PERCUTANEOUS CORONARY INTERVENTION IN THE COMMONWEALTH OF MASSACHUSETTS

January 1, 2004 – December 31, 2004

Mass-DAC

Department of Health Care Policy

Harvard Medical School

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MASSACHUSETTS PERCUTANEOUS CORONARY INTERVENTION HOSPITALS: 2004

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

MASSACHUSETTS PRIMARY PERCUTANEOUS CORONARY INTERVENTION PILOT HOSPITALS: 2004

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

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1 - KEY FINDINGS

- Between January1, 2004 and December 31, 2004, there were **17,110** hospital admissions in which at least one Percutaneous Coronary intervention (PCI) was performed in Massachusetts hospitals.

- **15.2%** (2606) of these admissions were "shock or STEMI" admissions - admissions in which the patient had an ST-elevated myocardial infarction (STEMI) within 24 hours of admission or was in shock.

- The remaining **14,504** admissions **(84.8%)** were "no shock and no STEMI" admissions - those for which the patient did not have an ST-elevated myocardial infarction and was not in shock.

- **Twenty one** hospitals performed at least one PCI in 2004, **seven** of which participated in the Massachusetts Primary PCI Pilot Program. Pilot programs are approved for "shock or STEMI" Admissions only.

- The majority of patients undergoing PCI were males **(68.3%)**, white **(91.1%)**, and approximately one-third were under 60 years of age.

- Of the 17,110 PCI admissions, **248** patients died during the same hospitalization in which the PCI was performed. Ninety eight **(0.68% mortality)** of the deaths occurred in the "no shock and no STEMI" population while 150 **(5.76% mortality)** occurred in the "shock or STEMI" population.

- Based on in-hospital mortality, no hospital was classified as a statistical outlier, i.e., no hospital had worse than expected or better than expected mortality in Massachusetts during 2004.

2 - INTRODUCTION

2.1 - What is in this Report?

This is the second report (all reports are available at www.massdac.org) that details 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 intervention. Interventions performed in United States Government Hospitals (e.g., VA Boston Healthcare System – Jamaica Plain Campus) are not included in this report.

In Massachusetts, not all hospitals are permitted to perform PCIs and those wishing to start performing PCI's must submit an application to the Determination of Need Program in the Massachusetts Department of Public Health. In 2004, there were eleven established PCI programs in Massachusetts, each with back up cardiac surgery programs. Three relatively new community hospital programs were granted approval for both cardiac surgery and PCI programs in 2003 (Cape Cod Hospital; Southcoast Hospital Group – Charlton Hospital; and North Shore Medical Center – Salem Hospital). Cape Cod Hospital and Charlton Hospital started performing PCIs in early 2003 while Salem Hospital did not perform their first PCI until November 3, 2003. Additionally, four community hospitals applied and received approval to perform primary PCI only under a **Primary PCI Pilot Program** with the Massachusetts Department of Public Health in 2003. Primary PCI Pilot Program hospitals do not have cardiac surgery programs on site but do have cardiac surgery available to their patients, if needed, from the hospitals with which they collaborate. These Pilot Programs provide PCIs to patients arriving at the hospital in shock or having a heart attack within 24 hours of admission. The four new Primary PCI Pilot hospitals include Brockton Hospital [first PCI on April 2, 2003]; Caritas Norwood Hospital [first PCI on April 17, 2003]; Metrowest Medical Center [first PCI on December 5, 2003]; and South Shore Hospital [first PCI on April 9, 2003]). Three additional hospitals were approved for the Primary PCI Pilot Program in 2004: Lowell General Hospital (first PCI on August 19, 2004); Melrose-Wakefield Hospital (first PCI on April 19, 2004); and Saints Memorial Hospital

(first PCI on August 23, 2004). Thus, in Massachusetts during 2004, there were seven hospitals involved in the Primary PCI Pilot Program.

This document reports hospital-specific standardized mortality incidences rates following PCI procedures for the twenty one PCI hospitals in Massachusetts that performed at least one PCI between January 1, 2004 and December 31, 2004. Because of the elevated risks associated with heart attack patients, results for two separate cohorts of patients are presented: 1) patients having an ST-elevated myocardial infarction (STEMI) within 24 hours of arrival to the hospital or having cardiogenic shock prior to the intervention (referred to as ''shock or STEMI") and 2) patients having no STEMI (NSTEMI) within 24 hours of arrival to the hospital and no cardiogenic shock prior to the PCI (referred to as "no shock and NSTEMI").

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

2.2 - What is a Percutaneous Coronary Intervention?

For a heart to function properly, it needs an oxygen-rich blood supply. Coronary arteries send oxygen-rich blood to the heart. When the coronary arteries are healthy, blood flows easily so that the heart muscle gets the oxygen it needs. Coronary artery disease begins when blood flow to the heart is reduced due to a build-up of plaque. Plaque may build up because of high cholesterol, high blood pressure, smoking, diabetes, genetic predisposition, or other factors. If the plaque build-up increases, the coronary arteries narrow and blood flow to the heart is reduced, often leading to angina (chest pain, arm pain, or jaw tightness that occurs with exertion or, in more serious cases, at rest). If blood flow is completely blocked by the sudden development of a clot within a coronary artery, this usually results in a heart attack or myocardial infarction (MI), which may irreversibly damage the heart muscle.

Coronary artery disease is usually treated by one of three methods (medication, coronary intervention, or cardiac surgery). The treatment choice depends on the degree

of the blockage, patient symptoms and the number of coronary arteries involved. Percutaneous Coronary Intervention is a procedure performed in the Catheterization Lab that unblocks a coronary artery without having to undergo surgery. Most Percutaneous Coronary Interventions involve either a balloon catheter and/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 the buildup of scar tissue which can occur in a small percentage of patients after the intervention.

2.3 - Why Report on Percutaneous Coronary Interventions?

A PCI offers a non-surgical alternative to Coronary Artery Bypass Surgery (CABG). PCI is less invasive, and the hospital stay and recovery is much shorter than with CABG surgery. CABG surgery has declined while PCI has increased considerably with the option for less invasive, successful treatment of their coronary artery disease.

2.4 - Who Receives Percutaneous Coronary Interventions in Massachusetts?

Between January 1, 2004 and December 31, 2004, there were 17110 admissions in which at least one PCI was performed. The majority of patients undergoing a PCI were male, white, and over 60 years of age (**Table 2.1**). Almost 97% of patients received only one PCI during their hospital admission.

Mass-DAC analyzed the first PCI for patients who received more than one PCI during their admission. Results do not change if the last PCI is used.

Table 2.1: Descriptive Summaries of Adult PCI Admissions in Massachusetts Hospitals, January 1 – December 31, 2004. If multiple PCIs occur during an admission, the **first** PCI is selected. ¶Patients arriving with no STEMI within 24 hours and no cardiogenic shock; §Patients having STEMI within 24 hours of hospital arrival or cardiogenic shock.

