**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0133

**Measure Title**: In-Hospital Risk Adjusted Rate of Mortality for Patients Undergoing PCI

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Click here to enter composite measure #/ title

**Date of Submission**: 11/8/2017

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| **Instructions**  *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*  *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Outcome: [**3**](#Note3) Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component. * For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful. * Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org) and/or modified GRADE.  **5.** 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 multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Outcome: Risk Adjusted Mortality for PCI

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process: Click here to name what is being measured

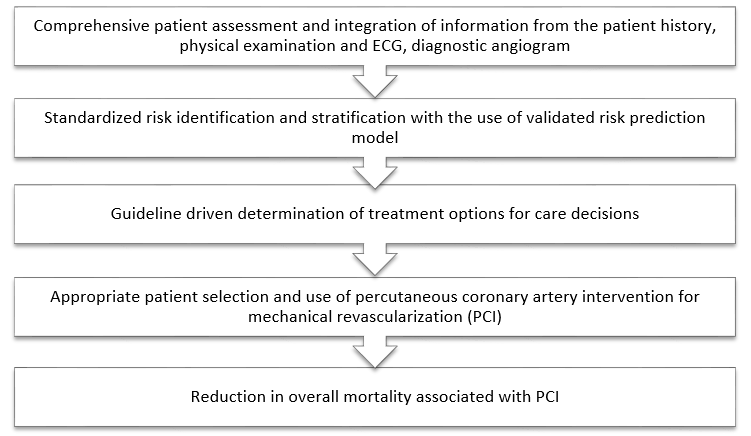
Appropriate use measure: Click here to name what is being measured

Structure: Click here to name the structure

Composite: Click here to name what is being measured

**1a.2** **LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Comprehensive, personalized risk assessment can lead to decreased mortality in the PCI patient population.



**1a.3** **Value and Meaningfulness:**  **IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

**Comprehensive patient assessment**

There is a socio-economic demand that cardiologists provide services in an accountable and cost-effective fashion. There are opportunities to improve the health of individuals and of populations by better coordination of all aspects of medical care, and by assessing and responding to each individual's health risks. This goal of individualized care can be achieved for patients requiring coronary artery revascularization with the use of risk models that identify PCI related risk factors and accurately quantify the procedural risks. Demographic, pre-catheterization clinical variables, and angiographic variables are incorporated in the CathPCI Registry PCI Risk Adjusted mortality measure to obtain this personalized patient care [1].

**Standardized risk identification and stratification with the use of validated risk prediction model**

The NCDR CathPCI risk score was developed and validated from an analysis of data from 1,208,137 PCI procedures performed in the United States in a broad range of institutions from 2009 to 2011. Our initial risk prediction model included 21 variables, the eight with the strongest association with in-hospital mortality were included in the risk score: age, cardiogenic shock, prior heart failure, peripheral artery disease, chronic lung disease, glomerular filtration rate, NYHA functional class IV, and PCI status (STEMI or no STEMI). “This model indicates that In-hospital mortality was 1.4%, ranging from 0.2% among elective cases (45.1% of total cases) to 65.9% among patients with shock and recent cardiac arrest (0.2% of total cases). Cardiogenic shock and procedure urgency were the most predictive of inpatient mortality, whereas the presence of a chronic total occlusion, subacute stent thrombosis, and left main lesion location were significant angiographic predictors. The full, pre-catheterization, and bedside risk prediction models performed well in the overall validation sample (C-indexes 0.930, 0.928, 0.925, respectively) and among pre-specified patient subgroups” [2].

Several other risk models have been developed to predict in-hospital mortality and major complications after PCI. There are limitations within these older models. Some were validated within the institution at which they were developed creating concerns about generalizability. Other models were developed before the routine use of drug-eluting stents or aggressive antithrombotic therapy and based upon patient populations treated with balloon angioplasty alone. Finally models focus on either acute coronary syndrome (ACS) or stable disease. These factors created limitations to the adoption of widespread use of these older models.

The National Heart, Lung and Blood Institute Dynamic Registry compared five multivariable mortality models for their ability to predict in-hospital mortality in 4448 patients undergoing PCI from 1997 to 1999. In this population, 64 patients died, for an in-hospital mortality rate of 1.4 percent. These models were developed and validated prior to the extensive use of stents in New York State, Northern New England Cooperative Group, Cleveland Clinic Foundation, and the University of Michigan as well as the original CathPCI Registry model [3]. The CathPCI Registry model has been updated and recalibrated. The volume of patients included in our model has expanded exponentially as it captures data from across the country.

