Hospital 30-Day Readmission Following Percutaneous Coronary Intervention Measure

Measure Methodology Report

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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 <u>Table 1</u>.

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

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

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).

and validation samples

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 (<u>Table 3 & Figure 4</u>) 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 (<u>https://www.cms.hhs.gov/apps/QMIS/publicComment.asp</u>). Public comments were summarized and publicly posted. The resulting content was taken into consideration during the final stages of measure development.

2.3 Outcome

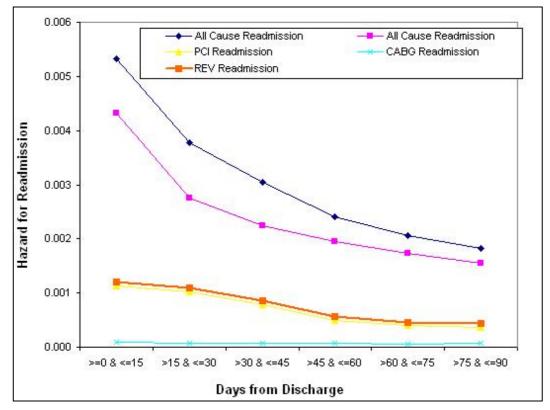
The outcome for this measure is 30-day all-cause readmission. We define a readmission as a subsequent hospital inpatient admission within 30 days of the discharge date of an admission in the index cohort or claim end date (for patients whose PCI was performed as an outpatient service).

We do not count readmissions associated with a 'staged' revascularization procedure, defined as readmissions with PCI or Coronary Artery Bypass Graft (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

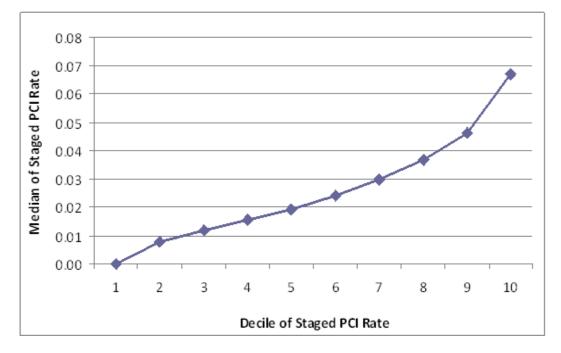
We used all-cause readmission (except for staged procedures) as opposed to cardiac specific readmission for several reasons. First, from the patient perspective, readmission for any reason is likely to be an undesirable outcome of care. Second, readmissions not associated with a cardiac diagnosis may 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 latepresenting 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 (p<0.001) (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 # (%)
All	1554 (100.00)	791 (100.00)	763 (100.00)
Number beds: < 300	858 (55.21)	484 (61.19)	374 (49.02)
Number beds: 300 to 600	545 (35.07)	242 (30.59)	303 (39.71)
Number beds: > 600	151 (9.72)	65 (8.22)	86 (11.27)
Number beds: Mean (SD)	325.83 (221.19)	301.41 (227.39)	351.14 (211.77)
Ownership: Government	182 (11.71)	111 (14.03)	71 (9.31)
Ownership: Not-for-profit	1072 (68.98)	493 (62.33)	579 (75.88)
Ownership: For profit	300 (19.31)	187 (23.64)	113 (14.81)
Associated area	10 (0.64)	10 (1.26)	0 (0.00)
New England Region	55 (3.54)	20 (2.53)	35 (4.59)
Middle Atlantic Region	171 (11.00)	104 (13.15)	67 (8.78)
South Atlantic Region	242 (15.57)	115 (14.54)	127 (16.64)
East North Central Region	280 (18.02)	116 (14.66)	164 (21.49)
East South Central Region	112 (7.21)	61 (7.71)	51 (6.68)
West North Central Region	130 (8.37)	50 (6.32)	80 (10.48)
West South Central Region	226 (14.54)	156 (19.72)	70 (9.17)
Mountain Region	127 (8.17)	63 (7.96)	64 (8.39)
Pacific Region	201 (12.93)	96 (12.14)	105 (13.76)
Council of Teaching Hospitals and Health Systems	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: 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 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).

