PERCUTANEOUS CORONARY INTERVENTION IN THE COMMONWEALTH OF MASSACHUSETTS

Fiscal Year 2006 Report

October 1, 2005 – September 30, 2006

Mass-DAC

Department of Health Care Policy

Harvard Medical School

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MASSACHUSETTS PERCUTANEOUS CORONARY INTERVENTION HOSPITALS

October 1, 2005 – September 30, 2006

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

MASSACHUSETTS PRIMARY PERCUTANEOUS CORONARY INTERVENTION PILOT HOSPITALS: OCTOBER 1, 2005—SEPTEMBER 30, 2006

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

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1 – A MESSAGE FROM THE DIRECTOR OF THE MASSACHUSETTS BUREAU OF HEALTH CARE SAFETY AND QUALITY

This is the fourth in a series of reports summarizing the quality of care provided by the 21 state licensed cardiac programs in the Commonwealth. The report – funded by the Division of Health Care Quality in the Massachusetts Department of Public Health -- is meant to provide residents with information about the relative performance of cardiac programs as an aid to elective decision making, and health care providers in the Commonwealth with information for quality improvement. Persons experiencing chest pain or other emergency conditions should call '911' immediately.

This report contains analysis of data on 15,571 hospital admissions in which at least one percutaneous coronary intervention (PCI) was performed during the period October 1, 2005 through September 30, 2006. Earlier reports used data for PCI admissions performed on a calendar year basis. Starting with the release of this report, the analysis will reflect coronary interventions performed on a fiscal year basis. The shift in period of admissions used for analysis permits the earlier release of information to the public.

Two additional points deserve mention. First, during this reporting period, a randomized trial comparing effectiveness and safety of "elective" angioplasty between community hospitals without cardiac surgery and hospitals with cardiac surgery was on-going. The MASS COMM trial includes patients with ischemic heart disease treated by elective PCI. Data for subjects participating in the MASS COMM trial were used to calculate mortality estimates in this report. To preserve the integrity of the trial, however, no mortality rates for MASS COMM participants treated electively at the community hospitals are published in this document.

Because MASS COMM trial participants treated electively at tertiary hospitals cannot be differentiated from non-MASS COMM participants treated electively at tertiary hospitals, all data from tertiary hospitals are reported. A Data Safety Monitoring Board closely monitors the progress of the Mass COMM trial.

Second, the fiscal year 2006 reporting period represents the first period in which additional data were collected to identify subjects with a very high risk of death who may not have been adequately identified using clinical elements collected in earlier reports. This report makes use of the new information.

The data collection, verification, audit, and analytical procedures implemented in this report constitute the most comprehensive, reliable, and rigorous used in the U.S. This is due in no small part to the dedicated work of the hospital data managers and cardiac interventionalists, many of whom volunteered their efforts to participate in many late night meetings at Harvard Medical School. I would also like to thank staff from the Board of Registration in Medicine and the Massachusetts Chapter of the American College of Cardiology for their ongoing support, and of course, all the staff at Mass-DAC for their hard work and dedication.

Paul Dreyer, Ph.D., Director
Bureau of Health Care Safety and Quality
Massachusetts Department of Public Health

2 - KEY FINDINGS

UPADTES:

Jan 24, 2011 Table 8.1, corrected FY 2006 Number of Admissions value from 12291 to 12921.

- Between October 1, 2005 and September 30, 2006, there were **15,721** hospital admissions in which at least one Percutaneous Coronary Intervention (PCI) was performed in Massachusetts hospitals.

- **17.8 %** (2,800) 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 between October 1, 2005 and September 30, 2006, **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 (**69.6%**), white (**88.5%**), and over 60 years of age (**63.8%**).

- Of the 15,721 PCI admissions, **241** patients died during the same hospitalization in which the PCI was performed.

    - 82 mortalities **(0.63%)** occurred in 12,921 patients not arriving in shock and not having an ST-elevated myocardial infarction within 24 hours of admission;
    - 159 mortalities **(5.68%)** occurred in the "shock or STEMI" (2800) population.

- After adjusting for patient risk, the odds of in-hospital mortality in a hospital one standard deviation above the state average was **twice** (odds of 2.14) that of a hospital one standard deviation below the state average, for patients having no STEMI and no shock. The odds was similar for patients having shock or STEMI; the odds of in-hospital mortality in a hospital one standard deviation above the state average was twice (odds of **1.92**) that of a hospital one standard deviation below the state average.

- There was no evidence of any hospital outlier for patients not arriving in shock or without a STEMI. South Shore hospital was identified as having lower than predicted mortality for patients arriving in shock or with a STEMI.

3 - INTRODUCTION

3.1 - What is in this Report?

This is the fourth report (available at http://massdac.org/reports/pci.html) describing 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. For this report, all procedures performed between October 1, 2005 and September 30, 2006 (fiscal year 2006) were included in the analysis. 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 fiscal year 2006, there were fourteen PCI programs in Massachusetts, each with back-up cardiac surgery programs and seven **Primary PCI Pilot programs**.

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.

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 October 1, 2005 and September 30, 2006. 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

[3] The definition of STEMI or SHOCK prior to 2005 was: STEMI within 24 hours of admission, OR cardiac shock at the time of the first PCI procedure. In 2005, because of a definition 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 on admission or any time prior to PCI the procedure.

the first PCI and no cardiogenic shock prior to the PCI (referred to as the "**no shock and no STEMI"** Cohort).

During this reporting period a randomized trial comparing the effectiveness and safety of "elective" angioplasty between Pilot programs and non-Pilot programs was on-going. The MASS COMM trial includes patients with ischemic heart disease treated by elective PCI. Data for subjects participating in the MASS COMM trial were **used** to calculate mortality estimates in this report. To preserve the integrity of the trial, however, no mortality rates for MASS COMM participants treated electively at the Pilot Programs are published in this document. This document therefore reports on mortality for 14 non-Pilot programs for the "no shock and no STEMI" patients. Because MASS COMM trial participants treated electively at non-pilot hospitals cannot be differentiated from non-MASS COMM participants treated electively at non-Pilot hospitals, all data from the non-Pilot hospitals are reported. In-hospital mortality is therefore reported for the 21 hospitals that treated "shock or STEMI" patients.

3.2 - 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 a buildup of scar tissue which can occur in a small percentage of patients after the intervention.

3.3 - 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 October 1, 2005 and September 30, 2006, there were 15,721 admissions in which at least one PCI was performed: 12,921 "no shock and NSTEMI" patients and 2,800 "shock or STEMI" patients (**Table 3.1**). Not surprisingly, the in-hospital mortality rate for "shock or STEMI" cases is 9 times that for "no shock and NSTEMI" cases (5.68% versus 0.63%).