The Mayo Clinic developed a risk score to identify patients at increased risk for major complications after PCI for procedures performed between January 1, 1996, and December 31, 1999. They validated their model in 2000. This model is relevant to current clinical practice since it was performed after stenting became routine, the patients were usually treated with clopidogrel or ticlopidine, and intravenous glycoprotein IIb/IIIa inhibitors were available. An updated report from the Mayo Clinic, using data from over 7457 PCI’s performed between 2000 and 2005, developed two risk-prediction models, one for mortality alone and one for all major adverse cardiovascular events [4].

Risk scores for procedural death, defined as any death during the index hospitalization, and MACE contained the same 7 variables (age, myocardial infarction less than or equal to 24 hours, preprocedural shock, serum creatinine level, left ventricular ejection fraction, congestive heart failure, and peripheral artery disease). The two models successfully predicted the risk of adverse events during the index hospitalization. The model is useful for providing patients with individualized, evidence-based estimates of procedural risk as part of the informed consent process. However, one study limitation related to this model is that it includes performance at a single, referral center in a lower-risk patient population [4].

The EVENT registry evaluated 7592 consecutive patients who underwent successful or attempted PCI 47 hospitals throughout the United States between July 2004 and September 2006 to determine it pre-procedural cardiac troponin (cTn) elevation in patients with stable coronary artery disease was a predictor of adverse postprocedural outcome. The frequency of an elevated cTn immediately before PCI and its relationship to in-hospital and 1-year outcomes among patients who underwent PCI for either stable angina or a positive stress test was analyzed. The multivariable analyses adjusted for demographic, clinical, angiographic, and procedural factors, baseline cTn elevation was found to be independently associated with the composite of death or myocardial infarction at hospital discharge (odds ratio, 2.1; 95% confidence interval, 1.2 to 3.8; P=0.01) and at the 1-year follow-up (odds ratio, 2.0; 95% confidence interval, 1.2 to 3.3; P=0.005) [5]. This limitation to this model is a focus on either acute coronary syndrome (ACS) or stable disease.

Clinical acuity is a strong predictor of PCI procedural mortality. With inclusion of variables that further characterize clinical stability, the updated CathPCI Registry mortality models remains a current, and well-calibrated across the spectrum of PCI risk [2].

**Guideline driven determination of treatment options for care decision**

Guidelines described in sections 1a.3.

**Appropriate patient selection and use of percutaneous coronary artery intervention for mechanical revascularization (PCI)**

Appropriate use criteria (AUC) for coronary revascularization are tailored to the specific characteristics of individual patients. The evaluation of AUC covers broader array of specific conditions, sometimes hundreds for a given test or treatment decision, to encompass the majority of practice situations. Appropriateness relate to individual patient demographic characteristics, clinical history, risk scores, and/or symptoms and signs. “The increasing prevalence of coronary artery disease (CAD), continued advances in surgical and percutaneous techniques for revascularization and concomitant medical therapy for CAD, and the costs of revascularization have resulted in heightened interest regarding the appropriate use of coronary revascularization. Clinicians, payers, and patients are interested in the specific benefits of revascularization. Inappropriate revascularization may be harmful to patients and generate unwarranted costs to the healthcare system, whereas appropriate revascularization procedures can improve patients' clinical outcomes” [7].

**Reduction in overall mortality associated with PCI**

Upon consideration of associated risk factors and evaluation of guidelines and appropriateness, coronary artery reperfusion improves clinical outcomes for patients. Statistics collected by the American Heart Association indicate that coronary heart disease caused an estimated 1 of every 6 deaths in the United States in 2008. Coronary heart disease mortality in 2008 was 405,309. Each year, an estimated 785,000 Americans will have a new MI, and approximately 470, 000 will have a recurrent MI. It is estimated that an additional 195 000 silent first MI occur each year. Approximately every 25 seconds, an American will have a coronary event, and approximately every minute, someone will die of one. The estimated direct and indirect cost of CVD for 2008 is $297.7 billion (MEPS, Agency for Healthcare Research and Quality, and NHLBI). In 2009, an estimated 7, 453,000 inpatient cardiovascular operations and procedures were performed in the United States (NHLBI tabulation of NHDS, NCHS). In-hospital death rates for PCI have remained stable although comorbidities increased for patients who received the procedure increases over time [8].