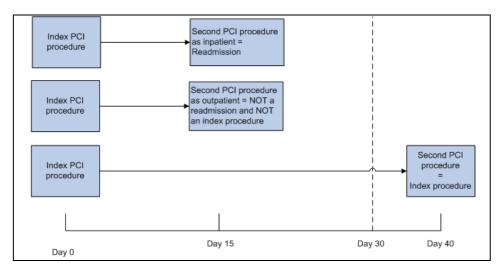
2.5 Cohort Derivation

Both the CathPCI Registry and CMS claims data were used to define the cohort of admissions with a PCI for model development. The algorithm used to derive the cohort is documented 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

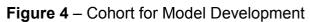
claims and Healthcare Common Procedure Coding System/Current Procedural Terminology (HCPCS/CPT) procedure codes from outpatient claims shown in <u>Table 3</u>.

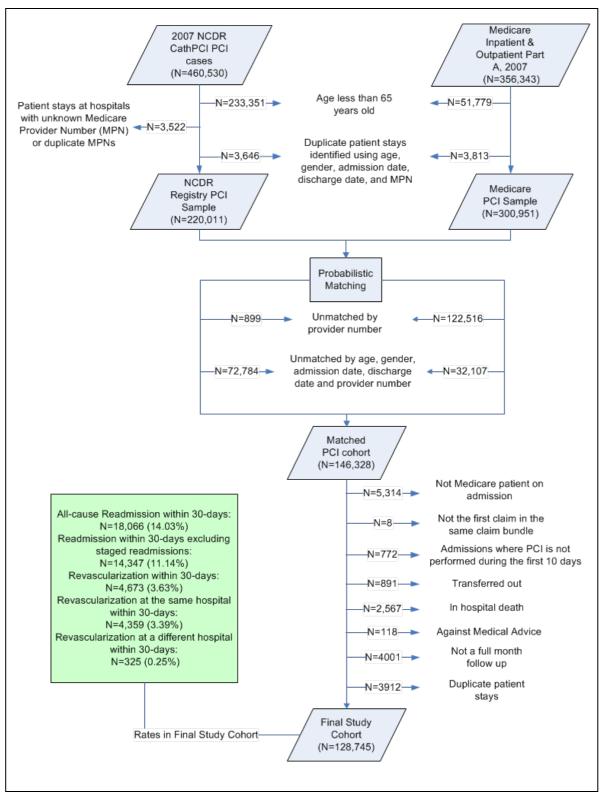
Code Type	Code	Description
ICD-9-CM	00.66	Percutaneous transluminal coronary angioplasty or coronary atherectomy
ICD-9-CM	36.01	Single vessel PTCA or coronary atherectomy
ICD-9-CM	36.02	Percutaneous transluminal coronary angioplasty or coronary atherectomy with mention of thrombolytic agent
ICD-9-CM	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]
СРТ	92981	Coronary Stents [each additional vessel]
СРТ	92982	Coronary Balloon Angioplasty [single vessel]
СРТ	92984	Coronary Balloon Angioplasty [each additional vessel]
СРТ	92995	Percutaneous Atherectomy
СРТ	92996	Percutaneous Atherectomy

Table 3 – ICD-9-CM and CPT Procedure Codes that Define an Admission

 with PCI in Medicare Inpatient & Outpatient Claims

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%.





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:

- 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.
- 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. <u>Patient stays with duplicate fields (Medicare and NCDR datasets)</u>. 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. <u>Unmatched patient stays</u>. 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:

- 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. <u>Not the first claim in the same claim bundle</u>. 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.
- 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. <u>Transfers out</u>. 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.

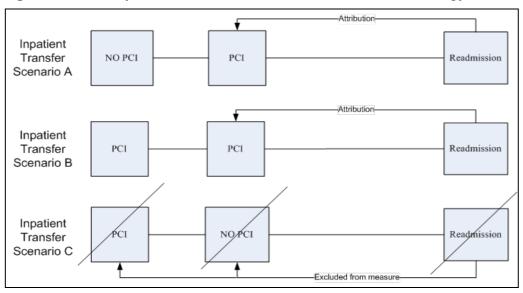


Figure 5 – 30-Day PCI Readmission Transfer Attribution Strategy

- 5. <u>The patient dies in the hospital</u>. *Rationale:* Subsequent admissions (readmissions) are not possible.
- 6. <u>The patient leaves against medical advice (AMA)</u>. *Rationale:* Physicians and hospitals do not have the opportunity to deliver the highest quality care.
- 7. <u>PCI in which 30-day follow up is not available</u>. 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.
- 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 nonwhite 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 (<u>Table 5</u>).

