

CBE ID

0695

Title

Hospital 30-Day Risk-Standardized Readmission Rates following Percutaneous Coronary Intervention (PCI)

Project

Cost and Efficiency

Endorsement Status

Endorsement Removed

E&M Committee Rationale/Justification

Endorsement was removed due to no consensus. The committee raised concern with the lack of updated data to determine whether a gap exists and for scientific acceptability. The measure is also not in use, which makes it challenging to know if the measure is improving over time.

Is Under Review

No

Previous Endorsement Cycle

Fall 2023

Removal Date

Mon, 03/18/2024 - 00:00

Initial Endorsement

Mon, 01/17/2011 - 13:40

1.0 New or Maintenance

Maintenance

1.3 Electronic Clinical Quality Measure (eCQM)

No

1.6 Measure Description

This measure estimates a hospital-level risk-standardized readmission rate (RSRR) following PCI for Medicare Fee-for-Service (FFS) patients who are 65 years of age or older. The outcome is defined as unplanned readmission for any cause within 30 days following hospital stays. The measure includes both patients who are admitted to the hospital (inpatients) for their PCI and patients who undergo PCI without being admitted (outpatient or observation stay). A specified set of planned readmissions do not count as readmissions. The measure uses clinical data available in the National Cardiovascular Disease Registry (NCDR) CathPCI Registry for risk adjustment and

Medicare claims to identify readmissions. Additionally, the measure uses direct patient identifiers including Social Security Number (SSN) and date of birth to link the datasets.

1.7 Composite Measure

Yes

1.7 Measure Type

Outcome

1.8 Level of Analysis

Facility

1.9 Care Setting

Hospital: Inpatient

1.10 Measure Rationale

Not applicable

1.11 Measure Webpage

<https://doesnotexist.org>

1.13 Data Dictionary

Attached

1.13a Attach Data Dictionary

[PCI_V5.0_DataDictionaryFullSpecifications_.zip](#)

1.14 Numerator

The outcome for this measure is 30-day all-cause readmission. We define readmission as an acute care inpatient hospital admission for any cause, with the exception of certain planned readmissions, within 30 days from the discharge date of the index PCI hospitalization or PCI outpatient claim end date (hereafter referred to as discharge). If a patient has more than one unplanned admission within 30 days of discharge from the index admission, only the first one is counted as a readmission. The measure looks for a dichotomous yes or no outcome of whether each admitted patient has an unplanned readmission within 30 days. However, if the first readmission after discharge is considered planned, then no readmission is counted, regardless of whether a subsequent unplanned readmission takes place. We use this approach because it would potentially be unfair to attribute an unplanned readmission that follows a planned readmission back to the care received during the initial index admission.

1.14a Numerator Details

The measure counts readmissions to any acute care hospital for any cause within 30 days of PCI discharge, excluding planned readmissions as defined below.

Planned Readmission Algorithm:

The Planned Readmission Algorithm is a set of criteria for classifying readmissions as planned among the general Medicare population using Medicare administrative claims data. The algorithm identifies admissions that are typically planned and may occur within 30 days of discharge from the hospital.

The Planned Readmission Algorithm has three fundamental principles:

1. A few specific, limited types of care are always considered planned (obstetric delivery, transplant surgery, maintenance chemotherapy/radiotherapy/immunotherapy, rehabilitation);
2. Otherwise, a planned readmission is defined as a non-acute readmission for a scheduled procedure; and
3. Admissions for acute illness or for complications of care are never planned.

The algorithm was developed in 2011 as part of the Hospital-Wide Readmission measure. In 2013, Centers for Medicare & Medicaid Services (CMS) applied the algorithm to its other readmission measures. NQF reviewed and endorsed the planned readmission algorithm as applied to the AMI readmission measure during an Ad Hoc review completed in January 2013. The Planned Readmission Algorithm replaced the definition of planned readmissions in the original PCI measure because the algorithm uses a more comprehensive definition. In applying the algorithm to condition- and procedure-specific measures, teams of clinical experts reviewed the algorithm in the context of each measure-specific patient cohort and, where clinically indicated, adapted the content of the algorithm to better reflect the likely clinical experience of each measure's patient cohort. For the AMI readmission measure, CMS used the Planned Readmission Algorithm without making any changes.

Customization for PCI Readmission Measure:

Yale New Haven Health Service Corporation Center for Outcomes Research and Evaluation (YNHHSC/CORE) updated the approach to identifying planned readmissions in the PCI readmission measure by replacing the original NQF-endorsed approach, which only identified revascularization procedures as planned, with a more comprehensive planned readmission algorithm. The revised approach uses a modified version of the Planned Readmission Algorithm Version 2.1 – General Population that has been customized for the PCI patient population. The approach takes into account differences in the likelihood that a procedure is planned depending on whether a coronary stent was implanted during the index PCI procedure.

A working group of YNHHSC/CORE cardiologists and clinicians that developed the Planned Readmission Algorithm reviewed the list of potentially planned procedures in the context of the PCI population. Patients who receive a stent during their PCI require at least four weeks of therapy with aspirin and a platelet inhibitor. During that time period, it is unusual to perform procedures that would require interruption of dual antiplatelet therapy. In contrast, if no stent is deployed, dual antiplatelet therapy is not required, and patients are more likely to undergo planned surgical procedures. Given these considerations, the working group developed different sets of potentially planned procedures for patients with and without stent implantation.

For all readmissions, the measure first identifies readmissions for procedures that are always considered planned (e.g., chemotherapy or organ transplantation). In the next step, the approach changes depending on whether or not a patient had a stent during the index PCI procedure. If a

stent was deployed, the algorithm uses a smaller set of potentially planned procedures than if a stent was not deployed. All potentially planned procedures identified in both patient populations are then checked for an accompanying primary discharge diagnosis that would more likely than not reflect an acute condition or complication of care.