RISK COHORT	¶No shock and NSTEMI		§ Shock or STEMI	
Characteristic	**Number**	**Percent**	**Number**	**Percent**
Admitted via Emergency Department or Transfer	7957	54.9	2527	97.0
Number of PCIs Per Admission				
1 PCI	14057	96.9	2438	93.6
≥ 2 PCIs	447	3.1	168	6.5
More than 70% stenosis in Left Anterior Descending Artery	8243	56.8	1428	54.8
At least One Stent	13355	92.1	2410	92.5
Drug Eluting if Stented	11920	89.3	1731	71.8
Total Length of Stay, days	Mean = 3.92 Median = 3.00		Mean = 6.26 Median = 5.00	
Post-Procedure Length of Stay, days	Mean = 3.12 Median = 2.00		Mean = 6.08 Median = 4.00	
Unadjusted Outcomes				
Any Vascular Complication	347	2.39	137	5.26
Unplanned CABG	28	0.20	10	0.39
In-Hospital Death	98	0.68	150	5.76
TOTAL NO. OF ADMISSIONS	**14504**	**100**	**2606**	**100**

Table 2.2 provides demographic summaries of the 14504 "no shock and NSTEMI" admissions and 2606 "shock or STEMI" admissions. The majority of "no shock and NSTEMI" admissions are male (68.1%), white (91.3%), and about 33% were less than 60 years of age at the time of their PCI. Patients residing outside Massachusetts at the time of their PCI constituted 7.4% of the "no shock and NSTEMI" admissions (data not shown).

The majority of "shock or STEMI" admissions are male (69.6%) and white (89.8%). A little less than half (44.4%) of the "shock or STEMI" admissions were less than 60 years old at

the time of their PCI. Finally, 7.1% of the "shock or STEMI" admissions were for patients residing out of state (data not shown).

Table 2.2: Age-Sex-Race Distribution for Adult PCI Admissions in Massachusetts Hospitals During January 1, 2004 – December 31, 2004: Stratified by Risk Cohort. Entries represent numbers of admissions.

14504 No shock and NSTEMI PCI ADMISSIONS

Age Group	Females					Males				
	White	African American	Hispanic	Other[§]	Total	White	African American	Hispanic	Other	Total
≤49	285	23	22	8	338	1067	50	49	61	1227
50-59	583	39	36	35	693	2282	48	66	125	2521
60-69	1059	38	48	48	1193	2595	60	77	99	2831
70-79	1367	30	33	51	1481	2223	29	29	68	2349
≥80	886	9	6	26	927	892	11	17	24	944
Total	4180	139	145	168	**4632**	9059	198	238	377	**9872**

2606 Shock or STEMI PCI ADMISSIONS

Age Group	Females					Males				
	White	African American	Hispanic	Other	Total	White	African American	Hispanic	Other	Total
≤49	82	4	4	3	93	334	12	25	20	391
50-59	107	7	7	3	124	480	20	19	29	548
60-69	160	3	7	6	176	396	10	13	20	439
70-79	187	4	5	6	202	259	4	6	11	280
≥80	190	1	1	4	196	145	0	3	9	157
Total	726	19	24	22	**791**	1614	46	66	89	**1815**

[§] Includes some missing

2.5 - Why Report Hospital-Specific In-Hospital Standardized Mortality Rates?

Quality data can be used to provide useful information to both patients and health care providers, stimulate additional research on cardiovascular disease and existing treatments, and foster improvements in quality of care. This report uses in-hospital mortality, defined as death occurring in the hospital during the same admission as for the procedure, regardless of cause, as a measure of hospital quality. While mortality is not the only important endpoint, it was selected as the primary measure of hospital quality because it is serious and unambiguous.

2.6 - 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 cardiac 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: the Massachusetts Cardiac Care Quality Advisory Commission, the Cardiac Advisory Board, and the PCI Data Adjudication Committee. In addition, both the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR) and the Massachusetts Chapter of the American College of Cardiology serve as resources.

2.7 - What Data Are Used in this Report?

Massachusetts hospitals are required by law to submit specific information to Mass-DAC. Data included in this report were submitted by Massachusetts hospitals that performed PCIs between January 1, 2004 and December 31, 2004.

Data was rigorously verified by Mass-DAC. This process involved: (1) continuous data quality reports to data managers located at each hospital; (2) discussions with the

Chiefs of Cardiology and the Directors of the Cardiac Catheterization Labs in Massachusetts; (3) audits of selected chart information by the PCI Data Adjudication Committee; (4) review by an external Cardiac Advisory Board; and (5) linkages and cross-checks with state administrative databases. . All participants in the audits and committees took the Harvard Medical School Human Subjects training and were approved by the Internal Review Board (IRB) of the medical school.

2.8 - Risk Adjustment for Quantifying In-Hospital Mortality

Specific risk factors are known to contribute to heart disease. These include high cholesterol, smoking, high blood pressure, family history of heart disease, diabetes, age and gender. General health status prior to a PCI is an important factor as well. Such factors also have an impact on the risk of mortality following a PCI. Sicker patients or patients with more health-related risks may be more likely to die following a PCI than healthier patients. Moreover, patients who are sicker may be more likely to be treated at particular hospitals, while patients who are healthier, may be more likely to be treated at other hospitals. To compare hospitals fairly, it is important to consider differences in patient health prior to a PCI.

The statistical process of adjusting for differences in patient sickness prior to their encounter with the health care system is called risk adjustment. This statistical process aims to "level the playing field" by accounting for health risks that patients have prior to a PCI. The hospital mortality rates in this report have been adjusted in order to account for differences in patient health prior to a PCI.

2.9 - How are Hospital Differences in Patient Outcomes Measured?

If there are differences in hospital quality, due to staff, experience, or other factors, then the risks of in-hospital mortality for two patients having <u>exactly the same risk factors</u> prior to a PCI but who are treated in different PCI hospitals will <u>not be the same</u>. The statistical model used to calculate mortality rates in this report - ***a hierarchical logistic regression model*** – models the difference between the risks of mortality for patients with the same risk factors who are treated at different hospitals. This is accomplished through

the inclusion of a hospital specific (random) effect. If no key risk factor is missing in the statistical model, then the hospital-specific random effect represents quality for each hospital. If there are no differences in the hospital-specific effects across the hospitals, then there is no evidence of quality differences.

3 - IDENTIFYING OUTLYING PERCUTANEOUS CORONARY INTERVENTION HOSPITALS

One of the purposes of this report is to identify hospitals that have ***unusually*** high or ***unusually*** low mortality rates. Such hospitals are denoted "outlying" – however, the designation of outlying depends on how large the difference is. Two methods were used to identify outlying hospitals. The first method calculates a 95% interval estimate for each hospital's risk-standardized mortality rate. If the interval estimate does not contain the state unadjusted in-hospital mortality rate, the hospital is designated as outlying.

However, because any one hospital could influence the estimates of the risk-standardized mortality rate for other hospitals, Mass-DAC also calculates the expected number of mortalities at each hospital using the experience of all **other** hospitals in Massachusetts. If there is a low probability that the actual number of mortalities and the predicted number of mortalities is the same, then the hospital is classified as "outlying."

If the 95% interval estimate for a particular hospital excludes the state unadjusted in-hospital mortality rate **or** if the probability of the observed mortality predicted from all other hospitals for a particular hospital is small, then Mass-DAC classified the hospital as outlying. It is important to note that the classification in this report is relative to all hospitals in Massachusetts performing PCI.

