# PERCUTANEOUS CORONARY INTERVENTION IN THE COMMONWEALTH OF MASSACHUSETTS

## January 1, 2005 – December 31, 2005

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 PERCUTANEOUS CORONARY INTERVENTION HOSPITALS 2005

| | |
|---|---|
| Baystate Medical Center<br>759 Chestnut Street<br>Springfield, MA 01199 | Massachusetts General Hospital (MGH)<br>12 Fruit Street<br>Boston, MA 02114 |
| Beth Israel Deaconess Medical Center (BIDMC)<br>330 Brookline Avenue<br>Boston, MA 02115 | Mount Auburn Hospital<br>330 Mount Auburn Street<br>Cambridge, MA 02138 |
| Boston Medical Center (BMC)<br>88 East Newton Street<br>Boston, MA 02118 | North Shore Medical Center - Salem Hospital<br>81 Highland Avenue<br>Salem, MA 01970 |
| Brigham & Women's Hospital (B&W)<br>75 Francis Street<br>Boston, MA 02115 | Southcoast Hospital Group -<br>Charlton Memorial Hospital<br>363 Highland Avenue<br>Fall River, MA 02720 |
| Cape Cod Hospital<br>27 Park Street<br>Hyannis, MA 02601 | Saint Vincent Hospital at Worcester Medical Center<br>123 Summer Street<br>Worcester, MA 01608 |
| Caritas Saint Elizabeth's Medical Center<br>736 Cambridge Street<br>Boston, MA 02135 | Tufts-New England Medical Center (NEMC)<br>750 Washington Street<br>Boston, MA 02111 |
| Lahey Clinic<br>41 Mall Road<br>Burlington, MA 01805 | UMass Memorial Medical Center<br>55 Lake Avenue North<br>Worcester, MA 01655 |

## MASSACHUSETTS PRIMARY PERCUTANEOUS CORONARY INTERVENTION PILOT HOSPITALS: 2005

| | |
|---|---|
| Brockton Hospital<br>680 Centre Street<br>Brockton, MA 02302 | MetroWest Medical Center<br>115 Lincoln Street<br>Framingham, MA 01702 |
| Caritas Norwood Hospital<br>800 Washington Street<br>Norwood, MA 02062 | Saints Memorial Medical Center<br>1 Hospital Drive<br>Lowell, MA 01852 |
| Lowell General Hospital<br>295 Varnum Avenue<br>Lowell, MA<br>01854 | South Shore Hospital<br>55 Fogg Road at Route 18<br>South Weymouth, MA 02190 |
| Melrose -Wakefield Hospital<br>585 Lebanon Street<br>Melrose, MA 02176 | |

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# 1 - KEY FINDINGS

- Between January 1, 2005 and December 31, 2005 there were **16,139** hospital admissions in which at least one Percutaneous Coronary Intervention (PCI) was performed in Massachusetts hospitals.

- **17.1 %** (2,752) of these admissions were "shock or stemi" admissions – admissions in which the patient had an ST-elevated myocardial infarction (STEMI) within 24 hours of admission or was in shock at the time of the procedure.

- **Twenty one** hospitals performed at least one PCI in 2005, **seven** of which participated in the Massachusetts Primary PCI Pilot Program. Primary PCI Pilot programs are approved for "shock or STEMI" admissions only.

- The majority of patients undergoing PCI were male (**69.5%**), white (**87.8%**), and under 60 years of age (**36%**).

- Of the 16,139 PCI admissions, **251** patients died during the same hospitalization in which the PCI was performed. Eighty-six mortalities **(0.64%)** occurred in patients not arriving in shock and not having an ST-elevated myocardial infarction within 24 hours of admission; 165 mortalities **(6.00%)** occurred in the "shock or STEMI" population.

- After adjusting for patient risk, the odds of in-hospital mortality in a hospital one standard deviation above the state average was **one and a half times** (odds of 1.6) that of a hospital one standard deviation below the state average, regardless of whether the patient had STEMI or shock. This represents a **reduction in between-hospital variation** from 2004 shock or STEMI patients from

2004 (odds in 2004 = 2.5) but an **increase in between-hospital variation** for patients not having shock or STEMI prior to their PCI (odds in 2004 = 1.4).

- Based on in-hospital mortality there was **one hospital** in Massachusetts that was a statistical outlier for STEMI or SHOCK mortalities. UMass Memorial Medical Center had higher than expected mortality for patients having STEMI or Shock prior to their PCI during 2005. **However**, based on internal awareness of these data, in late 2005 UMass Memorial Medical Center instituted programmatic changes to improve outcomes. Preliminary analysis of 2006 unadjusted data suggests improvements in outcomes consistent with the program changes -- UMass Memorial had an unadjusted in-hospital mortality rate lower than the 2006 state average for their STEMI or Shock patients.

# 2 - INTRODUCTION

## 2.1 - What is in this Report?

This is the third report (available at http://massdac.org/reports/pci.html) that describes methods and results for estimating hospital-specific in-hospital risk-standardardized mortality rates following Percutaneous Coronary Intervention (**PCI**) in Massachusetts. Information pertains to patients who were 18 years of age or older at the time of their intervention. Interventions performed in United States Government Hospitals (e.g., VA Boston Healthcare System – Jamaica Plain Campus) are not included in this report.

In Massachusetts, not all hospitals are permitted to perform PCIs and those wishing to start performing PCIs must submit an application to the Determination of Need Program in the Massachusetts Department of Public Health. In 2005, there were eleven established PCI programs in Massachusetts, each with back-up cardiac surgery programs. Three relatively new community hospital programs were granted approval for both cardiac surgery and PCI programs in 2003 (Cape Cod Hospital; Southcoast Hospital Group – Charlton Hospital; and North Shore Medical Center – Salem Hospital). Additionally, four community hospitals applied for and received approval to perform primary PCI only under a **Primary PCI Pilot Program** with the Massachusetts Department of Public Health in 2003.

Primary PCI Pilot Program hospitals 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. These Pilot Programs provide PCIs to patients arriving at the hospital in shock or having a heart attack within 24 hours of admission. The four new Primary PCI Pilot hospitals include Brockton Hospital; Caritas Norwood Hospital; Metrowest Medical Center; and South Shore Hospital. Three additional hospitals were approved for the Primary PCI Pilot Program in 2004: Lowell General Hospital; Melrose-Wakefield Hospital; and Saints Memorial Hospital. Thus, in Massachusetts during 2005, there were seven hospitals involved in the Primary PCI Pilot Program.

This document reports hospital-specific standardized mortality incidence rates following PCI procedures for the twenty-one PCI hospitals in Massachusetts that performed

at least one PCI between January 1, 2005 and December 31, 2005. Because of the elevated risks associated with heart attack patients, results for two separate cohorts of patients are presented: (1) patients having an ST-elevated myocardial infarction (STEMI) within 24 hours of arrival to the hospital or at the time of the first PCI procedure, or in cardiogenic shock prior to the intervention (referred to as the "**shock or STEMI"** cohort)[3]; and (2) patients having no STEMI within 24 hours of arrival to the hospital or at the time of the first PCI and no cardiogenic shock prior to the PCI (referred to as the "**no shock and NSTEMI"** Cohort).

In-hospital mortality is analyzed for the 21 hospitals that treated "shock or STEMI" patients. Because hospitals participating in the Massachusetts Primary PCI Pilot Program are permitted to treat only "shock or STEMI" cases, they are not included in the analysis for in-hospital mortality for "no shock and NSTEMI" patients. Thus, there are only 14 hospitals analyzed for "no shock and NSTEMI" 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

[3] The definition of STEMI or SHOCK prior to 2005 was: STEMI within 24 hours of admission, OR cardiac shock at any time up to the first PCI procedure. In 2005, because of a definitional change by in the NCDR instrument, STEMI or SHOCK is defined as STEMI within 24 hours of admission OR at the time of the first PCI procedure, OR cardiac shock at admission.

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 a buildup of scar tissue 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 Government hospitals in Massachusetts. Between January 1, 2005 and December 31, 2005, there were 16,139 admissions in which at least one PCI was performed: 13,387 "no shock and NSTEMI" patients and 2,752 "shock or STEMI" patients (**Table 2.1**). Not surprisingly, the in-hospital mortality rate for "shock or STEMI" cases is almost 10 times that for "no shock and NSTEMI" cases (6.00% versus 0.64%).

Mass-DAC analyzed the first PCI for patients who received more than one PCI during their admission. Almost 92% of patients received only one PCI during their hospital admission. Results in this report do not change if the last PCI is used.

