
CBE ID

4580

Title

Composite measure for the quality of care provided to patients undergoing percutaneous coronary interventions (PCI).

Project

Management of Acute Events, Chronic Disease, Surgery, and Behavioral Health

Endorsement Status

Endorsed

Is Under Review

No

Next Maintenance Cycle

Fall 2029

Previous Endorsement Cycle

Fall 2024

Initial Endorsement

Fri, 03/14/2025 - 10:07

Steward

American College of Cardiology

1.0 New or Maintenance

New

1.1 Measure Structure

Composite Measure

1.3 Electronic Clinical Quality Measure (eCQM)

No

1.6 Measure Description

This is a weighted composite measure comprised of six component measures: three all-cause risk standardized outcome measures on all-cause mortality, bleeding, acute kidney injury and three process measures focused on discharge on guideline directed medical therapy, referral to a cardiac rehabilitation program and PCI performed within ninety minutes of symptoms for patients with acute myocardial infarctions. The target population includes adults (age 18 and greater) undergoing percutaneous coronary interventions. The timeframe for reporting will be a rolling four quarters.

1.7 Composite Measure

Yes

1.7 Measure Type

Other

1.7a Other Measure Type

This is a weighted composite measure combining both outcome measures and process measures.

1.8 Level of Analysis

Facility

1.9 Care Setting

Hospital: Inpatient

1.10 Measure Rationale

Measured entities should report this Quality-of-Care composite measure to provide a comprehensive assessment of the processes of care and in-hospital outcomes of patients following a percutaneous coronary intervention (PCI). This composite measure will improve the quality of care associated with PCI by allowing both patients and hospitals to interpret quality by use of a performance score more easily than reporting the six component measures separately; and using the NCDR benchmark and reporting dashboard the measure will identify opportunities for improvement for poor performing hospitals. Additionally, this single composite score can be used in the NCDR voluntary hospital public reporting program which monitors the quality of cardiovascular care using high quality data while providing actionable insights to hospitals.

The most compelling benefit envisioned by use of this quality-of-care measure is reinforcing and supporting the right of an individual to know about the care that he or she is likely to receive. With the current national emphasis on the quality, accountability, and cost-effectiveness of health care, the various stakeholders and consumers of health care are eager to obtain information about health care facilities and providers. Many public reports use data that are several years old, were not designed for clinical performance reporting, or are constructed using proprietary analytic methods that are difficult to reproduce or verify. This diverse reporting environment can confuse patients and purchasers, has the potential to take our focus away from the rights of the individual patient, and has led to divergent public rankings of the same facility in different reporting systems.

Recognizing the challenges to developing accurate and meaningful reporting, the ACC and its partnering organizations believe that a thoughtful, measured public reporting program, which uses clinical data with scientifically open methodology, subject to iterative improvement and oversight by professional organizations, has significant benefits while minimizing potential unintended consequences. Patients, payers, health care quality organizations, and governmental agencies all desire transparent and accurate reporting of the performance of cardiovascular

programs. Clinicians and patients can benefit from access to this information as long as it is correct and provided in a fair and understandable format. The ACC believes it has a responsibility to move the profession toward acceptance of public reporting by using clinical data from the NCDR. Therefore, after careful study of the feasibility of public reporting using NCDR data, the ACC and its partnering organizations established the Public Reporting Advisory Group to oversee the implementation of the public reporting program and guide operational decisions necessary to achieve these goals. This composite measure that reports the quality of care for patients with PCI is a product of this Advisory Group work.

The potential population of patients and measured entities that can be informed by this measure is significant in size with significant associated healthcare costs. An estimated 20.5 million people in the US ≥ 20 years of age have coronary heart disease (CHD). Approximately every 40 seconds, someone in the US will have a myocardial infarction. The estimated direct and indirect cost of heart disease in the US between 2019 to 2020 (average annual) was \$252.2 billion. Myocardial infarction specifically cost at \$14.3 billion and coronary heart disease at \$8.7 billion were two of the ten most expensive conditions treated in US hospitals in 2017. (Martin et al.,) This composite measure reports the quality of care provided to a substantial portion of these patients.

Martin SS, Aday AW, Almarzooq ZI et al., 2024 Heart Disease and Stroke Statistics: A Report of US and Global Data From the American Heart Association. *Circulation*. 149; (8). doi: 10.1161/CIR.0000000000001209

1.13 Data Dictionary

Not attached. I attest that all information will be provided where codes and/or value sets are needed (1.14a - 1.15c).

1.13a Attach Data Dictionary

[1.13 data dictionary PCI_V5.0_Measure 4580.xlsx](#)

1.14 Numerator

A weighted composite score measuring all-cause mortality, bleeding, acute kidney injury risk standardized outcomes; and processes of care including discharge on guideline directed medical therapy, referral to a cardiac rehabilitation program, and PCI performed within ninety minutes of symptoms (for a sub-set of patients with acute myocardial infarctions).

1.14a Numerator Details

The following six measures are included in the composite.

Mortality

Patients deceased at discharge.

Bleeding

- Patients with a bleeding event that occurred between PCI procedure start date/time to PCI procedure end date/time, OR
- Patients with a bleeding event that occurred 72 hours after PCI procedure event date
- Patients with a hemorrhagic stroke OR
- Patients with cardiac tamponade, OR
- Patients with a post-PCI blood transfusion and a pre-procedure hemoglobin > 8 g/dL, OR
- Patients with an absolute hemoglobin decrease from pre-PCI to post-PCI of ≥ 4 g/dL.

-

Acute kidney injury

- Patients with a new requirement for dialysis
- Patients with an increase in serum creatinine of ≥ 0.3 mg/dL from baseline
- Patients with an increase in serum creatinine of 50% or more from baseline

Guideline directed medical therapy at discharge

- Patients with a stent placed who were prescribed* aspirin, statin and a P2Y12 inhibitor at discharge, OR
- Patients without a stent placed who were prescribed* aspirin and statin at discharge.

*Patients with a medical or patient reason for not prescribing a medication will still meet the numerator IF they were prescribed all other medication(s) for which they were eligible.

*Patients not prescribed aspirin but were prescribed an anticoagulant and a P2Y12 inhibitor will still meet the numerator IF they are prescribed all other medications for which they were eligible.

Reperfusion within 90 minutes

- Patients undergoing primary PCI for ST elevation myocardial infarction with a first reperfusion device within 90 minutes of hospital arrival.

Cardiac rehab patient referral

Patients post PCI during episode of care who have been referred to an outpatient cardiac rehabilitation/secondary prevention (CR/SP) program prior to hospital discharge.

1.15 Denominator

Patients undergoing a percutaneous coronary intervention (PCI)

1.15a Denominator Details

Denominator for all component measures:

Patients aged 18 or over.

Patients with a PCI procedure during the index cath lab visit of the episode of care.

Specific requirements for: Reperfusion within 90 minutes

Patients with an immediate PCI for an acute STEMI.

1.15b Denominator Exclusions

Patients transferred to another acute care facility.

Mortality

- Patients in cardiogenic shock
- Patients resuscitated from cardiac arrest that occurred either:
 - outside of the healthcare facility prior to arrival;
 - while being transferred to the facility;
 - while at the facility.
- Patients transferred to another facility or “Extended care/transitional care unit/Rehab” or patients that left “against medical advice”

Bleeding

- Patients with CABG during episode of care.

- Patients with a pre-procedure hemoglobin > 16g/dL or on any mechanical circulatory support device.

Acute kidney injury

- Patients missing a pre-procedure creatinine or post-procedure creatinine and new requirement for dialysis = No
- Patients that are currently on dialysis
- Patients discharged on the same day as their procedure

Guideline directed medical therapy at discharge

- Patients with comfort measures only
- Patients with death during hospitalization
- Patients who left against medical advice
- Patients transferred to another facility
- Patients who were discharged to hospice care
- Patients with a medical and/or patient reason for not prescribing aspirin **AND** statin **AND** all P2Y12 inhibitors at discharge

-

Reperfusion within 90 minutes

- Patients transferred in from another acute care facility for immediate PCI for STEMI.
- Patient centered reason for delay in PCI and a time to first device activation time of > 90 minutes.

Cardiac rehab patient referral

- Patients with medical reasons for not being referred to cardiac rehabilitation (e.g., patient deemed by provider to have a medically unstable, life-threatening condition).
- Health care system factors (e.g., no cardiac rehabilitation/secondary prevention (CR/SP) program available within 60 min of travel time from the patient's home).