3.1 - 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 2004. The SMIR consists of an estimate of the hospital's underlying (true) risk-adjusted rate divided by an estimate of the mortality rate expected at the hospital given its case-mix. Each hospital's SMIR should only be interpreted in the context of its posterior interval. If the 95% interval includes the unadjusted state rate, then the hospital mortality that is **not different than expected**. If the interval excludes the state unadjusted rate, then the hospital's SMIR is an outlier. In this case, if the upper limit of the interval is lower than the

unadjusted state rate, then fewer patients than expected died. Such a hospital would be categorized as having **lower than expected mortality**. If the lower limit of the interval is higher than the unadjusted rate, then more patients than expected died. Such a hospital would be categorized as having **higher than expected mortality**.

3.2 - 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 variation between hospitals in risk stratifying mortality rates. One method to identify hospitals as outlying is through "cross-validation". This process involves systematically dropping each hospital from the data set and re-estimating the risk-adjusted model. Using the new model, the predicted number of deaths at the dropped hospital is calculated. This predicted number may be interpreted as the number of mortalities expected at the dropped hospital if the dropped hospital had the same level of quality as the remaining hospitals.

Mass-DAC compared the predicted number of deaths to the actual number of deaths at the dropped hospital and calculated a "probability." This probability, loosely called a "p-value," quantifies how **likely** the observed number of deaths would be had the dropped hospital had the same level of quality as all remaining PCI hospitals. Small p-values (those ≤ 0.01) indicate that the dropped hospital is outlying. When the p-value is small and the actual number of deaths is larger than that predicted by the remaining hospitals, the dropped hospital is classified as having **higher than predicted mortality;** when the p-value is small and the actual number of deaths is smaller than predicted by its peers, then the hospital is classified as having **lower than predicted mortality**.

3.3 - Sensitivity Analyses

Several sensitivity analyses were undertaken to determine whether conclusions would change when making reasonable changes to some of the underlying assumptions. A key assumption, given the small number of hospitals in Massachusetts, is the assumed distribution for the between-hospital variance. The main analyses assumed the *precision*

(defined as one over the variance) arose from a gamma distribution. Because the prior distribution for the variance component can influence the results, Mass-DAC re-estimated the hierarchical model using different prior distributions for the between-hospital variance component.

In sensitivity analyses, two different prior distributions were assumed: (1) the between-hospital *standard deviation* arose from a uniform distribution over the range 0 to 1.5; and (2) the between-hospital *standard deviation* arose from a half normal distribution with mean 0 and variance 0.26. In the former case, we are giving equal weight to values across the range 0 to 1.5 – a value of 1.5 for the standard deviation implies a very large range in hospital odds ratios. In the latter case, the half normal distribution has its mode at 0 and its median at 0.39.

4 - HOSPITAL QUALITY FOLLOWING PCI: 2004

Of the 17,110 PCIs performed in Massachusetts, 248 patients died during the same admission as the PCI. **Table 4.1** lists the prevalence (%) of important risk factors and the relationship of each risk factor (controlling for all other risk factors) with in- hospital mortality for the "no shock and NSTEMI" cases following a PCI. For example, 31.5% of all PCI admissions included patients who had a history of diabetes. Because age is measured in years, the table reports the average number years over age 65 for the cohort. Odds ratios greater than 1 correspond to increased risk of mortality while those less than 1 correspond to decreased risk of mortality. The odds ratio of 1.46 for patients with diabetes indicates that those patients are 1.46 times as likely as a patient without diabetes to die within the hospital admission following PCI. In contrast, patients with renal failure prior to a PCI are 7.1 times more likely to die within the PCI hospital admission than patients without renal failure.

Table 4.2 lists the same information as in Table 4.1 but for the "shock or STEMI" cases.

Figure 4.1 displays the SMIRs and corresponding 95% posterior intervals. The solid black vertical line in the figure is the unadjusted state in-hospital mortality rate of 0.68% for "no shock and NSTEMI" cases (**Table 4.3** has the specific values listed). Listed on the left-hand side of the figure are the total number of PCI admissions and the expected in-hospital mortality rates for each hospital. The expected mortality rate provides an overall assessment of case-mix severity at each program – higher expected rates represent more severe case mix. Listed on the right-hand side are the estimated SMIRs. All 95% probability intervals contain the unadjusted state rate.

Figure 4.2 displays the SMIRs and corresponding 95% posterior intervals for "shock or STEMI" cases (**Table 4.4** has the actual values listed). The solid black vertical line in the figure is the unadjusted state in-hospital mortality rate of 5.76% for "shock or STEMI" cases. All 95% intervals cover the state unadjusted in-hospital mortality rate.

Figure 4.3 presents the cross-validated p-values of "no shock and NSTEMI" cohort, under a number of different distributional assumptions regarding the hierarchical regression model. **Figure 4.4** presents similar values for the "shock or STEMI" cohort. No hospital has a p-value smaller than or equal to 0.01, regardless of cohort examined.

Based on in-hospital mortality data, there is no evidence of any PCI hospital having higher or lower than expected mortality in Massachusetts during 2004.

Technical details can be found in **Technical Details on Percutaneous Coronary Intervention in the Commonwealth of Massachusetts: January 1 – December 31, 2004.**

Table 4.1: Adjusted Odds Ratios of In-Hospital Mortality Following PCI in Adults: No shock and NSTEMI Cases. January 1, 2004 – December 31, 2004. Based on 14,504 admissions with 98 deaths (0.68%).

Risk Factor	Prevalence (%)	Adjusted Odds Ratio	95% Interval for Adjusted Odds Ratio
Years over 65	Mean = 0.26 yrs	1.07	1.04, 1.09
Renal Failure	7.1	2.16	1.23, 3.43
Diabetes	31.5	1.46	0.93, 2.20
Chronic Lung Disease	12.2	2.70	1.68, 4.07
Ejection Fraction < 30%	3.0	2.33	1.13, 4.02
PCI Status (Elective)			
Urgent	45.4	3.16	1.79, 5.50
Emergent or Salvage	4.6	22.5	11.7, 41.0
High Lesion Risk	26.4	1.62	1.05, 2.38
Left Main Disease	6.7	2.06	1.12, 3.37
LAD > 70% Stenosis	56.8	1.84	1.11, 2.89
Between-Hospital Parameters		**Mean**	**95% Interval**
Between-Hospital Average logit, μ		-7.54	-8.16,-7.0
Average Between-Hospital Variance in logits, τ^2		0.02597	0.00066, 0.1498

Table 4.2: Adjusted Odds Ratios of In-Hospital Mortality Following PCI in Adults, January 1, 2004 – December 31, 2004: Shock or STEMI Cases. Based on 2,602 admissions with 150 deaths (5.76%).

