Adult Percutaneous Coronary Intervention in the Commonwealth of Massachusetts

Fiscal Year 2008 Report
October 1, 2007 through September 30, 2008

Hospital Risk-Standardized In-Hospital Mortality Rates

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Boston Medical Center
1 Boston Medical Center Place
Boston, MA 02118

Brigham and Women's Hospital
75 Francis Street
Boston, MA 02115

Cape Cod Hospital
27 Park Street
Hyannis, MA 02601

Caritas St. Elizabeth's Medical Center
736 Cambridge Street
Boston, MA 02135

Lahey Clinic
41 Mall Road
Burlington, MA 01805

Massachusetts General Hospital
55 Fruit Street
Boston, MA 02114

Mount Auburn Hospital
330 Mount Auburn Street
Cambridge, MA 02138

North Shore Medical Center
Salem Hospital
81 Highland Avenue
Salem, MA 01970

Southcoast Hospital Group
Charlton Memorial Hospital
363 Highland Avenue
Fall River, MA 02720

Saint Vincent Hospital at
Worcester Medical Center
123 Summer Street
Worcester, MA 01608

Tufts Medical Center
800 Washington Street
Boston, MA 02111

UMass Memorial Medical Center
55 Lake Avenue North
Worcester, MA 01655

Massachusetts Percutaneous Coronary Intervention Pilot Hospitals

Brockton Hospital
680 Centre Street
Brockton, MA 02302

Caritas Good Samaritan Medical Center
235 Pearl Street
Brockton, MA 02301

Caritas Holy Family Hospital
70 East Street
Methuen, MA 01844

Caritas Norwood Hospital
800 Washington Street
Norwood, MA 02062

Lawrence General Hospital
1 General Street
Lawrence, MA 01842

Lowell General Hospital
295 Varnum Avenue
Lowell, MA 01854

Melrose -Wakefield Hospital
585 Lebanon Street
Melrose, MA 02176

MetroWest Medical Center
115 Lincoln Street
Framingham, MA 01702

Saints Medical Center
1 Hospital Drive
Lowell, MA 01852

South Shore Hospital
55 Fogg Road at Route 18
South Weymouth, MA 02190

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1 A Message from the Director of the Massachusetts Bureau of Health Care Safety and Quality

This is the sixth in a series of reports summarizing the quality of care provided by the 24 state licensed cardiac programs in the Commonwealth. The report – contracted 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 13,842 hospital admissions in which at least one percutaneous coronary intervention (PCI) was performed during the period October 1, 2007 through September 30, 2008.

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 in progress. 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 2008 reporting period represents the third period in which additional data were collected to identify subjects with a very high risk of death. Procedures that fit the specific criteria are identified as Compassionate Use procedures (see Appendix B for the Compassionate Use criteria). This report makes use of that 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 of the staff at the Massachusetts Data Analysis Center (Mass-DAC) for their hard work and dedication.

Alice Bonner, PhD, RN
Director
Bureau of Health Care Safety and Quality
Massachusetts Department of Public Health

2 Key Hospital Findings

2.1 Updates

- **January 24, 2011:** Table 8.1, corrected FY 2006 Number of Admissions value from 12,291 to 12,921.
- **February 6, 2012:** Table 7.2, corrected the description of the between hospital parameters to indicate logits used.

2.2 Hospital Findings

- In the period October 1, 2007 through September 30, 2008 (Fiscal Year 2008), there were 13,842 hospital admissions in Massachusetts in which at least one Percutaneous Coronary Intervention (PCI) was performed.
- 19.7% (2,721) 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-four hospitals performed at least one PCI in the period October 1, 2007 through September 30, 2008; ten participated in the Massachusetts Primary PCI Pilot Program. Primary PCI Pilot programs are approved for *shock or STEMI admissions* only.
- Of the 13,842 PCI admissions, 200 (1.44%) patients died during the same hospitalization in which the PCI was performed: 70 mortalities (0.63%) occurred in 11,121 patients *not arriving in shock and not having a STEMI*; 130 mortalities (4.78%) occurred in 2,721 patients *arriving in shock or with a STEMI*.

- After adjusting for patient risk for those having *no shock and no STEMI*, the risk of in-hospital mortality in a hospital one standard deviation above the MA average was 1.6 times (relative risk of 1.60) that of a hospital one standard deviation below the MA average.

- The odds of in-hospital mortality in a hospital one standard deviation above the MA average was almost twice (odds of 1.69) that of a hospital one standard deviation below the MA average for patients with *shock or STEMI*.

- **There were no hospital outliers in FY 2008 for either the *shock or STEMI cohort* or the *no shock and no STEMI cohort*.**

3 Introduction

3.1 What is in this Report?

This is the sixth report (available at http://massdac.org/reports/pci.html) describing methods and results for estimating hospital-specific in-hospital risk-standardized mortality rates following PCI in Massachusetts. Information pertains to patients who were 18 years of age or older at the time of their PCI. Interventions performed in federal hospitals (e.g., VA Boston Healthcare System–Jamaica Plain Campus) are not included in this report. For this report, all procedures performed in the period October 1, 2007 through September 30, 2008 (Fiscal Year 2008) are 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 Massachusetts Department of Public Health. In Fiscal Year 2008, there were 14 PCI programs in Massachusetts, each with back-up cardiac surgery programs, and ten 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. Caritas Holy Family Hospital and Lawrence General Hospital were given approval to start a primary PCI program and joined the primary PCI pilot program in July of 2008. This document reports hospital-specific standardized mortality incidence rates following PCI for the 24 PCI hospitals in Massachusetts that performed at least one PCI in the period October 1, 2007 through September 30, 2008. Because of the elevated risks associated with heart attack patients, results for two separate cohorts of patients are presented.

3.1.1 Shock or STEMI Cohort

We define shock or STEMI as 'STEMI within 24 hours of admission OR at the time of the first PCI procedure OR cardiogenic shock on admission or any time prior to the PCI procedure.' This definition took effect in 2005. Prior to 2005, the definition of shock or STEMI was 'STEMI within 24 hours of admission OR cardiogenic shock at the time of the first PCI procedure'.

3.1.2 No Shock and No STEMI Cohort

This cohort includes admissions for 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.

3.1.3 Mass COMM Trial Participants

During Fiscal Year 2008, the randomized trial called Mass COMM was ongoing. Mass COMM's goal is to compare the effectiveness and safety of 'elective' angioplasty in pilot programs versus non-pilot programs. The 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 programs for the *no shock and no STEMI* admissions. Because Mass COMM trial participants treated electively at non-pilot hospitals cannot be differentiated from non-Mass COMM participants treated electively at hospitals with backup surgery, all data from these hospitals are reported. Therefore, in-hospital mortality is reported for all 24 hospitals that treated *shock or STEMI* admissions.

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. PCIs are performed in the Catheterization Lab, thus unblocking a patient's coronary artery without having to undergo surgery. Most PCIs 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 patients who were 18 years of age or older at the time of undergoing a PCI at non-federal hospitals in Massachusetts. In the period October 1, 2007 through September 30, 2008, there were 13,842 admissions in which at least one PCI was performed: 11,121 *no shock and no STEMI* admissions and 2,721 *shock or STEMI* admissions (Table 3.1). As expected, the in-hospital mortality rate for *shock or STEMI* admissions is almost eight times that for *no shock and no STEMI* admissions (4.78% versus 0.63%).

Mass-DAC analyzed the first PCI for patients who received more than one PCI during their admission: 96.5% of the no shock and no STEMI patients and 94.5% of the shock or STEMI patients received only one PCI during a hospital admission.

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. Many patients now have the option of undergoing 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, including the Massachusetts Cardiac Care Hospital Outlier Committee, The PCI

Physician Reporting Oversight Committee and the Data Adjudication Committee. In addition, both the national American College of Cardiology (ACC) and the Massachusetts ACC serve as resources.

