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

**Measure Number** (*if previously endorsed*)**:** 0536

**Measure Title**: 30-day all-cause risk-standardized mortality rate following Percutaneous Coronary Intervention (PCI) for patients with ST segment elevation myocardial infarction (STEMI) or cardiogenic shock

**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: 30-day mortality

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.

The goal of this measure is to reduce PCI 30-day mortality rates to best-in-class. Measurement of patient outcomes, including mortality, allows for a broad view of quality of care that encompasses more than what can be captured by individual process-of-care measures. As described below, mortality is likely to be influenced by a broad range of clinical activities such as the prevention of complications and the provision of evidenced-based care.

**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.)

Evidence that the outcome measure has been influenced by one or more clinical interventions:

Numerous studies have demonstrated the efficacy of interventions designed to improve patient outcomes following PCI. These include pharmacologic interventions such as the use of glycoprotein 2b/3a inhibitors, direct thrombin inhibitors, and pre-procedural thienopyridines such as clopidogrel and prasugrel, as well as advances in device technology such as use of stents,, thrombectomy for acute lesions with high thrombus burden, and distal embolic protection for PCI of degenerated saphenous vein grafts. Of note, the majority of these interventions have been shown to reduce endpoints other than mortality, most commonly rates of periprocedural MI, major bleeding, and target vessel revascularization for in-stent restenosis. Although few individual interventions have been shown to reduce mortality, they may collectively exert a favorable impact on hospital PCI mortality rates when implemented in a coordinated fashion.

There is a growing body of evidence that quality improvement efforts can improve outcomes of PCI patients, including survival. Rihal and colleagues examined patient outcomes before and after initiation of a program of continuous quality improvement (CQI) and found a significantly lower in-hospital mortality following PCI despite significant increases in the risk profile of PCI patients. Similar improvements were identified in studies of CQI by Brush et al and Moscucci et al, and improvements in survival were associated with greater adherence to evidence-based practices including preprocedural clopidogrel, use of glycoprotein 2b/3a inhibitors, and volume of iodinated contrast. The observational nature of these studies precludes drawing definitive conclusions, but they strongly suggest a

mechanism through which public reporting of hospital PCI outcomes could promote improvements in the care of PCI patients.

References:

Brush JE, Balakrishnan SA, Brough J, Hartman C, Hines G, Liverman DP, Parker JP, Rich J, Tindall N. (2006). “Implementation of a continuous quality improvement program for percutaneous coronary intervention and cardiac surgery at a large community hospital.” Am Heart J 152 (2):379-85 16875926 (P,S,E,B).

Krumholz HM, Brindis RG, et al. (2006). "Standards for statistical models used for public reporting of health outcomes: an American Heart Association Scientific Statement from the Quality of Care and Outcomes Research Interdisciplinary Writing Group: cosponsored by the Council on Epidemiology and Prevention and the Stroke Council. Endorsed by the American College of Cardiology Foundation." Circulation 113(3): 456-62.

Moscucci M, Kline Rogers E, Montoye C, Smith DE, Share D, O’Donnell M, Maxwell-Eward A, Meengs WL, De Franco AC, Patel K, McNamara R, McGinnity JG, Jani SM, Khanal S, Eagle KA. (2006). “Association of a Continuous Quality Improvement Initiative With Practice and Outcome Variations of Contemporary Percutaneous Coronary Interventions.” Circulation. 113:814-822.

Rihal C, Kamath C, Holmes D, et al. (2006). “Economic and clinical outcomes of a physician-led continuous quality improvement intervention in the delivery of percutaneous coronary intervention.” Am J Manag Care 12:445-452.

**\*\*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.**

See evidence/literature described above in 1a3.

**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** |  |
| 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. |  |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade |  |
| Provide all other grades and definitions from the evidence grading system |  |
| Grade assigned to the **recommendation** with definition of the grade |  |
| Provide all other grades and definitions from the recommendation grading system |  |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? |  |
| Estimates of benefit and consistency across studies |  |
| What harms were identified? |  |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? |  |

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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.**