1.15c Denominator Exclusions Details

Patients transferred to 'other acute care hospital' on discharge (10110)

Mortality

1) Patients in with Cardiovascular Instability Type (7415) = Cardiogenic Shock or Refractory Cardiogenic Shock

2) Patients resuscitated from cardiac arrest

- Cardiac arrest out of healthcare facility (4630) or
- Cardiac arrest at transferring facility (4635) or
- Cardiac arrest at this facility (7340)

3) Transferred to another facility after the index procedure or “Extended care/transitional care unit /Rehab” or patients that left “against medical advice” (10110)

Bleeding

- Patients with CABG (10030) = yes
- Any of the following: pre-procedure (6030) Hgb>16g/dL or Mechanical support device (7422) = yes)

Acute kidney injury

- Patients missing a pre-procedure Creatinine (6050) or post-procedure Creatine (8510) **and** new requirement for dialysis = No (9001/9002)
- Patients that are currently on dialysis (4560)
- Patients discharged (10101) on the same day as their procedure (7000)

Guideline directed medical therapy at discharge

Patients with **any** of the following:

- Comfort measures only (10075)
- Death during hospitalization (10105)
- Left against medical advice (10110)
- Discharge to another acute care hospital (10110)
- Discharge to hospice care (10115)
- Medical and/or patient reason for not prescribing aspirin **AND** statin **AND** all P2Y12 inhibitors (10205) at discharge

Reperfusion within 90 minutes

- Transferred in for immediate PCI for STEMI (7841)
- Patient centered reason for delay in PCI (7850) and a time to first device activation time of

> 90 minutes (7845, 3001)

Cardiac rehab patient referral

Medical or health care system reason (10116) for not providing a cardiac rehabilitation referral

1.15d Age Group

Adults (18-64 years), Older Adults (65 years and older)

1.16 Type of Score

Composite scale

1.17 Measure Score Interpretation

Better performance = Higher score

1.18 Calculation of Measure Score

The PCI Quality of Care Composite comprises six metrics, including three process metrics and three outcomes metrics. Each contributes uniquely to the overall PCI Quality of Care Composite score, as illustrated in the table below. The composite score ranges from 0-100, with a higher score indicative of better quality. These measures include:

PCI Quality of Care Composite Metrics Grouping

Metric 4: PCI within 90 minutes (patients with STEMI) Process

****Metric 38: Guideline medications prescribed at discharge (CBE 0964)** Process

****Metric 40: PCI in-hospital risk standardized rate of bleeding events (all patients) (CBE 2459)** Outcome

****Metric 45: Cardiac rehabilitation referral (CBE 0642; 0643)** Process

****Metric 49: PCI in-hospital risk standardized mortality (pts w/out cardiogenic shock or cardiac arrest) (CBE 0133)** Outcome

Metric 57: PCI in-hospital risk-standardized acute kidney injury Outcome

****Indicates metrics that are currently publicly reported (CBE Identifier)**

Weighting: In terms of weighting each of components, outcomes (metrics 40, 49 and 57) accounted for 75% of the weight whereas process measures (metrics 4, 38, and 45) accounted for 25% of the overall weight. Mortality has most weight (35%) whereas cardiac rehabilitation referral has the least weight (5%). The weightings were developed based on clinical and scientific rationale and were approved by consensus from the ACC scientific leadership committees.

Rescaling: As the PCI Quality of Care composite comprises both process and outcomes measures, we needed to ensure that the directionality of the measure was consistent across the metrics. Outcome measures typically have a descending directionality such that a lower score indicates better performance. Process measures often have an ascending directionality, where a higher score indicates better performance. Following the re-scaling of the components of the composite measure, higher scores for all measures indicate better quality. Therefore, the composite measure outcome metrics were re-scaled to a range of zero (0) to one hundred (100) and ascribed a p-score using the following formula:

$$Y = 100 * (\text{MAX}(X) - X) / (\text{MAX}(X) - \text{MIN}(X)) = 100 * \{[\text{MAX}(X) - (X)] / [\text{Range}]\}$$

Target population: Patients undergoing PCI

Time period of data: All metrics are derived from facility-level metric performance rates and are reported as a rolling four quarter value. The reported data are from calendar year 2022.

Eligibility criteria: To report a composite, sites must be able to contribute to all six metrics. Additionally, if there are no eligible cases within a metric, the hospital is not eligible to be included in the composite measure. In analysis of 2022 data, only 4.6% sites were excluded (n=77) due to these criteria. The index cath lab visit during the episode of care must include the PCI procedure. Those PCI procedures during a subsequent lab visit are excluded.

1.19 Measure Stratification Details

The measure is not stratified.

1.20 Types of Data Sources

Registries

1.25 Data Source Details

American College of Cardiology's (ACC) National Cardiovascular Data Registry (NCDR) CathPCI Registry.

1.26 Minimum Sample Size

There is no volume exclusion for the composite measure, ie. no minimum sample size to calculate the performance score.

2.1 Attach Logic Model

[#4580 Logic model.docx](#)

2.2 Evidence of Measure Importance

The American College of Cardiology's (ACC) CathPCI Registry was developed to characterize the quality of care provided to patients undergoing percutaneous coronary interventions (PCIs). Risk standardized models allow for the consideration of patients' pre-procedural risk factors when estimating PCI-associated mortality rates, bleeding rates and acute kidney injury rates (1). Process measures focus on the steps within the health care system's team approach that should be followed to provide high quality healthcare. This quality-of-care composite measure includes three risk models and three process measures. The importance and scientific evidence associated with each component measure is defined below.

-

Risk of mortality for patients without cardiac arrest/cardiogenic shock (CBE # 0133)

Mortality is arguably the worst outcome associated with an interventional procedure for patients. The risk standardized mortality prediction models have been important tools used in clinical decision making, quality improvement, and research by allowing appropriate comparison of site-specific outcomes that account for differences in case mix (1). The mortality risk model associated with percutaneous interventions (PCI) also plays an important role as public reporting and incorporation of outcomes measures into payment programs continues to evolve in the United States (1).

The 2013 and 2021 ACC/American Heart Association guidelines recommend that immediate angiography and PCI should be considered in resuscitated out-of-hospital cardiac arrest patients whose initial electrocardiography shows STEMI (2,3). Although the care of patients with out-of-hospital cardiac arrest has improved over time, outcomes in this population are extremely poor, with mortality rates of approximately 50%, primarily driven by non-cardiovascular sequelae (1). There are multiple factors that impact mortality in this high-risk cohort, including time to cardiopulmonary resuscitation, time to defibrillation, total ischemic time, and neurological status; the latter is shown to enhance mortality risk prediction when considered (1).

It is important for organizations that collect and publicly report STEMI and PCI data to consider resuscitated out-of-hospital cardiac arrest patients separately from their hospital and individual operator quality “scorecards” because such patients, even with optimal care, have a much higher mortality rate than that of patients with STEMI who have not had a cardiac arrest (1). Public reporting in this instance might have the unintended consequence of reducing appropriate care (1). The mortality measure included in this quality composite excludes patients with cardiac arrest and/or cardiogenic shock for these reasons.

Additionally, risk prediction models have not included frailty in the risk assessment of patients undergoing PCI. In studies with prospective evaluation and measurement of physical frailty, more than two-thirds of patients >65 years of age undergoing PCI have some degree of frailty (1). After PCI, frail patients are at increased risk for hospital mortality and cardiovascular complications, but PCI remains an important treatment option (1). Given this, the CathPCI Registry began collecting outcomes on patient frailty, designated based on the clinical status at the time of PCI. In our multivariate model, frailty was an important predictor that improved the discriminatory ability of the risk model. Although assessment of frailty can be subjective, this model incorporates a standardized definition and is monitored by the CathPCI Registry data monitoring and audit programs.

This in-hospital mortality model incorporates contemporary variables that are reflective of clinical acuity and allows for the accurate prediction of risk of mortality following PCI. Utilization of this model, both in public reporting and in quality improvement efforts, will help standardize the assessment of risk associated with PCI both for hospitals and patients.

Risk of bleeding (CBE # 2459)

Intra and post-procedural bleeding is recognized as a major risk factor for subsequent mortality. Bleeding may lead to mortality directly (because of the bleeding event) or through ischemic complications that occur when antiplatelet or anticoagulant agents are withdrawn in response to the bleeding. Bleeding may also be a marker of comorbidities associated with worse prognosis (e.g., occult cancer). The risk of bleeding is associated with several patient factors (e.g., advanced age, low body mass index, chronic kidney disease (CKD), baseline anemia), as well as the degree of platelet and thrombin inhibition, vascular access site, and sheath size. The overall approach to PCI should be individualized to minimize both ischemic and bleeding risks.

Identifying pre-operative risk factors for bleeding, understanding the benefits and risks of DAPT and adjusting the management of patients at risk for bleeding will lower the incidence of bleeding and improve 30-day mortality for patients who undergo PCI. Hospitals can adopt bleeding avoidance strategies such as appropriate use of anticoagulants, determination of best access site and sheath size for the patient and use of closure devices. Developments such as reducing sheath

sizes, alternative access sites and guidelines that optimize antithrombotic therapy are necessary to reduce the incidence of this detrimental complication (4).

