MAIN SUBMISSION FORM

1b.2. Provide performance scores on the measure as specified (**current and over time**) at the specified level of analysis. (This is required for maintenance of endorsement. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include). This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.

The study cohort for the validation of this measure includes NCDR CathPCI data linked with National Death Index (NDI) data to ascertain the specifications for 30-day RSMRs for all payers and all ages (>18 years). Using the previously endorsed measure (note: there have been no changes to the measure specifications), we analyzed variation in 30-day RSMRs among the hospitals in this linked dataset for a three-year period, from December 2011 to December 2014. We excluded two months of observation due to missing data during our sampling frame (October 2012 and November 2012). There were 1,127,423 admissions to 1,365 hospitals in the combined three-year sample. RSMRs varied among hospitals, with a mean of 1.07%, a standard deviation of 0.30%, and a range of 0.51% to 2.70%. The interquartile range was 0.87% to 1.24%. The range of performance is as follows:

Percentile of RSMR	Mean RSMR
100% Max	0.0270
99%	0.0211
95%	0.0163
90%	0.0147
75% Q3	0.0124
50% Median	0.0104
25% Q1	0.0087
10%	0.0073
5%	0.0067
1%	0.0057
0% Min	0.0051

Note: The measure is oriented so a lower rate equals better performance. For the purposes of interpreting the above tables, interpret the 0% Min as hospitals with the lowest mortality rate and 100% max as hospitals with the highest mortality rate (i.e. percentiles correspond with mortality rates <u>not</u> percentiles of performance). For example, among all hospitals, the top 1% of hospitals have a mortality rate of 0.57% vs hospitals ranked in the 99th percentile have a 2.1% mortality rate.

Table 1: Distribution of hospital 30-day RSMR for NSTEMI/No Shock, 2011-2014

Description and Percentile	Mean RSMR
N	1127423
Mean	0.0107
Std Deviation	0.0030
100% Max	0.0270
99%	0.0211
95%	0.0163
90%	0.0147
75% Q3	0.0124
50% Median	0.0104
25% Q1	0.0087
10%	0.0073
5%	0.0067
1%	0.0057
0% Min	0.0051

Figure 1: Histogram of hospital 30-day RSMR for NSTEMI/No Shock, 2011-2014

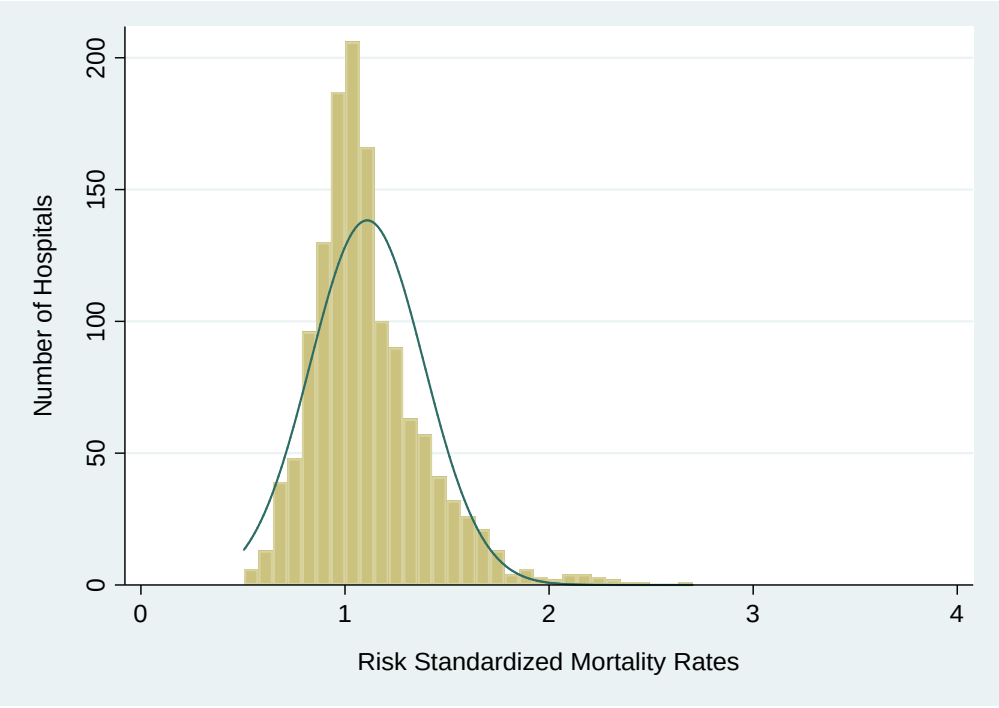
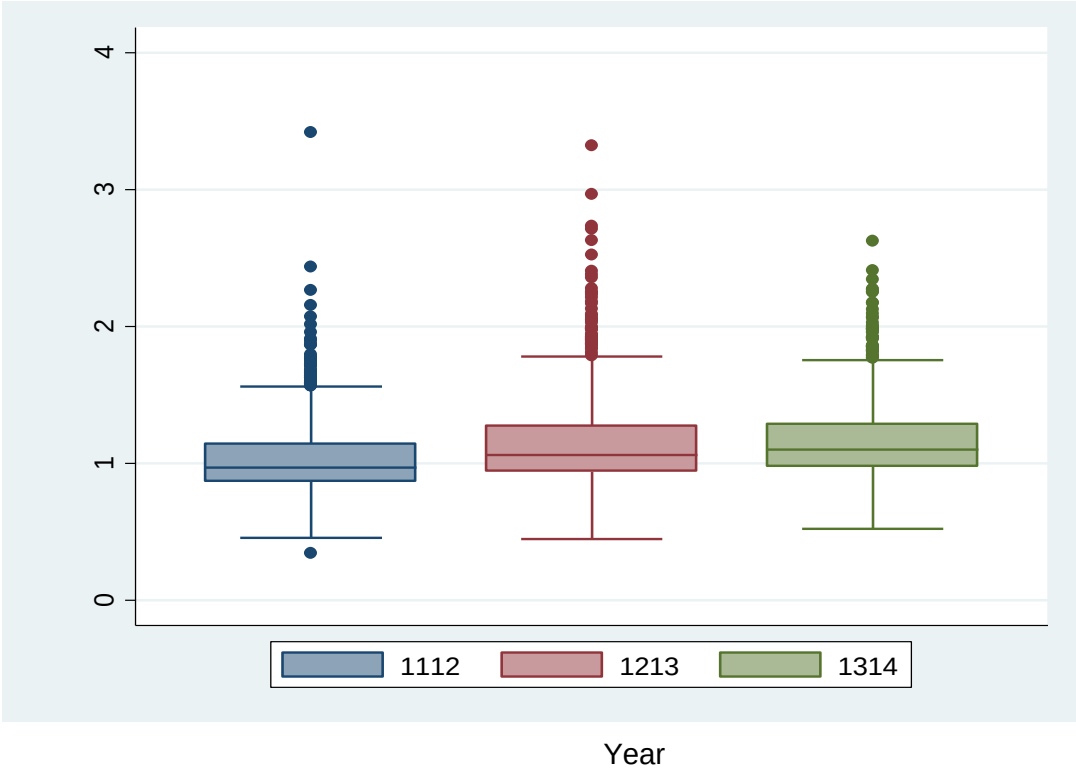


Table 2: Distribution of hospital 30-day RSMR for NSTEMI/No Shock by year

Description and	Mean RSMR by Year

Percentile	2011-2012	2012-2013	2013-2014
N	350941	345929	430553
Mean	0.0100	0.0112	0.0113
Std Deviation	0.0029	0.0034	0.0030
100% Max	0.0342	0.0332	0.0262
99%	0.0178	0.0221	0.0206
95%	0.0154	0.0175	0.0168
90%	0.0137	0.0154	0.0151
75% Q3	0.0115	0.0129	0.0129
50% Median	0.0095	0.0106	0.0108
25% Q1	0.0082	0.0089	0.0091
10%	0.0068	0.0076	0.0079
5%	0.0061	0.0069	0.0072
1%	0.0049	0.0060	0.0061
0% Min	0.0034	0.0045	0.0052

Figure 2: Boxplot of hospital 30-day RSMR for STEMI/Shock, by year



1b.4. **Provide disparities data from the measure as specified** (**current and over time**) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. (This is required for maintenance of endorsement. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included.) For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.

We analyzed whether disparities in performance on this measure exist at the hospital-level by race and hospital safety net status.

To identify potential disparities by race, we examined the relationship between hospital-level RSMR and hospital proportion of non-White patients among all hospitals grouped by quartile of the proportion of non-White patients.

Analyses demonstrated that the median RSMR for hospitals with the highest quartile of non-White patients was 1.04% compared with 1.07% among hospitals with the lowest quartile of non-White patients. The distributions for the RSMRs overlapped, and many hospitals caring for the highest quartile of non-White patients performed well or better on this measure. In addition, in comparison to the registry mean RSMR of 1.07%, hospitals with the highest proportions of non-White patients do not have worse 30-day RSMRs in the CathPCI-NDI linked cohort.

Distribution of 30-day RSMR for NSTEMI/No Shock Stratified by Quartile of Non-White Patients

Description	RMSRs by Hospital Quartile of Non-White Patients			
	Q1	Q2	Q3	Q4
N	341	341	342	341
Mean	0.0112	0.0109	0.0112	0.0111
Std Deviation	0.0027	0.0027	0.0028	0.0030
100% Max	0.0270	0.0227	0.0232	0.0245
99%	0.0199	0.0183	0.0213	0.0216
95%	0.0162	0.0155	0.0163	0.0167
90%	0.0150	0.0146	0.0147	0.0147
75% Q3	0.0123	0.0124	0.0125	0.0125
50% Median	0.0107	0.0105	0.0107	0.0104
25% Q1	0.0096	0.0090	0.0093	0.0093
10%	0.0085	0.0078	0.0082	0.0081
5%	0.0079	0.0071	0.0076	0.0071
1%	0.0065	0.0060	0.0067	0.0059
0% Min	0.0060	0.0051	0.0058	0.0056

Similarly, to identify potential disparities related to socoioeconomic status (SES), we examined the relationship between RSMR and hospital safety net status. Safety net status was defined as government (public) hospitals or non-government hospitals with a caseload that is higher than the average of the Medicaid caseloads of hospitals within a given state plus one standard deviation of Medicaid caseload of hospitals within that state. We used the American Hospital Association data (2010) to calculate the Medicaid caseload and define hospital safety net status (Yes/No). Hospital safety net status was used as a marker of SES because safety net hospitals serve a low income and vulnerable patient population.

Analyses demonstrated that the median RSMR was 1.08% for safety net hospitals compared with 1.05% for non-safety net hospitals. The interquartile range for safety net hospitals was 0.95% to 1.31%, whereas among non-safety net hospitals it was 0.93% to 1.23%. Overall, hospitals with a high proportion of vulnerable patients, as defined by safety net status, do not have substantially worse 30-day RSMRs in this cohort.

Consistent with NQF guidelines, this measure does not risk adjust for race or SES. Also, the results of the disparity data do not suggest the need to stratify by SDS.

Distribution of 30-day RSMR for NSTEMI/No Shock Stratified by Hospital Safety Net Status

Description	Safety Net Status	
	No	Yes
N	1025	205
Mean	0.0110	0.0117
Std Deviation	0.0027	0.0032
100% Max	0.0270	0.0237
99%	0.0197	0.0222
95%	0.0159	0.0174
90%	0.0145	0.0162
75% Q3	0.0123	0.0131
50% Median	0.0105	0.0108
25% Q1	0.0093	0.0095
10%	0.0080	0.0084
5%	0.0073	0.0078
1%	0.0060	0.0069
0% Min	0.0051	0.0063

Table of Contents:
Hospital 30-Day Mortality Following Percutaneous Coronary Intervention Measures

2013 Measure Specifications Report I

**This report is an addendum to the 2009 Hospital 30-Day PCI Mortality Measures Methodology Report and the 2010 PCI Mortality Measures Maintenance Report.*

2010 Measures Maintenance Technical Report II

**The original a 2009 Hospital 30-Day PCI Mortality Measures Methodology Report is included in the 2010 Measures Maintenance Technical Report.*

2013 Measure Specifications Report:

Hospital 30-Day Mortality Following Percutaneous Coronary Intervention Measures

Prepared By:

Yale New Haven Health Services Corporation - Center for Outcomes Research and Evaluation (YNHHSC/CORE)

Centers for Medicare & Medicaid Services (CMS)

September 2013

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Introduction

Under contract to the Centers for Medicare & Medicaid Services (CMS), the Yale New Haven Health Services Corporation - Center for Outcomes Research and Evaluation (YNHHSC/CORE), in partnership with the American College of Cardiology (ACC), developed two measures of hospital 30-day all-cause mortality following percutaneous coronary intervention (PCI). Each measure estimates hospital-specific, risk-standardized mortality rates for two distinct patient cohorts: (1) those with ST segment elevation myocardial infarction (STEMI) and/or cardiogenic shock during their initial hospitalization and (2) those without STEMI or cardiogenic shock during their initial hospitalization. These measures primarily use clinical data submitted to the ACC National Cardiovascular Data Registry® (NCDR) CathPCI Registry® by participating hospitals and also uses Medicare claims to identify deaths. The National Quality Forum (NQF) endorsed the measures in 2009.

This report is an addendum to the 2009 Hospital 30-Day PCI Mortality Measures Methodology Report and the 2010 PCI Mortality Measures Maintenance Report. This report describes two measure revisions and their rationale. In brief, the model has been updated by:

1. Specifying the claims-based codes in International Classification of Diseases, 10th Revision, Clinical Modification and Procedure Coding System (ICD-10-CM/PCS) as well as International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) in preparation for the transition to ICD-10-CM/PCS in October 2014.
2. Incorporating ICD-9-CM and Current Procedure Terminology (CPT) coding updates.

In addition, we have conducted additional measure testing to assess the measure for disparities in performance by socioeconomic status (SES) and race

Measure Specifications Updates

1. General Equivalence Mapping Crosswalk between ICD-9-CM to ICD-10-CM/PCS

In January 2009, the Department of Health and Human Services (HHS) issued a final rule to transition from coding ICD-9-CM to ICD-10-CM/PCS. HHS issued a final rule for mandatory implementation of ICD-10 by October 1, 2014. Operationally, this requires all outpatient claims with dates of service and inpatient claims with dates of discharge on and after October 1, 2014 to utilize ICD-10-CM/PCS codes.

In 2012, we used the General Equivalence Mapping (GEM) crosswalk between ICD-9-CM and ICD-10-CM/PCS to create specifications for each PCI mortality measure in ICD-10-CM/PCS. Our process for mapping procedural codes in the measures to ICD-10-CM consisted of a detailed clinical review, including manual review of related ICD-10-CM codes to determine that all appropriate codes are included, rather than relying exclusively on the GEM. To conduct the

crosswalk, we created a database to effectively use the mapping tables provided by CMS. We then compiled a list of ICD-9-CM codes that define PCI during hospitalization. Measure developers used these ICD-9-CM codes to build queries to extract the GEM results from the mapping table in the database. Table A1 displays the ICD-10-CM codes identified by the GEMs. We then applied those ICD-10-CM codes to the ICD-10-CM to ICD-9-CM mapping table to see if the reverse query produced ICD-9-CM codes that were not in the original measure specifications.

Our clinicians reviewed these results in detail and determined that many ICD-10-CM codes that should be included in our cohort were not being captured by the GEMs. We confirmed this by consulting the ICD-10-CM draft procedural codebook and identifying the ICD-10-CM codes that our clinicians felt should be included in our cohort (Table A2). As the tables demonstrate, the GEMs identified 16 ICD-10-CM codes for our PCI mortality cohort, while clinician review of the ICD-10-CM draft codebook resulted in 48 ICD-10-CM codes. In Table A3 and Table A4 we provide the ICD-9-CM to ICD-10-CM crosswalk.

2. **Update to Cohort Codes**

In 2013, we updated the codes defining the PCI mortality cohort by the assignment of new codes and the removal of retired codes. We added one new ICD-9-CM code (17.55 "transluminal coronary atherectomy") and seven new CPT codes to identify services rendered in the cohorts of both PCI mortality measures. Some ICD-9-CM codes in the original cohort definition were retired. After confirming in the 2010 data that these codes were no longer in use, we removed the ICD-9-CM codes 36.01, 36.02, and 36.05 from the cohort definition. The2013 cohort codes defining the PCI mortality measures' cohorts in the administrative claims data are shown in Table 1.

Table 1. Cohort Codes in PCI Mortality Measures

Code Type	Code	Description
ICD-9-CM	00.66	Percutaneous transluminal coronary angioplasty or coronary atherectomy
ICD-9-CM	17.55	Transluminal coronary atherectomy
ICD-9-CM	36.06	Insertion of non-drug-eluting coronary artery stent(s)
ICD-9-CM	36.07	Insertion of drug-eluting coronary artery stent(s)
CPT	92973	Percutaneous transluminal coronary thrombectomy
CPT	92980	Coronary Stents [single vessel]
CPT	92981	Coronary Stents [each additional vessel]
CPT	92982	Coronary Balloon Angioplasty [single vessel]
CPT	92984	Coronary Balloon Angioplasty [each additional vessel]
CPT	92995	Percutaneous Atherectomy
CPT	92996	Percutaneous Atherectomy

Disparity and Reliability Analyses

We conducted additional measure testing. Specifically, we examined (1) disparities in care and (2) the measure score reliability.

1. Disparities Analyses

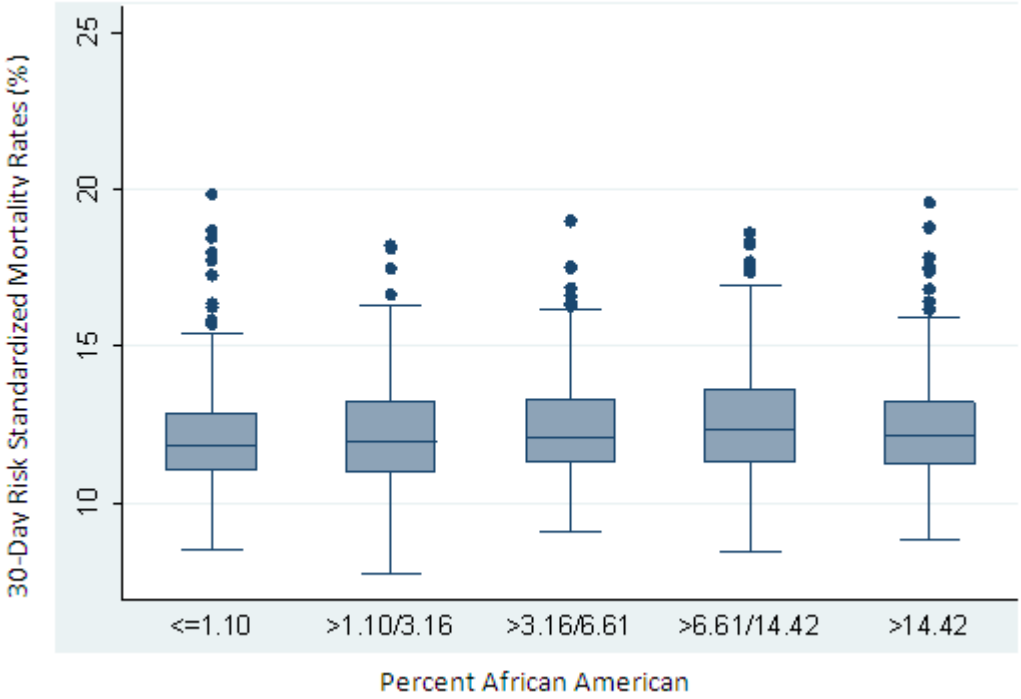
We reviewed evidence in the published literature to determine whether disparities in care for patients receiving PCI procedures have previously been documented. A study of 43,317 patients with high-risk non-ST segment elevation acute coronary syndromes, in which nearly 13% were black, reported that black patients were less likely than white patients to receive recommended and ideal care.[1]

Another study (Popescu, et al.) examined 1.2 million black and white Medicare patients with AMI and demonstrated that black patients admitted to hospitals with and without coronary revascularization services were less likely than white patients to receive recommended care and had higher 1 year mortality.[2] To expand on that review, we conducted analyses to explore disparities in hospitals' performance on each measure by race and SES.

We used the Medicare Provider Analysis and Review (MEDPAR) File for 2010 to calculate the percentage of African-American patients treated at each hospital, using all patients admitted to each hospital. We examined hospital-level risk standardized mortality rates (RSMR) across hospitals grouped by quintile of the proportion of African-American patients. For the no STEMI/no shock cohort, the median RSMR for hospitals with the highest proportion of African-American patients was 1.7% compared with 1.7% for hospitals with the lowest proportion of African-American patients. In comparison to the registry average of 1.8%, hospitals with high proportions of African-American patients do not have worse 30-day RSMRs in this cohort.

For the STEMI/shock cohort, the median RSMR for hospitals with the highest percentage of African-American patients was 12.2% compared with 11.7% for hospitals with the lowest percentage of African-American patients. The distributions for the RSMRs overlapped, and many hospitals caring for the highest percentage of African-American patients performed well on this measure (Figure 1). In comparison to the registry average of 12.3%, hospitals with high proportions of African-American patients do not have worse 30-day RSMRs in this cohort.

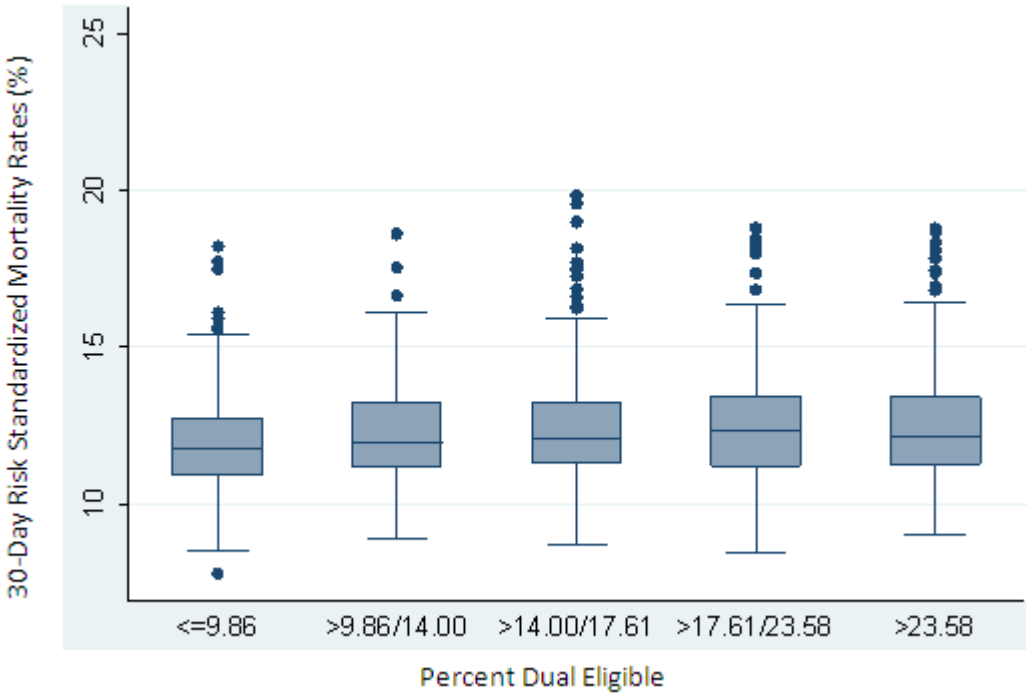
Figure 1. Distribution of RSMRs by Proportion of African American Patients (STEMI/shock cohort)



Similarly, we used the MEDPAR File for 2010 to calculate the percentage of patients 65 or older and eligible for both Medicare and Medicaid (dual eligible patients) treated at each hospital. The proportion of dual eligible patients was used as a marker for determining the SES status of hospitals' patients because this is a low income and vulnerable population. Similar to our analyses above, we examined hospital-level RSMRs across quintiles of the proportion of dual eligible patients. For the no STEMI/no shock cohort, the median RSMR for hospitals in the top quintile for dual eligible patients was 1.8% compared with 1.6% for hospitals in the bottom quintile for dual eligible patients. In comparison to the registry average of 1.8%, hospitals that treat a high percentage of dual eligible patients do not have worse 30-day RSMRs in this cohort.

For the STEMI/shock cohort, the median RSMR for hospitals with the highest proportion of dual eligible patients was 12.1% compared with 11.6% for hospitals with the lowest proportion dual eligible patients. The distributions for the RSMRs overlapped, and many hospitals in the quintile with the most dual eligible patients performed well on the measure (Figure 2). In comparison to the registry average of 12.3%, hospitals with high proportions of dual eligible patients do not have worse 30-day RSMRs in this cohort.

Figure 2. Distribution of RSMRs by Proportion Dual Eligible Patients (STEMI/shock cohort)



2. Measure Reliability

The reliability of a measurement is the degree to which repeated measurements of the same entity agree with each other. For measures of hospital performance, the measured entity is naturally the hospital, and reliability is the extent to which repeated measurements of the same hospital give similar results. Accordingly, our approach to assessing reliability is to consider the extent to which assessments of a hospital using different but randomly selected subsets of patients in the same time period produce similar measures of hospital performance. That is, we take a "test-retest" approach in which hospital performance is measured once using a random subset of patients, then measured again using a second random subset exclusive of the first, and calculate the agreement of the two resulting performance measures across hospitals.

For test-retest reliability of the measure in Medicare FFS patients aged 65 and older, we combined index admissions from two years (2010 and 2011) into a single dataset, randomly sampled half of patients within each hospital, calculated the measure for each hospital, and repeated the calculation using the second half. Thus, each hospital is measured twice, but each measurement is made using an entirely distinct set of patients. To the extent that the calculated measures of these two subsets agree, we have evidence that the measure is reliable. As a metric of agreement we calculated the intra-class correlation coefficient and assessed the values according to conventional standards.

Specifically, we used a combined 2010-2011 sample that had been linked with Medicare FFS claims data, and randomly split it into two approximately equal subsets of patients. We then calculated the RSMR for each hospital for each sample. The agreement of the two RSMRs was quantified for hospitals in each sample using the intra-class correlation. Using two independent samples provides an honest estimate of the measure's reliability, compared with using two random but potentially overlapping samples, which would exaggerate the agreement. Of note, because our final measure is derived using hierarchical logistic regression, a known property of hierarchical logistic regression models is that smaller volume hospitals contribute less ´signal´. As such a split sample using a single measurement period likely introduces extra noise; potentially underestimating the actual test-retest reliability that would be achieved if the measures were reported using additional years of data. Furthermore, the measure is specified for the entire PCI population, but we tested it only in the subset of Medicare FFS patients for whom information about vital status was available. This reduced the cohort available for testing by approximately 40%.

No STEMI/No Shock Cohort

In the combined two-year sample, there were 255,561 admissions to 1,170 hospitals with 127,781 admissions to 1,167 hospitals in one randomly selected sample and 127,780 admissions to 1,167 hospitals in the remaining sample. After excluding hospitals with fewer than 25 cases in each sample, the first sample contained 930 hospitals and the second sample contained 928 hospitals. The agreement between the two RSMRs for each hospital was 0.256, which according to the conventional interpretation is "fair."[3]

STEMI/Shock Cohort

There were 48,339 admissions to 1,182 hospitals in the combined two-year sample, with 24,170 admissions to 1,167 hospitals in one randomly selected sample and 24,169 admissions to 1,160 hospitals in the remaining sample. After excluding hospitals with fewer than 25 cases in each sample, the first sample contained 364 hospitals and the second sample contained 360 hospitals. The agreement between the two RSMRs for each hospital was 0.122, which according to the conventional interpretation is "slight".[3] This likely reflects the relatively low number of cases included in the cohort as outlined above. Nevertheless, the reliability of the measure should be assessed using larger split samples when available. Based on our experience with similar measures using split samples, using 4 years (and volume equivalent to 2 years) would result in higher intra-class correlation coefficient.

References

1. Sonel AF, Good CB, Mulgund J, et al. Racial variations in treatment and outcomes of black and white patients with high-risk non-ST-elevation acute coronary syndromes: insights from CRUSADE (Can Rapid Risk Stratification of Unstable Angina Patients Suppress Adverse Outcomes With Early Implementation of the ACC/AHA Guidelines?). *Circulation.* Mar 15 2005;111(10):1225-1232.
2. Popescu I, Vaughan-Sarrazin MS, Rosenthal GE. Differences in mortality and use of revascularization in black and white patients with acute MI admitted to hospitals with and without revascularization services. *JAMA.* Jun 13 2007;297(22):2489-2495.
3. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics.* Mar 1977;33(1):159-174.

