Adult Percutaneous Coronary Intervention in the Commonwealth of Massachusetts

Fiscal Year 2011 Report
(October 1, 2010 through September 30, 2011)

Hospital Risk-Standardized In-Hospital Mortality Rates

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1 Boston Medical Center Place
Boston, MA 02118

Brigham and Women's Hospital
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Cape Cod Hospital
27 Park Street
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Lahey Hospital & Medical Center
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Massachusetts General Hospital
55 Fruit Street
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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 Elizabeth's Medical Center
736 Cambridge Street
Boston, MA 02135

Saint Vincent Hospital
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

Beverly Hospital
85 Herrick Street
Beverly, MA 01915

Brockton Hospital
680 Centre Street
Brockton, MA 02302

Good Samaritan Medical Center
235 Pearl Street
Brockton, MA 02301

Holy Family Hospital
70 East Street
Methuen, MA 01844

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 ninth in a series of reports summarizing the quality of care provided by the 25 state licensed cardiac programs in the Commonwealth. The report is contracted by the Bureau of Health Care Safety and Quality in the Massachusetts Department of Public Health. The provision of these data is part of a broad, statewide initiative to increase accessibility of health care data to consumers, policy makers, and providers. This report is meant to give residents information about the relative performance of cardiac programs as an aid to decision making, and to provide hospitals in the Commonwealth with key information to help drive quality improvement.

This report contains analysis of data on 12,795 hospital admissions in which at least one percutaneous coronary intervention (PCI) was performed during the period October 1, 2010 through September 30, 2011. Mass-DAC and the Department of Public Health no longer publicly report on surgeon-specific mortality rates, to be consistent with the non-public reporting of Massachusetts interventional cardiologists performing percutaneous coronary interventions (PCI). Data on individual cardiac surgeons and PCI operators will continue to be collected and analyzed. After review by a committee of content experts, information about providers who have higher than expected mortality rates *and for whom there are serious concerns about the quality of care that is provided* will be shared with the leadership of the hospital department in which that provider operates, and with the Board of Registration in Medicine, the licensing body for physicians. The Department will continue to collect, monitor and validate patient-specific outcome data from all hospitals that perform cardiac surgery or PCI.

Several 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 (NCT01116882) 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 monitored the progress of the Mass-COMM trial.

Second, the fiscal year 2011 reporting period represents the sixth 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–Compassionate Use Criteria). This report makes use of that information.

An additional category of Exceptional Risk PCI, was added in fiscal year 2009, (see Appendix C–Exceptional Risk Criteria) and cases adjudicated as such were removed from the fiscal year 2011 analysis.

The data collection, verification, audit, and analytical procedures implemented in this report constitute the most comprehensive, reliable, and rigorous used in the United States. 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 to review and adjudicate data. 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.

Madeleine Biondolillo, M.D.
Director
Bureau of Health Care Safety and Quality
Massachusetts Department of Public Health

2 Key Hospital Findings

2.1 Updates

- **March 9, 2017:** Updated section 4.5.5 and the appendix describing the Exceptional Risk criteria used by the Exceptional Risk Committee. There was a typographical error with the inclusion of "or" between the two criteria required for an exceptional risk case. The "or" was removed. Its inclusion did not accurately reflect the way the committee adjudicated or approved Exceptional Risk cases. Cases to be considered for Exceptional Risk have always required both criteria. "*Refer to the Appendix C—Exceptional Risk Criteria for the complete definition and qualifying specifications.*"

2.2 Hospital Findings

- In the period October 1, 2010 through September 30, 2011 (fiscal year 2011), there were 12,795 hospital admissions, excluding exceptional risk cases, in Massachusetts in which at least one Percutaneous Coronary Intervention (PCI) was performed.

- 20.5% (2,618) 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-five hospitals performed at least one PCI during the period October 1, 2010 through September 30, 2011; eleven participated in the Massachusetts Primary PCI Pilot Program. Primary PCI Pilot programs are approved for *shock or STEMI admissions* only.

- Additional criteria for patients considered *exceptionally high risk* for death (Exceptional Risk) were collected and adjudicated by Mass-DAC. Approved exceptional risk cases were

eliminated from the analysis.

- 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 Massachusetts average was two times (relative risk of 2.1) that of a hospital one standard deviation below the Massachusetts average.

- The odds of in-hospital mortality in a hospital one standard deviation above the Massachusetts average was 1.6 times that of a hospital one standard deviation below the Massachusetts average for patients with *shock or STEMI*.

- The observed in-hospital all cause mortality for fiscal year 2011 in *the no shock and no STEMI* cohort is 0.47% (48 deaths) based on analysis of 10,177 admissions, which include Mass-COMM Trial Participants.

- The observed in-hospital all cause mortality for fiscal year 2011 in *the shock or STEMI* cohort is 5.04% (132 deaths) based on analysis of 2,618 (excludes Exceptional Risk) admissions.

- **There were no hospitals in FY 2011 that were outliers in either the *shock or STEMI* or the *no shock and no STEMI* cohorts.**

3 Introduction

3.1 What is in this Report?

This is the ninth report (available at http://massdac.org/reports/pci.html) describing methods and results for estimating hospital-specific in-hospital risk-standardized 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 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, 2010 through September 30, 2011 (fiscal year 2011) 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 2011, there were 14 PCI programs in Massachusetts, each with back-up cardiac surgery programs, and 11 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, at 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 in-hospital risk-standardized mortality rates following PCI for the 25 PCI hospitals in Massachusetts. Because of the elevated risks associated with heart attack patients, results for two separate cohorts of patients are presented. The two cohorts are:

- Shock or STEMI cohort;
- No shock and no STEMI cohort.

3.1.1 Shock or STEMI Cohort

The ACC-NCDR CathPCI Registry® data collection instrument (version 4) was used to compile data for the fiscal year 2011 report. The version, implemented July 1, 2009, instituted changes in the definitions of cardiogenic shock, symptom onset time, and STEMI at the time of the procedure. These changes allowed further refinements to the risk factor definitions of STEMI and cardiogenic shock at the time of the procedure for PCIs. This also allowed for more refinements in the model for both cohorts.

For fiscal year 2011, the *shock or STEMI* cohort was defined as cases having one of the following:

- Cardiogenic shock at the time of the PCI procedure meeting the ACC-NCDR cardiogenic shock definition, and having clinical symptoms of shock with treatment
- At the time of PCI procedure, indication of an immediate PCI for STEMI
- PCI procedures performed within 24 hours or less of symptom onset to PCI procedure and one of the following:
  - ◇ STEMI at the time of admission
  - ◇ At the time of PCI procedure, indication for STEMI > 12 hours from symptom onset
  - ◇ At the time of PCI procedure, indication for STEMI after successful full-dose thrombolytics
  - ◇ At the time of PCI procedure, rescue PCI is performed

3.1.2 No Shock and No STEMI Cohort

This cohort includes all admissions which are not in the *shock or STEMI* cohort. This includes all of the following:

- Admissions for patients having no STEMI within 24 hours of arrival to the hospital
- No STEMI at the time of the first PCI
- No cardiogenic shock prior to the PCI, as defined in section 3.1.1.

3.1.3 Mass-COMM Trial Participants

During fiscal year 2011, a randomized trial, Mass-COMM (NCT01116882), was ongoing. The goal of the trial is to compare the effectiveness and safety of "elective" angioplasty in pilot programs (without cardiac surgery) 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. Therefore, this document reports on only 14 programs for the *no shock and no STEMI* admissions. For the *shock or STEMI* admissions all 25 programs are reported because no Mass-COMM trial participants are in this cohort.

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 plaque buildup. Plaque may build up because of high cholesterol, high blood pressure, smoking, diabetes, genetic predisposition, or other factors. If the plaque buildup 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 Patient Population

The study population is patients who were 18 years of age or older at the time of undergoing a PCI at all non-federal hospitals in Massachusetts. During the period October 1, 2010 through September 30, 2011, there were 12,795 admissions, in which at least one PCI was performed: 10,177 *no shock and no STEMI* admissions and 2,618 *shock or STEMI* admissions (Table 3.1). The in-hospital mortality rate for *shock or STEMI* admissions is more than 10 times that for *no*

shock and no STEMI admissions (5.04% versus 0.47%). Mass-DAC analyzed the first PCI for patients who received more than one PCI during their admission: 2.28% of the *no shock and no STEMI* patients and 4.16% of the *shock or STEMI* patients received more than one PCI during a hospital admission.

Table 3.1: *Summary—First PCI of Admission—Adults in Massachusetts Hospitals: Oct 1, 2010–Sep 30, 2011.*

Risk Cohort	No Shock and No STEMI [a]		Shock or STEMI [b]	
Characteristic	**Number**	**Percent**	**Number**	**Percent**
Admitted via Emer. Dept. or Transfer	6,075	59.69	2,534	96.79
Number of PCIs per Admission				
One PCI	9,945	97.72	2,509	95.84
Two or More PCIs	232	2.28	109	4.16
Prior Cardiac Arrest	45	0.44	234	8.94
At Least One Stent	9,362	91.99	2,346	89.61
Drug-Eluting if Stented	6,770	72.31	1,163	49.57
Total Length of Stay (Days)	Mean = 3.71 Median = 3		Mean = 5.24 Median = 4	
Post-Procedure Length of Stay (Days)	Mean = 2.78 Median = 2		Mean = 5.09 Median = 4	
Unadjusted Outcomes				
Any Vascular Complication	36	0.35	10	0.38
Status of CABG During PCI Admission				
Elective	[c]	0.05	[c]	0.11
Urgent	50	0.49	29	1.11
Emergency	16	0.16	14	0.53
Salvage	[c]		[c]	
Transferred out for CABG	[c]		10	0.38
In-Hospital Death	48	0.47	132	5.04
Total Number of Admissions	10,177		2,618	

[a] Patients arriving with no STEMI within 24 hours and no cardiogenic shock with clinical symptoms and treatment prior to the procedure.