**Table 2.1: Descriptive Summaries of Adult PCI Admissions in Massachusetts Hospitals, January 1 – December 31, 2005.** 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 at time of first PCI or cardiogenic shock.

| RISK COHORT | ¶No Shock and NSTEMI | | §Shock or STEMI | |
|---|---|---|---|---|
| **Characteristic** | **Number** | **Percent** | **Number** | **Percent** |
| Admitted via Emergency Department or Transfer | 7812 | 58.36 | 2689 | 97.71 |
| Number of PCIs Per Admission | | | | |
| 1 PCI | 12323 | 92.05 | 2469 | 89.72 |
| ≥ 2 PCIs | 1064 | 7.95 | 283 | 10.28 |
| More than 70% stenosis in Left Anterior Descending Artery | 7895 | 58.98 | 1553 | 56.43 |
| At least One Stent | 12524 | 93.55 | 2531 | 91.97 |
| Drug Eluting if Stented | 11598 | 92.61 | 2134 | 84.31 |
| Total Length of Stay, days | Mean = 3.81 Median = 2 | | Mean = 6.16 Median = 5 | |
| **Post-Procedure** Length of Stay, days | Mean = 3.03 Median = 2 | | Mean = 5.90 Median = 4 | |
| Unadjusted Outcomes | | | | |
| Any Vascular Complication | 98 | 0.73 | 26 | 0.94 |
| CABG During Admission | | | | |
| Elective Status CABG | 18 | 0.13 | 11 | 0.40 |
| Urgent Status CABG | 63 | 0.47 | 54 | 1.96 |
| Emergent CABG | 15 | 0.11 | 12 | 0.44 |
| Salvage status CABG | 1 | 0.01 | 1 | 0.04 |
| Transferred for CABG | 5 | 0.04 | 9 | 0.33 |
| In-Hospital Death | 86 | 0.64 | 165 | 6.00 |
| TOTAL NO. OF ADMISSIONS | **13387** | | **2752** | |

## 2.4 - Why Report on Percutaneous Coronary Interventions?

A PCI offers a non-surgical alternative to Coronary Artery Bypass Graft (CABG) Surgery. PCI is less invasive, and the hospital stay and recovery is much shorter than with CABG surgery. As a result, 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 clinical 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: Massachusetts Cardiac Care Hospital Outlier Committee, The PCI Physician Reporting Oversight Committee and the Data 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 the first PCI until hospital discharge, is the primary patient outcome. Mortality was selected as the primary measure of quality because it is serious and unambiguous.

## 3.2 - Massachusetts PCI Hospitals

Twenty-one hospitals had Cardiac Catheterization Labs that performed PCIs between January 1, 2005 and December 31, 2005, eleven of which had established labs which had been performing PCIs prior to 2002. All non-government hospitals that performed PCIs were required to submit clinical 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 for 2005 were collected using the ACC-NCDR Version 3.04 Instrument containing 137 variables.

Massachusetts Inpatient Acute Hospital Case Mix and Charge Database. Hospital discharge data for fiscal years[4] 2002 – 2006 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 Diagnosis and Procedure codes;

[4] Fiscal year 2005 is October 1, 2004 – September 30, 2005

discharge status; dates of admission and discharge; date of procedure; and patient medical record number. Social security numbers were removed from this database.

Massachusetts Mortality Index Database. Dates of death obtained from Massachusetts death certificates available for all deaths occurring in Massachusetts between January 1, 2002 and September 30, 2006 from the Massachusetts Registry of Vital Records and Statistics. While the primary source of in-hospital mortality data was the data submitted by hospitals, the mortality index database was used in a verification procedure. Using a confidential and secure transmission procedure, Mass-DAC submitted patient names, dates of birth, and Social Security numbers for all Mass-DAC patients, regardless of hospital-reported survival status, to the Registry of Vital Records and Statistics. Registry personnel subsequently linked the data submitted by Mass-DAC to their mortality index database 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 in one of two ways: 1) directly into the ACC-NCDR software database by the clinical staff, or 2) 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 to Mass-DAC regularly (**Table 3.1**). This process involved submitting protected data during specific harvest periods. Hospitals submitted data electronically in a secure repository on a secure Mass-DAC website. 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 July 1, 2006, after which no changes were accepted without written permission from Mass-DAC.

| Table 3.1: PCI Data Harvest Schedule for PCIs Performed Between January 1, 2005 and December 31, 2005. | |
|---|---|
| **Month of Data Harvest** | **Corresponding Dates of PCI** |
| June, 2005 | January 1, 2005 – March 31, 2005 (Quarter 1) |
| September , 2005 | April 1, 2005 – June 30, 2005 (Quarter 2) |
| December, 2005 | July 1, 2005 – September 30, 2005 (Quarter 3) |
| March, 2006 | October 1, 2005 – December 31, 2005 (Quarter 4) |
| July, 2006 | 2005 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 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 297 data submissions to Mass-DAC for 2005 data with a mean of 3.5 submissions per hospital with a range of 1 to 8. A total of 284 quality reports were returned to the hospitals with a mean of 3.4 per hospital and a range of 1 to 8.

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. Mass-DAC found high agreement between the hospital mortality reports and the information provided by the Registry of Vital Records and Statistics. There were 4 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 4, Mass-DAC confirmed that 2 were in-hospital mortalities; 1 patient died after transfer to another acute care hospital; and 1 died at home after discharge. There were 6 in-hospital deaths

reported by the hospitals with dates of death that differed by a day or two with the Vital Statistics data. The state date of death was confirmed and the dates changed in the database. One patient was reported by the hospital as a mortality and was not listed in the Vital Statistics data. Mass-DAC confirmed that the death was an in-hospital mortality.

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 ACC-NCDR. Recent questions and answers were discussed at Data Manager meetings. Volunteers who attended the audit meetings shared definition information with their facilities.

Audit Data. In the spring of 2006, a sample of the 2005 PCI data was audited. Records requested from the hospitals included those for (1) **all** patients who died in hospital, (2) **all** patients who were coded as having shock or salvage status, and (3) **all** elective cases in the shock or STEMI cohort and (4) **all** emergent cases in the no shock and no STEMI cohort. The total number of records audited to determine data consistency and accuracy of coding for 2005 PCI data was 1052.

Documentation requested from the hospitals included admission, history and discharge summaries, catheterization lab records, and any other documentation that could support the coding. Institutions were required to provide this documentation to Mass-DAC. Mass-DAC requested that every PCI hospital in MA provide a physician volunteer to help in the audit process. Eighteen volunteers (14 physicians and 4 data managers) together with the Mass-DAC PCI Adjudication Committee (Section 9) reviewed all records. All reviewers were approved by the Internal Review Board (IRB) of Harvard Medical School and had current IRB Human Subjects Training certificates. Hospitals were notified of any disagreement that the committee had with their coding and given an opportunity to file an appeal of any decision. Appeals were reviewed by the PCI Adjudication Committee and hospitals were notified of the final decision and resulting coding changes in the dataset.

The coding was changed for only the variables for which there was a census[5] for the audit; 98 records coded yes for shock were changed to no shock; 29 records coded for salvage were changed to emergent status; 9 records coded for elective status were

[5] By census we mean that all occurrences of the value of the variable were reviewed rather than a sample of occurrences.

changed to urgent status; 3 records coded for elective status were changed to emergent status, 86 records coded for emergent status were changed to urgent status and 4 emergent status records were changed to elective status.

# 4 - RISK ADJUSTMENT

## 4.1 - Who Receives PCI in Massachusetts?

**Table 4.1** provides demographic summaries of the 13,387 "no shock and no STEMI" admissions and 2,752 "shock or STEMI" admissions. The majority of "no shock and no STEMI" admissions are male (69.4%), white (87.96%), and about one-third (33.9%) are less than 60 years of age at the time of their PCI. Patients residing out of state comprised 7.49% of the "no shock and no STEMI" admissions (data not shown).

The majority of "shock or STEMI" admissions are male (70.2%) and white (86.9%). Nearly one-half (48.3%) of the "shock or STEMI" admissions were less than 60 years old at the time of their PCI. Finally, 6.80% of the "shock or STEMI" admissions were patients residing out of state (data not shown).

**Table 4.1: Age-Sex-Race Distribution for Adult PCI Admissions in Massachusetts Hospitals During January 1, 2005 – December 31, 2005: Stratified by Risk Cohort.** Entries represent numbers of admissions.

