NATIONAL QUALITY FORUM

Measure Evaluation 4.1
December 2009

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

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

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

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

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

(for NQF staff use) **NQF Review #:** 0355 **NQF Project:** Cardiovascular Endorsement Maintenance 2010
MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** Bilateral Cardiac Catheterization Rate (IQI 25)
De.2 **Brief description of measure**: Percent of discharges with heart catheterizations in any procedure field with simultaneous right and left heart (bilateral) heart catheterizations.
1.1-2 **Type of Measure:** Outcome De.3 **If included in a composite or paired with another measure, please identify composite or paired measure** None
De.4 **National Priority Partners Priority Area:** Safety, Overuse De.5 **IOM Quality Domain**: Effectiveness De.6 **Consumer Care Need:** Getting better

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	**NQF Staff**
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.* A.1 **Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes A.2 **Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:** A.3 **Measure Steward Agreement:** Government entity and in the public domain - no agreement necessary A.4 **Measure Steward Agreement attached:**	**A** **Y**☒ **N**☐
B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least	**B** **Y**☐

every 3 years. Yes, information provided in contact section	N☐
C. The intended use of the measure includes both public reporting and quality improvement. ►**Purpose:** Public reporting, Internal quality improvement Accountability	C Y☒ N☐
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1**Testing:** Yes, fully developed and tested D.2 **Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?** Yes	D Y☒ N☐
(for NQF staff use) **Have all conditions for consideration been met?** **Staff Notes to Steward** (*if submission returned*)**:**	Met Y☒ N☐
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:** COnflicting statement on risk adjustment. recommends reliabilty adjustment bnut provides no details.	
Staff Reviewer Name(s): RWinkler	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. *Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.* (evaluation criteria) **1a. High Impact**	Eval Rating
(for NQF staff use) **Specific NPP goal**: Overuse	
1a.1 **Demonstrated High Impact Aspect of Healthcare:** Severity of illness, Patient/societal consequences of poor quality 1a.2 1a.3 **Summary of Evidence of High Impact:** From 1993 to 1999, Peer Review Organizations in 20 states developed programs to reduce excessive rates of bilateral cardiac catheterization through education and outreach. Ten of these projects have released results; all documented dramatic utilization changes at the targeted hospitals. It has been estimated that these programs averted at least 6,126 unnecessary bilateral catheterizations. 1a.4 **Citations for Evidence of High Impact:** American Health Quality Association. A Pillar of Quality:The Medicare Peer Review Organization/Quality Improvement Organization Program. In; 2000. Bing ML, Abel RL, Lee LJ, et al. Medical necessity for right heart catheterization. Tex Heart Inst J 1997;24(2):109- Fortune GJ, Schiffel F, Jr., Elder S. MPCRF: the Right Heart Catheterization Cooperative project. Mo Med 1996;93(10):657-61. Gold JA. Decreasing the rate of bilateral cardiac catheterization. Wis Med J 1995;94(10):569-70.	1a C☐ P☐ M☐ N☐

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable

Comment [KP1]: 1a. The measure focus addresses:
•a specific national health goal/priority identified by NQF's National Priorities Partners; OR
•a demonstrated high impact aspect of healthcare (e.g., affects large numbers, leading cause of morbidity/mortality, high resource use (current and/or future), severity of illness, and patient/societal consequences of poor quality).

Malach M, Imperato PJ, Nenner RP, et al. Impact of an educational program on bilateral heart catheterization practice patterns. Am J Med Qual 1998;13(4):213-22.

Imperato PJ, Malach M, Nenner RP, et al. Concurrent improvements in ambulatory cardiac catheterization practices following inpatient interventions. J Ambulatory Care Manage 1999;22(2):1-8.

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: Providers should reduce the rate of bilateral catheterization for patients where not indicated. Consumers should select providers with lower rates.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
5th 25th Median 75th 95th
0.011149 0.014403 0.017009 0.019913 0.024636

1b.3 Citations for data on performance gap:
Nationwide Inpatient Sample, 2007

1b.4 Summary of Data on disparities by population group:
Based on the 2007 national statistics for bilateral cardiac catheterization http://hcupnet.ahrq.gov the 2007 unadjusted rates are as follows:

Overall rate per 100: 6.51 ; Risk adjusted rate:
Male: 6.31
Female: 6.82

Age groups: 18-39: 3.80; 40-64: 4.56; 65-74: 7.10; 75+: 9.56

Payer
Medicare: 8.16
Medicaid: 5.56
Other: 4.50

1b.5 Citations for data on Disparities:
2007 AHRQ Nationwide Inpatient Sample (N=1000 hospitals; 7 million discharges)

1b
C ☐
P ☐
M ☐
N ☐

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** Performance of bilateral cathetrization where not indicated subjects patients to potential complications of care

1c.2-3. Type of Evidence: Systematic synthesis of research

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
Face validity: The diagnostic evaluation of patients with presumptive coronary artery disease often involves cardiac catheterization with coronary angiography. Left-sided catheterization provides very useful information about coronary anatomy, as well as left ventricular function and valvular anatomy. Right-sided catheterization is often performed at the same time, but this practice raises two appropriateness issues. First, without a specific indication for right heart catheterization, the clinical yield is extremely low. In the most rigorous prospective study of this phenomenon, case management was changed for only 1.5% of patients who received an incidental right heart catheterization without a listed indication.1 Similar results have been reported from two retrospective studies,2, 3 while other studies failed to distinguish unsuspected right-sided abnormalities that affected management from those that did not.4 Second, the marginal cost of right heart catheterization has been estimated to exceed $650 per case and $120 million for the nation.

In response to these research findings, the American College of Cardiology and the American Heart

1c
C ☐
P ☐
M ☐
N ☐

Comment [KP2]: 1b. Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating considerable variation, or overall poor performance, in the quality of care across providers and/or population groups (disparities in care).

Comment [k3]: 1 Examples of data on opportunity for improvement include, but are not limited to: prior studies, epidemiologic data, measure data from pilot testing or implementation. If data are not available, the measure focus is systematically assessed (e.g., expert panel rating) and judged to be a quality problem.

Comment [k4]: 1c. The measure focus is:
•an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;
OR
•if an intermediate outcome, process, structure, etc., there is **evidence** that supports the specific measure focus as follows:
oIntermediate outcome – evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
oProcess – evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and
if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
oStructure – evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
oPatient experience – evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of individuals/ the public.
oAccess – evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
oEfficiency – demonstration of an association between the measured resource use and level of performance with respect to one or more of the other five IOM aims of quality.

Comment [k5]: 4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., … [1]

Association published guidelines for cardiac catheterization laboratories stating that "without specific indications, routine right heart catheterizations…are unnecessary."5 Similar guidelines have been published by other medical and public health organizations, such as the Cardiac Advisory Committee of the New York State Department of Health and the Texas Medical Association's Committee on Cardiovascular Diseases.
In New York, a panel of recognized cardiologists was convened to assist in establishing consensus criteria for the performance of right heart catheterization, incorporating advice from the New York State chapter of the American College of Cardiology, the Committee on Cardiovascular Disease of the Medical Society of the State of New York, and the Cardiac Advisory Council of the New York State Department of Health.16 Certain conditions were specified as valid indications for the procedure, allowing exclusion of patients for whom bilateral catheterization may be appropriate: pulmonary hypertension (415.0, 416.0, 416.8), rheumatic heart disease except for isolated aortic valve disease (391-394, 396-398), hypertensive heart disease (402, 404), pulmonary embolus (415.1x), cor pulmonale and other pulmonary heart disease (416.1, 416.9, 417.x), right sided valvular disorders (424.2, 424.3), and congenital cardiac abnormalities (745-747). A somewhat broader list of potential indications for bilateral catheterization was developed with input from the Texas Medical Association Committee on Cardiovascular Diseases13. Their list
adds acute pericarditis (420), acute and subacute endocarditis (421, 424.9), acute myocarditis (422), pericarditis and hemopericardium (423), mitral valve disorders (424.0), aortic valve disorders (424.1), cardiomyopathy (425), and heart failure (428).

Precision: In 1996, about 23% of all Medicare beneficiaries who underwent left heart catheterization also underwent right heart catheterization. At the state level, this percentage varied from 11% in Oklahoma to 48% in Massachusetts and 53% in Washington, DC.6 AHRQ IQIs, including Bilateral Cardiac Catheterization Rate, were easily applied to Veterans Administration data (2004 – 2007). "The authors "found considerable Veterans Integrated Service Networks'-level variation in bilateral cardiac catheterization rates" with highest utilization in the Northeast.18 Given that more than 1.2 million inpatient cardiac catheterizations were performed in the US in 1998, this measure should be estimable with reasonable precision.7

Minimum bias: Bilateral cardiac catheterization is considered appropriate in the presence of certain clinical indications: suspected pulmonary hypertension or significant right-sided valvular abnormalities, congestive heart failure, cardiomyopathies, congenital heart disease, pericardial disease, and cardiac transplantation. The validity of this measure rests on the assumption that the prevalence of these clinical indications is low and/or relatively uniform across the country. Unfortunately, the true prevalence of these indications cannot be reliably derived from administrative data. However, Malone et al 8 found that substantial variation in the use of bilateral catheterization persisted among 37 cardiologists at two large community hospitals, even after adjusting for clinical indications. Bias is likely to account for an even smaller share of variation at the hospital level.
Another source of potential bias is the large number of catheterizations performed on an outpatient basis. In 1996, 472,000 of 1,633,000 catheterizations were performed on an outpatient basis.9 We found no information on the prevalence of bilateral versus left-only catheterizations in the outpatient setting.

Construct validity: We located no articles explicitly addressing the construct validity of this indicator. The rationale for this indicator is based on face validity (see above) and professional consensus.

Fosters true quality improvement: We found no evidence regarding gaming for this indicator. When bilateral cardiac catheterization does not affect hospital payment (as in the DRG system), widespread use of this indicator may lead to less frequent coding of the procedure, when it is performed. It seems unlikely that patients would be denied a bilateral catheterization when the clinical situation clearly warrants it. However, a reduction in the rate of routine bilateral catheterization may lead to rare, but potentially serious, missed diagnoses (e.g., pulmonary hypertension). The long-term significance of missing these rare diagnoses is unclear. One recent study reported significantly decreased utilization in two of three centers using an interrupted time series design.10 The results of these studies suggest that right heart catheterization rates represent an actionable opportunity for quality improvement.

Prior use: Bilateral cardiac catheterization has been widely used as an indicator of quality in the Medicare program. It is one of five quality indicators included in the Medicare Quality of Care Report of Surveillance Measures 11. From 1993 to 1999, Peer Review Organizations in 20 states developed programs to reduce excessive rates of bilateral cardiac catheterization through education and outreach. Ten of these projects have released results; all documented dramatic utilization changes at the targeted hospitals. It has been

estimated that these programs averted at least 6,126 unnecessary bilateral catheterizations.12 Four of these state-based quality improvement projects have been described in the peer-reviewed literature,13-16 and one documented a spillover effect in the ambulatory setting.17

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom***):** Not applicable

1c.6 Method for rating evidence: Not applicable

1c.7 Summary of Controversy/Contradictory Evidence: We found no evidence regarding gaming for this indicator. When bilateral cardiac catheterization does not affect hospital payment (as in the DRG system), widespread use of this indicator may lead to less frequent coding of the procedure, when it is performed. It seems unlikely that patients would be denied a bilateral catheterization when the clinical situation clearly warrants it. However, a reduction in the rate of routine bilateral catheterization may lead to rare, but potentially serious, missed diagnoses (e.g., pulmonary hypertension). The long-term significance of missing these rare diagnoses is unclear. One recent study reported significantly decreased utilization in two of three centers using an interrupted time series design.10 The results of these studies suggest that right heart catheterization rates represent an actionable opportunity for quality improvement.

American Health Quality Association. A Pillar of Quality:The Medicare Peer Review Organization/Quality Improvement Organization Program. In; 2000.

Bing ML, Abel RL, Lee LJ, et al. Medical necessity for right heart catheterization. Tex Heart Inst J 1997;24(2):109-

Fortune GJ, Schiffel F, Jr., Elder S. MPCRF: the Right Heart Catheterization Cooperative project. Mo Med 1996;93(10):657-61.

Gold JA. Decreasing the rate of bilateral cardiac catheterization. Wis Med J 1995;94(10):569-70.

Malach M, Imperato PJ, Nenner RP, et al. Impact of an educational program on bilateral heart catheterization practice patterns. Am J Med Qual 1998;13(4):213-22.

Imperato PJ, Malach M, Nenner RP, et al. Concurrent improvements in ambulatory cardiac catheterization practices following inpatient interventions. J Ambulatory Care Manage 1999;22(2):1-8.

1c.8 Citations for Evidence (*other than guidelines***):**

1. Hill JA, Miranda AA, Keim SG, et al. Value of right-sided cardiac catheterization in patients undergoing left-sided cardiac catheterization for evaluation of coronary artery disease. Am J Cardiol 1990;65(9):590-3.
2. Shanes JG, Stein MA, Dierenfeldt BJ, et al. The value of routine right heart catheterization in patients undergoing coronary arteriography. Am Heart J 1987;113(5):1261-3.
3. Friedman HS. Right-heart catheterization in coronary artery disease. Angiology 1978;29(12):878-87.
4. Barron JT, Ruggie N, Uretz E, et al. Findings on routine right heart catheterization in patients with suspected coronary artery disease. Am Heart J 1988;115(6):1193-8.
5. Pepine CJ, Allen HD, Bashore TM, et al. ACC/AHA guidelines for cardiac catheterization and cardiac catheterization laboratories. American College of Cardiology/American Heart Association Ad Hoc Task Force on Cardiac Catheterization. Circulation 1991;84(5):2213-47.
6. Quality Resume. Health Care Finiancing Administration´s Medicare Quality of Care Report of Surveillance Measures. In; 1998.
7. Hall M, Popovic J. 1998 summary: National Hospital Discharge Survey. Advance Data from Vital and Health Statistics 2000;316.
8. Malone ML, Bajwa TK, Battiola RJ, et al. Variation among cardiologists in the utilization of right heart catheterization at time of coronary angiography [see comments]. Cathet Cardiovasc Diagn 1996;37(2):125-30.
9. Owings MF, Kozak LJ. Ambulatory and inpatient procedures in the United States, 1996. Vital Health Stat 13 1998(139):1-119.
10. Cable G. Enhancing causal interpretations of quality improvement interventions. Qual Health Care 2001;10(3):179-86.

Comment [k6]: 3 The strength of the body of evidence for the specific measure focus should be systematically assessed and rated (e.g., USPSTF grading system http://www.ahrq.gov/clinic/uspstf07/methods/benefit.htm). If the USPSTF grading system was not used, the grading system is explained including how it relates to the USPSTF grades or why it does not. However, evidence is not limited to quantitative studies and the best type of evidence depends upon the question being studied (e.g., randomized controlled trials appropriate for studying drug efficacy are not well suited for complex system changes). When qualitative studies are used, appropriate qualitative research criteria are used to judge the strength of the evidence.

11. Medicare Quality of Care Report of Surveillance Measures. In: Health Care Financing Administration.
12. American Health Quality Association. A Pillar of Quality:The Medicare Peer Review Organization/Quality Improvement Organization Program. In; 2000.
13. Bing ML, Abel RL, Lee LJ, et al. Medical necessity for right heart catheterization. Tex Heart Inst J 1997;24(2):109-13.
14. Fortune GJ, Schiffel F, Jr., Elder S. MPCRF: the Right Heart Catheterization Cooperative project. Mo Med 1996;93(10):657-61.
15. Gold JA. Decreasing the rate of bilateral cardiac catheterization. Wis Med J 1995;94(10):569-70.
16. Malach M, Imperato PJ, Nenner RP, et al. Impact of an educational program on bilateral heart catheterization practice patterns. Am J Med Qual 1998;13(4):213-22.
17. Imperato PJ, Malach M, Nenner RP, et al. Concurrent improvements in ambulatory cardiac catheterization practices following inpatient interventions. J Ambulatory Care Manage 1999;22(2):1-8.
18. Borzecki Ann M; Christiansen Cindy L; Loveland Susan; Chew Priscilla; Rosen Amy K. Trends in the inpatient quality indicators: the Veterans Health Administration experience. Medical Care. 2010:48:694-702.

1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number***):**
Not applicable

1c.10 Clinical Practice Guideline Citation: Not applicable
1c.11 National Guideline Clearinghouse or other URL: Not applicable

1c.12 Rating of strength of recommendation (*also provide narrative description of the rating and by whom***):**
Not applicable

1c.13 Method for rating strength of recommendation (*If different from USPSTF system, also describe rating and how it relates to USPSTF)***:**
Not applicable

1c.14 Rationale for using this guideline over others:
None

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to Measure and Report?*	**1**
Steering Committee: Was the threshold criterion, *Importance to Measure and Report***, met?** **Rationale:**	**1** **Y☐** **N☐**
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	**Eval Rating**
2a. MEASURE SPECIFICATIONS	
S.1 Do you have a web page where current detailed measure specifications can be obtained? **S.2 If yes, provide web page URL:**	
2a. Precisely Specified	
2a.1 Numerator Statement (*Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):** Discharges with ICD-9-CM procedure code for right and left heart catheterization in any procedure code field	**2a-specs** **C☐** **P☐** **M☐** **N☐**
2a.2 Numerator Time Window (*The time period in which cases are eligible for inclusion in the numerator***):** Inpatient hospitalization	

Comment [k7]: USPSTF grading system **http://www.ahrq.gov/clinic/uspstf/grades.htm**: **A -** The USPSTF recommends the service. There is high certainty that the net benefit is substantial. **B -** The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. **C -** The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small. Offer or provide this service only if other considerations support the offering or providing the service in an individual patient. **D -** The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. **I -** The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

Comment [KP8]: 2a. The measure is well defined and precisely specified so that it can be implemented consistently within and across organizations and allow for comparability. The required data elements are of high quality as defined by NQF's Health Information Technology Expert Panel (HITEP) .

2a.3 Numerator Details (*All information required to collect/calculate the numerator, including all codes, logic, and definitions***):**

ICD-9-CM right and left heart catheterization procedure code:

3723 RT/LEFT HEART CARD CATH

Exclude cases:

- with valid indications for right-sided catheterization

ICD-9-CM Indications for Right Heart Catheterization diagnosis codes:

3910 ACUTE RHEUMATIC PERICARD
3911 ACUTE RHEUMATIC ENDOCARD
3912 AC RHEUMATIC MYOCARDITIS
3918 AC RHEUMAT HRT DIS NEC
3919 AC RHEUMAT HRT DIS NOS
3920 RHEUM CHOREA W HRT INVOL
3929 RHEUMATIC CHOREA NOS
393 CHR RHEUMATIC PERICARD
3940 MITRAL STENOSIS
3941 RHEUMATIC MITRAL INSUFF
3942 MITRAL STENOSIS W INSUFF
3949 MITRAL VALVE DIS NEC/NOS
3960 MITRAL/AORTIC STENOSIS
3961 MITRAL STENOS/AORT INSUF
3962 MITRAL INSUF/AORT STENOS
3963 MITRAL/AORTIC VAL INSUFF
3968 MITR/AORTIC MULT INVOLV
3969 MITRAL/AORTIC V DIS NOS
3970 TRICUSPID VALVE DISEASE
3971 RHEUM PULMON VALVE DIS
3979 RHEUM ENDOCARDITIS NOS
3980 RHEUMATIC MYOCARDITIS
39890 RHEUMATIC HEART DIS NOS
39891 RHEUMATIC HEART FAILURE
39899 RHEUMATIC HEART DIS NEC
40200 MAL HYPERTEN HRT DIS NOS
40201 MAL HYPERT HRT DIS W CHF
40210 BEN HYPERTEN HRT DIS NOS
40211 BENIGN HYP HRT DIS W CHF
40290 HYPERTENSIVE HRT DIS NOS
40291 HYPERTEN HEART DIS W CHF
40400 MAL HY HT/REN W/O HF/RF
40401 MAL HYPER HRT/REN W HF
40402 MAL HY HT/REN W REN FAIL
40403 MAL HYP HRT/REN W HF/RF
40410 BEN HY HT/REN W/O HF/RF
40411 BEN HYPER HRT/REN W HF
40412 BEN HY HT/REN W REN FAIL
40413 BEN HYP HRT/REN W HF/RF
40490 HY HT/REN NOS W/O HF/RF
40491 HYPER HRT/REN NOS W HF
40492 HY HT/REN NOS W REN FAIL
74684 OBSTRUCT HEART ANOM NEC
74685 CORONARY ARTERY ANOMALY
74686 CONGENITAL HEART BLOCK
74687 MALPOSITION OF HEART
74689 CONG HEART ANOMALY NEC
7469 CONG HEART ANOMALY NOS

7470	PATENT DUCTUS ARTERIOSUS
74710	COARCTATION OF AORTA
74711	INTERRUPT OF AORTIC ARCH
74720	CONG ANOM OF AORTA NOS
74721	ANOMALIES OF AORTIC ARCH
74722	AORTIC ATRESIA/STENOSIS
74729	CONG ANOM OF AORTA NEC
7473	PULMONARY ARTERY ANOM
74740	GREAT VEIN ANOMALY NOS
40493	HYP HRT/REN NOS W HF/RF
4150	ACUTE COR PULMONALE
4151	PULM EMBOLISM/INFARCT-
41511	IATROGENIC PULMON. EMBOLISM
41512	SEPTIC PULMONARY EMBOLSM
41519	OTHER PULMON EMBOLISM
4160	PRIM PULM HYPERTENSION
4161	KYPHOSCOLIOTIC HEART DIS
4168	CHR PULMON HEART DIS NEC
4169	CHR PULMON HEART DIS NOS
4170	ARTERIOVEN FISTU PUL VES
4171	PULMON ARTERY ANEURYSM
4178	PULMON CIRCULAT DIS NEC
4179	PULMON CIRCULAT DIS NOS
4200	AC PERICARDIT IN OTH DIS
42090	ACUTE PERICARDITIS NOS
42091	AC IDIOPATH PERICARDITIS
42099	ACUTE PERICARDITIS NEC
4210	AC/SUBAC BACT ENDOCARD
4211	AC ENDOCARDIT IN OTH DIS
4219	AC/SUBAC ENDOCARDIT NOS
4220	AC MYOCARDIT IN OTH DIS
42290	ACUTE MYOCARDITIS NOS
42291	IDIOPATHIC MYOCARDITIS
42292	SEPTIC MYOCARDITIS
42293	TOXIC MYOCARDITIS
42299	ACUTE MYOCARDITIS NEC
4230	HEMOPERICARDIUM
4231	ADHESIVE PERICARDITIS
4232	CONSTRICTIV PERICARDITIS
4233	CARDIAC TAMPONADE
4238	PERICARDIAL DISEASE NEC
4239	PERICARDIAL DISEASE NOS
4240	MITRAL VALVE DISORDER
4241	AORTIC VALVE DISORDER
4242	NONRHEUM TRICUSP VAL DIS
4243	PULMONARY VALVE DISORDER
42490	ENDOCARDITIS NOS
42491	ENDOCARDITIS IN OTH DIS
42499	ENDOCARDITIS NEC
4250	ENDOMYOCARDIAL FIBROSIS
4251	HYPERTR OBSTR CARDIOMYOP
4252	OBSC AFRIC CARDIOMYOPATH
4253	ENDOCARD FIBROELASTOSIS
4254	PRIM CARDIOMYOPATHY NEC
4255	ALCOHOLIC CARDIOMYOPATHY
4257	METABOLIC CARDIOMYOPATHY
4258	CARDIOMYOPATH IN OTH DIS
4259	SECOND CARDIOMYOPATH NOS

4280	CHF NOS
4281	LEFT HEART FAILURE
42820	SYSTOLIC HRT FAILURE NOS
42821	AC SYSTOLIC HRT FAILURE
42822	CHR SYSTOLIC HRT FAILURE
42823	AC ON CHR SYST HRT FAIL
42830	DIASTOLC HRT FAILURE NOS
42831	AC DIASTOLIC HRT FAILURE
42832	CHR DIASTOLIC HRT FAIL
42833	AC ON CHR DIAST HRT FAIL
42840	SYST/DIAST HRT FAIL NOS
42841	AC SYST/DIASTOL HRT FAIL
42842	CHR SYST/DIASTL HRT FAIL
42843	AC/CHR SYST/DIA HRT FAIL
4289	HEART FAILURE NOS
7450	COMMON TRUNCUS
74510	COMPL TRANSPOS GREAT VES
74511	DOUBLE OUTLET RT VENTRIC
74512	CORRECT TRANSPOS GRT VES
74519	TRANSPOS GREAT VESS NEC
7452	TETRALOGY OF FALLOT
7453	COMMON VENTRICLE
7454	VENTRICULAR SEPT DEFECT
7455	SECUNDUM ATRIAL SEPT DEF
74560	ENDOCARD CUSHION DEF NOS
74561	OSTIUM PRIMUM DEFECT
74569	ENDOCARD CUSHION DEF NEC
7457	COR BILOCULARE
7458	SEPTAL CLOSURE ANOM NEC
7459	SEPTAL CLOSURE ANOM NOS
74600	PULMONARY VALVE ANOM NOS
74601	CONG PULMON VALV ATRESIA
74602	CONG PULMON VALVE STENOS
74609	PULMONARY VALVE ANOM NEC
7461	CONG TRICUSP ATRES/STEN
7462	EBSTEIN´S ANOMALY
7463	CONG AORTA VALV STENOSIS
7464	CONG AORTA VALV INSUFFIC
7465	CONGEN MITRAL STENOSIS
7466	CONG MITRAL INSUFFICIENC
7467	HYPOPLAS LEFT HEART SYND
74681	CONG SUBAORTIC STENOSIS
74682	COR TRIATRIATUM
74683	INFUNDIB PULMON STENOSIS
74741	TOT ANOM PULM VEN CONNEC
74742	PART ANOM PULM VEN CONN
74749	GREAT VEIN ANOMALY NEC
7475	UMBILICAL ARTERY ABSENCE
74760	UNSP PRPHERL VASC ANOMAL
74761	GSTRONTEST VESL ANOMALY
74762	RENAL VESSEL ANOMALY
74763	UPR LIMB VESSEL ANOMALY
74764	LWR LIMB VESSEL ANOMALY
74769	OTH SPCF PRPH VSCL ANOML
74781	CEREBROVASCULAR ANOMALY
74782	SPINAL VESSEL ANOMALY
74783	PERSISTENT FETAL CIRC OCT02-
74789	CIRCULATORY ANOMALY NEC

7479 CIRCULATORY ANOMALY NOS

2a.4 Denominator Statement (*Brief, text description of the denominator - target population being measured***):**
Discharges with ICD-9-CM procedure code for heart catheterizations in any procedure code field

2a.5 Target population gender: Female, Male
2a.6 Target population age range: 18 and older

2a.7 Denominator Time Window (*The time period in which cases are eligible for inclusion in the denominator***):**
User defined; Most users use one calendar year

2a.8 Denominator Details (*All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):**
All discharges, age 18 years and older, with heart catheterization in any procedure field.
ICD-9-CM heart catheterization procedure codes:
3722 LEFT HEART CARDIAC CATH
3723RT/LEFT HEART CARD CATH

Include only cases with any diagnosis of coronary artery disease. ICD-9-CM coronary artery disease diagnosis codes:
41000 AMI ANTEROLATERAL, UNSPEC
41001 AMI ANTEROLATERAL, INIT
41002 AMI ANTEROLATERAL, SUBSEQ
41010 AMI ANTERIOR WALL, UNSPEC
41011 AMI ANTERIOR WALL, INIT
41012 AMI ANTERIOR WALL, SUBSEQ
41020 AMI INFEROLATERAL, UNSPEC
41021 AMI INFEROLATERAL, INIT
41022 AMI INFEROLATERAL, SUBSEQ
41030 AMI INFEROPOST, UNSPEC
41031 AMI INFEROPOST, INITIAL
41032 AMI INFEROPOST, SUBSEQ
41040 AMI INFERIOR WALL, UNSPEC
41041 AMI INFERIOR WALL, INIT
41042 AMI INFERIOR WALL, SUBSEQ
41050 AMI LATERAL NEC, UNSPEC
41051 AMI LATERAL NEC, INITIAL
41052 AMI LATERAL NEC, SUBSEQ
41060 TRUE POST INFARCT, UNSPEC
41061 TRUE POST INFARCT, INIT
41062 TRUE POST INFARCT, SUBSEQ
41070 SUBENDO INFARCT, UNSPEC
41071 SUBENDO INFARCT, INITIAL
41072 SUBENDO INFARCT, SUBSEQ
41080 AMI NEC, UNSPECIFIED
41081 AMI NEC, INITIAL
41082 AMI NEC, SUBSEQUENT
41090 AMI NOS, UNSPECIFIED
41091 AMI NOS, INITIAL
41092 AMI NOS, SUBSEQUENT
4110 POST MI SYNDROME
4111 INTERMED CORONARY SYND
41181 CORONARY OCCLSN W/O MI
41189 AC ISCHEMIC HRT DIS NEC
412 OLD MYOCARDIAL INFARCT
4130 ANGINA DECUBITUS
4131 PRINZMETAL ANGINA

4139 ANGINA PECTORIS NEC/NOS
4140 COR ATHEROSCLEROSIS OCT94-
41400 COR ATH UNSP VSL NTV/GFT OCT94-
41401 CRNRY ATHRSCL NATVE VSSL OCT94-
41402 CRN ATH ATLG VN BPS GRFT OCT94-
41403 CRN ATH NONATLG BLG GRFT OCT94-
41404 COR ATH ARTRY BYPAS GRFT OCT96-
41405 COR ATH BYPASS GRAFT NOS OCT96-
41406 COR ATH NATV ART TP HRT OCT02-
41407 COR ATH BPS GRAFT TP HRT OCT03-
41410 ANEURYSM, HEART (WALL)
41411 CORONARY VESSEL ANEURYSM
41412 DISSECTION COR ARTERY OCT02-
41419 ANEURYSM OF HEART NEC
4143 CORONARY ATHEROSCLEROSIS DUE TO LIPID RICH PLAQUE OCT08-
4148 CHR ISCHEMIC HRT DIS NEC
4149 CHR ISCHEMIC HRT DIS NOS

2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population***):** None

2a.10 Denominator Exclusion Details (*All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**
Not applicable

2a.11 Stratification Details/Variables (*All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
Observed (raw) rates may be stratified by gender, age groups, race/ethnicity categories and payer categories.
Risk adjustment of the data is recommended using age and sex. Reliability adjustment is also recommended.

2a.12-13 Risk Adjustment Type: No risk adjustment necessary

2a.14 Risk Adjustment Methodology/Variables (*List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**
None

2a.15-17 Detailed risk model available Web page URL or attachment:

2a.18-19 Type of Score: Rate/proportion
2a.20 Interpretation of Score: Better quality = Lower score
2a.21 Calculation Algorithm (*Describe the calculation of the measure as a flowchart or series of steps***):**
Each Inpatient Quality Indicator (IQI) expressed as a rate, is defined as outcome of interest/population at risk or numerator/denominator. The Quality Indicators software performs five steps to produce the IQI rates. 1) Discharge-level data is used to mark inpatient records containing outcomes of interest. 2) Identify populations at risk. 3) Calculate observed rates. 4) For rates that are not risk-adjusted, the risk-adjusted rate equals the observed rate. 5) Create multivariate signal extraction (MSX) smoothed rates. Shrinkage factors are applied to the risk-adjusted rates for each PQI in the MSX process. For each IQI, the shrinkage estimate reflects a reliability adjustment unique to each indicator. Full information on IQI algorithms and specification can be found at http://qualityindicators.ahrq.gov/Iqi_download.htm.

