



Measure Information

This document contains the information submitted by measure developers/stewards, but is organized according to NQF's measure evaluation criteria and process. The item numbers refer to those in the submission form but may be in a slightly different order here. In general, the item numbers also reference the related criteria (e.g., item 1b.1 relates to sub criterion 1b).

Brief Measure Information

NQF #: 2459

Corresponding Measures:

De.2. Measure Title: Risk Standardized Bleeding for patients undergoing percutaneous coronary intervention (PCI).

Co.1.1. Measure Steward: American College of Cardiology

De.3. Brief Description of Measure: Risk adjusted rate of intra and post procedure bleeding for all patients age 18 and over undergoing PCI.

1b.1. Developer Rationale: Bleeding is the second most common non-cardiac complication of PCI. It is associated with adverse patient outcomes (e.g. increased mortality, prolonged length of stay and costs) and – most importantly – is modifiable through the use of bleeding avoidance strategies such as radial arterial access. Moreover, studies document under-use of bleeding avoidance strategies in high-risk patients. Thus, as an adverse event that varies widely across providers and is modifiable, the use of risk-adjusted bleeding metrics can provide the foundation for quality improvement initiatives that improve the safety and outcomes of treatment.

References:

Levine, G. N., Bates, E. R., Blankenship, J. C., Bailey, S. R., Bittl, J. A., Cercek, B., Chambers, C. E., Ellis, S. G., Guyton, R. A., Hollenberg, S. M., Khot, U. N., Lange, R. A., Mauri, L., Mehran, R., Moussa, I. D., Mukherjee, D., Nallamothu, B. K., Ting, H. H. (2011) 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. *Journal of The American College of Cardiology*, 58(24), e44-e122.

Vora, A. N., Peterson, E. D., McCoy, L. A., Garratt, K. N., Kutcher, M. A., Marso, S. P., Roe, M. T., Messenger, J. C., & Rao, S. V. (2016). The impact of bleeding avoidance strategies on hospital-level variation in bleeding rates following percutaneous coronary intervention. *Journal of the American College of Cardiology: Cardiovascular Interventions*, 9(8), 771-779.

S.4. Numerator Statement: 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:

1. Bleeding event w/in 72 hours ; OR
2. Hemorrhagic stroke; OR
3. Cardiac Tamponade; OR
4. Post-PCI transfusion for patients with a pre-procedure hemoglobin (Hgb) >8 g/dL and pre-procedure Hgb not missing; OR
5. Absolute Hgb decrease from pre-PCI to post-PCI of ≥ 4 g/dl AND pre-procedure Hgb ≤ 16 g/dL AND pre-procedure Hgb not missing

S.6. Denominator Statement: Patients 18 years of age and older with a PCI procedure performed during admission

S.8. Denominator Exclusions: 1. Patients who did not have a PCI (episodes of care with a diagnostic catheterization only);

2. Patients who died on the same day of the procedure
3. Patients who underwent CABG during the episode of care

De.1. Measure Type: Outcome

S.17. Data Source: Registry Data

S.20. Level of Analysis: Facility
IF Endorsement Maintenance – Original Endorsement Date: Sep 08, 2014 Most Recent Endorsement Date: Jun 10, 2019
IF this measure is included in a composite, NQF Composite#/title:
IF this measure is paired/grouped, NQF#/title:
De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? N/A

