NATIONAL QUALITY FORUM

Measure Evaluation 4.1
December 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the evaluation criteria are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

TAP/Workgroup (if utilized)**:** Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: *If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).*

Steering Committee: Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met
C = Completely (unquestionably demonstrated to meet the criterion)
P = Partially (demonstrated to partially meet the criterion)
M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)
N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)
NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) **NQF Review #:** 0133 **NQF Project:** Cardiovascular Endorsement Maintenance 2010
MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** PCI mortality (risk-adjusted)©
De.2 **Brief description of measure**: Risk adjusted PCI mortality rate.
1.1-2 **Type of Measure:** Outcome De.3 **If included in a composite or paired with another measure, please identify composite or paired measure** N/A
De.4 **National Priority Partners Priority Area:** Safety De.5 **IOM Quality Domain**: Effectiveness, Safety, Timeliness De.6 **Consumer Care Need:** Getting better

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	**NQF Staff**
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.* A.1 **Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes A.2 **Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:** Proprietary measure A.3 **Measure Steward Agreement:** Agreement will be signed and submitted prior to or at the time of measure submission A.4 **Measure Steward Agreement attached:**	**A** **Y**☐ **N**☐
B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least	**B** **Y**☐

every 3 years. Yes, information provided in contact section	N☐
C. The intended use of the measure includes both public reporting and quality improvement. ►**Purpose:** Public reporting, Internal quality improvement Accountability, Payment incentive, Accreditation	C Y☐ N☐
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1**Testing:** Yes, fully developed and tested D.2 **Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?** Yes	D Y☐ N☐
(for NQF staff use) **Have all conditions for consideration been met?** **Staff Notes to Steward** (*if submission returned*)**:**	Met Y☐ N☐
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**	
Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. *Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.* (evaluation criteria) **1a. High Impact**	Eval Rating
(for NQF staff use) **Specific NPP goal**:	
1a.1 **Demonstrated High Impact Aspect of Healthcare:** Affects large numbers, Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Severity of illness, Patient/societal consequences of poor quality 1a.2 1a.3 **Summary of Evidence of High Impact:** 1.3 million Percutaneous Coronary Intervention (PCI) procedures were performed in 2006 (AHA 2009). From 1987–2004, the number of procedures increased 326 percent (AHA 2003). In 2006, $11.7 billion was paid to Medicare beneficiaries for in-hospital costs when CHD was the principal diagnosis ($14,009 per discharge for acute MI, $12,977 per discharge for coronary atherosclerosis, and $10,630 per discharge for other ischemic heart disease) (AHA 2009). After 3 years, average total costs are estimated at $63,896 for PCI (Stroupe 2006). Risk of mortality following PCI is the second highest among cardiac procedures, with a rate of 0.71 for in-hospital deaths in 2006 (AHA 2009). Analyses of large registries indicate overall unadjusted in-hospital death rates at 0.4% to 1.9%. 1a.4 **Citations for Evidence of High Impact:** 1. American Heart Association. Heart Disease and Stroke Statistics—2009 Update. Dallas, Texas: American Heart Association; 2009. 2. American Heart Association. Heart Disease and Stroke Statistics—2003 update. Dallas, TX: American Heart Association, 2002. 3. Smith SC Jr, Feldman TE, Hirshfeld JW Jr. et al. ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for	1a C☐ P☐ M☐ N☐

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable

Comment [KP1]: 1a. The measure focus addresses:
- a specific national health goal/priority identified by NQF's National Priorities Partners; OR
- a demonstrated high impact aspect of healthcare (e.g., affects large numbers, leading cause of morbidity/mortality, high resource use (current and/or future), severity of illness, and patient/societal consequences of poor quality).

Percutaneous Coronary Intervention). American College of Cardiology Web Site. Available at: http://www.acc.org/clinical/guidelines/percutaneous/update/index.pdf (Smith 2005).
3. Stroupe KT, Morrison DA, Hlatky MA et al. Cost-Effectiveness of Coronary Artery Bypass Grafts Versus Percutaneous Coronary Intervention for Revascularization of High-Risk Patients. Circulation. 2006;114:1251-1257.)

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: This measure allows benchmarking against the national aggregate and against hospitals with similar volume, so that hospitals will high rates can engage in quality improvement to reduce mortality following PCI procedures.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
Mean: 1.39
SD: 0.4

Measure Scores by Percentile:
0: 3.81
10: 2.94
25:2.13
50:1.48
75:1.06
90:0.73
100:0.21

1b.3 Citations for data on performance gap:
1058 facilities, 263,517 patients. July 1 2009 to December 31 2009.

1b.4 Summary of Data on disparities by population group:
None

1b.5 Citations for data on Disparities:
None

1b
C☐
P☐
M☐
N☐

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** This is an outcome measure that is relevant to the target population (patients undergoing PCI) because it is estimated that in-hospital mortality following PCI ranges from 0.4-1.9%. Hospital characteristics have been shown to impact mortality rates.

1c.2-3. Type of Evidence: Observational study, Evidence-based guideline

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
Evidence has demonstrated a relationship between hospital characteristics, including volume of PCIs performed annually and availability of on-site cardiac surgery and in-hospital PCI mortality.

Kimmel et al., using data from the SCAI, found that an inverse relationship existed between the number of angioplasty procedures performed at a hospital and the rate of major complications (Kimmel 1995). These results were risk stratified and independent of the patient-risk profile. Significantly fewer complications occurred in laboratories that performed at least 400 angioplasty procedures per year. Jollis et al. found that low-volume hospitals were associated with higher rates of emergency coronary artery bypass surgery and death (Jollis 1997). Improved outcomes were identified with a threshold volume of 75 Medicare angioplasties per physician and 200 Medicare angioplasty procedures per hospital. Using a 35% to 50% ratio of Medicare patients, the threshold value was 150 to 200 angioplasty procedures per cardiologist and 400 to 600 angioplasty procedures per institution (Ryan 1995).

1c
C☐
P☐
M☐
N☐

Comment [KP2]: 1b. Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating considerable variation, or overall poor performance, in the quality of care across providers and/or population groups (disparities in care).

Comment [k3]: 1 Examples of data on opportunity for improvement include, but are not limited to: prior studies, epidemiologic data, measure data from pilot testing or implementation. If data are not available, the measure focus is systematically assessed (e.g., expert panel rating) and judged to be a quality problem.

Comment [k4]: 1c. The measure focus is:
•an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;
OR
•if an intermediate outcome, process, structure, etc., there is **evidence** that supports the specific measure focus as follows:
oIntermediate outcome – evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
oProcess – evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and
if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
oStructure – evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
oPatient experience – evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of individuals/ the public.
oAccess – evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
oEfficiency – demonstration of an association between the measured resource use and level of performance with respect to one or more of the other five IOM aims of quality.

Comment [k5]: 4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., ... [1]

Vakili et al., analyzing primary PCI procedures for STEMI performed in New York State, found no relationship between physician total angioplasty procedure volume and mortality after primary PCI for STEMI but did find an association between an operator's primary PCI activity level and the outcome of primary PCI for STEMI that was independent of the operator's experience in elective PCI (Vakili 2001; Vakili 2003). Low-volume physicians, who performed 1 to 10 primary PCI procedures per year, had an unadjusted mortality rate of 7.1% compared with 3.8% for physicians who performed 11 or more primary PCI procedures per year.

For the nonprimary/rescue PCI population, mortality was higher in hospitals without onsite cardiac surgery (adjusted OR 1.38; 95% CI 1.14 to 1.67; P equals 0.001) (Wennberg 2004).

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom***):** N/A

1c.6 Method for rating evidence: N/A

1c.7 Summary of Controversy/Contradictory Evidence: None

1c.8 Citations for Evidence (*other than guidelines***):** 1. Kimmel SE, Berlin JA, Laskey WK. The relationship between coronary angioplasty procedure volume and major complications. JAMA 1995;274:1137-42.

2. Jollis JG, Peterson ED, Nelson CL, et al. Relationship between physician and hospital coronary angioplasty volume and outcome in elderly patients. Circulation 1997;95:2485-91.

3. Ryan TJ. The critical question of procedure volume minimums for coronary angioplasty. JAMA 1995;274:1169-70.

4. Vakili BA, Kaplan R, Brown DL. Volume-outcome relation for physicians and hospitals performing angioplasty for acute myocardial infarction in New York state. Circulation 2001; 104:2171-6.

5. Vakili BA, Brown DL. Relation of total annual coronary angioplasty volume of physicians and hospitals on outcomes of primary angioplasty for acute myocardial infarction (data from the 1995 Coronary Angioplasty Reporting System of the New York State Department of Health). Am J Cardiol 2003;91:726-8.

6. Wennberg DE, Lucas FL, Siewers AE, Kellett MA, Malenka DJ. Outcomes of percutaneous coronary interventions performed at centers without and with onsite coronary artery bypass graft surgery. JAMA 2004;292:1961-8.

1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number***):**
The following guideline recommendations relate to processes that can impact this outcome measure:

Class I
1. Elective PCI should be performed by operators with acceptable annual volume (at least 75 procedures) at high-volume centers (more than 400 procedures) with onsite cardiac surgery (310,312). (Level of Evidence: B)
2. Elective PCI should be performed by operators and institutions whose historical and current risk-adjusted outcomes statistics are comparable to those reported in contemporary national data registries. (Level of Evidence: C)
3. Primary PCI for STEMI should be performed by experienced operators who perform more than 75 elective PCI procedures per year and, ideally, at least 11 PCI procedures for STEMI per year. Ideally, these procedures should be performed in institutions that perform more than 400 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year. (Level of Evidence B)
Class IIa
1. It is reasonable that operators with acceptable volume (at least 75 PCI procedures per year) perform PCI at low-volume centers (200 to 400 PCI procedures per year) with onsite cardiac surgery (310,312). (Level of Evidence: B)
2. It is reasonable that low-volume operators (fewer than 75 PCI procedures per year) perform PCI at high-volume centers (more than 400 PCI procedures per year) with onsite cardiac surgery (310,312). Ideally,

Comment [k6]: 3 The strength of the body of evidence for the specific measure focus should be systematically assessed and rated (e.g., USPSTF grading system http://www.ahrq.gov/clinic/uspstf07/methods/benefit.htm). If the USPSTF grading system was not used, the grading system is explained including how it relates to the USPSTF grades or why it does not. However, evidence is not limited to quantitative studies and the best type of evidence depends upon the question being studied (e.g., randomized controlled trials appropriate for studying drug efficacy are not well suited for complex system changes). When qualitative studies are used, appropriate qualitative research criteria are used to judge the strength of the evidence.

operators with an annual procedure volume less than 75 should only work at institutions with an activity level of more than 600 procedures per year. Operators who perform fewer than 75 procedures per year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume of at least 150 procedures per year. (Level of Evidence: B)
Class IIb
The benefit of primary PCI for STEMI patients eligible for fibrinolysis when performed by an operator who performs fewer than 75 procedures per year (or fewer than 11 PCIs for STEMI per year) is not well established. (Level of Evidence: C)
Class III
It is not recommended that elective PCI be performed by low-volume operators (fewer than 75 procedures per year) at low-volume centers (200 to 400) with or without onsite cardiac surgery (310,312). An institution with a volume of fewer than 200 procedures per year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer this service. (Level of Evidence: B)
Class I
1. Elective PCI should be performed by operators with acceptable annual volume (at least 75 procedures per year) at high-volume centers (more than 400 procedures annually) that provide immediately available onsite emergency cardiac surgical services. (Level of Evidence: B) 2. Primary PCI for patients with STEMI should be performed in facilities with onsite cardiac surgery. (Level of Evidence: B)
Class III
Elective PCI should not be performed at institutions that do not provide onsite cardiac surgery. (Level of Evidence: C)*

1c.10 **Clinical Practice Guideline Citation:** Smith SC Jr, Feldman TE, Hirshfeld JW Jr. et al. ACC/AHA/SCAI 2005 guideline update for percutaneous
coronary intervention: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention). American College of Cardiology Web Site. Available at: http://www.acc.org/clinical/guidelines/percutaneous/update/index.pdf (Smith 2005).
1c.11 **National Guideline Clearinghouse or other URL:** N/A

1c.12 **Rating of strength of recommendation (***also provide narrative description of the rating and by whom***):**
N/A

1c.13 **Method for rating strength of recommendation** (*If different from USPSTF system, also describe rating and how it relates to USPSTF)***:**
N/A

1c.14 **Rationale for using this guideline over others:**
N/A

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to Measure and Report*?	**1**
Steering Committee: Was the threshold criterion, *Importance to Measure and Report***, met?** **Rationale:**	**1** **Y☐** **N☐**
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	**Eval Rating**
2a. MEASURE SPECIFICATIONS	
S.1 **Do you have a web page where current detailed measure specifications can be obtained?** S.2 **If yes, provide web page URL:** **2a. Precisely Specified**	**2a-specs** **C☐**

Comment [k7]: USPSTF grading system **http://www.ahrq.gov/clinic/uspstf/grades.htm**: **A -** The USPSTF recommends the service. There is high certainty that the net benefit is substantial. **B -** The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. **C -** The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small. Offer or provide this service only if other considerations support the offering or providing the service in an individual patient. **D -** The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. **I -** The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

Comment [KP8]: 2a. The measure is well defined and precisely specified so that it can be implemented consistently within and across organizations and allow for comparability. The required data elements are of high quality as defined by NQF's Health Information Technology Expert Panel (HITEP) .

2a.1 Numerator Statement (*Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):**
Patients 18 years of age and older with a PCI procedure performed during admission who expired

2a.2 Numerator Time Window (*The time period in which cases are eligible for inclusion in the numerator***):**
One year

2a.3 Numerator Details (*All information required to collect/calculate the numerator, including all codes, logic, and definitions***):**
PCI=yes
Coding instructions: indicate if the patient had a percutaneous coronary intervention (PCI)
Selections: yes/no
Supporting definitions: PCI: A 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 bypass graft for the purpose of mechanical coronary revascularization. Source: NCDR

Discharge status=deceased
Selections: Alive/deceased
Coding instructions: Indicate whether the patient was alive or deceased at discharge.

2a.4 Denominator Statement (*Brief, text description of the denominator - target population being measured***):**
Patients 18 years of age and older with a PCI procedure performed during admission

2a.5 Target population gender: Female, Male
2a.6 Target population age range: > 18 years of age

2a.7 Denominator Time Window (*The time period in which cases are eligible for inclusion in the denominator***):**
One year (quarterly to include previous four quarters of data)

2a.8 Denominator Details (*All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):**
PCI=yes
Coding instructions: indicate if the patient had a percutaneous coronary intervention (PCI)
Selections: yes/no
Supporting definitions: PCI: A 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 bypass graft for the purpose of mechanical coronary revascularization. Source: NCDR

Age: patients must be 18 years of age to be included in the registry.

2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population***):** 1. NCDR Registry patients who did not have a PCI (Patient admissions with a diagnostic cath only during that admission);
2. Data submissions that do not pass the data quality and completeness reports;
3. Procedure variables for subsequent PCIs during the same admission (if the patient had more than one PCI procedure during that admission).
4. Patient admissions with PCI who transferred to another facility on discharge;
5. Patient admissions with PCI who have more than two variables in the risk model that are missing.

2a.10 Denominator Exclusion Details (*All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**
1. PCI = yes
2. All data submissions must pass the data quality and completeness reports to be included. Note: If one or two variables are missing, the value is imputed for certain characteristics (see appendix 2 of the NCDR CathPCI Registry PCI Risk Adjusted Morality Model 2008 for more information). If the value is missing for more

P☐ M☐ N☐

Comment [k9]: 11 Risk factors that influence outcomes should not be specified as exclusions.
12 Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

than two variables, the patient record is excluded. However, in our data quality program, all variables in the risk model have a high "inclusion" criteria. This means that, when a hospital submits data to us, they need to have a high level of completeness (around 99%) for those variables. If they are not able to meet the criteria in our data quality program, they do not receive risk adjusted mortality for the records they submitted for that quarter.
3. PCI= yes for more than one procedure during the same admission.
4. Discharge location= transferred to another facility

2a.11 Stratification Details/Variables (*All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
N/A

2a.12-13 Risk Adjustment Type: Risk-adjustment devised specifically for this measure/condition

2a.14 Risk Adjustment Methodology/Variables (*List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**
Risk adjustment methodology is a logistic regression analysis.
Weights were assigned to risk factors or variables reflecting the strength of their association to PCI in-hospital mortality. Each patient in a facilities submission is given a risk score to predict risk of in hospital mortality and accurately report risk adjusted mortality rates during hospitalization.

Data from 181,775 procedures performed from January 2004 to March 2006 were used to develop risk models based on pre-procedural and/or angiographic factors using logistic regression.

The most noteworthy risk factors or variables in the model include:
1. ST-segment elevation MI defined as a patient who had a STEMI on admission, with an onset within 24 hours, or the procedure indication was primary, rescue or facilitated PCI.
2. Discharge status (alive or expired). The interaction between this variable with other variables were key in the analysis.
3. The glomerular filtration rate (GFR) variable is calculated using abbreviated MDRD formula [GFR = 186 ×?(last creatinine)-1.154 × (age)-0.203 × (gender factor) × (race factor) where (gender factor) = 1 for male and 0.742 for female, (race factor) = 1.21 for black and 1 for others].
4. The body mass index (BMI) (kg/m2) is calculated from height (cm) and weight (kg): BMI = weight × 10000 / (height) 2.

All Risk Adjustment Variables
STEMI patients
Age (for age<=70, for age>70)
Cardiogenic Shock at Admission
Previous History - CHF
Peripheral Vascular Disease
Chronic Lung Disease
GFR (for STEMI, for non-STEMI)
NYHA Class IV (for STEMI, for non-STEMI)
PCI Status (for STEMI, for non STEMI)
- Urgent
- Emergency
- Salvage
Previous Vascular Disease
Cerebrovascular Disease
Previous PCI
PreOp IABP
Ejection Fraction Percentage
Coronary Lesion >= 50%: Subacute
Thrombosis? Yes vs. No
Highest Risk Pre-Procedure TIMI Flow = None vs. Yes
1.19 1.02 1.38 4.84
Diabetes/Control (Non-Insulin Diabetes vs. No Diabetes; Insulin Diabetes vs. No Diabetes)
Highest Risk Lesion: SCAI Lesion Class (II or III vs. I; IV vs. I)

BMI [kg/m2] (for STEMI, for Non-STEMI)
Highest Risk Lesion - Segment Category (for STEMI, for non STEMI)
-pRCA/mLAD/pCIRC
-pLAD
-Left Main

2a.15-17 **Detailed risk model available Web page URL or attachment:** Attachment Contemporary Mortality Risk Prediction for PCI (2).pdf

2a.18-19 **Type of Score:** Weighted score/composite/scale
2a.20 **Interpretation of Score:** Better quality = Lower score
2a.21 **Calculation Algorithm (***Describe the calculation of the measure as a flowchart or series of steps***):**
1. Count of admissions from data submissions that pass NCDR data inclusion thresholds.
2. Exclude admissions without PCI during admission
3. Exclude variables from any subsequent PCI during the same admission
4. Exclude patient admissions with PCI who have more than two variables in the risk model that are missing.

2a.22 **Describe the method for discriminating performance** *(e.g., significance testing)***:**
Hospitals performance for this measure is benchmarked each quarter and annually against hospitals with similar procedural volume, as well as against the CathPCI Registry aggregate. These benchmarks identify superior performance and encourage poorer performers to improve. The methodology is a data-driven, peer-group performance feedback used to positively affect outcomes.

2a.23 **Sampling (Survey) Methodology** *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)*:
N/A

2a.24 **Data Source (***Check the source(s) for which the measure is specified and tested)*
Registry data

2a.25 **Data source/data collection instrument (***Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
National Cardiovascular Data Registry (NCDR) CathPCI Registry®

2a.26-28 **Data source/data collection instrument reference web page URL or attachment:** URL
http://www.ncdr.com/WebNCDR/ELEMENTS.ASPX

2a.29-31 **Data dictionary/code table web page URL or attachment:** URL
http://www.ncdr.com/WebNCDR/ELEMENTS.ASPX

2a.32-35 **Level of Measurement/Analysis** (*Check the level(s) for which the measure is specified and tested)*
Facility/Agency

2a.36-37 **Care Settings (***Check the setting(s) for which the measure is specified and tested)*
Hospital

2a.38-41 **Clinical Services** (*Healthcare services being measured, check all that apply*)
Clinicians: Physicians (MD/DO)

TESTING/ANALYSIS

2b. Reliability testing

2b.1 **Data/sample** *(description of data/sample and size)***:** Auditing through chart abstraction was performed at 15 NCDR sites in 2008 for data submitted between January and December of 2006.