Appendix A: ICD-10-CM Conversion Crosswalk

Table A1. ICD-10-CM Codes Identified by GEM for PCI Mortality Cohort

ICD-10-CM Code	Description
Ø27Ø3ZZ	Dilation of Coronary Artery, One Site, Percutaneous Approach
Ø27Ø4ZZ	Dilation of Coronary Artery, One Site, Percutaneous Endoscopic Approach
Ø2713ZZ	Dilation of Coronary Artery, Two Sites, Percutaneous Approach
Ø2714ZZ	Dilation of Coronary Artery, Two Sites, Percutaneous Endoscopic Approach
Ø2723ZZ	Dilation of Coronary Artery, Three Sites, Percutaneous Approach
Ø2724ZZ	Dilation of Coronary Artery, Three Sites, Percutaneous Endoscopic Approach
Ø2733ZZ	Dilation of Coronary Artery, Four or More Sites, Percutaneous Approach
Ø2734ZZ	Dilation of Coronary Artery, Four or More Sites, Percutaneous Endoscopic Approach
Ø2CØ3ZZ	Extirpation of Matter from Coronary Artery, One Site, Percutaneous Approach
Ø2CØ4ZZ	Extirpation of Matter from Coronary Artery, One Site, Percutaneous Endoscopic Approach
Ø2C13ZZ	Extirpation of Matter from Coronary Artery, Two Sites, Percutaneous Approach
Ø2C14ZZ	Extirpation of Matter from Coronary Artery, Two Sites, Percutaneous Endoscopic Approach
Ø2C23ZZ	Extirpation of Matter from Coronary Artery, Three Sites, Percutaneous Approach
Ø2C24ZZ	Extirpation of Matter from Coronary Artery, Three Sites, Percutaneous Endoscopic Approach
Ø2C33ZZ	Extirpation of Matter from Coronary Artery, Four or More Sites, Percutaneous Approach
Ø2C34ZZ	Extirpation of Matter from Coronary Artery, Four or More Sites, Percutaneous Endoscopic Approach

Table A2. ICD-10-CM Codes Identified by Clinicians for PCI Mortality Cohort

ICD-10-CM Code	Description
Ø27Ø346	Dilation of Coronary Artery, One Site, Bifurcation, with Drug-eluting Intraluminal Device, Percutaneous Approach
Ø27Ø34Z	Dilation of Coronary Artery, One Site with Drug-eluting Intraluminal Device, Percutaneous Approach
Ø27Ø3D6	Dilation of Coronary Artery, One Site, Bifurcation, with Intraluminal Device, Percutaneous Approach
Ø27Ø3DZ	Dilation of Coronary Artery, One Site with Intraluminal Device, Percutaneous Approach
Ø27Ø3T6	Dilation of Coronary Artery, One Site, Bifurcation, with Radioactive Intraluminal Device, Percutaneous Approach
Ø27Ø3TZ	Dilation of Coronary Artery, One Site with Radioactive Intraluminal Device, Percutaneous Approach
Ø27Ø3Z6	Dilation of Coronary Artery, One Site, Bifurcation, Percutaneous Approac
Ø27Ø3ZZ	Dilation of Coronary Artery, One Site, Percutaneous Approach
Ø271346	Dilation of Coronary Artery, Two Sites, Bifurcation, with Drug-eluting Intraluminal Device, Percutaneous Approach
Ø27134Z	Dilation of Coronary Artery, Two Sites with Drug-eluting Intraluminal Device, Percutaneous Approach
Ø2713D6	Dilation of Coronary Artery, Two Sites, Bifurcation, with Intraluminal Device, Percutaneous Approach
Ø2713DZ	Dilation of Coronary Artery, Two Sites with Intraluminal Device, Percutaneous Approach
Ø2713T6	Dilation of Coronary Artery, Two Sites, Bifurcation, with Radioactive Intraluminal Device, Percutaneous Approach
Ø2713TZ	Dilation of Coronary Artery, Two Sites with Radioactive Intraluminal Device, Percutaneous Approac
Ø2713Z6	Dilation of Coronary Artery, Two Sites, Bifurcation, Percutaneous Approach
Ø2713ZZ	Dilation of Coronary Artery, Two Sites, Percutaneous Approac
Ø272346	Dilation of Coronary Artery, Three Sites, Bifurcation, with Drug-eluting Intraluminal Device, Percutaneous Approach
Ø27234Z	Dilation of Coronary Artery, Three Sites with Drug-eluting Intraluminal Device, Percutaneous Approach
Ø2723D6	Dilation of Coronary Artery, Three Sites, Bifurcation, with Intraluminal Device, Percutaneous Approach
Ø2723DZ	Dilation of Coronary Artery, Three Sites with Intraluminal Device, Percutaneous Approach
Ø2723T6	Dilation of Coronary Artery, Three Sites, Bifurcation, with Radioactive Intraluminal Device, Percutaneous Approach
Ø2723TZ	Dilation of Coronary Artery, Three Sites with Radioactive Intraluminal Device, Percutaneous Approach
Ø2723Z6	Dilation of Coronary Artery, Three Sites, Bifurcation, Percutaneous Approach
Ø2723ZZ	Dilation of Coronary Artery, Three Sites, Percutaneous Approach
Ø273346	Dilation of Coronary Artery, Four or More Sites, Bifurcation, with Drug-eluting Intraluminal Device, Percutaneous Approach
Ø27334Z	Dilation of Coronary Artery, Four or More Sites with Drug-eluting Intraluminal Device, Percutaneous Approach

ICD-10-CM Code	Description
Ø2733D6	Dilation of Coronary Artery, Four or More Sites, Bifurcation, with Intraluminal Device, Percutaneous Approach
Ø2733DZ	Dilation of Coronary Artery, Four or More Sites with Intraluminal Device, Percutaneous Approach
Ø2733T6	Dilation of Coronary Artery, Four or More Sites, Bifurcation, with Radioactive Intraluminal Device, Percutaneous Approach
Ø2733TZ	Dilation of Coronary Artery, Four or More Sites with Radioactive Intraluminal Device, Percutaneous Approach
Ø2733Z6	Dilation of Coronary Artery, Four or More Sites, Bifurcation, Percutaneous Approach
Ø2733ZZ	Dilation of Coronary Artery, Four or More Sites, Percutaneous Approach
Ø2QØ3ZZ	Repair Coronary Artery, One Site, Percutaneous Approach
Ø2QØ4ZZ	Repair Coronary Artery, One Site, Percutaneous Endoscopic Approach
Ø2Q13ZZ	Repair Coronary Artery, Two Sites, Percutaneous Approach
Ø2Q14ZZ	Repair Coronary Artery, Two Sites, Percutaneous Endoscopic Approach
Ø2Q23ZZ	Repair Coronary Artery, Three Sites, Percutaneous Approach
Ø2Q24ZZ	Repair Coronary Artery, Three Sites, Percutaneous Endoscopic Approach
Ø2Q33ZZ	Repair Coronary Artery, Four or More Sites, Percutaneous Approach
Ø2Q34ZZ	Repair Coronary Artery, Four or More Sites, Percutaneous Endoscopic Approach
Ø2CØ3ZZ	Extirpation of Matter from Coronary Artery, One Site, Percutaneous Approach
Ø2CØ4ZZ	Extirpation of Matter from Coronary Artery, One Site, Percutaneous Endoscopic Approach
Ø2C13ZZ	Extirpation of Matter from Coronary Artery, Two Sites, Percutaneous Approach
Ø2C14ZZ	Extirpation of Matter from Coronary Artery, Two Sites, Percutaneous Endoscopic Approach
Ø2C23ZZ	Extirpation of Matter from Coronary Artery, Three Sites, Percutaneous Approach
Ø2C24ZZ	Extirpation of Matter from Coronary Artery, Three Sites, Percutaneous Endoscopic Approach
Ø2C33ZZ	Extirpation of Matter from Coronary Artery, Four or More Sites, Percutaneous Approach
Ø2C34ZZ	Extirpation of Matter from Coronary Artery, Four or More Sites, Percutaneous Endoscopic Approach

Table A3. PCI Mortality Cohort ICD-9-CM Codes

ICD-9-CM code	Description
00.66	Percutaneous transluminal coronary angioplasty or coronary atherectomy
36.06	Insertion of non-drug-eluting coronary artery stent(s)
36.07	Insertion of drug-eluting coronary artery stent(s)

Table A4. PCI Mortality Cohort ICD-10-CM Codes

ICD-10-CM code	Description
Ø27Ø346	Dilation of Coronary Artery, One Site, Bifurcation, with Drug-eluting Intraluminal Device, Percutaneous Approach
Ø27Ø34Z	Dilation of Coronary Artery, One Site with Drug-eluting Intraluminal Device, Percutaneous Approach
Ø27Ø3D6	Dilation of Coronary Artery, One Site, Bifurcation, with Intraluminal Device, Percutaneous Approach
Ø27Ø3DZ	Dilation of Coronary Artery, One Site with Intraluminal Device, Percutaneous Approach
Ø27Ø3T6	Dilation of Coronary Artery, One Site, Bifurcation, with Radioactive Intraluminal Device, Percutaneous Approach
Ø27Ø3TZ	Dilation of Coronary Artery, One Site with Radioactive Intraluminal Device, Percutaneous Approach
Ø27Ø3Z6	Dilation of Coronary Artery, One Site, Bifurcation, Percutaneous Approach
Ø27Ø3ZZ	Dilation of Coronary Artery, One Site, Percutaneous Approach
Ø271346	Dilation of Coronary Artery, Two Sites, Bifurcation, with Drug-eluting Intraluminal Device, Percutaneous Approach
Ø27134Z	Dilation of Coronary Artery, Two Sites with Drug-eluting Intraluminal Device, Percutaneous Approach
Ø2713D6	Dilation of Coronary Artery, Two Sites, Bifurcation, with Intraluminal Device, Percutaneous Approach
Ø2713DZ	Dilation of Coronary Artery, Two Sites with Intraluminal Device, Percutaneous Approach
Ø2713T6	Dilation of Coronary Artery, Two Sites, Bifurcation, with Radioactive Intraluminal Device, Percutaneous Approach
Ø2713TZ	Dilation of Coronary Artery, Two Sites with Radioactive Intraluminal Device, Percutaneous Approach
Ø2713Z6	Dilation of Coronary Artery, Two Sites, Bifurcation, Percutaneous Approach
Ø2713ZZ	Dilation of Coronary Artery, Two Sites, Percutaneous Approach
Ø272346	Dilation of Coronary Artery, Three Sites, Bifurcation, with Drug-eluting Intraluminal Device, Percutaneous Approach
Ø27234Z	Dilation of Coronary Artery, Three Sites with Drug-eluting Intraluminal Device, Percutaneous Approach

ICD-10-CM code	Description
Ø2723D6	Dilation of Coronary Artery, Three Sites, Bifurcation, with Intraluminal Device, Percutaneous Approach
Ø2723DZ	Dilation of Coronary Artery, Three Sites with Intraluminal Device, Percutaneous Approach
Ø2723T6	Dilation of Coronary Artery, Three Sites, Bifurcation, with Radioactive Intraluminal Device, Percutaneous Approach
Ø2723TZ	Dilation of Coronary Artery, Three Sites with Radioactive Intraluminal Device, Percutaneous Approach
Ø2723Z6	Dilation of Coronary Artery, Three Sites, Bifurcation, Percutaneous Approach
Ø2723ZZ	Dilation of Coronary Artery, Three Sites, Percutaneous Approach
Ø273346	Dilation of Coronary Artery, Four or More Sites, Bifurcation, with Drug-eluting Intraluminal Device, Percutaneous Approach
Ø27334Z	Dilation of Coronary Artery, Four or More Sites with Drug-eluting Intraluminal Device, Percutaneous Approach
Ø2733D6	Dilation of Coronary Artery, Four or More Sites, Bifurcation, with Intraluminal Device, Percutaneous Approach
Ø2733DZ	Dilation of Coronary Artery, Four or More Sites with Intraluminal Device, Percutaneous Approach
Ø2733T6	Dilation of Coronary Artery, Four or More Sites, Bifurcation, with Radioactive Intraluminal Device, Percutaneous Approach
Ø2733TZ	Dilation of Coronary Artery, Four or More Sites with Radioactive Intraluminal Device, Percutaneous Approach
Ø2733Z6	Dilation of Coronary Artery, Four or More Sites, Bifurcation, Percutaneous Approach
Ø2733ZZ	Dilation of Coronary Artery, Four or More Sites, Percutaneous Approach
Ø2QØ3ZZ	Repair Coronary Artery, One Site, Percutaneous Approach
Ø2QØ4ZZ	Repair Coronary Artery, One Site, Percutaneous Endoscopic Approach
Ø2Q13ZZ	Repair Coronary Artery, Two Sites, Percutaneous Approach
Ø2Q14ZZ	Repair Coronary Artery, Two Sites, Percutaneous Endoscopic Approach
Ø2Q23ZZ	Repair Coronary Artery, Three Sites, Percutaneous Approach
Ø2Q24ZZ	Repair Coronary Artery, Three Sites, Percutaneous Endoscopic Approach
Ø2Q33ZZ	Repair Coronary Artery, Four or More Sites, Percutaneous Approach
Ø2Q34ZZ	Repair Coronary Artery, Four or More Sites, Percutaneous Endoscopic Approach
Ø2CØ3ZZ	Extirpation of Matter from Coronary Artery, One Site, Percutaneous Approach
Ø2CØ4ZZ	Extirpation of Matter from Coronary Artery, One Site, Percutaneous Endoscopic Approach
Ø2C13ZZ	Extirpation of Matter from Coronary Artery, Two Sites, Percutaneous Approach
Ø2C14ZZ	Extirpation of Matter from Coronary Artery, Two Sites, Percutaneous Endoscopic Approach
Ø2C23ZZ	Extirpation of Matter from Coronary Artery, Three Sites, Percutaneous Approach
Ø2C24ZZ	Extirpation of Matter from Coronary Artery, Three Sites, Percutaneous Endoscopic Approach
Ø2C33ZZ	Extirpation of Matter from Coronary Artery, Four or More Sites, Percutaneous Approach
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Hospital 30-Day Percutaneous Coronary Intervention Mortality Measures

2010 Measures Maintenance Technical Report

Submitted By Yale New Haven Health Services Corporation / Center for Outcomes Research & Evaluation:

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Under Contract # HHSM-500-2008-0025I-MIDS Task Order T0001
From the Centers for Medicare & Medicaid Services

Prepared For:

Centers for Medicare & Medicaid Services

September 29, 2010

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1. INTRODUCTION

1.1 Background on Percutaneous Coronary Intervention Mortality Measures

The Centers for Medicare & Medicaid Services (CMS), in partnership with the American College of Cardiology (ACC), developed two 30-day all-cause percutaneous coronary intervention (PCI) mortality measures suitable for public reporting. These models use clinical data submitted through a data registry to provide hospital-specific, risk-standardized, 30-day mortality rates for two cohorts of patients who had a PCI during their hospitalization: (1) 30-day mortality following PCI in a cohort of patients with ST segment elevation myocardial infarction (STEMI) and/or cardiogenic shock; and (2) 30-day mortality following PCI in a cohort of patients with neither STEMI nor cardiogenic shock. The measures were developed in a cohort of Medicare fee-for-service (FFS) patients but are designed for use in the broader population of PCI patients.

In 2009, the measures were fully endorsed by the National Quality Forum (NQF). CMS has contracted with Yale New Haven Health Services Corporation / Center for Outcomes Research & Evaluation (YNHHSC/CORE) to provide routine maintenance of the 30-day mortality measures for PCI as they move toward implementation. This report summarizes our measure maintenance activities, describes the minor and material updates made to the measures, and presents the updated models using data from 2006 through 2008. It is a supplement to and update of the prior methodology report produced for the two measures rather than a comprehensive description of measure methods. The report that presents the measure methodology in full for the measures can be found in Appendix A.

1.2 Goals of Measure Maintenance

The overarching goal of measure maintenance is to continually improve the measures as they move forward towards implementation. Conducted annually, it is an opportunity: to reflect on and respond to feedback received in the previous year, to incorporate advances in the science and changes in clinical guidelines, and to modify measures as needed in response to updates to coding practices. As described below, YNHHSC/CORE undertook the following measure maintenance activities this year for the PCI mortality measures:

- Included PCIs performed on an outpatient basis (hereafter referred to as observation stay PCIs) to accommodate the increase in outpatient PCIs and ensure the measure is neutral with respect to the way the PCI services are billed to the Medicare program
- Confirmed stability of variables used for risk adjustment
- Cross-walked the risk adjustment variables in the version of the National Cardiovascular Data Registry (NCDR) CathPCI Registry used to develop the model to the newest version
- Analyzed the Social Security Death Master File (DMF) as a potential all-payer source of vital status to facilitate measure implementation (ongoing)

1.3 Overview of Measure Methodology

The 2010 mortality risk-adjustment models largely adhere to the NQF approved methodology set forth in the original methodology report (Appendix A). Below, we provide an overview of the methodology. Updates for 2010 are found in Section 2. The mortality measures use hierarchical generalized linear modeling (HGLM) to create a risk-standardized mortality rate (RSMR) at the hospital level that reflects hospital quality. The measures use information about patients' cardiac status and comorbidities submitted to the NCDR CathPCI Registry to adjust for differences in case mix at hospitals that perform PCI.

At present, the mechanisms necessary to implement these measures at all hospitals performing PCI have not been put into place. Accordingly, measure maintenance was conducted on a population of Medicare FFS patients who had undergone PCI at a hospital already participating in the NCDR CathPCI Registry.

1.3.1 Cohort

The cohort for these measures includes all patients age 18 or older undergoing PCI. This cohort is stratified into two groups: 1) PCI patients with STEMI and/or cardiogenic shock and 2) PCI patients with neither STEMI nor cardiogenic shock.

Index Cohort Exclusions (Excluded Procedures)

1) Age <18 years. Hospital stays for PCI patients aged less than 18 years are excluded.
   Rationale: Patients younger than 18 represent a small and unusual population whose characteristics and outcomes do not reflect the larger population of PCI patients.

2) Patients with unknown vital status. Patients with unknown vital status are excluded.
   Rationale: Records with no death information would prevent ascertainment of the outcome.

3) Patients with >10 days between date of hospitalization and date of PCI. Patients with prolonged hospitalizations prior to PCI are excluded.
   Rationale: The outcomes of patients with prolonged hospitalizations prior to PCI have a weaker relation to the PCI procedure.

4) Transfer-in admissions (PCI to PCI). Among patients transferred from one acute care institution to another who had a PCI at both hospitals, the second admission with PCI is not eligible as an index hospital stay.

Rationale: We define an episode of care as starting on the first day of the first admission with PCI regardless of whether additional procedures are performed at the same hospital or at a different hospital after transfer.

5) Admissions which would lead to duplicate attribution of 30-day deaths. Later admissions for the same patient are excluded.
Rationale: The 30-day follow-up period for patients with more than one hospital stay with PCI may overlap. In order to avoid attributing the same death to more than one admission with PCI (i.e. double counting a single patient death), later admissions with PCI are excluded.

1.3.2 Outcome

The outcome evaluated for each cohort is PCI 30-day all-cause mortality, measured as death within 30 days of the date of the PCI procedure.

1.3.2.1 30-Day Timeframe

The measures assess mortality within a 30-day period from admission for the index hospitalization. Models with a fixed outcome period are preferable because they ensure hospital variation in length of stay (LOS) does not affect performance and minimize the opportunity for misrepresentation (transferring of patients or other gaming mechanisms). [1] The use of the 30-day timeframe also places an emphasis on transitions of care and the suitability of the patient for discharge. As such, a 30-day mortality measure may stimulate better collaboration between hospitals and their surrounding medical communities, aimed at reducing mortality rates.

1.3.2.2 All-Cause Mortality

The measures assess all-cause mortality as opposed to cardiac specific mortality for several reasons. First, from the patient perspective, mortality from any cause is the critical measure. Second, different causes of death may still be directly related to the quality of care. Finally, even if using cardiac specific mortality were desirable, making accurate determinations of specific causes of death is difficult and prone to error, particularly if the patient dies outside the hospital setting.

1.3.3 Risk-Adjustment Variables

The measures adjust for key variables that are clinically relevant and have strong association with 30-day mortality (e.g. demographic factors, cardiac status, comorbid conditions, and coronary anatomy).

To select candidate variables, a team of clinicians reviewed all variables in the NCDR CathPCI Registry database (A copy of the data collection form and the complete list of variables collected and submitted by hospitals can be found at www.ncdr.com.). We did not consider as candidates variables we would not want to adjust for in a quality measure, such as potential complications, certain patient demographics (e.g., race, payor status, socioeconomic status), and patients' admission pathway (e.g., admitted from, or discharged to, a skilled nursing facility [SNF]). Variables were also considered ineligible if they were particularly vulnerable to gaming or deemed to lack clinical relevance. Based on careful review by a team of clinicians and further informed by a review of the literature, a total of 26 variables were determined to be appropriate for consideration as candidate variables. Our set of candidate variables (see Table 1) included two "demographic" variables (age and gender), 15 "history and risk factor" variables, four "cardiac status" variables, one "cath lab visit" variable and four "PCI procedure" variables. Several variables required particular consideration and are discussed in detail in the original technical report (Appendix A).

The models do not risk-adjust for patient socioeconomic status (SES) because the association between SES and health outcomes can be due, in part, to the quality of health care. Risk-adjusting for patient SES would suggest that hospitals with low SES patients are held to different standards for the risk of mortality than hospitals treating higher SES patient populations. The intent is for the measures to adjust for patient demographic and clinical characteristics while illuminating important quality differences. This methodology is consistent with guidance from NQF. We used logistic regression with stepwise selection (entry $p<0.05$; retention with $p<0.01$) for variable selection. We also assessed the direction and magnitude of the regression coefficients. This resulted in a final risk-adjustment model for the STEMI or shock cohort that included 13 variables and a final risk-adjustment model for the no STEMI and no shock cohort that included 16 variables. Table 2 and Table 3 show the final variables in each cohort.

Table 1 - PCI Mortality Candidate Variables

Description	NCDR Item Number	Name
Demographic		
Age	252	Age
Female	260	FEMALE
History and Risk Factors		
Body Mass Index (BMI)*	Derived (410, 412)	BMI
Previous MI	420	PrevMI
CHF-previous history	424	PrCHF
Previous valvular surgery	426	PrValve
Cerebrovascular Disease	450	CVD
Peripheral Vascular Disease	452	PVD
Chronic Lung Disease	454	CLD
Diabetes	Derived (430, 432)	NewDIAB
None	Reference	
Non-Insulin Diabetes		NEWDIAB1
Insulin Diabetes		NEWDIAB2
Glomerular Filtration Rate (GFR)	Derived (252, 260, 270, 439, 440)	GFR
Not measured	Derived	GFRGRP0
GFR<30	Derived	GFRGRP1
30≤GFR<60	Derived	GFRGRP2
60≤GFR<90	Reference	
GFR≥90	Derived	GFRGRP4
Renal Failure-Dialysis	444	Dialysis
Hypertension	456	Hypertn
Tobacco use	460	TOBACCO
Yes, Current		
Yes, Former		
No		
Family history of CAD	480	FHCAD
Previous PCI	490	PrPCI
Previous CABG	494	PrCAB
Cardiac Status		
Heart Failure - Current Status	500	CHF
NYHA	510	ClassNYH
Class I, II, or III	Reference	
Class IV		NYHC4
Cardiogenic Shock	520	
Symptoms present on admission	Derived (550, 560)	AdmSxPre
No Myocardial Infarction (MI)		ADMSX1
MI within 24 hours	Reference	
MI after 24 hours		ADMSX3
Cath Lab Visit		
Ejection Fraction Percentage	Derived (654, 656)	HDEFGRP
Not measured		HDEFGRP1
EF<30		HDEFGRP2
30≤EF<45		HDEFGRP3
EF≥45	Reference	
PCI Procedure		
PCI Status**	804	PCIStat

Description	NCDR Item Number	Name
Elective	Reference	
Urgent		PCIS2
Emergency		PCIS3
Salvage		PCIS4
Emergency or salvage		PCIS34
Highest Risk Lesion – Segment Category***	Derived (902)	NLESLOC
pRCA/mLAD/pCIRC	Derived	NLESLOC1
pLAD	Derived	NLESLOC2
Left Main	Derived	NLESLOC3
Other	Reference	
Highest pre-procedure TIMI flow: none***	Derived (920)	NPreTIMI
Highest Risk Lesion: SCAI Lesion Class*** I	Derived (910, 950) Reference	NSCAILC
I	Reference	
II or III	Derived	NSCAILC23
IV	Derived	NSCAILC4

*For missing data in BMI, data were stratified by gender first, then set to the median in corresponding groups
** Emergency or Salvage are combined into one category “PCIS34” for the measure in no STEMI and no shock cohort.
***Aggregated elements from lesions data-level to PCI data-level using MAX function

Table 2 - STEMI and/or Shock Final Model Variables

Category	Description
Demographic	
	Age
History and Risk Factors	
	BMI* Cerebrovascular Disease Chronic Lung Disease Glomerular Filtration Rate (GFR) Not measured GFR<30 30≤GFR<60 60≤GFR<90 GFR≥90 Previous PCI
Cardiac Status	
	Heart Failure - Current Status Cardiogenic Shock Symptoms present on admission No MI MI within 24 hours MI after 24 hours
Cath Lab Visit	
	Ejection Fraction Percentage Not measured EF<30 30≤EF<45 EF≥45
PCI Procedure	
	PCI Status** Elective Urgent Emergency Salvage Emergency or salvage Highest Risk Lesion – Segment Category*** pRCA/mLAD/pCIRC pLAD Left Main Other Highest Risk Lesion: SCAI Lesion Class*** I I II or III IV

*For missing data in BMI, data were stratified by gender first, then set to the median in corresponding groups
** Emergency or Salvage are combined into one category “PCIS34” for the measure in no STEMI and no shock cohort.
***Aggregated elements from lesions data-level to PCI data-level using MAX function

Table 3 - No STEMI and No Shock Final Model Variables

Category	Description
Demographic	
	Age
History and Risk Factors	
	BMI* CHF – previous history Cerebrovascular Disease Peripheral Vascular Disease Chronic Lung Disease Diabetes None Non-Insulin Diabetes Insulin Diabetes Glomerular Filtration Rate (GFR) Not measured GFR<30 30≤GFR<60 60≤GFR<90 GFR≥90 Previous PCI
Cardiac Status	
	Heart Failure - Current Status NYHA Class IV Symptoms present on admission No MI MI within 24 hours MI after 24 hours
Cath Lab Visit	
	Ejection Fraction Percentage Not measured EF<30 30≤EF<45 EF≥45
PCI Procedure	
	PCI Status** Elective Urgent Emergency Salvage Emergency or salvage Highest Risk Lesion – Segment Category*** pRCA/mLAD/pCIRC pLAD Left Main Other Highest Risk Lesion: SCAI Lesion Class*** I I II or III IV

*For missing data in BMI, data were stratified by gender first, then set to the median in corresponding groups
** Emergency or Salvage are combined into one category “PCIS34” for the measure in no STEMI and no shock cohort.
***Aggregated elements from lesions data-level to PCI data-level using MAX function

1.3.4 Calculating the RSMR

The measures estimate hospital-level 30-day all-cause RSMRs using HGLMs. In brief, the approach simultaneously models two levels (patient and hospital) to account for the variance in patient outcomes within and between hospitals. [2] At the patient level, the model adjusts the log-odds of mortality within 30-days of discharge for age, sex, selected clinical covariates, and a hospital-specific intercept. The second level models the hospital-specific intercepts as arising from a normal distribution. The hospital intercept represents the underlying risk of mortality at the hospital, after accounting for patient risk. The hospital-specific intercepts are given a distribution in order to account for the clustering (non-independence) of patients within the same hospital. If there were no differences among hospitals, then after adjusting for patient risk, the hospital intercepts should be identical across all hospitals.

The RSMR is calculated as the ratio of the number of "predicted" to the number of "expected" deaths, multiplied by the national unadjusted mortality rate. For each hospital, the "numerator" of the ratio is the number of deaths within 30 days predicted on the basis of the hospital's performance with its observed case mix, and the "denominator" is the number of deaths expected on the basis of the nation's performance with that hospital's case mix. This approach is analogous to a ratio of "observed" to "expected" used in other types of statistical analyses. It conceptually allows for a comparison of a particular hospital's performance given its case mix to an average hospital's performance with the same case mix. Thus a lower ratio indicates lower-than-expected mortality or better quality and a higher ratio indicates higher-than-expected mortality or worse quality.

The predicted hospital outcome (the numerator) is calculated by regressing the risk factors and the hospital-specific intercept on the risk of mortality, multiplying the estimated regression coefficients by the patient characteristics in the hospital, transforming, and then summing over all patients attributed to the hospital to get a value. The expected number of deaths (the denominator) is obtained by regressing the risk factors and a common intercept on the mortality outcome using all hospitals in our sample, multiplying the subsequent estimated regression coefficients by the patient characteristics observed in the hospital, transforming, and then summing over all patients in the hospital to get a value. To assess hospital performance in any reporting period, we re-estimate the model coefficients using the years of data in that period.
The statistical models used are described fully in the original methodology report (Appendix A).

2. UPDATES TO METHODS

2.1 Refinements to the PCI Mortality Measures

We made the following refinement to the model:

- Inclusion of patients who were not admitted before or following their observation stay PCI

We assessed the effects of this change using data from 2006-2008. This change is discussed in more detail below.

2.1.1 Change in Patient Cohort to Include Observation Stay PCIs

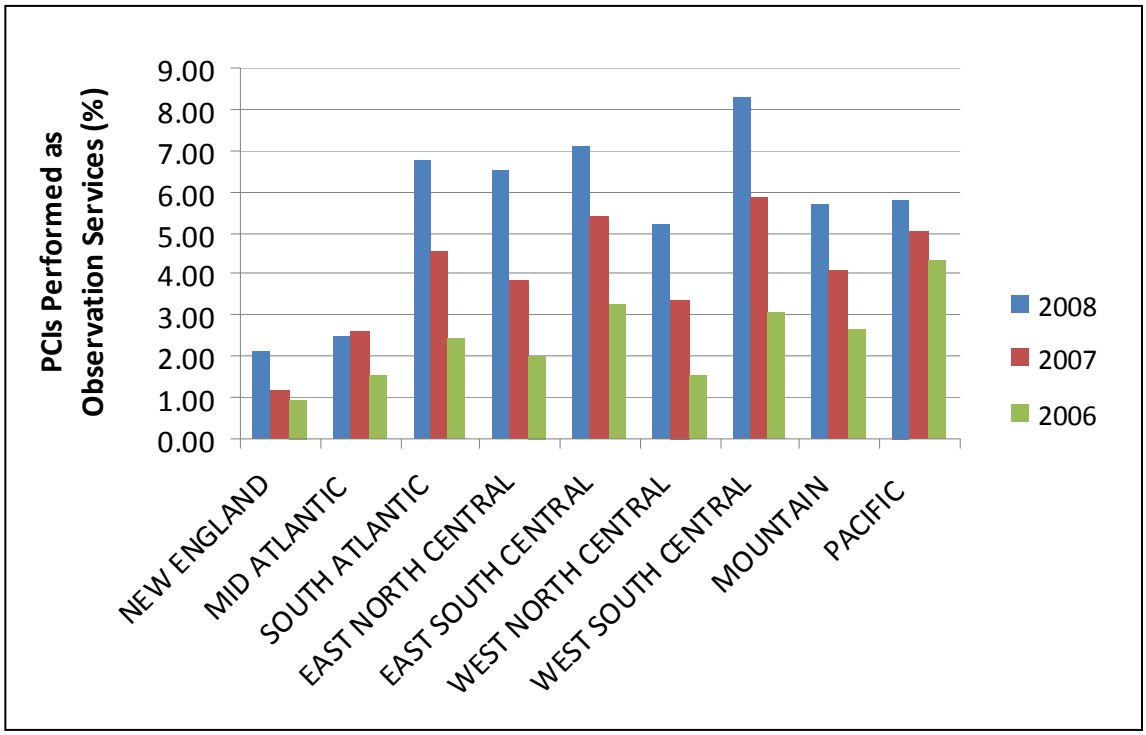
Modification: Previously, we excluded patients who underwent PCI but were not admitted to the hospital during the hospital stay in which the PCI was performed. This year, we included all PCIs performed at a hospital irrespective of whether they were performed as inpatient or observation stay procedures. Observation status stays with PCI were identified in Part A outpatient files and linked with CathPCI data using a process identical to that used for inpatient PCI.

Rationale: Changes in payment policy have placed pressure on hospitals to classify hospital stays following routine, elective PCI as an observation stay rather than a hospital admission. Inclusion of this growing proportion of PCI patients allows the measures to more fully capture the population of PCI patients and to more accurately reflect hospital performance. It also ensures that variation across hospitals in the use of observation stays does not affect the measure cohort or results.

Effects on patient cohort: Overall, observation stay PCI accounted for 4.1% of all PCI procedures performed on Medicare FFS patients age ≥65 between 2006 and 2008. The proportion of patients undergoing PCI as an observation stay increased from 2.4% in 2006 to 5.8% in 2008. Of note, there was substantial geographic variation in the PCI performed as an observation stay with consistently lower use of this practice in the New England and Mid-Central areas compared with other census regions (Figure 1). The addition of observation stay PCIs results in a slight lowering of the risk profile of PCI patients in the no STEMI and no Shock cohort. This change had no effect on the STEMI and/or Shock cohort.

Conclusion: Including observation stay PCI is warranted so that the measures accurately reflect the totality of the outcomes achieved by hospitals that perform PCI.

Figure 1 - Temporal Trends in PCIs Performed under Observation Services in Outpatient Setting



3. FINAL MODELS AND ASSESSMENT OF PERFORMANCE

3.1 Overview of Methodology and Results

The 2010 mortality models estimate hospital-specific 30-day all-cause RSMRs using HGLMs. To adjust for differences in hospital case mix, the models adjust for patient risk factors, including demographic characteristics and comorbidities present at the time of admission.

To evaluate the performance of the models used for 2010 reporting, we fit the revised models to three single, calendar-year datasets (2006, 2007, and 2008) and to the combined three-year 2006-2008 calendar-year dataset. We re-estimated the model variable coefficients, examined their trends across time periods, and examined the model performance in each of these datasets. We also examined trends in the frequency of patient risk factors. Although we made the cohort changes as described in Section 2, we otherwise preserved the original methodology and did not change variables included in the models.

For each of the three measures, we assessed HGLM performance in terms of discriminatory ability and overall fit for each calendar year of data (2006, 2007, and 2008) and for the three year combined period (2006-2008). We computed two summary statistics for assessing model performance: the adjusted R^2, which indicates the percentage of the patient-level variation in the outcome explained by the model variables, and the area under the receiver operating characteristic (ROC) curve (c-statistic), which is an indicator of the model's discriminatory ability, or ability to correctly classify those who die and do not die within 30 days (values range from 0.5 meaning no better than chance to 1.0 meaning perfect discrimination).

The data sources for the measure maintenance analyses are Medicare administrative datasets that contain claims and enrollment information for FFS hospitalizations that have been linked using indirect identifiers to clinical data in the CathPCI Registry for calendar years 2006–2008. Please see the methodology report (Appendix B) for complete descriptions of these data sources.

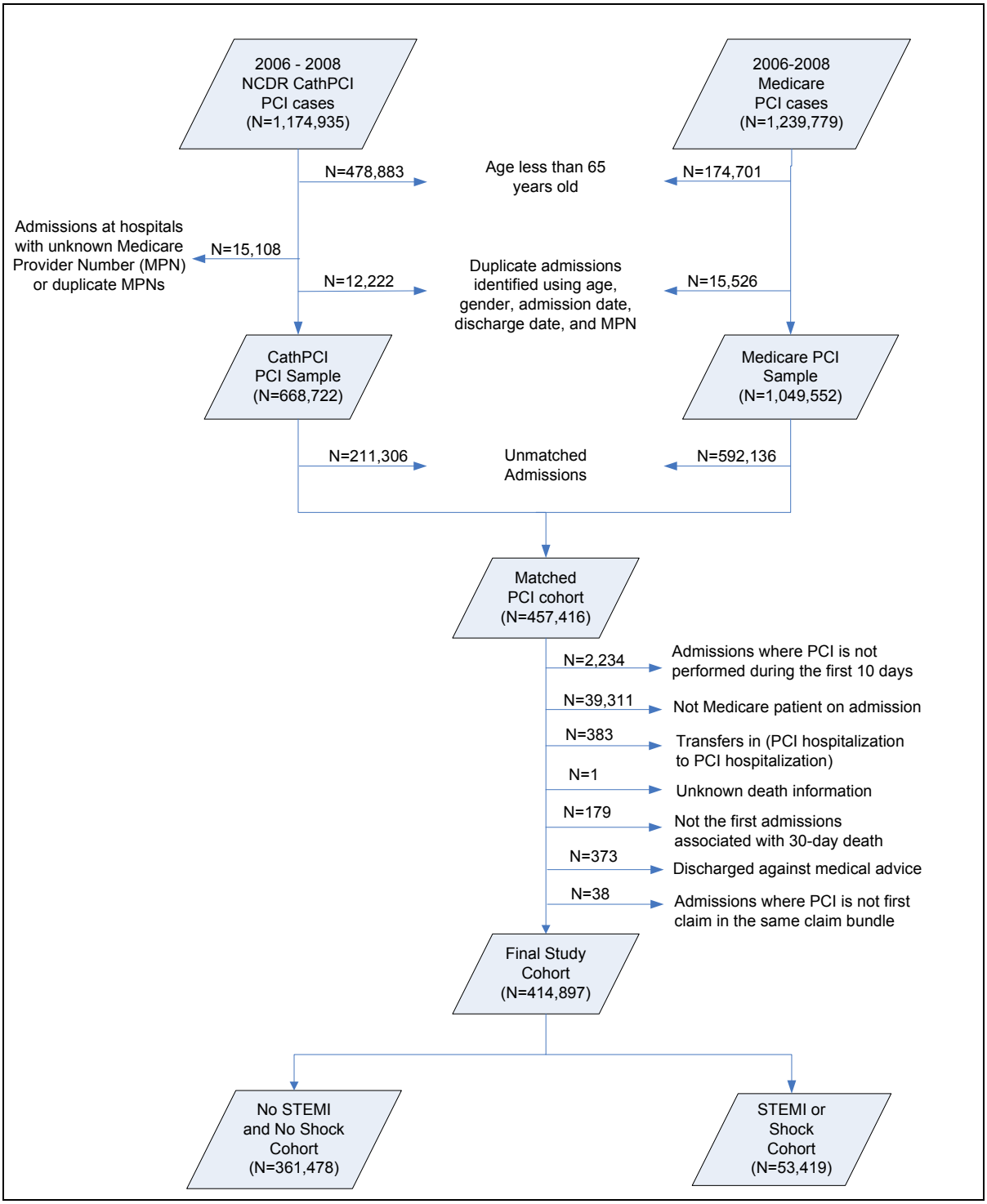
The results of these analyses for the two measures (STEMI and/or Shock; and no STEMI and no Shock) are presented below in Sections 3.3 and 3.4 respectively.