1. Evidence, Performance Gap, Priority – Importance to Measure and Report
Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. <i>Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria.</i>
1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form 2459_nqf_evidence_attachment_11.7.18_final.docx 1a.1 For Maintenance of Endorsement: Is there new evidence about the measure since the last update/submission? Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence. Yes
1b. Performance Gap Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating: <ul style="list-style-type: none"> considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or Disparities in care across population groups. 1b.1. Briefly explain the rationale for this measure (e.g., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure) <i>If a COMPOSITE (e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.</i> Bleeding is the second most common non-cardiac complication of PCI. It is associated with adverse patient outcomes (e.g. increased mortality, prolonged length of stay and costs) and – most importantly – is modifiable through the use of bleeding avoidance strategies such as radial arterial access. Moreover, studies document under-use of bleeding avoidance strategies in high-risk patients. Thus, as an adverse event that varies widely across providers and is modifiable, the use of risk-adjusted bleeding metrics can provide the foundation for quality improvement initiatives that improve the safety and outcomes of treatment. References: Levine, G. N., Bates, E. R., Blankenship, J. C., Bailey, S. R., Bittl, J. A., Cercek, B., Chambers, C. E., Ellis, S. G., Guyton, R. A., Hollenberg, S. M., Khot, U. N., Lange, R. A., Mauri, L., Mehran, R., Moussa, I. D., Mukherjee, D., Nallamothu, B. K., Ting, H. H. (2011) 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. Journal of The American College of Cardiology, 58(24), e44-e122. Vora, A. N., Peterson, E. D., McCoy, L. A., Garratt, K. N., Kutcher, M. A., Marso, S. P., Roe, M. T., Messenger, J. C., & Rao, S. V. (2016). The impact of bleeding avoidance strategies on hospital-level variation in bleeding rates following percutaneous coronary intervention. Journal of the American College of Cardiology: Cardiovascular Interventions, 9(8), 771-779. 1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis. (This is

required for maintenance of endorsement. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.

Please see the "2459 Main Submission Form Supplement" for the response to this question.

1b.3. If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.

As noted above, there is substantial variation across hospitals, ranging from a 1.7% rate in the top performing decile to an almost 3-fold greater rate of 5.0% in the worst performing decile. This suggest an important opportunity for improvement due to the observed variability across hospitals.

1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. *(This is required for maintenance of endorsement. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included.) For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.*

Please see "2459 Main Submission Form Supplement" for the response to this question.

1b.5. If no or limited data on disparities from the measure as specified is reported in 1b.4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in 1b.4

The opportunity to improve the safety of PCI by reducing bleeding exists for all patients, not just those of a specific race, gender, age or SES status.

2. Reliability and Validity—Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. **Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.**

2a.1. Specifications The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. Subject/Topic Area (check all the areas that apply):

Cardiovascular, Cardiovascular : Coronary Artery Disease (PCI)

De.6. Non-Condition Specific(check all the areas that apply):

De.7. Target Population Category (Check all the populations for which the measure is specified and tested if any):

Populations at Risk

S.1. Measure-specific Web Page (Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)

ACC does not have a measure specific webpage. However more information about the clinical registry that the measure is included in can be found at: <https://cvquality.acc.org/NCDR-Home/registries/hospital-registries/cathpci-registry>.

S.2a. If this is an eMeasure, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of

the specifications)

[This is not an eMeasure](#) **Attachment:**

S.2b. Data Dictionary, Code Table, or Value Sets (and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)

Attachment Attachment: [CathPCI_v4_CodersDictionary_4.4-635230481331385161-635854401108586219.pdf](#)

S.2c. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

[No, this is not an instrument-based measure](#) **Attachment:**

S.2d. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

[Not an instrument-based measure](#)

S.3.1. For maintenance of endorsement: Are there changes to the specifications since the last updates/submission. If yes, update the specifications for S1-2 and S4-22 and explain reasons for the changes in S3.2.

[Yes](#)

S.3.2. For maintenance of endorsement, please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.

[The PCI risk-adjusted bleeding model was updated in 2017 to a parsimonious hierarchical model. This means the risk model utilizes less patient variables \(than the previous model\) to determine individual patient risk of bleeding and the model will take into account the risk relationships within and amongst hospitals \(not utilized by the previous model and a hierarchical model feature\). Additionally, the hemoglobin parameter used to determine if a Post-PCI bleeding event has occurred, has been revised to assess an absolute hemoglobin \(hgb\) decrease from pre-PCI to post-PCI of = 4g/dL \(previously 3g/dL\). The Risk Adjusted Bleeding model provides accurate estimates of post-PCI bleeding risk and is helpful in providing risk-adjusted feedback on bleeding complications, informing clinical decision-making, and directing the use of bleeding avoidance strategies to improve the safety of PCI procedures.](#)

S.4. Numerator Statement (Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome) **DO NOT** include the rationale for the measure.

[IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm \(S.14\).](#)

[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:](#)

- [1. Bleeding event w/in 72 hours ; OR](#)
- [2. Hemorrhagic stroke; OR](#)
- [3. Cardiac Tamponade; OR](#)
- [4. Post-PCI transfusion for patients with a pre-procedure hemoglobin \(Hgb\) >8 g/dL and pre-procedure Hgb not missing; OR](#)
- [5. Absolute Hgb decrease from pre-PCI to post-PCI of >= 4 g/dl AND pre-procedure Hgb <=16 g/dL AND pre-procedure Hgb not missing](#)

S.5. Numerator Details (All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)

[IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm \(S.14\).](#)

[The numerator is defined as any patient ≥18 years of age, with post-PCI bleeding which includes meeting any one of the criteria listed below \(as shown below\).](#)

- [1. Bleeding event w/in 72 hours \(8050\); OR](#)
- [2. Hemorrhagic stroke \(8021\); OR](#)

3. Tamponade (8025); OR
4. Post-PCI transfusion (8040) for patients with a pre-procedure hgb >8 g/dL and pre-procedure hgb not missing; OR
5. Absolute hgb decrease (7320 and 7345) from pre-PCI to post-PCI of ≥ 4 g/dl (excluded if any of the following: pre-procedure (7320) hgb>16g/dl or IABP (5330) = yes or MVSupport (5340) = yes)

Note:

- All data element numbers listed above are included in the attach data dictionary which includes more detailed definitions for the above elements.
- The measure includes risk adjustment to account for differences in case mix across hospitals, thus the ratio determined by the numerator and denominator are modified based upon the adjustment.

S.6. Denominator Statement *(Brief, narrative description of the target population being measured)*

Patients 18 years of age and older with a PCI procedure performed during admission

S.7. Denominator Details *(All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*

IF an OUTCOME MEASURE, describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

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 are excluded).
4. Patient with procedures with non-missing values for outcome variables of bleeding event w/in 72 hours (8050) AND transfusion (8040).

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

S.8. Denominator Exclusions *(Brief narrative description of exclusions from the target population)*

1. Patients who did not have a PCI (episodes of care with a diagnostic catheterization only);
2. Patients who died on the same day of the procedure
3. Patients who underwent CABG during the episode of care

S.9. Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*

The following patients are excluded from the denominator:

1. Patients who died on the same day of the procedure [Discharge date (9035)=procedure date (5300) AND discharge status=deceased (9040)]
2. Patients with CABG (9000)=yes

Note that 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. Note: For some characteristics, missing values are imputed. 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.

Note that all data element numbers listed above are included in the attach 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. Note: If one or two variables are missing, the value is imputed for certain characteristics. In our data quality program, all key variables in the risk model have a high "inclusion" criteria. This means that, when a hospital submits data to us, they need to have a high level of completeness (around 95-99%) for those variables. If they are not able to meet the criteria in our data quality program, they do not receive risk adjusted mortality for the records they submitted for that quarter.

S.10. Stratification Information (Provide all information required to stratify the measure results, if necessary, including the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b.)

N/A

S.11. Risk Adjustment Type (Select type. Provide specifications for risk stratification in measure testing attachment)

Statistical risk model

If other:

S.12. Type of score:

Rate/proportion

If other:

S.13. Interpretation of Score (Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)

Better quality = Lower score

S.14. Calculation Algorithm/Measure Logic (Diagram or describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period for data, aggregating data; risk adjustment; etc.)

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 have do not have at least one patient with a pre-PCI or post-PCI hemoglobin value.
3. Remove patient's 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 cath 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 measure used weight system based on predictive variables as outlined in the accompanying testing documents and supplemental materials.

S.15. Sampling (If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)

IF an instrument-based performance measure (e.g., PRO-PM), identify whether (and how) proxy responses are allowed.

N/A

S.16. Survey/Patient-reported data (If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.)

Specify calculation of response rates to be reported with performance measure results.

N/A

S.17. Data Source (Check *ONLY* the sources for which the measure is SPECIFIED AND TESTED).

If other, please describe in S.18.

[Registry Data](#)

S.18. Data Source or Collection Instrument (Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc., and describe how data are collected.)

IF instrument-based, identify the specific instrument(s) and standard methods, modes, and languages of administration.