Table 3.1: *Descriptive Summaries of First PCI of Admission for Adults in Massachusetts Hospitals: Oct 1, 2007–Sep 30, 2008.*

Risk Cohort	No Shock and No STEMI [a]		Shock or STEMI [b]	
Characteristic	**Number**	**Percent**	**Number**	**Percent**
Admitted via Emergency Department or Transfer	6,656	59.85	2,672	98.20
Number of PCIs per Admission				
One PCI	10,729	96.48	2,570	94.45
Two or More PCIs	392	3.52	151	5.55
>70% Stenosis in Left Anterior Descending Artery (LAD)	6,579	59.16	1,567	57.59
At Least One Stent	10,293	92.55	2,444	89.82
Drug-Eluting if Stented	6,638	64.49	662	27.09
Total Length of Stay (Days)	Mean = 3.71 Median = 3		Mean = 6.05 Median = 4	
Post-Procedure Length of Stay (Days)	Mean = 2.95 Median = 2		Mean = 5.83 Median = 4	
Unadjusted Outcomes				
Any Vascular Complication	64	0.58	20	0.74
Status of CABG During PCI Admission				
Elective	11	0.10	6	0.22
Urgent	51	0.46	62	2.28
Emergency	19	0.17	16	0.59
Emergent Salvage	1	0.01	0	0.00
Transferred to Another Hospital	4	0.04	14	0.51
In-Hospital Death	70	0.63	130	4.78
Total Number of Admissions	11,121		2,721	

[a] Patients arriving with no STEMI within 24 hours and no cardiogenic shock on admission or prior to the procedure.

[b] Patients having STEMI within 24 hours of hospital arrival or at time of first PCI, or cardiogenic shock on admission or prior to the procedure.

4 Summary of Data Collection and Verification Procedures

4.1 Definition of Patient Outcome

Mortality, regardless of cause, measured from the 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-four hospitals had Cardiac Catheterization Labs that performed PCIs in the period October 1, 2007 through September 30, 2008, ten of which are primary pilot programs. All non-federal 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) data collection tool; hospital administrative discharge data; and vital statistics information provided by the Massachusetts Department of Public Health.

4.3.1 Mass-DAC PCI Data

Patient-specific risk factor and outcome data were collected by hospital personnel using the ACC-NCDR data collection tool. Data for Fiscal Year 2008 were collected using the ACC-NCDR Version 3.04 data collection tool containing 137 variables.

4.3.2 Massachusetts Inpatient Acute Hospital Case Mix and Charge Database

Hospital discharge data for Fiscal Years 2003 through 2008, (October 1, 2002 through September 30, 2008) were obtained from the Massachusetts Division of Health Care Finance and Policy. Data elements included hospital identifier, sex, race, age, patient zip code, ICD-9 codes, discharge status, dates of admission and discharge, date of surgery, and patient medical record number. Social Security numbers were removed from this database.

4.3.3 Massachusetts Mortality Index Database

Death date information obtained from the Massachusetts Registry of Vital Records and Statistics with Massachusetts death certificates was available for all deaths occurring in Massachusetts between April 1, 2003 and October 30, 2008. While the primary source for in-hospital mortality rates was the hospital-reported information, the mortality index database was employed as a verification procedure. Using a confidential and secure transmission procedure, Mass-DAC submitted to the Registry the following: patient names, dates of birth, and Social Security numbers for all Mass-DAC patients, regardless of hospital-reported survival status. Registry personnel subsequently linked the data submitted by Mass-DAC to the Registry mortality index database using these variables and supplied Mass-DAC with the date of death for all applicable patients. Based on the information merged with the Mass-DAC data and confirmation from the hospital, the in-hospital mortality status was changed from alive to dead for one record.

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) the clinical staff entered data into the ACC-NCDR vendor software database, 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 by 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 website. Harvests were scheduled quarterly for the collection of three months of data. Hospitals were permitted to submit corrected data as often as desired during the three months following a harvest, and they 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, 2009, after which no changes were accepted without written permission from Mass-DAC.

Table 4.1: *PCI Data Harvest Schedule for Procedures Performed: Oct 1, 2007–Sep 30, 2008*

Harvest Month	Corresponding Dates of PCI
March 2008	October 1, 2007 through December 31, 2007
June 2008	January 1, 2008 through March 31, 2008
September 2008	April 1, 2008 through June 30, 2008
December 2008	July 1, 2008 through September 30, 2008
April 1, 2009	Final close out date for Fiscal Year 2008 data

4.5 Cleaning and Validation Procedures

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

4.5.1 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 30 days to correct the data deficiencies identified by Mass-DAC following receipt of each quality report. There were a total of 225 data submissions to Mass-DAC for Fiscal Year 2008 data with a range of 1 to 8 per hospital, and a mean of 2.5 submissions per hospital.

4.5.2 Massachusetts 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 ten patients reported by the hospitals as in-hospital survivors who were reported in the Vital Statistics as having died on the day of discharge. All patients' death locations were confirmed, and one patient, whose death occurred in-hospital but had been miscoded, was changed to a hospital mortality. There were four 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.

4.5.3 Meetings and Communication

Mass-DAC communicated regularly via email 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 clarifications were discussed at data manager meetings. Volunteers who attended the audit meetings also shared variable definition information with their colleagues.

4.5.4 Audit Data

A sample of the Fiscal Year 2008 PCI data was audited. Records requested from the hospitals included those for:

1. All patients who died in the hospital during the PCI admission;
2. All patients who were coded as having cardiogenic shock or emergent salvage status;
3. All elective cases in the shock or STEMI cohort; and
4. All emergency cases in the no shock and no STEMI cohort.

In total, **902** data records were reviewed.

Documentation requested from the hospitals included admission, history and discharge summaries, catheterization lab records, and any other documentation that could support the coding. In addition, for all mortalities, Mass-DAC obtained videographic information of the procedure. Institutions were required to provide this documentation to Mass-DAC. Mass-DAC requested that every PCI hospital in Massachusetts provide a physician volunteer to help in the audit process. Twenty-four volunteers (21 physicians and three data managers) representing 11 of the 24 PCI programs comprised the Mass-DAC PCI Adjudication Committee. All reviewers were approved by the Institutional 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 appeals. 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 only for the variables for which there was a 'census ' for the audit.

Changes were made to 27% of shock admissions, 16% of No Shock and No STEMI admissions coded as emergency status, and 55% of admissions coded as emergent salvage status (Table 4.2).

Table 4.2: *Summary of Adjudication*

Risk Factor	Total Reviewed	Final Adjudicated Status	Number
Shock	278	Shock (no change)	204
		No Shock	74
Elective Status for Shock or STEMI	7	Elective(no change)	4
		Urgent	0
		Emergency	3
		Emergent Salvage	0
Emergency Status for No Shock and No STEMI	509	Elective	1
		Urgent	78
		Emergency (no change)	430
		Emergent Salvage	0
Emergent Salvage Status	33	Elective	0
		Urgent	0
		Emergency	18
		Emergent Salvage (no change)	15

4.5.5 Compassionate Use

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 ACC-NCDR data collection tool. A committee of Massachusetts interventionalists developed criteria that described

patients at substantially elevated mortality risk. The criteria included active cardiopulmonary resuscitation at initiation of the PCI, extreme anatomic risk, or coma prior to medication administration, any of which places a patient at an elevated mortality risk. Every record coded as compassionate use (98 in total) was reviewed by the Adjudication Committee to determine if it met the criteria established by Mass-DAC.

Fifty-nine out of 98 cases were determined to have met the criteria, while 39 cases were denied compassionate use status after review. Each year, the committee reviews and further defines the compassionate use criteria to ensure that the variable is capturing the correct elevated risk factors for mortality.