[b] Patients having STEMI within 24 hours of hospital arrival or at time of first PCI, or cardiogenic shock with clinical symptoms and treatment prior to the procedure.

[c] Frequencies from 1 to 6 suppressed as required by the Massachusetts Department of Public Health data security guidelines.

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.

3.6 Software Utilized in Analysis

The data collection and analysis for this report utilized three different statistical software applications;

- SAS®, version 9.2 and 9.3 Unix/Windows [8],
- WinBUGS version 1.4 [10],
- R version 2.6 [7].

The data collection process utilized Base SAS to aggregate the core data elements for the analytic data sets. The statistical analysis used a combination of SAS/Stat, WinBugs, and R, to generate the results in this report. SAS Institute Inc. and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA.

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-five hospitals had Cardiac Catheterization Labs that performed PCIs in the period October 1, 2010 through September 30, 2011, 11 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

Four different data sources were used to create this report:

- The Mass-DAC PCI procedures database with data collected using the American College of Cardiology – National Cardiovascular Data Registry (ACC-NCDR) (CathPCI Registry) data collection tool [4];
- Hospital administrative discharge billing data [5] from the Massachusetts Center for Health Information and Analysis;
- Vital statistics information [6] from the Massachusetts Registry of Vital Records and Statistics; and

- The Mass-DAC cardiac surgery patient-specific data collected using the Society of Thoracic Surgeons (STS) National Cardiac Surgery data collection tool [9];

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 tools. Data for fiscal year 2011 were collected using the Version 4.3 data collection tool (see Appendix A), which was implemented July 1, 2009. It includes 329 variables. The data collection tool was updated to version 4.4 with very minor changes and was used for data submissions for procedures performed April 1, 2011 or later.

4.3.2 Massachusetts Inpatient Acute Hospital Case Mix and Charge Database

Hospital discharge data for fiscal years 2003 through 2011 (October 1, 2002 through September 30, 2011) were obtained from the Massachusetts Division of Health Care Finance and Policy. Data elements included a hospital identifier, sex, race, age, patient's zip code, up to 15 discharge diagnoses and up to 15 procedure codes, discharge status, dates of admission and discharge, date of surgery, and patient medical record number. Social Security numbers were removed from this database. Data were used for validation of PCI procedure volume.

4.3.3 Massachusetts Mortality Index Database

Death date information obtained from the Massachusetts Registry of Vital Records and Statistics was available for deaths occurring in Massachusetts between April 1, 2003 and October 30, 2011. While the primary source for in-hospital mortality rates was the hospital-reported information, the mortality index database was employed as a verification tool. 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 hospitals, the in-hospital mortality status was changed for one patient.

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.

Table 4.1: *Fiscal Year 2011 PCI Data Harvest Schedule*

Harvest Month	Corresponding Dates of PCI
March 2011	October 1, 2010 through December 31, 2010
June 2011	January 1, 2011 through March 31, 2011
September 2011	April 1, 2011 through June 30, 2011
December 2011	July 1, 2011 through September 30, 2011
April 2012	Final close out date for fiscal year 2011 data

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, 2012, after which no changes were accepted without permission from Mass-DAC.

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 frequency distribution of all ACC-NCDR variables and identifying cases with missing, out of usual 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 256 data submissions to Mass-DAC for fiscal year 2011 data with a range of 1 to 6 per hospital, and a mean of 2.6 submissions per hospital per collection period.

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 was one change in the fiscal year 2011 mortalities reported by the hospitals. One in-hospital death was not reported by a hospital. The Vital Statistics date of death was confirmed and the mortality status and location was changed in the Mass-DAC data.

Case volumes were verified by linking with the Massachusetts acute hospital case mix databases [5]. Five cases were found that had not been submitted as a PCI. The five cases were confirmed with each hospital to be PCIs, the hospitals submitted the required Mass-DAC information, and were subsequently included in the Mass-DAC 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, to resolve data submission concerns, and to serve as a facilitator to the national ACC-NCDR. Questions and clarifications were also discussed at the data manager meetings, with the ACC-NCDR, and on an e-mail network. Volunteers who attended the adjudication audit meetings also shared variable definition information with their colleagues.

4.5.4 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 which was not medication induced. 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. All cases submitted and approved as compassionate use are included in the fiscal year 2011 analysis.

4.5.5 Exceptional Risk

A committee of interventionalists developed additional criteria for patients who were considered to have an exceptionally high risk of death but whose risk factors were not collected by the ACC-NCDR or included in the Mass-DAC criteria for Compassionate Use. PCI cases submitted as Exceptional Risk had to meet the following two criteria:

1. Extremely high risk features not captured by current risk adjustment covariates.
2. The PCI was the "best" or only option for improving chance of survival.

All cases submitted as Exceptional Risk required additional documentation and were reviewed by an Exceptional Risk committee. All cases approved by the committee for Exceptional Risk were removed from the fiscal year 2011 analysis. Refer to the Appendix C—Exceptional Risk Criteria for complete definition and qualifying specifications.

4.5.6 Audit Data

A sample of the fiscal year 2011 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 salvage status;
3. All elective or urgent cases in the *shock or STEMI* cohort;
4. A sample of patients with aortic stenosis < 0.7 cm^2 ;

5. All patients coded as having cardiac arrest within 24 hours prior to the procedure;

6. All patients coded as Compassionate Use;

7. All patients coded as Exceptional Risk.

In total, **696** data records were reviewed. 359 records were audited for Quarters 1 and 2 (October through March) and 337 records for Quarters 3 and 4 (April through September).

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, specific compassionate use categories, and all exceptional risk cases 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. Fourteen volunteers (12 physicians and 2 data managers) representing 9 of the 25 PCI programs comprised the Mass-DAC PCI Adjudication and the Exceptional Risk Committees. 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[1] for the audit.

All records coded as either Compassionate Use (133 in total) or Exceptional Risk (18 in total) were reviewed by the Adjudication Committee to determine if it met the criteria established by Mass-DAC. Eighty-one percent of the Compassionate Use cases reviewed and less than 33% of the Exceptional Risk cases submitted were accepted (see Table 4.2).

[1] Audit of the entire population meeting specific variable criteria as opposed to a sample.

Table 4.2: *Summary of Census Variables Adjudication*

Risk Factor	Total Reviewed	Final Adjudicated Status	Number
Shock prior to PCI	275	met shock definition with treatment	219
		met shock definition but no treatment	20
		No Shock	36
Elective Status for Shock or STEMI	11	Elective(no change)	[a]
		Urgent	[a]
		Emergency	[a]
		Salvage	0
Urgent Status for Shock or STEMI	84	Elective	0
		Urgent (no change)	58
		Emergency	26
		Salvage	0
Salvage Status	32	Elective	[a]
		Urgent	[a]
		Emergency	9
		Salvage (no change)	22
Prior Cardiac Arrest	314	No Cardiac Arrest within 24 hours	35
		Prior Cardiac Arrest	279
Compassionate Use	133	Not Compassionate Use	24
		Compassionate Use	109
Exceptional Risk	18	Not Exceptional Risk	[a]
		Exceptional Risk	[a]

[a]Frequencies from 1 to 6 suppressed as required by the Massachusetts Department of Public Health data security guidelines.

5 Risk Adjustment

5.1 Who Receives PCI in Massachusetts?

Tables 5.1 and 5.2 provides age, sex, and race summaries of the 10,177 *no shock and no STEMI* admissions and 2,618 *shock or STEMI* admissions. The ACC-NCDR allows patients to be identified with more than one race; in addition, Hispanic is an ethnicity choice and is separate from the race designations. Patients not selecting any race designation are defined as "Other Race." The majority of *no shock and no STEMI* admissions are associated with patients who are male (64.8%), and one-half (50.2%) of the patients are less than 65 years of age at the time of their PCI. Patients residing out of state comprised 7.3% of the *no shock and no STEMI* admissions (data not shown).

The majority of patients with *shock or STEMI* admissions are male (65.0%). More than one-half (62.5%) of the *shock or STEMI* admissions were less than 65 years old at the time of their PCI. Finally, 6.4% of the *shock or STEMI* admissions were performed on patients residing out of state (data not shown).

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. Risk factors that are related to both death and which hospital a

Table 5.1: *Demographic Distribution for no Shock and no STEMI PCI Admissions ($N = 10,177$) in Massachusetts Hospitals: Oct 1, 2010–Sep 30, 2011*

Patients may select more than one race category. The Ethnicity Hispanic category is independent of the race categories and may be selected in addition to a race.

Age Group	Total by Age	Age 65	White	African American	Other Race	Ethnicity Hispanic
Male						
18–44	316					
45–54	1,204	≤64	3,302	134	92	204
55–64	2,108					
65–74	2,035					
≥75	1,488	≥65	3,290	85	67	91
Total	**7,151**		**6,592**	**219**	**159**	**295**
Female						
18–44	93					
45–54	356	≤64	984	78	25	74
55–64	661					
65–74	865					
≥75	1,051	≥65	1,779	62	28	65
Total	**3,026**		**2,763**	**140**	**53**	**139**
Total Male and Female						
18–44	409					
45–54	1,560	≤64	4,286	212	117	278
55–64	2,769					
65–74	2,900					
≥75	2,539	≥65	5,069	147	95	156
Total	**10,177**		**9,355**	**359**	**212**	**434**

Table 5.2: *Demographic Distribution for Shock and STEMI PCI Admissions ($N = 2,618$) in Massachusetts Hospitals: Oct 1, 2010–Sep 30, 2011*

Patients may select more than one race category. The Ethnicity Hispanic category is independent of the race categories and may be selected in addition to a race.