[National Cardiovascular Data Registry CathPCI Registry](#)

S.19. Data Source or Collection Instrument (available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)

[Available at measure-specific web page URL identified in S.1](#)

S.20. Level of Analysis (Check *ONLY* the levels of analysis for which the measure is SPECIFIED AND TESTED)

[Facility](#)

S.21. Care Setting (Check *ONLY* the settings for which the measure is SPECIFIED AND TESTED)

[Inpatient/Hospital](#)

If other:

S.22. COMPOSITE Performance Measure - Additional Specifications (Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)

[N/A](#)

2. Validity – See attached Measure Testing Submission Form

[2459_testing_form_v7.1_8.1.18_FINAL_-_edits_for_methods_panel_8.16.18_FINAL.docx](#)

2.1 For maintenance of endorsement

Reliability testing: If testing of reliability of the measure score was not presented in prior submission(s), has reliability testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

[Yes](#)

2.2 For maintenance of endorsement

Has additional empirical validity testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

[Yes](#)

2.3 For maintenance of endorsement

Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes social risk factors is not prohibited at present. Please update sections 1.8, 2a2, 2b1,2b4.3 and 2b5 in the Testing attachment and S.140 and S.11 in the online submission form. NOTE: These sections must be updated even if social risk factors are not included in the risk-adjustment strategy. You MUST use the most current version of the Testing Attachment (v7.1) -- older versions of the form will not have all required questions.

[Yes - Updated information is included](#)

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure,

lab test, diagnosis, medication order).

3a.1. Data Elements Generated as Byproduct of Care Processes.

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score), Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims), Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

If other:

3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. To what extent are the specified data elements available electronically in defined fields (i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields) Update this field for **maintenance of endorsement**.

ALL data elements are in defined fields in electronic clinical data (e.g., clinical registry, nursing home MDS, home health OASIS)

3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources. For **maintenance of endorsement**, if this measure is not an eMeasure (eCQM), please describe any efforts to develop an eMeasure (eCQM).

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL. Please also complete and attach the NQF Feasibility Score Card.

Attachment:

3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. Required for maintenance of endorsement. Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

IF instrument-based, consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

There were no difficulties noted with regard to data collection, availability of data, missing data, the frequency of data collection, patient confidentiality, time and cost of data collection, or other feasibility/implementation issues. In addition, the NCDR has a robust data collection process as outlined below.

Availability:

Participating hospitals report patient demographics, medical history, risk factors, hospital presentation, initial cardiac status, procedural details, medications, laboratory values and in-hospital outcomes. The majority of the 32 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 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 within the hospital. Most data elements exist in a structured format within patient's electronic health record.

Sampling:

There is no sampling of patient data allowed within the contractual terms of participation in the CathPCI Registry in NCDR. 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 will be required outside of the normal course of care. There will be no discrimination or bias with respect to inclusion on the basis of sex, race, or religion.

Patient confidentiality:

Patient confidentiality is preserved as the data are in aggregate form. The CathPCI Registry dataset, comprised of approximately 263, data elements was created by a panel of experts using available ACC-AHA guidelines, data elements and definitions, and other evidentiary sources. Private health information (PHI), 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, however, so inclusion of direct identifiers in the registry is 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 Dataset as such term is defined by the Health Insurance Portability and Accountability Act of 1996.

Data collection within the NCDR conforms to laws regarding protected health information. Patient confidentiality is of utmost concern with all metrics. The proposed measure does not include a patient survey. Physician and/or institutional confidentiality is maintained by de-identified dashboard reports. 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 will be 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 protected health information 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 is communicated to participants. ACCF limits access to Protected Health Information, and to equipment, systems, and networks that contain, transmit, process or store Protected Health Information, 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 implement inactivity time-outs. Encryption of wireless network data transmission and authentication of wireless devices containing NCDR Participant's information ACCF's network is required. Protected Health Information may only be transmitted off of 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.

Time of Data collection:

1 Full time employee can enter on average roughly 1200 patient records per year
(citation: ACC Marketing Intelligence Team)

Annual Fee:

See section 3c2

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.

3c.2. Describe any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm).

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 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. For calendar year 2017 the annual pricing for hospitals, NCDR Analytic and Reporting Services, and licensing of measure specifications ranges from \$2900-\$50,000. 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.

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. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

4.1. Current and Planned Use

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.