2a.22 Describe the method for discriminating performance *(e.g., significance testing)***:**
Significance testing is not prescribed by the software. Users may define their methods of discriminating performance according to their application. Although all cases are measured, the rate is considered a sample in time, given the variations in case mix over time. Confidence intervals can be calculated, but again are not prescribed.

2a.23 Sampling (Survey) Methodology *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)*:
Not applicable

2a.24 Data Source (*Check the source(s) for which the measure is specified and tested)*

Comment [k9]: 11 Risk factors that influence outcomes should not be specified as exclusions.
12 Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

Electronic administrative data/claims

2a.25 **Data source/data collection instrument (***Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
Hospital administrative discharge data. See data requirements in the AHRQ QI Windows Application Documentation: http://www.qualityindicators.ahrq.gov/software.htm

2a.26-28 **Data source/data collection instrument reference web page URL or attachment:** URL
http://www.qualityindicators.ahrq.gov/software.htm

2a.29-31 **Data dictionary/code table web page URL or attachment:** URL
http://www.qualityindicators.ahrq.gov/downloads/winqi/AHRQ_QI_Windows_Software_Documentation_V41a.pdf

2a.32-35 **Level of Measurement/Analysis** (*Check the level(s) for which the measure is specified and tested)*
Facility/Agency

2a.36-37 **Care Settings (***Check the setting(s) for which the measure is specified and tested)*
Hospital

2a.38-41 **Clinical Services** (*Healthcare services being measured, check all that apply*)
Clinicians: Physicians (MD/DO)

TESTING/ANALYSIS

2b. Reliability testing

2b.1 **Data/sample** *(description of data/sample and size)***:** 2007 AHRQ State Inpatient Databases (N=4,000 hosptials and 38 million discharges)

2b.2 **Analytic Method** *(type of reliability & rationale, method for testing)***:**
Annual review of ICD-9-CM coding updates for numerator and denominator specifications

2b.3 **Testing Results** *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)***:**
Not applicable

2b C☐ P☐ M☐ N☐

2c. Validity testing

2c.1 **Data/sample** *(description of data/sample and size)***:** 2007 AHRQ State Inpatient Databases (N=4,000 hosptials and 38 million discharges)

2c.2 **Analytic Method** *(type of validity & rationale, method for testing)***:**
Annual update of comparative data

2c.3 **Testing Results** *(statistical results, assessment of adequacy in the context of norms for the test conducted)***:**
Signal variance of 0.000017035199; signal ratio of 0.90

2c C☐ P☐ M☐ N☐

2d. Exclusions Justified

2d.1 **Summary of Evidence supporting exclusion(s):**
Not applicable

2d.2 **Citations for Evidence:**
Not applicable

2d.3 **Data/sample** *(description of data/sample and size)***:** Not applicable

2d.4 **Analytic Method** *(type analysis & rationale)***:**

2d C☐ P☐ M☐ N☐ NA☐

Comment [KP10]: 2b. Reliability testing demonstrates the measure results are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period.

Comment [k11]: 8 Examples of reliability testing include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing may address the data items or final measure score.

Comment [KP12]: 2c. Validity testing demonstrates that the measure reflects the quality of care provided, adequately distinguishing good and poor quality. If face validity is the only validity addressed, it is systematically assessed.

Comment [k13]: 9 Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP < 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed (e.g., ratings by relevant stakeholders) and the measure is judged to represent quality care for the specific topic and that the measure focus is the most important aspect of quality for the specific topic.

Comment [KP14]: 2d. Clinically necessary measure exclusions are identified and must be:
•supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;
AND
•a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;
AND
•precisely defined and specified:
–if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);
if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category ... [2]

Comment [k15]: 10 Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, sensitivity analyses with and without the exclusion, and variability of exclusions across providers.

Not applicable

2d.5 **Testing Results** *(e.g., frequency, variability, sensitivity analyses)*:
Not applicable

2e. Risk Adjustment for Outcomes/ Resource Use Measures

2e.1 **Data/sample** *(description of data/sample and size)*: Not applicable

2e.2 **Analytic Method** *(type of risk adjustment, analysis, & rationale)*:
Not applicable

2e.3 **Testing Results** *(risk model performance metrics)*:
Not applicable

2e.4 **If outcome or resource use measure is not risk adjusted, provide rationale:** Not applicable

2e C☐ P☐ M☐ N☐ NA☐

2f. Identification of Meaningful Differences in Performance

2f.1 **Data/sample from Testing or Current Use** *(description of data/sample and size)*: 2007 AHRQ State Inpatient Databases (N=4,000 hosptials and 38 million discharges)

2f.2 **Methods to identify statistically significant and practically/meaningfully differences in performance** *(type of analysis & rationale)*:
Posterior probability (gamma) with 95% probability interval

2f.3 **Provide Measure Scores from Testing or Current Use** *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:
5th 25th Median 75th 95th
0.011149 0.014403 0.017009 0.019913 0.024636

2f C☐ P☐ M☐ N☐

2g. Comparability of Multiple Data Sources/Methods

2g.1 **Data/sample** *(description of data/sample and size)*: Not applicable

2g.2 **Analytic Method** *(type of analysis & rationale)*:
Not applicable

2g.3 **Testing Results** *(e.g., correlation statistics, comparison of rankings)*:
Not applicable

2g C☐ P☐ M☐ N☐ NA☐

2h. Disparities in Care

2h.**1 If measure is stratified, provide stratified results** *(scores by stratified categories/cohorts)*: Based on the 2008 national statistics for diabetes short-tem complications http://hcupnet.ahrq.gov the 2008 rates are as follows:

Overall rate per 100: 1.73 ; Risk adjusted rate: 1.73
Male: 1.71
Female: 1.78

Age groups: 18-39: 1.65; 40-64: 1.63; 65-74: 1.83; 75+: 1.83

Payer
Medicare: 1.85
Medicaid: 1.69
Other: 1.59

2h.2 **If disparities have been reported/identified, but measure is not specified to detect disparities,**

2h C☐ P☐ M☐ N☐ NA☐

Comment [KP16]: 2e. For outcome measures and other measures (e.g., resource use) when indicated:
•an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified and is based on patient clinical factors that influence the measured outcome (but not disparities in care) and are present at start of care;[Error! Bookmark not defined.] OR rationale/data support no risk adjustment.

Comment [k17]: 13 Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender (e.g., poorer treatment outcomes of African American men with prostate cancer, inequalities in treatment for CVD risk factors between men and women). It is preferable to stratify measures by race and socioeconomic status rather than adjusting out differences.

Comment [KP18]: 2f. Data analysis demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful differences in performance.

Comment [k19]: 14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% v. 75%) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v. $5,025) is practically meaningful. Measures with overall poor performance may not demonstrate much variability across providers.

Comment [KP20]: 2g. If multiple data sources/methods are allowed, there is demonstration they produce comparable results.

Comment [KP21]: 2h. If disparities in care have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results (e.g., by race, ethnicity, socioeconomic status, gender);OR rationale/data justifies why stratification is not necessary or not feasible.

provide follow-up plans: Rates may be reported by gender, age, race/ethnicity categories and payer categories	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Scientific Acceptability of Measure Properties?*	**2**
Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties*, **met?** **Rationale:**	*2* **C**☐ **P**☐ **M**☐ **N**☐
3. USABILITY	
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	**Eval Rating**
3a. Meaningful, Understandable, and Useful Information 3a.1 **Current Use:** In use 3a.2 **Use in a public reporting initiative (disclosure of performance results to the public at large)** (*If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years*)**:** 1) Illinois Hospital Association: Illinois Hospitals Caring for You, www.illinoishospitals.org 2) Iowa Healthcare Collaborative: http://www.ihconline.org/aspx/publicreporting/iowareport.aspx 3) Norton Healthcare (a multi-hospital system): Norton Healthcare Quality Report, http://www.nortonhealthcare.com/body.cfm?id=157 4) Kentucky Hospital Association: Kentucky Hospital Association Quality Data, http://info.kyha.com/QualityData/IQISite/ 5) State of Kentucky, http://chfs.ky.gov/ohp/healthdata 6) State of New Jersey: Find and Compare Quality Care in New Jersey Hospitals, http://www.nj.gov/health/healthcarequality/ 7) Niagara Health Quality Coalition and Alliance for Quality Health Care: New York State Hospital Report Card, http://www.myhealthfinder.com/ 8) State of Texas: Reports on Hospital Performance, http://www.dshs.state.tx.us/thcic/ 9) Niagara Health Quality Coalition and Alliance for Quality Health Care: Washington State Hospital Report Card, http://www.myhealthfinder.com/wa09/index.php 10) State of Nevada: Nevada Compare Care, http://nevadacomparecare.net/Monahrq/home.html 3a.3 **If used in other programs/initiatives (***If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years***):** University Healthcare Consortium - An alliance of 103 academic medical centers and 219 of their affiliated hospitals. Reporting the AHRQ QIs to their member hospitals. (see www.uhc.edu. Note: measure results reported to hospitals; not reported on site). Dallas Fort Worth Hospital Council – Reporting on measure results to over 70 hospitals in Texas (see www.dfwhc.ord. Note: measure results reported to hospitals; not reported on site). Norton Healthcare - a multi-hospital system in Kentucky (see http://www.nortonhealthcare.com/about/Our_Performance/index.aspx) Ministry Health Care - a multi-hospital system in Wisconsin (see http://ministryhealth.org/display/router.aspx. Note: measure results reported to hospitals; not reported on site). Minnesota Hospital Association http://www.mnhospitals.org/ Note: measure used in quality improvement. Not reported publicly by the association)	**3a** **C**☐ **P**☐ **M**☐ **N**☐

Comment [KP22]: 3a. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audience(s) for both public reporting (e.g., focus group, cognitive testing) and informing quality improvement (e.g., quality improvement initiatives). An important outcome that may not have an identified improvement strategy still can be useful for informing quality improvement by identifying the need for and stimulating new approaches to improvement.

Testing of Interpretability (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*)

3a.4 **Data/sample** *(description of data/sample and size)*: The AHRQ State Inpatient Databases (SID) consist of approximatley 4,000 hospitals and 38 million discharges

3a.5 **Methods** *(e.g., focus group, survey, QI project)*:
A research team from the School of Public Affairs, Baruch College, under contracts with the Department of Public Health, Weill Medical College and Battelle, Inc., has developed a pair of Hospital Quality Model Reports at the request of the Agency for Healthcare Research & Quality (AHRQ). The AHRQ hip fracture mortality measure is included in the reports. These reports are designed specifically to report comparative information on hospital performance based on the AHRQ Quality Indicators (QIs). The work was done in close collaboration with AHRQ staff and the AHRQ Quality Indicators team.

The Model Reports (discussed immediately above) are based on:

- Extensive search and analysis of the literature on hospital quality measurement and reporting, as well as public reporting on health care quality more broadly;
- Interviews with quality measurement and reporting experts, purchasers, staff of purchasing coalitions, and executives of integrated health care delivery systems who are responsible for quality in their facilities;
- Two focus groups with chief medical officers of hospitals and/or systems and two focus groups with quality managers from a broad mix of hospitals;
- Four focus groups with members of the public who had recently experienced a hospital admission; and
- Four rounds of cognitive interviews (a total of 62 interviews) to test draft versions of the two Model Reports with members of the public with recent hospital experience, basic computer literacy but widely varying levels of education.

3a.6 **Results** *(qualitative and/or quantitative results and conclusions)*:
Given the above review of the literature and original research that was conducted, a Model report was the result that could help sponsors use the best evidence on public reports so they are most likely to have the desired effects on quality.

3b/3c. Relation to other NQF-endorsed measures

3b.1 **NQF # and Title of similar or related measures:**

(for NQF staff use) **Notes on similar/related endorsed or submitted measures:**

3b. Harmonization
If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population):
3b.2 **Are the measure specifications harmonized? If not, why?**

3b C☐ P☐ M☐ N☐ NA☐

3c. Distinctive or Additive Value
3c.1 **Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:**

5.1 **If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:**

3c C☐ P☐ M☐ N☐ NA☐

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Usability*? **3**

Steering Committee: Overall, to what extent was the criterion, *Usability*, **met? 3**
Rationale:
C☐ P☐ M☐

Comment [KP23]: 3b. The measure specifications are harmonized with other measures, and are applicable to multiple levels and settings.

Comment [k24]: 16 Measure harmonization refers to the standardization of specifications for similar measures on the same topic (e.g., *influenza immunization* of patients in hospitals or nursing homes), or related measures for the same target population (e.g., eye exam and HbA1c for *patients with diabetes*), or definitions applicable to many measures (e.g., age designation for children) so that they are uniform or compatible, unless differences are dictated by the evidence. The dimensions of harmonization can include numerator, denominator, exclusions, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.

Comment [KP25]: 3c. Review of existing endorsed measures and measure sets demonstrates that the measure provides a distinctive or additive value to existing NQF-endorsed measures (e.g., provides a more complete picture of quality for a particular condition or aspect of healthcare, is a more valid or efficient way to measure).

	N☐
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	Eval Rating
4a. Data Generated as a Byproduct of Care Processes 4a.1-2 **How are the data elements that are needed to compute measure scores generated?** Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)	4a C☐ P☐ M☐ N☐
4b. Electronic Sources 4b.1 **Are all the data elements available electronically?** (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*) Yes 4b.2 **If not, specify the near-term path to achieve electronic capture by most providers.**	4b C☐ P☐ M☐ N☐
4c. Exclusions 4c.1 **Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?** No 4c.2 **If yes, provide justification.**	4c C☐ P☐ M☐ N☐ NA☐
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences 4d.1 **Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.** None identified	4d C☐ P☐ M☐ N☐
4e. Data Collection Strategy/Implementation 4e.1 **Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:** No issues have been identified 4e.2 **Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:** Administrative data is collected as part of routine operations. Some staff time is required to download and execute the software 4e.3 **Evidence for costs:** User reports 4e.4 **Business case documentation:** None	4e C☐ P☐ M☐ N☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility*?	4
Steering Committee: Overall, to what extent was the criterion, *Feasibility*, **met?** **Rationale:**	4 C☐ P☐ M☐ N☐

Comment [KP26]: 4a. For clinical measures, required data elements are routinely generated concurrent with and as a byproduct of care processes during care delivery. (e.g., BP recorded in the electronic record, not abstracted from the record later by other personnel; patient self-assessment tools, e.g., depression scale; lab values, meds, etc.)

Comment [KP27]: 4b. The required data elements are available in electronic sources. If the required data are not in existing electronic sources, a credible, near-term path to electronic collection by most providers is specified and clinical data elements are specified for transition to the electronic health record.

Comment [KP28]: 4c. Exclusions should not require additional data sources beyond what is required for scoring the measure (e.g., numerator and denominator) unless justified as supporting measure validity.

Comment [KP29]: 4d. Susceptibility to inaccuracies, errors, or unintended consequences and the ability to audit the data items to detect such problems are identified.

Comment [KP30]: 4e. Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, etc.) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use).

RECOMMENDATION	
(for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.**	**Time-limited** ☐
Steering Committee: Do you recommend for endorsement? **Comments:**	**Y** ☐ **N** ☐ **A** ☐

CONTACT INFORMATION
Co.1 Measure Steward (Intellectual Property Owner) **Co.1 Organization** Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland, 20850 **Co.2 Point of Contact** John, Bott, MSSW, MBA, john.bott@ahrq.hhs.gov, 301-427-1317-
Measure Developer If different from Measure Steward **Co.3 Organization** Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland, 20850 **Co.4 Point of Contact** John, Bott, MSSW, MBA, john.bott@ahrq.hhs.gov, 301-427-1317-
Co.5 Submitter If different from Measure Steward POC John, Bott, MSSW, MBA, john.bott@ahrq.hhs.gov, 301-427-1317-, Agency for Healthcare Research and Quality
Co.6 Additional organizations that sponsored/participated in measure development UC Davis Stanford University Battelle Memorial Institute

ADDITIONAL INFORMATION
Workgroup/Expert Panel involved in measure development **Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.**
Ad.2 If adapted, provide name of original measure: **Ad.3-5 If adapted, provide original specifications URL or attachment**
Measure Developer/Steward Updates and Ongoing Maintenance **Ad.6 Year the measure was first released:** 2002 **Ad.7 Month and Year of most recent revision:** 10, 2010 **Ad.8 What is your frequency for review/update of this measure?** annually **Ad.9 When is the next scheduled review/update for this measure?** 05, 2011
Ad.10 Copyright statement/disclaimers: The AHRQ QI software is publicly available. We have no copyright disclaimers.
Ad.11 -13 Additional Information web page URL or attachment:
Date of Submission (*MM/DD/YY*)**:** 12/31/2010

Page 3: [1] Comment [k5] **Karen Pace** **10/5/2009 8:59:00 AM**

4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., mammography) or measures for multiple care processes that affect a single outcome.

Page 12: [2] Comment [KP14] **Karen Pace** **10/5/2009 8:59:00 AM**

2d. Clinically necessary measure exclusions are identified and must be:

- supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;

AND

- a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;

AND

- precisely defined and specified:
  - if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);

if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

NATIONAL QUALITY FORUM

Measure Evaluation 4.1
December 2009

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

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

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

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

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

(for NQF staff use) **NQF Review #:** 0133 **NQF Project:** Cardiovascular Endorsement Maintenance 2010
MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** PCI mortality (risk-adjusted)©
De.2 **Brief description of measure**: Risk adjusted PCI mortality rate.
1.1-2 **Type of Measure:** Outcome De.3 **If included in a composite or paired with another measure, please identify composite or paired measure** N/A
De.4 **National Priority Partners Priority Area:** Safety De.5 **IOM Quality Domain**: Effectiveness, Safety, Timeliness De.6 **Consumer Care Need:** Getting better

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	**NQF Staff**
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.* A.1 **Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes A.2 **Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:** Proprietary measure A.3 **Measure Steward Agreement:** Agreement will be signed and submitted prior to or at the time of measure submission A.4 **Measure Steward Agreement attached:**	**A** **Y**☐ **N**☐
B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least	**B** **Y**☐

every 3 years. Yes, information provided in contact section	N☐
C. The intended use of the measure includes both public reporting and quality improvement. ►**Purpose:** Public reporting, Internal quality improvement Accountability, Payment incentive, Accreditation	C Y☐ N☐
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1**Testing:** Yes, fully developed and tested D.2 **Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?** Yes	D Y☐ N☐
(for NQF staff use) **Have all conditions for consideration been met?** **Staff Notes to Steward** (*if submission returned*)**:**	**Met** Y☐ N☐
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**	
Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. *Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.* (evaluation criteria) **1a. High Impact**	**Eval Rating**
(for NQF staff use) **Specific NPP goal**:	
1a.1 **Demonstrated High Impact Aspect of Healthcare:** Affects large numbers, Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Severity of illness, Patient/societal consequences of poor quality 1a.2 1a.3 **Summary of Evidence of High Impact:** 1.3 million Percutaneous Coronary Intervention (PCI) procedures were performed in 2006 (AHA 2009). From 1987–2004, the number of procedures increased 326 percent (AHA 2003). In 2006, $11.7 billion was paid to Medicare beneficiaries for in-hospital costs when CHD was the principal diagnosis ($14,009 per discharge for acute MI, $12,977 per discharge for coronary atherosclerosis, and $10,630 per discharge for other ischemic heart disease) (AHA 2009). After 3 years, average total costs are estimated at $63,896 for PCI (Stroupe 2006). Risk of mortality following PCI is the second highest among cardiac procedures, with a rate of 0.71 for in-hospital deaths in 2006 (AHA 2009). Analyses of large registries indicate overall unadjusted in-hospital death rates at 0.4% to 1.9%. 1a.4 **Citations for Evidence of High Impact:** 1. American Heart Association. Heart Disease and Stroke Statistics—2009 Update. Dallas, Texas: American Heart Association; 2009. 2. American Heart Association. Heart Disease and Stroke Statistics—2003 update. Dallas, TX: American Heart Association, 2002. 3. Smith SC Jr, Feldman TE, Hirshfeld JW Jr. et al. 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 (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for	**1a** C☐ P☐ M☐ N☐

Comment [KP1]: 1a. The measure focus addresses:
- a specific national health goal/priority identified by NQF's National Priorities Partners; OR
- a demonstrated high impact aspect of healthcare (e.g., affects large numbers, leading cause of morbidity/mortality, high resource use (current and/or future), severity of illness, and patient/societal consequences of poor quality).

Percutaneous Coronary Intervention). American College of Cardiology Web Site. Available at: http://www.acc.org/clinical/guidelines/percutaneous/update/index.pdf (Smith 2005).
3. Stroupe KT, Morrison DA, Hlatky MA et al. Cost-Effectiveness of Coronary Artery Bypass Grafts Versus Percutaneous Coronary Intervention for Revascularization of High-Risk Patients. Circulation. 2006;114:1251-1257.)

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: This measure allows benchmarking against the national aggregate and against hospitals with similar volume, so that hospitals will high rates can engage in quality improvement to reduce mortality following PCI procedures.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
Mean: 1.39
SD: 0.4

Measure Scores by Percentile:
0: 3.81
10: 2.94
25:2.13
50:1.48
75:1.06
90:0.73
100:0.21

1b.3 Citations for data on performance gap:
1058 facilities, 263,517 patients. July 1 2009 to December 31 2009.

1b.4 Summary of Data on disparities by population group:
None

1b.5 Citations for data on Disparities:
None

1b
C ☐
P ☐
M ☐
N ☐

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** This is an outcome measure that is relevant to the target population (patients undergoing PCI) because it is estimated that in-hospital mortality following PCI ranges from 0.4-1.9%. Hospital characteristics have been shown to impact mortality rates.

1c.2-3. Type of Evidence: Observational study, Evidence-based guideline

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
Evidence has demonstrated a relationship between hospital characteristics, including volume of PCIs performed annually and availability of on-site cardiac surgery and in-hospital PCI mortality.

Kimmel et al., using data from the SCAI, found that an inverse relationship existed between the number of angioplasty procedures performed at a hospital and the rate of major complications (Kimmel 1995). These results were risk stratified and independent of the patient-risk profile. Significantly fewer complications occurred in laboratories that performed at least 400 angioplasty procedures per year. Jollis et al. found that low-volume hospitals were associated with higher rates of emergency coronary artery bypass surgery and death (Jollis 1997). Improved outcomes were identified with a threshold volume of 75 Medicare angioplasties per physician and 200 Medicare angioplasty procedures per hospital. Using a 35% to 50% ratio of Medicare patients, the threshold value was 150 to 200 angioplasty procedures per cardiologist and 400 to 600 angioplasty procedures per institution (Ryan 1995).

1c
C ☐
P ☐
M ☐
N ☐

Comment [KP2]: 1b. Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating considerable variation, or overall poor performance, in the quality of care across providers and/or population groups (disparities in care).

Comment [k3]: 1 Examples of data on opportunity for improvement include, but are not limited to: prior studies, epidemiologic data, measure data from pilot testing or implementation. If data are not available, the measure focus is systematically assessed (e.g., expert panel rating) and judged to be a quality problem.

Comment [k4]: 1c. The measure focus is:
•an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;
OR
•if an intermediate outcome, process, structure, etc., there is **evidence** that supports the specific measure focus as follows:
oIntermediate outcome – evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
oProcess – evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and
if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
oStructure – evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
oPatient experience – evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of individuals/ the public.
oAccess – evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
oEfficiency – demonstration of an association between the measured resource use and level of performance with respect to one or more of the other five IOM aims of quality.

Comment [k5]: 4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., ... [1]

Vakili et al., analyzing primary PCI procedures for STEMI performed in New York State, found no relationship between physician total angioplasty procedure volume and mortality after primary PCI for STEMI but did find an association between an operator's primary PCI activity level and the outcome of primary PCI for STEMI that was independent of the operator's experience in elective PCI (Vakili 2001; Vakili 2003). Low-volume physicians, who performed 1 to 10 primary PCI procedures per year, had an unadjusted mortality rate of 7.1% compared with 3.8% for physicians who performed 11 or more primary PCI procedures per year.

For the nonprimary/rescue PCI population, mortality was higher in hospitals without onsite cardiac surgery (adjusted OR 1.38; 95% CI 1.14 to 1.67; P equals 0.001) (Wennberg 2004).

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom***):** N/A

1c.6 Method for rating evidence: N/A

1c.7 Summary of Controversy/Contradictory Evidence: None

1c.8 Citations for Evidence (*other than guidelines***):** 1. Kimmel SE, Berlin JA, Laskey WK. The relationship between coronary angioplasty procedure volume and major complications. JAMA 1995;274:1137-42.

2. Jollis JG, Peterson ED, Nelson CL, et al. Relationship between physician and hospital coronary angioplasty volume and outcome in elderly patients. Circulation 1997;95:2485-91.

3. Ryan TJ. The critical question of procedure volume minimums for coronary angioplasty. JAMA 1995;274:1169-70.

4. Vakili BA, Kaplan R, Brown DL. Volume-outcome relation for physicians and hospitals performing angioplasty for acute myocardial infarction in New York state. Circulation 2001; 104:2171-6.

5. Vakili BA, Brown DL. Relation of total annual coronary angioplasty volume of physicians and hospitals on outcomes of primary angioplasty for acute myocardial infarction (data from the 1995 Coronary Angioplasty Reporting System of the New York State Department of Health). Am J Cardiol 2003;91:726-8.

6. Wennberg DE, Lucas FL, Siewers AE, Kellett MA, Malenka DJ. Outcomes of percutaneous coronary interventions performed at centers without and with onsite coronary artery bypass graft surgery. JAMA 2004;292:1961-8.

1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number***):**
The following guideline recommendations relate to processes that can impact this outcome measure:

Class I
1. Elective PCI should be performed by operators with acceptable annual volume (at least 75 procedures) at high-volume centers (more than 400 procedures) with onsite cardiac surgery (310,312). (Level of Evidence: B)
2. Elective PCI should be performed by operators and institutions whose historical and current risk-adjusted outcomes statistics are comparable to those reported in contemporary national data registries. (Level of Evidence: C)
3. Primary PCI for STEMI should be performed by experienced operators who perform more than 75 elective PCI procedures per year and, ideally, at least 11 PCI procedures for STEMI per year. Ideally, these procedures should be performed in institutions that perform more than 400 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year. (Level of Evidence B)
Class IIa
1. It is reasonable that operators with acceptable volume (at least 75 PCI procedures per year) perform PCI at low-volume centers (200 to 400 PCI procedures per year) with onsite cardiac surgery (310,312). (Level of Evidence: B)
2. It is reasonable that low-volume operators (fewer than 75 PCI procedures per year) perform PCI at high-volume centers (more than 400 PCI procedures per year) with onsite cardiac surgery (310,312). Ideally,

Comment [k6]: 3 The strength of the body of evidence for the specific measure focus should be systematically assessed and rated (e.g., USPSTF grading system http://www.ahrq.gov/clinic/uspstf07/methods/benefit.htm). If the USPSTF grading system was not used, the grading system is explained including how it relates to the USPSTF grades or why it does not. However, evidence is not limited to quantitative studies and the best type of evidence depends upon the question being studied (e.g., randomized controlled trials appropriate for studying drug efficacy are not well suited for complex system changes). When qualitative studies are used, appropriate qualitative research criteria are used to judge the strength of the evidence.

operators with an annual procedure volume less than 75 should only work at institutions with an activity level of more than 600 procedures per year. Operators who perform fewer than 75 procedures per year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume of at least 150 procedures per year. (Level of Evidence: B)
Class IIb
The benefit of primary PCI for STEMI patients eligible for fibrinolysis when performed by an operator who performs fewer than 75 procedures per year (or fewer than 11 PCIs for STEMI per year) is not well established. (Level of Evidence: C)
Class III
It is not recommended that elective PCI be performed by low-volume operators (fewer than 75 procedures per year) at low-volume centers (200 to 400) with or without onsite cardiac surgery (310,312). An institution with a volume of fewer than 200 procedures per year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer this service. (Level of Evidence: B)
Class I
1. Elective PCI should be performed by operators with acceptable annual volume (at least 75 procedures per year) at high-volume centers (more than 400 procedures annually) that provide immediately available onsite emergency cardiac surgical services. (Level of Evidence: B) 2. Primary PCI for patients with STEMI should be performed in facilities with onsite cardiac surgery. (Level of Evidence: B)
Class III
Elective PCI should not be performed at institutions that do not provide onsite cardiac surgery. (Level of Evidence: C)*

1c.10 **Clinical Practice Guideline Citation:** Smith SC Jr, Feldman TE, Hirshfeld JW Jr. et al. 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 (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention). American College of Cardiology Web Site. Available at: http://www.acc.org/clinical/guidelines/percutaneous/update/index.pdf (Smith 2005).
1c.11 **National Guideline Clearinghouse or other URL:** N/A

1c.12 **Rating of strength of recommendation (***also provide narrative description of the rating and by whom***):**
N/A

1c.13 **Method for rating strength of recommendation** (*If different from USPSTF system, also describe rating and how it relates to USPSTF)***:**
N/A

1c.14 **Rationale for using this guideline over others:**
N/A

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to Measure and Report*?	**1**
Steering Committee: Was the threshold criterion, *Importance to Measure and Report***, met?** **Rationale:**	**1** **Y☐** **N☐**
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	**Eval Rating**
2a. MEASURE SPECIFICATIONS	
S.1 **Do you have a web page where current detailed measure specifications can be obtained?** S.2 **If yes, provide web page URL:** **2a. Precisely Specified**	**2a-specs C☐**

Comment [k7]: USPSTF grading system **http://www.ahrq.gov/clinic/uspstf/grades.htm**: **A -** The USPSTF recommends the service. There is high certainty that the net benefit is substantial. **B -** The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. **C -** The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small. Offer or provide this service only if other considerations support the offering or providing the service in an individual patient. **D -** The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. **I -** The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

Comment [KP8]: 2a. The measure is well defined and precisely specified so that it can be implemented consistently within and across organizations and allow for comparability. The required data elements are of high quality as defined by NQF's Health Information Technology Expert Panel (HITEP) .

2a.1 Numerator Statement (*Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):**
Patients 18 years of age and older with a PCI procedure performed during admission who expired

2a.2 Numerator Time Window (*The time period in which cases are eligible for inclusion in the numerator***):**
One year

2a.3 Numerator Details (*All information required to collect/calculate the numerator, including all codes, logic, and definitions***):**
PCI=yes
Coding instructions: indicate if the patient had a percutaneous coronary intervention (PCI)
Selections: yes/no
Supporting definitions: PCI: A percutaneous coronary intervention (PCI) is the placement of an angioplasty guide wire, balloon, or other device (e.g. stent, atherectomy, brachytherapy, or thrombectomy catheter) into a native coronary artery or coronary bypass graft for the purpose of mechanical coronary revascularization. Source: NCDR

Discharge status=deceased
Selections: Alive/deceased
Coding instructions: Indicate whether the patient was alive or deceased at discharge.