Risk Factor	Prevalence (%)	Adjusted Odds Ratio	95% Interval for Adjusted Odds Ratio
Age (Ref = < 60 years)			
60-69 yrs	23.6	2.12	1.05, 3.80
70-79 yrs	18.5	2.97	1.53, 5.29
≥ 80 yrs	13.6	6.94	3.77, 12.3
Renal Failure	4.5	2.15	1.12, 3.76
Ejection Fraction < 30%	4.6	2.16	1.11, 3.79
PCI Status (Urgent + Elective[2])			
Emergent or Salvage	90.5	1.04	0.48, 1.98
Pre-Procedure Cardiogenic Shock	9.8	19.1	12.4, 28.3
Left Main Disease	5.0	2.56	1.36, 4.37
Between-Hospital Parameters		**Mean**	**95% Interval**
Between-Hospital Average logit, μ		-4.875	-5.728, -4.077
Average Between-Hospital Variance in logits, τ^2		0.2055	0.001793, 0.7652

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

Figure 4.1: Ninety-Five Percent Posterior Intervals for Standardized In-Hospital Mortality Incidence Rates (SMIRs) Following PCI During January 1, 2004 – December 31, 2004: No shock and NSTEMI Admissions. # of cases refers to the number of No shock and NSTEMI PCI admissions; expected mortality rate is the percentage of cases expected to die given the case-mix of the patients in the hospital. The white vertical line in each box is the hospital's SMIR while the black vertical line denotes the unadjusted state in-hospital mortality rate of **0.68**%.

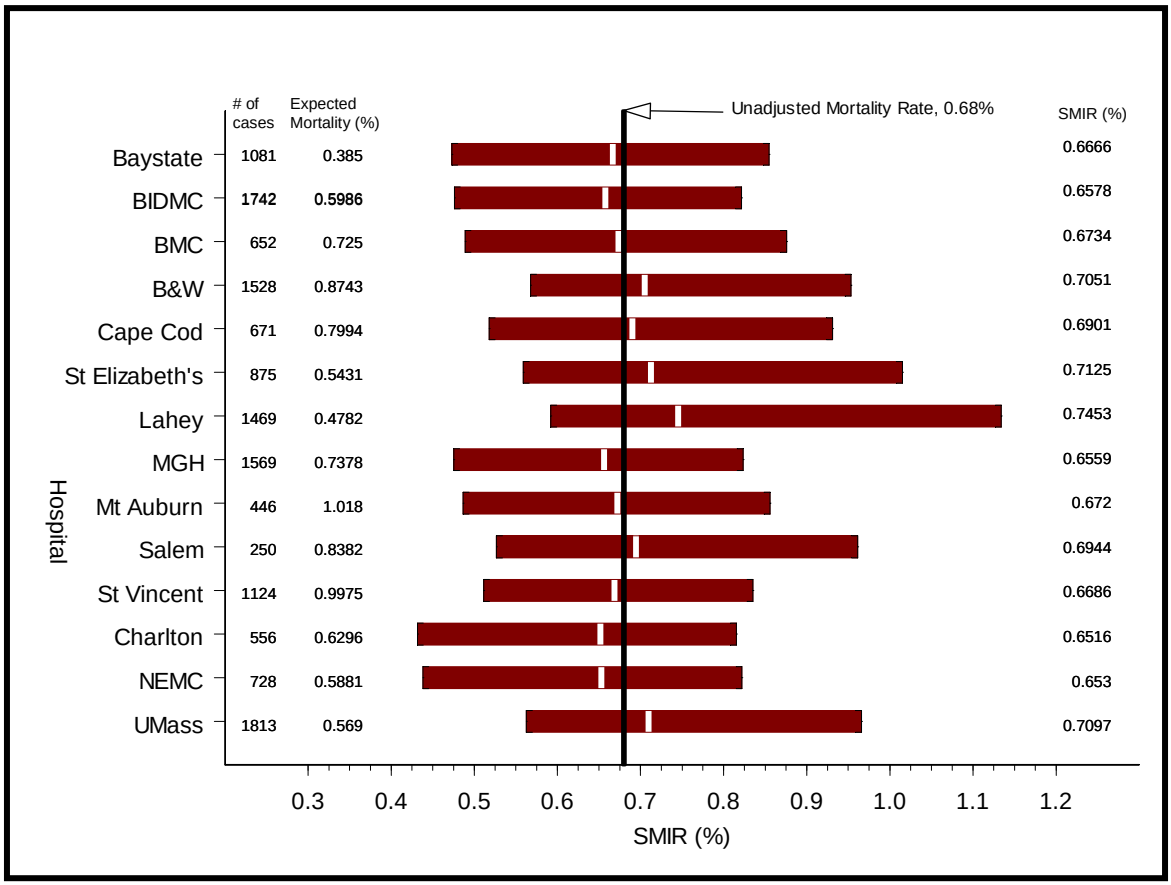


Table 4.3. Expected and Standardized In-Hospital Mortality Incidence Rates (SMIR) for No Shock and No STEMI Admissions, 2004. # of cases refers to the number of No shock and NSTEMI PCI admissions; expected mortality is the percentage of cases expected to die given the case-mix of the patients in the hospital. The SMIR is the hospital-specific standardized rate. Unadjusted state rate = **0.68**%.

Hospital	# of Cases	In-Hospital Mortality (%)			
		Expected	Lower Limit of 95% SMIR Interval	SMIR	Upper Limit of 95% SMIR Interval
Baystate Medical Center	1081	0.385	0.4729	0.6666	0.8548
Beth Israel Deaconess Medical Center (BIDMC)	1742	0.5986	0.4759	0.6578	0.8216
Boston Medical Center (BMC)	652	0.725	0.4889	0.6734	0.8758
Brigham and Women's Hospital (B&W)	1528	0.8743	0.5677	0.7051	0.9532
Cape Cod Hospital	671	0.7994	0.5178	0.6901	0.931
Caritas Saint Elizabeth's Medical Center (St. Elizabeth)	875	0.5431	0.5588	0.7125	1.015
Lahey Clinic	1469	0.4782	0.592	0.7453	1.134
Massachusetts General Hospital (MGH)	1569	0.7378	0.4752	0.6559	0.8232
Mount Auburn Hospital	446	1.018	0.4864	0.672	0.8558
North Shore Medical Center-Salem Hospital (Salem)	250	0.8382	0.5266	0.6944	0.9612
Saint Vincent Hospital at Worcester Medical Center (St. Vincent)	1124	0.9975	0.5112	0.6686	0.8352
Southcoast Hospital Group-Charlton Memorial Hospital (Charlton)	556	0.6296	0.4316	0.6516	0.8152
Tufts-New England Medical Center (NEMC)	728	0.5881	0.4381	0.653	0.822
UMass Memorial Medical Center (UMass)	1813	0.569	0.5625	0.7097	0.9658
ALL	**14,504**			**0.68**	

Figure 4.2: Ninety-Five Percent Probability Intervals for Standardized In-Hospital Mortality Incidence Rates (SMIRs) Following PCI During January 1, 2004 – December 31, 2004: Shock or STEMI Admissions. # of cases refers to the number of PCI admissions; expected mortality rate is the percentage of cases expected to die given the case-mix of the patients in the hospital. The white vertical line in each box is the hospital's SMIR while the black vertical line denotes the unadjusted state in-hospital mortality rate of 5.76%.