Mass-DAC analyzed the first PCI for patients who received more than one PCI during their admission. Ninety seven percent of patients received only one PCI during their hospital admission.

Table 3.1: Descriptive Summaries of Adult PCI Admissions in Massachusetts Hospitals, October 1, 2005 – September 20, 2006. 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	7479	57.88	2735	97.68
Number of PCIs Per Admission				
1 PCI	12485	96.63	2622	93.64
≥ 2 PCIs	436	3.37	178	6.36
More than 70% stenosis in Left Anterior Descending Artery	7829	60.59	1614	57.64
At least One Stent	11999	92.86	2591	92.54
Drug Eluting if Stented	10875	90.06	2190	84.52
Total Length of Stay, days	Mean = 3.77 Median = 2		Mean = 6.17 Median = 4	
Post-Procedure Length of Stay, days	Mean = 3.00 Median = 2		Mean = 5.96 Median = 4	
Unadjusted Outcomes				
Any Vascular Complication	86	0.67	25	0.89
CABG During Admission				
Elective Status CABG	23	0.18	6	0.21
Urgent Status CABG	48	0.37	41	1.46
Emergent CABG	18	0.14	25	0.89
Salvage status CABG	1	0.01	2	0.07
Transferred for CABG	13	0.10	15	0.54
In-Hospital Death	82	0.63	159	5.68
TOTAL NO. OF ADMISSIONS	**12921**		**2800**	

3.4 - 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. Many more patients now have the option for a less invasive, successful treatment of their coronary artery disease.

3.5 - 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.

4 - SUMMARY OF DATA COLLECTION & VERIFICATION PROCEDURES

4.1 - 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.

4.2 - Massachusetts PCI Hospitals

Twenty-one hospitals had Cardiac Catheterization Labs that performed PCIs between October 1, 2005 and September 30, 2006, seven of which are Primary Pilot programs. All non-government hospitals that performed PCIs were required to submit clinical data to Mass-DAC.

4.3 - 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 fiscal year 2006 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 2006 is October 1, 2005 – September 30, 2006

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 October 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.

4.4 - Mass-DAC Data Collection Procedures

The majority of Massachusetts hospitals used clinical staff, such as physicians, fellows, and nurses to collect information. Data were 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 4.1**). This process involved submitting protected data during specific harvest periods. Hospitals submitted data electronically in a secure repository on a secure Mass-DAC website. Harvests were scheduled quarterly for the collection of 3 months of data. Hospitals were permitted to submit corrected data as often as desired during the 3 months following a harvest, and could sign-off on its accuracy and completeness at any time during that period. However, all data were required to be complete by April 1, 2007 after which no changes were accepted without written permission from Mass-DAC.

Table 4.1: PCI Data Harvest Schedule for PCIs Performed Between October 1, 2005 and September 30, 2006.	
Month of Data Harvest	**Corresponding Dates of PCI**
March 1 , 2006	October 1, 2005 – December 31, 2005
June 1, 2006	January 1, 2006 – March 30, 2006
September 1, 2006	April 1, 2006 – June 30, 2006
December 1, 2006	July 1, 2006 – September 30, 2006
April 1, 2007	Final Fiscal Year 2006 Data Closeout

4.5 - 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 257 data submissions to Mass-DAC for fiscal year 2006 data with a mean of 3.1 submissions per hospital and a range of 1 to 9. A total of 252 quality reports were returned to the hospitals with a mean of 3.0 per hospital and a range of 1 to 9 reports. Five hospital submissions did not generate a quality report because they were incomplete and the data was resubmitted.

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 six patients reported by the hospitals as in-hospital survivors who were reported in the vital statistics as having died on the day of discharge. One patient

was determined to have been an in-hospital mortality, and the status was changed in the dataset. There were 3 in-hospital deaths reported by the hospitals with dates of death that differed with the Vital Statistics data. The vital statistics date of death was confirmed and the dates changed in the database.

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. A sample of the fiscal year 2006 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, (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 fiscal year 2006 PCI data was 973.

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. Twenty-three volunteers (19 physicians and 4 data managers) representing fourteen of the twenty-one MA PCI programs comprised the Mass-DAC PCI Adjudication Committee (Section 9). 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 were 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 data set.

The coding was changed for only the variables for which there was a census[5] for the audit; 99 records coded yes for shock were changed to no shock; 25 records coded for salvage were changed to emergent status; 1 record coded for elective status was changed to urgent status; 6 records coded for elective status were changed to emergent

[5] All occurrences of the value of the variable were reviewed rather than a sample of occurrences.

status, 70 records coded for emergent status were changed to urgent status and 3 emergent status records were changed to elective status.

Compassionate Use: This reporting period represents the first period in which additional data were collected to identify patients with a very high risk of death who may not have been adequately identified using clinical elements collected in the NCDR instrument. For example, a patient undergoing active cardiopulmonary resuscitation at initiation of the PCI, and a cardiopulmonary bypass or a percutaneous ventricular assist device prior to the time the guide wire was used to cross the lesion would characterize a patient at substantially elevated mortality risk. Several MA interventionalists discussed and then operationalized a variable, denoted "compassionate use", in order to identify such patients. Every patient classified as compassionate use (105 in total) were reviewed by the Adjudication Committee to determine if the cases meet the criteria established by Mass-DAC for compassionate use. Fifty-two out of 105 cases were determined to meet the criteria.

5 - RISK ADJUSTMENT

5.1 - Who Receives PCI in Massachusetts?

Table 5.1 provides demographic summaries of the 12921 "no shock and no STEMI" admissions and 2,800 "shock or STEMI" admissions. The majority of "no shock and no STEMI" admissions are male (69.2%), white (88.8%), and less than one-third (33.3%) are less than 60 years of age at the time of their PCI. Patients residing out of state comprised 7.46% of the "no shock and no STEMI" admissions (data not shown).

The majority of "shock or STEMI" admissions are male (71.4%) and white (86.8%). Just less than one-half (49.4%) of the "shock or STEMI" admissions were less than 60 years old at the time of their PCI. Finally, seven percent of the "shock or STEMI" admissions were patients residing out of state (data not shown).

Table 5.1: Age-Sex-Race Distribution for Adult PCI Admissions in Massachusetts Hospitals During October 1, 2005 – September 30, 2006: Stratified by Risk Cohort. Entries represent numbers of admissions.

