TECHNICAL REPORT ON PERCUTANEOUS CORONARY INTERVENTIONS IN THE COMMONWEALTH OF MASSACHUSETTS

April 1, 2003 – December 31, 2003

Mass-DAC

Department of Health Care Policy

Harvard Medical School

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MASSACHUSETTS PERCUTANEOUS CORONARY INTERVENTION HOSPITALS 2003

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Beth Israel Deaconess Medical Center (BIDMC) 330 Brookline Avenue Boston, MA 02115	Mount Auburn Hospital 330 Mount Auburn Street Cambridge, MA 02138
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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
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MASSACHUSETTS PRIMARY PERCUTANEOUS CORONARY INTERVENTION PILOT HOSPITALS: 2003

Brockton Hospital 680 Centre Street Brockton, MA 02302	MetroWest Medical Center 115 Lincoln Street Framingham, MA 01702
Caritas Norwood Hospital 800 Washington Street Norwood, Massachusetts 02062	South Shore Hospital 55 Fogg Road at Route 18 South Weymouth, Massachusetts 02190

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1 - KEY FINDINGS

- Between April 1, 2003 and December 31, 2003,* there were **12657** hospital admissions in which at least one Percutaneous Coronary Intervention (PCI) was performed in Massachusetts hospitals.

- **15.5 %**(1968) of these admission were "SOS" admissions – admissions in which the patient had an ST-elevated myocardial infarction or was in shock.

- The remaining 10689 admissions **(84.5%)** were "non-SOS" admissions – those for which the patient did not have an ST-elevated myocardial infarction and was not in shock.

- **Eighteen** hospitals performed at least one PCI in 2003, **four** of which participated in the Massachusetts Primary PCI Pilot Program. Pilot programs are approved for SOS admissions only.

- The majority of patients undergoing PCI are males (68.6%), white (88.8%), and one-third under 60 years of age.

- Of the 12657 PCI admissions, **216** patients died during the same hospitalization in which the PCI was performed. Eighty-one **(0.76% mortality)** of the deaths occurred in the Non-SOS population while 135 **(6.86% mortality)** occurred in the SOS population.

- **Based on in-hospital mortality, there were no statistically under-performing or over-performing PCI hospitals within Massachusetts.**

* Data collection for PCI began with procedures performed on April1, 2003.

2 - INTRODUCTION

2.1 - What is in this Report?

This is the first report describing methods and results for calculating hospital-specific in-hospital mortality rates following Percutaneous Coronary Intervention (**PCI**) in Massachusetts. Interventions 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 intervention.

In Massachusetts, not all hospitals are permitted to perform PCIs and hospitals wishing to start performing PCI's must submit an application to the Determination of Need Program in the Massachusetts Department of Public Health. In 2003, there were eleven established PCI programs in Massachusetts, all with back-up cardiac surgery programs. Three community hospitals applied and were granted approval for both cardiac surgery and PCI programs (Cape Cod Hospital, Southcoast Hospital Group – Charlton Hospital, and North Shore Medical Center – Salem Hospital). Cape Cod Hospital and Charlton Hospital started performing PCIs in early 2003, while Salem Hospital did not perform their first PCI until November 3, 2003. Four community hospitals applied and received approval to perform primary PCI only under a Primary PCI Pilot Program with the Massachusetts Department of Public Health: Brockton Hospital [first PCI on April 2, 2003], Caritas Norwood Hospital [April 17, 2003], Metrowest Medical Center [December 5, 2003], and South Shore Hospital [April 9, 2003]). The four hospitals in the Primary PCI Pilot Program do not have cardiac surgery programs on site, but do have cardiac surgery available to their patients, if needed, from the hospitals with which they collaborate.

This document reports hospital-specific standardized mortality incidence rates following PCI procedures for the eighteen PCI hospitals in Massachusetts that performed at least one PCI between April 1, 2003 and December 31, 2003.* Because of the elevated risks associated with heart attack patients, results for two separate cohorts of patients are

* Data collection for PCI began with procedures performed on April 1, 2003. Subsequent reports will be based on a calendar year.

presented: 1) patients having an ST-elevated myocardial infarction (STEMI) within 24 hours of arrival to the hospital or having cardiogenic shock prior to the intervention (referred to as the **SOS** Cohort); and 2) patients having no STEMI within 24 hours of arrival to the hospital and no cardiogenic shock prior to the PCI (referred to as the **Non-SOS** Cohort).

In-hospital mortality is analyzed for the 18 hospitals that treated SOS patients. Because hospitals participating in the Massachusetts Primary PCI Pilot Program are permitted to treat only SOS cases, they are not included in the analysis for in-hospital mortality for Non-SOS patients. Thus, there are only 14 hospitals analyzed for Non-SOS patients.

2.2 - What is a Percutaneous Coronary Intervention?

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, this 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 treatment choice depends on the degree of blockage, patient symptoms and the number of coronary arteries involved. Percutaneous Coronary Intervention is a procedure performed in the Catheterization Lab that unblocks a coronary artery without having to undergo surgery. Most Percutaneous Coronary Interventions involve either a balloon catheter or a stent (including drug eluting stents). The balloon is used to push the blockage against the walls of the artery reducing the narrowing of the artery. The balloon is then removed at the end of the procedure. The stent is a metal mesh tube that is inserted and left in the artery to maintain the opening,

preventing the closing of the artery after the procedure. Drug eluting stents are coated with a drug that interferes with the process of restenosis or collapse of the artery which can occur in a small percentage of patients after the intervention.

2.3 - Definition of Study Population

The study population is adults (patients who were 18 years of age or older at the time of their procedure) undergoing a PCI at Non-US Governmental hospitals in Massachusetts. Between April 1, 2003 and December 31, 2003, there were 12657 admissions in which at least one PCI was performed. The majority of patients undergoing a PCI were male, white, and over 60 years of age (**Table 2.1)**. More than 90% of patients received only one PCI during their hospital admission.

Not surprisingly, the in-hospital mortality rate for SOS cases is almost 10 times that for Non-SOS cases (6.86% versus 0.76%). Vascular complications and unplanned CABG for emergency cases are about two times and three times, respectively, the rates for Non-SOS cases. Mass-DAC analyzed the first PCI for patients who received more than one PCI during their admission. Results do not change if the last PCI is used.

Table 2.1: Descriptive Summaries of Adult PCI Admissions in Massachusetts Hospitals, April 1 – December 31, 2003. If multiple PCIs occur during an admission, the first PCI is selected. ¶Patients arriving with no STEMI within 24 hours and no cardiogenic shock; §Patients having STEMI within 24 hours of hospital arrival or cardiogenic shock.

RISK COHORT	¶Non-SOS		§ SOS	
Characteristic	**Number**	**Percent**	**Number**	**Percent**
Admitted via Emergency Department or Transfer	5445	50.9	1847	93.9
Number of PCIs Per Admission				
1 PCI	10355	96.9	1852	94.1
≥ 2 PCIs	334	3.1	116	5.9
More than 70% stenosis in Left Anterior Descending Artery	6009	56.2	1103	56.1
At least One Stent	9376	87.7	1782	90.6
Drug Eluting if Stented	5149	54.9	439	24.6
Total Length of Stay, days	Mean = 3.94 Median = 3.00		Mean = 6.49 Median = 5.00	
Post-Procedure Length of Stay, days	Mean = 3.16 Median = 2.00		Mean = 6.25 Median = 5.00	
Unadjusted Outcomes				
Any Vascular Complication	287	2.7	92	4.7
Unplanned CABG	23	0.21	13	0.66
In-Hospital Death	81	0.76	135	6.86
TOTAL NO. OF ADMISSIONS	10689	100	1968	100

2.4 - Why Report on Percutaneous Coronary Interventions?

