Adult Percutaneous Coronary Intervention in the Commonwealth of Massachusetts

Fiscal Year 2013 Report
(October 1, 2012 through September 30, 2013)

Hospital Risk-Standardized In-Hospital Mortality Rates

Massachusetts Data Analysis Center
Department of Health Care Policy
Harvard Medical School
180 Longwood Avenue
Boston, MA 02115
www.massdac.org

October 2015

Updated March 2017

Contracted by the Massachusetts Department of Public Health

Massachusetts Data Analysis Center

Director
Sharon-Lise Normand, Ph.D.
Professor of Health Care Policy (Biostatistics), Harvard Medical School
Professor, Department of Biostatistics, Harvard School of Public Health

Program Staff

Ann Lovett, R.N., M.A.
Program Manager
Harvard Medical School

Treacy Silverstein Silbaugh, B.S.
Programmer/Analyst
Harvard Medical School

Robert Wolf, M.S.
Biostatistician
Programmer/Analyst
Harvard Medical School

Matthew Cioffi, M.S.
Senior Data Manager/Programmer
Harvard Medical School

Katya Zelevinsky, B.A.
Programmer/Analyst
Harvard Medical School

Caroline Wood, M.S.
Project Assistant
Harvard Medical School

Senior Medical Advisors

Cardiac Surgery

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

Interventional Cardiology

Frederic Resnic, M.D.
Chairman
Department of Cardiovascular Medicine
Lahey Hospital & Medical Center

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

Massachusetts Percutaneous Coronary Intervention Hospitals with Back-up Cardiac Surgery

Baystate Medical Center
759 Chestnut Street
Springfield, MA 01199

Beth Israel Deaconess Medical Center
330 Brookline Avenue
Boston, MA 02215

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

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

Cape Cod Hospital
27 Park Street
Hyannis, MA 02601

Lahey Hospital & Medical Center
41 Mall Road
Burlington, MA 01805

Massachusetts General Hospital
55 Fruit Street
Boston, MA 02114

Mount Auburn Hospital
330 Mount Auburn Street
Cambridge, MA 02138

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

Southcoast Health
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

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

Norwood Hospital
800 Washington Street
Norwood, MA 02062

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

Contents

List of Tables

List of Figures

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

This is the eleventh in a series of reports on risk-standardized, in-hospital mortality for the 24 cardiac programs licensed by the Massachusetts Department of Public Health (the Department) in the Commonwealth. Risk-standardized, in-hospital mortality is one of several indicators used to assess quality of care.

The Bureau of Health Care Safety and Quality within the Department contracts with the Massachusetts Data Analysis Center (Mass-DAC) to complete this report. The provision of this 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.

The Department, in collaboration with Mass-DAC, collects, monitors, and validates patient-specific outcome data from all hospitals that perform percutaneous coronary intervention (PCI). This report contains analysis of data on 12,132 hospital admissions in which at least one PCI was performed during the period October 1, 2012 through September 30, 2013. The Department and Mass-DAC do not publicly report on physician-specific mortality rates. However, data on individual interventional cardiologists performing PCIs are collected and analyzed. After review by a committee of medical 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.

Several additional points deserve mention. First, a randomized trial comparing effectiveness and safety of “elective”, i.e., non-emergency, angioplasty between community hospitals without

cardiac surgery and hospitals with cardiac surgery concluded in September 2011. The MASS-COMM Trial (NCT01116882) included patients with ischemic heart disease treated by elective PCI. A MASS-COMM post-randomization phase cohort study was ongoing during fiscal year 2012. Beginning in August 2013, hospital participants in the MASS-COMM trial were approved by the Department to perform elective PCIs, with limited restrictions, in addition to primary PCIs. Beverly Hospital was not a participant in MASS-COMM and can only perform primary PCIs.

Second, the fiscal year 2013 reporting period represents the eighth 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 2013 analysis.

The Department began transitioning toward the public reporting of hospital risk-standardized 30-day mortality for PCIs in October 2014. This is consistent with the reporting for cardiac surgery. In addition, it is anticipated that there will be changes to the American College of Cardiology/National Cardiovascular Data Registry (ACC/NCDR) data instrument that is used to collect the PCI data. During the transition, the Department will share 30-day outcomes with each hospital as compared to aggregated data for the other hospitals performing PCI in the state. Thirty-day PCI mortality will start to be publicly reported beginning with the report that will be issued for fiscal year 2015 data (March 2017).

The data collection, verification, audit, and analytical procedures implemented in this report constitute are comprehensive, reliable, and rigorous. 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 Mass-DAC for their hard work and dedication.

Eric J. Sheehan, J.D.
Interim Bureau 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 4.5.6 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, 2012 through September 30, 2013 (fiscal year 2013), there were 12,132 Massachusetts hospital admissions, excluding patients meeting Exceptional Risk criteria (see definition in Appendix C on page 72), in which at least one percutaneous coronary intervention (PCI) was performed. All patients meeting the Exceptional Risk criteria are considered to have an *exceptionally high risk* for death. All patient records submitted by the hospitals as an Exceptional Risk case had their medical records reviewed and adjudicated by Mass-DAC to determine which cases would be removed from the final analysis data set.

- 77.94% (9,456) of the admissions were *no shock and no STEMI* admissions. The remaining 22.06% (2,676) of these admissions were *shock or STEMI* admissions. *Shock or STEMI* admissions are defined as patients that had an ST-elevated myocardial infarction (STEMI) within 24 hours of admission or were in shock at the time of the procedure.

- Twenty-four hospitals performed at least one PCI during the period October 1, 2012 through September 30, 2013; ten hospitals participated in the Massachusetts Primary PCI Pilot Program. All pilot hospitals are approved for *shock or STEMI* PCI admissions. Only pilot hospitals that participated in the MASS-COMM clinical trial were approved by the Massachusetts Department of Public Health to perform elective PCIs with limited restrictions beginning August 2013. Beverly Hospital did not participate in the MASS-COMM clinical trial and is approved to only perform *shock or STEMI* PCIs.

- After adjusting for patient risk for those having *no shock and no STEMI*, the relative risk of in-hospital mortality in a hospital one standard deviation above the Massachusetts average was 2.4 times 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 2.7 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 2013 in the *no shock and no STEMI* cohort is 0.53% (50 deaths) based on analysis of 9,456 (excludes Exceptional Risk) admissions.

- The observed in-hospital all cause mortality for fiscal year 2013 in the *shock or STEMI* cohort is 5.27% (141 deaths) based on analysis of 2,676 (excludes Exceptional Risk) admissions.

- **In FY 2013, no hospital was identified as a statistical outlier in the *no shock and no STEMI* cohort.**

- **In FY 2013, one hospital was identified as a better than expected in the *shock or STEMI* cohort.**

3 Introduction

3.1 What is in this Report?

This is the eleventh 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, 2012 through September 30, 2013 (fiscal year 2013) 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 2013, there were 14 PCI programs in Massachusetts, each with back-up cardiac surgery programs, and 10 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.

This document reports hospital-specific in-hospital risk-standardized mortality rates following PCI for the 24 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 2013 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 2013, 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, (see full definition on pg 51);
- At the time of PCI procedure, indication of an immediate PCI for STEMI;
- PCI procedures performed within 24 hours or less from 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 at the time of the PCI procedure meeting the ACC-NCDR cardiogenic shock definition, and not having clinical symptoms of shock with treatment, (see full definition on pg 51).

3.1.3 MASS-COMM Trial Participants

The randomized clinical trial, MASS-COMM (NCT01116882) ended September 30, 2011. The goal of the trial was to compare the effectiveness and safety of "elective" angioplasty in pilot hospital programs (without cardiac surgery) versus non-pilot programs (those with cardiac surgery onsite). The trial included patients with ischemic heart disease treated by elective PCI. Data for subjects participating in the trial were used to calculate mortality estimates for public reporting in the past reports, but to preserve the integrity of the trial, no mortality rates for MASS-COMM participants treated electively at the pilot programs were published in previous reports. While analysis from the trial was being reviewed, the Massachusetts Department of Public Health required data be submitted to the MASS-COMM registry. In August 2013 the Massachusetts Department of Public Health approved that all pilot hospitals who participated in the MASS-COMM clinical trial could continue to perform elective PCIs as well as primary PCIs with very limited restrictions. Beverly Hospital is the only pilot hospital that did not participate in the MASS-COMM clinical trial because of its late entry into the pilot program and thus cannot perform

elective PCIs. With the completion of the MASS-COMM clinical trial, all PCI programs will be publicly reported for both the *no shock and no STEMI* and *shock or STEMI* cohorts.

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 includes patients who were 18 years of age or older undergoing a PCI at all non-federal hospitals in Massachusetts. Patients meeting Exceptional Risk criteria (see Appendix C) were excluded. During the period October 1, 2012 through September 30, 2013, there were 12,132 admissions, in which at least one PCI was performed: 9,456 *no shock and no STEMI* admissions and 2,676 *shock or STEMI* admissions (Table 3.1). The in-hospital mortality rate for *shock or STEMI* admissions is almost 10 times that for *no shock and no STEMI* admissions (5.27% versus 0.53%). Mass-DAC analyzed the first PCI for patients who received more than one PCI during their admission: 1.84% of the *no shock and no STEMI* patients and 4.33% 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, 2012–Sep 30, 2013.*

Risk Cohort	No Shock and No STEMI [a]		Shock or STEMI [b]	
Characteristic	**Number**	**Percent**	**Number**	**Percent**
Admitted via Emer. Dept. or Transfer	5,547	58.66	2,606	97.38
Number of PCIs per Admission				
One PCI	9,282	98.16	2,560	95.67
Two or More PCIs	174	1.84	116	4.33
Prior Cardiac Arrest	57	0.60	255	9.53
At Least One Stent	8,700	92.01	2,423	90.55
Drug-Eluting if Stented	6,854	78.78	1,422	58.69
Total Length of Stay (Days)	Mean = 3.81 Median = 3		Mean = 5.22 Median = 4	
Post-Procedure Length of Stay (Days)	Mean = 2.86 Median = 2		Mean = 5.05 Median = 4	
Unadjusted Outcomes				
Any Vascular Complication	39	0.41	11	0.41
Status of CABG During PCI Admission				
Elective	[c]	[c]	[c]	[c]
Urgent	52	0.55	30	1.12
Emergency	15	0.16	[c]	[c]
Salvage	0	0.00	0	0.00
Transferred out for CABG	[c]	[c]	[c]	[c]
In-Hospital Death	50	0.53	141	5.27
Total Number of Admissions	9,456		2,676	

[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 and percentages used to compute frequencies from 1 to 10 are 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 9.4 Unix/Windows [10];
- WinBUGS version 1.4 [6];
- R version 3.1 [9].

