CBE ID

2459

Title

Risk Standardized Bleeding Rate for Patients Undergoing Percutaneous Coronary Intervention (PCI)

Project

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

Endorsement Status

Endorsed

Is Under Review

No

Next Maintenance Cycle

Fall 2030

Previous Endorsement Cycle

Fall 2025

Initial Endorsement

Mon, 09/08/2014 - 11:12

Steward

American College of Cardiology

1.0 New or Maintenance

Maintenance

1.1 Measure Structure

Single Measure

1.3 Electronic Clinical Quality Measure (eCQM)

No

1.6 Measure Description

Risk standardized rate of intra and post procedure bleeding for patients age 18 and over without cardiogenic shock or cardiac arrest undergoing PCI.

1.6a Material Specification Change(s)

Yes

1.6b Summary of Specification Changes

We have revised this model to no longer include “all patients” but instead exclude cardiogenic shock and cardiac arrest patients. The definition of bleeding was updated as reflected in the numerator statement. Transfusion criteria is now stratified by PCI indication with two separate Hgb thresholds (8 and 10 g/dL). We also added improved clarity on timing (post-procedure) for hemorrhagic stroke, tamponade, etc. The use of a mechanic ventricular support device no longer excludes the patient from the outcome measure.

1.7 Measure Type

Outcome

1.8 Level of Analysis

Facility

1.9 Care Setting

Hospital: Inpatient

1.10 Measure Rationale

Hospitals should continue to report this updated risk standardized bleeding performance measure because it provides a foundation for bleeding reduction quality improvement initiatives that can improve both the procedure safety and outcomes of treatment with PCI for patients with coronary artery disease and heart attacks.

This risk of bleeding for patients following percutaneous coronary interventions (PCI) continues to varying degrees across hospitals in the US (Price et al., 2024). Intra- and post-procedure bleeding is the most common non-cardiac complication of PCI, leading to adverse patient outcomes (e.g. increased morbidity and mortality, prolonged length of stay and costs) and, importantly, can be modified using bleeding avoidance strategies such as radial arterial access (Amin, 2022; Heidary Moghadam, 2024; Ndrepepa, 2013; Rao, 2025; Vora, 2016). Facility-focused quality improvement strategies are effective in reducing these bleeding events. For example, a recent hospital-based quality improvement campaign led by the American College of Cardiology (ACC) resulted in reductions in bleeding events across all hospitals, but rates were further reduced for those that implemented the toolkit and quality improvement strategies (Price, 2024). The use of risk-stratification is the first step towards identifying patients at highest risk to appropriately allocate bleeding avoidance strategies, and reduce unnecessary costs associated with bleeding events and prolonged length of stays. (Price et al., 2024; Capodanno et al., 2022)

The measure currently under review for endorsement maintenance reflects an updated bleeding model that aligns with updated clinical guidelines recommendations. The ACC developed and iterated on a bleeding model over the years for use within the National Cardiovascular Data Registry (NCDR) CathPCI Registry and received initial endorsement in 2014. Due to recent findings from the Myocardial Ischemia and Transfusion (MINT) trial, NCDR recognized that the

current bleeding model required update. Specifically, this trial examined the impact of a restrictive (cutoff for transfusion of hemoglobin less than 8 g/dL) versus liberal transfusion strategy (cutoff for transfusion of hemoglobin less than 10 g/dL) on two outcomes (myocardial infarction or death within 30 days of the procedure) and even though the results were not statistically significant, the findings indicated that the more liberal transfusion strategy had more short-term clinical benefit than the alternative restrictive approach (Carson, 2023). The trial's results are reflected in the updated clinical recommendations in the 2025 guideline on the management of patients with acute coronary syndromes (Rao, 2025). Specifically, clinical guidance now encourages blood transfusion for those individuals with acute coronary syndrome and a hemoglobin less than or equal to 10 g/dL as opposed to the previous assumption that transfusing a patient with that range of hemoglobin meant that a patient was bleeding and therefore had an adverse event. This change has been reflected in what is considered a bleeding event for the measure's outcome.

Both this measure and the PCI in-hospital mortality measure (CBE #133) were revised to address the concerns voiced by the medical community that the model did not adequately account for patients at extreme risk or facilities with lower volumes and therefore hospitals with larger numbers of these individuals would perform more poorly on these outcomes. ACC integrated additional variables (e.g., frailty, cardiovascular instability) into the CathPCI registry's dataset and subsequently developed a new hierarchical mortality model for mortality. The same methodology was applied to this bleeding model. This hierarchical model includes variables that identify if a patient is experiencing cardiogenic shock or is status post resuscitated cardiac arrest. The updates to the bleeding measure now focus on those patients who do not fall within this risk category and therefore minimizes the risk of penalizing clinicians and facilities who are willing to provide care for these individuals who are more likely to have poorer outcomes unrelated to the care that they subsequently receive at the facility.

As a result of this updated model, facilities have access to data that better classify a patient's bleeding risk and allows in-depth analyses of the causes behind variations in bleeding during or post PCI leading to the identification of best practices. In addition, detailed case reviews can identify clinicians with poorer performance for whom additional training or reduced caseloads could be considered. Active dissemination of those best practices and support to enable their adoption will improve outcomes and reduce variations in clinical practice. Improvements in the quality of care resulting from the evaluation of the risk of bleeding, before and after implementing quality improvement interventions, can enable facilities to quantify their improved outcomes and a reduction in cost associated with these events. Additionally, by putting the responsibility for improved quality in the hands of physicians and other healthcare providers, this updated risk standardized bleeding measure engages the medical community around the common goal of better healthcare value.