2b.2 **Analytic Method** *(type of reliability & rationale, method for testing)***:**
Inter-rater reliability between abstractors to assess reliability of coding for registry data collection. Retrospective chart abstraction was the method for testing.

2b.3 **Testing Results** *(reliability statistics, assessment of adequacy in the context of norms for the test*

2b
C☐
P☐
M☐
N☐

Comment [KP10]: 2b. Reliability testing demonstrates the measure results are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period.

Comment [k11]: 8 Examples of reliability testing include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing may address the data items or final measure score.

conducted):
Percent agreement:
252 Patient Age 100
260 Gender 100
310 Date of Admission 98
420 Previous MI (>7 Days) 86
430 Diabetes 95
432 Diabetes Control 90
442 Renal Failure - Previous History 97
454 Chronic Lung Disease 89
456 Hypertension 88
470 Dyslipidemia 78
480 Family History of CAD age <55 75
490 Previous PCI 94
494 Previous CABG 99
500 CHF - Current Status 92
510 NYHA 83
520 Cardiogenic Shock 98
550 Admission Sx Presentation 58
560 Time Period: Sx Onset to Admission 82
600 Date of Procedure 100
640 IABP 100
642 IABP Timing 100
654 Ejection Fraction Done 80
656 Ejection Fraction Percentage 58
661 LM Stenosis Percent 92
663 Proximal LAD Stenosis Percent 63
665 Mid/Distal LAD Stenosis Percent 65
667 CIRC Stenosis Percent 74
669 RCA Stenosis Percent 77
671 Ramus Stenosis Percent 95
675 Proximal LAD Graft Stenosis Percent 97
677 Mid/Distal LAD Graft Stenosis Percent 96
679 CIRC Graft Stenosis Percent 96
681 RCA Graft Stenosis Percent 96
683 Ramus Graft Stenosis Percent 100
804 PCI Status 93
962 Intracoronary Device Used - Stent 93
1000 Comp-Periprocedural MI 98
1010 Comp-Cardiogenic Shock 98
1020 Comp-Congestive Heart Failure 97
1030 Comp-CVA/Stroke 100
1040 Comp-Tamponade 100
1050 Comp-Thrombocytopenia 99
1060 Comp-Contrast Reaction 100
1070 Comp-Renal Failure 100
1080 Comp-Emergency PCI 99
1085 Comp-Bleeding - Percutaneous Entry Site 98
1086 Comp-Bleeding - Retroperitoneal 100
1087 Comp-Bleeding - Gastrointestinal 99
1088 Comp-Bleeding - Genital/Urinary 100
1092 Comp-Vascular - Access Site Occlusion 100
1094 Comp-Vascular - Peripheral Embolization 100
1096 Comp-Vascular - Dissection 100
1097 Comp-Vascular - Pseudoaneurysm 100
1099 Comp-Vascular - AV Fistula 100
1100 CABG During This Admission - Status 99
1150 Date of Discharge 99

1152	Discharge Status	100
1160	Death in Lab	99
	Overall Accuracy:	92

The Data Quality Report (DQR) program: The DQR program assesses the completeness of data submitted by participating hospitals. Hospitals must achieve a high level of completeness (>95% completeness of specific data elements identified as 'core fields' which encompass the variables included in our risk adjustment models) in order to have their data analyzed in the RAM model, and to be included in the aggregated data. The process is iterative, providing hospitals with the opportunity to correct errors and resubmit data for review.

The NCDR is implementing a new strategy, the Data Quality Program, to improve the data reported to each registry. The DQR and special analyses of the data are parts of the Program. Another part is the auditing of data, with results used for instructing participants on how to improve data submitted. Each year, participating sites are randomly selected to be audited. Trained nurse abstractors conduct medical record reviews and blind data abstraction of randomly selected patient medical records at each site. Audit results are analyzed for overall accuracy by comparing audit findings against data originally submitted from each site. Each participant receives a confidential audit report which displays their audit score and individual accuracy for each data element. In most audits, the median agreement between submitted and audited values is 92%.

Training and orientation are critical functions to ensure data quality and, ultimately, a high-quality registry. In addition to the "help desk" function provided by NCDR, training and orientation take the following forms:
-Introductory Calls and Webcasts: CathPCI Registry participants are invited on a routine basis to join calls and/or Webcasts where registry staff provide an overview to the CathPCI Registry program and answer questions.
-Electronic Data Capture Training: Participants who submit data via the NCDR Web-based Data Entry Tool will need to complete training for the system, either via Webcast or online module. This training educates users regarding platform functionality, including data entry and review, and user account management

2c. Validity testing

2c.1 **Data/sample** *(description of data/sample and size)*: Auditing through chart abstraction was performed at 15 NCDR sites in 2008 for data submitted between January and December of 2006.

2c.2 **Analytic Method** *(type of validity & rationale, method for testing)*:
Validity of data elements abstracted from medical record as compared to a criterion source of the same data through retrospective chart abstraction.

2c.3 **Testing Results** *(statistical results, assessment of adequacy in the context of norms for the test conducted)*:
Percent agreement:

Patient Age	100
Gender	100
Date of Admission	98
Previous MI (>7 Days)	86
Diabetes	95
Diabetes Control	90
Renal Failure - Previous History	97
Chronic Lung Disease	89
Hypertension	88
Dyslipidemia	78
Family History of CAD age <55	75
Previous PCI	94
Previous CABG	99
CHF - Current Status	92
NYHA	83
Cardiogenic Shock	98

2c
C☐
P☐
M☐
N☐

Comment [KP12]: 2c. Validity testing demonstrates that the measure reflects the quality of care provided, adequately distinguishing good and poor quality. If face validity is the only validity addressed, it is systematically assessed.

Comment [k13]: 9 Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP < 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed (e.g., ratings by relevant stakeholders) and the measure is judged to represent quality care for the specific topic and that the measure focus is the most important aspect of quality for the specific topic.

Admission Sx Presentation 58
Time Period: Sx Onset to Admission 82
Date of Procedure 100
IABP 100
IABP Timing 100
Ejection Fraction Done 80
Ejection Fraction Percentage 58
LM Stenosis Percent 92
Proximal LAD Stenosis Percent 63
Mid/Distal LAD Stenosis Percent 65
CIRC Stenosis Percent 74
RCA Stenosis Percent 77
Ramus Stenosis Percent 95
Proximal LAD Graft Stenosis Percent 97
Mid/Distal LAD Graft Stenosis Percent 96
CIRC Graft Stenosis Percent 96
RCA Graft Stenosis Percent 96
Ramus Graft Stenosis Percent 100
PCI Status 93
Intracoronary Device Used - Stent 93
Comp-Periprocedural MI 98
Comp-Cardiogenic Shock 98
Comp-Congestive Heart Failure 97
Comp-CVA/Stroke 100
Comp-Tamponade 100
Comp-Thrombocytopenia 99
Comp-Contrast Reaction 100
Comp-Renal Failure 100
Comp-Emergency PCI 99
Comp-Bleeding - Percutaneous Entry Site 98
Comp-Bleeding - Retroperitoneal 100
Comp-Bleeding - Gastrointestinal 99
Comp-Bleeding - Genital/Urinary 100
Comp-Vascular - Access Site Occlusion 100
Comp-Vascular - Peripheral Embolization 100
Comp-Vascular - Dissection 100
Comp-Vascular - Pseudoaneurysm 100
Comp-Vascular - AV Fistula 100
CABG During This Admission - Status 99
Date of Discharge 99
Discharge Status 100
Death in Lab 99
Overall Accuracy: 92

2d. Exclusions Justified

2d.1 Summary of Evidence supporting exclusion(s):
This measure has only 1 exclusion: transferred to another facility. This rationale for this exclusion is that these are patients whose episode of care is continuing past discharge.

2d.2 Citations for Evidence:

2d.3 Data/sample *(description of data/sample and size)*: July 1 2009-December 31 2009, 246,428 patients from 1058 facilities.

2d.4 Analytic Method *(type analysis & rationale)*:
Rate of exclusion coding.

2d
C☐
P☐
M☐
N☐
NA☐

Comment [KP14]: 2d. Clinically necessary measure exclusions are identified and must be:
•supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;
AND
•a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;
AND
•precisely defined and specified:
–if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);
if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

Comment [k15]: 10 Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, sensitivity analyses with and without the exclusion, and variability of exclusions across providers.

2d.5 Testing Results *(e.g., frequency, variability, sensitivity analyses)*:
0.7% of patients (1,725 patients) were coded as transferred to another facility.

2e. Risk Adjustment for Outcomes/ Resource Use Measures

2e.1 Data/sample *(description of data/sample and size)*: 2 validation cohorts: contemporary (n=121,183, January 2004 to March 2006) and prospective (n=285,440, March 2006 to March 2007).

2e.2 Analytic Method *(type of risk adjustment, analysis, & rationale)*:
Model discrimination was assessed using the c-index. To assess model calibration, patients were rank-ordered from lowest- to highest predicted risk. Comparison was then made of predicted versus observed event rates within risk strata. Model discrimination and calibration were assessed in the overall population, within the 2 validation samples, and among select subpopulations of both of these groups. Finally, the models' discrimination was assessed among patients age 65+ years who had been linked to CMS data to assess both in-hospital and 30-day mortality.

2e.3 Testing Results *(risk model performance metrics)*:
The full NCDR CathPCI Mortality Risk Prediction model in the contemporary and prospective validation cohorts performed exceptionally well, with a c-index of 0.925 and 0.924, respectively. Additionally, the full model performed well in each of the 8 predefined patient subgroups, with c-indices ranging from 0.892 to 0.930. Of note, the exclusion of angiographic details and EF from the full model resulted in only a slight decrement in the overall model accuracy. Similarly, there was limited loss in model discrimination when the model was transformed into the final, simplified NCDR CathPCI Risk Score, with c-indices of 0.901 and 0.905, respectively, in the validation samples. This simplified score also had good operating characteristics in all predefined patient subgroups. Notably, the majority of patients had a relatively low mortality risk (92.6% of patients had a predicted mortality risk between 0% and 2.5%). However, there was high concordance between model predicted risk and that which was actually observed. The simplified Risk Score was also well calibrated in both low- and moderate-risk populations, with only a slight underestimation of predicted risk in high-risk patients. Finally, we examined the full and simplified models' ability to estimate 30-day mortality among patients age 65 years or older who had been linked to CMS data. Among 204,111 Medicare patients, 4,068 (1.99%) died in-hospital and 6,011 (2.94%) died within 30 days of the procedure.

In addition, we ran the Hosmer and Lemeshow (H-L) Goodness-of-Fit Test for the full model in the Spring 2010: chi-square=18.13, D.F.=8, p-value=0.02.

2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: N/A

2e
C☐ P☐ M☐ N☐ NA☐

2f. Identification of Meaningful Differences in Performance

2f.1 Data/sample from Testing or Current Use *(description of data/sample and size)*: 1058 facilities, 263,517 patients. July 1 2009 to December 31 2009.

2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance *(type of analysis & rationale)*:
Distribution of rates of performance.

2f.3 Provide Measure Scores from Testing or Current Use *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:
Mean: 1.39
SD: 0.4

Measure Scores by Percentile:
0: 3.81
10: 2.94
25:2.13
50:1.48
75:1.06

2f
C☐ P☐ M☐ N☐

Comment [KP16]: 2e. For outcome measures and other measures (e.g., resource use) when indicated:
•an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified and is based on patient clinical factors that influence the measured outcome (but not disparities in care) and are present at start of care;[Error! Bookmark not defined.] OR rationale/data support no risk adjustment.

Comment [k17]: 13 Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender (e.g., poorer treatment outcomes of African American men with prostate cancer, inequalities in treatment for CVD risk factors between men and women). It is preferable to stratify measures by race and socioeconomic status rather than adjusting out differences.

Comment [KP18]: 2f. Data analysis demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful differences in performance.

Comment [k19]: 14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% v. 75%) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v. $5,025) is practically meaningful. Measures with overall poor performance may not demonstrate much variability across providers.

90:0.73
100:0.21

2g. Comparability of Multiple Data Sources/Methods

2g.1 Data/sample *(description of data/sample and size)*: N/A

2g.2 Analytic Method *(type of analysis & rationale)*:
N/A

2g.3 Testing Results *(e.g., correlation statistics, comparison of rankings)*:
N/A

2g
C☐
P☐
M☐
N☐
NA☐

Comment [KP20]: 2g. If multiple data sources/methods are allowed, there is demonstration they produce comparable results.

2h. Disparities in Care

2h.1 If measure is stratified, provide stratified results *(scores by stratified categories/cohorts)*: N/A

2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:
N/A

2h
C☐
P☐
M☐
N☐
NA☐

Comment [KP21]: 2h. If disparities in care have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results (e.g., by race, ethnicity, socioeconomic status, gender);OR rationale/data justifies why stratification is not necessary or not feasible.

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Scientific Acceptability of Measure Properties*?

2

Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties*, **met?**
Rationale:

2
C☐
P☐
M☐
N☐

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)

Eval Rating

3a. Meaningful, Understandable, and Useful Information

3a.1 Current Use: In use

3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (*If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years*):
The Leap Frog Group, United Health Services, and BCBSA use the PCI RAM in calculating scores, and the scores and/or designation resulting from the scores are reported to plan members.

A description of the methods used by BCBSA to designate "Blue Distinction Centers for Cardiac Care" using this measure (as well as others) is provided here: http://www.bcbs.com/innovations/bluedistinction/blue-distinction-cardiac/cardiacmid-levelselection-criteria.pdf

3a.3 If used in other programs/initiatives (*If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years***):**
Used for QI by NCDR CathPCI Registry participating institutions. For Q2 of 2010, 1174 institutions submitted data.Participating institutions receive an institutional outcomes report each quarter with their hospital´s data. Over 2000 metrics are included in each hospital´s outcomes report. 26 metrics are highlighted in the report executive summary. These metrics are selected by an NCDR panel of experts as presenting the greatest opportunity for care improvement. CathPCI "metrics", including this measure, appear in the executive summary of the outcomes report. Hospitals receive their measure score, as well as the rates for all hospitals in the CathPCI registry, and all hospitals in the same comparison group (based on volume), and the rate for the 90th percentile. A box and whisker plot is displayed for each metric to show hospitals how they compare to all hospitals in
the CathPCI registry.

3a
C☐
P☐
M☐
N☐

Comment [KP22]: 3a. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audience(s) for both public reporting (e.g., focus group, cognitive testing) and informing quality improvement (e.g., quality improvement initiatives). An important outcome that may not have an identified improvement strategy still can be useful for informing quality improvement by identifying the need for and stimulating new approaches to improvement.

This measure is also provided to the Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2) and Hospital Corporation of America (HCA) for incorporation in their QI program efforts.

Testing of Interpretability (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*)
3a.4 **Data/sample** *(description of data/sample and size)*: 1. 61 NCDR CathPCI Registry participants, Fall 2009.

2. Beta testing for version 4 of the CathPCI Registry institutional outcomes report, 80 sites

3a.5 **Methods** *(e.g., focus group, survey, QI project)*:
1. Survey
2. Sites provided feedback through an excel template

3a.6 **Results** *(qualitative and/or quantitative results and conclusions)*:
1. 96.2% responded yes to the question "Will this measure provide important information to you?"
2. Sites provided feedback on the institutional outcomes report that was used to modify the report. Sites provided feedback on
invalid data and aspects of the report that were unclear.

3b/3c. Relation to other NQF-endorsed measures

3b.1 **NQF # and Title of similar or related measures:**
#535: 30-day all-cause risk-standardized mortality rate of percutaneous coronary intervention (PCI) for patients without ST segment elevation myocardial infarction (STEMI) and without cardiogenic shock (CMS) and #536:30-day all-cause risk-standardized mortality rate of Percutaneous Coronary Intervention (PCI) for patients with ST segment elevation myocardial (STEMI) or cardiogenic shock (CMS)

(for NQF staff use) **Notes on similar/related endorsed or submitted measures:**

3b. Harmonization
If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population):
3b.2 **Are the measure specifications harmonized? If not, why?**
The overall methodological approach for developing the NCDR measure is similar to that used by the CMS endorsed NQF measures # 0535 and 0536. All three measures explored the same candidate variables for risk adjustment (the NCDR measure identified a larger number of prognostically important variables). The variables in all three measures are harmonized in that they use the same clinical registry data elements and definitions (derived from the NCDR CathPCI Registry). The NCDR model provides one measure for all patients while the CMS measures stratifies PCI patients into STEMI/shock cohorts.

3b C☐ P☐ M☐ N☐ NA☐

3c. Distinctive or Additive Value
3c.1 **Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:**
The CMS and NCDR measures complement each other by having different, but clinically important, endpoints (inpatient and 30 day mortality). While the CMS measure is restricted to Medicare beneficiaries, the NCDR measure is applicable to patients regardless of payer.

5.1 **If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:**

3c C☐ P☐ M☐ N☐ NA☐

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Usability*? **3**

Steering Committee: Overall, to what extent was the criterion, *Usability*, met? **3** C☐ P☐ M☐ N☐
Rationale:

4. FEASIBILITY

Comment [KP23]: 3b. The measure specifications are harmonized with other measures, and are applicable to multiple levels and settings.

Comment [k24]: 16 Measure harmonization refers to the standardization of specifications for similar measures on the same topic (e.g., *influenza immunization* of patients in hospitals or nursing homes), or related measures for the same target population (e.g., eye exam and HbA1c for *patients with diabetes*), or definitions applicable to many measures (e.g., age designation for children) so that they are uniform or compatible, unless differences are dictated by the evidence. The dimensions of harmonization can include numerator, denominator, exclusions, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.

Comment [KP25]: 3c. Review of existing endorsed measures and measure sets demonstrates that the measure provides a distinctive or additive value to existing NQF-endorsed measures (e.g., provides a more complete picture of quality for a particular condition or aspect of healthcare, is a more valid or efficient way to measure).

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	Eval Rating
4a. Data Generated as a Byproduct of Care Processes 4a.1-2 **How are the data elements that are needed to compute measure scores generated?** Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition), Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)	**4a** C☐ P☐ M☐ N☐
4b. Electronic Sources 4b.1 **Are all the data elements available electronically?** (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*) Yes 4b.2 **If not, specify the near-term path to achieve electronic capture by most providers.**	**4b** C☐ P☐ M☐ N☐
4c. Exclusions 4c.1 **Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?** No 4c.2 **If yes, provide justification.**	**4c** C☐ P☐ M☐ N☐ NA☐
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences 4d.1 **Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.** The NCDR program takes a number of steps to minimize any potential for inaccuracies or errors in data used to report on performance back to hospitals. The process begins with support provided to data abstractors, including webinars, meetings, resource guides on the website, and clinical quality consultants available via e-mail or toll free phone number, to ensure consistent data collection. The NCDR establishes a unified electronic platform for data capture and submission that includes a certification process of the technical data collection tool selected by the hospital (either a commercially available software vendor product, the NCDR's own web base data collection tool, or a hospital's customized electronic medical record system) that must occur prior to any data submissions. The certification process provides edit checks of data elements within data collection tool to ensure high quality data submission. The NCDR data submission process includes a Data Quality Report (DQR) process that checks for validity in submissions based upon predetermined thresholds for element and composite completeness. The NCDR is putting in place a new strategy to systematically review the DQR results. The NCDR on-site audit program has been developed to assess reliability of data abstraction. This annual process reviews key elements at a select number of patient reports at the select number of sites and provides feedback scores to the hospitals.	**4d** C☐ P☐ M☐ N☐
4e. Data Collection Strategy/Implementation 4e.1 **Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:** Beta testing with a set of registry participants takes place with each new registry version to identify errors in the data collection tool. In addition, modifications are made to metrics based on feedback during a public comment period. The Data Quality Report (DQR) program has been developed to ensure data are valid and complete. The DQR is a process for submitting data files to the NCDR®. Participants use their data collection	**4e** C☐ P☐ M☐ N☐

Comment [KP26]: 4a. For clinical measures, required data elements are routinely generated concurrent with and as a byproduct of care processes during care delivery. (e.g., BP recorded in the electronic record, not abstracted from the record later by other personnel; patient self-assessment tools, e.g., depression scale; lab values, meds, etc.)

Comment [KP27]: 4b. The required data elements are available in electronic sources. If the required data are not in existing electronic sources, a credible, near-term path to electronic collection by most providers is specified and clinical data elements are specified for transition to the electronic health record.

Comment [KP28]: 4c. Exclusions should not require additional data sources beyond what is required for scoring the measure (e.g., numerator and denominator) unless justified as supporting measure validity.

Comment [KP29]: 4d. Susceptibility to inaccuracies, errors, or unintended consequences and the ability to audit the data items to detect such problems are identified.