Analyzing Medicare Fee-For-Service data from July 2008 to June 2011, the crude 30-day measured readmission rate decreased by 0.5% to 11.8%, from 12.3% using the original planned readmission methodology.

1.15 Denominator

The target population for this includes hospital stays for patients who are 65 years of age or older who receive a PCI and who have matching records in the CathPCI Registry and Medicare claims.

1.15a Denominator Details

This outcome measure does not have a traditional numerator and denominator like a core process measure (e.g., percentage of adult patients with diabetes aged 18-75 years receiving one or more hemoglobin A1c tests per year); thus, we use this field to define the measure cohort.

The time window can be specified for two years. The index cohort includes hospital stays for patients aged 65 or older who receive a PCI and who have matching records in the CathPCI Registry and Medicare claims.

In the CathPCI Registry, eligible admissions are identified in the data collection form when PCI=yes.

In the Medicare claims, the patient cohort is defined by having one or more of the ICD-10-CM procedure codes and Current Procedural Terminology (CPT) procedure codes.

CPT codes:

92973 Percutaneous transluminal coronary thrombectomy 92980 Coronary Stents (single vessel)
92981 Coronary Stents (each additional vessel) 92982 Coronary Balloon Angioplasty (single vessel)
92984 Coronary Balloon Angioplasty (each additional vessel) 92995 Percutaneous Atherectomy
92996 Percutaneous Atherectomy

1.15b Denominator Exclusions

The following exclusions were applied to data during the merging of NCDR CathPCI and Medicare datasets:

1. Patients younger than 65 years of age.

Rationale: Patients younger than 65 in the Medicare dataset represent a distinct population that qualifies for Medicare due to disability. The characteristics and outcomes of these patients may be less representative of the larger population of PCI patients. Additionally, patients younger than 65 in the NCDR CathPCI dataset will not have corresponding data in the Medicare claims dataset to

obtain the readmission outcome.

2. Patient stays with duplicate fields (NCDR CathPCI and Medicare datasets).

Rationale: Two or more patient stays that have identical information for SSN, admission date, discharge date, and hospital MPN are excluded to avoid making matching errors upon merging of the two datasets.

3. Unmatched patient stays.

Rationale: The measure requires information from both the CathPCI Registry and corresponding Medicare claims data. Accordingly, the measure cannot be applied to patient stays that are not matched in both datasets.

Exclusions applied to the linked dataset:

1. Patients not enrolled in Medicare FFS at the start of the episode of care.

Rationale: Readmission data are currently available only for Medicare FFS patients.

2. Not the first claim in the same claim bundle.

Rationale: Multiple claims from an individual hospital can be bundled together. To ensure that the selected PCI is the index PCI, we exclude those PCI procedures that were not the first claim in a specific bundle. Inclusion of additional claims could lead to double counting of an index PCI procedure.

3. Instances when PCI is performed more than 10 days following admission.

Rationale: Patients who undergo PCI late into their hospitalization represent an unusual clinical situation in which it is less likely that the care delivered at the time of or following the PCI would be reasonably assumed to be associated with subsequent risk of readmission.

4. Transfers out.

Rationale: Patient stays in which the patient received a PCI and was then transferred to another hospital are excluded because the hospital that performed the PCI procedure does not provide discharge care and cannot fairly be held responsible for their outcomes following discharge.

5. In-hospital deaths (the patient dies in the hospital).

Rationale: Subsequent admissions (readmissions) are not possible.

6. Discharges Against Medical Advice (AMA).

Rationale: Physicians and hospitals do not have the opportunity to deliver the highest quality care.

7. PCI in which 30-day follow-up is not available.

Rationale: Patients who are not enrolled for 30 days in fee-for-service Medicare following their hospital stay are excluded because there is not adequate follow-up data to assess readmissions.

8. Admissions with a PCI occurring within 30-days of a prior PCI already included in the cohort.

Rationale: We do not want to count the same admission as both an index admission and an outcome.

1.15c Denominator Exclusions Details

Exclusions applied to data during the merging of NCDR CathPCI and Medicare datasets:

1. Patients younger than 65 years of age are identified through the date of birth and the date of admission in both the Medicare claims data and CathPCI data.
2. Patient stays with duplicate fields (NCDR CathPCI and CMS datasets) are identified through the linking fields in the matching process.
3. Unmatched patient stays are identified during the matching process.

Exclusions applied to the linked dataset:

1. Patients not enrolled in Medicare FFS at the start of the episode of care are identified through the indicator carried over from the Medicare claims data.
2. Not the first claim in the same claim bundle are identified by an indicator carried over from the Medicare claims when a patient is admitted within one day of the discharge date to the same hospital with the same diagnosis code and in the same group of procedure of PCI.
3. Instances when PCI is performed more than 10 days following admission are identified through the admission date and the procedure date carried over from the CathPCI data.
4. Transfers out to other acute care facilities are identified by indicators carried over from the Medicare claims when a patient with a qualifying admission is discharged from an acute care hospital and admitted to another acute care hospital on the same day or next day.
5. In-hospital deaths are identified using the discharge disposition vital status indicator indicators carried over from the Medicare claims data.
6. Discharges AMA are identified using the discharge disposition indicator carried over from the Medicare claims data.
7. PCI in which 30-day follow-up is not available is identified by patient enrollment status in the CMS' Enrollment Database (EDB).
8. Admissions with a PCI occurring within 30 days of a prior PCI already included in the cohort are identified by comparing the discharge date from the index admission with the readmission date for PCI using indicators carried over from the CathPCI data.

