocarditis: No Yes → If yes, Infectious Endocarditis Type: (Treated) (Active)

Chronic Lung Disease: (No) (Mild) (Moderate) (Severe)

Immunosuppressive Trtment: No Yes

Peripheral Vascular Disease: No Yes

Cerebrovascular Disease: No Yes → if yes, CVD Type: (Coma) (CVA) (RIND) (TIA) (Non Invasive > 75%) (Previous Carotid Surgery)

E. Previous Interventions

Previous CV Interventions: No Yes ↓ if yes, complete this section

# of Prior Cardiac Operations Requiring Cardiopulmonary Bypass: _____ # of Prior Cardiac Operations Without Cardiopulmonary Bypass: _____

Previous Surgery:

Coronary Artery Bypass: No Yes Valve: No Yes Previous Other Cardiac: No Yes

Prior PTCA including Balloon and/or Atherectomy: No Yes → if yes, Interval: <= 6 hours > 6 hours

Previous non-surgical Stent Placement: No Yes → if yes, Interval: <= 6 hours > 6 hours

Thrombolysis: No Yes → if yes, Interval: <= 6 hours > 6 hours

Previous non-surgical Balloon Valvuloplasty: No Yes

F. Pre Operative Cardiac Status

Myocardial Infarction: No Yes → if yes, When: (<= 6 hours) (> 6 hours but <24 hours) (1 - 7 days) (8 - 21 days) (> 21 days)

Congestive Heart Failure: No Yes

Angina: No Yes → if yes, Type: Stable Unstable ↓ if unstable

Unstable Type: (Rest Angina) (New Class 3) (Recent Accel) (Variant Angina) (Non-Q MI) (Post- Infarct Angina)

Cardiogenic Shock: No Yes → if yes Type: (Refractory Shock) (Hemodynamic Instability)

Resuscitation: No Yes

Arrhythmia: No Yes → if yes, Type: (Sust VT/VF) (Heart Block) (AFib/Flutter)

Classification: CCS: 0 I II III IV NYHA: I II III IV

G. Pre Operative Medications

Digitalis: No Yes	Beta Blockers: No Yes	Nitrates – I.V.: No Yes	Anticoagulants: No Yes	Diuretics: No Yes
Inotropic Agents: No Yes	Steroids: No Yes	Aspirin: No Yes	Ace Inhibitors: No Yes	Oth Anti-Platelets: No Yes

H. Pre Operative Hemodynamics and Cath

Number of Diseased Coronary Vessels: (None) (One) (Two) (Three)

Left Main Disease > 50%: No Yes

Ejection Fraction Done? No Yes → if yes, Ejection Fraction: _____ → Method: (LV gram) (Radionucleotide) (Estimate) (ECHO)

Pulmonary Artery Mean Pressure Done? No Yes → if yes, Pulmonary Artery Mean Pressure: _____

Aortic Stenosis: No Yes → If yes, Gradient: _____	Aortic Insufficiency:	0=None 1=Trivial 2=Mild 3= Moderate 4= Severe	
Mitral Stenosis: No Yes	Mitral Insufficiency:	0=None 1=Trivial 2=Mild 3= Moderate 4= Severe	
Tricuspid Stenosis: No Yes	Tricuspid Insufficiency:	0=None 1=Trivial 2=Mild 3= Moderate 4= Severe	
Pulmonic Stenosis: No Yes	Pulmonic Insufficiency:	0=None 1=Trivial 2=Mild 3= Moderate 4= Severe	

J. Operative

Surgeon's Name: _____ controlled list Surgeon Group: _____ controlled list

Status of the procedure:

Emergent Salvage

Emergent → Reason: (Shock Circ Supp) (Shock No Circ Supp) (Pulm Edema) (AEMI) (Ongoing Ischemia) (Valve Dysfnctn) (Aortic Dissection)

Urgent → Reason: (AMI) (IABP) (Worsening CP) (CHF) (Anatomy) (USA) (Rest Angina) (Valve Dysfunction) (Aortic Dissection)

Elective

Coronary Artery Bypass: No Yes (if yes, complete Section K)

Aortic:	Mitral:	Tricuspid:	Pulmonic:
No	No	No	No
Replacement	Annuloplasty only	Annuloplasty Only	Replacement
Repair/Reconstruction	Replacement	Replacement	Reconstruction
Root Reconstruction Valve Conduit	Reconstruction w/ Annuloplasty	Reconstruction w/ Annuloplasty	
Reconstruction w/ Valve Sparing	Reconstruction w/out Annuloplasty	Reconstruction w/out Annuloplasty	
Resuspension Aortic Valve		Valvectomy	
Resection Sub-Aortic Stenosis			

Other Cardiac Procedure: No Yes ↓ (if yes, complete Section N)

Other Non-Cardiac Procedure: No Yes ↓ (if yes, complete Section O)

K. Coronary Surgery

Unplanned CABG: No Yes

Number of Distal Anastomoses with Arterial Conduits: _____

Number of Distal Anastomoses with Vein Grafts: _____

IMAs Used as Grafts: (Left IMA) (Right IMA) (Both IMAs) (No IMA)