Comment [KP30]: 4e. Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, etc.) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use).

tool software to create a submission file which is uploaded to the NCDR website. After uploading, the data in the file is automatically checked for errors and completeness.Passing the DQR ensures well-formed data and a statistically significant submission. Types of errors detected by the DQR include: Schema:Structure doesn't match NCDR requirements Dates: Inconsistent dates Selection: Missing or mismatched data; Can be a parent/child errors where a field requests more data. Outlier: Anomalies or exceptions; Data exceeds the possible limits. For example: 1,000mm length lesion. Counter: errors deal with Closure Methods, Lesions, and Intracoronary Devices. Each one has a counter, when more than one is used List: Missing data in the Medications or either Device lists. Data is submitted on a quarterly basis. If a submission does not pass the DQR process, the entire submission is excluded from benchmarking. Hospitals may resubmit to pass the DQR process. Data is submitted on a quarterly basis. If a submission does not pass the DQR process, the entire submission is excluded from benchmarking. Hospitals may resubmit to pass the DQR process. 4e.2 **Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:** CathPCI Registry participants pay a fee of $3,800/year to enroll in the registry. Staff resources are needed for data collection and submission at the participating institution. Registry site managers/data collectors undergo (non-mandatory) training offered by the NCDR. 4e.3 **Evidence for costs:** http://www.ncdr.com/WebNCDR/ncdrdocuments/B08352N%20CathPCI%20Registry%20Enrollment%20Packet%20Complete.pdf 4e.4 **Business case documentation:**	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility*?	**4**
Steering Committee: Overall, to what extent was the criterion, *Feasibility*, **met?** **Rationale:**	**4** **C☐** **P☐** **M☐** **N☐**
RECOMMENDATION	
(for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.**	**Time-limited ☐**
Steering Committee: Do you recommend for endorsement? **Comments:**	**Y☐** **N☐** **A☐**
CONTACT INFORMATION	
Co.1 **Measure Steward (Intellectual Property Owner)** Co.1 **Organization** American College of Cardiology, 2400 N Street, NW, Washington, District Of Columbia~12:District Of Columbia, 20037 Co.2 **Point of Contact** Susan, Fitzgerald, sfitzger@acc.org, 240-620-5444-	
Measure Developer If different from Measure Steward Co.3 **Organization** American College of Cardiology, 2400 N Street, NW, Washington, District Of Columbia, 20037	

Co.4 **Point of Contact**
Susan, Fitzgerald, sfitzger@acc.org, 240-620-5444-

Co.5 **Submitter If different from Measure Steward POC**
Susan, Fitzgerald, sfitzger@acc.org, 240-620-5444-, American College of Cardiology

Co.6 **Additional organizations that sponsored/participated in measure development**

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 **Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.**
CathPCI Steering Committee:
Douglas Weaver, MD, FACC
Ronald Krone, MD, FACC
Gregory Dehmer, MD, FSCAI
John Messenger, MD, FACC
Lloyd Klein, MD, FACC
John Rumsfeld, MD, PhD, FACC
John Carroll, MD, FACC
Mauro Moscucci, MD, FACC
Jeffrey Popma, MD, FACC
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Kirk Garratt, MD, FSCAI
David Malenka, MD, FACC

RAM workgroup:
John Spertus MD
Kalon Ho MD
Ronald Krone MD
Eric Peterson MD
John Rumsfeld MD
Richard Shaw PhD
Mandeep Singh MBBS
William Weintraub MD
Liz Delong PhD

Ad.2 **If adapted, provide name of original measure:**
Ad.3-5 **If adapted, provide original specifications URL or attachment**

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.6 **Year the measure was first released:** 2005
Ad.7 **Month and Year of most recent revision:** 07, 2008
Ad.8 **What is your frequency for review/update of this measure?** Every 3-4 years or if guideline updates warrant more frequent update, or with new dataset version.
Ad.9 **When is the next scheduled review/update for this measure?** 06, 2011

Ad.10 **Copyright statement/disclaimers:**

Ad.11 -13 **Additional Information web page URL or attachment:**

Date of Submission (*MM/DD/YY*)**:** 01/13/2011

Page 3: [1] Comment [k5] **Karen Pace** **10/5/2009 8:59:00 AM**

4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., mammography) or measures for multiple care processes that affect a single outcome.

NCDR™ National Cardiovascular Data Registry

CathPCI Registry®

UNDERSTANDING RISK ADJUSTED MORTALITY (RAM) IN THE CATHPCI REGISTRY®

The CathPCI Registry® is the oldest of several registries in the National Cardiovascular Data Registry™ (NCDR™). Operated by the American College of Cardiology (ACC), which is a professional association for cardiologists, this Registry is a voluntary data registry in which participating hospitals collect and submit data about patients who had a diagnostic coronary catheterization and/or a percutaneous coronary intervention (PCI); in return, the hospitals receive detailed reports comparing their demographics, co-morbid conditions, cardiac status, coronary anatomy as well as process and outcome measures, as compared to aggregated data.

Hospitals' different patient populations reflect differences in patient risk factors prior to PCI; these differences will affect outcomes, notably patient mortality. In a similar fashion, the impact of treatment upon outcomes will vary among hospitals. Thus, variations in outcomes among hospitals make it imperative that mortality outcomes be made comparable using a risk-adjusted mortality (RAM) model.

Since mortality is the most important and widely used indicator of outcomes and quality of care, reporting hospital risk adjusted outcomes is crucial to hospitals' understanding of their treatment quality. The RAM model offers participating hospitals the ability to monitor outcomes of their patients undergoing PCI and to compare their outcomes to the overall experience reported in the Registry. By accounting for patient risk factors and hospital treatment, risk adjustment "levels the playing field" among participating institutions.

The RAM model was first applied to data for the years 1998 to 2000. To assure its validity and reassess clinical variables, it was substantially revised in 2007-2008. This current, substantially revised model was developed by the RAM Work Group, comprised of NCDR committee members who have expertise in epidemiology, biostatistics and coronary interventions. Analysis was performed by the Duke Clinical Research Institute. To develop the model, the Work Group had the following goals:

- Assess the quality of the data collected for the registry;
- Define the patient population for inclusion in the model;
- Select elements/clinical variables associated with PCI mortality;
- Compute a risk score for individual patients based on the presence of elements/clinical variables;
- Aggregate individual patient risk scores into a risk adjustment mortality model.

The new model was developed using patients discharged between January 1, 2004 and March 31, 2006. A total of 309,351 consecutive patients undergoing PCI at 470 hospitals in the United States were entered into the NCDR™ Cath Lab Module, version 3.04.

Upon implementation of the RAM model, several statistics are computed that allow for comparison between your institution and the Registry. In the NCDR report provided to each institution, observed, predicted, and adjusted mortality are presented.

DATA COLLECTION AND DATA QUALITY

The validity of risk adjustment models is almost entirely dependent on the accuracy and completeness of the dataset on which the models are based.

Inclusion criteria assess the level of completeness on key elements/clinical variables used in the model. There are 2 complementary components to Data Quality Program:

- The Data Quality Report (DQR) program: The DQR program assesses the completeness of data submitted by participating hospitals. Hospitals must achieve a high level of completeness (>95% completeness of specific data elements identified as 'core fields' which encompass the variables included in our risk adjustment models) in order to have their data analyzed in the RAM model, and to be included in the aggregated data. The process is iterative, providing hospitals with the opportunity to correct errors and resubmit data for review.
- The Data Audit Program (DAP). The DAP consists of annual on-site chart review and data abstraction. Among participating hospitals, a certain number are randomly selected to participate in the DAP. The audits focus on variables that are associated with PCI mortality including demographics, co morbidities, cardiac status, coronary anatomy, and PCI status. In most audits, the median agreement between submitted and audited values is 92%.

POPULATION DEFINITION

Who is included:

1. Data submissions that passed the data quality completeness checks;
2. Patient admissions with a PCI procedure performed during admission.

Who is excluded:

1. NCDR Registry patients who did not have a PCI (Patient admissions with a diagnostic cath only during that admission);
2. Data submissions that do not pass the data quality and completeness reports;

3. Procedure variables for subsequent PCIs during the same admission (if the patient had more than one PCI procedure during that admission).
4. Patient admissions with PCI who transferred to another facility on discharge;
5. Patient admissions with PCI who have more than two variables in the risk model that are missing. Note: If one or two variables are missing, the value is imputed for certain characteristics (see appendix 2 of the NCDR CathPCI Registry PCI Risk Adjusted Morality Model 2008 for more information). If the value is missing for more than two variables, the patient record is excluded. However, in our data quality program, all variables in the risk model have a high "inclusion" criteria. This means that, when a hospital submits data to us, they need to have a high level of completeness (around 99%) for those variables. If they are not able to meet the criteria in our data quality program, they do not receive risk adjusted mortality for the records they submitted for that quarter.

Patients with a first PCI procedure performed during an admission were included in the study population. After excluding 6,334 transfer-out patients and 39 patients who were missing more than 2 candidate variables for the mortality model, 302,958 patients with PCI procedures at 470 participating NCDR centers remained in the analysis population. Sixty percent of patients (n=181,775) were chosen at random for the model development, while the remaining 40% were taken as the first validation sample. The overall population (the development sample plus two validation samples) includes 588,398 admissions at 635 sites.

VARIABLE SELECTION

Before proceeding with developing a multivariate model, univariate analysis was used to identify the factors that had both clinical and statistical (i.e. p-value < 0.05) significance. A multivariate logistic regression with backward selection method was then performed to identify the predictive variables. The selection criterion was set to 0.05.

Weights were assigned to risk factors or variables reflecting the strength of their association to PCI in-hospital mortality. Each patient in a facilities submission is given a risk score to predict risk of in-hospital mortality and accurately report risk adjusted mortality rates during hospitalization.

The most noteworthy risk factors or variables include:

1. ST-segment elevation MI defined as a patient who had a STEMI on admission, with an onset within 24 hours, or the procedure indication was primary, rescue or facilitated PCI.
2. Discharge status (alive or expired). The interaction between this variable with other variables were key in the analysis.
3. The glomerular filtration rate (GFR) variable is calculated using abbreviated MDRD formula [GFR = 186 × (last creatinine)-1.154 × (age)-0.203 × (gender factor) × (race factor) where (gender factor) = 1 for male and 0.742 for female, (race factor) = 1.21 for black and 1 for others].

4. The body mass index (BMI) (kg/m2) is calculated from height (cm) and weight (kg): BMI = weight × 10000 / (height) 2.

Variables coded on admission include:

1. Age (<= or >70),
2. Body mass index (calculated using height and weight),
3. Cardiogenic shock on admission.
4. Previous history of congestive heart failure (CHF),
5. Previous valvular surgery,
6. Cerebrovascular disease,
7. Peripheral vascular disease,
8. Diabetes (and type of control),
9. Chronic lung disease,
10. Previous PCI,
11. Glomerular filtration rate (calculated using creatinine, age, sex and race),
12. Dialysis,
13. NYHA classification

Variables coded during the procedure include:

1. Pre-procedure IABP,
2. Ejection Fraction %;
3. PCI Status (urgent, emergency, salvage);
4. Coronary lesion >50% with subacute thrombosis;
5. Pre-procedure TIMI flow;
6. Highest lesion risk using SCAI lesion classification;
7. Lesion location (e.g. proximal LAD)

COMPUTING OBSERVED MORTALITY RATES

Observed mortality rates (OMR) represent an unadjusted measure of mortality. OMR was computed by dividing the number of patients who died in the hospital during or following a PCI by the number of patients who had PCI procedures performed during 2004-2006. For example, if an institution had 1,275 procedures in the Registry and 19 patients died, the OMR would be 1.5% (19/1275). Please note that this rate does not account for differences in patient risk.

COMPUTING EXPECTED MORTALITY RATES

To better assess the probability of death for each PCI patient prior to his or her procedure an expected mortality rate (EMR) was calculated. The EMR for each institution was determined by using a multivariate logistic regression mortality model. This was accomplished by summing the predicted probabilities of death that were calculated for each PCI patient from that institution and dividing by the total number of patients from that institution who had PCI procedures. The resulting rate represents what the model predicted as the mortality rate for an institution given the existence of risk factors for each patient, and the sum of the weights assigned by the model for

those risk factors. Because the regression model had been developed on the only 60% of the registry data (the remaining 40% were taken as the first validation sample), the overall EMR of all the patients in the registry was not exactly but nearly equal to the OMR of the registry (1.2%).

COMPUTING RISK-ADJUSTED MORTALITY RATES

The Risk-Adjusted Mortality Rate (RAMR) represents the mortality, based on the associated logistic regression model, that an institution would be predicted to have if the institution performed PCI on a randomly selected group of patients taken from the Registry experience. Statistically, if one were to randomly select 100 patients having PCI from the 301,118 patients in the Registry, the mortality of this group would be close to 1.2%.

Mathematically, the RAMR was calculated by taking the OMR for each institution and dividing it by the EMR for that institution, and multiplying the resulting ratio by the overall mortality rate for the entire registry (1.2%). Three scenarios are possible; either the institution's RAMR is higher, lower, or about the same as the overall Registry experience. Table 1 provides specific examples of the application of the calculations described above.

Table 1. Risk Adjustment

	INSTITUTION A	***INSTITUTION B***	***INSTITUTION C***	***NCDR™***
# PCI Procedures	1006	2240	968	588,398
# Deaths	20	25	9	7,123
OMR	1.99%	1.12%	0.93%	1.21%
EMR	1.77%	1.43%	0.93%	1.23%
OMR/EMR	1.12	0.783	1.00	0.984
RAMR	$1.12 \times 1.21\%$ 1.36%	$0.783 \times 1.21\%$ 0.95%	$1.00 \times 1.21\%$ 1.21%	$(1.21\%/1.23\%) \times 1.21\%$ 1.19%

INTERPRETING THE RAMR

An explanation of how to interpret your RAMR based on this model is outlined below. All examples refer back to Table 1.

STATISTIC	***INTERPRETATION***
OMR/EMR > 1	When the ratio of the OMR to EMR is greater than 1, the institution had an observed mortality for its patents that was greater than their expected mortality. In this scenario, adjusting for the risk of a group of patients similar

STATISTIC	*INTERPRETATION*
	to those found in the Registry, Institution A would have an adjusted mortality greater than 1.21%.
OMR/EMR <1	When the ratio of the OMR to EMR is less than 1, the institution had an observed mortality for its patents that was less than their expected mortality. In this scenario, adjusting for the risk of a group of patients similar to those found in the Registry, Institution B would have an adjusted mortality lower than 1.21%.
OMR/EMR =1	When the ratio of the OMR to EMR is close to 1, the institution had an observed mortality for its patents that was exactly what was expected. In this scenario, adjusting for the risk of a group of patients similar to those found in the Registry, Institution C would have an adjusted mortality rate of 1.21%.

LIMITATIONS

While the new NCDR model can provide quite accurate assessment of PCI mortality risks in the modern era and have application for informed clinical decision making as well as for appropriate risk adjusted hospital outcome comparisons, there are limitations. Some limitations include voluntary participation, limited auditing of data source (fewer than 5% of participating hospitals), no external validation of model, standardized angiographic data, no data on functional status and outcomes limited to in-hospital mortality. The factors used and the weights obtained from this analysis are model-specific. That is, the adjusted mortality from this analysis may not correspond exactly to that generated from other models. As a corollary, the absence of reported deaths will affect the RAMR.

There are challenges in interpreting the RAMR that must be kept in mind when reviewing your institutional results. Variation in volume from one institution to the next may influence that institution's EMR. For example, very high mortality rates may occur due to chance alone. This is particularly true for low volume institutions. Large differences between observed and expected mortality rates at institutions with small sample sizes may be due primarily to sampling variability. In addition, these risk-adjusted rates may be misleading because the overall pre-procedural severity of illness may not be accurately estimated if significant risk factors are missing. In contrast to cardiac surgery, the occurrence of the outcome of interest (in-hospital mortality) occurs very infrequently. This makes it extremely difficult to develop stable risk adjustment models and hinders the ability to apply these models to local datasets. Any risk-adjustment analysis and comparison will need to consider the number of cases upon which the predictions are based and refrain from over-interpreting results based on small sample sizes.

USING RISK ADJUSTED DATA - WHAT DOES IT MEAN?

How should risk adjusted data be used by participants? Obviously, most concern is generated when an institution has a RAMR that is substantially higher than the overall Registry mortality. The ratio between OMR and EMR for most institutions will vary somewhere between 0.7 and 1.3.

For institutions with OMR/EMR ratios greater than 1.3, there are a number of things the institutions might consider. First and foremost, the institution should not assume there is a problem with the quality of their program or the quality of the physicians involved with their program. The institution must embark on a systematic analysis of the data that was submitted to the NCDR. Three major areas should be addressed:

1. Missing Data

    - Are there substantial amounts of missing data on the factors used in the regression model? If so, are there ways to obtain that data on the current patients and insure that these variables are collected in the future?

2. Data Accuracy

    - The second level of analysis should involve the accuracy of the data. If a risk factor is missing when in fact the patient actually had the risk factor, the expected mortality will be lower and the adjusted morality will be higher than it should be. One approach to evaluate this situation is to take a random sample of cases and determine if the risk factors were coded correctly on these patients. If variance is found, what is the source of the variance? Are there ways to correct this problem? Is more education of coders necessary? Are definitions not being interpreted correctly? It is also possible that in settings where multiple people complete the data forms that some coders are applying the definitions differently than others. In this situation, it may be helpful to have ongoing meetings to discuss definitions and periodically have everyone code test cases and compare the results. Additionally, the NCDR™ Core Data Element FAQ is an important resource for data collectors while they interpret the definitions for differing case scenarios.

3. Data Collection and Entry

    - The third level of analysis should involve the processes around collection and entry of the data into the local database. Are the forms correct, but mistakes are being made on data entry? Is the database dependent on electronic interfaces from other data sources that may be incorrect? Are the interfaces populating data correctly in the local database? All of these areas are sources of error that can have significant impact on the accuracy of the data collected.

It is likely that any serious problems in one or more of the three areas above could have a substantial impact on the calculation of RAMR. The institution should contact the NCDR to discuss these issues and determine a course of action for future submissions to the Registry.

It is also important to remember that all mortality estimates are based on three years of data. We recommend that institutions refrain from making any major program decisions based on these results until several years of data are available for comparison.

Institutions that have a ratio of OMR/EMR of 0.7 or less also need to approach the use of this information with caution. As was stated earlier, chance variation related to sampling may affect these models. It is recommended that institutions wait for several years of data and observe their results over time.

As the overall Registry experience grows and the quality of the data improve, these risk adjustment models will become more stable and the results for individual institutions will be based on a larger volume of cases.

For other questions about PCI RAM, contact our CathPCI Registry Support Center at

ncdr@acc.org; or (800) 257-4737.