5 Risk Adjustment

5.1 Who Receives PCI in Massachusetts?

Table 5.1 provides age, sex, and race summaries of the 11,121 *no shock and no STEMI* admissions and 2,721 *shock or STEMI* admissions. The majority of *no shock and no STEMI* admissions are associated with patients who are male (70.1%) or white (90.2%), and approximately one-third (33.6%) are less than 60 years of age at the time of their PCI. Patients residing out of state comprised 6.8% of the *no shock and no STEMI* admissions (data not shown).

The majority of patients with *shock or STEMI* admissions are male (70.8%) and white (87.1%). Just less than one-half (46.9%) of the *shock or STEMI* admissions were less than 60 years old at the time of their PCI. Finally, 6.0% of the *shock or STEMI* admissions were performed on patients residing out of state (data not shown).

Table 5.1: *Demographic distribution for all PCI admissions ($N = 13,842$) in MA hospitals: Oct 1, 2007–Sep 30, 2008*

	Male					Female					Total
Age Group	White	African Amer.	Hispanic	Other	Race Total	White	African Amer.	Hispanic	Other	Race Total	
No Shock and No STEMI PCI Admissions N=11,121											
≤49	812	46	24	83	965	210	19	9	19	257	1,222
50–59	1,771	62	47	115	1,995	454	26	14	27	521	2,516
60–69	2,139	61	40	119	2,359	719	37	34	55	845	3,204
70–79	1,529	18	20	67	1,634	927	18	17	37	999	2,633
≥80	805	10	6	22	843	670	10	7	16	703	1,546
Total	7,056	197	137	406	7,796	2,980	110	81	154	3,325	11,121
Shock or STEMI PCI Admissions N=2,721											
≤49	360	16	15	39	430	83	3	5	5	96	526
50–59	525	20	14	40	599	121	8	6	16	151	750
60–69	417	12	12	34	475	148	10	7	10	175	650
70–79	265	6	4	21	296	164	9	3	12	188	484
≥80	118	1	2	6	127	169	3	2	10	184	311
Total	1,685	55	47	140	1,927	685	33	23	53	794	2,721

5.2 Risk Adjustment for Assessing Hospital Mortality

Specific **risk** factors are known to contribute to heart disease. These risk factors include high cholesterol, smoking, high blood pressure, family history of heart disease, diabetes, age, sex, and general health status prior to a PCI. 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. Mass-DAC uses several risk factors in the statistical model.

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 risk-adjusted to account for differences in patient health prior to a PCI. However, the numbers reported compare each hospital's outcome to what would be expected to happen given the types of patients undergoing PCIs in that hospital's PCI program. The information presented in this report is not designed to provide comparisons between pairs of hospitals. Such comparisons would only be valid to the extent that the pairs of hospitals treated patients with very similar health status prior to 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 exactly the same risk factors prior to a PCI but who are treated in different PCI hospitals would differ. The statistical model used to calculate mortality rates in this report – a hierarchical logistic or Poisson 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 by including a hospital-specific random effect. If no key risk factor that varies by hospital 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 a difference in quality.

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% posterior interval estimate for each hospital's risk-standardized mortality rate. If the posterior interval estimate excludes the MA 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 it is *unlikely* that the actual number of mortalities observed at a hospital and the number of mortalities predicted for the hospital using the combined experience of all other MA hospitals 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 its peers.

If the 95% interval estimate for a particular hospital excludes the Massachusetts unadjusted in-hospital mortality rate or if the probability that the observed mortality is the same as that 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. For example, a Massachusetts hospital identified as having higher (or lower) than expected mortality based on our analysis may not be classified as having higher (or lower) than expected mortality compared to hospitals outside of Massachusetts.

6.1 Standardized Mortality Incidence Rates (SMIR)

Mass-DAC calculated a standardized mortality incidence rate (SMIR) and a corresponding 95% **posterior** interval for each hospital. The SMIR is interpreted as the projected mortality rate at the hospital today if hospital quality remained the same as in Fiscal Year 2008. 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 MA rate, then the hospital mortality is not different than expected. If the interval excludes the MA unadjusted rate, then the hospital is an outlier. In this case, if the upper limit of the interval is lower than the unadjusted MA 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 MA 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 for *shock or STEMI admissions*. 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 let n_i equal the total number of PCI admissions at the hospital. The model estimated had the general form:

$$\text{Log-odds}[Probability(Y_{ij} = 1)] = \beta_{0i} + \beta(\text{Risk Factors})_{ij} \quad (1)$$

$$\text{where} \quad \beta_{0i} \sim \text{Normal}(\mu, \tau^2) \quad (2)$$

Because the risk of death is low (less than 1%) for patients not arriving in shock and not arriving with a STEMI, a hierarchical Poisson model was estimated. Thus, rather than modeling the Log-Odds(Probability(Y_{ij} = 1)), we model the log(Probability(Y_{ij} = 1)). The parameters, μ and τ^2 represent the overall mean risk-adjusted log-odds (or log) of mortality and between-hospital variation, respectively. If there are no mortality differences based on in-hospital mortality across the K PCI hospitals, then

$$\beta_{0,1} = \beta_{0,2} = \cdots = \beta_{0,K} = \beta_0 \quad \text{and this happens if and only if} \quad \tau^2 = 0 \tag{3}$$

The hierarchical regression models were estimated using WinBUGS software. The prior distributions assumed for β, μ, and τ^2 were, respectively: independent normal distributions with mean 0 and variance 1,000 for the components of β; μ from a normal distribution with mean 0 and variance 1,000; and τ^{-2} from a gamma distribution with shape and inverse scale 0.001. We vary these parameters as part of a sensitivity analysis. The hierarchical logistic regression models were estimated using the WinBUGS software. A burn-in of 5,000 draws was used and conclusions were based on an additional 5000 draws. Convergence of the model was assessed using the Gelman-Rubin statistic via three parallel chains.

2. The risk factors are those listed in Table 7.1 (for *no shock and no STEMI* admissions) and in Table 7.2 (for *shock or STEMI* admissions). The term β describes the association between each risk factor and the log-odds (or log) 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, π_i, is:

$$\pi_i = \frac{\sum_{j=1}^{n_i} \text{logit}^{-1}[\mu + \beta(\text{Risk Factors})_{ij}]}{n_i} \text{ for logistic outcomes and} \tag{4}$$

$$\pi_i = \frac{\sum_{j=1}^{n_i} \exp[\mu + \beta(\text{Risk Factors})_{ij}]}{n_i} \text{ for Poisson outcomes.} \tag{5}$$

This is the mortality rate expected using the mortality intensity for the entire state, β, and the case mix reported at the hospital, $(\text{Risk Factors})_{ij}$. Thus it represents the severity of cases at the institution.

4. The *observed* mortality rate at hospital i, p_i, is:

$$p_i = \frac{\sum_{j=1}^{n_i} \text{logit}^{-1}[\beta_{0i} + \beta(\text{Risk Factors})_{ij}]}{n_i} \text{ for logistic outcomes and} \quad (6)$$

$$p_i = \frac{\sum_{j=1}^{n_i} \exp[\beta_{0i} + \beta(\text{Risk Factors})_{ij}]}{n_i} \text{ for Poisson outcomes.} \quad (7)$$

This is interpreted as the mortality rate at the i^{th} hospital adjusted for case mix. This mortality rate is not the actual observed number of deaths but rather a *smoothed* estimate that 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:

$$\bar{Y} = 100 \times \frac{\sum_{ij} Y_{ij}}{\sum_i n_i} \quad (8)$$

6. The standardized mortality incidence rate (SMIR) at institution i is:

$$\text{SMIR}_i = \bar{Y} \times \frac{p_i}{\pi_i} \quad (9)$$

The SMIR is interpreted as the projected mortality rate at the hospital today if hospital quality remained the same as in Fiscal Year 2008.