Number of IMA Distal Anastomoses: _____

Radial Artery(ies) Used as Grafts: (No Radial) (Left Radial) (Right Radial) (Both Radials)

Number of Radial Artery Distal Anastomoses: _____

Number of Gastro-Epiploic Artery Distal Anastomoses: _____

L. Valve Surgery

↓ Key M = Mechanical, B = Bioprosthesis, H = Homograft, A = Autograft, R = Ring

Aortic Prosthesis -	Implant Type:	None M B H A R	Implant: _____ Size: _____(mm)
	Explant Type:	None M B H A R	Explant: _____ Size: _____(mm)
Mitral Prosthesis -	Implant Type:	None M B H A R	Implant: _____ Size: _____(mm)
	Explant Type:	None M B H A R	Explant: _____ Size: _____(mm)
Tricuspid Prosthesis -	Implant Type:	None M B H A R	Implant: _____ Size: _____(mm)
	Explant Type:	None M B H A R	Explant: _____ Size: _____(mm)
Pulmonic Prosthesis -	Implant Type:	None M B H A R	Implant: _____ Size: _____(mm)
	Explant Type:	None M B H A R	Explant: _____ Size: _____(mm)

Valve Key

Mechanical
M1= ATS Mechanical Prosthesis
M2= Björk-Shiley Convex-Concave Mechanical Prosthesis
M3= Björk-Shiley Monostrut Mechanical Prosthesis
M4= CarboMedics Mechanical Prosthesis
M5= Edwards Tekna Mechanical Prosthesis
M6= Lillehei-Kaster Mechanical Prosthesis
M7= Medtronic-Hall Mechanical Prosthesis
M8= OmniCarbon Mechanical Prosthesis
M9= OmniScience Mechanical Prosthesis
M10= On-X Mechanical Prosthesis
M11= Sorin Bicarbon (Baxter Mira) Mechanical Prosthesis
M12= Sorin Monoleaflet Allcarbon Mechanical Prosthesis
M13= St. Jude Medical Mechanical Prosthesis
M14= Starr-Edwards Caged-Ball Prosthesis
M15= Ultracor Mechanical Prosthesis

Bioprosthetic
B1= Baxter Prima Plus Stentless Porcine Bioprosthesis
B2= Baxter Prima Stentless Porcine Bioprosthesis
B3= Biocor Porcine Bioprosthesis
B4= Biocor Stentless Porcine Bioprosthesis
B5= CarboMedics PhotoFix Pericardial Bioprosthesis
B6= Carpentier-Edwards Pericardial Bioprosthesis
B7= Carpentier-Edwards Standard Porcine Bioprosthesis
B8= Carpentier-Edwards Supra-Annular Porcine Bioprosthesis
B9= Cryolife O'Brien Stentless Porcine Bioprosthesis
B10= Hancock Standard Porcine Bioprosthesis
B11= Hancock II Porcine Bioprosthesis
B12= Hancock Modified Orifice Porcine Bioprosthesis
B13= Ionescu-Shiley Pericardial Bioprosthesis
B14= Labcor Stented Porcine Bioprosthesis
B15= Labcor Stentless Porcine Bioprosthesis
B16= Medtronic Freestyle Stentless Porcine Bioprosthesis
B17= Medtronic Intact Porcine Bioprosthesis
B18= Medtronic Mosaic Porcine Bioprosthesis
B19= Mitroflow Pericardial Bioprosthesis
B20= Sorin Pericarbon Stentless Pericardial Bioprosthesis
B21= St. Jude Medical - Toronto SPV Stentless Porcine Bioprosthesis
B22= St. Jude Medical-Bioimplant Porcine Bioprosthesis

Homograft
H1= Homograft Aortic – Subcoronary
H2= Homograft Aortic Root/Cylinder
H3= Homograft Mitral
H4= Homograft Pulmonic Root
H5= Cryolife Homograft

Autograft
A1= Autograft Pulmonic Root

Ring
R1= Carpentier-Edwards Classic Ring
R2= Carpentier-Edwards Physio Ring
R3= Cosgrove-Edwards Ring
R4= Medtronic Sculptor Ring
R5= Medtronic-Duran Ring
R6= Sorin-Puig-Messana Ring
R7= St. Jude Medical Sequin Ring

777= Other

M. Operative Techniques

Cardiopulmonary Bypass Used: No Yes → if yes, Conversion to CPB: No Yes

Primary Indication for minimally Invasive approach: (Surg/Pat Choice) (ContraindicatedStd Approach) (Comb Cath Intervention)

Primary Incision:

Full Sternotomy Partial Sternotomy Transverse Sternotomy Right Vertical Parasternal Left Vertical Parasternal
Right Anterior Thoracotomy Left Anterior Thoracotomy Posterolateral Thoracotomy Xiphoid Epigastric Subcostal

Total # of Incisions: _____ Conversion to Stnd Incision: No Yes → if yes, Indication: (Exposure) (Bleeding) (Rhythm) (Hypotension) (Conduit)