A PCI offers a non-surgical alternative to Coronary Artery Bypass Surgery (CABG). PCI is less invasive, and the hospital stay and recovery is much shorter than with CABG surgery. With the recent availability of drug eluting stents that are clinically very successful, CABG surgery has declined while PCI has increased considerably. Many more patients

now have the option for a less invasive, successful treatment of their coronary artery disease.

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, and the PCI Adjudication Committee. In addition, both the American College of Cardiology and the Massachusetts chapter of the American College of Cardiology serve as resources.

3 - SUMMARY OF DATA COLLECTION & VERIFICATION PROCEDURES

3.1 - Definition of Patient Outcome

Mortality, regardless of cause, measured from time of PCI until hospital discharge is the primary patient outcome. In-hospital mortality was selected as the primary measure of quality because it is serious and unambiguous.

3.2 - Massachusetts PCI Hospitals

Eighteen hospitals had Cardiac Catheterization Labs that performed PCIs between April 1, 2003 and December 31, 2003. Eleven hospitals had established labs which had been performing PCIs prior to 2002. Seven hospitals had newly established PCI programs. All hospitals that performed PCIs were required to submit data to Mass-DAC.

3.3 - Data Sources

Three different data sources were used to collect and verify data: patient-specific data collected by hospital personnel using the American College of Cardiology National Cardiac Database Registry (ACC-NCDR) software; hospital administrative discharge data; and vital statistics information provided by the Massachusetts Department of Public Health.

Mass-DAC ACC Data. Patient-specific risk factor and outcome data were collected by hospital personnel using the ACC-NCDR software. Data were collected in the ACC-NCDR Version 2.0 containing 137 variables collected by Mass-DAC.
The Massachusetts Department of Health made the decision not to collect 5 additional variables for optional 6-month follow up. Only a limited number of hospital programs either had or were actively participating in the ACC registry prior to the regulations in 2002.

Massachusetts Inpatient Acute Hospital Case Mix and Charge Database. Hospital discharge data for fiscal years[1] 2002, 2003, and 2004 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 was available for all deaths occurring in Massachusetts between January 1, 2003 and January 31, 2004 from the Massachusetts Registry of Vital Records and Statistics. While the primary source of in-hospital mortality data was the hospital-reported data, 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 by the above mentioned 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, fellows, and nurses to collect information. Data were either entered directly into the ACC-NCDR software database by the clinical staff, by a data manager, or the data manager collected the ACC-NCDR 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 ACC-NCDR and Mass-DAC.

Data were transmitted by hospitals and harvested by Mass-DAC regularly (**Table 3.1**). This process involved submitting protected data during specific harvest periods. Hospitals had the option of encrypting, password protecting it, storing it on a disk, and

[1] Fiscal year 2003 is October 1, 2002 – September 30, 2003

sending by Federal Express or registered mail, or by transmitting data electronically using secure messaging software (PGP software). Hospitals were allowed up to four weeks to submit data during the harvest periods. Harvests were scheduled quarterly for the collection of 3 months of data. Hospitals were permitted to submit corrected data as often as desired and could sign-off on its accuracy and completeness at any time. However, all data were required to be complete by September 1, 2004, after which no changes were accepted without written permission from Mass-DAC.

Table 3.1: PCI Data Harvest Schedule for PCIs Performed Between April1, 2003 and December 31, 2003.

Month of Data Harvest	Dates of PCI
September, 2003	April 1, 2003 – June 30, 2003 (Quarter 2)
December, 2003	July 1, 2003 – September 30, 2003 (Quarter 3)
March, 2004	October 1, 2003 – December 31, 2003 (Quarter 4)
September, 2004	2003 Data Closeout

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, and review of concordance with both administrative datasets and 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 ACC-NCDR elements and identifying cases with missing, out-of-usual range, or inconsistent data. 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 217 quality reports returned to the hospitals for the three 2003 data harvests with a mean of 8.1 reports per hospital (range of 2 to 8 per harvest). With each data harvest, fewer quality reports were returned as data managers and data collectors became more comfortable with the data collection and submission process.

MA Administrative Datasets. In-hospital mortality was verified by linking the hospital report of mortality to the Registry of Vital Records and Statistics information. While the

Registry data records only deaths in Massachusetts, it does provide an additional mechanism to ascertain outcomes. The mortality index database was linked to the Mass-DAC database by the patient's last name, date of birth, and social security number. Mass-DAC found high agreement between the hospital mortality reports and the Vital Records. There were 11 patients reported by the hospitals as in-hospital survivors who were reported as deaths on the day of discharge in the Vital Records. Of these 11, Mass-DAC confirmed that 9 were in-hospital mortalities and determined that 2 patients died after transfer to another acute care hospital. Dates of death were inaccurate for an additional 8 patients and these were corrected in the data. There were 28 in-hospital deaths reported by the hospitals which were not recorded in the Vital Statistic dataset.

Meetings and Communication. Mass-DAC communicated regularly via electronic mail and telephone with the data managers to clarify definition or procedural issues, and to serve as a facilitator to the national ACC-NCDR. 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 Cardiology, Directors of the Cardiac Catheterization Labs, 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 2005, a sample of the 2003 PCI data was audited. Nurses with experience in Surgical Intensive Care, Emergency Room, cardiac surgery and Catheterization Labs were contracted to perform data abstraction of a sample of the 2003 records. Records requested from the hospitals included those for (1) **all** patients who died in hospital and (2) a random sample of records of patients with pre-procedure shock, non-elective status, or a pre-procedure myocardial infarction. Forty records per hospital were requested (between 3 and 38 records were requested from the 3 hospitals with newer programs and low volume) for a total of 676 records to determine data consistency and accuracy of coding. Documentation requested form the hospitals included admission and history summaries, discharge summaries and catheterization lab records. Institutions were required to provide Mass-DAC verification data by February 15, 2004.

A total of four nurses were trained by Mass-DAC staff in the ACC-NCDR data instrument and variable definitions. To ascertain the accuracy of the abstractors, a reliability study was conducted using 3 variables obtained from 20 charts. Kappa statistics

and agreement rates with the Mass-DAC Project Manager (Ann Lovett, RN) were computed. **Table 3.2** indicates that the nurses were reliable for MI and PCI status, with kappa statistics above 0.85, and high agreement rates with Ms. Lovett. However the kappa for shock was less than 0.80.

Table 3.2: Kappa and Reliability of Abstractors Based on Random Chart Audits	
Kappas for Inter-Abstractor Reliability	
Myocardial Infarction	0.92
Shock	0.76
Non-Elective Status	1.0
% Agreement (95%CI) with "Gold Standard"	
Myocardial Infarction	99 [0.95, 1.00]
Shock	96 [0.90, 0.99]
Non-Elective Status	100 [0.96, 1.00]

The charts were first reviewed by the nurse abstractor for agreement with the data submitted by the hospitals. A representative of the Mass-DAC PCI Adjudication Committee then reviewed all the medical records that we received of patients when shock was coded as yes. The hospitals were notified of any disagreement in coding.

Table 3.3 summarizes the agreement between the nurse abstractors and the hospital. Out of a total of 676 records that were identified for audit, there was disagreement with 41 records that had shock coded as "yes" and 10 cases that had shock coded as "no", resulting in 31 fewer patients that would have been coded for shock. Five records that had myocardial infarction prior to the PCI would have been down-coded to "no" while 13 records would have been up-coded to "yes". Two records coded as non-elective were considered to be elective while 10 records, coded as elective were considered to be non-elective.

Table 3.3: % Agreement [95%CI] with Hospital Submissions		
Myocardial Infarction	97.3 [96.0, 98.0]	Range: 87.5 to 100
Shock	92.31[90.0, 94.0]	Range: 82.5 to 100
Non-Elective Status	98.2[97.0, 99.0]	Range 95.0 to 100

4 - RISK ADJUSTMENT

4.1 - Who Receives PCI in Massachusetts?

