TECHNICAL REPORT ON ADULT CORONARY ARTERY BYPASS GRAFT SURGERY IN THE COMMONWEALTH OF MASSACHUSETTS

January 1 – December 31, 2004

Mass-DAC

Department of Health Care Policy

Harvard Medical School

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MASSACHUSETTS DATA ANALYSIS CENTER (MASS-DAC)

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MASSACHUSETTS CARDIAC SURGERY CENTERS 2004

Baystate Medical Center 759 Chestnut Street Springfield, MA 01199	Massachusetts General Hospital (MGH) 12 Fruit Street Boston, MA 02114
Beth Israel Deaconess Medical Center (BIDMC) 330 Brookline Avenue Boston, MA 02115	Mount Auburn Hospital 330 Mount Auburn Street Cambridge, MA 02138
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 02601	Saint Vincent Hospital at Worcester Medical Center 123 Summer Street Worcester, MA 01608
Caritas Saint Elizabeth's Medical Center 736 Cambridge Street Boston, MA 02135	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 2004, there were **7289** hospital admissions in which at least one cardiac surgery was performed in Massachusetts. More than half **(54.7**%) of the admissions were those in which an isolated coronary artery bypass graft (CABG) surgery was done.
- There were **407 fewer** isolated CABG surgery admissions performed in Massachusetts in 2004, as compared to 2003.
- Since January 1, 2002, there has been a decrease of **617** isolated CABG admissions in Massachusetts
- **Fourteen** hospitals performed at least one CABG operation in Massachusetts in 2004.
- In the fourteen hospitals that performed cardiac surgery in 2004, the number of CABG surgery admissions ranged from **101 to 537**.
- 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 2004 was **2.01%**.
- **Caritas Saint Elizabeth's Medical Center** was identified as a statistical outlier, having higher than expected 30-day mortality in 2004.

2 - INTRODUCTION

2.1 - What is in this Report?

This report describes procedures for calculating hospital-specific risk standardized 30-day mortality rates following isolated coronary artery bypass graft (**CABG**) surgery performed in Massachusetts hospitals in 2004. 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 2004, there were fourteen cardiac surgery programs in Massachusetts: eleven well established and three relatively new programs. Of the three newer 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 3rd annual report (all reports are available at www.massdac.org) describing hospital-specific risk 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, 2004 and December 31, 2004.

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 the sudden development of a clot within a coronary artery, the presence of the clot usually results in a heart attack or myocardial infarction (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, but 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*** procedures.

2.3 - Definition of Study Population

The patient population consists of all patients aged 18 years or older undergoing isolated CABG surgery in Massachusetts' adult acute care hospitals between January 1, 2004 and December 31, 2004. Surgeries performed in United States Government hospitals (e.g., VA Boston Healthcare System) are not included. If multiple cardiac surgeries occur during an admission, admissions are categorized by the primary (initial) surgery. Isolated CABG surgery included CABG alone as well as CABG undertaken in combination with the following procedures: maze (closed epicardial approach and radio frequency), pacemaker lead insertions, ventricular lead insertion for automatic implantable cardioverter defibrillator, patent foramen ovale closure, and femoral artery procedures. If CABG was performed in combination with maze (open heart approach), implantation of a cardioverter defibrillator, transmyocardial revascularization, or opening of the right atrium for tumor resection, then these procedures were classified as "Other Cardiac

Surgery." Lung biopsies performed in conjunction with a CABG were considered on a case by case basis **(see Appendix 1)**. **Table 2.1** lists the distribution of the 7289 cardiac surgery admissions stratified by surgical procedure type in Massachusetts' hospitals during 2004.

Table 2.1: Surgical Procedure Type Classification of Adult Cardiac Surgeries During January 1, 2004 - December 31, 2004, Commonwealth of Massachusetts.

Surgical Procedure Type	No. of Cardiac Surgery Admissions	% of Cardiac Surgery Admissions
Isolated CABG	**3986**	**54.7**
Mitral Valve Replacement (MVR)	131	1.8
Aortic Valve Replacement (AVR)	599	8.2
MVR + CABG	65	0.9
AVR + CABG	566	7.8
AVR + MVR	36	0.5
Other Cardiac Surgery	1837	25.2
Non-Cardiac (Thoracic) Procedures	69	1.0
All Cardiac Surgery Admissions	**7289**	**100**

2.4 - Why Report on CABG Surgery?

CABG surgeries account for the majority of cardiac surgeries performed nationally and are a costly procedure. In 2004, isolated CABG surgeries accounted for 54.7 percent of the 7289 cardiac surgery hospital admissions in Massachusetts. Only data on patients who have undergone isolated CABG surgery are used to determine the hospital mortality rates in this report.

2.5 - What is Mass-DAC?

Mass-DAC is a data-coordinating 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, the MA STS Outcomes Quality Improvement Committee, and the Cardiac Surgery Data Adjudication Committee. In addition, the National Society of Thoracic Surgeons (STS) and the Massachusetts STS chapter serve as resources.

3 - SUMMARY OF DATA COLLECTION & VERIFICATION PROCEDURES

3.1 - Definition of Patient Outcome

Mortality, regardless of cause, measured within 30 days from the date of CABG surgery is the primary patient outcome. Mortality was selected as the primary measure of quality because it is serious and unambiguous.

3.2 - Massachusetts Cardiac Surgery Programs

Fourteen cardiac surgery centers treated patients in Massachusetts in the calendar year 2004.

3.3 - Data Sources

Three different data sources were used to create this report: patient-specific data collected by hospital personnel using the Society of Thoracic Surgeons (STS) National Cardiac Surgery Database software; hospital administrative discharge data; and vital statistics information provided by the Massachusetts Department of Public Health.

Mass-DAC STS Data. Patient-specific risk factor and outcome data were collected by hospital personnel using the STS National Cardiac Surgery Database software. Version 2.41 (**see Appendix 2**) containing 217 variables was used for all data collection for the first six months of 2004. Version 2.52.1, a new version of the STS collection tool (**see Appendix 3**) containing 293 variables was used for all data collection and submissions for the last six months of 2004. In Version 2.52, additional variables were added by STS for Ventricular Assist Devices (VAD's), other cardiac surgery, and medications while other variables were deleted.

Massachusetts Inpatient Acute Hospital Case Mix and Charge Database. Hospital discharge data for fiscal years 2002, 2003, 2004 and 2005 (October 1, 2002 through September 30, 2005) were obtained from the Massachusetts Division of Health Care Finance and Policy. Data elements included: hospital identifier; gender, race, age and

home zip code of the patient; ICD-9 codes; discharge status; dates of admission and discharge; date of surgery; and patient medical record number. Social security numbers were removed from this database.

Massachusetts Mortality Index Database. Date of death information obtained from Massachusetts death certificates were available for all deaths occurring in Massachusetts between January 1, 2002 and January 31, 2005 from the Massachusetts Registry of Vital Records and Statistics. While the primary source of 30-day mortality rates was the hospital-reported rates, the mortality index database was used in a verification procedure. Using a confidential and secure transmission procedure, Mass-DAC submitted to the Registry patient names, dates of birth, and social security numbers for all Mass-DAC patients, regardless of hospital-reported survival status. Registry personnel subsequently linked the data submitted by Mass-DAC to the Registry mortality index database using these variables and supplied Mass-DAC with the date of death for all applicable patients.

3.4 - Mass-DAC Data Collection Procedures

The majority of Massachusetts hospitals used clinical staff, such as physicians, nurses, and perfusionists, to collect information. Data were entered directly into the STS software database by the clinical staff or by a data manager. Alternatively, the data manager collected the STS information under the direction of clinical staff and then entered the data following a retrospective chart review. Data managers were also responsible for maintaining their hospital database, ensuring the accuracy of the data, and transmitting data to both the STS and Mass-DAC.

