NATIONAL QUALITY FORUM

National Voluntary Consensus Standards for Patient Outcomes
Measure Summary

Measure number: OT1-008-09

Measure name: Hospital 30-day risk-standardized readmission rates following percutaneous coronary intervention (PCI)

Description: This measure estimates hospital risk-standardized 30-day readmission rates following PCI in Medicare fee-for-service (FFS) patients at least 65 years of age. As PCI patients may be readmitted electively for staged revascularization procedures, we will exclude such elective readmissions from the measure. The measure uses clinical data available in the National Cardiovascular Disease Registry (NCDR) CathPCI Registry for risk adjustment that has been linked with the CMS administrative claims data used to identify readmissions.

Numerator statement: 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 are using this field to define readmissions. The outcome for this measure is 30-day all-cause readmission. We define a readmission as a subsequent hospital inpatient admission within 30 days of either the discharge date of an admission with PCI (for admitted patients) or the outpatient PCI claim end date (for patients whose PCI was performed as an outpatient service).

Denominator statement: The target population for this measure includes inpatient or outpatient PCI procedures for Medicare FFS beneficiaries at least 65 years of age at the time of the procedure who have matching information in the National Cardiovascular Disease Registry (NCDR) CathPCI Registry.

The patient cohort is defined by International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) procedure codes for both inpatient and outpatient claims and Current Procedural Terminology (CPT) procedure codes for outpatient claims.

Level of Analysis: Population: national, Facility/Agency

Type of Measure: Outcome

Data Source: Electronic administrative data/claims, registry data

Measure developer: CMS / Yale New Haven Health Services Corporation Center for Outcomes Research & Evaluation (YNHHSC/CORE)

Type of Endorsement (full or time-limited): Recommended for endorsement (Steering Committee vote —May 17, 2010 [Recommend—12, Do not recommend—4, Abstain—1])

Summary Table of TAP Ratings of Subcriteria and Comments:

IMPORTANCE TO MEASURE AND REPORT		
1a. Impact	Completely	1a—High impact -commonly performed procedure; significant
1b. Gap	Completely	

1c. Relation to outcomes	Completely	readmission rate—15 percent. 1b—Opportunity for improvement—significant variation among hospitals. 1c—Important outcome measure—strategies exist to reduce readmissions.
SCIENTIFIC ACCEPTABILTY		
2a. Specs	Completely	2a—Specifications are precise; probabilistic matching questioned —specific matching better; is "staging" well defined? —yes for ACC registry—but for others? 2b—Reproducibility of the outliers has not been demonstrated; concerns about auditing of data quality—would like more information on NCDR auditing report; need for more transparency in auditing; concern subject to "gaming, "i.e., TAP members are aware of on-going "upcoding;" no demonstration
2b. Reliability	Partially	
2c. Validity	Partially	
2d. Exclusions	Partially	
2e. Risk adjustment	Partially	
2f. Meaningful differences	Completely	
2g. Comparability	Not applicable	

2h. Disparities	Not applicable	that admission coding captures the true reason for admission. 2c—Concerns about including "all causes" for readmission—as much as 10 percent for reasons not attributable to procedure though some TAP members noted that certain readmission such as pneumonia may be related to aspiration, etc.; concern about time window—7 or 15 days might be more appropriate to capture readmissions related to the PCI procedure; concerns about categorization and attribution. 2d—Exclusions generally appropriate. 2e—Risk adjustment does not include factors such as social support or resource challenges—other TAP members noted that readmissions for heart failure are the same for critical access hospital; CMS advised that it cannot establish different standards or expectations based on social factors as a matter of public policy; C statistic of 0.66 is good but not very good/excellent. 2f—Discrimination curve on p. 44 of technical appendix using 2007 data; CMS has not determined how it would portray results for public reporting. 2g—Only 40 percent PCIs are entered into ACC's NCDR registry—no details on comparability with data obtained through other vendors. Several additional questions to the measure developer: Has there been any assessment of differences in readmission to the same hospital or to another hospital? Any evaluation of different admitting policies of EDs? TAP members note there can be an "ownership" issue between ED and proceduralist on determining readmission. TAP members note that 40-50 percent of PCIs are not associated with an—what is the difference/impact? Are the PCIs asociated with AMI captured in the previously endorsed measures for AMI readmission? DEVELOPER comments: readmission plateau at 30-45 days; baseline Medicare readmission rate is 17 percent—consistent with the other readmission measures significant strength—based on clinical data.
USEABILITY		
3a. Distinctive	Completely	3a—Developer used a multistakeholder TEP; consumer testing planned.
3b. Harmonization	Completely	

3c. Added value	Completely	3b—Harmonization—aligned with previously endorsed PCI measures for mortality. 3c—Readmission is an important non-mortality outcome; some concern with potential increased length of stay for the index procedure.
FEASIBILITY		
4a. Data a byproduct of care	Completely	4a—Data requires abstraction to submit to registry. 4c—Appropriate exclusions. 4d—Concerns about adequacy of auditing of registry data; possible increased length of stay; "gaming" a concern. 4e—Data collection anticipated through usual CMS vendors as with PCI mortality measure.
4b. Electronic	Partially	
4c. Exclusions	Completely	
4d. Inaccuracies/errors	Partially	
4e. Implementation	Completely	

Measure Developer Responses: N/A

Summary Table of SC Ratings of Subcriteria and Comments:

IMPORTANCE TO MEASURE AND REPORT	
This measure is meant to be used with the endorsed PCI mortality measure for joint accountability. The measure developers advised the Committee that 29 percent of patients undergoing PCI have also had an AMI and would be captured in both readmission measures.	SC Vote on Importance Yes—17 No— 0
SCIENTIFIC ACCEPTABILITY	
Requires clinical data from the NCDR PCI registry and administrative Medicare data. The Committee discussed "all cause" readmissions, which aligns with previously endorsed readmission measures. Some Committee members suggested that a 15 day timeframe would be more directly related to the antecedent PCI procedure. The measure developer presented their hazard of readmission analysis over 90 days that found that risk of readmission was greatest in the first 15 days but remained elevated up to 60 days	SC Vote on Scientific Acceptability Completely—10 Partially—7 Minimally—0 Not at all—0

following discharge (with a plateau between 30-45 days). The developer asserted that a shorter timeframe would have a stronger association with the initial care of the patients, but would miss the substantial number of readmissions between 15-30 days that are likely attributable to the care delivered within the index hospitalization and during the transition from that setting. There is a strong auditing quality of the data elements. The developers presented an analysis of safety net hospitals—there was little difference compared to mainstream hospitals.	
USABILITY	
NQF has already endorsed a few measures that use a similar approach and methodology. Committee members urged the developers to broaden the target population for the measure—particularly the under 65 years population. The developer replied that the measure could apply to all patients undergoing PCI if the required data was available. (During development they only had access to Medicare FFS data.) Adjustment to the risk model covariates would be needed with a different population.	SC Vote on Usability Completely—11 Partially—6 Minimally—0 Not at all—0
FEASIBILITY	
The measure requires merging data from the PCI Registry and administrative data.	SC Vote on Feasibility Completely—12 Partially—5 Minimally—0 Not at all—0

Summary Table of Biostatistical Review:

Type of Risk Model : *Hierarchical logistic regression.*

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RISK FACTORS
Are the risk factors clearly identified in the submission information? *YES*

Does the model include risk factors associated with differences/inequalities with care such as race, socioeconomic status or gender? *NO*

Are the conceptual and quantitative criteria for inclusion or exclusion or combining of risk factors explained and appropriate? *YES*

Is quantitative assessment of the relative contribution of the model components described in detail?

Not described in detail, but relevant information is provided.

Does the measure have exclusions that influence outcomes that should be included as risk factors?

No.

Comments on risk factors:

See below.

VALIDATION OF THE RISK MODEL
Is information provided on the cross-validation of the model comparing a development sample and a validation sample? *YES*

Is there information on independent, external validation of the model in another data set?
NO

Are the results supportive of a valid model? *YES*

RISK MODEL PERFORMANCE (2e)

DISCRIMINATION: C-statistic = 0.663

Does the statistic support good discrimination? *C=0.663 indicates limited ability to predict the outcomes of individual patients. Perfect discrimination is not required for measure validity, as models with low discrimination may still succeed at removing case mix bias. A low C statistic should prompt the developers to search for important unmeasured risk factors that could be added to the NCDR data set in future releases.*

CALIBRATION: Is a calibration curve included? *YES*
Is a risk decile plot included? *Can be obtained from calibration curve*
Hosmer-Lemeshow statistic: *Not provided*

Does the data support good model calibration? *Calibration curves suggest excellent calibration in the overall population. It would be useful to assess calibration in subgroups.*

Comments on Risk Model Performance: *See below*

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Reliability testing (2b):
Is the reliability of the key data elements, such as risk factors and the outcome demonstrated?
Not assessed.

Is there information about the reliability of the measure score, such as signal-to-noise ratio?
Not assessed.

Has a sensitivity analysis been performed for problem or missing data? *Not discussed.*

Does the data demonstrate that the risk model is reliable? *Yes*
Comments on reliability testing:
See below.

Validity testing (2c):
Is validity testing of the measure to demonstrate results can be used to make conclusions about quality provided? *Yes*

Are the results supportive of a valid measure? *Yes*
Comments on validity testing:
See below.

Scoring Method Justification (2f):
Is the choice of method for computing risk-adjusted scores and identifying statistically significant differences justified? *Yes*
Comments on scoring methods:

Summary comments: *See below.*

Reviewer: Sean O'Brien, PhD
Assistant Professor, Department of Biostatistics and Bioinformatics
Duke University Medical Center, Duke Clinical Research Institute,
Durham, NC

Attachments: Attachment PCI_Technical Report_11-5-09_Final_to_NQF.pdf, PCI Calculation Algorithm

THE NATIONAL QUALITY FORUM

Measure Evaluation
September 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the evaluation criteria are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

TAP/Workgroup (if utilized)**:** Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: *If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).*

Steering Committee: Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met
C = Completely (unquestionably demonstrated to meet the criterion)
P = Partially (demonstrated to partially meet the criterion)
M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)
N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)
NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) **NQF Review #:** OT1-008-09 **NQF Project:** Patient Outcomes Measures: Phases I and II
MEASURE DESCRIPTIVE INFORMATION
Measure Title: Hospital 30-Day Risk-Standardized Readmission Rates following Percutaneous Coronary Intervention (PCI)
Brief description of measure*:* This measure estimates hospital risk-standardized 30-day readmission rates following PCI in Medicare Fee for Service (FFS) patients at least 65 years of age. As PCI patients may be readmitted electively for staged revascularization procedures, we will exclude such elective readmissions from the measure. The measure uses clinical data available in the National Cardiovascular Disease Registry (NCDR) CathPCI Registry for risk adjustment that has been linked with the CMS administrative claims data used to identify readmissions.
►**Type of Measure:** outcome ►**If included in a composite or paired with another measure, please identify composite or paired measure** This measure is not included in a composite or paired with another measure. However, the measure complements existing measures for 30-day readmission following admissions for AMI or HF in that it will help provide a more complete picture of the outcomes achieved by hospitals across cardiovascular services. Additionally, the measure adds to the existing pair of PCI mortality models recently endorsed by the National Quality Forum (NQF) in that it is suitable for public reporting and will promote greater investment in quality improvement efforts related to the care of PCI patients.
►**National Priority Partners Priority Area:** care coordination ►**IOM Quality Domain**: efficiency, safety, patient-centered ►**Consumer Care Need:** Getting Better, Living With Illness, Staying Healthy

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	**NQF Staff**
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a*	**A** **Y☒**

measure steward agreement even if measures are made publicly and freely available. ►**Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes ►**Measure Steward Agreement:** government entity- public domain- No Agreement ►**Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:**	**N**☐
B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	**B** **Y**☒ **N**☐
C. The intended use of the measure includes both public reporting and quality improvement. ►**Purpose:** public reporting, quality improvement 0,0,0,	**C** **Y**☒ **N**☐
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 24 months of endorsement. ►**Testing:** Yes, fully developed and tested ►**Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?** Yes ►**Is all requested information entered into this form?**	**D** **Y**☒ **N**☒
(for NQF staff use**) Have all conditions for consideration been met?** **Staff Notes to Steward** (*if submission returned*)**:**	**Met** **Y**☒ **N**☐
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:** Clarification - testing of the measure is completed, but testing of consumer comprehension for public reporting purposes is not yet completed	
Staff Reviewer Name(s): Ashley Morsell, Karen Pace	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. *Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.* (evaluation criteria) **1a. High Impact**	**Eval Rating**
(for NQF staff use) **Specific NPP goal**: Care Coordination: All healthcare organizations and their staff will work collaboratively with patients to reduce 30-day readmission rates.	
► **Demonstrated High Impact Aspect of Healthcare:** patient/societal consequences of poor quality, frequently performed procedure, high resource use ►**Summary of Evidence of High Impact:** PCI is one of the most commonly performed cardiac procedures in the United States. In 2005, an estimated 1,265,000 PCI procedures were performed in the United States (Rosamond, Flegal et al. 2008). From 1987–2003, the number of procedures increased 326% (Thom, Haase et al. 2006). Readmission within 30 days of PCI is often an unplanned, adverse event. Investigators have reported that approximately one in seven Medicare patients who undergo PCI are readmitted within 30 days of hospital discharge, and that readmission rates vary substantially across hospitals (Curtis, Schreiner et al. 2009). Analyses we conducted using 2007 Medicare FFS claims data to assess readmission rates following PCI found high readmission rates and significant variation across hospitals, which suggests that many hospitals could improve readmission rates. About two-thirds of readmissions are directly cardiac related. The most common principal discharge diagnostic code was chronic ischemic heart disease (ICD-9 414.x, 25.4%). However, a	**1a** **C**☒ **P**☐ **M**☐ **N**☐

small portion of readmissions are for acute cardiovascular conditions such as acute myocardial infarction (5.4%), unstable angina (7.4%), arrhythmia (4.3%), or heart failure (9.7%). These findings suggest that the majority of readmissions are for non-acute and thus potentially preventable reasons.
The Medicare Payment Advisory Committee (MedPAC) has called for hospital-specific public reporting of readmission rates and reports that Percutaneous Transluminal Coronary Angioplasty (PTCA) is one of the seven conditions that make up almost 30% of spending on readmissions. (The term "PCI" captures all coronary interventions, including PTCA, stents, and atherectomy; the populations covered by this measure and MedPAC's analysis are similar.) MedPAC has also reported that the rate of preventable admissions within 15 days of discharge following PTCA is 10% (44,293 in 2005 at a cost of $360 million) and has suggested consideration of a PTCA readmission measure (MedPAC 2006).

►**Citations for Evidence of High Impact:** Medicare Payment Advisory Committee (MedPAC) Report to the Congress: Promoting Greater Efficiency in Medicare. Available at http://www.medpac.gov/documents/Jun07_EntireReport.pdf, accessed October 29, 2008.
Rosamond W, Flegal K, Furie K, Go A, Greenlund K, Haase N, Hailpern SM, Ho M, Howard V, Kissela B, Kittner S, Lloyd-Jones D, McDermott M, Meigs J, Moy C, Nichol G, O'Donnell C, Roger V, Sorlie P, Steinberger J, Thom T, Wilson M, Hong Y. Heart Disease and Stroke Statistics_2008 Update: A Report From the American Heart Association Statistics Committee and Stroke Statistics Subcommittee and for the American Heart Association Statistics Committee and Stroke Statistics Subcommittee Circulation 2008;117;e25-e146; originally published online Dec 17, 2007; DOI: 10.1161/CIRCULATIONAHA.107.187998.
Thom, T., N. Haase, et al. (2006). "Heart disease and stroke statistics--2006 update: a report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee." Circulation 113(6): e85-151.
J.P. Curtis, G. Schreiner and Y. Wang et al., All-cause readmission and repeat revascularization after percutaneous coronary intervention in a cohort of Medicare patients, J Am Coll Cardiol 54 (2009), pp. 903–907.

1b. Opportunity for Improvement

►**Summary of data demonstrating performance gap (variation or overall poor performance) across providers:**
The PCI Readmission rate is high and varies significantly across hospitals. We conducted preliminary analyses of Medicare FFS claims data to assess readmission rates following PCI. In 2007, a total of 248,821 Medicare patient admissions at 1,566 hospitals in which a PCI was performed were analyzed.
The all-cause readmission rate following PCI is 15.1%. Although this rate is somewhat lower than that of acute medical conditions such as acute myocardial infarction (AMI, 18.9%), pneumonia (17.4%), and heart failure (23.6%), it may be more actionable because patients who undergo PCI are, overall, a healthier population than patients admitted with acute medical conditions (Ko, 2008). Accordingly, the proportion of potentially preventable readmissions may actually be higher for PCI patients than patients with acute medical conditions.
Finally, readmission rates vary substantially across hospitals. The median unadjusted readmission rates varied substantially across hospitals grouped by their all-cause readmission rate, from 0.0% at the lowest decile to 28.1% at the highest decile. These findings suggest that the majority of readmissions are for non-acute and potentially preventable reasons.

►**Citations for data on performance gap:**
Ko DT, Wang Y, Alter DA, Curtis JP, Rathore SS, Stukel TA, Masoudi FA, Ross JS, Foody JM, Krumholz HM. Regional Variation in Cardiac Catheterization Appropriateness and Baseline Risk After Acute Myocardial Infarction. J Am Coll Cardiol, 2008; 51:716-723.

►**Summary of Data on disparities by population group:**
We have not examined health disparities associated with this measure. This measure could be used to assess differences in performance among hospitals that care for different types of populations (e.g. those that serve primarily minority populations versus others).

►**Citations for data on Disparities:**
N/A

1b
C☒
P☐
M☐
N☐

1c. Outcome or Evidence to Support Measure Focus | **1c**

C☒
P☐
M☐
N☐

► **Relationship to Outcomes** (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** This measure will describe hospital-level readmission rates following PCI with the overriding goal to reduce preventable readmissions to best-in-class (NPP 3.3) and reduce readmissions following hospitalization for relevant conditions to best-in-class (NPP 3.4).
Additionally, the model is designed specifically for national public reporting. Once implemented, the measure can be used by hospitals to benchmark their performance and may motivate hospitals to enhance existing quality improvement efforts with the goal to reduce overall readmission rates. A reduction in readmissions translates into improved care for PCI patients.

Type of Evidence: expert opinion, systematic synthesis of research

►**Summary of Evidence** (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
A large body of evidence has demonstrated that differences in both PCI technique and subsequent hospital care can affect 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, Rogers et al. 2006). Research has 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, Wennberg et al. 1994). In addition, specific hospital processes such as discharge planning, medication reconciliation, and coordination of outpatient care have been shown to affect readmission rates (Nelson, Maruish et al. 2000).

►**Rating of strength/quality of evidence (***also provide narrative description of the rating and by whom***):**
N/A

►**Method for rating evidence:** N/A

►**Summary of Controversy/Contradictory Evidence:** (1) We used all-cause readmission (excepted for staged procedures) as opposed to cardiac specific readmission for several reasons. First, from the patient perspective, readmission for any reason is likely to be an undesirable outcome of care. Second, readmissions not associated with a cardiac diagnosis may in fact still be directly related to the care delivered during the index hospitalization. Examples include patients readmitted with acute renal failure, due to a nephropathy from the contrast medium used in the procedure, or patients readmitted with a pseudoaneurysm or other late vascular complication from the procedure. The range of potentially avoidable readmissions however, also includes those not directly related to the PCI but potentially related to the transition of care. Examples include errors in medication reconciliation, inadequate follow-up, and failure to ensure that patients discharged home have adequate support. The consequences of these events do not fit neatly into an existing methodology for categorizing readmissions, and as such, creating a comprehensive list of potential 'PCI-related' complications would be arbitrary. Using all-cause readmission, on the other hand, will undoubtedly include a mix of unavoidable and avoidable readmissions as not all readmissions are preventable. There is no reliable way to identify preventable readmissions. Thus, the goal is not to reduce readmissions to zero, rather, an all cause measure will assess hospital performance relative to what is expected given the performance of other hospitals with similar case mixes
(2) Readmissions that are staged are not considered a readmission in this measure. Current clinical guidelines for PCI do not endorse a specific approach to choosing when to stage procedures versus performing multivessel PCI. Expert cardiologists expressed concern that inclusion of staged procedures could undermine the measure. We developed an approach to identifying and excluding staged procedures. A staged procedure was defined as a readmission with a revascularization in patients without an acute cardiac diagnosis code. This approach is consistent with CMS' publicly reported and NQF-approved AMI readmission measure. Specifically, we discussed not counting as readmissions those admissions after discharge that include PCI or CABG procedures unless the principal discharge diagnosis for the readmission is one of the

following diagnoses: myocardial infarction, heart failure (HF), unstable angina, arrhythmia, and cardiac arrest.
Of note: the NCDR began systematically collecting information in 2009 regarding PCI indication, with one of the options being staged procedures for Version 4 of the CathPCI Registry. As a result of this new information, this approach to defining staged procedures can potentially be refined once these data are available.
(3) This measure was developed for Medicare fee-for-service patients because readmission information that covers readmissions to all hospitals is currently only available for this population. As such, the patient population being measured is patients 65 years of age or older. However, this measure could be implemented in a broader population when additional data become available or when patient health records are standardized nationally, e.g., electronic health records.