Table 4.1 provides demographic summaries of the 10689 Non-SOS admissions and 1968 SOS admissions. The majority of Non-SOS admissions are male (68.2%), white (89.2%), and about one-third less than 60 years of age at the time of their PCI. Out of state patients comprised 7.5% of the Non-SOS admissions (data not shown). Like the Non-SOS admissions, the majority of SOS admissions are male (70.8%) and white (86.8%). Nearly one-half (47.1%) of the SOS admissions were less than 60 years old at the time of their PCI. Finally, 7.4% of the SOS admissions were from patients residing out of state (data not shown).

Table 4.1: Age-Sex-Race Distribution for Adult PCI Admissions in Massachusetts Hospitals During April 1, 2003 – December 31, 2003: Stratified by Risk Cohort. Entries represent numbers of admissions.

10689 Non-SOS PCI ADMISSIONS

Age Group	Females					Males				
	White	African American	Hispanic	Other	Total	White	African American	Hispanic	Other	Total
≤49	225	16	20	11	272	845	42	44	76	1007
50-59	431	26	26	36	519	1606	40	49	119	1814
60-69	726	26	30	45	827	1814	32	32	133	2011
70-79	1023	21	22	69	1135	1602	15	25	95	1737
≥80	591	6	6	48	651	670	8	9	29	716
Total	2996	95	104	209	**3404**	6537	137	159	452	**7285**

1968 SOS PCI ADMISSIONS

Age Group	Females					Males				
	White	African American	Hispanic	Other	Total	White	African American	Hispanic	Other	Total
≤49	50	3	5	3	61	272	16	17	37	342
50-59	89	8	10	7	114	362	5	15	28	410
60-69	110	0	1	7	118	268	4	10	25	307
70-79	130	9	5	4	148	209	5	6	12	232
≥80	122	3	4	5	134	96	1	2	3	102
Total	501	23	25	26	**575**	1207	31	50	105	**1393**

4.2 - Risk Adjustment for Quantifying In-Hospital Mortality

Specific risk factors are known to contribute to heart disease. These include high cholesterol, smoking, high blood pressure, family history of heart disease, diabetes, age and gender. General health status prior to a PCI is an important factor as well. Such factors also have an impact on the risk of mortality following a PCI. Sicker patients or patients with more health-related risks may be more likely to die following a PCI 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, it is therefore important to consider differences in patient health prior to a PCI.

The statistical process of adjusting for differences in patient sickness prior to their encounter with the health care system is called risk adjustment. This statistical process aims to "level the playing field" by accounting for health risks that patients have prior to a PCI. The hospital mortality rates in this report have been adjusted in order to account for differences in patient health prior to a PCI.

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 in-hospital mortality for two patients having <u>exactly the same risk factors</u> prior to a PCI but who are treated in different PCI hospitals will <u>not be the same</u>. 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.

5 - IDENTIFYING OUTLYING PCI PROGRAMS

One of the purposes 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 in-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, 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 in-hospital mortality rate **or** if the mortality probability 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 PCI.

5.1 - Standardized Mortality Incidence Rates (SMIR)

Mass-DAC calculated a standardized mortality incidence rate (SMIR) and a corresponding 95% "posterior" interval for each PCI 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 not 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 categorizes as an under-performing hospital.

Hospital-specific in-hospital mortality rates, standardized to the population of adults undergoing PCI 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 in-hospital 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} PCI program died during the same admission as the PCI and 0 otherwise, and n_i the total number of PCI admissions at the hospital. 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 Non-SOS admissions) and in Table 6.2 (for SOS admissions).
3. The "expected" mortality rate at hospital "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 hospital. Thus it represents the severity of cases at the institution.
4. The "adjusted" mortality rate at hospital "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. Because the model assumes that the probability of dying is greater than 0, the adjusted 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:

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

   The SMIR is interpreted as the projected mortality rate at the hospital today if hospital quality remained the same as in 2003.
7. "Simultaneous" ninety-five percent posterior intervals were calculated for each PCI hospital's SMIR.

8. An implicit assumption is that the SMIR must be greater than 0.

The parameters, μ and τ^2, are called random effects and represent the overall mean risk-adjusted log-odds of mortality and between-hospital variation, respectively. If there are no quality differences across PCI 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 τ^{-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 used to risk-adjust. One method to identify hospitals as outlying is through "cross-validation" which systematically drops each hospital from the data set and re-estimates 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 of deaths 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 had the dropped hospital had the same level of quality as all remaining PCI 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

[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.

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 PCI 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.

In sensitivity analyses, two different prior distributions were assumed: 1) the between-hospital *standard deviation* arose from a uniform distribution over the range 0 to 1.5 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 PCI: 2003

Of the 12657 PCI admissions in Massachusetts, 216 patients died during the same admission as the PCI. **Table 6.1** lists the prevalence (%) of important risk factors and the relationship of each risk factor (controlling for all other risk factors) with in-hospital mortality for Non-SOS cases following a PCI. For example, 31.6% of all PCI admissions included patients who had a history of diabetes. Because age is measured in years, the table reports the average number years over age 65 for the cohort. 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 1.68 for patients with diabetes indicates that those patients are 1.68 times as likely as a patient without diabetes to die within the hospital admission of a PCI. In contrast, patients with renal failure prior to a PCI are 2.73 times more likely to die within the PCI hospital admission than patients without renal failure. **Table 6.2** lists the same information as in Table 4.1 but for the SOS cases.

Figure 6.1 displays the SMIRs and corresponding 95% posterior intervals. The solid black vertical line in the figure is the unadjusted state in-hospital mortality rate of 0.76% for Non-SOS cases. Listed on the left-hand side of the figure are the total number of PCI admissions and the expected in-hospital 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. **Figure 6.2** displays the SMIRs and corresponding 95% posterior intervals for SOS cases. The solid black vertical line in the figure is the unadjusted state in-hospital mortality rate of 6.86% for SOS cases. All 95% intervals cover the state unadjusted in-hospital mortality rate.

Figure 6.3 presents the cross-validated p-values of Non-SOS cohort, under a number of different distributional assumptions regarding the hierarchical regression model; **Figure 6.4** presents similar values for the SOS cohort. No hospital has a p-value smaller than or equal to 0.01, regardless of cohort examined.

Based on in-hospital mortality data, there is no evidence of any PCI hospital over-performing or under-performing in Massachusetts.

Table 6.1: Adjusted Odds Ratios of In-Hospital Mortality Following PCI in Adults: Non-SOS Cases, April 1, 2003 –December 31, 2003. Based on 10689 interventions with 81 deaths (0.76%). ROC area ≈ 0.87. Intercept = -7.44 (95% PI: -8.18,-6.81); Between-hospital variation: 0.0686 (0.000772, 0.362).

Risk Factor	Prevalence (%)	Adjusted Odds Ratio	95% Posterior Interval (PI)
Mean Age (years over 65)	0.04	1.07	1.044, 1.095
Renal Failure	7.6	2.73	1.551, 4.352
Diabetes	31.6	1.68	1.043, 2.609
Chronic Lung Disease	10.6	2.50	1.418, 4.013
Ejection Fraction < 30%	2.8	2.54	1.151, 4.714
PCI Status (Elective)	54.8	1.00	--
Urgent	40.5	3.63	1.956, 6.407
Emergent or Salvage	4.7	11.63	5.301, 22.27
High Lesion Risk	26.3	2.06	1.260, 3.206
Left Main Disease	6.8	1.34	0.661, 2.367
LAD > 70% Stenosis	56.2	1.75	1.011, 2.921

Table 6.2: Adjusted Odds Ratios of In-Hospital Mortality Following PCI in Adults: SOS Cases, April 1, 2003 – December 31, 2003. Based on 1968 interventions with 135 deaths (6.86%). ROC area ≈ 0.89. Intercept = -5.51 (95% PI: -6.27, -4.54); Between-hospital variation = 0.0393 (0.000749, 0.219).