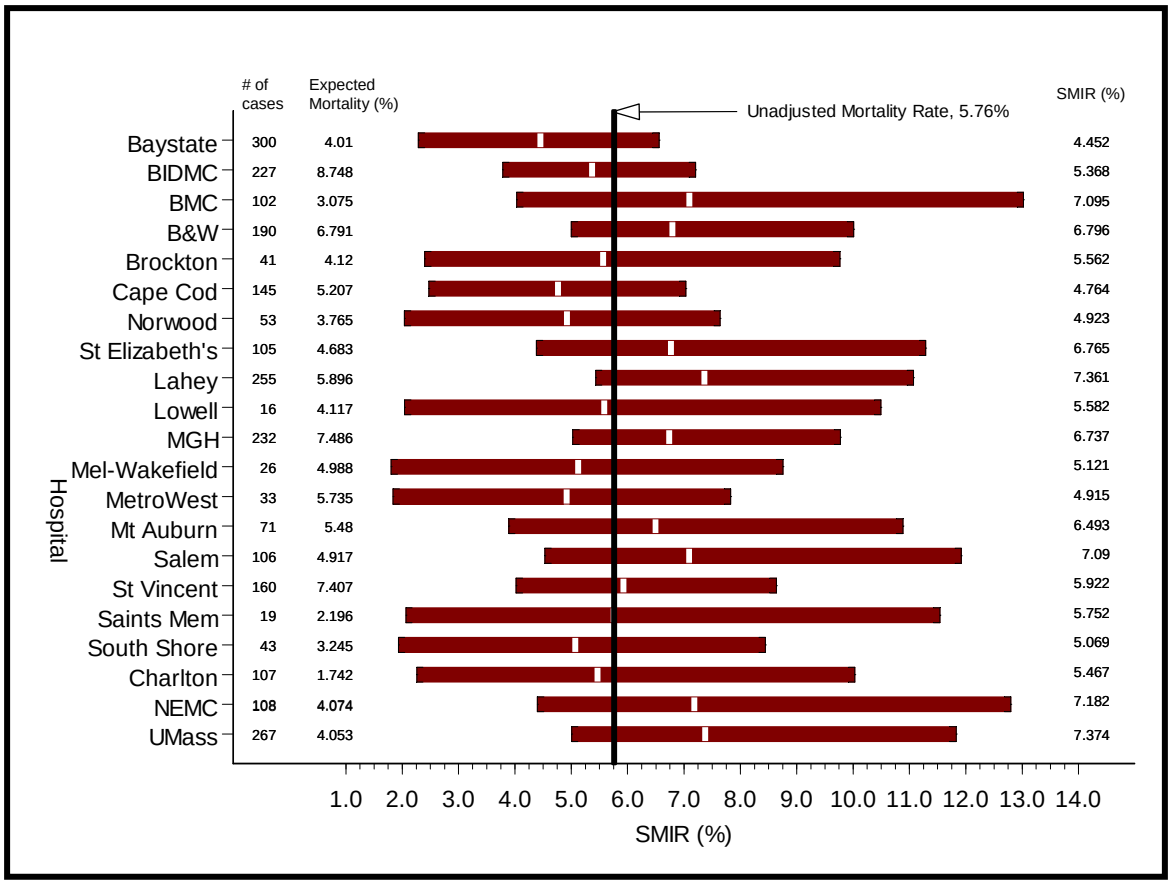


Table 4.4. Expected and Standardized In-Hospital Mortality Incidence Rates (SMIR) for Shock or STEMI Admissions, 2004. # of cases refers to the number of shock or STEMI PCI admissions; expected mortality is the percentage of cases expected to die given the case-mix of the patients in the hospital. The SMIR is the hospital-specific standardized rate. Overall State Mean = **5.76**%.

Hospital	# of Cases	In-Hospital Mortality (%)			
		Expected	Lower Limit of 95% SMIR Interval	SMIR	Upper Limit of 95% SMIR Interval
Baystate Medical Center	300	4.01	2.287	4.452	6.558
Beth Israel Deaconess Medical Center (BIDMC)	227	8.748	3.785	5.368	7.203
Boston Medical Center (BMC)	102	3.075	4.031	7.095	13.02
Brigham and Women's Hospital (B&W)	190	6.791	5.001	6.796	10.01
Brockton Hospital	41	4.12	2.398	5.562	9.764
Cape Cod Hospital	145	5.207	2.476	4.764	7.031
Caritas Norwood Hospital (Norwood)	53	3.765	2.038	4.923	7.64
Caritas Saint Elizabeth's Medical Center (St. Elizabeth's)	105	4.683	4.382	6.765	11.29
Lahey Clinic	255	5.896	5.43	7.361	11.07
Lowell General Hospital	16	4.117	2.043	5.582	10.49
Massachusetts General Hospital (MGH)	232	7.486	5.026	6.737	9.776
Melrose-Wakefield Hospital (Mel-Wakefield)	26	4.988	1.804	5.121	8.753
MetroWest Medical Center	33	5.735	1.837	4.915	7.829
Mount Auburn Hospital	71	5.48	3.89	6.493	10.88
North Shore Medical Center-Salem Hospital (Salem)	106	4.917	4.531	7.09	11.92
Saint Vincent Hospital at Worcester Medical Center (St. Vincent)	160	7.407	4.023	5.922	8.638
Saints Memorial Hospital (Saints Mem)	19	2.196	2.065	5.752	11.54
South Shore Hospital	43	3.245	1.932	5.069	8.442
Southcoast Hospital Group-Charlton Memorial Hospital (Charlton)	107	1.742	2.258	5.467	10.03
Tufts- New England Medical Center (NEMC)	108	4.074	4.40	7.182	12.8
UMass Memorial Medical Center (UMass)	267	4.053	5.007	7.374	11.83
ALL	**2,606**			**5.76**	

Figure 4.3: Cross-Validated P-Values, January 1, 2004 – December 31, 2004 (No shock and NSTEMI Cohort). . P-Values are listed on the y-axis; the x-axis identifies the hospital. Results are presented under a variety of assumptions for fitting the hierarchical regression model. Prior distributions for the between-hospital variance component are gamma, half normal, and uniform (left to right).