Age Group	Total by Age	Age 65	White	African American	Other Race	Ethnicity Hispanic
Male						
18–44	165					
45–54	513	≤64	1,137	62	40	75
55–64	589					
65–74	345					
≥75	257	≥65	565	10	19	20
Total	**1,869**		**1,702**	**72**	**59**	**95**
Female						
18–44	45					
45–54	111	≤64	287	18	[a]	15
55–64	155					
65–74	173					
≥75	265	≥65	418	11	[a]	13
Total	**749**		**705**	**29**	[a]	**28**
Total Male and Female						
18–44	210					
45–54	624	≤64	1,424	80	42	90
55–64	744					
65–74	518					
≥75	522	≥65	983	21	22	33
Total	**2,618**		**2,407**	**101**	**64**	**123**

[a] Frequencies from 1 to 6 suppressed as required by the Massachusetts Department of Public Health data security guidelines.

patient is admitted are called confounders. To fairly assess hospitals, it is important to consider differences in patient health prior to a PCI. Mass-DAC uses several confounders 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 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 exactly the same risk factors prior to a PCI but who are treated in different PCI hospitals would differ. The statistical models used to calculate mortality rates in this report—a hierarchical logistic regression for the *shock or STEMI* cohort and a hierarchical Poisson regression for the *no shock and no STEMI* cohort—model 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 confounder 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 Massachusetts 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 Massachusetts 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 2011. 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 Massachusetts rate, then the hospital mortality is not different than expected. If the interval excludes the Massachusetts unadjusted rate, then the hospital is an outlier. In this case, if the upper limit of the interval is lower than the unadjusted Massachusetts 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 Massachusetts 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. We assumed the between-hospital standard deviation, τ, 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, but has a median of 0.39, permitting the range in the log-odds of in-hospital mortality to be as large as 5. 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 70,000 draws was used and conclusions were based on an additional 5,000 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:

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

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

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 2011.

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 ≤ 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 Massachusetts 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 standard deviation, τ, arose from a half normal 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. Rather than modeling the standard deviation, we also modeled the between-hospital precision, defined as τ^{-2}. We assumed the precision arose from a gamma distribution with shape and inverse scale 0.001. This prior is very flat, implying very little a-priori knowledge.

2. The prior distributions assumed for β and μ were assumed independent normal distributions with mean 0 and variance 1,000 for the components of β and for μ.

7 Hospital Quality Following PCI: Fiscal Year 2011

Of the 12,795 PCI admissions in Massachusetts, 180 patients died during the same admission as the PCI. Table 7.1 on page 34 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 10,177 *no shock and no STEMI* admissions following a PCI. Of the *no shock and no STEMI* PCI admissions, 35.31% 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 one correspond to increased risk of mortality while those less than one correspond to decreased risk of mortality. Patients who had no shock and no STEMI, but were undergoing dialysis prior to a PCI, are 7.3 times more likely to die within the PCI hospital admission than patients not on dialysis. In the *no shock and no STEMI* cohort, 0.23% of the admissions (23 admissions) were adjudicated to belong to the Compassionate Use group with corresponding mortality of less than 27% (data not shown). Admissions in this category were 14.10 times more likely to die during the admission.

Figure 7.1: *ROC Curve-Hierarchical: No Shock and No STEMI Admissions*

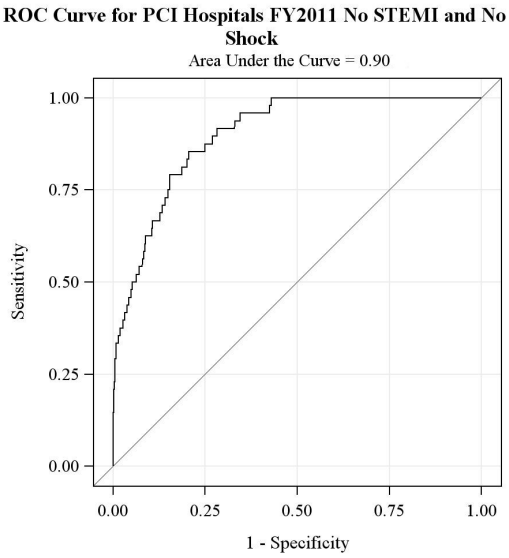


Figure 7.3 on page 35 displays the SMIRs and corresponding 95% posterior intervals. The solid black vertical line in the figure is the unadjusted Massachusetts in-hospital mortality rate of 0.47% for *no shock and no STEMI* admissions. Listed on the left-hand side of the figure are the total number of PCI admissions and the expected in-hospital mortality rates for each hospital. The expected mortality rate provides an overall as-

sessment of case mix severity at each hospital; where higher expected mortality 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 0.90 (Figure 7.1).

Table 7.2 on page 37 lists information similar to Table 7.1 but for the 2,618 *shock or STEMI* admissions. In this cohort, 3.28% of the admissions (86 admissions) were adjudicated to belong to the Compassionate Use group with corresponding mortality of 50.00%; patients falling into this category had approximately 7.99 times the odds of dying compared to those not belonging to the category. Model discrimination ranged from 0% (0 deaths in 26 admissions) in the lowest risk group to 25.73% (91 deaths in 368 admissions) in the highest risk group. A hierarchical logistic regression model indicated an area under the ROC curve of 0.92 (Figure 7.2).

Figure 7.2: *ROC Curve-Hierarchical: Shock or STEMI Admissions*

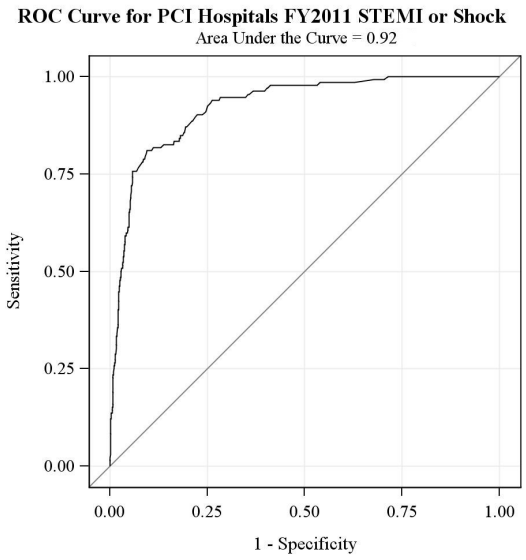


Figure 7.4 on page 36 presents the half normal cross-validated p-values for hospitals treating the *no shock and no STEMI* cohort. No hospital had a p-value smaller than 0.01. Figure 7.6 on page 39 presents similar values for the *shock or STEMI* cohort. The reference line on the graph at 0.01 indicates the cutoff for outliers based on the p-value of 0.01. Any hospital with a bar under this line is considered to be different than expected. No hospital had a p-value smaller than 0.01 for the *no shock and no STEMI* or the *shock or STEMI* cohorts.

Figure 7.5 on page 38 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 5.04% for *shock or STEMI* admissions. All hospitals' 95% intervals cover the Massachusetts unadjusted in-hospital mortality rate.

Table 7.1: *Prevalences and Adjusted Relative Risks of In-Hospital Mortality Following PCI in Adults: No Shock and No STEMI Admissions: Oct 1, 2010–Sep 30, 2011. Based on 10,177 admissions with 48 deaths (0.47%)*