7. Ninety-five percent posterior intervals were calculated for each PCI hospital's SMIR.

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 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 posterior '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 posterior 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 all other MA 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 data set, 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 in the data set, and Mass-DAC eliminated another hospital from the data set, 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 parameter τ represents the standard deviation of the hospital-specific risk-adjusted log-odds of mortality and the parameter τ^2 represents between-hospital variance. The main analyses assumed the precision, defined as $\frac{1}{\tau^2}$, arose from a gamma distribution. Because the prior distribution for the variance component can influence the results, Mass-DAC re-estimated the hierarchical model using different prior distributions for τ^2.

1. 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 (or log risks) could range anywhere from 1 to 1.5. We thus 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.

2. We assumed the between-hospital standard deviation arose from a half normal distribution with mean 0 and variance 0.26. This 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 2008

Of the 13,842 PCI admissions in Massachusetts, 200 patients died during the same admission as the PCI. Table 7.1 on page 29 lists the prevalence (percentage) of important risk factors and the relationship of each risk factor (controlling for all other risk factors) with in-hospital mortality for the 11,121 *no shock and no STEMI* admissions following a PCI. For example, 34.96% of all *no shock and no STEMI* PCI admissions were patients who had a history of diabetes. Because age is measured in years, the table reports the mean number of years over age 65 for the cohort. Odds ratios or relative risks greater than 1 correspond to increased risk of mortality while those less than 1 correspond to decreased risk of mortality. Patients who had no shock and no STEMI, but had renal failure prior to a PCI, are 2.8 times more likely to die within the PCI hospital admission than patients without renal failure. In the *no shock and no STEMI cohort*, 0.13% of the admissions (14 admissions) were adjudicated to belong to the compassionate use group with corresponding mortality of about 35.71%. Admissions in this category were 6.7 times more likely to die during the admission.

Figure 7.1 on page 30 displays the SMIRs and corresponding 95% posterior intervals. The solid black vertical line in the figure is the unadjusted MA in-hospital mortality rate of 0.63% for *no shock and no STEMI* admissions. 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. The hierarchical model had good discrimination with an area under the ROC curve of 0.831 (Figure 7.5).

Table 7.2 on page 31 lists information similar to Table 7.1 but for the 2,721 *shock or STEMI* admissions. In this cohort, 1.65% of the admissions (45 admissions) were adjudicated to belong to the compassionate use group with corresponding mortality of 57.78%; patients falling into this

category had approximately 21 times the odds of dying compared to those not belonging to the category. The Hosmer-Lemeshow Goodness-of-Fit test did not indicate a lack of fit (χ^2_5 = 9.54, p = 0.09). Model discrimination ranged from 0% (0 deaths in 52 admissions) in the lowest risk group to 25.77% (84 deaths in 326 admissions) in the highest risk group. A hierarchical logistic regression model indicated an area under the ROC curve of 0.885 (Figure 7.6).

Figure 7.2 on page 32 displays the SMIRs and corresponding 95% posterior intervals for *shock or STEMI* admissions. The solid black vertical line in the figure is the unadjusted state in-hospital mortality rate of 4.78% for *shock or STEMI* admissions. All hospitals' 95% intervals cover the Massachusetts unadjusted in-hospital mortality rate.

Figure 7.3 on page 33 presents the cross-validated p-values of *no shock and no STEMI* cohort, under a number of different distributional assumptions regarding the hierarchical Poisson regression model. No hospital had a p-value smaller than 0.01. Figure 7.4 on page 34 presents similar values for the *shock or STEMI* cohort. The reference line on the graph at 0.01 indicates the cutoff for outliers based on p value. Any hospital with a bar under this line is considered to be different than expected.

In summary, based on in-hospital mortality data, **there were no hospital outliers for FY 2008 for either the *shock or STEMI* or *no shock and no STEMI* cohorts**.

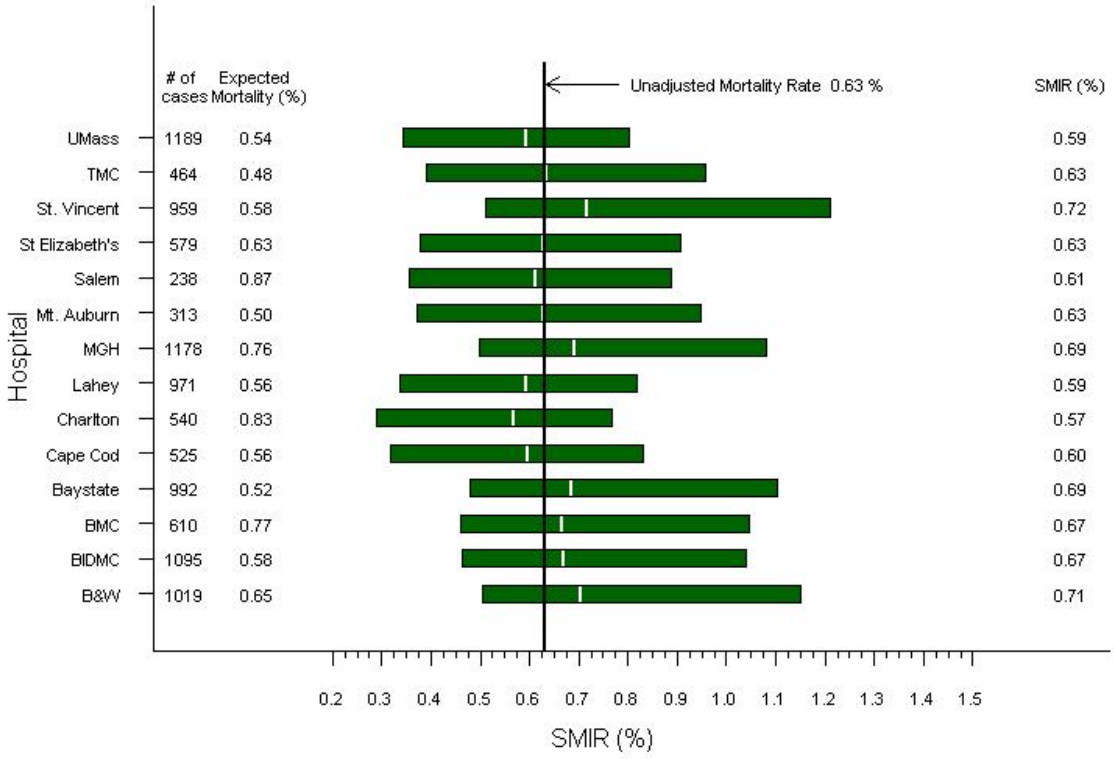
Table 7.1: *Adjusted Relative Risk of In-Hospital Mortality Following PCI in Adults: No Shock and No STEMI Admissions: Oct 1, 2007–Sep 30, 2008. Based on 11,121 admissions with 70 deaths (0.63%)*

Risk Factor	Prevalence (%)	Adjusted Relative Risk	95% Interval for the Adjusted Relative Risk
Mean Age (Years over 65)	0.08	1.04	(1.02, 1.07)
Renal Failure	6.50	2.83	(1.52, 4.67)
Diabetes	34.96	1.36	(0.80, 2.15)
Chronic Lung Disease	16.55	1.83	(1.02, 2.96)
Ejection Fraction $<$ 30% (Ref $\geq$30% or not measured)	3.10	3.27	(1.57, 5.83)
PCI Status (Ref = Elective)			
Urgent	60.24	6.38	(2.65, 14.61)
Emergency or Emergent Salvage	4.01	26.95	(9.18, 64.11)
Left Main Disease	7.11	2.00	(1.03, 3.43)
LAD >70% Stenosis	59.16	2.04	(1.10, 3.60)
Compassionate Use	0.13	6.66	(1.76, 16.29)

Between-Hospital Parameters	**Mean**	**95% Interval**
Between-Hospital Average log, μ	-8.02	(-8.85, -7.26)
Average Between-Hospital Variance in log, τ^2	0.0555	(0.0008012,0.2868)

Figure 7.1: *Ninety-Five Percent Posterior Intervals for Standardized Mortality Incidence Rates (SMIRs) Following PCI: Oct 1, 2007–Sep 30, 2008: No Shock and No STEMI Admissions*

# of cases refers to the number of PCI admissions; expected mortality rate is the percentage of admissions not expected to survive 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%.