References

[1] Peterson ED, Dai D, DeLong ER, et al. Contemporary Mortality Risk Prediction for Percutaneous Coronary Intervention: Results From 588,398 Procedures in the National Cardiovascular Data Registry. J Am Coll Cardiol. 2010;55(18):1923-1932. doi:10.1016/j.jacc.2010.02.005.

[2] Brennan J, Curtis JP, Dai D, et al. Enhanced Mortality Risk Prediction With a Focus on High-Risk Percutaneous Coronary Intervention: Results From 1,208,137 Procedures in the NCDR (National Cardiovascular Data Registry). J Am Coll Cardiol Intv. 2013;6(8):790-799. doi:10.1016/j.jcin.2013.03.020.

[3] Modeling and risk prediction in the current era of interventional cardiology: a report from the National Heart, Lung, and Blood Institute Dynamic Registry. Holmes DR, Selzer F, Johnston JM, Kelsey SF, Holubkov R, Cohen HA, Williams DO, Detre KM, National Heart, Lung, and Blood Institute Dynamic Registry. Circulation. 2003;107(14):1871.

[4] Bedside estimation of risk from percutaneous coronary intervention: the new Mayo Clinic risk scores. Singh M, Rihal CS, Lennon RJ, Spertus J, Rumsfeld JS, Holmes DR Jr. Mayo Clin Proc. 2007;82(6):701.

[5] Prevalence and prognostic significance of preprocedural cardiac troponin elevation among patients with stable coronary artery disease undergoing percutaneous coronary intervention: results from the evaluation of drug eluting stents and ischemic events registry. Jeremias A, Kleiman NS, Nassif D, Hsieh WH, Pencina M, Maresh K, Parikh M, Cutlip DE, Waksman R, Goldberg S, Berger PB, Cohen DJ, Evaluation of Drug Eluting Stents and Ischemic Events (EVENT) Registry Investigators. Circulation. 2008;118(6):632.

[6] Levine GN, Bates ER, Blankenship JC, et al. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. *J Am Coll Cardiol.* 2011;58(24):e44-e122. doi:10.1016/j.jacc.2011.08.007.

[7] Patel MR, Dehmer GJ, Hirshfeld JW, Smith PK, Spertus JA. ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT 2012 Appropriate Use Criteria for Coronary Revascularization Focused Update: A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Association for Thoracic Surgery, American Heart Association, American Society of Nuclear Cardiology, and the Society of Cardiovascular Computed Tomography. *J Am Coll Cardiol.* 2012;59(9):857-881. doi:10.1016/j.jacc.2011.12.001.

[8] AHA Statistical Update: Heart Disease and Stroke Statistics—2012 Update: A Report From the American Heart AssociationCirculation. 2012; 125: e2-e220 Published online before print December 15, 2011, doi: 10.1161/​CIR.0b013e31823ac046: Retrieved at <http://circ.ahajournals.org/content/125/1/e2.full#ref-288>]

**\*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\***

**1a.2** **FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

N/A

**1a.3.****SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measures, including those that are instrument-based) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

☐ Clinical Practice Guideline recommendation (with evidence review)

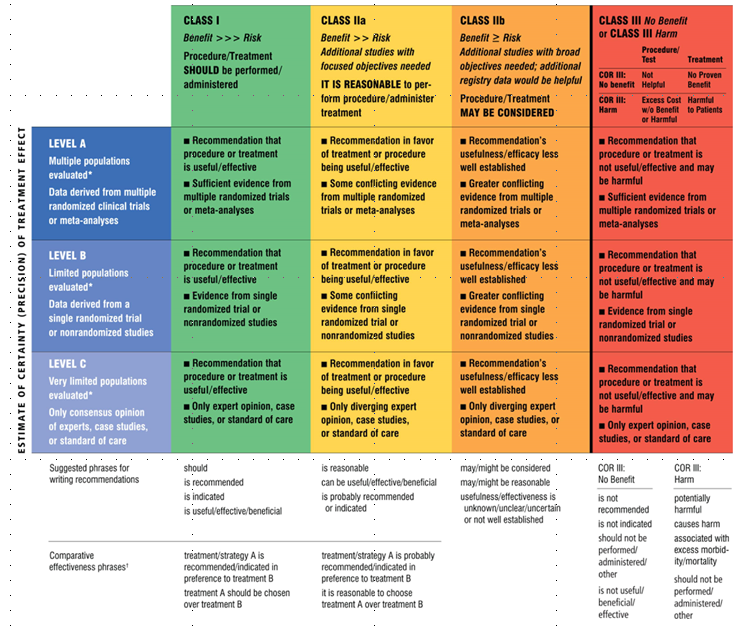
☐ US Preventive Services Task Force Recommendation