Specifications for the Updated 2009 NCDR® CathPCI Registry®
PCI In-Hospital Risk Adjusted Mortality Measure

Measure Specifications	
Numerator	Patients with a PCI procedure performed during admission who expired
Denominator	Patients with a PCI procedure performed during admission
Inclusion Criteria	Data submissions that passed the data quality completeness checks. Patient admissions with a PCI procedure performed during admission.
Exclusion Criteria	1. NCDR Registry patients who did not have a PCI (Patient admissions with a diagnostic cath only during that admission); 2. Data submissions that do not pass the data quality and completeness reports; 3. Procedure variables for subsequent PCIs during the same admission (if the patient had more than one PCI procedure during that admission). 4. Patient admissions with PCI who transferred to another facility on discharge; 5. Patient admissions with PCI who have more than two variables in the risk model that are missing. Note: If one or two variables are missing, the value is imputed for certain characteristics (see appendix 2 of the NCDR CathPCI Registry PCI Risk Adjusted Morality Model 2008 for more information). If the value is missing for more than two variables, the patient record is excluded. However, in our data quality program, all variables in the risk model have a high "inclusion" criteria. This means that, when a hospital submits data to us, they need to have a high level of completeness (around 99%) for those variables. If they are not able to meet the criteria in our data quality program, they do not receive risk adjusted mortality for the records they submitted for that quarter.
Period of Assessment	Quarterly, to include previous four quarters of data
Source of Data	CathPCI Registry – v3
Method of Reporting	ACC-NCDR® CathPCI Registry™ Institutional Reports
Clinical Rationale/ Recommendation	Although death in patients with serious heart disease is not completely unexpected, that rate (adjusted for case mix/patient risk factors) is sensitive to a number of controllable factors such as case selection, procedural judgment and operator skill, as well as institutional support and overall quality of care. The ACC-NCDR® risk adjustment model analyzes multiple elements to account for patient risk factors that are present prior to PCI. Risk adjustment “levels the playing field” among participating institutions and adjusts the “actual” mortality rate based on these factors. In other words, if you have several very sick patients die, your risk adjusted mortality rate would be lower than your actual mortality rate. If you had several very healthy patients die unexpectedly, your risk adjusted mortality rate would be higher than your actual mortality rate. Please refer to the detail section of the report and the risk adjustment technical notes for more information. Weights were assigned to risk factors or variables reflecting the strength of their association to PCI in-hospital mortality. Each patient

Measure Specifications	
	in a facilities submission is given a risk score to predict risk of in-hospital mortality and accurately report risk adjusted mortality rates during hospitalization. The most noteworthy risk factors or variables in the model include: 1. ST-segment elevation MI defined as a patient who had a STEMI on admission, with an onset within 24 hours, or the procedure indication was primary, rescue or facilitated PCI. 2. Discharge status (alive or expired). The interaction between this variable with other variables were key in the analysis. 3. The glomerular filtration rate (GFR) variable is calculated using abbreviated MDRD formula [GFR = 186 × (last creatinine)-1.154 × (age)-0.203 × (gender factor) × (race factor) where (gender factor) = 1 for male and 0.742 for female, (race factor) = 1.21 for black and 1 for others]. 4. The body mass index (BMI) (kg/m2) is calculated from height (cm) and weight (kg): BMI = weight × 10000 / (height) 2. Other variables: Variables coded on admission: Age (<= or >70), Body mass index, Cardiogenic shock on admission. Previous history of CHF, previous valvular surgery, cerebrobascular disease, peripheral vascular disease, diabetes (and type of control), chronic lung disease, previous PCI, glomerular filtration rate, dialysis, NYHA Variables coded during the procedure – Pre-procedure IABP, Ejection Fraction %; PCI Status; Coronary lesion >50% with subacute thrombosis; Pre-procedure TIMI flow; Lesion risk using SCAI lesion classification; lesion location (e.g. proximal LAD)
Relevant Citations	Refer to the document: NCDR CathPCI Registry PCI Risk Adjusted Morality Model 2008 for further description of the model.
Background	The risk adjusted mortality model was first developed in 2002 using NCDR data from 1998-2000. That model was revised in 2008. A committee of ACC physicians provided independent oversight and input to the Duke Clinical Research Institute who developed and tested the revised model, which is being implemented in 2009 institutional reports.

Contemporary Mortality Risk Prediction for Percutaneous Coronary Intervention: Results From 588,398 Procedures in the National Cardiovascular Data Registry

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Contemporary Mortality Risk Prediction for Percutaneous Coronary Intervention

Results From 588,398 Procedures in the National Cardiovascular Data Registry

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Durham, North Carolina; Rochester, Minnesota; San Francisco, California; Boston, Massachusetts; Chicago, Illinois; St. Louis, Missouri; Newark, Delaware; and Denver, Colorado

Objectives We sought to create contemporary models for predicting mortality risk following percutaneous coronary intervention (PCI).

Background There is a need to identify PCI risk factors and accurately quantify procedural risks to facilitate comparative effectiveness research, provider comparisons, and informed patient decision making.

Methods Data from 181,775 procedures performed from January 2004 to March 2006 were used to develop risk models based on pre-procedural and/or angiographic factors using logistic regression. These models were independently evaluated in 2 validation cohorts: contemporary (n = 121,183, January 2004 to March 2006) and prospective (n = 285,440, March 2006 to March 2007).

Results Overall, PCI in-hospital mortality was 1.27%, ranging from 0.65% in elective PCI to 4.81% in ST-segment elevation myocardial infarction patients. Multiple pre-procedural clinical factors were significantly associated with in-hospital mortality. Angiographic variables provided only modest incremental information to pre-procedural risk assessments. The overall National Cardiovascular Data Registry (NCDR) model, as well as a simplified NCDR risk score (based on 8 key pre-procedure factors), had excellent discrimination (c-index: 0.93 and 0.91, respectively). Discrimination and calibration of both risk tools were retained among specific patient subgroups, in the validation samples, and when used to estimate 30-day mortality rates among Medicare patients.

Conclusions Risks for early mortality following PCI can be accurately predicted in contemporary practice. Incorporation of such risk tools should facilitate research, clinical decisions, and policy applications. (J Am Coll Cardiol 2010; 55:1923–32) © 2010 by the American College of Cardiology Foundation

Percutaneous coronary intervention (PCI) has become one of the most widely applied treatments in current-day cardiology, facilitating the relief of angina and (in the setting of acute ST-segment elevation myocardial infarction [STEMI]), saving lives (1). Although the periprocedural complications of PCI have declined over time, tangible risks remain. Estimating patients' PCI mortality risk is important for several reasons. At the individual-patient level, knowing one's procedural risk can help physicians and patients make informed clinical decisions (2). Identification and quantification of clinical factors associated with procedural risk can also facilitate observational comparative effectiveness research (3). Finally, at a policy level, predicted risk estimates

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Abbreviations and Acronyms

BMI = body mass index

CathPCI = catheterization percutaneous coronary intervention

CHF = congestive heart failure

CMS = Centers for Medicare and Medicaid Services

EF = ejection fraction

GFR = glomerular filtration rate

NCDR = National Cardiovascular Data Registry

NYHA = New York Heart Association

PCI = percutaneous coronary intervention

STEMI = ST-segment elevation myocardial infarction

can help "level the playing field" of provider outcome metrics, helping to adjust for potential differences in cases treated (4).

To date, several PCI mortality risk models have been published. Yet many have become outdated and do not reflect contemporary care or outcomes (5–13). Other risk models were developed on select populations and may not be generalizable (7–9,11,14–19). Additionally, many models failed to consider angiographic features that are associated with procedural risk (9,20,21). The National Cardiovascular Data Registry (NCDR) for catheterization percutaneous coronary intervention (CathPCI) provides the ideal infrastructure to derive procedure risk models in a national representative contemporary U.S. sample. This database has a very large patient population, contains rich and complete clinical information, and is reflective of contemporary practice.

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Using the NCDR CathPCI database, our goals were to: 1) develop PCI risk tools for estimating mortality risks for both elective and primary PCI; 2) determine the incremental prognostic value of angiographic details beyond preprocedural risk factors; 3) develop a simplified, user-friendly, PCI risk score; 4) internally validate the PCI risk model and risk score in important subpopulations; and 5) assess the models' ability to estimate 30-day PCI mortality risk among Medicare patients whose status is defined via claims data.

Methods

The NCDR CathPCI Registry database. The NCDR CathPCI Registry is cosponsored by the American College of Cardiology and the Society for Cardiovascular Angiography and Interventions (22,23). The registry catalogs data on patient characteristics, clinical features, angiographic and procedural details, and in-hospital outcomes. Participating centers agree to submit complete information and outcomes from consecutive interventional cases performed at their institutions. The NCDR also has a comprehensive data quality program, including data abstraction training, data quality thresholds for inclusion, site data quality feedback reports, independent auditing, and data validation (22). Data elements and definitions are available at: http://www.ncdr.com/WebNCDR/ELEMENTS.ASPX#1. The Duke Clinical Research Institute (DCRI) serves as the primary analytic center for the CathPCI Registry, and performed the analyses for this report.

Variable selection. The NCDR established a risk adjustment model committee of American College of Cardiology volunteers to provide oversight for model development, including input on candidate variable selection and review of the model results. This group strictly adhered to current standards of model creation (24). The outcome of interest for these models was all-cause in-hospital mortality. Candidate variables were selected based on their relevance, as identified in prior research, or as identified in the committee's clinical experience.

Missing data. The rates of overall missing data in the NCDR CathPCI database are very low. Of the final model variables, only ejection fraction (EF) percentage had more than a 5% rate of missing data. For those few cases that contained missing information, the following imputation rules were used: 1) for elements dealing with a patient's past medical history, use of a pre-procedural intra-aortic balloon pump, presence of subacute thrombosis, and coronary lesion with highest risk lesion, missing data were imputed to "no"; 2) for body mass index (BMI), missing values were imputed to the gender-specific median; 3) for glomerular filtration rate (GFR), missing values were imputed to the gender-, prior renal failure-, and STEMI-specific median; and 4) for EF, missing data were imputed by stratifying the population based on a history of congestive heart failure (CHF), prior myocardial infarction, pre-procedural cardiogenic shock, and the presence of STEMI. Neither age nor the Society for Cardiovascular and Angiography and Interventions Lesion Class were imputed. We also performed a sensitivity analysis using multiple imputation methods. However, these results were nearly identical to the overall findings and are, therefore, not presented.

Population definition. Two separate patient populations were identified: one for model development and one for prospective validation. For the model development phase, patients were included if they received their first PCI procedure at any of the 470 hospitals submitting PCI records between January 1, 2004, and March 30, 2006. Patients were excluded if they transferred out or were missing more than 2 candidate variables (Fig. 1). The model development population was further randomly allocated to an initial model development dataset (60% of total), and a second group (40% of total) was used for an initial validation sample. A second prospective validation sample was identified from cases performed at the 608 NCDR hospitals submitting PCI cases between March 31, 2006, and March 30, 2007, using the same inclusion and exclusion criteria as noted in the previous text (Fig. 1).

Additionally, we examined the robustness of our models to predict 30-day mortality, as opposed to in-hospital mortality, in a Medicare-eligible population (25). Since

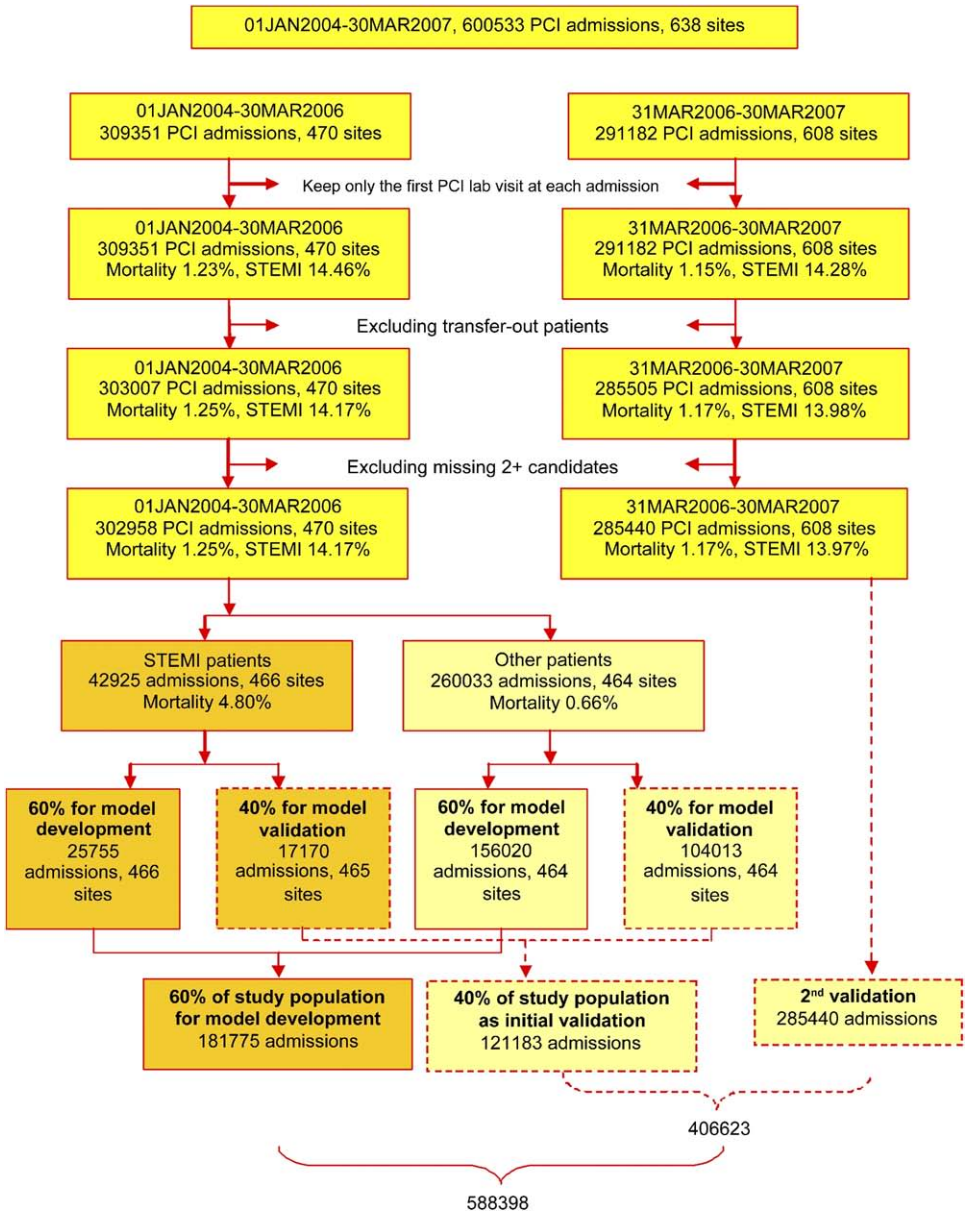

Figure 1 **Population Flow Diagram**

Between January 2004 and March 2007, 600,533 PCI admissions were recorded in the National Cardiovascular Data Registry (NCDR) Catheterization Percutaneous Coronary Intervention (CathPCI) Registry. Following exclusions, 588,398 total patients were included in the overall model development and validation cohort. STEMI = ST-segment elevation myocardial infarction.

outcomes beyond the initial hospital stay are not routinely collected in the NCDR, we linked NCDR records for those age 65 years or older to the national Centers for Medicare and Medicaid Services (CMS) inpatient claims data. The process used to do this has been previously described (26). For this specific linkage to occur, we began with Medicare-eligible NCDR CathPCI patients undergoing a PCI procedure between January 2005 and December 2006 (the last available data from CMS). Of the possible 348,370 records, we linked 253,081 records (72.7%), representing 204,111 unique patients. Baseline characteristics of the linked population and unlinked records were similar.

Statistical methods. An initial candidate variable list was generated using clinical judgment and prior known PCI risk factors. Univariate analysis was then used to identify which of the potential candidate variables had a statistical association with in-hospital mortality (e.g., $p < 0.05$). Based on this univariate analysis, the risk adjustment model committee selected the most clinically meaningful variables as potential candidates for inclusion in the multivariable

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model. Multivariate logistic regression with a backward selection method ($p < 0.05$ to remain in the model) was then performed to identify independent predictors of outcomes.

Three separate models were developed. First, a "full" model was created, which included all candidate variables (e.g., demographic, pre-catheterization clinical variables, and angiographic variables). Second, we contrasted this full model with a second "pre-cath" model, excluding detailed NCDR angiographic data. This second model assessed the incremental value of angiographic information for mortality prediction. Finally, we developed a "limited" pre-cath risk prediction model, which included only those variables with the strongest explanatory power based on their Wald chi-square value. The regression coefficients from the simplified pre-cath model were then converted into whole integers to create an NCDR CathPCI Risk Prediction score (27).

Model performance characteristics. After development, we applied these 3 models to the prospective validation

Table 1 Patient Clinical Characteristics

	Development (n = 181,775)	1st Validation (n = 121,183)	2nd Validation (n = 285,440)
Patient characteristics			
Age	63.9 ± 12.1	63.9 ± 12.1	64.1 ± 12.1
Female	33.4%	33.3%	33.3%
Caucasian	87.2%	87.1%	85.6%
BMI (kg/m^2)	29.6 ± 6.3	29.7 ± 6.3	29.8 ± 6.3
Prior MI (>7 days)	29.1%	29.1%	27.3%
Prior CHF	10.1%	10.0%	9.9%
Diabetes			
Noninsulin	21.5%	21.7%	22.3%
Insulin	10.0%	10.0%	10.3%
Mean GFR (MDRD)	73.6 ± 30.5	73.5 ± 29.0	73.2 ± 28.1
Dialysis	1.6%	1.5%	1.5%
Cerebral vascular disease	10.9%	11.1%	11.1%
Peripheral vascular disease	11.7%	11.7%	11.9%
CLD	16.0%	16.0%	15.8%
Prior PCI	35.1%	35.4%	36.6%
NYHA functional class IV	18.3%	18.3%	18.8%
Cardiogenic shock	1.9%	1.8%	1.7%
Hospital characteristics			
Number of beds	463 ± 221	463 ± 220	454 ± 225
Location			
Rural	12.6%	12.6%	12.1%
Urban	61.0%	61.3%	61.2%
Teaching	60.1%	60.0%	54.6%
Region			
West	14.1%	14.3%	16.2%
Northeast	9.0%	9.9%	10.4%
Midwest	36.9%	36.7%	35.8%
South	36.5%	36.8%	37.6%
Mean annual PCI volume	666 ± 550	668 ± 550	679 ± 573
Procedural characteristics			
LVEF	52.7 ± 12.7	52.7 ± 12.7	52.7 ± 12.7
PCI status			
Elective	49.3%	49.3%	50.2%
Urgent	36.1%	35.6%	34.7%
Emergency	14.4%	14.5%	15.0%
Salvage	0.2%	0.2%	0.2%
Highest risk coronary segment			
pLAD	18.2%	18.2%	18.2%
Left main	1.7%	1.8%	1.8%
TIMI flow grade 0	11.0%	10.7%	14.9%
Multivessel PCI	14.0%	13.9%	14.1%

BMI = body mass index; CHF = congestive heart failure; CLD = chronic lung disease; GFR = glomerular filtration rate; LVEF = left ventricular ejection fraction; MDRD = Modification of Diet in Renal Disease; MI = myocardial infarction; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; pLAD = proximal left anterior descending artery; TIMI = Thrombolysis In Myocardial Infarction.

Table 2 Unadjusted In-Hospital Mortality (%)

	Development (n = 181,775)	1st Validation (n = 121,183)	2nd Validation (n = 285,440)
Overall population	1.24	1.27	1.17
MI status			
STEMI	4.81	4.79	4.69
No STEMI	0.65	0.69	0.60
Gender			
Men	1.04	1.07	1.00
Women	1.63	1.67	1.50
Age group			
Age >70 yrs	2.25	2.32	2.02
Age ≤ 70 yrs	0.76	0.77	0.76
Diabetes status			
Diabetes	1.44	1.50	1.30
No diabetes	1.15	1.16	1.11

MI = myocardial infarction; STEMI = ST-segment elevation myocardial infarction.

sample sets. Model discrimination was assessed using the *c*-index. A model *c*-index can range from 0.50 (no predictive value) to 1.0 (perfect prediction). To assess model calibration, patients were rank-ordered from lowest- to highest-predicted risk. Comparison was then made of predicted versus observed event rates within risk strata. Model discrimination and calibration were assessed in the overall population, within the 2 validation samples, and among select subpopulations of both of these groups. Finally, we assessed the models' discrimination among patients age 65+ years who had been linked to CMS data to assess both in-hospital and 30-day mortality.

Results

Between January 2004 and March 2007, 600,533 consecutive PCI admissions were recorded in the NCDR CathPCI Registry. Following exclusions, 588,398 total patients were included in our overall model development and validation cohort. From this population, a model development sample (n = 181,775) was created from a random sample comprised of two-thirds the cases performed between January 2004 and March 2006. The final one-third of these cases was used to create a contemporary model validation sample (n = 121,183). Cases performed between March 2006 and March 2007 were used as a prospective validation sample (n = 285,440) (Fig. 1).

Table 1 provides demographic, clinical, and angiographic features of those patients in the development set, as well as in the 2 validation sets. The mean patient age was 64 years, 33% were female, 32% had diabetes mellitus, and 10% had a prior history of CHF. Overall, 51% of the patients underwent nonelective procedures, and 14% underwent multivessel PCI. The results were similar across the 3 samples, except that in-hospital mortality was slightly lower in the second prospective validation sample (1.17%), relative to the other 2 samples (1.24% and 1.27%).

Risk factors for in-hospital mortality. Table 2 provides observed in-hospital mortality rates for various patient subgroups. These mortality rates ranged from 0.65% in the non-primary PCI population to 4.81% in the STEMI population (Table 2). Older patients, women, and diabetic patients experienced higher unadjusted in-hospital mortality rates than younger patients, men, and non-diabetic patients (2.25% vs. 0.76%, 1.63% vs. 1.04%, and 1.44% vs. 1.15%, respectively).

Table 3 provides the final full model, which includes 21 separate clinical variables, as well as interaction terms for STEMI/shock, BMI, GFR, dialysis, New York Heart Association (NYHA) functional class, highest-risk lesion segment category, and PCI status. When model chi-square value was used as the metric, cardiogenic shock was the most predictive of in-hospital mortality, followed by renal function (estimated glomerular filtration rate [eGFR]) and age. In contrast, angiographic predictors were generally less prognostic. The angiographic feature most highly associated with in-hospital mortality was lesion location (e.g., left main lesions and proximal left anterior descending lesions).