2a.4 Denominator Statement (*Brief, text description of the denominator - target population being measured***):**
Patients 18 years of age and older with a PCI procedure performed during admission

2a.5 Target population gender: Female, Male
2a.6 Target population age range: > 18 years of age

2a.7 Denominator Time Window (*The time period in which cases are eligible for inclusion in the denominator***):**
One year (quarterly to include previous four quarters of data)

2a.8 Denominator Details (*All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):**
PCI=yes
Coding instructions: indicate if the patient had a percutaneous coronary intervention (PCI)
Selections: yes/no
Supporting definitions: PCI: A percutaneous coronary intervention (PCI) is the placement of an angioplasty guide wire, balloon, or other device (e.g. stent, atherectomy, brachytherapy, or thrombectomy catheter) into a native coronary artery or coronary bypass graft for the purpose of mechanical coronary revascularization. Source: NCDR

Age: patients must be 18 years of age to be included in the registry.

2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population***):** 1. NCDR Registry patients who did not have a PCI (Patient admissions with a diagnostic cath only during that admission);
2. Data submissions that do not pass the data quality and completeness reports;
3. Procedure variables for subsequent PCIs during the same admission (if the patient had more than one PCI procedure during that admission).
4. Patient admissions with PCI who transferred to another facility on discharge;
5. Patient admissions with PCI who have more than two variables in the risk model that are missing.

2a.10 Denominator Exclusion Details (*All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**
1. PCI = yes
2. All data submissions must pass the data quality and completeness reports to be included. Note: If one or two variables are missing, the value is imputed for certain characteristics (see appendix 2 of the NCDR CathPCI Registry PCI Risk Adjusted Morality Model 2008 for more information). If the value is missing for more

P☐
M☐
N☐

Comment [k9]: 11 Risk factors that influence outcomes should not be specified as exclusions.
12 Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

than two variables, the patient record is excluded. However, in our data quality program, all variables in the risk model have a high "inclusion" criteria. This means that, when a hospital submits data to us, they need to have a high level of completeness (around 99%) for those variables. If they are not able to meet the criteria in our data quality program, they do not receive risk adjusted mortality for the records they submitted for that quarter.
3. PCI= yes for more than one procedure during the same admission.
4. Discharge location= transferred to another facility

2a.11 Stratification Details/Variables (*All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
N/A

2a.12-13 Risk Adjustment Type: Risk-adjustment devised specifically for this measure/condition

2a.14 Risk Adjustment Methodology/Variables (*List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**
Risk adjustment methodology is a logistic regression analysis.
Weights were assigned to risk factors or variables reflecting the strength of their association to PCI in-hospital mortality. Each patient in a facilities submission is given a risk score to predict risk of in hospital mortality and accurately report risk adjusted mortality rates during hospitalization.

Data from 181,775 procedures performed from January 2004 to March 2006 were used to develop risk models based on pre-procedural and/or angiographic factors using logistic regression.

The most noteworthy risk factors or variables in the model include:
1. ST-segment elevation MI defined as a patient who had a STEMI on admission, with an onset within 24 hours, or the procedure indication was primary, rescue or facilitated PCI.
2. Discharge status (alive or expired). The interaction between this variable with other variables were key in the analysis.
3. The glomerular filtration rate (GFR) variable is calculated using abbreviated MDRD formula [GFR = 186 ×?(last creatinine)-1.154 × (age)-0.203 × (gender factor) × (race factor) where (gender factor) = 1 for male and 0.742 for female, (race factor) = 1.21 for black and 1 for others].
4. The body mass index (BMI) (kg/m2) is calculated from height (cm) and weight (kg): BMI = weight × 10000 / (height) 2.

All Risk Adjustment Variables
STEMI patients
Age (for age<=70, for age>70)
Cardiogenic Shock at Admission
Previous History - CHF
Peripheral Vascular Disease
Chronic Lung Disease
GFR (for STEMI, for non-STEMI)
NYHA Class IV (for STEMI, for non-STEMI)
PCI Status (for STEMI, for non STEMI)
- Urgent
- Emergency
- Salvage
Previous Vascular Disease
Cerebrovascular Disease
Previous PCI
PreOp IABP
Ejection Fraction Percentage
Coronary Lesion >= 50%: Subacute
Thrombosis? Yes vs. No
Highest Risk Pre-Procedure TIMI Flow = None vs. Yes
1.19 1.02 1.38 4.84
Diabetes/Control (Non-Insulin Diabetes vs. No Diabetes; Insulin Diabetes vs. No Diabetes)
Highest Risk Lesion: SCAI Lesion Class (II or III vs. I; IV vs. I)

BMI [kg/m2] (for STEMI, for Non-STEMI)
Highest Risk Lesion - Segment Category (for STEMI, for non STEMI)
-pRCA/mLAD/pCIRC
-pLAD
-Left Main

2a.15-17 **Detailed risk model available Web page URL or attachment:** Attachment Contemporary Mortality Risk Prediction for PCI (2).pdf

2a.18-19 **Type of Score:** Weighted score/composite/scale
2a.20 **Interpretation of Score:** Better quality = Lower score
2a.21 **Calculation Algorithm (***Describe the calculation of the measure as a flowchart or series of steps***):**
1. Count of admissions from data submissions that pass NCDR data inclusion thresholds.
2. Exclude admissions without PCI during admission
3. Exclude variables from any subsequent PCI during the same admission
4. Exclude patient admissions with PCI who have more than two variables in the risk model that are missing.

2a.22 **Describe the method for discriminating performance** *(e.g., significance testing)***:**
Hospitals performance for this measure is benchmarked each quarter and annually against hospitals with similar procedural volume, as well as against the CathPCI Registry aggregate. These benchmarks identify superior performance and encourage poorer performers to improve. The methodology is a data-driven, peer-group performance feedback used to positively affect outcomes.

2a.23 **Sampling (Survey) Methodology** *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)*:
N/A

2a.24 **Data Source (***Check the source(s) for which the measure is specified and tested)*
Registry data

2a.25 **Data source/data collection instrument (***Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
National Cardiovascular Data Registry (NCDR) CathPCI Registry®

2a.26-28 **Data source/data collection instrument reference web page URL or attachment:** URL
http://www.ncdr.com/WebNCDR/ELEMENTS.ASPX

2a.29-31 **Data dictionary/code table web page URL or attachment:** URL
http://www.ncdr.com/WebNCDR/ELEMENTS.ASPX

2a.32-35 **Level of Measurement/Analysis** (*Check the level(s) for which the measure is specified and tested)*
Facility/Agency

2a.36-37 **Care Settings (***Check the setting(s) for which the measure is specified and tested)*
Hospital

2a.38-41 **Clinical Services** (*Healthcare services being measured, check all that apply*)
Clinicians: Physicians (MD/DO)

TESTING/ANALYSIS

2b. Reliability testing

2b.1 **Data/sample** *(description of data/sample and size)***:** Auditing through chart abstraction was performed at 15 NCDR sites in 2008 for data submitted between January and December of 2006.

2b.2 **Analytic Method** *(type of reliability & rationale, method for testing)***:**
Inter-rater reliability between abstractors to assess reliability of coding for registry data collection. Retrospective chart abstraction was the method for testing.

2b.3 **Testing Results** *(reliability statistics, assessment of adequacy in the context of norms for the test*

2b
C☐
P☐
M☐
N☐

Comment [KP10]: 2b. Reliability testing demonstrates the measure results are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period.

Comment [k11]: 8 Examples of reliability testing include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing may address the data items or final measure score.

conducted):
Percent agreement:

252	Patient Age	100
260	Gender	100
310	Date of Admission	98
420	Previous MI (>7 Days)	86
430	Diabetes	95
432	Diabetes Control	90
442	Renal Failure - Previous History	97
454	Chronic Lung Disease	89
456	Hypertension	88
470	Dyslipidemia	78
480	Family History of CAD age <55	75
490	Previous PCI	94
494	Previous CABG	99
500	CHF - Current Status	92
510	NYHA	83
520	Cardiogenic Shock	98
550	Admission Sx Presentation	58
560	Time Period: Sx Onset to Admission	82
600	Date of Procedure	100
640	IABP	100
642	IABP Timing	100
654	Ejection Fraction Done	80
656	Ejection Fraction Percentage	58
661	LM Stenosis Percent	92
663	Proximal LAD Stenosis Percent	63
665	Mid/Distal LAD Stenosis Percent	65
667	CIRC Stenosis Percent	74
669	RCA Stenosis Percent	77
671	Ramus Stenosis Percent	95
675	Proximal LAD Graft Stenosis Percent	97
677	Mid/Distal LAD Graft Stenosis Percent	96
679	CIRC Graft Stenosis Percent	96
681	RCA Graft Stenosis Percent	96
683	Ramus Graft Stenosis Percent	100
804	PCI Status	93
962	Intracoronary Device Used - Stent	93
1000	Comp-Periprocedural MI	98
1010	Comp-Cardiogenic Shock	98
1020	Comp-Congestive Heart Failure	97
1030	Comp-CVA/Stroke	100
1040	Comp-Tamponade	100
1050	Comp-Thrombocytopenia	99
1060	Comp-Contrast Reaction	100
1070	Comp-Renal Failure	100
1080	Comp-Emergency PCI	99
1085	Comp-Bleeding - Percutaneous Entry Site	98
1086	Comp-Bleeding - Retroperitoneal	100
1087	Comp-Bleeding - Gastrointestinal	99
1088	Comp-Bleeding - Genital/Urinary	100
1092	Comp-Vascular - Access Site Occlusion	100
1094	Comp-Vascular - Peripheral Embolization	100
1096	Comp-Vascular - Dissection	100
1097	Comp-Vascular - Pseudoaneurysm	100
1099	Comp-Vascular - AV Fistula	100
1100	CABG During This Admission - Status	99
1150	Date of Discharge	99

1152	Discharge Status	100
1160	Death in Lab	99
	Overall Accuracy:	92

The Data Quality Report (DQR) program: The DQR program assesses the completeness of data submitted by participating hospitals. Hospitals must achieve a high level of completeness (>95% completeness of specific data elements identified as 'core fields' which encompass the variables included in our risk adjustment models) in order to have their data analyzed in the RAM model, and to be included in the aggregated data. The process is iterative, providing hospitals with the opportunity to correct errors and resubmit data for review.

The NCDR is implementing a new strategy, the Data Quality Program, to improve the data reported to each registry. The DQR and special analyses of the data are parts of the Program. Another part is the auditing of data, with results used for instructing participants on how to improve data submitted. Each year, participating sites are randomly selected to be audited. Trained nurse abstractors conduct medical record reviews and blind data abstraction of randomly selected patient medical records at each site. Audit results are analyzed for overall accuracy by comparing audit findings against data originally submitted from each site. Each participant receives a confidential audit report which displays their audit score and individual accuracy for each data element. In most audits, the median agreement between submitted and audited values is 92%.

Training and orientation are critical functions to ensure data quality and, ultimately, a high-quality registry. In addition to the "help desk" function provided by NCDR, training and orientation take the following forms:
-Introductory Calls and Webcasts: CathPCI Registry participants are invited on a routine basis to join calls and/or Webcasts where registry staff provide an overview to the CathPCI Registry program and answer questions.
-Electronic Data Capture Training: Participants who submit data via the NCDR Web-based Data Entry Tool will need to complete training for the system, either via Webcast or online module. This training educates users regarding platform functionality, including data entry and review, and user account management

2c. Validity testing

2c.1 **Data/sample** *(description of data/sample and size)*: Auditing through chart abstraction was performed at 15 NCDR sites in 2008 for data submitted between January and December of 2006.

2c.2 **Analytic Method** *(type of validity & rationale, method for testing)*:
Validity of data elements abstracted from medical record as compared to a criterion source of the same data through retrospective chart abstraction.

2c.3 **Testing Results** *(statistical results, assessment of adequacy in the context of norms for the test conducted)*:
Percent agreement:

Patient Age	100
Gender	100
Date of Admission	98
Previous MI (>7 Days)	86
Diabetes	95
Diabetes Control	90
Renal Failure - Previous History	97
Chronic Lung Disease	89
Hypertension	88
Dyslipidemia	78
Family History of CAD age <55	75
Previous PCI	94
Previous CABG	99
CHF - Current Status	92
NYHA	83
Cardiogenic Shock	98

2c
C☐
P☐
M☐
N☐

Comment [KP12]: 2c. Validity testing demonstrates that the measure reflects the quality of care provided, adequately distinguishing good and poor quality. If face validity is the only validity addressed, it is systematically assessed.

Comment [k13]: 9 Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP < 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed (e.g., ratings by relevant stakeholders) and the measure is judged to represent quality care for the specific topic and that the measure focus is the most important aspect of quality for the specific topic.

Admission Sx Presentation 58
Time Period: Sx Onset to Admission 82
Date of Procedure 100
IABP 100
IABP Timing 100
Ejection Fraction Done 80
Ejection Fraction Percentage 58
LM Stenosis Percent 92
Proximal LAD Stenosis Percent 63
Mid/Distal LAD Stenosis Percent 65
CIRC Stenosis Percent 74
RCA Stenosis Percent 77
Ramus Stenosis Percent 95
Proximal LAD Graft Stenosis Percent 97
Mid/Distal LAD Graft Stenosis Percent 96
CIRC Graft Stenosis Percent 96
RCA Graft Stenosis Percent 96
Ramus Graft Stenosis Percent 100
PCI Status 93
Intracoronary Device Used - Stent 93
Comp-Periprocedural MI 98
Comp-Cardiogenic Shock 98
Comp-Congestive Heart Failure 97
Comp-CVA/Stroke 100
Comp-Tamponade 100
Comp-Thrombocytopenia 99
Comp-Contrast Reaction 100
Comp-Renal Failure 100
Comp-Emergency PCI 99
Comp-Bleeding - Percutaneous Entry Site 98
Comp-Bleeding - Retroperitoneal 100
Comp-Bleeding - Gastrointestinal 99
Comp-Bleeding - Genital/Urinary 100
Comp-Vascular - Access Site Occlusion 100
Comp-Vascular - Peripheral Embolization 100
Comp-Vascular - Dissection 100
Comp-Vascular - Pseudoaneurysm 100
Comp-Vascular - AV Fistula 100
CABG During This Admission - Status 99
Date of Discharge 99
Discharge Status 100
Death in Lab 99
Overall Accuracy: 92

2d. Exclusions Justified

2d.1 Summary of Evidence supporting exclusion(s):
This measure has only 1 exclusion: transferred to another facility. This rationale for this exclusion is that these are patients whose episode of care is continuing past discharge.

2d.2 Citations for Evidence:

2d.3 Data/sample *(description of data/sample and size)*: July 1 2009-December 31 2009, 246,428 patients from 1058 facilities.

2d.4 Analytic Method *(type analysis & rationale)*:
Rate of exclusion coding.

2d
C☐
P☐
M☐
N☐
NA ☐

Comment [KP14]: 2d. Clinically necessary measure exclusions are identified and must be:
•supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;
AND
•a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;
AND
•precisely defined and specified:
–if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);
if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

Comment [k15]: 10 Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, sensitivity analyses with and without the exclusion, and variability of exclusions across providers.

2d.5 Testing Results *(e.g., frequency, variability, sensitivity analyses)*:
0.7% of patients (1,725 patients) were coded as transferred to another facility.

2e. Risk Adjustment for Outcomes/ Resource Use Measures

2e.1 Data/sample *(description of data/sample and size)*: 2 validation cohorts: contemporary (n=121,183, January 2004 to March 2006) and prospective (n=285,440, March 2006 to March 2007).

2e.2 Analytic Method *(type of risk adjustment, analysis, & rationale)*:
Model discrimination was assessed using the c-index. To assess model calibration, patients were rank-ordered from lowest- to highest predicted risk. Comparison was then made of predicted versus observed event rates within risk strata. Model discrimination and calibration were assessed in the overall population, within the 2 validation samples, and among select subpopulations of both of these groups. Finally, the models' discrimination was assessed among patients age 65+ years who had been linked to CMS data to assess both in-hospital and 30-day mortality.

2e.3 Testing Results *(risk model performance metrics)*:
The full NCDR CathPCI Mortality Risk Prediction model in the contemporary and prospective validation cohorts performed exceptionally well, with a c-index of 0.925 and 0.924, respectively. Additionally, the full model performed well in each of the 8 predefined patient subgroups, with c-indices ranging from 0.892 to 0.930. Of note, the exclusion of angiographic details and EF from the full model resulted in only a slight decrement in the overall model accuracy. Similarly, there was limited loss in model discrimination when the model was transformed into the final, simplified NCDR CathPCI Risk Score, with c-indices of 0.901 and 0.905, respectively, in the validation samples. This simplified score also had good operating characteristics in all predefined patient subgroups. Notably, the majority of patients had a relatively low mortality risk (92.6% of patients had a predicted mortality risk between 0% and 2.5%). However, there was high concordance between model predicted risk and that which was actually observed. The simplified Risk Score was also well calibrated in both low- and moderate-risk populations, with only a slight underestimation of predicted risk in high-risk patients. Finally, we examined the full and simplified models' ability to estimate 30-day mortality among patients age 65 years or older who had been linked to CMS data. Among 204,111 Medicare patients, 4,068 (1.99%) died in-hospital and 6,011 (2.94%) died within 30 days of the procedure.

In addition, we ran the Hosmer and Lemeshow (H-L) Goodness-of-Fit Test for the full model in the Spring 2010: chi-square=18.13, D.F.=8, p-value=0.02.

2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: N/A

2e
C☐ P☐ M☐ N☐ NA☐

2f. Identification of Meaningful Differences in Performance

2f.1 Data/sample from Testing or Current Use *(description of data/sample and size)*: 1058 facilities, 263,517 patients. July 1 2009 to December 31 2009.

2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance *(type of analysis & rationale)*:
Distribution of rates of performance.

2f.3 Provide Measure Scores from Testing or Current Use *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:
Mean: 1.39
SD: 0.4

Measure Scores by Percentile:
0: 3.81
10: 2.94
25:2.13
50:1.48
75:1.06

2f
C☐ P☐ M☐ N☐

Comment [KP16]: 2e. For outcome measures and other measures (e.g., resource use) when indicated:
•an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified and is based on patient clinical factors that influence the measured outcome (but not disparities in care) and are present at start of care;[Error! Bookmark not defined.] OR rationale/data support no risk adjustment.

Comment [k17]: 13 Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender (e.g., poorer treatment outcomes of African American men with prostate cancer, inequalities in treatment for CVD risk factors between men and women). It is preferable to stratify measures by race and socioeconomic status rather than adjusting out differences.

Comment [KP18]: 2f. Data analysis demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful differences in performance.

Comment [k19]: 14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% v. 75%) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v. $5,025) is practically meaningful. Measures with overall poor performance may not demonstrate much variability across providers.

90:0.73
100:0.21

2g. Comparability of Multiple Data Sources/Methods

2g.1 Data/sample *(description of data/sample and size)*: N/A

2g.2 Analytic Method *(type of analysis & rationale)*:
N/A

2g.3 Testing Results *(e.g., correlation statistics, comparison of rankings)*:
N/A

2g
C☐
P☐
M☐
N☐
NA☐

Comment [KP20]: 2g. If multiple data sources/methods are allowed, there is demonstration they produce comparable results.

2h. Disparities in Care

2h.1 If measure is stratified, provide stratified results *(scores by stratified categories/cohorts)*: N/A

2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:
N/A

2h
C☐
P☐
M☐
N☐
NA☐

Comment [KP21]: 2h. If disparities in care have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results (e.g., by race, ethnicity, socioeconomic status, gender);OR rationale/data justifies why stratification is not necessary or not feasible.

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Scientific Acceptability of Measure Properties*?

2

Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties*, **met?**
Rationale:

2
C☐
P☐
M☐
N☐

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)

Eval Rating

3a. Meaningful, Understandable, and Useful Information

3a.1 Current Use: In use

3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (*If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years*):
The Leap Frog Group, United Health Services, and BCBSA use the PCI RAM in calculating scores, and the scores and/or designation resulting from the scores are reported to plan members.

A description of the methods used by BCBSA to designate "Blue Distinction Centers for Cardiac Care" using this measure (as well as others) is provided here: http://www.bcbs.com/innovations/bluedistinction/blue-distinction-cardiac/cardiacmid-levelselection-criteria.pdf

3a.3 If used in other programs/initiatives (*If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years***):**
Used for QI by NCDR CathPCI Registry participating institutions. For Q2 of 2010, 1174 institutions submitted data.Participating institutions receive an institutional outcomes report each quarter with their hospital´s data. Over 2000 metrics are included in each hospital´s outcomes report. 26 metrics are highlighted in the report executive summary. These metrics are selected by an NCDR panel of experts as presenting the greatest opportunity for care improvement. CathPCI "metrics", including this measure, appear in the executive summary of the outcomes report. Hospitals receive their measure score, as well as the rates for all hospitals in the CathPCI registry, and all hospitals in the same comparison group (based on volume), and the rate for the 90th percentile. A box and whisker plot is displayed for each metric to show hospitals how they compare to all hospitals in
the CathPCI registry.

3a
C☐
P☐
M☐
N☐

Comment [KP22]: 3a. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audience(s) for both public reporting (e.g., focus group, cognitive testing) and informing quality improvement (e.g., quality improvement initiatives). An important outcome that may not have an identified improvement strategy still can be useful for informing quality improvement by identifying the need for and stimulating new approaches to improvement.

This measure is also provided to the Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2) and Hospital Corporation of America (HCA) for incorporation in their QI program efforts.

Testing of Interpretability (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*)
3a.4 **Data/sample** *(description of data/sample and size)*: 1. 61 NCDR CathPCI Registry participants, Fall 2009.

2. Beta testing for version 4 of the CathPCI Registry institutional outcomes report, 80 sites

3a.5 **Methods** *(e.g., focus group, survey, QI project)*:
1. Survey
2. Sites provided feedback through an excel template

3a.6 **Results** *(qualitative and/or quantitative results and conclusions)*:
1. 96.2% responded yes to the question "Will this measure provide important information to you?"
2. Sites provided feedback on the institutional outcomes report that was used to modify the report. Sites provided feedback on
invalid data and aspects of the report that were unclear.

3b/3c. Relation to other NQF-endorsed measures

3b.1 **NQF # and Title of similar or related measures:**
#535: 30-day all-cause risk-standardized mortality rate of percutaneous coronary intervention (PCI) for patients without ST segment elevation myocardial infarction (STEMI) and without cardiogenic shock (CMS) and #536:30-day all-cause risk-standardized mortality rate of Percutaneous Coronary Intervention (PCI) for patients with ST segment elevation myocardial (STEMI) or cardiogenic shock (CMS)

(for NQF staff use) **Notes on similar/related endorsed or submitted measures:**

3b. Harmonization
If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population):
3b.2 **Are the measure specifications harmonized? If not, why?**
The overall methodological approach for developing the NCDR measure is similar to that used by the CMS endorsed NQF measures # 0535 and 0536. All three measures explored the same candidate variables for risk adjustment (the NCDR measure identified a larger number of prognostically important variables). The variables in all three measures are harmonized in that they use the same clinical registry data elements and definitions (derived from the NCDR CathPCI Registry). The NCDR model provides one measure for all patients while the CMS measures stratifies PCI patients into STEMI/shock cohorts.

3b C☐ P☐ M☐ N☐ NA☐

3c. Distinctive or Additive Value
3c.1 **Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:**
The CMS and NCDR measures complement each other by having different, but clinically important, endpoints (inpatient and 30 day mortality). While the CMS measure is restricted to Medicare beneficiaries, the NCDR measure is applicable to patients regardless of payer.

5.1 **If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:**

3c C☐ P☐ M☐ N☐ NA☐

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Usability*? **3**

Steering Committee: Overall, to what extent was the criterion, *Usability*, met? **3** C☐ P☐ M☐ N☐
Rationale:

4. FEASIBILITY

Comment [KP23]: 3b. The measure specifications are harmonized with other measures, and are applicable to multiple levels and settings.

Comment [k24]: 16 Measure harmonization refers to the standardization of specifications for similar measures on the same topic (e.g., *influenza immunization* of patients in hospitals or nursing homes), or related measures for the same target population (e.g., eye exam and HbA1c for *patients with diabetes*), or definitions applicable to many measures (e.g., age designation for children) so that they are uniform or compatible, unless differences are dictated by the evidence. The dimensions of harmonization can include numerator, denominator, exclusions, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.

Comment [KP25]: 3c. Review of existing endorsed measures and measure sets demonstrates that the measure provides a distinctive or additive value to existing NQF-endorsed measures (e.g., provides a more complete picture of quality for a particular condition or aspect of healthcare, is a more valid or efficient way to measure).

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	Eval Rating
4a. Data Generated as a Byproduct of Care Processes 4a.1-2 **How are the data elements that are needed to compute measure scores generated?** Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition), Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)	**4a** C☐ P☐ M☐ N☐
4b. Electronic Sources 4b.1 **Are all the data elements available electronically?** (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*) Yes 4b.2 **If not, specify the near-term path to achieve electronic capture by most providers.**	**4b** C☐ P☐ M☐ N☐
4c. Exclusions 4c.1 **Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?** No 4c.2 **If yes, provide justification.**	**4c** C☐ P☐ M☐ N☐ NA☐
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences 4d.1 **Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.** The NCDR program takes a number of steps to minimize any potential for inaccuracies or errors in data used to report on performance back to hospitals. The process begins with support provided to data abstractors, including webinars, meetings, resource guides on the website, and clinical quality consultants available via e-mail or toll free phone number, to ensure consistent data collection. The NCDR establishes a unified electronic platform for data capture and submission that includes a certification process of the technical data collection tool selected by the hospital (either a commercially available software vendor product, the NCDR's own web base data collection tool, or a hospital's customized electronic medical record system) that must occur prior to any data submissions. The certification process provides edit checks of data elements within data collection tool to ensure high quality data submission. The NCDR data submission process includes a Data Quality Report (DQR) process that checks for validity in submissions based upon predetermined thresholds for element and composite completeness. The NCDR is putting in place a new strategy to systematically review the DQR results. The NCDR on-site audit program has been developed to assess reliability of data abstraction. This annual process reviews key elements at a select number of patient reports at the select number of sites and provides feedback scores to the hospitals.	**4d** C☐ P☐ M☐ N☐
4e. Data Collection Strategy/Implementation 4e.1 **Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:** Beta testing with a set of registry participants takes place with each new registry version to identify errors in the data collection tool. In addition, modifications are made to metrics based on feedback during a public comment period. The Data Quality Report (DQR) program has been developed to ensure data are valid and complete. The DQR is a process for submitting data files to the NCDR®. Participants use their data collection	**4e** C☐ P☐ M☐ N☐

Comment [KP26]: 4a. For clinical measures, required data elements are routinely generated concurrent with and as a byproduct of care processes during care delivery. (e.g., BP recorded in the electronic record, not abstracted from the record later by other personnel; patient self-assessment tools, e.g., depression scale; lab values, meds, etc.)

Comment [KP27]: 4b. The required data elements are available in electronic sources. If the required data are not in existing electronic sources, a credible, near-term path to electronic collection by most providers is specified and clinical data elements are specified for transition to the electronic health record.

Comment [KP28]: 4c. Exclusions should not require additional data sources beyond what is required for scoring the measure (e.g., numerator and denominator) unless justified as supporting measure validity.

Comment [KP29]: 4d. Susceptibility to inaccuracies, errors, or unintended consequences and the ability to audit the data items to detect such problems are identified.

Comment [KP30]: 4e. Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, etc.) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use).

tool software to create a submission file which is uploaded to the NCDR website. After uploading, the data in the file is automatically checked for errors and completeness.Passing the DQR ensures well-formed data and a statistically significant submission. Types of errors detected by the DQR include: Schema:Structure doesn't match NCDR requirements Dates: Inconsistent dates Selection: Missing or mismatched data; Can be a parent/child errors where a field requests more data. Outlier: Anomalies or exceptions; Data exceeds the possible limits. For example: 1,000mm length lesion. Counter: errors deal with Closure Methods, Lesions, and Intracoronary Devices. Each one has a counter, when more than one is used List: Missing data in the Medications or either Device lists. Data is submitted on a quarterly basis. If a submission does not pass the DQR process, the entire submission is excluded from benchmarking. Hospitals may resubmit to pass the DQR process. Data is submitted on a quarterly basis. If a submission does not pass the DQR process, the entire submission is excluded from benchmarking. Hospitals may resubmit to pass the DQR process. 4e.2 **Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:** CathPCI Registry participants pay a fee of $3,800/year to enroll in the registry. Staff resources are needed for data collection and submission at the participating institution. Registry site managers/data collectors undergo (non-mandatory) training offered by the NCDR. 4e.3 **Evidence for costs:** http://www.ncdr.com/WebNCDR/ncdrdocuments/B08352N%20CathPCI%20Registry%20Enrollment%20Packet%20Complete.pdf 4e.4 **Business case documentation:**	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility*?	**4**
Steering Committee: Overall, to what extent was the criterion, *Feasibility*, **met?** **Rationale:**	**4** **C☐** **P☐** **M☐** **N☐**
RECOMMENDATION	
(for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.**	**Time-limited ☐**
Steering Committee: Do you recommend for endorsement? **Comments:**	**Y☐** **N☐** **A☐**
CONTACT INFORMATION	
Co.1 **Measure Steward (Intellectual Property Owner)** Co.1 **Organization** American College of Cardiology, 2400 N Street, NW, Washington, District Of Columbia~12:District Of Columbia, 20037 Co.2 **Point of Contact** Susan, Fitzgerald, sfitzger@acc.org, 240-620-5444-	
Measure Developer If different from Measure Steward Co.3 **Organization** American College of Cardiology, 2400 N Street, NW, Washington, District Of Columbia, 20037	

Co.4 **Point of Contact**
Susan, Fitzgerald, sfitzger@acc.org, 240-620-5444-

Co.5 **Submitter If different from Measure Steward POC**
Susan, Fitzgerald, sfitzger@acc.org, 240-620-5444-, American College of Cardiology

Co.6 **Additional organizations that sponsored/participated in measure development**

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 **Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.**
CathPCI Steering Committee:
Douglas Weaver, MD, FACC
Ronald Krone, MD, FACC
Gregory Dehmer, MD, FSCAI
John Messenger, MD, FACC
Lloyd Klein, MD, FACC
John Rumsfeld, MD, PhD, FACC
John Carroll, MD, FACC
Mauro Moscucci, MD, FACC
Jeffrey Popma, MD, FACC
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Kirk Garratt, MD, FSCAI
David Malenka, MD, FACC

RAM workgroup:
John Spertus MD
Kalon Ho MD
Ronald Krone MD
Eric Peterson MD
John Rumsfeld MD
Richard Shaw PhD
Mandeep Singh MBBS
William Weintraub MD
Liz Delong PhD

Ad.2 **If adapted, provide name of original measure:**
Ad.3-5 **If adapted, provide original specifications URL or attachment**

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.6 **Year the measure was first released:** 2005
Ad.7 **Month and Year of most recent revision:** 07, 2008
Ad.8 **What is your frequency for review/update of this measure?** Every 3-4 years or if guideline updates warrant more frequent update, or with new dataset version.
Ad.9 **When is the next scheduled review/update for this measure?** 06, 2011

Ad.10 **Copyright statement/disclaimers:**

Ad.11 -13 **Additional Information web page URL or attachment:**

Date of Submission (*MM/DD/YY*)**:** 01/13/2011

Page 3: [1] Comment [k5] **Karen Pace** **10/5/2009 8:59:00 AM**

4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., mammography) or measures for multiple care processes that affect a single outcome.