Specific Plan for Use	Current Use (for current use provide URL)

4a1.1 For each CURRENT use, checked above (update for maintenance of endorsement), provide:

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included
- Level of measurement and setting

Payment Program

Name of program and sponsor: Blue Distinction Centers for Cardiac Care; Sponsor: Blue Cross Blue Shield Association

Purpose:

The Blue Distinction Centers for Cardiac Care is a national designation program that recognizes hospitals that demonstrate expertise in delivering quality specialty care, safely and effectively. To earn the Blue Distinction Centers+ designation, hospitals must meet the same quality criteria as Blue Distinction Centers, and go an extra step to demonstrate that they do so cost efficiently. Quality is key: only those facilities that first meet Blue Distinction's nationally established, objective quality measures will be considered for designation as a Blue Distinction Center+. Blue Distinction Centers' goal is to help consumers find both quality and value for their specialty care needs, on a consistent basis, while encouraging healthcare professionals to improve the overall quality and delivery of care nationwide. [Retrieved from <http://www.bcbs.com/healthcare-partners/blue-distinction-for-providers/cardiacprogramcriteria.pdf> on 11/25/13]

Geographic area and number and percentage of accountable entities and patients included

Geographic Area: National program.

Number: Directory of Providers available at <http://www.bcbs.com/why-bcbs/blue-distinction/blue-distinction-cardiac/bluedistinctioncardiac.pdf>

% of accountable entities: Total of 414 hospitals

Alabama	10
Arizona	4
Arkansas	3
California	46
Colorado	6
Connecticut	5
Delaware	3
Florida	29
Georgia	4
Hawaii	1
Idaho	3
Illinois	29
Indiana	12
Iowa	8
Kansas	5
Kentucky	5
Louisiana	5
Maine	1
Massachusetts	8
Michigan	23
Minnesota	12
Missouri	12
Nebraska	5
New Hampshire	2
New Jersey	3
New York	12
Nevada	2
North Carolina	10
North Dakota	4
Ohio	26
Oklahoma	4

Patients included: information not available .

The measure is also used in the Quality Insight Hospital Program with Anthem, which overlaps with what is included above for Blue Distinction program
NCDR Public Reporting

ACC's National Cardiovascular Data Registry (NCDR) Voluntary Hospital Public Reporting Program: The ACC currently runs a program to give hospitals the opportunity to voluntarily publicly report their measure results based on data from the National Cardiovascular Data Registry (NCDR). Hospitals that choose to participate have their results displayed on ACC's CardioSmart. Currently Hospitals can report on the following three NQF-endorsed measures:

NQF #0965: Use of all recommended medications (ACEI or ARB and beta-blocker) to improve heart function and blood pressure after ICD implant.

NQF # 0964: Therapy with aspirin, P2Y12 inhibitor, and statin at discharge following PCI in eligible patients (composite measure)

NQF: 2377: Overall Defect Free Care Composite (labeled as "Complete Heart Attack Care" on the website)

NCDR CathPCI Registry:

The CathPCI Registry is sponsored by ACC in conjunction with the Society for Cardiovascular Angiography and Interventions. The CathPCI Registry was designed to create a national surveillance system to assess the characteristics, treatments, and outcomes of patients with coronary heart disease who undergo procedures in cardiac catheterization laboratories. Eligible patients are adults (18 years of age and older) who undergo a diagnostic cardiac catheterization and/or PCI. More than 1,300 hospitals across the U.S submit data to the CathPCI registry. Participation in the CathPCI Registry provides risk-adjusted quarterly benchmark reports that compares an institution's performance with that of volume-based peer groups and the national experience. The registry includes standardized, evidence-based data elements and definitions, a Dashboard tool that provides a custom query to control for variables (facility size, number of procedures, teaching vs. non-teaching sites, states and regions) to compare the participating facility data, metrics and volumes. ABIM Diplomates can also meet MOC recertification requirements by using CathPCI Registry data to earn up to 80 points toward evaluation of practice performance through the Clinical Quality Coach mobile app

4a1.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?)

N/A

4a1.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.)

N/A

4a2.1.1. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

How many and which types of measured entities and/or others were included? If only a sample of measured entities were included, describe the full population and how the sample was selected.

Performance results are distributed to all CathPCI registry participants as part of quarterly benchmark reports, which provide a detailed analysis of an institution's individual performance in comparison to 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.