NCDR PCI bedside risk prediction score. Predictors containing the strongest association with mortality are described in Table 3. These risk factors were then converted to an integer score (based on their relative magnitude of association with mortality), to create the NCDR CathPCI Risk Prediction Score (Table 4). Using this scoring system, the risk of in-hospital mortality can be estimated by summating point scores between 0 and 100.

Model performance. The full NCDR CathPCI Mortality Risk Prediction model in the contemporary and prospective validation cohorts performed exceptionally well, with a *c*-index of 0.925 and 0.924, respectively. Additionally, the full model performed well in each of the 8 predefined patient subgroups, with *c*-indices ranging from 0.892 to 0.930 (Table 5). Of note, the exclusion of angiographic details and EF from the full model resulted in only a slight decrement in the overall model accuracy. Similarly, there was limited loss in model discrimination when the model was transformed into the final, simplified NCDR CathPCI Risk Score, with *c*-indices of 0.901 and 0.905, respectively, in the validation samples. This simplified score also had good operating characteristics in all predefined patient subgroups.

Model calibration plots are shown in Figures 2 and 3. Notably, the majority of patients had a relatively low mortality risk (92.6% of patients had a predicted mortality risk between 0% and 2.5%). However, there was high concordance between model predicted risk and that which was actually observed. The simplified NCDR CathPCI Risk Score was also well calibrated in both low- and moderate-risk populations, with only a slight underestimation of predicted risk in high-risk patients (Fig. 3).

Finally, we examined the full and simplified models' ability to estimate 30-day mortality among patients age 65 years or older who had been linked to CMS data. Among 204,111 Medicare patients, 4,068 (1.99%) died in-hospital and 6,011 (2.94%) died within 30 days of the procedure.

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Table 3 Full and Pre-Cath Simplified Risk Models

	Full Model			Pre-Cath Model		
Label	Odds Ratio	95% Confidence Interval	Chi-Square	Odds Ratio	95% Confidence Interval	Chi-Square
Intercept			171.14			708.97
STEMI patients			1.77			44.55
Cardiogenic shock at admission	8.35	7.40–9.44	1,168.28	12.19	10.86–13.68	1,804.73
PCI status						
For STEMI						
Urgent	1.09	0.64–1.83	0.09	1.25	0.75–2.07	0.71
Emergency	2.07	1.30–3.31	9.24	2.65	1.68–4.18	17.58
Salvage	14.55	8.39–25.21	91.08	21.45	12.57–36.61	126.36
For no STEMI						
Urgent	2.01	1.70–2.39	63.91	2.49	2.11–2.95	114.46
Emergency	7.29	5.91–8.99	343.95	11.79	9.69–14.34	606.91
Salvage	82.54	45.83–148.63	216.24	146.55	82.60–260.04	290.59
Age*						
For age >70 yrs	1.71	1.57–1.88	125.80	1.76	1.60–1.91	150.93
For age ≤70 yrs	1.55	1.44–1.69	115.33	1.52	1.40–1.64	107.92
GFR*						
For STEMI	0.77	0.74–0.80	181.90	0.77	0.75–0.78	377.55
For no STEMI	0.82	0.78–0.85	100.96			
NYHA functional class IV						
For no STEMI	1.74	1.50–2.02	52.82	1.61	1.46–1.79	81.71
For STEMI	1.21	1.05–1.39	6.74			
Chronic lung disease	1.48	1.31–1.66	43.04	1.52	1.36–1.71	52.87
Peripheral vascular disease	1.53	1.35–1.74	42.39	1.67	1.48–1.89	67.78
Previous history of CHF	1.29	1.13–1.47	13.85	1.75	1.54–1.98	77.25
Ejection fraction percentage*	0.73	0.70–0.76	234.09			
Highest risk lesion: SCAI lesion class						
IV vs. I	2.05	1.70–2.47	57.40			
II or III vs. I	1.47	1.29–1.67	33.84			
Diabetes/control						
Insulin diabetes vs. no diabetes	1.78	1.53–2.07	56.24			
Noninsulin diabetes vs. no diabetes	1.11	0.98–1.25	2.47			
Highest risk lesion: segment category						
For STEMI						
Left main	5.54	3.43–8.93	49.26			
pLAD	1.52	1.26–1.83	19.00			
pRCA/mLAD/pCIRC	1.34	1.13–1.59	11.18			
Previous PCI	0.69	0.61–0.78	36.59			
BMI, kg/m^2†						
For no STEMI	0.76	0.69–0.83	33.91			
For STEMI	0.93	0.85–1.03	1.97			
Pre-op IABP	3.14	2.12–4.65	32.64			
For no STEMI						
pLAD	1.65	1.38–1.98	29.257			
Left main	2.33	1.71–3.17	28.586			
pRCA/mLAD/pCIRC	1.26	1.07–1.48	7.721			
Subacute thrombosis? Yes vs. no	1.96	1.41–2.72	16.21			
Cerebrovascular disease	1.26	1.11–1.44	12.02			
Previous vascular disease	1.58	1.10–2.26	6.02			
Highest risk pre-procedure	1.19	1.02–1.38	4.84			
TIMI flow = 0 vs. other						

*Per 10-U increase; †per 5-U increase.

IABP = intra-aortic balloon pump; mLAD = mid left anterior descending artery; pRCA = proximal right coronary artery; pCIRC = proximal left circumflex artery; SCAI = Society for Cardiovascular Angiography and Interventions; STEMI = ST-segment elevation myocardial infarction; other abbreviations as in Table 1.

Table 4 NCDR CathPCI Risk Score System

Variable	Scoring Response Categories				Total Points	Risk of In-Patient Mortality
Age	<60	≥60, <70	≥70, <80	≥80	0	0.0%
	0	4	8	14	5	0.1%
Cardiogenic shock	No	Yes			10	0.1%
	0	25			15	0.2%
Prior CHF	No	Yes			20	0.3%
	0	5			25	0.6%
Peripheral vascular disease	No	Yes			30	1.1%
	0	5			35	2.0%
Chronic lung disease	No	Yes			40	3.6%
	0	4			45	6.3%
GFR	<30	30–60	60–90	>90	50	10.9%
	18	10	6	0	55	18.3%
NYHA functional class IV	No	Yes			60	29.0%
	0	4			65	42.7%
PCI status (STEMI)	Elective	Urgent	Emergent	Salvage	70	57.6%
	12	15	20	38	75	71.2%
PCI status (no STEMI)	Elective	Urgent	Emergent	Salvage	80	81.0%
	0	8	20	42	85	89.2%
					90	93.8%
					95	96.5%
					100	98.0%

CathPCI = Catheterization Percutaneous Coronary Intervention; NCDR = National Cardiovascular Data Registry; other abbreviations as in Tables 1 and 3.

C-indices for the full model in this population were: $c = 0.90$ for in-hospital and $c = 0.86$ for 30-day mortality, respectively. *C*-indices for the Simplified Risk Score in this population were: $c = 0.89$ for in-hospital and $c = 0.83$ for 30-day mortality, respectively.

Discussion

Despite tremendous advances in PCI over the past decade, early periprocedural mortality remains a concern. Using data from the NDCR, we identified demographics, clinical factors, and angiographic features associated with PCI in-hospital mortality. These were summarized into a full risk model (with both pre-procedure and angiographic features) and a simplified 8-item NCDR CathPCI Risk Score, to support both robust hospital outcome comparisons and patient-level pre-procedural risk estimation, respectively. Both the full and simplified models retain their predictive accuracy in important patient subsets, in separate internal validation samples, and when estimating 30-day mortality in Medicare patients.

Several risk-adjustment models have been previously developed for the prediction of mortality following PCI. However, many of these were developed using data that predates the generalized use of stents and/or contemporary adjuvant antithrombotic therapy (5–13). Other models have been developed

Table 5 *C*-Indices for NCDR Models

	Sample, n	Full Model (Pre-Cath + Cath Factors)	Pre-Cath Model Only	NCDR Simplified Risk Score
Development	181,775	0.926	0.911	0.911
1st validation	121,183	0.925	0.905	0.901
2nd validation	285,440	0.924	0.910	0.905
Subgroups (in 2nd validation)				
STEMI	39,889	0.902	0.890	0.884
No STEMI	245,551	0.892	0.896	0.862
Women	95,106	0.911	0.897	0.893
Men	190,334	0.930	0.916	0.911
Age >70 yrs	92,381	0.901	0.886	0.88
Age ≤70 yrs	193,059	0.927	0.911	0.906
Diabetes	92,974	0.924	0.910	0.903
No diabetes	192,466	0.923	0.910	0.906

Cath = catheterization; NCDR = National Cardiovascular Data Registry; STEMI = ST-segment elevation myocardial infarction.

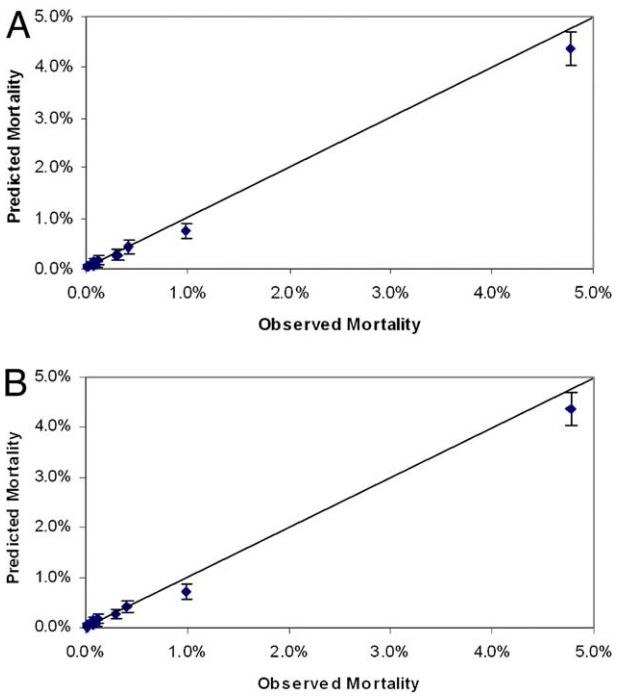

Figure 2 **Calibration for the Full Model Among Patients in the Validation Sample**

Demonstrates observed versus predicted mortality estimates (and the 95% confidence interval) for 10 equally sized risk groups of ST-segment elevation myocardial infarction **(A)** and non–ST-segment elevation myocardial infarction **(B)** patients, based on the full risk prediction model evaluated in the second validation sample.

from select referral centers or regional populations and may not be as generalizable across the nation (7–9,11,14–19). Still, other models were developed using databases that included only elderly patients, or used administrative data which lacked the clinical details necessary to capture the important clinical and angiographic risks factors associated with periprocedural mortality (9,20,21).

The models derived in this study expand on these prior models. First, the comprehensive and complete nature of the NCDR's clinical data allows for a more complete assessment of multiple risk predictors. For example, female sex has long been a feature predictive in many prior studies, yet this feature is no longer significantly associated with mortality after adjusting for multiple potential confounders (e.g., BMI, eGFR, and so on) and in the contemporary populations (28,29). Additionally, we have demonstrated that the inclusion of angiographic details (as they are defined in the NCDR CathPCI Registry) to a pre-cath risk prediction model, add marginal overall improvements in our ability to predict in-hospital mortality. Rather, in-hospital mortality was driven primarily by pre-existing patient comorbidities and markers of clinical instability. This finding is consistent with the work of others (16) and has important clinical implications in that it allows patients and physicians to obtain a reasonable estimate of procedural risk, prior to angiography.

In the aggregate population, angiographic risk factors added modest value, whereas in individual cases, their impact was more substantial. For example, the mean predicted PCI risk for patients with left main stenosis was 4.5% versus 2.4%, depending on whether or not the prediction included the angiographic left main risk feature. Other risk scores (such as the SYNTAX score), which arguably focus more heavily on collecting exhaustive angiographic data, have found some additional benefit from these angiographic variables (30).

We also found that patients presenting for PCI in the setting of STEMI, faced substantially higher procedural risk. However, the scope and relative impact of risk factors needed to predict risk in acute versus elective cases, were quite similar. Based on this observation, we were able to develop a unified model of risk estimation for all PCI cases, as opposed to separate STEMI and elective models. This unified model (e.g., the simplified NCDR PCI Mortality Risk Score) accurately predicts mortality in both acute and elective cases.

Utility of risk models. The NCDR CathPCI risk prediction tools developed and validated in this analysis cover the broad spectrum of anticipated model uses and address the needs of researchers, administrators, physicians, and patients. The full NCDR model provides a comprehensive tool to: 1) permit the most accurate adjustment of both pre-procedural and angiographic features for research projects; and 2) "level the playing field" for provider-level mortality results comparisons. Yet the full model is complex,

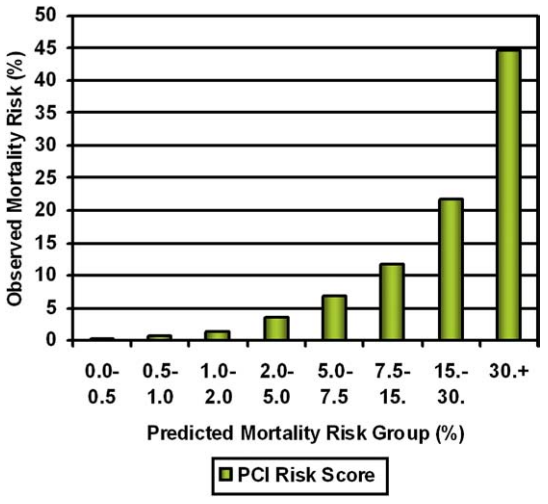

Figure 3 **Calibration of NCDR Bedside Risk Score in Validation Sample**

Based on their predicted risk, patients are grouped into 8 risk groups, using the full risk prediction model, and then plotted again the observed mortality rates for these in the second validation sample. NCDR = National Cardiovascular Data Registry; PCI = percutaneous coronary intervention.

inclusive of multiple data elements, spline-transformed continuous variables, and interaction terms—thus, the model is not practical to estimate patients' individual risk without computer assistance. Therefore, we also created the NCDR CathPCI Risk Score, whose simplified 8-item additive risk score can be used for bedside risk estimation.

Study limitations. Participation in the NCDR CathPCI centers is voluntarily and slightly under-represents smaller clinical practices. That said, the NCDR CathPCI Registry remains the largest, most generalizable U.S. data source. In-patient mortality, rather than 30-day mortality, has limitations as an end point (31). However, at the provider level, in-hospital and 30-day mortality results are highly correlated. Additionally, the only source of complete 30-day outcomes is Medicare data, which do not capture outcomes in those <65 years of age. When our models were applied to predict 30-day mortality in the Medicare population, they retained good discrimination (c = 0.86).

Future directions. As the practice of medicine continues to evolve, so will the use of risk prediction models. Clinically, computer-generated risk scores are being used to aid in the personalization of the procedural consent process (2). Although mortality is clearly an important outcome, modeling other modifiable outcomes, such as myocardial infarction, renal failure, bleeding complications, restenosis, stent thrombosis, and angina relief, could further advance the Institute of Medicine's goals for evidence-based, patient-centered, medical care (2,32). As advanced procedural support devices (e.g., hemodynamic support devices) continue to develop, risk prediction tools can be utilized to more clearly define the patient populations in which they will be maximally effective. From an administrative standpoint, the importance of these tools for provider-based risk-adjusted outcomes comparisons will continue to increase, as public reporting and pay-for-performance initiatives continue to grow in popularity. Finally, from a research perspective, these risk tools will be used to mitigate treatment selection bias when conducting comparative effectiveness analyses in observational data.

Conclusions

Using data from the NCDR CathPCI Registry, we have developed and validated contemporary models for assessing periprocedural PCI mortality risk. Each of these has excellent predictive accuracy throughout the full spectrum of patient risk, and important patient subgroups. We anticipate that these models will have multiple applications (including bedside risk estimation using the simplified risk score, comparison of hospital performance, and risk adjustment).

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Key Words: percutaneous coronary intervention ■ risk prediction ■ outcomes.

Contemporary Mortality Risk Prediction for Percutaneous Coronary Intervention: Results From 588,398 Procedures in the National Cardiovascular Data Registry

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NCDR™
National Cardiovascular Data Registry

CathPCI Registry™

In-Hospital Risk Adjusted Mortality for Percutaneous Coronary Intervention (PCI)© Model Predictors

[National Quality Forum Endorsed Measure #0133]

The mission of the NCDR® is to improve the quality of cardiovascular patient care by providing information, knowledge and tools; implementing quality initiatives; and supporting research that improves patient care and outcomes.

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ACC-NCDR MORTALITY MODEL
-- SUMARRY --

CONTENTS

Predictors of mortality in full model and pre-cath model

Full model

Label	Variable	Levels	Definition	Estimate	Standard Error	Wald Chi Square	p-Value	Odds Ratio Point Estimate	95% Wald Confidence Limits	
Intercept: Death = Yes	Intercept			-5.48553	0.419313	171.1431	4.16E-39			
STEMI patients	STEMI		Admission symptoms of STEMI where onset is within 24 hrs of admission OR Acute PCI is: Primary for STEMI/Rescue/Facilitated (i.e. (AdmSxPre *[NCDR Variable 550]* = 6 and SxOnset *[NCDR Variable 560]* in (1, 2, 3)) or AcutePCI *[NCDR Variable 812]* in (2, 3, 4))	0.61548	0.463011	1.76705	0.183748			
Age (for age<=70)	age_le70		Age (NCDR Variable 252), if > 110 or missing, then deleted from the data. Do not impute missing.	0.04421	0.004117	115.3315	6.66E-27	(per 10 units)1.553	1.438	1.692
Age (for age>70)	age_gt70		If patient's age <= 70, e.g. 60, then the logit(mortality) = … + estimate(age_le70) * 60 + …; if age > 70, e.g. 80, then logit(mortality)=… + estimate(age_le70)*70 + estimate(age_gt70)*(80-70) + ...	0.05392	0.004808	125.8004	3.4E-29	(per 10 units)1.708	1.568	1.877
Cardiogenic Shock at Admission	CarShock		NCDR Variable 520. Impute missing to no.	2.12275	0.062105	1168.28	4.8E-256	8.354	7.397	9.435
Previous History - CHF	PrCHF		NCDR Variable 424. Impute missing to no.	0.2526	0.067871	13.85136	0.000198	1.287	1.127	1.471
Previous Valvular Surgery	PrValve		NCDR Variable 426. Impute missing to no.	0.45399	0.18507	6.017447	0.014165	1.575	1.096	2.263
Cerebrovascular Disease	CVD		NCDR Variable 450. Impute missing to no.	0.23287	0.067153	12.02494	0.000525	1.262	1.107	1.44
Peripheral Vascular Disease	PVD		NCDR Variable 452. Impute missing to no.	0.42567	0.065382	42.38582	7.49E-11	1.531	1.347	1.74
Chronic Lung Disease	CLD		NCDR Variable 454. Impute missing to no.	0.38891	0.059284	43.03638	5.37E-11	1.475	1.314	1.657
Previous PCI	PrPCI		NCDR Variable 490. Impute missing to no.	-0.3722	0.061528	36.59382	1.45E-09	0.689	0.611	0.778
PreOp IABP (D)	PreIABP		DCRI Derived from IABP (NCDR Variable 640), IABPWhen (NCDR 642): `if (iabp eq . and iabpwhen eq .) or (iabp eq 1 and iabpwhen eq .) then PreIABP = .; else if iabpwhen eq 1 then PreIABP = 1; else PreIABP = 0;`	1.14427	0.20028	32.64229	1.11E-08	3.14	2.121	4.65
Ejection Fraction Percentage	HDEF		NCDR Variable 656. Impute missing by stratifying population based on CHF, carshock, prior MI, and STEMI. If HDEF > 60, set HDEF = 60 (flat).	-0.03166	0.002069	234.0855	7.66E-53	(per 10 units)0.730	0.7	0.761
Coronary Lesion >= 50%: Subacute Thrombosis? (Y/N)	corles50D		Yes if subacute thrombosis is checked for Lesion>=50% (NCDR Variable 810). Otherwise, no.	0.67359	0.167292	16.21221	5.66E-05	1.961	1.413	2.722
Highest Risk Pre-Procedure TIMIFlow = none?	mpretimiD		True if the highest risk lesion PreProc TIMIFlow (NCDR Variable 920) is no; else false.	0.17044	0.07748	4.838843	0.027826	1.186	1.019	1.38
Diabetes/Control (D) 1=Non-Insulin Diabetes	NewDiab	1=Non-Insulin Diabetes	Derived from NCDR Variables 430 (Diabetes) and 432 (DiabCtrl): `if diabetes eq . and diabctrl in (., 1) then NewDiab = .; else if diabctrl eq 4 then NewDiab = 2; else if diabetes eq 1 or diabctrl in (2, 3) then NewDiab = 1; else NewDiab = 0;`	0.10082	0.064128	2.47148	0.115929	1.106	0.975	1.254
Diabetes/Control (D) 2=Insulin Diabetes	NewDiab	2=Insulin Diabetes		0.578	0.077071	56.24434	6.4E-14	1.782	1.533	2.073
Highest Risk Lesion: SCAI Lesion Class 2 or 3	mLesSCAIDn	2 or 3	Highest risk lesion variable derived from NCDR Variables 950 (LesRisk), 910 (PreStePr): `if (lesrisk eq . or prestepr < 0 or prestepr > 100) then LesSCAI = .; else if (lesrisk eq 1) then do; if prestepr < 100 then LesSCAI = 1; else LesSCAI = 3; end; else if (lesrisk eq 2) then do; if prestepr < 100 then LesSCAI = 2; else LesSCAI = 4; end;` Missing imputation: `if mLesSCAI = . then do; if mPreStePr = 100 then mLesSCAI = 3; else if mLesRisk = 2 then mLesSCAI = 2; else mLesSCAI = 1; end;`	0.38316	0.065865	33.84142	5.98E-09	1.467	1.289	1.669
Highest Risk Lesion: SCAI Lesion Class 4	mLesSCAIDn	4		0.71903	0.094909	57.39562	3.56E-14	2.052	1.704	2.472