HOSPITAL KEY:
B&W = Brigham & Women's Hospital; **BIDMC** = Beth Israel Deaconess Medical Center; **BMC** = Boston Medical Center; **Baystate** = Baystate 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; **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; **TMC** = Tufts Medical Center; **UMass** = UMass Memorial Medical Center.

Table 7.2: *Prevalences and Adjusted Odds Ratios of In-Hospital Mortality Following PCI in Adults: Shock or STEMI Admissions: Oct 1, 2007–Sep 30, 2008. Based on 2,721 admissions with 130 deaths (4.78%)*

Risk Factor	Prevalence (%)	Adjusted Odds Ratio	95% Interval for the Adjusted Odds Ratio
Age (Ref = <60 Years)			
Age 60-70	23.89	3.23	(1.61, 6.05)
Age 70-80	17.79	4.26	(2.13, 7.87)
Age ≥80	11.43	9.31	(4.61, 17.09)
Renal Failure	5.18	3.08	(1.70, 5.10)
Ejection Fraction< 30% (Ref ≥30% or not measured)	6.21	1.76	(0.89, 3.05)
PCI Status (Ref = Urgent or Elective)			
Emergency or Emergent Salvage	95.37	3.77	(1.20, 9.06)
Cardiogenic Shock	7.50	10.57	(6.46, 16.16)
Left Main Disease	4.78	1.33	(0.64, 2.38)
Compassionate Use	1.65	21.48	(8.51, 46.33)

Between-Hospital Parameters	**Mean**	**95% Interval**
Between-Hospital Average logit, μ	-6.17	(-7.39, -5.14)
Average Between-Hospital Variance in logits, τ^2	0.0685	(0.0007514,0.3584)

Figure 7.2: *Ninety-Five Percent Posterior Intervals for Standardized Mortality Incidence Rates (SMIRs) Following PCI: Oct 1, 2007–Sep 30, 2008: Shock or STEMI Admissions*

# of cases refers to the number of PCI admissions; expected mortality rate is the percentage of admissions resulting in death 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 MA in-hospital mortality rate of 4.78%. **Note**: Caritas-Holy Family Hospital and Lawrence General Hospital are not presented in the figure below because they were approved as a pilot program in July 2008, near the end of the fiscal year. However, they were included in the model.

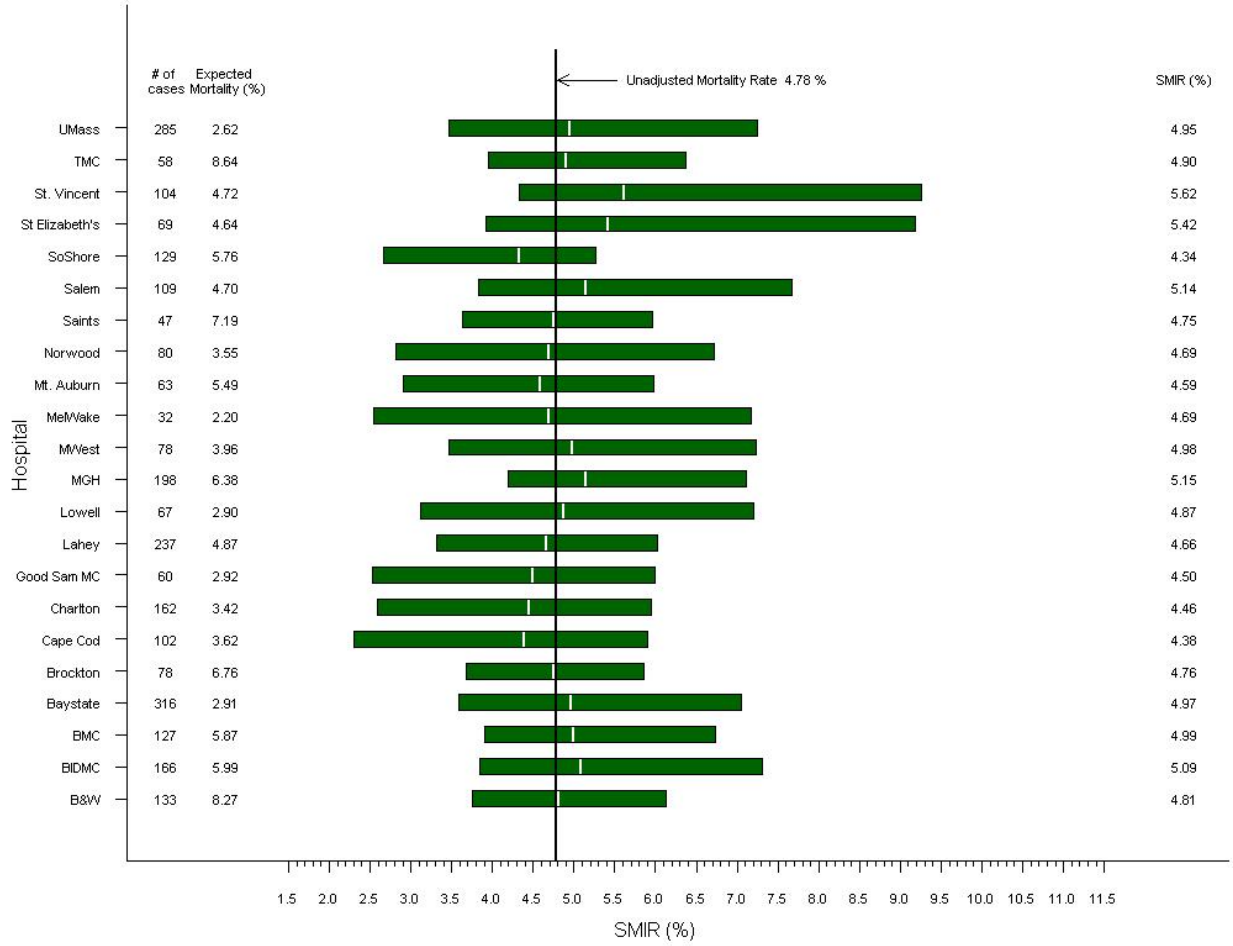


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Figure 7.3: *Cross-Validated Posterior P-Values: No Shock and No STEMI Admissions*

Posterior 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.

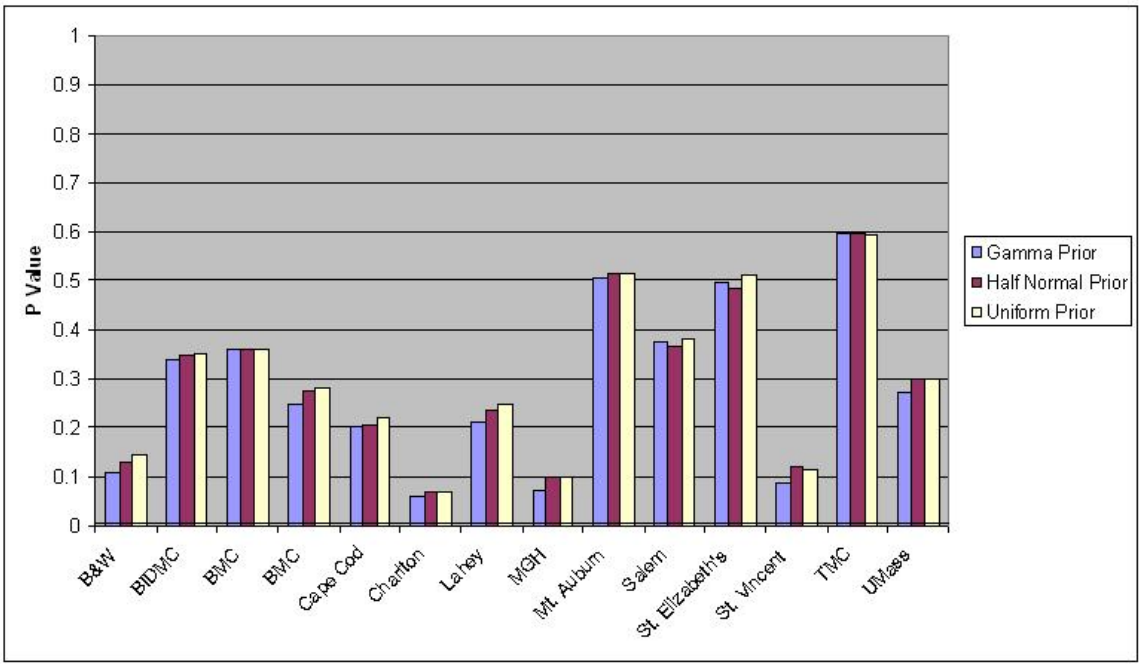

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Figure 7.4: *Cross-Validated Posterior P-Values: Shock or STEMI Admissions*

Posterior 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. **Note**: Caritas-Holy Family Hospital and Lawrence General Hospital are not presented in the figure below because they were approved as a pilot program in July 2008, near the end of the fiscal year. However, they were included in the model.