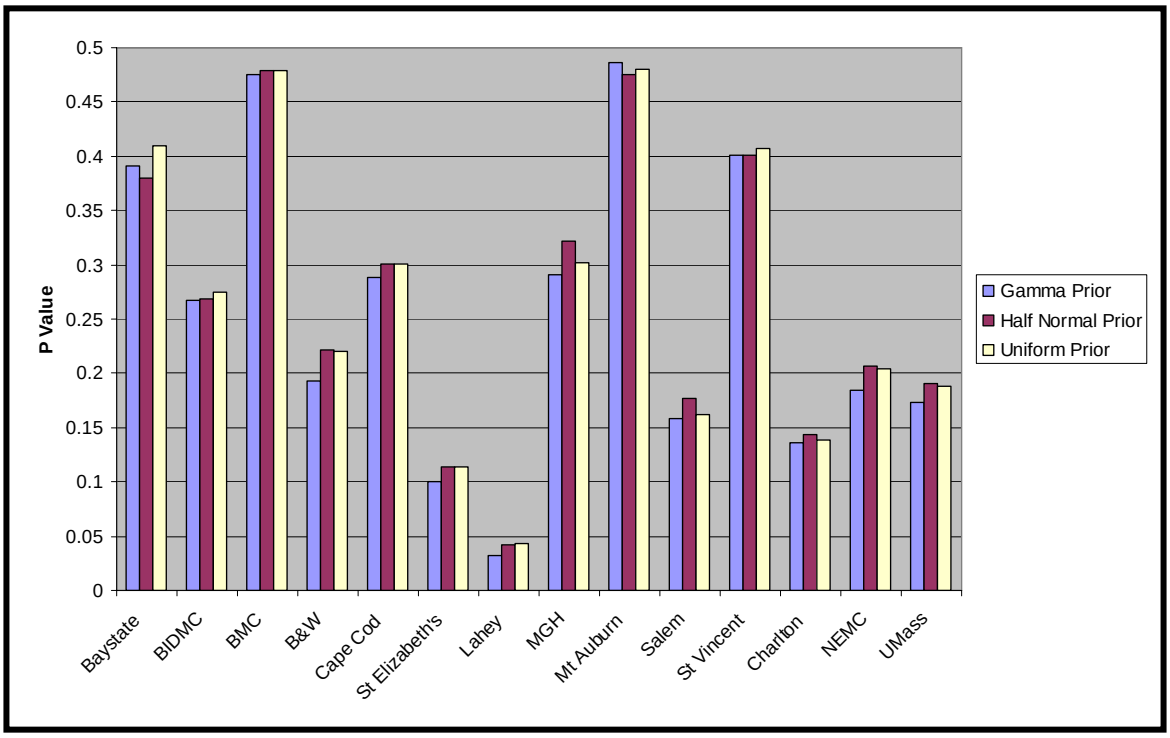
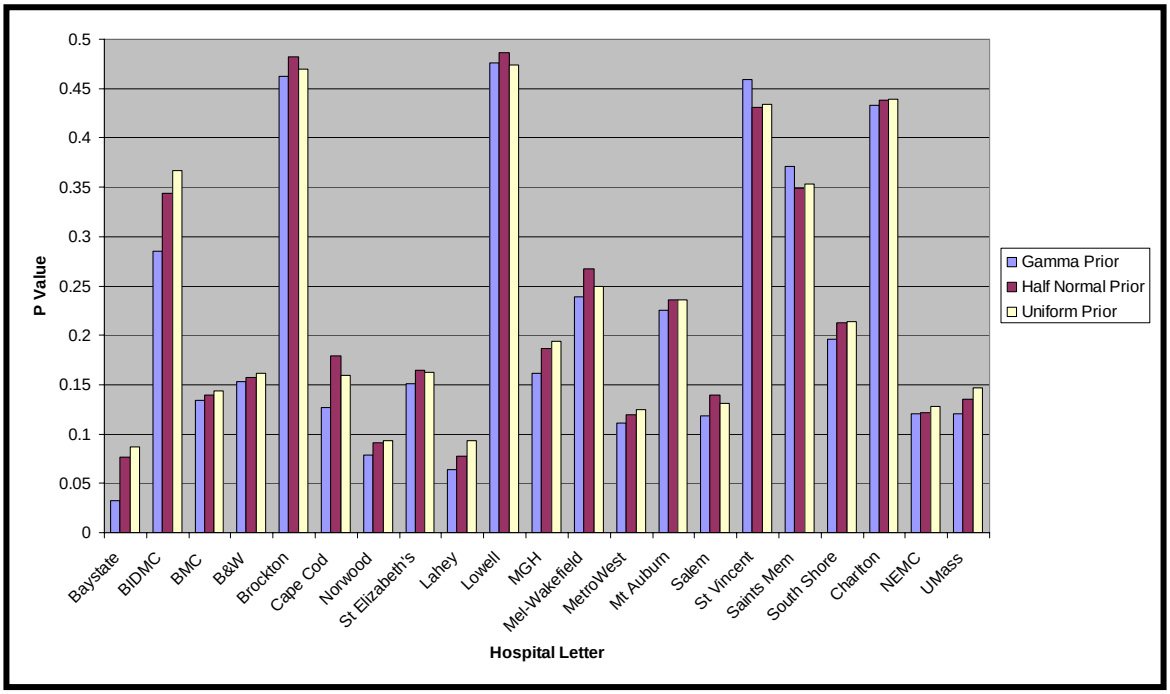


Figure 4.4: Cross-Validated P-Values, January 1, 2004 – December 31, 2004 (Shock or STEMI Cohort): P-Values are listed on the y-axis; the x-axis identifies the hospital. Results are presented under a variety of assumptions for fitting the hierarchical regression model. Prior distributions for the between-hospital variance component are gamma, half normal, and uniform (left to right).



5 - IMPORTANT DEFINITIONS

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

Cardiac Surgery (as defined by the Massachusetts legislature for the Massachusetts Cardiac Study): Surgery on the heart and the thoracic great vessels. Examples of cardiac surgery include coronary artery bypass grafts, heart valve repair or replacement, heart transplantation, surgery of the thoracic aorta, repair of congenital heart defects, and minimally invasive heart surgery.

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

Coronary Artery Disease: A disease affecting the coronary arteries in which the flow of oxygen-containing blood to the heart muscle is partially or completely blocked, resulting in angina or a heart attack.

Coronary Artery Bypass Graft [CABG] Surgery: Operations in which the blocked coronary vessels are bypassed with the patients' own vessels to improve flow to the heart muscle. Coronary vessels are those vessels that supply the heart muscle with blood and oxygen.

Cross-Validation: Model validation is done to ascertain whether predicted values from a statistical model are likely to accurately predict responses on future subjects or on subjects not used to develop the analytical model. Cross-validation involves dropping a set of observations from the analytical process and the outcomes for the dropped set are predicted. This process is repeated many times in order to characterize the accuracy of the predictions.

Drug Eluting Stent: Stents that are either coated or imbedded with time released medication, interrupting the biological process that causes the artery to close up again.

Mitral Valve Repair: Surgical repair of the mitral valve of the heart. The mitral valve is responsible for facilitating the flow of blood from the left atrium into the left ventricle.

Percutaneous Coronary Intervention: A non-surgical procedure designed to open and maintain the patency of obstructed coronary vessels. This treatment is an invasive procedure performed in the cardiac catheterization lab (i.e., outside of an operating room) by an interventional cardiologist in which a balloon, stent, or other device is delivered to the affected vessel to open and maintain its patency.

Risk Factors: Factors that contribute to an individual's risk of coronary artery disease or of death. These factors are classified as those that can be modified or changed by an individual, and those that cannot be changed. Examples of risk factors that cannot be modified include age, gender, family history of coronary artery disease, and ethnicity. Risk factors that can be controlled include diet, cholesterol levels, obesity, smoking, hypertension, inactive lifestyle, stress, and diabetes.

Standardized Mortality Incidence Rate (SMIR): The ratio of projected deaths (the number of deaths adjusted for the number of cases treated at the hospital and the hospital case mix) to expected deaths (the expected number of deaths calculated on the basis of the mortality experience of all cardiac surgery programs) multiplied by the state unadjusted rate. SMIRs are interpreted in terms of their corresponding probability intervals. If the probability interval includes the state rate, then the SMIR is no different from what was expected. If the interval excludes the state rate, then the SMIR is "significantly different" from what was expected. In this case, if the upper limit of the interval is lower than the state rate, then fewer patients than expected died; if the lower limit of the 95% interval is higher than the state rate, then more patients than expected died.