Label	Variable	Levels	Definition	Estimate	Standard Error	Wald Chi Square	p-Value	Odds Ratio Point Estimate	95% Wald Confidence Limits	
BMI [kg/m^2] for stemi	bmi_stemi		Calculated from NCDR Variables 410 (HeightCM) and 412 (WeightKG): `BMI = weightkg * 10000 / (heightcm * heightcm); if BMI < 5 or BMI > 100 then BMI = .;` Impute missing BMI to gender specific median. If BMI > 30, set BMI = 30 (flat). bmi_stemi for STEMI patients; bmi_nstemi for other patients.	-0.01405	0.010004	1.973952	0.160029	(per 5 units)0.932	0.846	1.03
BMI [kg/m^2] for nonstemi PCI	bmi_nstemi			-0.05593	0.009605	33.91321	5.76E-09	(per 5 units)0.758	0.688	0.833
GFR for stemi	gfr_stemi		Derived from NCDR Variables 252 (age), 260 (gender), 270 (race), and 440 (CreatLst): `if (creatlst ne .) then do; if gender = 1 then gendmult = 1; else if gender eq 2 then gendmult = 0.742; if race eq 2 then racemult = 1.21; else racemult = 1; GFR = 186 * creatlst**(-1.154) * age**(-.203) * gendmult * racemult; end; else GFR = .;` Impute missing to gender, prior renal failure (NCDR Variable 442), STEMI specific median. `if (gfr > 90) then gfr = 90; if (gfr < 30 or dialysis [NCDR Var. 444]) then gfr = 30;` gfr_stemi for STEMI patients; gfr_nstemi for other patients.	-0.02657	0.00197	181.901	1.86E-41	(per 10 units)0.768 §	0.737	0.801
GFR for nonstemi PCI	gfr_nstemi			-0.02015	0.002005	100.9603	9.38E-24	(per 10 units)0.817 §	0.784	0.851
Prev History - Dialysis (stemi PCI)	dialysis_stemi		NCDR Variable 444. Impute missing to no. dialysis_stemi for STEMI patients; dialysis_nstemi for other patients.	0.10597	0.242865	0.1904	0.662584	1.112‡	0.691	1.79
Prev History - Dialysis (nonstemi PCI)	dialysis_nstemi			0.56677	0.140052	16.37689	5.19E-05	1.763‡	1.339	2.319
NYHA Class 4 for stemi PCI	classnyhD_stemi		True if NYHA class IV (NCDR Variable 510); false if not class IV. classnyhD_stemi for STEMI patients; classnyhD_nstemi for other patients.	0.18911	0.072867	6.735636	0.009451	1.208	1.047	1.394
NYHA Class 4 for nonstemi PCI	classnyhD_nstemi			0.55297	0.076088	52.81723	3.66E-13	1.738	1.498	2.018
Highest Risk Lesion - Segment Category (stemi PCI) 1=pRCA/mLAD/pCIRC	mNewSeg_stemi	1=pRCA/mLAD/pCIRC	Highest risk lesion variable derived from NCDR Variable 902 (segmentn): `if segmentn eq . then NewSeg = .; else if segmentn eq 11 then NewSeg = 3; else if segmentn eq 12 then NewSeg = 2; else if segmentn in (1, 13, 18) then NewSeg = 1; else NewSeg = 0;` Impute missing to 0 (i.e. Other category) mNewSeg_stemi for STEMI patients; mNewSeg_nstemi for other patients.	0.29047	0.086866	11.18127	0.000826	1.337	1.128	1.585
Highest Risk Lesion - Segment Category (stemi PCI) 2=pLAD	mNewSeg_stemi	2=pLAD		0.41832	0.095973	18.99835	1.31E-05	1.519	1.259	1.834
Highest Risk Lesion - Segment Category (stemi PCI) 3=Left Main	mNewSeg_stemi	3=Left Main		1.71164	0.243874	49.26009	2.24E-12	5.538	3.434	8.932
Highest Risk Lesion - Segment Category (nonstemi PCI) 1=pRCA/mLAD/pCIRC	mNewSeg_nstemi	1=pRCA/mLAD/pCIRC		0.22946	0.082578	7.721107	0.005458	1.258	1.07	1.479
Highest Risk Lesion - Segment Category (nonstemi PCI) 2=pLAD	mNewSeg_nstemi	2=pLAD		0.5023	0.092864	29.25727	6.34E-08	1.653	1.378	1.982
Highest Risk Lesion - Segment Category (nonstemi PCI) 3=Left Main	mNewSeg_nstemi	3=Left Main		0.84429	0.157912	28.58639	8.96E-08	2.326	1.707	3.17
PCI Status for stemi 2=Urgent	PCIStat_stemi	2=Urgent	NCDR Variable 804 Impute missing to 1=Elective. PCIStat_stemi for STEMI patients; PCIStat_nstemi for other patients.	0.08189	0.266061	0.094733	0.758244	1.085	0.644	1.828
PCI Status for stemi 3=Emergency	PCIStat_stemi	3=Emergency		0.72833	0.239626	9.238116	0.00237	2.072	1.295	3.313
PCI Status for stemi 4=Salvage	PCIStat_stemi	4=Salvage		2.67727	0.280539	91.07499	1.38E-21	14.545	8.393	25.207
PCI Status for nonstemi PCI 2=Urgent	PCIStat_nstemi	2=Urgent		0.7002	0.087586	63.90964	1.3E-15	2.014	1.696	2.391
PCI Status for nonstemi PCI 3=Emergency	PCIStat_nstemi	3=Emergency		1.98619	0.107096	343.9473	8.82E-77	7.288	5.908	8.99
PCI Status for nonstemi PCI 4=Salvage	PCIStat_nstemi	4=Salvage		4.41325	0.300117	216.24	5.98E-49	82.537	45.834	148.63

Pre-cath model

Label	Variable	Levels	Definition	Estimate	Standard Error	Wald Chi Square	p-Value	Odds Ratio Point Estimate	95% Wald Confidence Limits	
Intercept: Death = Yes	Intercept			-6.380955885	0.397670562	257.46879	6.11E-58			
STEMI patients	STEMI		Admission symptoms of STEMI where onset is within 24 hrs of admission OR Acute PCI is: Primary for STEMI/Rescue/Facilitated (i.e. (AdmSxPre [NCDR Variable 550] = 6 and SxOnset [NCDR Variable 560] in (1, 2, 3)) or AcutePCI [NCDR Variable 812] in (2, 3, 4))	0.642880624	0.449086095	2.0492807	0.152278	1.902	0.789	4.586
Age (for age<=70)	age_le70		Age (NCDR Variable 252), if > 110 or missing, then deleted from the data. Do not impute missing.	0.041657719	0.0040481	105.89818	7.76E-25	(per 10 units) 1.524	1.397	1.644
Age (for age>70)	age_gt70		If patient's age <= 70, e.g. 60, then the logit(mortality) = … + estimate(age_le70) * 60 + …; if age > 70, e.g. 80, then logit(mortality)=… + estimate(age_le70)*70 + estimate(age_gt70)*(80-70) + ...	0.055280471	0.004745223	135.71572	2.3E-31	(per 10 units) 1.741	1.583	1.913
Cardiogenic Shock at Admission	CarShock		NCDR Variable 520. Impute missing to no.	2.455030571	0.059575834	1698.1402	0	11.647	10.363	13.089
Previous History - CHF	PrCHF		NCDR Variable 424. Impute missing to no.	0.487235902	0.06573266	54.943479	1.24E-13	1.628	1.431	1.852
Previous Valvular Surgery	PrValve		NCDR Variable 426. Impute missing to no.	0.414724444	0.184348864	5.0610233	0.02447	1.514	1.055	2.173
Cerebrovascular Disease	CVD		NCDR Variable 450. Impute missing to no.	0.22914408	0.066432065	11.897666	0.000562	1.258	1.104	1.432
Peripheral Vascular Disease	PVD		NCDR Variable 452. Impute missing to no.	0.427380473	0.064740821	43.578567	4.07E-11	1.533	1.351	1.741
Chronic Lung Disease	CLD		NCDR Variable 454. Impute missing to no.	0.41003954	0.058306494	49.455844	2.03E-12	1.507	1.344	1.689
Previous PCI	PrPCI		NCDR Variable 490. Impute missing to no.	-0.337350898	0.059943244	31.672566	1.82E-08	0.714	0.635	0.803
PreOp IABP (D)	PreIABP		DCRI Derived from IABP (NCDR Variable 640), IABPWhen (NCDR 642): if (iabp eq . and iabpwhen eq .) or (iabp eq 1 and iabpwhen eq .) then PreIABP = .; else if iabpwhen eq 1 then PreIABP = 1; else PreIABP = 0;	1.265524048	0.200634916	39.785771	2.83E-10	3.545	2.392	5.253
Diabetes/Control (D) 1=Non-Insulin Diabetes	NewDiab	1=Non-Insulin Diabetes	Derived from NCDR Variables 430 (Diabetes) and 432 (DiabCtrl): if diabetes eq . and diabctrl in (., 1) then NewDiab = .; else if diabctrl eq 4 then NewDiab = 2; else if diabetes eq 1 or diabctrl in (2, 3) then NewDiab = 1; else NewDiab = 0;	0.140966373	0.063190716	4.9765057	0.025694	1.151	1.017	1.303
Diabetes/Control (D) 2=Insulin Diabetes	NewDiab	2=Insulin Diabetes		0.586773653	0.07611441	59.430235	1.27E-14	1.798	1.549	2.087
BMI [kg/m^2] for stemi	bmi_stemi		Calculated from NCDR Variables 410 (HeightCM) and 412 (WeightKG): BMI = weightkg * 10000 / (heightcm * heightcm); if BMI < 5 or BMI > 100 then BMI = .; Impute missing BMI to gender specific median. If BMI > 30, set BMI = 30 (flat).	-0.013586859	0.009826602	1.9117515	0.166769	(per 5 units) 0.937	0.85	1.03
BMI [kg/m^2] for nonstemi PCI	bmi_nstemi		bmi_stemi for STEMI patients; bmi_nstemi for other patients.	-0.064043532	0.00944451	45.982402	1.19E-11	(per 5 units) 0.726	0.663	0.794
GFR for stemi	gfr_stemi		Derived from NCDR Variables 252 (age), 260 (gender), 270 (race), and 440 (CreatLst): if (creatlst ne .) then do; if gender = 1 then gendmult = 1; else if gender eq 2 then gendmult = 0.742; if race eq 2 then racemult = 1.21; else racemult = 1; GFR = 186 * creatlst**(-1.154) * age**(-.203) * gendmult * racemult; end; else GFR = .; Impute missing to gender, prior renal failure (NCDR Variable 442), STEMI specific median. if (gfr > 90) then gfr = 90; if (gfr < 30 or dialysis [NCDR Var. 444]) then gfr = 30;	-0.025901485	0.001931421	179.84379	5.24E-41	(per 10 units) 0.768	0.745	0.801
GFR for nonstemi PCI	gfr_nstemi		gfr_stemi for STEMI patients; gfr_nstemi for other patients.	-0.020589137	0.001977636	108.38856	2.21E-25	(per 10 units) 0.817	0.784	0.842
Prev History - Dialysis (stemi PCI)	dialysis_stemi		NCDR Variable 444. Impute missing to no.	0.143448255	0.238452033	0.3618999	0.547453	1.154	0.723	1.842
Prev History - Dialysis (nonstemi PCI)	dialysis_nstemi		dialysis_stemi for STEMI patients; dialysis_nstemi for other patients.	0.553078237	0.139096915	15.810228	7E-05	1.739	1.324	2.283
NYHA Class 4 for stemi PCI	classnyhD_stemi		True if NYHA class IV (NCDR Variable 510); false if not class IV.	0.248159955	0.071786924	11.950132	0.000546	1.282	1.113	1.475
NYHA Class 4 for nonstemi PCI	classnyhD_nstemi		classnyhD_stemi for STEMI patients; classnyhD_nstemi for other patients.	0.696278864	0.074698863	86.883726	1.15E-20	2.006	1.733	2.323

Label	Variable	Levels	Definition	Estimate	Standard Error	Wald Chi Square	p-Value	Odds Ratio Point Estimate	95% Wald Confidence Limits	
PCI Status for stemi 2=Urgent	PCIStat_stemi	2=Urgent	NCDR Variable 804	0.245593171	0.260300762	0.8901879	0.345426	1.278	0.768	2.129
PCI Status for stemi 3=Emergency	PCIStat_stemi	3=Emergency	Impute missing to 1=Elective.	1.068485078	0.233358075	20.964826	4.68E-06	2.911	1.842	4.599
PCI Status for stemi 4=Salvage	PCIStat_stemi	4=Salvage	PCIStat_stemi for STEMI patients;	3.154257989	0.273365081	133.13994	8.43E-31	23.436	13.715	40.047
PCI Status for nonstemi PCI 2=Urgent	PCIStat_nstemi	2=Urgent	PCIStat_nstemi for other patients.	0.805762738	0.086997318	85.783277	2.01E-20	2.238	1.887	2.655
PCI Status for nonstemi PCI 3=Emergency	PCIStat_nstemi	3=Emergency		2.326950724	0.103974709	500.86299	6.2E-111	10.247	8.358	12.563
PCI Status for nonstemi PCI 4=Salvage	PCIStat_nstemi	4=Salvage		4.865392175	0.295140217	271.75586	4.7E-61	129.722	72.743	231.333

Pre-cath point system

AGE	<60	60-70	70-80	>80
	0	4	8	14

CARSHOCK	No	Yes
	0	25

PrCHF	No	Yes
	0	5

PVD	No	Yes
	0	5

CLD	No	Yes
	0	4

GFR	<30	30-60	60-90	>90
	18	10	6	0

NYHA Class 4	No	Yes
	0	4

PCIStat(STEMI)	Elective	Urgent	Emergent	Salvage
	12	15	20	38

PCIStat(Other)	Elective	Urgent	Emergent	Salvage
	0	8	20	42

TOTALPTS	DPROB
0	0
5	0.001
10	0.001
15	0.002
20	0.003
25	0.006
30	0.011
35	0.02
40	0.036
45	0.063
50	0.109
55	0.183
60	0.29
65	0.427
70	0.576
75	0.712
80	0.819
85	0.892
90	0.938
95	0.965
100	0.98
105	0.989
110	0.994
115	0.997
120	0.998
125	0.999
130	0.999
135+	1

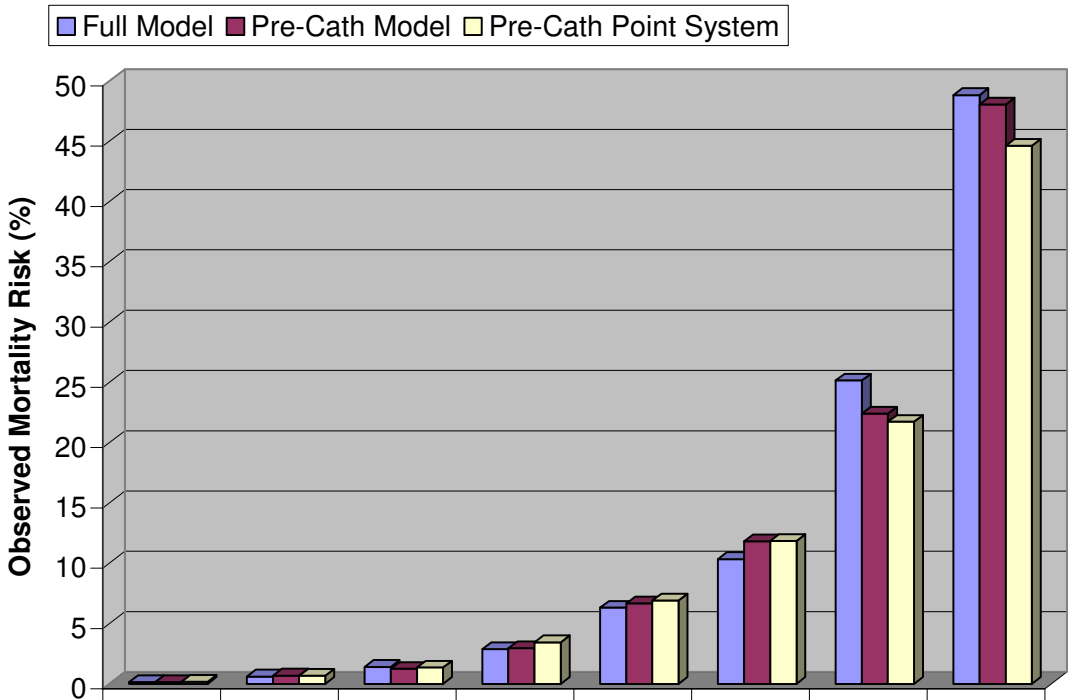
Reference: Model 13a (Pre-cath simplified)

Label	Variable	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq	Odds Ratio Point Estimate	95% Wald Confidence Limits	
Intercept: mort=(1) Yes	**Intercept**	-7.6973	0.2891	708.9718	<.0001			
STEMI patients	**STEMI**	1.5982	0.2395	44.5464	<.0001			
Age (for age<=70)	**age_le70**	0.0417	0.00401	107.9158	<.0001	(per 10 unit increase) 1.524	1.397	1.644
Age (for age>70)	**age_gt70**	0.0561	0.00457	150.9319	<.0001	(per 10 unit increase) 1.757	1.598	1.913
Cardiogenic Shock at Admission	**CarShock**	2.5006	0.0589	1804.7284	<.0001	12.190	10.862	13.681
Previous History - CHF	**PrCHF**	0.5583	0.0635	77.2459	<.0001	1.748	1.543	1.979
Peripheral Vascular Disease	**PVD**	0.5154	0.0626	67.7797	<.0001	1.674	1.481	1.893
Chronic Lung Disease	**CLD**	0.4212	0.0579	52.8667	<.0001	1.524	1.360	1.707
GFR (D)	**GFR**	-0.0265	0.00136	377.5512	<.0001	(per 10 unit increase) 0.768	0.745	0.784
NYHA Class 4? (Y/N)	**classnyhD**	0.4787	0.0530	81.7051	<.0001	1.614	1.455	1.790
PCI Status for stemi 2=Urgent	**PCIStat_stemi**	0.2189	0.2598	0.7098	0.3995	(vs. 1=Elective) 1.245	0.748	2.071
PCI Status for stemi 3=Emergency	**PCIStat_stemi**	0.9752	0.2326	17.5775	<.0001	(vs. 1=Elective) 2.652	1.681	4.184
PCI Status for stemi 4=Salvage	**PCIStat_stemi**	3.0657	0.2727	126.3614	<.0001	(vs. 1=Elective) 21.450	12.568	36.608
PCI Status for nonstemi PCI 2=Urgent	**PCIStat_nstemi**	0.9133	0.0854	114.4570	<.0001	(vs. 1=Elective) 2.493	2.109	2.947
PCI Status for nonstemi PCI 3=Emergency	**PCIStat_nstemi**	2.4670	0.1001	606.9067	<.0001	(vs. 1=Elective) 11.788	9.687	14.344
PCI Status for nonstemi PCI 4=Salvage	**PCIStat_nstemi**	4.9874	0.2926	290.5911	<.0001	(vs. 1=Elective) 146.554	82.596	260.037

Summary of c-index of each above model

	Sample Size	Full (model 12)	Pre-cath (complicated) (model 13)	Pre-cath (simplified) (model 13a)	Pre-cath (simplified) Point-System
Final model (from 60% pop04-06)	**181775**	**0.926**	**0.916**	**0.911**	
It is decided to use 100% pop06-07 as final validation data					
applied to overall validation data	**285440**	**0.924**	**0.914**	**0.910**	**0.905**
applied to STEMI in validation data	39889	0.902	0.892	0.890	0.884
applied to NonSTEMI in validation data	245551	0.892	0.878	0.869	0.862
applied to WOMEN in validation	95106	0.911	0.903	0.897	0.893
applied to MEN in validation	190334	0.930	0.920	0.916	0.911
applied to AGE>70 in validation	92381	0.901	0.891	0.886	0.880
applied to AGE<=70 in validation	193059	0.927	0.916	0.911	0.906
applied to ANY DIABETE in validation	92974	0.924	0.915	0.910	0.903
applied to NO DIABETE in validation	192466	0.923	0.914	0.910	0.906

Calibration curves



	0.0-0.5	0.5-1.0	1.0-2.0	2.0-5.0	5.0-7.5	7.5-15.	15.-30.	30.+
Full Model	0.14191	0.6079	1.4029	2.86448	6.31732	10.3335	25.155	48.8294
Pre-Cath Model	0.14688	0.6907	1.24738	2.95027	6.66265	11.8123	22.4031	48.0455
Pre-Cath Point System	0.1658	0.67002	1.34758	3.44485	6.90834	11.8519	21.7258	44.6065

Predicted Mortality Risk Group (%)

NCDR™
National Cardiovascular Data Registry
CathPCI Registry™

Percutaneous Coronary Intervention (PCI) Risk Adjustment Mortality Model 2008

CONTENTS

Risk Adjustment Model (RAM) Committee

Members

The Risk Adjustment Model (RAM) Committee is a group of ACC volunteers who have expertise in epidemiology, biostatistics and coronary interventions. The RAM group consists of the following experts: Chairperson, John Spertus MD; Kalon Ho MD, Ronald Krone MD, Eric Peterson MD, John Rumsfeld MD, Richard Shaw PhD, Mandeep Singh MBBS, William Weintraub MD and Liz Delong PhD.