NCDR™
National Cardiovascular Data Registry
CathPCI Registry™

Percutaneous Coronary Intervention (PCI) Risk Adjustment Mortality Model 2008

CONTENTS

Risk Adjustment Model (RAM) Committee

Members

The Risk Adjustment Model (RAM) Committee is a group of ACC volunteers who have expertise in epidemiology, biostatistics and coronary interventions. The RAM group consists of the following experts: Chairperson, John Spertus MD; Kalon Ho MD, Ronald Krone MD, Eric Peterson MD, John Rumsfeld MD, Richard Shaw PhD, Mandeep Singh MBBS, William Weintraub MD and Liz Delong PhD.

Committee meetings: Purpose and decisions

The RAM committee convened via conference calls and emails to develop a contemporary percutaneous coronary intervention (PCI) risk adjustment mortality model for patients receiving primary PCI and elective percutaneous procedure. The RAM committee provided independent oversight and input throughout the model development process, and defined a list of variables relevant to coronary interventional procedures. Candidate variables suggested by the RAM committee, as well as other variables in the dataset, were assessed for their association with mortality. The RAM committee relied on the existing RAM model and literature on other models in developing its initial list. A summary of RAM Committee meeting discussions and decisions are presented in Appendix 1.

Methods

Database Used

Between 1 January, 2004 and 31 March, 2006, a total of 309,351 consecutive patients undergoing PCI at 470 hospitals in the United States were entered into the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR) version 3 database.[1] Participation in ACC-NCDR was subject to the approval of the institutional review board of each hospital. Since the patient information collected excluded unique patient identifiers, individual informed consent was not required.

Population Definition

Patients with a first PCI procedure performed during an admission were included in the study population. Variables included in the model are shown in Appendix 2. After excluding 6,334 transfer-out patients and 39 patients who were missing more than 2 candidate variables [2] for the mortality model, 302,958 patients with PCI procedures at 470 participating NCDR centers remained in the analysis population. Sixty percent of

[1] For the data collection process, see Anderson HV, Shaw RE, Brindis RG, et al. A contemporary overview of percutaneous coronary interventions: the American College of Cardiology – National Cardiovascular Data Registry. J Am Coll Cardiol 2002; 39: 1096-103.

[2] Patients were excluded if more than 2 variables had a missing value. The following variables were used to screen patients:
Age, gender, race, previous MI, previous – CHF, previous valvular surgery, diabetes/control, renal failure/dialysis, cerebrovascular disease, peripheral vascular disease, chronic lung disease, hypertension, tobacco history, dyslipidemia, family history of CAD - age <55, previous PCI, previous CABG, CHF - current status, NYHA classification, cardiogenic shock, pre-op IABP, PCI status, coronary lesion >= 50%: subacute thrombosis, acute PCI and total lesions per lab visit.

Please note that this list is different from the list for backward selection. The variables with high missing rates such as BMI, GFR, symptoms onset, ejection fraction percentage, and highest-risk-lesion variables were not included in the above list, based on our data exploration. Using these variables, would limit the numbers of patients eligible for inclusion in the analysis and reduce the explanatory power of the model. The decision to do the exclusions in this way was made after discussions (with data explorations) during October 2006. The variables BMI, GFR, etc. were included in the backward selection procedure after imputation.

patients (n=181,775) were chosen at random for the model development, while the remaining 40% were taken as the first validation sample (**Figure 1**). By following the same inclusion and exclusion criteria, 285,440 patients who had PCI procedures between 31 March, 2006 and 30 March, 2007 at 608 participating NCDR centers were chosen as the second validation sample. The baseline characteristics and the mortality rate of the patients in the 3 samples are presented in **Tables 1 – 3** and **Figure 2**, respectively.

Variable Definition

Detailed definitions of all the variables in the model are presented in Appendix 2. Below are several noteworthy variables in the model.

- The ST-segment elevation myocardial infarction (STEMI) variable is defined as a patient who had admission symptoms of STEMI, where onset was within 24 hours of admission, or acute PCI was primary for STEMI/rescue/facilitated.
- The glomerular filtration rate (GFR) variable is calculated using abbreviated MDRD formula [GFR = $186 \times (\text{last creatinine})^{-1.154} \times (\text{age})^{-0.203} \times$ (gender factor) × (race factor) where (gender factor) = 1 for male and 0.742 for female, (race factor) = 1.21 for black and 1 for others].
- The body mass index (BMI) (kg/m^2) is calculated from height (cm) and weight (kg): BMI = weight × 10000 / $(\text{height})^2$.

Missing Data Imputation

The details of the imputation of all the variables are listed in Appendix 2. Listed below are several noteworthy imputations rules.

- The missing GFR was imputed to gender, prior renal failure, and STEMI specific median. In addition, GFR was set to 90 if over 90, and to 30 if less than 30 or dialysis.
- The missing ejection fraction (EF) was imputed to the CHF, cardiogenic shock at admission, prior MI, and STEMI specific median. If EF was over 60, EF was set as equal to 60.
- The missing BMI was imputed to the gender specific median; it was set to 30 if over 30.

Initial Variable Selection

Before proceeding with developing a multivariate model, univariate analysis was used to identify the factors that had both clinical and statistical (i.e. p-value < 0.05) significance. These variables included patient demographics, risk factor, cardiac status, cath lab visit, and PCI procedure factors. Based on the univariate analysis, potential risk factors identified included STEMI, age, cardiogenic shock at admission, BMI, prior CHF, prior valvular surgery, GFR, dialysis, cerebrovascular disease, peripheral vascular disease, chronic lung disease, hypertension, tobacco use, dyslipidemia, prior PCI, NYHA class, IABP before lab visit, ejection fraction, coronary lesion $\geq 50\%$ in a major artery, highest-risk lesion pre-procedure TIMI flow, highest-risk segment in graft, highest-risk segment category, diabetes control, PCI status, and SCAI lesion class, as well as their interaction with STEMI.

Model Variable Selection

A multivariate logistic regression with backward selection method was then performed to identify the predictive variables. The selection criterion was set to 0.05. Neither the highest-risk segment in graft variable nor the hypertension variable achieved a significance level of <0.05 and were excluded from the regression model. Most of the interaction terms were also removed from the model because of their insignificance, except for the interactions between STEMI and BMI, GFR, dialysis, NYHA class, highest-risk lesion segment category, and PCI status. These variables were included in the final model. (**Table 4**)

Calibration and Discrimination

After the risk factors were identified and their coefficient estimates calculated from the development sample, the variables' estimates were applied to the validation sample sets to determine the risk of mortality for each patient. The logistic risk model's accuracy for prediction was measured using the c-index, a widely-used measure of model discrimination. Model calibration, the degree to which observed outcomes are similar to the predicted outcomes from the model across patients, was examined by comparing average observed and predicted values within each risk sub-group arranged in increasing order of patient risk. Then, the c-index was calculated on the overall population and subpopulations stratified by STEMI, gender, age, and diabetes. The calibration was plotted.

Nomogram

Based on the full model, the pre-cath model was developed by removing the cath-related variables, such as ejection fraction, coronary lesion, highest risk pre-procedure TIMI flow, and highest risk lesion variables from the model and by restricting the number of variables in the model to fewer than 10. Only age, cardiogenic shock, prior CHF, peripheral vascular disease (PVD), chronic lung disease (CLD), GFR, NYHA class, and PCI status remained (**Table 4**). The regression coefficients from the pre-cath model were then converted into whole integers to create a bedside risk prediction tool [3] i.e. the pre-cath risk score system was developed (**Table 5**).

Example:

Patient is a **70-year-old** male with a history of **diabetes**, cerebrovascular accident (1997) followed by bilateral carotid endarectomy, hypertension, hyperlipidemia, **peripheral vascular disease,** and smoker with chronic obstructive pulmonary disease.
On the evening of 16-Aug-2007, the patient began having substernal chest pain and shortness of breath. Emergency medical services were called and the patient was taken to the hospital, and intubated for respiratory distress. The patient was diagnosed with **ST-elevation myocardial infarction.** Left cardiac catherization was done showing a 100% occlusion of the left anterior descending artery, and an intra-aortic balloon pump was placed. The patient became hypotensive and remained hypotensive despite inotropic, vasopressor and balloon pump support.

PCI Risk Score
70-year-old = 8
PVD = 5

[3] Sullivan LM, Massaro JM, D'Agostino RB Sr., Tutorial in biostatistics: presentation of multivariate data for clinical use: the Framingham study risk score function. *Stat. Med.* 2004; 23: 1631-1660.

CLD = 4
ST-elevation myocardial infarction = 15
Cardiogenic shock = 25

Total = 57
Risk of in-hospital mortality = 18 %-29%

Tables

Table 1 Patient Clinical Characteristics

	Development (181,775)	1st validation (121,183)	2nd validation (285,440)
Age	63.9±12.1	63.9±12.1	64.1±12.1
Female	33.4%	33.3%	33.3%
Caucasian	87.2%	87.1%	85.6%
BMI (kg/m^2)	29.6±6.3	29.7±6.3	29.8±6.3
Prior MI (>7days)	29.1%	29.1%	27.3%
Prior CHF	10.1%	10.0%	9.9%
Diabetes			
– Non-insulin	21.5%	21.7%	22.3%
– Insulin	10.0%	10.0%	10.3%
Mean GFR (MDRD)	73.6±30.5	73.5±29.0	73.2±28.1
Dialysis	1.6%	1.5%	1.5%
Cerebral Vascular Disease	10.9%	11.1%	11.1%
Peripheral Vascular Disease	11.7%	11.7%	11.9%
COPD	16.0%	16.0%	15.8%
Prior PCI	35.1%	35.4%	36.6%
NYHA Class IV	18.3%	18.3%	18.8%
Cardiogenic Shock	1.9%	1.8%	1.7%

Table 2 Hospital Characteristics

	Development (181,775)	1st validation (121,183)	2nd validation (285,440)
Number of Beds	463±221	463±220	454±225
Location			
- Rural	12.6%	12.6%	12.1%
- Urban	61.0%	61.3%	61.2%
Teaching	60.1%	60.0%	54.6%
Region			
- West	14.1%	14.3%	16.2%
- Northeast	9.0%	9.9%	10.4%
- Midwest	36.9%	36.7%	35.8%
- South	36.5%	36.8%	37.6%
Mean Annual PCI Volume	1151±762	1151±763	1159±807

Table 3 Procedural Characteristics

	Development (181,775)	1st validation (121,183)	2nd validation (285,440)
LVEF	52.7±12.7	52.7±12.7	52.7±12.7
PCI Status			
- Elective	49.3%	49.3%	50.2%
- Urgent	36.1%	35.6%	34.7%
- Emergency	14.4%	14.5%	15.0%
- Salvage	0.2%	0.2%	0.2%
Highest Risk Lesion – Segment Category			
-pLAD	18.2%	18.2%	18.2%
-Left Main	1.7%	1.8%	1.8%
Highest Risk Lesion – Pre-procedure TIMI Flow			
TIMI 0 Flow	11.0%	10.7%	14.9%
Multivessel PCI	14.0%	13.9%	14.1%

Table 4 Full and Pre-Cath Simplified Risk Models

Label	Full Model				Pre-Cath Simplified Model			
	Odds Ratio	95% Confidence Limits		χ^2	Odds Ratio	95% Confidence Limits		χ^2
Intercept: Death				171.14				708.97
STEMI patients				1.77				44.55
Age §								
for age≤70	1.55	1.44	1.69	115.33	1.52	1.40	1.64	107.92
for age>70	1.71	1.57	1.88	125.80	1.76	1.60	1.91	150.93
Cardiogenic Shock at Admission	8.35	7.40	9.44	1168.28	12.19	10.86	13.68	1804.73
Previous History - CHF	1.29	1.13	1.47	13.85	1.75	1.54	1.98	77.25
Peripheral Vascular Disease	1.53	1.35	1.74	42.39	1.67	1.48	1.89	67.78
Chronic Lung Disease	1.48	1.31	1.66	43.04	1.52	1.36	1.71	52.87
GFR §								
for STEMI	0.77	0.74	0.80	181.90	0.77	0.75	0.78	377.55
for non-STEMI	0.82	0.78	0.85	100.96				
NYHA Class IV								
for STEMI	1.21	1.05	1.39	6.74	1.61	1.46	1.79	81.71
for non-STEMI	1.74	1.50	2.02	52.82				
PCI Status								
for STEMI								
- Urgent	1.09	0.64	1.83	0.09	1.25	0.75	2.07	0.71
- Emergency	2.07	1.30	3.31	9.24	2.65	1.68	4.18	17.58
- Salvage	14.55	8.39	25.21	91.08	21.45	12.57	36.61	126.36
for non STEMI								
- Urgent	2.01	1.70	2.39	63.91	2.49	2.11	2.95	114.46
- Emergency	7.29	5.91	8.99	343.95	11.79	9.69	14.34	606.91
- Salvage	82.54	45.83	148.63	216.24	146.55	82.60	260.04	290.59
Previous Vascular Disease	1.58	1.10	2.26	6.02				
Cerebrovascular Disease	1.26	1.11	1.44	12.02				
Previous PCI	0.69	0.61	0.78	36.59				
PreOp IABP	3.14	2.12	4.65	32.64				
Ejection Fraction Percentage §	0.73	0.70	0.76	234.09				
Coronary Lesion >= 50%: Subacute Thrombosis? Yes vs. No	1.96	1.41	2.72	16.21				
Highest Risk Pre-Procedure TIMI Flow = None vs. Yes	1.19	1.02	1.38	4.84				
Diabetes/Control								
Non-Insulin Diabetes vs. No Diabetes	1.11	0.98	1.25	2.47				
Insulin Diabetes vs. No Diabetes	1.78	1.53	2.07	56.24				
Highest Risk Lesion: SCAI Lesion Class								
II or III vs. I	1.47	1.29	1.67	33.84				
IV vs. I	2.05	1.70	2.47	57.40				
BMI [kg/m^2] †								
for STEMI	0.93	0.85	1.03	1.97				
for Non-STEMI	0.76	0.69	0.83	33.91				
Highest Risk Lesion - Segment Category								
for STEMI								
pRCA/mLAD/pCIRC	1.34	1.13	1.59	11.18				
pLAD	1.52	1.26	1.83	19.00				
Left Main	5.54	3.43	8.93	49.26				
for non STEMI								
pRCA/mLAD/pCIRC	1.26	1.07	1.48	7.721				
pLAD	1.65	1.38	1.98	29.257				
Left Main	2.33	1.71	3.17	28.586				

§ Per 10 unit increase.
† Per 5 unit increase.

Table 5 PCI Risk Score System

Variable	Scoring Response Categories			
Age	<60	≥60,<70	≥70,<80	≥80
	0	4	8	14
Cardiogenic Shock	No	Yes		
	0	25		
Prior CHF	No	Yes		
	0	5		
PVD	No	Yes		
	0	5		
CLD	No	Yes		
	0	4		
GFR	<30	30-60	60-90	>90
	18	10	6	0
NYHA Class IV	No	Yes		
	0	4		
PCI Status (STEMI)	Elective	Urgent	Emergent	Salvage
	12	15	20	38
PCI Status (Not-STEMI)	Elective	Urgent	Emergent	Salvage
	0	8	20	42

Total Points	Risk of In-patient Mortality
0	0.0%
5	0.1%
10	0.1%
15	0.2%
20	0.3%
25	0.6%
30	1.1%
35	2.0%
40	3.6%
45	6.3%
50	10.9%
55	18.3%
60	29.0%
65	42.7%
70	57.6%
75	71.2%
80	81.%
85	89.2%
90	93.8%
95	96.5%
100	98.0%

Table 6 C-Indices to Compare the Models

	Sample N	Full Model	Pre-Cath Model	Risk Score
Development	181,775	0.926	0.911	0.911
1st validation	121,183	0.925	0.905	0.901
2nd validation	285,440	0.924	0.910	0.905
Subgroups (in 2nd validation)				
STEMI	39,889	0.902	0.890	0.884
Non-STEMI	245,551	0.892	0.896	0.862
Women	95,106	0.911	0.897	0.893
Men	190,334	0.930	0.916	0.911
Age>70	92,381	0.901	0.886	0.88
Age<=70	193,059	0.927	0.911	0.906
Diabetes	92,974	0.924	0.910	0.903
No Diabetes	192,466	0.923	0.910	0.906

Figures

Figure 1 Population

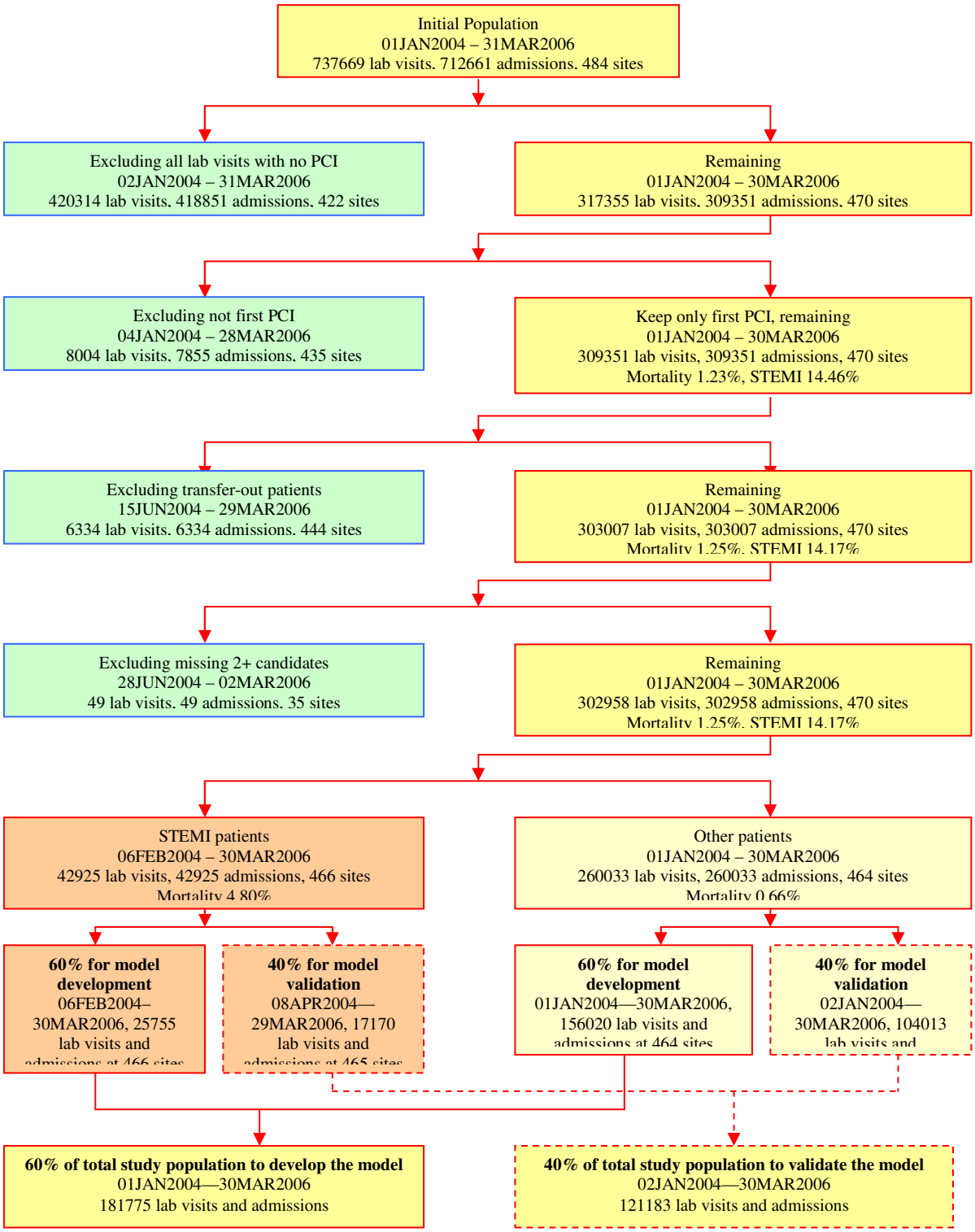


Figure 2 Outcome

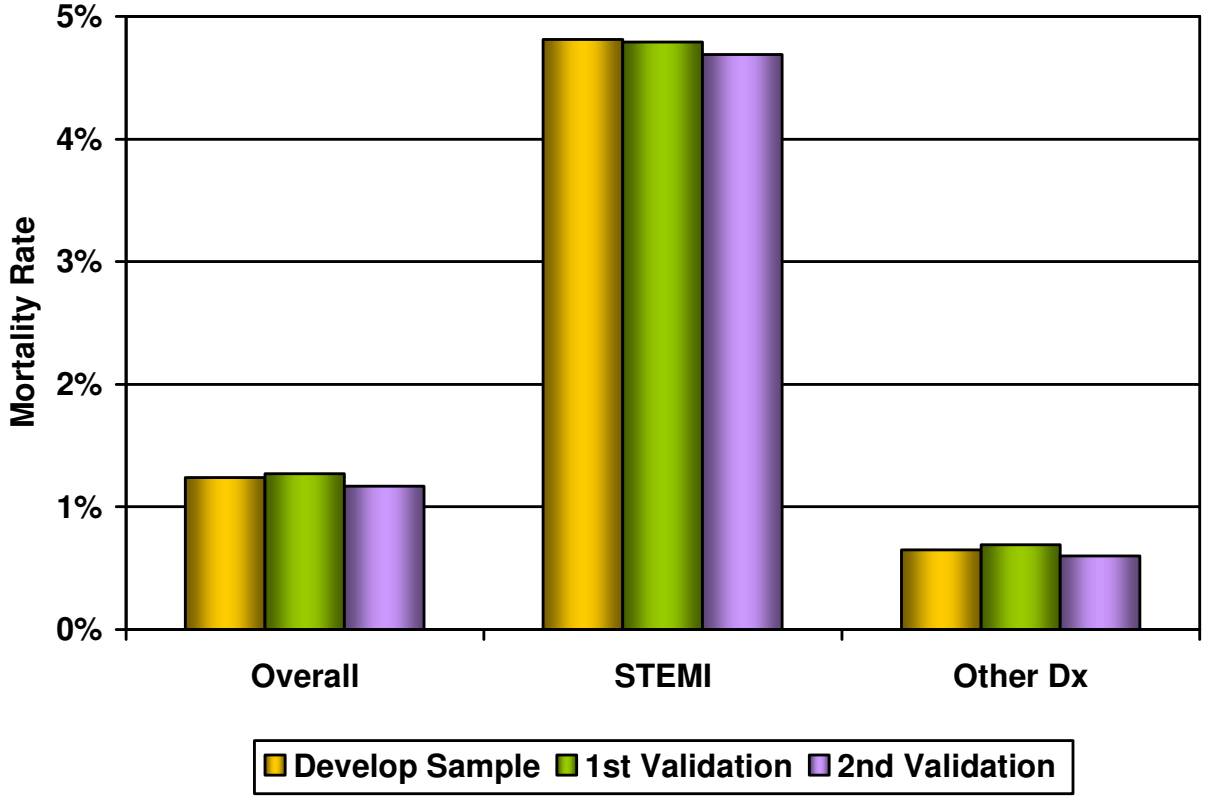


Figure 3 Calibration for Full Model

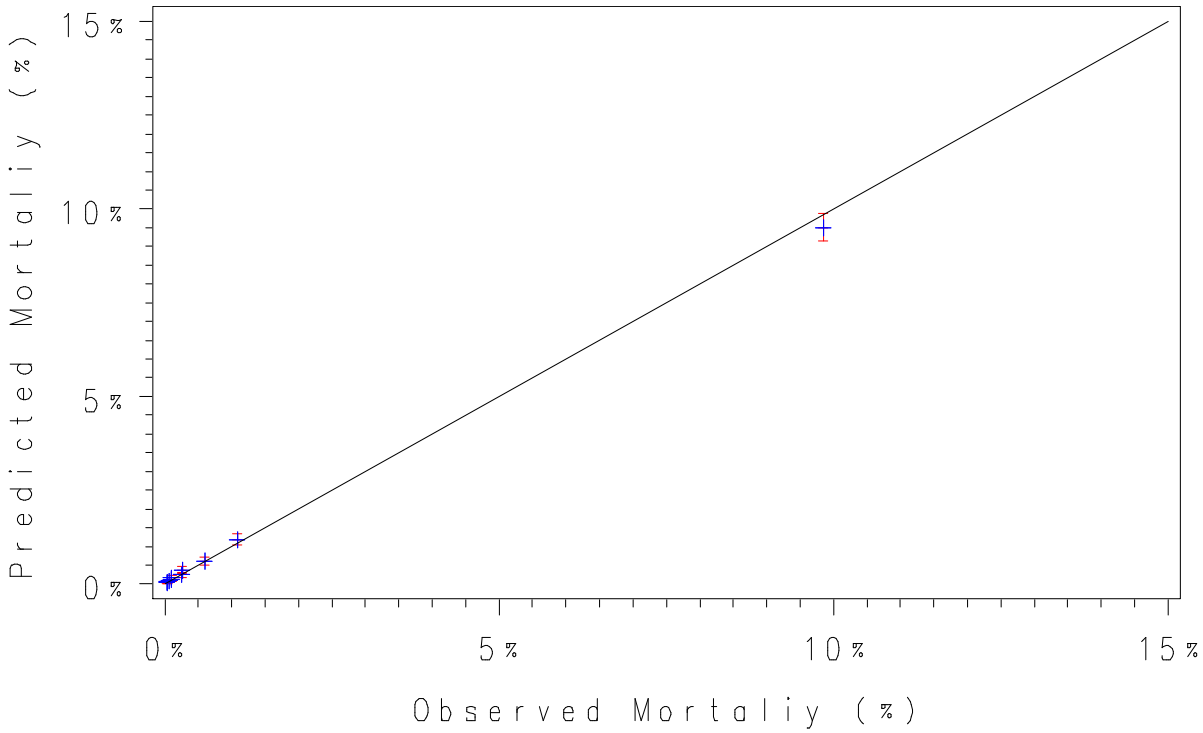
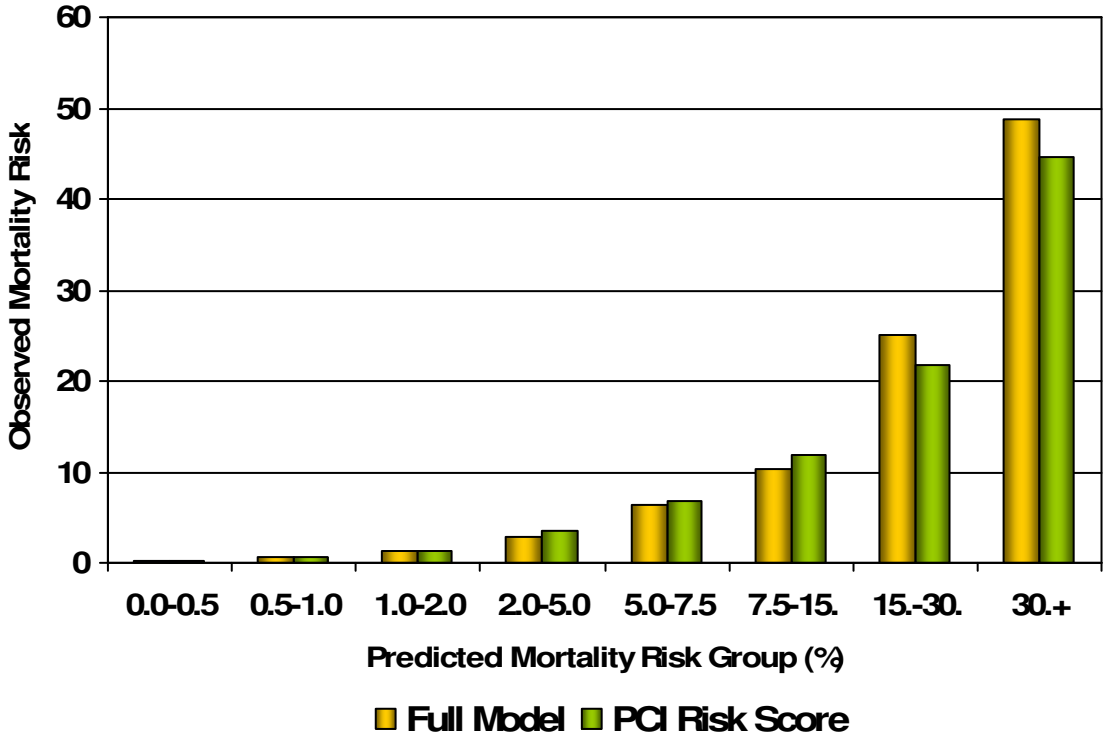


Figure 4 Calibration in Risk Groups in Validation Sample



Appendices

Appendix 1

RAM Committee meetings and decisions

During the first RAM committee meeting in August 2006, the purpose and general approach for creating the mortality risk adjustment model were defined. Candidate variables suggested by the RAM committee, as well as other variables in the dataset, were assessed.
It was decided to exclude:

- Patients with missing BMI because of the extremely high mortality rate among those patients, and the inability to accurately predict what these values might be.
- PCI procedures with more than 2 variables with missing values on key patient characteristic variables.
- PCI procedures where the lesion length was missing because of the extremely high mortality rate among those patients.

It was decided to include:

- Only the index PCI for each hospital stay

Decisions were circulated to the committee via email and DCRI was given approval to begin work on developing the mortality model in September 2006.

During the second committee meeting in October 2006, initial descriptive statistics were disseminated and discussed. It was decided to:

- Use only version 3 of the data collection form
- Exclude diagnostic cath variables from the model
- Include patients in the model with Cardiogenic Shock and where PCI status is described as Salvage.
- Request clinical input from the committee to categorize PCI status as. critical PCI, acute PCI (Primary PCI for STEMI) and acute PCI (Facilitated PCI), all of the above + acute PCI (rescue PCI), all of the above + salvage PCI status and emergency PCI status and cardiogenic shock.
- Impute "EF not assessed" by CHF, cardiogenic shock & prior MI specific medians.
- Lump cardiogenic shock patients in STEMI group as opposed to Non-Critical group, or we could include shock patients in both models and simply remove this criterion from "Critical PCI" definition if desired.
- Select the highest risk characteristic of all lesions attempted. These are not necessarily characteristics from a single lesion but rather a highest risk "dummy" lesion that is a combination of all the worst characteristics of the attempted lesions.
- Set patients with GFR < 30 OR dialysis to GFR = 30. The GFR parameter was then coded as a linear effect for GFR in 30-90 range and truncated at 90 (so same effect for all patients with GFR >= 90).