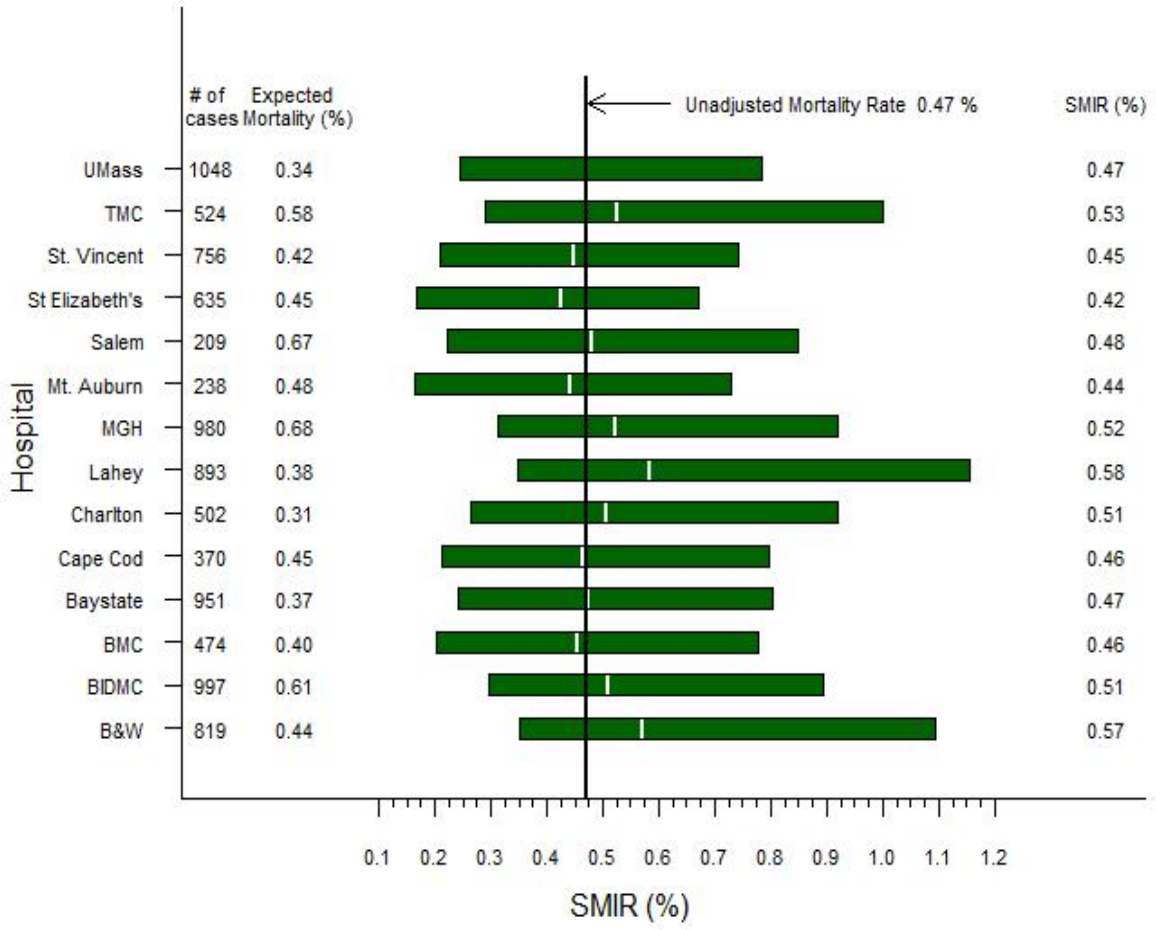
Risk Factor	Prevalence (%)	Relative Risk	95% Interval for Relative Risk
Years over 65	1.07[a]	1.11	(1.07, 1.14)
Dialysis	2.13	7.23	(2.26, 15.91)
Diabetes	35.31	1.35	(0.69, 2.32)
Chronic Lung Disease	15.54	2.77	(1.34, 5.00)
Ejection Fraction <30%	3.00	0.82	(0.15, 2.12)
PCI Status (Ref = Elective)			
Urgent	58.56	10.65	(2.77, 34.54)
Emergency or Salvage	4.14	58.55	(12.22, 198.80)
Proximal LAD ≥70% Stenosis (Target Lesion–see def. on pg 49)	14.23	1.05	(0.39, 2.13)
Compassionate Use	0.23	14.10	(3.94, 33.66)
Transfer In From Another PCI Hospital	10.86	0.79	(0.25, 1.73)
Prior Cardiac Arrest	0.44	7.12	(1.67, 19.00)

Between-Hospital Parameters	**Mean**	**95% Interval**
Between-Hospital Average $\log, \mu$	-8.81	(-10.16, -7.83)
Average Between-Hospital Variance in $\log s, \tau^2$	0.1379	$(5.268 \times 10^{-4}, 0.7269)$

[a] Average age of patients undergoing a PCI procedure is $65 + 1.07 = 66.07$ years of age. For Age, the mean is used instead of prevalence because Age is continuous and not categorical.

Figure 7.3: *Ninety-Five Percent Posterior Intervals for Standardized Mortality Incidence Rates (SMIRs) Following PCI: Oct 1, 2010–Sep 30, 2011: 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 0.47%.



HOSPITAL KEY:
B&W = Brigham and 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 Hospital & Medical Center; **MGH** = Massachusetts General Hospital ; **Mt. Auburn** = Mount Auburn Hospital; **Salem** = North Shore Medical Center–Salem Hospital; **St. Elizabeth's** = Saint Elizabeth's Medical Center; **St. Vincent** = Saint Vincent Hospital; **TMC** = Tufts Medical Center; **UMass** = UMass Memorial Medical Center.

Figure 7.4: *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 present the half normal prior for fitting the hierarchical regression model.

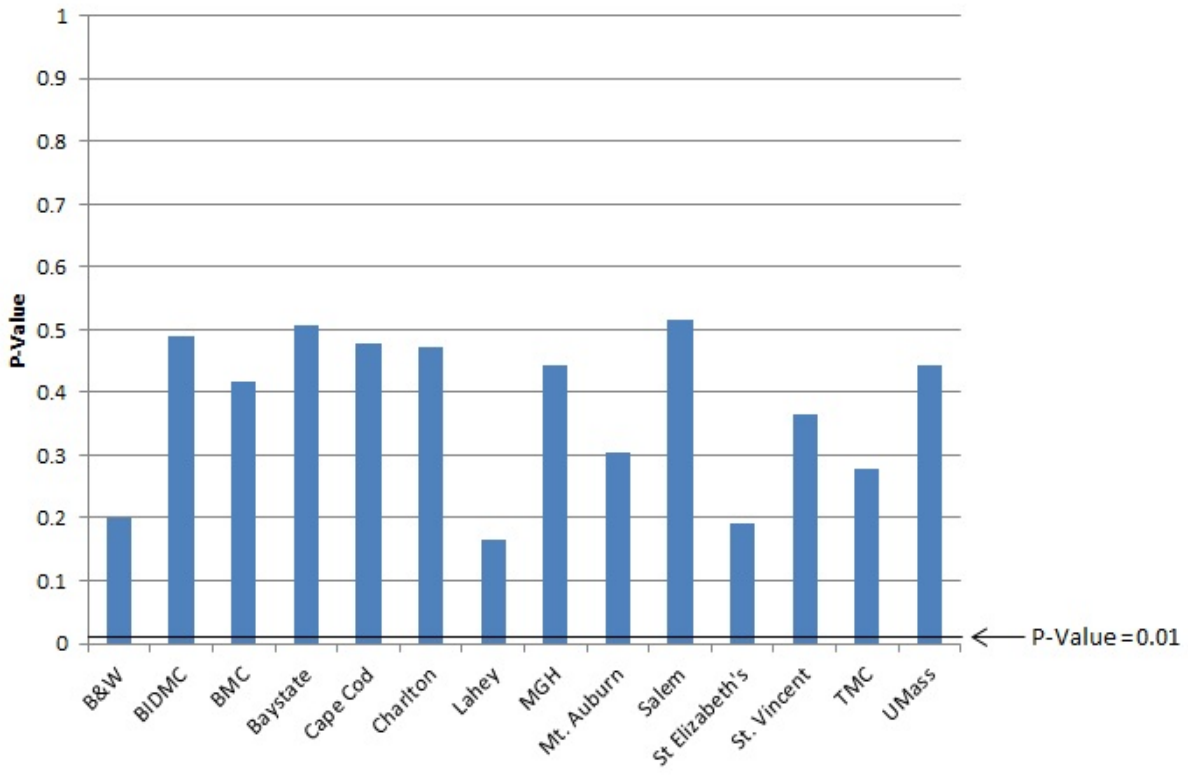


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Table 7.2: *Prevalences and Adjusted Odds Ratios of In-Hospital Mortality Following PCI in Adults: Shock or STEMI Admissions: Oct 1, 2010–Sep 30, 2011. Based on 2,618 admissions with 132 deaths (5.04%)*

Risk Factor	Prevalence (%)	Odds Ratio	95% Interval for Odds Ratio
Age (Ref = <60 Years)			
Age 60-69	26.36	2.72	(1.29, 5.30)
Age 70-79	17.27	6.29	(3.02, 11.93)
Age ≥80	11.96	15.09	(7.40, 28.42)
Ejection Fraction <30%	2.48	2.27	(0.92, 4.70)
PCI Status Emergency or Salvage	98.32	8.56	(0.97, 28.47)
Cardiogenic Shock	8.21	10.39	(6.38, 16.31)
Compassionate Use	3.28	7.20	(3.45, 13.52)
Transfer In From Another PCI Hospital	1.26	0.61	(0.08, 2.00)
Prior Cardiac Arrest	8.94	2.97	(1.63, 4.96)
STEMI Rescue Unstable[a]	4.89	1.48	(0.54, 3.04)

Between-Hospital Parameters	Mean	95% Interval
Between-Hospital Average logit, μ	-7.05	(-8.68, -5.26)
Average Between-Hospital Variance in logits, τ^2	0.0607	(9.649×10^{-5}, 0.289)

[a]The STEMI Rescue Unstable risk factor refers to any admission where the PCI Indication is either for an unstable STEMI >12 hrs from symptom onset or for a Rescue PCI for a STEMI after failed lytics.

Figure 7.5: *Ninety-Five Percent Posterior Intervals for Standardized Mortality Incidence Rates (SMIRs) Following PCI: Oct 1, 2010–Sep 30, 2011: 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 Massachusetts in-hospital mortality rate of 5.04%.