4a2.1.2. Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

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 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 within the hospital. Most data elements exist in a structured format within patient's electronic health record.

There are a number of methods used to educate and provide general support to registry participants. This includes 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.

4a2.2.1. Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.

Describe how feedback was obtained.

Feedback is typically obtained through monthly registry site manager monthly calls, ad hoc phone calls tracked with salesforce software, and during registry –specific break-out sessions at the NCDR’s annual meeting. Registry Steering Committee members may also provide feedback during regularly scheduled calls.

4a2.2.2. Summarize the feedback obtained from those being measured.

Users have not reported any difficulties with reporting this measure.

4a2.2.3. Summarize the feedback obtained from other users

No other feedback was received from other users

4a2.3. Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

N/A

Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b1. Refer to data provided in 1b but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included.)

If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

See "2459 Main Submission Form Supplement" for a response to this question.

4b2. Unintended Consequences

The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

4b2.1. Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients.

N/A

4b2.2. Please explain any unexpected benefits from implementation of this measure.

The most vulnerable aspect of this measure pertains to physician transparency and willingness to report and record adverse events.

5. Comparison to Related or Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.
[No](#)

5.1a. List of related or competing measures (selected from NQF-endorsed measures)

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

5a. Harmonization of Related Measures

The measure specifications are harmonized with related measures;

OR

The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):

Are the measure specifications harmonized to the extent possible?

[No](#)

5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

[N/A](#)

5b. Competing Measures

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);

OR

Multiple measures are justified.

5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):

Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)

[There are no bleeding related risk standardized measures endorsed by NQF currently for the PCI patient population.](#)

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

[Attachment](#) **Attachment:** [2013_JACC_Updated_Model_to_Predict_Risk_of_Post_PCI_Bleeding.pdf](#)

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): [American College of Cardiology](#)

Co.2 Point of Contact: [Jarrott, Mayfield, jmayfield@acc.org](#)

<p>Co.3 Measure Developer if different from Measure Steward: American College of Cardiology</p> <p>Co.4 Point of Contact: Kim, Lavin, klavin@acc.org</p>
<p>Additional Information</p>
<p>Ad.1 Workgroup/Expert Panel involved in measure development Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.</p> <p>At the time of initial endorsement of this measure, the individuals who were involved in identifying the key attributes and variables for this process measure were leaders and experts in the field of interventional cardiology and quality measurement. Serial phone calls were held to both define the eligible population and given process. These clinical leaders are noted below.</p> <p>NCDR Clinical workgroup ensured the measure demonstrated an opportunity for improvement, had strong clinical evidence, and was a reliable and valid measure. These members included Drs. Jephtha Curtis (Chair), Frederick Masoudi, John Rumsfeld, Issam Moussa, and David Malenka.</p> <p>NCDR Scientific Quality and Oversight Committee—a committee that served as the primary resource for crosscutting scientific and quality of care methodological issues. These members included Drs. Frederick Masoudi (Chair) , David Malenka, Thomas Tsai, Matthew Reynolds, David Shahian, John Windle, Fred Resnic, John Moore, Deepak Bhatt, James Tcheng, Jephtha Curtis, Paul Chan, Matthew Roe, and John Rumsfeld.</p>
<p>Measure Developer/Steward Updates and Ongoing Maintenance</p> <p>Ad.2 Year the measure was first released: 2011</p> <p>Ad.3 Month and Year of most recent revision: 12, 2017</p> <p>Ad.4 What is your frequency for review/update of this measure? With dataset revisions and based on new evidence.</p> <p>Ad.5 When is the next scheduled review/update for this measure? 12, 2019</p>
<p>Ad.6 Copyright statement: American College of Cardiology Foundation All Rights Reserved</p> <p>Ad.7 Disclaimers: ACC realizes the various NCDR endorsed measures are not readily available on their own main webpage. However, ACCF plans to update their main webpage (cardiosource.org) to include the macrospecifications of the NQF endorsed measures. ACC hopes to work collaboratively with NQF to create a consistent and standard format would be helpful for various end users. In the interim, the supplemental materials include the details needed to understand this model.</p>
<p>Ad.8 Additional Information/Comments: ACC appreciates the opportunity to submit measures for this NQF endorsement maintenance project.</p>