During the third committee meeting in January, 2007 the committee reviewed and discussed the candidate variables to include in the separate models, critical PCI and non-critical PCI. As a result of that call, work continued with refinement of the model as delineated below.

- Change the definition of critical PCI population: Specifically, add patients with acute PCI = primary for STEMI/rescue/facilitated to critical PCI population. Rationale: The change in the population was made to better capture this subgroup of patients than the previous definition which was limited to admission symptoms of STEMI within 24 hours.
- Explore the possibility of combining critical and non-critical PCI populations to develop single overall model, which allows for interactions between critical PCI and other single variables.
- Combine acute PCI primary, acute PCI rescue and acute PCI facilitated lumped together vs. all others to create binary variable.

In March 2007, the final population definitions were adopted, population *1 = Patients with admission symptoms of STEMI within 24 hrs **OR** Acute PCI = Primary for STEMI or Rescue PCI or Facilitated PCI. Population *2 = all remaining pts. It was believed that this change would better capture all of the Acute PCI = STEMI/Rescue/Facilitated patients than just the admission symptoms of STEMI within 24 hrs.

Appendix 2

Variable Definitions and Imputation

Label	Variable	Levels	Definition
Intercept: Death = Yes	Intercept		
STEMI patients	STEMI		Admission symptoms of STEMI where onset is within 24 hrs of admission OR Acute PCI is: Primary for STEMI/Rescue/Facilitated (i.e. `(AdmSxPre [NCDR Variable 550] = 6 and SxOnset [NCDR Variable 560] in (1, 2, 3)) or AcutePCI [NCDR Variable 812] in (2, 3, 4)`)
Age (for age<=70)	age_le70		Age (NCDR Variable 252), if > 110 or missing, then deleted from the data. Do not impute missing.
Age (for age>70)	age_gt70		If patient's age <= 70, e.g. 60, then the logit(mortality) = … + estimate(age_le70) * 60 + …; if age > 70, e.g. 80, then logit(mortality)=… + estimate(age_le70)*70 + estimate(age_gt70)*(80-70) + ...
Cardiogenic Shock at Admission	CarShock		NCDR Variable 520. Impute missing to no.
Previous History - CHF	PrCHF		NCDR Variable 424. Impute missing to no.
Previous Valvular Surgery	PrValve		NCDR Variable 426. Impute missing to no.
Cerebrovascular Disease	CVD		NCDR Variable 450. Impute missing to no.
Peripheral Vascular Disease	PVD		NCDR Variable 452. Impute missing to no.
Chronic Lung Disease	CLD		NCDR Variable 454. Impute missing to no.
Previous PCI	PrPCI		NCDR Variable 490. Impute missing to no.
PreOp IABP (D)	PreIABP		DCRI Derived from IABP (NCDR Variable 640), IABPWhen (NCDR 642): `if (iabp eq . and iabpwhen eq .) or (iabp eq 1 and iabpwhen eq .) then PreIABP = .; else if iabpwhen eq 1 then PreIABP = 1; else PreIABP = 0;`
Ejection Fraction Percentage	HDEF		NCDR Variable 656. Impute missing by stratifying population based on CHF, carshock, prior MI, and STEMI. If HDEF > 60, set HDEF = 60 (flat).
Coronary Lesion >= 50%: Subacute Thrombosis? (Y/N)	corles50D		Yes if subacute thrombosis is checked for Lesion>=50% (NCDR Variable 810). Otherwise, no.
Highest Risk Pre-Procedure TIMIFlow = none?	mpretimiD		True if the highest risk lesion PreProc TIMIFlow (NCDR Variable 920) is no; else false.
Diabetes/Control (D) 1=Non-Insulin Diabetes	NewDiab	1=Non-Insulin Diabetes	Derived from NCDR Variables 430 (Diabetes) and 432 (DiabCtrl): `if diabetes eq . and diabctrl in (., 1) then NewDiab = .; else if diabctrl eq 4 then NewDiab = 2; else if diabetes eq 1 or diabctrl in (2, 3) then NewDiab = 1; else NewDiab = 0;`
Diabetes/Control (D) 2=Insulin Diabetes	NewDiab	2=Insulin Diabetes	
Highest Risk Lesion: SCAI Lesion Class 2 or 3	mLesSCAIDn	2 or 3	Highest risk lesion variable derived from NCDR Variables 950 (LesRisk), 910 (PreStePr): `if (lesrisk eq . or prestepr < 0 or prestepr > 100) then LesSCAI = .; else if (lesrisk eq 1) then do; if prestepr < 100 then LesSCAI = 1; else LesSCAI = 3; end; else if (lesrisk eq 2) then do; if prestepr < 100 then LesSCAI = 2; else LesSCAI = 4; end;` Missing imputation: `if mLesSCAI = . then do; if mPreStePr = 100 then mLesSCAI = 3; else if mLesRisk = 2 then mLesSCAI = 2; else mLesSCAI = 1; end;`
Highest Risk Lesion: SCAI Lesion Class 4	mLesSCAIDn	4	
BMI [kg/m^2] for stemi	bmi_stemi		Calculated from NCDR Variables 410 (HeightCM) and

Label	Variable	Levels	Definition
			412 (WeightKG): `BMI = weightkg * 10000 / (heightcm * heightcm); if BMI < 5 or BMI > 100 then BMI = .;` Impute missing BMI to gender specific median. If BMI > 30, set BMI = 30 (flat). bmi_stemi for STEMI patients; bmi_nstemi for other patients.
BMI [kg/m^2] for nonstemi PCI	bmi_nstemi		
GFR for stemi	gfr_stemi		Derived from NCDR Variables 252 (age), 260 (gender), 270 (race), and 440 (CreatLst): `if (creatlst ne .) then do;` `if gender = 1 then gendmult = 1;` `else if gender eq 2 then gendmult = 0.742;` `if race eq 2 then racemult = 1.21;` `else racemult = 1;` `GFR = 186 * creatlst**(-1.154) * age**(-.203) * gendmult * racemult;` `end;` `else GFR = .;` Impute missing to gender, prior renal failure (NCDR Variable 442), STEMI specific median. `if (gfr > 90) then gfr = 90; if (gfr < 30 or dialysis [NCDR Var. 444]) then gfr = 30;` gfr_stemi for STEMI patients; gfr_nstemi for other patients.
GFR for nonstemi PCI	gfr_nstemi		
Prev History - Dialysis (stemi PCI)	dialysis_stemi		NCDR Variable 444. Impute missing to no. dialysis_stemi for STEMI patients; dialysis_nstemi for other patients.
Prev History - Dialysis (nonstemi PCI)	dialysis_nstemi		
NYHA Class 4 for stemi PCI	classnyhD_stemi		True if NYHA class IV (NCDR Variable 510); false if not class IV. classnyhD_stemi for STEMI patients; classnyhD_nstemi for other patients.
NYHA Class 4 for nonstemi PCI	classnyhD_nstemi		
Highest Risk Lesion - Segment Category (stemi PCI) 1=pRCA/mLAD/pCIRC	mNewSeg_stemi	1=pRCA/mLAD/pCIRC	Highest risk lesion variable derived from NCDR Variable 902 (segmentn): `if segmentn eq . then NewSeg = .;` `else if segmentn eq 11 then NewSeg = 3;` `else if segmentn eq 12 then NewSeg = 2;` `else if segmentn in (1, 13, 18) then NewSeg = 1;` `else NewSeg = 0;` Impute missing to 0 (i.e. Other category) mNewSeg_stemi for STEMI patients; mNewSeg_nstemi for other patients.
Highest Risk Lesion - Segment Category (stemi PCI) 2=pLAD	mNewSeg_stemi	2=pLAD	
Highest Risk Lesion - Segment Category (stemi PCI) 3=Left Main	mNewSeg_stemi	3=Left Main	
Highest Risk Lesion - Segment Category (nonstemi PCI) 1=pRCA/mLAD/pCIRC	mNewSeg_nstemi	1=pRCA/mLAD/pCIRC	
Highest Risk Lesion - Segment Category (nonstemi PCI) 2=pLAD	mNewSeg_nstemi	2=pLAD	
Highest Risk Lesion - Segment Category (nonstemi PCI) 3=Left Main	mNewSeg_nstemi	3=Left Main	
PCI Status for stemi 2=Urgent	PCIStat_stemi	2=Urgent	NCDR Variable 804 Impute missing to 1=Elective. PCIStat_stemi for STEMI patients; PCIStat_nstemi for other patients.
PCI Status for stemi 3=Emergency	PCIStat_stemi	3=Emergency	
PCI Status for stemi 4=Salvage	PCIStat_stemi	4=Salvage	
PCI Status for nonstemi PCI 2=Urgent	PCIStat_nstemi	2=Urgent	
PCI Status for nonstemi	PCIStat_nstemi	3=Emergen	

Label	Variable	Levels	Definition
PCI 3=Emergency		y	
PCI Status for nonstemi PCI 4=Salvage	PCIStat_nstemi	4=Salvage	

Contemporary Mortality Risk Prediction for Percutaneous Coronary Intervention: Results From 588,398 Procedures in the National Cardiovascular Data Registry

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Contemporary Mortality Risk Prediction for Percutaneous Coronary Intervention

Results From 588,398 Procedures in the National Cardiovascular Data Registry

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Durham, North Carolina; Rochester, Minnesota; San Francisco, California; Boston, Massachusetts; Chicago, Illinois; St. Louis, Missouri; Newark, Delaware; and Denver, Colorado

Objectives We sought to create contemporary models for predicting mortality risk following percutaneous coronary intervention (PCI).

Background There is a need to identify PCI risk factors and accurately quantify procedural risks to facilitate comparative effectiveness research, provider comparisons, and informed patient decision making.

Methods Data from 181,775 procedures performed from January 2004 to March 2006 were used to develop risk models based on pre-procedural and/or angiographic factors using logistic regression. These models were independently evaluated in 2 validation cohorts: contemporary (n = 121,183, January 2004 to March 2006) and prospective (n = 285,440, March 2006 to March 2007).

Results Overall, PCI in-hospital mortality was 1.27%, ranging from 0.65% in elective PCI to 4.81% in ST-segment elevation myocardial infarction patients. Multiple pre-procedural clinical factors were significantly associated with in-hospital mortality. Angiographic variables provided only modest incremental information to pre-procedural risk assessments. The overall National Cardiovascular Data Registry (NCDR) model, as well as a simplified NCDR risk score (based on 8 key pre-procedure factors), had excellent discrimination (c-index: 0.93 and 0.91, respectively). Discrimination and calibration of both risk tools were retained among specific patient subgroups, in the validation samples, and when used to estimate 30-day mortality rates among Medicare patients.

Conclusions Risks for early mortality following PCI can be accurately predicted in contemporary practice. Incorporation of such risk tools should facilitate research, clinical decisions, and policy applications. (J Am Coll Cardiol 2010; 55:1923–32) © 2010 by the American College of Cardiology Foundation

Percutaneous coronary intervention (PCI) has become one of the most widely applied treatments in current-day cardiology, facilitating the relief of angina and (in the setting of acute ST-segment elevation myocardial infarction [STEMI]), saving lives (1). Although the periprocedural complications of PCI have declined over time, tangible risks remain. Estimating patients' PCI mortality risk is important for several reasons. At the individual-patient level, knowing one's procedural risk can help physicians and patients make informed clinical decisions (2). Identification and quantification of clinical factors associated with procedural risk can also facilitate observational comparative effectiveness research (3). Finally, at a policy level, predicted risk estimates

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Abbreviations and Acronyms

BMI = body mass index

CathPCI = catheterization percutaneous coronary intervention

CHF = congestive heart failure

CMS = Centers for Medicare and Medicaid Services

EF = ejection fraction

GFR = glomerular filtration rate

NCDR = National Cardiovascular Data Registry

NYHA = New York Heart Association

PCI = percutaneous coronary intervention

STEMI = ST-segment elevation myocardial infarction

can help "level the playing field" of provider outcome metrics, helping to adjust for potential differences in cases treated (4).

To date, several PCI mortality risk models have been published. Yet many have become outdated and do not reflect contemporary care or outcomes (5–13). Other risk models were developed on select populations and may not be generalizable (7–9,11,14–19). Additionally, many models failed to consider angiographic features that are associated with procedural risk (9,20,21). The National Cardiovascular Data Registry (NCDR) for catheterization percutaneous coronary intervention (CathPCI) provides the ideal infrastructure to derive procedure risk models in a national representative contemporary U.S. sample. This database has a very large patient population, contains rich and complete clinical information, and is reflective of contemporary practice.

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Using the NCDR CathPCI database, our goals were to: 1) develop PCI risk tools for estimating mortality risks for both elective and primary PCI; 2) determine the incremental prognostic value of angiographic details beyond preprocedural risk factors; 3) develop a simplified, user-friendly, PCI risk score; 4) internally validate the PCI risk model and risk score in important subpopulations; and 5) assess the models' ability to estimate 30-day PCI mortality risk among Medicare patients whose status is defined via claims data.

Methods

The NCDR CathPCI Registry database. The NCDR CathPCI Registry is cosponsored by the American College of Cardiology and the Society for Cardiovascular Angiography and Interventions (22,23). The registry catalogs data on patient characteristics, clinical features, angiographic and procedural details, and in-hospital outcomes. Participating centers agree to submit complete information and outcomes from consecutive interventional cases performed at their institutions. The NCDR also has a comprehensive data quality program, including data abstraction training, data quality thresholds for inclusion, site data quality feedback reports, independent auditing, and data validation (22). Data elements and definitions are available at: http://www.ncdr.com/WebNCDR/ELEMENTS.ASPX#1. The Duke Clinical Research Institute (DCRI) serves as the primary analytic center for the CathPCI Registry, and performed the analyses for this report.

Variable selection. The NCDR established a risk adjustment model committee of American College of Cardiology volunteers to provide oversight for model development, including input on candidate variable selection and review of the model results. This group strictly adhered to current standards of model creation (24). The outcome of interest for these models was all-cause in-hospital mortality. Candidate variables were selected based on their relevance, as identified in prior research, or as identified in the committee's clinical experience.

Missing data. The rates of overall missing data in the NCDR CathPCI database are very low. Of the final model variables, only ejection fraction (EF) percentage had more than a 5% rate of missing data. For those few cases that contained missing information, the following imputation rules were used: 1) for elements dealing with a patient's past medical history, use of a pre-procedural intra-aortic balloon pump, presence of subacute thrombosis, and coronary lesion with highest risk lesion, missing data were imputed to "no"; 2) for body mass index (BMI), missing values were imputed to the gender-specific median; 3) for glomerular filtration rate (GFR), missing values were imputed to the gender-, prior renal failure-, and STEMI-specific median; and 4) for EF, missing data were imputed by stratifying the population based on a history of congestive heart failure (CHF), prior myocardial infarction, pre-procedural cardiogenic shock, and the presence of STEMI. Neither age nor the Society for Cardiovascular and Angiography and Interventions Lesion Class were imputed. We also performed a sensitivity analysis using multiple imputation methods. However, these results were nearly identical to the overall findings and are, therefore, not presented.

Population definition. Two separate patient populations were identified: one for model development and one for prospective validation. For the model development phase, patients were included if they received their first PCI procedure at any of the 470 hospitals submitting PCI records between January 1, 2004, and March 30, 2006. Patients were excluded if they transferred out or were missing more than 2 candidate variables (Fig. 1). The model development population was further randomly allocated to an initial model development dataset (60% of total), and a second group (40% of total) was used for an initial validation sample. A second prospective validation sample was identified from cases performed at the 608 NCDR hospitals submitting PCI cases between March 31, 2006, and March 30, 2007, using the same inclusion and exclusion criteria as noted in the previous text (Fig. 1).

Additionally, we examined the robustness of our models to predict 30-day mortality, as opposed to in-hospital mortality, in a Medicare-eligible population (25). Since

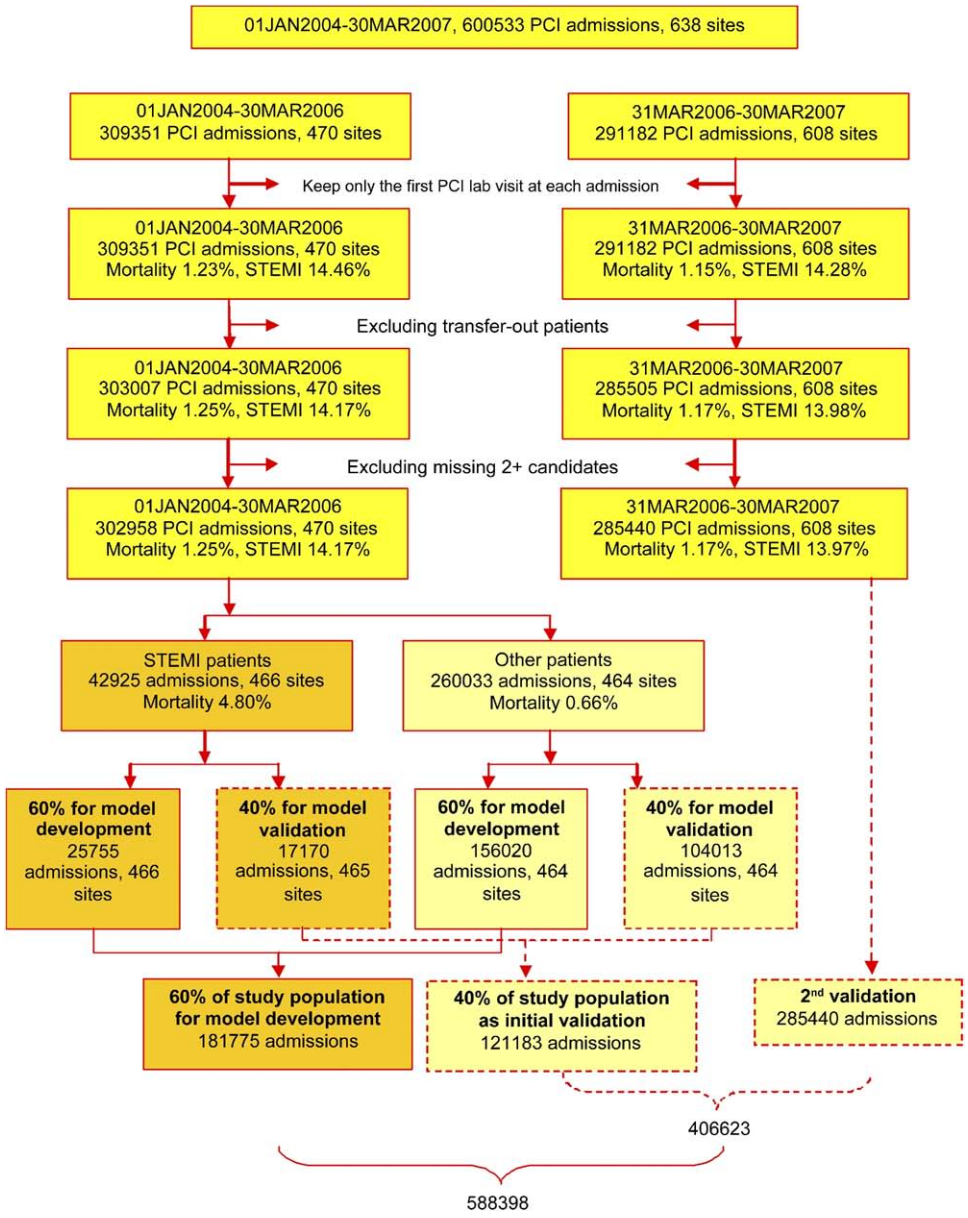

Figure 1 **Population Flow Diagram**

Between January 2004 and March 2007, 600,533 PCI admissions were recorded in the National Cardiovascular Data Registry (NCDR) Catheterization Percutaneous Coronary Intervention (CathPCI) Registry. Following exclusions, 588,398 total patients were included in the overall model development and validation cohort. STEMI = ST-segment elevation myocardial infarction.

outcomes beyond the initial hospital stay are not routinely collected in the NCDR, we linked NCDR records for those age 65 years or older to the national Centers for Medicare and Medicaid Services (CMS) inpatient claims data. The process used to do this has been previously described (26). For this specific linkage to occur, we began with Medicare-eligible NCDR CathPCI patients undergoing a PCI procedure between January 2005 and December 2006 (the last available data from CMS). Of the possible 348,370 records, we linked 253,081 records (72.7%), representing 204,111 unique patients. Baseline characteristics of the linked population and unlinked records were similar.

Statistical methods. An initial candidate variable list was generated using clinical judgment and prior known PCI risk factors. Univariate analysis was then used to identify which of the potential candidate variables had a statistical association with in-hospital mortality (e.g., $p < 0.05$). Based on this univariate analysis, the risk adjustment model committee selected the most clinically meaningful variables as potential candidates for inclusion in the multivariable

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model. Multivariate logistic regression with a backward selection method ($p < 0.05$ to remain in the model) was then performed to identify independent predictors of outcomes.

Three separate models were developed. First, a "full" model was created, which included all candidate variables (e.g., demographic, pre-catheterization clinical variables, and angiographic variables). Second, we contrasted this full model with a second "pre-cath" model, excluding detailed NCDR angiographic data. This second model assessed the incremental value of angiographic information for mortality prediction. Finally, we developed a "limited" pre-cath risk prediction model, which included only those variables with the strongest explanatory power based on their Wald chi-square value. The regression coefficients from the simplified pre-cath model were then converted into whole integers to create an NCDR CathPCI Risk Prediction score (27).

Model performance characteristics. After development, we applied these 3 models to the prospective validation

Table 1 Patient Clinical Characteristics

	Development (n = 181,775)	1st Validation (n = 121,183)	2nd Validation (n = 285,440)
Patient characteristics			
Age	63.9 ± 12.1	63.9 ± 12.1	64.1 ± 12.1
Female	33.4%	33.3%	33.3%
Caucasian	87.2%	87.1%	85.6%
BMI (kg/m^2)	29.6 ± 6.3	29.7 ± 6.3	29.8 ± 6.3
Prior MI (>7 days)	29.1%	29.1%	27.3%
Prior CHF	10.1%	10.0%	9.9%
Diabetes			
Noninsulin	21.5%	21.7%	22.3%
Insulin	10.0%	10.0%	10.3%
Mean GFR (MDRD)	73.6 ± 30.5	73.5 ± 29.0	73.2 ± 28.1
Dialysis	1.6%	1.5%	1.5%
Cerebral vascular disease	10.9%	11.1%	11.1%
Peripheral vascular disease	11.7%	11.7%	11.9%
CLD	16.0%	16.0%	15.8%
Prior PCI	35.1%	35.4%	36.6%
NYHA functional class IV	18.3%	18.3%	18.8%
Cardiogenic shock	1.9%	1.8%	1.7%
Hospital characteristics			
Number of beds	463 ± 221	463 ± 220	454 ± 225
Location			
Rural	12.6%	12.6%	12.1%
Urban	61.0%	61.3%	61.2%
Teaching	60.1%	60.0%	54.6%
Region			
West	14.1%	14.3%	16.2%
Northeast	9.0%	9.9%	10.4%
Midwest	36.9%	36.7%	35.8%
South	36.5%	36.8%	37.6%
Mean annual PCI volume	666 ± 550	668 ± 550	679 ± 573
Procedural characteristics			
LVEF	52.7 ± 12.7	52.7 ± 12.7	52.7 ± 12.7
PCI status			
Elective	49.3%	49.3%	50.2%
Urgent	36.1%	35.6%	34.7%
Emergency	14.4%	14.5%	15.0%
Salvage	0.2%	0.2%	0.2%
Highest risk coronary segment			
pLAD	18.2%	18.2%	18.2%
Left main	1.7%	1.8%	1.8%
TIMI flow grade 0	11.0%	10.7%	14.9%
Multivessel PCI	14.0%	13.9%	14.1%

BMI = body mass index; CHF = congestive heart failure; CLD = chronic lung disease; GFR = glomerular filtration rate; LVEF = left ventricular ejection fraction; MDRD = Modification of Diet in Renal Disease; MI = myocardial infarction; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; pLAD = proximal left anterior descending artery; TIMI = Thrombolysis In Myocardial Infarction.

Table 2 Unadjusted In-Hospital Mortality (%)

	Development (n = 181,775)	1st Validation (n = 121,183)	2nd Validation (n = 285,440)
Overall population	1.24	1.27	1.17
MI status			
STEMI	4.81	4.79	4.69
No STEMI	0.65	0.69	0.60
Gender			
Men	1.04	1.07	1.00
Women	1.63	1.67	1.50
Age group			
Age >70 yrs	2.25	2.32	2.02
Age ≤ 70 yrs	0.76	0.77	0.76
Diabetes status			
Diabetes	1.44	1.50	1.30
No diabetes	1.15	1.16	1.11

MI = myocardial infarction; STEMI = ST-segment elevation myocardial infarction.

sample sets. Model discrimination was assessed using the *c*-index. A model *c*-index can range from 0.50 (no predictive value) to 1.0 (perfect prediction). To assess model calibration, patients were rank-ordered from lowest- to highest-predicted risk. Comparison was then made of predicted versus observed event rates within risk strata. Model discrimination and calibration were assessed in the overall population, within the 2 validation samples, and among select subpopulations of both of these groups. Finally, we assessed the models' discrimination among patients age 65+ years who had been linked to CMS data to assess both in-hospital and 30-day mortality.

Results

Between January 2004 and March 2007, 600,533 consecutive PCI admissions were recorded in the NCDR CathPCI Registry. Following exclusions, 588,398 total patients were included in our overall model development and validation cohort. From this population, a model development sample (n = 181,775) was created from a random sample comprised of two-thirds the cases performed between January 2004 and March 2006. The final one-third of these cases was used to create a contemporary model validation sample (n = 121,183). Cases performed between March 2006 and March 2007 were used as a prospective validation sample (n = 285,440) (Fig. 1).

Table 1 provides demographic, clinical, and angiographic features of those patients in the development set, as well as in the 2 validation sets. The mean patient age was 64 years, 33% were female, 32% had diabetes mellitus, and 10% had a prior history of CHF. Overall, 51% of the patients underwent nonelective procedures, and 14% underwent multivessel PCI. The results were similar across the 3 samples, except that in-hospital mortality was slightly lower in the second prospective validation sample (1.17%), relative to the other 2 samples (1.24% and 1.27%).

Risk factors for in-hospital mortality. Table 2 provides observed in-hospital mortality rates for various patient subgroups. These mortality rates ranged from 0.65% in the non-primary PCI population to 4.81% in the STEMI population (Table 2). Older patients, women, and diabetic patients experienced higher unadjusted in-hospital mortality rates than younger patients, men, and non-diabetic patients (2.25% vs. 0.76%, 1.63% vs. 1.04%, and 1.44% vs. 1.15%, respectively).

Table 3 provides the final full model, which includes 21 separate clinical variables, as well as interaction terms for STEMI/shock, BMI, GFR, dialysis, New York Heart Association (NYHA) functional class, highest-risk lesion segment category, and PCI status. When model chi-square value was used as the metric, cardiogenic shock was the most predictive of in-hospital mortality, followed by renal function (estimated glomerular filtration rate [eGFR]) and age. In contrast, angiographic predictors were generally less prognostic. The angiographic feature most highly associated with in-hospital mortality was lesion location (e.g., left main lesions and proximal left anterior descending lesions).

NCDR PCI bedside risk prediction score. Predictors containing the strongest association with mortality are described in Table 3. These risk factors were then converted to an integer score (based on their relative magnitude of association with mortality), to create the NCDR CathPCI Risk Prediction Score (Table 4). Using this scoring system, the risk of in-hospital mortality can be estimated by summating point scores between 0 and 100.

Model performance. The full NCDR CathPCI Mortality Risk Prediction model in the contemporary and prospective validation cohorts performed exceptionally well, with a *c*-index of 0.925 and 0.924, respectively. Additionally, the full model performed well in each of the 8 predefined patient subgroups, with *c*-indices ranging from 0.892 to 0.930 (Table 5). Of note, the exclusion of angiographic details and EF from the full model resulted in only a slight decrement in the overall model accuracy. Similarly, there was limited loss in model discrimination when the model was transformed into the final, simplified NCDR CathPCI Risk Score, with *c*-indices of 0.901 and 0.905, respectively, in the validation samples. This simplified score also had good operating characteristics in all predefined patient subgroups.

Model calibration plots are shown in Figures 2 and 3. Notably, the majority of patients had a relatively low mortality risk (92.6% of patients had a predicted mortality risk between 0% and 2.5%). However, there was high concordance between model predicted risk and that which was actually observed. The simplified NCDR CathPCI Risk Score was also well calibrated in both low- and moderate-risk populations, with only a slight underestimation of predicted risk in high-risk patients (Fig. 3).

Finally, we examined the full and simplified models' ability to estimate 30-day mortality among patients age 65 years or older who had been linked to CMS data. Among 204,111 Medicare patients, 4,068 (1.99%) died in-hospital and 6,011 (2.94%) died within 30 days of the procedure.

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Table 3 Full and Pre-Cath Simplified Risk Models

	Full Model			Pre-Cath Model		
Label	Odds Ratio	95% Confidence Interval	Chi-Square	Odds Ratio	95% Confidence Interval	Chi-Square
Intercept			171.14			708.97
STEMI patients			1.77			44.55
Cardiogenic shock at admission	8.35	7.40–9.44	1,168.28	12.19	10.86–13.68	1,804.73
PCI status						
For STEMI						
Urgent	1.09	0.64–1.83	0.09	1.25	0.75–2.07	0.71
Emergency	2.07	1.30–3.31	9.24	2.65	1.68–4.18	17.58
Salvage	14.55	8.39–25.21	91.08	21.45	12.57–36.61	126.36
For no STEMI						
Urgent	2.01	1.70–2.39	63.91	2.49	2.11–2.95	114.46
Emergency	7.29	5.91–8.99	343.95	11.79	9.69–14.34	606.91
Salvage	82.54	45.83–148.63	216.24	146.55	82.60–260.04	290.59
Age*						
For age >70 yrs	1.71	1.57–1.88	125.80	1.76	1.60–1.91	150.93
For age ≤70 yrs	1.55	1.44–1.69	115.33	1.52	1.40–1.64	107.92
GFR*						
For STEMI	0.77	0.74–0.80	181.90	0.77	0.75–0.78	377.55
For no STEMI	0.82	0.78–0.85	100.96			
NYHA functional class IV						
For no STEMI	1.74	1.50–2.02	52.82	1.61	1.46–1.79	81.71
For STEMI	1.21	1.05–1.39	6.74			
Chronic lung disease	1.48	1.31–1.66	43.04	1.52	1.36–1.71	52.87
Peripheral vascular disease	1.53	1.35–1.74	42.39	1.67	1.48–1.89	67.78
Previous history of CHF	1.29	1.13–1.47	13.85	1.75	1.54–1.98	77.25
Ejection fraction percentage*	0.73	0.70–0.76	234.09			
Highest risk lesion: SCAI lesion class						
IV vs. I	2.05	1.70–2.47	57.40			
II or III vs. I	1.47	1.29–1.67	33.84			
Diabetes/control						
Insulin diabetes vs. no diabetes	1.78	1.53–2.07	56.24			
Noninsulin diabetes vs. no diabetes	1.11	0.98–1.25	2.47			
Highest risk lesion: segment category						
For STEMI						
Left main	5.54	3.43–8.93	49.26			
pLAD	1.52	1.26–1.83	19.00			
pRCA/mLAD/pCIRC	1.34	1.13–1.59	11.18			
Previous PCI	0.69	0.61–0.78	36.59			
BMI, kg/m^2†						
For no STEMI	0.76	0.69–0.83	33.91			
For STEMI	0.93	0.85–1.03	1.97			
Pre-op IABP	3.14	2.12–4.65	32.64			
For no STEMI						
pLAD	1.65	1.38–1.98	29.257			
Left main	2.33	1.71–3.17	28.586			
pRCA/mLAD/pCIRC	1.26	1.07–1.48	7.721			
Subacute thrombosis? Yes vs. no	1.96	1.41–2.72	16.21			
Cerebrovascular disease	1.26	1.11–1.44	12.02			
Previous vascular disease	1.58	1.10–2.26	6.02			
Highest risk pre-procedure	1.19	1.02–1.38	4.84			
TIMI flow = 0 vs. other						

*Per 10-U increase; †per 5-U increase.