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).

Characteristic		Not Matched	Matched
Category	Description	# (%)	# (%)
Demographics	Age: Mean (SD)	73.87 (6.5)	74.71 (6.6)
Demographics	Gender	28,668 (39.4)	59,907 (40.9)
Demographics	Race: non-white	12,103 (16.6)	16,931 (11.6)
History & Risk Factors	Body Mass Index (BMI): Unknown	102 (0.1)	200 (0.1)
History & Risk Factors	BMI: Mean (SD)	28.66 (5.8)	28.57 (5.8)
History & Risk Factors	Heart failure - previous history	9,679 (13.3)	20,742 (14.2)
History & Risk Factors	Previous valvular surgery	1102 (1.5)	2,460 (1.7)
History & Risk Factors	Cerebrovascular Disease	10,866 (14.9)	23,538 (16.1)
History & Risk Factors	Peripheral Vascular Disease	10,670 (14.7)	22,942 (15.7)
History & Risk Factors	Chronic Lung Disease	12,974 (17.8)	27,518 (18.8)
History & Risk Factors	Diabetes/control: No	48,064 (66.0)	97,813 (66.8)
History & Risk Factors	Diabetes/control: Non-insulin diabetes	17,135 (23.5)	33,233 (22.7)
History & Risk Factors	Diabetes/control: Insulin diabetes	7,585 (10.4)	15,282 (10.4)
-		1,000 (10.1)	10,202 (10.1)
History & Risk Factors	Glomerular Filtration Rate (GFR): not measured	2,612 (3.6)	5,545 (3.8)
History & Risk Factors	GFR<30	2,898 (4.0)	6,704 (4.6)
History & Risk Factors	30<=GFR<60	26,238 (36.0)	54,623 (37.3)
History & Risk Factors	60<=GFR<90	34,609 (47.6)	67,309 (46.0)
History & Risk Factors	GFR>=90	6,427 (8.8)	12,147 (8.3)
History & Risk Factors	Previous PCI	27,133 (37.3)	56,012 (38.3)
History & Risk Factors	Previous CABG	16,591 (22.8)	35,189 (24.0)
Cardiac Status	Heart Failure - current status	8,607 (11.8)	18,480 (12.6)
Cardiac Status	New York Heart Association (NYHA) Class I	22,642 (31.1)	44,995 (30.7)
Cardiac Status	NYHA Class II	18,181 (25.0)	35,707 (24.4)
Cardiac Status	NYHA Class III	19,025 (26.1)	39,294 (26.9)
Cardiac Status	NYHA Class IV	12,936 (17.8)	26,332 (18.0)
Cardiac Status	Cardiogenic shock	1,792 (2.5)	3,551 (2.4)
Quardia a Otatura	Symptoms present on admission : No		
Cardiac Status	M	54,087 (74.3)	106,156 (72.5)
Cardiac Status	Symptoms present on admission: MI within 24 hours	14,445 (19.8)	31,299 (21.4)
Cardiac Status	Symptoms present on admission: 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)
Cath Lab Visit	EF percentage: EF<30	2,870 (3.9)	6,229 (4.3)
Cath Lab Visit	EF percentage: 30<=EF<45	8,083 (11.1)	17,545 (12.0)
Cath Lab Visit	EF percentage: EF>=45	39,434 (54.2)	79,121 (54.1)
PCI Procedure	PCI status: Elective	38,165 (52.4)	74,061 (50.6)
PCI Procedure	PCI status: Urgent	25,602 (35.2)	52,571 (35.9)
PCI Procedure	PCI status: Emergency	8,782 (12.1)	19,263 (13.2)
PCI Procedure	PCI status: Salvage	235 (0.3)	433 (0.3)
	Highest risk lesion: Society for	()	()
PCI Procedure	Cardiovascular Angiography and	38,251 (52.6)	77769 (53.1)
	Interventions (SCAI) lesion class I		()
PCI Procedure	Highest risk lesion: SCAI lesion class II	24,442 (33.6)	49,575 (33.9)
PCI Procedure	Highest risk lesion: SCAI lesion class III	3,504 (4.8)	6,719 (4.6)
PCI Procedure	Highest risk lesion: SCAI lesion class IV	6,587 (9.1)	12,265 (8.4)

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

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

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

Description	Not 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 (ICD-9-CM diagnosis codes 428.XX, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, or 404.93)	629 (2.0)	2,329 (1.6)
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)

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

 Matched and Unmatched Patients

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

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 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).