References:

Amin AP, Frogge N, Kulkarni H, et al. The bleeding risk treatment paradox at the physician and hospital level: Implications for reducing bleeding in patients undergoing percutaneous coronary intervention. *Am Heart J*. 2022;243:221-231. doi:10.1016/j.ahj.2021.08.021

Capodanno, D., Bhatt, D.L., Gibson, C.M. *et al.* Bleeding avoidance strategies in percutaneous coronary intervention. *Nat Rev Cardiol* 19, 117–132 (2022). https://doi.org/10.1038/s41569-021-00598-1

Carson JL, Brooks MM, Hébert PC, et al. Restrictive or Liberal Transfusion Strategy in Myocardial Infarction and Anemia. *N Engl J Med*. 2023;389(26):2446-2456. doi:10.1056/NEJMoa2307983

Heidary Moghadam R, Mohammadi A, Salari N, Ahmed A, Shohaimi S, Mohammadi M. The prevalence of bleeding after percutaneous coronary interventions: A systematic review and meta-analysis. *Indian Heart J*. 2024;76(1):16-21. doi:10.1016/j.ihj.2024.01.009

Inohara T, Kohsaka S, Spertus JA, et al. Comparative Trends in Percutaneous Coronary Intervention in Japan and the United States, 2013 to 2017. *J Am Coll Cardiol*. 2020;76(11):1328-1340. doi:10.1016/j.jacc.2020.07.037

Ndrepepa G, Neumann FJ, Richardt G, et al. Prognostic value of access and non-access sites bleeding after percutaneous coronary intervention. *Circ Cardiovasc Interv*. 2013;6(4):354-361. doi:10.1161/CIRCINTERVENTIONS.113.000433

Price AL, Amin AP, Rogers S, et al. Implementation of a Multidimensional Strategy to Reduce Post-PCI Bleeding Risk. *Circ Cardiovasc Interv*. 2024;17(3):e013003. doi:10.1161/CIRCINTERVENTIONS.123.013003

Rao SV, O'Donoghue ML, Ruel M, et al. 2025 ACC/AHA/ACEP/NAEMSP/SCAI Guideline for the Management of Patients With Acute Coronary Syndromes: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2025;151(13):e771-e862. doi:10.1161/CIR.0000000000001309

Vora AN, Peterson ED, McCoy LA, et al. 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 Cardiovasc Interv*. 2016;9(8):771-779. doi:10.1016/j.jcin.2016.01.033

1.13 Data Dictionary

Attached

1.13a Attach Data Dictionary

pci_v5-0_datadictionarycoderspecifications_rtd_10012025.pdf

1.14 Numerator

Patients 18 years of age and older with a post-PCI bleeding event as defined below Post-PCI bleeding defined as any ONE of the following: Bleeding event within 72 hoursHemorrhagic stroke post procedureTamponade post procedureTransfusion PCI = yes AND pre-procedure hemoglobin greater than 8 g/dL AND PCI Indication = New onset angina ≤2 months or stable angina or CAD without ischemic Symptoms.Transfusion PCI = yes AND pre-procedure hemoglobin greater than 10 g/dL AND PCI Indication in STEMI, NSTEMI or unstable angina.Absolute Hgb decrease of >= 4g/dL from pre-PCI to post-PCI

1.14a Numerator Details

Bleeding defined as any ONE of the following:

1. Bleeding event within 72 hours post PCI
2. Hemorrhagic stroke within 72 hours post PCI
3. Tamponade within 72 hours post PCI
4. Blood transfusion AND pre-procedure hemoglobin greater than 8 g/dL AND PCI Indication = New onset angina ≤2 months or stable angina or CAD without ischemic symptoms.
5. Blood transfusion AND pre-procedure hemoglobin greater than 10 g/dL AND PCI Indication in STEMI, NSTEMI or unstable angina.
6. Absolute hemoglobin level decrease of >= 4g/dL from pre-PCI to post-PCI

Note:

• All data element numbers listed above are included in the attached data dictionary which includes more detailed definitions for the above elements.

• The measure includes risk standardization to account for differences in case mix across hospitals, thus the ratio determined by the numerator and denominator are modified based upon the adjustment.

1.15 Denominator

Patients 18 years of age and older with a PCI procedure performed during admission (excluding cardiogenic shock and cardiac arrest)

1.15a Denominator Details

The following patients are included in the denominator:

1. Patients 18 years of age or older
2. Patients undergoing PCI during the episode of care
3. Initial PCI procedures for patients who underwent multiple PCI procedures during the episode of care (subsequent PCIs during a single episode of care excluded).

Note: All data element numbers listed above are included in the attached data dictionary, which includes more detailed definitions for the above elements.

1.15b Denominator Exclusions

This measure excludes the following:

1. Patients who died within 24 hours of the PCI procedure.
2. Patients who have CABG during the episode of care.
3. Patients with cardiogenic shock.
4. Patients resuscitated from cardiac arrest that occurred either: 1) outside of the healthcare facility prior to arrival; 2) while being transferred to the facility; or 3) while at the facility and prior to PCI.
5. Subsequent PCI procedures (when the patient has more than one PCI during the episode of care).

1.15c Denominator Exclusions Details

The measure has the following exclusions:

1. Patients who died (10105) within 24 hours (10101) of the PCI procedure (7000).
2. Patients who have CABG during the episode of care (10030/10031).
3. Patients with cardiogenic shock prior to the PCI (7415) [Cardiovascular instability type = cardiogenic shock OR refractory cardiogenic shock]
4. Patients resuscitated from cardiac arrest (7400) that occurred either: 1) outside of the healthcare facility prior to arrival; 2b while being transferred to the facility; or 3) while at the facility and prior to the PCI
5. Subsequent PCI procedures (7050) when the patient has had more than one during the episode of care.

Note: All data element numbers listed above are included in the attached data dictionary which includes more detailed definitions for the above elements.

At the facility level, all data submissions must pass the data quality and completeness reports to

be included. Of note we used imputation for some variables with missing values. In the NCDR data quality program, all key variables in the risk model have a high “inclusion” criteria, meaning that when a hospital submits data, they need to have a high level of completeness (>95%) for those variables. If they are not able to meet the criteria in our data quality program, they do not receive risk-adjusted outcomes for any of the records they submitted for that quarter. Because the high-threshold for inclusion is present, the impact of imputation on hospital-specific rates is minimal but enables a more complete assessment of hospital performance.

1.15d Age Group

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

1.16 Type of Score

Rate/proportion

1.17 Measure Score Interpretation

Better performance = Lower score

1.18 Calculation of Measure Score

1. Remove hospitals who fail data quality and completeness reports as outlined in the NCDR Data Quality Program (further discussed in the Testing Supplement)
2. Remove hospitals who do not have at least one patient with a pre-PCI or post-PCI hemoglobin value.
3. Remove subsequent PCIs during the same admission (if the patient had more than one PCI procedure during that episode of care).
4. Remove patients who did not have a PCI (Patient admissions with a diagnostic catheterization only during that episode of care)
5. Remove patients who died on the same day of the procedure
6. Remove patients who had CABG during the episode of care
7. Remove patients with pre-procedure hemoglobin <8 g/dL patients (severely anemic) who did not also have a documented bleeding event other than transfusion were not counted in the numerator if they received a transfusion.
8. Calculate the measure using weight system based on predictive variables as outlined in the accompanying testing documents and supplemental materials.