Risk Factor	Prevalence (%)	Adjusted Odds Ratio	95% Posterior Interval
Age (Ref = < 60 years)			
60-69 yrs	21.6	2.45	1.209, 4.445
70-79 yrs	19.3	4.24	2.220, 7.467
≥ 80 yrs	12.0	6.52	3.290, 11.73
Renal Failure	4.5	2.30	1.133, 4.179
Ejection Fraction < 30%	4.2	2.18	1.030, 4.023
PCI Status (Urgent + Elective)	15.6	1.00	--
Emergent or Salvage	84.5	2.57	1.167, 4.906
Pre-Procedure Cardiogenic Shock	14.7	16.16	10.19, 24.79
Left Main Disease	4.6	1.13	0.5258, 2.075

Figure 6.1: Ninety-Five Percent Posterior Intervals for Standardized Mortality Incidence Rates (SMIRs) Following PCI During April 1, 2003 – December 31, 2003: Non-SOS Admissions. # of cases refers to the number of PCI 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 in-hospital mortality rate of 0.76%.

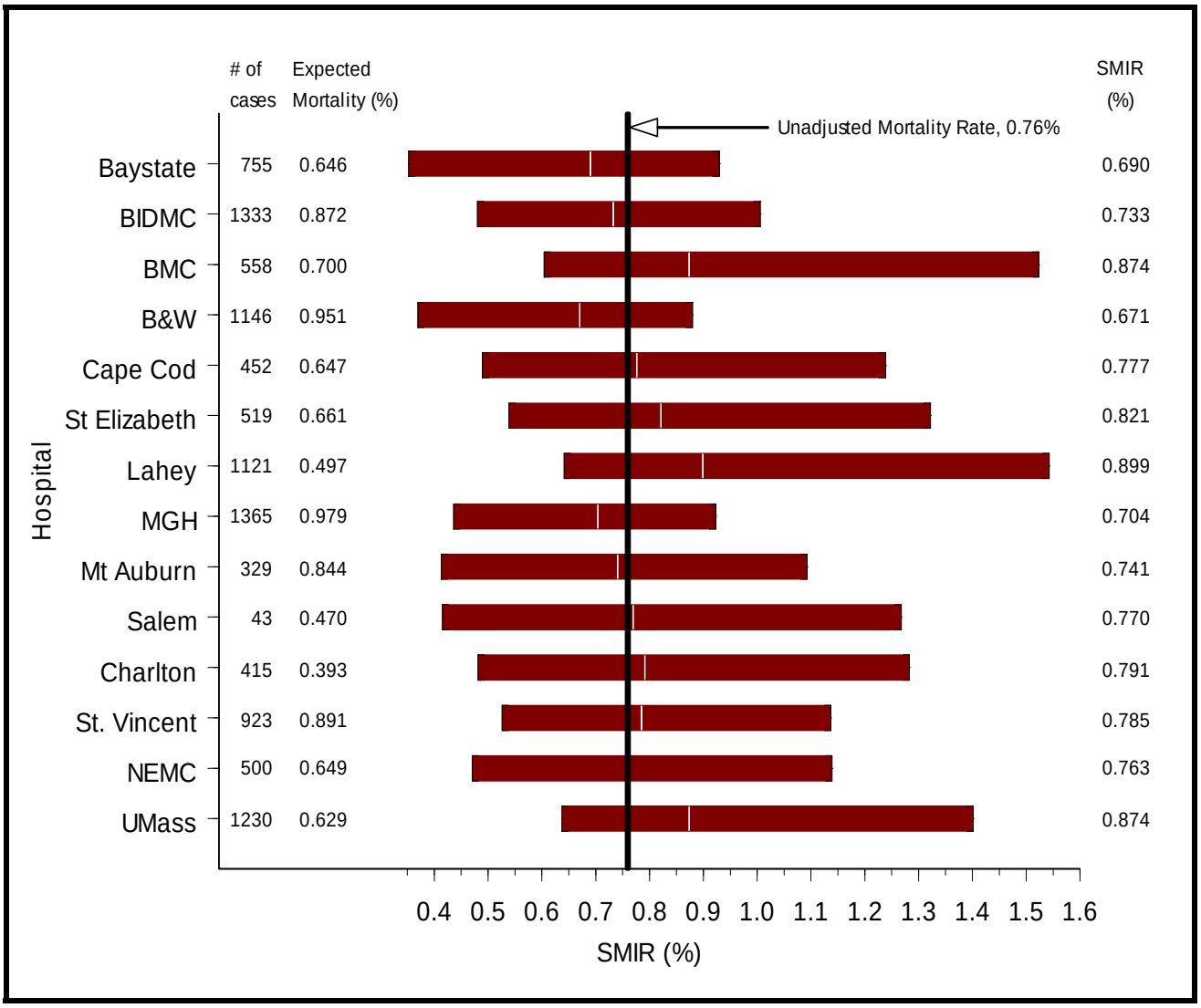


Figure 6.2: Ninety-Five Percent Probability Intervals for Standardized Mortality Incidence Rates (SMIRs) Following PCI During April 1, 2003 – December 31, 2003: SOS Admissions. # of cases refers to the number of SOS PCI admissions; expected mortality rate is the percentage of cases expected to die given 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 in-hospital mortality rate of 6.86%.