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 Programs

Twenty-four hospitals had cardiac catheterization labs that performed PCIs in the period October 1, 2012 through September 30, 2013, ten of which were primary pilot programs. All non-federal hospitals that performed PCIs were required to submit clinical data to Mass-DAC.

4.3 Data Sources

The analytic data set for this report was created from Mass-DAC registry data and elements from external data resources used to validate hospital submitted data. Data sets included:

1. The Mass-DAC PCI database with data collected using the American College of Cardiology–National Cardiovascular Data Registry (ACC-NCDR–CathPCI) data collection tool [4];

2. Mass-DAC cardiac surgery patient-specific data collected using the Society of Thoracic Surgeons (STS) National Cardiac Surgery data collection tool version 2.73 [11, 12] and supplemental Massachusetts data elements;

3. Acute Hospital Case Mix Databases [7] from the Massachusetts Center for Health Information and Analysis;

4. Mortality data from the Massachusetts Registry of Vital Records and Statistics [8]; and

5. Mortality data from the Centers for Disease Control National Death Index [5];

4.3.1 Mass-DAC PCI Registry Data

Patient-specific risk factor and outcome data were collected by hospital personnel using the ACC-NCDR CathPCI data collection tools. Data for fiscal year 2013 were collected using the version 4.3 CathPCI data collection tool (see Appendix A–implemented July 1, 2009) and supplemental Massachusetts variables for PCI procedures. The PCI registry includes 329 variables. The CathPCI data collection tool was updated, with minor changes, to version 4.4 in April 2011 and has been used for data submissions for procedures performed April 1, 2011 or later.

4.3.2 Mass-DAC STS Registry Data

Patient-specific risk factor and outcome data were collected by hospital personnel using the STS data collection tools. Patient information in the STS registry was linked to the PCI registry to validate patient information submitted in the PCI registry. Fields validated include patient name, date of birth, gender, Social Security number, address, and consistency of dates related to episodes of care.

4.3.3 Massachusetts Acute Hospital Case Mix Database

The Massachusetts Center for Health Information and Analysis (CHIA) Acute Hospital Case Mix Databases were merged with Mass-DAC registry data to determine if all Massachusetts percutaneous coronary intervention (PCI) procedures performed during the fiscal year, October 1, 2012 through September 30, 2013, were submitted by the participating Massachusetts hospitals as re-

quired by the Department of Public Health contract with Mass-DAC. Any PCI record in the CHIA data that did not merge to a Mass-DAC record was verified with the hospital data manager to see if the case must be submitted to the Mass-DAC registry. CHIA data elements included hospital identifiers, patient date of birth, patient zip code, medical record number, diagnoses codes, procedure codes, procedure dates, admission date, discharge date, and discharge disposition. All cases determined to be a PCI procedure were submitted by the hospital, and processed through the normal Mass-DAC adjudication and validation processes.

4.3.4 Massachusetts Registry of Vital Records

The Registry of Vital Records and Statistics collects, processes, corrects and issues copies of birth, death and marriage records that occur in Massachusetts. Mass-DAC used the Registry to obtain death dates for deaths occurring in Massachusetts during the fiscal year, October 1, 2012 through September 30, 2013. While the primary source of in-hospital mortality was the hospital-reported information, the mortality index database was employed as a verification tool to find deaths occurring on the same day as discharge.

Using a confidential and secure transmission procedure, Mass-DAC submitted records with the following information for all Mass-DAC patients: patient name, last known alive date (i.e., last discharge date or death date), date of birth, gender, and Social Security number. Registry personnel linked the Mass-DAC patient data to the mortality index using the following criteria:

- Any match on SSN (All invalid SSN set to 000000000);
- Any match on date of birth and first 3 letters of last name and first 3 letters of first name;
- Any match on full last name and first 3 letters of first name.

The result files were returned to Mass-DAC where additional processing was done to determine

exact matches and possible matches on patient records and the Registry death dates. If a new death date was discovered, Mass-DAC contacted the hospital data manager to validate the new mortality for the patient.

4.3.5 National Death Index

The National Death Index (NDI) is a centralized database of death certificate information from all state vital statistics offices. NDI is maintained within the Census Bureau and the Centers for Disease Control (CDC) and Prevention's National Center for Health Statistics (NCHS). Identifiable data submitted to NCHS are kept confidential and secure before, during, and after the NDI computer matches. The data are protected by the Public Health Service Act [42 U.S.C. 242m Section 308(d)], as well as by the federal Privacy Act of 1974. Once the search is completed backups of the NDI user's records and of the NDI search results are removed from both the server at the CDC computer center in Atlanta and from the NDI programmers' computers in Hyattsville.

Due to cost limitations, Mass-DAC only submitted non-Massachusetts resident patient information to NDI to find deaths occurring in states other than Massachusetts. The Massachusetts Registry of Vital Records can only search for deaths that occurred within Massachusetts. The data was sent via express mail on a password-protected CD and NDI search result files were returned in the same manner. The search for possible matches was done on NDI calendar year 2012 and 2013 final files for patients having a procedure done during the fiscal year October 1, 2012 through September 30, 2013.

While the primary source of in-hospital mortality was the hospital-reported information, the NDI database was employed as a verification tool to find deaths occurring on the same day as discharge. Mass-DAC submitted records with the following information for all Mass-DAC patients: patient name, last known alive date (i.e., last discharge date or death date), date of birth, gender, race, and Social Security number for Mass-DAC patients that were non-Massachusetts residents.

NDI personnel linked the Mass-DAC records and provided results files with information on exact matches, probable matches, and probabilistic scores. Mass-DAC used the results to validate submitted in-hospital death dates and discover possible death dates not reported. If a new death date was discovered, Mass-DAC contacted the hospital data manager to validate the new mortality for the 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 2013 PCI Data Harvest Schedule*

Harvest Month	Corresponding Dates of PCI
March 2013	October 1, 2012–December 31, 2012
June 2013	January 1, 2013–March 31, 2013
September 2013	April 1, 2013–June 30, 2013
December 2013	July 1, 2013–September 30, 2013
April 2014	Final close date for fiscal year 2013 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, 2014, 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 268 data submissions to Mass-DAC for fiscal year 2013 data with a range of 1 to 6 per hospital with a mean of 2.8 submissions per hospital per collection period.

4.5.2 Mortality Registry Data

Two mortality data sources, (the CDC National Death Index and Massachusetts Registry of Vital Records), were used to validate known in-hospital mortalities and find unknown mortality dates the same day as discharge for matched patient records. Both merge results were found to have high agreement between the reported in-hospital mortality information from the hospital and the registry death dates. No new in-hospital mortalities were found.

4.5.3 Massachusetts Acute Hospital Case Mix Data

The Massachusetts CHIA inpatient and outpatient observation room case mix data was used as an additional method in determining whether all appropriate PCI cases from each institution were submitted to Mass-DAC. Case volumes were verified by linking with the Massachusetts acute hospital case mix databases [7]. Ten PCI cases were found in the case mix data that had not been submitted to the Mass-DAC database. The cases were confirmed with each hospital and each case was submitted to the Mass-DAC registry.

4.5.4 Meetings and Communication

Mass-DAC communicated regularly via e-mail 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.

4.5.5 Compassionate Use

Additional data were collected to identify patients with a very high risk of death who may not have been adequately identified using clinical elements collected in the ACC-NCDR data collection tool. A committee of Massachusetts interventionalists developed criteria that described patients at substantially elevated mortality risk. The criteria included active cardiopulmonary resuscitation at initiation of the PCI, extreme anatomic risk, or coma 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 as Compassionate Use are included in the fiscal year 2013 analysis and Compassionate Use is utilized as a risk adjustment covariate in the models.

4.5.6 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 2013 analysis. Refer to the Appendix C—Exceptional Risk Criteria for complete definition and qualifying specifications.

4.5.7 Audit Data

A sample of the fiscal year 2013 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 pre-procedure cardiogenic shock or salvage status;

3. All elective or urgent cases in the *shock or STEMI* cohort;

4. All patients coded as Compassionate Use;

5. All patients coded as Exceptional Risk.

In total, 506 data records were requested from the 24 hospitals. The records were reviewed to determine data consistency and accuracy of coding. A total of 233 changes to variables were made.

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. Twenty-five volunteers (21 physicians and 4 data managers) representing 20 of the 24 PCI programs comprised the Mass-DAC PCI Adjudication and the Exceptional Risk committees. 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. All coding changes made by the Adjudication Committee were implemented in the Mass-DAC database.

All records coded as Compassionate Use (163 in total) were reviewed by the Data Adjudication Committee to determine if they met the criteria established by Mass-DAC, accepting 81.0% of the cases. The 19 records coded as Exceptional Risk were reviewed by the Exceptional Risk Committee to determine if they met the criteria established by Mass-DAC (see Appendix C on page 72). There were less than 11 cases accepted as Exceptional Risk and removed from the final analysis cohort.