Data were regularly transmitted by hospitals and harvested by Mass-DAC (**Table 3.1**). This process involved submitting protected data during specific harvest periods. Hospitals had the option of encrypting data and 1) password protecting it, storing it on a disk, and sending it by Federal Express or registered mail or 2) transmitting data electronically using secure messaging software (PGP software). Because 30-day mortality information for patients undergoing cardiac surgery between January 1, 2004 and June 30, 2004 would be complete by July 30, 2004, the harvest began September 1, 2004, one month after the last 30-day follow-up. Data harvests were scheduled in September, 2004

for surgeries between January 1, 2004 and June 30, 2004; data on surgeries performed between July 1, 2004 and December 31, 2004 were collected in the March 2005 harvest. Hospitals were allowed up to one month to submit data during the harvest periods. Hospitals submitted subsequent corrected data as often as desired, and could sign-off on its accuracy and completeness at any time. However, all 2004 cardiac surgery data were required to be complete by September 1, 2005 after which no changes were accepted without written permission from Mass-DAC.

Table 3.1: Cardiac Surgery Data Harvest Schedule for Surgeries Performed in 2004.

Month of Data Harvest	Dates of Cardiac Surgery
September, 2004	January 1, 2004 – June 30, 2004
March, 2005	July 1, 2004 – December 31, 2004
September, 2005	2004 **Data Close-Out** for January 1, 2004 – December 31, 2004

3.5 - Cleaning and Validation Procedures

Hospital data submissions were cleaned and verified using a variety of procedures: continuous feedback via ongoing data quality reports, meetings and communication, review of concordance with administrative datasets, and review of concordance with medical chart audits.

Hospital-Specific Data Quality Reports. For each data submission, Mass-DAC provided a data Quality Report to each hospital describing the distribution of all STS elements and identifying cases with missing, out of usual range, or inconsistent data.

The hospitals were given thirty days to correct the data deficiencies identified by Mass-DAC following receipt of each Quality Report.

There were a total of 88 data submissions sent in by 14 hospitals during 2004 with a mean of 3.1 submissions per hospital. Data submissions for 2004, ranged from 1 to 7 per hospital. Mass-DAC returned a total of 81 Quality Reports with a mean of 2.9 quality reports per hospital. The discrepancy between the submissions and the quality reports is the result of several updated submissions of the same data by some of the hospitals which did not require an additional Quality Report.

MA Administrative Datasets. Mass-DAC found high agreement between the hospital report of 30-day mortality and information linked to Vital Records. There were 23 patients where disagreement was observed. After verifying the mortality status of these patients, there was a net increase of **10** thirty-day mortalities (11 were changed from alive to dead and 1 was changed from dead to alive). There was a net increase of **3** thirty-day mortalities for isolated CABG patients (4 were changed from alive to dead and 1 was changed from dead to alive). The Massachusetts Inpatient Case Mix Dataset was used to determine whether all appropriate cases of cardiac surgery from each institution were submitted to Mass-DAC.

Meetings and Communication. Mass-DAC communicated regularly via electronic mail and telephone with the data managers to clarify definitions or procedural issues, and to serve as a facilitator to the national STS. Recently asked and answered questions were posted on a public website (www.massdac.org) and were discussed at data manager meetings. Meetings with the data managers, Chiefs of Cardiac Surgery, and the Cardiac Advisory Board were scheduled to share preliminary results. This process helped identify areas where data may be inconsistent, incorrectly coded, or outlying.

Audit Data. In the spring of 2006, a sample of the 2004 isolated CABG data was audited. Six cardiac surgeons, (members of the Cardiac Surgery Adjudication Committee, and 3 additional cardiac surgeons who volunteered to assist the committee), performed the audits on the 2004 records. All participants took the Harvard Medical School Human Subjects training prior to review of records and were approved by the Harvard Medical School Internal Review Board (IRB). Records requested from the hospitals included those for (1) **all** patients who died within 30 days of surgery, (2) **all** patients reported to have shock prior to surgery, (3) **all** patients coded with emergent or emergent

salvage status, and (4) **all** Myocardial Infarction less than 24 hours prior to surgery. The total number of records requested amounted to 368 from the 14 hospitals. The records were reviewed to determine data consistency and accuracy of coding.

An additional 221 records were also requested for a subset of procedures that were coded as "CABG + other" cardiac surgery. These records were reviewed to determine if some of them might actually be considered Isolated CABG surgery. Documentation requested from the hospitals included discharge summaries, operative reports, admission and history summaries, and catheterization reports. Institutions were required to provide Mass-DAC verification data by February 15, 2006.

In all, 589 records were reviewed by the surgeons to determine agreement with the information submitted by the hospitals. The subset of records where procedures were coded as "CABG + other" were reviewed by the committee to determine whether the "other" procedures were appropriate to move the entire surgery into the isolated CABG category **(see Appendix 1),** while the additional records were audited to determine justification of shock, emergent or salvage status, and myocardial infarction and timing.). If the Committee did not agree with the designations (of shock, emergent or salvage status or MI less than 24 hours before surgery) the designation was changed. Hospitals were notified of any disagreement in coding and given an opportunity to appeal the Adjudication Committee decisions. All final decision changes were then made in the Mass-DAC database.

Of the 368 records that were identified for audit, 63 records had the surgery status of emergent changed to urgent, 1 from emergent salvage to urgent, and 4 from emergent salvage to emergent status. 48 records indicating shock were changed to no shock, and 15 records indicating MI were changed to no MI. The timing of the MI was changed for 7 records to greater than 24 hours (1 to 7 days). In addition, 72 of the 221 "CABG + other" procedure records reviewed were changed to isolated CABG, 6 of whom were 30- day mortalities.

4 - RISK ADJUSTMENT

4.1 - Who Receives Isolated CABG Surgery in Massachusetts?

Table 4.1 lists the age-sex-race distribution for 3986 adult CABG surgery patients at 14 cardiac surgery programs in Massachusetts. The majority of patients were male (75%) and white (91%). In 2004, 60% of the cases were age 65 years or older at the time of their surgery. Patients who resided outside of Massachusetts at the time of their surgery comprised 9% of the 3986 CABG admissions (data not shown).

Table 4.1: Age-Sex-Race distribution for all adult Isolated CABG surgery admissions (N = 3986) in MA hospitals during January 1, 2004 - December 31, 2004. Entries represent numbers of patients.

Age Group	Females					Males				
	White	African American	Hispanic	Other§	Total	White	African American	Hispanic	Other	Total
18–44	20	2	1	2	25	51	2	2	6	61
45–54	60	4	2	2	68	345	14	19	12	390
55–64	154	14	15	5	188	785	16	31	32	864
65–74	278	8	21	15	322	880	16	29	37	962
≥ 75	388	9	4	12	413	665	6	10	12	693
Total	900	37	43	36	**1016**	2726	54	91	99	**2970**

4.2 - 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

§ Includes some missing

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 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 accounting for 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.

4.3 - 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 30-day mortality for two patients having exactly the same risk factors prior to a CABG surgery but who are treated in different hospitals may 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. If no key risk factor is missing in the statistical model, then the hospital-specific random effect represents quality for each hospital. If there are no differences in the hospital-specific effects across the hospitals, then there is no evidence of quality differences.

5 - 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 classified as "outlying" – however, the designation of outlying depends on how large the difference 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 as outlying.

However, because any one hospital could influence the estimates of the risk-standardized mortality rate for other hospitals in the state, Mass-DAC also calculates the predicted 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 predicted 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.

5.1 - 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 2004. The SMIR consists of an estimate of the hospital's underlying (true) risk-adjusted rate divided by an estimate of the mortality rate expected at the hospital given its case-mix. 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 mortality is **not different than expected**. If the interval excludes the state unadjusted rate, then the hospital's SMIR is different 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 having **lower than expected mortality**. If the lower limit of the interval is higher than the state unadjusted rate, then more patients than expected died. Such a hospital would be categorized as having **higher than expected mortality**.