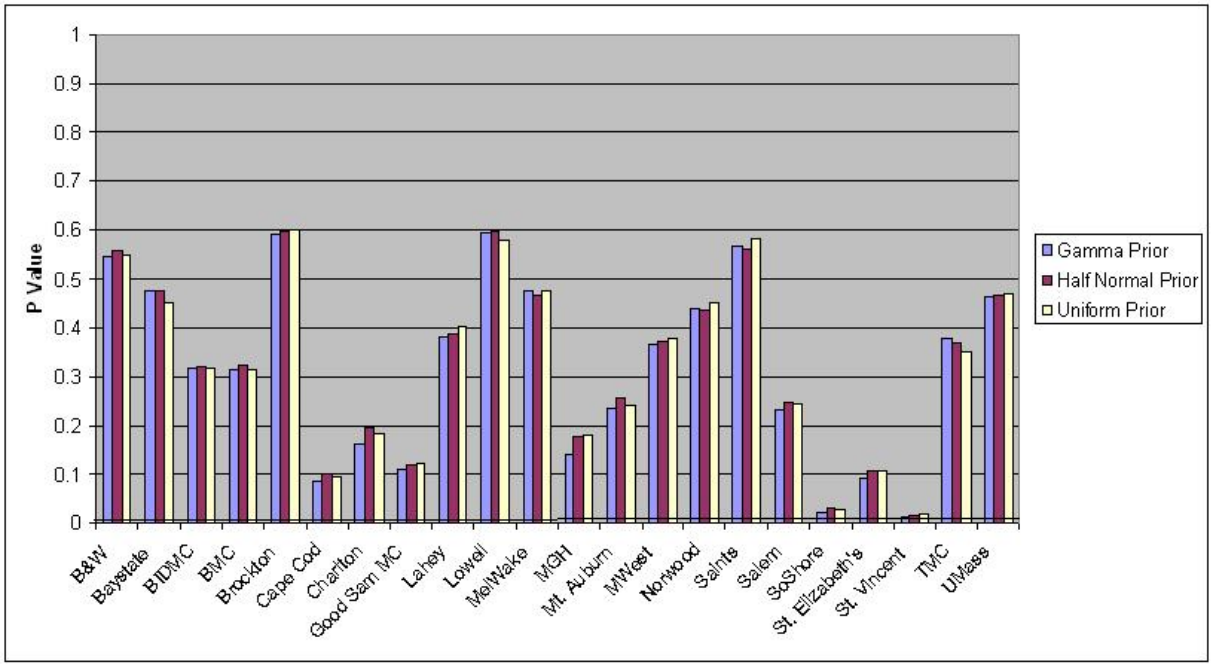

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Figure 7.5: *ROC Curve-Hierarchical: No Shock and No STEMI Admissions*

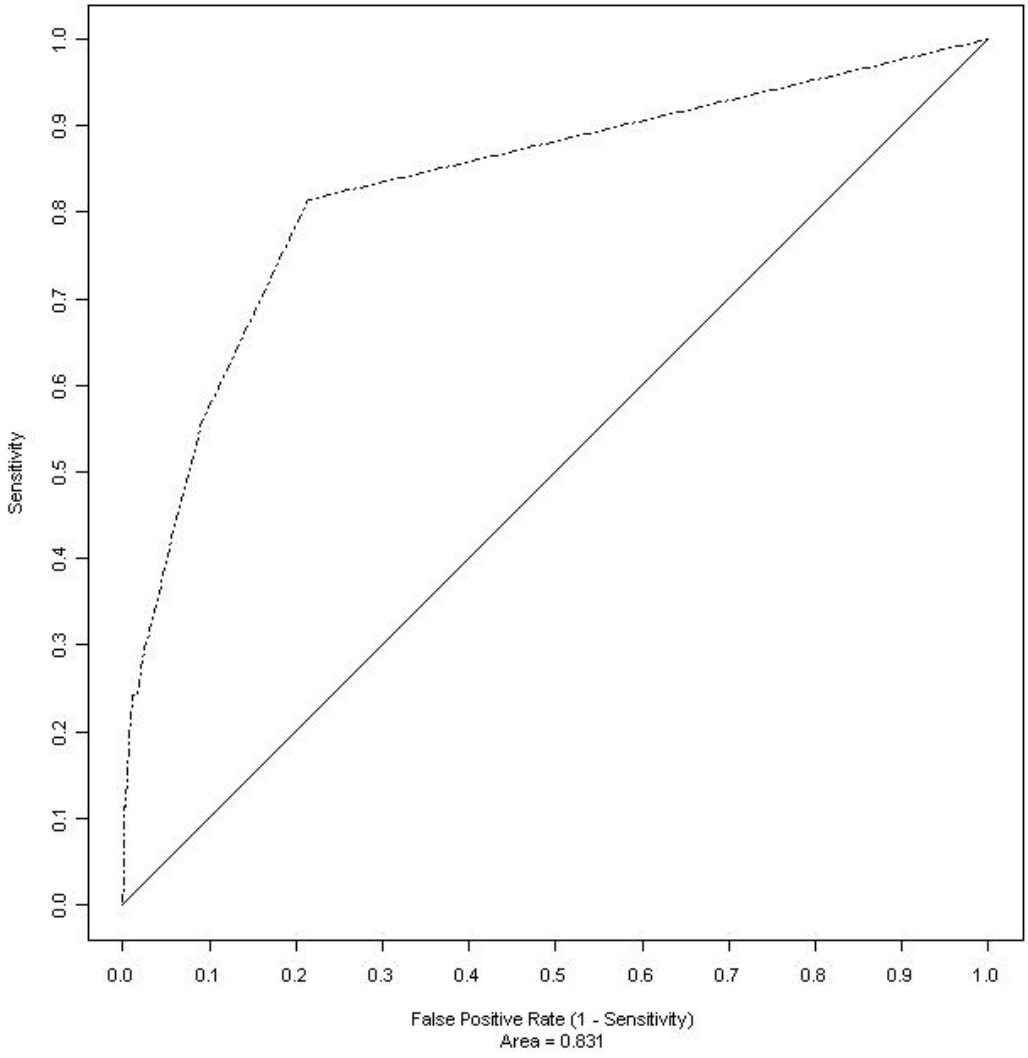
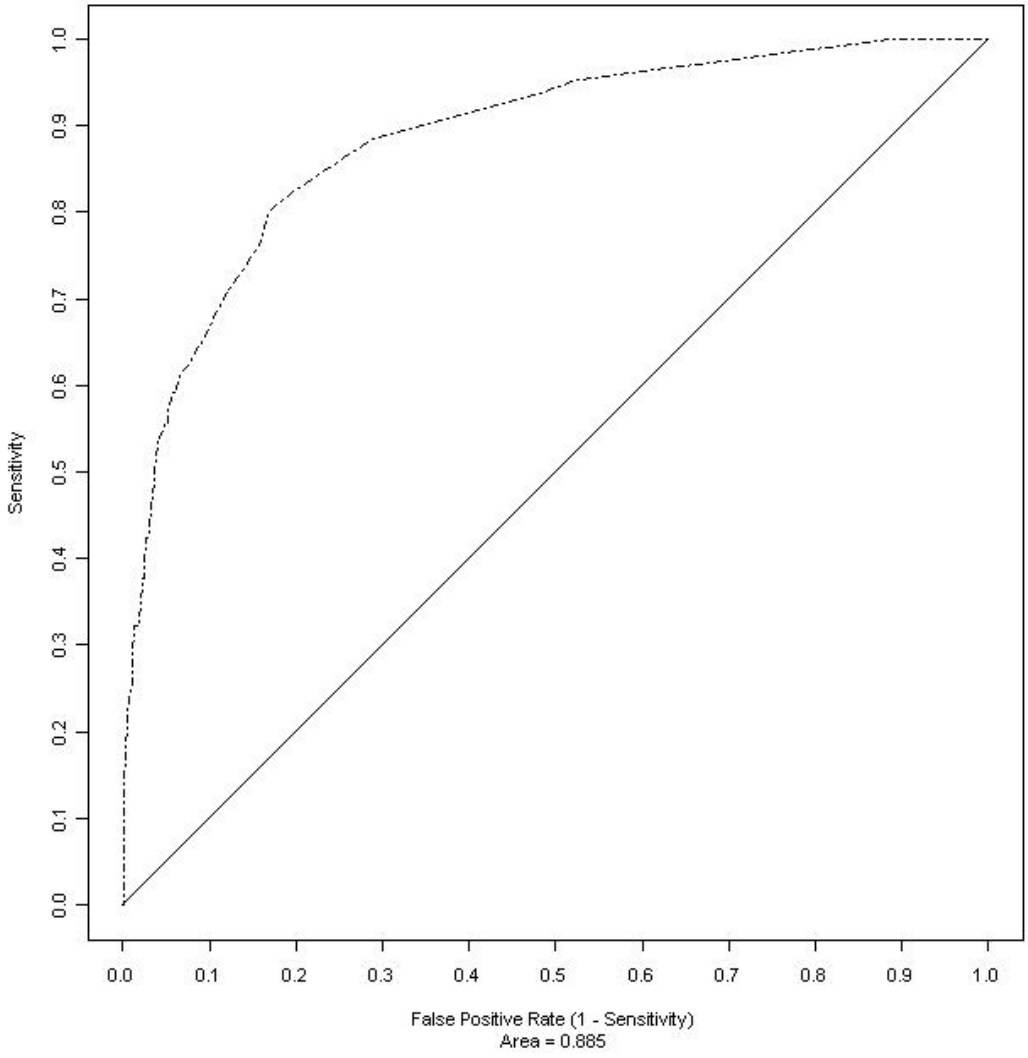