**13,387 No shock and No STEMI PCI ADMISSIONS**

| Age Group | Females | | | | | Males | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | White | African American | Hispanic | Other†† | Total | White | African American | Hispanic | Other | Total |
| ≤49 | 248 | 18 | 29 | 24 | 319 | 997 | 35 | 64 | 91 | 1187 |
| 50-59 | 524 | 40 | 30 | 47 | 641 | 2100 | 57 | 63 | 166 | 2386 |
| 60-69 | 807 | 47 | 31 | 73 | 958 | 2277 | 48 | 68 | 190 | 2583 |
| 70-79 | 1141 | 30 | 24 | 107 | 1302 | 1962 | 35 | 38 | 117 | 2152 |
| ≥80 | 809 | 12 | 6 | 50 | 877 | 911 | 6 | 6 | 59 | 982 |
| **Total** | 3529 | 147 | 120 | 301 | **4097** | 8247 | 181 | 239 | 623 | **9290** |

**2,752 STEMI or Shock PCI Admissions**

| Age Group | Females | | | | | Males | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | White | African American | Hispanic | Other†† | Total | White | African American | Hispanic | Other†† | Total |
| ≤49 | 90 | 3 | 6 | 6 | 105 | 375 | 18 | 31 | 41 | 465 |
| 50-59 | 127 | 9 | 4 | 8 | 148 | 538 | 13 | 25 | 35 | 611 |
| 60-69 | 153 | 6 | 5 | 14 | 178 | 372 | 13 | 9 | 31 | 425 |
| 70-79 | 182 | 6 | 4 | 10 | 202 | 248 | 2 | 10 | 22 | 282 |
| ≥80 | 169 | 8 | 3 | 7 | 187 | 137 | 1 | 2 | 9 | 149 |
| **Total** | 721 | 32 | 22 | 45 | **820** | 1670 | 47 | 77 | 138 | **1932** |

†† Includes some patients with unknown or missing race information.

## 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 fairly assess hospitals, it is 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 exactly the same risk factors prior to a PCI but who are treated in different PCI 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 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 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 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 there is a low probability that the actual number of mortalities and the predicted number of mortalities is the same, 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 probability of the observed 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 PCI.

## 5.1 - Standardized In-Hospital 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 2005. 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 is an outlier. 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 unadjusted rate, then more patients than expected died. Such a hospital would be categorized as having **higher than expected mortality**.

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 "no shock or NSTEMI" admissions) and in Table 6.2 (for "shock or STEMI" 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 "true" mortality rate at hospital "i" is estimated as: $1/n_i \sum_j \text{logit}^{-1}[\beta_{0i} + \beta(\text{Risk Factors})]$. 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 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 2005.
7. 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, $\mu$ and $\tau^2$ represent the overall mean risk-adjusted log-odds of mortality and between-hospital variation, respectively. If there are no quality differences based on in-hospital mortality across PCI hospitals, then

$$\beta_{0,1} = \beta_{0,2} = \ldots = \beta_{0,21} = \beta_0 \text{ and this happens if and only if } \tau^2 = 0$$

The hierarchical model was estimated using WinBUGS software.[5] The prior distributions assumed for $\beta$, $\mu$, and $\tau^2$ were, respectively: independent normal distributions with mean 0 and variance 1000 for the components of $\beta$; $\mu$ from a normal distribution with mean 0 and variance 1000; and $\tau^{-2}$ 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 $\mu$ and $\tau^2$. 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.

Mass-DAC compared the predicted number of deaths to the actual number of deaths at the dropped hospital and calculated a "probability." This probability, loosely called a "p-value," quantifies how **likely** the observed number of deaths would be if the dropped hospital had the same level of quality as all remaining PCI hospitals, small p-values (those $\leq 0.01$) 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

[5] 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.

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 predicted by its peers, then the hospital is classified as having **lower than predicted mortality**. 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 $\tau^2$.

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; 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 PCI: 2005

Of the 16,139 PCI admissions in Massachusetts, 251 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 "no shock and no STEMI" cases following a PCI. For example, 32.7% of all "no shock or no STEMI" 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 1.94 for patients with diabetes indicates that those patients are about twice 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 about three times more likely to die within the PCI hospital admission than patients without renal failure.

A non-hierarchical logistic regression model indicated area under the ROC curve of 0.89. The Hosmer-Lemeshow Goodness-of-Fit test did not indicate a lack of fit ($\chi 2$ (8 dof) = 6.65, p = 0.57). Model discrimination ranged from 0% (0 deaths in 1301 admissions) in the lowest risk decile to 4.3% (52 deaths in 1211 admissions) in the highest risk decile.

**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 0.64% for "no shock and no STEMI" 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 a more severe case-mix. Listed on the right-hand side are the estimated SMIRs. All 95% probability intervals contain the unadjusted state rate indicating no statistical outliers.

**Table 6.2** lists information similar to Table 6.1 but for the "shock or STEMI" cases. A non-hierarchical logistic regression model indicated area under the ROC curve of 0.86. While the Hosmer-Lemeshow Goodness-of-Fit test did not indicate a lack of fit ($\chi 2$ (5 dof) = 11, p = 0.05, these findings are not as supportive as for the no shock and no STEMI model.

Model discrimination ranged form 0.8% (1 death in 125 admissions) in the lowest risk group to 38.5% (92 deaths in 239 admissions) in the highest risk group.

**Figure 6.2** displays the SMIRs and corresponding 95% posterior intervals for "shock or STEMI" cases. The solid black vertical line in the figure is the unadjusted state in-hospital mortality rate of 6.0% for "shock or STEMI" cases. All 95% intervals cover the state unadjusted in-hospital mortality rate.

**Figure 6.3** presents the cross-validated p-values of "no shock and no STEMI" cohort, under a number of different distributional assumptions regarding the hierarchical regression model; **Figure 6.4** presents similar values for the "shock or STEMI" cohort. One hospital, UMass Memorial Medical Center, has a p-value smaller than 0.01. This hospital had higher mortality than that predicted by all other MA hospitals.

In summary, based on in-hospital mortality data, there is evidence that one hospital in Massachusetts had higher than expected in-hospital mortality in Massachusetts during 2005. UMass Memorial Medical Center had statistically significantly higher than predicted in-hospital mortality for shock or STEMI cases. However, based on internal awareness of this data, in late 2005 UMass Memorial instituted programmatic changes. Preliminary analysis of 2006 unadjusted data suggests improvements in outcomes consistent with these program changes -- UMass Memorial had an unadjusted in-hospital mortality rate lower than the 2006 state average for their STEMI or Shock patients.

**Table 6.1: Adjusted Odds Ratios of In-Hospital Mortality Following PCI in Adults: No shock or No STEMI Cases, January 1, 2005 –December 31, 2005.** Based on **13387** PCI admissions with 86 deaths (0.64%).

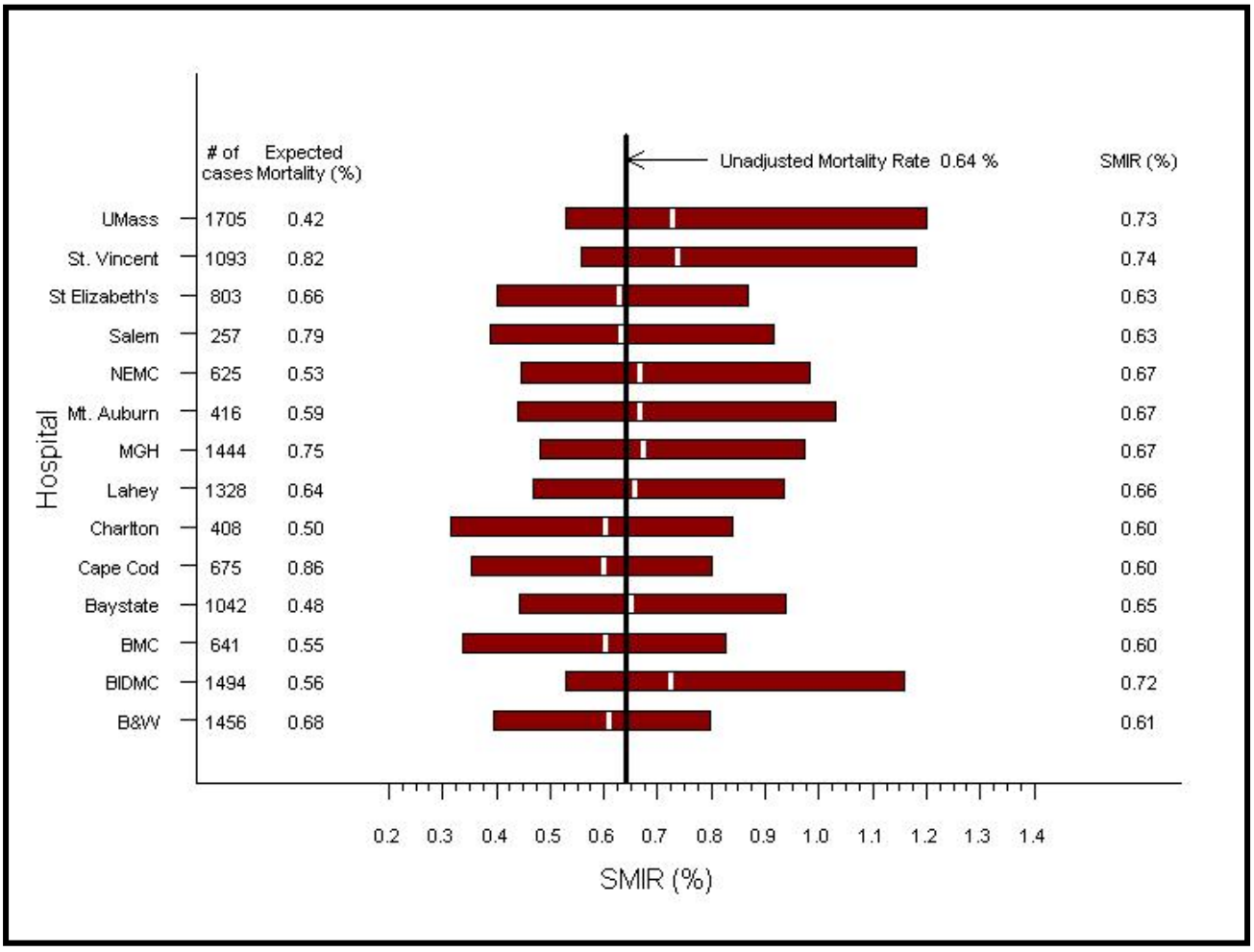
| Risk Factor | Prevalence (%) | Adjusted Odds Ratio | 95% Interval for Adjusted Odds Ratio |
|---|---|---|---|
| Mean Age (years over 65) | 0.29 | 1.09 | (1.06, 1.12) |
| Renal Failure | 6.60 | 2.97 | (1.71, 4.73) |
| Diabetes | 32.66 | 1.94 | (1.20, 2.98) |
| Chronic Lung Disease | 14.12 | 1.80 | (1.04, 2.77) |
| Ejection Fraction < 30% | 3.12 | 3.03 | (1.47, 5.42) |
| PCI Status (Ref=Elective) | | | |
| Urgent | 55.24 | 7.93 | (2.68, 19.71) |
| Emergent or Salvage | 2.73 | 48.25 | (13.66, 135.30) |
| Left Main Disease | 7.16 | 1.48 | (0.79, 2.44) |
| LAD > 70% Stenosis | 58.98 | 1.65 | (0.93, 2.78) |
| **Between-Hospital Parameters** | | | |
| Between-Hospital Average logit, $\mu$ | | -8.383 | (-9.593, -7.286) |
| Average Between-Hospital Variance in logits, $\tau^2$ | | 0.05235 | (0.0008117, 0.2838) |