Guideline recommendations to reduce the risk of bleeding (5)

- In patients with acute coronary syndrome (ACS) undergoing PCI, a radial approach is indicated in preference to a femoral approach to reduce the risk of death, vascular complications, or bleeding [COR 1 LOE A].
- In patients with stable ischemic heart disease (SIHD) undergoing PCI, the radial approach is recommended to reduce access site bleeding and vascular complications [COR 1 LOE A].

Risk of acute kidney injury

Assessing glomerular filtration rates pre- and post-procedure, identifying other pre-procedure risk factors for acute kidney injury (AKI), and adjusting the management of this high-risk group accordingly will reduce the incidence of AKI and mortality in patients who undergo PCI.

Alsabbagh et al., found hemodynamic monitoring approaches, composition of fluids in intravenous replacement therapy and avoidance of nephrotoxic agents, especially for patients deemed to be higher risk for AKI, can each result in lower incidence of AKI. (6) Amin et al, identified that contrast use varies among physicians and the amount of contrast used was not decreased for patients with higher risk of AKI. (7) These findings identify opportunities to reduce AKI in patients who undergo PCI.

The National Kidney Foundation recommends that “all patients undergoing contrast-enhanced imaging procedures should be evaluated for risk of AKI”. Additionally, the “risks and benefits of contrast administration need to be carefully evaluated in patients at high risk of contrast-induced AKI. The risk of contrast-induced AKI should not preclude the performance of needed diagnostic imaging and therapeutic procedures in high-risk patients”. (8)

Guideline recommendations to reduce the risk of acute kidney injury (8)

- Define and stage AKI after administration of intravascular contrast media as per Recommendations 2.1.1-2.1.2. (Not Graded)
- In individuals who develop changes in kidney function after administration of IV contrast media, evaluate for CI-AKI as well as for other possible causes of AKI. (Not Graded)
- Assess the risk for CI-AKI and screen for pre-existing impairment of kidney function in all patients who are considered for a procedure that requires intravascular (i.v. or i.a.) administration of iodinated contrast medium. (Not Graded)

- Consider alternative imaging methods in patients at increased risk for CI-AKI. (Not Graded)
- Use the lowest possible dose of contrast medium in patients at risk for CI-AKI. (Not Graded)
- Use either iso-osmolar or low-osmolar iodinated contrast media, rather than high-osmolar iodinated contrast media in patients at increased risk of CI-AKI. [COR 1, LOE B]
- Recommend i.v. volume expansion with either isotonic sodium chloride or sodium bicarbonate solutions, rather than no i.v. volume expansion, in patients at increased risk for CI-AKI. [COR 1, LOE A]
- Recommend not using oral fluids alone in patients at increased risk of CI-AKI. [COR 1, LOE C]

Guideline directed medical therapy at discharge (CBE # 0964)

Aspirin at discharge (9)

- In patients treated with DAPT, a daily aspirin dose of 81 mg (range, 75 mg to 100 mg) is recommended. [COR 1, LOE B]

P2Y12 Inhibitor at discharge (9)

- In selected patients undergoing PCI, shorter-duration DAPT (1-3 months) is reasonable, with subsequent transition to P2Y12 inhibitor monotherapy to reduce the risk of bleeding events. [COR 2a, LOE A]
- In patients with SIHD treated with DAPT after BMS implantation, P2Y12 inhibitor therapy (clopidogrel) should be given for a minimum of 1 month. [COR 1, LOE A]
- In patients with SIHD treated with DAPT after DES implantation, P2Y 12 inhibitor therapy (clopidogrel) should be given for at least 6 months. [COR 1, LOE B]
- In patients with ACS (NSTEMI-ACS or STEMI) treated with DAPT after BMS or DES implantation, P2Y12 inhibitor therapy (clopidogrel, prasugrel, or ticagrelor) should be given for at least 12 months. [COR 1, LOE B]

Statin at discharge (10)

- In patients who are 75 years of age or younger with clinical ASCVD,* high-intensity statin therapy should be initiated or continued with the aim of achieving a 50% or greater reduction in LDL-C levels. [COR 1, LOE A]
- In patients with clinical ASCVD in whom high-intensity statin therapy is contraindicated or who experience statin-associated side effects, moderate-intensity statin therapy should be initiated or continued with the aim of achieving a 30% to 49% reduction in LDL-C levels. [COR 1, LOE A]
- In patients with clinical ASCVD who are judged to be very high risk and considered for PCSK9 inhibitor therapy, maximally tolerated LDL-C lowering therapy should include

maximally tolerated statin therapy and ezetimibe. [COR 1, LOE B]

- In patients with clinical ASCVD who are judged to be very high risk and who are on maximally tolerated LDL-C lowering therapy with LDL-C 70 mg/dL or higher (≥ 1.8 mmol/L) or a non-HDL-C level of 100 mg/dL or higher (≥ 2.6 mmol/L) it is reasonable to add a PCSK9 inhibitor following a clinician-patient discussion about the net benefit, safety, and cost. [COR 2a, LOE A]

Revascularization within 90 minutes for patients with STEMI

Immediate reperfusion therapy for patients with STEMI improves mortality rate, and primary PCI has been shown to be superior to fibrinolytic therapy. (3)

Guideline recommendations for patients with STEMI (3)

- In patients with STEMI and ischemic symptoms for <12 hours, PCI should be performed to improve survival. [COR 1, LOE A]
- In patients with STEMI and cardiogenic shock or hemodynamic instability, PCI or CABG (when PCI is not feasible) is indicated to improve survival, irrespective of the time delay from MI onset. [COR 1, LOE B]

Referral provided at discharge to cardiac a rehabilitation program (CBE 0642, CBE 0643)

Cardiac rehabilitation services have been shown to help reduce morbidity and mortality in persons who have experienced a recent coronary artery disease event, but these services are used in <30% of eligible patients. (11) Cardiac rehabilitation is an evidence-based intervention comprising patient education, behavior modification, and exercise training to improve secondary prevention outcomes in patients with CVD. Cardiac rehabilitation assists patients with adherence to healthy lifestyle habits; addresses comorbid conditions (e.g., diabetes); monitors for safety issues, including new or recurrent symptoms; and facilitates adherence to evidence-based medical therapies. Cardiac rehabilitation may include a center-based cardiac rehabilitation program that incorporates face-to-face supervised exercise or an alternative cardiac rehabilitation delivery model that meets criteria for safety and effectiveness, as specified by the cardiac rehabilitation guidelines of the American Association of Cardiovascular and Pulmonary Rehabilitation. (3)

ACC/AHA/SCAI Guideline for Coronary Artery Revascularization

- In patients who have undergone revascularization, a comprehensive cardiac rehabilitation program (home based or center based) should be prescribed either before hospital discharge or during the first outpatient visit to reduce deaths and hospital readmissions and improve quality of life. [COR 1 LOE A] (3)
- Patients who have undergone revascularization should be educated about CVD risk factors and their modification to reduce cardiovascular events. [COR 1 LOE C-LD] (3)
- All eligible patients with NSTEMI-ACS should be referred to a comprehensive cardiovascular

rehabilitation program either before hospital discharge or during the first outpatient visit. (COR I, LOE B) (12)

- Exercise-based cardiac rehabilitation/secondary prevention programs are recommended for patients with STEMI. (COR I, LOE B) (12)

References

1. Castro-Dominguez YS, Wang Y, Mingos KE, et al., Predicting In-Hospital Mortality in Patients Undergoing Percutaneous Coronary Intervention. JACC. 2021. 20;78(3):216-229. doi: 10.1016/j.jacc.2021.04.067.
2. O'Gara PT, Kushner FG, Ascheim DD, et al., 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, JACC. 2013. 61 (4): e78-e140. <https://doi.org/10.1016/j.jacc.2012.11.019>.
3. Lawton, J, Tamis-Holland, J. et al. 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. JACC. 2022 Jan, 79 (2) e21-e129. <https://doi.org/10.1016/j.jacc.2021.09.006>
4. Vora, A.N., Peterson, E.D, McCoy, L.A. The Impact of Bleeding Avoidance Strategies on Hospital-Level Variation in Bleeding Rates Following Percutaneous Coronary Intervention Insights From the National Cardiovascular Data Registry CathPCI Registry. JACC Interventions, 2016; 9(8): 771-9.
5. 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.
6. Alsabbagh MM, Asmar A, Ejaz NI, et al. Update on clinical trials for the prevention of acute kidney injury in patients undergoing cardiac surgery. Am J Surg 2013;206:86-95
7. Amin, A.P., Bach, R. G, Caruso, M.L. Association of Variation in Contrast Volume With Acute Kidney Injury in Patients Undergoing Percutaneous Coronary Intervention JAMA Cardiol. 2017;2(9):1007-1012.
8. Palevsky, PM, Liu KD, Brophy PD., et al., KDOQI US Commentary on the 2012 KDIGO Clinical Practice Guideline for Acute Kidney Injury. 2012. American Journal of Kidney Disease.61(5);649-672. <https://doi.org/10.1053/j.ajkd.2013.02.349>
9. Levine, G, Bates, E, Bittl, J. et al. 2016 ACC/AHA Guideline Focused Update on Duration of Dual Antiplatelet Therapy in Patients With Coronary Artery Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. JACC. 2016 Sep, 68 (10) 1082-1115. <https://doi.org/10.1016/j.jacc.2016.03.513>
10. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APHA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. JACC. 2019;73:e285-350.2
11. Thomas, R, Balady, G, Banka, G. et al. 2018 ACC/AHA Clinical Performance and Quality Measures for Cardiac Rehabilitation: A Report of the American College of