►**Citations for Evidence (***other than guidelines***):** 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.
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.
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.
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.
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.

►**Quote the Specific guideline recommendation (***including guideline number and/or page number***):**
N/A

►**Clinical Practice Guideline Citation:** N/A
National Guideline Clearinghouse or other URL: N/A

►**Rating of strength of recommendation (***also provide narrative description of the rating and by whom***):**
N/A

►**Method for rating strength of recommendation** (*If different from USPSTF system, also describe rating and how it relates to USPSTF)***:**
N/A

►**Rationale for using this guideline over others:**
N/A

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to Measure and Report?* Importance: 1a - high impact -commonly performed procedure; significant readmission rate - 15% 1b. Opportunity for improvement -- significant variation among hospitals; 1c. Important outcome measure - strategies exist to reduce readmissions;

1

Steering Committee: Was the threshold criterion, *Importance to Measure and Report***, met?**
Rationale:

- This measure is meant to be used with the endorsed PCI mortality measure for joint accountability.
- The measure developers advised the Committee that 29% of patients undergoing PCI have also had an AMI and would be captured in both readmission measures.

1
Y☒
N☐

2. 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. (evaluation criteria)	**Eval Rating**
2a. MEASURE SPECIFICATIONS	
►Do you have a web page where current detailed measure specifications can be obtained? **►If yes, provide web page URL:** **2a. Precisely Specified**	
Numerator Statement (*Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):** 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 are using this field to define readmissions. The outcome for this measure is 30-day all-cause readmission. We define a readmission as a subsequent hospital inpatient admission within 30 days of either the discharge date of an admission with PCI (for admitted patients) or the outpatient PCI claim end date (for patients whose PCI was performed as an outpatient service). **Numerator Time Window (***The time period in which cases are eligible for inclusion in the numerator***):** 30 days from discharge or outpatient claim end date. **Numerator Details (***All information required to collect/calculate the numerator, including all codes, logic, and definitions***):** In the CathPCI Registry, admissions are identified with field 614 (PCI=Yes). We do not count readmissions associated with a 'staged' revascularization procedure. Staged readmissions are not counted in this measure as readmissions (some patients have planned readmissions for revascularization procedures – for example, to perform PCI on a second vessel or a second location in the same vessel, or to perform coronary artery bypass graft (CABG) surgery after AMI and a period of recovery outside the hospital). Because admissions for PCI and CABG may be staged or scheduled readmissions, we do not count as readmissions those admissions after discharge that include PCI or CABG procedures unless the principal discharge diagnosis for the readmission is one of the following diagnoses (which are not consistent with a scheduled readmission): heart failure (HF), acute myocardial infarction (AMI), unstable angina, arrhythmia, and cardiac arrest (i.e., readmissions with these diagnoses and a PCI or CABG procedure are counted as readmissions.	
Denominator Statement (*Brief, text description of the denominator - target population being measured***):** The target population for this measure includes inpatient or outpatient PCI procedures for Medicare FFS beneficiaries at least 65 years of age at the time of the procedure who have matching information in the National Cardiovascular Disease Registry (NCDR) CathPCI Registry. The patient cohort is defined by International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) procedure codes for both inpatient and outpatient claims and Current Procedural Terminology (CPT) procedure codes for outpatient claims. **Target population gender:** Female, Male **Target population age range:** 65 years of age and older **Denominator Time Window (***The time period in which cases are eligible for inclusion in the denominator***):** This measure is being developed with 12 months of data. The time period for public reporting has not been determined. **Denominator Details (***All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):** ICD-9 and CPT odes used to define the target population are listed below: ICD-9 codes 00.66 Percutaneous transluminal coronary angioplasty or coronary atherectomy 36.01 Single vessel PTCA or coronary atherectomy	**2a-specs** **C☒** **P☐** **M☐** **N☐**

36.02 Percutaneous transluminal coronary angioplasty or coronary atherectomy with mention of thrombolytic agent
36.05 Multiple vessel PTCA or coronary atherectomy
36.06 Insertion of non-drug-eluting coronary artery stent(s)
36.07 Insertion of drug-eluting coronary artery stent (s)
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

Denominator Exclusions (*Brief text description of exclusions from the target population***):** Note: We are using this field to define exclusions to the patient cohort.
(1) PCIs for patients who are not Medicare FFS beneficiaries on admission
Rationale: Patients not enrolled in Medicare FFS at the start of the episode of care are excluded as readmission information is currently available only for FFS patients.
(2) Patient stays that are not the first claim in the same claim bundle
Rationale: Multiple claims from an individual hospital can be bundled together. In order to ensure that the selected PCI is the index PCI, those PCI procedures that were not the first claim in a specific bundle are excluded.
(3) The PCI is not performed within 10 days of admission
Rationale: Patients who have a PCI after many days of hospitalization are rare and represent a distinct population that likely has risk factors for readmission related to the hospitalization that are not well quantified in the registry. It seems clinically sensible to exclude these patients.
(4) The patient is transferred out
Rationale: Patient stays in which the patient received a PCI and was then transferred to another hospital are excluded as the hospital that performed the PCI procedure does not provide discharge care and cannot be fairly held responsible for their outcomes following discharge.
(5) The patient dies during hospitalization
Rationale: Subsequent admissions (readmissions) are not possible.
(6) The patient leaves against medical advice (AMA)
Rationale: Hospitals and physicians do not have the opportunity to provide highest quality care.
(7) The patient lacks a full month of follow-up in the Medicare program
Rationale: Patient stays that cannot be tracked for the full 30-day follow-up period do not provide adequate information to determine readmissions.
(8) A subsequent admission with PCI within 30-days of an index admission
Rationale: A subsequent readmission for PCI within 30 days of the index PCI cannot be considered an index hospital stay; it is a readmission.

Denominator Exclusion Details (*All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**
See above. We are deriving the corresponding codes based on the data for exclusion.

►**Stratification Details/Variables (***All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
This measure is not stratified.

Risk Adjustment Type: risk-adjustment devised specifically for this measure/condition

►**Risk Adjustment Methodology/Variables (***List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**
We developed a risk adjustment model for the measure and calculate hospital 30-day risk-standardized readmission rates (RSRRs) using hierarchical logistic regression. Because of the natural clustering of the observations within hospitals, we estimated hierarchical generalized linear models (HGLMs). These models extend generalized linear models (GLMs) to include random effect on the intercept in the models.
As described in the "Calculation Algorithm", we perform risk adjustment to account for differences in patient severity present before the performance of the PCI using a hierarchical logistic regression model to

calculate RSRRs. The risk adjustment variables are abstracted from the CathPCI Registry data.
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. The final risk adjustment variables include:

Demographic
(1) Age (10 year increments)
(2) Female

History and Risk Factors
(3) Body Mass Index
(4) Heart failure-previous history
(5) Previous valvular surgery
(6) Cerebrovascular Disease
(7) Peripheral Vascular Disease
(8) Chronic Lung Disease
(9) Diabetes
None
Non-Insulin Diabetes
Insulin Diabetes
(10) Glomerular Filtration Rate (GFR)
Not Measured
GFR<30
30=GFR<60
60=GFR<90
GFR=90
(11) Renal Failure – dialysis
(12) Hypertension
(13) History of tobacco use
(14) Previous PCI

Cardiac Status
(15) Heart failure – current status
(16) Symptoms present on admission
No MI
MI within 24 hours
MI after 24 hours

Cath Lab Visit
(17) Ejection Fraction (EF) Percentage
Not Measured
EF<30
30=EF<45
EF=45

PCI Procedure
(18) PCI status
Elective
Urgent
Emergency
Salvage
(19) Highest Risk Lesion – location
pRCA/mLAD/pCIRC
pLAD
Left main
Other
(20) Highest pre-procedure TIMI flow: none

►**Detailed risk model available Web page URL or attachment:** Attachment PCI Calculation Algorithm.pdf

Type of Score: rate/proportion
►**Interpretation of Score:** better quality = lower score
►**Calculation Algorithm (***Describe the calculation of the measure as a flowchart or series of steps***):**

We use hierarchical logistic regression modeling to calculate hospital-specific risk-standardized readmission rates (RSRRs). These rates are calculated as the ratio of the predicted number of readmissions to the expected number of readmissions, multiplied by the national unadjusted readmission rate. The expected number of readmissions for each hospital was estimated using its patient mix and the average hospital-specific intercept. The predicted number of readmissions in each hospital was estimated given the same patient mix but an estimated hospital-specific intercept. Operationally, the expected number of readmissions for each hospital is obtained by summing the expected readmission rates for all patients in the hospital. The expected readmission rate for each patient is calculated via the hierarchical model by applying the subsequent estimated regression coefficients to the observed patient characteristics and adding the average of the hospital-specific intercepts. The predicted number of readmissions for each hospital is calculated by summing the predicted readmission rates for all patients in the hospital. The predicted readmission rate for each patient is calculated through the hierarchical model by applying the estimated regression coefficients to the patient characteristics observed and adding the hospital-specific intercept. In order to assess hospital performance in any specific year (e.g. the validation cohort), we re-estimate the model coefficients using that year's data.
For additional information on the calculation algorithm, please see attached "PCI Calculation Algorithm" under "Detailed Risk Model" section, and "PCI_Technical_Report_11-5-09_Final_to_NQF.pdf" attached at the end of this application.

►**Describe the method for discriminating performance** *(e.g., significance testing)***:**
The method for discriminating hospital performance has not been determined. This process relates to implementation and will be addressed during measure implementation planning. However, for 6 publicly-reported CMS measures of hospital outcomes developed with similar methodology (e.g., 30-Day Heart Failure Mortality) CMS currently estimates an interval estimate for each risk-standardized rate to characterize the amount of uncertainty associated with the rate, compares the interval estimate to the national crude rate for the outcome, and categorizes hospitals as "better than the US national rate," "worse than the US national rate," or "no different than the US national rate." CMS has not yet determined if it would use a similar approach to publicly reporting this measure.

Sampling (Survey) Methodology *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)*:
This measure is not based on a sample or a survey.

►**Data Source (***Check the source(s) for which the measure is specified and tested)*
Electronic adminstrative data/claims, registry data

►**Data source/data collection instrument (***Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
The datasets used to create the measure are described below.
1)NCDR CathPCI Registry data
The model uses ACC NCDR CathPCI Registry data to adjust for differences in patient risk of readmission (comorbid conditions). 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 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 (the data collection form and the complete list of variables collected and submitted by hospitals can be found at http://www.ncdr.com). The patient records submitted to the registry focus on acute episodes of care, from admission to discharge, and the NCDR does not link patient records longitudinally across episodes of care.
For development and validation purposes, we identified comparable cohorts of PCIs in which the patient was released from the hospital between January and December 2007 and 2006, respectively.
(2)Medicare Data
The model uses Medicare claims data to identify readmissions

(a) Part A inpatient and outpatient data: 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 PCIs performed either as an inpatient or outpatient (ie outpatient or observation stay). 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 PCIs with the corresponding data from the CathPCI Registry. (b) 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, including in-hospital death, Medicare status on admission, and ability to retrieve a full month 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). Fleming C, Fisher ES, Chang CH, Bubolz TA, Malenka DJ. Study outcomes and hospital utilization in the elderly: the advantages of a merged database for Medicare and Veterans Affairs hospitals. Med Care. 1992;30:377-391. ►**Data source/data collection instrument reference web page URL or attachment:** URL http://www.ncdr.com/WebNCDR/NCDRDocuments/CathPCI_v4_DataCollectionForm_4.3.pdf ►**Data dictionary/code table web page URL or attachment:** URL http://www.ncdr.com/WebNCDR/NCDRDocuments/CathPCI_v4_CodersDictionary_4.3.pdf ►**Level of Measurement/Analysis** (*Check the level(s) for which the measure is specified and tested)* Population: national, Facility/Agency ►**Care Settings (***Check the setting(s) for which the measure is specified and tested)* Ambulatory Care: Hospital Outpatient, Hospital ►**Clinical Services** (*Healthcare services being measured, check all that apply*)	
TESTING/ANALYSIS	
2b. Reliability testing ►**Data/sample** *(description of data/sample and size)***:** N/A ►**Analytic Method** *(type of reliability & rationale, method for testing)***:** N/A ►**Testing Results** *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)***:** As part of NCDR's Data Quality Program (DQP), the Data Quality Report (DQR) process assesses the completeness and validity of the electronic data submitted by participating hospitals. The 2007 DQR audit was completed but ACC has not yet compiled the results into a report. We will update with results as the information becomes available.	**2b** C☐ P☒ M☐ N☐
2c. Validity testing ►**Data/sample** *(description of data/sample and size)***:** We are using this section to describe approach to model validation. ►**Analytic Method** *(type of validity & rationale, method for testing)***:** Overview of development and validation models: A risk adjustment model was derived using all matched admissions in 2007 ("development sample"). The performance of the models was validated using a similar cohort of patients who underwent PCI in 2006 ("validation sample"). For both models, we computed indices that describe their respective performance in terms of predictive ability, discriminant ability, and overall fit, and generated hospital risk-standardized mortality rates and corresponding interval estimates for the development sample. ►**Testing Results** *(statistical results, assessment of adequacy in the context of norms for the test conducted)***:** Results for both the development and validation sample are presented in 2e.	**2c** C☐ P☒ M☐ N☐

2d. Exclusions Justified

►**Summary of Evidence supporting exclusion(s):**
Rationale for each exclusion is described in "Denominator Exclusions." There were no clinically driven cohort exclusions.

►**Citations for Evidence:**
N/A

►**Data/sample** *(description of data/sample and size)*: See "data sample" under "Validity Testing." Please see attached methodology report for more details.

►**Analytic Method** *(type analysis & rationale)*:
See "analytic method" under "Validity Testing." Please see attached methodology report for more details.

►**Testing Results** *(e.g., frequency, variability, sensitivity analyses)*:
See "testing results" under "Validity Testing." Please see attached methodology report for more details.

2d
C☐
P☒
M☐
N☐
NA☐

2e. Risk Adjustment for Outcomes/ Resource Use Measures

►**Data/sample** *(description of data/sample and size)*: N/A

►**Analytic Method** *(type of risk adjustment, analysis, & rationale)*:
This measure is fully risk-adjusted using a hierarchical logistic regression model to calculate hospital 30-day risk-standardized readmission rates (RSRR).
Approach to probabilistic matching:
Because patient identifiers are not currently available in the CathPCI registry, a probabilistic match is utilized to link patient stays with PCI in the CathPCI Registry with corresponding patient stays in the CMS claims data. Only Medicare Fee For Service patients are able to be linked. The probabilistic match was performed using the following indirect patient identifiers:
-Hospital Medicare Provider Number (MPN)
-Patient age
-Gender
-Date of admission (claim begin date for Medicare Part A outpatient claims)
-Date of discharge (claim end date for Medicare Part A outpatient claims
The following steps for linkage are performed:
(1) Hospital information assembled from the CathPCI Registry (hospital identification number, name and address) is used to retrieve each hospital's self- reported hospital MPN from the NCDR
(2) MPN is manually searched and confirmed in the CathPCI Registry data for hospitals with either no self-reported MPN or a duplicate MPN
(3) A unique dataset is derived from the CathPCI Registry (including patients' clinical factors) with patient stays determined by hospital MPN, patient age, gender, admission date, and discharge date. Of note, the CathPCI Registry does not distinguish between inpatient and outpatient status; it uses 'admission' date and 'discharge' date for both outpatients and inpatients.
(4) A comparable dataset is created from CMS claims data by removing direct patient identifiers (i.e., Health Insurance Claim [HIC] number) which contains unique patient admissions determined by hospital MPN, patient age, gender, admission date, and discharge date.
The two datasets derived in steps 3 and 4 are merged using hospital MPN, patient age, gender, admission date, and discharge date as the linking fields.
Among PCI patients =65 years old in the CathPCI Registry, 67% were successfully matched to CMS claims data for 2007 data. The characteristics and outcomes of matched and unmatched patients were very similar. When we compared the outcomes of patients in the Medicare claims data who did and did not match, the overall readmission and mortality rates were comparable.
Approach to assessing model performance:
We computed 6 summary statistics for assessing model performance (Harrell, 2001):
(1) 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)
(2) percentage of variation explained by the risk factors (R2)

2e
C☐
P☒
M☐
N☐
NA☐

(3) predictive ability
(4) area under the receiver operating characteristic (ROC) curve
(5) distribution of residuals
(6) model chi-square (A test of statistical significance usually employed for categorical data to determine whether there is a good fit between the observed data and expected values; i.e., whether the differences between observed and expected values are attributable to true differences in characteristics or instead the result of chance variation.
For exact method of computing chi square, see section 3.1.2 of the attached "PCI_Technical_Report_11-5-09_Final_to_NQF.pdf".
Harrell and Shih, 2001 F.E. Harrell and Y.C.T. Shih, Using full probability models to compute probabilities of actual interest to decision makers, Int. J. Technol. Assess. Health Care 17 (2001), pp. 17–26.

►**Testing Results** *(risk model performance metrics)*:
Model Development Dataset: We identified PCI procedures in the CathPCI Registry in which the patient was released from the hospital between January and December 2007. The development cohort consisted of 128,745 patient stays at 766 hospitals, with an overall unadjusted 30-day readmission rate of 11.1%.
Model Performance: Six summary statistics, noted in the "discriminating performance" section above (over-fitting indices, residuals lack of fit (percentage of variation explained by the risk factors), predictive ability, area under the receiver operating characteristic (ROC) curve, distribution of residuals, and model chi-square), were computed to assess model performance.
The development model has strong discrimination and fit. The readmission rate ranges from 4.1% in the lowest predicted decile to 25.1% in the highest predicted decile, a range of 21.0%. Results are summarized below:
Residuals lack of fit: <-2 = 0.0%; [-2, 0) = 88.9%; [0, 2) = 2.2%; [2+ = 8.9%
Adjusted R-square: 0.07
Model Chi-square [# of covariates]: 4448.36 [31]
Predictive ability (lowest decile %, highest decile %): (4.05, 25.08)
Area under the ROC curve = 0.665 (GLM)
The discrimination and the explained variation of the model are consistent with those of published in AMI, HF, and Pneumonia readmission measures. The ROC is higher than that of previously published models for readmission, likely reflecting the advantages of using registry as opposed to claims data for risk adjustment. Nevertheless, the ROC is substantially lower than that of the NQF approved PCI mortality measures. First, readmissions are inherently more difficult to predict than mortality, with the risk of readmission more dependent on local practice patterns than patient characteristics. Second, we did not consider covariates that could be potential complications, certain patient demographics (e.g., race), and patients' admission path (e.g., outpatient, emergency department), and discharge destination (e.g. Discharged to home versus other facilities, both non-acute and acute care). These characteristics may be associated with readmission and thus could increase the model performance to predict patient readmission. However, these variables may be related to quality or supply factors that should not be included in an adjustment that seeks to control for patient clinical characteristics. As a result of these considerations the choice was made to focus on adjustment for clinical differences in the populations among hospitals. That is, we focused on patient characteristics at the time of admission even though the time zero was discharge.
Model Validation Dataset: We identified a comparable cohort of PCIs in which the patient was released from the hospital between January and December 2006. The validation cohort consisted of 117,375 patient stays at 618 hospitals, with a risk-standardized readmission rate of 10.7%.
We compared the model performance in the development sample with its performance in the validation dataset. The model performance was not substantively different in the validation sample. The 2006 and 2007 models are similarly calibrated. Results are summarized below:
Over-fitting indices: (-0.06, 0.99)
Residuals lack of fit: <-2 = 0.0%; [-2, 0) = 89.3%; [0, 2) = 1.9%; [2+ = 8.8%
Adjusted R-square: 0.06
Model Chi-square [# of covariates]: 3812.62 [31]
Predictive ability (lowest decile %, highest decile %): (3.8, 23.8)
Area under the ROC curve = 0.663 (GLM)