**Table 6.2: Adjusted Odds Ratios of In-Hospital Mortality Following PCI in Adults: Shock or STEMI Cases, January 1, 2005 – December 31, 2005.** Based on 2752 PCI admissions with 165 deaths (5.996%).

| Risk Factor | Prevalence (%) | Adjusted Odds Ratio | 95% Interval for Adjusted Odds Ratio |
|---|---|---|---|
| Age (Ref = < 60 years) | | | |
| 60-69 yrs | 21.91 | 1.20 | (0.66, 2.03) |
| 70-79 yrs | 17.59 | 2.01 | 1.13, 3.30) |
| ≥ 80 yrs | 12.21 | 4.86 | (2.85, 7.80) |
| Renal Failure | 4.87 | 3.15 | (1.83, 5.050) |
| Ejection Fraction < 30% | 5.41 | 2.26 | (1.23, 3.76) |
| PCI Status (Ref =Urgent or Elective[6]) | | | |
| Emergent or Salvage | 92.01 | 1.90 | (0.91, 3.86) |
| Pre-Procedure Cardiogenic Shock | 7.59 | 12.09 | (7.89, 17.86) |
| Left Main Disease | 5.85 | 2.08 | (1.18, 3.33) |
| **Between-Hospital Parameters** | | | |
| Between-Hospital Average logit, $\mu$ | | -4.659 | (-5.598, -3.919) |
| Average Between-Hospital Variance in logits, $\tau^2$ | | 0.05453 | (0.0008011, 0.2453) |

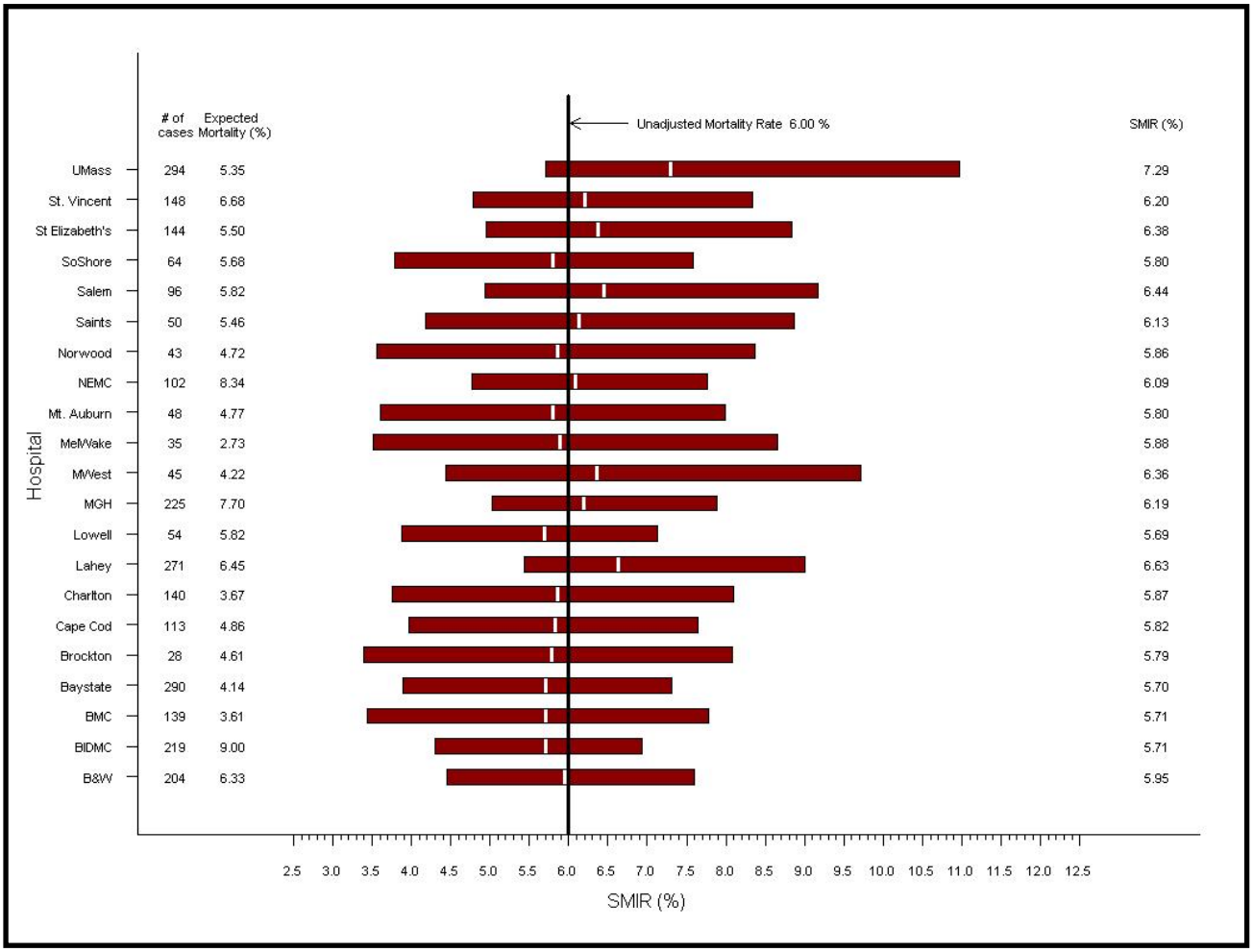
[6] Mass-DAC queried hospitals about the seven patients who had either "shock or STEMI" yet were coded as elective cases; the hospitals indicated that these cases should remain as elective.

**Figure 6.1: Ninety-Five Percent Posterior Intervals for Standardized Mortality Incidence Rates (SMIRs) Following PCI During January 1, 2005 – December 31, 2005: No shock and NSTEMI 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 **0.64**%.