Cardiology/American Heart Association Task Force on Performance Measures. JACC. 2018 Apr, 71 (16) 1814-1837. <https://doi.org/10.1016/j.jacc.2018.01.004>

12. Amsterdam, E, Wenger, N, Brindis, R. et al. 2014 AHA/ACC Guideline for the Management of Patients With Non-ST-Elevation Acute Coronary Syndromes: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. JACC. 2014 Dec, 64 (24) e139-e228. <https://doi.org/10.1016/j.jacc.2014.09.017>

2.3 Anticipated Impact

The anticipated impact is multi-factorial. Ideally, our target audience, the consumers of healthcare, will have the ability to assess their regional cardiovascular care providers during their own decision-making process. We anticipate some concerns voiced by the cardiovascular community.

The medical community continues to have an understandable degree of anxiety over the unintended consequences of public reporting and the ability of the public and others to misuse or misinterpret the results. The ACC is firmly committed to developing a cardiovascular public reporting program using high-quality clinical data that fairly and accurately characterizes the care provided while delivering usable and understandable information to the public. Voluntary participation in public reporting has the potential to enhance a health care facility's standing and linkage to the community.

Advocates argue that public reporting enables patients to identify the best hospitals, simultaneously giving clinicians and health care organizations incentives to improve quality (1). Some studies have shown associations between public reporting and higher quality of care (2, 3).

Opponents counter that data used in some measures lack adequate clinical granularity to accurately reflect quality or that outcomes reporting may encourage denial of care to the sickest patients who might benefit most from treatment, but are also at highest risk for poor outcomes (4-11). Risk adjustment is intended to correct for the inclusion of sicker patients (12,13), but in practice, risk adjustment is imperfect; variability in how high-risk features are documented in the medical record and then abstracted into registry data are common (14-16).

To make public reporting helpful to consumers, it is important to understand that consumers and clinical experts may define quality differently. The top factors consumers identified as being most important in determining the quality of health care were affordability, the physician's qualifications, and access to care for everyone. This is clearly different from the concept of healthcare quality represented in most public performance reports, which often include technical measures of quality and patient experiences. Consumers can also misunderstand reported quality measures. For example, longer length of stay is intended to indicate poor performance, but some

consumers may incorrectly believe this a favorable finding. Other measures may be incomprehensible to consumers, such as why certain medications are necessary for some conditions. (17) This composite measure balances reporting on proven clinical best practices and guideline directed medical care with a straight forward scoring system that patients can interpret.

- 1.Hafner JM, Williams SC, Koss RG, et al. The perceived impact of public reporting hospital performance data: interviews with hospital staff. *Int J Qual Health Care*. 2011;23:697-704. doi: 10.1093/intqhc/mzr056.
- 2.Cavender MA, Joynt KE, Parzynski CS, et al. State mandated public reporting and outcomes of percutaneous coronary intervention in the United States. *Am J Cardiol*. 2015;115:1494-501. doi: 10.1016/j.amjcard.2015.02.050.
- 3.Boyden TF, Joynt KE, McCoy L, et al. Collaborative quality improvement versus public reporting for percutaneous coronary intervention: a comparison of PCI in New York versus Michigan. *Am Heart J*. 2015;170:1227-33. doi: 10.1016/j.ahj.2015.09.006.
- 4.Resnic FS, Welt FG. The public health hazards of risk avoidance associated with public reporting of risk-adjusted outcomes in coronary intervention. *J Am Coll Cardiol*. 2009;53:825-30. doi: 10.1016/j.jacc.2008.11.034.
- 5.Joynt KE, Blumenthal DM, Orav EJ, et al. Association of public reporting for percutaneous coronary intervention with utilization and outcomes among Medicare beneficiaries with acute myocardial infarction. *JAMA*. 2012;308:1460-8. doi: 10.1001/jama.2012.12922.
- 6.Chassin M, Hannan E, DeBuono B. Benefits and hazards of reporting medical outcomes publicly. *N Engl J Med*. 1996;334:394-8. doi: 10.1056/NEJM199602083340611.
- 7.Ettinger WH, Hylka SM, Phillips RA, et al. When things go wrong: the impact of being a statistical outlier in publicly reported coronary artery bypass graft surgery mortality data. *Am J Med Qual*. 2008;23:90-5. doi: 10.1177/1062860607313141.
- 8.Werner RM, Asch DA. The unintended consequences of publicly reporting quality information. *JAMA*. 2005;293:1239-44. doi: 10.1001/jama.293.10.1239.
- 9.Marshall MN, Shekelle PG, Leatherman S, Brook RH. The public release of performance data: What do we expect to gain? A review of the evidence. *JAMA*. 2000;283:1866-74. doi: 10.1001/jama.283.14.1866.
- 10.Potter BJ, Yeh RW, Pinto DS. Public reporting of PCI outcomes: for better or for worse. *Curr Cardiol Rep*. 2014;16:500. doi: 10.1007/s11886-014-0500-9.
- 11.Spertus JA, Furmann MI. Translating evidence into practice: are we neglecting the neediest? *Arch Int Med*. 2007;167:987-8. doi: 10.1001/archinte.167.10.987.
- 12.Resnic FS, Normand SL, Piemonte TC, et al. Improvement in mortality risk prediction after

percutaneous coronary intervention through the addition of a “compassionate use” variable to the National Cardiovascular Data Registry CathPCI dataset: a study from the Massachusetts Angioplasty Registry. J Am Coll Cardiol. 2011;57:904–11. doi: 10.1016/j.jacc.2010.09.057.

13. Peterson ED. The need for “compassionate provider profiling” refining risk assessment for percutaneous coronary intervention. J Am Coll Cardiol. 2011;57:912–3. doi: 10.1016/j.jacc.2010.10.022.

14. Lilford R, Pronovost P. Using hospital mortality rates to judge hospital performance: a bad idea that just won’t go away. BMJ. 2010;340:c2016. doi: 10.1136/bmj.c2016.

15. Sherwood MW, Brennan JM, Ho KK, et al. The impact of extreme-risk cases on hospitals’ risk-adjusted percutaneous coronary intervention mortality ratings. J Am Coll Cardiol Interv. 2015;8:10–6. doi: 10.1016/j.jcin.2014.07.025.

16. Barringhaus KG, Zelevinsky K, Lovett A, et al. Impact of independent data adjudication on hospital-specific estimates of risk-adjusted mortality following percutaneous coronary interventions in Massachusetts. Circ Cardiovasc Qual Outcomes. 2011;4:92–8. doi: 10.1161/CIRCOUTCOMES.110.957597.

17. Dehmer GJ, Drozda JP, Brindis RG, et al., 2014. Public Reporting of Clinical Quality Data: An Update for Cardiovascular Specialists. JACC. 63; (13) 1239-1245.
<https://doi.org/10.1016/j.jacc.2013.11.050>.

2.4 Performance Gap

Please see page 4 tables 1-3 and figures 2-4 in the tables and figures document attached.

Table 1. Performance Scores by Decile

	Performance Gap												
	Overall	Minimum	Decile_1	Decile_2	Decile_3	Decile_4	Decile_5	Decile_6	Decile_7	Decile_8	Decile_9	Decile_10	Maximum
Mean Performance Score	83.63	49.77	72.76	78.29	80.67	82.25	83.57	84.84	86.19	87.43	88.83	91.47	95.63
N of Entities	1608	1	160	161	161	161	161	161	161	161	161	160	1
N of Persons / Encounters / Episodes													

2.5 Health Care Quality Landscape

ACC created a composite measure to assess and report the quality of care associated with PCI. No other composite measure exists to inform patients in this area of healthcare. This composite

measure uniquely fills the gap within the complicated healthcare landscape for both the patient and the clinician community.