3.2 Derivation of Index Cohorts

3.2.1 Index Cohort

The cohort includes Medicare FFS beneficiaries 65 years of age or older who underwent a PCI during a hospital admission and who had been successfully matched with corresponding data in the CathPCI Registry (see measure methodology report for details). Figure 2 shows the derivation of the measure cohort through systematic exclusions and the number of patients meeting each exclusion criteria. For the STEMI and/or Shock cohort, analyses were restricted to patients who had their PCI in the setting of a STEMI or who had cardiogenic shock prior to the performance of the PCI. For the no STEMI and no Shock cohort, analyses were restricted to patients who had neither STEMI nor cardiogenic shock prior to the PCI.

Figure 2 - Patient Sample for PCI Mortality Cohorts in the 2006 - 2008 Dataset



3.3 STEMI and/or Shock Model Results

3.3.1 Frequency of Model Variables over Different Time Periods

We examined the temporal variation in frequency of clinical and demographic variables. The crude 30-day mortality rate across the cohorts increased from 10.4% in 2006 to 11.2% in 2008. There were no major changes in patients' cardiac status or prevalence of major comorbid conditions. The frequency of cardiogenic shock increased from 16.8% to 18.4% (Table 4).

3.3.2 Model Parameters

Table 5 conveys the risk-adjusted odds ratios (ORs) and 95% confidence intervals (CIs) for the PCI Mortality STEMI and/or Shock cohort model by individual year and for the 2006-2008 calendar year dataset. The parameters are consistent across all time periods. Higher BMI was consistently associated with lower risk of mortality. All other variables were associated with higher risk of mortality.

3.3.3 Distribution of Hospital RSMRs

Table 7 shows the distributions of hospital volume, hospital RSMR and between-hospital variance over different time periods. Mean volume of PCIs performed in the STEMI and/or Shock cohort decreased from 25 hospital stays (standard deviation (SD): 22) per hospital in 2006, to 23 hospital stays (SD: 19) per hospital in 2008.

RSMR increased slightly over the three year period, from 10.5% in 2006 to 11.2% in 2008. The mean hospital RSMR for the combined three-year data was 11.1% (SD: 1.0%; range 8.5% – 14.0%), with 25th and 75th percentiles equal to 10.3% and 11.7%, respectively. Between-hospital variance remained stable across all years ranging from 0.092 (standard error (SE): 0.028) to 0.148 (SE: 0.033). Between-hospital variance in the combined, three-year dataset was 0.061 (SE: 0.013). If there were no systematic differences between hospitals, the between-hospital variance would be 0.

Figure 3 shows the overall distribution of the hospital RSMRs for the three year dataset. The odds of all-cause mortality for a hospital that was one SD above average were 1.64 times that of a hospital that was one SD below average. If there were no systematic differences between hospitals, the OR would be 1.0.[3]

Table 4 - Temporal Variation in Frequencies of Clinical and Demographic Variables – STEMI and/or Shock Cohort

Description	2006		2007		2008		2006-2008	
	#	%	#	%	#	%	#	%
ALL	15230		18107		20082		53419	
Demographics								
Age: Mean (SD)	74.82	6.99	75.05	7.18	75.07	7.30	74.99	7.17
Gender	6334	41.59	7518	41.52	8308	41.37	22160	41.48
History and Risk Factors								
BMI								
Unknown	40	0.26	55	0.30	74	0.37	169	0.32
Mean (SD)	27.46	5.56	27.52	5.65	27.57	5.65	27.52	5.62
Previous MI	3044	19.99	3544	19.57	4136	20.60	10724	20.08
CHF - Previous History	1328	8.72	1633	9.02	1921	9.57	4882	9.14
Previous Valvular Surgery	131	0.86	159	0.88	191	0.95	481	0.90
Cerebrovascular Disease	1846	12.12	2195	12.12	2460	12.25	6501	12.17
Peripheral Vascular Disease	1627	10.68	1932	10.67	2068	10.30	5627	10.53
Chronic Lung Disease	2489	16.34	2968	16.39	3312	16.49	8769	16.42
Diabetes/Control								
No	11649	76.49	13801	76.22	15234	75.86	40684	76.16
Non-Insulin diabetes	2616	17.18	3033	16.75	3325	16.56	8974	16.80
Insulin diabetes	965	6.34	1273	7.03	1523	7.58	3761	7.04
GFR								
Not measured	1103	7.24	1510	8.34	1712	8.53	4325	8.10
GFR<30	795	5.22	964	5.32	1111	5.53	2870	5.37
30<=GFR<60	5704	37.45	6916	38.20	7190	35.80	19810	37.08
60<=GFR<90	6496	42.65	7417	40.96	8287	41.27	22200	41.56
GFR>=90	1132	7.43	1300	7.18	1782	8.87	4214	7.89
Renal Failure - Dialysis	218	1.43	256	1.41	315	1.57	789	1.48
Hypertension	10772	70.73	12970	71.63	14780	73.60	38522	72.11
Tobacco Use								
Current	2967	19.48	3560	19.66	3797	18.91	10324	19.33
Former	5011	32.90	5796	32.01	6350	31.62	17157	32.12
No	7252	47.62	8751	48.33	9935	49.47	25938	48.56
History of Tobacco Use	2967	19.48	3560	19.66	3797	18.91	10324	19.33
Family History of CAD	2216	14.55	2457	13.57	2801	13.95	7474	13.99
Previous PCI	2916	19.15	3636	20.08	4528	22.55	11080	20.74
Previous CABG	1618	10.62	1873	10.34	2078	10.35	5569	10.43
Cardiac Status								
CHF - Current Status	2376	15.60	2806	15.50	3219	16.03	8401	15.73
NYHA								
Class I	3419	22.45	3875	21.40	4160	20.72	11454	21.44
Class II	1225	8.04	1615	8.92	1942	9.67	4782	8.95
Class III	2807	18.43	3162	17.46	3818	19.01	9787	18.32
Class IV	7779	51.08	9455	52.22	10162	50.60	27396	51.29
Cardiogenic Shock	2555	16.78	3375	18.64	3700	18.42	9630	18.03
Admission Symptom Presentation								
No MI	1364	8.96	1378	7.61	1555	7.74	4297	8.04
MI within 24 hours	12892	84.65	15606	86.19	17369	86.49	45867	85.86
MI after 24 hours	974	6.40	1123	6.20	1158	5.77	3255	6.09
Cath Lab Visit								
Ejection Fraction Percentage								
Not measured	4276	28.08	5185	28.64	5760	28.68	15221	28.49
EF<30	1178	7.73	1451	8.01	1584	7.89	4213	7.89
30<=EF<45	3404	22.35	4006	22.12	4421	22.01	11831	22.15
EF>=45	6372	41.84	7465	41.23	8317	41.42	22154	41.47

Description	2006		2007		2008		2006-2008	
	#	%	#	%	#	%	#	%
PCI Procedure								
PCI Status								
Elective	983	6.45	885	4.89	1010	5.03	2878	5.39
Urgent	2562	16.82	2616	14.45	2558	12.74	7736	14.48
Emergency	11439	75.11	14255	78.73	16071	80.03	41765	78.18
Salvage	246	1.62	351	1.94	443	2.21	1040	1.95
Highest Lesion location								
pRCA/mLAD/pCIRC	6029	39.59	7085	39.13	7920	39.44	21034	39.38
pLAD	3309	21.73	3939	21.75	4304	21.43	11552	21.63
Left Main	202	1.33	272	1.50	308	1.53	782	1.46
Other	5690	37.36	6811	37.62	7550	37.60	20051	37.54
Highest Pre-Procedure TIMI Flow: None	6301	41.37	8041	44.41	9148	45.55	23490	43.97
Highest Risk Lesion: SCAI Lesion Class								
I	3404	22.35	3965	21.90	4242	21.12	11611	21.74
II	3778	24.81	4058	22.41	4531	22.56	12367	23.15
III	2631	17.28	3453	19.07	3948	19.66	10032	18.78
IV	5417	35.57	6631	36.62	7361	36.65	19409	36.33
In-hospital Death	1336	8.77	1690	9.33	1861	9.27	4887	9.15

Table 5 - Risk-Adjusted Odds Ratios (ORs) and 95% Confidence Intervals (CIs) for PCI STEMI or Shock Cohort GLM over Different Time Periods

Variable	2006 OR (95% CI)		2007 OR (95% CI)		2008 OR (95% CI)		2006-2008 OR (95% CI)	
Age (Per 10 years)	1.66	(1.52, 1.80)	1.66	(1.54, 1.79)	1.65	(1.54, 1.77)	1.65	(1.58, 1.73)
BMI (Per 5 units)	0.90	(0.82, 0.97)	0.87	(0.81, 0.93)	0.89	(0.83, 0.96)	0.88	(0.85, 0.92)
Cerebrovascular disease	1.44	(1.25, 1.66)	1.39	(1.23, 1.58)	1.30	(1.15, 1.47)	1.37	(1.27, 1.47)
Chronic Lung disease	1.45	(1.24, 1.70)	1.34	(1.16, 1.54)	1.16	(1.01, 1.33)	1.29	(1.19, 1.41)
GFR								
Not measured	1.66	(1.31, 2.10)	1.99	(1.64, 2.42)	1.49	(1.22, 1.83)	1.70	(1.51, 1.92)
"GFR<30"	3.55	(2.88, 4.38)	3.33	(2.75, 4.03)	3.84	(3.21, 4.60)	3.56	(3.19, 3.98)
"30≤GFR<60"	1.62	(1.41, 1.86)	1.73	(1.53, 1.97)	1.91	(1.69, 2.16)	1.76	(1.64, 1.90)
"60≤GFR<90"	(Reference Group)							
"GFR≥90"	0.90	(0.66, 1.22)	1.00	(0.76, 1.30)	1.23	(0.98, 1.54)	1.05	(0.91, 1.22)
Previous PCI	0.74	(0.63, 0.87)	0.72	(0.63, 0.83)	0.68	(0.60, 0.77)	0.71	(0.65, 0.77)
CHF - Current Status	1.48	(1.28, 1.70)	1.28	(1.12, 1.46)	1.34	(1.18, 1.52)	1.35	(1.25, 1.46)
Cardiogenic shock on admission	4.79	(4.20, 5.45)	5.33	(4.75, 5.97)	5.29	(4.73, 5.92)	5.15	(4.82, 5.52)
Admission Symptom Presentation								
No MI	0.89	(0.70, 1.12)	0.91	(0.74, 1.12)	1.14	(0.94, 1.40)	0.98	(0.87, 1.11)
MI within 24 hours	(Reference Group)							
MI after 24 hours	1.29	(1.04, 1.59)	1.13	(0.93, 1.37)	1.31	(1.09, 1.59)	1.24	(1.11, 1.39)
Ejection Fraction Percentage (EFP)								
Not measured	2.27	(1.94, 2.66)	2.34	(2.03, 2.69)	2.38	(2.07, 2.72)	2.33	(2.14, 2.53)
"0≤EFP<30"	3.17	(2.58, 3.88)	3.51	(2.94, 4.20)	3.22	(2.70, 3.84)	3.29	(2.96, 3.67)
"30≤EFP<45"	1.72	(1.44, 2.04)	1.86	(1.59, 2.17)	1.88	(1.62, 2.19)	1.83	(1.67, 2.00)
“EFP≥45”	(Reference Group)							
PCI Status								
Elective	(Reference Group)							
Urgent	1.29	(0.90, 1.84)	1.43	(1.04, 1.96)	1.50	(1.07, 2.11)	1.42	(1.17, 1.72)
Emergency	2.40	(1.72, 3.34)	2.03	(1.50, 2.73)	2.99	(2.18, 4.09)	2.44	(2.03, 2.93)
Salvage	9.06	(5.82, 14.10)	9.12	(6.23, 13.37)	14.08	(9.63, 20.60)	10.79	(8.59, 13.56)
Highest Lesion Location								
pRCA/mLAD/Pcirc	1.05	(0.91, 1.21)	1.19	(1.05, 1.35)	1.19	(1.05, 1.34)	1.15	(1.07, 1.24)
pLAD	1.35	(1.15, 1.58)	1.37	(1.18, 1.57)	1.44	(1.25, 1.65)	1.39	(1.27, 1.51)
Left Main	2.59	(1.80, 3.72)	2.55	(1.87, 3.47)	3.02	(2.26, 4.03)	2.71	(2.26, 3.25)
Other	(Reference Group)							
Highest Risk Lesion: SCAI Lesion Class								
I	(Reference Group)							
II or III	1.28	(1.07, 1.53)	1.25	(1.07, 1.46)	1.16	(1.00, 1.35)	1.22	(1.11, 1.34)
IV	1.82	(1.52, 2.18)	1.72	(1.47, 2.02)	1.54	(1.32, 1.79)	1.68	(1.53, 1.84)

Table 6 - PCI STEMI or Shock Cohort Model Performance: Results based on the GLM

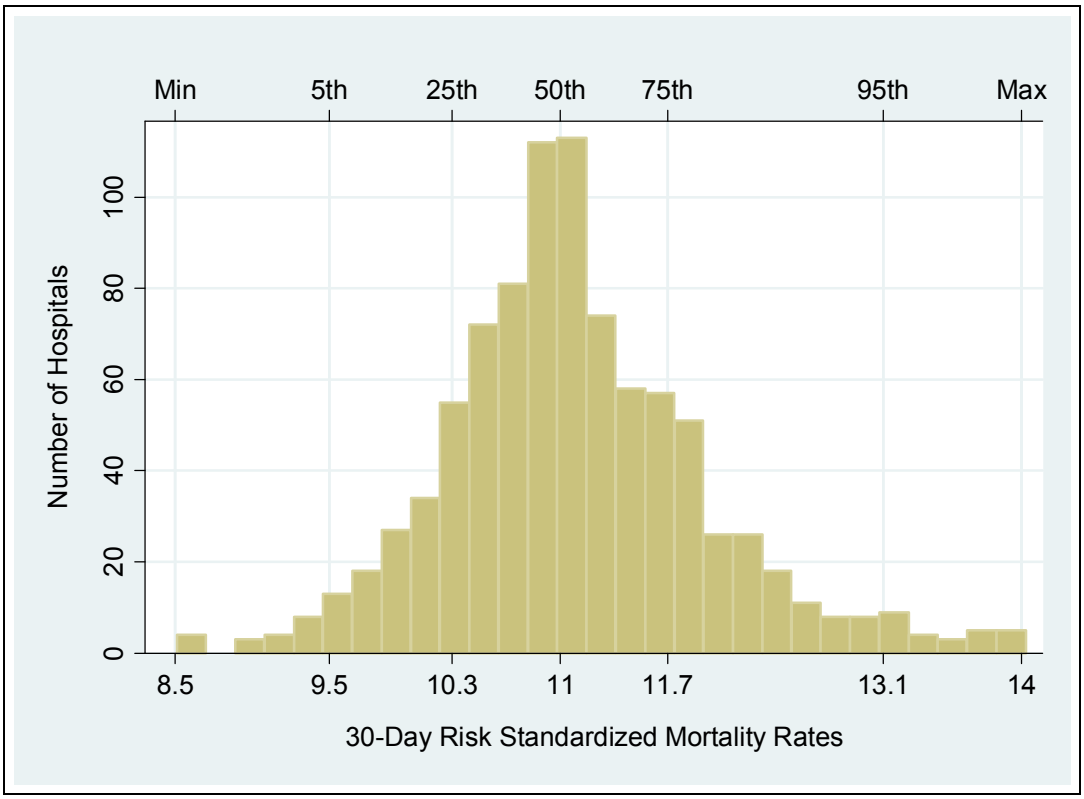
			Calibration		Discrimination				Residuals Lack of Fit (Pearson Residual Fall %)				Model Fitting	
						Predictive Ability								
Data Source	Number of Records	Mortality Rate	*γ0*	*γ1*	Adjusted R-Square	Lowest Decile	Highest Decile	ROC	<-2	[-2, 0)	[0, 2)	[2+	Chi-Square	Number of Covariates
Derivation														
2008	20082	11.179	0.000	1.000	0.324	0.014	0.514	0.841	0.139	88.681	6.618	4.561	2664.053	24
Validation														
2007	18107	11.449	0.024	0.983	0.310	0.012	0.508	0.832	0.127	88.424	6.655	4.794	2355.758	24
2006	15230	10.427	-0.038	0.964	0.292	0.013	0.456	0.831	0.125	89.448	5.785	4.642	1804.179	24

Table 7 - Distribution of Hospital Volume and RSMR in PCI STEMI or Shock Cohort over Different Time Periods

Characteristic	**2006**	**2007**	**2008**	**2006-2008**
Number of Hospitals	605	751	878	907
Hospital Volume				
Mean (SD)	25.17 (21.83)	24.11 (19.94)	22.87 (19.44)	58.90 (55.21)
Range (min. – max.)	(1 - 134)	(1 – 126)	(1 – 138)	(1 – 368)
25th Percentile	9	10	10	19
50th Percentile	20	19	18	45
75th Percentile	34	32	29	82
RSMR (%) (weighted by hospital volume)				
Mean (SD)	10.46 (1.41)	11.48 (1.12)	11.19 (1.58)	11.05 (1.04)
Range (min. – max.)	(6.74 – 15.65)	(8.71 – 15.99)	(6.95 – 18.60)	(8.5 – 14.0)
25th Percentile	9.50	10.73	10.14	10.34
50th Percentile	10.25	11.38	11.04	10.96
75th Percentile	11.33	12.12	12.04	11.68
Between Hospital Variance* (SE)	0.133 (0.036)	0.092 (0.028)	0.148 (0.033)	0.061 (0.013)

* Results from hierarchical model

Figure 3 - Distribution of Hospital 30-day RSMRs for PCI STEMI or Shock Cohort 2006-2008



3.4 No STEMI and No Shock Results

3.4.1 Frequency of Model Variables over Different Time Periods

We examined the temporal variation in frequency of clinical and demographic variables. The crude 30-day mortality rate across the cohorts increased slightly from 1.4% in 2006 to 1.6% in 2008. The proportion of patients who had an MI within 24 hours of the procedure increased from 10.7% to 13.1%. Similarly, the proportion of patients whose PCI was performed on an 'urgent' (as opposed to elective) basis increased from 37.6% to 41.7% (Table 8). These findings indicate that the overall risk profile of patients undergoing PCI has increased. There were no other notable changes in patients' cardiac status or prevalence of major comorbid conditions.

3.4.2 Model Parameters

Table 9 conveys the risk-adjusted ORs and 95% CIs for the PCI Mortality no STEMI and no Shock cohort model by individual year and for the 2006-2008 calendar year dataset. The parameters are consistent across all time periods. Higher BMI, peripheral vascular disease, and the absence of MI were all consistently associated with lower risk of mortality. All other variables were associated with higher risk of mortality.

3.4.3 Distribution of Hospital RSMRs

Table 11 shows the distributions of hospital volume, hospital RSMR and between-hospital variance over different time periods. Mean PCI volume in the no STEMI and no Shock cohort decreased from 185 hospital stays (SD: 190) per hospital in 2006, to 144 hospital stays (SD: 150) per hospital in 2008.

RSMR increased over the three-year period, from 1.4% in 2006 to 1.6% in 2008. The mean hospital RSMR for the combined three-year data was 1.4% (SD: 0.3%; range 0.8% – 2.7%), with 25^{th} and 75^{th} percentiles equal to 1.2% and 1.6%, respectively. Between-hospital variance remained stable across all cohort years ranging from 0.141 (SE: 0.030) to 0.180 (SE: 0.032). Between-hospital variance in the combined, three-year dataset was 0.120 (SE: 0.015). If there were no systematic differences between hospitals, the between-hospital variance would be 0.

Figure 4 shows the overall distribution of the hospital RSMRs for the three-year calendar year dataset. The odds of all-cause mortality for a hospital one standard deviation above average were 2.00 times that of a hospital one standard deviation below average. If there were no systematic differences between hospitals, the OR would be 1.0. [3]

Table 8 -Temporal Variation in Frequencies of Clinical and Demographic Variables – No STEMI and No Shock Cohort

Description	2006		2007		2008		2006-2008	
	#	%	#	%	#	%	#	%
ALL	111712		111712		126582		361478	
Demographics								
Age: Mean (SD)	74.59	6.46	74.64	6.54	74.79	6.68	74.68	6.57
Female	46289	41.44	50280	40.82	51469	40.66	148038	40.95
History and Risk Factors								
BMI								
Unknown	99	0.09	141	0.11	107	0.08	347	0.10
Mean (SD)	28.64	5.76	28.70	5.80	28.69	5.80	28.68	5.79
Previous MI	32822	29.38	35543	28.85	36731	29.02	105096	29.07
CHF - Previous History	16280	14.57	17956	14.58	19544	15.44	53780	14.88
Previous Valvular Surgery	1843	1.65	2190	1.78	2301	1.82	6334	1.75
Cerebrovascular Disease	18439	16.51	20392	16.55	21686	17.13	60517	16.74
Peripheral Vascular Disease	18144	16.24	20061	16.29	21277	16.81	59482	16.46
Chronic Lung Disease	21185	18.96	23426	19.02	25105	19.83	69716	19.29
Diabetes/Control								
No	74516	66.70	81440	66.11	82171	64.92	238127	65.88
Non-Insulin diabetes	25740	23.04	28715	23.31	29779	23.53	84234	23.30
Insulin diabetes	11456	10.25	13029	10.58	14632	11.56	39117	10.82
GFR								
Not measured	4052	3.63	3863	3.14	3384	2.67	11299	3.13
GFR<30	4553	4.08	5301	4.30	5462	4.31	15316	4.24
30<=GFR<60	40667	36.40	45616	37.03	44048	34.80	130331	36.06
60<=GFR<90	52943	47.39	57955	47.05	60432	47.74	171330	47.40
GFR>=90	9497	8.50	10449	8.48	13256	10.47	33202	9.19
Renal Failure - Dialysis	1853	1.66	2415	1.96	2641	2.09	6909	1.91
Hypertension	92856	83.12	104063	84.48	108930	86.05	305849	84.61
Tobacco Use								
Current	12176	10.90	13408	10.88	13987	11.05	39571	10.95
Former	47917	42.89	52082	42.28	53309	42.11	153308	42.41
No	51619	46.21	57694	46.84	59286	46.84	168599	46.64
Family History of CAD	23853	21.35	24022	19.50	23809	18.81	71684	19.83
Previous PCI	44446	39.79	50561	41.05	53196	42.02	148203	41.00
Previous CABG	28758	25.74	32094	26.05	33060	26.12	93912	25.98
Cardiac Status								
CHF - Current Status	13289	11.90	14629	11.88	15799	12.48	43717	12.09
NYHA								
Class I	37638	33.69	38956	31.62	37329	29.49	113923	31.52
Class II	28150	25.20	33139	26.90	33979	26.84	95268	26.36
Class III	31773	28.44	35217	28.59	38525	30.43	105515	29.19
Class IV	14151	12.67	15872	12.88	16749	13.23	46772	12.94
Admission Symptom Presentation								
No MI	93449	83.65	101517	82.41	102076	80.64	297042	82.17
MI within 24 hours	11901	10.65	14377	11.67	16576	13.10	42854	11.86
MI after 24 hours	6362	5.70	7290	5.92	7930	6.26	21582	5.97
Cath Lab Visit								
Ejection Fraction Percentage								
Not measured	33277	29.79	36738	29.82	37154	29.35	107169	29.65
EF<30	3993	3.57	4461	3.62	4790	3.78	13244	3.66
30<=EF<45	11681	10.46	12853	10.43	13582	10.73	38116	10.54
EF>=45	62761	56.18	69132	56.12	71056	56.13	202949	56.14
PCI Procedure								
PCI Status								
Elective	65911	59.00	71124	57.74	69654	55.03	206689	57.18
Urgent	42059	37.65	47727	38.74	52761	41.68	142547	39.43
Emergency or Salvage	3742	3.35	4333	3.52	4167	3.29	12242	3.39

Description	2006		2007		2008		2006-2008	
	#	%	#	%	#	%	#	%
Highest Lesion location								
pRCA/mLAD/pCIRC	42395	37.95	46411	37.68	48285	38.15	137091	37.93
pLAD	19142	17.14	20850	16.93	21472	16.96	61464	17.00
Left Main	2919	2.61	3195	2.59	3556	2.81	9670	2.68
Other	47256	42.30	52728	42.80	53269	42.08	153253	42.40
Highest Pre-Procedure TIMI Flow: None	4390	3.93	5267	4.28	5614	4.44	15271	4.22
Highest Risk Lesion: SCAI Lesion Class								
I	64413	57.66	71413	57.97	71980	56.86	207806	57.49
II	40141	35.93	43587	35.38	45971	36.32	129699	35.88
III	2678	2.40	3012	2.45	3204	2.53	8894	2.46
IV	4480	4.01	5172	4.20	5427	4.29	15079	4.17
In-hospital Death	791	0.71	864	0.70	993	0.78	2648	0.73

Table 9 - Adjusted ORs and 95% CIs for PCI No STEMI and No Shock Cohort GLM over Different Time Periods

Variable	2006 OR (95% CI)		2007 OR (95% CI)		2008 OR (95% CI)		2006-2008 OR (95% CI)	
Age (per 10 years)	1.61	(1.49, 1.74)	1.82	(1.69, 1.96)	1.75	(1.63, 1.87)	1.73	(1.66, 1.81)
BMI (per 5 units)	0.75	(0.69, 0.80)	0.75	(0.70, 0.81)	0.74	(0.69, 0.79)	0.75	(0.72, 0.78)
CHF - Previous History	1.35	(1.19, 1.52)	1.31	(1.16, 1.47)	1.23	(1.11, 1.38)	1.29	(1.21, 1.38)
Cerebrovascular disease	1.24	(1.10, 1.40)	1.16	(1.03, 1.30)	1.31	(1.18, 1.46)	1.24	(1.16, 1.32)
Peripheral Vascular Disease	1.18	(1.04, 1.35)	1.42	(1.25, 1.60)	1.31	(1.17, 1.47)	1.31	(1.22, 1.40)
Chronic Lung disease	1.59	(1.42, 1.78)	1.60	(1.44, 1.79)	1.62	(1.46, 1.79)	1.61	(1.51, 1.71)
Diabetes/Control								
No	Reference group							
Non-Insulin diabetes	1.08	(0.94, 1.23)	1.10	(0.97, 1.24)	1.12	(1.00, 1.26)	1.10	(1.02, 1.18)
Insulin diabetes	1.89	(1.64, 2.19)	1.66	(1.44, 1.91)	1.53	(1.34, 1.74)	1.67	(1.54, 1.81)
GFR								
Not measured	1.34	(0.99, 1.83)	1.30	(0.94, 1.79)	1.16	(0.84, 1.59)	1.25	(1.04, 1.50)
"GFR<30"	2.52	(2.10, 3.01)	3.01	(2.56, 3.53)	3.23	(2.79, 3.75)	2.93	(2.67, 3.22)
"30≤GFR<60"	1.44	(1.27, 1.63)	1.34	(1.19, 1.51)	1.30	(1.17, 1.45)	1.35	(1.26, 1.44)
"60≤GFR<90"	Reference group							
"GFR≥90"	1.61	(1.31, 1.98)	1.24	(1.00, 1.53)	1.16	(0.97, 1.40)	1.31	(1.17, 1.47)
Previous PCI	0.64	(0.57, 0.72)	0.67	(0.60, 0.74)	0.70	(0.64, 0.78)	0.67	(0.63, 0.72)
CHF - Current Status	2.04	(1.80, 2.31)	1.90	(1.69, 2.15)	1.90	(1.70, 2.13)	1.94	(1.81, 2.08)
NYHAC: Class IV	1.41	(1.25, 1.59)	1.27	(1.13, 1.43)	1.26	(1.13, 1.40)	1.30	(1.22, 1.39)
Admission Symptom Presentation								
No MI	0.54	(0.47, 0.62)	0.64	(0.56, 0.73)	0.67	(0.59, 0.75)	0.62	(0.57, 0.66)
MI within 24 hours	Reference group							
MI after 24 hours	1.06	(0.90, 1.25)	1.19	(1.02, 1.40)	1.10	(0.95, 1.28)	1.12	(1.02, 1.23)
Ejection Fraction Percentage								
Not measured	1.69	(1.48, 1.91)	1.37	(1.21, 1.54)	1.46	(1.31, 1.64)	1.49	(1.39, 1.60)
"0≤EF<30"	2.64	(2.20, 3.17)	2.39	(2.02, 2.83)	2.13	(1.81, 2.50)	2.36	(2.13, 2.60)
"30≤EF<45"	1.73	(1.49, 2.01)	1.56	(1.36, 1.81)	1.55	(1.35, 1.77)	1.60	(1.48, 1.74)
“EF≥45”	Reference group							
PCI Status								
Elective	Reference group							
Urgent	1.44	(1.27, 1.63)	1.39	(1.24, 1.57)	1.40	(1.25, 1.56)	1.41	(1.32, 1.51)
Emergency or Salvage	3.49	(2.89, 4.21)	3.01	(2.50, 3.61)	3.60	(3.03, 4.29)	3.36	(3.02, 3.73)
Highest Lesion location								
pRCA/mLAD/pCIRC	1.15	(1.02, 1.29)	1.24	(1.11, 1.40)	1.13	(1.02, 1.26)	1.17	(1.10, 1.25)
pLAD	1.19	(1.03, 1.38)	1.39	(1.21, 1.59)	1.35	(1.19, 1.53)	1.31	(1.21, 1.42)
Left Main	1.60	(1.25, 2.04)	2.16	(1.74, 2.69)	1.81	(1.48, 2.21)	1.85	(1.63, 2.10)
Other	Reference group							
Highest Risk Lesion: SCAI Lesion Class								
I	Reference group							
II or III	1.41	(1.27, 1.58)	1.35	(1.21, 1.50)	1.38	(1.25, 1.52)	1.38	(1.30, 1.46)
IV	1.96	(1.61, 2.38)	2.08	(1.74, 2.49)	2.21	(1.86, 2.61)	2.09	(1.89, 2.32)

Table 10 - PCI No STEMI and No Shock Cohort Model Performance: Results based on the GLM

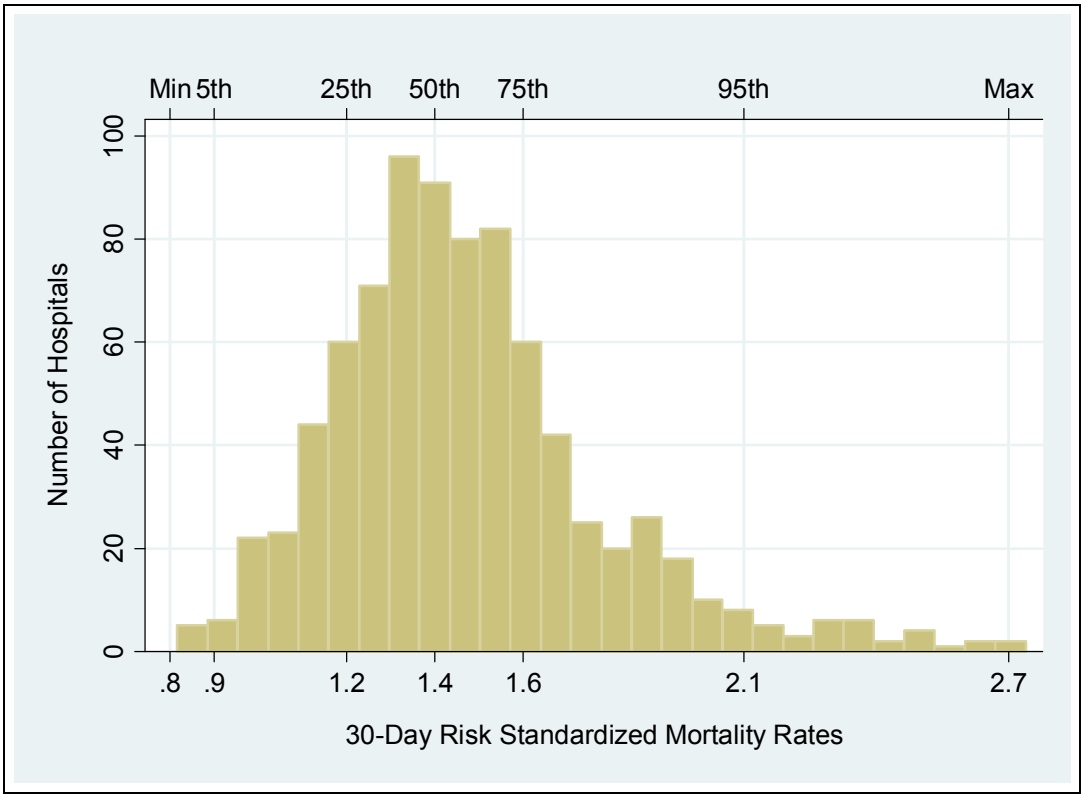
Data Source	Number of Records	Mortality Rate	Calibration		Discrimination				Residuals Lack of Fit (Pearson Residual Fall %)				Model Fitting	
						Predictive Ability								
			γ0	*γ1*	Adjusted R-Square	Lowest Decile	Highest Decile	ROC	<-2	[-2, 0)	[0, 2)	[2+	Chi-Square	Number of Covariates
Derivation														
2008	126582	1.555	0.000	1.000	0.154	0.001	0.074	0.816	0.000	98.445	0.082	1.473	2976.455	27
Validation														
2007	123184	1.393	-0.147	0.965	0.161	0.001	0.071	0.819	0.000	98.607	0.090	1.303	2806.912	27
2006	111712	1.377	0.025	1.022	0.162	0.001	0.070	0.822	0.000	98.623	0.072	1.305	2533.955	27

Table 11 - Distribution of Hospital Volume and RSMR in PCI No STEMI and No Shock Cohort over Different Time Periods

Characteristic	2006	2007	2008	2006-2008
Number of Hospitals	605	747	876	898
Hospital Volume				
Mean (SD)	184.65 (190.44)	164.90 (169.12)	144.50 (149.71)	402.54 (455.91)
Range (min. – max.)	(1 – 1406)	(1 – 1169)	(1 – 1213)	(1 – 3416)
25th Percentile	56	52	48	100
50th Percentile	135	119	105.5	273
75th Percentile	243	213	179.5	536
RSMR (%) (weighted by hospital volume)				
Mean (SD)	1.39 (0.38)	1.40 (0.28)	1.55 (0.37)	1.43 (0.34)
Range (min. – max.)	(0.78 – 3.26)	(0.81 – 2.66)	(0.92 – 3.19)	(0.82 – 2.74)
25th Percentile	1.14	1.21	1.29	1.20
50th Percentile	1.31	1.35	1.51	1.39
75th Percentile	1.58	1.56	1.76	1.58
Between Hospital Variance* (SE)	0.1797 (0.032)	0.1405 (0.030)	0.1696 (0.028)	0.1202 (0.015)

* Results from hierarchical model

Figure 4 - Distribution of Hospital 30-day RSMRs for PCI No STEMI and No Shock Cohort 2006-2008



4. Evaluation of Variables Used for Risk Adjustment

4.1 Background

The original PCI 30-day mortality models were developed using a single stepwise selection process to identify variables most strongly associated with 30-day mortality. During NQF review, a recommendation was made to perform additional analyses to minimize the chances of inappropriately including or excluding individual variables. Accordingly, we conducted bootstrap analyses to evaluate the consistency with which candidate variables were selected for inclusion in the risk models.