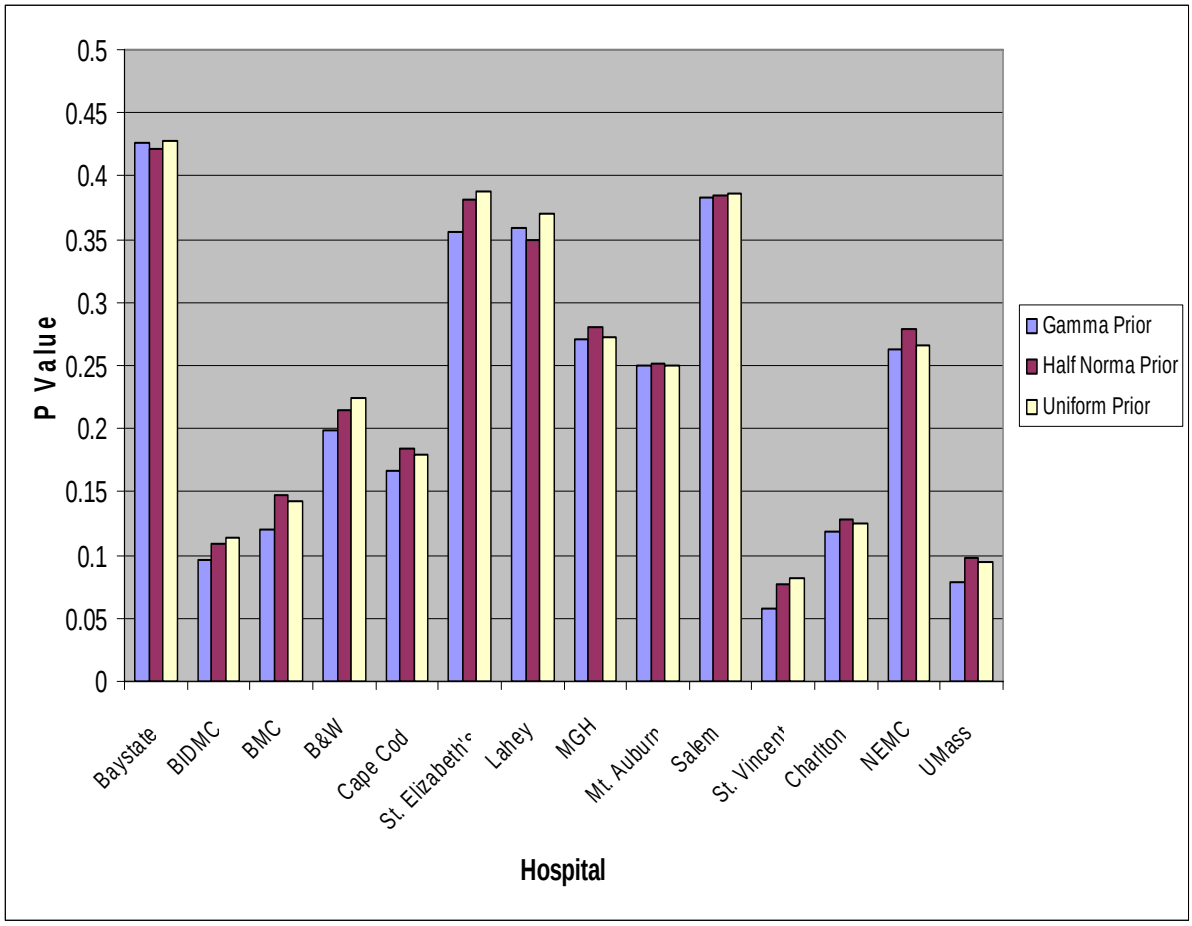

**Key**: ; **B&W** = Brigham & Women's Hospital; **BIDMC** = Beth Israel Deaconess Medical Center; **BMC** = Boston Medical Center; **Baystate** = Baytstate Medical Center; **Cape Cod** = Cape Cod Hospital; **Charlton** = Southcoast Hospital Group – Charlton Memorial Hospital; **Lahey** = Lahey Clinic; **MGH** = Massachusetts General Hospital; **Mt. Auburn** = Mount Auburn Hospital; **NEMC** = Tufts New England Medical Center; **Salem** = North Shore Medical Center-Salem Hospital; **St. Elizabeth's** = Caritas Saint Elizabeth's Medical Center; **St. Vincent** = Saint Vincent Hospital at Worcester Medical Center; **UMass** = UMass Memorial Medical Center.

**Figure 6.2: Ninety-Five Percent Probability Intervals for Standardized Mortality Incidence Rates (SMIRs) Following PCI During January 1, 2005 – December 31, 2005: Shock or STEMI Admissions.** # of cases refers to the number of Shock or STEMI 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 6.0%.



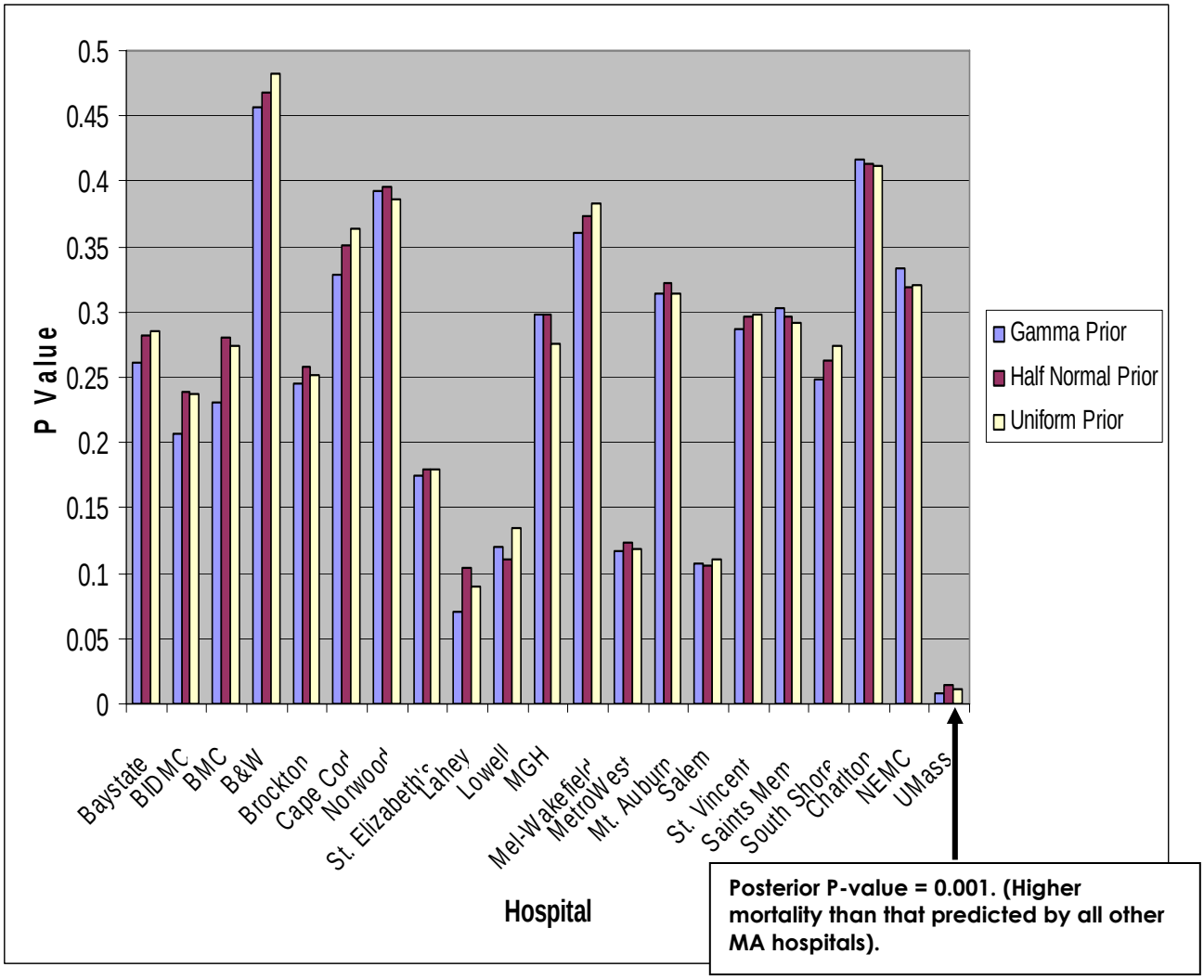

**Key**: **B&W** = Brigham & Women's Hospital; **BIDMC** = Beth Israel Deaconess Medical Center; **BMC** = Boston Medical Center; **Baystate** = Baytstate Medical Center; **Brockton** = Brockton Hospital; **Cape Cod** = Cape Cod Hospital; **Charlton** = Southcoast Hospital Group – Charlton Memorial Hospital **Lahey** = Lahey Clinic; **Lowell** = Lowell General Hospital; **MGH** = Massachusetts General Hospital ; **MWest** = MetroWest Medical Center; **Mel-Wakefield** = Melrose-Wakefield Hospital; **Mt. Auburn** = Mount Auburn Hospital; **NEMC** = Tufts New England Medical Center; **Norwood** = Caritas Norwood Hospital; **Saints** = Saints Memorial Hospital; **Salem** = North Shore Medical Center-Salem Hospital; **SoShore** = South Shore Hospital; ; **St. Elizabeth's** = Caritas Saint Elizabeth's Medical Center; **St. Vincent** = Saint Vincent Hospital at Worcester Medical Center; **UMass** = UMass Memorial Medical Center.