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | Levine GN, Bates ER, Blankenship JC, et al. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. *J Am Coll Cardiol.* 2011;58(24):e44-e122. doi:10.1016/j.jacc.2011.08.007. Available at: <http://content.onlinejacc.org/article.aspx?articleid=1147816> |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | 5.2.1 UA/NSTEMI: Recommendations  CLASS I:  3. The selection of PCI or CABG as the means of revascularization in the patient with ACS should generally be based on the same considerations as those without ACS . (Level of Evidence: B)  5.2.2.2 Primary PCI of the Infarct Artery: Recommendations  CLASS I:  4. Primary PCI should be performed in patients with STEMI who develop severe heart failure or cardiogenic shock and are suitable candidates for revascularization as soon as possible, irrespective of time delay. (Level of Evidence: B)  CLASS IIb:  1. Primary PCI might be considered in asymptomatic patients with STEMI and higher risk presenting between 12 and 24 hours after symptom onset. (Level of Evidence: C)  Revascularization to Improve Survival Recommendations  CLASS IIa:  1. PCI to improve survival is reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcome (e.g., a low SYNTAX score [≤22], ostial or trunk left main CAD); and 2) clinical characteristics that predict a significantly increased risk of adverse surgical outcomes (e.g., STS-predicted risk of operative mortality ≥5%) . (Level of Evidence: B)  2. PCI to improve survival may be reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low to intermediate risk of PCI procedural complications and an intermediate to high likelihood of good long-term outcome (e.g., low-intermediate SYNTAX score of <33, bifurcation left main CAD); and 2) clinical characteristics that predict an increased risk of adverse surgical outcomes (e.g., moderate-severe chronic obstructive pulmonary disease, disability from previous stroke, or previous cardiac surgery; STS-predicted risk of operative mortality >2%). (Level of Evidence: B) |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | Recommendation classification is listed with each of the 5 recommendations above for clarity. ACCF/AHA/SCAI recommendations have been assigned a Class I and Class II recommendation. Class I recommendations refer to “Conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.” Class II recommendations refer to “Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment. IIa) Weight of evidence/opinion is in favor of usefulness/efficacy. IIb) Usefulness/efficacy is less well established by evidence/opinion”. |
| Provide all other grades and definitions from the evidence grading system | * No Benefit- Procedure/Test not helpful or Treatment w/o established proven benefit * Harm- Procedure/Test leads to excess cost w/o benefit or is harmful, and or Treatment is harmful   **(See Table 1 below)** |
| Grade assigned to the **recommendation** with definition of the grade | The section of the ACCF/AHA/SCAI PCI guideline which includes the recommendations referenced above pertains to the necessity to evaluate a patients risk factors and incorporating ACS symptoms and hemodynamic stability into the determination for appropriate revascularization  The weight of the evidence in support of the ACCF/AHA/SCAI recommendations is rated as Level B and Level C as noted parenthetically. Level B evidence refers to “Data derived from a single randomized trial, or nonrandomized studies” while Level C evidence refers to “Only consensus opinion of experts, case studies, or standard-of-care.” |
| Provide all other grades and definitions from the recommendation grading system | **(See Table 1 below)** |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | Observational hypothesis-generating analysis, pooled meta- analyses of randomized trials, multi- centered, and single centered study designs were all deployed in the creation of these guidelines.  Information regarding the overall quality of evidence across the studies does not exist. |
| Estimates of benefit and consistency across studies | The focus of the data included for these guidelines were the benefits of treating the Left Main via PCI and the benefits of DES vs. BMS for device choice. The guidelines included here demonstrate the importance of evaluating the personal risk of for PCI. The process of the PCI is not the intent of this measure but only one step in the decision making process of achieving a decreased mortality for this patient population. Thus an extensive evaluation of the magnitude and direction of effect within the evidence used to support PCI was not conducted for the purpose of this application. |
| What harms were identified? | An extensive evaluation of the harms described within the evidence used to support PCI was not conducted for the purpose of this application. |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | TheACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention has not been updated since the 2011 document referenced in the citations above. |

**Table 1**

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**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1** **Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

**1a.4.2 What process was used to identify the evidence?**

**1a.4.3.** **Provide the citation(s) for the evidence.**