Figure 7.6: *ROC Curve-Hierarchical: Shock or STEMI Admissions*



8 Annual In-Hospital Mortality Trends Following PCI in Massachusetts: April 1, 2003 through September 30, 2008

Table 8.1: *Summary of PCI Admissions and In-Hospital Crude Mortality Percentages: CY 2003-FY 2008*

Year of PCI	CY 2003[a]	CY 2004	CY 2005	FY 2006	FY 2007	FY 2008
No Shock and No STEMI						
Number of Hospitals	14	14	14	20	21	22
Number of Admissions	10,689	14,504	13,387	12,921	11,275	11,121
In-Hospital Crude Mortality, %	0.76	0.68	0.64	0.64	0.50	0.63
Shock or STEMI						
Number of Hospitals	18	21	21	21	22	24
Number of Admissions	1,968	2,606	2,752	2,800	2,788	2,721
In-Hospital Crude Mortality, %	6.86	5.76	6.00	5.60	5.49	4.78

[a]Represents nine months of admissions.

9 Important Definitions

Admission: A single episode of care, including outpatient procedures, at one facility from the date of admission to the date of discharge in which at least one PCI was performed.

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

Cardiac Surgery: (Massachusetts legislature for the Massachusetts Cardiac Study definition) 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 pharmacologic 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 ll 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 anti-diabetic agents. This includes diagnosis on admission or pre-procedure. It does not include gestational diabetes.

Drug Eluting Stent: Stents that are either coated or embedded 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 must be met:

a. Not elective status; and

b. Not emergency status; and

c. Procedure required during same hospitalization in order to minimize chance of further clinical deterioration; and

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)); or

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 the members of the Mass-DAC Committees who have donated their time to improve the database and the quality of cardiac care in the Commonwealth of Massachusetts.

FY 2008 Massachusetts Cardiac Care Hospital Outlier Committee

A Massachusetts Department of Public Health Committee charged with reviewing hospital outlier findings.

Alice Bonner. Ph.D., R.N.
Director (current)
Bureau of Health Care Safety and Quality
Massachusetts Department of Public Health

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

Nancy Murphy
Policy Analyst
Massachusetts Department of Public Health

Elizabeth Daake
Director of Policy Development and Planning
Massachusetts Department of Public Health

Thomas Piemonte, M.D.
Director, Cardiac Catheterization Laboratory
Lahey Clinic

David Shahian, M.D.
Chair, Center for Quality and Safety
Department of Surgery
Massachusetts General Hospital

Sharon-Lise Normand, Ph.D.
Professor of Health Care Policy
Department of Health Care Policy
Harvard Medical School

Stanley Lewis, M.D.
Associate Professor of Medicine
Harvard Medical School
Beth Israel Deaconess Medical Center

John Pastore, M.D.
Clinical Cardiologist
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Frank Sellke, M.D.
Professor of Surgery
Harvard Medical School
Beth Israel Deaconess Medical Center

David Torchiana, M.D.
Chairman and Chief Executive Officer
Mass. General Physicians Organization

FY 2008 Mass-DAC Oversight Committee for PCI

Some members of this committee reviewed blinded summary data for all operators in Massachusetts 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. For operators identified as having statistically significant higher than expected mortality, unblinded case fatality reports are also reviewed. Other members of the committee reviewed and updated compassionate use criteria. Selection of Committee members is the responsibility of the current Governor of the Massachusetts Chapter of the ACC. 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.

Cliff Berger, M.D.
Boston University School of Medicine

Gregory Giugliano, M.D.
Interventional Cardiologist
Baystate Medical Center

Joseph Hannan, M.D.
Interventional Cardiologist
St. Vincent Hospital

Kalon Ho, M.D., M.Sc.
Director of Quality Assurance
Cardiovascular Division
Beth Israel Deaconess Medical Center

Zoran Nedeljkovic, M.D.
Interventional Cardiologist
Boston Medical Center

Sharon-Lise Normand, Ph.D.
Mass-DAC Liaison
Professor of Health Care Policy (Biostatistics)
Harvard Medical School

Thomas Piemonte, M.D.
Director, Cardiac Catheterization Laboratory
Lahey Clinic

Frederic Resnic, M.D., M.Sc.
Director, Cardiac Catheterization Laboratory
Brigham and Women's Hospital

Kenneth Rosenfield, M.D.
Interventional Cardiologist
Massachusetts General Hospital

Paul Schwerdt, M.D.
Interventional Cardiologist
Caritas Norwood Hospital

Samuel Shubrooks, Jr., M.D.
Interventional Cardiologist
Beth Israel Deaconess Medical Center

FY 2008 Mass-DAC PCI Data Adjudication Committee

This committee reviewed patient-specific data elements and corresponding data documentation submitted by hospitals to Mass-DAC in order to determine validity of coding.