**Figure 6.3: Cross-Validated P-Values: No shock and No STEMI 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.




**Key**: **Baystate** = Baytstate Medical Center; **BIDMC** = Beth Israel Deaconess Medical Center; BMC = Boston Medical Center; **B&W** = Brigham & Women's Hospital; **Cape Cod** = Cape Cod Hospital; **St. Elizabeth's** = Caritas Saint Elizabeth's Medical Center; **Lahey** = Lahey Clinic; **MGH** = Massachusetts General Hospital ; **Mt. Auburn** = Mount Auburn Hospital; **Salem** = North Shore Medical Center-Salem Hospital; **St. Vincent** = Saint Vincent Hospital at Worcester Medical Center; **Charlton** = Southcoast Hospital Group – Charlton Memorial Hospital; **NEMC** = Tufts New England Medical Center; **UMass** = UMass Memorial Medical Center.

**Figure 6.4: Cross-Validated P-Values: Shock or STEMI 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.




**Key: Baystate =** Baystate Medical Center**; BIDMC =** Beth Israel Deaconess Medical Center; **BMC** = Boston Medical Center; **Brockton** = Brockton Hospital; **B&W** = Brigham & Women's Hospital; **Norwood** = Caritas Norwood Hospital; **Cape Cod** = Cape Cod Hospital**; St. Elizabeth's** = Caritas Saint Elizabeth's Medical Center; **Lahey** = Lahey Clinic; **Lowell** = Lowell General Hospital; **MGH** = Massachusetts General Hospital **; Mel-Wakefield** = Melrose-Wakefield Hospital; **MetroWest** = MetroWest Medical Center**; Mt. Auburn** = Mount Auburn Hospital; **Saints Mem**= Saints Memorial Hospital; **Salem** = North Shore Medical Center-Salem Hospital; **South Shore** = South Shore Hospital; **St. Vincent** = Saint Vincent Hospital at Worcester Medical Center; **Charlton** = Southcoast Hospital Group – Charlton Memorial Hospital; **NEMC** = Tufts New England Medical Center; **UMass** = UMass Memorial Medical Center.

# 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 (i.e., 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 the Mass-DAC Committees that have donated their time to improve the quality of cardiac care in the Commonwealth of Massachusetts.

| **Massachusetts Cardiac Care Hospital Outlier Committee.** A MA Department of Public Health Committee charged with reviewing hospital outlier findings. | |
|---|---|
| David Shahian, M.D.,<br>Chair, Center for Quality and Safety;<br>Department of Surgery<br>Massachusetts General Hospital<br>Boston, MA | Sharon-Lise Normand, Ph.D.<br>Professor of Health Care Policy (Biostatistics)<br>Department of Health Care Policy<br>Harvard Medical School<br>Boston, MA |
| Paul Dreyer, Ph.D.<br>Director, Division of Health Care Quality<br>Massachusetts Department of Public Health<br>Boston, MA | John Pastore, M.D.<br>Clinical Cardiologist<br>St. Elizabeth's Medical Center<br>Boston, MA |
| Stanley Lewis, M.D.<br>Associate Professor of Medicine<br>Harvard Medical School<br>Beth Israel Deaconess Medical Center<br>Boston, MA | David Torchiana, M.D.<br>Chairman and Chief Executive Officer<br>Massachusetts General Physicians Organization<br>Boston, MA |
| Frank Sellke, M.D.<br>Professor of Surgery<br>Harvard Medical School<br>Beth Israel Deaconess Medical Center<br>Boston, MA | Thomas Piemonte, M.D.<br>Director, Cardiac Catheterization Laboratory<br>Lahey Clinic<br>Burlington, MA |
| Gail Palmeri<br>Massachusetts Department of Public Health<br>Boston, MA | Nancy Murphy<br>Massachusetts Department of Public Health<br>Boston, MA |

**The Mass-DAC Physician Reporting Oversight Committee for PCI:** The charge of this Committee is to first review blinded summary data for all operators in MA in the review year. Such data include risk-standardized in-hospital all-cause mortality rates (SMIR), operator volume, operator complication rates, and operator infection rates. Selection of Committee members is the responsibility of the current Governor of the MA Chapter of the ACC. For operators identified as having statistically significant higher than expected mortality, unblinded case fatality reports are also reviewed. Committee members are drawn from the pool of operators who have participated in the Mass-DAC chart audit review within two years of the first meeting of the Committee in the given review year.

| | |
|---|---|
| Frederic S. Resnic, M.D. MSc<br>Director, Cardiac Catheterization Laboratory<br>Brigham and Women's Hospital<br>Boston, MA | Frederick Welt, M.D.<br>Director, Experimental Cardiovascular Interventional Lab<br>Brigham and Women's Hospital<br>Boston, MA |
| Samuel J. Shubrooks Jr., M.D.<br>Interventional Cardiologist<br>Beth Israel Deaconess Medical Center<br>Boston, MA | Kalon Ho, M.D. MSc<br>Director of Quality Assurance<br>Cardiovascular Division<br>Beth Israel Deaconess Medical Center<br>Boston, MA |
| Thomas Piemonte, M.D.<br>Director, Cardiac Catheterization Laboratory<br>Lahey Clinic<br>Burlington, MA | Sharon-Lise Normand, Ph.D.<br>Professor of Health Care Policy (Biostatistics)<br>Department of Health Care Policy<br>Harvard Medical School<br>Boston, MA |

**The 2005 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.

| | |
|---|---|
| Thomas C. Piemonte, M.D.<br>Lahey Clinic | Clifford J. Berger, M.D.<br>Boston University School of Medicine |
| Samuel J. Shubrooks Jr., M.D.<br>Beth Israel Deaconess Medical Center | Theo E. Meyer, M.D., Ph.D.<br>UMass Memorial Medical Center |
| Kurt Barringhaus, M.D.<br>UMass Memorial Medical Center | Josh Krasnow, M.D.<br>UMass Memorial Medical Center |
| Joe Garasic, M.D.<br>Massachusetts General Hospital | Tony Marks, M.D.<br>South Shore Hospital |
| Jean-Pierre Geagea, M.D.<br>Brockton Hospital | Zoran Nedeljkovic, M.D.<br>Boston Medical Center |
| Gregory Giugliano, M.D.<br>Baystate Medical Center | Fred Resnic, M.D.<br>Brigham and Women's Hospital |
| Kalon Ho, M.D.<br>Beth Israel Deaconess Medical Center | Ken Rosenfield, M.D.<br>Massachusetts General Hospital |
| Alice Jacobs, M.D.<br>Boston Medical Center | Pinak Shah, M.D.<br>Caritas St. Elizabeth's Medical Center |
| James Kirshenbaum, M.D.<br>Brigham and Women's Hospital | Bonnie Weiner, M.D.<br>Saint Vincent Hospital |
| Angela Corey<br>Data Manager<br>UMass Memorial Medical Center | Kathy Minahan, R.N.<br>Data Manager<br>Melrose-Wakefield Hospital |
| Jean Crossman, R.N.<br>Data Manager<br>South Shore Hospital | Barbara Oxley, R.N.<br>Data Manager<br>Tufts New England Medical Center |