This measure uses predictive variables to estimate in-hospital bleeding following PCI using a hierarchical risk model. The approach simultaneously models data at the patient and hospital levels to account for variance in patient outcomes within and between hospitals [Normand and Shahian, 2007; Krumholz H, Normand S, Galusha D, et al., 2005]. At the patient level, it models the log-odds of bleeding within 30 days of index admission using age, sex, selected clinical covariates, and a hospital-specific intercept. At the hospital level, it models the hospital-specific intercepts as arising from a normal distribution. The hospital intercept represents the underlying risk of a bleed at the hospital, after accounting for patient risk. The hospital-specific intercepts are given a distribution to account for the clustering (non-independence) of patients within the same hospital. If there were no differences among hospitals, then after adjusting for patient risk, the

hospital intercepts should be identical across all hospitals.

The risk standardized bleeding rate (RSBR) is calculated as the ratio of the number of "predicted" to the number of "expected" bleeds at a given hospital. For each hospital, the numerator of the ratio is the number of bleeds following a PCI procedure predicted based on the hospital's performance with its observed case mix, and the denominator is the number of bleeds expected based on the nation's performance with that hospital's case mix. A series of denominator exclusions (summarized in Table 8. "Development of the Study Cohort" of section 5.1.3) were applied to define the study sample during a rolling four quarter period. For this sample, patients were excluded if their discharges were not between January 1, 2021 and December 31, 2022 or if they did not undergo percutaneous coronary intervention (PCI) during their admission. Furthermore, only the index PCI procedure was included. Cases were further excluded if in-hospital death occurred within 24 hours of the procedure. Patients who underwent coronary artery bypass (CABG) during the same hospitalization were removed. Additionally, patients presenting with resuscitated cardiac arrest or cardiogenic shock on admission, as well as those who underwent "salvage PCI" were excluded.

This approach is analogous to a ratio of "observed" to "expected" used in other types of statistical analyses. It conceptually allows for a comparison of a particular hospital's performance given its case mix to an average hospital's performance with the same case mix. Thus, a lower ratio indicates lower-than-expected bleeding rates or better quality, and a higher ratio indicates higher-than-expected bleeding rates or worse quality. The "predicted" number of bleeds (the numerator) is calculated by using the coefficients estimated by regressing the risk factors and the hospital-specific intercept on the risk of mortality. The estimated hospital-specific intercept is added coefficients multiplied by the patient characteristics. The results are transformed and summed over all patients attributed to a hospital to get a predicted value. The "expected" number of bleeds (the denominator) is obtained in the same manner, but a common intercept using all hospitals in our sample is added in place of the hospital-specific intercept. The results are transformed and summed over all patients in the hospital to get an expected value. To assess hospital performance for each reporting period, we re-estimate the model coefficients using the years of data in that period.

This calculation transforms the ratio of predicted over expected into a rate that is compared to the national observed rates. The hierarchical logistic regression models are described fully in the original methodology report posted on QualityNet [https://qualitynet.org/inpatient/measures/mortality/methodology].

References:

Normand S-LT, Shahian DM. 2007. Statistical and Clinical Aspects of Hospital Outcomes Profiling.

Stat Sci 22(2): 206-226.

Krumholz H, Normand S, Galusha D, et al. Risk-Adjustment Models for AMI and HF 30-Day Mortality Methodology. 2005.

1.19 Measure Stratification Details

The measure is not stratified.

1.20 Types of Data Sources

Registries

1.21a Data Collection Tool URL(s)

http://example.com

1.25 Data Source Details

National Cardiovascular Data Registry (NCDR®) CathPCI Registry®

The details listed here are repeated in the Feasibility section of this application.

The data elements required to generate this measure are, to the best of our knowledge, abstracted from the electronic medical record by someone other than 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. This measure has been in use for many years and as a result, while the CathPCI Registry continues to monitor the feasibility and data collection burden of this measure, minimal changes to how the data are collected and reported have been required in recent years. We outline the general process used by any hospital reporting to an NCDR registry below.

Availability:

Participating hospitals report patient demographics, medical history, risk factors, hospital presentation, procedural details, medications, laboratory values and in-hospital outcomes as the key activity of participating in the NCDR registries. All of the required data elements for this measure are routinely generated and acquired during the hospitalization. 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.

1.26 Minimum Sample Size

No minimum sample size is required.

2.1 Attach Logic Model

2459-EM-Logic-Model-Fall-2025.pdf

2.2 Evidence of Measure Importance

Evidence specific to the measure updates include recent findings from the Myocardial Ischemia and Transfusion (MINT) trial, which examined the impact of a restrictive (hemoglobin cutoff for transfusion of <7-8 g/dL) versus liberal transfusion strategy (hemoglobin cutoff for transfusion of <10 g/dL) on two outcomes – myocardial infarction or death within 30 days of the procedure, proved integral to the recent update to this measure as well as the 2025 guideline on the management of patients with acute coronary syndromes (Rao, 2025). While the results from the trial were not statistically significant, they indicated that a liberal strategy may have more short-term clinical benefit than the alternative restrictive approach (Carson, 2023). As a result, clinical guidance was updated to encourage blood transfusion for those individuals with acute coronary syndrome and a hemoglobin <10 g/dL as opposed to the previous assumption that transfusing a patient meant that a patient was bleeding and therefore had an adverse event. This change has been reflected in what is considered a bleeding event for inclusion in this measure.

Additionally, evidence exists to demonstrate that facilities can implement various structures and processes to further decrease the risk of bleeding following a PCI. As noted in section 1.10, a recent hospital-based quality improvement campaign led by the ACC led to reductions in bleeding events across all hospitals, but rates were further reduced for those that implemented the toolkit and quality improvement strategies (Price, 2024). The use of this risk-adjusted measure when paired with quality improvement activities can improve clinical outcomes for patients. Additionally, the 2025 ACC/AHA Guidelines for the treatment of patients with acute coronary syndrome (ACS) recommended bleeding avoidance strategy of radial access for PCI as a class 1, A recommendation. The class of recommendation (COR) reflects the magnitude of benefit over risk and corresponds to the strength of the recommendation. Class I recommendations are strong and indicate that the treatment, procedure, or intervention is useful and effective and should be performed or administered for most patients under most circumstances. The level of evidence (LOE) of A indicates high-quality evidence from more than one random controlled clinical trial or a meta-analysis of random controlled trials. [In patients with ACS undergoing PCI, a radial approach is preferred to a femoral approach to reduce bleeding, vascular complications, and death. (Class 1, LOE A)]. (Rao, et al., 2025)