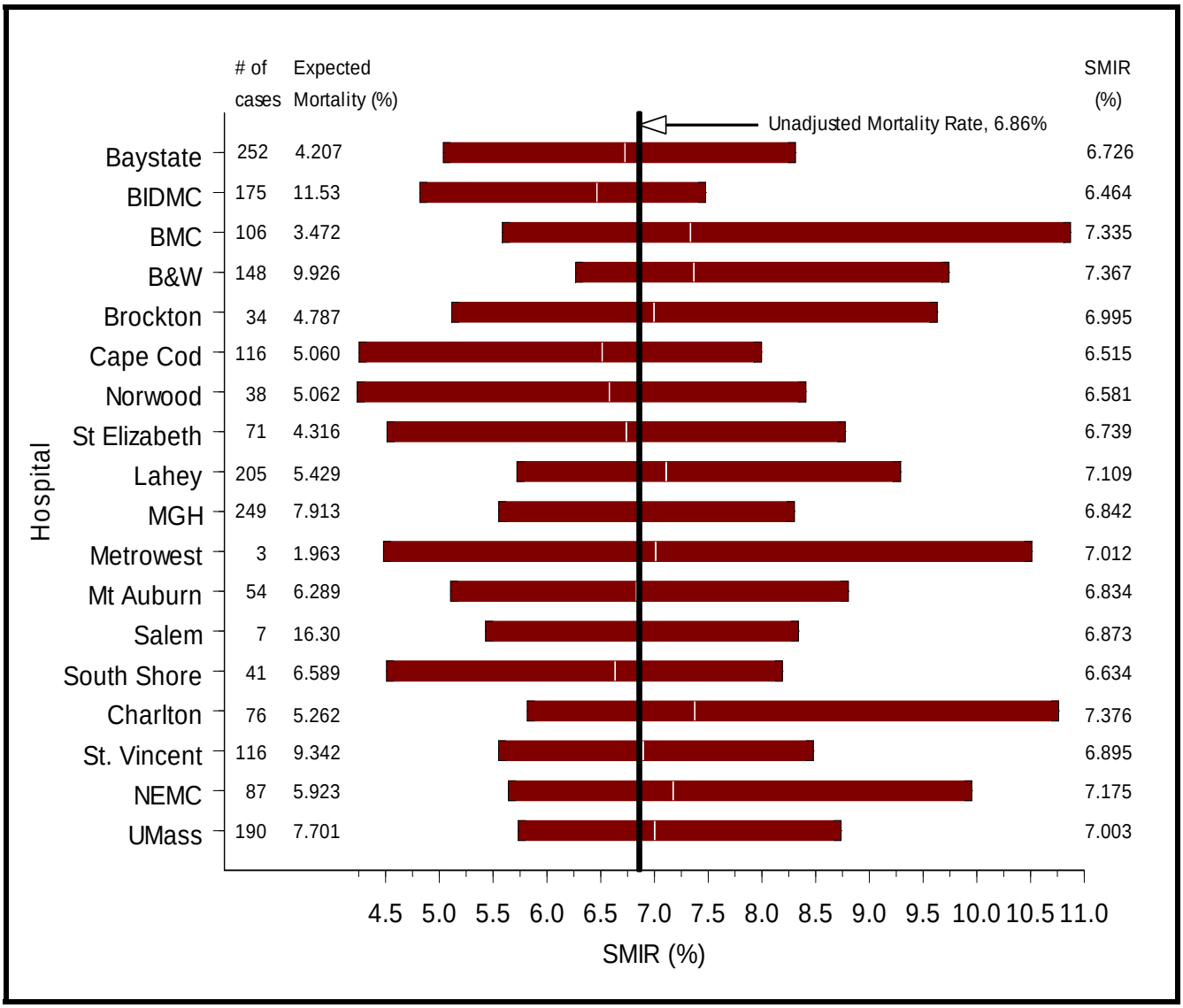


Figure 6.3: Cross-Validated P-Values: Non-SOS Cohort. P-Values are listed on the y-axis; the x-axis identifies the hospital. Results are presented under a variety of assumptions for fitting the hierarchical regression model.

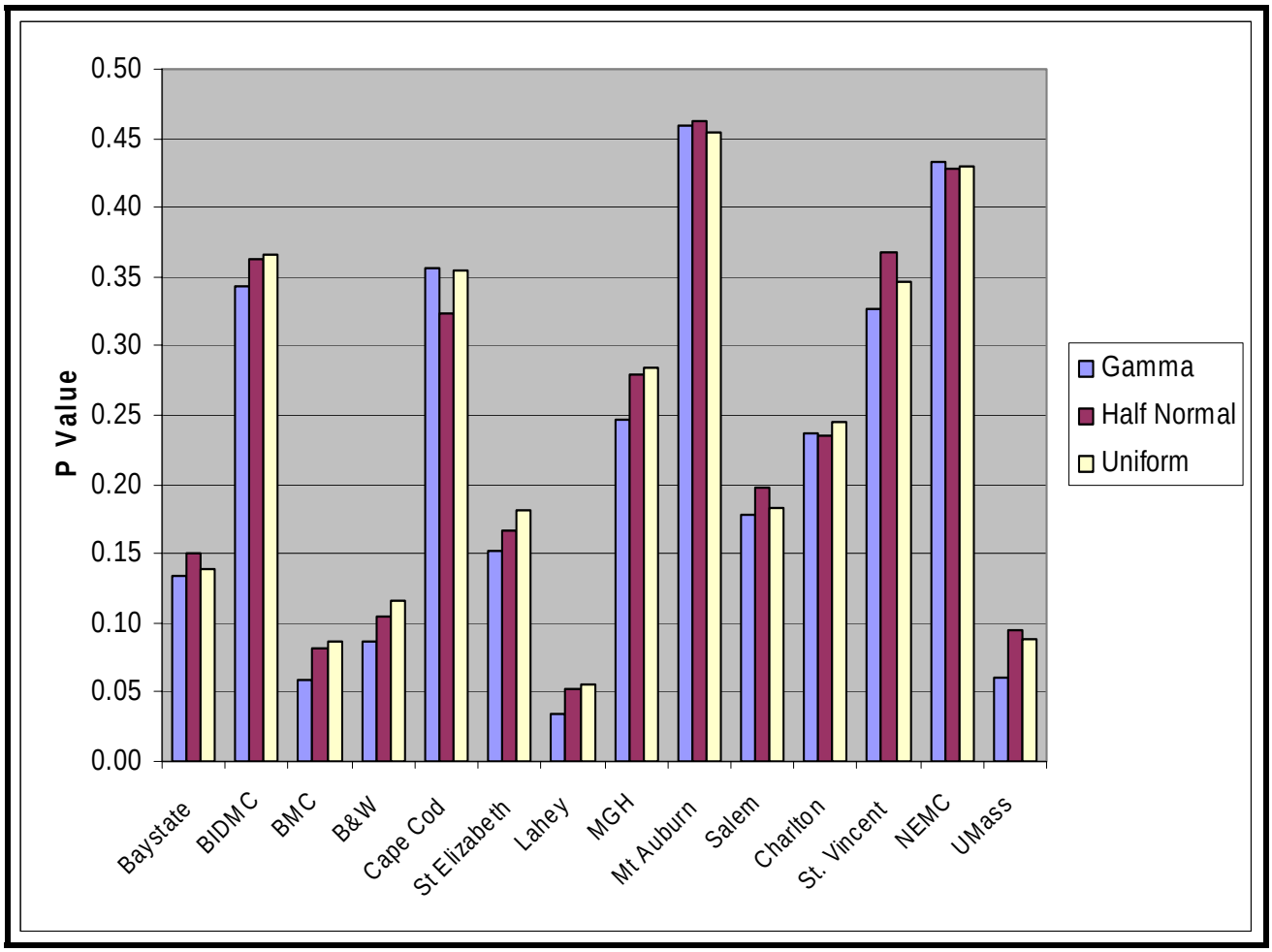
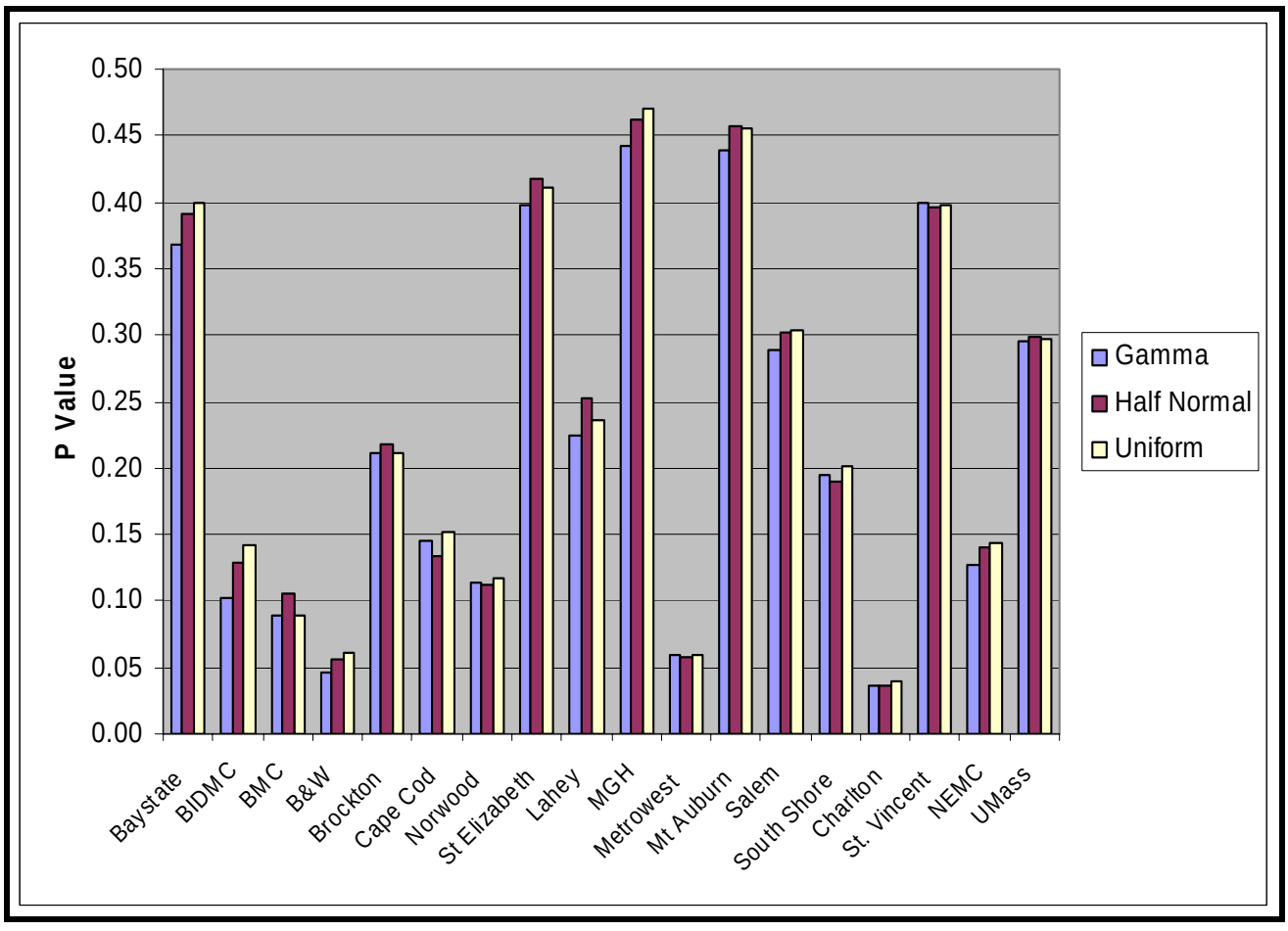