We also examined the temporal variation of the standardized estimates and frequencies of the variables in the models. The frequencies and regression coefficients are fairly consistent over the two years of data.
To assess the predictive ability of the model, we grouped patients into deciles of predicted 30-day

readmission. We then compared predicted readmission with observed readmission for each decile in the derivation cohort. Overall there was excellent correlation between predicted and observed readmission. ►**If outcome or resource use measure is not risk adjusted, provide rationale:** N/A	
2f. Identification of Meaningful Differences in Performance ►**Data/sample from Testing or Current Use** *(description of data/sample and size)***:** N/A ►**Methods to identify statistically significant and practically/meaningfully differences in performance** *(type of analysis & rationale)***:** N/A ► **Provide Measure Scores from Testing or Current Use** *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)***:** N/A	**2f** **C**☒ **P**☐ **M**☐ **N**☐
2g. Comparability of Multiple Data Sources/Methods ►**Data/sample** *(description of data/sample and size)***:** No comparable data source is available at this time. We performed validity testing of the development model using the same cohort definition but in a different time frame. ►**Analytic Method** *(type of analysis & rationale)***:** N/A ►**Testing Results** *(e.g., correlation statistics, comparison of rankings)***:** N/A	**2g** **C**☐ **P**☐ **M**☐ **N**☐ **NA**☒
2h. Disparities in Care ►**If measure is stratified, provide stratified results** *(scores by stratified categories/cohorts)***:** We have not examined health disparities associated with this measure. ►**If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:** There are no plans to detect disparities during measure development.	**2h** **C**☐ **P**☐ **M**☐ **N**☐ **NA**☒
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Scientific Acceptability of Measure Properties*? Scientific Acceptability - 2a. Specifications are precise; probabilistic matching questioned - specific matching would be better; is "staging" well defined? -- yes for ACC registry data- but unknown for others 2b. reproducibility of the outliers has not been demonstrated; concerns about auditing of data quality - would like more inforation on NCDR auditing report; need for more transparency in auditing; concern may be subject to "gaming", i.e., TAP members are aware of on-going "upcoding" ; no demonstration that admission coding captures the true reason for admission 2c. concerns about includng "all causes" for readmission - as much as 40% for reasons likly not attributable to procedure though some TAP members noted that certain readmission such as pneumonia may be related to aspiration, etc; concern about time window - 7 or 15 days might be more appropriate to capture readmissions more often specifically related to the PCI procedure; concerns about categorization and attribution. Several members suggest that readmisssions related to ICD-9 codes obviously unrelated to the PCI procedure (eg chronic bronchitis) not be included in the outcome measure 2d. exclusions generally appropriate 2e. Risk adjustment doesn't include factors such as social support or resource challenges - other TAP members noted that readmission rates for heart failure are the same for critical access hosptial that are resource-challenged; CMS advised that it cannot establish different standards or expectations based on social factors as a matter of public policy; C statistic of 0.66 is good but not very good/excellent; 2f. discrimination curve on p 44 of technical appendix using 2007 data; CMS has not determined how it would portray results for public reporting 2g. only 40% PCIs are entered into ACC's NCDR registry --no details on comparabilty with data obtained through other vendors Several additional questions to the measure developer: Has there been any assessment of differences in readmission to the same hospital or to another hospital? Any evaluation of different admitting policies of EDs? TAP members note there can be an	**2**

"ownership" issue between ED and proceduralist on determining readmission. TAP members note that 40-50% of PCIs are not associated with an AMI - what is the difference/impact? Are the PCIs asociated with AMI captured in the previously endorsed measures for AMI readmission? DEVELOPER comments: readmissions plateau at 30-45 days; baseline Medicare readmission rate is 17% - consistent with the other readmission measures Significant Strength --based on clinical data	
Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties*, **met?** **Rationale:** • Requires clinical data from the NCDR PCI registry and administrative Medicare data. • The Committee discussed "all cause" readmissions, which aligns with previously endorsed readmission measures. • Some Committee members suggested that a 15 day timeframe would be more directly related to the antecedent PCI procedure. The measure developer presented their hazard of readmission analysis over 90 days that found that risk of readmission was greatest in the first 15 days but remained elevated up to 60 days following discharge (with a plateau between 30-45 days). The developer asserted that a shorter timeframe would have a stronger association with the initial care of the patients, but would miss the substantial number of readmissions between 15-30 days that are likely attributable to the care delivered within the index hospitalization and during the transition from that setting. • There is a strong auditing quality of the data elements. • The developers presented an analysis of safety net hospitals – there was little difference compared to mainstream hospitals.	*2* **C**☒ **P**☐ **M**☐ **N**☐
3. USABILITY	
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	**Eval Rating**
3a. Meaningful, Understandable, and Useful Information **Current Use:** testing not yet completed **Use in a public reporting initiative** (*Provide name of initiative(s), locations, Web page URL(s)*)**:** The measure is designed for use in public reporting but is not currently in use. **If used in other programs/initiatives (***e.g., quality improvement; provide name of initiative(s), locations, Web page URL(s)*)**:** The measure is designed for use in public reporting but is not currently in use. **Testing of Interpretability** (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*) ►**Data/sample** *(description of data/sample and size)***:** Consumer testing will be completed prior to implementation. ►**Methods** *(e.g., focus group, survey, QI project)***:** Under "Current Use", we indicate "Testing not yet completed." No consumer or other field testing has been completed at this time. However, during measure development, we consulted with representatives from potential users of this measure including clinicians, professional societies, and consumers. We use this field to describe the role that these representatives played on the working group and Technical Expert Panel (TEP). We assembled and held regular conference calls with a working group, including individuals from YNHHSC/CORE, ACC, SCAI, and NCDR. The specific members of the working group were tailored for the	**3a** **C**☒ **P**☐ **M**☐ **N**☐

measure and structured to provide regular feedback on measure and development issues and to guide key decisions inherent to measure development. The group included clinicians and other professionals with expertise in interventional cardiology, biostatistics, measure methodology, and quality improvement. The group also included individuals experienced in working with ACC data registries and in model development using ACC registry data. The calls were designed to address key issues, explore options, and reach closure on analytic questions. The working group calls provided an opportunity to discuss issues raised during development and determine the approach that is brought to the TEP. In addition to the working group, and in alignment with the CMS Measures Management System (MMS), we released a public call for nominations and convened a TEP. The purpose of convening the TEP is to provide input and feedback during measure development from a group of recognized experts in relevant fields. The TEP represents physician, consumer, hospital, and purchaser perspectives, chosen to represent a diversity of perspectives and backgrounds. Three TEP meetings were conducted during development. In contrast to the working group calls, the TEP calls follow a more structured format consisting of presentation of key issues and our proposed approach, followed by open discussion of these issues by the TEP members. Having distinct interest groups present on the calls, the TEP was able to focus broadly on high level issues, including approaches to maximizing consumer interpretability and securing physician acceptance of the measure. Additional consumer testing will be completed prior to implementation. ►**Results** *(qualitative and/or quantitative results and conclusions)*: Consumer testing will be completed prior to implementation.	
3b/3c. Relation to other NQF-endorsed measures ►**NQF # and Title of similar or related measures:** NQF #0535: 30-day all cause risk-standardized mortality rate following percutaneous coronary intervention (PCI) for patients without ST segment elevation myocardial infarction (STEMI) and without cardiogenic shock; NQF #0536: 30-day all cause risk-standardized mortality rate following percutaneous coronary intervention (PCI) for patients with ST segment elevation myocardial infarction (STEMI) or cardiogenic shock; NQF #0505: Thirty-day all-cause risk-standardized readmission rate following acute myocardial infarction (AMI) hospitalization; NQF# 0330: 30-day all-cause risk-standardized readmission rate following heart failure (HF) hospitalization	
(for NQF staff use) **Notes on similar/related endorsed or submitted measures:**	
3b. Harmonization If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population): ►**Are the measure specifications harmonized? If not, why?** There are two related measures developed by CMS using the CathPCI Registry currently under National Quality Forum (NQF) review: 30-day risk-standardized mortality rates following PCI in patients with ST segment elevation myocardial infarction (STEMI) or cardiogenic shock and 30-day risk-standardized mortality rates in all other PCI patients. Although some states publicly report PCI mortality rates, there are no other nationally reported PCI measures at this time. Adding a PCI Readmission measure to the pair of 30-day mortality measures will provide a more comprehensive view of PCI care. These measures were developed from the same data source, and utilize a uniform approach to cohort definition and risk adjustment variable definitions.	**3b** **C**☒ **P**☐ **M**☐ **N**☐ **NA**☐
3c. Distinctive or Additive Value If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population): ►**Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:** PCI readmissions represent an important outcome that is distinct from PCI mortality. Adding a PCI readmission measure to the pair of 30-day mortality measures will provide a more comprehensive view of PCI care.	**3c** **C**☒ **P**☐ **M**☐ **N**☐ **NA**☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Usability*? Usability -3a - developer used a multistakehodler Technical Expert Panel; consumer testing planned 3b - harmonization -- aligned with previously endorsed PCI measures for mortality 3c - readmission is an important non-mortality outcome	**3**

some concern with potential increased length of stay for the index procedure	
Steering Committee: Overall, to what extent was the criterion, *Usability*, met? **Rationale:** • NQF has already endorsed a few measures that use a similar approach and methodology. • Committee members urged the developers to broaden the target population for the measure – particularly the under 65 years population. The developer replied that the measure could apply to all patients undergoing PCI if the required data was available. (During development they only had access to Medicare FFS data.) Adjustment to the risk model covariates would be needed with a different population.	**3** **C☒** **P☐** **M☐** **N☐**
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	**Eval Rating**
4a. Data Generated as a Byproduct of Care Processes **How are the data elements that are needed to compute measure scores generated?** coding/abstraction performed by someone other than person obtaining original information,	**4a** **C☒** **P☐** **M☐** **N☐** **NA☐**
4b. Electronic Sources ►**Are all the data elements available electronically?** (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*) Yes ►**If not, specify the near-term path to achieve electronic capture by most providers.**	**4b** **C☐** **P☒** **M☐** **N☐**
4c. Exclusions ►**Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?** No ►**If yes, provide justification.**	**4c** **C☒** **P☐** **M☐** **N☐** **NA☐**
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences ►**Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.** As noted earlier, publicly reporting hospital risk-standardized 30-day readmission rates requires that the data submitted by hospitals be complete, consistent, and accurate. The program implementing the measure should include steps to ensure data quality could include monitoring data for variances in case mix (e.g., unexpectedly high proportion of salvage PCI or cardiogenic shock), chart audits, and possibly adjudicating cases that are vulnerable to systematic misclassification. This would help to ensure that potential unintended consequences, such as reduced patient access to PCIs, are minimized. 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 components 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 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 DQR for a minimum of two quarters, at least 5% are randomly selected to participate in the DAP. At individual sites, on-site auditors	**4d** **C☐** **P☒** **M☐** **N☐**

review charts of 10% of submitted cases. The CathPCI Registry audit focuses on variables used for the existing PCI mortality models. The DAP includes an appeals process that allows hospitals to reconcile audit findings.	
4e. Data Collection Strategy/Implementation ►**Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:** The measure is not currently in use. ►**Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:** As designed, the measure utilizes data that are already collected in more than half of PCI hospitals, demonstrating the feasibility of data collection. Public reporting would therefore result in a low incremental burden of data collection to most hospitals. The cost to CMS potentially includes investment in data processing, data monitoring, data use, and measure maintenance. The extent to which this would represent additional cost burden will vary across hospitals. On balance, a PCI Readmission measure could conceivably improve hospital efficiency and overall quality of care for PCI patients, ultimately reducing costs associated with preventable readmissions. ►**Evidence for costs:** Cost would vary by implementation strategy. ►**Business case documentation:** Key points as noted in various sections of this document are as follows: (1) MedPAC identifies PCI as one of seven conditions or procedures that account for 30% of preventable readmissions at a cost of $360 million year (2) Readmission rate is high – 15% within 30 days (all cause unadjusted) (3) There is substantial variation across hospitals (as determined by preliminary data analysis of 2007 claims data) (4) PCI readmission complements recently NQF endorsed PCI mortality measures	**4e** **C☒** **P☐** **M☐** **N☐**
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility*? 4a - data requires abstration to submit to registry 4c - appropriate exlcusions 4d - concerns about adequacy of auditing of registry data; possible increased length of stay; "gaming" a concern 4e - data collection anticipated through usual CMS vendors as with PCI mortality measure	**4**
Steering Committee: Overall, to what extent was the criterion, *Feasibility***, met?** **Rationale:** The measure requires merging data from the PCI Registry and administrative data.	**4** **C☒** **P☐** **M☐** **N☐**
RECOMMENDATION	
(for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.**	**Time-limited ☐**
Steering Committee: Do you recommend for endorsement? **Comments:**	**Y☒** **N☐** **A☐**
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ADDITIONAL INFORMATION

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►Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.
The group's respective roles are described under the "Testing of Interpretability" section.
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►If adapted, provide name of original measure:
►If adapted, provide original specifications URL or attachment

Measure Developer/Steward Updates and Ongoing Maintenance
►Year the measure was first released:
►Month and Year of most recent revision:
►What is your frequency for review/update of this measure? Annual
►When is the next scheduled review/update for this measure? 2010-03

Copyright statement/disclaimers:

Additional Information web page URL or attachment: Attachment PCI_Technical Report_11-5-09_Final_to_NQF.pdf
Date of Submission (*MM/DD/YY*)**:** 11/10/2009

PCI Calculation Algorithm

Let *I* denote the total number of hospitals in the sample. We repeat steps 1 – 4 below for b = 1,2,…B times:

1. Sample *I* hospitals with replacement.

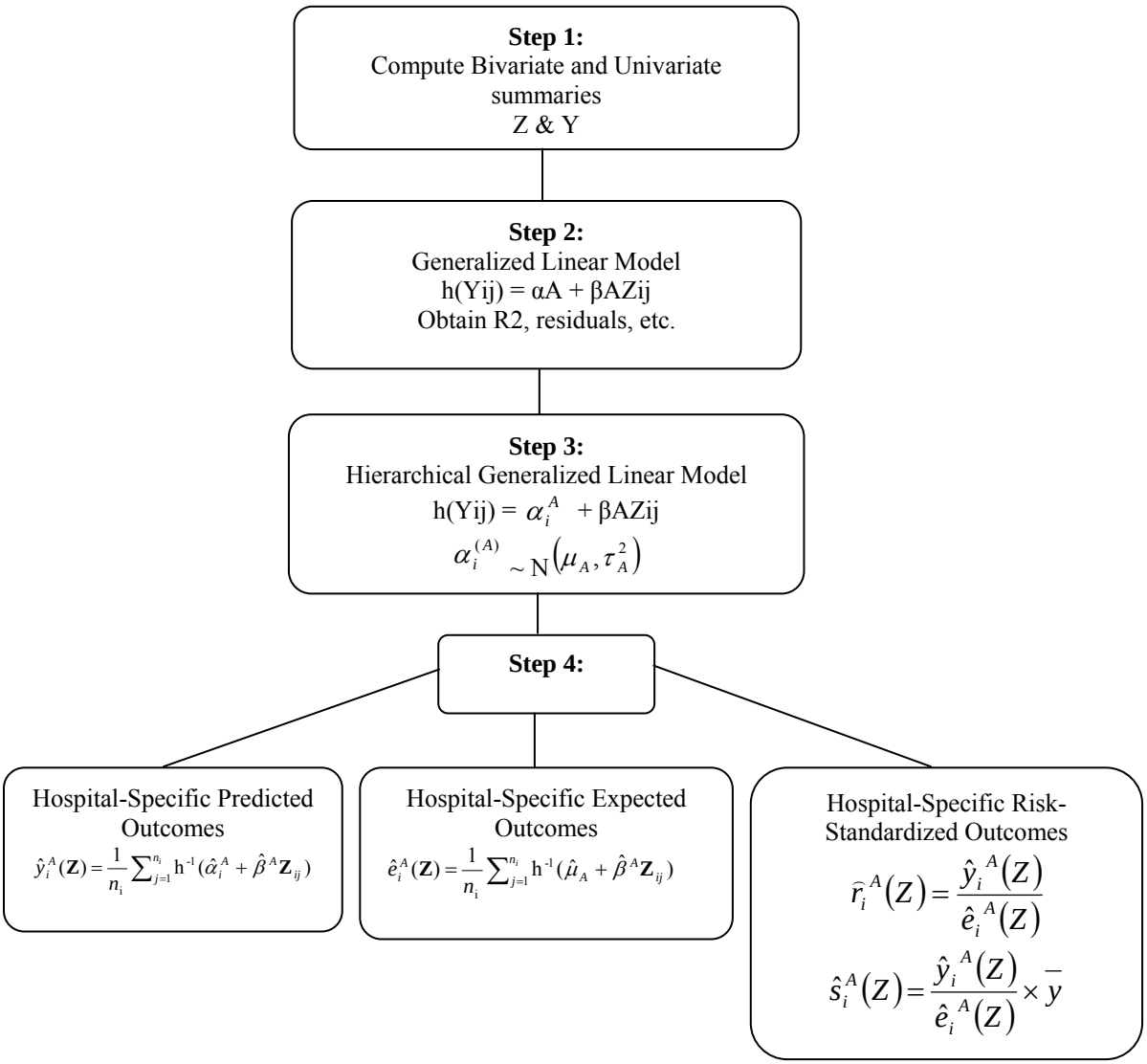
2. Fit the HGLM using all patients within each sampled hospital. We use as starting values the parameter estimates obtained by fitting the model to all hospitals. If some hospitals are selected more than once in a bootstrapped sample, we treat them as distinct so that we have *I* random effects to estimate the variance components. At the conclusion of Step 2, we have:
   a. $\hat{\beta}^{(b)}$ (the estimated regression coefficients of the risk factors).
   b. The parameters governing the random effects, hospital adjusted outcomes, distribution, $\hat{\mu}^{(b)}$ and $\hat{\tau}^{2(b)}$.
   c. The set of hospital-specific intercepts and corresponding variances, $\{\hat{\alpha}_i^{(b)}, \hat{\text{var}}(\alpha_i^{(b)}); i = 1,2,\ldots,I\}$.

3. We generate a hospital random effect by sampling from the distribution of the hospital-specific distribution obtained in Step 2c. We approximate the distribution for each random effect by a normal distribution. Thus, we draw $\alpha_i^{(b*)} \sim N\left(\hat{\alpha}_i^{(b)}, \hat{\text{var}}\left(\hat{\alpha}_i^{(b)}\right)\right)$ for the unique set of hospitals sampled in Step 1.

4. Within each unique hospital *i* sampled in Step 1, and for each case *j* in that hospital, we calculate $\hat{y}_{ij}^{(b)}$, $\hat{e}_{ij}^{(b)}$, and $\hat{s}_i(Z)^{(b)}$ where $\hat{\beta}^{(b)}$ and $\hat{\mu}^{(b)}$ are obtained from Step 2 and $\hat{\alpha}_i^{(b*)}$ is obtained from Step 3.

Ninety-five percent interval estimates (or alternative interval estimates) for the hospital-standardized outcome can be computed by identifying the 2.5th and 97.5th percentiles of randomly half of the B estimates (or the percentiles corresponding to the alternative desired intervals) (Normand, Wang et al. 2007).

Figure 1. – Analysis Steps



Hospital 30-Day Readmission Following Percutaneous Coronary Intervention Measure

Measure Methodology Report

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Jim Beachy, RCIS
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1. INTRODUCTION

1.1 Overview of Measure

Approximately one in seven Medicare patients who undergo percutaneous coronary intervention (PCI) is readmitted within 30 days of hospital discharge, and readmission rates vary across hospitals (Curtis, Schreiner et al. 2009). This variation in readmission rates following PCI (herein referred to as PCI readmission) is clinically significant and may in part reflect variations in quality of care. The Medicare Payment Advisory Committee (MedPAC) previously concluded that many readmissions following the performance of percutaneous transluminal coronary angioplasty (PTCA), used in this report as a synonym for PCI, are preventable and has recommended consideration of a PTCA readmission measure (MedPAC, 2006).

The Centers for Medicare & Medicaid Services (CMS) publicly report outcomes and efficiency measures on the consumer Web site, Hospital Compare (http://www.hospitalcompare.hhs.gov), as mandated by the 2005 Deficit Reduction Act. Consistent with this mandate and reflecting the importance of PCI readmission, CMS contracted with Yale New-Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNNHSC/CORE) to develop a PCI readmission measure. To pursue this measure Yale worked in partnership with the American College of Cardiology Foundation (ACCF), the Society for Cardiovascular Angiography and Interventions (SCAI), and the National Cardiovascular Data Registry (NCDR). This effort builds on YNHHSC/CORE and ACC's recent effort to develop CMS 30-day all-cause PCI mortality measures for PCI in two distinct cohorts (patients with ST elevation MI or cardiogenic shock and all other patients). These measures, which utilize the robust clinical data collected by the NCDR's CathPCI Registry, are suitable for public reporting and were recently endorsed by the National Quality Forum (NQF).