2.6 Meaningfulness to Target Population

This measure was developed with input from a technical expert panel that includes patient and caregiver representation. As regaining and preserving health is likely the goal of most patients, overall quality of care during PCI as a composite measure is easily understood and will help patients in understanding quality of care across facilities and in making decisions about where to receive their care.

3.1 Contributions Towards Closing Care Gaps

Please see page 29 table 15 in the attached tables and figures document.

4.1 Feasibility Assessment

The data elements required to generate this measure are abstracted from a medical record by someone other than the person obtaining original information (e.g., chart abstraction for quality measure or registry). All data elements are available in defined fields in electronic clinical data (e.g., clinical registry). This measure uses clinical data from the NCDR CathPCI Registry.

Availability: Data elements routing generated and used during care delivery

Participating hospitals report patient demographics, medical history, risk factors, hospital presentation, initial cardiac status, procedural details, medications, laboratory values and in-hospital outcomes as the key activity of participating in the NCDR CathPCI registry. The majority of the required data elements are routinely generated and acquired during the delivery of standard cardiac care to this patient population. Electronic extraction of data recorded as part of the procedure expedites data collection. This strategy offers point of care data collection and minimizes time and cost. Institutions can manually report using a free web-based tool or automate the reporting by using certified software developed by third-party vendors. The data elements required for this measure are readily available within the patient's medical record or can be attained without undue burden by the hospital. Most data elements exist in a structured format within the patient's electronic health record.

Sampling:

There is no sampling of patient data allowed within the contractual terms of participation in the NCDR CathPCI Registry. The registry is designed to include 100 percent of consecutive adult patients who undergo PCI at participating institutions. Section 2.b of the NCDR Master Agreement with participants includes 'Participant Responsibilities': "b. Use of ACCF Data Set and ACCF-Approved Software. Participant will submit a data record on each patient who receives medical care and who is eligible for inclusion in the Registries in which Participant is participating under this Agreement." Adult patients, ages 18 years and older, who undergo a diagnostic cardiac catheterization and/or PCI. Eligible diagnostic catheterizations are characterized by the passage of a catheter into the aortic root for pressure measurements and/or angiography and can include

Left Ventricle (LV) pressure measurements, LV angiography, coronary angiography, and coronary artery bypass angiography. Eligible PCI procedures include those that involve passage or attempted passage of a coronary device across one or more coronary lesions for purposes of increasing the intraluminal diameter of the vessel and/or restoring or improving circulation. Patients are selected for inclusion by reviewing existing medical records and no direct interaction with the patient is required outside of the normal course of care. There is no discrimination or bias with respect to inclusion based on sex, race, or religion.

Patient confidentiality:

The CathPCI Registry dataset was created by a panel of experts using available ACC-AHA guidelines, data elements and definitions, and other evidentiary sources. Protected Health Information (PHI) as such term is defined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), such as social security number, is collected. The intent for collection of PHI is to allow for registry interoperability and the potential for future generation of patient-level drill downs in Quality and Outcomes Reports. Registry sites can opt out of transmitting direct identifiers to the NCDR, enabling inclusion of direct identifiers in the registry to be at the discretion of the registry participants themselves. When using the NCDR web-based data collection tool, direct identifiers are entered but a partition between the data collection process and the data warehouse maintains the direct identifiers separate from the analysis datasets. The minimum level of PHI transmitted to the ACCF when a participant opts out of submitting direct identifiers meets the definition of a Limited Data Set as such term is defined by HIPAA. All analyses are performed by contracted data analytic centers who conduct such analysis on a Limited Data Set.

Data collection within the NCDR conforms to laws regarding PHI. Each participant signs a Business Associate Agreement with the ACCF permitting the use and disclosure of PHI. Patient confidentiality is of utmost concern with all metrics. The proposed measure does not currently include a patient survey. There is no added procedural risk to patients through involvement in the CathPCI Registry. No testing, time, risk, or procedures beyond those required for routine care are imposed. The primary risk associated with this measure is the potential for a breach of patient confidentiality. The ACCF has established a robust plan for ensuring appropriate and commercially reasonable physical, technical, and administrative safeguards are in place to mitigate such risks.

Data are maintained on secure servers with appropriate safeguards in place. The project team periodically reviews all activities involving PHI to ensure that such safeguards including standard operating procedures are being followed. The procedure for notifying the ACCF of any breach of confidentiality and immediate mitigation standards that need to be followed are communicated to participants. ACCF limits access to PHI, and to equipment, systems, and networks that contain, transmit, process or store PHI, to employees who need to access the PHI for purposes of performing ACCF's obligations to participants who are in a contractual relationship with the ACCF. All PHI are stored in a secure facility or secure area within ACCF's facilities which has separate physical controls to limit access, such as locks or physical tokens. The secured areas are monitored 24 hours per day, 7 days per week, either by employees or agents of ACCF, by video surveillance, or by intrusion detection systems.

Each participant who has access to the NCDR website must have a unique identifier. The password protected webpages have implemented inactivity time-outs. Encryption of wireless

networks, data transmission and authentication of wireless devices containing NCDR Participant's information is required. PHI may only be transmitted from ACCF's premises to approved parties, which shall mean: A subcontractor who has agreed to be bound by the terms of the Business Associate Agreement between the ACCF and the NCDR participant.

Overall, there is no added procedural risk to patients through their hospital's involvement in the CathPCI Registry. No testing, time, risk, or procedures beyond those required for routine care will be imposed.

4.3 Feasibility Informed Final Measure

Please also see sections 1.10 and 3.1. A summary is below.

The feasibility of data collection was used to inform the measure specifications of this composite measure. Participating hospitals report patient demographics, medical history, risk factors, hospital presentation, initial cardiac status, procedural details, medications, laboratory values and in-hospital outcomes as the key activity of participating in the NCDR CathPCI registry. The majority of the required data elements are routinely generated and acquired during the delivery of standard cardiac care to this patient population. The data elements required for this measure are readily available within the patient's medical record or can be attained without undue burden by the hospital. Most data elements exist in a structured format within the patient's electronic health record.

The ACC believes it has a responsibility to move the profession toward acceptance of public reporting by using clinical data from the NCDR. Therefore, after careful study of the feasibility of public reporting using NCDR data, the ACC and its partnering organizations established the Public Reporting Advisory Group to oversee the implementation of the public reporting program and guide operational decisions necessary to achieve these goals. This composite measure that reports the quality of care for patients with PCI is a product of this Advisory Group work.

4.4 Proprietary Information

Proprietary measure or components with fees

4.4a Fees, Licensing, or Other Requirements

The ACCF's program the National Cardiovascular Data Registry (NCDR) provides evidence-based solutions for cardiologists and other medical professionals committed to excellence in cardiovascular care. NCDR hospital participants receive confidential benchmark reports that include access to measure macro specifications and micro specifications, the eligible patient population, exclusions, and model variables (when applicable). In addition to hospital sites, NCDR Analytic and Reporting Services provides consenting hospitals' aggregated data reports to interested federal and state regulatory agencies, multi-system provider groups, third-party payers, and other organizations that have an identified quality improvement initiative that supports

NCDR-participating facilities. Lastly, the ACCF also allows for licensing of the measure specifications outside of the Registry.

Measures that are aggregated by ACCF and submitted to NQF are intended for public reporting and therefore there is no charge for a standard export package. However, on a case-by-case basis, requests for modifications to the standard export package will be available for a separate charge.

5.1.1 Data Used for Testing

We used a clinical registry, the National Cardiovascular Data Registry (NCDR) for CathPCI Registry, to support this measure. This is a national quality improvement registry with >1,700 US hospitals participating. Some states and healthcare systems mandate participation. Rigorous quality standards are applied to the data and both quarterly and ad hoc performance reports are generated for participating centers to track and improve their performance.

Dates of testing for scientific acceptability: January 1, 2022 – December 31, 2022

5.1.2 Differences in Data

All the data used for testing herein was derived from the CathPCI Registry. The analysis to examine trends in data were conducted using calendar year 2021 and 2022 data to provide two time periods of observation.

Analyses that assessed reliability used 2021 and 2022 data. The validity testing elements were informed by 2022 data.

5.1.3 Characteristics of Measured Entities

Please see page 7, tables 4-9 in the tables and figures document attached.

5.1.4 Characteristics of Units of the Eligible Population

Please see page 9 tables 10 & 11 in the tables and figures document attached.

5.2.1 Level(s) of Reliability Testing Conducted

Person or encounter level (i.e., data element) (e.g., inter-abstractor reliability)

5.2.2 Method(s) of Reliability Testing

Assessment of reliability of the data collection at the patient level

This composite measure involves the data collection of 108 data elements. The numerator, denominator and exclusion criteria are listed above for each component measure in section “Numerator Details”, “Denominator Details”, and “Denominator Exclusions Details”. The registry data dictionary is also attached to this application and can be used to crosswalk Table 12 with the data elements listed in the above sections for full transparency. The 108 data elements are listed in Table 12. We provide audit results from two years of registry audits, 2022 and 2021. There are two columns within Table 12 labelled Agreement rate. This column indicates how closely the audited data was consistent with the original submitted data.