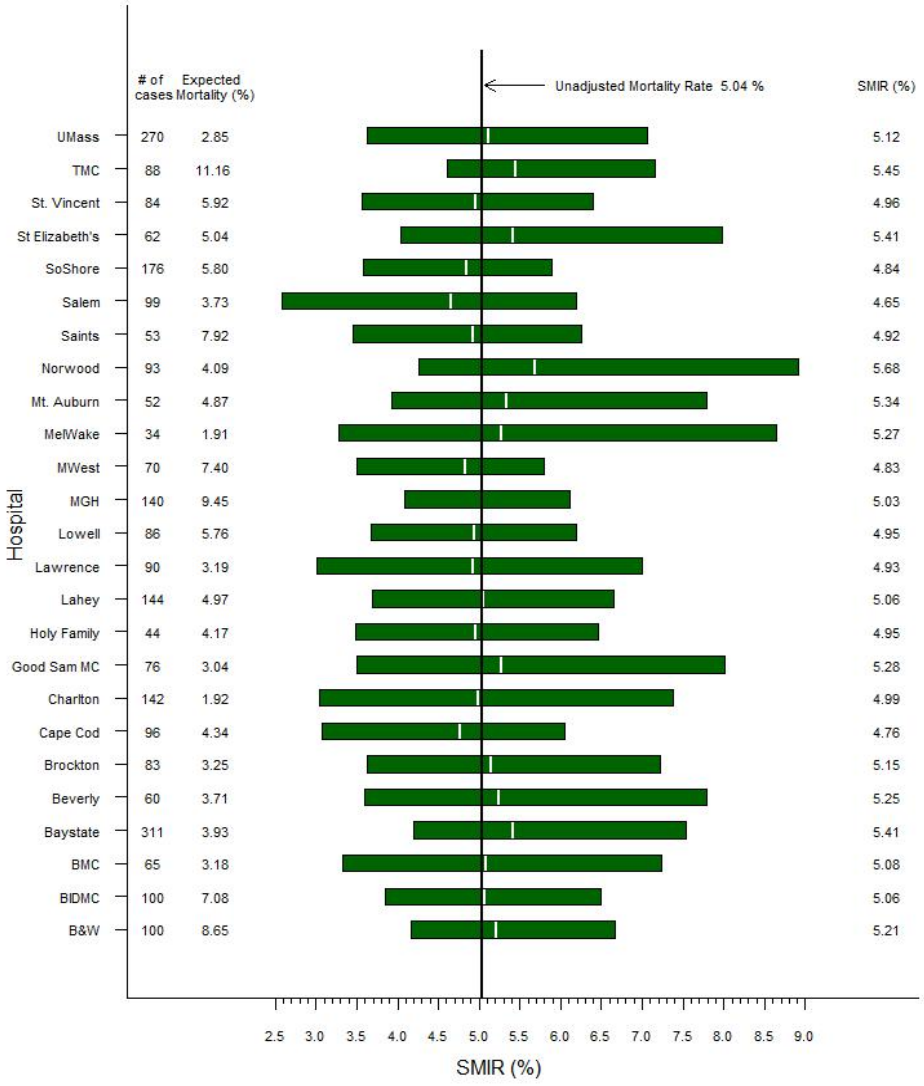

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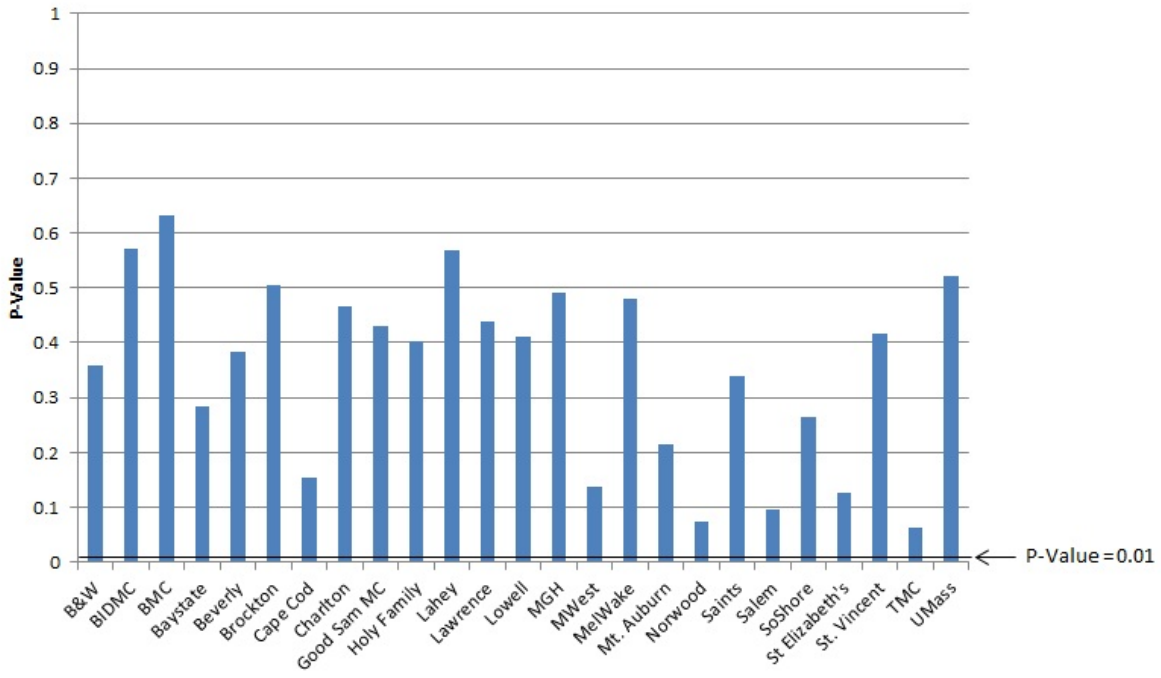
Figure 7.6: *Cross-Validated Posterior P-Values: Shock or STEMI Admissions*

Posterior p-values are listed on the y-axis; the x-axis identifies the hospital. Results present the half normal prior for fitting the hierarchical regression model.



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8 Annual In-Hospital Mortality Trends Following PCI in Massachusetts: April 1, 2003 through September 30, 2011

8.1 Key Changes in Reporting

- FY2006:
  1. Cohorts analyzed over fiscal year October–September rather than calendar year January–December.
  2. Compassionate Use defined as a new category, with collection beginning with procedures performed on October 1, 2005.
  3. Risk model included Compassionate Use for the *shock or STEMI* cohort.
- FY2009:
  1. Exceptional Risk defined as a new category, with collection beginning with procedures performed on October 1, 2008. Admissions falling into this category are eliminated from all models.
  2. Symptom onset timing variable changed, using time from symptom onset to procedure, rather than time from admission.
  3. *Shock and STEMI* cohort definition changed with ACC-NCDR Version 4; see additional details in section 3.1.1.
  4. Risk model included transfer from another acute facility in both the *shock or STEMI* and the *no shock and no STEMI* cohorts.
  5. Risk model replaced renal failure with pre-procedure dialysis.

- FY2010:

    1. Clarified the definition of cardiogenic shock at the time of the PCI procedure to meet the ACC-NCDR cardiogenic shock definition, as well as having clinical symptoms and treatment of shock.

    2. Changes for the Shock or STEMI Model:

        ◇ Added cardiac arrest as a covariate,

        ◇ Added rescue PCI for STEMI (after failed full-dose lytics), and PCI for STEMI (Unstable, >12 hrs from symptom onset) as covariates.

    3. Changes for the No Shock and No STEMI Model:

        ◇ Added cardiac arrest as a covariate,

        ◇ Changed the definition of the covariate LAD to Proximal only, and included target lesion and no prior CABG.

- FY2011:

    1. All tables and figures exclude Exceptional Risk cases in this year's report.

    2. Left main was excluded from both cohort models.

    3. The transfer variable was changed from all acute care hospitals to transfer from another PCI hospital for both cohort models.

    4. Dialysis was removed from the *shock or STEMI* model.

Table 8.1: *Summary of No Shock and No STEMI PCI Admissions and In-Hospital Crude Mortality Percentages: CY 2003-FY 2011*

Year of PCI[a]	Number of Hospitals	Number of Admissions	In-Hospital Crude Mortality (%)	Between-Hospital Variance in logits/logs Mortality	Between-Hospital Standard Deviation in SMIRS (%)
CY 2003[b]	14	10,689	0.76	0.069	0.070
CY 2004	14	14,504	0.68	0.026	0.028
CY 2005	14	13,387	0.64	0.052	0.047
FY 2006	20	12,921	0.64	0.145	0.102
FY 2007	21	11,275	0.50	0.144	0.079
FY 2008	22	11,121	0.63	0.056	0.039
FY 2009	24	10,908[c]	0.46	0.102	0.049
FY 2010	24	10,709[d]	0.40	0.492	0.156
FY 2011[e]	24	10,177	0.47	0.138	0.064

[a] CY denotes calendar year (Jan-Dec); FY denotes fiscal year (Oct-Sep).
[b] Represents nine months of admissions.
[c] 10,909 cases includes Exceptional Risk admissions; (mortality=0.47).
[d] There were no Exceptional Risk admissions in this cohort.
[e] No Exceptional Risk admissions reported in this fiscal year.

Table 8.2: *Summary of Shock or STEMI PCI Admissions and In-Hospital Crude Mortality Percentages: CY 2003-FY 2011*

Year of PCI[a]	Number of Hospitals	Number of Admissions	In-Hospital Crude Mortality (%)	Between-Hospital Variance in logits/logs Mortality	Between-Hospital Standard Deviation in SMIRS (%)
CY 2003[b]	18	1,968	6.86	0.039	0.282
CY 2004	21	2,606	5.76	0.206	0.963
CY 2005	21	2,752	6.00	0.055	0.395
FY 2006	21	2,800	5.60	0.106	0.533
FY 2007	22	2,788	5.49	0.854	2.550
FY 2008	24	2,721	4.78	0.069	0.306
FY 2009	24	2,578[c]	5.12	0.052	0.206
FY 2010	25	2,485[d]	5.07	0.216	0.772
FY 2011[e]	25	2,618	5.04	0.061	0.243

[a] CY denotes calendar year (Jan-Dec); FY denotes fiscal year (Oct-Sep).
[b] Represents nine months of admissions.
[c] 2,584 cases includes Exceptional Risk admissions; (mortality=5.34).
[d] 2,493 cases includes Exceptional Risk admissions; (mortality=5.38).
[e] No Exceptional Risk admissions reported in this fiscal year.