The goal of the present work is to improve patient outcomes by providing patients, physicians, and hospitals with information about risk adjusted readmission rates following PCI. All-cause PCI readmission is a patient-centered measure not focused solely on procedural issues or other processes of care, but rather on patients and the need for broad improvement in the transitions of care. Using registry data for the measure has several advantages for reaching this goal, including more robust risk adjustment and direct engagement of the clinicians and professional societies who have developed these registries.

We developed a model that estimates hospital-specific, risk-standardized, 30-day all-cause readmission rates following PCI. The measures were developed using data from the CathPCI Registry linked with CMS Medicare Part A claims and enrollment data using a probabilistic match. This approach is consistent with that previously

used for the PCI mortality measures (YNHHSC/CORE PCI Mortality Measures Methodology Report 2008). Clinical registry data were used for risk adjustment and the Medicare data for ascertainment of readmissions.

To account for the clustering of observations within hospitals and differences in the number of patient admissions across hospitals, risk-standardized readmission rates (RSRRs) were estimated with hierarchical logistic regression models. The hierarchical model has properties that make it appropriate to estimate rates for national public reporting. The development of the model proceeded with two assumptions about how it would be implemented. First, the model was derived with hospitals participating in NCDR, but the parameters would need to be re-estimated using the entire cohort of Medicare Fee-For-Service patients undergoing PCI. Second, direct identifiers would be required to link registry and claims data.

This report conveys the goals of the measure, development methodology, and results. First, we describe the purpose of the measure and its function in public reporting. Second, we present the methodology used to develop the measure and results of key preliminary analyses and the results of both the final risk adjustment model and the validation model. Next, we discuss a preliminary approach to implementation of the measure. Finally, we summarize the main findings of this project.

1.2 Purpose of the Measure

PCI is a cardiac procedure commonly performed on patients with coronary artery disease (CAD), a prevalent and costly condition. The intent of PCI is to improve coronary blood flow by treating obstructive epicardial coronary artery disease. In appropriately selected patients, PCI improves quality of life, increases exercise capacity, and reduces the burden of angina. Furthermore, in the emergency treatment of certain types of heart attacks, PCI improves survival and reduces the risk of adverse cardiovascular outcomes such as myocardial infarction, heart failure, and cardiac arrhythmias. Although a number of technologies are used to perform PCI, the most commonly used approach includes the dilation of a blockage with a small balloon followed by the deployment of a coronary stent (a slotted metal tube) used to brace the artery open. Although advances in technology have improved procedural success and safety, the performance of PCI still carries significant risks of short-term adverse outcomes including procedural complications, readmission and death. Many patients undergoing PCI have coexisting illnesses that increase their risk for readmission. Focusing on readmission rates will provide an incentive for hospitals to reduce related risks during hospitalizations in which a PCI is performed. Of note, the proposed measure does not attempt to judge the quality of individual interventional cardiologists who perform PCI procedures, but rather reflects the outcomes achieved by the systems of care within which the procedure is performed. Publicly reporting PCI readmission rates will provide patients, physicians, and

hospitals with information that could be used to understand and improve quality of care and outcomes.

1.3 Why PCI Readmission

PCI is one of the most commonly performed cardiac procedures in the United States. In 2007, an estimated 722,000 inpatient admissions had an associated PCI procedure, and from 1997-2007, the number of PCI procedures increased by 24% (Levit, Wier, et al. 2007). Readmission within 30 days of PCI is often an unplanned, adverse event. Approximately one in seven Medicare patients who undergo PCI is readmitted within 30 days of hospital discharge, and that readmission rates vary substantially across hospitals (Curtis, Schreiner et al. 2009). 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, Wennberg et al. 1994). In addition, specific hospital processes such as discharge planning, medication reconciliation, and coordination of outpatient care have been shown to affect readmission rates (Nelson, Maruish et al. 2000). MedPAC noted that the rate of preventable admissions within 15 days of discharge following PTCA (used in this report as a synonym for PCI), is 10% (44,293 in 2005 at a cost of $360 million) and has called for hospital-specific public reporting of readmission rates (MedPAC, 2006).

To further assess the need for a PCI readmission measure for Medicare patients, we conducted analyses using 2007 Medicare FFS claims. These analyses confirmed that crude readmission rates following PCI are high and vary significantly across hospitals, from 0% to 100% with a mean (SD) of 15.5% (10.6%) and a median (quartile range) of 14.5% (11.1%, 18.0%). Approximately three-fifths of readmissions are associated with a cardiovascular principal diagnostic code. The most common principal discharge diagnostic code (25.4%) was chronic ischemic heart disease (ICD-9 414.x), and a similar proportion (26.8%) of patients had discharge diagnostic codes consistent with an acute cardiovascular conditions such as acute myocardial infarction, unstable angina, arrhythmia, or heart failure. These findings suggest that the majority of readmissions are for either non-acute cardiac or non-cardiac reasons.

1.4 Core Principles for Hospital Outcomes Models Suitable for Public Reporting

We developed models using an approach that is consistent with the rationale articulated in the AHA scientific statement, “Standards for Statistical Models Used for Public Reporting of Health Outcomes” (Krumholz, Brindis et al. 2006), outlined below in Table 1.

Table 1 – Preferred Attributes of Models Used for Publicly Reported Outcomes

	Preferred Attribute
1	Clear and explicit definition of an appropriate patient sample
2	Clinical coherence of model variables
3	Sufficiently high-quality and timely data
4	Designation of an appropriate reference time before which covariates are derived and after which outcomes are measured
5	Use of an appropriate outcome and a standardized period of outcome assessment
6	Application of an analytical approach that takes into account the multilevel organization of data
7	Disclosure of the methods used to compare outcomes, including disclosure of performance of risk-adjustment methodology in derivation and validation samples

We designed the readmission measure model to reflect all of these attributes. We derived the model using a risk adjustment method that excluded potential complications of care so that the estimated risks adjusted for pre-existing conditions but not complications related to the procedure. To calculate risk-standardized readmission rates (RSRRs), we used a hierarchical logistic regression model, a statistical approach that takes into account the clustering of patients within hospitals and differences in sample size across hospitals. We computed indices that describe model performance in terms of calibration (over-fitting indices), discriminant ability (R-Square, ROC, and predicted vs. observed readmission), and overall fit (residuals, lack of fit, and model chi-square).

2. METHODS

2.1 Overview

We developed a measure of 30-day readmission following PCI using data from the NCDR CathPCI Registry for risk adjustment linked with CMS claims data for outcome information. We developed this model for all inpatient admissions or outpatient services with a PCI procedure (herein referred to as patient stays) that met the cohort criteria (Table 3 & Figure 4) and could be linked to the outcome data. [Note: Only Medicare FFS patients could be linked.] We fit a hierarchical generalized linear model (HGLM) that estimates hospital-level risk-standardized 30-day readmission rates.

To develop the model, we first used Medicare Part A inpatient and outpatient claims data to identify a cohort of patient stays with PCI between January and December 2007 (index cohort). Using the inpatient claims data, we then identified inpatient readmissions within 30 days of the discharge date of an index admission. We linked the resulting patient cohort with a comparable cohort of patients undergoing PCI included in the NCDR CathPCI Registry's analytic file. Because the current version of the NCDR CathPCI database does not include direct patient identifiers, we linked the two datasets using a probabilistic match. We matched patient admissions using six indirect patient identifiers: hospital Medicare Provider Number (MPN), patient age, gender, admission date, procedure date, and discharge date. In the future, the NCDR registries will contain identifiers such as social security number and/or a health insurance claim number that will allow a direct match between the two sources of data. The performance of the model was validated using a similar cohort of patients who underwent PCI in 2006 ("validation sample"). For both the development and validation models, we computed indices that describe their respective performance in terms of predictive ability, discriminant ability, and overall fit.

2.2 Technical Expert Consultation

Throughout measure development, we obtained expert and stakeholder input via two mechanisms: first, through regular discussions with a Working Group, and second, through a national Technical Expert Panel (TEP).

The working group was assembled and regular conference calls were held throughout the development phase. The working group included individuals from YNHHSC/CORE, the ACC, NCDR, and the Society for Cardiovascular

Angiography and Interventions (SCAI). The working group was tailored for this measure development, and included clinicians and other professionals with expertise in interventional cardiology, biostatistics, measure methodology, and quality improvement. The group also included individuals from the NCDR with extensive registry experience as well as experience in the use of registry data to develop the risk adjustment method. The working group meetings were held on a bimonthly basis and addressed key issues surrounding measure development including, detailed discussions regarding the pros and cons of specific decisions (such as the appropriate period of assessment and use of all-cause versus cause-specific readmission), and to ensure the methodological rigor of the measure.

In addition to the working groups, and in alignment with the CMS Measures Management System (MMS), we convened a TEP to provide input and feedback during measure development from a group of recognized experts in relevant fields. To create the TEP, we released a public call for nominations (YNHHSC-CORE TEP Summary Report 2009) and selected individuals in order to provide representation from a range of perspectives including those of physicians, consumers, hospitals, and purchasers. For the PCI readmission measure, we convened three TEP conference calls. In contrast to the working group calls, the TEP calls followed a more structured format consisting of presentation of key issues, relevant data, and our proposed approach. This presentation was followed by open discussion of these issues by the TEP members.

Finally, we solicited public comment on the proposed measure through the MMS Web site (https://www.cms.hhs.gov/apps/QMIS/publicComment.asp). Public comments were summarized and publicly posted. The resulting content was taken into consideration during the final stages of measure development.

2.3 Outcome

The outcome for this measure is 30-day all-cause readmission. We define a readmission as a subsequent hospital inpatient admission within 30 days of the discharge date of an admission in the index cohort or claim end date (for patients whose PCI was performed as an outpatient service).

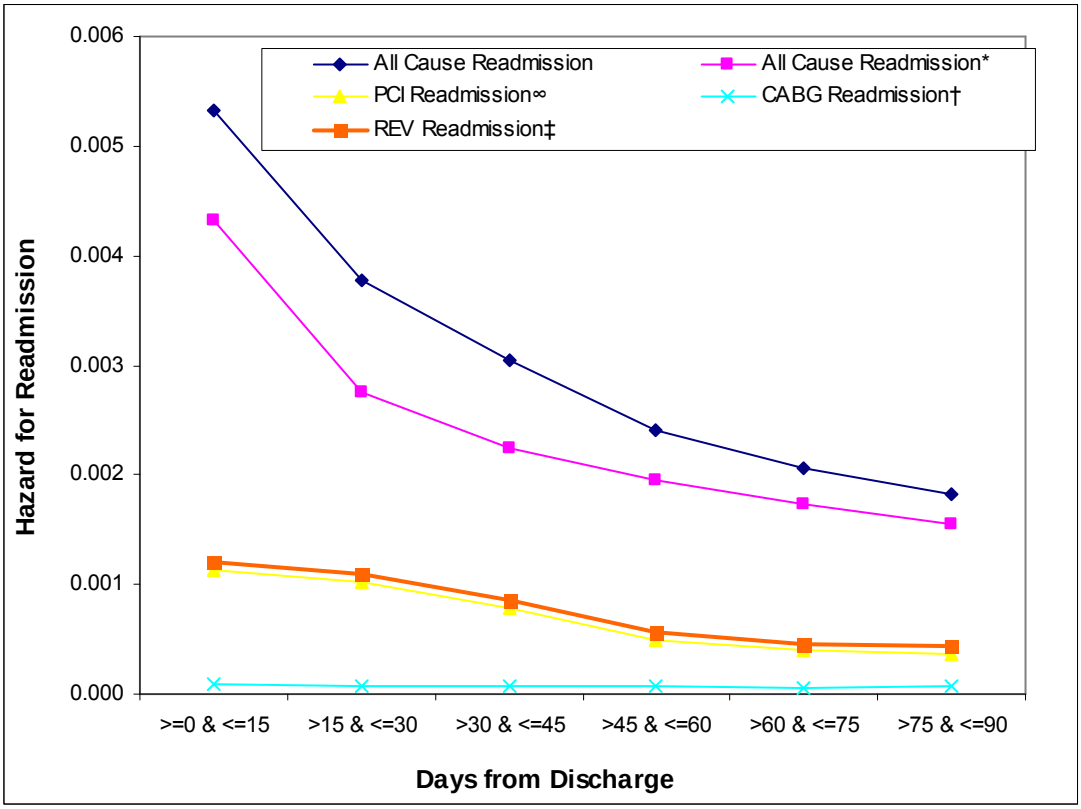
We do not count readmissions associated with a ‘staged’ revascularization procedure, defined as readmissions with PCI or CABG codes that do not have a principal discharge diagnosis code consistent with an acute cardiac event (heart failure, acute myocardial infarction, arrhythmia, unstable angina, and cardiac arrest). The rationale for this exclusion is that physicians caring for patients with multivessel disease may opt to perform the revascularization procedures over multiple visits to the catheterization laboratory, which may

occur during a single or multiple hospitalizations. This readmission exclusion criterion is consistent with that used by the NQF-approved AMI readmission measures. Unadjusted rates of readmissions including staged revascularization may be reported in parallel when the measure is implemented.

2.3.1 30-Day Timeframe

We considered a range of time periods for the outcome and ultimately selected a 30-day timeframe for several reasons. First, we reviewed a preliminary analysis of the hazard of readmission over a 90-day period (Figure 1). The risk of readmission was highest within the first 15 days but remained elevated up to 60 days following discharge. There was, however, the appearance of a plateau that occurred between 30 and 45 days after discharge. These results suggested that a 30-day timeframe would capture the time period at which patients are at highest risk for readmission. Furthermore, readmissions in this time period would more likely be attributable to the care delivered both within an index hospitalization and during the transition from that setting. A shorter timeframe such as 15 days would have an even stronger association with the initial care of the patient, but would miss the substantial number of readmissions occurring between 15 and 30 days. Both the working group and TEP agreed that a 30-day readmission measure had the greatest potential to stimulate better collaboration between hospitals and their surrounding medical communities aimed at reducing readmission rates. These activities may include providing better, safer care during the patient stay, attention to patient's medication needs at discharge, improving communication with patients before and after discharge, improving communication with other providers; reviewing practice patterns; and implementing systems to reduce readmissions. Finally, this timeframe is consistent with the other readmission measures approved by NQF.

Figure 1 – Hazard of Readmission Following PCI (Medicare Part A Inpatient and Outpatient, 2007)



2.3.2 All-Cause Readmission

We used all-cause readmission (except for staged procedures) as opposed to cardiac specific readmission for several reasons. First, from the patient perspective, readmission for any reason is likely to be an undesirable outcome of care. Second, readmissions not associated with a cardiac diagnosis may in fact still be directly related to the care delivered during the index hospitalization. Examples include patients readmitted with acute renal failure due to a contrast nephropathy caused by the initial procedure, or patients readmitted with a pseudoaneurysm or other

* Readmissions with revascularization but without myocardial infarction, heart failure, unstable angina, cardiac arrest or arrhythmia are not counted as readmissions

∞PCI=Percutaneous Coronary Intervention

†CABG=Coronary Artery Bypass Graft

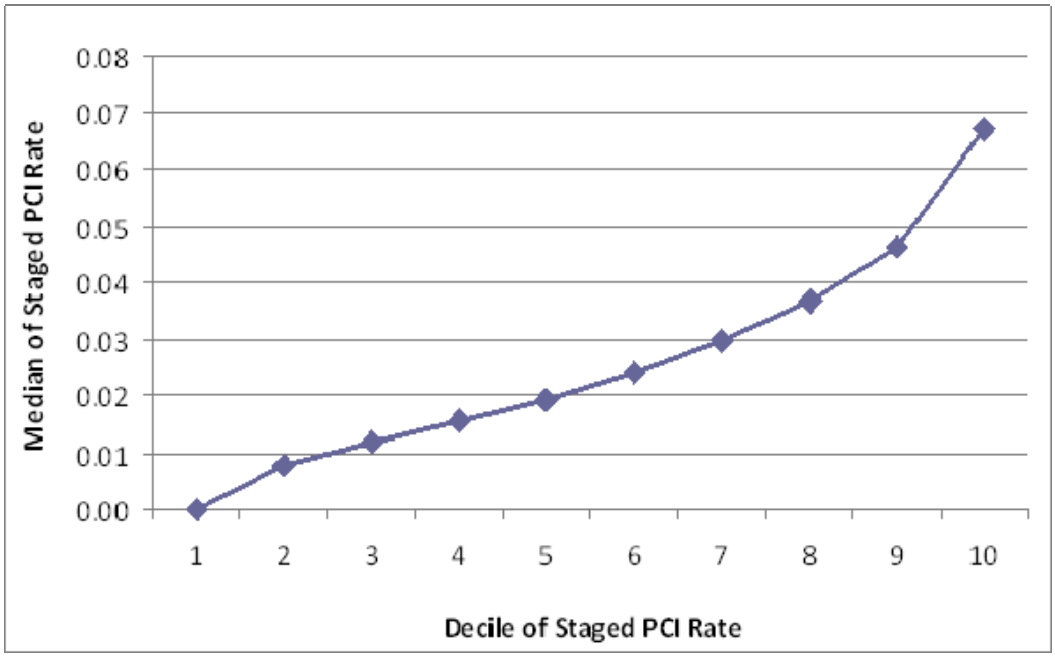
‡REV=Coronary Revascularization

late-presenting vascular complication resulting from the initial procedure. In addition, the range of potentially avoidable readmissions also includes those not directly related to the PCI such as those resulting from poor communication or inadequate follow-up. As such, creating a comprehensive list of potential 'PCI-related' complications would be arbitrary and, ultimately, impossible to implement. Using all-cause readmission, on the other hand, will undoubtedly include a mix of unavoidable and avoidable readmissions as not all readmissions are preventable. Review of the most frequent codes associated with readmissions (Appendices A and B) reveals a wide variety of cardiovascular and non-cardiovascular conditions and procedures. Although there is no reliable way to accurately identify preventable readmissions, there are undoubtedly opportunities to improve care of PCI patients. Thus, the goal of this measure is not to reduce readmissions to zero. Instead, an all cause measure will assess hospital performance relative to what is expected given the performance of other hospitals with similar case mixes.

2.3.3 Readmissions for Staged Procedures not Counted as Readmissions

We identify readmissions for staged PCI procedures and do not count them as readmissions for the index procedure. The rationale for this exclusion is that physicians caring for patients with multivessel disease may opt to perform the revascularization procedures over multiple visits to the catheterization laboratory, which may occur during a single or multiple hospitalizations. Current clinical practice guidelines (King, Smith et al. 2007) and appropriateness criteria (Patel, Dehmer et al. 2009) for PCI do not address the appropriateness of these staging procedures, and there is certainly significant variation in the frequency with which patients are readmitted for staged procedures among hospitals with at least 50 PCI procedures (Figure 2). Although this variation has significant clinical and cost implications, at this time the appropriateness of this approach is controversial and therefore an admission for a staged procedure cannot necessarily be considered an undesirable event. This issue was the topic of much discussion with the working group and Technical Expert Panel. As a result of consensus opinion, the measure will not include readmissions with a PCI or CABG code that do not have a principal discharge diagnosis code consistent with an acute cardiac event (i.e. heart failure, acute myocardial infarction, arrhythmia, unstable angina, and cardiac arrest). These admissions will be viewed as staged revascularizations and will not be included in this readmission measure. The approach to identifying elective revascularizations is comparable to that currently used for the 30-day AMI readmission measure.

Figure 2 – Hospital variation in Readmission for Staged Procedures (Medicare Inpatient Part A, 2007; in hospitals with at least 50 PCI procedures)



2.4 Data Sources

The datasets used to create the measure are described below.

2.4.1 NCDR CathPCI Registry data

The model uses ACC NCDR CathPCI Registry data to adjust for differences in patient risk of readmission. 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 (the data collection form and the complete list of variables collected and submitted by hospitals can be found at http://www.ncdr.com). The patient records submitted to the registry focus on acute episodes of care, from admission to discharge, and

the NCDR does not link patient records longitudinally across episodes of care.

Institutions that participate in the CathPCI Registry reflect the full spectrum of hospitals that perform PCI. We compared characteristics of hospitals that do participate in the CathPCI Registry with hospitals that perform PCI but do not participate in the CathPCI registry using data from the 2007 Medicare claims data linked with 2007 American Hospital Association (AHA) Survey data. Compared with hospitals that do not participate in the CathPCI Registry, hospitals that participate are larger and more likely to be located in the Northeast. Furthermore, a higher proportion of those in the CathPCI Registry are not-for-profit, teaching, and perform open heart surgeries including coronary artery bypass grafting (Table 2).