Figure 6.4: Cross-Validated P-Values: SOS Cohort. P-Values are listed on the y-axis; the x-axis identifies the hospital. Results are presented under a variety of assumptions for fitting the hierarchical regression model.



7 - IMPORTANT DEFINITIONS

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 patients' 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.

Drug Eluting Stent: Stents that are either coated or imbedded with time released medication, interrupting the biological process that causes the artery to close up again.

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.

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 can not 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.

Stent: a metal tube that is inserted after a balloon angioplasty to prevent abrupt artery closure.

8 - 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 review and editing and to the Massachusetts PCI 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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Mass-DAC Cardiac Advisory Board advises Mass-DAC on data quality, identification of risk factors affecting patient outcomes; and appropriateness, interpretation, and limitations of analytic results.

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Mass-DAC PCI 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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APPENDIX:

ACC-NCDR DATA COLLECTION TOOL - VERSION 2.0

Data Collection Form

ADMINISTRATIVE

Participant ID[5] __ __ __ __ __ __ (mandatory)

Participant Name[6] _____

DEMOGRAPHICS (complete this section on admission to the facility)

Last Name[8] ❍ Missing
_____

First Name[9] ❍ Missing
_____

MI[10] ❍ Missing ❍ No MI
___

SSN + Country Code[11] ❍ Missing
__ __ __ - __ __ - __ __ __ __ + __ __

Gender[12] ❍ Missing
❍ Male
❍ Female

Race[13] ❍ Missing
❍ Caucasian
❍ Black
❍ Hispanic
❍ Asian
❍ Native American
❍ Other

Date of Birth[14] ❍ Missing
_____/_____/_____
mm dd yyyy

ADMISSION/DISCHARGE (complete this section on admission/discharge to the facility)

Admit Date[15] (mandatory)
_____/_____/_____
mm dd yyyy

Admit Status[17] ❍ Missing
❍ Referral
❍ Emergency Department
❍ Transfer – other Facility
❍ Other

CAB Status[21] ❍ Missing
(During This Admission)
❍ No CAB
❍ Elective
❍ Urgent
❍ Emergency
❍ Salvage

CAB Date[22] ❍ Missing
(During This Admission)
_____/_____/_____
mm dd yyyy

Insurance Payor[18] ❍ Missing
❍ Government
❍ Commercial
❍ HMO
❍ None

 # PCI Lab Visits[19]: | Calc |

Multiple PCIs–Same Lesion[20]: | Calc |

Discharge Date[16] (mandatory)
_____/_____/_____
mm dd yyyy

Discharge Status[23] ❍ Missing
❍ Alive
❍ Expired

(Complete if patient Expired)
Date of Death[24] ❍ Missing
_____/_____/_____
mm dd yyyy

(Complete if patient Expired)
Prim Cause Death[25] ❍ Missing
❍ Cardiac
❍ Neurologic
❍ Renal
❍ Vascular
❍ Infection
❍ Pulmonary
❍ Valvular
❍ Other

(Complete if patient Expired)
Location - Death[26] ❍ Missing
❍ During CL Visit
❍ After CL Visit

HISTORY AND RISK FACTORS (complete this section on admission to the facility)

_____cm **Height**[27] ❍ Missing
_____kg **Weight**[28] ❍ Missing

Family Hx CAD[29] ❍ Missing
❍ No
❍ Yes

CHF[30] ❍ Missing
❍ No
❍ Yes

Diabetes[31] ❍ Missing
❍ No Diabetes (Treatments)
❍ No Treatment - OR - (select multiple below)
❍ Diabetes – Insulin
❍ Diabetes – Oral
❍ Diabetes – Diet

Renal Failure[32] ❍ Missing
❍ No
❍ Yes – Dialysis
❍ Yes – No Dialysis

Chron. Lung Dise[33] ❍ Missing
❍ No
❍ Yes

Cerebrovas. Dise[34] ❍ Missing
❍ No
❍ Yes

Peripheral Vascular Disease[35] ❍ Missing
❍ No
❍ Yes

Previous MI[36] ❍ Missing
❍ No
❍ Yes

Hypertension[37] ❍ Missing
❍ No
❍ Yes

Smoking History[38] ❍ Missing
❍ Current
❍ Former
❍ Never

Hypercholesterolemia[39] ❍ Missing
❍ No
❍ Yes – Treated with Lipid Lowering Therapy
❍ Yes – Not treated with Lipid Lowering Therapy

PREVIOUS INTERVENTIONS (complete this section on admission to the facility)

Previous PCI[40] ❍ Missing
❍ No
❍ Yes
Prev. PCI Date[41] ❍ Missing
_____/_____/_____
mm dd yyyy

Previous CAB[42] ❍ Missing
❍ No
❍ Yes
Prev. CAB Date[43] ❍ Missing
_____/_____/_____
mm dd yyyy

Previous Valve Surgery[44] ❍ Missing
❍ No
❍ Yes
Prev. Valve Surgery Date[45] ❍ Missing
_____/_____/_____
mm dd yyyy

CARDIAC STATUS (complete this section on admission to the facility)

CHF – Prior Proc.[46] ❍ Missing
❍ No
❍ Yes

NYHA[47] (Yes only) ❍ Missing
❍1 ❍2 ❍3 ❍4

Non-Invasive Test-Ischemia[48] ❍ Missing
❍ None
❍ Positive
❍ Negative
❍ Equivocal
❍ Arrhythmia

Canadian Clinical Classification[50] ❍ Missing
❍ No Angina
❍ Class 1
❍ Class 2
❍ Class 3
❍ Class 4

Angina Type (choose one)[49] ❍ Missing
❍ No Angina
❍ Atypical Chest Pain
❍ Stable Angina
❍ ACS: Unstable Angina
❍ ACS: Non-ST Elev MI
❍ ACS: ST Elev MI

ACS Time Period[51]

	No MI	<6°	6°-24°	24°-7d	7d-2m	Miss
ACS: Unstable Angina	❍	❍	❍	❍	❍	❍
ACS: Non-ST Elev MI		❍	❍	❍	❍	❍
ACS: ST Elev MI		❍	❍	❍	❍	❍

Instructions: < or = 6 hrs
> 6 hrs and < or = 24 hrs
> 24hrs and < or = 7 days
> 7 days and < or = 2 months

CATH LAB VISIT (complete this section for each Cath Lab visit)