In total, the composite measure requires 108 unique data elements from the CathPCI registry, 85% (92 data elements) of these data elements have recently been included in data audits. The remaining 15% (16 data elements) will be included in next year’s audit program. The reliability results from the audit indicate consistency and reliability for the significant portion of data elements used in the measure. For the few data elements that do not have high agreement rates, we will focus on including these data elements in education initiatives for improving the accuracy of data collection for our participating hospitals. We anticipate the consistency of data capture will improve over time as focused education efforts are made towards that goal. We have successfully achieved this goal for other measures in the past.

Steps used reliability testing of data at the patient level

For the audit of 2022 data, eight hospitals from the pool of 100 audited hospitals were randomly selected to ensure that the auditors were abstracting the data consistently. Five records from each of the selected facilities for a total of 40 records were evaluated. The audit vendor assigned the records from each facility to another nurse for re-abstraction of data. The re-assignment was such that each nurse was represented at least one in the inter-rater reliability assessment audit (IRRA) on either the original abstraction or the re-abstraction. The IRRA involved both new and experienced nurses responsible for data abstraction. The datasets from the two auditors were then compared to detect if there was miscoding or a need to re-train the auditors.

Statistical analysis used

Agreement rate can be interpreted as follows based on the data assessed:

- Exceeds Expectations: agreement rate $\geq 93\%$
- Meets Expectation: agreement rate 85% - 93%
- Needs Improvements: agreement rate $< 85\%$

A 95% confidence interval was calculated for each PABAK statistic to reflect sampling error and indicate a range of plausible values for the PABAK statistic for discrete variables.

General interpretation of the PABAK statistic is similar to the KAPPA.

PABAK score:

Interpretation

0.00 Poor agreement

0.01-0.20 Slight agreement

0.21-0.40 Fair agreement

0.41-0.60 Moderate agreement

0.61-0.80 Substantial agreement

0.81-1.00 Almost perfect agreement

Pearson correlation coefficients were calculated for continuous variables. These results are listed in bold and italicized.

Pearson Correlation Coefficient

Interpretation

0.70 - 1.0 Strong linear relationship

0.50 - 0.70 Moderate linear relationship

0.30 - .50 Fair linear relationship

< 0.30 Poor linear relationship

To assess reliability of the composite, we examined the extent to which one time period of evaluation (2021) compared to a different time period of evaluation (2022). That is, we took a 'test-retest' approach in which hospital performance is measured using 2021 data, then again measured using 2022 data, and calculated the agreement of the two resulting performance measures across hospitals. As a metric of agreement, we calculated the intra-class correlation coefficient.

We used test-retest reliability for the PCI Quality of Care Composite as it is an assessment of the stability and consistency of a measurement over time, mitigating the impact of random measurement errors. Through using this split-sample approach, we could average a series of reliability estimates calculated from many resamples of the data without replacement to obtain a more stable reliability estimate. (1)

1. Nieser, K. J., & Harris, A. H. (2024). Split-sample reliability estimation in health care quality measurement: Once is not enough. Health Services Research. doi:
<https://doi.org/10.1111/1475-6773.14310>

This is also documented on page 11 in the attached tables and figures document.

5.2.3 Reliability Testing Results

Please see table 12 in the attached tables and figures document in question 4.2.3a.

5.2.3a Attach Additional Reliability Testing Results

[Table 12 Reliability and validity testing results.docx](#)

5.2.4 Interpretation of Reliability Results

Agreement rates, PABAK scores and Pearson Correlation Coefficients are provided for audited data elements in the attachment 4.2.3a Table 12. The third-party reliability testing (via the audit) demonstrates that the composite measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period. This result demonstrates the measure output is a reliable reflection of the patient's medical record at the data element level.

5.3.1 Level(s) of Validity Testing Conducted

Person or encounter level (i.e., data element) (e.g., sensitivity and specificity), Accountable entity level (i.e., measure score) (e.g., criterion validity)

5.3.3 Method(s) of Validity Testing

Also located on page 14 and table 13 in the attached tables and figures document.

Patient and/or encounter level validity testing

One hundred randomly selected hospitals were chosen to participate in an audit of the 2022 CathPCI Registry data, this was repeated for 2021 data. Sites with a minimum of ten baseline records during the audit period were selected were randomly selected for abstraction. Trained nurse auditors re-abstracted preselected data elements from the medical record and these results were compared against the original registry data submitted for that procedure.

Agreement rate can be interpreted as follows based on the data assessed:

- Exceeds Expectations: agreement rate $\geq 93\%$
- Meets Expectation: agreement rate 85% - 93%
- Needs Improvements: agreement rate $< 85\%$

A 95% confidence interval was calculated for each PABAK statistic to reflect sampling error and indicate a range of plausible values for the PABAK statistic. General interpretation of the PABAK statistic is similar to the KAPPA:

PABAK Interpretations:

0.00 Poor agreement

0.01-0.20 Slight agreement

0.21-0.40 Fair agreement

0.41-0.60 Moderate agreement

0.61-0.80 Substantial agreement

0.81-1.00 Almost perfect agreement

Pearson Correlation Coefficients were also calculated for continuous variables.

Pearson Correlation Coefficient

Interpretation

0.70 - 1.0 Strong linear relationship

0.50 - 0.70 Moderate linear relationship

0.30 - .50 Fair linear relationship

< 0.30 Poor linear relationship

Face validity testing

Each measure submitted to a consensus-based entity for public reported from by the ACC undergoes extensive discussion and review. This composite measure was created by a joint effort between NCDR's Public Reporting Advisory Group (PRAG) and NCDR's Measure and Reporting Methodology (MRM) committee. As part of the development process the MRM met to discuss each decision within the development process. This included discussing the merits of each proposed component measure. The members voted and reached consensus to include the six included. MRM also reviewed the specific weighting for the component measures and reviewed results on P score thresholds would affect the overall star scoring. These star rating distributions were discussed by the MRM until the final proposed measure received unanimous approval. After voting, the measure goes through a 30-day public comment period. The responses are available if requested.

Once the public comment period is completed, any comments are discussed by MRM and voted on once again. If the committee passes the measure, it is recommended for review by the Clinical Science and Quality Committee (CSQC). This committee voted to approve this measure for implementation in the CathPCI registry and for use in public reporting. Throughout the process, the CathPCI Registry Steering Committee provided strategic direction for the registry and ensuring that this measure submitted for endorsement meets key criterion such as reliability, feasibility, and that there is compelling evidence base behind the development and implementation of this measure. A summary of this process is below.

- CathPCI registry steering committee provides strategic direction for future registry measures based on current evidence.
- NCDR Measures and Reporting Methodology committee creates a measure development plan.
- Yale Center for Outcomes Research and Evaluation (CORE) conducts analysis using past NCDR data.
- MRM reviews the results of the analysis and votes to approve or to run further analysis.
- 30-day public comment period is opened after MRM approval.
- Comments are reviewed by the MRM and, if necessary, the measure is changed in response to feedback. If no changes, this measure is considered approved by the MRM.
- The NCDR CSQC provides final review of the measure. The committee voted to approve this measure for implementation as a test metric for 1 year and then review the data.

In summary, face validity testing was accomplished by expert consensus, measure development that is led by those that will be measured (cardiologists), extensive committee review and comments from the public.

MRM: The Measure and Reporting Methodology committee is a designated set of experts that oversees this application. Prior to submission, it ensures there is variation in care, disparities data, and that the measure is a true reflection of quality care at a particular site and can also be used to improve quality. This committee made up of physicians with a background in measure development and statistics and, most importantly, made up of those that will directly be measured.

CSQC: NCDR Clinical Science and Quality is an ACC leadership committee that serves as the primary resource for crosscutting scientific and quality of care methodological issues. This committee ensures the metrics are consistent across registries. They also reviewed and approved the methodology and results of this measure.

Data Element:

The NCDR Data Quality Program ensures that data submitted to the NCDR are complete and validly collected. The NCDR Data Quality Program consists of 3 main components: data completeness, consistency, and accuracy. Completeness focuses on the proportion of missing data within fields, whereas consistency determines the extent to which logically related fields contain

values consistent with other fields. Accuracy characterizes the agreement between registry data and the contents of original charts from the hospitals submitting data. Before entering the Enterprise Data Warehouse (EDW), all submissions are scored for file integrity and data completeness, receiving 1 of 3 scores that are transmitted back to facilities using a color-coding scheme. A “red light” means that a submission has failed because of file integrity problems such as excessive missing data and internally inconsistent data.