4.2 Methodology

Using data from the 2008 patient cohort, we performed bootstrap analyses separately in the STEMI and/or cardiogenic shock population and in the no STEMI and no shock population. Specifically, for each cohort we performed 1000 iterations of the stepwise variable selection process using an entry criterion of 0.05 and a retention criterion of 0.01. We used the 26 candidate variables originally identified during measure development (Table 1).

4.3 Results

Analyses demonstrated a high degree of consistency with regard to the variables selected for both populations of patients.

4.3.1. STEMI/Shock Cohort

In the original STEMI or shock measure using 2006 data, 13 candidate variables were included in the risk adjustment model. In bootstrap analysis of 2008 data, 11 of these 13 variables were selected in more than 75% of the iterations. Two of the original model variables, “admission symptoms” and “history of cerebrovascular disease” were selected in 59% and 17% of iterations. No additional variables were selected in more than 75% of iterations. When we reran the model in the combined 2006-2008 data excluding “admission symptoms” and “history of cerebrovascular disease”, the model performance was virtually unchanged (e.g. the c-statistic was 0.834 without the variables and 0.835 with the variables).

4.3.2. No STEMI/No Shock Cohort

The original no STEMI and no shock measure contains 16 candidate variables. With bootstrapping using 2008 data, all 16 variables were selected in more than 75% of the iterations. Two additional variables, “history of coronary artery bypass grafting” and “end stage renal disease on dialysis” were also selected in more than 75% of iterations. When we

reran the model in the combined 2006-2008 data including these additional variables, the model performance was virtually unchanged (e.g. the c-statistic was 0.818 without the variables and 0.820 with the variables).

4.4 Conclusions

Overall, these analyses provide additional statistical justification of the variables currently included in the two measures. They raise the possibility that two variables could be excluded from the STEMI or shock model without affecting its statistical validity. However, their exclusion would reduce the clinical sensibility of the risk adjustment methodology. Our analyses suggest that two additional variables could provide small incremental value to the no STEMI and no shock model. However, it is not clear that their inclusion would be warranted given the burden of obtaining this additional information. Upon review, the Yale team did not feel that making changes in the models was justified at this time. Nevertheless, further consideration of these modifications would be warranted as the measures move closer to implementation.

5. Cross-walk of Versions 3.0 and 4.0 of the CathPCI Registry

5.1 Background

In July 2009, the NCDR introduced a new version of the CathPCI Registry. Changes include updated data definitions, modification of previously collected data elements, and addition of new fields that capture more information about comorbidities, cardiac status, and procedural specifics.

5.2 Methodology

In order to assess the potential impact of these updates on our models, we cross-walked the data elements used to define the final model variables in Versions 3.04 and 4.3.1 of the NCDR CathPCI Registry. We compared the data element names and definitions.

5.3 Results and Next Steps

Version 4 of the CathPCI registry did not substantively change either the collection or definitions of the variables included in the PCI mortality measures. There were, however, updates that may require coding changes to future versions of the SAS pack. In addition, when a sufficient amount of Version 4 data has been collected that can be linked with 30 day vital status (likely first quarter of 2011); we will determine if additional candidate variables should be considered for inclusion in the model. We will continue detailed evaluation of possible implications on the PCI Mortality measures. See Appendix B for the version cross-walk.

6. Analysis of the Social Security Death Master File as Alternative Source of Vital Status

6.1 Background

The PCI mortality measures are designed to reflect the outcomes of all patients undergoing PCI. Hospitals will submit the data used for risk adjustment, but reporting 30-day vital status will require linking the registry data to another data source. Available options include the Social Security Administration's (SSA) Death Master File (DMF) and the National Death Index (NDI). The NDI and DMF include death records for all deaths, as compared to Medicare's Enrollment Database (EDB), which is limited to Medicare and Medicaid beneficiaries.

6.2 Methodology

We assessed the potential use of the DMF database as a source of vital status. The DMF contains over 83 million records of death as reported to the SSA and is updated weekly, eliminating the lag time seen in similar databases. We conducted analyses to compare the DMF with the EDB.

At present, the CathPCI Registry does not routinely collect direct patient identifiers including Social Security number (SSN). Accordingly, we ran our analysis on data from the CMS mandated registry of implantable cardioverter defibrillators (ICD) operated by the NCDR. Although not directly applicable to PCI patients, the data does reflect the experience of collecting direct patient identifiers from a government mandated registry of cardiovascular procedures. Specifically, we ran these analyses using ICD data from 2006 to 2007 that had been linked by CMS to the EDB (N=41,221). Seventy (70) patients in this file had no SSN.

We determined 30-day vital status from the DMF and EDB separately as follows:

For the DMF, we determined vital status and date of death in two steps. First, we searched the DMF from 2009 using SSN, and identified 11,943 patients who had died. Second, for the remaining 29,278 patients, we searched using patient name (first, middle, last name) and date of birth. This returned an additional 196 patients who had died during the follow up period. In addition, we examined the SSNs of these patients to understand why they did not initially match:

- 164 patients did not have SSN in the CMS ICD data or had a SSN that is similar to the SSN in the DMF data (only one digit is different)
- 32 patients had SSNs that are not similar (more than two digits are different)

These findings suggest that matching using name and date of birth is reasonable but will likely result in some mismatches.

For the EDB, we used indicators in administrative data from 2006 to 2008 to determine vital status and date of death. We then determined the agreement between 30 day death rates using the EDB and DMF.

6.3 Results

Table 12 - Patient Matches between Enrollment Database and Death Master File within 30 days of Discharge

Match Description	N	Percent
Patient matches in both EDB and DMF (no death)	40,626	98.56
Patients matched with death in EDB but not in DMF	23	0.06
Patients matched with death in DMF but not in EDB	5	0.01
Patient matches in both EDB and DMF (with death)	567	1.38
Total	41,221	100.0

Overall agreement is high, 96.1% of EDB deaths were also present in the DMF, and 99.1% of DMF deaths were also present in the EDB.

6.4 Next Steps

During maintenance in the upcoming year, we will perform a detailed examination of discrepant cases. Potential contributing factors include inaccurate ICD Registry Data (i.e. incorrect SSN), disagreement as to specific date of death, and effects of searching on name and DOB as opposed to SSN. Additionally, we will acquire NDI data and complete similar analyses in that dataset.

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8. APPENDICES

8.1 Appendix A - PCI Mortality Methodology Report

8.2 Appendix B – NCDR CathPCI Registry Version Update Cross-walk

Hospital 30-Day Percutaneous Coronary Intervention Mortality Measures

Measures Methodology Report

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Under Subcontract # HHSM-500-2005-CO001C/CO0018
from the Colorado Foundation for Medical Care (CFMC)
PM # 419-056 CO 2008

Prepared For:

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Submitted July 31, 2008
(Revised October 28, 2009)

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ACKNOWLEDGEMENTS

We would like to acknowledge the ongoing support from our colleagues affiliated with the American College of Cardiology, the National Cardiovascular Data Registry, and the Duke Clinical Research Institute. Without their continued support, this project would not have been possible.

Special thanks are due to the working group members. These individuals participated on weekly calls, provided insight and guidance, and otherwise contributed to this work on a regular basis. These individuals include:

Ralph Brindis, M.D., M.P.H.,F.A.C.C.
Barbara Christensen, R.N., M.H.A.
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Eric Peterson, M.D., M.P.H., F.A.C.C.
Lara Slattery, M.H.S.
Al Woodward, Ph.D., M.B.A.

We would also like to thank all of the ACCF Task Force on Public Reporting of Hospital-Level Cardiovascular Outcomes Measures members, who provided great support and insight on key measure decisions. These members include:

John Brush, M.D., F.A.C.C.
Vincent J. Bufalino, M.D., F.A.C.C.
James Dove, M.D., F.A.C.C.
Frank E Harrell Jr, PhD
Barry K. Lewis, D.O., F.A.C.C.
William R. Lewis, M.D., F.A.C.C.
Fred Masoudi, M.D., M.S.P.H., F.A.C.C.
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1. INTRODUCTION

1.1 Overview of Measure

Mortality following Percutaneous Coronary Intervention (PCI) is an important patient outcome that may reflect quality of care. The Deficit Reduction Act (DRA) of 2005 requires that the Centers for Medicare & Medicaid Services (CMS) publicly report outcomes and efficiency measures on the consumer Web site, Hospital Compare (www.hospitalcompare.hhs.gov). CMS began publicly reporting acute myocardial infarction (AMI) and heart failure (HF) 30-day mortality measures as outcome measures in June 2007, and will start reporting a pneumonia 30-day mortality measure in August 2008. Building on this foundation, CMS, in partnership with the American College of Cardiology (ACC), developed two 30-day all-cause PCI mortality measures that are suitable for public reporting. Advantages of this approach include improving measures through clinical leadership and access to clinical registry data, promoting physician acceptance of and familiarity with performance measures, and ultimately speeding performance improvement. Specifically, we developed measures using data from the National Cardiovascular Data Registry (NCDR) CathPCI Registry combined with data from CMS claims data. The overarching goal of this work is to improve the quality of care delivered to patients undergoing PCI.

We developed models that estimate hospital-specific, risk-standardized, 30-day mortality for two cohorts of Medicare fee-for-service (FFS) patients who had a PCI during their hospitalization: (1) 30-day mortality following PCI in a cohort of patients with ST segment elevation myocardial infarction (STEMI) and/or cardiogenic shock; and (2) 30-day mortality following PCI in a cohort of patients with neither STEMI nor cardiogenic shock. For model development, we used clinical registry data from the NCDR CathPCI Registry for risk adjustment linked to CMS claims and enrollment data. We linked clinical and vital status data using a probabilistic match. To account for the clustering of observations within hospitals and differences in the number of admissions across hospitals, we used hierarchical logistic regression to estimate risk-standardized mortality rates (RSMRs).

These models are designed for use in national public reporting. They are aligned with the American Heart Association (AHA) published standards for publicly reported outcomes measures (Krumholz, Brindis et al. 2006). Several steps would need to be taken, however, to use them for public reporting. First, the parameters would need to be re-estimated using the national data. Second, direct identifiers would be required to link clinical data and vital status. Finally, adequate mechanisms would need to be established in order to ensure data quality.

1.2 Purpose of the Measure

The performance of PCI carries a low but unavoidable risk of mortality. This risk varies substantially depending on patients' clinical status. The risk of mortality can be modified by the type and quality of care provided to patients. Improving mortality rates is the joint responsibility of hospitals and clinicians. Measuring mortality can create incentives to invest in interventions to improve patient care.

1.3 Why PCI Mortality

PCI is one of the most commonly performed cardiac procedures in the United States. In 2005, an estimated 1,265,000 PCI procedures were performed in the United States (Rosamond Flegal et al. 2008). From 1987–2003, the number of procedures increased 326% (Thom, Haase et al. 2006). Inpatient mortality is the indicator that has been most widely used to evaluate cardiac procedures and is arguably the most important adverse outcome measure. The ACC summarized the experience of the NCDR CathPCI Registry from 1998-2000 and found that in-hospital mortality occurred in 1,422 of 100,253 PCI procedures (1.4%) (Shaw, Anderson et al. 2002). In the present era, mortality rates for PCI in large series from experienced operators ranged from 0.5 to 1.7 percent (Carrozza 2008). Prior studies have demonstrated significant variability in in-hospital PCI mortality across age groups, gender, geographic regions, socioeconomic status, and by hospital volume (Mukherjee, Wainess et al. 2005). Although twelve states already report PCI outcomes, to date there has not been a unified national effort to publicly report hospital PCI mortality rates.

1.4 Core Values for Hospital Outcomes Models Suitable for Public Reporting

We developed models using an approach that is consistent with the rationale articulated in the AHA scientific statement, "Standards for Statistical Models Used for Public Reporting of Health Outcomes" (Krumholz, Brindis et al. 2006). First, a description of the methodological development of the model, the model components, and its performance should be publicly available. Second, each model should have a clear and justifiable strategy for developing the sample of patients to be included, exclude those unlikely to have the condition, and account for transfers and other applicable factors. Third, the model should adjust for comorbidities, but not complications or clinical conditions that develop during hospitalization, and should evaluate the outcomes of a hospitalization using a pre-specified, standardized follow-up time (e.g., 30-days after the procedure), rather than a non-standardized period of assessment (such as during the hospitalization). The model should incorporate design features to account for patient clustering. Finally, the results should be presented in an understandable and informative way.

The methodological approach to develop the mortality measures was designed to reflect all of these attributes. We derived the models using risk adjustment variables that exclude potential complications so that the estimated risks were based on characteristics prior to, rather than during or after, the procedure. To calculate risk-standardized mortality rates (RSMRs), we used a hierarchical logistic regression

model, a statistical approach that takes into account the clustering of patients within hospitals and differences in sample size across hospitals. We computed indices that describe model performance in terms of calibration (over-fitting indices), discriminant ability (R-Square, ROC, and predicted vs. observed mortality), and overall fit (residuals, lack of fit, and model chi-square).

2. METHODS

2.1 Overview

We developed measures of 30-day mortality following PCI using data from the NCDR CathPCI Registry linked with CMS claims data. We developed these models for two mutually exclusive cohorts of PCI patients: (1) patients with STEMI or cardiogenic shock; and (2) patients without STEMI and without cardiogenic shock. For each cohort we fit a hierarchical generalized linear model (HGLM) that estimates hospital-level all cause risk-standardized 30-day mortality rate.

To develop the models, we first linked Medicare Part A administrative claims to the Medicare Enrollment Database (EDB) to retrieve mortality information for each PCI using a unique patient identifier. We then linked the CathPCI Registry data to a Medicare dataset that contained patient-level data, including mortality, on admissions with an associated PCI. Because the current version of the NCDR CathPCI database does not include direct patient identifiers, these admissions were linked using a probabilistic match. Specifically, the admissions are matched using indirect patient identifiers including hospital Medicare Provider Number (MPN), patient age, gender, admission date, and discharge date. In the future, the NCDR registries will contain identifiers that will allow a direct match. Admissions were then stratified by the patient's cardiac status into two groups: 1) admissions for patients with STEMI or cardiogenic shock (STEMI or shock) and 2) admissions for patients without STEMI and without cardiogenic shock (no STEMI and no shock). In both groups, a risk adjustment model was derived using all matched admissions in 2006 ("development sample"). The performance of the models was validated using a similar cohort of patients who underwent PCI in 2005 ("validation sample"). For both models, we computed indices that describe their respective performance in terms of predictive ability, discriminant ability, and overall fit. Finally, we re-estimated the models using combined data from 2005 and 2006 ("application sample") and generated hospitals' RSMRs and corresponding interval estimates.

2.2 Outcome

The outcome evaluated for each cohort is PCI 30-day all-cause mortality, measured as death within 30 days of the date of the PCI.

2.2.1 30-Day Timeframe

We chose a 30-day timeframe for several reasons. As compared to an inpatient mortality measure, a 30-day measure provides a standardized period of assessment, which may represent a more equitable approach to

measuring hospital performance. Models with a fixed outcome period are preferable because they ensure hospital variation in length of stay (LOS) does not affect performance and minimizes the opportunity for misrepresentation (transferring of patients or other gaming mechanisms) (Krumholz, Brindis et al. 2006). In addition, the 30-day period of assessment may be a more clinically meaningful timeframe for patients, reflecting not only the outcomes of inpatient processes of care but also the transition of care to the outpatient setting. As such, a 30-day mortality measure may stimulate better collaboration between hospitals and their surrounding medical communities aimed at reducing mortality rates. These activities may include: ensuring patients are clinically appropriate for discharge; improving communication among providers in transitions of care; and encouraging strategies that promote disease management principles and educate patients on what symptoms to monitor, whom to contact with questions, and where and when to seek follow-up care. Thus, information about 30-day mortality rates following PCI, which is currently unavailable to CathPCI hospitals, could be used to supplement existing quality improvement efforts.

We performed analyses determining whether there are clinically meaningful differences between in-hospital and 30-day mortality at hospitals participating in the NCDR CathPCI Registry. We found that although in the majority of hospitals, the difference between in-hospital and 30-day mortality was small (<1%), a significant number of hospitals had differences in excess of 1.5% (Table 1). Furthermore, the observed differences in mortality were associated with differences in hospital decile ranking, with 26% moving more than one decile of performance when using 30-day mortality compared with in-hospital mortality (Table 2). These finding suggest that in-hospital mortality may not be an adequate surrogate for 30-day mortality.

Table 1 – Difference Between Unadjusted 30-Day Mortality and In-Hospital Mortality

Difference between 30-day and in-hospital mortality rate	Number of hospitals	Percent of all hospitals
<1%	445	71.3
1-1.4%	81	13.0
1.5-2.0%	43	6.9
>2%	55	8.8

Table 2 – Decile Ranking Shifts When Comparing Unadjusted 30-Day Mortality to In-Hospital Mortality

Decile Change	Number of hospitals	Percent of all hospitals
Did not change deciles	246	39.0
Stayed within one decile	464	74.0
Moved more than one decile	160	26.0

2.2.2 All-Cause Mortality

We used all-cause mortality as opposed to cardiac specific mortality for several reasons. First, from the patient perspective, mortality from any cause is the critical measure. Second, different causes of death may still be directly related to the quality of care. Finally, even if using cardiac specific mortality were desirable, making accurate determinations of specific causes of death is difficult and prone to error, particularly if the patient dies outside the hospital setting.

2.3 Data Sources

The datasets used to create the measures are described below.

1) NCDR CathPCI Registry data
   The CathPCI Registry is a voluntary cardiovascular data registry. The registry captures detailed information about patients at least 18 years of age undergoing cardiac catheterization and PCI. This includes demographics, comorbid conditions, cardiac status, and coronary anatomy. Hospitals that join the CathPCI Registry agree to submit data for 100% of patients undergoing PCI procedures, including all related cardiac cath data. These data are collected by hospitals and submitted electronically on a quarterly basis to NCDR (the data collection form and the complete list of variables collected and submitted by hospitals can be found at www.ncdr.com). The patient records that are submitted to the registry focus on acute episodes of care, from admission to discharge. The NCDR does not currently link patient records longitudinally across episodes of care.

   Institutions that participate in the CathPCI Registry represent the full spectrum of hospitals. We compared characteristics of hospitals that do participate in the CathPCI Registry with hospitals that do not participate using data from the 2005 American Hospital Association Survey. Compared with PCI hospitals that do not participate in the CathPCI Registry, hospitals that do participate are larger and more likely to be located in the Northeast. Furthermore, a higher proportion of those in the CathPCI Registry are not-for-profit, teaching, and provide coronary artery bypass grafting (Table 3).

Table 3 – Characteristics of PCI Hospitals in the CathPCI Registry and PCI Hospitals not in the CathPCI Registry

Description	Total		CathPCI Hospitals		Non-CathPCI Hospitals		P
	#	%	#	%	#	%	
All	1565	100.0	623	100.0	942	100.0	
Number of beds							<0.001
< 300	881	56.3	301	48.3	580	61.6	
300 to 600	543	34.7	257	41.3	286	30.4	
> 600	141	9.0	65	10.4	76	8.1	
Mean (SD)	320.4	217.3	348.1	196.3	302.1	228.4	<0.001
Ownership							<0.001
Government	176	11.2	52	8.3	124	13.2	
Not-for-profit	1078	68.9	489	78.5	589	62.5	
For profit	311	19.9	82	13.2	229	24.3	
Region							<0.001
Associated area	9	0.6	0	0.0	9	1.0	
New England	58	3.7	33	5.3	25	2.7	
Middle Atlantic	173	11.1	43	6.9	130	13.8	
South Atlantic	253	16.2	102	16.4	151	16.0	
East North Central	280	17.9	151	24.2	129	13.7	
East South Central	117	7.5	43	6.9	74	7.9	
West North Central	128	8.2	61	9.8	67	7.1	
West South Central	225	14.4	55	8.8	170	18.0	
Mountain	126	8.1	58	9.3	68	7.2	
Pacific	196	12.5	77	12.4	119	12.6	
Teaching status							0.013
COTH	254	16.2	112	18.0	142	15.1	
Teaching	313	20.0	141	22.6	172	18.3	
Non-Teaching	998	63.8	370	59.4	628	66.7	
Cardiac facility							<0.001
CABG surgery	991	63.3	489	78.5	502	53.3	

The NCDR CathPCI Registry has an established Data Quality Program that serves to assess and improve the quality of the data submitted to the registry. There are two complementary components to the Data Quality Program- the Data Quality Report (DQR) and the Data Audit Program (DAP). The DQR process assesses the completeness of the electronic data submitted by participating hospitals. Hospitals must achieve >95% completeness of specific data elements identified as 'core fields' to be included in the registry's data warehouse for analysis. The 'core fields' encompass the variables included in our risk adjustment models. The process is iterative, providing hospitals with the opportunity to correct errors and resubmit data for review and acceptance into the data warehouse. All data for this analysis passed the DQR completeness

thresholds. The DAP consists of annual on-site chart review and data abstraction. Among participating hospitals that pass the DQR for a minimum of two quarters, at least 5% are randomly selected to participate in the DAP. At individual sites, auditors review charts of 10% of submitted cases. The audits focus on variables that are used in the NCDR risk-adjusted in-hospital mortality model including demographics, comorbidities, cardiac status, coronary anatomy, and PCI status. The DAP includes an appeals process for hospitals to dispute the audit findings. The NCDR DAP was accepted by the National Quality Forum as part of its endorsement of the CathPCI Registry's in-hospital risk-adjusted mortality measure. In the most recently completed audit, which assessed cases submitted in 2005, the median agreement between submitted and audited values was 92%. There was consistency across sites, with agreement in the lowest and highest deciles of hospitals ranging from 90% to 95%.

For model development, we used admissions of PCI patients discharged from January through December 2006. For validation purposes, we used admissions of patients discharged from January through December 2005.

2) Medicare Data
   - Part A (inpatient) data
     Part A inpatient data refers to claims paid for Medicare inpatient hospital care, skilled nursing facility care, some home health agency services, and hospice care. For purposes of this project, Part A is used to refer to inpatient services only and includes data from two time periods. For model development, we used 2006 Medicare Part A data to match index admissions from CathPCI Registry for the above time periods. For validation, we used 2005 Medicare Part A data to match index admissions from the CathPCI Registry for the above time periods.

   - Medicare Enrollment Database (EDB)
     This database contains Medicare beneficiary demographic, benefit/ coverage, and vital status information. Patient death information was linked by patient HIC number to the Part A admissions with PCI for 2005 and 2006. This data has previously been shown to accurately reflect patient vital status (Fleming Fisher et al. 1992).

2.4 Cohort Derivation

We initially considered data from the CathPCI Registry and CMS claims data separately. In each dataset, a potential index admission was one in which a PCI was performed. The algorithm used to derive the set of admissions is documented in Figure 1.

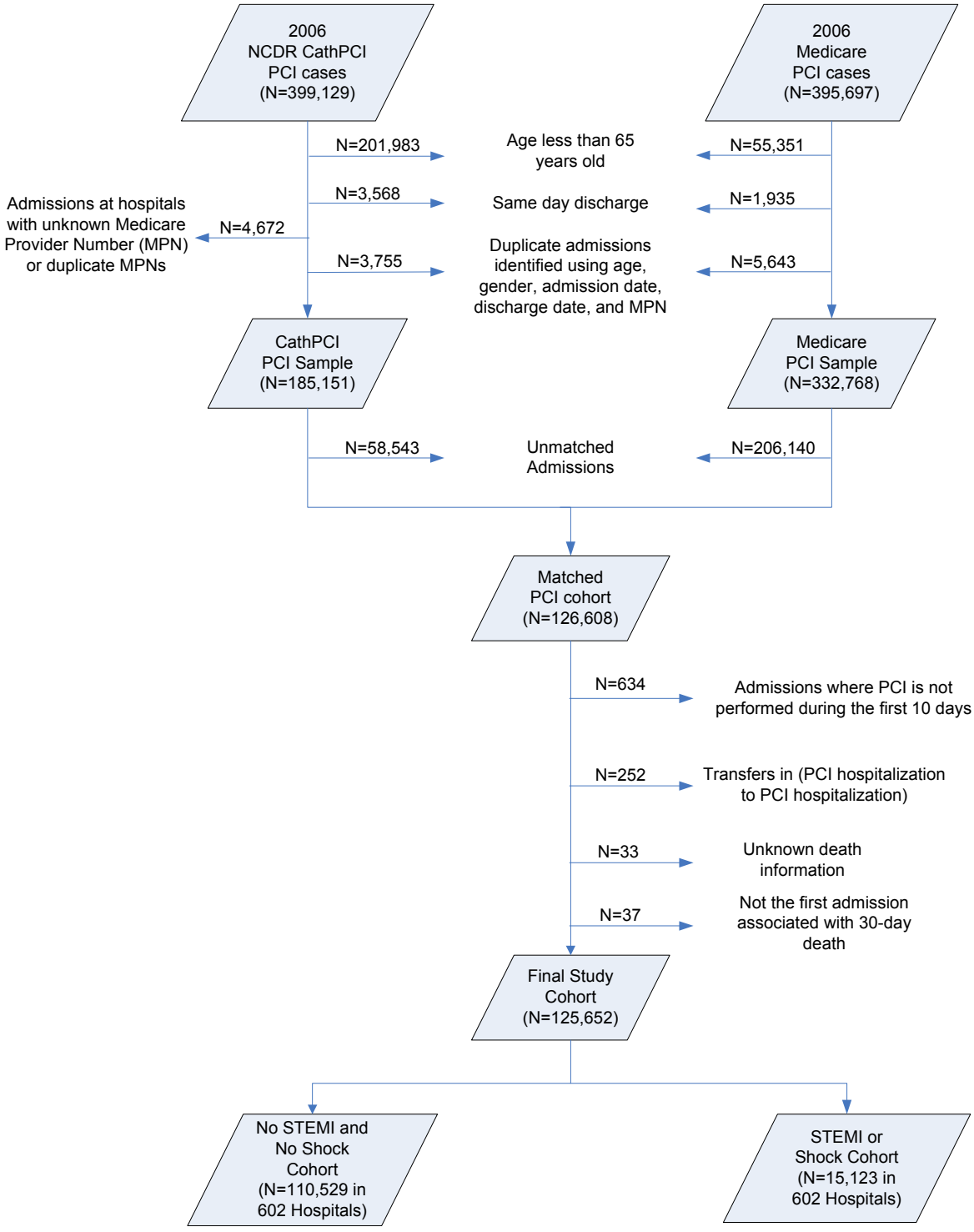
When patients underwent more than one PCI during an admission, we considered only the data from the first PCI in the analysis. We chose this approach because information obtained from additional PCI procedures may reflect complications of care following the first PCI. For example, if a patient undergoes elective PCI and subsequently experiences acute vessel closure due to an unrecognized dissection, the patient's myocardial infarction status would reflect a complication of care and accordingly be inappropriate for consideration in risk adjustment. If a patient had more than one admission with a PCI during the study period but not within the same admission, each PCI was considered as an independent index procedure. The information from prior PCI admissions was not considered for risk adjustment.

In the CathPCI Registry, admissions with PCI are identified by field 614 (PCI=Yes). In the CMS claims data, admissions with PCI are identified by the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) procedure codes shown in Table 4.

Table 4 – ICD-9-CM Codes that Define PCI During Hospitalization in the Medicare Dataset

ICD-9-CM	Description
00.66	Percutaneous transluminal coronary angioplasty or coronary atherectomy
36.01	Single vessel PTCA or coronary atherectomy
36.02	Percutaneous transluminal coronary angioplasty or coronary atherectomy with mention of thrombolytic agent
36.05	Multiple vessel PTCA or coronary atherectomy
36.06	Insertion of non-drug-eluting coronary artery stent(s)
36.07	Insertion of drug-eluting coronary artery stent(s)

Figure 1 – Cohort for Model Development



2.4.1 Probabilistic Matching Methodology for Merging CathPCI Data and CMS Claims Data for Measure Development

As the NCDR CathPCI Registry is limited to in-hospital outcomes, both measures required linking registry data to external databases to accurately determine 30-day mortality rates. Since the CathPCI Registry does not currently capture the direct patient identifiers necessary to make these linkages, we performed a probabilistic match linking hospitalizations with PCI in the CathPCI Registry with corresponding hospitalizations in the CMS claims data using indirect patient identifiers. Specifically, we used hospital Medicare Provider Number (MPN), patient age, gender, date of admission, and date of discharge. To accomplish this, we performed the following steps:

1. Hospital information assembled from the CathPCI Registry (hospital identification number, name and address) was used to retrieve each hospital's self-reported hospital MPN from the NCDR;

2. MPN was manually searched and confirmed in the CathPCI Registry data for hospitals with either no self-reported MPN or a duplicate MPN;

3. A unique dataset was derived from the CathPCI Registry (including patients' clinical factors) with patient admissions determined by hospital MPN, patient age, gender, admission date, and discharge date;

4. A comparable dataset was created from CMS claims data. After linking hospitalizations to the Medicare EDB to determine mortality status, direct patient identifiers, such as Health Insurance Claim (HIC) number, were removed. The resulting dataset contained unique patient admissions determined by hospital MPN, patient age, gender, admission date, and discharge date;

5. The two datasets derived in steps 3 and 4 were merged using hospital MPN, patient age, gender, admission date, and discharge date as the linking fields.