12,921 No shock and No STEMI PCI ADMISSIONS

Age Group	Females					Males				
	White	African American	Hispanic	Other††	Total	White	African American	Hispanic	Other	Total
≤49	234	22	26	21	303	916	31	57	93	1097
50-59	527	29	28	38	622	2012	51	54	163	2280
60-69	825	39	24	76	964	2276	49	62	166	2553
70-79	1139	27	34	74	1274	1939	20	28	103	2090
≥80	757	9	8	43	817	854	7	5	55	921
Total	3482	126	120	252	**3980**	7997	158	206	580	**8941**

2,800 STEMI or Shock PCI Admissions

Age Group	Females					Males				
	White	African American	Hispanic	Other††	Total	White	African American	Hispanic	Other††	Total
≤49	98	2	5	8	113	394	15	27	47	483
50-59	101	4	7	13	125	566	16	37	44	663
60-69	152	4	4	15	175	364	9	12	31	417
70-79	199	6	3	8	216	248	5	8	20	281
≥80	163	4	1	4	172	143	2	2	8	155
Total	713	20	20	48	**801**	1716	47	86	50	**1999**

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

5.2 - 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.

5.3 - 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 <u>may 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. 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.

6 - 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.

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." Intuitively, this strategy provides a quantitative measure of how **likely** the hospital's outcome is compared to the rest of the state.

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 the hospital is designated as outlying. It is important to note that the classification in this report is relative to all hospitals in Massachusetts performing PCI.

6.1 - 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 fiscal year 2006. 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 7.1 (for "no shock or NSTEMI" admissions) and in Table 7.2 (for "shock or STEMI" admissions). The term β describes the association of each risk factor and the log-odds of in-hospital mortality. Large values of β indicate patients with the particular risk factor are at higher risk of dying compared to patients without the risk factor.
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 "smoothed" 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. This mortality rate is termed "smoothed" as it weights the observed mortality rate by the amount of information available at the hospital relative to the amount of information available between-hospitals. Because the model assumes that the

probability of dying is greater than 0, then the smoothed 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:

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

   The SMIR is interpreted as the projected mortality rate at the hospital today if hospital quality remained the same as in fiscal year 2006.
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, μ and τ^2 represent the overall mean risk-adjusted log-odds of mortality and between-hospital variation, respectively. If there are no mortality 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 logistic model was estimated using WinBUGS software.[5] 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.

6.2 - Cross-Validated P-Values

Because data from all hospitals are used to estimate the expected number of deaths in any hospital, there is a risk that outlying hospitals may influence the estimates of μ and τ^2. One method to identify hospitals as outlying is through "cross-validation". This process involves systematically dropping each hospital from the data set and re-estimating the risk-adjusted model. Using the new model, the predicted number of deaths at the dropped hospital is calculated. This predicted number may be interpreted

[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.

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 ≤ 0.01) indicate that the dropped hospital is outlying. When the p-value is small and the actual number of deaths is larger than that predicted by the remaining hospitals, the dropped hospital is classified as **having higher than predicted mortality**; when the p-value is small and the actual number of deaths is smaller than predicted by its peers, then the hospital is classified as having **lower than predicted mortality**. Mass-DAC eliminated each PCI hospital from the dataset, re-estimated the regression parameters, predicted mortality at the eliminated hospital, and calculated a p-value corresponding to the comparison of the observed mortality and the predicted mortality. The eliminated hospital was replaced into the dataset, and Mass-DAC eliminated another hospital from the dataset, repeating the entire process.

6.3 - 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 divided by 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. Because the parameter τ represents the standard deviation of the hospital –specific risk-adjusted log-odds of mortality, we changed our assumptions regarding the likely values of the standard deviation. For example, a value of $\tau = 0.75$ implies that between-hospital mortality log-odds could range anywhere from 1 to 15. We thus first assumed that the between-hospital *standard deviation* arose from a uniform distribution over the range 0 to 1.5. This translates to assuming that small values in between-hospital heterogeneity are just as likely as large

values. We also assumed the between-hospital *standard deviation* arose from a half normal distribution with mean 0 and variance 0.26. The half normal distribution has its mode at 0 (permitting no differences in between-hospital log-odds of mortality) and its median at 0.39 (permitting the range in hospital log-odds of mortality of about 5).

7 - HOSPITAL QUALITY FOLLOWING PCI: FISCAL YEAR 2006

Of the 15,721 PCI admissions in Massachusetts, 241 patients died during the same admission as the PCI. **Table 7.1** 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 the 12,921 "no shock and no STEMI" cases following a PCI. For example, 33.5% 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. Patients with renal failure prior to a PCI are more than four times more likely to die within the PCI hospital admission than patients without renal failure. Of the 12,921 patients, only four were confirmed to fall into the compassionate use category. Because of such a small number of patients having this characteristic, the regression coefficient relating compassionate use and in-hospital mortality could not be reliably estimated. For this reason, compassionate use variable was excluded as a predictor in the model for the analysis of the no shock and no STEMI cohort.

A non-hierarchical logistic regression model indicated area under the ROC curve of 0.86. The Hosmer-Lemeshow Goodness-of-Fit test did not indicate a lack of fit ($\chi 2$ (8 dof) = 5.51, p = 0.70). Model discrimination ranged from 0.1% (1 death in 1300 admissions) in the lowest risk decile to 3.9% (49 deaths in 1265 admissions) in the highest risk decile.

Figure 7.1 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 providing no evidence of a statistical outlier.

Table 7.2 lists information similar to Table 7.1 but for the 2800 "shock or STEMI" cases. In this cohort, 1.7% of the patients (48 patients) were adjudicated to belong to the compassionate use group with corresponding mortality of 68.8%; patients falling into this

category had almost twenty-five times the odds of dying compared to those not belonging to the category. 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 ($\chi 2$ (5 dof) = 4.90, p = 0.43). Model discrimination ranged form 0% (0 deaths in 76 admissions) in the lowest risk group to 37.1% (99 deaths in 267 admissions) in the highest risk group. **Figure 7.2** 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 5.68% for "shock or STEMI" cases. All 95% intervals cover the state unadjusted in-hospital mortality rate.

Figure 7.3 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. All p-values are larger than 0.01 again indicating no statistical outlier. **Figure 7.4** presents similar values for the "shock or STEMI" cohort. South Shore Hospital has a predictive p-value of .0098 with its observed mortality less than that predicted by its peers.

In summary, based on in-hospital mortality data, no evidence of a hospital outlier for no shock and no STEMI patients was found. However, South Shore Hospital was determined to have lower than predicted in-hospital mortality for patients having shock or STEMI who underwent a PCI.