Such data are not processed or loaded into the EDW. A “yellow light” status means that a submission has passed the integrity checks but failed in completeness according to predetermined thresholds. Such data are processed and loaded into the EDW but are not included in any registry aggregate computations until corrected. Facilities are notified about data submission problems and provided an opportunity to resubmit data. Finally, a “green light” means that a submission has passed all integrity and quality checks. Such submissions are loaded to the EDW. After passing the DQR, data are loaded into a common EDW that houses data from all registries and included for all registry aggregate computations. In a secondary transaction process, data are loaded into registry-specific, dimensionally modeled data marts. A summary of the Program is noted under Table 13.

5.3.4 Validity Testing Results

Patient and/or encounter level validity testing

Agreement rates, PABAK scores and Pearson Correlation Coefficients are provided for variables in the attachment for 4.2.3a Table 12. Numbers in italics indicate the Pearson Correlation Coefficients.

5.3.5 Interpretation of Validity Results

The overall accuracy for the 2022 data meets expectations as the overall agreement is 93%. The statistics illustrate differences on some elements between the reviewer and the hospital. However, it is important to note that none of these rates are particularly low, and some of the disagreement is readily explicable. It is unlikely that even under ideal circumstances we would anticipate near perfect agreement rates on all items.

The calculated PABAK statistics varied but generally indicated a high agreement. The 10th

percentile was 0.529 (i.e. moderate agreement) while the median PABAK was 0.909 (almost perfect agreement). The 90th percentile was 0.994 (almost perfect agreement). While most of the discrete variables had high agreement rates along with high PABAK scores, indicating high reliability there were a few exceptions. Items such as 'stress test results' (SEQ#5202), 'Chronic Total Occlusion' (SEQ#8006), and 'Pre-Procedure Troponin' (SEQ#6090) have a low reliability and low agreement rate. The data elements, while included within the audit for other measures, and not included within the composite measure.

The reliability of continuous variables was assessed with the Pearson correlation coefficient. Twenty-eight of 31 correlations were significant ($p < 0.001$) with twenty-six with a strong linear relationship.

For the 2021 data, the overall agreement reaches 96.7% which exceeds expectations. The 10th percentile was 0.645 (i.e. substantial agreement) while the median PABAK was 0.963 (almost perfect agreement). The 90th percentile was 0.998 (almost perfect agreement). The reliability of continuous variables was assessed with the Pearson correlation coefficient. Fourteen of 16 correlations were significant. Time of Procedure (SEQ#7000) and First Device Activation Time (SEQ#7845) have a poor linear relationship. The data elements with poor linear relationships will be targeted for additional training.

5.3.2 Type of Accountable Entity Level Validity Testing Conducted (derived)

Systematic assessment of face validity of the measure's performance score as an indicator of quality or resource use

5.4.1 Methods Used to Address Risk Factors

Other, No risk adjustment or stratification

5.4.1a Other Methods Used

This composite measure is not risk adjusted.

However, the three outcome measures comprising half of the component measures are risk adjusted. The associated method for each of the three models was statistical risk adjustment models with risk factors. The respective methodology papers are included in this submission. The risk factors, coefficients and model performance indicators for each of the three outcomes models are listed below.

5.4.2 Conceptual Model Rationale

Rationale: Appropriate risk adjustment is necessary to prevent potential risk-adverse behaviors that may negatively affect patients who are at highest risk, particularly those with cardiogenic

shock and cardiac arrest, who may benefit the most from revascularization.

Approach to Risk Model Development: Prior to the development of the new model, the NCDR defined new variables that could potentially be incorporated into the new model. The CathPCI registry version 5 data collection form (DCFv5) integrated a series of new variables that further characterize patients' clinical status. For example, to better characterize cardiovascular instability, new variables included ventricular arrhythmias, acute heart failure symptoms, hemodynamic instability without cardiogenic shock, cardiogenic shock, and refractory cardiogenic shock (defined as persistent hypotension despite mechanical or pharmacologic vasopressor support). Additionally, a composite ordinal variable was created combining the components of cardiovascular instability with the procedural status, assigned into 6 mutually exclusive categories in decreasing order of procedural urgency and mortality risk: 1) salvage PCI or refractory shock; 2) cardiogenic shock (not refractory) without salvage; 3) cardiovascular instability [CVI] (includes hemodynamic instability, acute heart failure symptoms, and ventricular arrhythmia in the absence of shock) without salvage; 4) emergency PCI without shock or CVI; 5) urgent PCI without shock or CVI; and 6) elective PCI without shock or CVI.

The new frailty variable included in DCFv5 was based on the Canadian Study of Health and Aging clinical frailty scale. Patients were classified as nonfrail, intermediately frail (mild and moderate frailty), and severely frail (severe, severely frail, and terminally ill). Per the data definitions for DCFv5, frailty was based on the clinical condition prior to the start of the procedure, which could lead to patients presenting with cardiac arrest, cardiogenic shock, or salvage being coded as severely frail irrespective of their baseline status before admission. For purposes of the model, only those patients without cardiac arrest, shock, or undergoing salvage PCI were eligible to be considered as severely frail and were compared with all other patients (non-severe frailty).

A new variable that captured level of consciousness at start of PCI in patients who have suffered cardiac arrest was also incorporated. Patients were categorized as unresponsive if they were not responsive to verbal or painful stimuli or if their level of consciousness was unable to be assessed (e.g., patients who are intubated and sedated). In addition, surgical evaluation prior to PCI was also integrated as new variable. Patients were considered to be a surgical turn-down in those cases in which a cardiac surgical consult was obtained before engaging in PCI but surgery was not recommended. Aortic stenosis severity as an indication for cath lab visit was also a newly collected variable. The definitions for number of diseased vessels have been updated to include not only angiographically significant stenosis, but also fractional flow reserve and instantaneous wave-free ratio values indicative of ischemia. Finally, estimated glomerular filtration rate (GFR) was calculated based on the Chronic Kidney Disease Epidemiology Collaboration equation. Chronic kidney disease was classified according to latest guideline-recommended definition: stage 3a, GFR 45 to 60 ml/min/1.73 m²; stage 3b, GFR 30 to 44 ml/min/1.73 m²; stage 4, GFR 15 to 29 ml/min/1.73 m²; stage 5, GFR <15 ml/min/1.73 m² or dialysis. The full definitions of the data elements in the registry are available on the NCDR website.

The standard approach for all risk models developed within NCDR is to establish a Risk-Standardized outcome measure work group of physicians and research scientists to oversee model development and provide input on variable selection and considerations for the model. Candidate variables were screened and selected by the workgroup based on their clinical relevance, association with outcomes from prior research, and importance in model development.

For final variable selection, bootstrap analysis was performed. First, the development sample was used to create 1,000 “bootstrap” samples. For each sample, we ran a logistic regression that included the candidate variables using stepwise selection method (entry = 0.0005, exit = 0.0001). We then calculated the percentage of times each of the variables was selected in each of the 1,000 samples. The variables that were selected in at least 70% of bootstrap samples were then included in the final model. All clinical variables that had been identified a priori as being clinically relevant met this threshold except patients turned down for surgery. Given that this variable represents a unique population that may be clustered at certain facilities and high-risk patients with limited treatment options, it was forced into the final model.

This methodology was repeated for each risk model within this composite measure.

Social risk factors were not used in this composite measure for the following reasons:

While proxy variables could be considered, these were not believed to be relevant to an inpatient mortality model, in contrast to a longer-term outcome model where difficulties with access to care, affording medications or cardiac rehabilitation would be more important. Moreover, while it may be true that worse social risk factors might be associated with more severe illness at the time of presentation, we had direct access to detailed clinical variables describing the severity of illness and believe that incorporating such factors (e.g. severe frailty, clinical instability, LVEF, etc.) is a much more accurate means of stratifying risk. Accordingly, given the rich clinical data available through the NCDR CathPCI registry, social risk factors would not likely contribute much improvement to this particular risk model, which exhibits excellent goodness of fit.

5.4.2a Attach Conceptual Model

[4580 Conceptual Model_0.pdf](#)

5.4.3 Variable Distribution Across Measured Entities

Please see the attached tables and figures document page 19 table 14.

5.4.4 Risk/Case-Mix Adjustment Modeling and/or Stratification Results

Please refer to the tables and figures attachment page 20 Tables 15- 20 for the specifications, coefficients, codes with descriptors and definitions. Additionally, the statistical risk model was developed accordingly:

Graphical functions were evaluated for all continuous variables to test for a linear relationship with the respective outcome of either mortality, bleeding or acute kidney injury.