Characteristic Category	Description	NCDR Item Number	Name
Demographic	Age	252	Age
Demographic	Female	260	FEMALE
History and Risk Factors	BMI	Derived (410, 412)	BMI
History and Risk Factors	Previous MI	420	PrevMI
History and Risk Factors	Heart Failure-previous history	424	PrCHF
History and Risk Factors	Previous valvular surgery	426	PrValve
History and Risk Factors	Cerebrovascular Disease	450	CVD
History and Risk Factors	Peripheral Vascular Disease	452	PVD
History and Risk Factors	Chronic Lung Disease	454	CLD
History and Risk Factors	Diabetes	Derived (430, 432)	NewDIAB
History and Risk Factors	No diabetes	Reference	-
History and Risk Factors	Non-insulin diabetes	-	NEWDIAB1
History and Risk Factors	Insulin diabetes	-	NEWDIAB2
History and Risk Factors	Glomerular Filtration Rate (GFR)	Derived (252, 260, 270, 439, 440)	GFR
History and Risk Factors	GFR Not measured	Derived	GFRGRP0
History and Risk Factors	GFR<30	Derived	GFRGRP1
History and Risk Factors	30≤GFR<60	Derived	GFRGRP2
History and Risk Factors	60≤GFR<90	Reference	-
History and Risk Factors	GFR≥90	Derived	GFRGRP4
History and Risk Factors	Renal failure-dialysis	444	Dialysis
History and Risk Factors	Hypertension	456	Hypertn
History and Risk Factors	History of tobacco use	460	Tobacco
History and Risk Factors	Family history of CAD	480	FHCAD
History and Risk Factors	Previous PCI	490	PrPCI
History and Risk Factors	Previous CABG	494	PrCAB
Cardiac Status	Heart failure - current status	500	CHF
Cardiac Status	NYHA	510	ClassNYH
Cardiac Status	NYHA Class I or II	Reference	-
Cardiac Status	NYHA Class III	Derived	NYHC3
Cardiac Status	NYHA Class IV	Derived	NYHC4
Cardiac Status	Cardiogenic shock	520	-
Cardiac Status	ST elevation MI (STEMI)	Derived (550, 560, 812)	STEMI
Cardiac Status	Symptoms present on admission	Derived (550, 560)	AdmSxPre
	Symptoms present on admission: No		
Cardiac Status	M	-	ADMSX1
	Symptoms present on admission: MI		
Cardiac Status	within 24 hours	Reference	-
Operations Obstant	Symptoms present on admission: MI		
Cardiac Status	after 24 hours	-	ADMSX3
Cardiac Status	Cath Lab Visit	-	-
Cardiac Status	Ejection Fraction (EF) Percentage	Derived (654, 656)	HDEFGRP
Cardiac Status	EF Not measured	-	HDEFGRP1
Cardiac Status	EF<30	-	HDEFGRP2
Cardiac Status	30≤EF<45	-	HDEFGRP3
Cardiac Status	EF≥45	Reference	-
Cardiac Status	Left main disease	Derived (660, 661)	LMGT50
Cardiac Status	Number of vessels with disease	Derived (662 to 671)	VESSELD
Cardiac Status	≤1 vessel with disease	Reference	-
Cardiac Status	2 vessels with disease	Derived	VESSELD2
Cardiac Status	3 vessels with disease	Derived	VESSELD3
PCI Procedure	PCI status	804	PCIStat