Procedure Date[52] (mandatory)
_____/_____/_____
mm dd yyyy

Procedure Type[54]
❍ Right Heart Cath
❍ Left Heart Cath
❍ PCI

SUMMARY
Fluro Time[55]: ❍ Missing
|_____| minutes

Cath/PCI Same Lab Visit[56]:
| Calc |

CORONARY ANATOMY
Dominance[68] ❍ Missing
❍ Not Assessed
❍ Left
❍ Right
❍ Mixed

Stenosis % (0 if None)
Left Main[69]: ❍ Missing
|____|% ❍ Not Assessed
Prox LAD[70] ❍ Missing
|____|% ❍ Not Assessed
Mid/Dist LAD[71]: ❍ Missing
|____|% ❍ Not Assessed
RCA/PDA if R or Mixed Dom.[72]: ❍ Missing
|____|% ❍ Not Assessed
CIRC[73]: ❍ Missing
|____|% ❍ Not Assessed

MEDICATIONS
Aspirin[60] ❍ Missing
❍ Not Administered
❍ Contraindicated
❍ Yes

IIB/IIIA[58] ❍ Missing
❍ Not Administered
❍ Contraindicated
❍ Yes – Before Lab Visit
❍ Yes – During Lab Visit
❍ Yes – After Lab Visit

Percutaneous Entry Location[74] (select mult below) ❍ Missing
Closure Device[75]

	No Art	No Sut	Seal	Oth	Ms
❍ Femor	❍	❍	❍	❍	❍
❍ Brachi	❍	❍	❍	❍	❍
❍ Radial	❍	❍	❍	❍	❍
❍ Other	❍	❍	❍	❍	❍

HEMODYNAMIC SUPPORT
IABP[62] ❍ Missing
❍ No
❍ Yes – Arrived with
❍ Yes – Placed During

CP Bypass[63] ❍ Missing
❍ No
❍ Yes

LV STATUS
LV Gram[64] ❍ Missing
❍ No
❍ Yes

LV Wall Motion[65] ❍ Missing
❍ Not Assessed
❍ Yes – Normal
❍ Yes – Abnormal

EF STATUS
EF Testing[66] ❍ Missing
❍ Not Assessed
❍ Contrast: Calculated
❍ Contrast: Estimated
❍ Non-Invasive: Calculated
❍ Non-Invasive: Estimated

Ejection Fraction %[67] ❍ Missing
|_____| % ❍ Not Assessed

DIAGNOSTIC CATH (skip this section if no Diagnostic Cath is performed)

GENERAL
Operator Name[76] ❍ Missing
_____

Operator SSN[77] ❍ Missing
— — — -— —-— — — —

Card. Cat. Stat[78] ❍ Missing
❍ Elective
❍ Urgent
❍ Emergency
❍ Salvage

INDICATIONS
Card. Shock[79] ❍ Missing
❍ No
❍ Yes

Val. Hrt. Dis.[80] ❍ Missing
❍ No
❍ Yes

Arrhythmia[81] ❍ Missing
❍ No
❍ Yes

Isch. Hrt. Dis.[82] ❍ Missing
❍ No
❍ Yes

Positive Functional Tests[83] ❍ Missing
❍ No
❍ Yes

Heart Disease of Other Etiology[84] ❍ Missing
❍ No Heart Disease
❍ Yes – Transplant
❍ Yes – Congenital
❍ Yes – Cardiomyopathy
❍ Yes – Other

FINDINGS
Pulmonary Hypertension[85] ❍ Missing
❍ No
❍ Yes
❍ Not Assessed

Valve Disease – Mitral[86] ❍ Missing
❍ Not Assessed
❍ No Valve Disease
❍ Stenosis
❍ Regurgitation
❍ Stenosis/ Regurgitation

Valve Disease – Tricuspid[87] ❍ Missing
❍ Not Assessed
❍ No Valve Disease
❍ Stenosis
❍ Regurgitation
❍ Stenosis/ Regurgitation

Valve Disease – Aortic[88] ❍ Missing
❍ Not Assessed
❍ No Valve Disease
❍ Stenosis
❍ Regurgitation
❍ Stenosis/ Regurgitation

Valve Disease – Pulmonic[89] ❍ Missing
❍ Not Assessed
❍ No Valve Disease
❍ Stenosis
❍ Regurgitation
❍ Stenosis/Regurgitation

P C I (skip this section if no PCI is performed)

GENERAL

Operator Name[90] ❍ Missing

____

Operator SSN[91] ❍ Missing

— — — -— —-— — — —

PCI Status[92] ❍ Missing
- ❍ Elective
- ❍ Urgent
- ❍ Emergency
- ❍ Salvage

MEDICATIONS

Thrombolytics[57] ❍ Missing
- ❍ Not Administered
- ❍ Contraindicated
- ❍ Yes – < 3°
- ❍ Yes – 3° to 6°
- ❍ Yes – >6° to ≤ 7d

Heparin[59] ❍ Missing
- ❍ Not Administered
- ❍ Contraindicated
- ❍ Yes – Prior
- ❍ Yes – During
- ❍ Yes – After
- ❍ Yes – Prior/During
- ❍ Yes – Prior/After
- ❍ Yes – During/After
- ❍ Yes – Prior/During/After

Clopidogrel[61] ❍ Missing
- ❍ Not Administered
- ❍ Contraindicated
- ❍ Yes – <= 72 hrs of PCI
- ❍ Yes – After PCI

INDICATIONS

Lesion >=50%[93] ❍ Missing
- ❍ No
- ❍ Yes – De novo
- ❍ Yes – Restenosis
- ❍ Yes – De novo/Restenosis

Acute MI[94] ❍ Missing
- ❍ No
- ❍ Yes – Non ST Elev MI
- ❍ Yes – ST Elevation MI

ST Elevation Onset Date/Time[95] ❍ Missing

_____/_____/_________
mm dd yyyy

_____:_____:_____
hh mm ss

Ballon/Stent Deployment Date/Time[96] ❍ Missing

_____/_____/_________
mm dd yyyy

_____:_____:_____
hh mm ss

Cardiogenic Shock[97] ❍ Missing
- ❍ No
- ❍ Yes

CALCULATIONS

# of Lesions Attempted[98]: | Calc |

# of Lesions Successfully Dilated[99]: | Calc |

Result of Procedure[100]: | Calc |

L E S I O N S (skip this section if no PCI is performed)