1.16 Type of Score

Rate/proportion

1.17 Measure Score Interpretation

Better performance = Lower score

1.18 Calculation of Measure Score

The measure employs a hierarchical logistic regression model to create a hospital-level 30-day RSRR. In brief, the approach simultaneously models two levels (patient and hospital) to account for the variance in patient outcomes within and between hospitals (Normand & Shahian, 2007). At the patient level, the model adjusts the log-odds of readmission within 30 days of discharge for age, sex, and selected clinical covariates. The second level models the hospital-specific intercepts as arising from a normal distribution. The hospital intercept represents the underlying risk of readmission at the hospital, after accounting for patient risk. The hospital-specific intercepts are given a distribution in order 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 RSRR is calculated as the ratio of the number of “predicted” to the number of “expected” readmissions, multiplied by the national unadjusted readmission rate. For each hospital, the numerator of the ratio (“predicted”) is the number of readmissions within 30 days predicted on the basis of the hospital’s performance with its observed case mix, and the denominator (“expected”) is the number of readmissions expected on the basis of the nation’s performance with that hospital’s case mix. 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 readmission or better quality and a higher ratio indicates higher-than-expected readmission or worse quality.

The predicted hospital outcome (the numerator) is the sum of the predicted probabilities of readmission for all patients at a particular hospital. The predicted probability of each patient in that hospital is calculated using the hospital-specific intercept and patient risk factors. The expected number of readmissions (the denominator) is the sum of the expected probabilities of readmission for all patients at a hospital. The expected probability of each patient in a hospital is calculated using a common intercept and patient risk factors.

Reference:

Normand S-LT, Shahian DM. 2007. Statistical and Clinical Aspects of Hospital Outcomes Profiling. Stat Sci 22(2): 206-226.

1.19 Measure Stratification Details

Results of this measure will not be stratified.

1.20 Types of Data Sources

Claims Data, Registries

1.25 Data Source Details

This measure relies on claims data. As of Fall 2023 claims data use is currently restricted and

unavailable to support performance measures. Legislation to change this has been introduced.

We used the following data sources for initial model development:

1) Medicare Part A data

IMPORTANT NOTE: ACC is not currently able to use this data source as Medicare claims are not currently available for performance measure reporting. This has limited our ability to update and report this measure.

Part A data refers to claims paid for Medicare inpatient hospital care, outpatient services, skilled nursing facility care, some home health agency services, and hospice care. For this measure, we used Part A data to identify patient stays with a PCI performed either as an inpatient admission or outpatient service. For model development, we used 2007 Medicare Part A data to match patient stays associated with a PCI with comparable data from the CathPCI Registry. For validation, we used 2006 Medicare Part A data to match patient stays with a PCI performed with the corresponding 2006 data from the CathPCI Registry.

2) Medicare Enrollment Database

This database contains Medicare beneficiary demographic, benefit/coverage, and vital status information. This dataset was used to obtain information on several inclusion/exclusion indicators such as Medicare status on admission as well as vital status. These data have previously been shown to accurately reflect patient vital status (Fleming et al., 1992).

3) NCDR CathPCI Registry

The CathPCI Registry is the largest voluntary cardiovascular data registry in the United States. The registry captures detailed information about patients at least 18 years of age undergoing cardiac catheterization and PCI. Information collected by the registry includes demographics, comorbid conditions, cardiac status, and coronary anatomy. Hospitals that join the CathPCI Registry agree to submit data for 100% of patients undergoing cardiac catheterization and PCI procedures. These data are collected by hospitals and submitted electronically on a quarterly basis to NCDR.

Reference:

Fleming C, Fisher ES, Chang CH, Bubolz TA, Malenka DJ. Studying outcomes and hospital utilization in the elderly: The advantages of a merged data base for Medicare and Veterans Affairs hospitals. Medical Care. 1992; 30(5): 377-91. Data sources for the all-payer update

1.26 Minimum Sample Size

This measure requires a minimum sample of 25 patients per facility.

2.1 Attach Logic Model

[0695 Attachment 20231101.pdf](#)

2.2 Evidence of Measure Importance

Numerous studies have demonstrated that differences in both PCI technique and subsequent hospital care affect patient outcomes following PCI. For example, the choice of procedural anticoagulation has been shown to affect both immediate and midterm outcomes following PCI (Giugliano 2005, Lincoff 2004). Similarly, a number of studies have demonstrated that appropriate device choice (such as intracoronary stents and thrombectomy) can improve patient outcomes. Finally, prior research has suggested that patients treated at hospitals with active PCI quality improvement programs have better outcomes than patients treated at hospitals that do not have these processes in place (Moscucci 2006).

Research has also shown that readmission rates for many conditions and procedures are influenced by the quality of inpatient and outpatient care, as well as hospital system characteristics, such as bed capacity of the local health care

system (Fisher 1994). In addition, specific hospital processes such as discharge planning, medication reconciliation, and coordination of outpatient care have been shown to positively affect readmission rates (Nelson 2000). Post-discharge follow-up and management during the transition to home also contribute to reducing readmissions (Mols 2019, Wu 2019). A recent meta-analysis of 39 studies recommended several interventions that could be considered to reduce 30-day readmissions including discharge checklists and ensuring compliance with medications during follow-up (Kwok 2020).

References:

Fisher ES, Wennberg JE, Stukel TA, Sharp SM. Hospital readmission rates for cohorts of Medicare beneficiaries in Boston and New Haven. *N Engl J Med*. 1994;331(15):989-995.

R.P. Giugliano, L.K. Newby and R.A. Harrington et al., The early glycoprotein IIb-IIIa inhibition in non-ST-segment elevation acute coronary syndrome (EARLY ACS) trial: a randomized placebo-controlled trial evaluating the clinical benefits of early front-loaded eptifibatide in the treatment of patients with non-ST-segment elevation acute coronary syndrome—study design and rationale, *Am Heart J* 149 (2005), pp. 994–1002.