Scientific and clinical evidence continues to support the ongoing use of this outcome measure. Individuals in the United States received more than 600,000 percutaneous coronary interventions (PCIs) in 2017 and roughly 60% of these procedures were elective (Inohara, 2020). Intra- and post-operative bleeding following PCI is an important outcome and lower rates can be achieved if

clinicians and facilities use evidence-based criteria to assess a patient's bleeding risk and implement effective strategies to reduce its occurrence. Implementation of the criteria and treatments decrease the likelihood of death, longer hospital stays and increase costs (Amin, 2022; Heidary Moghadam, 2024; Ndrepepa, 2013; Rao, 2025; Vora, 2016). One study using the CathPCI Registry data of more than 3 million procedures from 2004 to 2011 determined that post PCI bleeding events were associated with increased risk of in-hospital mortality, with an estimated 12.1% of deaths related to bleeding complications (Chhatriwalla, 2013).

For many years, data from clinical trials have been analyzed to identify the baseline characteristics that can predict bleeding. The most recent effort was by the Academic Research Consortium for High Bleeding Risk (ARC-HBR), which was published in 2019 (Urban, 2019). The 20 clinical criteria on which consensus across multiple clinical experts was reached ensure that a consistent definition on individuals at high risk of bleeding will be used in clinical trials and is used to define high risk patients within the CathPCI registry and this measure.

Published trials and observational studies have found that specific processes of care, including the use of radial arterial access (Jhand, 2021), mechanical closure devices when femoral access is used (Kreutz, 2022), and bivalirudin for anticoagulation (Al-Abdouh, 2024), are associated with lower risks of bleeding. All these processes resulted in the reduction of complications and death.

References:

Al-Abdouh A, Mhanna M, Jabri A, et al. Bivalirudin versus unfractionated heparin in patients with myocardial infarction undergoing percutaneous coronary intervention: A systematic review and meta-analysis of randomized controlled trials. *Cardiovasc Revasc Med*. 2024;61:52-61. doi:10.1016/j.carrev.2023.10.014

Amin AP, Frogge N, Kulkarni H, et al. The bleeding risk treatment paradox at the physician and hospital level: Implications for reducing bleeding in patients undergoing percutaneous coronary intervention. *Am Heart J*. 2022;243:221-231. doi:10.1016/j.ahj.2021.08.021

Carson JL, Brooks MM, Hébert PC, et al. Restrictive or Liberal Transfusion Strategy in Myocardial Infarction and Anemia. *N Engl J Med*. 2023;389(26):2446-2456. doi:10.1056/NEJMoa2307983

Chhatriwalla AK, Amin AP, Kennedy KF, et al. Association between bleeding events and in-hospital

mortality after percutaneous coronary intervention. *JAMA*. 2013;309(10):1022-1029. doi:10.1001/jama.2013.1556

Heidary Moghadam R, Mohammadi A, Salari N, Ahmed A, Shohaimi S, Mohammadi M. The prevalence of bleeding after percutaneous coronary interventions: A systematic review and meta-analysis. *Indian Heart J*. 2024;76(1):16-21. doi:10.1016/j.ihj.2024.01.009

Jhand A, Atti V, Gwon Y, et al. Meta-Analysis of Transradial vs Transfemoral Access for Percutaneous Coronary Intervention in Patients With ST Elevation Myocardial Infarction. *Am J Cardiol*. 2021;141:23-30. doi:10.1016/j.amjcard.2020.11.016

Kreutz RP, Phookan S, Bahrami H, et al. Femoral Artery Closure Devices vs Manual Compression During Cardiac Catheterization and Percutaneous Coronary Intervention. *J Soc Cardiovasc Angiogr Interv*. 2022;1(5):100370. Published 2022 Jun 29. doi:10.1016/j.jscai.2022.100370

Inohara T, Kohsaka S, Spertus JA, et al. Comparative Trends in Percutaneous Coronary Intervention in Japan and the United States, 2013 to 2017. *J Am Coll Cardiol*. 2020;76(11):1328-1340. doi:10.1016/j.jacc.2020.07.037

Ndrepepa G, Neumann FJ, Richardt G, et al. Prognostic value of access and non-access sites bleeding after percutaneous coronary intervention. *Circ Cardiovasc Interv*. 2013;6(4):354-361. doi:10.1161/CIRCINTERVENTIONS.113.000433

Price AL, Amin AP, Rogers S, et al. Implementation of a Multidimensional Strategy to Reduce Post-PCI Bleeding Risk. *Circ Cardiovasc Interv*. 2024;17(3):e013003. doi:10.1161/CIRCINTERVENTIONS.123.013003

Rao SV, O'Donoghue ML, Ruel M, et al. 2025 ACC/AHA/ACEP/NAEMSP/SCAI Guideline for the Management of Patients With Acute Coronary Syndromes: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2025;151(13):e771-e862. doi:10.1161/CIR.0000000000001309

Urban P, Mehran R, Colleran R, et al. Defining high bleeding risk in patients undergoing

percutaneous coronary intervention: a consensus document from the Academic Research Consortium for High Bleeding Risk. *Eur Heart J*. 2019;40(31):2632-2653. doi:10.1093/eurheartj/ehz372

Vora AN, Peterson ED, McCoy LA, et al. 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 Cardiovasc Interv*. 2016;9(8):771-779. doi:10.1016/j.jcin.2016.01.033

2.4 Performance Gap

Table 1 below illustrates the distribution of the risk-standardized bleeding rates during the two-year observation period between 2021 and 2022. Included is the mean score, entities (or hospitals), and total encounters (or admissions), all evaluated by decile of performance from data collected from abstractors and reported to the CathPCI Registry. As illustrated in Table 1, the minimum RSBR was 0.55% whereas the maximum score was 26.7%, suggesting a wide gap in performance. Further, comparing those sites with the lowest and highest deciles of performance, 0.10% vs. 3.34%, respectively, demonstrates more than a 3% difference in bleeding rates. While 3% may not appear to be a considerable gap, it translates to an additional 39,380 bleeds per year, justifying the importance of capturing and reporting these data.