Among PCI patients ≥65 years old in the CathPCI Registry, 65% were successfully matched to CMS claims data. Results of the match were similar when we varied matching criteria (e.g., removing discharge date as a linking field). Although 35% of patients did not match, the observed characteristics of patients who did match are very similar to those of patients who did not match, supporting the representativeness of our cohort to the larger population of Medicare-eligible patients ≥65 (Table 5). One likely explanation for patients ≥65 not matching is that 20% of Medicare patients ≥65 are enrolled in Medicare managed care plans.

Other contributing factors include patients ineligible for Medicare (e.g., non-U.S. citizens), patients with non-governmental insurance, and inaccuracies in linking fields (e.g., substituting age for date of birth).

Table 5 – Selected Patient Characteristics and Outcomes in NCDR Data for Matched and Unmatched Patients

Description		Not Matched		Matched	
		#	%	#	%
Demographics	Age: Mean (SD)	73.9	6.4	74.7	6.5
	Gender	22,541	39.6	52,458	42.0
	Race: non-white	9,199	16.2	13,070	10.5
History and Risk Factors	BMI				
	Unknown	82	0.1	146	0.1
	Mean (SD)	28.6	5.7	28.5	5.8
	Heart Failure - Previous History	7,346	12.9	17,819	14.3
	Previous Valvular Surgery	807	1.4	1,994	1.6
	Cerebrovascular Disease	8,432	14.8	20,169	16.1
	Peripheral Vascular Disease	8,172	14.4	19,641	15.7
	Chronic Lung Disease	9,658	17.0	23,557	18.9
	Diabetes/Control				
	No	38,183	67.2	84,326	67.5
	Non-Insulin diabetes	13,157	23.1	28,120	22.5
	Insulin diabetes	5,515	9.7	12,509	10.0
	GFR*				
	Unknown	2,387	4.2	4,985	4.0
	Mean (SD)	66	25.4	65	25.2
	Previous PCI	20,361	35.8	46,083	36.9
Cardiac Status	CHF - Current Status	6,439	11.3	15,986	12.8
	NYHA				
	Class I	18,549	32.6	40,472	32.4
	Class II	13,802	24.3	28,617	22.9
	Class III	14,795	26.0	34,035	27.2
	Class IV	9,709	17.1	21,831	17.5
	Cardiogenic Shock	1,187	2.1	2,644	2.1
	Symptoms present on admission				
	ACS: Non-ST Elevated MI within 24 hrs	5,155	9.1	12,772	10.2
	ACS: Non-ST Elevated MI after 24 hrs	2,594	4.6	6,115	4.9
Cath Lab Visit	Ejection Fraction Percentage				
	NA or Missing	18,322	32.2	37,004	29.6
	Mean (SD)	53	13.4	52	13.3
PCI Procedure	PCI Status				
	Elective	31,049	54.6	65,084	52.1
	Urgent	19,469	34.2	44,446	35.6
	Emergency	6,145	10.8	15,137	12.1
	Salvage	181	0.3	275	0.2
	Highest Risk Lesion: SCAI Lesion Class				
	II	18,603	32.7	43,082	34.5
	III	2,547	4.5	5,214	4.2
	IV	5,188	9.1	9,728	7.8
Outcome	In-Hospital Mortality	1,005	1.8	2,174	1.7

*Calculated using Modification of Diet and Renal Disease (MDRD) equation

2.4.2 Exclusion Criteria

We excluded the following hospitalizations as admissions from the measure calculation prior to the merge:

1) Age <65 (Medicare and NCDR datasets). Admissions for patients less than 65 years old at the time of an admission were excluded.
   Rationale: Patients younger than 65 in the Medicare dataset represent a distinct population that qualifies for Medicare due to disability. The characteristics and outcomes of these patients may not be representative of the larger population of PCI patients.

2) LOS < 1 day in Medicare and NCDR datasets. Same-day discharges (LOS=0) are excluded.
   Rationale: Some hospitals perform outpatient PCI, but we would be unable to determine the 30-day mortality rates of these patients as we can only match NCDR patients to CMS patients who are admitted (i.e. not outpatients). Similarly, same-day discharges in the CMS data may represent a miscoded PCI.

3) Admissions at hospitals with missing or duplicate MPN (NCDR dataset). Any admissions to hospitals with a missing or duplicate MPN number are excluded.
   Rationale: If the MPN number is unreliable, we are unable to match NCDR patients to CMS claims data or assign mortality rates to hospitals with certainty.

4) Admissions with duplicate fields (Medicare and NCDR datasets). Admissions for patients that have identical information indicated for age, gender, admission date, discharge date, and MPN are excluded.
   Rationale: Admissions with identical demographics are excluded to avoid making matching errors upon merging of the two datasets.

5) Unmatched admissions. Admissions that are not matched based on age, gender, admission date, discharge date and MPN are excluded.

The following exclusions are applied to the merged dataset:

1) Patients with >10 days between date of admission and date of PCI. Patients with prolonged hospitalizations prior to PCI are excluded
   Rationale: The outcomes of patients with prolonged hospitalizations prior to PCI are less likely to be related to the PCI procedure.

2) Transfer-in admissions (PCI to PCI). Among patients transferred from one acute care institution to another who had a PCI at both hospitals,

the second admission with PCI is not eligible as an index admission. We used Medicare data to define transfers as two admissions that occur within 1 day of each other and identified patients in this cohort who had a PCI during both admissions.
Rationale: We define an episode of care as starting on the first day of the first admission with PCI regardless of whether additional procedures are performed at the same hospital or at a different hospital after transfer.

3) Admissions with missing death. Records with missing vital status in the Medicare enrollment file are excluded.
Rationale: Records with no death information would prevent ascertainment of the outcome.

4) Admissions which would lead to duplicate attribution of 30-day deaths.
Rationale: The 30-day follow-up period for patients with more than one admission with PCI may overlap. In order to avoid attributing the same death to more than one admission with PCI (i.e. double counting a single patient death), later admissions with PCI were excluded. In Figure 2, for example, patient A had 2 admissions within 30 days of death and patient A's death was attributed to the first admission, while patient B had 2 admissions within 30 days, but death occurred within 30 days of the second admission only. As a result, patient B's death was attributed to the second admission.
2).

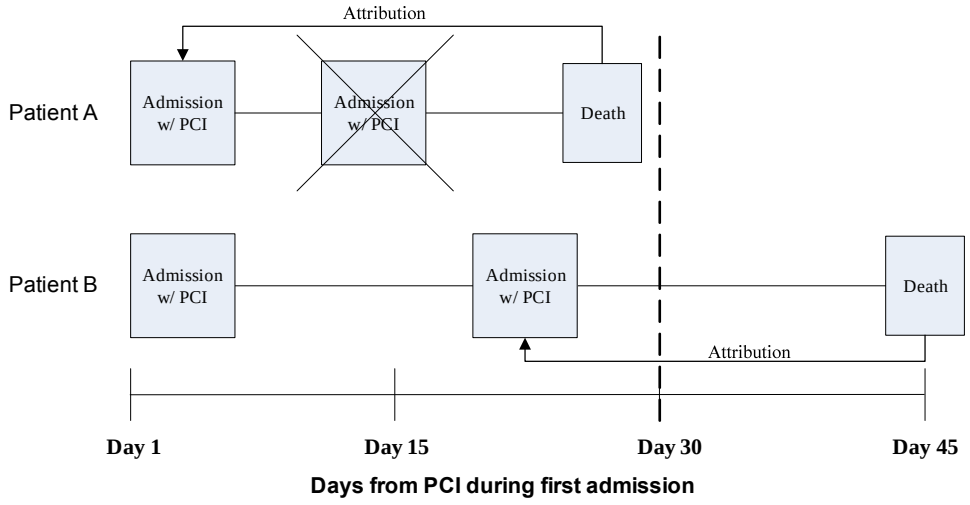


Figure 2 – Process of Attributing 30-Day Mortality Outcome Associated with Multiple PCI Admissions

2.4.3 Segregate sample into two cohorts

Among patients undergoing PCI, the risk of mortality differs considerably depending on the clinical context in which it is performed. For example the mortality of PCI patients with an evolving STEMI is substantially higher than that of outpatients undergoing elective procedures. In addition, many hospitals (e.g., primary PCI centers) can only perform PCI on STEMI patients. In order to make fair and accurate comparisons of patients treated at different types of hospitals, we chose to segregate the study sample into two cohorts and to develop a distinct 30-day mortality measure for each cohort. This strategy has previously been implemented by the Massachusetts program for publicly reporting of mortality following PCI (www.massdac.org/pic/index.htm). The state of New York reports outcomes for both the combined cohort as well as a stratified cohort (www.health.state.ny.us/statistics/diseases/cardiovascular).

The two cohorts include:

- Patients having an STEMI within 24 hours of arrival to the hospital, or patients in cardiogenic shock prior to the intervention (referred to as the "shock or STEMI" cohort), defined in the CathPCI Registry as:
  - Symptoms present on admission = ACS:STEMI (field 550 = 6) with Time Period Symptom Onset to Admission within 24 hours (field 560 = 1,2,3) or Acute PCI = Yes (field 812 = 2,3,4); *OR*
  - Cardiogenic shock = Yes (field 520=1)

- Patients having no STEMI within 24 hours of arrival to the hospital and no cardiogenic shock prior to the PCI (referred to as the "no STEMI and no shock" cohort).

2.5 Observation Period

For model development and validation, we used observations for one calendar year. We apply the model to assess hospital performance for a 2-year period.

2.6 Registry Model Development

2.6.1 Model Overview

We use NCDR CathPCI Registry data that contains admissions with PCI. The model is derived using admissions with PCI for patients discharged in 2006 ("development sample"). The performance of the model is then validated using admissions with PCI for patients discharged in 2005 ("validation sample"). We compute indices that describe model performance in terms of predictive ability, discriminant ability, and overall fit.

Specific information about each step in the process of PCI mortality model development and validation, as summarized in the Overview section of this report, is described below.

2.7 Developmental Dataset

We use admissions with PCI in the merged data from 2006. Figure 1 presents the total number of admissions with PCI, the proportion excluded as a result of each exclusion criterion, and the number included in the final sample as index admissions. The development sample consisted of 15,123 admissions at 602 hospitals in the STEMI or shock cohort and 110,529 admissions at 602 hospitals in the no STEMI and no shock cohort. The overall unadjusted 30-day mortality rate is 9.2% in the STEMI or shock cohort and 1.4% in the no STEMI and no shock cohort. The unadjusted in-hospital mortality rate in the STEMI or shock cohort is 7.5% and 0.7% in the no STEMI and no shock cohort.

2.8 Candidate and Final Variables

We sought to develop a model that included key variables that were clinically relevant and based on strong association with 30-day mortality.

To select candidate variables, a team of clinicians reviewed all variables in the NCDR CathPCI Registry database (a copy of the data collection form and the complete list of variables collected and submitted by hospitals can be found at www.ncdr.com). We did not consider as candidate variables those that we would not want to adjust for in a quality measure, such as potential

complications, certain patient demographics (e.g., race, socioeconomic status), and patients' admission path (e.g., admitted from, or discharged to, a skilled nursing facility [SNF]). Variables were also considered ineligible if they were particularly vulnerable to gaming or were deemed to lack clinical relevance. Based on careful review by a team of clinicians and further informed by a review of the literature, a total of 26 variables were determined to be appropriate for consideration as candidate variables. Our set of candidate variables (see Table 6) included two "demographic" variables (age and gender), 15 "history and risk factor" variables, four "cardiac status" variables, one "cath lab visit" variable and four "PCI procedure" variables.

Several variables required particular consideration. First, in the current version of the CathPCI registry, participants are instructed to use New York Heart Association (NYHA) classification to capture symptom severity for both heart failure and angina. Accordingly, the resulting variable is a hybrid which may dilute the prognostic importance usually associated with NYHA class. Second, variables such as PCI status and cardiogenic shock impart important prognostic information but are vulnerable to systematic misclassification. This is relevant to efforts to publicly report 30-day PCI mortality in that several key variables (e.g., cardiogenic shock and PCI status) may be consistently coded differently across sites. For example, although the CathPCI data dictionary provides detailed definitions of PCI status (http://www.ncdr.com/WebNCDR/ELEMENTS.ASPX), sites may differ in their interpretation of these definitions such that a patient considered an emergent PCI at hospital A may be considered an urgent PCI at hospital B. If differences in coding occur with sufficient frequency, the risk-standardized mortality rate for hospital A might appear lower than hospital B, even if their case mixes and outcomes were otherwise identical.

To examine this issue, we compared the frequency of different PCI status categories at hospitals with risk adjusted mortality rates that were above and below the median using the STEMI or shock cohort. We found that rates of cardiogenic shock were comparable, but that hospitals with below average risk-standardized mortality had modestly higher rates of emergency and salvage PCI (76.7% and 1.4%), compared with hospitals with above average risk-standardized mortality (72.3% and 1.2%). We cannot determine whether these differences accurately reflect differences in case mix or are due to systematic differences in coding. Nevertheless, these results highlight the need to further ensure data accuracy.

For categorical variables with missing values, the value from the reference group was added. The percentage of missing values for all categorical variables was very small (<1%). There were three continuous variables with significant numbers of missing values: body mass index (BMI), glomerular filtration rate (GFR), and left ventricular ejection fraction (LVEF). For BMI, we stratified by gender and imputed the missing values to the median of the

corresponding groups. For GFR, we stratified patients into five categories: <30, 31-60, 61-90, >90, and missing. For LVEF, we stratified patients into four categories- <30%, 31-45%, >45%, and missing.

We used logistic regression with stepwise selection (entry $p<0.05$; retention with $p<0.01$) for variable selection. We also assessed the direction and magnitude of the regression coefficients. This resulted in a final risk-adjustment model for the STEMI or shock cohort that included 13 variables and a final risk-adjustment model for the no STEMI and no shock cohort that included 16 variables. Tables 7 and 8 show the final variables in each cohort.

Table 6 – PCI Model Candidate Variables

Description	NCDR Item Number	Name
Demographic		
Age	252	Age
Female	260	FEMALE
History and Risk Factors		
BMI*	Derived (410, 412)	BMI
Previous MI	420	PrevMI
CHF-previous history	424	PrCHF
Previous valvular surgery	426	PrValve
Cerebrovascular Disease	450	CVD
Peripheral Vascular Disease	452	PVD
Chronic Lung Disease	454	CLD
Diabetes	Derived (430, 432)	NewDIAB
None	Reference	
Non-Insulin Diabetes		NEWDIAB1
Insulin Diabetes		NEWDIAB2
Glomerular Filtration Rate (GFR)	Derived (252, 260, 270, 439, 440)	GFR
Not measured	Derived	GFRGRP0
GFR<30	Derived	GFRGRP1
30≤GFR<60	Derived	GFRGRP2
60≤GFR<90	Reference	
GFR≥90	Derived	GFRGRP4
Renal Failure-Dialysis	444	Dialysis
Hypertension	456	Hypertn
History of tobacco use	460	Tobacco
Family history of CAD	480	FHCAD
Previous PCI	490	PrPCI
Previous CABG	494	PrCAB
Cardiac Status		
Heart Failure - Current Status	500	CHF
NYHA	510	ClassNYH
Class I, II, or III	Reference	
Class IV		NYHC4
Cardiogenic Shock	520	
Symptoms present on admission	Derived (550, 560)	AdmSxPre
No MI		ADMSX1
MI within 24 hours	Reference	
MI after 24 hours		ADMSX3
Cath Lab Visit		
Ejection Fraction Percentage	Derived (654, 656)	HDEFGRP
Not measured		HDEFGRP1
EF<30		HDEFGRP2
30≤EF<45		HDEFGRP3
EF≥45	Reference	

Description	NCDR Item Number	Name
PCI Procedure		
PCI Status**	804	PCIStat
Elective	Reference	
Urgent		PCIS2
Emergency		PCIS3
Salvage		PCIS4
Emergency or salvage		PCIS34
Highest Risk Lesion – Segment Category***	Derived (902)	NLESLOC
pRCA/mLAD/pCIRC	Derived	NLESLOC1
pLAD	Derived	NLESLOC2
Left Main	Derived	NLESLOC3
Other	Reference	
Highest pre-procedure TIMI flow: none***	Derived (920)	NPreTIMI
Highest Risk Lesion: SCAI Lesion Class***	Derived (910, 950)	NSCAILC
I	Reference	
II or III	Derived	NSCAILC23
IV	Derived	NSCAILC4

*For missing data in BMI, data were stratified by gender first, then set to the median in corresponding groups
** Emergency or Salvage are combined into one category “PCIS34” for the measure in no STEMI and no shock cohort.
***Aggregated elements from lesions data-level to PCI data-level using MAX function

Table 7 – Final STEMI or Shock Model Variables

Category	Variable	Code(s)
Demographic	Age	Age
History and Risk Factors	BMI	BMI
	Cerebrovascular Disease	CVD
	Chronic Lung Disease	CLD
	GFR	
	Not measured	GFRGRP0
	GFR<30	GFRGRP1
	30≤GFR<60	GFRGRP2
	GFR≥90	GFRGRP4
	Previous PCI	PrPCI
Cardiac Status	CHF – Current Status	CHF
	Cardiogenic Shock	CarShock
	Symptoms present on admission	
	No MI	ADMSX1
	MI after 24 hours	ADMSX3
Cath Lab Visit	Ejection Fraction Percentage	
	Not measured	HDEFGRP1
	EF<30	HDEFGRP2
	30≤EF<45	HDEFGRP3
PCI Procedure	PCI Status	
	Urgent	PCIS2
	Emergency	PCIS3
	Salvage	PCIS4
	Highest Risk Lesion – Segment Category	
	pRCA/mLAD/pCIRC	NLESLOC1
	pLAD	NLESLOC2
	Left Main	NLESLOC3
	Highest Risk Lesion: SCAI Lesion Class	
	II or III	NSCAILC23
	IV	NSCAILC4

Table 8 – Final No STEMI and No Shock Model Variables

Category	Variable	Code(s)
Demographic	Age	Age
History and Risk Factors	BMI	BMI
	CHF-previous history	PrCHF
	Cerebrovascular Disease	CVD
	Peripheral Vascular Disease	PVD
	Chronic Lung Disease	CLD
	Diabetes/Control	
	Non-Insulin Diabetes	NEWDIAB1
	Insulin Diabetes	NEWDIAB2
	GFR	
	Not measured	GFRGRP0
	GFR<30	GFRGRP1
	30≤GFR<60	GFRGRP2
	GFR≥90	GFRGRP4
	Previous PCI	PrPCI
Cardiac Status	CHF – Current Status	CHF
	NYHA	NYHC4
	Symptoms present on admission	
	No MI	ADMSX1
	MI after 24 hours	ADMSX3
Cath Lab Visit	Ejection Fraction Percentage	
	Not measured	HDEFGRP1
	EF<30	HDEFGRP2
	30≤EF<45	HDEFGRP3
PCI Procedure	PCI Status	
	Urgent	PCIS2
	Emergency or salvage	PCIS34
	Highest Risk Lesion – Segment Category	
	pRCA/mLAD/pCIRC	NLESLOC1
	pLAD	NLESLOC2
	Left Main	NLESLOC3
	Highest Risk Lesion: SCAI Lesion Class	
	II or III	NSCAILC2
	IV	NSCAILC4

2.9 Statistical Approach to Model Development

We developed risk adjustment models for each cohort (STEMI or shock; No STEMI and No shock) using the following methodology:

Because of the natural clustering of the observations within hospitals, we estimated hierarchical generalized linear models (HGLMs). We modeled the log-odds of mortality within 30 days of PCI as a function of patient demographic and clinical characteristics and a random hospital-specific intercept. This strategy accounts for within-hospital correlation of the observed outcomes and models the assumption that underlying differences in quality among the health care facilities being evaluated lead to systematic differences in outcomes.

We then calculated hospital-specific mortality rates. These rates are calculated as the ratio of predicted to expected mortality, multiplied by the overall unadjusted mortality rate. The expected number of deaths in each hospital was estimated using its patient mix and the average hospital-specific intercept. The predicted number of deaths in each hospital was estimated given the same patient mix but an estimated hospital-specific intercept. Operationally, the expected number of deaths for each hospital is obtained by regressing the risk factors on the mortality outcome using all hospitals in our sample, applying the subsequent estimated regression coefficients to the patient characteristics observed in the hospital, adding the average of the hospital-specific intercepts, transforming, and then summing over all patients in the hospital to get a value. This is a form of indirect standardization. The predicted hospital outcome is the number of deaths in the "specific" hospital estimated given its performance and case mix. Operationally, this is accomplished by estimating a hospital-specific intercept that herein represents baseline mortality risk within the hospital, applying the estimated regression coefficients to the patient characteristics in the hospital, transforming, and then summing over all patients in the hospital to get a value. In order to assess hospital performance in any other year (e.g. the validation cohort), we re-estimate the model coefficients using that year's data.

More specifically, we estimate 2 types of regression models using the administrative data (Table 10). First, we fit a generalized linear model (GLM) linking the outcome to the risk factors (McCullagh P 1989). Let Y_{ij} denote the outcome (equal to 1 if patient dies within 30 days, zero otherwise) for the j^{th} patient who underwent PCI at the i^{th} hospital; $\mathbf{Z}_{ij}$ denotes a set of risk factors based on the administrative data. Let I denote the total number of hospitals and n_i the number of index admissions to hospital i. We assume the outcome is related linearly to the covariates via a known linked function, h, where

$$\text{GLM} \qquad h(Y_{ij}) = \alpha + \beta \mathbf{Z}_{ij} \qquad (1)$$

and $\mathbf{Z}_{ij} = (Z_{1ij}, Z_{2ij}, \ldots, Z_{pij})$ is a set of p patient-specific covariates. In our case, h = the logit link.

To account for the natural clustering of observations within hospitals, we estimate an HGLM that links the risk factors to the same outcome and a hospital-specific random effect,

$$\text{HGLM} \qquad h(Y_{ij}) = \alpha_i + \beta \mathbf{Z}_{ij} \qquad (2)$$

$$\alpha_i = \mu + \omega_i; \omega_i \sim N(0, \tau^2) \qquad (3)$$

where α_i represents the hospital-specific intercept, $\mathbf{Z}_{ij}$ is defined as above, μ the adjusted average outcome over all hospitals in the sample, and τ^2 the between-hospital variance component (Gatsonia CA 1999). This model separates within-hospital variation from between-hospital variation. Both HGLMs and GLMs are estimated using the SAS software system (GLIMMIX and LOGISTIC procedures, respectfully).

We first fit the GLM described in Equation (1) using the logit link.
Having identified the covariates that remained, we next fit the HGLM described in Equations (2) and (3), again using the logit link function; e.g.,

$$\text{Logit}\left(P\left(Y_{ij} = 1\right)\right) = \alpha_i + \beta \mathbf{Z}_{ij}$$

$$\alpha_i = \mu + \omega_i \quad \omega_i \sim N\left(0, \tau^2\right)$$

where $\mathbf{Z}_{ij}$ consisted of the covariates retained in the GLM model. As before, $Y_{ij} = 1$ if patient *j* treated at hospital *i* had the event; 0 otherwise.

2.10 Hospital Performance Reporting

Using the set of risk factors in the GLM, we fit the HGLM defined by Equations (2) - (3) and estimate the parameters, $\hat{\mu}$, $\{\hat{\omega}_i, \hat{\omega}_2, ..., \hat{\omega}_I\}$, $\hat{\beta}$, and $\hat{\tau}^2$. We calculate a standardized outcome, s_i, for each hospital by computing the ratio of the predicted to expected mean outcomes, multiplied by the unadjusted mean mortality rate, $\bar{y}$. Specifically, we calculate

$$\text{Predicted } \hat{y}_{ij}(Z) = h^{-1}(\hat{\alpha}_i + \hat{\beta} \mathbf{Z}_{ij}) \qquad (4)$$

$$\text{Expected } \hat{e}_{ij}(Z) = h^{-1}(\hat{\mu} + \hat{\beta} \mathbf{Z}_{ij}) \qquad (5)$$

$$\hat{s}_i(Z) = \frac{\sum_{j=1}^{n_i} \hat{y}_{ij}(Z)}{\sum_{j=1}^{n_i} \hat{e}_{ij}(Z)} \times \bar{y} \qquad (6)$$

If more (fewer) cases than "expected" have the outcome in a hospital, then $\hat{s}_i$ will be higher (lower) than the unadjusted average. For each hospital, we compute an interval estimate of s_i to characterize the level of uncertainty around the point estimate. The point estimate and interval estimate can be used to characterize and

compare hospital performance (e.g., higher than expected, as expected, or lower than expected).

2.11.1 Creating Interval Estimates

Because the statistic described in Equation (6) is a complex function of parameter estimates, we use re-sampling and simulation techniques to derive an interval estimate. The bootstrap has the advantage of avoiding unnecessary distributional assumptions.

2.11.2 Algorithm

Let *I* denote the total number of hospitals in the sample. We repeat steps 1 – 4 below for $\mathrm{b} = 1,2,...,\mathrm{B}$ times:

1. Sample *I* hospitals with replacement.

2. Fit the HGLM using all patients within each sampled hospital. We use as starting values the parameter estimates obtained by fitting the model to all hospitals. If some hospitals are selected more than once in a bootstrapped sample, we treat them as distinct so that we have *I* random effects to estimate the variance components. At the conclusion of Step 2, we have:
   a. $\hat{\beta}^{(b)}$ (the estimated regression coefficients of the risk factors).
   b. The parameters governing the random effects, hospital adjusted outcomes, distribution, $\hat{\mu}^{(b)}$ and $\hat{\tau}^{2(b)}$.
   c. The set of hospital-specific intercepts and corresponding variances, $\{\hat{\alpha}_i^{(b)},\ \hat{\mathrm{var}}\left(\alpha_i^{(b)}\right);\ i = 1,2,...,I\}$.

3. We generate a hospital random effect by sampling from the distribution of the hospital-specific distribution obtained in Step 2c. We approximate the distribution for each random effect by a normal distribution. Thus, we draw $\alpha_i^{(b*)} \sim N\left(\hat{\alpha}_i^{(b)}, \hat{\mathrm{var}}\left(\hat{\alpha}_i^{(b)}\right)\right)$ for the unique set of hospitals sampled in Step 1.

4. Within each unique hospital *i* sampled in Step 1, and for each case *j* in that hospital, we calculate $\hat{y}_{ij}^{(b)}$, $\hat{e}_{ij}^{(b)}$, and $\hat{s}_i\left(Z\right)^{(b)}$ where $\hat{\beta}^{(b)}$ and $\hat{\mu}^{(b)}$ are obtained from Step 2 and $\hat{\alpha}_i^{(b*)}$ is obtained from Step 3.

Ninety-five percent interval estimates (or alternative interval estimates) for the hospital-standardized outcome can be computed by identifying the 2.5th and 97.5th percentiles of randomly half of the B estimates (or the percentiles

corresponding to the alternative desired intervals) (Normand, Wang et al. 2007).

Table 9 – Analysis Steps

Step	Risk Factors Based on: NCDR CathPCI Registry Data
1	Compute Bivariate and Univariate summaries **Z** & Y
2	Generalized Linear Model $h(Y_{ij}) = \alpha^A + \beta^A \mathbf{Z}_{ij}$ Obtain R^2, residuals, etc.
3	Hierarchical Generalized Linear Model $h(Y_{ij}) = \alpha_i^A + \beta^A \mathbf{Z}_{ij}$ $\alpha_i^{(A)} \sim N(\mu_A, \tau_A^2)$
4	Hospital-Specific Predicted Outcomes $\hat{p}_i^A(\mathbf{Z}) = \frac{1}{n_i} \sum_{j=1}^{n_i} h^{-1}(\hat{\alpha}_i^A + \hat{\beta}^A \mathbf{Z}_{ij})$ Hospital-Specific Expected Outcomes $\hat{e}_i^A(\mathbf{Z}) = \frac{1}{n_i} \sum_{j=1}^{n_i} h^{-1}(\hat{\mu}_A + \hat{\beta}^A \mathbf{Z}_{ij})$ Hospital-Specific Risk-Standardized Outcomes $\hat{r}_i^A(\mathbf{Z}) = \frac{\hat{y}_i^A(\mathbf{Z})}{\hat{e}_i^A(\mathbf{Z})}$, $\hat{s}_i^A(\mathbf{Z}) = \frac{\hat{y}_i^A(\mathbf{Z})}{\hat{e}_i^A(\mathbf{Z})} \times \bar{y}$

3. RESULTS

3.1 Model Results

3.1.1 STEMI or Shock Cohort

The variable descriptions, standardized estimates, and standard errors are shown in Table 11. The standardized estimates are regression coefficients expressed in units of standard deviations and can range between -1 and 1, with ±1 indicating a perfect linear relationship and 0 indicating no linear relationship.[3]

3.1.1.1 Model Performance

We computed 6 summary statistics for assessing model performance (Harrell, 2001): over-fitting indices,[4] percentage of variation explained by the risk factors, predictive ability, area under the receiver operating characteristic (ROC) curve, distribution of residuals, and model chi-square[5] (see Table 13).

The development model has excellent discrimination, calibration, and fit. The patient-level mortality rate ranges from 1.4% in the lowest predicted decile to 40.3% in the highest predicted decile, a range of 38.9%. The area under the ROC curve is 0.825.

The discrimination and the explained variation of the model at the patient-level are consistent with those of published PCI in-hospital mortality models (Yale-CORE 2008). The ROC is modestly lower than that of previously published models due to several factors. First, we stratified the entire population of PCI patients into two populations based on the presence or absence of two prognostically important variables: STEMI and cardiogenic shock. Second, we excluded covariates such as potential complications, certain patient demographics (e.g., race), and patients' admission path (e.g., outpatient, emergency department, transfers-in from other facilities (non-acute care or acute care). These characteristics may be associated

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[3] Standardized estimates are like correlation coefficients. We compute them in order to compare the size of the coefficients by standardizing the coefficients to be unitless.

[4] Over-fitting refers to the phenomenon in which a model well describes the relationship between predictive variables and outcome in the development dataset, but fails to provide valid predictions in new patients.

[5] Chi-Square – A test of statistical significance usually employed for categorical data to determine whether there is a good fit between the observed data and expected values; i.e., whether the differences between observed and expected values are attributable to true differences in characteristics or instead the result of chance variation. The formula for computing the chi-square is as follows:

$$\sum \frac{(O-E)^2}{E}$$

where O = observed value
E = expected value, and
degrees of freedom (df) = (rows-1)(columns-1)

with mortality and thus could increase the model performance to predict patient mortality. However, these variables may be related to quality or supply factors that should not be included in an adjustment that seeks to control for patient clinical characteristics. Thus, the choice was to focus on adjustment for clinical differences in the populations among hospitals.