5 Risk Adjustment

5.1 Who Receives PCI in Massachusetts?

Tables 5.1 and 5.2 provide age, sex, and race summaries of the 9,456 *no shock and no STEMI* admissions and 2,676 *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." 71.5% of the *no shock and no STEMI* admissions are associated with patients who are male and 46.3% of the patients are less than 65 years of age at the time of their PCI. Patients residing out of state comprised 8.1% of the *no shock and no STEMI* admissions (data not shown). The majority of patients with *shock or STEMI* admissions are male (72.8%), and 57.4% of the *shock or STEMI* admissions are less than 65 years old at the time of their PCI. Finally, 6.5% of the *shock or STEMI* admissions are 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 patient is admitted are called confounders. To fairly assess hospitals, it is important to consider

Table 5.1: *Demographic Distribution for No Shock and No STEMI PCI Admissions ($N = 9,456$) in Massachusetts Hospitals: Oct 1, 2012–Sep 30, 2013*

Entries are counts. 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	262					
45–54	1,132	≤64	3,123	127	160	232
55–64	2,012					
65–74	1,947					
≥75	1,412	≥65	3,175	74	114	76
Total	**6,765**		**6,298**	**201**	**274**	**308**
Female						
18–44	82					
45–54	298	≤64	876	63	39	94
55–64	594					
65–74	832					
≥75	885	≥65	1,586	63	68	78
Total	**2,691**		**2,462**	**126**	**107**	**172**
Total Male and Female						
18–44	344					
45–54	1,430	≤64	3,999	190	199	326
55–64	2,606					
65–74	2,779					
≥75	2,297	≥65	4,761	137	182	154
Total	**9,456**		**8,760**	**327**	**381**	**480**

Table 5.2: *Demographic Distribution for Shock and STEMI PCI Admissions ($N = 2,676$) in Massachusetts Hospitals: Oct 1, 2012–Sep 30, 2013*

Entries are counts. 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	162					
45–54	466	≤64	1,134	55	62	90
55–64	618					
65–74	433					
≥75	268	≥65	652	24	25	28
Total	**1,947**		**1,786**	**79**	**87**	**118**
Female						
18–44	38					
45–54	96	≤64	266	[a]	[a]	14
55–64	155					
65–74	173					
≥75	267	≥65	420	[a]	[a]	13
Total	**729**		**686**	**26**	**17**	**27**
Total Male and Female						
18–44	200					
45–54	562	≤64	1,400	71	69	104
55–64	773					
65–74	606					
≥75	535	≥65	1,072	34	35	41
Total	**2,676**		**2,472**	**105**	**104**	**145**

[a] Frequencies from 1 to 10 and frequencies enabling one to determine a frequency between 1 and 10 are suppressed as required by the Massachusetts Department of Public Health data security guidelines.

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% interval estimate for each hospital's risk-standardized mortality rate. If the 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 predicted 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 (1) the 95% interval estimate for a particular hospital excludes the Massachusetts unadjusted in-hospital mortality rate or (2) the probability that the observed mortality is no different from that predicted from all other hospitals for a particular hospital **is small**, then the hospital is designated as outlying. 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 2013. 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. A burn-in of 70,000 draws was used for the *shock or STEMI* cohort and 100,000 for the *no shock and no STEMI* cohort. Conclusions were based on an additional 5,000 draws for each cohort. 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 2013.

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(mortality) and τ^2 represents between-hospital variance. The main analyses assumed that τ arose from a half normal distribution with mean 0 and variance 0.26. Mass-DAC re-estimated the hierarchical model using different prior distributions for τ^2 to determine how sensitive results are to the assumed prior distribution of the variance component.

1. We assumed that the between-hospital standard deviation arose from a uniform distribution over the range 0 to 1.5. This translates to assuming that small values in between-hospital heterogeneity are just as likely as large values.

2. We assumed a vague prior distribution for the precision, $\frac{1}{\tau^2}$. Specifically, we assumed the precision parameter arose from a highly dispersed Gamma distribution having scale parameter 0.001 and rate parameter 0.001.

The original conclusions remained unchanged after running the sensitivity analyses.

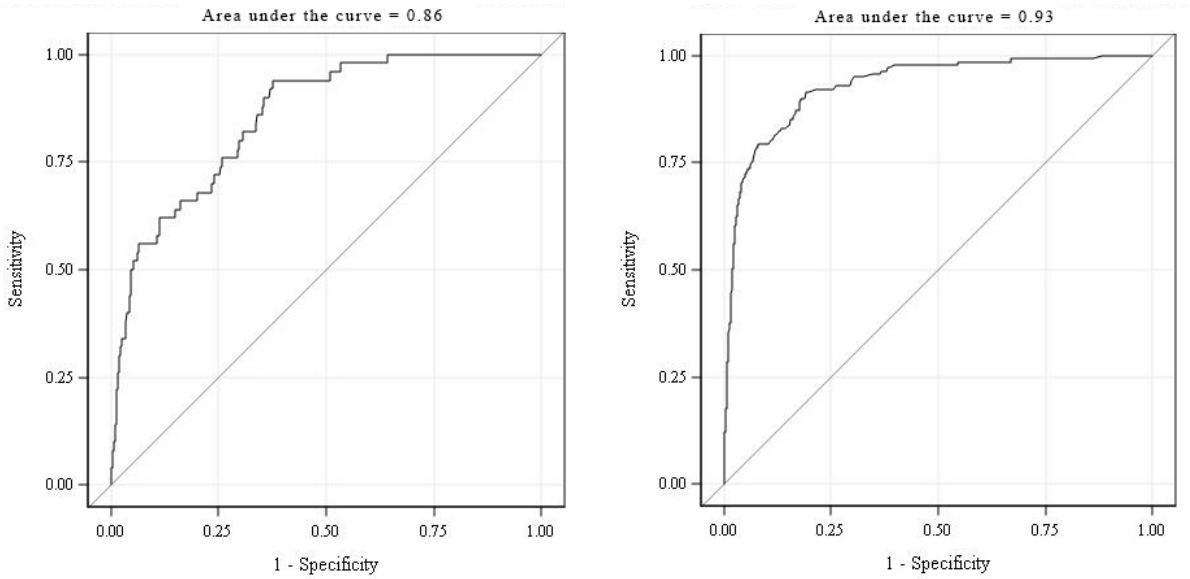
7 Hospital Quality Following PCI

Of the 12,132 PCI admissions in Massachusetts, 191 patients died during the same admission as the PCI. Table 7.1 on page 36 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 9,456 *no shock and no STEMI* admissions following a PCI. Of the *no shock and no STEMI* PCI admissions, 36.18% 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. For example, for patients who had no shock and no STEMI on dialysis prior to their PCI are 2.1 times more likely to die within the PCI hospital admission than no shock and no STEMI patients not on dialysis. In the *no shock and no STEMI* cohort, 0.24% of the admissions (23 admissions) were adjudicated to belong to the Compassionate Use group with corresponding mortality of 13.0% (data not shown). Admissions in this category were 6.5 times more likely to die during the admission.

Figure 7.2 on page 37 displays the frequencies of the model covariates by hospital for the *no shock and no STEMI* cohort. For age, the mean is reported rather than the percentage. The red horizontal line on each chart is the Massachusetts state average (prevalences) shown in Table 7.1 on page 36. Each chart point represents one of the PCI programs and is sorted from lowest to highest prevalence for each covariate. For example, the percentage of admissions with ejection fraction less than 30% ranges from 0 to just over 6% across hospitals.

Figure 7.3 on page 38 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 0.53% 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.

Figure 7.1: *ROC Curve-Hierarchical*



(a) *No Shock and No STEMI Admissions*

(b) *Shock or STEMI Admissions*

The expected mortality rate provides an overall assessment of case mix severity at each hospital; higher expected mortality rates represent a more severe case mix. Listed on the right-hand side are the estimated SMIRs.

After adjusting for patient risk for those having *no shock and no STEMI*, the relative risk of in-hospital mortality in a hospital one standard deviation above the Massachusetts average mortality was 1.9 times that of a hospital one standard deviation below the Massachusetts average mortality. The hierarchical model had good discrimination with an area under the ROC curve of 0.86 (Figure 7.1.(a)).

Table 7.2 on page 41 lists information for the 2,676 *shock or STEMI* cohort admissions, which is similar to Table 7.1 on page 36 for the *no shock or no STEMI* cohort admissions. In this cohort, 3.96% of the admissions (106 admissions) were adjudicated to belong to the Compassionate Use group with a corresponding mortality rate of 58.5% (data not shown); patients falling into this category had approximately 16.2 times the odds of dying compared to those not belong-

ing to the category. The *shock or STEMI* model discrimination ranged from 0% (0 deaths in 28 admissions) in the lowest risk group to 35.45% (106 deaths in 299 admissions) in the highest risk group.

The odds of in-hospital mortality in a hospital one standard deviation above the Massachusetts average mortality was 2.7 times that of a hospital one standard deviation below the Massachusetts average mortality for patients with *shock or STEMI*. A hierarchical logistic regression model indicated an area under the ROC curve of 0.93 (Figure 7.1.(b) on page 34).

Figure 7.5 on page 40 presents the half normal cross-validated p-values for hospitals treating the *no shock and no STEMI* cohort. Figure 7.9 on page 45 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 7.6 on page 42 displays summaries of the model covariates by hospital similar to what is shown in Figure 7.2. For example, the percentage of admissions classified as Compassionate Use ranges from 0 to 0.7 across hospitals.

Figure 7.7 on page 43 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 5.27% for *shock or STEMI* admissions. All hospitals' 95% intervals cover the Massachusetts unadjusted in-hospital mortality rate.

Figure 7.4 on page 39 and Figure 7.8 on page 44 graphically depict within and between-hospital differences in risk of PCI cases treated in fiscal year 2013. We multiplied the risk factors for each hospital's PCI cases observed in fiscal year 2013 by the regression coefficients estimated

in the prior year's report, summed this quantity within a case, and converted it to a probability. This probability represents the predicted risk of in-hospital mortality. We then summarized the distribution of these predicted probabilities within each hospital. This was accomplished using a density estimator. For each PCI hospital in the figure, the number of isolated PCI cases relative to its total number of PCI cases is plotted against the "severity" (the predicted probability multiplied by 100) of its cases. Hospitals having long right tails correspond to those predicted to have treated sicker patients.