Kwok CS, Narain A, Pacha HM, et al. Readmissions to Hospital After Percutaneous Coronary Intervention: A Systematic Review and Meta-Analysis of Factors Associated with Readmissions. *Cardiovasc Revasc Med*. 2020;21(3):375-391. doi:10.1016/j.carrev.2019.05.016

Lincoff AM, Kleiman NS, Kereiakes DJ, Feit F, Bittl JA, Jackman JD, Sarembock IJ, Cohen DJ, Spriggs D, Ebrahimi R, et al. (2004) Long-term efficacy of bivalirudin and provisional glycoprotein IIb/IIIa blockade vs heparin and planned glycoprotein IIb/IIIa blockade during percutaneous coronary revascularization: REPLACE-2 randomized trial. *J Am Med Assoc* 292: 696-703.

Mols RE, Hald M, Vistisen HS, Lomborg K, Maeng M. Nurse-led Motivational Telephone Follow-up After Same-day Percutaneous Coronary Intervention Reduces Readmission and Contacts to General Practice. *J Cardiovasc Nurs*. 2019;34(3):222-230. doi:10.1097/JCN.0000000000000566

Moscucci M, Rogers EK, Montoye C; et al. Association of a continuous quality improvement initiative with practice and outcome variations of contemporary percutaneous coronary interventions. *Circulation*. 2006;113(6):814-822.

Nelson EA, Maruish ME, Axler JL. Effects of discharge planning and compliance with outpatient appointments on readmission rates. *Psychiatr Serv*. 2000;51(7):885-889.

Wu Q, Zhang D, Zhao Q, et al. Effects of transitional health management on adherence and prognosis in elderly patients with acute myocardial infarction in percutaneous coronary intervention: A cluster randomized controlled trial. *PLoS One*. 2019;14(5):e0217535. Published 2019 May 31. doi:10.1371/journal.pone.0217535

2.4 Performance Gap

See Table 1. Below

Table 1. Performance Scores by Decile

	Performance Gap										Maximum
	Overall Minimum	Decile_1	Decile_2	Decile_3	Decile_4	Decile_5	Decile_6	Decile_7	Decile_8	Decile_9	Decile_10
Mean Performance Score		6.2%/5.5%	7.2%/7.0%	8.2%/8.1%	9.3%/9.5%	10.6%/11.1%	12.2%/12.8%	14.3%/14.8%	17.6%/18.6%	27.1%/26.1%	
N of Entities		1197	1197	1197	1197	1197	1197	1197	1197	1197	
N of Persons / Encounters / Episodes		27751	27751	27751	27751	27751	27751	27751	27751	27751	

2.6 Meaningfulness to Target Population

This measure was developed with input from a technical expert panel that includes patient and caregiver representation. Generally, patients indicate that outcomes such as readmission rates in the 30 days following a procedure are useful for decision-making purposes and we believe that this measure would be found meaningful by them.

3.1 Contributions Towards Closing Care Gaps

optional question

4.1 Feasibility Assessment

Not applicable during the Fall 2023 cycle.

4.3 Feasibility Informed Final Measure

The data elements required to generate this measure are coded by an individual other than the person obtaining the original information (e.g., DRG, ICD-10 codes on claims) or abstracted from a 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 for risk adjustment and that data are linked to CMS administrative claims data to identify the readmissions.

As noted, the PCI readmission measure was successfully implemented with voluntary public reporting of hospitals that participate in the NCDR CathPCI Registry. In March 2013, all NCDR CathPCI hospitals received a hospital-specific report (HSR) detailing the results of the measure which included their RSRR, interval estimate, the reasons why patients were readmitted, and the hospitals to which their patients were readmitted. The measure uses data that is already routinely being collected by hospitals participating in the registry. Furthermore, the administrative data used to identify readmissions are routinely collected as part of the billing process. As such this measure did not add any incremental cost to participating sites. We did not experience any feedback from sites regarding issues of patient confidentiality or our approach to missing data.

We received feedback from several hospitals who stated that they erroneously received HSRs stating that they had no eligible cases. After inspecting the data, we determined that these represented cases in which several hospitals submitted cases using the same MPN. In our existing methodology, we excluded these cases due to concerns that we would be unable to accurately attribute cases to a specific hospital. In the future, however, we will be able to overcome this hurdle by using the NCDR's hospital identifiers to correctly attribute cases to hospitals.

4.4 Proprietary Information

Not a proprietary measure and no proprietary components

4.4a Fees, Licensing, or Other Requirements

The ACCF's program the National Cardiovascular Data Registry (NCDR) provides evidence based solutions for cardiologists and other medical professionals committed to excellence in cardiovascular care. NCDR hospital participants receive confidential benchmark reports that

include access to measure macro specifications and micro specifications, the eligible patient population, exclusions, and model variables (when applicable). In addition to hospital sites, NCDR Analytic and Reporting Services provides consenting hospitals' aggregated data reports to interested federal and state regulatory agencies, multi-system provider groups, third-party payers, and other organizations that have an identified quality improvement initiative that supports NCDR-participating facilities. Lastly, the ACCF also allows for licensing of the measure specifications outside of the Registry.

There are no fees associated with the use of this measure. However, the measure is specified in a manner that requires participation in the NCDR CathPCI registry. Theoretically, one could create a parallel pathway for data submission that would not require registry participation, but this process has not been initiated and would be challenging. For example, there would not be the same efforts to ensure the quality and accuracy of submitted data.

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

5.1.1 Data Used for Testing

The specifications for this measure have not changed since the prior review.

Several sections of this application for this measure could not be updated, including information on reliability and validity. This uniquely valuable measure was developed when access to CMS claims data was feasible. Current data access restrictions to the same CMS claims data prevents ACC from conducting the patient matching to assess long term follow up. Imposing requirements upon hospitals to acquire follow up data themselves during the past two plus years of the pandemic-induced hospital crisis was not possible. Thus, ACC-NCDR was prevented from linking claims data to our registry data.