Table 2 – Comparison of the characteristics of hospitals that perform PCI and participate in the CathPCI Registry with PCI Hospitals that do not participate in the CathPCI Registry (hospitals in both CMS Part A [inpatient & outpatient] and AHA 2007 data)

Description	Total		Non-Participating CathPCI Registry Hospitals		Participating CathPCI Registry Hospitals		P
	#	%	#	%	#	%	
All	1554	100.00	791	100.00	763	100.00	
Number of beds							<0.001
< 300	858	55.21	484	61.19	374	49.02	
300 to 600	545	35.07	242	30.59	303	39.71	
> 600	151	9.72	65	8.22	86	11.27	
Mean (SD)	325.83	221.19	301.41	227.39	351.14	211.77	<0.001
Ownership							<0.001
Government	182	11.71	111	14.03	71	9.31	
Not-for-profit	1072	68.98	493	62.33	579	75.88	
For profit	300	19.31	187	23.64	113	14.81	
Region							<0.001
Associated area	10	0.64	10	1.26	0	0.00	
New England	55	3.54	20	2.53	35	4.59	
Middle Atlantic	171	11.00	104	13.15	67	8.78	
South Atlantic	242	15.57	115	14.54	127	16.64	
East North Central	280	18.02	116	14.66	164	21.49	
East South Central	112	7.21	61	7.71	51	6.68	
West North Central	130	8.37	50	6.32	80	10.48	
West South Central	226	14.54	156	19.72	70	9.17	
Mountain	127	8.17	63	7.96	64	8.39	
Pacific	201	12.93	96	12.14	105	13.76	
Teaching status							<0.001
COTH*	255	16.41	122	15.42	133	17.43	
Teaching	376	24.20	163	20.61	213	27.92	
Non-Teaching	923	59.40	506	63.97	417	54.65	
Cardiac facility							<0.001
CABG** surgery	1123	72.27	511	64.60	612	80.21	

The NCDR possesses a Data Quality Program (DQP) to ensure validity of the data collected. The two main components 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

* Council of Teaching Hospitals and Health Systems

** Coronary Artery Bypass Graft

identified as 'core fields' to be included in the registry's data warehouse for analysis. The 'core fields' include 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. The entire quarter of patient discharge information is not accepted until the DQR completeness thresholds are met for all patient data. 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, on-site auditors review up to 50 submitted patient charts. The CathPCI Registry audit focuses on variables used for the existing PCI mortality models. However, the scope of the audit could be expanded to include additional fields. The DAP includes an appeals process that allows hospitals to reconcile audit findings.

For model development, we identified PCI procedures in the CathPCI Registry in which the patient was released from the hospital between January and December 2007. For validation purposes, we identified a comparable cohort of patients released from the hospital following a PCI between January and December 2006.

2.4.2 Medicare Data

The model uses Medicare claims data to identify readmissions

- Part A inpatient and outpatient data
  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.

- 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, including in-hospital death, Medicare status on admission, and ability to retrieve a full month 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).

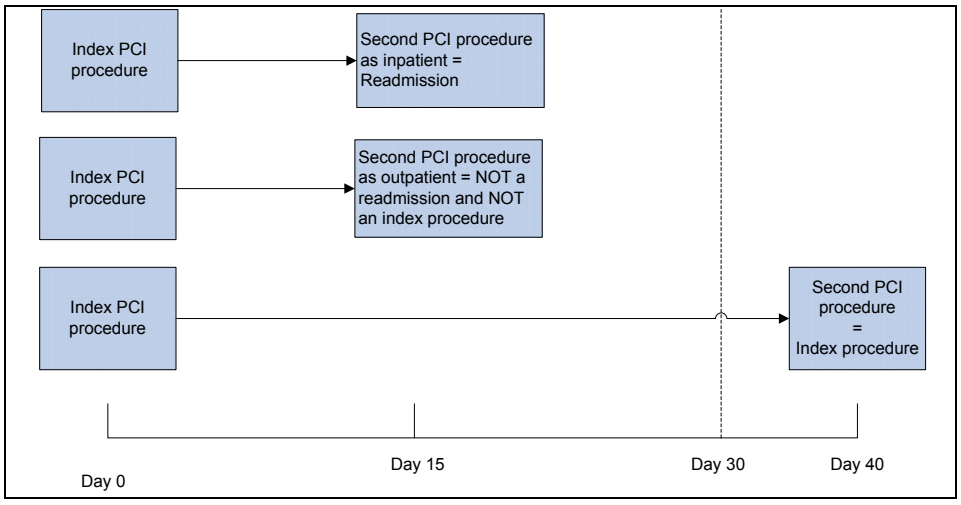
2.5 Cohort Derivation

Both the CathPCI Registry and CMS claims data were used to define the cohort of admissions with a PCI for model development. The flow chart depicting the derivation of the set of patient stays is presented in Figure 4.

From the CathPCI Registry data, we identified a patient stay with PCI as a PCI admission using the item 614 (PCI=Yes).When patients underwent multiple PCIs during one hospital stay, the first PCI performed during that stay was considered to be the index PCI admission and only information related to that index PCI was included in the measure. We chose this approach because information obtained from subsequent PCI procedures during one hospital stay may actually reflect complications of care following the initial procedure. Consider the example of a patient who underwent elective PCI and subsequently experienced an acute myocardial infarction (AMI) due to an unrecognized dissection. If the patient had to undergo an emergency repeat PCI, it would be inappropriate to include that information in the risk adjustment process as it reflected a complication of care.

If a patient had more than one PCI during the 30 day outcome period, the subsequent PCI was not considered to be a new index procedure (Figure 3). If a patient underwent more than one PCI procedure within a calendar year, (but not within the same hospitalization) that PCI was eligible for consideration as another index procedure.

Figure 3 – Index Procedure Derivation for Patients with Subsequent PCI Procedures



In the CathPCI Registry, patient stays with PCI are identified by field 614 (PCI=Yes). In the CMS claims data, patient stays with PCI are identified by the International Classification of Diseases, 9th Revision, Clinical

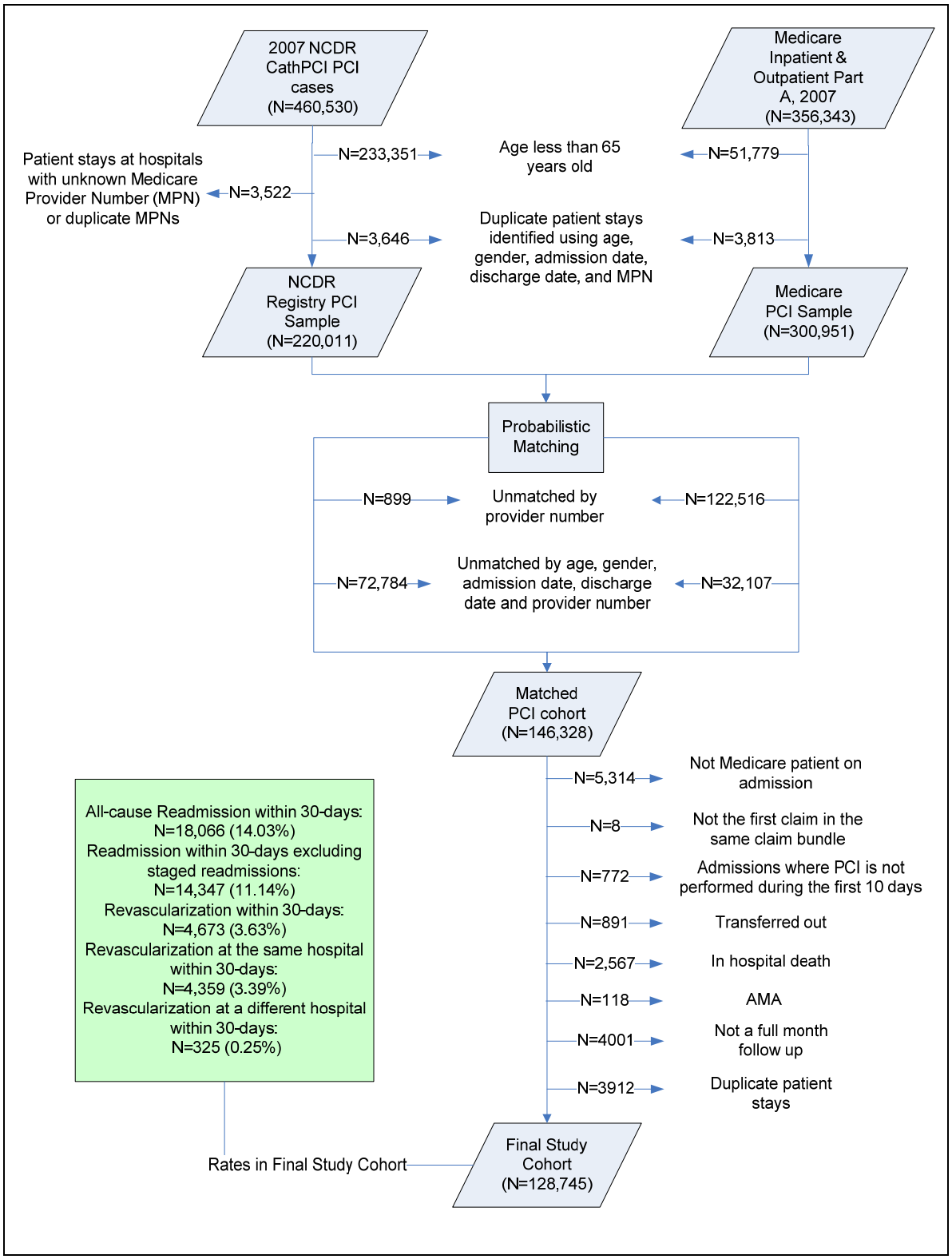
Modification (ICD-9-CM) procedure codes from inpatient and outpatient claims and Healthcare Common Procedure Coding System/Current Procedural Terminology (HCPCS/CPT) procedure codes from outpatient claims shown in Table 3.

Table 3 – ICD-9-CM and CPT Procedure Codes that Define an Admission with PCI in Medicare Inpatient & Outpatient Claims

Code Type	Code	Description
ICD-9-CM	00.66	Percutaneous transluminal coronary angioplasty or coronary atherectomy
ICD-9-CM	36.01	Single vessel PTCA or coronary atherectomy
ICD-9-CM	36.02	Percutaneous transluminal coronary angioplasty or coronary atherectomy with mention of thrombolytic agent
ICD-9-CM	36.05	Multiple vessel PTCA or coronary atherectomy
ICD-9-CM	36.06	Insertion of non-drug-eluting coronary artery stent(s)
ICD-9-CM	36.07	Insertion of drug-eluting coronary artery stent(s)
CPT	92973	Percutaneous transluminal coronary thrombectomy
CPT	92980	Coronary Stents [single vessel]
CPT	92981	Coronary Stents [each additional vessel]
CPT	92982	Coronary Balloon Angioplasty [single vessel]
CPT	92984	Coronary Balloon Angioplasty [each additional vessel]
CPT	92995	Percutaneous Atherectomy
CPT	92996	Percutaneous Atherectomy

We merged PCI admissions in the NCDR CathPCI Registry data and PCI admissions in Medicare claims data to derive cohorts for development (2007) and validation (2006). Figure 4 presents the details of the derivation of the development cohort, which includes the total number of patient stays with PCI, the proportion excluded as a result of each exclusion criterion, and the number included in the final sample as index hospitalizations. The development sample consisted of 128,745 admissions at 766 hospitals. The overall unadjusted all-cause 30-day readmission rate is 14.0%, and after excluding staged procedures, 11.1%.

Figure 4 – Cohort for Model Development*



* AMA= Against Medical Advice; NCDR=National Cardiovascular Data Registry; MPN=Medicare Provider Number; PCI=Percutaneous Coronary Intervention

2.5.1 Probabilistic Matching Methodology for Merging CathPCI Data and CMS Claims Data for Measure Development

Since the CathPCI Registry does not currently capture the direct patient identifiers necessary to make these linkages, we performed a probabilistic matching between patient stays with PCI in the CathPCI Registry and corresponding patient stays in the CMS claims data using the following indirect patient identifiers: hospital Medicare Provider Number (MPN), patient age, gender, date of admission (for Medicare Part-A outpatient claims, this is the claim begin date), and date of discharge (for Medicare Part-A outpatient claims, this is the claim end date). We performed the following steps for linkage:

1. Hospital information assembled from the CathPCI Registry (hospital identification number, name and address) was used to retrieve each hospital's self-reported hospital MPN from the NCDR;

2. MPN was manually searched and confirmed in the CathPCI Registry. Data for hospitals with either no self-reported MPN or a duplicate MPN were excluded;

3. A unique dataset was derived from the CathPCI Registry (including patients' clinical factors) with patient stays determined by hospital MPN, patient age, gender, admission date, and discharge date. Of note, the CathPCI Registry does not distinguish between inpatient and outpatient status; it uses 'admission' date and 'discharge' date for outpatients and inpatients.

4. A comparable dataset was created from CMS claims data by removing direct patient identifiers (i.e. Health Insurance Claim [HIC] number) and the resulting dataset contained unique patient admissions determined by hospital MPN, patient age, gender, admission date (for Medicare Part-A outpatient claims, this is the claim begin date), and discharge date (for Medicare Part-A outpatient claims, this is the claim end date).

5. The two datasets derived in steps 3 and 4 were merged using hospital MPN, patient age, gender, admission date, and discharge date as the linking fields.

Results of the probabilistic match are presented in the Section 2.8.

2.5.2 Exclusion Criteria

We excluded the following patient stays from the measure calculation prior to the merge:

1) Age <65 (Medicare and NCDR datasets). Stays for patients less than 65 years old at the time of the patient stay were excluded.
   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.

2) Patient stays at hospitals with missing or duplicate MPN (NCDR dataset). Any patient stays with a missing or duplicate MPN number are excluded.
   Rationale: If the MPN number is unreliable, we are unable to match NCDR patients to CMS claims data or assign the readmission to a hospital with certainty.

3) Patient stays with duplicate fields (Medicare and NCDR datasets). Patient stays that have identical information indicated for age, gender, admission date, discharge date, and MPN are excluded.
   Rationale: Patient stays with identical demographics are excluded to avoid making matching errors upon merging of the two datasets.

4) Unmatched patient stays. Patient stays that are not matched based on age, gender, admission date, discharge date, and MPN are excluded.

The following exclusions are applied to the merged dataset:

1) Patients not enrolled in Medicare fee-for service (FFS) at the start of the episode of care.
   Rationale: readmission data is currently available only for Medicare fee-for-service patients.

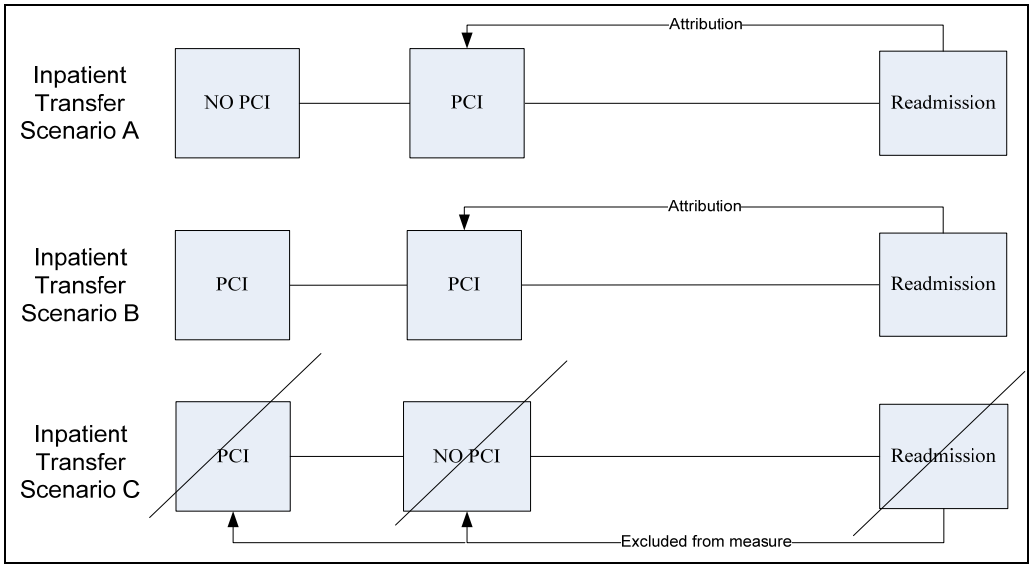
2) Not the first claim in the same claim bundle. Multiple claims from an individual hospital can be bundled together. To ensure that the selected PCI is the index PCI, we exclude those PCI procedures that were not the first claim in a specific bundle.
   Rationale: Inclusion of additional claims could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

3) Instances when PCI is performed >10 days following admission. Patients with prolonged hospitalizations prior to PCI are excluded.

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. Patient stays in which the patient received a PCI and was then transferred to another hospital are excluded (Figure 5).
Rationale: In this instance, the hospital that performed the PCI procedure does not provide discharge care and cannot be fairly held responsible for their outcomes following discharge.

Figure 5 – 30-Day PCI Readmission Transfer Attribution Strategy



5) The patient dies in the hospital.
Rationale: Subsequent admissions (readmissions) are not possible.

6) The patient leaves 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. Patients who cannot be tracked for 30 days following their hospital stay are excluded.
Rationale: There will not be 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.

2.6 Observation Period

For model development and validation, we used observations for one calendar year.

2.7 Registry Model Development

2.7.1 Model Overview

We used NCDR CathPCI Registry data that contains hospitalization associated with PCI. We derived the model using PCI hospitalizations for patients treated in 2007 ("development sample"). The performance of the model was then validated using patient stays with PCI for patients discharged in 2006 ("validation sample"). We computed indices that describe model performance in terms of predictive ability, discriminant ability, and overall fit.

2.8 Developmental Dataset

For development, CathPCI Registry data were linked to Medicare data using the probabilistic matching methodology described earlier. Among PCI patients ≥65 years old in the CathPCI Registry, 67% were successfully matched to CMS claims data for 2007 data. Results of the match were similar when we varied matching criteria (e.g., removing discharge date as a linking field). This rate is similar to that found during development of the two 30-day PCI mortality measures YNHHSC/CORE developed in 2008, and similar to that achieved by other investigators utilizing the same data (Douglas, Brennan et al. 2009). The characteristics and outcomes of matched and unmatched patients were similar, suggesting that the match was adequate for measure development, but not for measure implementation. Although 33% of patients did not match, the observed differences in characteristics of patients who did match and those who did not match were clinically modest (Table 4). Age, for example, was roughly one year higher in the matched group as compared to the unmatched group, which was statistically significant but clinically comparable. One area of concern was race; a much lower percentage of patients who matched were non-white, compared with those who did not match (11% and 16%, respectively). It was speculated during Technical Expert Panel (TEP) meetings that this difference may differences in demographics of patients across participating hospitals that participate in the NCDR, or differences in hospital resources of those hospitals that treat a high proportion of non-white patients.

When we compared the outcomes of patients in the Medicare claims data who did and did not match, the overall readmission and mortality rates were comparable. This finding suggests that the patients included in the derivation cohort are likely representative of the broader population of Medicare patients undergoing PCI (Table 5).

They are several factors that may influence the likelihood of a patient match. First, up to 14% of patients ≥65 years of age are enrolled in Medicare Advantage (Friedman, Jiang et al. 2006). Information about Medicare Advantage patients are not included in the FFS claims data and, accordingly, would not be available for matching. In addition, approximately 6-8% of cases submitted to the CathPCI Registry are not included in the analytic file because they did not pass the DQR process. Other contributing factors include patients ineligible for Medicare (e.g., non-U.S. citizens), patients with non-governmental insurance, and inaccuracies in linking fields (e.g., substituting age for date of birth).