Table 7.1: Adjusted Odds Ratios of In-Hospital Mortality Following PCI in Adults: No shock or No STEMI Cases, October 1, 2005 –September 30, 2006. Based on **12921** PCI admissions with 82 deaths (0.64%).

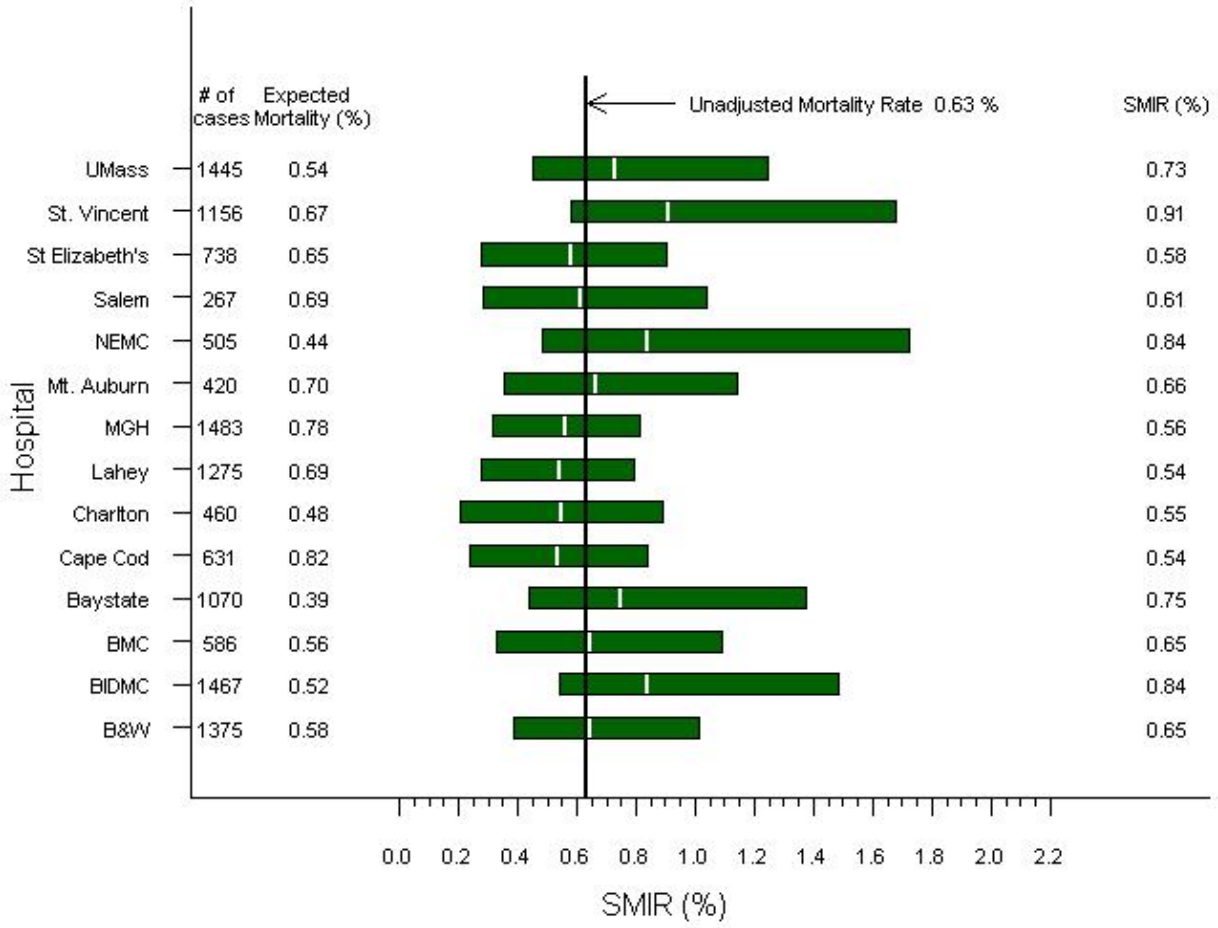
Risk Factor	Prevalence (%)	Adjusted Odds Ratio	95% Interval for Adjusted Odds Ratio
Mean Age (years over 65)	0.34	1.08	(1.05, 1.10)
Renal Failure	5.60	4.26	(2.41, 6.91)
Diabetes	33.48	1.29	(0.79, 1.98)
Chronic Lung Disease	14.26	1.03	(0.53, 1.74)
Ejection Fraction < 30%	3.19	3.20	(1.55, 5.69)
PCI Status (Ref=Elective)			
Urgent	56.69	8.61	(3.17, 21.43)
Emergent or Salvage	3.24	72.29	(23.86, 188.6)
Left Main Disease	7.64	1.28	(0.65, 2.21)
LAD > 70% Stenosis	60.59	1.52	(0.87, 2.54)
Between-Hospital Parameters			
Between-Hospital Average logit, μ		-8.14	(-9.20, -7.13)
Average Between-Hospital Variance in logits, τ^2		0.145	(0.00144, 0.6477)

Table 7.2: Adjusted Odds Ratios of In-Hospital Mortality Following PCI in Adults: Shock or STEMI Cases, October 1, 2005 – September 30, 2006. Based on 2800 PCI admissions with 159 deaths (5.68%).

Risk Factor	Prevalence (%)	Adjusted Odds Ratio	95% Interval for Adjusted Odds Ratio
Age (Ref = < 60 years)			
60-69 yrs	21.14	2.37	(1.21, 4.30)
70-79 yrs	17.75	3.34	(1.73, 6.06)
≥ 80 yrs	11.68	9.51	(5.12, 16.75)
Renal Failure	3.93	2.61	(1.36, 4.43)
Ejection Fraction < 30%	5.18	1.77	(0.87, 3.08)
PCI Status (Ref =Urgent or Elective[6])			
Emergent or Salvage	93.25	1.35	(0.57, 3.03)
Pre-Procedure Cardiogenic Shock	8.00	8.65	(5.42, 13.20)
Left Main Disease	5.18	2.01	(1.08, 3.38)
Compassionate Use	1.71	23.03	(9.26, 49.89)
Between-Hospital Parameters			
Between-Hospital Average logit, μ		-4.82	(-5.93, -3.95)
Average Between-Hospital Variance in logits, τ^2		0.106	(0.00155, 0.433)