IABP = intra-aortic balloon pump; mLAD = mid left anterior descending artery; pRCA = proximal right coronary artery; pCIRC = proximal left circumflex artery; SCAI = Society for Cardiovascular Angiography and Interventions; STEMI = ST-segment elevation myocardial infarction; other abbreviations as in Table 1.

Table 4 NCDR CathPCI Risk Score System

Variable	Scoring Response Categories				Total Points	Risk of In-Patient Mortality
Age	<60	≥60, <70	≥70, <80	≥80	0	0.0%
	0	4	8	14	5	0.1%
Cardiogenic shock	No	Yes			10	0.1%
	0	25			15	0.2%
Prior CHF	No	Yes			20	0.3%
	0	5			25	0.6%
Peripheral vascular disease	No	Yes			30	1.1%
	0	5			35	2.0%
Chronic lung disease	No	Yes			40	3.6%
	0	4			45	6.3%
GFR	<30	30–60	60–90	>90	50	10.9%
	18	10	6	0	55	18.3%
NYHA functional class IV	No	Yes			60	29.0%
	0	4			65	42.7%
PCI status (STEMI)	Elective	Urgent	Emergent	Salvage	70	57.6%
	12	15	20	38	75	71.2%
PCI status (no STEMI)	Elective	Urgent	Emergent	Salvage	80	81.0%
	0	8	20	42	85	89.2%
					90	93.8%
					95	96.5%
					100	98.0%

CathPCI = Catheterization Percutaneous Coronary Intervention; NCDR = National Cardiovascular Data Registry; other abbreviations as in Tables 1 and 3.

C-indices for the full model in this population were: $c = 0.90$ for in-hospital and $c = 0.86$ for 30-day mortality, respectively. *C*-indices for the Simplified Risk Score in this population were: $c = 0.89$ for in-hospital and $c = 0.83$ for 30-day mortality, respectively.

Discussion

Despite tremendous advances in PCI over the past decade, early periprocedural mortality remains a concern. Using data from the NDCR, we identified demographics, clinical factors, and angiographic features associated with PCI in-hospital mortality. These were summarized into a full risk model (with both pre-procedure and angiographic features) and a simplified 8-item NCDR CathPCI Risk Score, to support both robust hospital outcome comparisons and patient-level pre-procedural risk estimation, respectively. Both the full and simplified models retain their predictive accuracy in important patient subsets, in separate internal validation samples, and when estimating 30-day mortality in Medicare patients.

Several risk-adjustment models have been previously developed for the prediction of mortality following PCI. However, many of these were developed using data that predates the generalized use of stents and/or contemporary adjuvant antithrombotic therapy (5–13). Other models have been developed

Table 5 *C*-Indices for NCDR Models

	Sample, n	Full Model (Pre-Cath + Cath Factors)	Pre-Cath Model Only	NCDR Simplified Risk Score
Development	181,775	0.926	0.911	0.911
1st validation	121,183	0.925	0.905	0.901
2nd validation	285,440	0.924	0.910	0.905
Subgroups (in 2nd validation)				
STEMI	39,889	0.902	0.890	0.884
No STEMI	245,551	0.892	0.896	0.862
Women	95,106	0.911	0.897	0.893
Men	190,334	0.930	0.916	0.911
Age >70 yrs	92,381	0.901	0.886	0.88
Age ≤70 yrs	193,059	0.927	0.911	0.906
Diabetes	92,974	0.924	0.910	0.903
No diabetes	192,466	0.923	0.910	0.906

Cath = catheterization; NCDR = National Cardiovascular Data Registry; STEMI = ST-segment elevation myocardial infarction.

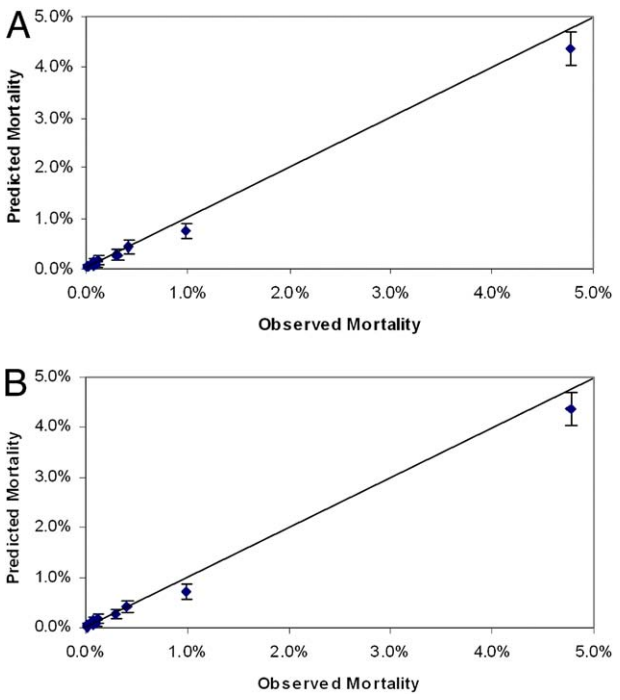

Figure 2 **Calibration for the Full Model Among Patients in the Validation Sample**

Demonstrates observed versus predicted mortality estimates (and the 95% confidence interval) for 10 equally sized risk groups of ST-segment elevation myocardial infarction **(A)** and non–ST-segment elevation myocardial infarction **(B)** patients, based on the full risk prediction model evaluated in the second validation sample.

from select referral centers or regional populations and may not be as generalizable across the nation (7–9,11,14–19). Still, other models were developed using databases that included only elderly patients, or used administrative data which lacked the clinical details necessary to capture the important clinical and angiographic risks factors associated with periprocedural mortality (9,20,21).

The models derived in this study expand on these prior models. First, the comprehensive and complete nature of the NCDR's clinical data allows for a more complete assessment of multiple risk predictors. For example, female sex has long been a feature predictive in many prior studies, yet this feature is no longer significantly associated with mortality after adjusting for multiple potential confounders (e.g., BMI, eGFR, and so on) and in the contemporary populations (28,29). Additionally, we have demonstrated that the inclusion of angiographic details (as they are defined in the NCDR CathPCI Registry) to a pre-cath risk prediction model, add marginal overall improvements in our ability to predict in-hospital mortality. Rather, in-hospital mortality was driven primarily by pre-existing patient comorbidities and markers of clinical instability. This finding is consistent with the work of others (16) and has important clinical implications in that it allows patients and physicians to obtain a reasonable estimate of procedural risk, prior to angiography.

In the aggregate population, angiographic risk factors added modest value, whereas in individual cases, their impact was more substantial. For example, the mean predicted PCI risk for patients with left main stenosis was 4.5% versus 2.4%, depending on whether or not the prediction included the angiographic left main risk feature. Other risk scores (such as the SYNTAX score), which arguably focus more heavily on collecting exhaustive angiographic data, have found some additional benefit from these angiographic variables (30).

We also found that patients presenting for PCI in the setting of STEMI, faced substantially higher procedural risk. However, the scope and relative impact of risk factors needed to predict risk in acute versus elective cases, were quite similar. Based on this observation, we were able to develop a unified model of risk estimation for all PCI cases, as opposed to separate STEMI and elective models. This unified model (e.g., the simplified NCDR PCI Mortality Risk Score) accurately predicts mortality in both acute and elective cases.

Utility of risk models. The NCDR CathPCI risk prediction tools developed and validated in this analysis cover the broad spectrum of anticipated model uses and address the needs of researchers, administrators, physicians, and patients. The full NCDR model provides a comprehensive tool to: 1) permit the most accurate adjustment of both pre-procedural and angiographic features for research projects; and 2) "level the playing field" for provider-level mortality results comparisons. Yet the full model is complex,

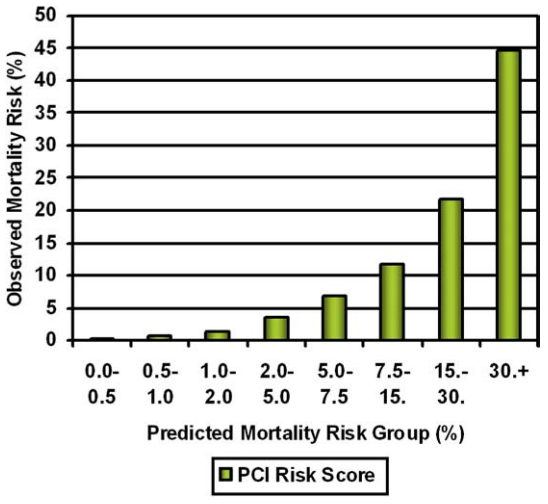

Figure 3 **Calibration of NCDR Bedside Risk Score in Validation Sample**

Based on their predicted risk, patients are grouped into 8 risk groups, using the full risk prediction model, and then plotted again the observed mortality rates for these in the second validation sample. NCDR = National Cardiovascular Data Registry; PCI = percutaneous coronary intervention.

inclusive of multiple data elements, spline-transformed continuous variables, and interaction terms—thus, the model is not practical to estimate patients' individual risk without computer assistance. Therefore, we also created the NCDR CathPCI Risk Score, whose simplified 8-item additive risk score can be used for bedside risk estimation.

Study limitations. Participation in the NCDR CathPCI centers is voluntarily and slightly under-represents smaller clinical practices. That said, the NCDR CathPCI Registry remains the largest, most generalizable U.S. data source. In-patient mortality, rather than 30-day mortality, has limitations as an end point (31). However, at the provider level, in-hospital and 30-day mortality results are highly correlated. Additionally, the only source of complete 30-day outcomes is Medicare data, which do not capture outcomes in those <65 years of age. When our models were applied to predict 30-day mortality in the Medicare population, they retained good discrimination (c = 0.86).

Future directions. As the practice of medicine continues to evolve, so will the use of risk prediction models. Clinically, computer-generated risk scores are being used to aid in the personalization of the procedural consent process (2). Although mortality is clearly an important outcome, modeling other modifiable outcomes, such as myocardial infarction, renal failure, bleeding complications, restenosis, stent thrombosis, and angina relief, could further advance the Institute of Medicine's goals for evidence-based, patient-centered, medical care (2,32). As advanced procedural support devices (e.g., hemodynamic support devices) continue to develop, risk prediction tools can be utilized to more clearly define the patient populations in which they will be maximally effective. From an administrative standpoint, the importance of these tools for provider-based risk-adjusted outcomes comparisons will continue to increase, as public reporting and pay-for-performance initiatives continue to grow in popularity. Finally, from a research perspective, these risk tools will be used to mitigate treatment selection bias when conducting comparative effectiveness analyses in observational data.

Conclusions

Using data from the NCDR CathPCI Registry, we have developed and validated contemporary models for assessing periprocedural PCI mortality risk. Each of these has excellent predictive accuracy throughout the full spectrum of patient risk, and important patient subgroups. We anticipate that these models will have multiple applications (including bedside risk estimation using the simplified risk score, comparison of hospital performance, and risk adjustment).

Author Disclosures

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Key Words: percutaneous coronary intervention ■ risk prediction ■ outcomes.

Contemporary Mortality Risk Prediction for Percutaneous Coronary Intervention: Results From 588,398 Procedures in the National Cardiovascular Data Registry

Eric D. Peterson, David Dai, Elizabeth R. DeLong, J. Matthew Brennan, Mandeep Singh, Sunil V. Rao, Richard E. Shaw, Matthew T. Roe, Kalon K.L. Ho, Lloyd W. Klein, Ronald J. Krone, William S. Weintraub, Ralph G. Brindis, John S. Rumsfeld, John A. Spertus, on behalf of the NCDR Registry Participants

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ACC-NCDR MORTALITY MODEL
-- SUMARRY --

CONTENTS

Predictors of mortality in full model and pre-cath model

Full model

Label	Variable	Levels	Definition	Estimate	Standard Error	Wald Chi Square	p-Value	Odds Ratio Point Estimate	95% Wald Confidence Limits	
Intercept: Death = Yes	Intercept			-5.48553	0.419313	171.1431	4.16E-39			
STEMI patients	STEMI		Admission symptoms of STEMI where onset is within 24 hrs of admission OR Acute PCI is: Primary for STEMI/Rescue/Facilitated (i.e. (AdmSxPre *[NCDR Variable 550]* = 6 and SxOnset *[NCDR Variable 560]* in (1, 2, 3)) or AcutePCI *[NCDR Variable 812]* in (2, 3, 4))	0.61548	0.463011	1.76705	0.183748			
Age (for age<=70)	age_le70		Age (NCDR Variable 252), if > 110 or missing, then deleted from the data. Do not impute missing.	0.04421	0.004117	115.3315	6.66E-27	(per 10 units)1.553	1.438	1.692
Age (for age>70)	age_gt70		If patient's age <= 70, e.g. 60, then the logit(mortality) = … + estimate(age_le70) * 60 + …; if age > 70, e.g. 80, then logit(mortality)=… + estimate(age_le70)*70 + estimate(age_gt70)*(80-70) + ...	0.05392	0.004808	125.8004	3.4E-29	(per 10 units)1.708	1.568	1.877
Cardiogenic Shock at Admission	CarShock		NCDR Variable 520. Impute missing to no.	2.12275	0.062105	1168.28	4.8E-256	8.354	7.397	9.435
Previous History - CHF	PrCHF		NCDR Variable 424. Impute missing to no.	0.2526	0.067871	13.85136	0.000198	1.287	1.127	1.471
Previous Valvular Surgery	PrValve		NCDR Variable 426. Impute missing to no.	0.45399	0.18507	6.017447	0.014165	1.575	1.096	2.263
Cerebrovascular Disease	CVD		NCDR Variable 450. Impute missing to no.	0.23287	0.067153	12.02494	0.000525	1.262	1.107	1.44
Peripheral Vascular Disease	PVD		NCDR Variable 452. Impute missing to no.	0.42567	0.065382	42.38582	7.49E-11	1.531	1.347	1.74
Chronic Lung Disease	CLD		NCDR Variable 454. Impute missing to no.	0.38891	0.059284	43.03638	5.37E-11	1.475	1.314	1.657
Previous PCI	PrPCI		NCDR Variable 490. Impute missing to no.	-0.3722	0.061528	36.59382	1.45E-09	0.689	0.611	0.778
PreOp IABP (D)	PreIABP		DCRI Derived from IABP (NCDR Variable 640), IABPWhen (NCDR 642): `if (iabp eq . and iabpwhen eq .) or (iabp eq 1 and iabpwhen eq .) then PreIABP = .; else if iabpwhen eq 1 then PreIABP = 1; else PreIABP = 0;`	1.14427	0.20028	32.64229	1.11E-08	3.14	2.121	4.65
Ejection Fraction Percentage	HDEF		NCDR Variable 656. Impute missing by stratifying population based on CHF, carshock, prior MI, and STEMI. If HDEF > 60, set HDEF = 60 (flat).	-0.03166	0.002069	234.0855	7.66E-53	(per 10 units)0.730	0.7	0.761
Coronary Lesion >= 50%: Subacute Thrombosis? (Y/N)	corles50D		Yes if subacute thrombosis is checked for Lesion>=50% (NCDR Variable 810). Otherwise, no.	0.67359	0.167292	16.21221	5.66E-05	1.961	1.413	2.722
Highest Risk Pre-Procedure TIMIFlow = none?	mpretimiD		True if the highest risk lesion PreProc TIMIFlow (NCDR Variable 920) is no; else false.	0.17044	0.07748	4.838843	0.027826	1.186	1.019	1.38
Diabetes/Control (D) 1=Non-Insulin Diabetes	NewDiab	1=Non-Insulin Diabetes	Derived from NCDR Variables 430 (Diabetes) and 432 (DiabCtrl): `if diabetes eq . and diabctrl in (., 1) then NewDiab = .; else if diabctrl eq 4 then NewDiab = 2; else if diabetes eq 1 or diabctrl in (2, 3) then NewDiab = 1; else NewDiab = 0;`	0.10082	0.064128	2.47148	0.115929	1.106	0.975	1.254
Diabetes/Control (D) 2=Insulin Diabetes	NewDiab	2=Insulin Diabetes		0.578	0.077071	56.24434	6.4E-14	1.782	1.533	2.073
Highest Risk Lesion: SCAI Lesion Class 2 or 3	mLesSCAIDn	2 or 3	Highest risk lesion variable derived from NCDR Variables 950 (LesRisk), 910 (PreStePr): `if (lesrisk eq . or prestepr < 0 or prestepr > 100) then LesSCAI = .; else if (lesrisk eq 1) then do; if prestepr < 100 then LesSCAI = 1; else LesSCAI = 3; end; else if (lesrisk eq 2) then do; if prestepr < 100 then LesSCAI = 2; else LesSCAI = 4; end;` Missing imputation: `if mLesSCAI = . then do; if mPreStePr = 100 then mLesSCAI = 3; else if mLesRisk = 2 then mLesSCAI = 2; else mLesSCAI = 1; end;`	0.38316	0.065865	33.84142	5.98E-09	1.467	1.289	1.669
Highest Risk Lesion: SCAI Lesion Class 4	mLesSCAIDn	4		0.71903	0.094909	57.39562	3.56E-14	2.052	1.704	2.472

Label	Variable	Levels	Definition	Estimate	Standard Error	Wald Chi Square	p-Value	Odds Ratio Point Estimate	95% Wald Confidence Limits	
BMI [kg/m^2] for stemi	bmi_stemi		Calculated from NCDR Variables 410 (HeightCM) and 412 (WeightKG): `BMI = weightkg * 10000 / (heightcm * heightcm); if BMI < 5 or BMI > 100 then BMI = .;` Impute missing BMI to gender specific median. If BMI > 30, set BMI = 30 (flat). bmi_stemi for STEMI patients; bmi_nstemi for other patients.	-0.01405	0.010004	1.973952	0.160029	(per 5 units)0.932	0.846	1.03
BMI [kg/m^2] for nonstemi PCI	bmi_nstemi			-0.05593	0.009605	33.91321	5.76E-09	(per 5 units)0.758	0.688	0.833
GFR for stemi	gfr_stemi		Derived from NCDR Variables 252 (age), 260 (gender), 270 (race), and 440 (CreatLst): `if (creatlst ne .) then do; if gender = 1 then gendmult = 1; else if gender eq 2 then gendmult = 0.742; if race eq 2 then racemult = 1.21; else racemult = 1; GFR = 186 * creatlst**(-1.154) * age**(-.203) * gendmult * racemult; end; else GFR = .;` Impute missing to gender, prior renal failure (NCDR Variable 442), STEMI specific median. `if (gfr > 90) then gfr = 90; if (gfr < 30 or dialysis [NCDR Var. 444]) then gfr = 30;` gfr_stemi for STEMI patients; gfr_nstemi for other patients.	-0.02657	0.00197	181.901	1.86E-41	(per 10 units)0.768 §	0.737	0.801
GFR for nonstemi PCI	gfr_nstemi			-0.02015	0.002005	100.9603	9.38E-24	(per 10 units)0.817 §	0.784	0.851
Prev History - Dialysis (stemi PCI)	dialysis_stemi		NCDR Variable 444. Impute missing to no. dialysis_stemi for STEMI patients; dialysis_nstemi for other patients.	0.10597	0.242865	0.1904	0.662584	1.112‡	0.691	1.79
Prev History - Dialysis (nonstemi PCI)	dialysis_nstemi			0.56677	0.140052	16.37689	5.19E-05	1.763‡	1.339	2.319
NYHA Class 4 for stemi PCI	classnyhD_stemi		True if NYHA class IV (NCDR Variable 510); false if not class IV. classnyhD_stemi for STEMI patients; classnyhD_nstemi for other patients.	0.18911	0.072867	6.735636	0.009451	1.208	1.047	1.394
NYHA Class 4 for nonstemi PCI	classnyhD_nstemi			0.55297	0.076088	52.81723	3.66E-13	1.738	1.498	2.018
Highest Risk Lesion - Segment Category (stemi PCI) 1=pRCA/mLAD/pCIRC	mNewSeg_stemi	1=pRCA/mLAD/pCIRC	Highest risk lesion variable derived from NCDR Variable 902 (segmentn): `if segmentn eq . then NewSeg = .; else if segmentn eq 11 then NewSeg = 3; else if segmentn eq 12 then NewSeg = 2; else if segmentn in (1, 13, 18) then NewSeg = 1; else NewSeg = 0;` Impute missing to 0 (i.e. Other category) mNewSeg_stemi for STEMI patients; mNewSeg_nstemi for other patients.	0.29047	0.086866	11.18127	0.000826	1.337	1.128	1.585
Highest Risk Lesion - Segment Category (stemi PCI) 2=pLAD	mNewSeg_stemi	2=pLAD		0.41832	0.095973	18.99835	1.31E-05	1.519	1.259	1.834
Highest Risk Lesion - Segment Category (stemi PCI) 3=Left Main	mNewSeg_stemi	3=Left Main		1.71164	0.243874	49.26009	2.24E-12	5.538	3.434	8.932
Highest Risk Lesion - Segment Category (nonstemi PCI) 1=pRCA/mLAD/pCIRC	mNewSeg_nstemi	1=pRCA/mLAD/pCIRC		0.22946	0.082578	7.721107	0.005458	1.258	1.07	1.479
Highest Risk Lesion - Segment Category (nonstemi PCI) 2=pLAD	mNewSeg_nstemi	2=pLAD		0.5023	0.092864	29.25727	6.34E-08	1.653	1.378	1.982
Highest Risk Lesion - Segment Category (nonstemi PCI) 3=Left Main	mNewSeg_nstemi	3=Left Main		0.84429	0.157912	28.58639	8.96E-08	2.326	1.707	3.17
PCI Status for stemi 2=Urgent	PCIStat_stemi	2=Urgent	NCDR Variable 804 Impute missing to 1=Elective. PCIStat_stemi for STEMI patients; PCIStat_nstemi for other patients.	0.08189	0.266061	0.094733	0.758244	1.085	0.644	1.828
PCI Status for stemi 3=Emergency	PCIStat_stemi	3=Emergency		0.72833	0.239626	9.238116	0.00237	2.072	1.295	3.313
PCI Status for stemi 4=Salvage	PCIStat_stemi	4=Salvage		2.67727	0.280539	91.07499	1.38E-21	14.545	8.393	25.207
PCI Status for nonstemi PCI 2=Urgent	PCIStat_nstemi	2=Urgent		0.7002	0.087586	63.90964	1.3E-15	2.014	1.696	2.391
PCI Status for nonstemi PCI 3=Emergency	PCIStat_nstemi	3=Emergency		1.98619	0.107096	343.9473	8.82E-77	7.288	5.908	8.99
PCI Status for nonstemi PCI 4=Salvage	PCIStat_nstemi	4=Salvage		4.41325	0.300117	216.24	5.98E-49	82.537	45.834	148.63

Pre-cath model

Label	Variable	Levels	Definition	Estimate	Standard Error	Wald Chi Square	p-Value	Odds Ratio Point Estimate	95% Wald Confidence Limits	
Intercept: Death = Yes	Intercept			-6.380955885	0.397670562	257.46879	6.11E-58			
STEMI patients	STEMI		Admission symptoms of STEMI where onset is within 24 hrs of admission OR Acute PCI is: Primary for STEMI/Rescue/Facilitated (i.e. (AdmSxPre [NCDR Variable 550] = 6 and SxOnset [NCDR Variable 560] in (1, 2, 3)) or AcutePCI [NCDR Variable 812] in (2, 3, 4))	0.642880624	0.449086095	2.0492807	0.152278	1.902	0.789	4.586
Age (for age<=70)	age_le70		Age (NCDR Variable 252), if > 110 or missing, then deleted from the data. Do not impute missing.	0.041657719	0.0040481	105.89818	7.76E-25	(per 10 units) 1.524	1.397	1.644
Age (for age>70)	age_gt70		If patient's age <= 70, e.g. 60, then the logit(mortality) = … + estimate(age_le70) * 60 + …; if age > 70, e.g. 80, then logit(mortality)=… + estimate(age_le70)*70 + estimate(age_gt70)*(80-70) + ...	0.055280471	0.004745223	135.71572	2.3E-31	(per 10 units) 1.741	1.583	1.913
Cardiogenic Shock at Admission	CarShock		NCDR Variable 520. Impute missing to no.	2.455030571	0.059575834	1698.1402	0	11.647	10.363	13.089
Previous History - CHF	PrCHF		NCDR Variable 424. Impute missing to no.	0.487235902	0.06573266	54.943479	1.24E-13	1.628	1.431	1.852
Previous Valvular Surgery	PrValve		NCDR Variable 426. Impute missing to no.	0.414724444	0.184348864	5.0610233	0.02447	1.514	1.055	2.173
Cerebrovascular Disease	CVD		NCDR Variable 450. Impute missing to no.	0.22914408	0.066432065	11.897666	0.000562	1.258	1.104	1.432
Peripheral Vascular Disease	PVD		NCDR Variable 452. Impute missing to no.	0.427380473	0.064740821	43.578567	4.07E-11	1.533	1.351	1.741
Chronic Lung Disease	CLD		NCDR Variable 454. Impute missing to no.	0.41003954	0.058306494	49.455844	2.03E-12	1.507	1.344	1.689
Previous PCI	PrPCI		NCDR Variable 490. Impute missing to no.	-0.337350898	0.059943244	31.672566	1.82E-08	0.714	0.635	0.803
PreOp IABP (D)	PreIABP		DCRI Derived from IABP (NCDR Variable 640), IABPWhen (NCDR 642): if (iabp eq . and iabpwhen eq .) or (iabp eq 1 and iabpwhen eq .) then PreIABP = .; else if iabpwhen eq 1 then PreIABP = 1; else PreIABP = 0;	1.265524048	0.200634916	39.785771	2.83E-10	3.545	2.392	5.253
Diabetes/Control (D) 1=Non-Insulin Diabetes	NewDiab	1=Non-Insulin Diabetes	Derived from NCDR Variables 430 (Diabetes) and 432 (DiabCtrl): if diabetes eq . and diabctrl in (., 1) then NewDiab = .; else if diabctrl eq 4 then NewDiab = 2; else if diabetes eq 1 or diabctrl in (2, 3) then NewDiab = 1; else NewDiab = 0;	0.140966373	0.063190716	4.9765057	0.025694	1.151	1.017	1.303
Diabetes/Control (D) 2=Insulin Diabetes	NewDiab	2=Insulin Diabetes		0.586773653	0.07611441	59.430235	1.27E-14	1.798	1.549	2.087
BMI [kg/m^2] for stemi	bmi_stemi		Calculated from NCDR Variables 410 (HeightCM) and 412 (WeightKG): BMI = weightkg * 10000 / (heightcm * heightcm); if BMI < 5 or BMI > 100 then BMI = .; Impute missing BMI to gender specific median. If BMI > 30, set BMI = 30 (flat).	-0.013586859	0.009826602	1.9117515	0.166769	(per 5 units) 0.937	0.85	1.03
BMI [kg/m^2] for nonstemi PCI	bmi_nstemi		bmi_stemi for STEMI patients; bmi_nstemi for other patients.	-0.064043532	0.00944451	45.982402	1.19E-11	(per 5 units) 0.726	0.663	0.794
GFR for stemi	gfr_stemi		Derived from NCDR Variables 252 (age), 260 (gender), 270 (race), and 440 (CreatLst): if (creatlst ne .) then do; if gender = 1 then gendmult = 1; else if gender eq 2 then gendmult = 0.742; if race eq 2 then racemult = 1.21; else racemult = 1; GFR = 186 * creatlst**(-1.154) * age**(-.203) * gendmult * racemult; end; else GFR = .; Impute missing to gender, prior renal failure (NCDR Variable 442), STEMI specific median. if (gfr > 90) then gfr = 90; if (gfr < 30 or dialysis [NCDR Var. 444]) then gfr = 30;	-0.025901485	0.001931421	179.84379	5.24E-41	(per 10 units) 0.768	0.745	0.801
GFR for nonstemi PCI	gfr_nstemi		gfr_stemi for STEMI patients; gfr_nstemi for other patients.	-0.020589137	0.001977636	108.38856	2.21E-25	(per 10 units) 0.817	0.784	0.842
Prev History - Dialysis (stemi PCI)	dialysis_stemi		NCDR Variable 444. Impute missing to no.	0.143448255	0.238452033	0.3618999	0.547453	1.154	0.723	1.842
Prev History - Dialysis (nonstemi PCI)	dialysis_nstemi		dialysis_stemi for STEMI patients; dialysis_nstemi for other patients.	0.553078237	0.139096915	15.810228	7E-05	1.739	1.324	2.283
NYHA Class 4 for stemi PCI	classnyhD_stemi		True if NYHA class IV (NCDR Variable 510); false if not class IV.	0.248159955	0.071786924	11.950132	0.000546	1.282	1.113	1.475
NYHA Class 4 for nonstemi PCI	classnyhD_nstemi		classnyhD_stemi for STEMI patients; classnyhD_nstemi for other patients.	0.696278864	0.074698863	86.883726	1.15E-20	2.006	1.733	2.323

Label	Variable	Levels	Definition	Estimate	Standard Error	Wald Chi Square	p-Value	Odds Ratio Point Estimate	95% Wald Confidence Limits	
PCI Status for stemi 2=Urgent	PCIStat_stemi	2=Urgent	NCDR Variable 804	0.245593171	0.260300762	0.8901879	0.345426	1.278	0.768	2.129
PCI Status for stemi 3=Emergency	PCIStat_stemi	3=Emergency	Impute missing to 1=Elective.	1.068485078	0.233358075	20.964826	4.68E-06	2.911	1.842	4.599
PCI Status for stemi 4=Salvage	PCIStat_stemi	4=Salvage	PCIStat_stemi for STEMI patients;	3.154257989	0.273365081	133.13994	8.43E-31	23.436	13.715	40.047
PCI Status for nonstemi PCI 2=Urgent	PCIStat_nstemi	2=Urgent	PCIStat_nstemi for other patients.	0.805762738	0.086997318	85.783277	2.01E-20	2.238	1.887	2.655
PCI Status for nonstemi PCI 3=Emergency	PCIStat_nstemi	3=Emergency		2.326950724	0.103974709	500.86299	6.2E-111	10.247	8.358	12.563
PCI Status for nonstemi PCI 4=Salvage	PCIStat_nstemi	4=Salvage		4.865392175	0.295140217	271.75586	4.7E-61	129.722	72.743	231.333