Lesion ID #[101]	1	2	3	4	5
Segment #[102]					
Guidewire Success[103]	❍No ❍Yes	❍No ❍Yes	❍No ❍Yes	❍No ❍Yes	❍No ❍Yes
% Pre-Stenosis[104]	______%	______%	______%	______%	______%
% Post-Stenosis[105]	______% ❍N/A	______% ❍N/A	______% ❍N/A	______% ❍N/A	______% ❍N/A
PreProc TIMIFlow[106]	❍No ❍Slow ❍Part ❍Comp	❍No ❍Slow ❍Part ❍Comp	❍No ❍Slow ❍Part ❍Comp	❍No ❍Slow ❍Part ❍Comp	❍No ❍Slow ❍Part ❍Comp
PostProc TIMIFlow[107]	❍No ❍Slow ❍Part ❍Comp ❍N/A	❍No ❍Slow ❍Part ❍Comp ❍N/A	❍No ❍Slow ❍Part ❍Comp ❍N/A	❍No ❍Slow ❍Part ❍Comp ❍N/A	❍No ❍Slow ❍Part ❍Comp ❍N/A
Prev Dilated Lesion[108]	❍No ❍Unknown (select mult below) ❍Balloon ❍Stent ❍Other	❍No ❍Unknown (select mult below) ❍Balloon ❍Stent ❍Other	❍No ❍Unknown (select mult below) ❍Balloon ❍Stent ❍Other	❍No ❍Unknown (select mult below) ❍Balloon ❍Stent ❍Other	❍No ❍Unknown (select mult below) ❍Balloon ❍Stent ❍Other
Cited Segment in Graft[109]	❍No ❍Yes-Artery ❍Yes-Vein	❍No ❍Yes-Artery ❍Yes-Vein	❍No ❍Yes-Artery ❍Yes-Vein	❍No ❍Yes-Artery ❍Yes-Vein	❍No ❍Yes-Artery ❍Yes-Vein
Location in Graft[110]	❍No (select one below) ❍Aortic ❍Body ❍Distal	❍No (select one below) ❍Aortic ❍Body ❍Distal	❍No (select one below) ❍Aortic ❍Body ❍Distal	❍No (select one below) ❍Aortic ❍Body ❍Distal	❍No (select one below) ❍Aortic ❍Body ❍Distal
Lesion Risk[111]	❍Low ❍Med ❍High	❍Low ❍Med ❍High	❍Low ❍Med ❍High	❍Low ❍Med ❍High	❍Low ❍Med ❍High
Intracoronary Device(s)[113] **Primary Intracoronary Device**[114] (circle primary device)	__Ballo __BareMetStent __TEC__IVUS__PreWire __Cut.Ballo __Rotational __SiroliStent __Angiojet __PaclitStent __Flowire __HeparinStent __Laser __CoveredStent __DCA __GamBrach__BetBrach __DistEmbProt __Other	__Ballo __BareMetStent __TEC__IVUS__PreWire __Cut.Ballo __Rotational __SiroliStent __Angiojet __PaclitStent __Flowire __HeparinStent __Laser __CoveredStent __DCA __GamBrach__BetBrach __DistEmbProt __Other	__Ballo __BareMetStent __TEC__IVUS__PreWire __Cut.Ballo __Rotational __SiroliStent __Angiojet __PaclitStent __Flowire __HeparinStent __Laser __CoveredStent __DCA __GamBrach__BetBrach __DistEmbProt __Other	__Ballo __BareMetStent __TEC__IVUS__PreWire __Cut.Ballo __Rotational __SiroliStent __Angiojet __PaclitStent __Flowire __HeparinStent __Laser __CoveredStent __DCA __GamBrach__BetBrach __DistEmbProt __Other	__Ballo __BareMetStent __TEC__IVUS__PreWire __Cut.Ballo __Rotational __SiroliStent __Angiojet __PaclitStent __Flowire __HeparinStent __Laser __CoveredStent __DCA __GamBrach__BetBrach __DistEmbProt __Other
Dissection[115]	❍No ❍Yes	❍No ❍Yes	❍No ❍Yes	❍No ❍Yes	❍No ❍Yes
Acute Closure[116]	❍No ❍Yes	❍No ❍Yes	❍No ❍Yes	❍No ❍Yes	❍No ❍Yes
Succ. Reopening[117]	❍N/A ❍No ❍Yes	❍N/A ❍No ❍Yes	❍N/A ❍No ❍Yes	❍N/A ❍No ❍Yes	❍N/A ❍No ❍Yes
Perforation[118]	❍No ❍Yes	❍No ❍Yes	❍No ❍Yes	❍No ❍Yes	❍No ❍Yes

Notes: (1) When the Guidewire is unsuccessful, the % Post-Stenosis[105] and PostProc TIMIFlow[107] items should be marked N/A. Also, the Intracoronary Device(s)[113], Primary Intracoronary Device[114], Acute Closure[116] and Successful Reopening[117] items should be skipped/missing. (2) When Cited Segment in Graft[109] is No then Location in Graft[110] must also be No. (3) When Acute Closure[116] is No then Succ. Reopening[117] must also be N/A.

A D V E R S E O U T C O M E S (complete this section for each Cath Lab visit)

Periprocedural MI[119] ❍ Missing
- ❍ No
- ❍ Yes – During Cath Lab Visit
- ❍ Yes – After Cath Lab Visit
- ❍ Yes – During/After Cath Lab Visit

CK-MB UNL[120] ❍ Missing
|_____| (complete if Peri. MI is Yes)
- ❍ Unavailable
- ❍ No Periprocedural MI

CK-MB Baseline[121] ❍ Missing
|_____| (complete if Peri. MI is Yes)
- ❍ Unavailable
- ❍ No Periprocedural MI

CK-MB Peak[122] ❍ Missing
|_____| (complete if Peri. MI is Yes)
- ❍ Unavailable
- ❍ No Periprocedural MI

Cardiogenic Shock[123] ❍ Missing
- ❍ No
- ❍ Yes – During Cath Lab Visit
- ❍ Yes – After Cath Lab Visit
- ❍ Yes – During/After Cath Lab Visit

Arrhythmia[124] ❍ Missing
- ❍ No
- ❍ Yes – During Cath Lab Visit
- ❍ Yes – After Cath Lab Visit
- ❍ Yes – During/After Cath Lab Visit

CVA/Stoke[125] ❍ Missing
- ❍ No
- ❍ Yes – During Cath Lab Visit
- ❍ Yes – After Cath Lab Visit
- ❍ Yes – During/After Cath Lab Visit

Tamponade[126] ❍ Missing
- ❍ No
- ❍ Yes – During Cath Lab Visit
- ❍ Yes – After Cath Lab Visit
- ❍ Yes – During/After Cath Lab Visit

VASCULAR COMPLICATIONS

Bleeding[127] ❍ Missing
- ❍ No
- ❍ Yes – During Cath Lab Visit
- ❍ Yes – After Cath Lab Visit
- ❍ Yes – During/After Cath Lab Visit

Occlusion[128] ❍ Missing
- ❍ No
- ❍ Yes – During Cath Lab Visit
- ❍ Yes – After Cath Lab Visit
- ❍ Yes – During/After Cath Lab Visit

Loss of Distal Pulse[129] ❍ Missing
- ❍ No
- ❍ Yes – During Cath Lab Visit
- ❍ Yes – After Cath Lab Visit
- ❍ Yes – During/After Cath Lab Visit

Dissection[130] ❍ Missing
- ❍ No
- ❍ Yes – During Cath Lab Visit
- ❍ Yes – After Cath Lab Visit
- ❍ Yes – During/After Cath Lab Visit

Pseudoaneurysm[131] ❍ Missing
- ❍ No
- ❍ Yes – After Cath Lab Visit

AV Fistula[132] ❍ Missing
- ❍ No
- ❍ Yes – After Cath Lab Visit

Contrast Reaction[133] ❍ Missing
- ❍ No
- ❍ Yes – During Cath Lab Visit
- ❍ Yes – After Cath Lab Visit
- ❍ Yes – During/After Cath Lab Visit

CHF[134] ❍ Missing
- ❍ No
- ❍ Yes – After Cath Lab Visit

Renal Failure[135] ❍ Missing
- ❍ No
- ❍ Yes – After Cath Lab Visit

Emergency PCI[136] (Cath only) ❍ Missing
- ❍ No
- ❍ Yes – During Cath Lab Visit

Unplanned CAB [137](PCI only) ❍ Missing
- ❍ No
- ❍ Yes – During Cath Lab Visit
- ❍ Yes – After Cath Lab Visit

OPTIONAL

PCI FOLLOW-UP AT 6 MONTHS

PCI FOLLOW-UP AT 6 MONTHS

Date of Follow Up[138]
_____/_____/_____
mm dd yyyy

Vital Status[139] ❍ Missing

❍ Unable to contact
❍ Alive
❍ Dead

(Complete if Vital Status[139] is Dead)

Primary Cause of Death[140] ❍ Missing

❍ Cardiac
❍ Noncardiac
❍ Unknown

Readmission[141] ❍ Missing

❍ No
❍ Yes

(Complete if Readmission[141] is Yes. Select all that apply.)

Readmission Reason[142] ❍ Missing

❍ Myocardial Infarction (documented)
❍ Coronary Artery Bypass Surgery
❍ Percutaneous Coronary Intervention
❍ Congestive Heart Failure (without MI)
❍ Arrhythmia or Conduction Disturbance (without MI)
❍ Recurrent Angina (without MI)
❍ Cardiac Catheterization
❍ Other Medical Problem