# APPENDIX I: ACC-NCDR DATA COLLECTION TOOL - VERSION 3.04

# ACC-National Cardiovascular Data Registry® Cath Lab Module v3.04
# Data Collection Form

**A. ADMINISTRATIVE:** **Participant ID[110]:** _____ **Participant Name[120]:** _____

**Diagnostic Cath - Minimum Data set[170]:** Yes; No

**B. DEMOGRAPHICS:**

**Last Name*[230]:** _____ **First Name*[210]:** _____ **MI*[220]:** ____

**SSN*[240]:** _____ mm dd yyyy **Unique Patient ID[242]:** _____ (automatic)

**Date of Birth*[250]:** ____/____/_____ **Age[252]:** _____ (calculated)

**Gender[260]:** Male; Female **Race/Ethnicity[270]:** Caucasian; Black; Hispanic; Asian; Native American; Other

**C. ADMISSION:** mm dd yyyy

**Admission Date[310]:** ____/____/_____

**Admit Status[320]:** Outpatient Referral; ED; Transfer–Acute Care Facility; Transfer–Non-Acute Care Facility; Other

**Inpatient Status[321]:** Yes; No **Insurance Payor[330]:** Government; Commercial; HMO; Non-U.S. Insurance; None

***ADMISSION/LAB MEDICATIONS:*** (Administered on admission up to and including all cath lab visits.)

| Category | Medication Name[350] | Admin[352] Yes | No | Con | Blind | Category | Medication Name[350] | Admin[352] Yes | No | Con | Blind |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Aspirin | Aspirin | ❒ | ❒ | ❒ | ❒ | Platelet Aggreg Inhibitors | Clopidogrel (Plavix) | ❒ | ❒ | ❒ | ❒ |
| | | ❒ | ❒ | ❒ | ❒ | | Ticlopidine (Ticlid) | ❒ | ❒ | ❒ | ❒ |
| Beta Blocker | Beta Blocker | ❒ | ❒ | ❒ | ❒ | | | ❒ | ❒ | ❒ | ❒ |
| | | ❒ | ❒ | ❒ | ❒ | Renal Adj. Thrpy | Mucomyst | ❒ | ❒ | ❒ | ❒ |
| Coumadin | Coumadin | ❒ | ❒ | ❒ | ❒ | | | ❒ | ❒ | ❒ | ❒ |
| | | ❒ | ❒ | ❒ | ❒ | Statins | Statins (any) | ❒ | ❒ | ❒ | ❒ |
| Glycoprotein IIbIIIa Inhibitors | Abciximab (ReoPro) | ❒ | ❒ | ❒ | ❒ | | | ❒ | ❒ | ❒ | ❒ |
| | Eptifibatide (Integrilin) | ❒ | ❒ | ❒ | ❒ | Other Lipid Lower Med (non-statin) | Lipid Lowering (non-statin) | ❒ | ❒ | ❒ | ❒ |
| | Tirofiban (Aggrastat) | ❒ | ❒ | ❒ | ❒ | | | ❒ | ❒ | ❒ | ❒ |
| | | ❒ | ❒ | ❒ | ❒ | Thrombin Inhibitors | Argatroban (Acova) | ❒ | ❒ | ❒ | ❒ |
| Heparin Low Molecular Weight | Dalteparin (Fragmin) | ❒ | ❒ | ❒ | ❒ | | Bivalirudin (Angiomax) | ❒ | ❒ | ❒ | ❒ |
| | Enoxaparin (Lovenox) | ❒ | ❒ | ❒ | ❒ | | Lepirudin-rDNA- (Refludan) | ❒ | ❒ | ❒ | ❒ |
| | Nadroparin (Fraxiparine) | ❒ | ❒ | ❒ | ❒ | | | ❒ | ❒ | ❒ | ❒ |
| | | ❒ | ❒ | ❒ | ❒ | Thrombolytics | Thrombolytics (any) | ❒ | ❒ | ❒ | ❒ |
| Heparin Unfract. | Heparin (Unfractionated) | ❒ | ❒ | ❒ | ❒ | | | ❒ | ❒ | ❒ | ❒ |
| | | ❒ | ❒ | ❒ | ❒ | | | ❒ | ❒ | ❒ | ❒ |
| | | ❒ | ❒ | ❒ | ❒ | | | ❒ | ❒ | ❒ | ❒ |
| | | ❒ | ❒ | ❒ | ❒ | | | ❒ | ❒ | ❒ | ❒ |
| | | ❒ | ❒ | ❒ | ❒ | | | ❒ | ❒ | ❒ | ❒ |

**D. HISTORY AND RISK FACTORS:**

**Height[410]:** _____ cm **Weight[412]:** _____ kg

**Previous MI (>7 days)[420]:** Yes; No

**CHF - Previous History[424]:** Yes; No

**Previous Valve Surgery[426]:** Yes; No

**Previous Cardiac Transplant[428]:** Yes; No

**Diabetes[430]:** Yes; No

→ if Yes **Diabetes Control[432]:** None; Diet; Oral; Insulin

**Creatinine Assessed[439]:** Yes; No

→ if Yes **Last Creatinine[440]:** _____ mg/dl

**Renal Failure – Previous History[442]:** Yes; No

→ if Yes **Dialysis[444]:** Yes; No

**Cerebrovascular Disease[450]:** Yes; No

**Peripheral Vascular Disease[452]:** Yes; No

**Chronic Lung Disease[454]:** Yes; No

**Hypertension[456]:** Yes; No

**Tobacco History[460]:** Current; Former; Never

**Dyslipidemia[470]:** Yes; No

**Family History CAD-Age <55[480]:** Yes; No mm dd yyyy

**Previous PCI[490]:** Yes; No → if Yes **Date[492]:** mm ____/dd ____/yyyy _____

**Previous CABG[494]:** Yes; No → if Yes **Date[496]:** ____/____/_____

**E. CARDIAC STATUS:**

**CHF (Current Status)[500]:** Yes; No

**NYHA[510]:** I II III IV

**Cardiogenic Shock[520]:** Yes; No

**Non-Invasive Test[530]:** Yes; No

→ if Yes **Outcome[540]:** Positive; Negative; Equivocal

**Admission Sx Presentation[550]:**

No Sx/No Angina; Atypical Chest Pain;
Stable Angina; ACS:Unstable Angina;
ACS:Non-STEMI; ACS:STEMI

→ if ACS:Non-STEMI or ACS:STEMI

**Time Period Sx Onset to Admission[560]:**

>0° - <=6 hrs;
>6° - <=12°;
>12° - <=24°;
>24° - <=48°;
>48° - <=7d;
Silent MI (No Time Period)

**Legend:** (*) Indicates Non-harvested; ( ) Indicates Diagnostic Cath Minimum Data Set (MDS); (†) Indicates Optional Element

## F. CATH LAB VISIT:

**Procedure Date**[600]: mm / dd / yyyy

**Fluoro Time**[632]: _____ minutes

**Contrast Volume**[634]: _____ ml/cc

**Right Heart Cath**[610]: Yes; No

**Left Heart Cath**[612]: Yes; No

**PCI**[614]: Yes; No

***HEMODYNAMIC SUPPORT:***

**IABP**[640]: Yes; No → if Yes **IABP Placement Timing**[642]: Before Lab Visit; During Lab Visit; After Lab Visit

***LV STATUS:***

**LV Function Assessed**[650]: Yes; No → if Yes **LV Wall Motion**[652]: Normal; Abnormal

**EF Done**[654]: Yes; No → if Yes **EF**[656]: _____% →**EF Method**[658]: LV Gram; Radionucleotide; Estimate; Echo

| Coronary Anatomy: | Native Artery | | Grafts (Complete below ↓ if Previous CABG[494] = Yes) | |
|---|---|---|---|---|
| | Assessed | Percent Stenosis | Assessed | Percent Stenosis |
| Left Main | [660]: Yes; No → if Yes | [661]: % | | |
| Prox LAD | [662]: Yes; No → if Yes | [663]: % | [674]: Yes; No → if Yes | [675]: % |
| Mid/Distal LAD | [664]: Yes; No → if Yes | [665]: % | [676]: Yes; No → if Yes | [677]: % |
| Circumflex | [666]: Yes; No → if Yes | [667]: % | [678]: Yes; No → if Yes | [679]: % |
| RCA | [668]: Yes; No → if Yes | [669]: % | [680]: Yes; No → if Yes | [681]: % |
| Ramus | [670]: Yes; No → if Yes | [671]: % | [682]: Yes; No → if Yes | [683]: % |

**Percutaneous Entry Location**[695]: No Arterial Access; Femoral; Brachial; Radial; Other

***CLOSURE DEVICES:*** (List devices used)

| Closure Devices<br><br>**Note:** For each attempted closure enter following for each device used:<br>Closure Dev[697]<br>Closure Dev Succ[698] | 1. ❒ | 5. ❒ |
|---|---|---|
| | 2. ❒ | 6. ❒ |
| | 3. ❒ | 7. ❒ |
| | 4. ❒ | 8. ❒ |

## G. DIAGNOSTIC CATH PROCEDURE: (Skip this section if no diagnostic cath performed)

**Operator UPIN**[702]: _____ **Operator Name***[703]: _____

(Note: Operator Name will not be harvested. The Operator Name may be required to lookup the Operator's UPIN which will be harvested.)

**Cardiac Cath Status**[704]: Elective; Urgent; Emergency; Salvage

***INDICATIONS:***

**Valvular Heart Disease**[710]: Yes; No **Arrhythmia**[712]: Yes; No

**R/O CAD**[714]: Yes; No

→ if Yes: **Positive Stress Test**[724]: Yes; No

**Other Diagnostic Cath Indications**[726]: Yes; No

→ if Yes: **Other Cardiac Indications**[728]: None; Congenital Heart Disease; Cardiomyopathy; Heart Failure; Cardiomyopathy/Heart Failure

→ if Yes: **Other Miscellaneous Indications**[730]: None; Preop Eval for Non-Cardiac Surgery; Occupational Clear; Research Study; Syncope; Other Indication

→ if Yes: **Transplant**[732]: None; Cardiac Donor; Cardiac Recipient; Pre-op Workup for Non-Cardiac Transplant

***VALVE FINDINGS:***

**Mitral Valve Disease - Stenosis**[740]: Yes; No; Not Assessed

**Mitral Valve Disease - Insufficiency**[744]: No Insufficiency; Grade 1; Grade 2; Grade 3; Grade 4; Not Assessed

**Aortic Valve Disease - Stenosis**[746]: Yes; No; Not Assessed

**Aortic Valve Disease - Insufficiency**[750]: No Insufficiency; Grade 1; Grade 2; Grade 3; Grade 4; Not Assessed

## H. PCI PROCEDURE: (Skip this section if no PCI performed)

**Operator UPIN[802]:** _____ **Operator Name*[803]:** _____

(Note: Operator Name will not be harvested. The Operator Name may be required to lookup the Operator's UPIN which will be harvested.)