Table 4 – Selected Patient Characteristics in NCDR Data for Matched and Unmatched Patients

Description	Not Matched #	Not Matched %	Matched #	Matched %
Demographics				
Age: Mean (SD)	73.87	6.5	74.71	6.6
Gender	28,668	39.4	59,907	40.9
Race: non-white	12,103	16.6	16,931	11.6
History and Risk Factors				
Body Mass Index (BMI)				
unknown	102	0.1	200	0.1
mean (SD)	28.66	5.8	28.57	5.8
Heart failure - previous history	9,679	13.3	20,742	14.2
Previous valvular surgery	1102	1.5	2,460	1.7
Cerebrovascular Disease	10,866	14.9	23,538	16.1
Peripheral Vascular Disease	10,670	14.7	22,942	15.7
Chronic Lung Disease	12,974	17.8	27,518	18.8
Diabetes/control				
No	48,064	66.0	97,813	66.8
Non-insulin diabetes	17,135	23.5	33,233	22.7
Insulin diabetes	7,585	10.4	15,282	10.4
Glomerular Filtration Rate (GFR)*				
not measured	2,612	3.6	5,545	3.8
GFR<30	2,898	4.0	6,704	4.6
30<=GFR<60	26,238	36.0	54,623	37.3
60<=GFR<90	34,609	47.6	67,309	46.0
GFR>=90	6,427	8.8	12,147	8.3
Previous PCI	27,133	37.3	56,012	38.3
Previous CABG	16,591	22.8	35,189	24.0
Cardiac Status				
Heart Failure - current status	8,607	11.8	18,480	12.6
New York Heart Association (NYHA)				
Class I	22,642	31.1	44,995	30.7
Class II	18,181	25.0	35,707	24.4
Class III	19,025	26.1	39,294	26.9
Class IV	12,936	17.8	26,332	18.0
Cardiogenic shock	1,792	2.5	3,551	2.4
Symptoms present on admission				
No MI	54,087	74.3	106,156	72.5
MI within 24 hours	14,445	19.8	31,299	21.4
MI after 24 hours	4,252	5.8	8,873	6.1
Cath Lab Visit				
Ejection fraction (EF) percentage				
not measured	22,397	30.8	43,433	29.7
EF<30	2,870	3.9	6,229	4.3
30<=EF<45	8,083	11.1	17,545	12.0
EF>=45	39,434	54.2	79,121	54.1
PCI Procedure				
PCI status				
Elective	38,165	52.4	74,061	50.6
Urgent	25,602	35.2	52,571	35.9
Emergency	8,782	12.1	19,263	13.2
Salvage	235	0.3	433	0.3
Highest risk lesion: SCAI** lesion class				
I	38,251	52.6	77769	53.1
II	24,442	33.6	49,575	33.9
III	3,504	4.8	6,719	4.6
IV	6,587	9.1	12,265	8.4

* Calculated using Modification of Diet and Renal Disease (MDRD) equation

** Society for Cardiovascular Angiography and Interventions

In addition, we examined characteristics and outcomes of the matched and unmatched cohorts derived from the Medicare data (Table 5).

Table 5 – Selected Patient Characteristics and Outcomes in Medicare Data for Matched and Unmatched Patients

Description	Not Matched #	Not Matched %	Matched #	Matched %
Total	32,107		146,328	
Age: Mean (SD)	74.8	6.7	74.7	6.6
Female	13,662	42.6	59,907	40.9
Unstable angina (Index principle code 411)	91	0.3	281	0.2
AMI (Index principle code: 410)	9,302	29.0	42,279	28.9
Coronary Atherosclerosis (Index principle code: 414)	19503	60.7	91,670	62.7
Heart failure (HF)*	629	2.0	2,329	1.6
Outcome				
In-hospital mortality	676	2.1	2,602	1.8
Mortality within one month of discharge	401	1.3	1,561	1.1
Readmission within one month of discharge	4,466	14.7	19,359	13.7
Readmission** within one month of discharge	3,597	11.8	15,448	11.0

2.9 Candidate and Final Variables

Our goal was to develop a model that included clinically relevant variables that are strongly associated with risk of 30-day readmission.

To select candidate variables, a team of clinicians reviewed the variables collected in the NCDR CathPCI Registry database that were previously considered as candidates in the PCI mortality models. We then modified the list of candidate variables as appropriate for a readmission measure such as the total number of significantly diseased arteries. A copy of the data collection form and the complete list of variables collected and submitted by hospitals can be found at http://www.ncdr.com. We excluded variables not deemed appropriate as 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]). Variables were also considered ineligible if they were particularly vulnerable to gaming or were deemed to lack clinical relevance. Based on careful review by our

* HF defined by ICD-9 diagnosis codes 428.XX, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, or 404.93.

** Readmissions with revascularization in patients without myocardial infarction, heart failure, unstable angina, cardiac arrest or arrhythmia were not considered readmissions.

working group members and the TEP, and further informed by a review of the literature, a total of 29 variables were determined to be appropriate for consideration as candidate variables. Our set of candidate variables (see Table 6) included two “demographic” variables (age and gender), 15 “history and risk factor” variables, five “cardiac status” variables, three “cath lab visit” variables, and four “PCI procedure” variables.

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 7).

Table 6 – PCI Model Candidate Variables

Description	NCDR Item Number	Name
Demographic		
Age	252	Age
Female	260	FEMALE
History and Risk Factors		
BMI*	Derived (410, 412)	BMI
Previous MI	420	PrevMI
Heart Failure-previous history	424	PrCHF
Previous valvular surgery	426	PrValve
Cerebrovascular Disease	450	CVD
Peripheral Vascular Disease	452	PVD
Chronic Lung Disease	454	CLD
Diabetes	Derived (430, 432)	NewDIAB
None	Reference	
Non-insulin diabetes		NEWDIAB1
Insulin diabetes		NEWDIAB2
Glomerular Filtration Rate (GFR)	Derived (252, 260, 270, 439, 440)	GFR
Not measured	Derived	GFRGRP0
GFR<30	Derived	GFRGRP1
30≤GFR<60	Derived	GFRGRP2
60≤GFR<90	Reference	
GFR≥90	Derived	GFRGRP4
Renal failure-dialysis	444	Dialysis
Hypertension	456	Hypertn
History of tobacco use	460	Tobacco
Family history of CAD	480	FHCAD
Previous PCI	490	PrPCI
Previous CABG	494	PrCAB
Cardiac Status		
Heart failure - current status	500	CHF
NYHA	510	ClassNYH
Class I or II	Reference	
Class III	Derived	NYHC3
Class IV	Derived	NYHC4
Cardiogenic shock	520	
ST elevation MI (STEMI)	Derived (550, 560, 812)	STEMI
Symptoms present on admission	Derived (550, 560)	AdmSxPre
No MI		ADMSX1
MI within 24 hours	Reference	
MI after 24 hours		ADMSX3
Cath Lab Visit		
Ejection Fraction (EF) Percentage	Derived (654, 656)	HDEFGRP
Not measured		HDEFGRP1
EF<30		HDEFGRP2
30≤EF<45		HDEFGRP3
EF≥45	Reference	
Left main disease	Derived (660, 661)	LMGT50

* For missing data in BMI, data were stratified by gender first, then set to the median in corresponding groups

Table 6 – PCI Model Candidate Variables (*cont.*)

Description	NCDR Item Number	Name
Number of vessels with disease	Derived (662 to 671)	VESSELD
≤1	Reference	
2	Derived	VESSELD2
3	Derived	VESSELD3
PCI Procedure		
PCI status	804	PCIStat
Elective	Reference	
Urgent	Derived	PCIS2
Emergency	Derived	PCIS3
Salvage	Derived	PCIS4
Highest Lesion location	Derived (900, 902)	NLESLOC
pRCA/mLAD/pCIRC	Derived	NLESLOC1
pLAD	Derived	NLESLOC2
Left main	Derived	NLESLOC3
Other	Derived	
Highest pre-procedure TIMI** flow: none	920	NPRETIMI
Highest risk lesion: SCAI*** lesion class	Derived (910, 950)	NSCAILC
I	Reference	
II	Derived	NSCAILC2
III	Derived	NSCAILC3
IV	Derived	NSCAILC4

** Thrombolysis in Myocardial Infarction

*** Society for Cardiovascular Angiography and Interventions

Table 7 – Final PCI Readmission Model Variables

Variable	Code
Demographic	
Age	Age
Female	FEMALE
History and Risk Factors	
Body Mass Index	BMI
Heart failure-previous history	PRCHF
Previous valvular surgery	PRVALVE
Cerebrovascular Disease	CVD
Peripheral Vascular Disease	PVD
Chronic Lung Disease	CLD
Diabetes	
None	Reference
Non-insulin diabetes	NEWDIAB1
Insulin diabetes	NEWDIAB2
Glomerular Filtration Rate (GFR)	
Not measured	GFRGRP0
GFR<30	GFRGRP1
30≤GFR<60	GFRGRP2
60≤GFR<90	Reference
GFR≥90	GFRGRP4
Renal failure - dialysis	DIALYSIS
Hypertension	HYPERTN
History of tobacco use	TOBACCO
Previous PCI	PrPCI
Cardiac Status	
Heart failure – current status	CHF
Symptoms present on admission	
No MI	ADMSX1
MI within 24 hours	Reference
MI after 24 hours	ADMSX3
Cath Lab Visit	
Ejection Fraction (EF) Percentage	
Not measured	HDEFGRP1
EF<30	HDEFGRP2
30≤EF<45	HDEFGRP3
EF≥45	Reference
PCI Procedure	
PCI status	
Elective	Reference
Urgent	PCIS2
Emergency	PCIS3
Salvage	PCIS4
Highest risk lesion – location	
pRCA/mLAD/pCIRC	NLESLOC1
pLAD	NLESLOC2
Left main	NLESLOC3
Other	Reference
Highest pre-procedure TIMI flow: none	

2.10 Statistical Approach to Model Development

We developed the risk adjustment model for the measure using the following methodology:

Because of the natural clustering of the observations within hospitals, we estimated hierarchical generalized linear models (HGLMs). We modeled the log-odds of readmission within 30 days of PCI hospitalization as a function of patient demographic and clinical characteristics and a random hospital-specific intercept. This strategy accounts for within-hospital correlation of the observed outcomes and models the assumption that underlying differences in quality among the health care facilities being evaluated lead to systematic differences in outcomes.

We used the above strategy to calculate the hospital-specific readmission rates. We use hierarchical logistic regression modeling to calculate hospital-specific risk-standardized readmission rates (RSRRs). These rates are calculated as the ratio of the predicted number of readmissions to the expected number of readmissions, multiplied by the national unadjusted readmission rate. The expected number of readmissions for each hospital was estimated using its patient mix and the average hospital-specific intercept. The predicted number of readmissions in each hospital was estimated given the same patient mix but an estimated hospital-specific intercept. Operationally, the expected number of readmissions for each hospital is obtained by summing the expected readmission rates for all patients in the hospital. The expected readmission rate for each patient is calculated via the hierarchical model by applying the subsequent estimated regression coefficients to the observed patient characteristics and adding the average of the hospital-specific intercepts. The predicted number of readmissions for each hospital is calculated by summing the predicted readmission rates for all patients in the hospital. The predicted readmission rate for each patient is calculated through the hierarchical model by applying the estimated regression coefficients to the patient characteristics observed and adding the hospital-specific intercept. In order to assess hospital performance in any specific year (e.g. the validation cohort), we re-estimate the model coefficients using that year's data.

More specifically, we estimate 2 types of regression models (Table 8, Table 13). First, we fit a generalized linear model (GLM) linking the outcome to the risk factors (McCullagh P 1989). Let Y_{ij} denote the outcome (equal to 1 if patient readmitted within 30 days, zero otherwise) for the j^{th} patient who underwent PCI at the i^{th} hospital; $\mathbf{Z}_{ij}$ denotes a set of risk factors, identified via administrative data. Let I denote the total number of hospitals and n_i the number of index patient stays in hospital i. We assume the outcome is related linearly to the covariates via a known linked function, h, where

$$\text{GLM} \qquad h(Y_{ij}) = \alpha + \beta \mathbf{Z}_{ij} \qquad (1)$$

and $\mathbf{Z}_{ij} = (Z_{1ij}, Z_{2ij}, \ldots, Z_{pij})$ is a set of p patient-specific covariates. In our case, h = the logit link.

To account for the natural clustering of observations within hospitals, we estimate a HGLM that links the risk factors to the same outcome and a hospital-specific random effect,

$$\text{HGLM} \qquad h(Y_{ij}) = \alpha_i + \beta \mathbf{Z}_{ij} \qquad (2)$$

$$\alpha_i = \mu + \omega_i; \qquad \omega_i \sim N(0, \tau^2) \qquad (3)$$

where α_i represents the hospital-specific intercept, $\mathbf{Z}_{ij}$ is defined as above, μ the adjusted average outcome over all hospitals in the sample, and τ^2 the between-hospital variance component (Gatsonia CA 1999). This model separates within-hospital variation from between-hospital variation. Both HGLMs and GLMs are estimated using the SAS software system (GLIMMIX and LOGISTIC procedures, respectfully).

We first fit the GLM described in Equation (1) using the logit link.
Having identified the covariates that remained, we next fit the HGLM described in Equations (2) and (3), again using the logit link function; e.g.,

$$\text{Logit}\mathbf{Z}_{ij} \; (P(Y_{ij} = 1)) = \alpha_i + \beta$$
$$\alpha_i = \mu + \omega_i; \;\; \omega_i \sim N(0, \tau^2)$$

where $\mathbf{Z}_{ij}$ consisted of the covariates retained in the GLM model. As before, $Y_{ij} = 1$ if patient j treated at hospital i had the event; 0 otherwise.

2.11 Hospital Performance Reporting

Using the set of risk factors in the GLM, we fit the HGLM defined by Equations (2) - (3) and estimate the parameters, $\hat{\mu}$, $\{\hat{\alpha}_i, \hat{\alpha}_2, \ldots, \hat{\alpha}_I\}$, $\hat{\beta}$, and $\hat{\tau}^2$. We calculate a standardized outcome, s_i, for each hospital by computing the ratio of the number of predicted readmissions to the number of expected readmissions, multiplied by the unadjusted overall readmission rate, $\bar{y}$. Specifically, we calculate

$$\text{Predicted} \qquad \hat{y}_{ij}(Z) = h^{-1}(\hat{\alpha}_i + \hat{\beta}\mathbf{Z}_{ij}) \qquad (4)$$

$$\text{Expected} \qquad \hat{e}_{ij}(Z) = h^{-1}(\hat{\mu} + \hat{\beta}\mathbf{Z}_{ij}) \qquad (5)$$

$$\hat{s}_i(Z) = \frac{\sum_{j=1}^{n_i} \hat{y}_{ij}(Z)}{\sum_{j=1}^{n_i} \hat{e}_{ij}(Z)} \times \bar{y} \qquad (6)$$

If more (fewer) "predicted" cases than "expected" cases have the outcome in a hospital, then $\hat{s}_i$ will be higher (lower) than the unadjusted average. For each hospital, we compute an interval estimate of s_i to characterize the level of uncertainty around the point estimate using bootstrapping simulations. The point estimate and interval estimate can be used to characterize and compare hospital performance (e.g., higher than expected, as expected, or lower than expected).

2.11.1 Creating Interval Estimates

Because the statistic described in Equation 6 (Section 2.11) is a complex function of parameter estimates, we use re-sampling and simulation techniques to derive an interval estimate. The bootstrapping simulation has the advantage of avoiding unnecessary distributional assumptions.

2.11.2 Algorithm

Let *I* denote the total number of hospitals in the sample. We repeat steps 1 – 4 below for b = 1,2,…B times:

1. Sample *I* hospitals with replacement.

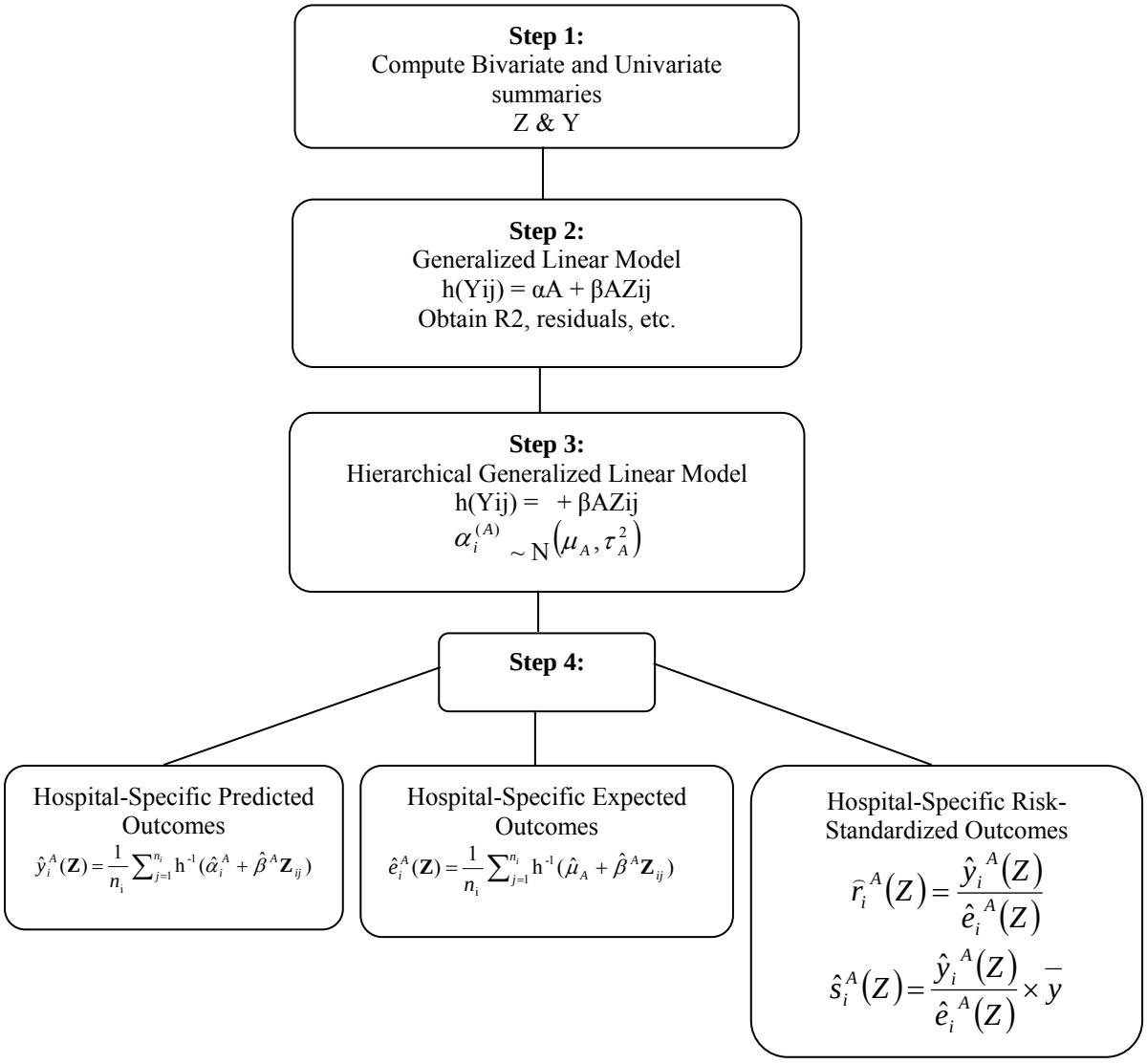
2. Fit the HGLM using all patients within each sampled hospital. We use as starting values the parameter estimates obtained by fitting the model to all hospitals. If some hospitals are selected more than once in a bootstrapped sample, we treat them as distinct so that we have *I* random effects to estimate the variance components. At the conclusion of Step 2, we have:
   a. $\hat{\beta}^{(b)}$ (the estimated regression coefficients of the risk factors).
   b. The parameters governing the random effects, hospital adjusted outcomes, distribution, $\hat{\mu}^{(b)}$ and $\hat{\tau}^{2(b)}$.
   c. The set of hospital-specific intercepts and corresponding variances, $\{\hat{\alpha}_i^{(b)}, \hat{\mathrm{var}}(\alpha_i^{(b)}); i = 1,2,\ldots,I\}$.

3. We generate a hospital random effect by sampling from the distribution of the hospital-specific distribution obtained in Step 2c. We approximate the distribution for each random effect by a normal distribution. Thus, we draw $\alpha_i^{(b^*)} \sim N\left(\hat{\alpha}_i^{(b)}, \hat{\mathrm{var}}\left(\hat{\alpha}_i^{(b)}\right)\right)$ for the unique set of hospitals sampled in Step 1.

4. Within each unique hospital *i* sampled in Step 1, and for each case *j* in that hospital, we calculate $\hat{y}_{ij}^{(b)}$, $\hat{e}_{ij}^{(b)}$, and $\hat{s}_i(Z)^{(b)}$ where $\hat{\beta}^{(b)}$ and $\hat{\mu}^{(b)}$ are obtained from Step 2 and $\hat{\alpha}_i^{(b*)}$ is obtained from Step 3.

Ninety-five percent interval estimates (or alternative interval estimates) for the hospital-standardized outcome can be computed by identifying the 2.5th and 97.5th percentiles of randomly half of the B estimates (or the percentiles corresponding to the alternative desired intervals) (Normand, Wang et al. 2007).