Stent: a metal tube that is inserted after a balloon angioplasty to prevent abrupt artery closure.

6 - ADVISORY COMMITTEES

Mass-DAC gratefully acknowledges the support from members of several Advisory Committees as well as the physician volunteers (for data adjudication) who have donated their time to improve the quality of cardiac care in the Commonwealth of Massachusetts.

The Massachusetts Cardiac Care Quality Advisory Commission develops standards and criteria to be used by the Department of Public Health and Mass-DAC for the purpose of collecting, monitoring, and validating patient specific outcome data from all hospitals in the Commonwealth of Massachusetts performing cardiac surgery or PCIs.

David Shahian, M.D., Chair Tufts University School of Medicine Boston, MA	Sharon-Lise Normand, Ph.D. Professor of Health Care Policy (Biostatistics) Department of Health Care Policy Harvard Medical School Boston, MA
Paul Dreyer, Ph.D. Director, Division of Health Care Quality Massachusetts Department of Public Health Boston, MA	John Pastore, M.D. Director, Echocardiography Saint Elizabeth's Medical Center Boston, MA
Stanley Lewis, M.D. Associate Professor of Medicine Harvard Medical School Beth Israel Deaconess Medical Center Boston, MA	David Torchiana, M.D. Chairman and Chief Executive Officer Massachusetts General Physicians Organization Boston, MA

The Mass-DAC Cardiac Advisory Board advises Mass-DAC on data quality; on identification of risk factors affecting patient outcomes; and on appropriateness, interpretation, and limitations of analytic results.

Shukri Khuri, M.D. Chief of Surgery VA-Boston Healthcare Systems Boston, MA	Thomas Ryan, M.D. Senior Consultant in Cardiology Professor of Medicine Boston University Medical Center Boston, MA
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Eric Peterson, M.D., M.P.H. Director, Cardiovascular Outcomes and Quality Duke Clinical Research Institute Durham, NC	

The Mass-DAC PCI Data Adjudication Committees review patient-specific data elements and corresponding data documentation submitted by hospitals to Mass-DAC in order to determine validity.

Clifford J. Berger M.D. Brockton Cardiology Associates Assistant Clinical Professor of Medicine Boston University School of Medicine Boston, MA	Theo E. Meyer, MD, PhD Director, Cardiac Catheterization Laboratory Professor of Medicine UMass Memorial Medical Center Worcester, MA
Thomas C. Piemonte, M.D. Director, Cardiac Catheterization Laboratory and Interventional Cardiovascular Medicine Lahey Clinic Burlington, MA	Samuel J. Shubrooks Jr., M.D. President, Mass. Chapter American College of Cardiology Co-Director, Cardiac Catheterization Lab Beth Israel Deaconess Medical Center Boston, MA

The following Cardiac Interventionalists generously volunteered their time to join the PCI Adjudication Committee in adjudicating the 2004 data:

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Boston, MA

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Boston Medical Center
Boston, MA

Daniel Fisher, M.D.
UMass Memorial Medical Center
North Worcester, MA

Fred Resnic, M.D.
Brigham and Women's Hospital
Boston, MA

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

Pinak Shah, M.D.
Caritas Saint Elizabeth's Medical Center
Brighton, MA

Alice Jacobs, M.D.
Boston Medical Center
Boston, MA

James Waters, M.D.
Lahey Clinic
Burlington,

APPENDIX:

ACC-NCDR DATA COLLECTION TOOL - VERSION 2.0

Sample Data Collection Form

ADMINISTRATIVE

Participant ID[5] |__|__|__|__|__|__|__| **Participant Name**[6] _____

DEMOGRAPHICS (complete this section on admission to the facility)

Last Name[8] _____ **First Name**[9] _____ **MI**[10] _____ **Social Security # + Country Code**[11] |__|__|__|-|__|__|-|__|__|__|__| + |__|__|

Gender[12]
- ❍ Male
- ❍ Female

Race[13]
- ❍ Caucasian
- ❍ Black
- ❍ Hispanic
- ❍ Asian
- ❍ Native American
- ❍ Other

Date of Birth[14] |__|__|/|__|__|/|__|__|__|__| M D Y

ADMISSION/DISCHARGE (complete this section on admission/discharge to the facility)

Date of Admission[15] |__|__|/|__|__|/|__|__|__|__| M D Y

Admission Status[17]
- ❍ Referral
- ❍ Emergency Department
- ❍ Transfer – other Facility
- ❍ Other

❍ **CAB – This Adm**[22] |__|__|/|__|__|/|__|__|__|__| M D Y

CAB Status[21]
- ❍ Elective
- ❍ Urgent
- ❍ Emergency
- ❍ Salvage

Insurance Payor[18] (choose one)
- ❍ Government
- ❍ Commercial
- ❍ HMO
- ❍ None

|Calculated| **# PCI's Lab Visits**[19]

|Calculated| **Multiple PCI–Same Lesion**[20]

Date of Discharge[16] |__|__|/|__|__|/|__|__|__|__| M D Y

Discharge Status[23]
- ❍ Alive
- ❍ Expired

Date of Death[24] |__|__|/|__|__|/|__|__|__|__| M D Y

Location of Death[26]
- ❍ During CL Visit
- ❍ After CL Visit

Primary Cause of Death[25]
- ❍ Cardiac
- ❍ Neurologic
- ❍ Renal
- ❍ Vascular
- ❍ Infection
- ❍ Pulmonary
- ❍ Valvular
- ❍ Other

HISTORY AND RISK FACTORS (complete this section on admission to the facility)

____ cm **Height**[27]
____ kg **Weight**[28]

- ❍ **Family Hx CAD**[29]
- ❍ **CHF**[30]

❍ **Diabetes**[31] (✓all that apply)
- ❍ Diet
- ❍ Oral
- ❍ Insulin

❍ **Renal Failure**[32]
- ❍ Current Dialysis
- ❍ No Dialysis

- ❍ **Chronic Lung Disease**[33]
- ❍ **Cerebrovasc. Disease**[34]
- ❍ **Peripheral Vascular Disease**[35]
- ❍ **Previous MI**[36]

- ❍ **Hypertension**[37]
- ❍ **Smoking** (choose one)[38]
  - ❍ Current
  - ❍ Former
- ❍ **Hypercholesterolemia**[39]
  - ❍ w/ Lipid Lowering Ther.
  - ❍ w/o Lipid Lowering Ther.