Hospital-specific 30-day mortality rates, standardized to the population of adults undergoing CABG surgery in Massachusetts hospitals were calculated using the following procedure:

1. A hierarchical logistic regression model was estimated. This model assumes that the log-odds of 30-day mortality is related linearly to the set of risk factors and permits baseline risk to vary across hospitals. Let $Y_{ij} = 1$ if the j^{th} patient treated at the i^{th} cardiac surgery program died within 30-days of surgery and 0 otherwise, and n_i the total number of isolated CABG cases at the institution in 2004. The model estimated was:

$$\text{Log-odds}[\text{Probability}\ (Y_{ij} = 1)] = \beta_{0i} + \beta(\text{Risk Factors})$$
$$\beta_{0i} \sim \text{Normal}(\mu, \tau^2)$$

2. The Risk Factors are those listed in **Table 6.1** (for surgeries performed between January 1, 2004, and December 31, 2004).
3. The "expected" mortality rate at institution "i" is: $1/n_i \sum_j \text{logit}^{-1}[\mu + \beta(\text{Risk Factors})]$. This is the mortality rate expected using the mortality intensity for the entire state and the case mix reported at the institute. Thus it represents the severity of cases at the institution.
4. The "true" mortality rate at institution "i" is: $1/n_i \sum_j \text{logit}^{-1}[\beta_{0i} + \beta(\text{Risk Factors})]$. This is interpreted as the mortality rate at the i^{th} hospital adjusted for case-mix, with larger values generally meaning a sicker baseline population. Note that because the model assumes that the probability of dying is greater than 0, then the true estimate must be greater than 0.
5. The Massachusetts unadjusted rate is: $Y = 100\times (\sum_{ij} Y_{ij})/\sum_i n_i$.
6. The standardized mortality incidence rate (SMIR) at institution "i" is:

$$Y \times (\text{true})/(\text{expected}).$$

The SMIR is interpreted as the projected mortality rate at the hospital today if hospital quality remained the same as in 2004.

7. Ninety-five percent posterior intervals were calculated for each cardiac program's SMIR.
8. An implicit assumption is that the SMIR must be greater than 0.

The parameters μ and τ^2 represent the overall mean risk-adjusted log-odds of mortality and between-hospital variation, respectively. If there are no quality differences (based on mortality) across cardiac surgery hospitals, then

$$\beta_{0,1} = \beta_{0,2} = \ldots = \beta_{0,14} = \beta_0 \text{ and this happens if and only if } \tau^2 = 0$$

The hierarchical model was estimated using WinBUGS software.[2] The prior distributions assumed for β, μ, and τ^2 were, respectively: independent normal distributions with mean 0 and variance 1000 for the components of β; μ from a normal distribution with mean 0 and variance 1000; and $1/\tau^2$ from a gamma distribution with shape and inverse scale 0.001.

5.2 - 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 of μ and τ^2. One method to identify hospitals as outlying is through "cross-validation." This process involves systematically dropping each hospital from the data set and re-estimating the risk-adjusted model. Using the new model, the predicted number of deaths at the dropped hospital is calculated. This predicted 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 in the Commonwealth.

Mass-DAC compared the predicted number to the observed number of deaths at the dropped hospital and calculated a "probability." This probability, loosely called a "p-

[2] A burn-in of 5000 draws and inference based on a subsequent 5000 draws. Convergence was assessed using the Gelman-Rubin statistics via 3 parallel chains.

value" quantifies how **likely** the observed 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 having **higher than predicted mortality**; when the p-value is small and the actual number of deaths is smaller than the number of deaths predicted by its peers, then the hospital is classified as having **lower than predicted mortality**. Mass-DAC repeated this procedure, eliminating each cardiac surgery hospital, and calculating a p-value for each hospital.

5.3 - Sensitivity Analyses

Several sensitivity analyses were undertaken to determine whether conclusions would change when making reasonable changes to some of the underlying assumptions. A key assumption, given the small number of hospitals in Massachusetts, is the assumed distribution for the between-hospital variance. The main analyses assumed the *precision* (defined as one over the variance) arose from a gamma distribution. Because the prior distribution for the variance component can influence the results, Mass-DAC re-estimated the hierarchical model using different prior distributions for τ^2: 1) the between-hospital *standard deviation* arose from a uniform distribution over the range 0 to 1.5 and 2) the between-hospital *standard deviation* arose from a half normal distribution with mean 0 and variance 0.26. In the former case, we are giving equal weight to values across the range 0 to 1.5 – a value of 1.5 for the standard deviation implies a very large range in hospital odds ratios. In the latter case, the half normal distribution has its mode at 0 and its median at 0.39.

6 - HOSPITAL QUALITY FOLLOWING ISOLATED CABG SURGERY: 2004

Of the 3986 isolated CABG surgery admissions in 2004 in Massachusetts, 80 patients (2.01%) died within 30 days of their surgery. **Table 6.1** 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[3]. For example, 75% of the 3986 CABG surgery admissions were 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 0.64 for males indicates that males are 0.64 times as likely as females to die within 30 days of CABG surgery. In contrast, patients having cardiogenic shock prior to isolated CABG surgery are 5.53 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 6.1 displays the SMIRs and corresponding 95% posterior intervals **(Table 6.2** lists the values). The solid black vertical line in the figure is the unadjusted state 30-day mortality rate of 2.01%. Listed on the left-hand side of the figure are the total number of isolated CABG surgery 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 program. Increasing values of the expected 30-day mortality rates correspond to increasing admission severity of the cases. Listed on the right-hand side are the estimated SMIRs. All 95% probability intervals, with the exception of Saint Elizabeth's Medical Center, include the unadjusted state rate of 2.01%.

Figure 6.2 presents the cross-validated p-values under the different assumed prior distributions for the between-hospital variation parameter. This analysis indicated one hospital with a small p-value (p = 0.0054). The cross-validation analysis indicated that the observed number of mortalities was statistically higher than the predicted number of mortalities. This evidence suggests that, relative to all other cardiac surgery programs in

[3] Fit using a non-hierarchical logistic regression model indicated area under the ROC curve of 0.82. The Hosmer-Lemeshow Goodness-of-Fit test did not indicate a lack of fit ($\chi 2$ (8 dof) = 3.63, p = 0.90). Model discrimination ranged form 10.6% (37 deaths in 349 cases) in the highest decile to 0 (0 deaths in 416 cases) in the lowest decile.

Massachusetts, mortality following isolated CABG surgery at Saint Elizabeth's Medical Center is higher than expected.

The 2004 data provide evidence of one statistical outlier. The 95% SMIR interval for Saint Elizabeth's Medical Center lies above the state rate of 2.01% (95% Interval: 2.03%, 7.47%). The cross-validated p-value indicates that Saint Elizabeth's Medical Center had higher than predicted mortality relative to all other Massachusetts cardiac surgery hospitals. These results remained unchanged relative to different modeling assumptions.

Table 6.1: Prevalences and Adjusted Odds Ratios of 30-Day Mortality Following Isolated CABG Surgery in Adults: 2004. Based on 3986 surgeries with 80 deaths (2.01%). *Average age of patients undergoing isolated CABG surgery is 65 + 1.9 = 66.9 years of age.