Table 10 – 30-Day Mortality Model for the STEMI or Shock Cohort (2006 Development Sample-GLM Results [ROC=0.825])*

Name	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq	Standardized Estimates	Odds Ratio (95% CI)
Intercept	-8.07	0.50	263.3	0.00		
Age/10	0.49	0.05	117.3	0.00	0.19	1.64 (1.50, 1.79)
BMI/5	-0.12	0.04	7.3	0.01	-0.05	0.89 (0.82, 0.97)
Cerebrovascular disease	0.44	0.08	29.1	0.00	0.08	1.56 (1.33, 1.83)
Chronic Lung disease	0.48	0.07	40.6	0.00	0.10	1.61 (1.39, 1.87)
GFR: 0=Not measured	0.49	0.13	15.1	0.00	0.07	1.64 (1.28, 2.10)
GFR: 1="GFR<30"	1.27	0.11	132.2	0.00	0.15	3.54 (2.86, 4.40)
GFR: 2="30≤GFR<60"	0.42	0.08	31.9	0.00	0.11	1.53 (1.32, 1.77)
GFR: 4="GFR≥90"	-0.02	0.16	0.0	0.89	0.00	0.98 (0.72, 1.33)
Previous PCI	-0.32	0.09	13.5	0.00	-0.07	0.73 (0.62, 0.86)
CHF - Current Status	0.41	0.07	30.8	0.00	0.08	1.51 (1.31, 1.75)
Cardiogenic shock on admission	1.52	0.07	477.3	0.00	0.31	4.59 (4.00, 5.26)
No MI on admission	-0.04	0.12	0.1	0.73	-0.01	0.96 (0.76, 1.22)
MI > 24 hours after admission	0.27	0.11	5.8	0.02	0.04	1.31 (1.05, 1.62)
EF: 1=Not measured	0.69	0.08	68.2	0.00	0.17	2.00 (1.70, 2.36)
EF: 2="0≤EF<30"	1.10	0.11	104.0	0.00	0.16	2.99 (2.42, 3.70)
EF: 3="30≤EF<45"	0.56	0.09	38.1	0.00	0.13	1.76 (1.47, 2.10)
PCI status: 2=Urgent	0.32	0.19	3.1	0.08	0.07	1.38 (0.96, 1.99)
PCI status: 3=Emergency	0.84	0.17	23.1	0.00	0.20	2.31 (1.64, 3.25)
PCI status: 4=Salvage	1.93	0.24	65.5	0.00	0.12	6.92 (4.33, 11.06)
Highest Risk Lesion – Segment category: 1=pRCA/mLAD/Pcirc	0.03	0.08	0.1	0.71	0.01	1.03 (0.89, 1.19)
Highest Risk Lesion – Segment category: 2=pLAD	0.25	0.09	8.6	0.00	0.06	1.29 (1.09, 1.52)
Highest Risk Lesion – Segment category: 3=Left Main	0.97	0.19	25.7	0.00	0.06	2.65 (1.82, 3.86)
Highest Risk Lesion: SCAI lesion class 2 or 3	0.21	0.09	5.1	0.02	0.06	1.24 (1.03, 1.49)
Highest Risk Lesion: SCAI lesion class 4	0.54	0.09	32.9	0.00	0.14	1.72 (1.43, 2.07)

*N=15,123 in 602 hospitals; mortality rate=9.2%

3.1.1.2 Model Validation

We compared the model performance in the development sample with its performance in a similarly derived sample from patients discharged in 2005 who had undergone PCI. There were 12,052 cases discharged from the 458 hospitals in the 2005 validation dataset. This validation sample had a crude mortality rate of 9.0%.

The standardized estimates and standard errors for the 2005 validation dataset are shown in Table 11, and the performance metrics are shown in Table 12. The performance was not substantively different in this validation sample (ROC=0.84), as compared to the development sample (ROC=0.83). As the results in Table 12 show, the 2005 and 2006 models are similarly calibrated.

We also examined the temporal variation of the standardized estimates and frequencies of the variables in the models (Tables 13 and 14). The frequencies and regression coefficients are fairly consistent over the two years of data.

To assess the predictive ability of the model, we grouped patients into deciles of predicted 30-day mortality. We then compared predicted mortality with observed mortality for each decile (Figure 3). Overall there was excellent correlation between predicted and observed mortality.

Figure 3 – Observed Mortality by Predicted Mortality per Decile in Patients with STEMI or Shock

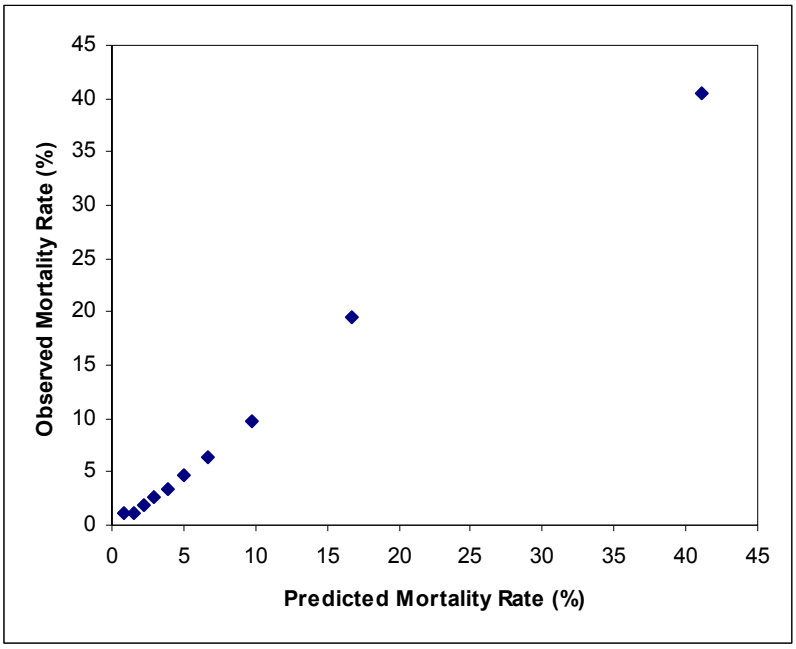


Table 11 – 30-Day Mortality Model for the STEMI or Shock Cohort (2005 Validation Sample-GLM Results [ROC:0.838])*

Name	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq	Standardized Estimates	Odds Ratio (95% CI)
Intercept	-9.50	0.58	269.8	0.00		
Age/10	0.59	0.05	125.0	0.00	0.23	1.80 (1.63, 2.00)
BMI/5	-0.07	0.05	2.3	0.13	-0.03	0.93 (0.84, 1.02)
Cerebrovascular disease	0.43	0.09	21.5	0.00	0.08	1.54 (1.28, 1.85)
Chronic Lung disease	0.38	0.09	19.7	0.00	0.08	1.47 (1.24, 1.74)
GFR: 0=Not measured	0.56	0.14	15.5	0.00	0.08	1.75 (1.32, 2.32)
GFR: 1="GFR<30"	1.46	0.13	126.1	0.00	0.17	4.30 (3.34, 5.55)
GFR: 2="30≤GFR<60"	0.58	0.09	44.6	0.00	0.15	1.79 (1.51, 2.12)
GFR: 4="GFR≥90"	-0.10	0.19	0.3	0.60	-0.01	0.91 (0.63, 1.30)
Previous PCI	-0.33	0.10	11.6	0.00	-0.07	0.72 (0.59, 0.87)
CHF - Current Status	0.40	0.09	21.9	0.00	0.08	1.49 (1.26, 1.76)
Cardiogenic shock on admission	1.47	0.08	350.6	0.00	0.30	4.33 (3.71, 5.05)
No MI on admission	0.02	0.14	0.0	0.87	0.00	1.02 (0.77, 1.36)
MI > 24 hours after admission	0.06	0.14	0.2	0.67	0.01	1.06 (0.81, 1.38)
EF: 1=Not measured	0.71	0.10	52.8	0.00	0.17	2.02 (1.67, 2.45)
EF: 2="0≤EF<30"	1.01	0.12	69.5	0.00	0.15	2.75 (2.17, 3.49)
EF: 3="30≤EF<45"	0.51	0.10	24.5	0.00	0.12	1.67 (1.36, 2.05)
PCI status: 2=Urgent	0.38	0.21	3.2	0.08	0.08	1.46 (0.96, 2.23)
PCI status: 3=Emergency	1.03	0.20	26.3	0.00	0.26	2.81 (1.89, 4.16)
PCI status: 4=Salvage	2.14	0.27	63.4	0.00	0.14	8.47 (5.01, 14.34)
Highest Risk Lesion – Segment category: 1=pRCA/mLAD/Pcirc	0.37	0.09	18.0	0.00	0.10	1.45 (1.22, 1.73)
Highest Risk Lesion – Segment category: 2=pLAD	0.43	0.10	17.8	0.00	0.10	1.53 (1.26, 1.87)
Highest Risk Lesion – Segment category: 3=Left Main	1.04	0.22	22.3	0.00	0.06	2.82 (1.83, 4.35)
Highest Risk Lesion: SCAI lesion class 2 or 3	0.29	0.11	7.3	0.01	0.08	1.34 (1.08, 1.66)
Highest Risk Lesion: SCAI lesion class 4	0.59	0.11	28.3	0.00	0.15	1.80 (1.45, 2.23)

*N=12,052 in 458 hospitals; mortality rate=9.0%

Table 12 – 30-Day Mortality Model Performance for the STEMI or Shock Cohort: Results Based on the GLM

Data Source		Calibration	Discrimination		Residuals Lack of Fit (Pearson Residual Fall %)				Model χ^2 [Number of Covariates]#
		(γ_0, γ_1)[6]	Adjusted R-Square*	Predictive Ability+ (lowest decile %, highest decile %)	ROC	<-2	[-2, 0)	[0, 2)	[2+	
Development Sample										
2006	N = 15,123 30-day mortality = 9.2%	(0, 1)	0.27	(1.4, 40.3)	0.83	0.07	90.75	4.52	4.66	1,605 (24)
Validation Sample										
2005	N = 12,052 30-day mortality = 9.0%	(-0.03, 1.01)	0.29	(0.8, 40.4)	0.84	0.07	90.97	4.56	4.39	1,307 (24)

* Max-rescaled R-Square
# Wald Chi-Square
+ Observed Rates

[6] Over-Fitting Indices (γ_0, γ_1) provide evidence of over-fitting and require several steps to calculate. Let *b* denote the *estimated vector* of regression coefficients. *Predicted Probabilities* ($\hat{p}$) = 1/(1+exp{-Xb}), and *Z* = *Xb* (e.g., the linear predictor that is a scalar value for everyone). A new logistic regression model that includes only an intercept and a slope by regressing the logits on Z is fitted in the validation sample; e.g., Logit(P(Y=1|Z)) = γ_0 + γ_1Z. Estimated values of γ_0 far from 0 and estimated values of γ_1 far from 1 provide evidence of over-fitting.

Table 13 – 30-Day Mortality Model for the STEMI or Shock Cohort (GLM)
Standardized Estimates by Year of Discharge (2005-2006)

Variable	**2005 (Validation)** [N=12,052 in 458 hospitals; 9.0% MR]	**2006 (Development)** [N=15,123 in 602 hospitals; 9.2% MR]	**2005-2006 (Application)*** [N=27,175 in 614 hospitals; 9.1% MR]
Age/10	0.23	0.19	0.20
BMI/5	-0.03	-0.05	-0.04
Cerebrovascular disease	0.08	0.08	0.08
Chronic Lung disease	0.08	0.10	0.09
GFR: 0=Not measured	0.08	0.07	0.07
GFR: 1="GFR<30"	0.17	0.15	0.16
GFR: 2="30≤GFR<60"	0.15	0.11	0.13
GFR: 4="GFR≥90"	-0.01	0.00	-0.01
Previous PCI	-0.07	-0.07	-0.07
CHF - Current Status	0.08	0.08	0.08
Cardiogenic shock on admission	0.30	0.31	0.31
No MI on admission	0.00	-0.01	0.00
MI > 24 hours after admission	0.01	0.04	0.02
EF: 1=Not measured	0.17	0.17	0.17
EF: 2="0≤EF<30"	0.15	0.16	0.16
EF: 3="30≤EF<45"	0.12	0.13	0.13
PCI status: 2=Urgent	0.08	0.07	0.07
PCI status: 3=Emergency	0.26	0.20	0.23
PCI status: 4=Salvage	0.14	0.12	0.13
Highest Risk Lesion – Segment category: 1=pRCA/mLAD/Pcirc	0.10	0.01	0.05
Highest Risk Lesion – Segment category: 2=pLAD	0.10	0.06	0.07
Highest Risk Lesion – Segment category: 3=Left Main	0.06	0.06	0.06
Highest Risk Lesion: SCAI lesion class 2 or 3	0.08	0.06	0.07
Highest Risk Lesion: SCAI lesion class 4	0.15	0.14	0.15

*Application sample refers to the combined 2005 and 2006 data used to optimize the number of cases available in final model presentation

Table 14 – 30-Day Mortality Model for the STEMI or Shock Cohort (GLM) Risk Factor Frequency by Year of Discharge (2005-2006)

Variable	2005 (Validation) [N=12,052 in 458 hospitals; 9.0% MR]	2006 (Development) [N=15,123 in 602 hospitals; 9.2%MR]	2005-2006 (Application)* [N=27,175 in 614 hospitals; 9.1% MR]
Age, Mean (SD)	74.8 (6.9)	74.8 (7.0)	74.8 (6.9)
BMI, Mean (SD)	27.4 (5.5)	27.5 (5.6)	27.4 (5.5)
Cerebrovascular disease	12.0	12.2	12.1
Chronic Lung disease	16.5	16.5	16.5
GFR: 0=Not measured	7.4	7.1	7.2
GFR: 1="GFR<30"	4.6	5.1	4.9
GFR: 2="30≤GFR<60"	37.4	37.3	37.3
GFR: 4="GFR≥90"	8.3	7.4	7.8
Previous PCI	18.2	19.1	18.7
CHF - Current Status	14.7	15.4	15.1
Cardiogenic shock on admission	16.9	16.1	16.5
No MI on Admission	10.3	9.0	9.6
MI > 24 hours after admission	6.8	6.4	6.5
EF: 1=Not measured	25.9	27.3	26.7
EF: 2="0≤EF<30"	8.0	7.6	7.8
EF: 3="30≤EF<45"	23.4	22.7	23.0
PCI status: 2=Urgent	17.9	17.2	17.5
PCI status: 3=Emergency	71.9	74.9	73.6
PCI status: 4=Salvage	1.4	1.4	1.4
Highest risk lesion– Segment category: 1=pRCA/mLAD/Pcirc	40.5	39.6	40.0
Highest risk lesion – Segment category: 2=pLAD	20.9	21.6	21.3
Highest risk lesion – Segment category: 3=Left Main	1.2	1.2	1.2
Highest risk lesion: SCAI lesion class 2 or 3	41.4	42.2	41.9
Highest risk lesion: SCAI lesion class 4	33.3	35.2	34.3

*Application sample refers to the combined 2005 and 2006 data used to optimize the number of cases available in final model presentation

3.1.1.3 Model Application

Table 15 shows the point estimates, standard errors, and associated T values for the HGLM for the 2005-2006 combined dataset, calculated using the SAS GLIMMIX procedure. The estimated between-hospital variance in the adjusted log-odds of mortality is 0.1024, based on the 2005-2006 combined dataset. This result implies that the odds of mortality for a high-mortality hospital (+1 SD) are 1.90 times that in a low-mortality hospital (-1 SD). If there were no differences between hospitals, the between-hospital variance would be 0 and the odds ratio would be 1.0.

Table 15 – 30-Day Mortality for STEMI or Shock Cohort (2005-2006 Application Sample – HGLM Results [ROC=0.840])*+

Name	Estimate	Standard Error	T-Value	Pr > T-Value	Odds Ratio (95% CI)
Intercept	-8.75	0.37	-24.0	0.00	
Age/10	0.54	0.03	16.2	0.00	1.72 (1.61, 1.83)
BMI/5	-0.10	0.03	-3.3	0.00	0.90 (0.85, 0.96)
Cerebrovascular disease	0.45	0.06	7.5	0.00	1.56 (1.39, 1.76)
Chronic Lung disease	0.44	0.05	8.0	0.00	1.55 (1.39, 1.73)
GFR: 0=Not measured	0.52	0.09	5.6	0.00	1.68 (1.40, 2.02)
GFR: 1="GFR<30"	1.34	0.08	16.6	0.00	3.84 (3.27, 4.50)
GFR: 2="30≤GFR<60"	0.49	0.05	8.9	0.00	1.63 (1.46, 1.81)
GFR: 4="GFR≥90"	-0.07	0.12	-0.6	0.53	0.93 (0.74, 1.17)
Previous PCI	-0.33	0.06	-5.2	0.00	0.72 (0.64, 0.82)
CHF - Current Status	0.44	0.05	8.0	0.00	1.55 (1.40, 1.73)
Cardiogenic shock on admission	1.50	0.05	29.7	0.00	4.49 (4.06, 4.95)
No MI on admission	-0.02	0.09	-0.2	0.82	0.98 (0.82, 1.17)
MI > 24 hours after admission	0.17	0.08	2.1	0.04	1.19 (1.01, 1.40)
EF: 1=Not measured	0.71	0.06	11.3	0.00	2.03 (1.79, 2.29)
EF: 2="0≤EF<30"	1.07	0.08	13.7	0.00	2.91 (2.50, 3.39)
EF: 3="30≤EF<45"	0.54	0.07	8.2	0.00	1.72 (1.51, 1.96)
PCI status: 2=Urgent	0.38	0.14	2.8	0.01	1.46 (1.12, 1.91)
PCI status: 3=Emergency	0.96	0.13	7.5	0.00	2.60 (2.02, 3.35)
PCI status: 4=Salvage	2.11	0.17	12.1	0.00	8.26 (5.87, 11.62)
Highest Risk Lesion – Segment category: 1=pRCA/mLAD/Pcirc	0.18	0.06	3.2	0.00	1.19 (1.07, 1.33)
Highest Risk Lesion – Segment category: 2=pLAD	0.33	0.06	5.2	0.00	1.39 (1.23, 1.57)
Highest Risk Lesion – Segment category: 3=Left Main	1.00	0.14	7.2	0.00	2.73 (2.07, 3.59)
Highest Risk Lesion: SCAI lesion class 2 or 3	0.26	0.07	3.8	0.00	1.30 (1.14, 1.49)
Highest Risk Lesion: SCAI lesion class 4	0.59	0.07	8.4	0.00	1.80 (1.57, 2.06)

*Between hospital variance = 0.1024, standard error = 0.02325.

+ N=15,123 in 614 hospitals; 9.2% MR

3.1.1.4 30-Day Mortality Rate Distribution - With and Without Risk-Adjustment

Figures 4 and 5 display the frequency distributions of the hospital-specific 30-day mortality rates, with and without risk-adjustment for the 2005-2006 combined cohort. Figures 6 and 7 display these results by hospital volume quartiles for the unadjusted and adjusted rates, respectively.

The observed mortality rate ranged from 0% to 100% across the 614 hospitals (Figure 4), with low-volume hospitals demonstrating the greatest variation in crude rates (Figure 6). After adjusting for patient and clinical characteristics, the risk-standardized rates were found to be more normally distributed, both overall (Figure 5) and by quartile of hospital volume (Figure 7).

Figure 4 – Distribution of Unadjusted Hospital-level 30-Day Mortality Rates in the STEMI or Shock Cohort (2005-2006 Application Sample; N=614 Hospitals)

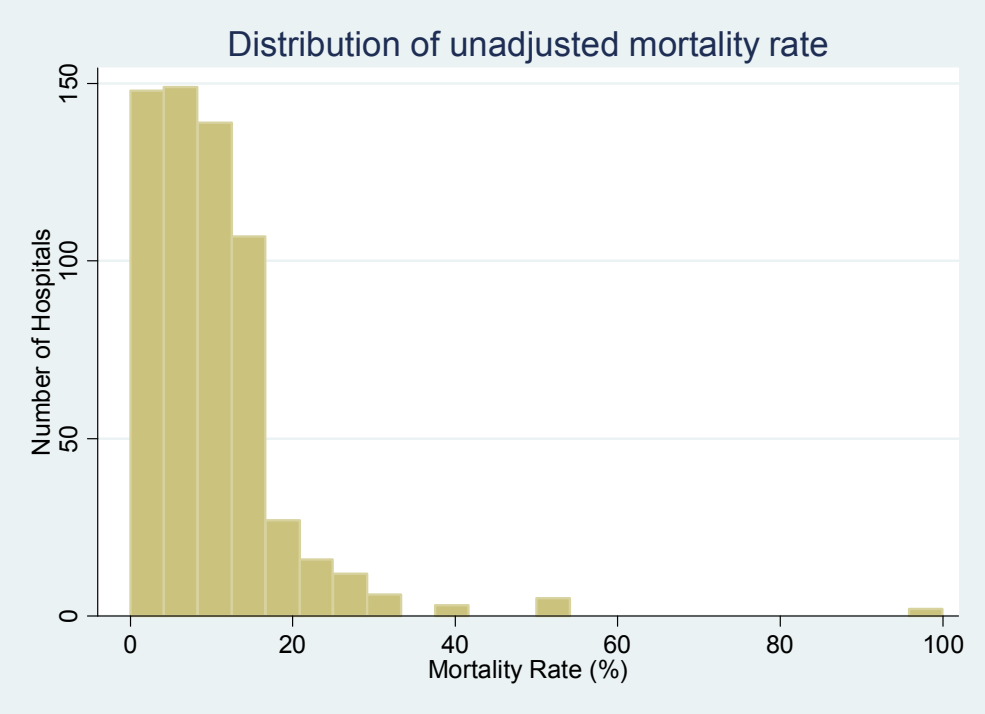


Figure 5 – Distribution of Risk-Standardized Hospital-level 30-Day Mortality Rates in the STEMI or Shock Cohort (2005-2006 Application Sample; N=614 Hospitals) – HGLM

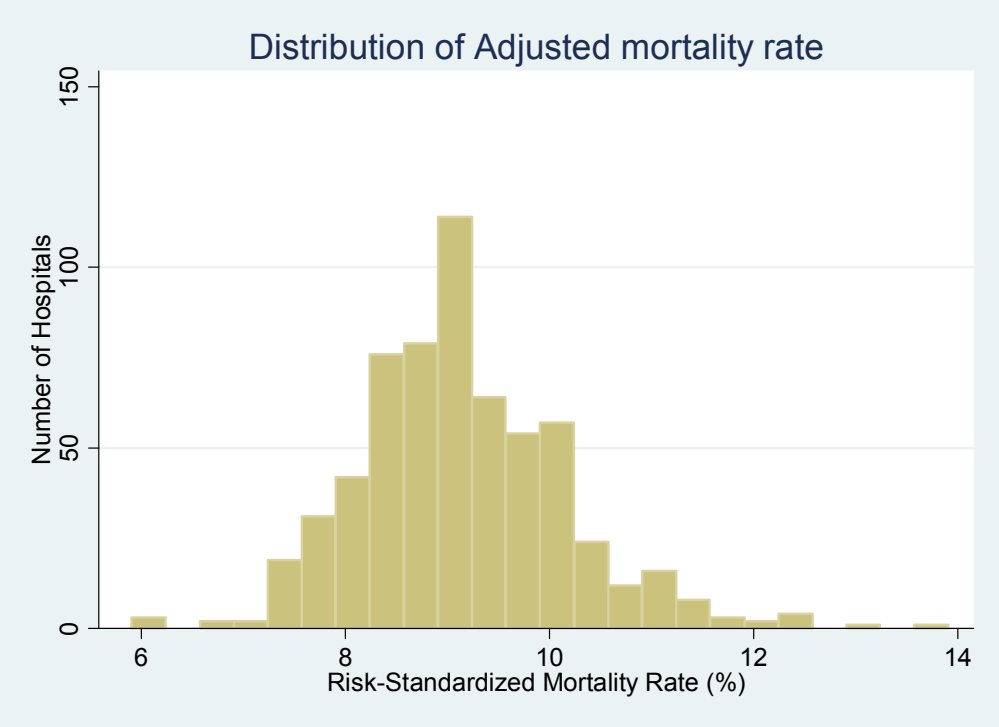


Figure 6 – Distribution of Unadjusted Hospital-level 30-Day Mortality Rates in the STEMI or Shock Cohort (2005-2006 Application Sample; N=614 Hospitals)

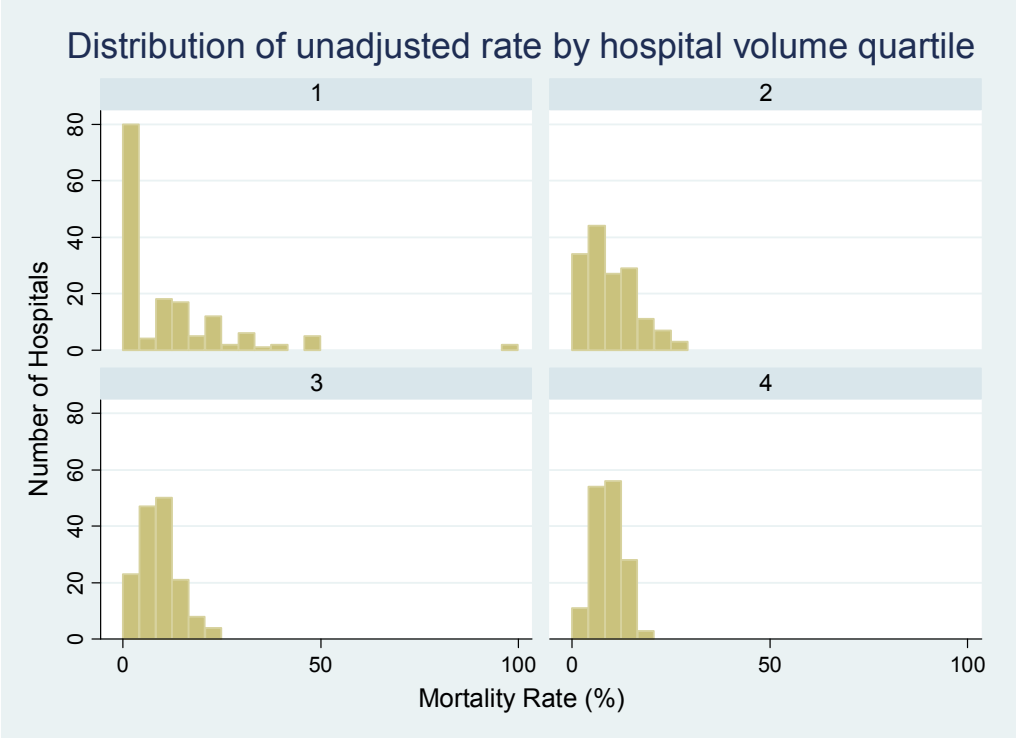
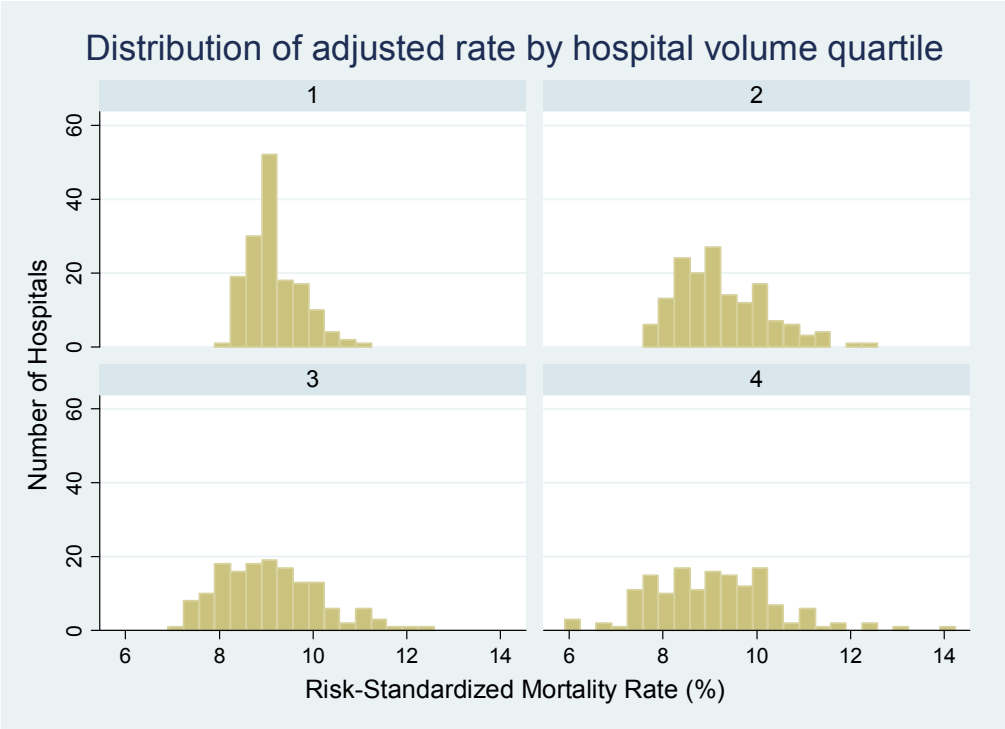


Figure 7 – Distribution of Risk-Standardized Hospital-level 30-Day Mortality Rates in the STEMI or Shock Cohort (2005-2006 Application Sample; N=614 Hospitals) – HGLM



3.1.2 Model Results for the No STEMI and No Shock Cohort

The variable descriptions, standardized estimates, and standard errors are shown in Table 16. The standardized estimates are regression coefficients expressed in units of standard deviations and can range between -1 and 1, with ±1 indicating a perfect linear relationship and 0 indicating no linear relationship.

3.1.2.1 Model Performance

Employing the same approach as for the STEMI or shock cohort, we computed 6 summary statistics for assessing model performance: over-fitting indices, percentage of variation explained by the risk factors, predictive ability, area under the receiver operating characteristic (ROC) curve, distribution of residuals, and model chi-square (see Table 18).

The development model has excellent discrimination, calibration, and fit. The patient-level predicted mortality rate ranges from 0.1% in the lowest predicted decile to 7.0% in the highest predicted decile, a range of 6.9%. The area under the ROC curve is 0.821.

As with the STEMI or shock model, the discrimination and the explained variation of the model at the patient-level are consistent with those of published models of in-hospital PCI mortality (Yale-CORE 2008). The ROC is modestly lower than that for the STEMI or shock model since we had lost two prognostically important variables (STEMI, shock) for the no STEMI and no shock cohort due to stratification.

Table 16 – 30-Day Mortality Model for the No STEMI and No Shock Cohort (2006 Development Sample-GLM Results [ROC=0.821])*

Name	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq	Standardized Estimates	Odds Ratio (95% CI)
Intercept	-7.58	0.42	331.24	0.00		
Age/10	0.48	0.04	135.82	0.00	0.17	1.61 (1.49, 1.75)
BMI/5	-0.30	0.04	62.81	0.00	-0.11	0.74 (0.69, 0.80)
CHF - Previous History	0.22	0.07	11.07	0.00	0.04	1.24 (1.09, 1.41)
Cerebrovascular disease	0.21	0.06	11.22	0.00	0.04	1.23 (1.09, 1.40)
Peripheral Vascular Disease	0.26	0.06	16.39	0.00	0.05	1.29 (1.14, 1.46)
Chronic Lung disease	0.47	0.06	63.15	0.00	0.10	1.59 (1.42, 1.79)
Diabetes/Control: Non-Insulin diabetes	0.10	0.07	2.12	0.15	0.02	1.10 (0.97, 1.26)
Diabetes/Control: Insulin diabetes	0.66	0.07	79.09	0.00	0.11	1.93 (1.67, 2.23)
GFR: 0=Not measured	0.28	0.16	2.80	0.09	0.03	1.32 (0.95, 1.82)
GFR: 1="GFR<30"	0.97	0.09	113.03	0.00	0.11	2.63 (2.20, 3.14)
GFR: 2="30≤GFR<60"	0.37	0.06	32.93	0.00	0.10	1.45 (1.27, 1.64)
GFR: 4="GFR≥90"	0.49	0.10	21.96	0.00	0.08	1.63 (1.33, 2.01)
Previous PCI	-0.43	0.06	50.70	0.00	-0.12	0.65 (0.58, 0.73)
CHF - Current Status	0.68	0.06	111.60	0.00	0.12	1.97 (1.73, 2.23)
NYHAC: Class IV	0.36	0.06	33.22	0.00	0.07	1.43 (1.27, 1.62)
No MI on admission	-0.61	0.07	77.18	0.00	-0.13	0.54 (0.47, 0.62)
MI > 24 hours after admission	0.05	0.09	0.30	0.59	0.01	1.05 (0.89, 1.24)
EF: 1=Not measured	0.57	0.06	77.37	0.00	0.14	1.77 (1.56, 2.01)
EF: 2="0≤EF<30"	0.95	0.10	99.02	0.00	0.10	2.58 (2.14, 3.11)
EF: 3="30≤EF<45"	0.59	0.08	58.30	0.00	0.10	1.81 (1.55, 2.10)
PCI status: 2=Urgent	0.37	0.06	34.88	0.00	0.10	1.45 (1.28, 1.64)
PCI status: 3=Emergency or 4=Salvage	1.21	0.10	151.19	0.00	0.12	3.34 (2.76, 4.05)
Highest risk lesion – Segment category: 1=pRCA/mLAD/Pcirc	0.16	0.06	7.11	0.01	0.04	1.18 (1.04, 1.33)
Highest risk lesion – Segment category: 2=pLAD	0.15	0.08	4.04	0.04	0.03	1.16 (1.00, 1.35)
Highest risk lesion – Segment category: 3=Left Main	0.43	0.13	11.23	0.00	0.04	1.53 (1.19, 1.97)
Highest risk lesion: SCAI lesion class 2 or 3	0.36	0.06	41.24	0.00	0.10	1.43 (1.28, 1.60)
Highest risk lesion: SCAI lesion class 4	0.58	0.10	31.22	0.00	0.06	1.78 (1.46, 2.18)

*N=110,529 in 602 hospitals; mortality rate=1.4%

3.1.2.2 Model Validation

We compared the model performance in the development sample with its performance in a similarly derived validation sample from patients discharged in 2005 who had undergone PCI. This represented 88,630 cases discharged from the 457 hospitals in the 2005 validation dataset. This validation sample had a crude mortality rate of 1.4 %.

The standardized estimates and standard errors for the 2005 validation dataset are shown in Table 17, and the performance metrics are shown in Table 18. The performance was not substantively different in this validation sample (ROC area = 0.815). As the results in Table 19 show, the 2005 and 2006 models appear well-calibrated.