Table 7.1: *Prevalences and Adjusted Relative Risks of In-Hospital Mortality Following PCI in Adults: No Shock and No STEMI Admissions: Oct 1, 2012–Sep 30, 2013. Based on 9,456 admissions with 50 deaths (0.53%)*

Risk Factor	Prevalence (%)	Relative Risk	95% Interval for Relative Risk
Age in Years over 65	1.07[a]	1.08	(1.05, 1.10)
Dialysis	2.27	2.14	(0.38, 5.54)
Diabetes	36.18	1.40	(0.76, 2.31)
Ejection Fraction (Ref: $\geq$ 30% or missing)	96.79	1.00	—
Less than 30%	3.21	2.25	(0.65, 5.21)
PCI Status (Ref: Elective or Urgent)	95.83	1.00	—
Emergency or Salvage	4.17	7.46	(3.43, 13.53)
Proximal LAD $\geq$70% Stenosis (Target Lesion–see def. on pg 56)	15.68	1.36	(0.60, 2.51)
Compassionate Use	0.24	6.47	(0.97, 19.19)
Transfer In From Another PCI Hospital	7.02	2.54	(1.10, 4.73)

Between-Hospital Parameters	**Mean**	**95% Interval**
Between-Hospital Average $\log, \mu$	-6.400	(-6.970, -5.800)
Average Between-Hospital Variance[b] in $\log$s, τ^2	0.190	$(1.381\times10^{-3}, 0.649)$

[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.

[b] The between-hospital variance may be roughly interpreted as the odds of dying when treated by a hospital one standard deviation above the average state mortality is twice that when treated by a hospital one standard deviation below the average state mortality.

Figure 7.2: *Model Covariate Frequencies by Hospital Oct 1, 2012–Sep 30, 2013: No Shock and No STEMI Admissions*

Each point corresponds to a Massachusetts PCI hospital. Hospitals sorted from lowest value to highest value.

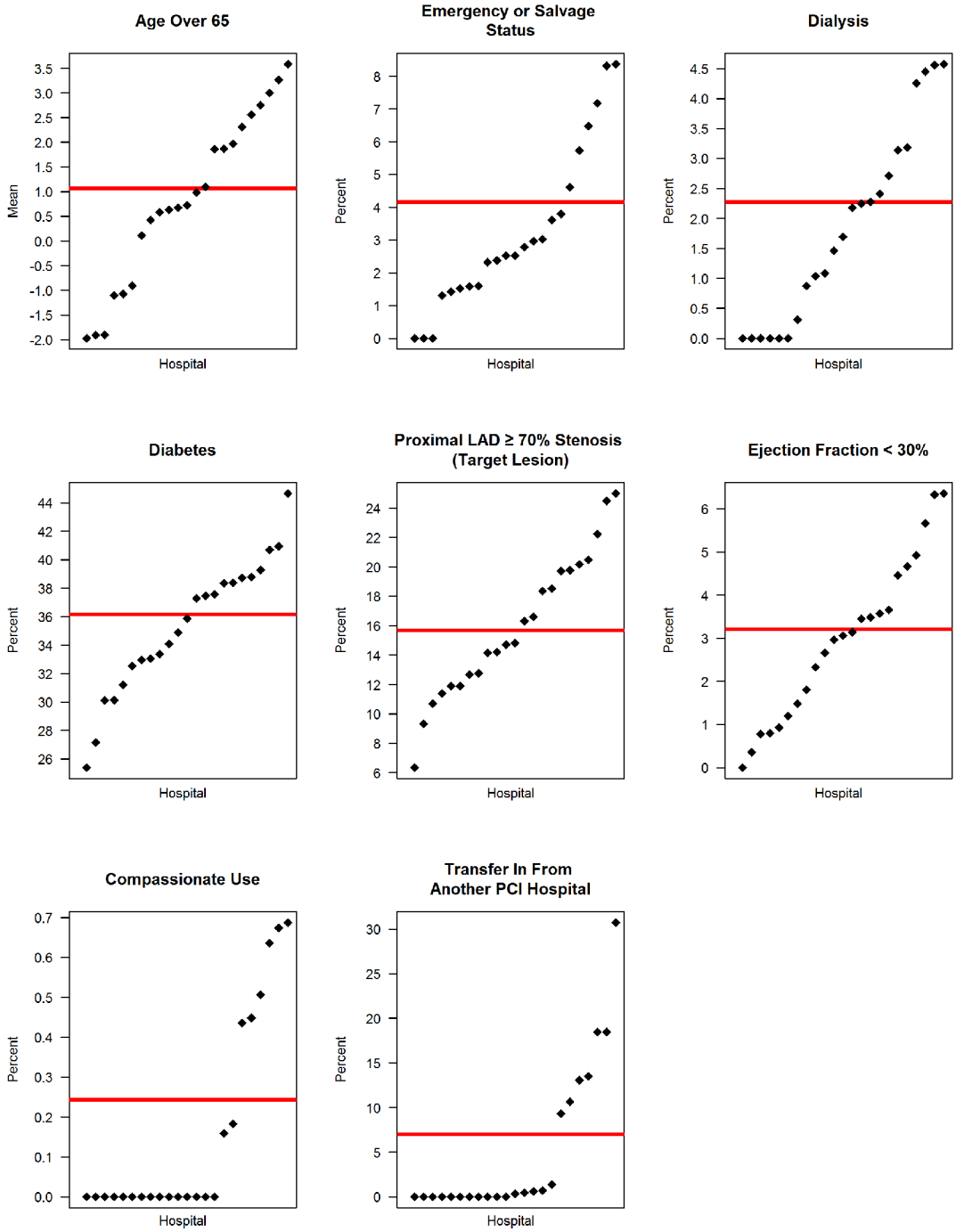
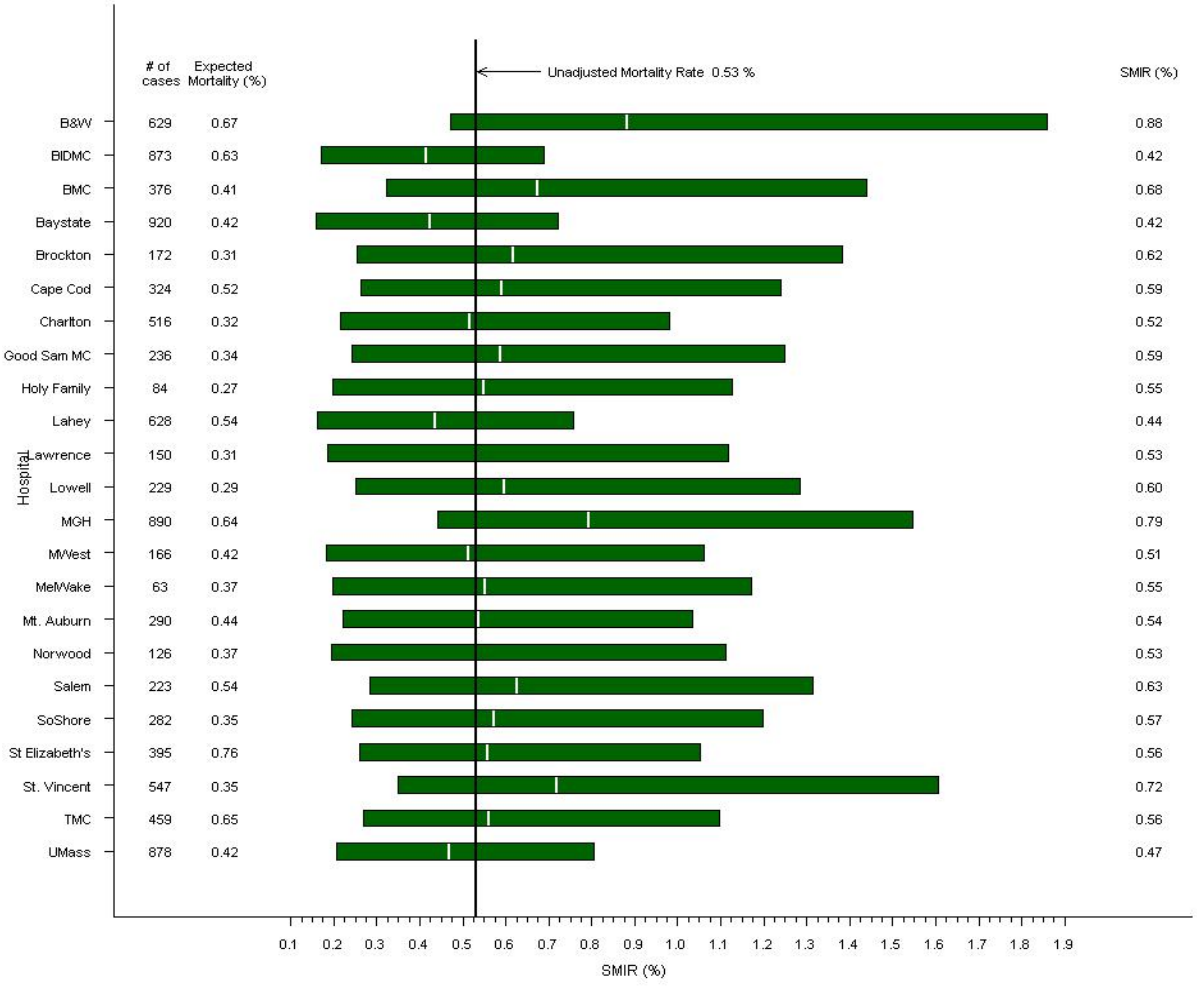


Figure 7.3: *Ninety-Five Percent Posterior Intervals for Standardized Mortality Incidence Rates (SMIRs) Following PCI: Oct 1, 2012–Sep 30, 2013: No Shock and No STEMI Admissions*