Risk Factor	Prevalence (%)	Adjusted Odds Ratio	95% Interval for the Adjusted Odds Ratio
Years over 65*	Mean = 1.9 yrs	1.05	1.02, 1.07
Male	74.5	0.64	0.40, 1.11
Renal Failure	5.8	3.83	1.92, 6.65
Diabetes	37.0	1.72	0.99, 2.74
Hypertension	82.7	0.67	0.35, 1.26
Peripheral Vascular Disease	17.7	3.55	2.07, 5.54
Prior CABG surgery	2.6	2.43	0.67, 5.69
Prior Percutaneous Coronary Intervention (PCI)	19.7	1.05	0.54, 1.77
Cardiogenic Shock	1.1	5.53	1.36, 15.02
Ejection Fraction (Ref = ≥ 40%)			
< 30% or missing	11.8	3.97	2.15, 6.65
30 - 39	11.0	1.85	0.82, 3.47
Myocardial Infarction (MI) (Ref = None)			
< 6 hours	0.9	1.64	0.11, 6.38
7 – 24 hours	3.0	1.91	0.50, 4.85
1 – 7 days	22.1	0.95	0.44, 1.76
8 – 21 days	5.3	0.82	0.22, 1.93
> 21 days	21.8	1.71	0.85, 3.05
Status of CABG (Ref = Elective)			
Urgent	66.6	1.86	0.87, 3.57
Emergent/Salvage	3.1	2.15	0.43, 6.13
Pre-Op Intra-Aortic Balloon Pump	11.6	1.66	0.73, 3.14
Between-Hospital Parameters		**Mean**	**95% Interval**
Between-Hospital Average logit, μ		-5.94	(-6.92, -5.00)
Between-Hospital Variance in logits, τ^2		0.3494	(0.0136, 1.252)

Figure 6.1. Ninety-Five Percent Posterior Intervals for Standardized Mortality Incidence Rates (SMIRs) Following Isolated CABG Surgery in Massachusetts, 2004. # of cases refers to the number of isolated CABG surgery admissions; expected mortality 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 **2.01**%.

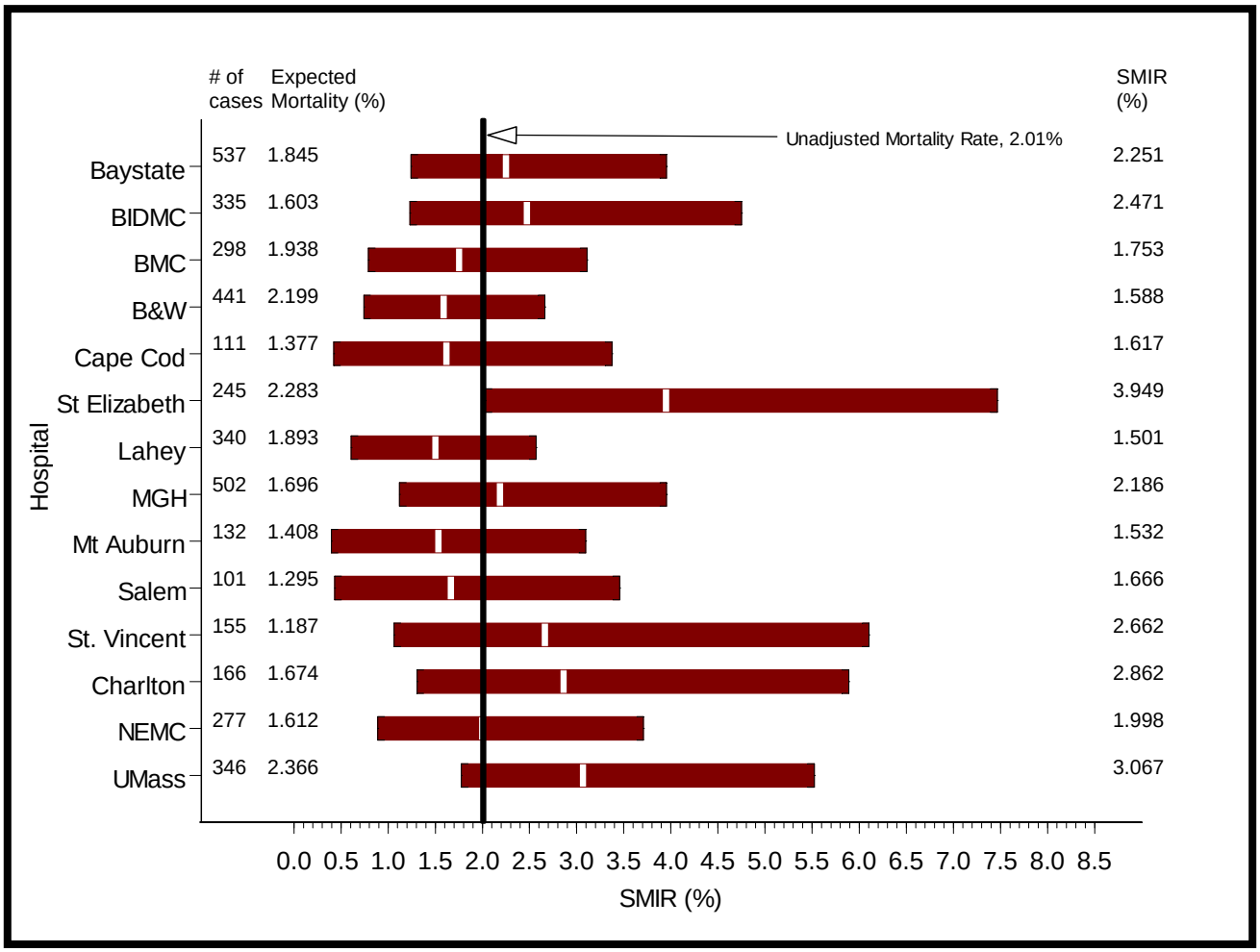
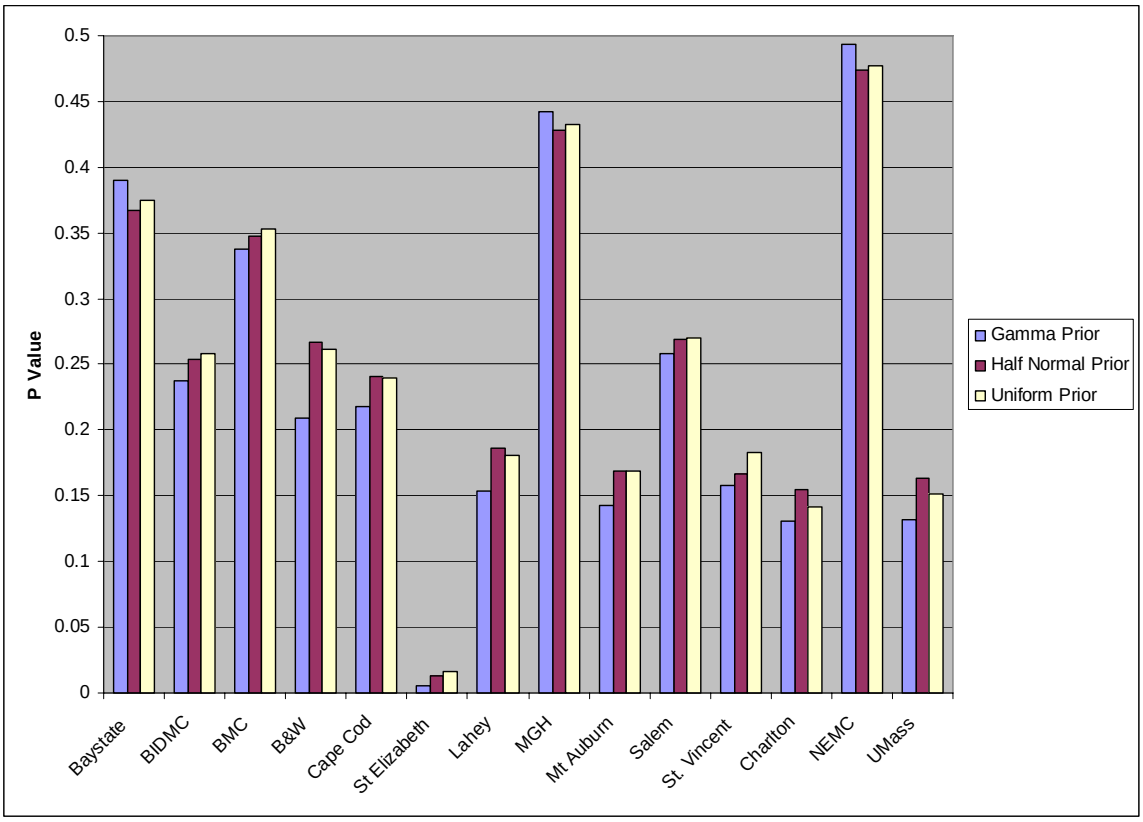


Table 6.2: Expected 30-Day Mortality Rates, and Standardized 30-Day Mortality Incidence Rates (SMIR) point and interval estimates. # of CABG cases refers to the number of Isolated CABG surgery admissions; expected mortality is the percentage of cases expected to die given the case-mix of the patients in the hospital. The SMIR is the hospital-specific standardized rate. Overall State Mean = **2.01**%. **Higher than expected mortality.