Pre-cath point system

AGE	<60	60-70	70-80	>80
	0	4	8	14

CARSHOCK	No	Yes
	0	25

PrCHF	No	Yes
	0	5

PVD	No	Yes
	0	5

CLD	No	Yes
	0	4

GFR	<30	30-60	60-90	>90
	18	10	6	0

NYHA Class 4	No	Yes
	0	4

PCIStat(STEMI)	Elective	Urgent	Emergent	Salvage
	12	15	20	38

PCIStat(Other)	Elective	Urgent	Emergent	Salvage
	0	8	20	42

TOTALPTS	DPROB
0	0
5	0.001
10	0.001
15	0.002
20	0.003
25	0.006
30	0.011
35	0.02
40	0.036
45	0.063
50	0.109
55	0.183
60	0.29
65	0.427
70	0.576
75	0.712
80	0.819
85	0.892
90	0.938
95	0.965
100	0.98
105	0.989
110	0.994
115	0.997
120	0.998
125	0.999
130	0.999
135+	1

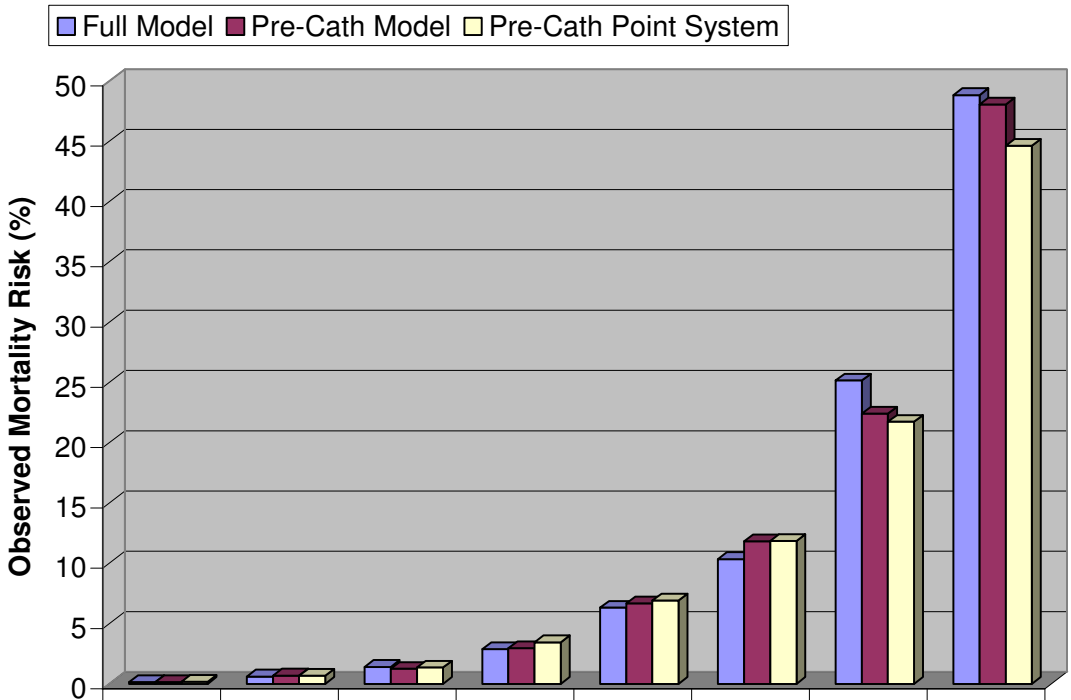
Reference: Model 13a (Pre-cath simplified)

Label	Variable	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq	Odds Ratio Point Estimate	95% Wald Confidence Limits	
Intercept: mort=(1) Yes	**Intercept**	-7.6973	0.2891	708.9718	<.0001			
STEMI patients	**STEMI**	1.5982	0.2395	44.5464	<.0001			
Age (for age<=70)	**age_le70**	0.0417	0.00401	107.9158	<.0001	(per 10 unit increase) 1.524	1.397	1.644
Age (for age>70)	**age_gt70**	0.0561	0.00457	150.9319	<.0001	(per 10 unit increase) 1.757	1.598	1.913
Cardiogenic Shock at Admission	**CarShock**	2.5006	0.0589	1804.7284	<.0001	12.190	10.862	13.681
Previous History - CHF	**PrCHF**	0.5583	0.0635	77.2459	<.0001	1.748	1.543	1.979
Peripheral Vascular Disease	**PVD**	0.5154	0.0626	67.7797	<.0001	1.674	1.481	1.893
Chronic Lung Disease	**CLD**	0.4212	0.0579	52.8667	<.0001	1.524	1.360	1.707
GFR (D)	**GFR**	-0.0265	0.00136	377.5512	<.0001	(per 10 unit increase) 0.768	0.745	0.784
NYHA Class 4? (Y/N)	**classnyhD**	0.4787	0.0530	81.7051	<.0001	1.614	1.455	1.790
PCI Status for stemi 2=Urgent	**PCIStat_stemi**	0.2189	0.2598	0.7098	0.3995	(vs. 1=Elective) 1.245	0.748	2.071
PCI Status for stemi 3=Emergency	**PCIStat_stemi**	0.9752	0.2326	17.5775	<.0001	(vs. 1=Elective) 2.652	1.681	4.184
PCI Status for stemi 4=Salvage	**PCIStat_stemi**	3.0657	0.2727	126.3614	<.0001	(vs. 1=Elective) 21.450	12.568	36.608
PCI Status for nonstemi PCI 2=Urgent	**PCIStat_nstemi**	0.9133	0.0854	114.4570	<.0001	(vs. 1=Elective) 2.493	2.109	2.947
PCI Status for nonstemi PCI 3=Emergency	**PCIStat_nstemi**	2.4670	0.1001	606.9067	<.0001	(vs. 1=Elective) 11.788	9.687	14.344
PCI Status for nonstemi PCI 4=Salvage	**PCIStat_nstemi**	4.9874	0.2926	290.5911	<.0001	(vs. 1=Elective) 146.554	82.596	260.037

Summary of c-index of each above model

	Sample Size	Full (model 12)	Pre-cath (complicated) (model 13)	Pre-cath (simplified) (model 13a)	Pre-cath (simplified) Point-System
Final model (from 60% pop04-06)	**181775**	**0.926**	**0.916**	**0.911**	
It is decided to use 100% pop06-07 as final validation data					
applied to overall validation data	**285440**	**0.924**	**0.914**	**0.910**	**0.905**
applied to STEMI in validation data	39889	0.902	0.892	0.890	0.884
applied to NonSTEMI in validation data	245551	0.892	0.878	0.869	0.862
applied to WOMEN in validation	95106	0.911	0.903	0.897	0.893
applied to MEN in validation	190334	0.930	0.920	0.916	0.911
applied to AGE>70 in validation	92381	0.901	0.891	0.886	0.880
applied to AGE<=70 in validation	193059	0.927	0.916	0.911	0.906
applied to ANY DIABETE in validation	92974	0.924	0.915	0.910	0.903
applied to NO DIABETE in validation	192466	0.923	0.914	0.910	0.906

Calibration curves



	0.0-0.5	0.5-1.0	1.0-2.0	2.0-5.0	5.0-7.5	7.5-15.	15.-30.	30.+
Full Model	0.14191	0.6079	1.4029	2.86448	6.31732	10.3335	25.155	48.8294
Pre-Cath Model	0.14688	0.6907	1.24738	2.95027	6.66265	11.8123	22.4031	48.0455
Pre-Cath Point System	0.1658	0.67002	1.34758	3.44485	6.90834	11.8519	21.7258	44.6065

Predicted Mortality Risk Group (%)

NATIONAL QUALITY FORUM

Measure Evaluation 4.1
December 2009

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

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

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

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

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

(for NQF staff use) **NQF Review #:** 1495 **NQF Project:** Cardiovascular Endorsement Maintenance 2010
MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** P2Y12 Inhibitor at discharge for patients with Percutaneous Coronary Intervention (PCI) (with stents)
De.2 **Brief description of measure**: Proportion of adult patients (age 18 or older) who undergo a percutaneous coronary intervention (PCI) (without a documented contraindication) with a stent implanted that had a P2Y12 inhibitor prescribed at discharge.
1.1-2 **Type of Measure:** Process De.3 **If included in a composite or paired with another measure, please identify composite or paired measure** N/A
De.4 **National Priority Partners Priority Area:** De.5 **IOM Quality Domain**: Effectiveness, Safety, Timeliness De.6 **Consumer Care Need:** Getting better, Staying healthy, Living with illness

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	**NQF Staff**
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.* A.1 **Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes A.2 **Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:** A.3 **Measure Steward Agreement:** Agreement will be signed and submitted prior to or at the time of measure submission A.4 **Measure Steward Agreement attached:** NQF - signed-634238762228916780.pdf	**A** **Y**☐ **N**☐

B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	**B** Y☐ N☐
C. The intended use of the measure includes both public reporting and quality improvement. ►**Purpose:** Public reporting, Internal quality improvement Accountability, Payment incentive, Accreditation	**C** Y☐ N☐
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1**Testing:** Yes, fully developed and tested D.2 **Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?** Yes	**D** Y☐ N☐
(for NQF staff use**) Have all conditions for consideration been met?** **Staff Notes to Steward** (*if submission returned*)**:**	**Met** Y☐ N☐
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**	
Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. *Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.* (evaluation criteria) **1a. High Impact**	Eval Rating
(for NQF staff use) Specific NPP goal:	
1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Severity of illness **1a.2** **1a.3 Summary of Evidence of High Impact:** Cardiovascular disease is the single most common cause of death in the U.S. There are an estimated 64 million people with cardiovascular disease with direct costs totaling over 226 billion dollars in 2004. Estimates of direct costs due to cardiovascular disease are projected to be 503.2 billion dollars in 2010. In 2002, approximately 864,480 deaths were attributable to cardiovascular disease, or 1 in 2.9 deaths in the US. Approximately 1 million PCI procedures are performed annually. 6.1 million hospital discharges listed cardiovascular disease as the primary diagnosis in 2006. In 2004 coronary artherosclerosis attributed to 1.2 million hospital stays, with 44 billion in associated expenses. More than half of hospital stays were due to PCI or cardiac revascularization. **1a.4 Citations for Evidence of High Impact:** American Heart Association. Heart disease and stroke statistics- 2010 update: A report of the American Heart Association. Available at:http://circ.ahajournals.org/cgi/content/full/103/24/3019. Accessed October 13, 2010.	**1a** C☐ P☐ M☐ N☐
1b. Opportunity for Improvement **1b.1 Benefits (improvements in quality) envisioned by use of this measure:** P2Y12 inhibitors, including	**1b** C☐ P☐

Comment [KP1]: 1a. The measure focus addresses:
•a specific national health goal/priority identified by NQF's National Priorities Partners; OR
•a demonstrated high impact aspect of healthcare (e.g., affects large numbers, leading cause of morbidity/mortality, high resource use (current and/or future), severity of illness, and patient/societal consequences of poor quality).

Comment [KP2]: 1b. Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating considerable variation, or overall poor performance, in the quality of care across providers and/or population groups (disparities in care).

clopidogrel and prasugrel, reduce the risk of ischemic events following PCI. This measure will improve rates of P2Y12 inhibitor prescribing (as recommended by relevant guidelines) at discharge following PCI and subsequently reduce rates of adverse outcomes after PCI.

M☐ N☐

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
Data from the NCDR CathPCI Registry for 1121 facilities (521,617 records) showed some variation in performance for this measure. Performance ranged from 93% at the 5th percentile to 100% at the 95th percentile. 25% of hospitals did not prescribe P2Y12 inhibitors at discharge for 3% of its patients. Please see documentation provided in Ad.11 for detailed analyses.

1b.3 Citations for data on performance gap:
Unpublished NCDR data. Please see documentation attached.

1b.4 Summary of Data on disparities by population group:
We conducted stratified analyses of hospital performance for this measure by (a) hospital safety net status (defined as government hospitals or non-government hosptials with high medicaid caseload using AHA 2008) and (b) quartiles based on proportion of white patients. Both sets of analyses suggested that the range of hospital performance is similar irrespective of the SES of the patients treated. Specifically, the median for Safety Net hospitals was 98.8% with the lowest decile 94.9% and highest decile 100%. This is similar to that observed for non-Safety Net hospitals (median 98.3%, lowest decile 93.7%, highest decile 100%). Similarly, median hospital performance was similar across quartiles of proportion of white patients (quartile 1: 98.5%, quartile 2: 98.6%, quartile 3: 98.7%, quartile 4: 99.1%).

1b.5 Citations for data on Disparities:
Unpublished NCDR data. Please see documentation attached.

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** P2Y12 Inhibitors (including clopidogrel, ticlopidine, prasugrel) have been found to reduce the rate of thrombotic events following PCI. P2Y12 Inhibitors provide greater protection from ischemic events than aspirin alone.

1c.2-3. Type of Evidence: Evidence-based guideline, Randomized controlled trial, Expert opinion

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
The use of P2Y12 inhibitors after PCI appears to reduce rates of cardiovascular ischemic events. For example, the efficacy of combination antiplatelet therapy (aspirin plus thienopyridine) in patients undergoing urgent and elective stent implantation was demonstrated in the Intracoronary Stenting and Antithrombotic Regimen (ISAR) trial of 517 patients treating with BMS for MI, suboptimal angioplasty, or other high-risk clinical and anatomic features. Patients were randomly assigned to treatment with aspirin plus ticlopidine or aspirin, intravenous heparin, and phenprocoumon after successful stent placement. The primary end point of cardiac death, MI, CABG, or repeat angioplasty occurred in 1.5% of patients assigned to antiplatelet therapy and 6.2% of those assigned to anticoagulant therapy (relative risk 0.25; 95% CI 0.06 to 0.77).

The benefits of long-term treatment with clopidogrel after PCI and the benefit of initiating pretreatment with clopidogrel with a preprocedural loading dose in addition to aspirin therapy were tested in CREDO (Clopidogrel for the Reduction of Events During Observation), a randomized, double-blind, controlled trial of early and sustained dual oral antiplatelet therapy after PCI. In this trial of 2116 patients undergoin PCI from 99 North American centers, the patients received either a loading dose of clopidogrel or placebo, and all patients received clopidogrel thereafter through day 28. In the following 12 months, patients in the loading dose group received clopidogrel and those in the control group received placebo. All patients received aspirin. At 1 year, long-term clopidogrel therapy was associated with a 27% RRR in the combined risk of death, MI, or stroke for an absolute reduction of 3%.

Steinhubl et al found 1 year, long-term clopidogrel therapy was associated with a 26.9% relative reduction

1c
C☐ P☐ M☐ N☐

Comment [k3]: 1 Examples of data on opportunity for improvement include, but are not limited to: prior studies, epidemiologic data, measure data from pilot testing or implementation. If data are not available, the measure focus is systematically assessed (e.g., expert panel rating) and judged to be a quality problem.

Comment [k4]: 1c. The measure focus is:
•an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;
OR
•if an intermediate outcome, process, structure, etc., there is **evidence** that supports the specific measure focus as follows:
oIntermediate outcome – evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
oProcess – evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and
if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
oStructure – evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
oPatient experience – evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of individuals/ the public.
oAccess – evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
oEfficiency – demonstration of an association between the measured resource use and level of performance with respect to one or more of the other five IOM aims of quality.

Comment [k5]: 4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., mammography) or measures for multiple care processes that affect a single outcome.

in the combined risk of death, MI, or stroke (95% confidence interval [CI], 3.9%-44.4%; P=.02; absolute reduction, 3%).

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom***):**
Level B: Data derived from a single randomized trial or nonrandomized studies (American College of Cardiology/ American Heart Association TaskForce on Practice Guidelines)

1c.6 Method for rating evidence: The weight of evidence in support of the recommendation is listed as follows:
• Level of Evidence A: Data derived from multiple randomized clinical trials or meta-analyses.
• Level of Evidence B: Data derived from a single randomized trial or nonrandomized studies.
• Level of Evidence C: Only consensus opinion of experts, case studies, or standard-of-care.

1c.7 Summary of Controversy/Contradictory Evidence:

1c.8 Citations for Evidence (*other than guidelines***):** Steinhubl SR, Berger PB, Mann JT, III, et al. Early and sustained dual oral antiplatelet therapy following percutaneous coronary intervention: a randomized controlled trial. JAMA 2002;288: 2411-20.

Mehta SR, Yusuf S, Peters RJ, et al. Effects of pretreatment with clopidogrel and aspirin followed by long-term therapy in patients undergoing percutaneous coronary intervention: the PCI-CURE study. Lancet 2001;358:527-33.

Stone GW, Ellis SG, Cox DA, et al. One-year clinical results with the slow-release, polymer-based, paclitaxel-eluting TAXUS stent: the TAXUS-IV trial. Circulation 2004;109:1942-7.

Holmes DR Jr, Leon MB, Moses JW, et al. Analysis of 1-year clinical outcomes in the SIRIUS trial: a randomized trial of a sirolimus-eluting stent versus a standard stent in patients at high risk for coronary restenosis. Circulation 2004;109:634-40.

1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number***):**
ACC/AHA 2009 Focused Update for PCI:
Class 1
2. The duration of thienopyridine therapy should be as follows: a. In patients receiving a stent (BMS or drug-eluting stent [DES]) during PCI for ACS, clopidogrel 75 mg daily† (27–29) (Level of Evidence: B) or prasugrel 10 mg daily§ (27) (Level of Evidence:
B) should be given for at least 12 months; b. If the risk of morbidity because of bleeding outweighs the anticipated benefit afforded by thienopyridine therapy, earlier discontinuation should be considered. (Level of Evidence: C)
Class 1
3. In patients taking a thienopyridine in whom CABG is planned and can be delayed, it is recommended that the drug be discontinued to allow for dissipation of the antiplatelet effect. (Level of Evidence: C) The period of withdrawal should be at least 5 days in patients receiving clopidogrel (2,30) (Level of Evidence: B) and at least 7 days in patients receiving prasugrel (27) (Level of Evidence: C), unless the need for revascularization and/or the net benefit of the thienopyridine outweighs the potential risks of excess bleeding (31). (Level of Evidence: C)

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ACC/AHA NSTEMI Guidelines 2007:
Class 1:
5. For UA/NSTEMI patients in whom an initial conservative (i.e., noninvasive) strategy is selected clopidogrel (loading dose followed by daily maintenance dose)* should be added to ASA and anticoagulant therapy as soon as possible after admission and administered for at least 1 month (Level of Evidence: A) and ideally up to 1 year. (Level of Evidence: B)

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Comment [k6]: 3 The strength of the body of evidence for the specific measure focus should be systematically assessed and rated (e.g., USPSTF grading system http://www.ahrq.gov/clinic/uspstf07/methods/benefit.htm). If the USPSTF grading system was not used, the grading system is explained including how it relates to the USPSTF grades or why it does not. However, evidence is not limited to quantitative studies and the best type of evidence depends upon the question being studied (e.g., randomized controlled trials appropriate for studying drug efficacy are not well suited for complex system changes). When qualitative studies are used, appropriate qualitative research criteria are used to judge the strength of the evidence.

ACC/AHA guidelines for secondary prevention for patients with coronary and other atherosclerotic vascular disease:
• Start aspirin 75 to 162 mg/d and continue indefinitely in all patients unless contraindicated. I (A)
For patients undergoing coronary artery bypass grafting, aspirin should be started within 48 hours after surgery to reduce saphenous vein graft closure. Dosing regimens ranging from 100 to 325mg/d appear to be efficacious. Doses higher than 162 mg/d can be continued for up to 1 year. I (B)
• Start and continue clopidogrel 75 mg/d in combination with aspirin for up to 12 months in patients after acute coronary syndrome or percutaneous coronary intervention with stent placement (>=1 month for bare metal stent, >=3 months for sirolimus-eluting stent, and >=6 months for paclitaxel-eluting stent). I (B)
Patients who have undergone percutaneous coronary intervention with stent placement should initially receive higher-dose aspirin at 325 mg/d for 1 month for bare metal stent, 3 months for sirolimus-eluting stent, and 6 months for paclitaxel-eluting stent. I (B

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ACC/AHA STEMI Guidelines 2004:
Class I
1. A daily dose of aspirin 75 to 162 mg orally should be given indefinitely to patients recovering from STEMI. (Level of Evidence: A)
2. If true aspirin allergy is present, preferably clopidogrel (75 mg orally per day) or, alternatively, ticlopidine (250 mg orally twice daily) should be substituted. (Level of Evidence: C)

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1c.10 Clinical Practice Guideline Citation: 1. Kushner FG, Hand M, Smith SC, Jr., et al. 2009 focused updates: ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction (updating the 2004 guideline and 2007 focused update) and ACC/AHA/SCAI guidelines on percutaneous coronary intervention (updating the 2005 guideline and 2007 focused update) a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2009;54:2205-41.

2. Anderson JL, Adams CD, Antman EM, et al. ACC/AHA 2007 guidelines for the management of patients with unstable angina/non-ST-Elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 2002 Guidelines for the Management of Patients With Unstable Angina/Non-ST-Elevation Myocardial Infarction) developed in collaboration with the American College of Emergency Physicians, the Society for Cardiovascular Angiography and Interventions, and the Society of Thoracic Surgeons endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation and the Society for Academic Emergency Medicine. J Am Coll Cardiol. 2007;50:e1-e157.

3. Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Management of Patients with Acute Myocardial Infarction). Circulation. 2004;110:e82-292.

4. Smith SC, Jr., Allen J, Blair SN, et al. AHA/ACC guidelines for secondary prevention for patients with coronary and other atherosclerotic vascular disease: 2006 update endorsed by the National Heart, Lung, and Blood Institute. J Am Coll Cardiol. 2006;47:2130-9.

1c.11 National Guideline Clearinghouse or other URL:
http://circ.ahajournals.org/cgi/content/short/120/22/2271

1c.12 Rating of strength of recommendation (*also provide narrative description of the rating and by whom***):**
Class 1: Conditions for which there is evidence for and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.

1c.13 Method for rating strength of recommendation (*If different from* USPSTF system*, also describe*

Comment [k7]: USPSTF grading system **http://www.ahrq.gov/clinic/uspstf/grades.htm**: **A -** The USPSTF recommends the service. There is high certainty that the net benefit is substantial. **B -** The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. **C -** The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small. Offer or provide this service only if other considerations support the offering or providing the service in an individual patient. **D -** The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. **I -** The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

rating and how it relates to USPSTF): ACC/AHA Taskforce on Practice Guidelines Method: Indications are categorized as class I, II, or III on the basis of a multifactorial assessment of risk and expected efficacy viewed in the context of current knowledge and the relative strength of this knowledge. These classes summarize the recommendations for procedures or treatments as follows: Class I: Conditions for which there is evidence for and/or general agreement that a given procedure or treatment is beneficial, useful, and effective. Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment. Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy. Class IIb: Usefulness/efficacy is less well established by evidence/opinion. Class III: Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful. **1c.14 Rationale for using this guideline over others:** This guideline is the most widely recognized professional guideline in the US for cardiovascular medicine in the area of percutaneous coronary intervention care.	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to Measure and Report*?	**1**
Steering Committee: Was the threshold criterion, *Importance to Measure and Report*, **met?** **Rationale:**	**1** **Y☐** **N☐**
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	Eval Rating
2a. MEASURE SPECIFICATIONS	
S.1 Do you have a web page where current detailed measure specifications can be obtained? **S.2 If yes, provide web page URL:** **2a. Precisely Specified**	
2a.1 Numerator Statement (*Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):** Count of patients with a PCI procedure with a P2Y12 inhibitor (Clopidogrel, Prasugrel or Ticlopidine) prescribed at discharge. **2a.2 Numerator Time Window (***The time period in which cases are eligible for inclusion in the numerator***):** 1 year **2a.3 Numerator Details (***All information required to collect/calculate the numerator, including all codes, logic, and definitions***):** Element Name: Discharge Medications Discharge medication=clopidogrel, ticlopidine, or prasugrel. Coding Instructions: Indicate which of the following medications the patient was prescribed upon discharge. Note(s): Complete only for patients who had a PCI procedure attempted or performed during this episode of care. Discharge medications not required for patients who were discharged to "Other acute care	**2a-specs** **C☐** **P☐** **M☐** **N☐**

Comment [KP8]: 2a. The measure is well defined and precisely specified so that it can be implemented consistently within and across organizations and allow for comparability. The required data elements are of high quality as defined by NQF's Health Information Technology Expert Panel (HITEP) .

hopsital","Hospice", or Left against medical advice (AMA)."
To code ´yes´ for aspirin, the minimum dose should be at least 75mg.

Element Name: Medication Administered
Medication administered= Yes
Coding Instructions: Indicates if the medication was administered, not administered, contraindicated or blinded.
Selections:
No- Medication was not administered or prescribed.
Yes- Medication was administered or prescribed.
Contraindicated- Medication was not administered because of a contraindication.
(Contraindications must be documented explicitly by the physician, or
clearly evidenced within the medical record.)
Blinded- Patient was in a research study or clinical trial and the administration of this specific medication or class of medications is unknown.

2a.4 Denominator Statement (*Brief, text description of the denominator - target population being measured***):**
Count of patients with a PCI procedure with a stent implanted

2a.5 Target population gender: Female, Male
2a.6 Target population age range: All patients >= 18 years of age.

2a.7 Denominator Time Window (*The time period in which cases are eligible for inclusion in the denominator***):**
1 year

2a.8 Denominator Details (*All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):**
Element name: PCI
PCI=Yes
Coding Instructions: Indicate if the patient had a percutaneous coronary intervention (PCI).
Selections: No/Yes
Supporting Definitions: PCI:A percutaneous coronary intervention (PCI) is the placement of an angioplasty guide wire, balloon, or other device (e.g. stent, atherectomy, brachytherapy, or thrombectomy catheter) into a native coronary artery or coronary artery bypass graft for the purpose of mechanical coronary revascularization.Source: NCDR

Element Name: Intracoronary Device(s) Used
Intracoronary device(s) used= stent
Coding instructions: Indicate all devices utilized during the current procedure. If a device was utilized on multiple lesions, specify it only once (e.g., if a balloon was used to dilate two separate lesions, list it only once). Every treatment and support device utilized during the procedure should be specified.
Note(s): Each intracoronary device must be associated with at least one lesion via the Lesion Counter (7100) if Device Deployed (7220) is ´Yes´. An intracoronary device may be associated with more than one lesion.The devices available for selection in your application are controlled by the intracoronary device downloadable file. This file and its updates will be maintained by the ACC and will be made available on the Internet for downloading and importing into your application.

2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population***):** -P2Y12 coded as contraindicated or blinded
-Discharge status of expired
-Discharge location of “other acute care hospital”, “hospice” or “against medical advice”.

2a.10 Denominator Exclusion Details (*All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**
Element name: Discharge Status
Discharge status= deceased
Coding Instructions: Indicate whether the patient was alive or deceased at discharge.

Comment [k9]: 11 Risk factors that influence outcomes should not be specified as exclusions.
12 Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

Selections: Alive/Deceased

Element name: Discharge Location
Discharge location="other acute hospital","hospice", or "left against medical advice"
Coding Instructions: Indicate the location to which the patient was discharged.
Selections:
-Home
-Extended care/TCU/rehabilitation
-Other acute care hospital
-Nursing home
-Hospice
-Other
-Left against medical advice (The patient was discharged or eloped against medical advice.)

Medication Administered=contraindicated or blinded
Name: Medication Administered
Coding Instructions: Indicates if the medication was administered, not administered, contraindicated or blinded.
Selections:
No- Medication was not administered or prescribed.
Yes- Medication was administered or prescribed.
Contraindicated- Medication was not administered because of a contraindication.
(Contraindications must be documented explicitly by the physician, or
clearly evidenced within the medical record.)
Blinded- Patient was in a research study or clinical trial and the administration of this specific medication or class of medications is unknown.

2a.11 Stratification Details/Variables (*All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
N/A

2a.12-13 Risk Adjustment Type: No risk adjustment necessary

2a.14 Risk Adjustment Methodology/Variables (*List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**
N/A

2a.15-17 Detailed risk model available Web page URL or attachment:

2a.18-19 Type of Score: Rate/proportion
2a.20 Interpretation of Score: Better quality = Higher score
2a.21 Calculation Algorithm (*Describe the calculation of the measure as a flowchart or series of steps***):**
Denominator calculation:
1. Count of patients with arrival/discharge dates from data submissions that pass NCDR data inclusion thresholds
2. Exclude patients with arrival/discharge dates without PCI during episode
3. Exclude patients with discharge status=deceased
4. Exclude patients with Discharge Location: Other acute care hospital
5. Exclude patients with Discharge Location: Left against medical advice
6. Exclude patients with Discharge Location: Hospice
7. Exclude patients with Statin at discharge: contraindicated or blinded
8. Exclude patients with a stent.

Numerator calculation:
9. From denominator population, count of patients with Discharge medication of clopidogrel, ticlopidine, or prasugrel=yes

Calculation of score:
10. Numerator count/Denominator count

2a.22 Describe the method for discriminating performance *(e.g., significance testing)*:
Hospitals performance for this measure is benchmarked each quarter and annually against hospitals with similar procedural volume, as well as against the CathPCI Registry aggregate. These benchmarks identify superior performance and encourage poorer performers to improve. The methodology is a data-driven, peer-group performance feedback used to positively affect outcomes.

2a.23 Sampling (Survey) Methodology *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)*:
N/A

2a.24 Data Source (*Check the source(s) for which the measure is specified and tested)*
Registry data

2a.25 Data source/data collection instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
National Cardiovascular Data Registry (NCDR®) CathPCI Registry®

2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL
http://www.ncdr.com/WebNCDR/ELEMENTS.ASPX

2a.29-31 Data dictionary/code table web page URL or attachment: URL
http://www.ncdr.com/WebNCDR/ELEMENTS.ASPX

2a.32-35 Level of Measurement/Analysis (*Check the level(s) for which the measure is specified and tested)*
Facility/Agency

2a.36-37 Care Settings (*Check the setting(s) for which the measure is specified and tested)*
Hospital, Ambulatory Care: Hospital Outpatient

2a.38-41 Clinical Services (*Healthcare services being measured, check all that apply*)
Clinicians: PA/NP/Advanced Practice Nurse, Clinicians: Physicians (MD/DO)

TESTING/ANALYSIS

2b. Reliability testing

2b.1 Data/sample *(description of data/sample and size)*: Reliability was established by validating the derivation cohort from version 4 CathPCI data with a testing cohort from version 3 CathPCI data. 511,557 patient records were analyzed from 1007 facilities between July 2008 and June 2009.

2b.2 Analytic Method *(type of reliability & rationale, method for testing)*:
Reliability was established by validating the derivation cohort from version 4 CathPCI data with a testing cohort from version 3 CathPCI data.

2b.3 Testing Results *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
Results were consistent among the derivation cohort and the testing cohort. Specifically, the median for hospitals in the derivation cohort was 98.7% with the lowest decile 94.6% and highest decile 100%. This is similar to that observed in the testing cohort (median 98.8%, lowest decile 95.2%, highest decile 100%).