**PCI Status[804]:** Elective; Urgent; Emergency; Salvage

***INDICATIONS:***

**Lesion >=50%[810]:** No; Yes-De novo; Yes-Restenosis; Yes-De novo/Restenosis; Yes-Subacute Thrombosis

**Acute PCI[812]:** No; Yes-Primary PCI for STEMI; Yes-Rescue PCI; Yes-Facilitated PCI; Yes-Non-STEMI/Unstable Angina

→ if Yes-Primary PCI for STEMI: **Date/Time of Arrival[814]:** mm/dd/yyyy hh:mm

→ if Yes-Primary PCI for STEMI: **Reperfusion Date/Time[816]:** mm/dd/yyyy hh:mm

→ if Yes-Primary PCI for STEMI: **Transfer for Primary PCI[818]:** Yes; No

→ if Yes **Date/Time ED Presentation at Referring Facility[820]:** mm/dd/yyyy hh:mm

## I. LESIONS/DEVICES: (Skip this section if no PCI is performed)

| **Lesion Counter[900]** | | **1** | **2** | **3** |
|---|---|---|---|---|
| **Segment Number[902]** | | _____ | _____ | _____ |
| **% Pre-Stenosis[910]** | | _____% | _____% | _____% |
| **% Post-Stenosis[912]** | | _____% | _____% | _____% |
| **PreProc TIMIFlow[920]** | | No Slow Partial Complete | No Slow Partial Complete | No Slow Partial Complete |
| **PostProc TIMIFlow[922]** | | No Slow Partial Complete | No Slow Partial Complete | No Slow Partial Complete |
| **Prev Treated Lesion[930]** | | Yes No | Yes No | Yes No |
| → If Yes | select multiple | Balloon[932] DES or NonDES[934] Radiation[936] Other/Unknown[938] | Balloon[932] DES or NonDES[934] Radiation[936] Other/Unknown[938] | Balloon[932] DES or NonDES[934] Radiation[936] Other/Unknown[938] |
| | **Prev Treat Date Avail[940]** | Yes No | Yes No | Yes No |
| | → If Yes | **Date[941]:** mm/dd/yyyy | **Date[941]:** mm/dd/yyyy | **Date[941]:** mm/dd/yyyy |
| **Segment In Graft[942]** | | No Yes-Vein Yes-Artery | No Yes-Vein Yes-Artery | No Yes-Vein Yes-Artery |
| → If Yes **Loc. in Graft[944]** | | Aortic Body Distal | Aortic Body Distal | Aortic Body Distal |
| **Lesion Risk[950]** | | Non-High/Non-C High/C | Non-High/Non-C High/C | Non-High/Non-C High/C |
| **Lesion Length (mm)[952]** | | _____mm | _____mm | _____mm |
| **Bifurcation Lesion[954]** | | Yes No | Yes No | Yes No |
| **Intracoronary Devices**<br><br>**Note:** For each lesion enter either "No Device Deployed" or the following for each device used:<br>IC Device Used[962]<br>IC Device Diameter[964]<br>IC Device Length[965]<br>IC Device Barcode†[967]<br><br>check Primary Device[966] | | 1. ❒<br>2. ❒<br>3. ❒<br>4. ❒<br>5. ❒ | 1. ❒<br>2. ❒<br>3. ❒<br>4. ❒<br>5. ❒ | 1. ❒<br>2. ❒<br>3. ❒<br>4. ❒<br>5. ❒ |
| **No Reflow Phenom[970]** | | Yes No | Yes No | Yes No |
| **Dissection[972]** | | Yes No | Yes No | Yes No |
| **Acute Closure[974]** | | Yes No | Yes No | Yes No |
| → If Yes **Successful Reopening[976]** | | Yes No | Yes No | Yes No |
| **Perforation[978]** | | Yes No | Yes No | Yes No |

**Legend:** (*) Indicates Non-harvested; ( ) Indicates Diagnostic Cath Minimum Data Set (MDS); (†) Indicates Optional Element

## J. ADVERSE OUTCOMES: (Complete this section for each Lab Visit)

***GENERAL COMPLICATIONS:***

**Periprocedural MI[1000]:** Yes; No
**Cardiogenic Shock[1010]:** Yes; No
**CHF[1020]:** Yes; No
**CVA/Stroke[1030]:** Yes; No
**Tamponade[1040]:** Yes; No
**Thrombocytopenia[1050]:** Yes; No
**Contrast Reaction[1060]:** Yes; No
**Renal Failure[1070]:** Yes; No
**Emergency PCI[1080]:** Yes; No

***VASCULAR/BLEEDING COMPLICATIONS:***

**Bleeding at Percutaneous Entry Site[1085]:** Yes; No
**Retroperitoneal Bleeding[1086]:** Yes; No
**Gastrointestinal Bleeding[1087]:** Yes; No
**Genital-Urinary Bleeding[1088]:** Yes; No
**Bleeding - Other/Unknown Cause[1089]:** Yes; No
**Access Site Occlusion[1092]:** Yes; No
**Peripheral Embolization[1094]:** Yes; No
**Dissection[1096]:** Yes; No
**Pseudoaneurysm[1097]:** Yes; No
→ if Yes **Treatment[1098]:** None; Pressure; Fibrin Injection; Surgery
**AV Fistula[1099]:** Yes; No

## K. DISCHARGE: (Complete this section for each Admission/Discharge)

**CABG Status - During This Admission[1100]:** No CABG; Elective; Urgent; Emergency; Salvage; Transferred for CABG

→ if Yes **CAB Date[1102]:** mm / dd / yyyy

**CK-MB Post Proc Peak Assessed[1114]:** Yes; No → if Yes **CK-MB Peak[1115]:** _____

→ if Yes **CK-MB Pre Proc Baseline Assessed[1112]:** Yes; No → if Yes **Baseline[1113]:** _____

**Troponin Post Proc Peak Assessed[1118]:** Yes; No → if Yes **Troponin Peak[1119]:** _____

→ if Yes **Troponin Pre Proc Baseline Assessed[1116]:** Yes; No → if Yes **Baseline[1117]:** _____

**Post Proc Creatinine Level Assessed[1120]:** Yes; No → if Yes **Post Proc Creatinine[1122]:** _____ mg/dl

**Blood products transfused after lab visit[1130]:** Yes; No

**Discharge Date[1150]:** mm / dd / yyyy

**Discharge Status[1152]:** Alive; Dead

→ if Dead **Date of Death[1156]:** mm / dd / yyyy

→ if Dead **Primary Cause Death[1158]:** Cardiac; Neurologic; Renal; Vascular; Infection; Pulmonary; Valvular; Unknown; Other

→ if Dead **Death in Lab[1160]:** Yes; No

→ if Alive **Discharge Location[1154]:** Home; Extended Care/TCU; Other Hospital; Nursing Home; Other

→ if Alive **Smoking Cessation Counseling[1140]:** Yes; No (Required if Tobacco History[460] = Current)

→ if Alive **Cardiac Rehab Referral[1141]:** Yes; No

→ if Alive (complete Discharge Medications below)

***DISCHARGE MEDICATIONS:*** (Prescribed at Discharge)

| Category | Medication Name[350] | Admin[352] Yes | No | Con | Blin | Category | Medication Name[350] | Admin[352] Yes | No | Con | Blin |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Ace Inhibitor | Ace Inhibitor | ❒ | ❒ | ❒ | ❒ | Platelet Aggregation Inhibitors | Clopidogrel (Plavix) | ❒ | ❒ | ❒ | ❒ |
| | | ❒ | ❒ | ❒ | ❒ | | Ticlopidine (Ticlid) | ❒ | ❒ | ❒ | ❒ |
| Angiotensin Rcptr Blocker | Angiotensin Rcptr Blocker | ❒ | ❒ | ❒ | ❒ | | | ❒ | ❒ | ❒ | ❒ |
| | | ❒ | ❒ | ❒ | ❒ | Other Lipid Lower Med (non-statin) | Lipid Lowering (non-statin) | ❒ | ❒ | ❒ | ❒ |
| Aspirin | Aspirin | ❒ | ❒ | ❒ | ❒ | | | ❒ | ❒ | ❒ | ❒ |
| | | ❒ | ❒ | ❒ | ❒ | Statins | Statins (any) | ❒ | ❒ | ❒ | ❒ |
| Beta Blocker | Beta Blocker | ❒ | ❒ | ❒ | ❒ | | | ❒ | ❒ | ❒ | ❒ |
| | | ❒ | ❒ | ❒ | ❒ | | | ❒ | ❒ | ❒ | ❒ |
| | | ❒ | ❒ | ❒ | ❒ | | | ❒ | ❒ | ❒ | ❒ |

**Reserved 1[360]:** _____ **Reserved 2[361]:** _____ **Reserved 3[362]:** _____