Hospital	# CABG Cases	30-Day Mortality (%)			
		Expected	Lower Limit of 95%SMIR Interval	SMIR	Upper Limit of 95% SMIR Interval
Baystate Medical Center	537	1.845	1.242	2.251	3.955
Beth Israel Deaconess Medical Center (BIDMC)	335	1.603	1.232	2.471	4.75
Boston Medical Center (BMC)	298	1.938	0.7889	1.753	3.109
Brigham & Women's Hospital (B&W)	441	2.199	0.7406	1.588	2.664
Cape Cod Hospital	111	1.377	0.421	1.617	3.375
Caritas Saint Elizabeth's Medical Center (St. Elizabeth)**	245	2.283	2.031	3.949	7.466
Lahey Clinic	340	1.893	0.6059	1.501	2.57
Massachusetts General Hospital (MGH)	502	1.696	1.12	2.186	3.955
Mount Auburn Hospital	132	1.408	0.3961	1.532	3.096
North Shore Medical Center-Salem Hospital (Salem)	101	1.295	0.4317	1.666	3.457
Saint Vincent Hospital at Worcester Medical Center (St. Vincent)	155	1.187	1.062	2.662	6.104
Southcoast Hospital Group-Charlton Memorial Hospital (Charlton)	166	1.674	1.307	2.862	5.889
Tufts- New England Medical Center (NEMC)	277	1.612	0.8899	1.998	3.709
UMass Memorial Medical Center (UMass)	346	2.366	1.776	3.067	5.524
ALL	**3986**			**2.01**	

Figure 6.2: Cross-Validated P-Values: Isolated Cardiac Surgery Admissions in 2004. P-values for each of the 14 cardiac surgery programs are listed on the y-axis; the x-axis identifies the hospital. Results are presented under a variety of assumptions for fitting the hierarchical regression model. From left to right, bars represent gamma, half normal and uniform prior distributions.



Cross-Validated P-Values: One hospital (Saint Elizabeth's) identified as a statistical outlier.

Hospital	PROBABILITY OF OBSERVED MORTALITY		
	GAMMA	UNIFORM	HALF-NORMAL
Baystate Medical Center	0.390	0.374	0.368
Beth Israel Deaconess Medical Center (BIDMC)	0.237	0.258	0.254
Boston Medical Center (BMC)	0.337	0.353	0.348
Brigham & Women's Hospital (B&W)	0.210	0.262	0.266
Cape Cod Hospital	0.218	0.239	0.240
Caritas Saint Elizabeth's Medical Center (St. Elizabeth)	0.005	0.016	0.013
Lahey Clinic	0.154	0.180	0.187
Massachusetts General Hospital (MGH)	0.443	0.432	0.428
Mount Auburn Hospital	0.142	0.169	0.169
North Shore Medical Center- Salem Hospital (Salem)	0.258	0.270	0.269
Saint Vincent Hospital at Worcester Medical Center (St. Vincent)	0.158	0.183	0.167
Southcoast Hospital Group-Charlton Memorial Hospital (Charlton)	0.130	0.141	0.155
Tufts- New England Medical Center (NEMC)	0.493	0.477	0.473
UMass Memorial Medical Center (UMass)	0.131	0.151	0.163

7. 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 done 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.

8 - ADVISORY COMMITTEES

Mass-DAC gratefully acknowledges the support from members of several Advisory Committees and physician volunteers (for data adjudication) who have donated their time to improve the quality of cardiac care in the Commonwealth of Massachusetts.

The 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.

David Shahian, M.D., Chair Tufts University School of Medicine Boston, MA	Sharon-Lise Normand, Ph.D. Professor of Health Care Policy (Biostatistics) Department of Health Care Policy Harvard Medical School Boston, MA
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The Mass-DAC Cardiac Advisory Board advises Mass-DAC on data quality; on identification of risk factors affecting patient outcomes; and on appropriateness, interpretation, and limitations of analytic results.

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The Mass-DAC Cardiac Surgery Data Adjudication Committee reviews patient-specific data elements and corresponding data documentation submitted by hospitals to Mass-DAC in order to determine validity.

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The following Cardiac Surgeons generously volunteered their time to join the Cardiac Surgery Adjudication Committee in adjudicating the 2004 data:

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The Massachusetts STS Quality and Outcomes Committee advises Mass-DAC on surgeon and operator specific mortality.

Richard Shemin, M.D., Chair Professor and Chairman Department of Cardiothoracic Surgery Boston Medical Center Boston, MA	David Shahian, M.D. Tufts University School of Medicine Boston, MA
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David Torchiana, M.D. Chairman and Chief Executive Officer Massachusetts General Physicians Organization Boston, MA	

APPENDIX 1:

PROCEDURE IDENTIFICATION GUIDELINES FOR ADULT CARDIAC SURGERY

Appendix 1: Procedure Identification Guidelines for Adult Cardiac Surgery. New York State refers to classification of cardiac surgery procedures used in that State's public reporting system. *Refers to the National STS Procedure ID Table.

Procedure	Mass-DAC	New York State	STS*
Maze: Open heart approach Maze: Closed epicardial approach and radio frequency	"Other" "CABG"	All Maze procedures are excluded	"Other" "Other"
Implantable Cardioverter Defibrillator (ICD)	"Other"	"CABG"	"Other"
Ventricular lead insertion for ICD	"CABG"	"CABG"	"Other"
Pacemaker lead insertions	"CABG"	"CABG"	"CABG"
Lung biopsy	Case by case basis	"CABG"	"Other"
Patent Foramen Ovale Closure	"CABG"	"CABG"	"Other"
Femoral Artery Procedures	"CABG"	"CABG"	"Other"
Transmyocardial Revascularization	"Other"	"CABG"	"Other"
Opening of the right atrium for tumor resection	"Other"	"Other"	"Other"
Atrial Appendage	"CABG"		
Myoxoma	"Other"		
Unplanned Ventricular Assist Device (VAD) placement	"CABG"		
Planned Ventricular Assist Device (VAD) placement	"Other"		
Carotid Surgery	"Other"		
Lead and device explants	"Other"		

APPENDIX 2: STS DATA ABSTRACTION 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)

APPENDIX 3: STS DATA ABSTRACTION TOOL - VERSION 2.52.1

(Variables not harvested by STS are harvested by Mass-DAC)

The Society of Thoracic Surgeons
Adult Cardiac Surgery Database
Data Collection Form
Version 2.52.1

A. Administrative

Participant ID: |___|___|___|___|___|___| Record ID _____

Cost Link Field: _____ STS Trial Link Number: |___|___|___|___|___|___| Patient ID _____