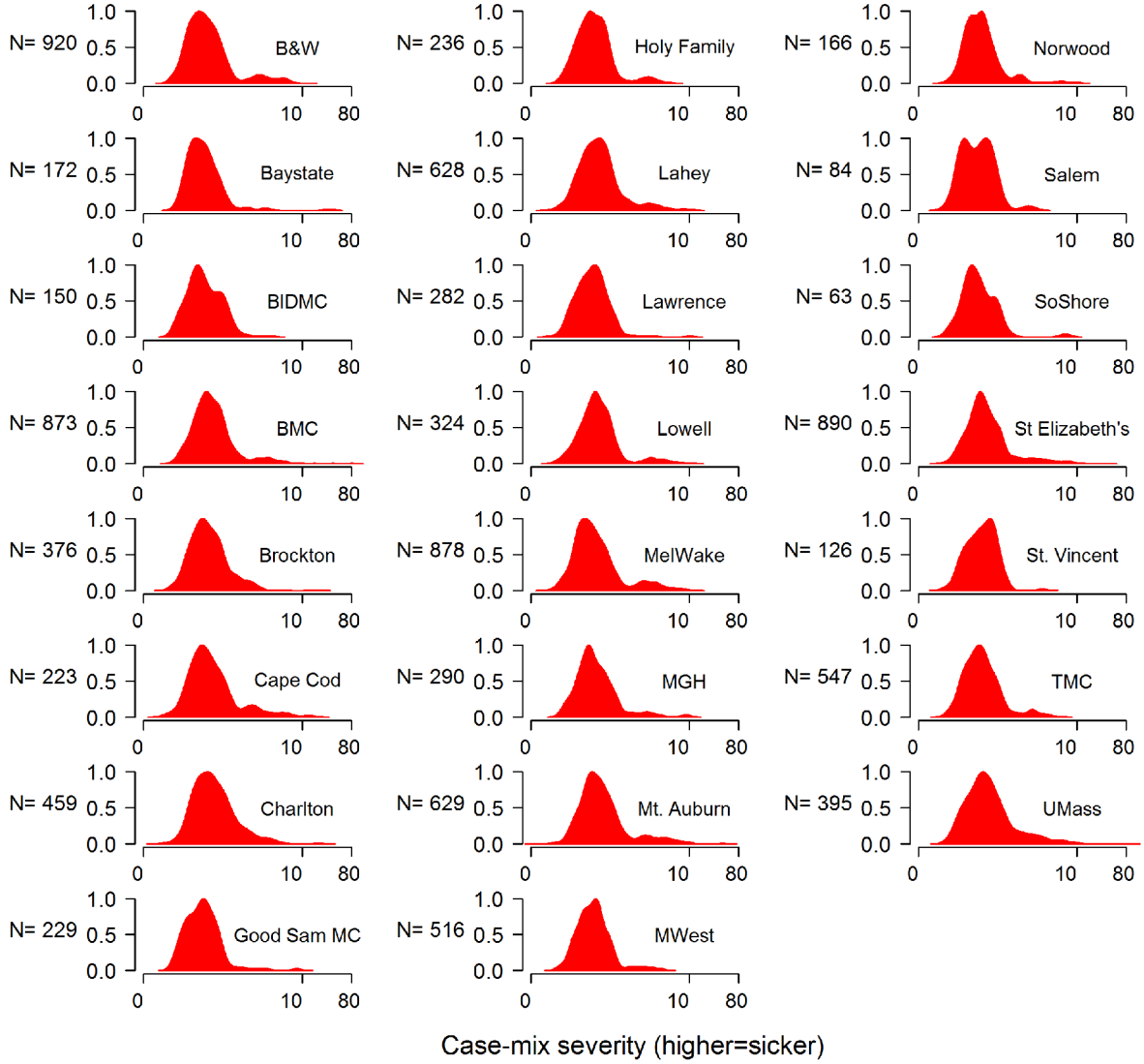
# of cases refers to the number of PCI admissions; expected mortality rate is the percentage of admissions not expected to survive given the case mix of the patients in the hospital. The white vertical line in each box is the hospital's SMIR while the black vertical line denotes the unadjusted state in-hospital mortality rate of 0.53%.



HOSPITAL KEY:
B&W = Brigham and Women's Hospital; **BIDMC** = Beth Israel Deaconess Medical Center; **BMC** = Boston Medical Center; **Baystate** = Baystate Medical Center; **Brockton** = Brockton Hospital; **Cape Cod** = Cape Cod Hospital; **Charlton** = Southcoast Health–Charlton Memorial Hospital; **Good Sam MC** = Good Samaritan Medical Center; **Holy Family** = Holy Family Hospital; **Lahey** = Lahey Hospital & Medical Center; **Lawrence** = Lawrence General Hospital; **Lowell** = Lowell General Hospital; **MGH** = Massachusetts General Hospital ; **MWest** = MetroWest Medical Center; **MelWake** = Melrose-Wakefield Hospital; **Mt. Auburn** = Mount Auburn Hospital; **Norwood** = Norwood Hospital; **Saints** = Saints Medical Center; **Salem** = North Shore Medical Center–Salem Hospital; **SoShore** = South Shore 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: *Case Mix Severity, By Hospital: No Shock and No STEMI Admissions*

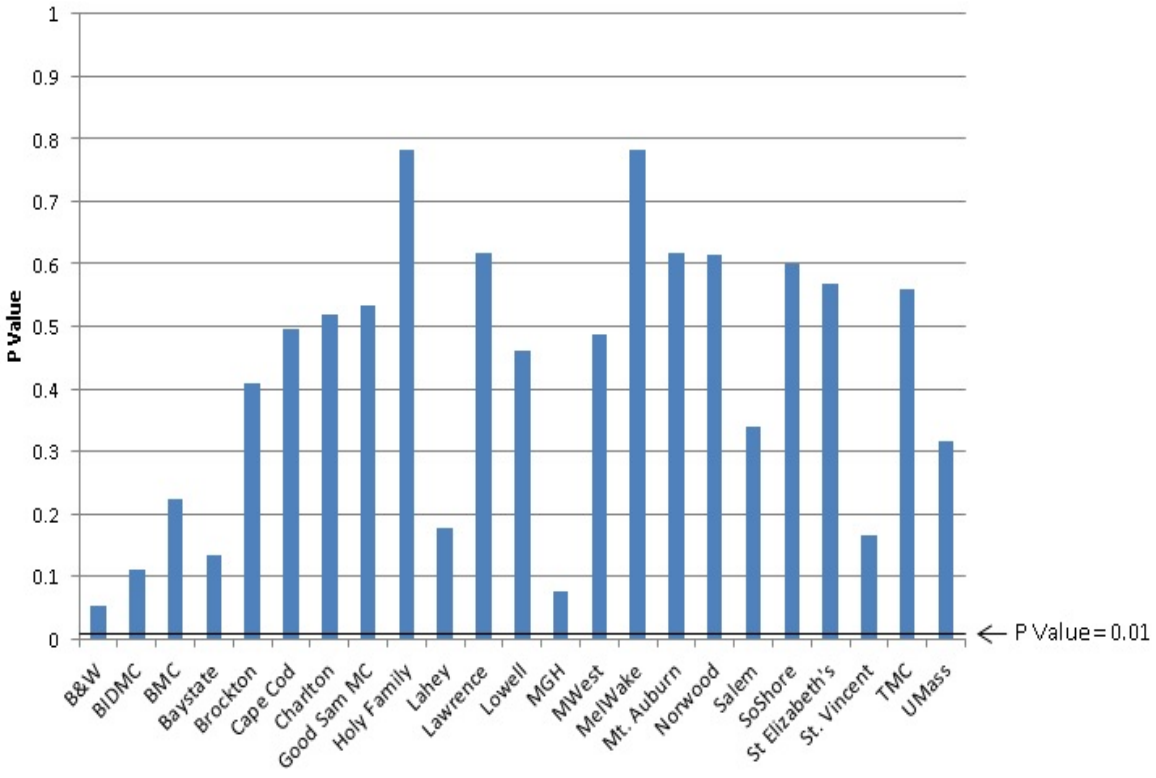
The x-axis depicts the predicted risk (multiplied by 100) of dying during hospitalization and the y-axis represents the relative number of PCI admissions at the predicted risk.



HOSPITAL KEY:
B&W = Brigham and Women's Hospital; **BIDMC** = Beth Israel Deaconess Medical Center; **BMC** = Boston Medical Center; **Baystate** = Baystate Medical Center; **Brockton** = Brockton Hospital; **Cape Cod** = Cape Cod Hospital; **Charlton** = Southcoast Health–Charlton Memorial Hospital; **Good Sam MC** = Good Samaritan Medical Center; **Holy Family** = Holy Family Hospital; **Lahey** = Lahey Hospital & Medical Center; **Lawrence** = Lawrence General Hospital; **Lowell** = Lowell General Hospital; **MGH** = Massachusetts General Hospital ; **MWest** = MetroWest Medical Center; **MelWake** = Melrose-Wakefield Hospital; **Mt. Auburn** = Mount Auburn Hospital; **Norwood** = Norwood Hospital; **Saints** = Saints Medical Center; **Salem** = North Shore Medical Center–Salem Hospital; **SoShore** = South Shore Hospital; **St. Elizabeth's** = Saint Elizabeth's Medical Center; **St. Vincent** = Saint Vincent Hospital; **TMC** = Tufts Medical Center; **UMass** = UMass Memorial Medical Center.

Figure 7.5: *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.



HOSPITAL KEY:
B&W = Brigham and Women's Hospital; **BIDMC** = Beth Israel Deaconess Medical Center; **BMC** = Boston Medical Center; **Baystate** = Baystate Medical Center; **Brockton** = Brockton Hospital; **Cape Cod** = Cape Cod Hospital; **Charlton** = Southcoast Health–Charlton Memorial Hospital; **Good Sam MC** = Good Samaritan Medical Center; **Holy Family** = Holy Family Hospital; **Lahey** = Lahey Hospital & Medical Center; **Lawrence** = Lawrence General Hospital; **Lowell** = Lowell General Hospital; **MGH** = Massachusetts General Hospital ; **MWest** = MetroWest Medical Center; **MelWake** = Melrose-Wakefield Hospital; **Mt. Auburn** = Mount Auburn Hospital; **Norwood** = Norwood Hospital; **Saints** = Saints Medical Center; **Salem** = North Shore Medical Center–Salem Hospital; **SoShore** = South Shore Hospital; **St. Elizabeth's** = Saint Elizabeth's Medical Center; **St. Vincent** = Saint Vincent Hospital; **TMC** = Tufts Medical Center; **UMass** = UMass Memorial Medical Center.