For non-linear relationships the variable was transformed using spline functions. Extreme values for continuous variables were set to outer limits based on clinical judgment. A multivariate logistic regression model linking mortality to the selected variables was fitted. To account for the natural clustering of observations within hospitals, a hierarchical logistic regression model was fitted, linking the outcomes to the selected variables with a hospital-specific random effect.

Hospital-specific risk standardized outcome rates (RSRs) for each hospital were calculated using the regression coefficients from the hierarchical model. RSRs were obtained as the ratio of hospital-specific predicted outcome to the hospital-specific expected outcome, multiplied by the overall outcome rate in the study cohort. The expected number of respective outcomes for each hospital was calculated by summing over the predicted outcome risks for all patients in the hospital using the average of all hospital specific intercepts, and the predicted number of outcomes was calculated in the same manner but using an estimated intercept that is specific for that hospital. This ratio was then multiplied by the outcome rate in the study cohort to calculate the RSR for that particular site.

5.4.4a Attach Risk/Case-mix Adjustment Modeling and/or Stratification Specifications

[4580 4.4.4a Risk Adjustment tables.pdf](#)

5.4.6 Interpretation of Risk/Case-mix Factor Findings

Mortality

We believe that our mortality model performs exceedingly well in adjusting for patient characteristics present prior to the conduct of PCI and is able to discriminate well across a wide variety of important clinical subsets of patients. Moreover, there is substantial hospital variation before and after risk-adjusting patient characteristics. The distribution of hospitals' O/E ratios show that there are some sites with excellent performance and others with mortality rates that are more than 2-fold greater than expected. These would be sites where substantial opportunities to improve patient safety likely exist.

Mortality: Castro-Dominguez YS, Wang Y, Mingos KE, et al., Predicting In-Hospital Mortality in Patients Undergoing Percutaneous Coronary Intervention. JACC. 2021. 20;78(3):216-229. doi: 10.1016/j.jacc.2021.04.067

Bleeding

The full bleeding risk model had good discrimination in both the development and validation samples (c-index, development sample 0.78; validation sample 0.77).

Rao SV, McCoy LA, Spertus JA et al., An updated bleeding model to predict the risk of post-procedure bleeding among patients undergoing percutaneous coronary intervention: a report using an expanded bleeding definition from the National Cardiovascular Data Registry CathPCI Registry. JACC Cardiovasc Interv. 2013 Sep;6(9):897-904. doi: 10.1016/j.jcin.2013.04.016. PMID: 24050858.

Acute kidney injury

Acute kidney injury (AKI) is the most common complication after PCI. Accurately estimating patients' risks not only creates a means of benchmarking performance but can also be used prospectively to inform practice. Among 455,806 PCI procedures, the median age was 67 years (IQR: 58.0-75.0 years), 68.8% were men, and 86.8% were White. The incidence of AKI and new dialysis was 7.2% and 0.7%, respectively. Baseline renal function and variables associated with clinical instability were the strongest predictors of AKI. The final AKI model included 13 variables, with a C-statistic of 0.798 and excellent calibration (intercept = -0.03 and slope = 0.97) in the validation cohort. The updated NCDR AKI risk model further refines AKI prediction after PCI, facilitating enhanced clinical care, benchmarking, and quality improvement.

Acute kidney injury: Uzendu A, Kennedy K, Chertow G, et al., Contemporary Methods for Predicting Acute Kidney Injury After Coronary Intervention. JACC Cardiovasc Interv. 2023 Sep 25;16(18):2294-2305. doi: 10.1016/j.jcin.2023.07.041.

5.4.7 Final Approach to Address Risk Factors

Other

5.4.7a Other Methods Used

Statistical risk model with risk factors for the relevant component measures

6.1.1 Current Status

In use

6.1.2 Current or Planned Use(s)

Public Reporting, Quality Improvement with Benchmarking (external benchmarking to multiple

organizations), Quality Improvement (Internal to the specific organization)

6.1.3 Program Details

Name of the program and sponsor

CathPCI Registry®

URL of the program

<https://cvquality.acc.org/NCDR-Home/registries/hospital-registries/cathpci-regi...>

Purpose of the program

The CathPCI Registry® assesses the characteristics, treatments and outcomes of cardiac disease patients who receive diagnostic catheterization and/or percutaneous coronary intervention (PCI) procedures. This powerful tool, available for any facility that

Geographic area and percentage of accountable entities and patients included

Geographic area is an estimated 90% of all US based cardiac cath labs. CathPCI Registry specific participants are around 1,800. Total patient records are over 22 million.

Applicable level of analysis and care setting

Facility level of analysis/hospital

6.2.1 Actions of Measured Entities to Improve Performance

Performance results are provided as part of quarterly performance report which includes a rolling 4 quarters of data. These reports provide a detailed analysis of an individual institution's performance in comparison with the entire registry population from participating hospitals across the nation. Reports include an executive summary dashboard, at-a-glance assessments, and patient level drill-downs. Registry participants also have access to an outcome report companion guide which provides common definitions and detailed metric specifications to assist with interpretation of performance rates. This information along with the other process and outcome measures included in the CathPCI registry enable participants to identify interventions that will lead to improvement in in-patient mortality rates.

There are a number of methods used to educate and provide general support to registry participants. These include the following:

- Registry Site Manager Calls are available for all NCDR participants. RSM calls are provided as a source of communication between NCDR and participants to provide a live chat Q and A session on a continuous basis.
- New User Calls are available for NCDR participants, and are intended for assisting new users with their questions.
- NCDR Annual Conference
The NCDR Annual Conference is a well-attended and energetic two-day program at which participants from across the country come together to hear about new NCDR and registry-specific updates. During informative general sessions, attendees can learn about topics such as transcatheter therapies, the NCDR dashboard, risk models, data quality and validation, and value-based purchasing. Attendees also receive registry updates and participate in advanced case studies covering such topics as Appropriate Use Criteria and outcomes report interpretation.
- Release notes (for outcomes reports)

- Clinical Support

The NCDR Product Support and Clinical Quality Consultant Teams are available to assist participating sites with questions Monday through Friday, 9:00 a.m. - 5:00 p.m. ET.

6.2.2 Feedback on Measure Performance

Health care facilities, physicians, data abstractors, registry steering committee members, and other stakeholders routinely provide feedback to the Registry support team via email or phone (i.e., Salesforce). Additional opportunities for detailed composite measure discussion can occur on bi-monthly registry site manager calls or annually at the in-person NCDR Quality Summit conference where registry management and physician leadership will explore the measure in detail followed by an open Q&A session.

Feedback varies from detailed comments on the composite measure criteria, reflections and examples of how the measure handles a health care facility's specific patient population (i.e., high-risk vs stable), and general questions about how end-point decisions were made. When stakeholders fully understand the measure and the logic used to create it, they have expressed it is valuable in helping to guide their quality-of-care improvement efforts.

6.2.3 Consideration of Measure Feedback

Any concerns regarding the composite or observational data on performance are escalated to the applicable ACC team(s) (i.e., Registry management, Science leadership, Data Analytic Center, etc.) for consideration. If the feedback represents an opportunity for improvement, the Data Analytic Center is engaged to provide data insights. These data are reviewed by the Senior NCDR Leadership & Science Leadership team which may lead to updating the composite or confirm that it is functioning as expected. If an adjustment is needed the change is approved and cascades to the various teams and implemented. The opportunity for these types of refinements is always available. Feedback which represents a desire for a fundamental shift in criteria or patient cohort will be assessed when the composite measure is re-evaluated during a cyclical review process by a designated workgroup.

6.2.4 Progress on Improvement

The measure was in use on the CathPCI Registry participant Dashboard for one quarter. After that time, measure maintenance was needed on two component measures (AKI and Mortality) and the measure was suppressed. The measure has been updated and will be reporting for 2025 Q1. It will also retroactively report the prior quarters that fall in the rolling four quarter report cycle. At this time there is one quarter of data available from the 'in use' period. Thus, there is no trending data, progress on improvement or unexpected findings data available to report.

6.2.5 Unexpected Findings

The measure was in use on the CathPCI Registry participant Dashboard for one quarter. After that time, measure maintenance was needed on two component measures (AKI and Mortality) and the measure was suppressed. The measure has been updated and will be reporting for 2025 Q1. It will also retroactively report the prior quarters that fall in the rolling four quarter report cycle. At this time there is one quarter of data available from the 'in use' period. Thus, there is no trending data, progress on improvement or unexpected findings data available to report.

7.1 Supplemental Attachment

[4580 Tables and Figures.pdf](#)

Measure Developer POC

United States

The measure developer is different from the measure steward

No

Steward Address

Mary McCutcheon
Washington , DC
United States

Steward Organization

American College of Cardiology

Steward Organization URL

<https://www.acc.org/>

Steward POC email

ncdrscience@acc.org