We examined the temporal variation of the standardized estimates and frequencies of the variables in the models (Tables 19 and 20). The frequencies and regression coefficients are fairly consistent over the two years of data.

To assess the predictive ability of this model, we again grouped patients into deciles of predicted 30-day mortality. We then compared predicted mortality with observed mortality for each decile (Figure 8). Once again there was excellent correlation between predicted and observed mortality.

Figure 8 – Observed Mortality by Predicted Mortality per Decile in Patients with no STEMI and no Shock

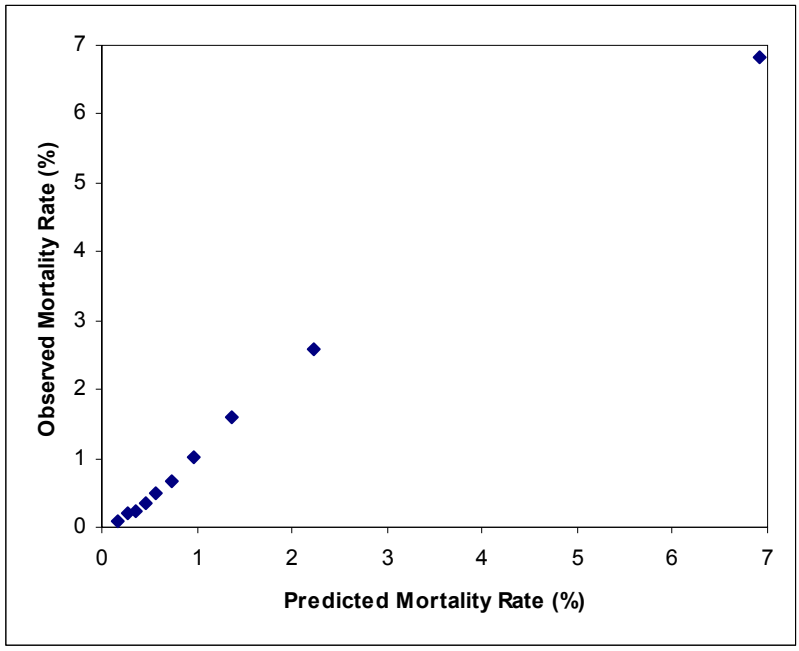


Table 17 – 30-Day Mortality Model for the No STEMI and No Shock Cohort (2005 Validation Sample-GLM Results [ROC:0.815])*

Name	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq	Standardized Estimates	Odds Ratio (95% CI)
Intercept	-7.36	0.46	257.28	0.00		
Age/10	0.46	0.05	104.03	0.00	0.16	1.59 (1.46, 1.74)
BMI/5	-0.31	0.04	57.98	0.00	-0.11	0.73 (0.68, 0.79)
CHF - Previous History	0.31	0.07	18.18	0.00	0.06	1.36 (1.18, 1.57)
Cerebrovascular disease	0.27	0.07	15.54	0.00	0.05	1.31 (1.14, 1.49)
Peripheral Vascular Disease	0.25	0.07	13.41	0.00	0.05	1.29 (1.12, 1.48)
Chronic Lung disease	0.48	0.06	56.36	0.00	0.10	1.62 (1.43, 1.83)
Diabetes/Control: Non-Insulin diabetes	0.15	0.07	4.43	0.04	0.04	1.17 (1.01, 1.35)
Diabetes/Control: Insulin diabetes	0.50	0.08	35.27	0.00	0.08	1.65 (1.40, 1.95)
GFR: 0=Not measured	0.42	0.16	7.07	0.01	0.04	1.52 (1.12, 2.06)
GFR: 1="GFR<30"	1.05	0.10	119.56	0.00	0.12	2.87 (2.38, 3.47)
GFR: 2="30≤GFR<60"	0.22	0.07	9.81	0.00	0.06	1.24 (1.09, 1.43)
GFR: 4="GFR≥90"	0.26	0.12	4.66	0.03	0.04	1.30 (1.02, 1.64)
Previous PCI	-0.31	0.07	22.04	0.00	-0.08	0.74 (0.65, 0.84)
CHF - Current Status	0.72	0.07	97.75	0.00	0.12	2.05 (1.78, 2.36)
NYHAC: Class IV	0.29	0.07	18.16	0.00	0.06	1.34 (1.17, 1.54)
No MI on admission	-0.47	0.08	36.56	0.00	-0.10	0.62 (0.53, 0.73)
MI > 24 hours after admission	0.05	0.09	0.24	0.62	0.01	1.05 (0.87, 1.26)
EF: 1=Not measured	0.32	0.07	20.55	0.00	0.08	1.38 (1.20, 1.59)
EF: 2="0≤EF<30"	0.78	0.10	58.27	0.00	0.08	2.18 (1.78, 2.66)
EF: 3="30≤EF<45"	0.44	0.08	27.42	0.00	0.07	1.55 (1.32, 1.83)
PCI status: 2=Urgent	0.37	0.07	29.67	0.00	0.10	1.45 (1.27, 1.66)
PCI status: 3=Emergency or 4=Salvage	1.08	0.11	91.68	0.00	0.11	2.94 (2.36, 3.67)
Highest risk lesion – Segment category: 1=pRCA/mLAD/Pcirc	0.17	0.07	6.29	0.01	0.05	1.19 (1.04, 1.36)
Highest risk lesion – Segment category: 2=pLAD	0.35	0.08	19.14	0.00	0.07	1.41 (1.21, 1.65)
Highest risk lesion – Segment category: 3=Left Main	0.55	0.14	15.37	0.00	0.05	1.74 (1.32, 2.29)
Highest risk lesion: SCAI lesion class 2 or 3	0.36	0.06	33.11	0.00	0.09	1.43 (1.26, 1.61)
Highest risk lesion: SCAI lesion class 4	0.81	0.11	55.37	0.00	0.09	2.26 (1.82, 2.80)

N=88,630 in 457 hospitals; mortality rate=1.4%

Table 18 – 30-Day Mortality Model Performance for the No STEMI and No Shock Cohort: Results Based on the GLM

Data Source		Calibration	Discrimination		Residuals Lack of Fit (Pearson Residual Fall %)				Model χ^2 [Number of Covariates]#
		(γ_0, γ_1)	Adjusted R-Square*	Predictive Ability+ (lowest decile %, highest decile %)	ROC	<-2	[-2, 0)	[0, 2)	2+	
Development Sample										
2006	N = 110,529 30-day mortality = 1.4%	(0, 1)	0.16	(0.1, 7.0)	0.82	0.00	98.62	0.06	1.32	2,473 (27)
Validation Sample										
2005	N = 88,630 30-day mortality = 1.4%	(-0.14, 0.95)	0.15	(0.1, 6.8)	0.81	0.00	98.56	0.07	1.36	1,969 (27)

* Max-rescaled R-Square
# Wald Chi-Square
+ Observed Rates

Table 19 – 30-Day Mortality Model for the No STEMI and No Shock Cohort (GLM) Standardized Estimates by Year of Discharge (2005-2006)

Variable	2005 (Validation) [N=88,630 in 457 hospitals; 1.4% MR]	2006 (Development) [N=110,529 in 602 hospitals; 1.4% MR]	2005-2006 (Application) [N=199,159 in 612 hospitals; 1.4% MR]
Age/10	0.16	0.17	0.17
BMI/5	-0.11	-0.11	-0.11
CHF - Previous History	0.06	0.04	0.05
Cerebrovascular disease	0.05	0.04	0.05
Peripheral Vascular Disease	0.05	0.05	0.05
Chronic Lung disease	0.10	0.10	0.10
Diabetes/Control: Non-Insulin diabetes	0.04	0.02	0.03
Diabetes/Control: Insulin diabetes	0.08	0.11	0.10
GFR: 0=Not measured	0.04	0.03	0.04
GFR: 1="GFR<30"	0.12	0.11	0.11
GFR: 2="30≤GFR<60"	0.06	0.10	0.08
GFR: 4="GFR≥90"	0.04	0.08	0.06
Previous PCI	-0.08	-0.12	-0.10
CHF - Current Status	0.12	0.12	0.12
NYHAC: Class IV	0.06	0.07	0.06
No MI on admission	-0.10	-0.13	-0.11
MI > 24 hours after admission	0.01	0.01	0.01
EF: 1=Not measured	0.08	0.14	0.12
EF: 2="0≤EF<30"	0.08	0.10	0.09
EF: 3="30≤EF<45"	0.07	0.10	0.09
PCI status: 2=Urgent	0.10	0.10	0.10
PCI status: 3=Emergency or 4=Salvage	0.11	0.12	0.11
Highest risk lesion – Segment category: 1=pRCA/mLAD/Pcirc	0.05	0.04	0.04
Highest risk lesion – Segment category: 2=pLAD	0.07	0.03	0.05
Highest risk lesion – Segment category: 3=Left Main	0.05	0.04	0.04
Highest risk lesion: SCAI lesion class 2 or 3	0.09	0.10	0.10
Highest risk lesion: SCAI lesion class 4	0.09	0.06	0.07

Table 20 – 30-Day Mortality Model for the No STEMI and No Shock Cohort (GLM) Risk Factor Frequency by Year of Discharge (2005-2006)

Variable	2005 (Validation) [N=88,630 in 457 hospitals; 1.4% MR]	2006 (Development) [N=110,529 in 602 hospitals; 1.4% MR]	2005-2006 (Application) [N=199,159 in 612 hospitals; 1.4% MR]
Age, Mean (SD)	74.5 (6.4)	74.6 (6.5)	74.6 (6.4)
BMI, Mean (SD)	28.5 (5.7)	28.6 (5.8)	28.6 (5.7)
CHF - Previous History	14.8	14.9	14.9
Cerebrovascular disease	16.6	16.6	16.6
Peripheral Vascular Disease	16.3	16.3	16.3
Chronic Lung disease	19.0	19.1	19.1
Diabetes/Control: Non-Insulin diabetes	22.7	23.3	23.0
Diabetes/Control: Insulin diabetes	10.2	10.4	10.3
GFR: 0=Not measured	4.0	3.5	3.7
GFR: 1="GFR<30"	4.1	4.1	4.1
GFR: 2="30≤GFR<60"	36.3	36.7	36.5
GFR: 4="GFR≥90"	8.5	8.5	8.5
Previous PCI	38.0	39.4	38.8
CHF - Current Status	11.0	12.2	11.6
NYHAC: Class IV	13.3	12.7	13.0
No MI on Admission	82.3	83.3	82.9
MI > 24 hours after admission	6.7	5.8	6.2
EF: 1=Not measured	29.8	29.8	29.8
EF: 2="0≤EF<30"	3.7	3.6	3.6
EF: 3="30≤EF<45"	10.5	10.5	10.5
PCI status: 2=Urgent	40.3	38.1	39.1
PCI status: 3=Emergency or 4=Salvage	3.4	3.3	3.4
Highest risk lesion – Segment category: 1=pRCA/mLAD/Pcirc	37.7	38.0	37.9
Highest risk lesion – Segment category: 2=pLAD	17.7	17.2	17.4
Highest risk lesion – Segment category: 3=Left Main	2.5	2.6	2.6
Highest risk lesion: SCAI lesion class 2 or 3	37.3	38.2	37.8
Highest risk lesion: SCAI lesion class 4	3.9	3.9	3.9

3.1.2.3 Model Application for the no STEMI and no Shock Cohort

Table 21 shows the point estimates, standard errors, and associated T values for the HGLM for the full 2005-2006 application sample, calculated using the SAS GLIMMIX procedure. The estimated between-hospital variance in the adjusted log-odds of mortality is 0.1325 based on the full 2005-2006 dataset. This result implies that the odds of mortality for a high-mortality hospital (+1 SD) are 2.07 times that in a low-mortality hospital (-1 SD). If there were no differences between hospitals, the between-hospital variance would be 0 and the odds ratio would be 1.0.

Table 21 – 30-Day Mortality for No STEMI and No Shock Cohort (2005-2006 Application Sample – HGLM Results [ROC=0.816])*+

Name	Estimate	Standard Error	T-Value	Pr > T-Value	Odds Ratio (95% CI)
Intercept	-7.52	0.29	-26.27	0.00	
Age/10	0.47	0.03	16.70	0.00	1.60 (1.52, 1.69)
BMI/5	-0.30	0.03	-11.81	0.00	0.74 (0.70, 0.78)
CHF - Previous History	0.27	0.04	5.91	0.00	1.30 (1.19, 1.42)
Cerebrovascular disease	0.25	0.04	5.85	0.00	1.28 (1.18, 1.40)
Peripheral Vascular Disease	0.26	0.04	6.09	0.00	1.30 (1.20, 1.42)
Chronic Lung disease	0.47	0.04	11.62	0.00	1.59 (1.47, 1.72)
Diabetes/Control: Non-Insulin diabetes	0.12	0.05	2.58	0.01	1.13 (1.03, 1.23)
Diabetes/Control: Insulin diabetes	0.58	0.05	11.39	0.00	1.79 (1.62, 1.98)
GFR: 0=Not measured	0.36	0.11	3.34	0.00	1.43 (1.16, 1.77)
GFR: 1="GFR<30"	0.99	0.06	16.22	0.00	2.70 (2.39, 3.04)
GFR: 2="30≤GFR<60"	0.30	0.04	6.92	0.00	1.35 (1.24, 1.47)
GFR: 4="GFR≥90"	0.37	0.07	5.08	0.00	1.45 (1.26, 1.67)
Previous PCI	-0.36	0.04	-8.83	0.00	0.70 (0.64, 0.75)
CHF - Current Status	0.69	0.04	15.41	0.00	2.00 (1.83, 2.18)
NYHAC: Class IV	0.39	0.05	8.56	0.00	1.47 (1.35, 1.61)
No MI on admission	-0.55	0.05	-11.24	0.00	0.58 (0.53, 0.64)
MI > 24 hours after admission	0.08	0.06	1.30	0.19	1.08 (0.96, 1.21)
EF: 1=Not measured	0.45	0.05	9.94	0.00	1.57 (1.44, 1.72)
EF: 2="0≤EF<30"	0.86	0.06	13.29	0.00	2.36 (2.08, 2.68)
EF: 3="30≤EF<45"	0.52	0.05	9.80	0.00	1.67 (1.51, 1.86)
PCI status: 2=Urgent	0.43	0.05	9.56	0.00	1.54 (1.41, 1.69)
PCI status: 3=Emergency or 4=Salvage	1.17	0.07	16.89	0.00	3.22 (2.81, 3.69)
Highest risk lesion – Segment category: 1=pRCA/mLAD/Pcirc	0.16	0.04	3.78	0.00	1.17 (1.08, 1.27)
Highest risk lesion – Segment category: 2=pLAD	0.23	0.05	4.57	0.00	1.26 (1.14, 1.39)
Highest risk lesion – Segment category: 3=Left Main	0.49	0.09	5.60	0.00	1.63 (1.38, 1.94)
Highest risk lesion: SCAI lesion class 2 or 3	0.37	0.04	9.50	0.00	1.45 (1.34, 1.57)
Highest risk lesion: SCAI lesion class 4	0.68	0.07	9.67	0.00	1.97 (1.72, 2.26)

*Between hospital variance = 0.1325, standard error = 0.02161.
+ N=199,159 in 612 hospitals; mortality rate=1.4%

3.1.2.4 30-Day Mortality Rate Distribution – With and Without Risk- Adjustment

Figures 9 and 10 display the frequency distributions of the hospital-specific 30-day mortality rates, with and without risk-adjustment for the 2005-2006 combined cohort. Figures 11 and 12 display these results by hospital volume quartiles for the unadjusted and adjusted rates, respectively.

The observed mortality rate ranged from 0% to 50% across the 612 hospitals (Figure 9), with low-volume hospitals demonstrating the greatest variation in crude rates (Figure 11). After adjusting for patient and clinical characteristics, the risk-standardized rates were found to be more normally distributed, both overall (Figure10) and by quartile of hospital volume (Figure 12).

Figure 9 – Distribution of Hospital-level Unadjusted 30-Day Mortality Rates in the No STEMI and No Shock Cohort (2005-2006 Application Sample; N=612 Hospitals)

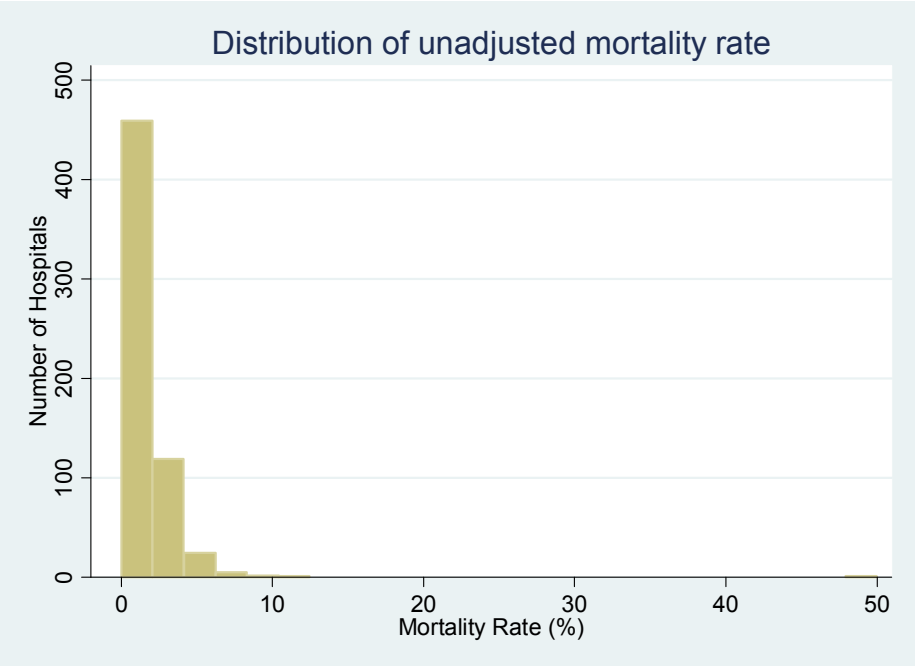


Figure 10 – Distribution of Risk-Standardized Hospital-level 30-Day Mortality Rates in the No STEMI and No Shock Cohort (2005-2006 Application Sample; N=612 Hospitals) – HGLM

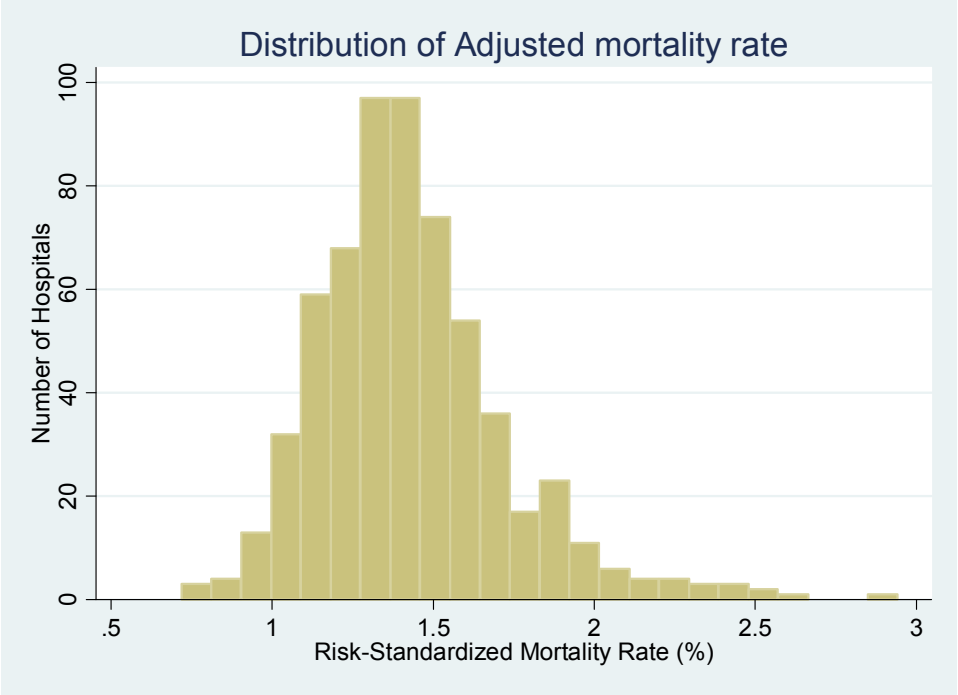


Figure 11 – Distribution of Hospital-level Unadjusted 30-Day Mortality Rates in the No STEMI and No Shock Cohort, by Hospital Volume Quartile (2005-2006 Application Sample; N=612 Hospitals)

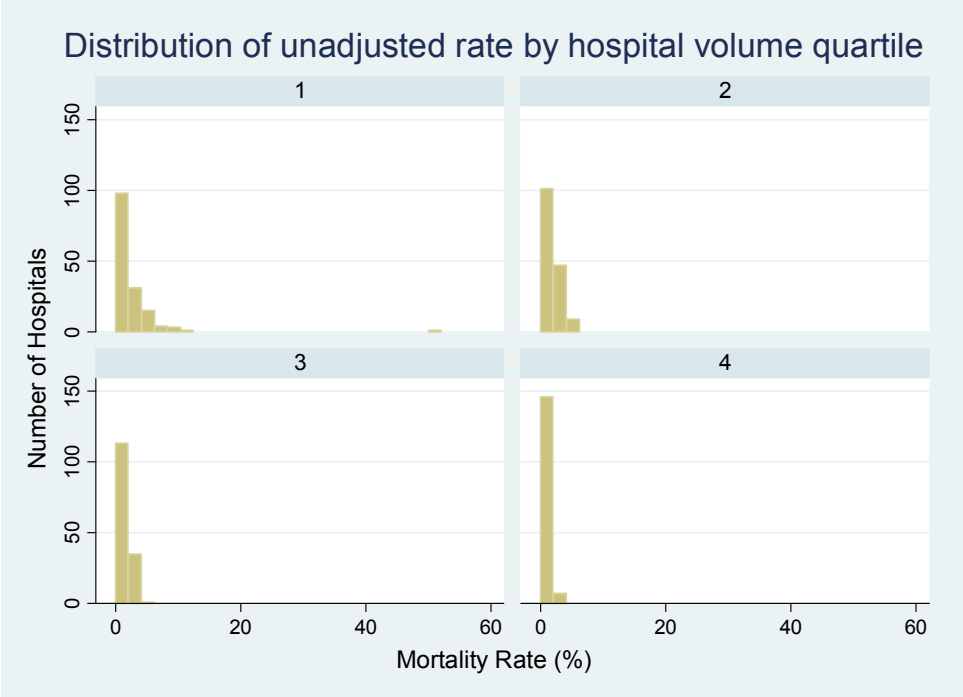
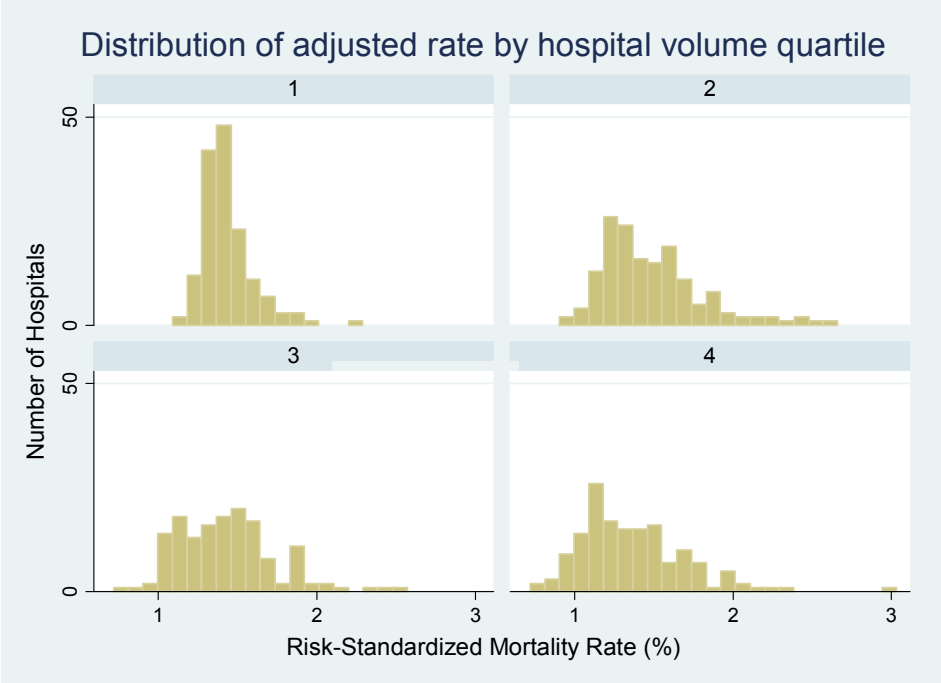


Figure 12 – Distribution of Risk-Standardized Hospital-level 30-Day Mortality Rates in the No STEMI and No Shock Cohort, by Hospital Volume Quartile (2005-2006 Application Sample; N=612 Hospitals) – HGLM



4. MAIN FINDINGS / SUMMARY

We present two hierarchical logistic regression models for 30-day mortality after PCI that are based on data from the NCDR CathPCI Registry and are suitable for public reporting. The study samples are appropriately defined, consisting of two PCI populations that have distinctly different outcomes that will allow for valid comparisons of hospital outcomes. The 30-day outcome provides a standardized period of follow-up. Our approach to risk adjustment is tailored to and appropriate for a publicly reported outcome measure. We excluded covariates that we would not want to adjust for in a quality measure. The statistical approach takes into account the clustering of patients within hospitals and differences in sample size across hospitals. The models have excellent patient-level discrimination and explained variation and are consistent with those observed in previous studies of in-hospital PCI mortality (Yale-CORE 2008).

As discussed, publicly reporting hospital risk standardized 30-day mortality rates requires that the data submitted by hospitals be complete, consistent, and accurate. Steps necessary to ensure data quality would include monitoring data for variances in case mix (e.g., unexpectedly high proportion of salvage PCI or cardiogenic shock), chart audits, and possibly adjudicating cases that are vulnerable to systematic misclassification. This approach has been successfully implemented in the Massachusetts program for public reporting of PCI mortality, with significant rates of reclassification of cases initially classified as cardiogenic shock or salvage PCI, and elimination of some variables with poor reliability (Normand 2008).

While the models we developed have attributes that make them suitable for public reporting, additional steps will be necessary prior to implementation. First, the models were derived from a population of fee-for-service Medicare patients undergoing PCI treated at programs that participated in the NCDR CathPCI Registry. Although the variables included in the models have face validity, we will need to validate and optimize the models in the broader population of all PCI patients. Nevertheless, the variables and explained variation of our models are similar to those of prior efforts to model in-hospital mortality following PCI, and it is unlikely that the final models will be significantly different. Second, we developed the models from a dataset that merged CathPCI Registry data with administrative data using a probabilistic match. The resulting data were adequate for developing models of 30-day PCI mortality. However, using direct patient identifiers to link to external databases such as the Social Security Death Index or National Death Index would be necessary to ensure the accurate determination of patients' vital status. Finally, less than half of hospitals that perform PCI in the United States currently participate in the CathPCI Registry. Public reporting will require collecting and merging data from all hospitals through CathPCI and/or other mechanisms prior to implementation.

In summary, we present two registry-based models of 30-day PCI mortality that are suitable for public reporting. These models are consistent with the consensus standards for publicly reported outcomes measures.

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8.2 Appendix B - NCDR CathPCI Registry Version Update Cross-walk

Version 3.04			Variable in PCI Model	Version 4.3.1		
NCDR No.	Variable Name	Variable Definition		NCDR No.	Variable Name	Variable Definition
252	Patient Age	Patient age in years, at time of admission. This should be calculated from the date of birth and the date of admission, according to the convention used in the USA (the number of birthdate anniversaries reached by the date of admission).	**Age**	2050	Birth Date	**Coding Instructions:** Indicate the patient's date of birth. **Target Value:** The value on arrival at this facility
260	Gender	Indicate the patient's gender at birth as either male or female. Choose one of the following: Male, Female	**Female**	2060	Sex	**Coding Instructions:** Indicate the patient's sex at birth. **Target Value:** The value on arrival at this facility **Selections:** Male, Female
410	Height (cm)	Indicate the patient's height in centimeters.	**BMI**	4055	Height	**Coding Instructions:** Indicate the patient's height in centimeters. **Target Value:** First value between arrival at this facility and discharge
412	Weight (kg)	Indicate the weight of the patient in kilograms.		4060	Weight	**Coding Instructions:** Indicate the patient's weight in kilograms. **Target Value:** Last value between arrival at this facility and first procedure
424	CHF - Previous History	Indicate if the patient has a history of congestive heart failure (CHF) documented in the medical record. History is defined as any time prior to two weeks before the current date of admission. Besides physician documentation of the CHF history, CHF can also be defined by one of the following: 1. Paroxysmal nocturnal dyspnea (PND); 2. Dyspnea on exertion (DOE) due to heart failure; or 3. Chest X-Ray (CXR) showing pulmonary congestion. 4. Pedal edema or dyspnea treated with medical therapy for heart failure. Choose one of the following: - No - Yes	**Heart Failure - Previous History**	4025	Prior Heart Failure	**Coding Instructions:** Indicate if there is a previous history of heart failure **Note(s):** A previous hospital admission with principal diagnosis of heart failure is considered evidence of heart failure history. **Target Value:** Any occurrence between birth and arrival at this facility **Selections:** No, Yes **Supporting Definitions:** Heart Failure: Heart failure is defined as physician documentation or report of any of the following clinical symptoms of heart failure described as unusual dyspnea on light exertion, recurrent dyspnea occurring in the supine position, fluid retention; or the description of rales, jugular venous distension, pulmonary edema on physical exam, or pulmonary edema on chest x-ray. A low ejection fraction alone, without clinical evidence of heart failure does not qualify as heart failure. *Note: Killip Class 2 is defined as rales covering 50% or less of the lung fields or the presence of an S3. Killip Class 3 is defined as rales covering more than 50% of the lung fields. Either class would qualify as a "yes." **Source** Acute Coronary Syndromes Data Standards (JACC 2001 38: 2114 - 30), The Society of Thoracic Surgeons
426	Previous Valvular Surgery	Indicate if the patient had a previous surgical replacement and/or repair of a cardiac valve, by any approach prior to the current admission. Choose one of the following: - Yes - No	**Previous Valvular Surgery**	4030	Prior Valve Surgery/ Procedure	**Coding Instructions:** Indicate if the patient had a previous surgical replacement and/or repair of a cardiac valve, by any approach prior to arrival. **Target Value:** Any occurrence between birth and arrival at this facility **Selections:** No, Yes **Note(s):** This also includes percutaneous valve procedures and valvuloplasty.
450	Cerebro-vascular Disease	Indicate if the patient has a history of cerebrovascular disease, documented by any one of the following: 1. Unresponsive Coma greater than 24 hours: Patient experienced complete mental unresponsiveness and no evidence of psychological or physiologically appropriate responses to stimulation. 2. Cerebrovascular Accident (CVA): Patient has a history of stroke, i.e., loss of neurological function with residual symptoms at least 72 hours after onset. 3. Reversible Ischemic Neurologic Deficit (RIND): Patient has a history of loss of neurological function with symptoms at least 24 hours after onset but with complete return of function within 72 hours. 4. Transient Ischemic Attack (TIA): Patient has a history of loss of neurological function that was abrupt in onset but with complete return of function within 24 hours. 5. Non-invasive/invasive carotid test with greater than 75% occlusion. 6. Previous carotid artery surgery. This does not include neurological disease processes such as metabolic and/or anoxic ischemic encephalopathy. Choose one of the following: Yes, No	**Cerebro-vascular Disease**	4070	Cerebro-vascular Disease	**Coding Instructions:** Indicate if the patient has a history of cerebrovascular disease. **Target Value:** Any occurrence between birth and arrival at this facility **Selections:** No, Yes **Supporting Definitions:** Cerebrovascular Disease: Cerebrovascular Disease documented by any one of the following: 1. Cerebrovascular Accident (CVA): Patient has a history of stroke, i.e., loss of neurological function with residual symptoms at least 24 hrs after onset, presumed to be from vascular etiology. 2. Transient Ischemic Attack (TIA): Patient has a history of loss of neurological function that was abrupt in onset but with complete return of function within 24 hrs, presumed to be due to vascular etiology 3. Non-invasive/invasive carotid test with > 79% occlusion. 4. Previous carotid artery surgery/intervention for carotid artery stenosis. This does not include neurological disease processes such as metabolic and/or anoxic ischemic encephalopathy. **Source** Acute Coronary Syndromes Data Standards (JACC 2001 38: 2114 -30), The