9 Important Definitions

ACC-NCDR definition refers to the ACC-NCDR data collection variable definitions used by the Massachusetts hospitals for data collection for PCIs from October 2010 through September 2011. Many of the definitions used in this section were extracted from the ACC-NCDR CathPCI Data Specifications.[1, 2]

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 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 at Start of PCI: (ACC-NCDR definition) Indicate if the patient is in cardiogenic shock at the start of the PCI procedure.

Cardiogenic shock is defined as a sustained (> 30 minutes) episode of systolic blood pressure < 90mmHg, and/or cardiac index < 2.2 L/min/m^2 determined to be secondary to cardiac dysfunction, and/or the requirement for parenteral inotropic or vasopressor agents or mechanical support (e.g., IABP, extracorporeal circulation, ventricular assist devices) to maintain blood pressure and cardiac index above those specified levels.

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 definition) Indicate if the patient has a history of chronic lung disease. Chronic lung disease can include patients with chronic obstructive pulmonary disease, chronic bronchitis, or emphysema. It can also include a patient who is currently being chronically treated with inhaled or oral pharmacological therapy (e.g., beta-adrenergic agonist, anti-inflammatory agent, leukotriene receptor antagonist, or steroid). Patients with asthma or seasonal allergies are not considered to have chronic lung disease.

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 B 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 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 definition) A history of diabetes, regardless of duration of disease, or need for anti-diabetic agents.

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 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.

Exceptional Risk: Exceptional Risk is used to categorize rare high-risk cases, with high potential patient benefit, in which the predictors of risk are not included in the current risk-adjustment model. See Appendix B for Exceptional Risk criteria.

Left Main Stenosis Percent: (ACC-NCDR definition) Indicate the percent of most severe stenosis assessed, for the Left Main coronary artery. Stenosis represents the percentage diameter reduction, ranging from 0 to 100, associated with the identified vessels. 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 percent stenosis noted.

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 definition) The PCI status is determined at the time the operator decides to perform a PCI.

Elective: The procedure can be performed on an outpatient basis or during a subsequent hospitalization without significant risk of infarction or death. For stable inpatients, the procedure is being performed during this hospitalization for convenience and ease of

scheduling and NOT because the patient's clinical situation demands the procedure prior to discharge. If the diagnostic catheterization was elective and there were no complications, the PCI would also be elective.

Urgent: The procedure should be performed on an inpatient basis and prior to discharge because of significant concerns that there is risk of ischemia, infarction and/or death. Patients who are outpatients or in the emergency department at the time that the cardiac catheterization is requested would warrant an admission based on their clinical presentation.

Emergency: The procedure should be performed as soon as possible because of substantial concerns that ongoing ischemia and/or infarction could lead to death. "As soon as possible" refers to a patient who is of sufficient acuity that you would cancel a scheduled case to perform this procedure immediately in the next available room during business hours, or you would activate the on-call team were this to occur during off-hours.

Salvage: The procedure is a last resort. The patient is in cardiogenic shock when the PCI begins (i.e., at the time of introduction into a coronary artery or bypass graft of the first guidewire or intracoronary device for the purpose of mechanical revascularization). Within the last ten minutes prior to the start of the case or during the diagnostic portion of the case, the patient has also received chest compressions for a total of at least sixty seconds or has been on unanticipated extracorporeal circulatory support (e.g., extracorporeal mechanical oxygenation, or cardiopulmonary support).

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.

PCI Indication: (ACC-NCDR definition) Indicate the reason the PCI is being performed.

- Immediate PCI for patient with STEMI (or STEMI equivalent).
- PCI for patient with STEMI (or STEMI equivalent) more than 12 hours from symptom onset with recurrent or persistent symptoms, symptoms of heart failure or ventricular arrhythmia.

- Patient with STEMI (or STEMI equivalent) who is stable, and is more than 12 hours from symptom onset. The patient does not have any symptoms of recurrent or persistent ischemia, symptoms of heart failure, or electrical instability.
- PCI for patient with STEMI (or STEMI equivalent) who is stable after receiving full-dose thrombolysis.
- Rescue PCI for patient with STEMI (or STEMI equivalent) after failed full-dose lytics.
- Includes patients with unstable angina or Non-STEMI who have high risk features for short-term risk of death or nonfatal MI.
- The second PCI of a planned, staged procedure (the first PCI could have been during a prior admission, or during this admission).
- Other: Includes patients that don't fit into any of the above categories. This can include patients with elective or urgent status, status/post cardiac arrest or cardiogenic shock but without ECG or biomarker evidence of acute infarction.

Prior Cardiac Arrest within 24 Hours: (ACC-NCDR definition) Indicate if the patient has had an episode of cardiac arrest within 24 hours of procedure.

Proximal LAD Stenosis Percent: (ACC-NCDR definition) Indicate the best estimate of most severe percent stenosis in the proximal left anterior descending (LAD) coronary artery. This does not include collateral circulation. Stenosis represents the percentage diameter reduction, ranging from 0 to 100, associated with the identified vessels. 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 percent stenosis noted.

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 fac-

tors 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 PCI programs) multiplied by the state unadjusted mortality 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.

Target Lesion: (ACC-NCDR definition) A stenosis within a coronary artery or coronary artery bypass graft on which mechanical coronary revascularization is attempted during a single procedure.

Transfer in from another PCI Hospital: The patient was transferred from another acute care facility that has a PCI program in the Commonwealth of Massachusetts (even if he/she was transferred to the emergency department) for this episode of care.

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 2011 Massachusetts Cardiac Care Hospital Outlier Committee

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

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FY 2011 Massachusetts Cardiac Care Hospital Outlier Committee

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

. . . Continued from prior page

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FY 2011 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.

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FY 2011 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.

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FY 2011 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 approve or deny the request before sending the proposal to the Massachusetts Department of Public Health for final approval.

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FY 2011 Exceptional Risk Committee for PCI

This committee reviews cases submitted as Exceptional Risk to determine if they meet the Exceptional Risk Criteria.

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A Appendix

ACC-NCDR DATA ABSTRACTION TOOL[1, 2]
VERSION 4

Mass-DAC harvests all optional and not harvested ACC-NCDR variables

CathPCI Registry®

NCDR® CathPCI Registry® v4.4

Diagnostic Catheterization and Percutaneous Coronary Intervention Registry

A. Demographics

Last Name[2000]: | **First Name**[2010]: | **Middle Name**[2020]:

SSN[2030]: - - ☐ SSN N/A[2031] | **Patient ID**[2040]: (auto) | **Other ID**[2045]:

Birth Date[2050]: | **Sex**[2060]: O Male O Female

Race: (check all that apply)
☐ White[2070] ☐ Black/African American[2071] ☐ Asian[2072]
☐ American Indian/Alaskan Native[2073] ☐ Native Hawaiian/Pacific Islander[2074]

Hispanic or Latino Ethnicity[2076]: O No O Yes

B. Episode of Care

Arrival Date/Time[3000,3001]: | **Patient Zip Code**[3005]: | ☐ Zip Code N/A[3006]

Admit Source[3010]: O Emergency department O Transfer in from another acute care facility O Other

Insurance Payors: (check all that apply)
☐ Private Health Insurance[3020] ☐ Medicare[3021] ☐ Medicaid[3022] ☐ Military Health Care[3023]
☐ State-Specific Plan (non-Medicaid)[3024] ☐ Indian Health Service[3025] ☐ Non-US Insurance[3026] ☐ None[3027]

HIC #[3030]:

C. History and Risk Factors (On arrival to CathPCI facility)

Current/Recent Smoker (< 1 year)[4000]:	O No	O Yes	**Height**[4055]: (cm)		
Hypertension[4005]:	O No	O Yes	**Weight**[4060]: (kg)		
Dyslipidemia[4010]:	O No	O Yes	**Currently On Dialysis**[4065]:	O No	O Yes
Family History of Premature CAD[4015]:	O No	O Yes	**Cerebrovascular Disease**[4070]:	O No	O Yes
Prior MI[4020]:	O No	O Yes	**Peripheral Arterial Disease**[4075]:	O No	O Yes
Prior Heart Failure[4025]:	O No	O Yes	**Chronic Lung Disease**[4080]:	O No	O Yes
Prior Valve Surgery/Procedure[4030]:	O No	O Yes	**Diabetes Mellitus**[4085]:	O No	O Yes
Prior PCI[4035]:	O No	O Yes	→**If** Yes, **Diabetes Therapy**[4090]:	O None O Diet O Oral O Insulin O Other	
→**If** Yes, **Most Recent PCI Date**[4040]:					
Prior CABG[4045]:	O No	O Yes			
→**If** Yes, **Most Recent CABG Date**[4050]:					

D. Cath Lab Visit (Complete For Each Cath Lab Visit)

Clinical Evaluation Leading To The Procedure

CAD Presentation[5000]: O No Sxs, no angina *(14 days)* O Sx unlikely to be ischemic *(14 days)* O Stable angina *(42 days)*
O Unstable angina *(60 days)* O Non-STEMI *(7 days)* O STEMI *(7 days)*

→**If** STEMI or Non-STEMI, **Symptom Onset Date/Time**[5005,5006] *(7 days)*: _____ ☐ Time Estimated[5007] ☐ Time Not Available[5008]

→**If** STEMI, **Thrombolytics**[5010]: O No O Yes →**If** Yes, **Start Date/Time**[5015,5016]:

Anginal Classification w/in 2 Weeks[5020]: O No symptoms O CCS I O CCS II O CCS III O CCS IV