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	0.0186	0.0055	0.0104	0.0128	0.0142	0.0156	0.0169	0.0181	0.0195	0.0215	0.0241	0.0334	0.2668
N of Entities	1704	1	170	170	171	170	171	170	171	170	171	170	1
N of Persons / Encounters / Episodes	1312961	1483	164404	132126	127997	110913	114943	115963	130561	121578	144116	150360	475

2.6 Meaningfulness to Target Population

This measure was developed with input from a technical expert panel that included patient and caregiver representation. As regaining function and preserving and improving quality of life is the goal of most patients, decreasing the rate of bleeding during or after PCI is easily understood and will help patients in understanding the quality of care provided by facilities and in making decisions about where to receive their care.

Between April 11, 2025, and May 10, 2025, this measure and updated risk model underwent peer review and public comment during which ACC members, NCDR participants, patient advocacy groups, healthcare systems, private payors and other healthcare professionals had the opportunity to review and comment on the methodology and construct before ACC final approval for use. The distribution list used for this comment contains over 1200 names. In addition, ACC social media

outlet and the NCDR participant webpage provides public access to the comment questions and content. Forty-nine reviewers provided 72 individual comments and scored the associated questionnaire. While most respondents are anonymous, patient support groups (such as Mended Hearts Mended Hearts Non-profit Organization) patient centered research systems (such as https://www.pcori.org/| PCORI) have equal opportunity to provide feedback and comment.

3.1 Contributions Towards Closing Care Gaps

We attributed social risk factors at the hospital-level for the purpose of this analysis. We used Medicaid insurance status as the economic indicator of social risk. We also examined age, sex, and race/ethnicity to determine if there were differences in these demographic indicators of social risk. Analyses of differences by subgroup were based on registry data procured from years 2021-22.

In terms of the overall distribution, the median risk standardized rate of bleeding was 1.74%, with an interquartile range of 1.43% to 2.16%. There is a right skew to the bleeding rates (Figure 1).

See attached Tables and Figures document in 7.1:

Tables 2-6

Figures 1-5

4.1a Data Structure and Availability

The data elements required to generate this measure are abstracted from a medical record by someone other than 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. This measure has been in use for many years and as a result, while the CathPCI Registry continues to monitor the feasibility and data collection burden of this measure, minimal changes to how the data are collected and reported have been required in recent years. We outline the general process used by any hospital reporting to an NCDR registry below.

Availability:
Participating hospitals report patient demographics, medical history, risk factors, hospital presentation, procedural details, medications, laboratory values and in-hospital outcomes as the key activity of participating in the NCDR registries. All of the required data elements for this measure are routinely generated and acquired during the hospitalization. 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.

Sampling:
There is no sampling of patient data allowed within the contractual terms of participation in the NCDR registries. 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." 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 on the basis of sex, race, or religion.

4.1b Implementation Costs and Burden

This measure was developed and designed to be used across other organizations and by other measure implementers. The fee and licensing information include below is specific to NCDR program requirements:

The 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 for endorsement 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.

4.1c Confidentiality

Each NCDR institution signs a Participant Agreement with the American College of Cardiology Foundation ("ACCF") including a Business Associate Agreement and Data Use Agreement. The NCDR requires the collection of protected health information as such term is defined by the Health Insurance Portability and Accountability Act of 1996 as amended ("HIPAA"). Submission of Protected Health Information is considered permissible as a healthcare operations disclosure not requiring a HIPAA authorization from individuals. Consistent with the requirements of HIPAA, ACCF has designed a comprehensive security program that protects the confidentiality, integrity

and availability of protected health information through the implementation of administrative, physical, and technical safeguards. ACCF's security program was designed using the NIST Cybersecurity Framework. ACCF periodically conducts an independent control assessment to confirm alignment with the HIPAA Security Rule and NIST Cybersecurity Framework. This measure does not include a patient survey. There is no added procedural risk to patients through involvement in the NCDR and no testing, time, risk, or procedures beyond those required for routine care are imposed.

4.3 Feasibility Informed Final Measure

The measure has been in use for many years and as a result, while the CathPCI Registry continues to monitor the feasibility and data collection burden of this measure, the most significant set of changes to how the data are collected and reported was the revisions to improve the capture of cardiogenic shock and cardiac arrest in 2018. ACC dedicated significant time and resources developing education and guidance to ensure that hospitals were able to accurately capture these data. Minimal changes have been made to this registry since then.

4.4 Proprietary Information

Proprietary measure or components with fees

4.4a Fees, Licensing, or Other Requirements

This measure is feasible to report and utilize as demonstrated by the more than 1,600 hospitals currently submitting data for this measure. Outside of participation in NCDR, there are no licensing or fees associated with this specific measure.

5.1.1 Data Used for Testing

We used the National Cardiovascular Data Registry for CathPCI Registry. This is a national quality improvement registry with over 1700 participating US hospitals. Participation is largely voluntary though 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.

5.1.1a Dates of Testing Data

01/2021–12/2022

5.1.2 Differences in Data

None.

5.1.3 Characteristics of Measured Entities

See attached tables and figures document in 7.1 table 7 & 8.

5.1.4 Characteristics of Units of the Eligible Population

See attached tables and figures document in 7.1 tables 9 & 10.

5.2.1 Level(s) of Reliability Testing Conducted

Person or encounter level (i.e., data element) (e.g., inter–abstractor reliability), Accountable entity level (i.e., measure score) (e.g., signal-to-noise analysis)

5.2.2 Method(s) of Reliability Testing

Performance Measure Score (Signal-to-Noise):

ACCF performed the signal-to-noise analysis on the same cohort of individuals as noted under Section 5.1. For the signal-to-noise analysis, we followed the methodology as outlined in a Rand Corporation technical report by John L Adams. The document is available at the following URL (https://www.rand.org/content/dam/rand/pubs/technical_reports/2009/RAND_...). This approach uses a beta-binomial model that assumes the physician's score is a binomial random variable conditional on the physician's true value that comes from a beta distribution. The beta distribution is a very flexible distribution on the interval from 0 to 1 and can have any mean within the interval and can be skewed left or right or even U-shaped. It is the most common distribution for probabilities on the 0-1 interval. A higher SNR indicates a stronger signal relative to the noise, which suggests better reliability and accuracy in signal detection and processing.

Second, we pursued a split sample methodology to assess the consistency or reliability of the measure by dividing it into two halves and comparing the results obtained from each half. For the performance rates, raw rates were calculated, and a correlation coefficient was computed. The split samples were calculated during the same timeframe to mitigate confounding factors based on time differences. The cohort was split into two random samples to compare measure scores. The type of error tested by a split-sample reliability test is primarily related to the consistency or stability of measurements obtained from the measure. This test helps identify errors or sources of variability that may affect the reliability of the measurement process, ensuring that the measure results are trustworthy and replicable.