Version 3.04			Variable in PCI Model	Version 4.3.1		
NCDR No.	Variable Name	Variable Definition		NCDR No.	Variable Name	Variable Definition
						Society of Thoracic Surgeons
452	Peripheral Vascular Disease	Indicate if the patient has a history of peripheral vascular disease. This can include: 1. Claudication either with exertion or at rest. 2. Amputation for arterial vascular insufficiency. 3. Aorto-iliac occlusive disease reconstruction, peripheral vascular bypass surgery, angioplasty or stent; or percutaneous intervention to the extremities. 4. Documented AAA repair or stent. 5. Positive non-invasive/invasive test. This does not include procedures such as vein stripping, carotid disease, or procedures originating above the diaphragm. Choose one of the following: - Yes - No	**Peripheral Vascular Disease**	4075	Peripheral Arterial Disease	**Coding Instructions:** Indicate if the patient has a history of peripheral arterial disease (PAD) (includes upper and lower extremity, renal, mesenteric, and abdominal aortic systems). **Target Value:** Any occurrence between birth and arrival at this facility **Selections:** No, Yes **Supporting Definitions:** PAD: Peripheral arterial disease can include: 1. Claudication, either with exertion or at rest. 2. Amputation for arterial vascular insufficiency. 3. Vascular reconstruction, bypass surgery, or percutaneous intervention to extremities (excluding dialysis fistulas & vein stripping) 4. Documented aortic aneurysm with or without repair. 5. Positive non-invasive test (e.g., ankle brachial index <=0.9); ultrasound, magnetic resonance, computed tomography, or angiographic imaging of > 50% diameter stenosis in any peripheral artery (e.g., renal, subclavian, femoral, iliac). For purposes of the Registry, peripheral arterial disease excludes disease in the carotid and cerebrovascular arteries. **Source** ACC Clinical Data Standards, The Society of Thoracic Surgeons
454	Chronic Lung Disease	Indicate if the patient has a documented history of chronic lung disease (i.e. chronic obstructive pulmonary disease, asthma, bronchitis), or has been or is currently treated with pharmocologic therapy. Choose one of the following: - Yes - No	**Chronic Lung Disease**	4080	Chronic Lung Disease	**Coding Instructions:** Indicate if the patient has a history of chronic lung disease **Target Value:** Any occurrence between birth and arrival at this facility **Selections:** No, Yes **Supporting Definitions:** 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. **Source** NCDR
430	Diabetes	A history of diabetes, regardless of duration of disease, or need for anti-diabetic agents. This includes diagnosis on admission or pre-procedure. It does not include gestational diabetes. Choose one of the following: Yes, No	**Diabetes**	4085	Diabetes Mellitus	**Coding Instructions:** Indicate if the patient has a history of diabetes mellitus regardless of duration of disease or need for antidiabetic agents. **Note(s):** If the patient is diagnosed within 24 hours of arrival, code "yes." **Target Value:** Any occurrence between birth and arrival at this facility **Selections:** No, Yes **Supporting Definitions:** Diabetes Mellitus: Diabetes mellitus is diagnosed by a physician or can be defined as a fasting blood sugar greater than 7 mmol/l or 126 mg/dL. It does not include gestational diabetes. **Source** Acute Coronary Syndromes Data Standards (JACC 2001 38: 2114-30), The Society of Thoracic Surgeons
432	Diabetes Control	Code the control method patient presented with on admission. Patients placed on a pre-procedure diabetic pathway of insulin drip but at admission were controlled with diet or oral method are not coded as insulin dependent. Choose one of the following: - None: No treatment for diabetes - Diet: Diet treatment only - Oral: Oral agent treatment (includes oral agent with/without diet treatment) - Insulin: Insulin treatment (includes any combination with insulin)		4090	Diabetes Therapy	Indicate the most aggressive therapy the patient **Coding Instructions:** presented with. **Note(s):** Patients placed on a pre-procedure diabetic pathway of insulin drip after arrival but were not on insulin therapy (treated by diet or oral method) are not coded as insulin treatment. If a patient had a pancreatic transplant, code "other", since the insulin from the new pancreas is not exogenous insulin. **Target Value:** The value on arrival at this facility **Selections:** None - No treatment for diabetes Diet - Diet treatment only Oral - Oral agent treatment (includes oral agent with/without diet treatment) Insulin - Insulin treatment (includes any combination with insulin) Other - Other adjunctive treatment, non-oral/insulin/diet

Version 3.04			Variable in PCI Model NCDR No.	Version 4.3.1		
NCDR No.	Variable Name	Variable Definition		Variable Name	Variable Definition	NCDR No.
252	Patient Age	See Above	GFR	2050	Birth Date	**Coding Instructions:** Indicate the patient's date of birth. **Target Value:** The value on arrival at this facility
260	Gender	See Above		2060	Sex	**Coding Instructions:** Indicate the patient's sex at birth. **Target Value:** The value on arrival at this facility **Selections:** Male, Female
270	Race/ Ethnicity	Patient race as determined by the patient/family. Choose one of the following: - Caucasian - Black - Hispanic - Asian - Native American - Other		2070	Race - White	**Coding Instructions:** Indicate if the patient is White as determined by the patient/family. **Note(s):** If the patient has multiple race origins, specify them using the other race selections in addition to this one. **Target Value:** The value on arrival at this facility **Selections:** No, Yes **Supporting Definitions:** White (Race): Having origins in any of the original peoples of Europe, the Middle East, or North Africa. **Source** U.S. Census Bureau
				2071	Race - Black or African American	**Coding Instructions:** Indicate if the patient is Black or African American as determined by the patient/family. **Note(s):** If the patient has multiple race origins, specify them using the other race selections in addition to this one. **Target Value:** The value on arrival at this facility **Selections:** No, Yes **Supporting Definitions:** Black/African American (Race): Having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American." **Source** U.S. Census Bureau
				2072	Race - Asian	**Coding Instructions:** Indicate if the patient is Asian as determined by the patient/family. **Note(s):** If the patient has multiple race origins, specify them using the other race selections in addition to this one. **Target Value:** The value on arrival at this facility **Selections:** No, Yes **Supporting Definitions:** Asian (Race): Having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. **Source** U.S. Census Bureau
				2073	Race - American Indian or Alaskan Native	**Coding Instructions:** Indicate if the patient is American Indian or Alaskan Native as determined by the patient/family. **Note(s):** If the patient has multiple race origins, specify them using the other race selections in addition to this one. **Target Value:** The value on arrival at this facility **Selections:** No, Yes **Supporting Definitions:** American Indian or Alaskan Native (Race): Having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment. **Source** U.S. Census Bureau
				2074	Race - Native Hawaiian or Pacific Islander	**Coding Instructions:** Indicate if the patient is Native Hawaiian or Pacific Islander as determined by the patient/family. **Note(s):** If the patient has multiple race origins, specify them using the other race selections in addition to this one. **Target Value:** The value on arrival at this facility **Selections:** No, Yes **Supporting Definitions:** Native Hawaiian or Pacific Islander (Race): Having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. **Source** U.S. Census Bureau

Version 3.04			Variable in PCI Model NCDR No.	Version 4.3.1		
NCDR No.	Variable Name	Variable Definition		Variable Name	Variable Definition	NCDR No.
			GFR	2076	Hispanic of Latino Ethnicity	**Coding Instructions:** Indicate if the patient is of Hispanic or Latino ethnicity as determined by the patient/family. **Target Value:** The value on arrival at this facility **Selections:** No, Yes **Supporting Definitions:** Hispanic or Latino Ethnicity: A person of Cuban, Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino." **Source** U.S. Office of Management and Budget. Classification of Federal Data on Race and Ethnicity
439	Creatinine Assessed on Admission	Indicate if the patient's creatinine level was assessed prior to day of procedure. Choose one of the following: Yes, No		7315	Pre-Procedure Creatinine	**Coding Instructions:** Indicate the patient's most recent creatinine level in mg/dL. **Target Value:** The last value between 1 month prior to arrival and current procedure
				7316	Pre-Procedure Creatinine Not Drawn	**Coding Instructions:** Indicate if the patient's creatinine level was not collected. **Selections:** No, Yes - Code "yes" when pre-procedure Creatinine level was not collected.
440	Last Creatinine	Indicate the patient's most recent creatinine level prior to day of procedure. Creatinine should be collected on all patients for consistency, even if they have no prior history of renal failure.		7340	Post-Procedure Creatinine	**Coding Instructions:** Indicate the post-procedure creatinine level in mg/dL. If more than one level is available, code the peak level. **Note(s):** For patients with extended hospital stays, restrict coding of post-procedure creatinine to 30 days after the last procedure. **Target Value:** The highest value between current procedure and until next procedure or discharge
				7341	Post-Procedure Creatinine Not Drawn	**Coding Instructions:** Indicate if a post-procedure creatinine level was not collected. **Note(s):** For patients with extended hospital stays, restrict coding of post-procedure creatinine to 30 days after the last procedure. **Selections:** No, Yes - Code "yes" when pre-procedure Creatinine level was not collected.
444	Renal Failure - Dialysis	Indicate if the patient received dialysis as a result of his/her renal failure. Choose one of the following: - Yes - No	**Renal Failure - Dialysis**	4065	Currently on Dialysis	**Coding Instructions:** Indicate if the patient is currently undergoing either hemodialysis or peritoneal dialysis on an ongoing basis as a result of renal failure. **Note(s):** If a patient is on receiving continuous veno-venous hemofiltration (CVVH) as a result of renal failure (and not as treatment to remove fluid for heart failure), code "yes." **Target Value:** The value on arrival at this facility **Selections:** No, Yes
456	Hyper-tension	Indicate if the patient has hypertension as documented by one of the following: 1. History of hypertension diagnosed and treated with medication, diet and/or exercise. 2. Blood pressure greater than 140 systolic or 90 diastolic on at least 2 occasions. 3. Currently on antihypertensive pharmacologic therapy. Choose one of the following: - Yes - No	**Hypertension**	4005	Hyper-tension	**Coding Instructions:** Indicate if the patient has a current diagnosis of hypertension. **Note(s):** If the patient is diagnosed within 24 hours of arrival, code "yes." **Target Value:** Any occurrence between birth and arrival at this facility **Selections:** No, Yes **Supporting Definitions:** Hypertension: Hypertension is defined by any one of the following: 1. History of hypertension diagnosed and treated with medication, diet and/or exercise 2. Prior documentation of blood pressure greater than 140 mm Hg systolic and/or 90 mm Hg diastolic for patients without diabetes or chronic kidney disease, or prior documentation of blood pressure greater than 130 mm Hg systolic and/or 80 mm Hg diastolic on at least two occasions for patients with diabetes or chronic kidney disease 3. Currently on pharmacologic therapy for treatment of hypertension. **Source** Acute Coronary Syndromes Data Standards (JACC 2001 38: 2114 - 30), The Society of Thoracic Surgeons
460	History of Tobacco Use	Indicate if the patient has a history confirming any form of tobacco use in the past. This includes cigarettes, cigar, tobacco chew, etc. Choose one of the following: - Yes, Current: Use of tobacco within one month of this admission. - Yes, Former: Use of tobacco greater than one month prior to this admission. - Never	**History of Tobacco Use**	4000	Current/ Recent Smoker (w/in 1 year)	**Coding Instructions:** Indicate if the patient has smoked cigarettes anytime during the year prior to arrival at your facility. **Target Value:** Any occurrence between 1 year prior to arrival at this facility and arrival at this facility **Selections:** No, Yes
490	Previous PCI	Indicate if the patient had a previous percutaneous coronary intervention (even if unsuccessful) of any type (balloon angioplasty, stent or other), performed prior to the current admission. Choose one of the following: - Yes - No	**Previous PCI**	4035	Prior PCI	**Coding Instructions:** Indicate if the patient had a previous percutaneous coronary intervention. **Note(s):** Timeframe does NOT include PCIs performed after arrival. **Target Value:** Any occurrence between birth and arrival at this facility **Selections:** No, Yes **Supporting Definitions:** PCI: Percutaneous coronary intervention (PCI) is the placement of an angioplasty guide wire, balloon, or other device (e.g. stent, atherectomy, brachytherapy, or thrombectomy catheter) into a native coronary artery or coronary artery bypass graft for the purpose of mechanical coronary revascularization.

Version 3.04			Variable in PCI Model NCDR No.	Version 4.3.1		
NCDR No.	Variable Name	Variable Definition		Variable Name	Variable Definition	NCDR No.
						Source NCDR
500	CHF - Current Status	Indicate whether, within 2 weeks prior to the first procedure, a physician has diagnosed that the patient is currently in congestive heart failure (CHF). CHF can be diagnosed bases on careful history and physical exam, or by one of the following criteria: 1. Paroxysmal nocturnal dyspnea (PND) and/or fatigue; 2. Dyspnea on exertion (DOE) due to heart failure; or 3. Chest X-Ray (CXR) showing pulmonary congestion. 4. Pedal edema or dyspnea treated with medical therapy for heart failure. Choose one of the following: - Yes - No	**Heart Failure - Current Status**	5040	Heart Failure w/in 2 Weeks	**Coding Instructions:** Indicate if there is physician documentation or report that the patient has been in a state of heart failure within the past 2 weeks. **Note(s):** If this is a subsequent episode of care (within 2 weeks), do not code the Heart Failure w/in 2 Weeks (5040) from the previous episode of care. **Target Value:** Any occurrence between 2 weeks prior to current procedure and current procedure **Selections:** No, Yes **Supporting Definitions:** Heart failure: Heart failure is defined as physician documentation or report of any of the following clinical symptoms of heart failure described as unusual dyspnea on light exertion, recurrent dyspnea occurring in the supine position, fluid retention; or the description of rales, jugular venous distension, pulmonary edema on physical exam, or pulmonary edema on chest x-ray presumed to be cardiac dysfunction. A low ejection fraction alone, without clinical evidence of heart failure does not qualify as heart failure. ***Note:** Killip Class 2 is defined as rales covering 50% or less of the lung fields or the presence of an S3. Killip Class 3 is defined as rales covering more than 50% of the lung fields. Either class would qualify as a "yes." **Source:** Acute Coronary Syndromes Data Standards (JACC 2001 38: 2114 - 30), The Society of Thoracic Surgeons
550	Admission Sx Presentation	Indicate the patient's symptom presentation or angina type on admission. Choose one of the following: - No Symptoms or Angina. - Atypical Chest Pain: Pain, pressure or discomfort in the chest, neck or arms not clearly exertional or not otherwise consistent with pain or discomfort of myocardial ischemic origin. - Stable Angina: Angina without a change in frequency or pattern for the six weeks prior to this cath lab visit. Angina is controlled by rest and/or oral or transcutaneous medications. - Acute Coronary Syndrome (ACS) - Unstable Angina. - Acute Coronary Syndrome (ACS) - Non-ST Elevation MI (Non-STEMI). - Acute Coronary Syndrome (ACS) - ST Elevation MI (STEMI). --- UNSTABLE ANGINA is defined as: The patient was hospitalized for unstable angina documented in the medical record with serial ECG's and biochemical profiles. One of the following criteria is necessary: 1. Angina at rest (usually prolonged >20 minutes). 2. New onset angina (<2 months) exertional angina of at least Canadian Cardiovascular Society Classification (CCSC) Class III. 3. *new per guidelines* Increasing angina - previously diagnosed angina that has become distinctly more frequent, longer in duration, or lower in threshold (i.e., increased by greater than or equal to 1 CCS class to at least CCS Class III severity). NON ST ELEVATION MYOCARDIAL INFARCTION (Non-STEMI) is defined as:	**Symptoms Present on Admission**	5000	CAD Presentation	**Coding Instructions:** Indicate the patient's coronary artery disease (CAD) presentation. Choose the worst status. **Note(s):** If the patient presents with atypical symptoms of myocardial ischemia (i.e. only shortness of breath, upper abdominal pain, left arm pain, etc.) that is known and documented to be myocardial ischemia, and is considered to be an anginal equivalent, code the selection that fits their presentation. If these symptoms are not thought to be or have not been proven to be the anginal equivalent, code "Symptom unlikely to be ischemic." If this is a subsequent episode of care (within 2 weeks), do not code the CAD Presentation from the previous episode of care. For STEMI and NSTEMI, code the highest value within 1 week of the current procedure. If this is a repeat visit to the cath lab during the same episode of care, code the CAD presentation based on the patients clinical status prior to the subsequent procedure. **Target Value:** The highest value between 2 weeks prior to arrival and current procedure **Selections:** -No symptom, no angina - No symptoms, No angina. -Symptom unlikely to be ischemic - Pain, pressure or discomfort in the chest, neck or arms NOT clearly exertional or NOT otherwise consistent with pain or discomfort of myocardial ischemic origin. This includes patients with non-cardiac pain (e.g. pulmonary embolism, musculoskeletal, or esophageal discomfort), or cardiac pain not caused by myocardial ischemia (e.g., acute pericarditis). -Stable angina - Angina without a change in frequency or pattern for the 6 weeks prior to this cath lab visit. Angina is controlled by rest and/or oral or transcutaneous medications.

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		occasion during the first hours after the index clinical event. OR b) Maximal value of CK-MB, preferable CK-MB mass, > upper limit of normal on two successive samples. 3) Total CK: a) In the absence of availability of a troponin or CK-MB assay, total CK > 2 x the upper limit of normal, or the B fraction of CK may be employed, but these last two biomarkers are considerably less satisfactory than CK-MB. AND ONE OF THE FOLLOWING: 1) Either ST segment depression or T wave abnormalities; or 2) Ischemic symptoms in the presence or absence of chest discomfort. Ischemic symptoms may include: a) unexplained nausea and vomiting; or b) persistent shortness of breath secondary to left ventricular failure; or c) unexplained weakness, dizziness, lightheadedness, or syncope. ST ELEVATION MYOCARDIAL INFARCTION (STEMI) is defined as: Indicate whether the patient was hospitalized for an ST Elevation Myocardial Infarction (STEMI) documented in the medical record. AT LEAST ONE OF THE FOLLOWING BIOCHEMICAL INDICATORS for detecting myocardial necrosis must be present (see below for a definition of Reference Control Limits): 1) Troponin T or I: a) Maximal concentration of troponin T or I > the MI decision limit on at least one occasion during the first 24 hours after the index clinical event. 2) CK-MB: a) Maximal value of CK-MB > 2 x the upper limit of normal on one occasion during the first hours after the index clinical event; OR b) Maximal value of CK-MB, preferable CK-MB mass, > upper limit of normal on two successive samples. 3) Total CK a) In the absence of availability of a troponin or CK-MB assay, total CK > 2 x the upper limit of normal, or the B fraction of CK may be employed, but these last two biomarkers are considerably less satisfactory than CK-MB. AND ONE OF THE FOLLOWING ECG CHANGES: 1) ST-segment elevation: New or presumed new ST segment elevation at the J point in two or more contiguous leads with the cut-off points >=0.2 mV in leads V1, V2, or V3, or >=0.1 mV in other leads; OR	**Symptoms Present on Admission**			upper limit of normal according to the individual hospital's laboratory parameters with a clinical presentation which is consistent or suggestive of ischemia. ECG changes and/or ischemic symptoms may or may not be present. b. Absence of ECG changes diagnostic of a STEMI (see STEMI). ST-Elevation MI (STEMI) or equivalent - The patient presented with a ST elevation myocardial infarction (STEMI) or its equivalent as documented in the medical record. STEMIs are characterized by the presence of both criteria: a. ECG evidence of STEMI: New or presumed new ST-segment elevation or new left bundle branch block not documented to be resolved within 20 minutes. ST-segment elevation is defined by new or presumed new sustained ST-segment elevation at the J-point in two contiguous electrocardiogram (ECG) leads with the cut-off points: >=0.2 mV in men or >= 0.15mV in women in leads V2-V3 and/or >= 0.1 mV in other leads and lasting greater than or equal to 20 minutes. If no exact ST-elevation measurement is recorded in the medical chart, physician's written documentation of ST-elevation or Q-waves is acceptable. If only one ECG is performed, then the assumption that the ST elevation persisted at least the required 20 minutes is acceptable. Left bundle branch block (LBBB) refers to new or presumed new LBBB on the initial ECG. b. Cardiac biomarkers (creatinine kinase-myocardial band, Troponin T or I) exceed the upper limit of normal according to the individual hospital's laboratory parameters a clinical presentation which is consistent or suggestive of ischemia which is consistent or suggestive of ischemia. **Note:** For purposes of the Registry, ST elevation in the posterior chest leads (V7 through V9), or ST depression that is maximal in V1-3, without ST-segment elevation in other leads, demonstrating posterobasal myocardial infarction, is considered a STEMI equivalent and qualifies the patient for reperfusion therapy.
560	Time Period: Sx Onset to Admission	MI Patients Only: Indicate the time from the documented onset of symptoms of acute MI to the time of admission to your facility. Choose one of the following: - Less than or equal to 6 hrs: - Greater than 6 hrs and less than or equal to 12 hrs: - Greater than 12 hrs and less than or equal to 24 hrs: - Greater than 24 hours and less than or equal to 48 hrs: - Greater than 48 hours and less than or equal to 7 days: - No time period noted. Patient presented as a silent MI.		3000	Arrival Date	Indicate the date the patient arrived **Coding Instructions:** at your facility.
				3001	Arrival Time	**Coding Instructions:** Indicate the time patient arrived at your facility. **Note(s):** Indicate the time (hours: minutes) using the military 24-hour clock, beginning at midnight (0000 hours). If the patient came to your facility for an elective or outpatient procedure and the time was not documented, code the scheduled time of arrival.

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			Symptoms Present on Admission	5005	Symptom Onset Date	**Coding Instructions:** Indicate the date the patient first noted ischemic symptoms lasting greater than or equal to 10 minutes. **Note(s):** If the patient had intermittent ischemic symptoms, record the date and time of the most recent ischemic symptoms prior to hospital presentation. Symptoms may include jaw pain, arm pain, shortness of breath, nausea, vomiting, fatigue/malaise, or other equivalent discomfort suggestive of a myocardial infarction. In the event of stuttering symptoms, Acute Coronary Syndrome (ACS) symptom onset is the time at which symptoms became constant in quality or intensity. **Target Value:** The first value between 1 week prior to current procedure and current procedure
				5006	Symptom Onset Time	**Coding Instructions:** Indicate the time the patient first noted ischemic symptoms lasting greater than or equal to 10 minutes. **Note(s):** If an estimated symptom onset time is recorded, code "Symptom Onset Time Estimated" as "Yes." Indicate the time (hours: minutes) using the military 24-hour clock, beginning at midnight (0000 hours). If the symptom onset time is not specified in the medical record, it may be recorded as 0700 for morning; 1200 for lunchtime; 1500 for afternoon; 1800 for dinnertime; 2200 for evening and 0300 if awakened from sleep. **Target Value:** The first value between 1 week prior to current procedure and current procedure
				5007	Symptom Onset Time Estimated	**Coding Instructions:** Indicate if the symptom onset time was estimated. **Selections:** No, Yes
				5008	Symptom Onset Time Not Available	**Coding Instructions:** Indicate if the symptom onset time was not available. **Selections:** No, yes
654	Ejection Fraction Done	Indicate whether the patient had Ejection Fraction assessed before or during the cath lab visit via invasive (i.e. LV gram) or non-invasive testing (i.e. Echo). Choose one of the following: - Yes - No	**Ejection Fraction Percentage**	7026	Pre-PCI Left Ventricular Ejection Fraction Not Assessed	**Coding Instructions:** Indicate whether the left ventricular ejection fraction was not assessed. **Target Value:** The last value between 6 months prior to current procedure and prior to the intervention **Selections:** No, Yes
656	Ejection Fraction Percentage	The percentage of the blood emptied from the ventricle at the end of the contraction. Use the most recent determination during or prior to intervention. Enter a percentage in the range of 01 - 99.		7025	Pre-PCI Left Ventricular Ejection Fraction	**Coding Instructions:** Code the best estimate of current left ventricular ejection fraction. **Note(s):** If only a range is reported, report the median of the range (i.e.50-55%, is reported as 53%). If only a descriptive value is reported (i.e. normal), enter the corresponding percentage value from the list below: Normal = 60% Good function = 50% Mildly reduced = 45% Fair function = 40% Moderately reduced = 30% Poor function = 25% Severely reduced = 20% **Fits into current percentage breakdowns:** EF<30 30≤EF<45 EF≥ The Left Ventricular Ejection Fraction can be assessed via invasive (i.e. LV gram) or non-invasive (i.e. Echo, MR, CT or Nuclear) testing. If an ejection fraction is not measured during this admission and prior to the PCI, and their clinical status has not changed, it is acceptable to code an ejection fraction that was obtained prior to arrival. **Target Value:** The last value between 6 months prior to current procedure and prior to the intervention Selection Definitions: LVEF: The left ventricular ejection fraction is the percentage of the blood emptied from the left ventricle at the end of the contraction. **Source:** ACC Clinical Data Standards, The Society of Thoracic Surgeons

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804	PCI Status	Indicate the status of the PCI. Choose one of the following: - Elective: The patient's cardiac function has been stable in the days or weeks prior to the procedure. The procedure could be deferred without increased risk of compromised cardiac outcome. - Urgent: ALL of the following conditions are met: a. Not elective status. b. Not emergency status. c. Procedure required during same hospitalization in order to minimize chance of further clinical deterioration. d. Worsening, sudden chest pain, CHF, acute myocardial infarction (AMI), anatomy, IABP, unstable angina (USA) with intravenous (IV) nitroglycerin (TNG) or rest angina (but stabilized patient) may be included. - Emergency: The patient's clinical status includes any of the following: a. Ischemic dysfunction (any of the following): (1) Ongoing ischemia including rest angina despite maximal medical therapy (medical and/or IABP)); (2) Acute Evolving Myocardial Infarction within 24 hours before Cardiac Cath Lab Procedure; or (3) pulmonary edema requiring intubation. b. Mechanical dysfunction (either of the following): (1) shock with circulatory support; or (2) shock without circulatory support. - Emergent Salvage: The patient is undergoing CPR en route to the Cardiac Cath Lab or prior to procedure.	**PCI Status**	7020	PCI Status	**Coding Instructions:** Indicate the status of the PCI. The status is determined at the time the operator decides to perform a PCI. **Target Value:** The highest value on current procedure **Selections:** 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).
900	Lesion Counter	The software assigned lesion counter should start at one and be incremented by one for each lesion guidewire crossing attempted. This is NOT the Segment Number. The lesion counter is used to distinguish between multiple lesions in the same segment/segment number. The lesion counter number should be assigned in ascending order and should not skip numbers. The highest lesion counter number assigned will be used to determine the total number of lesion guidewire crossing attempts made during the PCI lab visit. Note: The lesion counter is reset back to one for each new PCI lab visit.	**Highest Lesion Location**	7100	Lesion Counter	**Coding Instructions:** The lesion counter is used to distinguish between multiple lesions on which a PCI is attempted or performed. When specifying intracoronary devices, list all treated lesions in which the device was utilized. **Note(s):** The software-assigned lesion counter should start at one and be incremented by one for each lesion. The lesion counter is reset back to one for each new PCI lab visit. At least one lesion must be specified for each PCI procedure. **Supporting Definitions:** Lesion: A target lesion is defined as a stenosis within a coronary artery or coronary artery bypass graft on which mechanical coronary revascularization is attempted during the current procedure. **Source** NCDR
902	Segment Number	Use the following numeric reference points to identify segments where procedures were attempted and its proximal reference number. 1 Proximal right coronary artery conduit segment - pRCA 2 Mid-right coronary artery conduit segment - mRCA 3 Distal right coronary artery conduit segment - dRCA 4 Right posterior descending artery segment - rPDA 5 Right posterior atrioventricular segment - rPAV 6 First right posterolateral segment - 1st RPL 7 Second right posterolateral segment - 2nd RPL 8 Third right posterolateral segment - 3rd RPL 9 Posterior descending septal perforators segment - pDSP 10 Acute marginal segment(s) - aMarg 11 Left main coronary artery segment - LM 12 Proximal LAD artery segment - pLAD 13 Mid-LAD artery segment - mLAD 14 Distal LAD artery segment - dLAD 15 First diagonal branch segment - 1st Diag 15a Lateral first diagonal branch segment - Lat 1st Diag 16 Second diagonal branch segment - 2nd Diag 16a Lateral second diagonal branch segment - Lat 2nd Diag 17 LAD septal perforator segments - LAD SP 18 Proximal circumflex artery segment - pCIRC 19 Mid-circumflex artery segment - mCIRC 19a Distal circumflex artery segment - dCIRC		7105	Segment Number	Coding Instruction: Indicate the segment(s) that the current lesion spans (a lesion can span one or more segments). Use the following numeric reference points to identify segments where procedures were attempted and its proximal reference number. 1 Proximal right coronary artery conduit segment - pRCA 2 Mid-right coronary artery conduit segment - mRCA 3 Distal right coronary artery conduit segment - dRCA 4 Right posterior descending artery segment - rPDA 5 Right posterior atrioventricular segment - rPAV 6 First right posterolateral segment - 1st RPL 7 Second right posterolateral segment - 2nd RPL 8 Third right posterolateral segment - 3rd RPL 9 Posterior descending septal perforators segment - pDSP 10 Acute marginal segment(s) - aMarg 11 Left main coronary artery segment - LM 12 Proximal LAD artery segment - pLAD 13 Mid-LAD artery segment - mLAD 14 Distal LAD artery segment - dLAD 15 First diagonal branch segment - 1st Diag 15a Lateral first diagonal branch segment - Lat 1st Diag 16 Second diagonal branch segment - 2nd Diag 16a Lateral second diagonal branch segment - Lat 2nd Diag 17 LAD septal perforator segments - LAD SP 18 Proximal circumflex artery segment - pCIRC

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NCDR No.	Variable Name	Variable Definition		Variable Name	Variable Definition	NCDR No.
		20 First obtuse marginal branch segment - 1st OM 20a Lateral first obtuse marginal branch segment - Lat 1st OM 21 Second obtuse marginal branch segment - 2nd OM 21a Lateral second obtuse marginal branch segment - Lat 2nd OM 22 Third obtuse marginal branch segment - 3rd OM 22a Lateral third obtuse marginal branch segment - Lat 3rd OM 23 Circumflex artery AV groove continuation segment - CIRC AV 24 First left posterolateral branch segment - 1st LPL 25 Second left posterolateral branch segment - 2nd LPL 26 Third posterolateral descending artery segment - 3rd LPL 27 Left posterolateral descending artery segment - LPDA 28 Ramus intermedius segment - Ramus 28a Lateral ramus intermedius segment - Lat Ramus 29 Third diagonal branch segment - 3rd Diag 29a Lateral third diagonal branch segment - Lat 3rd Diag ---------- Note: For T or Y grafts connected to 2 areas of the native vessels, code using the most dominant vessel or the first one addressed in the procedure.	**Highest Lesion Location**			19 Mid-circumflex artery segment - mCIRC 19a Distal circumflex artery segment - dCIRC 20 First obtuse marginal branch segment - 1st OM 20a Lateral first obtuse marginal branch segment - Lat 1st OM 21 Second obtuse marginal branch segment - 2nd OM 21a Lateral second obtuse marginal branch segment - Lat 2nd OM 22 Third obtuse marginal branch segment - 3rd OM 22a Lateral third obtuse marginal branch segment - Lat 3rd OM 23 Circumflex artery AV groove continuation segment - CIRC AV 24 First left posterolateral branch segment - 1st LPL 25 Second left posterolateral branch segment - 2nd LPL 26 Third posterolateral descending artery segment - 3rd LPL 27 Left posterolateral descending artery segment - LPDA 28 Ramus intermedius segment - Ramus 28a Lateral ramus intermedius segment - Lat Ramus 29 Third diagonal branch segment - 3rd Diag 29a Lateral third diagonal branch segment - Lat 3rd Diag **Note(s):** A segment is a defined region of a coronary artery, as illustrated in the CathPCI Registry coronary anatomy segment diagram. If the target lesion is in a bypass graft, indicate the segment location of the first anastomosis distal to the lesion (and if it's above a Y graft, indicate the segment location of the most important distal vessel). If a PCI of a left subclavian supplying a LIMA is performed, it is not considered a PCI. **Supporting Definitions:** Lesion: A target lesion is defined as a stenosis within a coronary artery or coronary artery bypass graft on which mechanical coronary revascularization is attempted. **Source** NCDR
920	Pre-Procedure TIMI Flow	Indicate for the segment identified the pre-procedure TIMI flow. Choose one of the following: - TIMI-0: No flow/no perfusion. - TIMI-1:Slow penetration without perfusion. - TIMI-2:Partial flow/partial perfusion (greater than TIMI-1 but less than TIMI-3). - TIMI-3:Complete and brisk flow/complete perfusion.	**Pre-Procedure TIMI Flow: none**	7140	Pre-Procedure TIMI Flow	Coding Instruction: Indicate the pre-procedure TIMI flow value. **Note(s):** If a lesion spans multiple segments with different TIMI flows, coded the lowest TIMI flow within the entire lesion. **Target Value:** Any occurrence on current procedure **Selections:** TIMI - 0 No flow/no perfusion TIMI - 1 Slow penetration without perfusion TIMI - 2 Partial flow/partial perfusion (greater than TIMI-1 but less than TIMI-3. TIMI - 3 Complete and brisk flow/complete perfusion.