Table 7.2: *Prevalences and Adjusted Odds Ratios of In-Hospital Mortality Following PCI in Adults: Shock or STEMI Admissions: Oct 1, 2012–Sep 30, 2013. Based on 2,676 admissions with 141 deaths (5.27%)*

Risk Factor	Prevalence (%)	Odds Ratio	95% Interval for Odds Ratio
Age (Ref = <60 Years)	41.11	1.00	—
Age 60-69	28.51	2.13	(1.03, 3.94)
Age 70-79	17.23	3.65	(1.70, 6.94)
Age ≥80	13.15	10.13	(4.95, 19.02)
Ejection Fraction (Ref: ≥ 30% or missing)	97.05	1.00	—
Less than 30%	2.95	3.26	(1.37, 6.45)
PCI Status (Ref: Elective or Urgent)	2.09	1.00	—
PCI Status Emergency or Salvage	97.91	4.79	(1.12, 15.13)
Cardiogenic Shock with Treatment (see def. on pg 51)	8.93	6.49	(3.86, 10.15)
Compassionate Use	3.96	16.22	(8.13, 30.09)
Transfer In From Another PCI Hospital	2.13	0.88	(0.23, 2.24)
Prior Cardiac Arrest	9.53	4.47	(2.15, 7.20)
STEMI Rescue Unstable[a]	4.56	1.64	(0.57, 3.38)
Between-Hospital Parameters		**Mean**	**95% Interval**
Between-Hospital Average logit, μ		-6.600	(-8.130, -5.190)
Average Between-Hospital Variance[b] in logits, τ^2		0.240	$(3.354\times10^{-3}, 0.705)$

[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.

[b]The between-hospital variance may be roughly interpreted as the odds of dying when treated by a hospital one standard deviation above average mortality is twice that when treated by a hospital one standard deviation below average mortality.

Figure 7.6: *Model Covariate Frequencies by Hospital Oct 1, 2012–Sep 30, 2013: Shock or STEMI Admissions*

Each point corresponds to a Massachusetts PCI hospital. Hospitals sorted from lowest value to highest value.

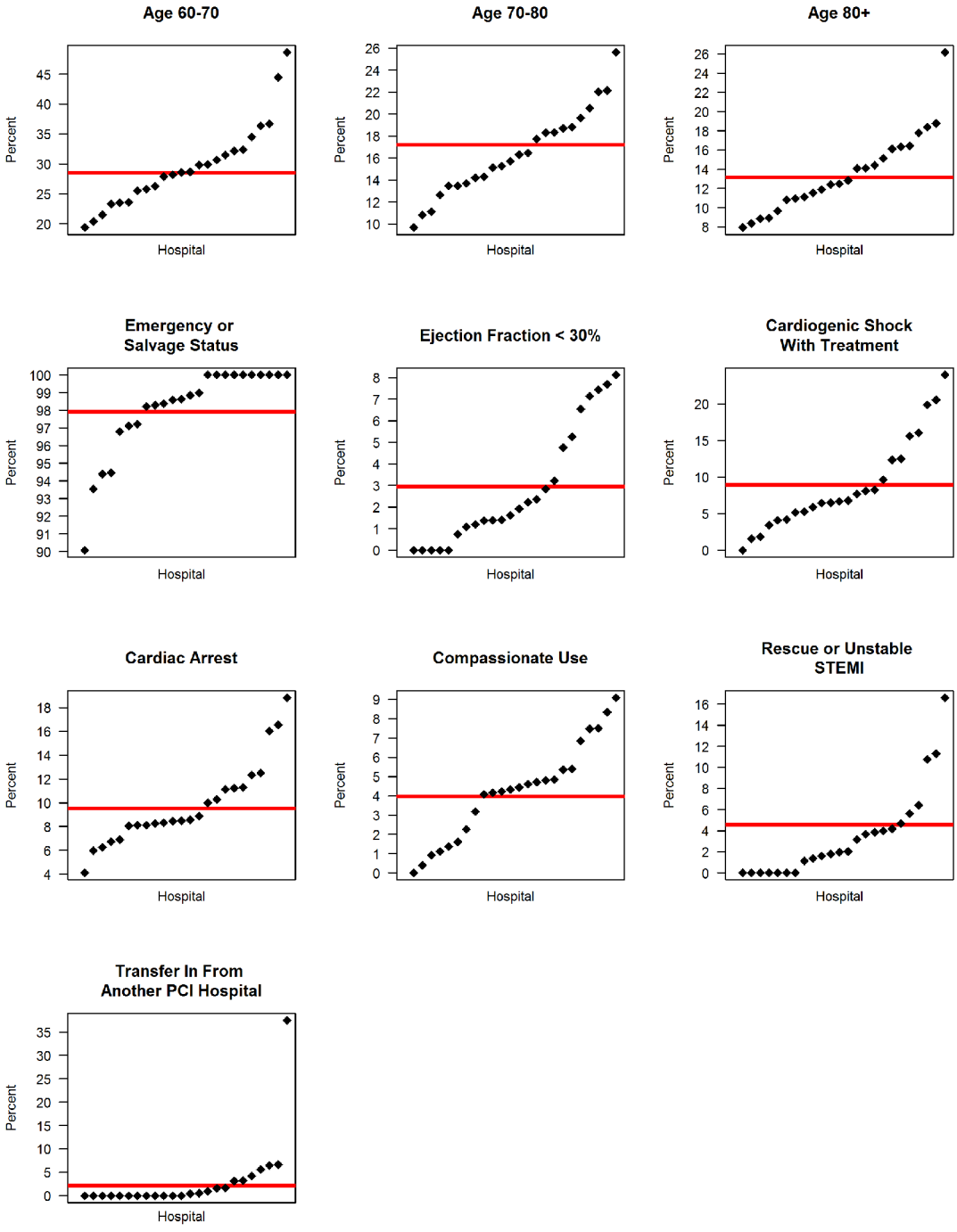
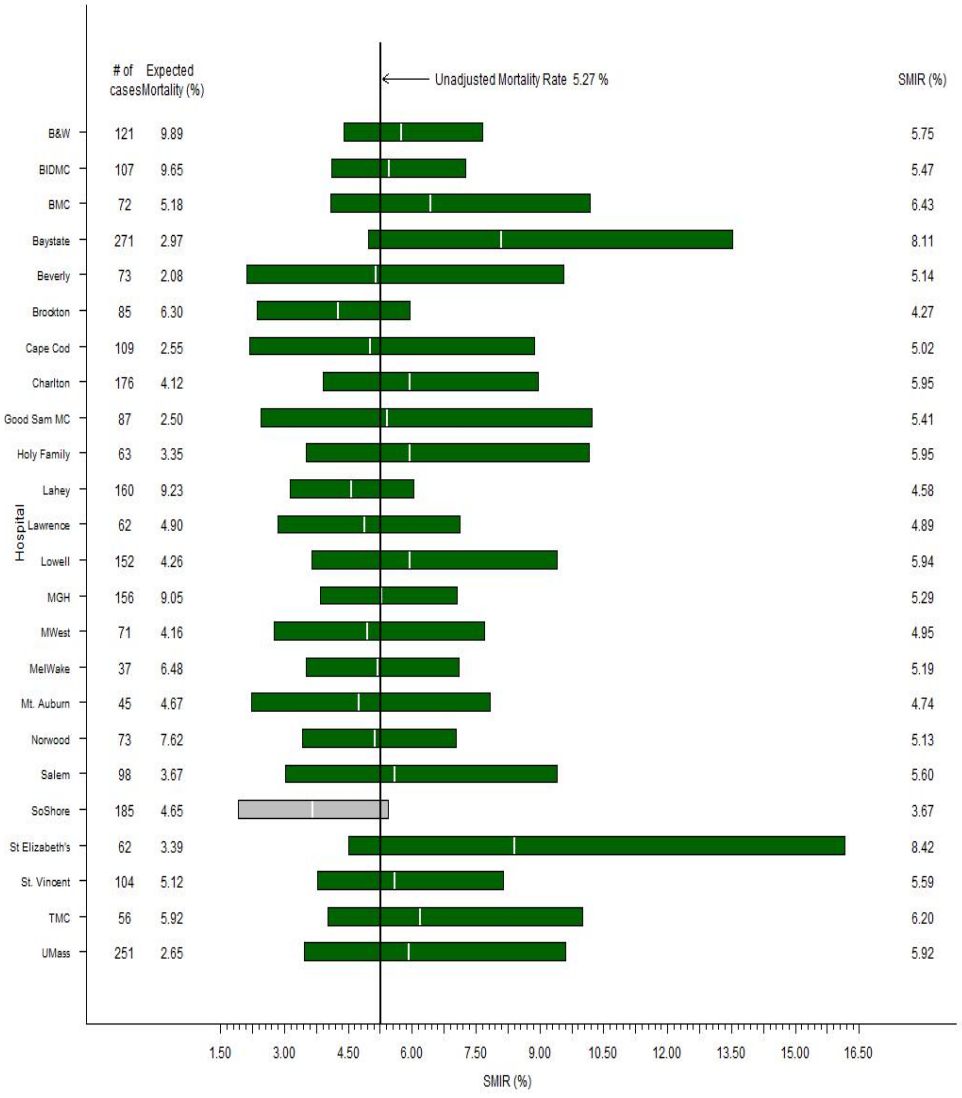


Figure 7.7: *Ninety-Five Percent Posterior Intervals for Standardized Mortality Incidence Rates (SMIRs) Following PCI: Oct 1, 2012–Sep 30, 2013: Shock or STEMI Admissions*