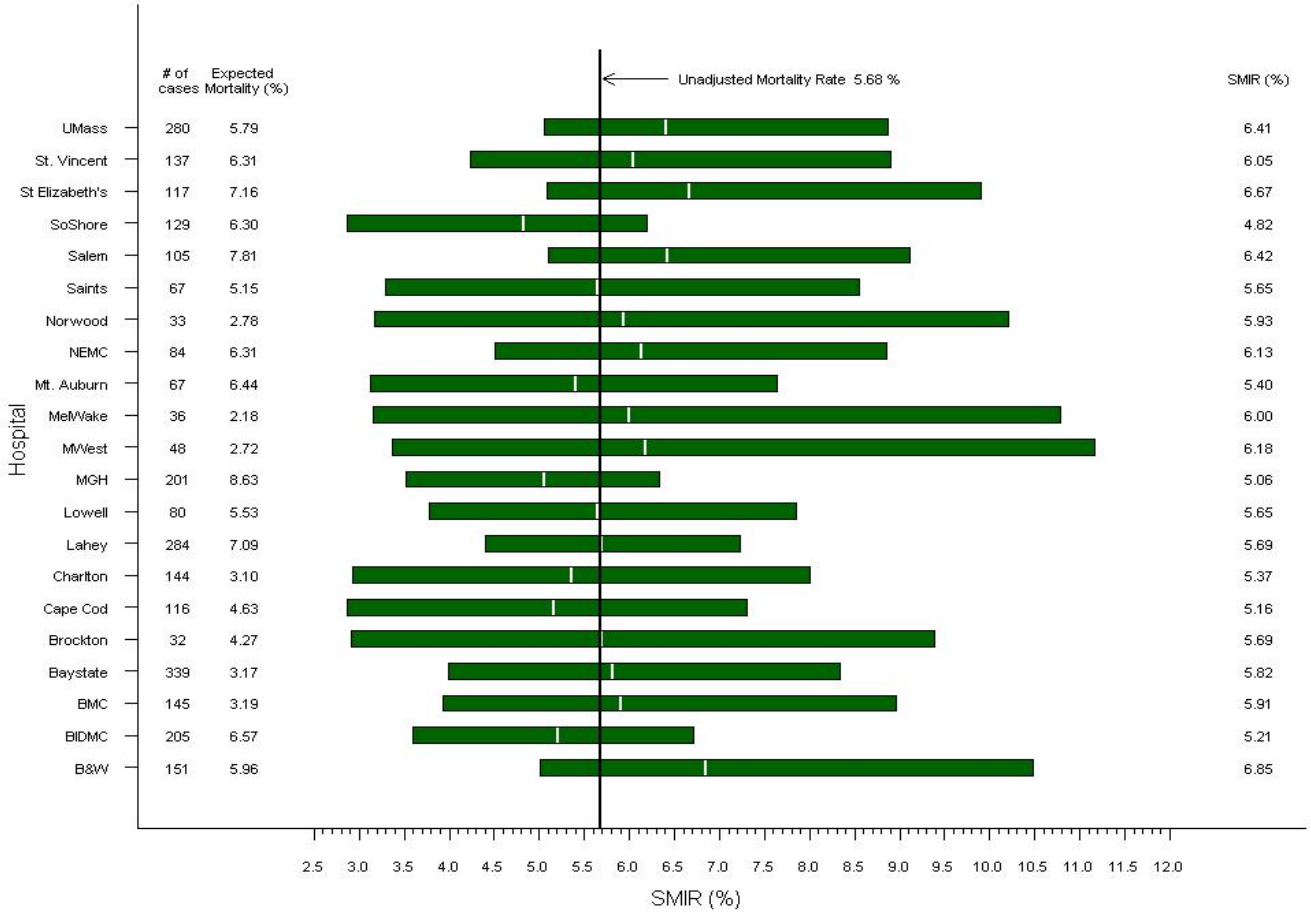
[6] Mass-DAC queried hospitals about the seven patients who had either "shock or STEMI" yet were coded as elective cases; the hospitals indicated that these cases should remain as elective.

Figure 7.1: Ninety-Five Percent Posterior Intervals for Standardized Mortality Incidence Rates (SMIRs) Following PCI During October 1, 2005 – September 30, 2006: 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 **0.63**%.



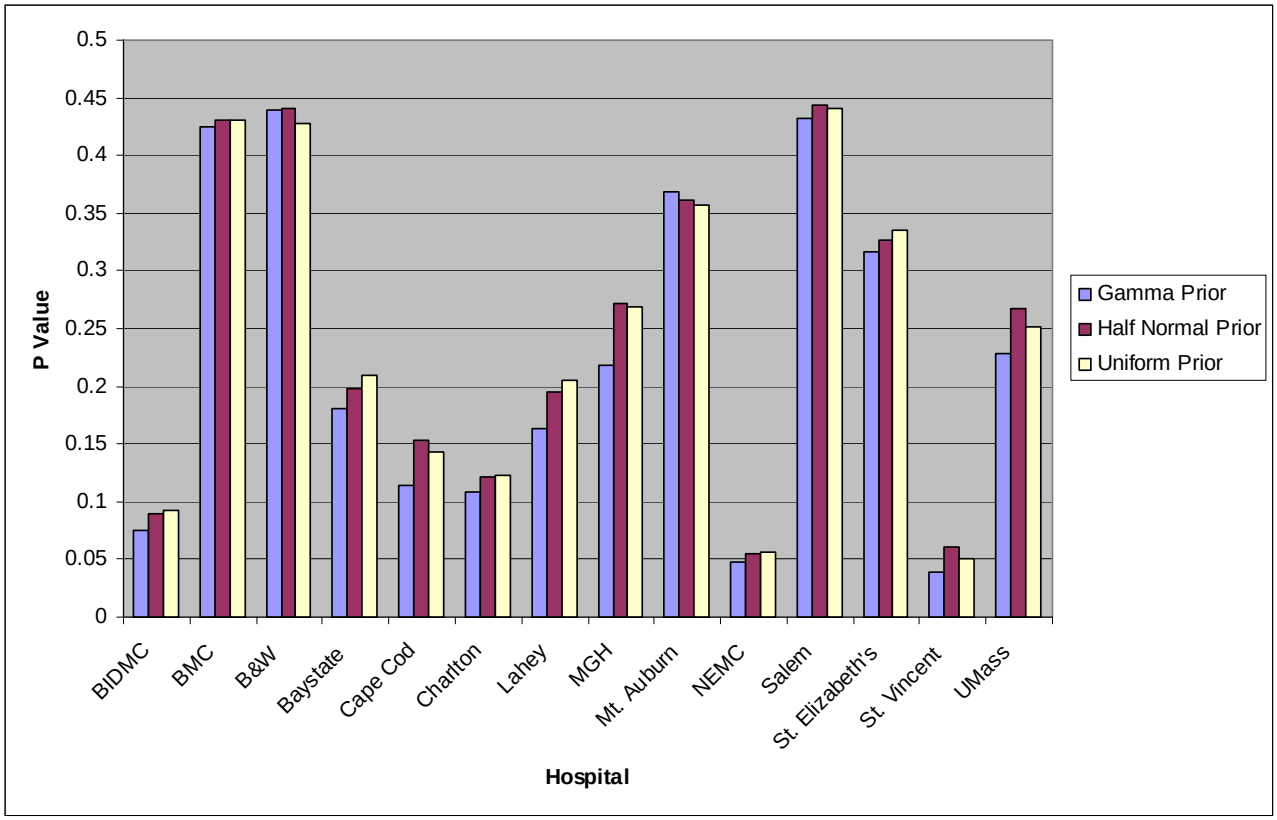
Key: **B&W** = Brigham & Women's Hospital; **BIDMC** = Beth Israel Deaconess Medical Center; **BMC** = Boston Medical Center; **Baystate** = Baytstate Medical Center; **Cape Cod** = Cape Cod Hospital; **Charlton** = Southcoast Hospital Group – Charlton Memorial Hospital; **Lahey** = Lahey Clinic; **MGH** = 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 7.2: Ninety-Five Percent Probability Intervals for Standardized Mortality Incidence Rates (SMIRs) Following PCI During October 1, 2005 – September 30, 2006: 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 5.68%.