B. Demographics

Last Name: _____ First Name: _____ Patient M.I.: ____ Name Fields Not Harvested

Date of Birth (mm/dd/yyyy): __ __/__ __/__ __ __ __ Patient Age: _____ System Calculation

Gender: Male Female

Social Security (or National Patient ID) Number: _____ Not Harvested Medical Record Number: _____ Not Harvested

Patient ZIP or Postal Code: _____ Race: Caucasian Black Hispanic Asian Native American Other

Referring Cardiologist's Name: _____ Not Harvested Referring Physician's Name: _____ Not Harvested

C. Hospitalization

Hospital Name: _____ Hospital ZIP Code |_____| Hospital State |___|___|

Payor: _____ Not Harvested

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

ICU Visit: Yes No If Yes, → Initial ICU Hours:_____

Readmn to ICU: Yes No If Yes, → Additional ICU Hours _____

Total Hours in ICU:_____

D. Risk Factors

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

Smoker: Yes No If Yes, → Current Smoker: Yes No

Family History of Coronary Artery Disease: Yes No

Diabetes: Yes No If Yes, select one: → Diabetes Control: None Diet Oral Insulin

Dyslipidemia: Yes No

Last Creatinine Level Preop: _____

Renal Failure: Yes No If Yes, → Dialysis: Yes No

Hypertension: Yes No

Cerebrovascular Accident: Yes No If Yes, → When: Recent <= 2 weeks Remote > 2 weeks

Infectious Endocarditis: Yes No If Yes, → Infectious Endocarditis Type: Treated Active

Chronic Lung Disease: No Mild Moderate Severe

Immunosuppressive Therapy: Yes No

Peripheral Vascular Disease: Yes No

Cerebrovascular Disease: Yes No If Yes, → CVD Type: Coma CVA RIND TIA Non Invasive > 75% Prior Carotid Surgery

E. Previous CV Interventions

Incidence: First CV Surgery First Re-op CV Surgery Second Re-op CV Surgery Third Re-op CV Surgery Fourth or More Re-op Surgery

Previous CV Interventions: Yes No If Yes, complete the rest of this section ↓

Previous Coronary Artery Bypass: Yes No

Previous Valve: Yes No

Previous Other Cardiac – Intrapericardial or Great Vessel: Yes No

Previous Other Cardiac – AICD: Yes No

Previous Other Cardiac – Pacemaker: Yes No If Yes, → Previous Other Cardiac – Pacemaker Type: Biventricular Univentricular

Previous Other Cardiac – PCI: Yes No If Yes, → Previous Other Cardiac – PCI Interval: <= 6 Hours > 6 Hours

F. Preoperative Cardiac Status

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

Congestive Heart Failure: Yes No

Angina: Yes No If Yes, → Angina Type: Stable Unstable

Cardiogenic Shock: Yes No If Yes, → Cardiogenic Shock Type: Refractory Shock Hemodynamic Instability

Resuscitation: Yes No

Arrhythmia: Yes No If Yes, → Arrhythmia Type: Sust VT/VF Heart Block AFib/Flutter None

Classification - NYHA: I II III IV

G.. Preoperative Medications

Beta Blockers: Yes No

ACE Inhibitors: Yes No

Nitrates I.V.: Yes No

Anticoagulants: Yes No If Yes, → Anticoagulants Medication Name: Heparin (Unfractionated) Heparin (Low Molecular) Thrombin Inhibitors

Coumadin: Yes No

Inotropes: Yes No

Steroids: Yes No

Aspirin: Yes No

Lipid-Lowering: Yes No If Yes, → Lipid Lowering Medication Name: Statin Non statin

ADP Inhibitors: Yes No

Glycoprotein IIbIIIa Inhibitor: Yes No If Yes, → Glycoprotein IIbIIIa Inhibitor Medication Name: Abciximab (ReoPro)
Eptifibatied (Integrilin)
Tirofiban (Aggrastat)

H. Hemodynamics and Cath

Number of Diseased Coronary Vessels: None One Two Three

Left Main Disease >= 50%: Yes No

Ejection Fraction Done? Yes No If Yes, → Ejection Fraction: _____
Method: LV gram Radionucleotide Estimate ECHO

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

Aortic Stenosis: Yes No If Yes, → Gradient: _____

Mitral Stenosis: Yes No

Tricuspid Stenosis: Yes No

Pulmonic Stenosis: Yes No

Aortic Insufficiency: 0=None 1=Trivial 2=Mild 3= Moderate 4= Severe

Mitral Insufficiency: 0=None 1=Trivial 2=Mild 3= Moderate 4= Severe

Tricuspid Insufficiency: 0=None 1=Trivial 2=Mild 3= Moderate 4= Severe

Pulmonic Insufficiency: 0=None 1=Trivial 2=Mild 3= Moderate 4= Severe

I. Operative

Surgeon's Name: _____ Surgeon ID: _____

Status of the procedure: ↓

Elective

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

Emergent → Reason: Shock Circ Support Shock No Circ Support Pulmonary Edema AEMI
Ongoing Ischemia Valve Dysfunction Aortic Dissection Angiographic Accident

Emergent Salvage

Robotic Technology Assisted: Yes No

Coronary Artery Bypass: Yes No → If Yes, also complete Section J

Valve Surgery : Yes No → If Yes, also complete Section K

Ventricular Assist Device: Yes No → If Yes, also complete Section L

Other Cardiac Procedure: Yes No → If Yes, also complete Section M

Other Non-Cardiac Procedure: Yes No → If Yes, also complete Section N

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

CPB Utilization: None Combination Full ↓

If Combination, → Combination Plan: Planned Unplanned → If Unplanned, Unplanned Combination Reason: Exposure/visualization
Bleeding
Inadequate size and/or diffuse disease of distal vessel
Hemodynamic Instability
Conduit quality and/or trauma
Other

If Combination or Full, → Perfusion Time (min): _____

Cannulation Method: → Aorta and Fem/Jug Vein
Fem Art and Fem/Jug Vein
Aorta and Atrial/Caval
Fem Art and Atrial/Caval
Other

Aortic Occlusion: → None
Aortic Crossclamp → If Aortic Crossclamp or Balloon Occlusion, → Cross Clamp Time (min): _____
Balloon Occlusion
Partial Crossclamp

Cardioplegia: Yes No

IABP: Yes No → If Yes, When Inserted: → Preoperatively Intraoperatively Postoperatively
Indication: → Hemodynamic Instab PTCA Support Unstable Angina CPB Wean Prophylactic

Intraop Blood Products: Yes No → If Yes, Red Blood Cell Units _____
Fresh Frozen Plasma Units _____
Cryoprecipitate Units _____
Platelet Units _____

J. Coronary Bypass

Number of Distal Anastomoses with Arterial Conduits: _____

Number of Distal Anastomoses with Venous Conduits: _____

Anastomotic Device Used: Yes No If Yes, → Anastomotic Device: Glue Magnets Clips Staples Other

IMAs Used as Grafts: Left IMA Right IMA Both IMAs No IMA If Left, Right, or Both ↓
IMA Harvest Technique: Direct Vision Thoracoscopy Combination Robotic Assisted
Number of IMA Distal Anastomoses: _____

Radial Artery Used: No Radial Left Radial Right Radial Both Radials If Left, Right, or Both ↓
Number of Radial Artery Distal Anastomoses: _____

Number of Gastro-Epiploic Artery Distal Anastomoses: _____

Number of Other Arterial Distal Anastomoses: _____

K. **Valve Surgery**

Aortic:	Mitral:	Tricuspid:	Pulmonic:
No	No	No	No
Replacement	Annuloplasty Only	Annuloplasty Only	Replacement
Repair/Reconstruction	Replacement	Replacement	Reconstruction
Root Reconstruction w/ Valve Conduit	Reconstruction w/ Annuloplasty	Reconstruction w/ Annuloplasty	
Replacement + Aortic Graft Conduit	Reconstruction w/out Annuloplasty	Reconstruction w/out Annuloplasty	
Root Reconstruction w/ Valve Sparing		Valvectomy	
Resuspension Aortic Valve with replacement ascending Aorta			
Resuspension Aortic Valve without replacement ascending Aorta			
Resection Sub-Aortic Stenosis			