The dataset used for testing included Medicare Part A claims, the National Cardiovascular Data Registry (NCDR) CathPCI Registry, and the Medicare Enrollment Database.

1. NCDR CathPCI Registry Data

This is a national quality improvement registry with more than 1200 participating U.S. 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.

1. Medicare Data

Medicare Enrollment Database (EDB): This database contains Medicare beneficiary demographic, benefit/coverage, and vital status information. This dataset was used to obtain information on several inclusion/exclusion indicators, such as Medicare status on admission, and provided the ability to retrieve 90 days follow-up, linking patient Health Insurance Claim (HIC) number to the Part A data. These data have previously been shown to accurately reflect patient vital status (Fleming Fisher et al. 1992).

The datasets, dates, number of measured entities, and number of admissions used in each type of testing are as follows. For most testing requirements, we used data and analyses from the original submission to the CBE of the PCI readmission measure. These analyses used a cohort of patients undergoing PCI in 2006-2007 for whom NCDR CathPCI Registry data had been successfully linked with corresponding administrative claims data. However, we also conducted additional analyses to meet newer testing requirements, and these analyses were performed using comparable linked data from 2010-2011. Details are provided below.

Reliability testing and exclusions testing

The measure reliability dataset linked the CathPCI and Medicare Part A claims data from 2010-2011. The combined two-year sample included 277,512 PCIs on Medicare FFS patients aged 65 years and older performed in 1,197 hospitals (mean age 75.15 years; % female=39.95%). We then randomly split the sample, leaving 138,756 admissions to 1,190 hospitals in one randomly selected sample and 138,756 admissions to 1,193 hospitals in the remaining sample for patients aged 65 years and older. After excluding hospitals with fewer than 25 cases in each sample, the first sample contained 970 hospitals and the second sample contained 969 hospitals.

For data element reliability, we utilized data and analyses from the original measure NQF submission as part of initial measure development. For these analyses, we identified PCI procedures in the CathPCI Registry in which the patient was released from the hospital between January and December 2007. This development sample consisted of 128,745 patient stays at 766 hospitals. For measure testing, we identified a cohort of PCIs in which the patient was released from the hospital between January and December 2006. This validation sample consisted of 117,375 patient stays at 618 hospitals.

Validity testing

Results of validity testing use data from the original measure NQF submission. For measure development, we identified PCI procedures in the CathPCI Registry in which the patient was released from the hospital between January and December 2007. This development sample consisted of 128,745 patient stays at 766 hospitals. For measure testing, we identified a cohort of PCIs in which the patient was released from the hospital between January and December 2006. This validation sample consisted of 117,375 patient stays at 618 hospitals.

Measure development and risk-adjustment dataset

In measure development, we identified PCI procedures in the CathPCI Registry in which the patient was released from the hospital between January and December 2007. We merged PCI admissions in the NCDR CathPCI Registry data and PCI admissions in Medicare claims data to derive cohorts for development using probabilistic matching methodology. There were 128,745 cases discharged from the 766 hospitals in the validation sample. This development sample had a crude readmission rate of 11.1%.

5.1.2 Differences in Data

Information on the differences with the data used is described above.

5.1.3 Characteristics of Measured Entities

For this measure, hospitals are the measured entities. All non-federal, acute inpatient US hospitals (including territories) that participate in the American College of Cardiology (ACC) NCDR's CathPCI Registry and care for Medicare Fee-for-Service (FFS) beneficiaries who are 65 years of age or older are included. The number of measured entities (hospitals) varies by testing type as described in the question above.

5.1.4 Characteristics of Units of the Eligible Population

The number of admissions varies by testing type as described in the question above.

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

The specifications for this measure have not changed since the prior review.

Patient or Encounter-Level Reliability

In constructing the measure we aim to utilize only those data elements from the claims that have both face validity and reliability. We avoid the use of fields that are thought to be coded inconsistently across hospitals or providers. Specifically, we use fields that are consequential for payment and which are audited. We identify such variables through empiric analyses and our understanding of CMS auditing and billing policies and seek to avoid variables which do not meet this standard. For example, “discharge disposition” is a variable in Medicare claims data that is not thought to be a reliable variable for identifying a transfer between two acute care facilities. Thus, we derive a variable using admission and discharge dates as a surrogate for “discharge disposition” to identify hospital admissions involving transfers. This allows us to identify these admissions using variables in the claims data which have greater reliability than the “discharge disposition” variable. In addition, CMS has in place several hospital auditing programs used to assess overall claims code accuracy, to ensure appropriate billing, and for overpayment recoupment. CMS routinely conducts data analysis to identify potential problem areas and detect fraud, and audits important data fields used in our measures, including diagnosis and procedure codes and other elements that are consequential to payment.

In addition, as an example of some of the methods that could be used to ensure data quality, we describe the NCDR’s existing Data Quality Program (DQP). The two main component of the DQP are complementary and consist of the Data Quality Report (DQR) and the Data Audit Program (DAP). The DQR process assesses the completeness and validity of the electronic data submitted by participating hospitals. Hospitals must achieve >95% completeness of specific data elements identified as ‘core fields’ to be included in the registry’s data warehouse for analysis. The ‘core fields’ include the variables included in 25 our risk adjustment models. The process is iterative, providing hospitals with the opportunity to correct errors and resubmit data for review and acceptance into the data warehouse. The DAP consists of annual on-site chart review and data abstraction. Among participating hospitals that pass the DQ random charts of 10% of submitted cases. The CathPCI Registry audit focuses on variables used for the existing PCI mortality models.

Finally, we assess the reliability of the data elements by comparing model variable frequencies and odds ratios in two years of data.