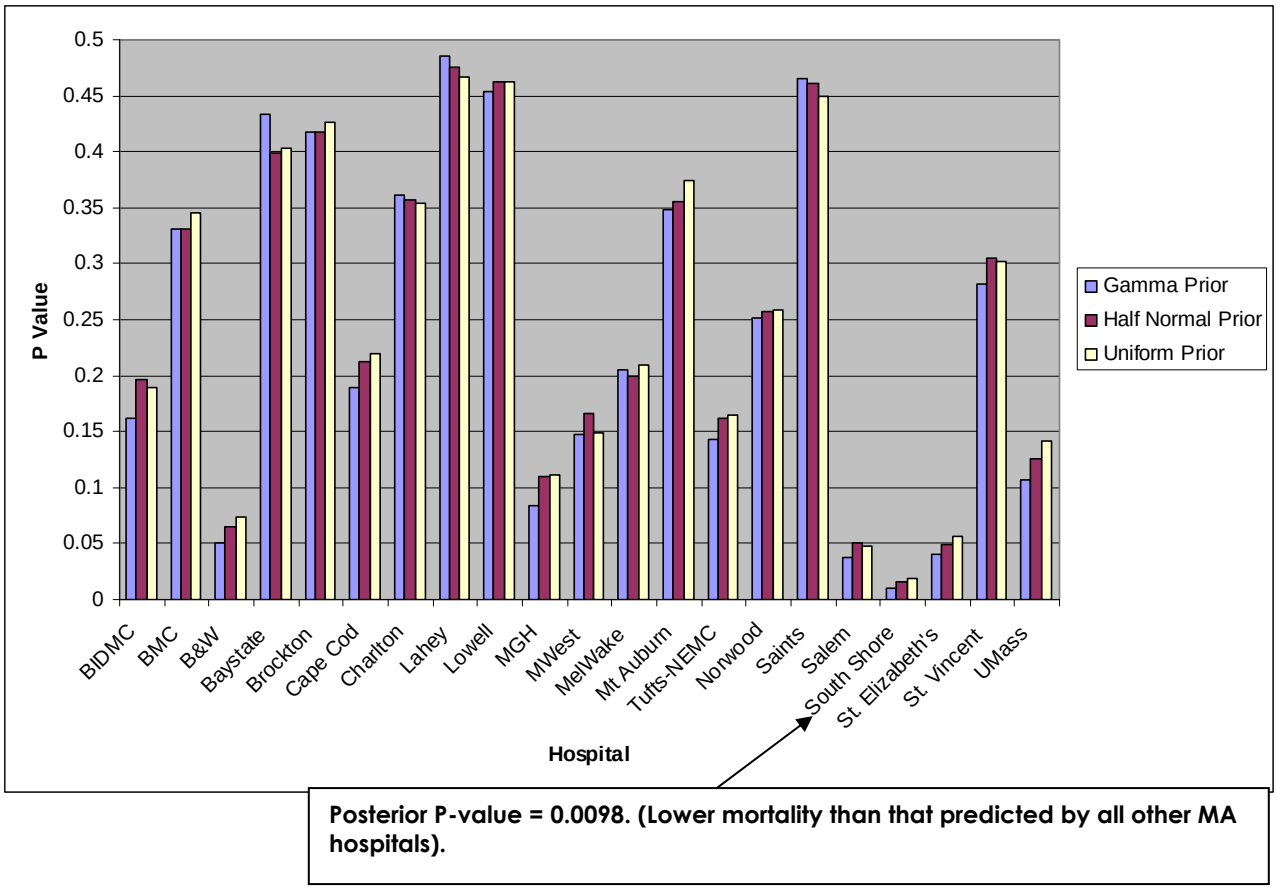
Key: **B&W** = Brigham & Women's Hospital; **BIDMC** = Beth Israel Deaconess Medical Center; **BMC** = Boston Medical Center; **Baystate** = Baytstate Medical Center; **Brockton** = Brockton Hospital; **Cape Cod** = Cape Cod Hospital; **Charlton** = Southcoast Hospital Group – Charlton Memorial Hospital **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 7.3: 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 7.4: 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.

8- TRENDS IN MORTALITY FOLLOWING PCI

Table 8.1: SUMMARY OF PCI ADMISSIONS AND IN-HOUSE CRUDE MORTALITY RATES CY 2003 – FY 2006				
No Shock and No STEMI Admissions				
Year of PCI	**CY2003***	**CY2004**	**CY2005**	**FY2006**
Number of Hospitals	14	14	14	14
Number of Admissions	10689	14504	13387	12921
In-Hospital Crude Mortality, %	0.76	0.68	0.64	0.64
Shock or STEMI Admissions				
Number of Hospitals	18	21	21	21
Number of Admissions	1968	2606	2752	2800
In-Hospital Crude Mortality, %	6.86	5.76	6.00	5.60
*Represents 9 months of admissions.				

Note: The definition of STEMI or SHOCK prior to 2005 was: STEMI within 24 hours of admission, OR cardiac shock at the time of 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 on admission or any time prior to PCI the procedure.

9 - 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.