Figure 6 – Analysis Steps



3. RESULTS

3.1 Model Results

3.1.1 Development

The variable descriptions, standardized estimates, and standard errors for the GLM model are shown in Table 8. The standardized estimates are regression coefficients expressed in units of standard deviations and can range between -1 and 1, with ±1 indicating a perfect linear relationship and 0 indicating no linear relationship.1 The corresponding descriptions, estimates, and standard errors for the HGLM model are shown in Table 13 (HGLM).[1]

3.1.2 Model Performance

We computed 6 summary statistics for assessing model performance (Harrell, 2001): over-fitting indices[2], percentage of variation explained by the risk factors, predictive ability, area under the receiver operating characteristic (ROC) curve, distribution of residuals, and model chi-square[3] (see Table 10).

The development model has strong discrimination and fit. The readmission rate ranges from 4.1% in the lowest predicted decile to 25.1% in the highest predicted decile, a range of 21.0%. The area under the ROC curve is 0.665 (GLM).

The discrimination and the explained variation of the model are consistent with those of published AMI, HF, and Pneumonia. The ROC is higher than that of previously published models for readmission, likely reflecting the advantages of using registry as opposed to claims data for risk adjustment. Nevertheless, the ROC is substantially lower than that of the NQF

[1] Standardized estimates are like correlation coefficients. We compute them in order to compare the size of the coefficients by standardizing the coefficients to be unitless.

[2] Over-fitting refers to the phenomenon in which a model well describes the relationship between predictive variables and outcome in the development dataset, but fails to provide valid predictions in new patients.

[3] Chi-Square – A test of statistical significance usually employed for categorical data to determine whether there is a good fit between the observed data and expected values; i.e., whether the differences between observed and expected values are attributable to true differences in characteristics or instead the result of chance variation. The formula for computing the chi-square is as follows:

$$\sum \frac{(O-E)^2}{E}$$

where O = observed value
E = expected value, and
degrees of freedom (df) = (rows-1)(columns-1)

approved PCI mortality measures. Readmissions are inherently more difficult to predict than mortality, with the risk of readmission more dependent on local practice patterns than patient characteristics. In addition, we did not consider covariates such as potential complications, certain patient demographics (e.g., race), and patients' admission path (e.g., outpatient, emergency department), and discharge destination (e.g. Discharged to home versus other facilities, both non-acute and acute care). These characteristics may be associated with readmission and thus could increase the model performance to predict patient readmission. However, these variables may be related to quality or supply factors that should not be included in an adjustment that seeks to control for patient clinical characteristics. As a result of these considerations the choice was made to focus on adjustment for clinical differences in the populations among hospitals. That is, we focused on patient characteristics present at the time of the procedure even though the time zero for the measure was discharge.

Table 8 – 30-Day Readmission Model (2007 Development Sample-GLM Results [ROC=0.665])*

Description	Estimate	S.E.	Wald Chi-Square	Pr > ChiSq	Standardized Estimates	OR (LOR, UOR)
Intercept	-3.84	0.15	689.5	0.00		
Age/10	0.23	0.01	246.4	0.00	0.08	1.26 (1.22, 1.29)
Female	0.26	0.02	184.4	0.00	0.07	1.29 (1.25, 1.34)
BMI/5	-0.13	0.01	84.8	0.00	-0.05	0.88 (0.86, 0.90)
CHF - Previous History	0.27	0.03	109.9	0.00	0.05	1.31 (1.25, 1.38)
Previous Valvular Surgery	0.19	0.06	9.4	0.00	0.01	1.21 (1.07, 1.37)
Cerebrovascular disease	0.19	0.02	66.3	0.00	0.04	1.21 (1.15, 1.26)
Peripheral Vascular Disease	0.20	0.02	67.5	0.00	0.04	1.22 (1.16, 1.28)
Chronic Lung disease	0.33	0.02	226.0	0.00	0.07	1.40 (1.34, 1.46)
Non-Insulin diabetes	0.12	0.02	26.7	0.00	0.03	1.12 (1.08, 1.18)
Insulin diabetes	0.33	0.03	127.1	0.00	0.05	1.39 (1.31, 1.47)
GFR: 0=Not measured	0.04	0.05	0.5	0.49	0.00	1.04 (0.94, 1.15)
GFR: 1="0<=GFR<30"	0.56	0.04	156.8	0.00	0.06	1.76 (1.61, 1.92)
GFR: 2="30<=GFR<60"	0.16	0.02	56.4	0.00	0.04	1.17 (1.12, 1.22)
GFR: 4="GFR>=90"	0.15	0.04	19.2	0.00	0.02	1.17 (1.09, 1.25)
Renal Failure - Dialysis	0.39	0.06	42.0	0.00	0.03	1.48 (1.32, 1.67)
Hypertension	0.08	0.03	9.7	0.00	0.02	1.08 (1.03, 1.14)
History of Tobacco Use	-0.05	0.01	11.0	0.00	-0.02	0.95 (0.93, 0.98)
Previous PCI	-0.08	0.02	18.2	0.00	-0.02	0.92 (0.89, 0.96)
CHF - Current Status	0.29	0.03	124.3	0.00	0.05	1.34 (1.27, 1.41)
No MI on admission	-0.13	0.03	23.8	0.00	-0.03	0.88 (0.83, 0.92)
MI after 24 hours on admission	0.10	0.04	7.2	0.01	0.01	1.11 (1.03, 1.19)
EFP: 1=Not measured	0.21	0.02	98.5	0.00	0.05	1.23 (1.18, 1.29)
EFP: 2="0<=EFP<30"	0.37	0.04	81.1	0.00	0.04	1.45 (1.34, 1.57)
EFP: 3="30<=EFP<45"	0.22	0.03	61.8	0.00	0.04	1.25 (1.18, 1.32)
PCI status: 2=Urgent	0.33	0.02	246.7	0.00	0.09	1.39 (1.33, 1.45)
PCI status: 3=Emergency	0.38	0.04	108.6	0.00	0.07	1.46 (1.36, 1.57)
PCI status: 4=Salvage	0.54	0.20	7.4	0.01	0.01	1.71 (1.16, 2.52)
pRCA/mLAD/pCIRC	0.04	0.02	4.4	0.04	0.01	1.04 (1.00, 1.09)
pLAD	0.12	0.03	21.8	0.00	0.02	1.13 (1.07, 1.19)
Left Main	0.15	0.06	7.2	0.01	0.01	1.16 (1.04, 1.30)
Highest Pre-Procedure TIMI Flow: None	0.08	0.03	5.8	0.02	0.01	1.09 (1.02, 1.16)

* N=128,745 in 766 hospitals; 11.1% readmission rate

3.1.3 Model Validation

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 standardized estimates and standard errors for the 2006 validation dataset are shown in Table 9, and the performance metrics are shown in Table 10. The performance was not substantively different in this validation sample (ROC=0.663), as compared to the development sample (ROC=0.665). As the results in Table 10 show, the 2006 and 2007 models are similarly calibrated.

We also examined the temporal variation of the standardized estimates and frequencies of the variables in the models (Tables 11 and 12). The frequencies and regression coefficients are fairly consistent over the two years of data.

To assess the predictive ability of the model, we grouped patients into deciles of predicted 30-day readmission. We then compared predicted readmission with observed readmission for each decile in the derivation cohort (Figure 7). Overall there was excellent correlation between predicted and observed readmission.

Figure 7 – Observed Readmission by Predicted Readmission per Decile (R^2=0.999)

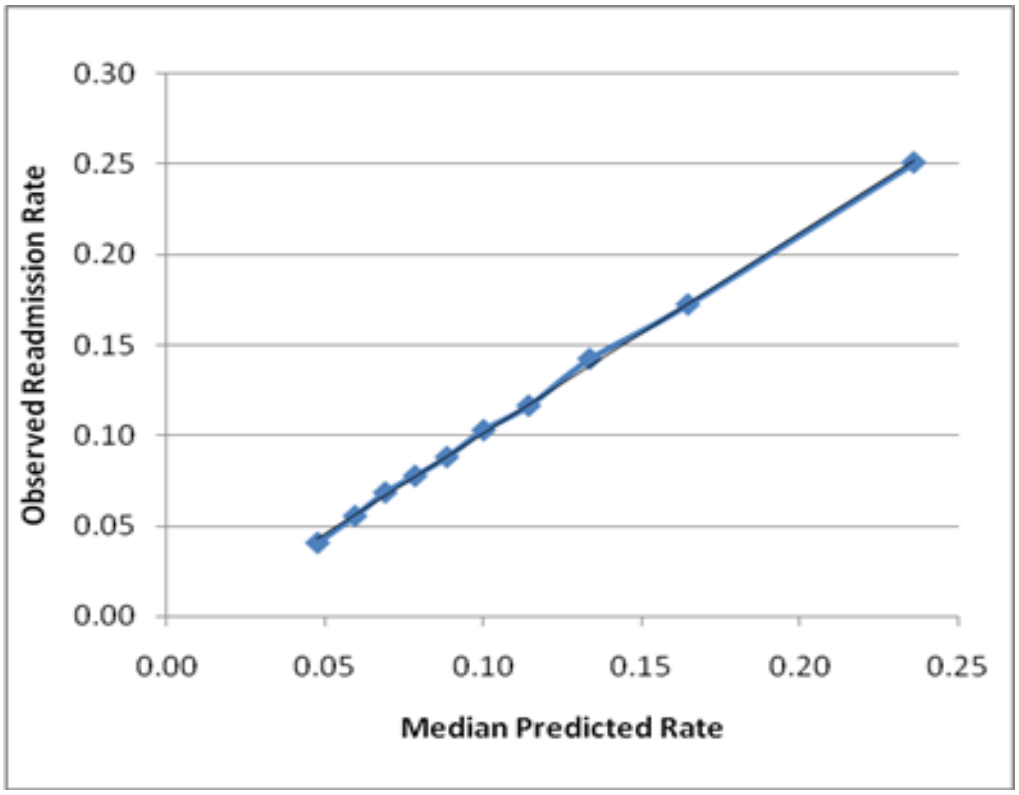


Table 9 – 30-Day Readmission* Model (2006 Validation Sample-GLM Results [ROC:0.663])**

Label	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq	Standardized Estimates	OR (LOR, UOR)
Intercept	-4.25	0.16	730.5	0.00		
Age/10	0.27	0.02	290.2	0.00	0.10	1.31 (1.27, 1.35)
Female	0.24	0.02	135.2	0.00	0.06	1.27 (1.22, 1.32)
BMI/5	-0.11	0.01	57.3	0.00	-0.04	0.89 (0.87, 0.92)
Heart Failure - previous history	0.31	0.03	127.5	0.00	0.06	1.36 (1.29, 1.43)
Previous valvular surgery	0.17	0.07	5.9	0.01	0.01	1.18 (1.03, 1.35)
Cerebrovascular disease	0.13	0.02	28.3	0.00	0.03	1.14 (1.09, 1.20)
Peripheral Vascular Disease	0.26	0.03	105.1	0.00	0.05	1.29 (1.23, 1.36)
Chronic Lung Disease	0.32	0.02	183.4	0.00	0.07	1.38 (1.31, 1.44)
Non-insulin diabetes	0.15	0.02	38.9	0.00	0.03	1.16 (1.11, 1.22)
Insulin diabetes	0.37	0.03	141.0	0.00	0.06	1.45 (1.36, 1.54)
GFR: 0=not measured	0.08	0.05	2.6	0.11	0.01	1.09 (0.98, 1.20)
GFR: 1="0<=GFR<30"	0.57	0.05	143.1	0.00	0.06	1.77 (1.61, 1.94)
GFR: 2="30<=GFR<60"	0.15	0.02	46.0	0.00	0.04	1.16 (1.11, 1.21)
GFR: 4="GFR>=90"	0.11	0.04	7.6	0.01	0.02	1.11 (1.03, 1.20)
Renal failure - dialysis	0.35	0.07	27.2	0.00	0.02	1.42 (1.25, 1.62)
Hypertension	0.02	0.03	0.7	0.39	0.00	1.02 (0.97, 1.08)
History of tobacco use	-0.06	0.02	17.9	0.00	-0.02	0.94 (0.91, 0.97)
Previous PCI	-0.10	0.02	23.4	0.00	-0.03	0.90 (0.87, 0.94)
Heart failure - current status	0.24	0.03	72.8	0.00	0.04	1.27 (1.20, 1.34)
No MI on admission	-0.03	0.03	0.7	0.40	-0.01	0.98 (0.92, 1.03)
MI after 24 hours on admission	0.14	0.04	11.7	0.00	0.02	1.15 (1.06, 1.25)
EFP: 1=not measured	0.16	0.02	48.3	0.00	0.04	1.17 (1.12, 1.22)
EFP: 2="0<=EFP<30"	0.41	0.04	88.4	0.00	0.04	1.51 (1.38, 1.64)
EFP: 3="30<=EFP<45"	0.17	0.03	31.7	0.00	0.03	1.18 (1.12, 1.26)
PCI status: 2=urgent	0.38	0.02	293.9	0.00	0.10	1.46 (1.40, 1.52)
PCI status: 3=emergency	0.46	0.04	135.3	0.00	0.08	1.58 (1.46, 1.71)
PCI status: 4=salvage	0.44	0.25	3.1	0.08	0.01	1.55 (0.95, 2.53)
pRCA/mLAD/pCIRC	0.09	0.02	18.1	0.00	0.02	1.10 (1.05, 1.14)
pLAD	0.11	0.03	15.4	0.00	0.02	1.11 (1.06, 1.18)
Left main	0.07	0.06	1.1	0.28	0.01	1.07 (0.95, 1.20)
Highest pre-procedure TIMI flow: none	0.08	0.04	4.4	0.04	0.01	1.08 (1.01, 1.17)

* Readmissions with revascularization but without myocardial infarction, heart failure, unstable angina, cardiac arrest or arrhythmia are not counted as readmissions

** N=117,375 in 618 hospitals; 10.7% readmission rate

Table 10 – 30-Day Readmission Model Performance: Results Based on the GLM

Indices	Development Sample	Validation Sample
Year	2007	2006
N	128745	117375
RR	11.1%	10.7%
Calibration (γ0, γ1)[1]	(0.00, 1.00)	(-0.06, 0.99)
Discrimination- Adjusted R-Square[2]	0.07	0.06
Discrimination -Predictive Ability[3] (lowest decile %, highest decile %)	(4.05, 25.08)	(3.80, 23.80)
Discrimination – ROC	0.665	0.663
Residuals Lack of Fit (Pearson Residual Fall %)		
<-2	0.00	0.00
[-2, 0)	88.86	89.33
[0, 2)	2.21	1.85
[2+	8.93	8.82
Model χ^2 [Number of Covariates][4]	4448.36 [31]	3812.62 [31]

[1] Over-Fitting Indices (γ_0, γ_1) provide evidence of over-fitting and require several steps to calculate. Let *b* denote the *estimated vector* of regression coefficients. *Predicted Probabilities* ($\hat{p}$) = 1/(1+exp{-Xb}), and *Z* = *Xb* (e.g., the linear predictor that is a scalar value for everyone). A new logistic regression model that includes only an intercept and a slope by regressing the logits on *Z* is fitted in the validation sample; e.g., Logit(P(Y=1|Z)) = $\gamma_0 + \gamma_1 Z$. Estimated values of γ_0 far from 0 and estimated values of γ_1 far from 1 provide evidence of over-fitting.

[2] Max-rescaled R-Square

[3] Observed Rates

[4] Wald Chi-Square

Table 11 – 30-Day Readmission Model (GLM) Standardized Estimates by Year of Discharge (2006-2007)

Description	2006 (Validation) (N=117,375 in 618 hospitals; 10.7% RR*)	2007 (Development) (N=128,745 in 766 hospitals; 11.1% RR)
Age/10	0.10	0.08
Female	0.06	0.07
Body Mass Index/5	-0.04	-0.05
Heart Failure - previous history	0.06	0.05
Previous valvular surgery	0.01	0.01
Cerebrovascular Disease	0.03	0.04
Peripheral Vascular Disease	0.05	0.04
Chronic Lung disease	0.07	0.07
Non-insulin diabetes	0.03	0.03
Insulin diabetes	0.06	0.05
Glomerular Filtration Rate (GFR): 0=not measured	0.01	0.00
GFR: 1="0<=GFR<30"	0.06	0.06
GFR: 2="30<=GFR<60"	0.04	0.04
GFR: 4="GFR>=90"	0.02	0.02
Renal failure - dialysis	0.02	0.03
Hypertension	0.00	0.02
History of tobacco use	-0.02	-0.02
Previous PCI	-0.03	-0.02
Heart failure - current status	0.04	0.05
No MI on admission	-0.01	-0.03
MI after 24 hours on admission	0.02	0.01
Ejection Fraction Percentage (EFP): 1=not measured	0.04	0.05
EFP: 2="0<=EFP<30"	0.04	0.04
EFP: 3="30<=EFP<45"	0.03	0.04
PCI status: 2=urgent	0.10	0.09
PCI status: 3=emergency	0.08	0.07
PCI status: 4=salvage	0.01	0.01
pRCA/mLAD/pCIRC	0.02	0.01
pLAD	0.02	0.02
Left main	0.01	0.01
Highest pre-procedure TIMI flow: none	0.01	0.01

* Readmission rate

Table 12 – 30-Day Readmission Model (GLM) Risk Factor Frequency by Year of Discharge (2005-2007)

Description	2006 (Validation) N=117,375 in 618 Hospitals with a 10.7 RR* %	2007 (Development) N=128,745 in 766 Hospitals with a 11.1 RR %
Age/10	74.7 (6.5)	74.7 (6.6)
Female	41.8	41.2
BMI/5		
Unknown	0.1	0.1
Mean (SD)	28.5 (5.7)	28.6 (5.8)
Heart failure - previous history	13.8	13.8
Previous valvular surgery	1.6	1.7
Cerebrovascular Disease	16.0	16.0
Peripheral Vascular Disease	15.6	15.6
Chronic Lung Disease	18.6	18.6
Non-Insulin diabetes	22.4	22.6
Insulin diabetes	9.8	10.1
GFR: 0=Not measured	4.0	3.7
GFR: 1="0<=GFR<30"	4.0	4.3
GFR: 2="30<=GFR<60"	36.6	37.2
GFR: 4="GFR>=90"	8.3	8.3
Renal Failure - Dialysis	1.6	1.9
Hypertension	81.8	82.9
History of Tobacco Use	11.8	11.9
Previous PCI	35.9	37.2
Heart failure - current status	12.0	11.9
No MI on admission	75.4	73.5
MI after 24 hours on admission	5.7	6.0
EFP: 1=Not measured	28.3	28.5
EFP: 2="0<=EFP<30"	3.9	3.9
EFP: 3="30<=EFP<45"	11.9	11.9
PCI status: 2=Urgent	36.0	36.4
PCI status: 3=Emergency	11.1	12.2
PCI status: 4=Salvage	0.1	0.1
pRCA/mLAD/pCIRC	38.2	37.9
pLAD	17.6	17.3
Left main	2.4	2.4
Highest Pre-Procedure TIMI Flow: None	7.8	8.7

* Readmission rate

Table 13 – 30-Day Readmission[*] (2007 Development Sample – HGLM Results [ROC=0.677])[#] [+]

Description	Estimate	Standard Error	T-Value	Pr > T-Value	Odds Ratio (95% CI)
Intercept	-3.84	0.15	-26.38	0.00	
Age/10	0.23	0.01	15.67	0.00	1.26 (1.22, 1.29)
Female	0.25	0.02	13.42	0.00	1.29 (1.24, 1.33)
BMI/5	-0.13	0.01	-9.27	0.00	0.88 (0.86, 0.90)
Heart failure - previous history	0.27	0.03	10.68	0.00	1.32 (1.25, 1.38)
Previous valvular surgery	0.20	0.06	3.28	0.00	1.23 (1.09, 1.38)
Cerebrovascular Disease	0.19	0.02	8.37	0.00	1.21 (1.16, 1.27)
Peripheral Vascular Disease	0.20	0.02	8.38	0.00	1.22 (1.16, 1.28)
Chronic Lung Disease	0.33	0.02	15.11	0.00	1.40 (1.34, 1.46)
Non-Insulin diabetes	0.11	0.02	5.11	0.00	1.12 (1.07, 1.17)
Insulin diabetes	0.32	0.03	11.18	0.00	1.38 (1.30, 1.46)
GFR: 0=Not measured	0.03	0.05	0.58	0.56	1.03 (0.93, 1.14)
GFR: 1="0<=GFR<30"	0.57	0.04	12.72	0.00	1.76 (1.62, 1.92)
GFR: 2="30<=GFR<60"	0.16	0.02	7.75	0.00	1.17 (1.13, 1.22)
GFR: 4="GFR>=90"	0.15	0.04	4.20	0.00	1.16 (1.08, 1.24)
Renal failure - dialysis	0.38	0.06	6.29	0.00	1.46 (1.40, 1.65)
Hypertension	0.08	0.03	3.08	0.00	1.08 (1.03, 1.14)
History of tobacco use	-0.05	0.01	-3.38	0.00	0.95 (0.93, 0.98)
Previous PCI	-0.08	0.02	-4.26	0.00	0.92 (0.89, 0.96)
Heart failure - current status	0.30	0.03	11.27	0.00	1.35 (1.28, 1.42)
No MI on admission	-0.13	0.03	-4.70	0.00	0.88 (0.83, 0.93)
MI after 24 hours on admission	0.10	0.04	2.73	0.01	1.11 (1.03, 1.19)
EFP: 1=Not measured	0.19	0.02	8.76	0.00	1.21 (1.16, 1.26)
EFP: 2="0<=EFP<30"	0.36	0.04	8.74	0.00	1.43 (1.32, 1.55)
EFP: 3="30<=EFP<45"	0.21	0.03	7.66	0.00	1.24 (1.17, 1.31)
PCI status: 2=Urgent	0.36	0.02	16.40	0.00	1.43 (1.37, 1.50)
PCI status: 3=Emergency	0.40	0.04	11.00	0.00	1.49 (1.39, 1.60)
PCI status: 4=Salvage	0.59	0.20	3.01	0.00	1.81 (1.23, 2.65)
pRCA/mLAD/pCIRC	0.04	0.02	2.12	0.03	1.04 (1.00, 1.09)
pLAD	0.12	0.03	4.72	0.00	1.13 (1.07, 1.19)
Left main	0.15	0.06	2.77	0.01	1.17 (1.05, 1.30)
Highest pre-procedure TIMI flow: none	0.09	0.03	2.64	0.01	1.09 (1.02, 1.17)

[*] Between hospital variance=0.03813. Standard error=0.005500.