Accountable Entity-Level Reliability

The reliability of a measurement is the degree to which repeated measurements of the same entity agree with each other. For measures of hospital performance, the measured entity is naturally the hospital, and reliability is the extent to which repeated measurements of the same hospital give similar results. In line with this thinking, our approach to asses reliability is to consider the extent

to which assessments of a hospital using different, but randomly selected subsets of patients, produce similar measures of hospital performance. That is, we take a "test-retest" approach in which hospital performance is measured once using a random subset of patients, then measured again using a second random subset exclusive of the first, and finally comparing the agreement between the two resulting performance measures across hospitals (Rousson et al., 2002).

For test-retest reliability, we combined index admissions from successive measurement periods into one dataset (2010 and 2011), randomly sampled half of patients within each hospital, calculated the measure for each hospital, and repeated the calculation using the second half. Thus, each hospital is measured twice, but each measurement is made using an entirely distinct set of patients. To the extent that the calculated measures of these two subsets agree, we have evidence that the measure is assessing an attribute of the hospital, not of the patients. As a metric of agreement we calculated the intra-class correlation coefficient (ICC) (Shrout and Fleiss, 1979), and assessed the values according to conventional standards (Landis and Koch, 1977). Specifically, we used the two data samples and calculated the risk-standardized readmission rate (RSRR) for each hospital for each sample. The agreement of the two RSRRs was quantified for hospitals in each sample using the intra-class correlation (ICC) as defined by Shrout and Fleiss (1979).

Using two independent samples provides an honest estimate of the measure's reliability, compared with using two random, but potentially overlapping samples, which would exaggerate the agreement. Moreover, because our final measure is derived using hierarchical logistic regression, and a known property of hierarchical logistic regression models is that small volume hospitals contribute less 'signal'. As such a split sample using a single measurement period likely introduces extra noise; potentially underestimating the actual test-retest reliability that would be achieved if the measures were reported using additional years of data. Furthermore, the measure is specified for the entire PCI population, but we tested it only in the subset of Medicare FFS patients for whom information about vital status was available. This reduced the cohort available for testing by approximately 40%.

References:

- 1) Rousson V, Gasser T, Seifert B. Assessing intrarater, interrater and test-retest reliability of continuous measurements. *Statistics in Medicine* 2002;21:3431-3446.
- 2) Shrout P, Fleiss J. Intraclass correlations: uses in assessing rater reliability. *Psychological Bulletin* 1979;86:420-428.
- 3) Landis J, Koch G, The measurement of observer agreement for categorical data. *Biometrics* 1977;33:159-174

5.2.3 Reliability Testing Results

Patient or Encounter-Level Reliability

Overall, risk factor frequencies changed little across years, and there were no notable differences in the odds ratios across years of data (Table 1 in attachment).

Accountable Entity-Level Reliability

In the most recent years of data (2010-2011), there were 277,512 admissions in the combined two-year sample, with 138,756 admissions to 1,190 hospitals in the first randomly selected sample (mean RSRR 12.5%), and 138,756 admissions to 1,193 hospitals in the second randomly-selected sample (mean RSRR 12.1%). The agreement between the two RSRRs for each hospital was 0.3711, which according to the conventional interpretation is “fair” (Landis & Koch, 1977). The intra-class correlation coefficient is based on a split sample of 2 years of data, resulting in a volume of patients in each sample equivalent to only 1 year of data, whereas the measure is likely to be reported with a full two years of data.

The stability over time of the risk factor frequencies and odds ratios indicate that the underlying data elements are reliable. Additionally, the ICC score demonstrates fair agreement across samples using a “strict” approach to assessment that would likely improve with greater sample size.

Reference.

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

5.2.4 Interpretation of Reliability Results

The reliability testing demonstrated that the measure data elements are repeatable, and capable of producing the same results a high proportion of the time when assessed in the same population in the same time period.

5.3.1 Level(s) of Validity Testing Conducted

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

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

5.3.3 Method(s) of Validity Testing

The specifications for this measure have not changed since the prior review.

Measure validity is demonstrated through prior validity testing done on our other measures, through use of established measure development guidelines, by systematic assessment of measure face validity by a technical expert panel (TEP) of national experts and stakeholder organizations, and through registry data validation.

Validity of Registry Data

Data element validity testing was done on the specified measure by comparing with variables in the ACC audit program. The NCDR CathPCI Registry has an established DQP that serves to assess and improve the quality of the data submitted to the registry. There are two complementary components to the Data Quality Program- the Data Quality Report (DQR) and the Data Audit Program (DAP). The DQR process assesses the completeness of the electronic data submitted by participating hospitals. Hospitals must achieve >95% completeness of specific data elements identified as “core fields” to be included in the registry’s data warehouse for analysis. The “core fields” encompass the variables included in our risk adjustment models. The process is iterative, providing hospitals with the opportunity to correct errors and resubmit data for review and acceptance into the data warehouse. All data for this analysis passed the DQR completeness thresholds.

The DAP consists of annual on-site chart review and data abstraction. Among participating hospitals that pass the DQR for a minimum of two quarters, at least 5% are randomly selected to participate in the DAP. At individual sites, auditors review charts of 10% of submitted cases. The audits focus on variables that are used in the NCDR risk-adjusted in-hospital mortality model including demographics, comorbidities, cardiac status, coronary anatomy, and PCI status. However, the scope of the audit could be expanded to include additional fields. The DAP includes an appeals process for hospitals to dispute the audit findings. The NCDR DAP was accepted by the National Quality Forum as part of its endorsement of the CathPCI Registry’s in-hospital risk-adjusted mortality measure.

Additionally, we compared the model performance in the development sample with its performance in a similarly derived sample from patients discharged in 2006 who had undergone PCI. There were 117,375 cases discharged from the 618 hospitals in the 2006 validation dataset. This validation sample had a crude readmission rate of 10.7%. The performance was not substantively different in this validation sample (ROC=0.663), as compared to the development sample (ROC=0.665). The results show the 2006 and 2007 models are similarly calibrated (see

table 2 in the attachment).