Committee meetings: Purpose and decisions

The RAM committee convened via conference calls and emails to develop a contemporary percutaneous coronary intervention (PCI) risk adjustment mortality model for patients receiving primary PCI and elective percutaneous procedure. The RAM committee provided independent oversight and input throughout the model development process, and defined a list of variables relevant to coronary interventional procedures. Candidate variables suggested by the RAM committee, as well as other variables in the dataset, were assessed for their association with mortality. The RAM committee relied on the existing RAM model and literature on other models in developing its initial list. A summary of RAM Committee meeting discussions and decisions are presented in Appendix 1.

Methods

Database Used

Between 1 January, 2004 and 31 March, 2006, a total of 309,351 consecutive patients undergoing PCI at 470 hospitals in the United States were entered into the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR) version 3 database.[1] Participation in ACC-NCDR was subject to the approval of the institutional review board of each hospital. Since the patient information collected excluded unique patient identifiers, individual informed consent was not required.

Population Definition

Patients with a first PCI procedure performed during an admission were included in the study population. Variables included in the model are shown in Appendix 2. After excluding 6,334 transfer-out patients and 39 patients who were missing more than 2 candidate variables [2] for the mortality model, 302,958 patients with PCI procedures at 470 participating NCDR centers remained in the analysis population. Sixty percent of

[1] For the data collection process, see Anderson HV, Shaw RE, Brindis RG, et al. A contemporary overview of percutaneous coronary interventions: the American College of Cardiology – National Cardiovascular Data Registry. J Am Coll Cardiol 2002; 39: 1096-103.

[2] Patients were excluded if more than 2 variables had a missing value. The following variables were used to screen patients:
Age, gender, race, previous MI, previous – CHF, previous valvular surgery, diabetes/control, renal failure/dialysis, cerebrovascular disease, peripheral vascular disease, chronic lung disease, hypertension, tobacco history, dyslipidemia, family history of CAD - age <55, previous PCI, previous CABG, CHF - current status, NYHA classification, cardiogenic shock, pre-op IABP, PCI status, coronary lesion >= 50%: subacute thrombosis, acute PCI and total lesions per lab visit.

Please note that this list is different from the list for backward selection. The variables with high missing rates such as BMI, GFR, symptoms onset, ejection fraction percentage, and highest-risk-lesion variables were not included in the above list, based on our data exploration. Using these variables, would limit the numbers of patients eligible for inclusion in the analysis and reduce the explanatory power of the model. The decision to do the exclusions in this way was made after discussions (with data explorations) during October 2006. The variables BMI, GFR, etc. were included in the backward selection procedure after imputation.

patients (n=181,775) were chosen at random for the model development, while the remaining 40% were taken as the first validation sample (**Figure 1**). By following the same inclusion and exclusion criteria, 285,440 patients who had PCI procedures between 31 March, 2006 and 30 March, 2007 at 608 participating NCDR centers were chosen as the second validation sample. The baseline characteristics and the mortality rate of the patients in the 3 samples are presented in **Tables 1 – 3** and **Figure 2**, respectively.

Variable Definition

Detailed definitions of all the variables in the model are presented in Appendix 2. Below are several noteworthy variables in the model.

- The ST-segment elevation myocardial infarction (STEMI) variable is defined as a patient who had admission symptoms of STEMI, where onset was within 24 hours of admission, or acute PCI was primary for STEMI/rescue/facilitated.
- The glomerular filtration rate (GFR) variable is calculated using abbreviated MDRD formula [GFR = $186 \times (\text{last creatinine})^{-1.154} \times (\text{age})^{-0.203} \times$ (gender factor) × (race factor) where (gender factor) = 1 for male and 0.742 for female, (race factor) = 1.21 for black and 1 for others].
- The body mass index (BMI) (kg/m^2) is calculated from height (cm) and weight (kg): BMI = weight × 10000 / $(\text{height})^2$.

Missing Data Imputation

The details of the imputation of all the variables are listed in Appendix 2. Listed below are several noteworthy imputations rules.

- The missing GFR was imputed to gender, prior renal failure, and STEMI specific median. In addition, GFR was set to 90 if over 90, and to 30 if less than 30 or dialysis.
- The missing ejection fraction (EF) was imputed to the CHF, cardiogenic shock at admission, prior MI, and STEMI specific median. If EF was over 60, EF was set as equal to 60.
- The missing BMI was imputed to the gender specific median; it was set to 30 if over 30.

Initial Variable Selection

Before proceeding with developing a multivariate model, univariate analysis was used to identify the factors that had both clinical and statistical (i.e. p-value < 0.05) significance. These variables included patient demographics, risk factor, cardiac status, cath lab visit, and PCI procedure factors. Based on the univariate analysis, potential risk factors identified included STEMI, age, cardiogenic shock at admission, BMI, prior CHF, prior valvular surgery, GFR, dialysis, cerebrovascular disease, peripheral vascular disease, chronic lung disease, hypertension, tobacco use, dyslipidemia, prior PCI, NYHA class, IABP before lab visit, ejection fraction, coronary lesion $\geq 50\%$ in a major artery, highest-risk lesion pre-procedure TIMI flow, highest-risk segment in graft, highest-risk segment category, diabetes control, PCI status, and SCAI lesion class, as well as their interaction with STEMI.

Model Variable Selection

A multivariate logistic regression with backward selection method was then performed to identify the predictive variables. The selection criterion was set to 0.05. Neither the highest-risk segment in graft variable nor the hypertension variable achieved a significance level of <0.05 and were excluded from the regression model. Most of the interaction terms were also removed from the model because of their insignificance, except for the interactions between STEMI and BMI, GFR, dialysis, NYHA class, highest-risk lesion segment category, and PCI status. These variables were included in the final model. (**Table 4**)

Calibration and Discrimination

After the risk factors were identified and their coefficient estimates calculated from the development sample, the variables' estimates were applied to the validation sample sets to determine the risk of mortality for each patient. The logistic risk model's accuracy for prediction was measured using the c-index, a widely-used measure of model discrimination. Model calibration, the degree to which observed outcomes are similar to the predicted outcomes from the model across patients, was examined by comparing average observed and predicted values within each risk sub-group arranged in increasing order of patient risk. Then, the c-index was calculated on the overall population and subpopulations stratified by STEMI, gender, age, and diabetes. The calibration was plotted.

Nomogram

Based on the full model, the pre-cath model was developed by removing the cath-related variables, such as ejection fraction, coronary lesion, highest risk pre-procedure TIMI flow, and highest risk lesion variables from the model and by restricting the number of variables in the model to fewer than 10. Only age, cardiogenic shock, prior CHF, peripheral vascular disease (PVD), chronic lung disease (CLD), GFR, NYHA class, and PCI status remained (**Table 4**). The regression coefficients from the pre-cath model were then converted into whole integers to create a bedside risk prediction tool [3] i.e. the pre-cath risk score system was developed (**Table 5**).

Example:

Patient is a **70-year-old** male with a history of **diabetes**, cerebrovascular accident (1997) followed by bilateral carotid endarectomy, hypertension, hyperlipidemia, **peripheral vascular disease,** and smoker with chronic obstructive pulmonary disease.
On the evening of 16-Aug-2007, the patient began having substernal chest pain and shortness of breath. Emergency medical services were called and the patient was taken to the hospital, and intubated for respiratory distress. The patient was diagnosed with **ST-elevation myocardial infarction.** Left cardiac catherization was done showing a 100% occlusion of the left anterior descending artery, and an intra-aortic balloon pump was placed. The patient became hypotensive and remained hypotensive despite inotropic, vasopressor and balloon pump support.

PCI Risk Score
70-year-old = 8
PVD = 5

[3] Sullivan LM, Massaro JM, D'Agostino RB Sr., Tutorial in biostatistics: presentation of multivariate data for clinical use: the Framingham study risk score function. *Stat. Med.* 2004; 23: 1631-1660.

CLD = 4
ST-elevation myocardial infarction = 15
Cardiogenic shock = 25

Total = 57
Risk of in-hospital mortality = 18 %-29%

Tables

Table 1 Patient Clinical Characteristics

	Development (181,775)	1st validation (121,183)	2nd validation (285,440)
Age	63.9±12.1	63.9±12.1	64.1±12.1
Female	33.4%	33.3%	33.3%
Caucasian	87.2%	87.1%	85.6%
BMI (kg/m^2)	29.6±6.3	29.7±6.3	29.8±6.3
Prior MI (>7days)	29.1%	29.1%	27.3%
Prior CHF	10.1%	10.0%	9.9%
Diabetes			
– Non-insulin	21.5%	21.7%	22.3%
– Insulin	10.0%	10.0%	10.3%
Mean GFR (MDRD)	73.6±30.5	73.5±29.0	73.2±28.1
Dialysis	1.6%	1.5%	1.5%
Cerebral Vascular Disease	10.9%	11.1%	11.1%
Peripheral Vascular Disease	11.7%	11.7%	11.9%
COPD	16.0%	16.0%	15.8%
Prior PCI	35.1%	35.4%	36.6%
NYHA Class IV	18.3%	18.3%	18.8%
Cardiogenic Shock	1.9%	1.8%	1.7%

Table 2 Hospital Characteristics

	Development (181,775)	1st validation (121,183)	2nd validation (285,440)
Number of Beds	463±221	463±220	454±225
Location			
- Rural	12.6%	12.6%	12.1%
- Urban	61.0%	61.3%	61.2%
Teaching	60.1%	60.0%	54.6%
Region			
- West	14.1%	14.3%	16.2%
- Northeast	9.0%	9.9%	10.4%
- Midwest	36.9%	36.7%	35.8%
- South	36.5%	36.8%	37.6%
Mean Annual PCI Volume	1151±762	1151±763	1159±807

Table 3 Procedural Characteristics

	Development (181,775)	1st validation (121,183)	2nd validation (285,440)
LVEF	52.7±12.7	52.7±12.7	52.7±12.7
PCI Status			
- Elective	49.3%	49.3%	50.2%
- Urgent	36.1%	35.6%	34.7%
- Emergency	14.4%	14.5%	15.0%
- Salvage	0.2%	0.2%	0.2%
Highest Risk Lesion – Segment Category			
-pLAD	18.2%	18.2%	18.2%
-Left Main	1.7%	1.8%	1.8%
Highest Risk Lesion – Pre-procedure TIMI Flow			
TIMI 0 Flow	11.0%	10.7%	14.9%
Multivessel PCI	14.0%	13.9%	14.1%

Table 4 Full and Pre-Cath Simplified Risk Models

Label	Full Model				Pre-Cath Simplified Model			
	Odds Ratio	95% Confidence Limits		χ^2	Odds Ratio	95% Confidence Limits		χ^2
Intercept: Death				171.14				708.97
STEMI patients				1.77				44.55
Age §								
for age≤70	1.55	1.44	1.69	115.33	1.52	1.40	1.64	107.92
for age>70	1.71	1.57	1.88	125.80	1.76	1.60	1.91	150.93
Cardiogenic Shock at Admission	8.35	7.40	9.44	1168.28	12.19	10.86	13.68	1804.73
Previous History - CHF	1.29	1.13	1.47	13.85	1.75	1.54	1.98	77.25
Peripheral Vascular Disease	1.53	1.35	1.74	42.39	1.67	1.48	1.89	67.78
Chronic Lung Disease	1.48	1.31	1.66	43.04	1.52	1.36	1.71	52.87
GFR §								
for STEMI	0.77	0.74	0.80	181.90	0.77	0.75	0.78	377.55
for non-STEMI	0.82	0.78	0.85	100.96				
NYHA Class IV								
for STEMI	1.21	1.05	1.39	6.74	1.61	1.46	1.79	81.71
for non-STEMI	1.74	1.50	2.02	52.82				
PCI Status								
for STEMI								
- Urgent	1.09	0.64	1.83	0.09	1.25	0.75	2.07	0.71
- Emergency	2.07	1.30	3.31	9.24	2.65	1.68	4.18	17.58
- Salvage	14.55	8.39	25.21	91.08	21.45	12.57	36.61	126.36
for non STEMI								
- Urgent	2.01	1.70	2.39	63.91	2.49	2.11	2.95	114.46
- Emergency	7.29	5.91	8.99	343.95	11.79	9.69	14.34	606.91
- Salvage	82.54	45.83	148.63	216.24	146.55	82.60	260.04	290.59
Previous Vascular Disease	1.58	1.10	2.26	6.02				
Cerebrovascular Disease	1.26	1.11	1.44	12.02				
Previous PCI	0.69	0.61	0.78	36.59				
PreOp IABP	3.14	2.12	4.65	32.64				
Ejection Fraction Percentage §	0.73	0.70	0.76	234.09				
Coronary Lesion >= 50%: Subacute Thrombosis? Yes vs. No	1.96	1.41	2.72	16.21				
Highest Risk Pre-Procedure TIMI Flow = None vs. Yes	1.19	1.02	1.38	4.84				
Diabetes/Control								
Non-Insulin Diabetes vs. No Diabetes	1.11	0.98	1.25	2.47				
Insulin Diabetes vs. No Diabetes	1.78	1.53	2.07	56.24				
Highest Risk Lesion: SCAI Lesion Class								
II or III vs. I	1.47	1.29	1.67	33.84				
IV vs. I	2.05	1.70	2.47	57.40				
BMI [kg/m^2] †								
for STEMI	0.93	0.85	1.03	1.97				
for Non-STEMI	0.76	0.69	0.83	33.91				
Highest Risk Lesion - Segment Category								
for STEMI								
pRCA/mLAD/pCIRC	1.34	1.13	1.59	11.18				
pLAD	1.52	1.26	1.83	19.00				
Left Main	5.54	3.43	8.93	49.26				
for non STEMI								
pRCA/mLAD/pCIRC	1.26	1.07	1.48	7.721				
pLAD	1.65	1.38	1.98	29.257				
Left Main	2.33	1.71	3.17	28.586				

§ Per 10 unit increase.
† Per 5 unit increase.

Table 5 PCI Risk Score System

Variable	Scoring Response Categories			
Age	<60	≥60,<70	≥70,<80	≥80
	0	4	8	14
Cardiogenic Shock	No	Yes		
	0	25		
Prior CHF	No	Yes		
	0	5		
PVD	No	Yes		
	0	5		
CLD	No	Yes		
	0	4		
GFR	<30	30-60	60-90	>90
	18	10	6	0
NYHA Class IV	No	Yes		
	0	4		
PCI Status (STEMI)	Elective	Urgent	Emergent	Salvage
	12	15	20	38
PCI Status (Not-STEMI)	Elective	Urgent	Emergent	Salvage
	0	8	20	42

Total Points	Risk of In-patient Mortality
0	0.0%
5	0.1%
10	0.1%
15	0.2%
20	0.3%
25	0.6%
30	1.1%
35	2.0%
40	3.6%
45	6.3%
50	10.9%
55	18.3%
60	29.0%
65	42.7%
70	57.6%
75	71.2%
80	81.%
85	89.2%
90	93.8%
95	96.5%
100	98.0%

Table 6 C-Indices to Compare the Models

	Sample N	Full Model	Pre-Cath Model	Risk Score
Development	181,775	0.926	0.911	0.911
1st validation	121,183	0.925	0.905	0.901
2nd validation	285,440	0.924	0.910	0.905
Subgroups (in 2nd validation)				
STEMI	39,889	0.902	0.890	0.884
Non-STEMI	245,551	0.892	0.896	0.862
Women	95,106	0.911	0.897	0.893
Men	190,334	0.930	0.916	0.911
Age>70	92,381	0.901	0.886	0.88
Age<=70	193,059	0.927	0.911	0.906
Diabetes	92,974	0.924	0.910	0.903
No Diabetes	192,466	0.923	0.910	0.906