Cannulation Meth: (Aorta and Fem/Jug Vein) (Fem Art and Fem/Jug Vein) (Aorta and Atrial/Caval) (Fem Art and Atrial/Caval) (Other)

Aortic Occlusion Method: (None) (Cross-clamp) (Balloon Occlusion)

Intracoronary Shunt used during distal anastomoses: No Yes

Suture Technique: (Running) (Interrupted) (Stapler) (Combination)

Vessel Stabilization Technique: (None) (Suture Snare) (Suction Device) (Compression) (Other)

IMA Harvest Technique: (None) (Direct Vision) (Thoracoscopy) (Combination)

Acute Flow Patency Assess of Grafts (Periop): (None) (IntaOp Doppler) (IntraOp Angio) ()Postop Angio) (Postop Doppler)

N. Other Cardiac Procedures

No Yes Left Ventricular Aneurysm Repair	No Yes Vent Septal Defect Repair	No Yes Atrial Septal Defect Repair
No Yes Batista	No Yes SVR	No Yes Congenital Defect Repair
No Yes Transmyocard Laser Revasc	No Yes Cardiac Trauma	No Yes Cardiac Transplant
No Yes Permanent Pacemaker	No Yes AICD	No Yes Other

O. Other Non Cardiac Procedures

No Yes Aortic Aneurysm No Yes Carotid Endarterectomy No Yes Other Vascular No Yes Other Thoracic

P. CPB and Support

Skin Incision Start Time: _____ 24 hour clock Skin Incision Stop Time: _____ 24 hour clock

Cross Clamp Time (min): _____ Perfusion Time (min): _____ Cardioplegia: No Yes

IABP No Yes → if yes, When Inserted: (Preop) (Intraop) (Postop)

If yes, → Indication: (Hemodynamic Instab) (PTCA Support) (Unst. Angina) (CPB Wean) (Prophylatic)

Ventricular Assist Device: No Yes

Q. Post Operative

Blood Products Used: No Yes

Initial # of Hrs Ventilated Postop: _____ Re-intubated During Hosp Stay: No Yes → if yes, Addl Hours Ventilated Postop: _____

Total Hours Ventilated Postop: _____

R. Complications In hospital Complications: No Yes ↓ if yes, at least one complication below must be selected

Operative	No Yes	ReOp for Bleeding/Tamponade	Infection	No Yes	Sternum – Deep
	No Yes	ReOp for Valvular Dysfunction		No Yes	Thoracotomy
	No Yes	ReOp for Graft Occlusion		No Yes	Leg
	No Yes	ReOp for Other Cardiac Problem		No Yes	Septicemia
	No Yes	ReOp for Other Non Cardiac Problem		No Yes	Urinary Tract Infection
	No Yes	Perioperative Myocardial Infarction			
Neurologic	No Yes	Stroke	Pulmonary	No Yes	Prolonged Ventilation
	No Yes	Transient		No Yes	Pulmonary Embolism
	No Yes	Continuous Coma >=24Hrs		No Yes	Pneumonia
Renal	No Yes	Renal Failure	Vascular	No Yes	Vascular - Aortic Dissection
	No Yes	Dialysis		No Yes	Illiac/Femoral Dissection
				No Yes	Acute Limb Ischemia
Other	No Yes	Heart Block			
	No Yes	Cardiac Arrest		No Yes	Gastro-Intestinal Complication
	No Yes	Anticoagulant Complication		No Yes	Multi-System Failure
	No Yes	Tamponade		No Yes	Atrial Fibrillation

S. Discharge (Note: this section is blank if patient dies during initial hospital stay)

Aspirin: No Yes | Ace-Inhibitors: No Yes | Beta Blockers: No Yes | Lipid Lowering: No Yes | Other Anti-Platelets: No Yes

Discharge Location: (Home) (Extended Care/TCU) (Other Hospital) (Nursing Home) (Other)

T. Mortality

Mortality - Mortality: No Yes Discharge Status: Alive Dead Status at 30 days after surgery: Alive Dead

Mortality - Operative Death: No Yes Mortality - Date __ __/__ __/__ __ __ __ (mm/dd/yyyy)

Location of Death: (OR) (Hospital) (Home) (Other Facility)

Primary Cause of Death (select only one): (Cardiac) (Neurological) (Renal) (Vascular) (Infection) (Pulmonary) (Valvular) (Other)

U. Readmission (Note: this section is blank if patient dies during initial hospital stay)

Readmit <=30 Days from Date of Procedure: No Yes↓ if yes, select the most predominate reason

Readmission Reason:

(Anticoagulant Complications)	(Arrhythmias/Heart Block/Pacemaker Insertion/AICD)	(CHF)
(MI/Recurrent Angina)	(Pericardial Effusion/Tamponade)	(Pneumonia/ Respiratory Complication)
(Valve Dysfunction)	(Infection Deep Sternum)	(Infection Leg)
Cardiac Cath)	(PTCA Stent)	(Renal Failure)
TIA)	(Reop for Graft Occlusion)	(Reop for Bleeding)
(Permanent CVA)	(Acute Vascular Complication)	(Other)