5.2.3 Reliability Testing Results

See tables 11 & 12 and figures 6 & 7 in the attached tables & figures document in 7.1.

5.2.4 Interpretation of Reliability Results

Signal to Noise Analysis:

The signal to noise ratio analysis measures the confidence levels in differentiating performance between hospitals. Our analyses found the median SNR was 0.97 and had a fairly narrow interquartile range of 0.95 and 0.98. These numbers demonstrate variability that is attributable to real differences in hospital quality as opposed to measurement error. Collectively, we believe that the data strongly support the reliability of the data elements used in the model.

(Reference: Landis J, Koch G, The measurement of observer agreement for categorical data, Biometrics, 1977;33:159-174.)

Split Sample Methodology:

The box and whisper plot of the distribution of hospital performance for the model shows a similar distribution of use of the risk standardized bleeding rates for both split samples. Figures 7 (in the attached tables and figures document in 7.1) shows the scatterplot of the distribution of hospital performance when assessed in randomly split samples. Overall hospital performance in one random sample was correlated with hospital performance in the other split sample (r= 0.70943, P<0.0001), which is consistent with a reliable measure.

Table 2. Accountable Entity Level Reliability Testing Results by Denominator, Target Population Size

Accountable Entity-Level Reliability Testing Results

	Overall	Minimum	Decile_1	Decile_2	Decile_3	Decile_4	Decile_5	Decile_6	Decile_7	Decile_8	Decile_9	Decile_10	Maximum
Reliability	0.9458	0.9886	0.9751	0.9651	0.9507	0.9296	0.8987	0.9170	0.9438	0.9550	0.9586	0.9640	0.9654
Mean Performance Score	0.0186	0.0055	0.0104	0.0128	0.0142	0.0156	0.0169	0.0181	0.0195	0.0215	0.0241	0.0334	0.2668
N of Entities	1704	1	170	170	171	170	171	170	171	170	171	170	1
N of Persons / Encounters / Episodes	1312961	1483	164404	132126	127997	110913	114943	115963	130561	121578	144116	150360	475

5.3.1 Level(s) of Validity Testing Conducted

Accountable entity level (i.e., measure score) (e.g., criterion validity)

5.3.2 Type of Accountable Entity Level Validity Testing Conducted

Empirical validity testing at the accountable entity-level (e.g., criterion validity, construct validity, known groups analysis), Systematic assessment of face validity of the measure's performance score as an indicator of quality or resource use

5.3.3 Method(s) of Validity Testing

We performed 2 different strategies for assessing the validity of this measure. First, we underwent a rigorous process for establishing the face validity of the measure. Because it is a

clinically meaningful outcome, we sought to make sure that a broad range of experts and clinicians concurred that this was a clinically important outcome measure. Second, we hypothesized that it would be associated with other clinically important outcomes and sought to establish the predictive validity of the measure. These are described in more detail below:

Systematic Assessment of Face Validity of the Performance Measure:

Bleeding remains one of the most common non-cardiac complications of PCI. It is a serious adverse consequence and, most importantly, is modifiable. The 2011 ACC/AHA guidelines provide for a Level IC recommendation for the assessment of bleeding prior to PCI. This is grounded in the realization that there are several strategies, such as radial approaches and the use of bivalirudin, that can be applied to mitigate the risk of bleeding, particularly in high-risk patients. The first bleeding risk model was published in 2009 (Circ Cardiovasc Intervent. 2009;2:222-229) and the update was published in 2013 (JACC Cardiovasc Intervention, 2013;6:897-904).

Content validity of this outcome – and the specific definition used in defining a bleeding event – was achieved by the specialized expertise of those individuals who developed this model as well as the structured discussions that the group conducted. For this particular topic those individuals who were involved in identifying the key attributes and variables for this risk model were leaders and experts in the field of interventional cardiology. Multiple conference calls were held to both define a bleeding event and to examine and vet the risk model. These individuals within specific committees and workgroups are noted below:

NCDR Science and Quality Oversight Committee— an ACC leadership oversight committee that serves as the primary resource for crosscutting scientific and quality of care methodological issues – ensured the data dictionaries and metrics are consistent across registries. They also reviewed and approved the methodology and results of the bleeding outcome and model.

These members included:

John C. Messenger, MD, FACC (Chair); David M. Shahian, MD, FACC; Thomas T Tsai, MD, MSC; Charles A. Henrikson, MD, MPH; Jeff Jacobs, MD, FACC; John R. Windle, MD, FACC; Amit Amin, MD; John W. M. Moore, MD, FACC; Deepak L. Bhatt, MD, MPH, FACC; Jeffrey Westcott, MD, FACC; Gregory M. Marcus, MD FACC; David J. Slotwiner, MD, FACC; Jeptha P. Curtis, MD, FACC; John Spertus, MD, FACC; Matthew T. Roe, MD, FACC; and Frederick A. Masoudi, MD, MSPH, FACC

NCDR Clinical SubWorkgroup was a designated workgroup that oversaw the initial NQF application. Prior to submission, the group ensured there was 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.

Dr. Jeptha Curtis (chair), Dr. Frederick Masoudi, Dr. John Rumsfeld, Dr. David Malenka, and Dr. Issam Moussa.

NCDR Registry Steering Committee provided strategic direction for the Registry and ensures the measures submitted to NQF met key criterion such as reliability, feasibility, and that there is compelling evidence base behind the development and implementation of this measure. Dr. Issam D. Moussa (chair), Dr. Kirk N. Garratt, Dr. Lloyd W. Klein, Dr. Kendrick A. Shunk, Dr. Samir R. Kapadia, Dr. Robert N. Piana, Dr. Roxana Mehran, Dr. Frederic S. Resnic, Dr. Aaron D. Kugelmass, Dr. Sunil V. Rao, Dr. W. Douglas Weaver, and Dr. John C. Messenger.

The NCDR Metrics and Reporting Methodology (MRM) Subcommittee of the Science and Quality Oversight Committee, reviews for re-endorsement and a data analytic center is involved in evaluating data, providing corresponding analysis/interpretation of data. The review included guidance and oversight from both NCDR's Chief Science Officer (Frederick Masoudi) and chair of MRM (Jeptha Curtis).Lastly the 16 member NCDR Management Board and 31 member ACCF Board of Trustees originally approved these measures for submission to NQF.