Cardiogenic Shock: (ACC-NCDR variable definition) Indicates if the patient is in a clinical state of hypoperfusion on admission, according to either of the following criteria:
1. Systolic BP < 80 and/or Cardiac Index < 1.8 despite maximal treatment;
2. IV inotropes and/or IABP necessary to maintain Systolic BP > 80 and/or CI > 1.8.

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

Chronic Lung Disease: (ACC-NCDR variable definition) Indicate if the patient has a documented history of chronic lung disease (i.e. chronic obstructive pulmonary disease, asthma, bronchitis), or has been or is currently treated with pharmocologic therapy.

Compassionate Use: Patients who present for a PCI with a very high expected risk of death and meet the Mass-DAC Compassionate Use Criteria. Most of these patients would be felt to be suboptimal candidates for PCI, but PCI may represent the only option for improvement of cardiac status despite the high anticipated risks. See Appendix II for Compassionate Use Criteria.

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 systematically eliminating a set of observations from the dataset, estimating a model or computing a statistics using the remaining data, predicting the outcome for the eliminated observations, and then comparing the observed outcomes with the predicted outcomes for the eliminated set of observations.

Diabetes: (ACC-NCDR variable definition) A history of diabetes, regardless of duration of disease, or need for antidiabetic agents. This includes diagnosis on admission or pre-procedure. It does not include gestational diabetes.

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.

Ejection Fraction: (ACC-NCDR variable Definition) The percentage of the blood emptied from the ventricle at the end of the contraction. Use the most recent determination during or prior to intervention. Enter a percentage in the range of 01 - 99.

LAD greater than 70% Stenosis: (ACC-NCDR variable definition) The percent of most severe stenosis assessed, in the Proximal Left Anterior Descending coronary artery and or the Mid/Distal Left Anterior Descending coronary artery. This does not include collateral circulation. If no stenosis, then the percent is 0. Stenosis represents the percentage

diameter reduction, from 0 to 100, associated with the identified vessel systems. Percent stenosis at its maximal point is estimated to be the amount of reduction in the diameter of the "normal" reference vessel proximal to the lesion. In instances where multiple lesions are present, enter the single highest percentage stenosis noted. The LM, LAD, RCA/PDA, CIRC and Ramus are the systems of interest and should include major branch vessels of > 2.0 mm in diameter.

Left Main Disease: (ACC-NCDR variable definition) the percent of most severe stenosis assessed, for the Left Main coronary artery. This does not include collaterals. If no stenosis then the percent is 0. Stenosis represents the percentage diameter reduction, from 0 to 100, associated with the identified vessel systems. Percent stenosis at its maximal point is estimated to be the amount of reduction in the diameter of the "normal" reference vessel proximal to the lesion. In instances where multiple lesions are present, enter the single highest percentage stenosis noted. The LM, LAD, RCA/PDA, CIRC and Ramus are the systems of interest and should include major branch vessels of > 2.0 mm in diameter.

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.

PCI Status: (ACC-NCDR variable definition)

Elective: The patient's cardiac function has been stable in the days or weeks prior to the procedure. The procedure could be deferred without increased risk of compromised cardiac outcome.

Urgent: ALL of the following conditions are met: a. Not elective status. b. Not emergency status. c. Procedure required during same hospitalization in order to minimize chance of further clinical deterioration. d. Worsening, sudden chest pain, CHF, acute myocardial infarction (AMI), anatomy, IABP, unstable angina (USA) with intravenous (IV) nitroglycerin (TNG) or rest angina (but stabilized patient) may be included.

Emergency: The patient's clinical status includes any of the following: a. Ischemic dysfunction (any of the following): (1) Ongoing ischemia including rest angina despite maximal medical therapy (medical and/or IABP)); (2) Acute Evolving

Myocardial Infarction within 24 hours before Cardiac Cath Lab Procedure; or (3) pulmonary edema requiring intubation. b. Mechanical dysfunction (either of the following): (1) shock with circulatory support; or (2) shock without circulatory support.

Emergent Salvage: The patient is undergoing CPR en route to the Cardiac Cath Lab or prior to procedure.

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.

Renal Failure: (ACC-NCDR Variable Definition) Indicates if patient has a documented history of renal (kidney) failure or indicates if the patient has a history of a creatinine > 2.0 mg/dl. Note: Renal transplant patients are considered to have renal failure if their creatinine level has exceeded 2.0mg/dl since the transplant.

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 smoothed 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.

10 - 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., Chair, Center for Quality and Safety; Department of Surgery Massachusetts General Hospital Boston, MA	Sharon-Lise Normand, Ph.D. Professor of Health Care Policy (Biostatistics) Department of Health Care Policy Harvard Medical School Boston, MA
Paul Dreyer, Ph.D. Director, Division of Health Care Quality Massachusetts Department of Public Health Boston, MA	John Pastore, M.D. Clinical Cardiologist St. Elizabeth's Medical Center Boston, MA
Stanley Lewis, M.D. Associate Professor of Medicine Harvard Medical School Beth Israel Deaconess Medical Center Boston, MA	David Torchiana, M.D. Chairman and Chief Executive Officer Massachusetts General Physicians Organization Boston, MA
Frank Sellke, M.D. Professor of Surgery Harvard Medical School Beth Israel Deaconess Medical Center Boston, MA	Thomas Piemonte, M.D. Director, Cardiac Catheterization Laboratory Lahey Clinic Burlington, MA
Gail Palmeri Massachusetts Department of Public Health Boston, MA	Nancy Murphy Massachusetts Department of Public Health 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 Director, Cardiac Catheterization Laboratory Brigham and Women's Hospital Boston, MA	Frederick Welt, M.D. Director, Experimental Cardiovascular Interventional Lab Brigham and Women's Hospital Boston, MA
Samuel J. Shubrooks Jr., M.D. Interventional Cardiologist Beth Israel Deaconess Medical Center Boston, MA	Kalon Ho, M.D. MSc Director of Quality Assurance Cardiovascular Division Beth Israel Deaconess Medical Center Boston, MA
Thomas Piemonte, M.D. Director, Cardiac Catheterization Laboratory Lahey Clinic Burlington, MA	Sharon-Lise Normand, Ph.D. Professor of Health Care Policy (Biostatistics) Department of Health Care Policy Harvard Medical School 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. Lahey Clinic	Clifford J. Berger, M.D. Boston University School of Medicine
Samuel J. Shubrooks Jr., M.D. Beth Israel Deaconess Medical Center	Theo E. Meyer, M.D., Ph.D. UMass Memorial Medical Center
Kurt Barringhaus, M.D. UMass Memorial Medical Center	Josh Krasnow, M.D. UMass Memorial Medical Center
Joe Garasic, M.D. Massachusetts General Hospital	Tony Marks, M.D. South Shore Hospital
Jean-Pierre Geagea, M.D. Brockton Hospital	Zoran Nedeljkovic, M.D. Boston Medical Center
Gregory Giugliano, M.D. Baystate Medical Center	Fred Resnic, M.D. Brigham and Women's Hospital
Kalon Ho, M.D. Beth Israel Deaconess Medical Center	Ken Rosenfield, M.D. Massachusetts General Hospital
Alice Jacobs, M.D. Boston Medical Center	Pinak Shah, M.D. Caritas St. Elizabeth's Medical Center
James Kirshenbaum, M.D. Brigham and Women's Hospital	Bonnie Weiner, M.D. Saint Vincent Hospital
Angela Corey Data Manager UMass Memorial Medical Center	Kathy Minahan, R.N. Data Manager Melrose-Wakefield Hospital
Jean Crossman, R.N. Data Manager South Shore Hospital	Barbara Oxley, R.N. Data Manager 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]: _____ **Unique Patient ID**[242]: _____ (automatic)