Anti-Anginal meds w/in 2 Weeks[5025]: O No O Yes → **If** Yes, **Type** (check all that apply):
☐ Beta Blockers[5026] ☐ Ca Channel Blockers[5027] ☐ Long Acting Nitrates[5028] ☐ Ranolazine[5029] ☐ Other[5030]

Heart Failure w/in 2 Weeks[5040]: O No O Yes

→**If** Yes, **NYHA Class w/in 2 Weeks**[5045]: O Class I O Class II O Class III O Class IV

Cardiomyopathy or LV Systolic Dysfunction[5050]:	O No	O Yes	**Cardiogenic Shock w/in 24 Hours**[5060]:	O No	O Yes
Pre-operative Evaluation Before Non-Cardiac Surgery[5055]:	O No	O Yes	**Cardiac Arrest w/in 24 Hours**[5065]:	O No	O Yes

Stress or Imaging Studies Performed[5100]: O No O Yes →**If** Yes, **Specify Test Performed:**

Test Performed	No	Yes		Result		Risk/Extent Of Ischemia
Standard Exercise Stress Test[5200,5201,5202]: (w/o imaging)	O	O	→ **If** Yes,	O Negative O Positive O Indeterminant O Unavailable	→ **If** Positive,	O Low O Intermediate O High O Unavailable
Stress Echocardiogram[5210,5211,5212]:	O	O	→ **If** Yes,	O Negative O Positive O Indeterminant O Unavailable	→ **If** Positive,	O Low O Intermediate O High O Unavailable
Stress Testing w/SPECT MPI[5220,5221,5222]:	O	O	→ **If** Yes,	O Negative O Positive O Indeterminant O Unavailable	→ **If** Positive,	O Low O Intermediate O High O Unavailable
Stress Testing w/CMR[5230,5231,5232]:	O	O	→ **If** Yes,	O Negative O Positive O Indeterminant O Unavailable	→ **If** Positive,	O Low O Intermediate O High O Unavailable
Cardiac CTA[5240,5241]:	O	O	→ **If** Yes,	O No disease O 1VD O Indeterminant O Unavailable	O 2VD	O 3VD
Coronary Calcium Score[5250]:	O	O	→ **If** Yes,	**Calcium Score:**[5251] _____		

PROCEDURE INFORMATION

Procedure Date/Time[5300/5301]: | **Fluoro Time/Dose**[5320,5321]: minutes **OR** mGy

PCI[5305]: O No O Yes | **Contrast Volume**[5325]:

Diagnostic Cath[5310]: O No O Yes

Other Procedure (in conj w/Dx Cath or PCI)[5315]: O No O Yes

MECHANICAL VENTRICULAR SUPPORT

IABP[5330]: O No O Yes

→ **If** Yes, **Timing**[5335]: O In place at start of procedure O Inserted during procedure and prior to PCI O Inserted after PCI has begun

Other Mechanical Ventricular Support[5340]: O No O Yes

→ **If** Yes, **Timing**[5345]: O In place at start of procedure O Inserted during procedure and prior to PCI O Inserted after PCI has begun

ARTERIAL ACCESS:

Arterial Access Site[5350]: O Femoral O Brachial O Radial O Other

Closure Method(s)[5355]:

1
2
3
4

☐ Method Not Documented[5356]

E. DIAGNOSTIC CATHETERIZATION PROCEDURE (COMPLETE FOR EACH DIAGNOSTIC CATH)

Operator's Name[6000, 6005, 6010]: | **Operator's NPI**[6015]:

Diagnostic Coronary Angiography[6020]: O No O Yes

Left Heart Cath[6025]: O No O Yes

Cardiac Transplant Evaluation[6030]: O No O Yes

→ **If** Yes, **Type**[6035]: O Donor for cardiac transplant O Candidate to receive a cardiac transplant O Post cardiac transplant follow up

Diag Cath Status[6040]: O Elective O Urgent O Emergency O Salvage

Rx Recommendation[6045]: (after diagnostic cath) O None O Medical therapy and/or counseling O PCI w/o planned CABG O CABG (including planned hybrid CABG/PCI procedures) O Other cardiac therapy without CABG or PCI

F. Best Estimate of Coronary Anatomy (Complete for each Cath Lab visit)

Dominance[6100]: O Left O Right O Co-dominant

Coronary Territory	Native Artery Percent Stenosis in >=2mm vessels	Grafts Supplying Coronary Territory (Note 1) Percent Stenosis
Left Main	_____%[6110] ☐ Not Available[6111]	
Prox LAD	_____%[6120] ☐ Not Available[6121]	_____%[6170] ☐ Not Available[6171]
Mid/Distal LAD, Diag Branches	_____%[6130] ☐ Not Available[6131]	_____%[6180] ☐ Not Available[6181]
Circ, OMs, LPDA, LPL Branches	_____%[6140] ☐ Not Available[6141]	_____%[6190] ☐ Not Available[6191]
RCA, RPDA, RPL, AM Branches	_____%[6150] ☐ Not Available[6151]	_____%[6200] ☐ Not Available[6201]
Ramus	_____%[6160] ☐ Not Available[6161]	_____%[6210] ☐ Not Available[6211]

G. PCI Procedure (Complete for each Cath Lab visit in which a PCI was attempted or performed)

Operator's Name[7000,7005,7010]: **Operator's NPI**[7015]:

PCI Status[7020]: O Elective O Urgent O Emergency O Salvage

Pre-PCI LVEF[7025]: **%** ☐ Pre-PCI LVEF Not Assessed[7026]

Cardiogenic Shock at Start of PCI[7030]: O No O Yes

PCI Indication[7035]:
O Immediate PCI for STEMI
O PCI for STEMI (Unstable, >12 hrs from Sx onset)
O PCI for STEMI (Stable, >12 from hrs Sx onset)
O PCI for STEMI (stable after successful full-dose Thrombolysis)
O Rescue PCI for STEMI (after failed full-dose lytics)
O PCI for high risk Non-STEMI or unstable angina
O Staged PCI
O Other

→ **If** Immediate PCI for STEMI, **STEMI or STEMI Equivalent First Noted**[7040]: O First ECG O Subsequent ECG

→ **If** Subsequent ECG, **Subsequent ECG with STEMI or STEMI Equivalent Date/Time**[7045, 7046]: _____

→ **If** Immediate PCI for STEMI, **First Device Activation Date/Time**[7050,7051]: _____

→ **If** Immediate PCI for STEMI, **Transferred In for Immediate PCI for STEMI**[7055]: O No O Yes

→ **If** Yes, **Date/Time ED Presentation at Referring Facility**[7060,7061]: _____

→ **If** Immediate PCI for STEMI, **Non-System Reason for Delay in PCI**[7065]:

O Difficult vascular access
O Cardiac arrest and/or need for intubation before PCI
O Patient delays in providing consent for the procedure
O Difficulty crossing the culprit lesion during the PCI procedure
O Other
O None

Procedure Medications (Administered within 24 hours prior to and during the PCI procedure)

Category	Medication[9500]	Administered[9510]
Anticoagulants	Fondaparinux	O No O Yes O Contraindicated O Blinded
	Low Molecular Weight Heparin (any)	O No O Yes O Contraindicated O Blinded
	Unfractionated Heparin (any)	O No O Yes O Contraindicated O Blinded
Aspirin	Aspirin (any)	O No O Yes O Contraindicated O Blinded
Direct Thrombin Inhibitors	Bivalirudin	O No O Yes O Contraindicated O Blinded
	Direct Thrombin Inhibitor (other)	O No O Yes O Contraindicated O Blinded
Glycoprotein IIb/IIIa Inhibitors	GP IIb/IIIa (any)	O No O Yes O Contraindicated O Blinded
Thienopyridines	Clopidogrel	O No O Yes O Contraindicated O Blinded
	Ticlopidine	O No O Yes O Contraindicated O Blinded
	Prasugrel	O No O Yes O Contraindicated O Blinded

Note 1: CABG Date[9020] must be less than Procedure Date/Time[5300/5301] or Prior CABG[4045] = "Yes" to complete these elements.

H. Lesions and Devices (Complete for each PCI attempted or performed)

	1	2
Lesion Counter[7100]:		
Segment Number(s)[7105]:	_____ , _____, _____, _____, _____	_____ , _____, _____, _____, _____
If CAD Presentation[5000] is 'STEMI', 'Non-STEMI', or 'Unstable angina', **Culprit Lesion**[7110]:	O No O Yes O Unknown	O No O Yes O Unknown
Stenosis Immediately Prior to Rx[7115]:	_____%	_____%
→ **If** 100%, **Chronic Total Occlusion**[7120]:	O No O Yes	O No O Yes
→ **If** 40-70%, **IVUS**[7125]:	O No O Yes	O No O Yes
→ **If** 40-70%, **FFR**[7130]:	O No O Yes	O No O Yes
→ **If** Yes, **FFR Ratio**[7135]:	_____	_____
Pre-procedure TIMI Flow[7140]:	O 0 O 1 O 2 O 3	O 0 O 1 O 2 O 3
Prev Treated Lesion[7145]:	O No O Yes	O No O Yes
→ **If** Yes, **Timeframe**[7150]:	O < 1 month O 1-5 months O 6-12 months O 1-2 years O >2 years O Time unknown	O < 1 month O 1-5 months O 6-12 months O 1-2 years O >2 years O Time unknown
→ **If** Yes, **Treated with Stent**[7155]:	O No O Yes	O No O Yes
→ **If** Yes, **In-Stent Restenosis**[7160]:	O No O Yes	O No O Yes
In-Stent Thrombosis[7165]:	O No O Yes	O No O Yes
Stent Type[7170]:	O DES O Non-DES O Type unknown	O DES O Non-DES O Type unknown
Lesion in Graft[7175]:	O Not in Graft O Vein O LIMA O Other artery	O Not in Graft O Vein O LIMA O Other artery
→**If** Vein, LIMA, Other, **Location in Graft**[7180]:	O Aortic O Body O Distal	O Aortic O Body O Distal
Lesion Complexity[7185]:	O Non-High/Non-C O High/C	O Non-High/Non-C O High/C
Lesion Length (mm)[7190]:	_____mm	_____mm
Thrombus Present[7195]:	O No O Yes	O No O Yes
Bifurcation Lesion[7200]:	O No O Yes	O No O Yes
Guidewire Across Lesion[7205]:	O No O Yes	O No O Yes
→ **If** Yes, **Stenosis Post-Procedure**[7210]:	_____%	_____%
→ **If** Yes, **Post-Procedure TIMI Flow**[7215]:	O 0 O 1 O 2 O 3	O 0 O 1 O 2 O 3
→ **If** Yes, **Device(s) Deployed**[7220]:	O No O Yes	O No O Yes