[#] Readmissions with revascularization but without myocardial infarction, heart failure, unstable angina, cardiac arrest or arrhythmia are not counted as readmissions

[+] N=128,745 in 766 hospitals; 11.1% readmission rate

3.1.4 30-Day Readmission Rate Distribution - With and Without Risk-Adjustment

Figure 8 and Figure 9 display the frequency distributions of the hospital-specific 30-day readmission rates, with and without risk-adjustment in the 2007 cohort. Figure 10 and Figure 11 display these results by hospital volume quartiles for the unadjusted and adjusted rates, respectively.

The observed readmission rate ranged from 0% to 100% across the 766 hospitals with a median (quartile range) of 10.8% (8.6%, 13.4%) (Figure 8), with low-volume hospitals demonstrating the greatest variation in crude rates (Figure 10). After adjusting for patient and clinical characteristics, the risk-standardized rates were found to be more normally distributed, both overall (Figure 9) and by hospital volume (Figure 11).

Figure 8 – Distribution of Unadjusted Hospital-level 30-Day Readmission Rates (2007 Development Sample; N=766 Hospitals)

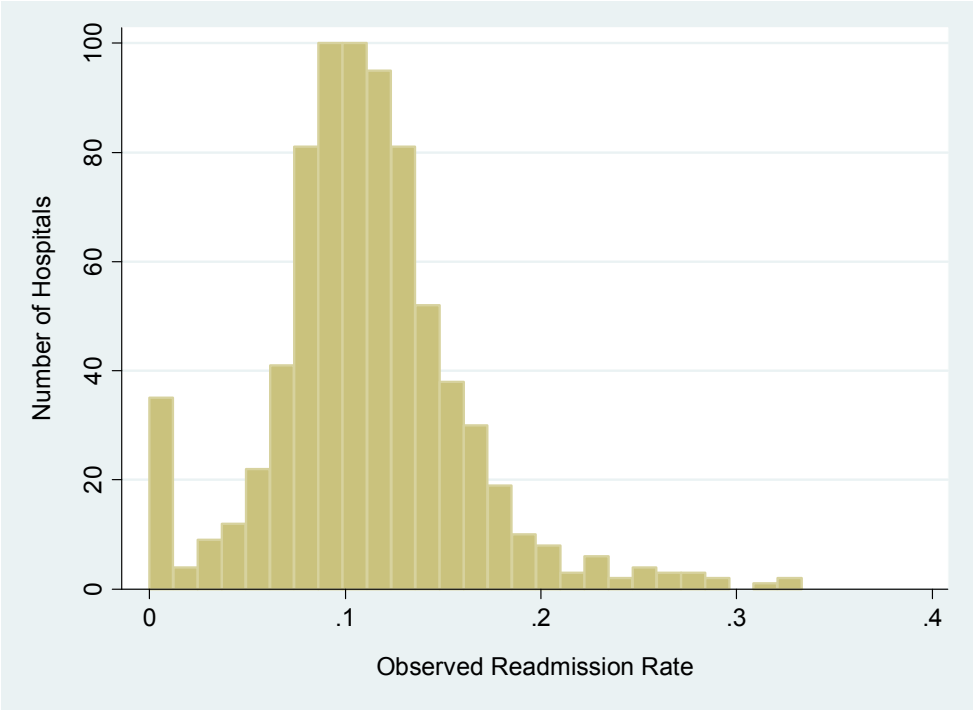


Figure 9 – Distribution of Risk-Standardized Hospital-level 30-Day Readmission Rates (2007 Development Sample; N=766 Hospitals) – HGLM

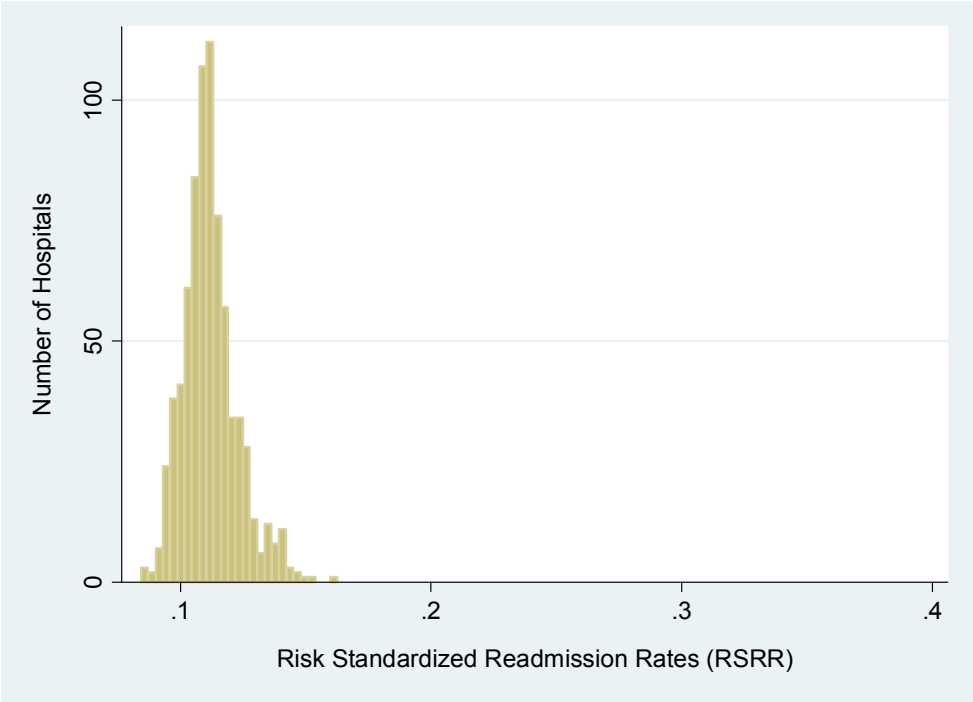


Figure 10 – Distribution of Unadjusted Hospital-level 30-Day Readmission Rates by Hospital Volume (2007 Development Sample; N=766 Hospitals)

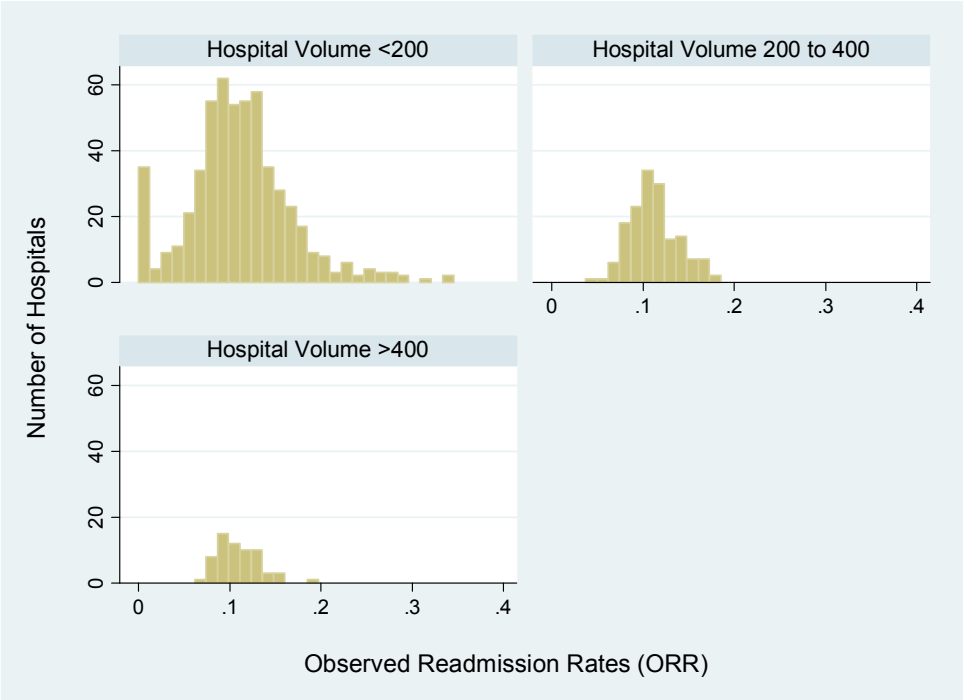
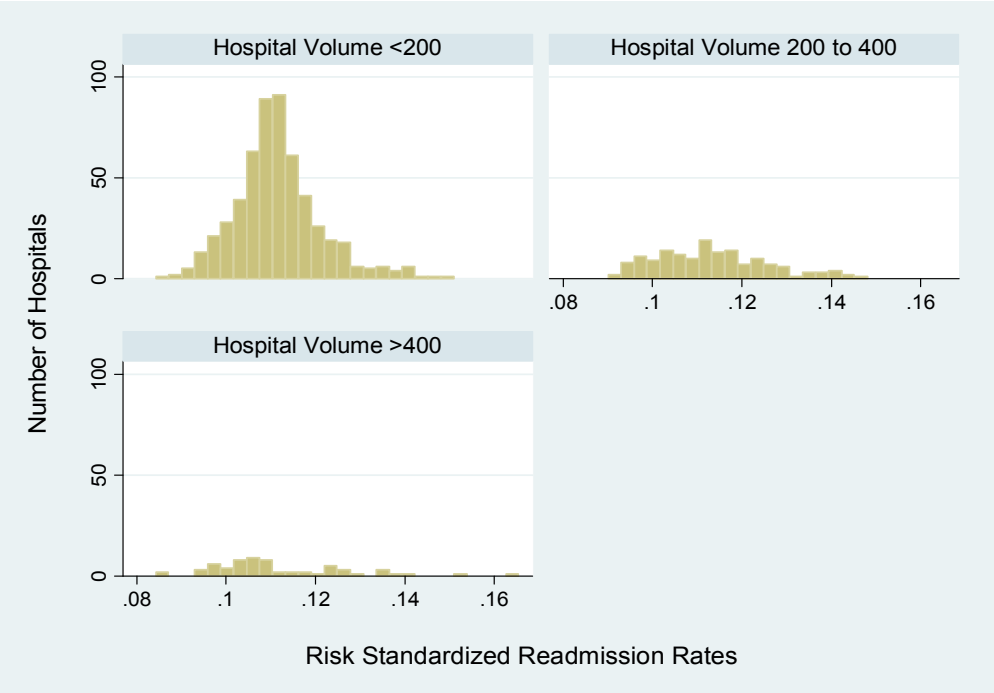


Figure 11 – Distribution of Risk-Standardized Hospital-level 30-Day Readmission Rates by Hospital Volume (2007 Development Sample; N=766)



4. POTENTIAL APPROACHES TO IMPLEMENTATION

While the model we developed has attributes that make it suitable for public reporting, additional steps will be necessary prior to implementation. We developed the model from a dataset that merged CathPCI Registry data with administrative claims data using a probabilistic match. The resulting dataset was adequate for developing a model of 30-day PCI readmission. However, implementing the measure will ideally require linking the NCDR data with administrative data sources based on a unique patient identifier common to both the NCDR and administrative data sets. This unique identifier is not yet in place for all patients undergoing PCI. However, processes necessary to routinely collect patient identifiers will have to be implemented prior to efforts to publicly report these measures. Additionally, although more than half of hospitals that perform PCI in the United States currently participate in the CathPCI Registry; public reporting will require collecting and merging data from all hospitals through CathPCI and/or other mechanisms prior to implementation.

As discussed, publicly reporting hospital risk standardized 30-day readmission rates requires that the data submitted by hospitals be complete, consistent, and accurate. Steps to ensure data quality could include monitoring data for variances in case mix (e.g., unexpectedly high proportion of salvage PCI or cardiogenic shock), chart audits, and possibly adjudicating cases that are vulnerable to systematic misclassification. This approach has been successfully implemented in the Massachusetts program for public reporting of PCI mortality, with significant rates of reclassification of cases initially classified as cardiogenic shock or salvage PCI, and elimination of some variables with poor reliability (Normand 2008).

5. MAIN FINDINGS / SUMMARY

We present a hierarchical logistic regression model for 30-day PCI readmission that is based on data from the NCDR CathPCI Registry and is suitable for public reporting. Our approach to risk adjustment is tailored to and appropriate for a publicly reported outcome measure. The study sample is appropriately defined, consisting of a PCI population that has distinct outcomes that will allow for valid comparisons of hospital outcomes. The 30-day outcome provides a standardized period of follow-up. The statistical approach takes into account the clustering of patients within hospitals and differences in sample size across hospitals. The models have good patient-level discrimination and explained variation. Finally, the overall approach is consistent with previously developed 30-day PCI mortality measures (Yale-CORE 2008).

In summary, we present a registry-based model of 30-day PCI readmission that is suitable for public reporting.

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7. APPENDIX

7.1 Appendix A- Top 50 ICD-9 Diagnosis Codes Associated with PCI Readmissions

Diagnosis Code	Count	Percent	Description
428	5791	12.10	Heart failure
414	4411	9.22	Other forms of chronic ischemic heart disease
786	4379	9.15	Symptoms involving respiratory system and other chest symptoms
410	3080	6.44	Acute myocardial infarction
427	2578	5.39	Cardiac dysrhythmias
486	1037	2.17	Pneumonia
584	986	2.06	Acute renal failure
440	952	1.99	Atherosclerosis
038	926	1.94	Septicemia
780	922	1.93	General Symptoms
578	894	1.87	Gastrointestinal hemorrhage
996	861	1.80	Complications peculiar to certain specified procedures
518	824	1.72	Other diseases of lung
998	805	1.68	Other complications of procedures not elsewhere classified
491	799	1.67	Chronic bronchitis
276	756	1.58	Disorders of fluid electrolyte and acid-base balance
997	692	1.45	Complications affecting specified body system not elsewhere classified
250	646	1.35	Diabetes mellitus
599	613	1.28	Other disorders of urethra and urinary tract
433	582	1.22	Occlusion and stenosis of precerebral arteries
458	577	1.21	Hypotension
434	529	1.11	Occlusion of cerebral arteries
530	475	0.99	Diseases of esophagus
562	419	0.88	Diverticula of intestine
535	405	0.85	Gastritis and duodenitis
008	366	0.76	Intestinal infections due to other organisms
415	357	0.75	Acute pulmonary heart disease
411	336	0.70	Other acute and subacute forms of ischemic heart disease
569	307	0.64	Other disorders of intestine
574	286	0.60	Cholelithiasis
285	281	0.59	Other and unspecified anemias
560	261	0.55	Intestinal obstruction without mention of hernia
531	260	0.54	Gastric ulcer
435	250	0.52	Transient cerebral ischemia
453	244	0.51	Other venous embolism and thrombosis
789	244	0.51	Other symptoms involving abdomen and pelvis
682	208	0.43	Other cellulitis and abscess
404	205	0.43	Hypertensive heart and kidney disease
403	194	0.41	Hypertensive kidney disease
537	184	0.38	Other disorders of stomach and duodenum
441	181	0.38	Aortic aneurysm and dissection

7.1 Appendix A- Top 50 ICD-9 Diagnosis Codes Associated with PCI Readmissions *(cont.)*

Diagnosis Code	Count	Percent	Description
507	180	0.38	Pneumonitis due to solids and liquids
577	176	0.37	Diseases of pancreas
558	173	0.36	Other and unspecified noninfectious gastroenteritis and colitis
532	168	0.35	Duodenal ulcer
820	167	0.35	Fracture of neck of femur
402	162	0.34	Hypertensive heart disease
401	160	0.33	Essential hypertension
162	159	0.33	Malignant neoplasm of trachea bronchus and lung
787	155	0.32	Symptoms involving digestive system

7.2 Appendix B- Top 50 ICD-9 Procedure Codes Associated with PCI Readmissions

Procedure Code	Count	Percent	Description
3722	3578	13.04	Left heart cardiac catheterization
9904	1714	6.25	Transfusion of packed cells
3995	1705	6.21	Hemodialysis
0066	1336	4.87	Percutaneous transluminal coronary angioplasty [ptca] or coronary atherectomy
4516	1049	3.82	Esophagogastroduodenoscopy [egd] with closed biopsy
3950	1031	3.76	Angioplasty or atherectomy of non-coronary vessel
4513	983	3.58	Other endoscopy of small intestine
3893	904	3.29	Venous catheterization, not elsewhere classified
8872	625	2.28	Diagnostic ultrasound of heart
9671	507	1.85	Continuous mechanical ventilation for less than 96 consecutive hours
3794	505	1.84	Implantation or replacement of automatic cardioverter/defibrillator, total system [aicd]
8856	483	1.76	Coronary arteriography using two catheters
3772	419	1.53	Initial insertion of transvenous leads [electrodes] into atrium and ventricle
3491	359	1.31	Thoracentesis
3812	341	1.24	Endarterectomy, other vessels of head and neck
4523	287	1.05	Colonoscopy
4443	274	1.00	Endoscopic control of gastric or duodenal bleeding
9390	268	0.98	Continuous positive airway pressure [cpap]
9929	268	0.98	Injection or infusion of other therapeutic or prophylactic substance
0051	263	0.96	Implantation of cardiac resynchronization defibrillator, total system [crt-d]
3952	204	0.74	Other repair of aneurysm
387	198	0.72	Interruption of vena cava
4525	188	0.69	Closed [endoscopic] biopsy of large intestine
9672	186	0.68	Continuous mechanical ventilation for 96 consecutive hours or more
8622	185	0.67	Excisional debridement of wound, infection, or burn
9604	180	0.66	Insertion of endotracheal tube
3783	176	0.64	Initial insertion of dual-chamber device
3723	174	0.63	Combined right and left heart cardiac catheterization
3761	170	0.62	Implant of pulsation balloon
3895	165	0.60	Venous catheterization for renal dialysis
5794	164	0.60	Insertion of indwelling urinary catheter
0061	161	0.59	Percutaneous angioplasty or atherectomy of precerebral (extracranial) vessel(s)
5123	158	0.58	Laparoscopic cholecystectomy
8944	157	0.57	Other cardiovascular stress test

7.2 Appendix B- Top 50 ICD-9 Procedure Codes Associated with PCI Readmissions *(cont.)*

Procedure Code	Count	Percent	Description
3734	137	0.50	Excision or destruction of other lesion or tissue of heart, other approach
8703	126	0.46	Computerized axial tomography of bead
8604	117	0.43	Other incision with drainage of skin and subcutaneous tissue
3971	111	0.40	Endovascular implantation of graft in abdominal aorta
3324	108	0.39	Closed [endoscopic] biopsy of bronchus
4542	103	0.38	Endoscopic polypectomy of large intestine
8741	103	0.38	Computerized axial tomography of thorax
8954	102	0.37	Electrographic monitoring
9962	99	0.36	Other electric countershock of heart
9919	94	0.34	Injection of anticoagulant
9907	87	0.32	Transfusion of other serum
4573	83	0.30	Right hemicolectomy
3726	82	0.30	Cardiac electrophysiologic stimulation and recording studies
9921	82	0.30	Injection of antibiotic
8949	80	0.29	Automatic implantable cardioverter/defibrillator (aicd) check