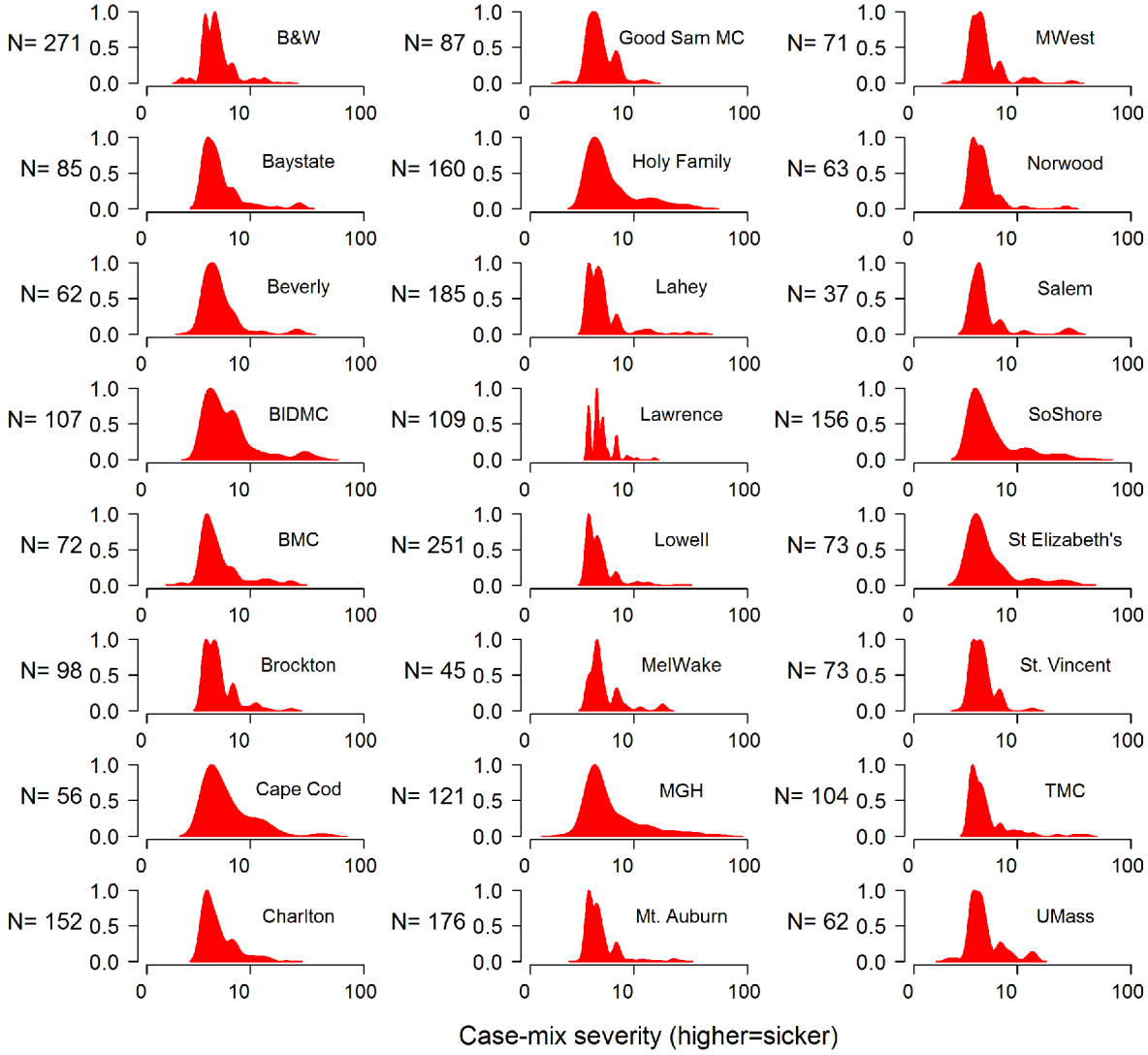
# of cases refers to the number of PCI admissions; expected mortality rate is the percentage of admissions resulting in death given the case mix of the patients in the hospital. The white vertical line in each box is the hospital's SMIR while the black vertical line denotes the unadjusted Massachusetts in-hospital mortality rate of 5.27%. The silver bar identifies South Shore Hospital as a **better than expected** statistical outlier.



HOSPITAL KEY:
B&W = Brigham and Women's Hospital; **BIDMC** = Beth Israel Deaconess Medical Center; **BMC** = Boston Medical Center; **Baystate** = Baystate Medical Center; **Beverly** = Beverly Hospital; **Brockton** = Brockton Hospital; **Cape Cod** = Cape Cod Hospital; **Charlton** = Southcoast Health–Charlton Memorial Hospital; **Good Sam MC** = Good Samaritan Medical Center; **Holy Family** = Holy Family Hospital; **Lahey** = Lahey Hospital & Medical Center; **Lawrence** = Lawrence General Hospital; **Lowell** = Lowell General Hospital; **MGH** = Massachusetts General Hospital ; **MWest** = MetroWest Medical Center; **MelWake** = Melrose-Wakefield Hospital; **Mt. Auburn** = Mount Auburn Hospital; **Norwood** = Norwood Hospital; **Saints** = Saints Medical Center; **Salem** = North Shore Medical Center–Salem Hospital; **SoShore** = South Shore Hospital; **St. Elizabeth's** = Saint Elizabeth's Medical Center; **St. Vincent** = Saint Vincent Hospital; **TMC** = Tufts Medical Center; **UMass** = UMass Memorial Medical Center.

Figure 7.8: *Case-Mix Severity, By Hospital: Shock or STEMI Admissions*

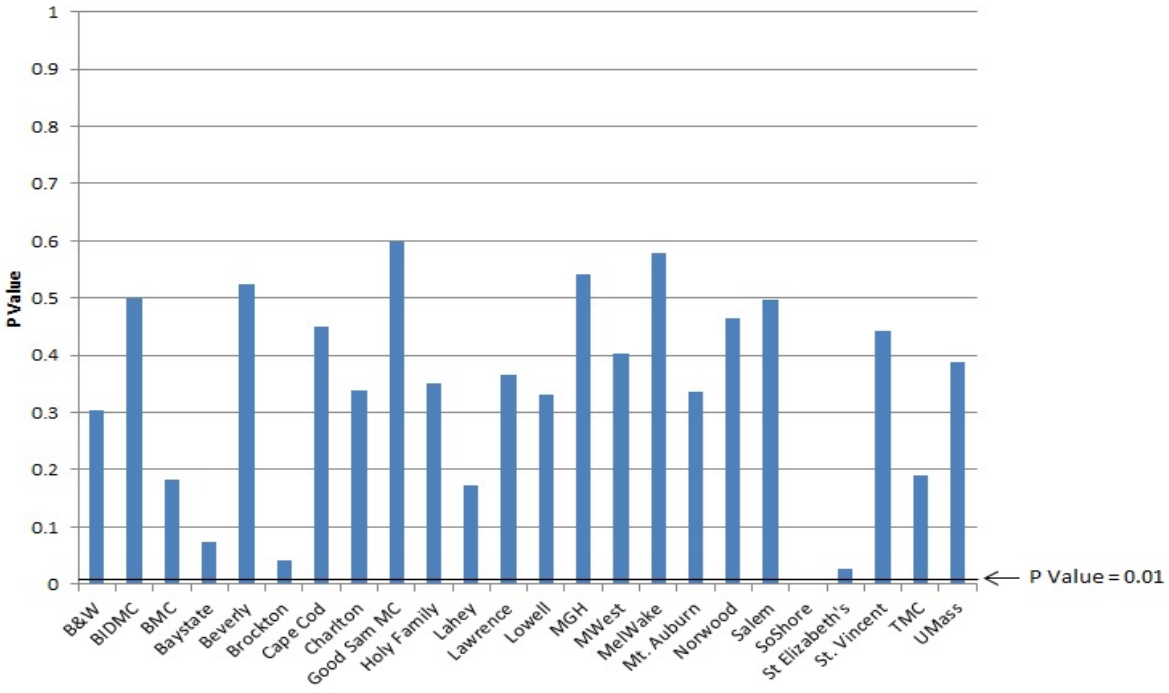
The x-axis depicts the predicted risk (multiplied by 100) of dying during hospitalization and the y-axis represents the relative number of PCI admissions at the predicted risk.



HOSPITAL KEY:
B&W = Brigham and Women's Hospital; **BIDMC** = Beth Israel Deaconess Medical Center; **BMC** = Boston Medical Center; **Baystate** = Baystate Medical Center; **Beverly** = Beverly Hospital; **Brockton** = Brockton Hospital; **Cape Cod** = Cape Cod Hospital; **Charlton** = Southcoast Health–Charlton Memorial Hospital; **Good Sam MC** = Good Samaritan Medical Center; **Holy Family** = Holy Family Hospital; **Lahey** = Lahey Hospital & Medical Center; **Lawrence** = Lawrence General Hospital; **Lowell** = Lowell General Hospital; **MGH** = Massachusetts General Hospital ; **MWest** = MetroWest Medical Center; **MelWake** = Melrose-Wakefield Hospital; **Mt. Auburn** = Mount Auburn Hospital; **Norwood** = Norwood Hospital; **Saints** = Saints Medical Center; **Salem** = North Shore Medical Center–Salem Hospital; **SoShore** = South Shore Hospital; **St. Elizabeth's** = Saint Elizabeth's Medical Center; **St. Vincent** = Saint Vincent Hospital; **TMC** = Tufts Medical Center; **UMass** = UMass Memorial Medical Center.

Figure 7.9: *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. South Shore Hospital's P-Value is less than 0.01 and is a **better than expected** statistical outlier.



HOSPITAL KEY:
B&W = Brigham and Women's Hospital; **BIDMC** = Beth Israel Deaconess Medical Center; **BMC** = Boston Medical Center; **Baystate** = Baystate Medical Center; **Beverly** = Beverly Hospital; **Brockton** = Brockton Hospital; **Cape Cod** = Cape Cod Hospital; **Charlton** = Southcoast Health–Charlton Memorial Hospital; **Good Sam MC** = Good Samaritan Medical Center; **Holy Family** = Holy Family Hospital; **Lahey** = Lahey Hospital & Medical Center; **Lawrence** = Lawrence General Hospital; **Lowell** = Lowell General Hospital; **MGH** = Massachusetts General Hospital ; **MWest** = MetroWest Medical Center; **MelWake** = Melrose-Wakefield Hospital; **Mt. Auburn** = Mount Auburn Hospital; **Norwood** = Norwood Hospital; **Saints** = Saints Medical Center; **Salem** = North Shore Medical Center–Salem Hospital; **SoShore** = South Shore Hospital; **St. Elizabeth's** = Saint Elizabeth's Medical Center; **St. Vincent** = Saint Vincent Hospital; **TMC** = Tufts Medical Center; **UMass** = UMass Memorial Medical Center.

8 Annual In-Hospital Mortality Trends Following PCI in Massachusetts: April 1, 2003 through September 30, 2013

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, including target lesion and no prior CABG.

- FY2011:

    1. All tables and figures exclude Exceptional Risk cases;

    2. Left main disease 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.

- FY2012:

    1. Patients having PCI at pilot hospitals who participated in the MASS-COMM clinical trial are now reported on in both cohorts; Beverly Hospital, who did not participate in the MASS-COMM clinical trial is only reported in the *shock or STEMI* cohort.