We also examined the temporal variation of the standardized estimates and frequencies of the variables in the development and validation models.

To assess the predictive ability of the model, we grouped patients into deciles of predicted 30-day readmission and compared predicted readmission with observed readmission for each decile in the derivation cohort.

To evaluate model performance after the re-specification to Version 4 variables, we compared the odds ratios (OR) and c-statistics in 2008 Version 3 data and 2010 Version 4 data.

Validity as Assessed by External Groups

During original measure development and in alignment with the CMS Measures Management System (MMS), we released a public call for nominations and convened a TEP when originally developing the measure. The purpose of convening the TEP was to provide input and feedback during measure development from a group of recognized experts in relevant fields. The TEP represented physician, consumer, hospital, and purchaser perspectives, chosen to represent a diverse of perspectives and backgrounds.

5.3.4 Validity Testing Results

The performance of the development and validation samples is similar. The areas under the receiver operating characteristic (ROC) curve are 0.665 and 0.663, respectively, for the two samples. In addition, they are similar with respect to predictive ability. For the development sample, the predicted readmission rate ranges from 4% in the lowest predicted decile to 25% in the highest predicted decile, a range of 21%. For the validation sample, the corresponding range is 4% to 24%, a range of 20%.

Additionally, the frequencies and regression coefficients are fairly consistent over the two years of data. Also, there was excellent correlation between predicted and observed readmission.

We estimated hospital-level RSRRs using the corresponding hierarchical logistic regression

samples for the linked patient sample with cases performed in 2010-2011. We then examined the linear relationship between the two sets of estimates using regression techniques and weighting by the total number of cases in each hospital. The correlation coefficient of the standardized rates from the administrative and medical record models is 0.999.

The c-statistic for the 2010, Version 4 model was 0.680. This is a negligible change from the 2008, Version 3 model, which had a c-statistic of 0.676. Odds ratios in both data years are comparable, further indicating that model performance was not significantly altered by re-specification to Version 4 variables. The current model can use the Version 4 registry data.

5.3.5 Interpretation of Validity Results

The audits conducted by the ACC support the overall validity of the data elements included in this measure. The data elements used for risk adjustment were consistently found for all patients and were accurately extracted from the medical record.

Additionally, the results between the development and validation samples proved to be similar in each of the model testing that was performed. The ROC results were nearly identical. The correlation between the resulting RSRRs calculated from both models was 0.999 which demonstrates observed readmission is similar to predicted readmission.

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

Empirical validity testing at the accountable entity-level (e.g., criterion validity, construct validity, known groups analysis)

5.4.1 Methods Used to Address Risk Factors

Statistical risk adjustment model with risk factors

5.4.2 Conceptual Model Rationale

We sought to develop a model that included key variables that were clinically relevant and based on strong association with 30-day readmission.

To create a model with increased usability while retaining excellent model performance, we tested the performance of the model without those variables considered to be questionably feasible. To select candidate variables, a team of clinicians reviewed all variables in the NCDR CathPCI Registry database (a copy of the data collection form and the complete list of variables collected and submitted by hospitals can be found at www.ncdr.com). We did not consider as candidate variables those that we would not want to adjust for in a quality measure, such as potential complications, certain patient demographics (e.g., race, socioeconomic status), and patients' admission path (e.g., admitted from a skilled nursing facility [SNF]).

Based on careful clinical review and further informed by a review of the literature, a total of 29 variables were determined to be appropriate for consideration as candidate variables (Table 3 in attachment).

For categorical variables with missing values, the value from the reference group was added. The percentage of missing values for all categorical variables was very small (<1%). There were three continuous variables with missing values: body mass index (BMI, 0.1%), glomerular filtration rate (GFR, 3.7%), and left ventricular ejection fraction (LVEF, 28.5%); we considered the missing of GFR and LVEF as an independent category of “unmeasured” and for BMI; we stratified by gender and imputed the missing values to the median of the corresponding groups.

We used logistic regression with stepwise selection (entry $p < 0.05$; retention with $p < 0.01$) for variable selection. We also assessed the direction and magnitude of the regression coefficients. This resulted in a final risk-adjusted readmission model that included 20 variables (table 4 in attachment). There were variables for demographics (age and gender), history and risk factors, cardiac status (heart failure, symptoms present on admission), cath lab visits (ejection fraction percentage), and PCI procedure (PCI status, highest risk lesion, highest pre-procedure TIMI flow).

5.4.3 Variable Distribution Across Measured Entities

Information on the descriptive statistics on the distribution across the measured entities of the risk variables identified was not previously required and as a result, we do not have these data to share.

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

Please see table 5 in the attachment.

5.4.5 Calibration and Discrimination

Approach to assessing model performance

During measure development, we computed three summary statistics for assessing model performance (Harrell and Shih, 2001) for the development and validation cohort:

Discrimination Statistics:

(1) Area under the receiver operating characteristic (ROC) curve (the c statistic (also called ROC) is the probability that predicting the outcome is better than chance, which is a measure of how accurately a statistical model is able to distinguish between a patient with and without an outcome.)

(2) Predictive ability (discrimination in predictive ability measures the ability to distinguish high-risk subjects from low-risk subjects. Therefore, we would hope to see a wide range between the lowest decile and highest decile)

Calibration Statistics:

(3) Over-fitting indices (over-fitting refers to the phenomenon in which a model accurately describes the relationship between predictive variables and outcome in the development dataset but fails to provide valid predictions in new patients)

We compared the model performance in the development sample with its performance in a similarly derived sample from patients discharged in 2006 who had undergone PCI. There were 117,375 cases discharged from the 618 hospitals in the 2006 validation dataset. This validation sample had a crude readmission rate of 10.7%. We also computed statistics (1) and (2) for the current measure cohort, which includes discharges from 2010-2011.