In addition, the NCDR provides an open comment period (typically between 15 and 30 days) for: 1) all registry data set version changes, 2) new registry version measures and 3) significant changes/additions to registry version metrics/measures, including risk models and appropriate use criteria. The open comment period engages key registry shareholders (i.e., physicians and clinical care team members and hospital or practice representatives) as well as other external stakeholders (i.e., hospitals, physicians, payers, regulators, consumers, purchasers, etc.) Comments submitted are considered for modification of the version change. NCDR staff and members involved in developing the measures and reports receive all the comments submitted including the name of the individual and organization submitting comment. The NCDR determines which comments to incorporate into modifications and the internal timeline for any modifications. No formal response is provided back to individuals submitting comments through this process. The NCDR may choose to provide a report of comments received and decisions made regarding the various feedback to a broader audience.

Beyond the inherent content validity of this process, we have data showing that the bleeding risk score is highly actionable – a critical feature for moving beyond quality assessment to quality improvement. For example, a comparative effectiveness analysis of bivaluridin use by bleeding risk suggested that bivalirudin was preferentially used in low-risk patients (NNT=224) and least

often used in patients at high risk for bleeding (NNT=43; JAMA 2010;303(21):2156-2164). At Saint Luke's Mid America Heart Institute, the original bleeding model was executed prior to non-emergent PCI in all patients undergoing the procedure. Not only was the 'risk-treatment' paradox reversed, but the bleeding rate at that institution decreased by 40% (J Am Coll Cardiol 2013;61: 1847–52). More recently, a 9-center study of providing pre-procedural bleeding risks demonstrated a fully-adjusted 44% lower odds of bleeding when the models were used (BMJ, 2015;350:h1302). The ultimate validity of the model is that the use of the model to target therapy improves outcomes strongly supports the appropriateness and capacity of this model to measure and improve quality.

Empirical Validity:

To further underscore the importance of the bleeding measure, we examined the association of bleeding rates, by quintiles, with in-hospital mortality rates. We hypothesized that hospitals having a higher bleeding complication rate would also have higher rates of in-hospital mortality. Both of bleeding and mortality are important signals of quality.

References:

- Mehta SK, Frutkin AD, Lindsey JB, et al. Bleeding in patients undergoing percutaneous coronary intervention: the development of a clinical risk algorithm from the National Cardiovascular Data Registry. Circulation: Cardiovascular Interventions. 2009;2(3):222–229. doi: 10.1161/CIRCINTERVENTIONS.108.846741

- Rao SV, McCoy LA, Spertus JA, Krone RJ, Singh M, Fitzgerald S, Peterson ED. 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.

- Marso SP, Amin AP, House JA, Kennedy KF, Spertus JA, Rao SV, Cohen DJ, Messenger JC, Rumsfeld JS; National Cardiovascular Data Registry. Association between use of bleeding avoidance strategies and risk of periprocedural bleeding among patients undergoing percutaneous coronary intervention. JAMA. 2010 Jun 2;303(21):2156-64. doi: 10.1001/jama.2010.708. PMID: 20516416.

- Rao SC, Chhatriwalla AK, Kennedy KF, Decker CJ, Gialde E, Spertus JA, Marso SP. Pre-procedural estimate of individualized bleeding risk impacts physicians' utilization of bivalirudin during percutaneous coronary intervention. J Am Coll Cardiol. 2013 May 7;61(18):1847-52. doi: 10.1016/j.jacc.2013.02.017. Epub 2013 Mar 7. PMID: 23500304.

- Spertus JA, Decker C, Gialde E, Jones PG, McNulty EJ, Bach R, Chhatriwalla AK. Precision medicine to improve use of bleeding avoidance strategies and reduce bleeding in patients

undergoing percutaneous coronary intervention: prospective cohort study before and after implementation of personalized bleeding risks. BMJ. 2015 Mar 24;350:h1302. doi: 10.1136/bmj.h1302. PMID: 25805158; PMCID: PMC4462518.

5.3.4 Validity Testing Results

See attached tables and figures document in 7.1 table 14 and figure 8.

5.3.5 Interpretation of Validity Results

Face-Validity:

As described above, we undertook an extensive effort to establish the definition and utility of risk-adjusted bleeding as a quality metric. These included an expert team developing the model, a group of experts, the Strategic Oversight Committee, overseeing the work and reporting of the measure – including ascertaining its alignment with both ACC/AHA PCI Guidelines and the Society of Coronary Angiography and Intervention's (SCAI's) 2016 Expert Consensus Statement – and an NCDR Oversight Group for NQF measures. It further underwent public comment and approval by the NCDR Management Board of the ACC's Board of Trustees. Beyond these traditional ascertainments of its face validity, we further leveraged evidence that the prospective use of the model was associated with a substantial reduction in bleeding after PCI, clearly demonstrating the model to serve as a means for improving the safety of PCI.

Empirical Validity:

The model's empirical validity was tested to assess the correlation between two outcome measures: risk-standardized bleeding and risk-standardized mortality (a recently endorsed measure (CBE 0133)). There was a small, but positive correlation between the two measures, such that higher bleeding rates were correlated with higher in-hospital mortality rates (r=0.223). This is the signal that is clinically sensible.

5.4.1 Methods Used to Address Risk Factors

Statistical risk adjustment model with risk factors

5.4.2 Conceptual Model Rationale

A hierarchical logistic regression model was created for this model, with the relevant variables and odds ratios posed below in Table 15 (5.4.2a.). The data definitions are available on the NCDR website (https://cvquality.acc.org/NCDR-Home/registries/hospital-registries/cath…). The beta coefficients and covariance matrix are available from NCDR upon request.

We believe that social factors did not need to be included as variables in risk-adjustment for peri-procedural bleeding after PCI. This was predicated on the feasibility of patient-level social factors. The belief that the consequence of adverse social factors (e.g. leading to greater rates of obesity, hypertension, smoking or other comorbidities) would be directly captured by our rich clinical data, and that the short duration of follow-up (72 hours, during which the patient was hospitalized), would negate potential barriers to healthcare access and treatment that might be more relevant with longer-term outcomes. Accordingly, we feel that in this model of in-hospital risk-adjusted bleeding rate, given the rich clinical data available through the NCDR CathPCI registry, that social risk factors, which are not readily available, would not likely improve this particular risk model.