    2. Changes for the *no shock and no STEMI* model:

        ◇ Moved urgent PCI status to the reference group;

        ◇ Removed cardiac arrest;

        ◇ Removed chronic lung disease.

- FY2013: **No changes made to the model.**

Table 8.1: *Summary of No Shock and No STEMI PCI Admissions and In-Hospital Crude Mortality Percentages: CY 2003-FY 2013*

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	0.63	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[c]	24	10,908	0.46	0.102	0.049
FY 2010[c]	24	10,709	0.40	0.492	0.156
FY 2011[c]	24	10,177	0.47	0.138	0.064
FY 2012[c]	24	9,528	0.52	0.103	0.051
FY 2013[c]	23	9,456	0.53	0.190	0.111

[a]CY denotes calendar year (Jan-Dec); FY denotes fiscal year (Oct-Sep).
[b]Represents nine months of admissions.
[c]Excludes Exceptional Risk admissions.

Table 8.2: *Summary of Shock or STEMI PCI Admissions and In-Hospital Crude Mortality Percentages: CY 2003-FY 2013*

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	5.68	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[c]	24	2,578	5.12	0.052	0.206
FY 2010[c]	25	2,485	5.07	0.216	0.772
FY 2011[c]	25	2,618	5.04	0.061	0.243
FY 2012[c]	25	2,712	4.06	0.126	0.413
FY 2013[c]	24	2,676	5.27	0.240	0.413

[a] CY denotes calendar year (Jan-Dec); FY denotes fiscal year (Oct-Sep).
[b] Represents nine months of admissions.
[c] Excludes Exceptional Risk admissions.

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. 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: 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 with Treatment: (Mass-DAC definition) Indicate if the patient is in cardiogenic shock at the start of the PCI procedure. The ACC-NCDR definition does not require treatment to maintain blood pressure and cardiac index in addition to other criteria.

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 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 C 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.

Primary Percutaneous Coronary Intervention (PCI): The PCI performed as the initial approach to reperfusion for patients in the acute phase of STEMI with the goal of promptly restoring blood flow and function to the portion of the heart that is jeopardized by an acute coronary artery occlusion.

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.

Massachusetts Cardiac Care Hospital Outlier Committee

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

Suzanne Cray
Director, Office of Health Care Integration
Bureau of Health Care Safety & Quality
Massachusetts Department of Public Health

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

Ann Lovett, R.N., M.A.
Project Manager, Mass-DAC
Department of Health Care Policy
Harvard Medical School

Duane Pinto, M.D.
Interventional Cardiologist
Beth Israel Deaconess Medical Center
Governor Elect of Mass. Chapter of ACC

Jean-Pierre Geagea, M.D.
Cardiology Chief
Brockton Hospital

Mitchel Sklar, M.D.
Cardiology Chief
Charlton Memorial Hospital

Richard D'Agostino, M.D.
Chief of Cardiac Surgery
Lahey Hospital & Medical Center

Kurt Barringhaus, M.D.
Interventional Cardiologist
UMass Memorial Medical Center

Anthony Marks, M.D.
Cath Lab Director
Chief of Cardiology
South Shore Hospital

Kenneth Rosenfield, M.D.
Interventional Cardiologist
Massachusetts General Hospital
Governor of Mass. Chapter of ACC

Continued on next page . . .

Massachusetts Cardiac Care Hospital Outlier Committee

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

. . . Continued from prior page

Thomas Carr, M.D.
Cardiac Surgeon
North Shore Medical Center–Salem Hospital

Cliff Berger, M.D.
Interventional Cardiologist
Good Samaritan Medical Center

Frederic Resnic, M.D.
Chairman
Department of Cardiovascular Medicine
Lahey Hospital & Medical Center

Daniel Engelman, M.D.
Cardiac Surgeon
Baystate Medical Center
President-Elect of Mass. Chapter of STS

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

Mass-DAC Oversight Committee for PCI

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

Cliff Berger, M.D.
Interventional Cardiologist
Good Samaritan Medical Center

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

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

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

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

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

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

Frederic Resnic, M.D.
Interventional Cardiologist
Chairman
Department of Cardiovascular Medicine
Lahey Hospital & Medical Center

Kenneth Rosenfield, M.D.
Interventional Cardiologist
Massachusetts General Hospital
Governor of Mass. Chapter of ACC

Paul Schwerdt, M.D.
Interventional Cardiologist
Norwood Hospital

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.

Kurt Barringhaus, M.D.
Interventional Cardiologist
UMass Memorial Medical Center

Edward Loughery, M.D.
Interventional Cardiologist
Beverly Hospital

Nikolaos Kakouros, M.D.
Interventional Cardiologist
UMass Memorial Medical Center

Eddison Ramsaran, M.D.
Interventional Cardiologist
Saint Vincent Hospital

Jean-Pierre Geagea, M.D.
Interventional Cardiologist
Brockton Hospital

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

Susan April, R.N.
Data Manager
North Shore Medical Center–Salem Hospital

Julie Bonenfant, R.N.
Data Manager
Beth Israel Deaconess Medical Center

Susan Riley, R.N.
Data Manager
Norwood Hospital

Robert Yeh, M.D.
Interventional Cardiologist
Massachusetts General Hospital

Jane Leopold, M.D.
Interventional Cardiologist
Brigham and Women's Hospital

Joseph Carrozza, Jr., M.D.
Interventional Cardiologist
Saint Elizabeth's Medical Center

Ibrahim Domain, M.D.
Interventional Cardiologist
North Shore Medical Center–Salem Hospital

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

Mitchel Sklar, M.D.
Interventional Cardiologist
Charlton Memorial Hospital
Director Cardiac Catheterization Laboratory

Angela Corey Cahill
Data Manager
South Shore Hospital

Jeanne Watrous, R.N.
Data Manager
Saint Elizabeth's Medical Center

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.

Donald Cutlip, M.D.
Interventional Cardiologist
Director, Cardiac Catheterization Laboratory
Beth Israel Deaconess Medical Center

Igor Palacios, M.D.
Interventional Cardiologist
Director, Cardiac Catheterization
Massachusetts General Hospital

Alice Jacobs, M.D.
Interventional Cardiologist
Boston Medical Center

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

Thomas Piemonte, M.D.
Interventional Cardiologist
Director, Cardiac Catheterization Laboratory
Lahey Hospital & Medical Center

Marc Schweiger, M.D.
Interventional Cardiologist
Director, Cardiac Catheterization Laboratory
Baystate Medical Center

Exceptional Risk Committee for PCI

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

Frederic Resnic, M.D.
Interventional Cardiologist
Chairman
Department of Cardiovascular Medicine
Lahey Hospital & Medical Center

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

Kenneth Rosenfield, M.D.
Interventional Cardiologist
Massachusetts General Hospital
Governor of Mass. Chapter of ACC

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

Robert Yeh, M.D.
Interventional Cardiologist
Massachusetts General Hospital

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

Jean Pierre Geagea, M.D.
Interventional Cardiologist
Brockton Hospital

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

Terry Bard, D.D.
Rabbi, Clinical Psychologist, Ethicist
Harvard Medical School

Thomas Piemonte, M.D.
Interventional Cardiologist
Director, Cardiac Catheterization Laboratory
Lahey Hospital & Medical Center

Daniel Z. Fisher, M.D., Ph.D.
Interventional Cardiologist
Director, Interventional Cardiology
UMass Memorial Medical Center

Alice Jacobs, M.D.
Interventional Cardiologist
Boston Medical Center

Andrew Weintraub, M.D.
Interventional Cardiologist
Tufts Medical Center

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 2013

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 2013

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.

Bibliography

[1] American College of Cardiology, *NCDR CathPCI registry elements and definitions*, 2011, Accessed August 14, 2015, at http://cvquality.acc.org/~/media/QII/NCDR/Data%20Collection%20Forms/cathpci_v4_codersdictionary_4-4.ashx.

[2] _____, *NCDR CathPCI registry v4.4 data collection form*, 2011, Accessed August 14, 2015, at http://cvquality.acc.org/~/media/QII/NCDR/Data%20Collection%20Forms/CathPCI%20Registry_DataCollectionForm.ashx.

[3] _____, *American college of cardiology*, 2015, Accessed August 14, 2015, at http://www.cardiosource.org/acc.

[4] _____, *NCDR CathPCI registry*, 2015, Accessed August 14, 2015, at http://cvquality.acc.org/NCDR-Home.aspx.

[5] Centers for Disease Control , *National death index (ndi)*, 2015, Accessed August 14, 2015, at http://www.cdc.gov/nchs/ndi.htm.

[6] Dave Lunn, Andrew Thomas, Nicky Best, and David Spiegelhalter, *WinBUGS - a bayesian modelling framework: Concepts, structure, and extensibility*, Statistics and Computing **10** (2000), no. 1.4.3, 325–337, Accessed August 14, 2015, at http://www.mrc-bsu.cam.ac.uk/software/bugs/ Version 1.4.3.

[7] Massachusetts Center for Health Information and Analysis , *Acute hospital case mix databases*, August 2015, Accessed August 14, 2015, at http://www.chiamass.gov/case-mix-data/.

[8] Massachusetts Registry of Vital Records and Statistics, *Vital records database*, 2015, Accessed August 14, 2015, at http://http://www.mass.gov/dph/rvrs.

[9] R Development Core Team, *R: A language and environment for statistical computing-reference index*, R Foundation for Statistical Computing, Vienna, Austria, September 2015, ISBN 3-900051-07-0; Accessed August 13, 2015, at http://www.r-project.org/.

[10] SAS Institute Inc, *SAS system for unix/windows – version 9.4*, SAS Institute Inc, Cary, North Carolina, 2015, © 2015; Accessed August 13, 2015, at http://www.sas.com/.

[11] Society of Thoracic Surgeons, *STS adult cardiac data specifications – version 2.73*, 2011, © 2011; Accessed August 14, 2015, at http://www.sts.org/sites/default/files/documents/word/STSAdultCVDataSpecificationsV2_73withcorrection.pdf.

[12] _____, *The society of thoracic surgeons adult cardiac data collection form – version 2.73*, 2011, © 2011; Accessed August 14, 2015, at http://www.sts.org/sites/default/files/documents/STSAdultCVDataCollectionForm2_73.pdf.