 Table 6 – PCI Model Candidate Variables

Characteristic Category	Description	NCDR Item Number	Name
PCI Procedure	PCI status: Elective	Reference	-
PCI Procedure	PCI status: Urgent	Derived	PCIS2
PCI Procedure	PCI status: Emergency	Derived	PCIS3
PCI Procedure	PCI status: Salvage	Derived	PCIS4
PCI Procedure	Highest Lesion location	Derived (900, 902)	NLESLOC
PCI Procedure	Highest Lesion location: pRCA/mLAD/pCIRC	Derived	NLESLOC1
PCI Procedure	Highest Lesion location: pLAD	Derived	NLESLOC2
PCI Procedure	Highest Lesion location: Left main	Derived	NLESLOC3
PCI Procedure	Highest Lesion location: Other	Derived	-
PCI Procedure	Highest pre-procedure TIMI flow: none	920	NPRETIMI
PCI Procedure	Highest risk lesion: SCAI lesion class	Derived (910, 950)	NSCAILC
PCI Procedure	Highest risk lesion: SCAI lesion class I	Reference	-
PCI Procedure	Highest risk lesion: SCAI lesion class II	Derived	NSCAILC2
PCI Procedure	Highest risk lesion: SCAI lesion class	Derived	NSCAILC3
PCI Procedure	Highest risk lesion: SCAI lesion class IV	Derived	NSCAILC4

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

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

Table 7 – Final PCI Readmission Model Variables

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 a hospital-specific riskstandardized readmission rates (RSRRs). These rates are calculated as the ratio of predicted number of readmissions to 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 hospitalspecific 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; **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

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

and $\mathbf{Z}_{ij} = (Z_{1ij}, Z_{2ij}, ..., Z_{pij})$ 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,

HGLM
$$\begin{array}{c} h(Y_{ij}) = \alpha_i + \beta \mathbf{Z}_{ij} \\ \alpha_i = \mu + \omega_i; \quad \omega_i \sim N(0, \tau^2) \end{array}$$
(2) (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.,

Logit**Z**_{ij}
$$(P(Y_{ij} = 1)) = \alpha_i + \beta$$

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

where 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, $_{\hat{\mu}}$, $\{\hat{\alpha}_i, \hat{\alpha}_2, ..., \hat{\alpha}_I\}$, $\hat{\beta}$, 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, $_{\bar{\gamma}}$. Specifically, we calculate

Predicted $\hat{y}_{ij}(Z) = h^{-1}(\hat{a}_i + \hat{\beta} Z_{ij})$ (4) Expected $\hat{e}_{ij}(Z) = h^{-1}(_{\hat{\mu}} + \hat{\beta} Z_{ij})$ (5) $\hat{s}_i(Z) = \frac{\sum_{j=1}^{n_i} \hat{y}_{ij}(Z)}{\sum_{i=1}^{n_i} \hat{e}_{ij}(Z)} \times \overline{y}$ (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.

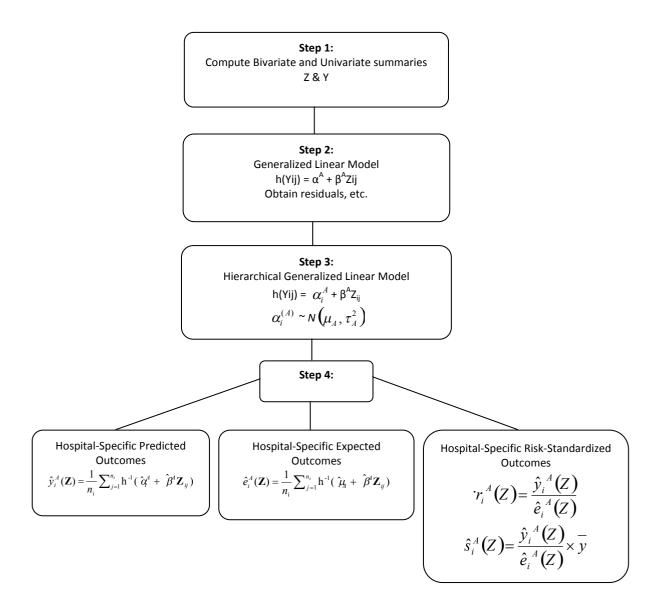
2.11.2 Algorithm

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 / 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, $\{\hat{\alpha}_{i}^{(\delta)}, v\hat{a}r(\alpha_{i}^{(\delta)})\}$; $i = 1, 2, ..., i\}$.
- 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 $\alpha_i^{(b^*)} \sim N(\hat{\alpha}_i^{(b)}, \hat{var}(\hat{\alpha}_i^{(b)}))$ 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 <u>Table 8</u>. 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 <u>Table 13</u> (HGLM).