For the development cohort the results are summarized below:

C-statistic=0.665

Predictive ability (lowest decile %, highest decile %): 4.05%, 25.08%

For the validation cohort the results are summarized below:

C statistic=0.663

Predictive ability (lowest decile %, highest decile %): 3.80%, 23.80%

For the current measure cohort (combined data from 2010 and 2011) the results are summarized below:

C statistic=0.668

Predictive ability (lowest decile %, highest decile %): 4.2%, 26.1%

For the development cohort the results are summarized below:

Calibration: (0.00,1.00)

For the validation cohort the results are summarized below:

Calibration: (-0.06, 0.99)

For the current measure cohort the results are summarized below:

Calibration: (-0.004, 1.008)

The risk decile plot is a graphical depiction of the deciles calculated to measure predictive ability. Below, we present the risk decile plot showing the distributions for the current measure cohort. See figure 2 in the attachment.

Discrimination Statistics

The C-statistics of 0.665, 0.663 and 0.668 indicate good model discrimination. Readmission, as opposed to other outcomes such as mortality consistently has a lower c-statistic, even in medical record models. This is likely because readmission is less determined by patient comorbidities and more by health system factors. The model indicated a wide range between the lowest decile and highest decile, indicating the ability to distinguish high-risk patients from low-risk patients.

Calibration Statistics

Over-fitting (Calibration γ_0 , γ_1)

If the γ_0 in the validation samples are substantially far from zero and the γ_1 is substantially far from 1, there is potential evidence of over-fitting. The calibration value close to 0 at one end and close to 1 on the other end indicates good calibration of the model.

Risk Decile Plots

Higher deciles of the predicted outcomes are associated with higher observed outcomes, which show a good calibration of the model. This plot indicates excellent discrimination of the model and good predictive ability.

Overall Interpretation

Interpreted together, our diagnostic results demonstrate the risk-adjustment model adequately controls for differences in patient characteristics (case mix).

5.4.6 Interpretation of Risk/Case-mix Factor Findings

See fields above.

5.4.7 Final Approach to Address Risk Factors

Statistical risk adjustment model with risk factors

6.1.3b Rationale for Not In Use

Efforts have been unsuccessful to gain access to CMS claims data. Should these become available to the ACC we will provide a detailed plan of implementation.

6.1.3 Current Use(s)

Not in use

6.1.3 Program Details

Name of the program and sponsor

N/A

URL of the program

<https://doesnotexist.org>

Purpose of the program

N/A

Geographic area and percentage of accountable entities and patients included

N/A

Applicable level of analysis and care setting

N/A

6.2.1 Actions of Measured Entities to Improve Performance

In general, registry participants receive feedback through quarterly benchmark reports. These reports contain detailed analyses of the institution's performance. In these reports, institutional performance is compared to national aggregates. A thorough understanding of performance can be gleaned from the executive summary dashboard which contains visual displays of metric performance as well as patient level drill downs. Sites have the capability to export their information into their own excel spreadsheets to conduct their own analysis. Supporting documentation in the form of the coder's dictionary and outcome reports guide includes additional support for the sites. Monthly Registry Site Manager (RSM) Calls, sessions at the NCDR annual conference and access to Clinical Quality Associates are other ways that sites can get updates on data interpretation.

6.2.2 Feedback on Measure Performance

Because ACC is unable to currently report on the measure, we have not received any new feedback on measure performance and implementation.

Once implemented, feedback will be collected during monthly RSM 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.

6.2.3 Consideration of Measure Feedback

Because ACC is unable to currently report on the measure, we have not received any new feedback on measure performance and implementation.

6.2.4 Progress on Improvement

Because ACC is unable to currently report on the measure, we have not received any new feedback on measure performance and implementation.

6.2.5 Unexpected Findings

In the first year of measure implementation, we did not find evidence of unintended negative consequences to individuals or populations.

Ensuring data quality is critical so that the RSRRs can provide fair and accurate estimates of outcomes across hospitals. However, all data sources are potentially prone to misclassifications. Accordingly, adequate mechanisms need to be implemented to ensure data quality (such as monitoring data for variances in case mix), chart audits, and possibly adjudicating cases that are vulnerable to systematic misclassification). The NCDR CathPCI registry has successfully implemented methods to ensure the quality of data used for the risk adjustment methodology.

Studies suggest that public reporting of the outcomes of cardiovascular procedures may have unintended consequences. Moscucci and colleagues compared the characteristics and outcomes of patients undergoing PCI in states with (New York) and without (Michigan) public reporting and found that patients undergoing PCI in New York were substantially lower risk than PCI patients in Michigan. Determining the underlying causes and appropriateness of these differences is impossible, but there is concern that physicians in states that publicly report PCI outcomes would either refer high risk cases to states without public reporting or avoid such cases altogether. Implementing a national measure of PCI outcomes would avoid the former problem in that public reporting would be consistent across states. Nevertheless, the measure requires close attention to the possibility that high risk patients are not receiving PCI when clinically indicated.

Continued measure implementation will require close attention to data quality. Potential solutions include continued chart audits and attention to variances in case mix.

Reference

Moscucci M, Eagle KA, Share D, et al. Public Reporting and Case Selection for Percutaneous Coronary Interventions An Analysis From Two Large Multicenter Percutaneous Coronary Intervention Databases. Journal of the American College of Cardiology. 2005;45(11):1759-1765.

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Measure Developer POC

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Measured/accountable entity (reliability and/or validity) methodology and results (if available)

Measured entity (reliability and validity) methodology and results (if available)

Responder for Survey

Patient

Specify number of risk factors

20

The measure developer is different from the measure steward

No

Steward Address

United States