Annular Enlargement: Yes No

↓ Key M = Mechanical B = Bioprosthesis H = Homograft A = Autograft (Ross) R = Ring/Annuloplasty BA = Band/Annuloplasty

Aortic Prosthesis -	Implant Type:	None	M	B	H	A	R	BA	Implant: _____	Size: _____
Mitral Prosthesis -	Implant Type:	None	M	B	H	A	R	BA	Implant: _____	Size: _____
Tricuspid Prosthesis -	Implant Type:	None	M	B	H	A	R	BA	Implant: _____	Size: _____
Pulmonic Prosthesis -	Implant Type:	None	M	B	H	A	R	BA	Implant: _____	Size: _____

Valve Key

Mechanical
ATS Mechanical Prosthesis = M1
Björk-Shiley Convex-Concave Mechanical Prosthesis = M2
Björk-Shiley Monostrut Mechanical Prosthesis = M3
CarboMedics Mechanical Prosthesis = M4
CarboMedics Carbo-Seal Ascending Aortic Valved Conduit Prosthesis = M16
CarboMedics Carbo-Seal Valsalva Ascending Aortic Valved Conduit Prosthesis = M17
CarboMedics Reduced Cuff Aortic Valve = M18
CarboMedics Standard Aortic Valve = M19
CarboMedics Top-Hat Supra-annular Aortic Valve = M20
CarboMedics OptiForm Mitral Valve = M21
CarboMedics Standard Mitral Valve = M22
CarboMedics Orbis Universal Valve = M23
CarboMedics Small Adult Aortic and Mitral Valves = M24
Edwards Tekna Mechanical Prosthesis = M5
Lillehei-Kaster Mechanical Prosthesis = M6
MCRI On-X Mechanical Prosthesis = M10
Medtronic-Hall/Hall Easy-Fit Mechanical Prosthesis = M7
Medtronic ADVANTAGE Mechanical Prosthesis= M25
OmniCarbon Mechanical Prosthesis = M8
OmniScience Mechanical Prosthesis = M9
Sorin Bicarbon (Baxter Mira) Mechanical Prosthesis = M11
Sorin Monoleaflet Allcarbon Mechanical Prosthesis = M12
St. Jude Medical Mechanical Prosthesis or St. Jude Medical® Mechanical Heart Valve = M13
SJM® Masters Series Mechanical Heart Valve = M26
SJM® Masters Series Aortic Valve Graft Prosthesis = M27
St. Jude Medical® Mechanical Heart Valve Hemodynamic Plus (HP) Series = M28
SJM® Masters Series Hemodynamic Plus Valve with FlexCuff™ Sewing Ring = M29
SJM Regent™ Valve = M30
Starr-Edwards Caged-Ball Prosthesis = M14
Ultracor Mechanical Prosthesis = M15

Bioprosthetic
Baxter Prima Stentless Porcine Bioprosthesis – Subcoronary = B24
Baxter Prima Stentless Porcine Bioprosthesis – Root = B25
Biocor Porcine Bioprosthesis = B3
Biocor Stentless Porcine Bioprosthesis – Subcoronary = B26
Biocor Stentless Porcine Bioprosthesis – Root = B27
CarboMedics PhotoFix Pericardial Bioprosthesis = B5
Carpentier-Edwards Duraflex Porcine Bioprosthesis = B28
Carpentier-Edwards Prima Plus Stentless Porcine Bioprosthesis – Subcoronary = B29
Carpentier-Edwards Prima Plus Stentless Porcine Bioprosthesis – Root = B30
Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis = B6
Carpentier-Edwards Standard Porcine Bioprosthesis = B7
Carpentier-Edwards Supra-Annular Aortic Porcine Bioprosthesis = B8
Cryolife O'Brien Stentless Porcine Bioprosthesis – Subcoronary = B31
Cryolife O'Brien Stentless Porcine Bioprosthesis – Root = B32
Hancock Standard Porcine Bioprosthesis = B10
Hancock II Porcine Bioprosthesis = B11
Hancock Modified Orifice Porcine Bioprosthesis = B12
Ionescu-Shiley Pericardial Bioprosthesis = B13
Labcor Stented Porcine Bioprosthesis = B14
Labcor Stentless Porcine Bioprosthesis – Subcoronary = B33
Labcor Stentless Porcine Bioprosthesis – Root = B34
Medtronic Freestyle Stentless Porcine Bioprosthesis – Subcoronary = B35
Medtronic Freestyle Stentless Porcine Bioprosthesis – Root = B36
Medtronic Intact Porcine Bioprosthesis = B17
Medtronic Mosaic Porcine Bioprosthesis = B18
Medtronic Contegra Bovine Jugular Bioprosthesis = B37
Mitroflow Pericardial Bioprosthesis = B19
St. Jude Medical - Toronto SPV Stentless Porcine Bioprosthesis or SJM Toronto SPV® Valve = B21
St. Jude Medical-Bioimplant Porcine Bioprosthesis = B22
SJM Biocor™ Valve = B38
SJM Epic™ Valve = B39
SJM Toronto Root™ Bioprosthesis = B40
Sorin Pericarbon Stentless Pericardial Bioprosthesis = B20

Homograft
CryoLife Aortic Homograft = H6
CryoLife Pulmonary Homograft = H7
CryoLife CryoValve SG(Decellularized)Aortic Homograft = H8
CryoLife CryoValve SG Pulmonary Homograft = H9
Homograft Aortic – Subcoronary = H1
Homograft Aortic Root = H2
Homograft Mitral = H3
Homograft Pulmonic Root = H4
LifeNet CV Allografts = H10

Autograft
Pulmonary Autograft to aortic root (Ross Procedure) = A1

Ring - Annuloplasty
CarboMedics AnnuloFlo Ring = R8
CarboMedics AnnuloFlex Ring = R9
CarboMedics CardioFix Bovine Pericardium with PhotoFix Technology = R10
Carpentier-Edwards Classic Annuloplasty Ring = R1
Carpentier-Edwards Physio Annuloplasty System Ring = R2
Cosgrove-Edwards Annuloplasty System Ring = R3
Edwards MC³ Tricuspid Annuloplasty System G Future Band = R11
Genesee Sculptor Annuloplasty Ring = R12
Medtronic Sculptor Ring = R4
Medtronic-Duran AnCore Ring = R5
Sorin-Puig-Messana Ring = R6
St. Jude Medical Sequin Ring or SJM® Séguin Annuloplasty Ring = R7
SJM Tailor™ Annuloplasty Ring = R13

Band – Annuloplasty
Medtronic Colvin Galloway Future Band = Ba1
Medtronic Duran Band = Ba2
Medtronic Duran – Ancore Band = Ba3

Other = 777

L. **VAD**

Previous VAD: Yes No
Please note that future references to "initial VAD" refer to the initial VAD for this hospitalization, not a VAD placed during a previous hospitalization.