	Intracoronary Device(s) Used[7225]	Associated Lesion(s)[7100]	Diameter[7235]	Length[7240]
1		_____ , _____, _____		
2		_____ , _____, _____		
3				
4				
5				

Intraprocedure Events — **Significant Dissection**[7245]: O No O Yes — **Perforation**[7250]: O No O Yes

I. Labs (Complete for each Cath Lab visit in which a PCI was attempted or performed)

Pre-Procedure (performed at your facility)			**Post-Procedure** (post-procedure only)			
CK-MB[7300]	_____ ng/mL	☐ CK Not Applicable[7301] ☐ CK Drawn and Normal[7302]	**CK-MB**[7325]	_____ ng/mL	☐ CK Not Applicable[7326] ☐ CK Drawn and Normal[7327]	(peak value 6-24 hrs)
Troponin I[7305]	_____ ng/mL	☐ Not Drawn[7306]	**Troponin I**[7330]	_____ ng/mL	☐ Not Drawn[7331]	(peak value 6-24 hrs)
Troponin T[7310]	_____ ng/mL	☐ Not Drawn[7311]	**Troponin T**[7335]	_____ ng/mL	☐ Not Drawn[7336]	(peak value 6-24 hrs)
Creatinine[7315]	_____ mg/dL	☐ Not Drawn[7316]	**Creatinine**[7340]	_____ mg/dL	☐ Not Drawn[7341]	(highest value)
Hemoglobin[7320]	_____ g/dL	☐ Not Drawn[7321]	**Hemoglobin**[7345]	_____ g/dL	☐ Not Drawn[7346]	(lowest w/in 72 hrs)

J. Intra and Post-Procedure Events (Complete For Each Cath Lab Visit)

Myocardial Infarction[8000]: (Positive Biomarkers)	O No	O Yes	**Bleeding Event w/in 72 Hours**[8050]:	O No O Yes
Cardiogenic Shock[8005]:	O No	O Yes	→**If Yes, Bleeding at Access Site**[8055]:	O No O Yes
Heart Failure[8010]:	O No	O Yes	→**If Yes, Hematoma at Access Site**[8060]:	O No O Yes
CVA/Stroke[8015]:	O No	O Yes	→**If Yes, Size**[8061]: O <3cm O 3-5cm O >5-10 O >10cm	
→**If Yes, Hemorrhagic Stroke**[8021]:	O No	O Yes	→**If Yes, Retroperitoneal Bleeding**[8070]:	O No O Yes
Tamponade[8025]:	O No	O Yes	→**If Yes, GI Bleed**[8080]:	O No O Yes
New Requirement for Dialysis[8030]:	O No	O Yes	→**If Yes, GU Bleed**[8090]:	O No O Yes
Other Vascular Complications Req Rx[8035]:	O No	O Yes	→**If Yes, Other Bleed**[8100]:	O No O Yes
RBC/Whole Blood Transfusion [8040]:	O No	O Yes		
→**If Yes, Hgb Prior to Transfusion**[8041]:	_____ g/dL			

K. Discharge (Complete this section for each Episode of Care)

CABG[9000]: O No O Yes

→ **If Yes, CABG Status**[9005]: O Elective O Urgent O Emergency O Salvage

→ **If Yes, CABG Indication**[9010]: O PCI complication O PCI failure without clinical deterioration
O Treatment of CAD without PCI immediately preceding CABG O PCI/CABG hybrid procedure

→**If Yes, Location**[9015]: O At your facility O Transferred to other facility

→**If At your facility, CABG Date/Time**[9020,9021]:

Other Major Surgery[9025]: O No O Yes

LVEF[9030]: % ☐ LVEF Not Assessed[9031]

Discharge Date[9035]:

Discharge Status[9040]: O Alive O Deceased

→**If Alive, Discharge Location**[9045]: O Home O Extended care/TCU/rehab O Other acute care hospital
O Nursing home O Hospice O Other O Left against medical advice (AMA)

→**If Alive, Cardiac Rehabilitation Referral**[9050]: O No O Yes O Ineligible

→**If Deceased, Death in Lab**[9055]: O No O Yes

→**If Deceased, Primary Cause of Death**[9060]: O Cardiac O Neurologic O Renal O Vascular O Infection
O Valvular O Pulmonary O Unknown O Other

Hospital Status[9065]: O Outpatient O Outpatient converted to inpatient O Inpatient

Discharge Medications (Prescribed at Discharge – Complete for each Episode of Care in which a PCI was attempted or performed)

Category	Medication[9505]	Administered[9510]
Discharge medications are not required for patients who expired or were discharged to 'Other acute care Hospital', 'Hospice', or 'AMA'.		
ACE Inhibitors	ACE Inhibitor (any)	O No O Yes O Contraindicated O Blinded
ARBs	ARB (any)	O No O Yes O Contraindicated O Blinded
Aspirin	Aspirin (any)	O No O Yes O Contraindicated O Blinded
Beta Blockers	Beta Blocker (any)	O No O Yes O Contraindicated O Blinded
Lipid Lowering Agents	Statin (any)	O No O Yes O Contraindicated O Blinded
	Non-Statin (any)	O No O Yes O Contraindicated O Blinded
Thienopyridines	Clopidogrel	O No O Yes O Contraindicated O Blinded
	Ticlopidine	O No O Yes O Contraindicated O Blinded
	Prasugrel	O No O Yes O Contraindicated O Blinded

B Appendix

MASS-DAC FISCAL YEAR 2011

COMPASSIONATE USE CRITERIA

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. (patient must be in the first 24 hours of their STEMI or the STEMI is incomplete or the patient is in shock at the start of the PCI.) 4. Last remaining coronary vessel intervention in the setting of STEMI or cardiogenic shock (patient must be in the first 24 hours of their STEMI or the STEMI is incomplete or the patient is in shock at the start of the PCI.)	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.

COMPASSIONATE USE CRITERIA

Criteria	Definition	Additional Information
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.
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.

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 or Exceptional Risk.

C Appendix

MASS-DAC FISCAL YEAR 2011

EXCEPTIONAL RISK CRITERIA

EXCEPTIONAL RISK CRITERIA

Criteria	Definition	Additional Information
Exceptional Risk PCI **(Effective as of Fiscal Year 2009 PCI cases)**	The category for Exceptional Risk consideration began 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 believes that the case in question met the following two 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 **Exceptional Risk is a separate category from Compassionate Use**.	**Please review the Exceptional Risk Adjudication Protocol and the Exceptional Risk case studies, on the Mass-DAC Website, http://www.massdac.org/PCICompUse, for additional information and requirements for submitting an exceptional case for audit.** The intent of the exceptional risk designation is to categorize rare uniquely high risk cases, with high potential patient benefit, in which the predictors of risk are not included in the current Mass-DAC risk adjustment model. The risk of in-hospital mortality can be based on anatomical or clinical considerations, but will typically involve a second, acutely life-threatening condition for which PCI is urgently required in order to allow continued treatment. It is expected that nearly all exceptional risk cases will involve severe time pressure in order to make a therapeutic decision (such as the need to treat STEMI in a patient with a second severe medical co morbidity) and that elective/urgent cases will rarely qualify for exceptional risk designation. Of note, a case being declined by cardiac surgery or by patient preference is not sufficient to warrant exceptional risk designation. Refractory ischemic instability may not, in and of itself, qualify for exceptional risk designation unless all reasonable medical options have been exhausted. Finally, it is important to note that a non-cardiac cause of death is not, in and of itself, justification for exceptional risk designation. **Combined Structural Heart Procedures** – Patients who undergo PCI as part of a therapy for combined coronary disease and structural heart interventional therapies and meet the criteria for Exceptional Risk can be submitted for review by the Exceptional Risk Committee. Such concomitant structural interventional procedures may include (but are not limited to): ventricular septal closure procedures, aortic valvuloplasty procedures, mitral valvuloplasty procedures, ASD closures, surgical/PCI hybrid revascularization and valvular therapies, and endovascular valve implantation procedures. Combined structural interventions with PCI are very rare procedures (estimated to represent less than 30 total procedures per year in MA). These cases should be submitted using the current "Exceptional Risk" process. Continued on next page …

EXCEPTIONAL RISK CRITERIA

Criteria	Definition	Additional Information
		An example of exceptional risk case could include a patient presenting with simultaneous life-threatening medical condition such as a STEMI as well as impending rupture of an abdominal aortic aneurysm. 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 (such as a rupturing abdominal aortic aneurysm). The review committee will require the following: 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 CD containing the diagnostic and PCI procedure imaging.

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 or Exceptional Risk.

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