Date of Birth*[250]: mm / dd / yyyy **Age**[252]: _____ (calculated)

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

C. ADMISSION:

Admission Date[310]: mm / dd / yyyy

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
Aspirin	Aspirin	❒	❒	❒	❒
		❒	❒	❒	❒
Beta Blocker	Beta Blocker	❒	❒	❒	❒
		❒	❒	❒	❒
Coumadin	Coumadin	❒	❒	❒	❒
		❒	❒	❒	❒
Glycoprotein IIbIIIa Inhibitors	Abciximab (ReoPro)	❒	❒	❒	❒
	Eptifibatide (Integrilin)	❒	❒	❒	❒
	Tirofiban (Aggrastat)	❒	❒	❒	❒
		❒	❒	❒	❒
Heparin Low Molecular Weight	Dalteparin (Fragmin)	❒	❒	❒	❒
	Enoxaparin (Lovenox)	❒	❒	❒	❒
	Nadroparin (Fraxiparine)	❒	❒	❒	❒
		❒	❒	❒	❒
Heparin Unfract.	Heparin (Unfractionated)	❒	❒	❒	❒
		❒	❒	❒	❒
		❒	❒	❒	❒
		❒	❒	❒	❒
		❒	❒	❒	❒
		❒	❒	❒	❒

Category	Medication Name[350]	Admin[352] Yes	No	Con	Blind
Platelet Aggreg Inhibitors	Clopidogrel (Plavix)	❒	❒	❒	❒
	Ticlopidine (Ticlid)	❒	❒	❒	❒
		❒	❒	❒	❒
Renal Adj. Thrpy	Mucomyst	❒	❒	❒	❒
		❒	❒	❒	❒
Statins	Statins (any)	❒	❒	❒	❒
		❒	❒	❒	❒
Thrombin Inhibitors	Argatroban (Acova)	❒	❒	❒	❒
	Bivalirudin (Angiomax)	❒	❒	❒	❒
	Lepirudin-rDNA- (Refludan)	❒	❒	❒	❒
		❒	❒	❒	❒
Thrombolytics	Thrombolytics (any)	❒	❒	❒	❒
		❒	❒	❒	❒
		❒	❒	❒	❒
		❒	❒	❒	❒
		❒	❒	❒	❒
		❒	❒	❒	❒

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

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

Previous CABG[494]: Yes; No → if Yes **Date**[496]: mm / dd / yyyy

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 **Note:** For each attempted closure enter following for each device used: Closure Dev[697] 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]
→ If Yes	**Prev Treat Date Avail[940]**	Yes No	Yes No	Yes No
→ If Yes	→ 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 **Note:** For each lesion enter either "No Device Deployed" or the following for each device used: IC Device Used[962] IC Device Diameter[964] IC Device Length[965] IC Device Barcode†[967] check Primary Device[966]		1. ❒ 2. ❒ 3. ❒ 4. ❒ 5. ❒	1. ❒ 2. ❒ 3. ❒ 4. ❒ 5. ❒	1. ❒ 2. ❒ 3. ❒ 4. ❒ 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	❒	❒	❒	❒			❒	❒	❒	❒
		❒	❒	❒	❒	Statins	Statins (any)	❒	❒	❒	❒
Aspirin	Aspirin	❒	❒	❒	❒			❒	❒	❒	❒
		❒	❒	❒	❒			❒	❒	❒	❒
Beta Blocker	Beta Blocker	❒	❒	❒	❒			❒	❒	❒	❒
		❒	❒	❒	❒			❒	❒	❒	❒
		❒	❒	❒	❒			❒	❒	❒	❒

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

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

APPENDIX II: COMPASSIONATE USE CRITERIA

Mass-DAC Risk Factors for Identifying Compassionate Use PCI

Criteria	Definition	Additional Information
Use of CPB or PVAD	The medical record must indicate the use of PVAD or CPB support prior to the start of the PCI (i.e. prior to the time that the guide wire was used to cross the lesion.	The medical record must justify the need for CPB or PVAD support prior to the PCI. Justifications can include but are not limited to extremely high risk anatomy, patient not a candidate for CABG with severely depressed resting LV function, or lack of response to conventional therapy to hemodynamic support. Utilizing CPB /PVAD to rescue a diagnostic case complication would not be a criteria for compassionate use.
CPR ongoing	The patient presents with CPR in progress at start of PCI. The medical record must indicate that spontaneous circulation was not restored prior to the start of the PCI, therefore requiring CPR. The patient must be coded as salvage status.	The medical record must reflect that the patient was receiving active CPR at the start of the procedure. This group excludes patients successfully resuscitated in the field without the need for ongoing CPR. Utilizing CPR to rescue a diagnostic case complication would not be a criteria for compassionate use.
Coma on presentation	The patient presents to the ER or the lab with a Glasgow Coma Score of <7 and is coded as emergent status. The medical record must indicate that the coma was diagnosed prior to the start of the procedure and the components of the score must be documented.	There must be clear documentation that the patient was in a coma which was not medication induced. The following should be clearly documented and without contradiction: • The amount of time that the patient was down • The components of the Glasgow Coma Score (i.e. E+V+M = Total) • Neurological status • Unresponsiveness • Log of what medications were given prior to the PCI Documentation should be part of the legal medical record and in ongoing notes. If the arrest is in the ER, the treatment/intubation, etc must be part of the ER protocol. If the coma happens during the diagnostic procedure, it is not a compassionate use case. A PCI done to rescue a complication of a diagnostic cath would not meet criteria for a compassionate use PCI.