Current Circulatory Support: For Initial VAD only

Indication for VAD: (Bridge to Transplant) (Bridge to Recovery) (Destination) (Separation from CPB) (Device Malfunction)

Intubated Pre VAD: Yes No

Hemodynamics Pre VAD: May be obtained Prior to induction in the OR, or in an ICU immediately prior to OR

PCWP: _____mm/Hg CVP: _____mm/Hg PVR: _____woods units CI: _____L/ (min x m2)

RV Function: (Normal) (Mildly Impaired) (Moderately Impaired) (Severely Impaired)

RV Function method: _____ (Pre-op ECHO) (Intra-op pre VAD TEE)

VO2 Measured: Yes No

Peak VO2:_____ml/kg/min

VAD Device Data:

Implant Type: Fill in below: (RVAD) (LVAD) (BiVAD)
Product Type: Fill in below: 1. HeartQuest VAD 2. Lion Heart 3. Novacor LVAS 4. Heartsaver VAD 5. Jarvik 2000 6. Debakey VAD 7. TandemHeart pVAD 8. AB-180 iVAD 9. CardioWest TAH 10. Thoratec IVAD 11. HeartMate VE 12. HeartMate IP LVAS 13. HeartMate SNAP-VE 14. HeartMate XVE 15. HeartMate II 16. HeartMate III 17. BVS5000i 18. AbioCor 19. Incor 20. Excor 21. Other

Explant Reason: Fill in below: 1. Cardiac Transplant 2. Recovery 3. Device Transfer 4. Device Related Infection 5. Device Malfunction

Initial Implant Data

Implant Type	Product Type	Implant Date	Explant	Explant Date	Explant Reason	Cardiac Tx	Tx Date
_____	_____	___ / __ / ___	Y N	___ / ___ / ___	_____	Y N	___ / ___ / ___

Initial VAD Cannulation/Attachment Sites:

LVAD Inflow: (LA) (LV)

RVAD Inflow: (RA) (RV)

Additional Implant(s) Data

Implant(s) Type	Product Type	Implant Date	Explant	Explant Date	Explant Reason	Cardiac Tx	Tx Date
_____	_____	___ / ___ / ___	Y N	___ / ___ / ___	_____	Y N	___ / ___ / ___
_____	_____	___ / ___ / ___	Y N	___ / ___ / ___	_____	Y N	___ / ___ / ___

Primary VAD Complications Data:

Intracranial Bleed: Yes No

Embolic Stroke: Yes No

Driveline/Cannula Infection: Yes No

Pump Pocket Infection: Yes No

VAD Endocarditis: Yes No

Device Malfunction: Yes No

Additional Complications (not specific to initial VAD as above) to be collected in section "P", Complications.

VAD Status: Discharged from hospital: (with VAD) (without VAD)

M. **Other Cardiac Procedures**

Yes	No	Left Ventricular Aneurysm Repair	Yes	No	Ventricular Septal Defect Repair	Yes	No	Atrial Septal Defect Repair
Yes	No	Batista	Yes	No	Surgical Ventricular Restoration	Yes	No	Congenital Defect Repair
Yes	No	Transmyocard Laser Revasc	Yes	No	Cardiac Trauma	Yes	No	Cardiac Transplant

Arrhythmia Correction Surgery → None
Permanent Pacemaker
Permanent Pacemaker with Cardiac Resynchronization Therapy (CRT)
Implanted Cardioverter Defibrillator (ICD)
ICD with CRT

If "Permanent Pacemaker with CRT" or "ICD with CRT", then answer ↓

Arrhythmia Correction Surgery – Lead Placement → Epicardial Endocardial

Atrial Fibrillation Correction Surgery → None
Standard Surgical Maze Procedure
Other Surgical Ablative Procedure
Combination of Standard and Other If Other or Combo, then answer ↓

Atrial Fibrillation Surgery – Energy Source → Unipolar Radiofrequency
Bipolar Radiofrequency
Microwave
Cryothermia
Other
Combination of above

Yes No Aortic Aneurysm If Yes, → Yes No Ascending Aorta
Yes No Aortic Arch
Yes No Descending Aorta
Yes No Thoracoabdominal Aorta

Yes No Other

N. **Other Non Cardiac Procedures**

Yes No Carotid Endarterectomy Yes No Other Vascular Yes No Other Thoracic Yes No Other

O. **Post Operative**

Blood Products Used Postoperatively: Yes No → If Yes, Red Blood Cell Units _____
Fresh Frozen Plasma Units _____
Cryoprecipitate Units _____
Platelet Units _____

Extubated in OR: Yes No If No, → Initial # Hrs Ventilated Postop: _____

Re-intubated During Hosp Stay: Yes No If Yes, → Addl Hours Ventilated Postop: _____

Total Hours Ventilated Postop: _____

P. **Complications** In Hospital Complications: Yes No

Operative:

Yes No ReOp for Bleeding Tamponade
Yes No ReOp for Valvular Dysfunction
Yes No ReOp for Graft Occlusion
Yes No ReOp for Other Cardiac Problem
Yes No ReOp for Other Non Cardiac Problem
Yes No Perioperative MI

Infection:

Yes No Sternum – Deep
Yes No Thoracotomy
Yes No Leg
Yes No Septicemia

Neurologic:

Yes No Postoperative Stroke for >72 hours

Yes No Transient Neurologic Deficit

Yes No Continuous Coma >=24Hrs

Pulmonary:

Yes No Prolonged Ventilation

Yes No Pulmonary Embolism

Yes No Pneumonia

Renal:

Yes No Renal Failure If Yes, ↓

Yes No Dialysis (Newly Required)

Vascular:

Yes No Illiac/Femoral Dissection

Yes No Acute Limb Ischemia

Other:

Yes No Heart Block

Yes No Cardiac Arrest

Yes No Anticoagulant Complication

Yes No Tamponade

Yes No Gastro-Intestinal Complication

Yes No Multi-System Failure

Yes No Atrial Fibrillation

Yes No Aortic Dissection

Yes No Other

Q. **Mortality**

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

Operative Death: Yes No Only answered if Mortality = Yes

Mortality - Date __ __/__ __/__ __ __ __ (mm/dd/yyyy) Only answered if Mortality = Yes

Location of Death: OR during initial surgery Hospital Home Other Care Facility OR during reoperation Only answered if Mortality = Yes

Primary Cause of Death (select only one): Only answered if Mortality = Yes

Cardiac Neurologic Renal Vascular Infection Pulmonary Valvular Unknown Other

R. **Discharge** (Note: This section is only answered if Discharge Status is "Alive")

ADP Inhibitors: Yes No

Antiarrhythmics: Yes No If Yes, ↓

Antiarrhythmics – Discharge – Medication Name: Amiodarone Other

Aspirin: Yes No

Ace-Inhibitors: Yes No

Beta Blockers: Yes No

Lipid Lowering: Yes No If Yes, ↓

Lipid Lowering – Discharge – Medication Type: Statin Non statin

Coumadin: Yes No

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

Cardiac Rehabilitation Referral: Yes No Not Applicable

Smoking Cessation Counseling: Yes No Not Applicable

S. **Readmission** (Note: This section is only answered if Discharge Status is "Alive")

Readmit <=30 Days from Date of Procedure: Yes No ↓ If Yes, select the primary reason and procedure

Readmit Reason:

- Anticoagulation Complication – Valvular
- Anticoagulation Complication - Pharmacological
- Arrhythmias/Heart Block
- Congestive Heart Failure
- Myocardial Infarction and/or Recurrent Angina
- Pericardial Effusion and/or Tamponade
- Pneumonia or other Respiratory Complication
- Coronary Artery Dysfunction
- Valve Dysfunction
- Infection - Deep Sternum
- Infection – Conduit Harvest Site
- Renal Failure
- TIA
- Permanent CVA
- Acute Vascular Complication
- Subacute Endocarditis
- VAD Complication
- Other – Related Readmission
- Other – Nonrelated Readmission

Readmit Reason – Primary Procedure:

- OR for Bleeding
- Pacemaker Insertion/AICD
- PCI
- Pericardiotomy/Pericardiocentesis
- OR for Coronary Arteries
- OR for Valve
- OR for Sternal Debridement/Muscle Flap
- Dialysis
- OR for Vascular
- No Procedure Performed
- Other Procedure
- Unknown