3.1.2 Model Performance

We computed 6 summary statistics for assessing model performance (Harrell, 2001): over-fitting indices, 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 (see <u>Table 10</u>). Explanations of standardized estimates, over-fitting, and the chi-square test are provided in <u>Appendix C</u>.

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 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.

Wald Chi-Pr > Standardized OR (LOR, UOR) Description Estimate S.E. ChiSa Square **Estimates** Intercept -3.84 0.15 689.5 0.00 n/a n/a 1.26 (1.22, 1.29) Aae/10 0.23 246.4 0.00 0.08 0.01 Female 0.26 0.00 0.07 0.02 184.4 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) 0.19 0.00 Previous Valvular Surgery 0.06 9.4 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) 0.33 0.00 0.07 Chronic Lung disease 0.02 226.0 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) 0.16 0.00 0.04 GFR: 2="30<=GFR<60" 0.02 56.4 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 - Dialvsis 0.39 0.06 42.0 0.00 0.03 1.48 (1.32, 1.67) Hypertension 0.08 9.7 0.00 0.02 0.03 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) 0.37 EFP: 2="0<=EFP<30" 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 0.00 0.04 108.6 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 0.01 0.06 7.2 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)

Table 8 – 30-Day Readmission Model (2007 Development Sample-GLM Results [ROC=0.665]; 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 <u>Table 9</u>, and the performance metrics are shown in <u>Table 10</u>. 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 <u>Table 10</u> 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 (<u>Table 11</u> and <u>Table 12</u>). 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.

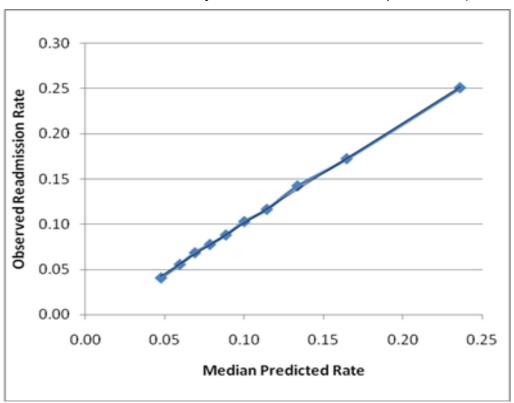


Figure 7 – Observed Readmission by Predicted Readmission per Decile (R^2 =0.999)

Description	Estimate	Standard Error	Wald Chi- Square	Pr > ChiSq	Standardized Estimates	OR (LOR, UOR)
Intercept	-4.25	0.16	730.5	0.00		n/a
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)

Table 9 – 30-Day Readmission Model (2006 Validation Sample-GLM Results [ROC: 0.663]; N=117,375 in 618 hospitals; 10.7% readmission rate)

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

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

Indices	Development Sample	Validation Sample
Year	2007	2006
Ν	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
Residuals Lack of Fit (Pearson Residual Fall %) [-2, 0)	88.86	89.33
Residuals Lack of Fit (Pearson Residual Fall %) [0, 2)	2.21	1.85
Residuals Lack of Fit (Pearson Residual Fall %) [2+	8.93	8.82
Model χ^2 [Number of Covariates] ⁴	4448.36 [31]	3812.62 [31]

Notes:

- 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

Description	2006 (Validation) (N=117,375 in 618 hospitals; 10.7% Readmission Rate)	2007 (Development) (N=128,745 in 766 hospitals; 11.1% Readmission Rate)
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

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

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; 10.7% Readmission Rate	2007 (Development) N=128,745 in 766 Hospitals 11.1% Readmission Rate
Age/10	74.7 (6.5)	74.7 (6.6)
Female	41.8	41.2
BMI/5 - Unknown	0.1	0.1
BMI/5 - 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

Table 13 – 30-Day Readmission (2007 Development Sample – HGLM Results)
[ROC=0.677]; N=128,745 in 766 hospitals; 11.1% readmission rate)

Description	Estimate	Standard Error	T-Value	Pr > T- Value	Odds Ratio (95% Cl)
Intercept	-3.84	0.15	-26.38	0.00	n/a
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)

Notes:

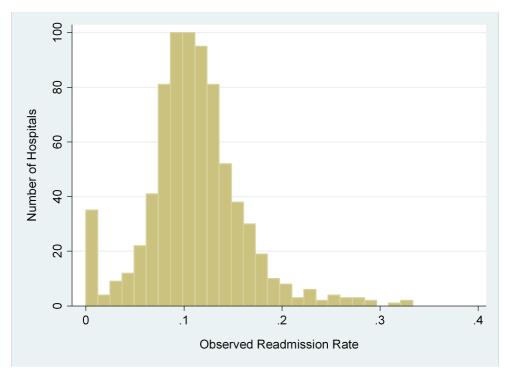
- Between hospital variance=0.03813. Standard error=0.005500.
- Readmissions with revascularization but without myocardial infarction, heart failure, unstable angina, cardiac arrest or arrhythmia are not counted as readmissions

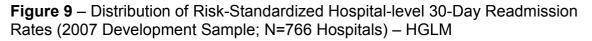
3.1.4 30-Day Readmission Rate Distribution - With and Without Risk-Adjustment

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)





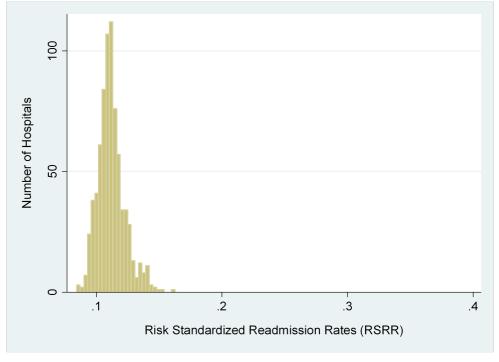


Figure 10 – Distribution of Unadjusted Hospital-level 30-Day Readmission Rates by Hospital Volume (2007 Development Sample; N=766 Hospitals)

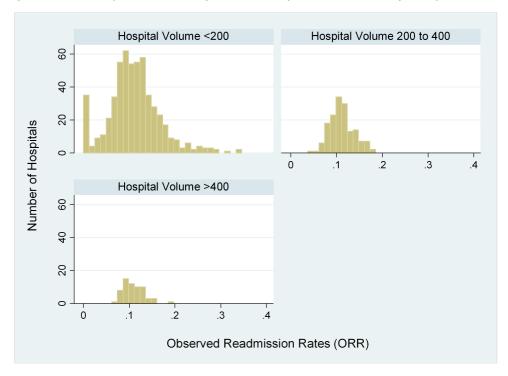
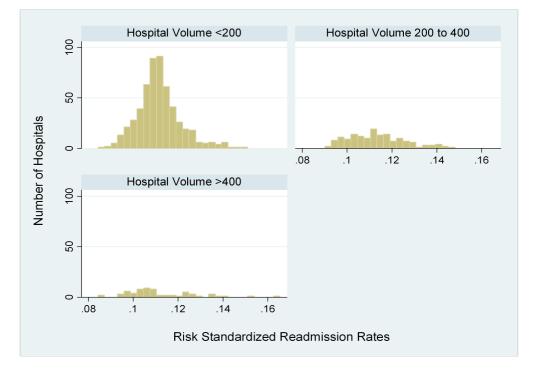


Figure 11 – Distribution of Risk-Standardized Hospital-level 30-Day Readmission Rates by Hospital Volume (2007 Development Sample; N=766)



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.

6. REFERENCES

- Carrozza, J., Cutlip, D, Levin, T (2008). Periprocedural complications of percutaneous coronary intervention. <u>UpToDate</u>. B. Rose. Waltham, MA.
- Curtis JP, Schreiner G, Wang Y, et al. All-Cause Readmission and Repeat Revascularization after Percutaneous Coronary Intervention in a Cohort of Medicare Patients. J Am Coll Cardiol. 2009;54:903-7.
- Douglas, PS, Brennan JM, et al. Clinical Effectiveness of Coronary Stents in Elderly Persons: Results from 262,700 Medicare Patients in the American College of Cardiology-National Cardiovascular Data Registry. Journal of the American College of Cardiology. 2009; 53 (18): 1629-1641.
- 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.
- 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. 992;30:377-391.
- Friedman, B. (AHRQ), Jiang, H.J. (AHRQ) and Russo, C.A. (Thomson Rueters). *Medicare Hospital Stays: Comparisons between the Fee-for-Service Plan and Alternative Plans, 2006.* HCUP Statistical Brief #66. January 2009. Agency for Healthcare Research and Quality, Rockville, MD. <u>http://www.hcup-us.ahrq.gov/reports/statbriefs/sb66.pdf</u>
- Gatsonia CA, D. M. (1999). "Hierarchical Generalized Linear Models in the Analysis of Variations in Health Care Utilization." <u>Journal of the American Statistical</u> <u>Assocation</u> 94(445): 29.
- Harrell, FE. (2001) Regression modeling strategies. Springer-Verlag, Inc., New York, NY.
- King SB, Smith SC, Hirshfeld JW, et al. 2007 focused update of the ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines: (2007 Writing Group to Review New Evidence and Update the 2005 ACC/AHA/SCAI Guideline Update for Percutaneous Coronary Intervention). *Circulation* 2007; DOI: 10.1161/CIRCULATIONAHA.107.188208.
- Krumholz, H. M., R. G. Brindis, et al. (2006). "Standards for statistical models used for public reporting of health outcomes: an American Heart Association Scientific Statement from the Quality of Care and Outcomes Research Interdisciplinary Writing Group: cosponsored by the Council on Epidemiology and Prevention and the Stroke Council. Endorsed by the American College of Cardiology Foundation." <u>Circulation</u> 113(3): 456-62.