There was an extensive process to develop the face and content validity of the measure. To ensure our model achieved its purported goals, an expert panel was assembled to assess inclusion criteria, definitions, and risk-adjustment methodology. After settling on the outcome definition and candidate variables, categorical variables were summarized as frequencies and percentages and compared with Pearson chi-squared tests. Continuous variables were summarized as medians (interquartile range) and compared using Wilcoxon rank-sum tests. Ordinal variables were tested using a chi-square test based on the rank of the group mean score. The study population was then randomly split into a development sample consisting of 70% of PCI procedures and a validation sample consisting of the remaining 30% of admissions.

Due to high rates of missing data and possible biased data as a result, the following variables were forced out of the model: stress test results; Seattle Angina Questionnaire (SAQ) results; Rose Dyspnea Scale (RDS) results; assessment of chest pain symptoms; new antiarrhythmic therapy. Desire to exclude variables possibly related to physician choice and decision-making, as opposed to intrinsic patient-level risk, led to forcing out the following variables from the model: concomitant peripheral intervention, peripheral angiogram, heart biopsy, or procedure type not listed; arterial access site; arterial cross over; venous access; multivessel procedure type; pre-procedure hemoglobin; procedure medications. Of note, the original model selected the following variables into the risk model: right heart catheterization, mitral valve or percutaneous replacement of aortic valve using fluoroscopic guidance, insertion of temporary cardiac pacemaker, and arch aortogram. To make the model more parsimonious, we combined concomitant procedures into one yes/no variable. The following variables without clear clinical meaning were forced out: BMI unknown; GFR unknown; heart rate unknown; Troponin I unknown; Troponin T unknown; Ejection Fraction unknown; Systolic Blood Pressure unknown; Closure method not documented. Finally, to account for various metrics of clinical instability and procedural status, a “clinical instability” composite variable was created to reduce compounding effects of the following multiple associated variables: cardiogenic shock; ventricular support; pharmacologic vasopressor support; mechanical ventricular support; level of consciousness; STEMI; PCI status; hypothermia induced; hypothermia induction timing. Instead, the following composite variables of “clinical instability” were created: elective PCI without any cardiovascular instability; urgent PCI without any cardiovascular instability; emergency PCI without any cardiovascular instability; any cardiovascular instability without salvage PCI; cardiogenic shock (not refractory) without salvage PCI; refractory shock or salvage PCI; other. Ultimately, at the

discretion of the workgroup members, no variables were identified that required “forcing in” to the model.

Stepwise selection logistic regression was used on 1,000 bootstrapped samples from the development cohort. The final model included variables that were selected in at least 70% of the bootstrapped samples and those identified a priori due to clinical relevance.

The C-statistic was used to describe the discrimination of the model. All statistical analyses were performed using SAS software (version 9.3, SAS Institute, Cary, NC).

5.4.2a Attach Conceptual Model

-2459-Conceptual-Model.pdf

5.4.3 Variable Distribution Across Measured Entities

See attached tables and figures document in 7.1 table 16.

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

As described above, bivariate analyses were done to identify candidate variables that differed significantly between those with and without a clinically important bleeding event. Multivariable, hierarchical logistic regression analyses were then performed to retain those with a statistically significant association with bleeding ($p<0.05$ for each). Table 10 Predicted Probability of Bleeding in Section 5.1.4 demonstrates the difference between those with and without bleeding events.

See attached document in 5.4.4a. tables 17 & 18.

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

-2459_5.4.4a-modeling_specifications.pdf

5.4.5 Calibration and Discrimination

We developed the model in the 70% derivation set and tested its discrimination and calibration (using both the Hosmer-Lemeshow test and the slope of the predicted vs. observed risk).

The c-statistic is 0.772 for the model, which means that the probability that predicting the outcome is better than chance. This method is used to compare the goodness of fit of logistic regression models. The range is between 0.5 to 1.0. A value of 0.5 indicates that the model is no better than chance at making a prediction of membership in a group and a value of 1.0 indicates that the model perfectly identifies those within a group and those not. Models are typically considered reasonable when the C-statistic is higher than 0.7. (Hosmer & Lemeshow, 2000).

See attached document in 5.4.5a. table 19 and figures 9-12.

5.4.5a Attach Calibration and Discrimination Testing Results

-2459-Calibration-and-Discrimination-Testing-Results.pdf

5.4.6 Interpretation of Risk/Case-mix Factor Findings

We believe this model performs very well, accounting for patient characteristics present prior to the conduct of PCI and discriminating within important clinical subsets of patients. Moreover, there is substantial hospital variation before and after risk-adjustment. The distribution of institutional predicted to expected (P/E) ratios identifies some sites with excellent performance and others with rates of bleeding that are 80% or greater than expected. These would be sites where substantial opportunities to improve patient safety likely exist.

5.4.7 Final Approach to Address Risk Factors

Statistical risk adjustment model with risk factors

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.

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 in-patient.

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 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 detailed followed by an open Q&A session.

Feedback varies from detailed comments on the measure criteria, reflections, and general questions about how end-point decisions were made. When stakeholders fully understand the measure, they have expressed it is valuable in helping to guide their quality-of-care improvement efforts. Feedback following the changes to this measure has been generally positive.

6.2.3 Consideration of Measure Feedback

Any criticism of the observational data on performance is escalated to the applicable ACC team(s) (i.e., Registry management, Science leadership, Data Analytic Center) for consideration. If the feedback represents an opportunity for measure 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 updates. 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.

6.2.4 Progress on Improvement

As mentioned earlier, this model is used in performance improvement and quality initiatives to reduce the risk of patients undergoing PCI at many hospitals across the country. With the refinement of the cohort, to exclude patients status post cardiac arrest or experiencing cardiogenic shock, the outcome performance identifies those at lower absolute risk and highlights any bleeding event experienced. This should sharpen hospitals focus on the patients who experience any bleeding and allow them to initial quality improvement programs to reduce the risk. While this measure before undergoing recent refinement demonstrated improvement over time, additional data are needed post implementation to perform any new analyses.

6.2.5 Unexpected Findings

ACC determined that the measure required updates including revising the criteria used to define a bleeding event and the model to accurately define risk among “extreme risk” patients, such as those with cardiogenic shock and those who have suffered cardiac arrest prior to PCI. Additional detail justifying these revisions were outlined in Sections 1.10 and 2.2. We have not identified any unexpected findings since these changes were implemented but will continue to monitor any feedback that is received.

7.1 Supplemental Attachment

CBE--2459-Tables-and-Figures.pdf

Developer POC email

NCDRscience@acc.org

Measure Developer POC

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American College of Cardiology

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The measure developer is different from the measure steward

No

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