PREVIOUS INTERVENTIONS (complete this section on admission to the facility)

❍ **Previous PCI**[40] |__|__|/|__|__|/|__|__|__|__| **M D Y**[41]

❍ **Previous CAB**[42] |__|__|/|__|__|/|__|__|__|__| **M D Y**[43]

❍ **Previous Valve Surgery**[44] |__|__|/|__|__|/|__|__|__|__| **M D Y**[45]

CARDIAC STATUS (complete this section on admission to the facility)

❍ **CHF – Prior Proc.**[46]
NYHA[47] ❍1 ❍2 ❍3 ❍4

❍ **Non-Inv. Test –Ischemia**[48]
- ❍ Positive
- ❍ Negative
- ❍ Equivocal
- ❍ Arrhythmia

❍ **CCS**[50]
- ❍ No Angina
- ❍ I
- ❍ II
- ❍ III
- ❍ IV

❍ **Angina Type** (choose one)[49]
- ❍ Atypical Chest Pain
- ❍ Stable Angina
- ❍ Acute Coronary Syndrome

ACS Time Period[51]

ACS Type:	<6°	6-24°	25°-7d	7d-2m
❍ Unst. Angina	❍	❍	❍	❍
❍ Non ST ↑ MI	❍	❍	❍	❍
❍ ST ↑ MI	❍	❍	❍	❍

CATH LAB VISIT (complete this section for each Cath Lab visit)

Date of Procedure[52]
|__|__|/|__|__|/|__|__|__|__|
M D Y

Procedure Type[54]
❍ Right Heart Cath
❍ Left Heart Cath
❍ PCI

SUMMARY
|___|min. **Fluro Time**[55]
|*Calc*| **Cath/PCI Same Lab Visit**[56]

CORONARY ANATOMY
Dominance (check 1)[68]
❍ Left
❍ Right
❍ Mixed

Stenosis % (enter 0 if no stenosis)
|___|%LM[69] |___|%Mid/Dist LAD[71]
|___|%Prox LAD[70] |___|%CIRC[73]
|___|%RCA/PDA if R or Mixed Dom.[72]

MEDICATIONS
❍ **ASA**[60]
❍ **IIB/IIIA**[58]

	Prior	During	After
	❍	❍	❍

Percutaneous Entry[74]

Closure Device[75]	Sut.	Seal	Other
❍ Femoral	❍	❍	❍
❍ Brachial	❍	❍	❍
❍ Radial	❍	❍	❍
❍ Other	❍	❍	❍

HEMODYNAMIC SUPPORT
❍ **IABP**[62]
❍ **CP Bypass**[63]

LV Status
❍ **LV Gram**[64]
❍ **LV Wall Motion**[65]
❍ Normal
❍ Abnormal

EF STATUS
|___|**% EF**[67]

EF Test Obtained by[66]
❍ Contrast
❍ Non-Invasive

EF Measurement[66]
❍ Estimated
❍ Calculated

DIAGNOSTIC CATH (skip this section if Diagnostic Cath not performed)

Operator's Name[76]
_____

Operators SSN[77]
|__|__|__|-|__|__|-|__|__|__|__|

Status[78]
❍ Elective ❍ Emergency
❍ Urgent ❍ Salvage

INDICATIONS
❍ **Card. Shock**[79]
❍ **Valv. Hrt. Dis.**[80]
❍ **Arrhythmia**[81]
❍ **Isch. Hrt. Dis.**[82]
❍ **Positive Functional Test**[83]

Heart Dis. Other Etiology[84]
❍ Transplant
❍ Congenital
❍ Cardiomyopathy
❍ Other

FINDINGS
❍ **Pulmonary Hypertension**[85]
❍ Valve Disease If yes, specify

	Stenosis	Regurge
Mitral[86]	❍	❍
Tricuspid[87]	❍	❍
Aortic[88]	❍	❍
Pulmonic[89]	❍	❍

PCI (skip this section if PCI not performed)

Operator's Name[90]
_____

Operators SSN[91]
|__|__|__|-|__|__|-|__|__|__|__|

Status[92]
❍ Elective ❍ Emergency
❍ Urgent ❍ Salvage

MEDICATIONS
❍ **Thrombolytics**[57]

< 3°	3°–6°	>6°≤ 7d
❍	❍	❍

❍ **Heparin**[59]

Prior	During	After
❍	❍	❍

❍ **Clopidogrel**[61]

≤72 hrs	After
❍	❍

INDICATIONS
❍ **Lesion >50**[93]
❍ De novo
❍ Restenosis
❍ **Acute MI**[94]
❍ NON STEMI
❍ STEMI
Onset Time[95] _____
Ballo/Stnt Time[96] _____
❍ **Cardiogenic Shock**[97]

SUMMARY
|calc| **# Attempt Lesion**[98]
|calc| **# Lesion Success. Dilated**[99]
|calc| **Procedure Result**[100]

Lesion Identification Number[101]	1	2	3	4	5	6	7	8
Segment #[102]								
Guidewire[103] (S, U)								
% Pre-Stenosis[104]								
% Post-Stenosis[105]								
Pre Procedure TIMI Flow[106] (0,1,2,3)								
Post Procedure TIMI Flow[107] (0, 1, 2, 3)								
Previously Dilated Les.[108] (Yes, B, S, O)								
In Graft to Cited Segment[109] (V, A)								
Location in Graft[110] (Aortic, Body, Distal)								
Lesion Risk[111] (L, M, H)								
IC Device(s)[113] (circle **primary device**[114]) Balloon, Cutting Balloon, Bare Metal Stent, DCA, Rotational Atherectomy, AngioJet,TEC, Laser, IVUS, Flowire,Pressure Wire, Sirolimus-Eluting Stent, Paclitaxel-Eluting Stent, Heparin Coated Stent, Covered Stent, Gamma Brachytherapy, Beta Brachytherapy, Distal Embolic Protection, Other Device								
Dissection[115] (Yes, No)								
Acute Closure[116] (Yes, No)								
Successful Reopening[117] (Yes, No)								
Perforation[118] (Yes, No)								

ADVERSE OUTCOMES (complete this section for each Cath Lab visit)

	During Lab Visit	After Lab Visit
Periproc. MI[119]	❍	❍
UNL CK[120] ____	n/a	n/a
Base CK[121] ____	n/a	n/a
Peak CK[122] ____	n/a	n/a
Card Shock[123]	❍	❍
Arrhythmia[124]	❍	❍
CVA/Stoke[125]	❍	❍

	During Lab Visit	After Lab Visit
Tamponade[126]	❍	❍
Vascular Comp.[127-132]	L B O D	P B O L A D
Contrast Reaction[133]	❍	❍
CHF[134]	n/a	❍
Renal Failure[135]	n/a	❍
Emergency PCI[136]	❍	❍
Unplanned CAB[137]	❍	❍

OPTIONAL

PCI FOLLOW-UP AT 6 MONTHS

PCI FOLLOW-UP AT 6 MONTHS

Date of Follow Up[138]

|__|__|/|__|__|/|__|__|__|__|

M D Y

Vital Status[139]

- ❍ Alive
- ❍ Dead

Primary Cause of Death[140]

- ❍ Cardiac
- ❍ Noncardiac
- ❍ Unknown

Readmission[141]

(Complete if Readmission is Yes. Select all that apply.)

Readmission Reason[142]

- ❍ Myocardial Infarction (documented)
- ❍ Coronary Artery Bypass Surgery
- ❍ Percutaneous Coronary Intervention
- ❍ Congestive Heart Failure (without MI)
- ❍ Arrhythmia or Conduction Disturbance (without MI)
- ❍ Recurrent Angina (without MI)
- ❍ Cardiac Catheterization
- ❍ Other Medical Problem