Susan April, Data Manager
North Shore Medical Center - Salem Hospital

Kurt Barringhaus, M.D.
UMass Memorial Medical Center

Angela Corey, Data Manager
South Shore Hospital

Kevin Croce, M.D.
Brigham and Women's Hospital

Douglas Drachman, M.D.
Massachusetts General Hospital

Daniel Fisher, M.D.
UMass Memorial Medical Center

Joseph Garasic, M.D.
Massachusetts General Hospital

Jean-Pierre Geagea, M.D.
Brockton Hospital

Kalon Ho, M.D.
Beth Israel Deaconess Medical Center

Claudia Hochberg, M.D.
Boston Medical Center

Farouc Jaffer, M.D.
Massachusetts General Hospital

Ik-Kyung Jang, M.D.
Massachusetts General Hospital

Kirk MacNaught, M.D.
Lowell General Hospital

Laura Mauri, M.D.
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Zoran Nedeljkovic, M.D.
Boston Medical Center

Igor Palacios, M.D.
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Ashvin Pande, M.D.
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Samuel Shubrooks, M.D.
Beth Israel Deaconess Medical Center

Piotr Sobieszczyk, M.D.
Brigham and Women's Hospital

Andrew Weintraub, M.D.
Tufts/New England Medical Center

Frederick Welt, M.D.
Brigham and Women's Hospital

FY 2008 Publications Committee for PCI

The charge of this committee is to facilitate utilization of shared data from the Massachusetts PCI Data Registry for purposes of reporting observations that are of interest to the medical community and are based on sound scientific principles of study design and analysis. This committee will review and comment on the request before sending the proposal to the Massachusetts Department of Public Health for final approval.

Donald Cutlip, M.D.
Beth Israel Deaconess Medical Center

Alice Jacobs, M.D.
Boston Medical Center

Jeffrey Popma, M.D.
Beth Israel Deaconess Medical Center

Marc Schweiger, M.D.
Baystate Medical Center

Fredrick Welt,, M.D.
Brigham and Women's Hospital

Igor Palacios, M.D.
Massachusetts General Hospital

Thomas Piemonte, M.D.
Lahey Clinic

A Appendix

ACC DATA ABSTRACTION TOOL – VERSION 3.04

(Variables considered optional and not harvested by ACC are harvested by Mass-DAC)

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]: ____/____/____ **Age**[252]: _____ (calculated)

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

C. ADMISSION:

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
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]: ____/____/____

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

Fluoro Time[632]: _____ minutes **Left Heart Cath**[612]: Yes; No

Contrast Volume[634]: _____ ml/cc **PCI**[614]: Yes; No

HEMODYNAMIC SUPPORT:

IABP[640]: Yes; No → if Yes **IAPB 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		**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] x 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 Pecutaneous 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

B Appendix

MASS-DAC COMPASSIONATE USE CRITERIA – VERSION III

Mass-DAC PCI Compassionate Use Criteria

Criteria	Definition	Additional Information
Extreme Anatomic Risk	A case will be considered "extreme anatomic risk" if the index PCI during a hospital admission includes any of the following conditions: 1. Unprotected left main coronary intervention with ejection fraction documented to be <=35% 2. Last remaining coronary vessel intervention associated with ejection fraction of <=35%. 3. Unprotected LMCA intervention in the setting of STEMI or cardiogenic shock. 4. Last remaining coronary vessel intervention in the setting of STEMI or cardiogenic shock	The use of CPB or PVAD has been modified to be based on clinical criteria rather than on the use of specific technology. Angiograms and procedural reports must be submitted for these cases for review by the Mass-DAC Adjudications Committee. 1. Unprotected LMCA intervention requires either no history of CABG or history of CABG with documentation that all grafts to the LAD and LCx territories are occluded 2. A procedure includes PCI of the last remaining vessel if there is documentation of occlusion of the other two major epicardial vessels (and all bypass grafts to these vessels if S/P CABG), and PCI is performed on the remaining patent vessel. Note that PCI procedures that involve a successful attempt to open a chronic occlusion of one major epicardial vessel followed by PCI of the last remaining vessel do not qualify under this definition. Also, the target lesion must subtend most of myocardium in order to qualify as a significant epicardial vessel (i.e. branch vessel interventions of the last remaining vessel do not generally qualify). 3. In this circumstance, documentation of the left ventricular ejection fraction is not required to qualify for classification of compassionate use. 4. (See definition of last remaining vessel above) In this circumstance, documentation of the ejection fraction is not required to qualify for classification of 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 criteria for compassionate use.

Mass-DAC PCI Compassionate Use Criteria

Criteria	Definition	Additional Information
Coma on Presentation	Coma on presentation is defined as a Glasgow Coma Score (GCS) of <7 in the absence of sedatives and documented prior to the start of the emergent PCI.	In those situations where a Glasgow Coma Score was not formally computed or recorded, documentation in the medical record of equivalent severity of neurologic compromise prior to the PCI may be used to justify classification as "coma on presentation." Documentation of the components of the GCS is encouraged, and as much documentation as possible of the patient's neurological status prior to intubation should be provided. The medical record (catheterization report or physician notes) must document that the patient appeared, at the start of the emergent procedure, to be in a coma that was not medication induced. The compassionate use case review process used by Mass-DAC will consider all elements of the clinical record provided for review to establish whether there was clear and convincing evidence of non-medication induced coma prior to the start of the diagnostic procedure. Note that coma developing during the diagnostic procedure would not qualify for this category of compassionate use. Although documentation of GCS is not required, it will continue to provide supportive evidence of the severity of neurologic compromise at the start of the procedure; and therefore documentation in the medical record is encouraged.

Mass-DAC PCI Compassionate Use Criteria

Criteria	Definition	Additional Information
Exceptional Use (Effective as of Oct 2008, Fiscal Year 2009 PCI cases)	This category for Compassionate use consideration will begin with the Fiscal Year 2009 cases (PCI procedures on or after October 1, 2008). An exceptional use case will be considered for review if the operator or institution feels that the case met the following criteria: 1. Extremely high risk features not captured by current risk adjustment covariates 2. PCI was the "best" or only option for improving chance for survival	The review committee will require two items of documentation in addition to documentation from the medical record: 1. A detailed letter from the treating physician documenting the unusual circumstances and extreme risk of the procedure, and the justification for performing the procedure in terms of potential benefit for the patient. Specifically, the letter should reference the particular elements of the medical record where the additional objective risk factors are documented. The letter will need to have at least the following issues clearly addressed (in detail): a. Clinical presentation with justification for appropriateness of intervention b. Clear documentation and supporting evidence for high risk features for the case. These clinical features must not be currently included in the Mass-DAC risk adjustment covariates and may not be included in the current ACC-NCDR instrument. c. Documentation of consideration of alternative treatments (medical therapy, surgical therapy) and why PCI was selected. References to clinical notes from consultants and other caregivers will be important. Review of procedural details as well as clinical course The source clinical records referenced in the letter will be required during the review process. 2. A form to be developed by the Cardiology Quality Oversight Committee which will help categorize the factors that may justify classification as an exceptional risk case, and will provide some guidance in the construction of the required letter. An example of a potential "compassionate use other" designation case could include a patient presenting with simultaneous life-threatening medical conditions such as a STEMI as well as impending rupture of an abdominal aortic aneurysm. Such a case could reasonably be considered extremely high risk for death following PCI. In such cases, there may not be an opportunity to attempt to stabilize the patient from the second medical condition before treating the acute coronary syndrome. Treating the STEMI with PCI is a prerequisite to safe treatment of the second life-threatening condition (impending rupture of aortic aneurysm).

Note: Cases in which a diagnostic procedure is performed by a separate operator (typically an invasive, non-interventional cardiologist) in which a catastrophic complication develops from the diagnostic procedure (such as catheter induced dissection of the left main coronary artery) can qualify for coding as compassionate use if the PCI operator is different from the diagnostic operator. Complications of a diagnostic catheterization in which the treating interventional cardiologist performed the diagnostic procedure cannot be coded as compassionate use.