Figures

Figure 1 Population

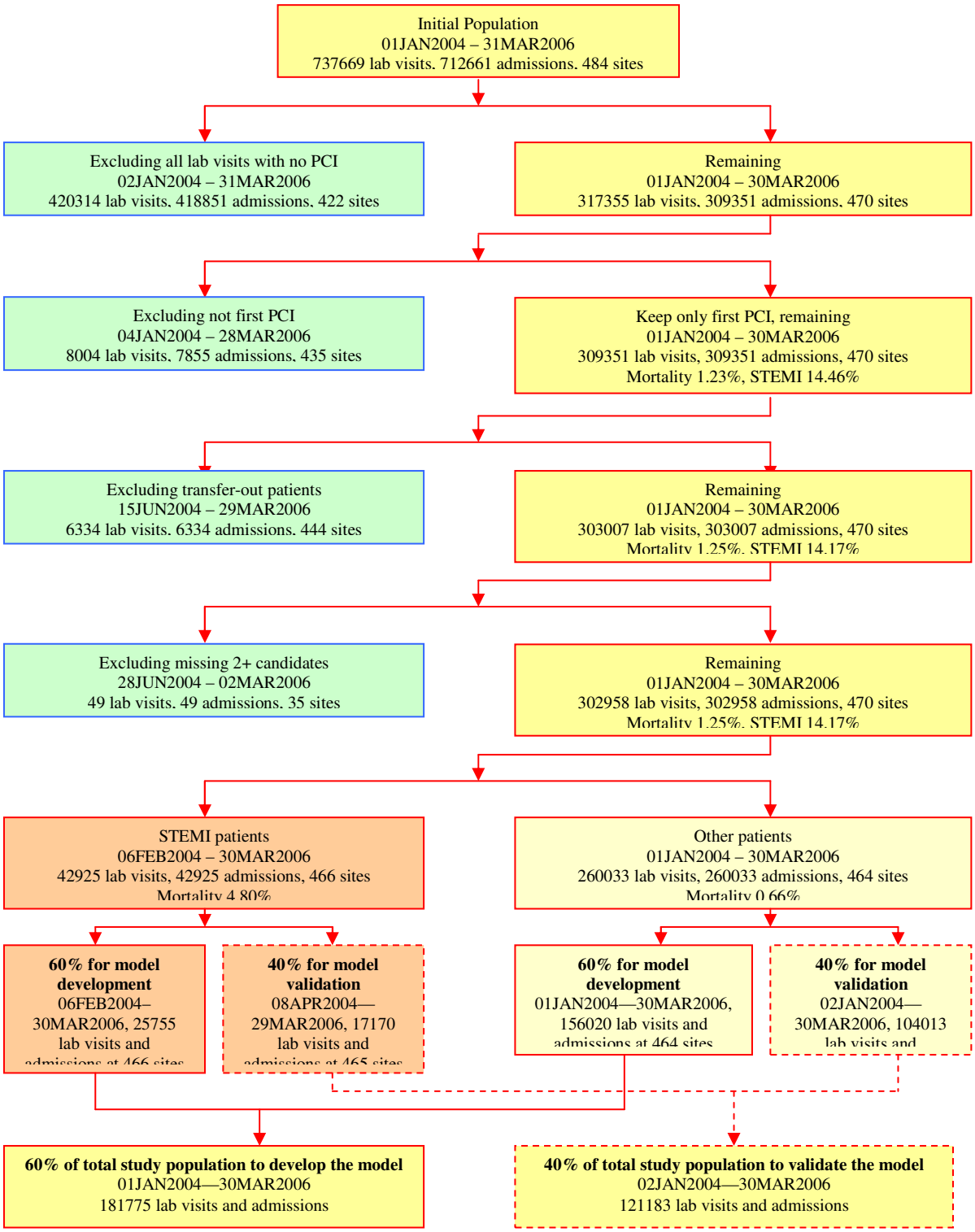


Figure 2 Outcome

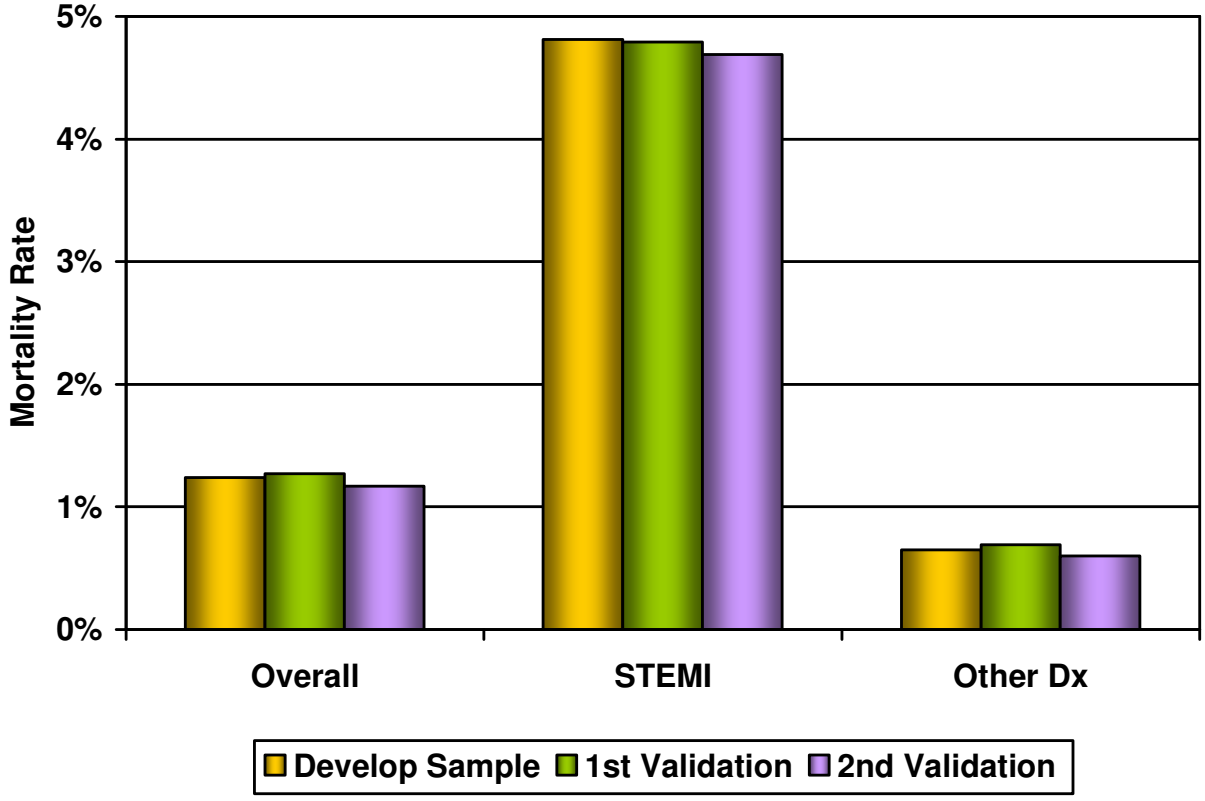


Figure 3 Calibration for Full Model

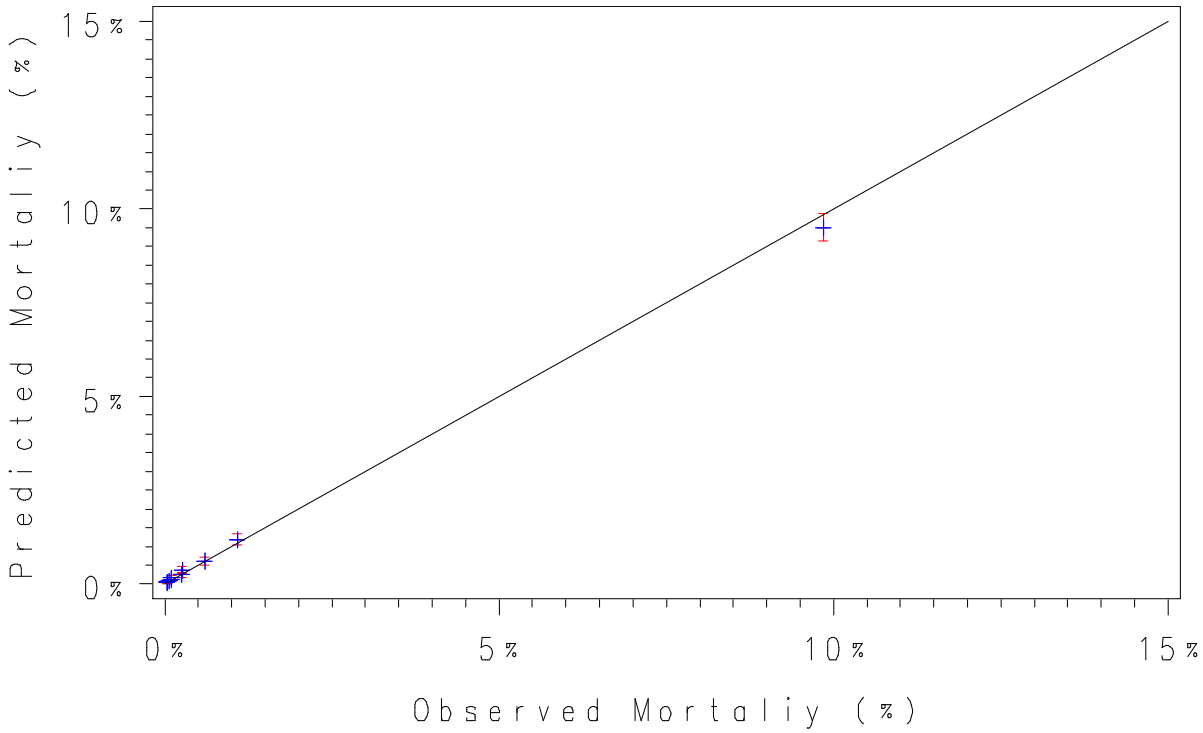
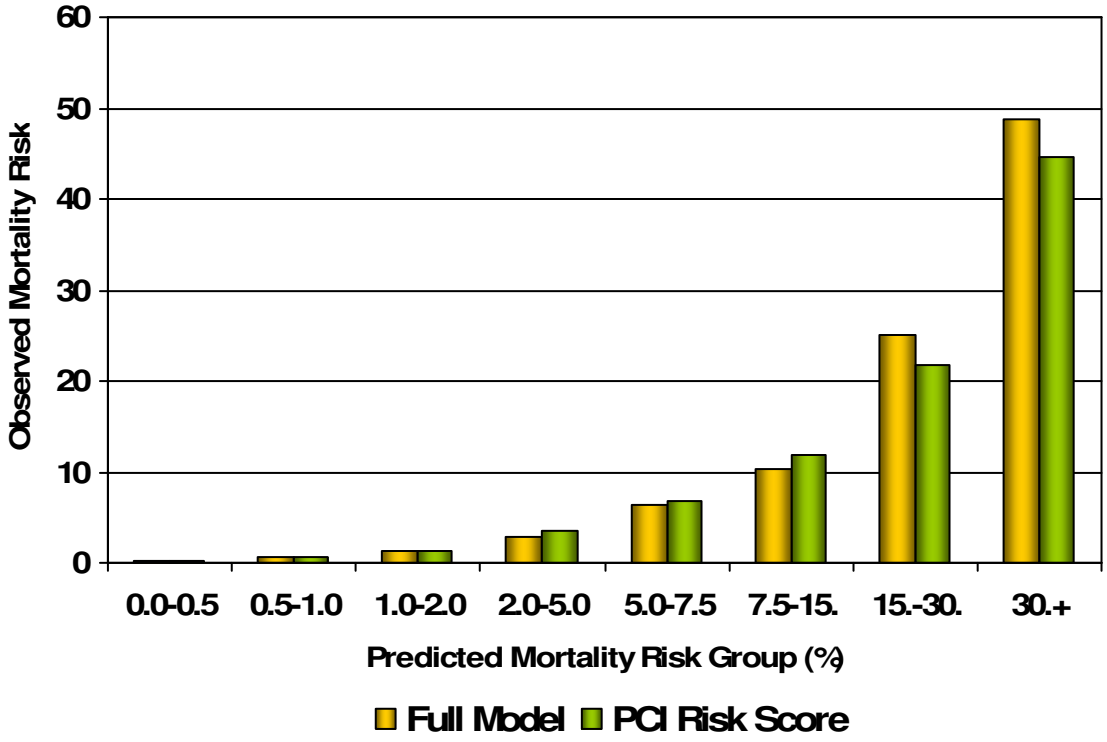


Figure 4 Calibration in Risk Groups in Validation Sample



Appendices

Appendix 1

RAM Committee meetings and decisions

During the first RAM committee meeting in August 2006, the purpose and general approach for creating the mortality risk adjustment model were defined. Candidate variables suggested by the RAM committee, as well as other variables in the dataset, were assessed.
It was decided to exclude:

- Patients with missing BMI because of the extremely high mortality rate among those patients, and the inability to accurately predict what these values might be.
- PCI procedures with more than 2 variables with missing values on key patient characteristic variables.
- PCI procedures where the lesion length was missing because of the extremely high mortality rate among those patients.

It was decided to include:

- Only the index PCI for each hospital stay

Decisions were circulated to the committee via email and DCRI was given approval to begin work on developing the mortality model in September 2006.

During the second committee meeting in October 2006, initial descriptive statistics were disseminated and discussed. It was decided to:

- Use only version 3 of the data collection form
- Exclude diagnostic cath variables from the model
- Include patients in the model with Cardiogenic Shock and where PCI status is described as Salvage.
- Request clinical input from the committee to categorize PCI status as. critical PCI, acute PCI (Primary PCI for STEMI) and acute PCI (Facilitated PCI), all of the above + acute PCI (rescue PCI), all of the above + salvage PCI status and emergency PCI status and cardiogenic shock.
- Impute "EF not assessed" by CHF, cardiogenic shock & prior MI specific medians.
- Lump cardiogenic shock patients in STEMI group as opposed to Non-Critical group, or we could include shock patients in both models and simply remove this criterion from "Critical PCI" definition if desired.
- Select the highest risk characteristic of all lesions attempted. These are not necessarily characteristics from a single lesion but rather a highest risk "dummy" lesion that is a combination of all the worst characteristics of the attempted lesions.
- Set patients with GFR < 30 OR dialysis to GFR = 30. The GFR parameter was then coded as a linear effect for GFR in 30-90 range and truncated at 90 (so same effect for all patients with GFR >= 90).

During the third committee meeting in January, 2007 the committee reviewed and discussed the candidate variables to include in the separate models, critical PCI and non-critical PCI. As a result of that call, work continued with refinement of the model as delineated below.

- Change the definition of critical PCI population: Specifically, add patients with acute PCI = primary for STEMI/rescue/facilitated to critical PCI population. Rationale: The change in the population was made to better capture this subgroup of patients than the previous definition which was limited to admission symptoms of STEMI within 24 hours.
- Explore the possibility of combining critical and non-critical PCI populations to develop single overall model, which allows for interactions between critical PCI and other single variables.
- Combine acute PCI primary, acute PCI rescue and acute PCI facilitated lumped together vs. all others to create binary variable.

In March 2007, the final population definitions were adopted, population *1 = Patients with admission symptoms of STEMI within 24 hrs **OR** Acute PCI = Primary for STEMI or Rescue PCI or Facilitated PCI. Population *2 = all remaining pts. It was believed that this change would better capture all of the Acute PCI = STEMI/Rescue/Facilitated patients than just the admission symptoms of STEMI within 24 hrs.

Appendix 2

Variable Definitions and Imputation

Label	Variable	Levels	Definition
Intercept: Death = Yes	Intercept		
STEMI patients	STEMI		Admission symptoms of STEMI where onset is within 24 hrs of admission OR Acute PCI is: Primary for STEMI/Rescue/Facilitated (i.e. `(AdmSxPre [NCDR Variable 550] = 6 and SxOnset [NCDR Variable 560] in (1, 2, 3)) or AcutePCI [NCDR Variable 812] in (2, 3, 4)`)
Age (for age<=70)	age_le70		Age (NCDR Variable 252), if > 110 or missing, then deleted from the data. Do not impute missing.
Age (for age>70)	age_gt70		If patient's age <= 70, e.g. 60, then the logit(mortality) = … + estimate(age_le70) * 60 + …; if age > 70, e.g. 80, then logit(mortality)=… + estimate(age_le70)*70 + estimate(age_gt70)*(80-70) + ...
Cardiogenic Shock at Admission	CarShock		NCDR Variable 520. Impute missing to no.
Previous History - CHF	PrCHF		NCDR Variable 424. Impute missing to no.
Previous Valvular Surgery	PrValve		NCDR Variable 426. Impute missing to no.
Cerebrovascular Disease	CVD		NCDR Variable 450. Impute missing to no.
Peripheral Vascular Disease	PVD		NCDR Variable 452. Impute missing to no.
Chronic Lung Disease	CLD		NCDR Variable 454. Impute missing to no.
Previous PCI	PrPCI		NCDR Variable 490. Impute missing to no.
PreOp IABP (D)	PreIABP		DCRI Derived from IABP (NCDR Variable 640), IABPWhen (NCDR 642): `if (iabp eq . and iabpwhen eq .) or (iabp eq 1 and iabpwhen eq .) then PreIABP = .; else if iabpwhen eq 1 then PreIABP = 1; else PreIABP = 0;`
Ejection Fraction Percentage	HDEF		NCDR Variable 656. Impute missing by stratifying population based on CHF, carshock, prior MI, and STEMI. If HDEF > 60, set HDEF = 60 (flat).
Coronary Lesion >= 50%: Subacute Thrombosis? (Y/N)	corles50D		Yes if subacute thrombosis is checked for Lesion>=50% (NCDR Variable 810). Otherwise, no.
Highest Risk Pre-Procedure TIMIFlow = none?	mpretimiD		True if the highest risk lesion PreProc TIMIFlow (NCDR Variable 920) is no; else false.
Diabetes/Control (D) 1=Non-Insulin Diabetes	NewDiab	1=Non-Insulin Diabetes	Derived from NCDR Variables 430 (Diabetes) and 432 (DiabCtrl): `if diabetes eq . and diabctrl in (., 1) then NewDiab = .; else if diabctrl eq 4 then NewDiab = 2; else if diabetes eq 1 or diabctrl in (2, 3) then NewDiab = 1; else NewDiab = 0;`
Diabetes/Control (D) 2=Insulin Diabetes	NewDiab	2=Insulin Diabetes	
Highest Risk Lesion: SCAI Lesion Class 2 or 3	mLesSCAIDn	2 or 3	Highest risk lesion variable derived from NCDR Variables 950 (LesRisk), 910 (PreStePr): `if (lesrisk eq . or prestepr < 0 or prestepr > 100) then LesSCAI = .; else if (lesrisk eq 1) then do; if prestepr < 100 then LesSCAI = 1; else LesSCAI = 3; end; else if (lesrisk eq 2) then do; if prestepr < 100 then LesSCAI = 2; else LesSCAI = 4; end;` Missing imputation: `if mLesSCAI = . then do; if mPreStePr = 100 then mLesSCAI = 3; else if mLesRisk = 2 then mLesSCAI = 2; else mLesSCAI = 1; end;`
Highest Risk Lesion: SCAI Lesion Class 4	mLesSCAIDn	4	
BMI [kg/m^2] for stemi	bmi_stemi		Calculated from NCDR Variables 410 (HeightCM) and

Label	Variable	Levels	Definition
			412 (WeightKG): `BMI = weightkg * 10000 / (heightcm * heightcm); if BMI < 5 or BMI > 100 then BMI = .;` Impute missing BMI to gender specific median. If BMI > 30, set BMI = 30 (flat). bmi_stemi for STEMI patients; bmi_nstemi for other patients.
BMI [kg/m^2] for nonstemi PCI	bmi_nstemi		
GFR for stemi	gfr_stemi		Derived from NCDR Variables 252 (age), 260 (gender), 270 (race), and 440 (CreatLst): `if (creatlst ne .) then do;` `if gender = 1 then gendmult = 1;` `else if gender eq 2 then gendmult = 0.742;` `if race eq 2 then racemult = 1.21;` `else racemult = 1;` `GFR = 186 * creatlst**(-1.154) * age**(-.203) * gendmult * racemult;` `end;` `else GFR = .;` Impute missing to gender, prior renal failure (NCDR Variable 442), STEMI specific median. `if (gfr > 90) then gfr = 90; if (gfr < 30 or dialysis [NCDR Var. 444]) then gfr = 30;` gfr_stemi for STEMI patients; gfr_nstemi for other patients.
GFR for nonstemi PCI	gfr_nstemi		
Prev History - Dialysis (stemi PCI)	dialysis_stemi		NCDR Variable 444. Impute missing to no. dialysis_stemi for STEMI patients; dialysis_nstemi for other patients.
Prev History - Dialysis (nonstemi PCI)	dialysis_nstemi		
NYHA Class 4 for stemi PCI	classnyhD_stemi		True if NYHA class IV (NCDR Variable 510); false if not class IV. classnyhD_stemi for STEMI patients; classnyhD_nstemi for other patients.
NYHA Class 4 for nonstemi PCI	classnyhD_nstemi		
Highest Risk Lesion - Segment Category (stemi PCI) 1=pRCA/mLAD/pCIRC	mNewSeg_stemi	1=pRCA/mLAD/pCIRC	Highest risk lesion variable derived from NCDR Variable 902 (segmentn): `if segmentn eq . then NewSeg = .;` `else if segmentn eq 11 then NewSeg = 3;` `else if segmentn eq 12 then NewSeg = 2;` `else if segmentn in (1, 13, 18) then NewSeg = 1;` `else NewSeg = 0;` Impute missing to 0 (i.e. Other category) mNewSeg_stemi for STEMI patients; mNewSeg_nstemi for other patients.
Highest Risk Lesion - Segment Category (stemi PCI) 2=pLAD	mNewSeg_stemi	2=pLAD	
Highest Risk Lesion - Segment Category (stemi PCI) 3=Left Main	mNewSeg_stemi	3=Left Main	
Highest Risk Lesion - Segment Category (nonstemi PCI) 1=pRCA/mLAD/pCIRC	mNewSeg_nstemi	1=pRCA/mLAD/pCIRC	
Highest Risk Lesion - Segment Category (nonstemi PCI) 2=pLAD	mNewSeg_nstemi	2=pLAD	
Highest Risk Lesion - Segment Category (nonstemi PCI) 3=Left Main	mNewSeg_nstemi	3=Left Main	
PCI Status for stemi 2=Urgent	PCIStat_stemi	2=Urgent	NCDR Variable 804 Impute missing to 1=Elective. PCIStat_stemi for STEMI patients; PCIStat_nstemi for other patients.
PCI Status for stemi 3=Emergency	PCIStat_stemi	3=Emergency	
PCI Status for stemi 4=Salvage	PCIStat_stemi	4=Salvage	
PCI Status for nonstemi PCI 2=Urgent	PCIStat_nstemi	2=Urgent	
PCI Status for nonstemi	PCIStat_nstemi	3=Emergen	

Label	Variable	Levels	Definition
PCI 3=Emergency		y	
PCI Status for nonstemi PCI 4=Salvage	PCIStat_nstemi	4=Salvage	