Levit K (Thomson Reuters), Wier L (Thomson Reuters), Stranges E (Thomson Reuters), Ryan K (Thomson Reuters), Elixhauser A (AHRQ). *HCUP Facts and Figures: Statistics on Hospital-based Care in the United States, 2007.* Rockville, MD: Agency for Healthcare Research and Quality, 2009 (<u>http://www.hcup-us.ahrq.gov/reports.jsp</u>).

McCullagh P, N. J. (1989). Generalized Linear Models, Chapman and Hall.

- 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 August 3, 2009.
- Mukherjee, D., R. M. Wainess, et al. (2005). "Variation in outcomes after percutaneous coronary intervention in the United States and predictors of periprocedural mortality." <u>Cardiology</u> 103(3): 143-7.
- 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.
- Normand, S. L. (2008). Percutaneous Coronary Intervention in the Commonwealth of Massachusetts Fiscal Year 2006 Report: October 1, 2005 - September 30, 2006. Boston, MA, Massachusetts Data Analysis Center, Department of Health Care Policy-Harvard Medical School: 1-52.
- Normand, S. L., Y Wang, et al. (2007). "Assessing surrogacy of data sources for institutional comparisons." <u>Health Services and Outcomes Research Methodology</u> 7:79-96.
- Patel, M. R., G.J. Dehmer, et al. (2009). ACCF/SCAI/STS/AATS/AHA/ASNC 2009 appropriateness criteria for coronary revascularization, *J Am Coll Cardiol* 53, pp. 530–553.
- 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.
- Shaw, R. E., H. V. Anderson, et al. (2002). "Development of a risk adjustment mortality model using the American College of Cardiology-National Cardiovascular Data Registry (ACC-NCDR) experience: 1998-2000." <u>J Am Coll Cardiol</u> 39(7): 1104-12.

- 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." <u>Circulation</u> 113(6): e85-151.
- YNHH-CORE (2008). Medicare Quality Measurement Support Project: Mortality Implementation and Measure Development and Monitoring: Measure Specific Literature Review-Cardiac Registry Task. New Haven, CT, Yale New Haven Hospital-Center for Outcomes Research & Evaluation: 1-21.
- YNHH-CORE (2008). Medicare Quality Measurement Support Project: Mortality Implementation and Measure Development and Monitoring: Hospital 30-Day Percutaneous Coronary Intervention Mortality Measures: Measures Methodology Report. New Haven, CT, Yale New Haven Hospital-Center for Outcomes Research & Evaluation: 1-55.
- YNHHSC-CORE (2009). Measure and Instrument Development and Support (MIDS) Subtask 3.1 Deliverable 19: Hospital 30-Day Readmission Following Percutaneous Coronary Intervention Measure: Technical Expert Panel Summary Report. New Haven, CT, Yale New Haven Hospital Health Systems Corporation-Center for Outcomes Research & Evaluation: 1-56.

7. APPENDIX

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

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
	175	0.00	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

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

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

Procedure Code	Count	Percent	Description
8944	157	0.57	Other cardiovascular stress test
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

7.2 Appendix C- Explanation of Statistical Features

Standardized Estimates: 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.

Over-fitting: 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.

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)