Elements included in this measure will be included in the CathPCI registry audit program in the future. Reliability is ensured through the Data Quality Report (DQR), clearly defined and specified data elements, and through the vendor certification process to ensure data submission vendors collect data elements reliably.

The Data Quality Report (DQR) program has been developed to ensure data are valid and complete. The DQR is a process for submitting data files to the NCDR®. Participants use their data collection tool software to create a submission file which is uploaded to the NCDR website. After uploading, the data in the file is

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N☐

Comment [KP10]: 2b. Reliability testing demonstrates the measure results are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period.

Comment [k11]: 8 Examples of reliability testing include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing may address the data items or final measure score.

automatically checked for errors and completeness. Passing the DQR ensures well-formed data and a statistically significant submission. Types of errors detected by the DQR include:
Schema:Structure doesn't match NCDR requirements
Dates: Inconsistent dates
Selection: Missing or mismatched data; Can be a parent/child errors where a field requests more data.
Outlier: Anomalies or exceptions; Data exceeds the possible limits. For example: 1,000mm length lesion.
Counter: errors deal with Closure Methods, Lesions, and Intracoronary Devices. Each one has a counter, when more than one is used
List: Missing data in the Medications or either Device lists

Reliability of the element "PCI" is strengthened because submitters to the CathPCI registry are required to complete this element. In addition, submitters cannot enter any of the elements in the "PCI Procedure" section if they do not answer "yes" to this element. In addition, the "discharge status" (alive or

2c. Validity testing

2c.1 **Data/sample** *(description of data/sample and size)*: Face/content validity: review of relevant evidence and guidelines and expert panel consensus process.

2c.2 **Analytic Method** *(type of validity & rationale, method for testing)*:
Face/content validity was established to ensure this measure represented an important aspect of cardiovascular care for which improvement is needed.

2c.3 **Testing Results** *(statistical results, assessment of adequacy in the context of norms for the test conducted)*:
A review of the relevant evidence and guidelines and expert panel consensus process resulted in the conclusion that this is a valid measure of quality of cardiovascular care for patients with PCI where variation in practice exists.

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2d. Exclusions Justified

2d.1 **Summary of Evidence supporting exclusion(s):**
This measure excludes patients with evidence-based contraindications, or patients who are participating in a blinded research study and out of necessity the hospital is not aware of the prescribed discharge medications. This measure also excludes patients discharged to hospice, against medical advice, to another acute care hospital, or who expired prior to discharge as discharge medications to not apply to these patients. No evidence is necessary or available for these exclusions.

2d.2 **Citations for Evidence:**
N/A

2d.3 **Data/sample** *(description of data/sample and size)*: 1,282,945 patient records from the CathPCI registry between July 2009 and June 2010 were analyzed from 1168 CathPCI Registry participating institutions.

2d.4 **Analytic Method** *(type analysis & rationale)*:
Frequency of exclusion coding.

2d.5 **Testing Results** *(e.g., frequency, variability, sensitivity analyses)*:
Rates of exclusion coding:
-Discharged to other acute care hospital: 3,022 (0.57%)
-Discharged to hospice: 661 (0.13%)
-Discharged against medical advice: 1,054 (0.20%)
-Aspirin contraindicated or blinded: 1,991 (0.38%)
-Discharge status of deceased: 6,280 (1.17%)

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NA☐

2e. Risk Adjustment for Outcomes/ Resource Use Measures

2e.1 **Data/sample** *(description of data/sample and size)*: N/A

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Comment [KP12]: 2c. Validity testing demonstrates that the measure reflects the quality of care provided, adequately distinguishing good and poor quality. If face validity is the only validity addressed, it is systematically assessed.

Comment [k13]: 9 Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP < 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed (e.g., ratings by relevant stakeholders) and the measure is judged to represent quality care for the specific topic and that the measure focus is the most important aspect of quality for the specific topic.

Comment [KP14]: 2d. Clinically necessary measure exclusions are identified and must be:
•supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;
AND
•a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;
AND
•precisely defined and specified:
–if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);
if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

Comment [k15]: 10 Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, sensitivity analyses with and without the exclusion, and variability of exclusions across providers.

Comment [KP16]: 2e. For outcome measures and other measures (e.g., resource use) when indicated:
•an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified and is based on patient clinical factors that influence the measured outcome (but not disparities in care) and are present at start of care;[Error! Bookmark not defined.] OR rationale/data support no risk adjustment.

2e.2 Analytic Method *(type of risk adjustment, analysis, & rationale)*:
N/A

2e.3 Testing Results *(risk model performance metrics)*:
N/A

2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: N/A

N☐
NA☐

Comment [k17]: 13 Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender (e.g., poorer treatment outcomes of African American men with prostate cancer, inequalities in treatment for CVD risk factors between men and women). It is preferable to stratify measures by race and socioeconomic status rather than adjusting out differences.

2f. Identification of Meaningful Differences in Performance

2f.1 Data/sample from Testing or Current Use *(description of data/sample and size)*: 521,617 patients from 1,121 hospitals from the CathPCI Registry.

2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance *(type of analysis & rationale)*:
Distribution by quartile, mean, median, SD.

2f.3 Provide Measure Scores from Testing or Current Use *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:

Description	Volume	Rate
N	1121	1121
Mean	465.31	0.9765
Std Deviation	426.42	0.0457
100% Max	3422	1.0000
99%	2036	1.0000
95%	1274	1.0000
90%	970	1.0000
75% Q3	629	0.9953
50% Median	361	0.9873
25% Q1	168	0.9721
10%	70	0.9464
5%	36	0.9268
1%	11	0.8195
0% Min	1	0.0000

Comment [KP18]: 2f. Data analysis demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful differences in performance.

Comment [k19]: 14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% v. 75%) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v. $5,025) is practically meaningful. Measures with overall poor performance may not demonstrate much variability across providers.

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N☐

2g. Comparability of Multiple Data Sources/Methods

2g.1 Data/sample *(description of data/sample and size)*: N/A

2g.2 Analytic Method *(type of analysis & rationale)*:
N/A

2g.3 Testing Results *(e.g., correlation statistics, comparison of rankings)*:
N/A

Comment [KP20]: 2g. If multiple data sources/methods are allowed, there is demonstration they produce comparable results.

2g
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N☐
NA☐

2h. Disparities in Care

2h.1 If measure is stratified, provide stratified results *(scores by stratified categories/cohorts)*: We conducted stratified analyses of hospital performance for this measure by (a) hospital safety net status (defined as government hospitals or non-government hosptials with high medicaid caseload using AHA 2008) and (b) quartiles based on proportion of white patients. Both sets of analyses suggested that the range of hospital performance is similar irrespective of the SES of the patients treated. Specifically, the median for Safety Net hospitals was 98.8% with the lowest decile 94.9% and highest decile 100%. This is similar to that observed for non-Safety Net hospitals (median 98.3%, lowest decile 93.7%, highest decile 100%). Similarly, median hospital performance was similar across quartiles of proportion of white patients (quartile 1: 98.5%, quartile 2: 98.6%, quartile 3: 98.7%, quartile 4: 99.1%).Based on these analyses, we do not believe that a stratified measure is necessary.

Comment [KP21]: 2h. If disparities in care have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results (e.g., by race, ethnicity, socioeconomic status, gender);OR rationale/data justifies why stratification is not necessary or not feasible.

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NA☐

2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Scientific Acceptability of Measure Properties?*

2

Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties*, **met?**
Rationale:

2
C☐ P☐ M☐ N☐

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)

Eval Rating

3a. Meaningful, Understandable, and Useful Information

3a.1 Current Use: In use

3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (*If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years*)**:**
ACCF plans to begin voluntary public reporting of NCDR measures, including this measure, by 2012. ACCF is currently evaluating public reporting options and finalizing decisions related to location and display of information to be reported as well as communication plans.

This measure is currently used by United Healthcare Services in their UnitedHealth Premium Cardiac Specialty Center designation program. Wellpoint, Inc. currently uses this measure in its Quality-In-Sights: Hospital Incentive Program (Q-HIP).

3a.3 If used in other programs/initiatives (*If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years***):**
Used for QI by NCDR CathPCI participating institutions. For Q2 of 2010, 1174 institutions submitted data.

Participating institutions receive an institutional outcomes report each quarter with their hospital´s data. Over 2000 metrics are included in each hospital´s outcomes report. 26 metrics are highlighted in the report executive summary. These metrics are selected by an NCDR panel of experts as presenting the greatest opportunity for care improvement. CathPCI "metrics", including this measure, appear in the executive summary of the outcomes report. Hospitals receive their measure score, as well as the rates for all hospitals in the CathPCI registry, and all hospitals in the same comparison group (based on volume), and the rate for the 90th percentile. A box and whisker plot is displayed for each metric to show hospitals how they compare to all hospitals in the CathPCI registry.

This measure is also provided to the Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2) and Hospital Corporation of America (HCA) for incorporation in their QI program efforts.

Testing of Interpretability (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*)
3a.4 Data/sample *(description of data/sample and size)***:** 1. 61 NCDR CathPCI Registry participants, Fall 2009.
2. Beta testing for version 4 of the CathPCI Registry institutional outcomes report, 80 sites

3a.5 Methods *(e.g., focus group, survey, QI project)***:**
1. Survey
2. Sites provided feedback through an excel template

3a
C☐ P☐ M☐ N☐

Comment [KP22]: 3a. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audience(s) for both public reporting (e.g., focus group, cognitive testing) and informing quality improvement (e.g., quality improvement initiatives). An important outcome that may not have an identified improvement strategy still can be useful for informing quality improvement by identifying the need for and stimulating new approaches to improvement.

3a.6 Results *(qualitative and/or quantitative results and conclusions)*:
1. 90.5% responded yes to the question "Will this measure provide important information to you?"
2. Sites provided feedback on the institutional outcomes report that was used to modify the report. Sites provided feedback on invalid data and aspects of the report that were unclear.

3b/3c. Relation to other NQF-endorsed measures

3b.1 NQF # and Title of similar or related measures:
#588: Stent drug-eluting clopidogrel, #465: Perioperative Anti-platelet Therapy for Patients undergoing Carotid Endarterectomy, #325: Discharged on Antiplatelet Therapy

(for NQF staff use) **Notes on similar/related** endorsed **or submitted measures:**

3b. Harmonization
If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population):
3b.2 Are the measure specifications harmonized? If not, why?
This measure is most similar to #588, "stent drug-eluting clopidogrel". This measure applies to all stents, and includes the P2Y12 inhibitor ticlopidine and prasugrel as well. These differences are supported by evidence-based guidelines.

3b
C☐ P☐ M☐ N☐ NA☐

3c. Distinctive or Additive Value
3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:
This measure provides additive value to existing NQF-endorsed measures because it would be the first NQF-endorsed measure for P2Y12 inhibitors prescribed at discharge following PCI (with stent) for use in a registry. This measure applies to a broader population than the endorsed "stent drug-eluting clopidogrel." The expanded numerator and denominator of this measure compared with the endorsed measure is supported by available evidence and guidelines.

5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:

3c
C☐ P☐ M☐ N☐ NA☐

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Usability*?

3

Steering Committee: Overall, to what extent was the criterion, *Usability*, **met?**
Rationale:

3
C☐ P☐ M☐ N☐

4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)

Eval Rating

4a. Data Generated as a Byproduct of Care Processes

4a.1-2 How are the data elements that are needed to compute measure scores generated?
Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)

4a
C☐ P☐ M☐ N☐

4b. Electronic Sources

4b.1 Are all the data elements available electronically? (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*)
Yes

4b.2 If not, specify the near-term path to achieve electronic capture by most providers.

4b
C☐ P☐ M☐ N☐

Comment [KP23]: 3b. The measure specifications are harmonized with other measures, and are applicable to multiple levels and settings.

Comment [k24]: 16 Measure harmonization refers to the standardization of specifications for similar measures on the same topic (e.g., *influenza immunization* of patients in hospitals or nursing homes), or related measures for the same target population (e.g., eye exam and HbA1c for *patients with diabetes*), or definitions applicable to many measures (e.g., age designation for children) so that they are uniform or compatible, unless differences are dictated by the evidence. The dimensions of harmonization can include numerator, denominator, exclusions, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.

Comment [KP25]: 3c. Review of existing endorsed measures and measure sets demonstrates that the measure provides a distinctive or additive value to existing NQF-endorsed measures (e.g., provides a more complete picture of quality for a particular condition or aspect of healthcare, is a more valid or efficient way to measure).

Comment [KP26]: 4a. For clinical measures, required data elements are routinely generated concurrent with and as a byproduct of care processes during care delivery. (e.g., BP recorded in the electronic record, not abstracted from the record later by other personnel; patient self-assessment tools, e.g., depression scale; lab values, meds, etc.)

Comment [KP27]: 4b. The required data elements are available in electronic sources. If the required data are not in existing electronic sources, a credible, near-term path to electronic collection by most providers is specified and clinical data elements are specified for transition to the electronic health record.

4c. Exclusions

4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?
No

4c.2 If yes, provide justification.

4c
C☐
P☐
M☐
N☐
NA☐

Comment [KP28]: 4c. Exclusions should not require additional data sources beyond what is required for scoring the measure (e.g., numerator and denominator) unless justified as supporting measure validity.

4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences

4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.
The NCDR program takes a number of steps to minimize any potential for inaccuracies or errors in data used to report on performance back to hospitals. The process begins with support provided to data abstractors, including webinars, meetings, resource guides on the website, and clinical quality consultants available via e-mail or toll free phone number, to ensure consistent data collection. The NCDR establishes a unified electronic platform for data capture and submission that includes a certification process of the technical data collection tool selected by the hospital (either a commercially available software vendor product, the NCDR's own web base data collection tool, or a hospital's customized electronic medical record system) that must occur prior to any data submissions. The certification process provides edit checks of data elements within data collection tool to ensure high quality data submission.

The NCDR data submission process includes a Data Quality Report (DQR) process that checks for validity in submissions based upon predetermined thresholds for element and composite completeness. The NCDR is putting in place a new strategy to systematically review the DQR results.

The NCDR on-site audit program has been developed to assess reliability of data abstraction. This annual process reviews key elements at a select number of patient reports at the select number of sites and provides feedback scores to the hospitals. Any elements not currently included in the on-site audit process and deemed critical to capture for this measure will be added upon NQF endorsement.

4d
C☐
P☐
M☐
N☐

Comment [KP29]: 4d. Susceptibility to inaccuracies, errors, or unintended consequences and the ability to audit the data items to detect such problems are identified.

4e. Data Collection Strategy/Implementation

4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:
Beta testing with a set of registry participants takes place with each new registry version to identify errors in the data collection tool. In addition, modifications are made to metrics based on feedback during a public comment period.

The Data Quality Report (DQR) program has been developed to ensure data are valid and complete. The DQR is a process for submitting data files to the NCDR®. Participants use their data collection tool software to create a submission file which is uploaded to the NCDR website. After uploading, the data in the file is automatically checked for errors and completeness. Passing the DQR ensures well-formed data and a statistically significant submission. Types of errors detected by the DQR include:
-Schema:Structure doesn't match NCDR requirements
-Dates: Inconsistent dates
-Selection: Missing or mismatched data; Can be a parent/child errors where a field requests more data.
-Outlier: Anomalies or exceptions; Data exceeds the possible limits. For example: 1,000mm length lesion.
-Counter: errors deal with Closure Methods, Lesions, and Intracoronary Devices. Each one has a counter, when more than one is used
-List: Missing data in the Medications or either Device lists.

Data is submitted on a quarterly basis. If a submission does not pass the DQR process, the entire submission is excluded from benchmarking. Hospitals may resubmit to pass the DQR process.

4e
C☐
P☐
M☐
N☐

Comment [KP30]: 4e. Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, etc.) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use).

4e.2 Costs to implement the measure (*costs of data collection, fees associated with proprietary measures*)**:** CathPCI Registry participants pay a fee of $3,800/year to enroll in the registry. Staff resources are needed for data collection and submission at the participating institution. Registry site managers/data collectors undergo (non-mandatory) training offered by the NCDR. **4e.3 Evidence for costs:** http://www.ncdr.com/WebNCDR/ncdrdocuments/B08352N%20CathPCI%20Registry%20Enrollment%20Packet%20Complete.pdf **4e.4 Business case documentation:**	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility*?	**4**
Steering Committee: Overall, to what extent was the criterion, *Feasibility*, **met?** **Rationale:**	**4** **C☐** **P☐** **M☐** **N☐**
RECOMMENDATION	
(for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.**	**Time-limited ☐**
Steering Committee: Do you recommend for endorsement? **Comments:**	**Y☐** **N☐** **A☐**
CONTACT INFORMATION	
Co.1 Measure Steward (Intellectual Property Owner) **Co.1 Organization** American College of Cardiology Foundation, 2400 N Street NW, Washington, District Of Columbia, 20037 **Co.2 Point of Contact** Kristyne, McGuinn, MHS, kmcguinn@acc.org, 202-375-6529-	
Measure Developer If different from Measure Steward **Co.3 Organization** American College of Cardiology Foundation, 2400 N Street NW, Washington, District Of Columbia, 20037 **Co.4 Point of Contact** Kristyne, McGuinn, MHS, kmcguinn@acc.org, 202-375-6529-	
Co.5 Submitter If different from Measure Steward POC Kristyne, McGuinn, MHS, kmcguinn@acc.org, 202-375-6529-, American College of Cardiology Foundation	
Co.6 Additional organizations that sponsored/participated in measure development Society for Cardiovascular Angiography and Interventions (SCAI)	
ADDITIONAL INFORMATION	
Workgroup/Expert Panel involved in measure development **Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.** The CathPCI Steering Committee developed the initial metrics used for quality improvement in the CathPCI outcomes reports. The measures were selected for appropriateness for public reporting by the NCDR public reporting workgroup. CathPCI Steering Committee: Douglas Weaver, MD, FACC	

Ronald Krone, MD, FACC
Gregory Dehmer, MD, FSCAI
John Messenger, MD, FACC
Lloyd Klein, MD, FACC
John Rumsfeld, MD, PhD, FACC
John Carroll, MD, FACC
Mauro Moscucci, MD, FACC
Jeffrey Popma, MD, FACC
Issam Moussa, MD, FSCAI
Kirk Garratt, MD, FSCAI
David Malenka, MD, FACC

Public Reporting Workgroup:
Fred Masoudi, MD, MSPH, FACC, FAHA, FACP
H. Vernon Anderson,MD, FACC, FSCAI
David Malenka, MD, FACC
Matt Roe, MD, FACC
Steve Hammill, MD, FHRS, FACC
Jeptha Curtis, MD, FACC
Paul Heidenreich, MD, MS, FACC
Brahmajee Nallamothu, MD, MPH, FACC
Mark Kremers, MD, FACC
Christopher White MD, FACC
Carl Tommaso, MD, FACC, FAHA, FSCAI
Sunil Rao, MD, FACC, FSCAI
Andrea Russo, MD, FACC, FHRS
Debabrata Mukherjee MD, FACC

Ad.2 If adapted, provide name of original measure: N/A
Ad.3-5 If adapted, provide original specifications URL or attachment

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.6 Year the measure was first released: 2005
Ad.7 Month and Year of most recent revision: 07, 2009
Ad.8 What is your frequency for review/update of this measure? Every 3-4 years or if guideline updates warrant more frequent update, or with new dataset version.
Ad.9 When is the next scheduled review/update for this measure? 06, 2011

Ad.11 -13 Additional Information web page URL or attachment: Attachment DTNPRD Final.pdf

Date of Submission (*MM/DD/YY*)**:** 10/28/2010

NCDR™ National Cardiovascular Data Registry

CathPCI Registry®

ENROLLMENT INSTRUCTIONS

Thank you for your interest in the NCDR® CathPCI Registry®. Enrolling is as easy as 1-2-3:

1. The first step in completing the enrollment process is for you to review the following documents:

- **Participant Contact Information Form:** This form provides the CathPCI Registry account management team with appropriate contact information for your hospital.
- **NCDR Master Agreement:** This 22-page agreement details the obligations of NCDR and the obligations of the hospital entity as they relate to general registry operations.
- **CathPCI Registry-Specific Addendum:** This 3-page document details the obligations of both parties that are unique to the CathPCI Registry.
- **An invoice for 2010 participation dues and implementation fee** based on your date of enrollment.

2. Next, fill out the contact information form, sign and date the master agreement and addendum, and include the completed documents with your check made payable to the *American College of Cardiology Foundation*. Annual participation dues are prorated as outlined in the chart below:

Date of Enrollment	Participation Dues	Implementation Fee	Total Due
January 1, 2010 – June 30, 2010	$3,685	$1,000	**$4,685**
July 1, 2010 – December 31, 2010	$1,845	$1,000	**$2,845**

3. Send your completed enrollment packet: 1) the Participant Contact Information form, 2) the NCDR Master Agreement, 3) the CathPCI Registry-Specific Addendum, 4) your invoice, and 5) your check for your participation dues and implementation fee to:

American College of Cardiology Foundation
Attn: 2009 NCDR CathPCI Registry Enrollment
P.O. Box 79231
Baltimore, MD 21279-0231

As soon as we receive and process your documents and check (please allow 10 business days for processing of your enrollment materials), we'll send you an email with your NCDR Participant ID Number and your User ID and Password for the CathPCI Registry User Website.

NCDR offers a Web-based data entry tool as a benefit of participation in the CathPCI Registry. We have also contracted with several commercial vendors that offer a wide range of certified software packages. We encourage you to explore all of your options for data collection by visiting **www.ncdr.com**. After enrollment, you'll be asked to select either the Web-based data entry tool or one of the vendor software packages.

If you have any questions about the enrollment process, please call a CathPCI Registry Support Specialist at **800-257-4737.**

On behalf of NCDR, we look forward to your participation in the CathPCI Registry.

Sincerely,

The NCDR CathPCI Registry Account Management Team

The CathPCI Registry is an initiative of the American College of Cardiology Foundation, with partnering support from the Society for Cardiovascular Angiography and Interventions.

B08352N-P

NCDR™ National Cardiovascular Data Registry

CathPCI Registry®

PARTICIPANT CONTACT INFORMATION

Please complete the information requested below and include this document when you return your enrollment materials. *Only completed forms with valid email addresses will be processed.*

NOTE: Health systems must complete one form for each hospital enrolling.

HOSPITAL (please print clearly and legibly)

Health System (if applicable)	
Hospital Name	
Address 1	
Address 2	
City/State/ZIP Code	

REGISTRY SITE MANAGER (please print clearly and legibly)

Contact (First Name, Last Name)	
Title	
Address 1	
Address 2	
City/State/ZIP Code	
Telephone	( )
Fax	( )
Email	@

CONTRACT MANAGER (please print clearly and legibly)

Contact (First Name, Last Name)	
Title	
Address 1	
Address 2	
City/State/ZIP Code	
Telephone	( )
Fax	( )
Email	@

CARDIOSOURCE® SETUP (please print clearly and legibly): Registry participation also includes free access to Cardiosource, our educational Website that includes over 1,000 clinical trials, all ACC evidence-based practice guidelines, study guides, and more.

Technical Contact (First Name, Last Name)	
Email	@
IP Address Range*	

IP addresses may be obtained from your Information Technology network staff. Please advise them we need the network source address block(s) for your NAT range or any proxy servers which provide your users with access to the internet. These are the IP range(s) from which we would see them as originating. For example, if you own the following 25.254..* network range but your users only originate from a smaller subnet range (ex. 25.254.5.*), please submit that subnet range. We are only interested in network addresses, not subnet masks (ex. 255.255.255.0). If you have multiple addresses, please separate by a semicolon (ex. 155.246.*.*; 129.35.2.*). For additional information, please contact technical support at csinst@acc.org.

2010 MASTER AGREEMENT

NCDR® AGREEMENT BY AND BETWEEN
THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION
AND

_____

THIS AGREEMENT is made this ____ day of _____, 20___ ("Effective Date"), between the American College of Cardiology Foundation ("ACCF"), a non-profit, tax–exempt District of Columbia corporation located at 2400 N Street NW, Washington, DC 20037 and _____ ("Participant"), located at _____ (city/state). ACCF and Participant shall be referred to herein collectively as the "Parties" and individually as a "Party."

WHEREAS, ACCF has developed the National Cardiovascular Data Registry Program ("NCDR") to collect and report on standardized, national, clinical cardiovascular data in connection with different cardiovascular procedures, in which Participant desires to participate;

WHEREAS, NCDR permits comparisons of Participant data with national or regional summary data to aid Participants in their data completeness and consistency programs and other efforts to improve patient care;

WHEREAS, NCDR now consists of five unique hospital-based registries: the CathPCI Registry®, the ICD Registry™, the CARE Registry®, and the ACTION Registry®–GWTG™, and the IMPACT Registry™, as well as one office-based registry, the PINNACLE Registry™; (individually a "Registry" or collectively as the "Registries");

WHEREAS, Participant desires to participate in NCDR in one or more of the Registries to improve the quality of cardiovascular care;

WHEREAS, the Parties understand that the provision by ACCF of benchmarking and data aggregation services to Participant qualifies ACCF as a "Business Associate" with respect to Participant pursuant to the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (45 C.F.R. Parts 160 and 164, as amended) ("HIPAA"); and

NOW, THEREFORE, in consideration of the mutual promises and Agreements set forth, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by ACCF and Participant:

IT IS AGREED:

1. Participation in NCDR. Participant hereby agrees to participate in NCDR, and ACCF hereby agrees to permit Participant to participate in one or more of the Registries as provided herein. For purposes of this Agreement, a Participant is defined as a single facility or practice located in a discrete geographic area that is enrolled in NCDR through a Participant Agreement, and is eligible to submit relevant cardiovascular data to one of the Registries.

a. Additional Registries. If NCDR elects to establish an additional Registry, Participant may elect whether to participate in it.

2. Participant Responsibilities.

a. Submission of Clinical Data. Participant agrees to furnish clinical data in a manner consistent with this Agreement, relevant to the Registries in which it is participating, directly to NCDR in quarterly installments for at least a twelve (12) month period as provided under this Agreement.

i. Participant agrees that its data may be rejected by ACCF if Participant data is determined by ACCF to fail the NCDR data evaluation and acceptance process.

ii. Participant agrees to submit quarterly data within the "call for data period" as published by the ACCF.

iii. Participant agrees that submitted data will conform to Paragraphs 2.b., 2.d., 2.e., 2.f., and 2.h. of this Agreement.

b. Use of ACCF Data Set and ACCF-Approved Software. Participant will submit a data record on each patient who receives medical care and who is eligible for inclusion in the Registries in which Participant is participating under this Agreement. Participant agrees to use the Registry-specific data elements, definitions, and transmission format approved by ACCF and published in the NCDR Core Data Element Documentation ("ACCF Data Set") provided to Participant, and as amended by ACCF from time to time. Data must be submitted using ACCF-approved software from either ACCF or a vendor otherwise contracting with ACCF to provide such software, in formats that meet required transmission specifications as set forth in Section 2.c., or otherwise communicated to the Participant by ACCF from time to time. Participant agrees that Participant is solely responsible for selecting a software vendor from those vendors approved by ACCF, and that ACCF approval does not constitute an endorsement or guarantee of the performance of the selected vendor or the selected vendor's product.

c. Manner of Communication. Participant shall provide data to ACCF for purposes of the NCDR by secure website at www.ncdr.com. In addition, Participant shall designate a valid e-mail address that ACCF shall utilize to communicate with the Participant; such e-mail address shall only be accessible by the Participant's Registry Site Manager. Participant hereby acknowledges that ACCF will use such e-mail address to communicate pertinent information regarding Registry-specific issues. Participant shall submit data to ACCF for Registries electronically, utilizing methods determined by the ACCF. All submissions of data shall be submitted to ACCF utilizing ACCF-approved encryption software. Furthermore, the Participant shall maintain an updated institutional profile including ensuring that ACCF has a

valid e-mail address for the Registry Site Manager at all times in the form identified by ACCF.

d. Corroboration of Patient Data. Participant will furnish to NCDR independent corroboration, in a form satisfactory to ACCF in its sole, reasonable discretion, that all eligible patients' records have been submitted, based upon case volume counts or similar data from Participant's admitting/registration, cath lab log, billing, and/or medical records information or other hospital-based information system.

e. Data Collection Staff. Participant's data collection shall be performed by staff trained through the ACCF training program including Registry-specific offerings from ACCF promptly after any such training program is made available by ACCF to Participant. Participant agrees that its data collection staff shall adhere to the standards published in the current NCDR Core Data Element Documentation provided to Participant, and as updated from time to time. The current ACCF training program, included in the annual fee, consists of webinars, self-directed study using resources on the NCDR website as well as individualized clinical support. ACCF also offers additional and optional training, available for an additional charge at ACCF workshops which Participant shall encourage its staff to attend.

f. Registry Site Manager. Participant will designate a Registry Site Manager who will serve as the primary point of contact for each Registry and will supervise the data collection, confirm the accuracy of the data, receive the confidential reports, and act as direct liaison with ACCF. ACCF recommends that the Registry Site Manager be an experienced clinical professional such as the Clinical Service Line Director, a senior-level Registered Nurse, or a similarly trained and qualified representative of the quality improvement department; and if ACCF determines that any Registry Site Manager is not sufficiently trained or credentialed in this manner, Participant will identify an alternate individual to serve in that capacity. Participant also agrees to notify ACCF within ten (10) working days of any change in the Registry Site Manager. The Participant's Medical Director or his/her designee, identified to ACCF in writing as such, must approve all data submissions.

g. Data Evaluation and Acceptance Process. Participant agrees that its submitted patient data may be audited for accuracy and completeness by or on behalf of ACCF. In addition, all submissions are required to meet the NCDR inclusion threshold as defined in the current NCDR release provided to Participant, and as updated by ACCF from time to time, in order for Participant's data to be included in the national averages. Participant understands and agrees that auditing may include an onsite review of patient medical records and additional supporting documentation. The onsite audit process will consist of an audit of randomly selected charts and an evaluation of the process for data collection. In the event that a Participant is selected for an audit, the initial audit will be at the expense of ACCF, and Participant agrees to cooperate in such audit through making available documentation and access to Participant's staff. Participant agrees that if an audit

process or the application of threshold criteria find the data do not conform to ACCF standards, as a condition of continued participation in NCDR, the Participant shall submit within forty-five (45) days of notice of the audit an action plan, in a form acceptable to ACCF, to correct such data issues, as well as, in the sole discretion of ACCF, submit to an onsite audit conducted by a third-party auditor chosen by ACCF at the Participant's sole expense. Furthermore, the non-conforming data submitted by the Participant will be withheld from the ACCF database for national reporting purposes until such data is brought up to standard and re-submitted to ACCF by the Participant. Moreover, during any such correction period, while Participant may receive information comparing its data to general data from a Registry, ACCF makes no representation or warranty concerning the reliability of any such comparison or the conclusions Participant may draw from it.

h. Voluntary Audit Process. If Participant voluntarily chooses to have its data audited, Participant will fund the full cost of the audit, the results of which shall be available to both Parties. Only ACCF-approved auditors may perform the audit process. If such voluntary audit reveals data do not conform to ACCF standards or this Agreement, the process described in Section 2.g. shall be enforced.

i. Identifiers. Participant agrees that unique patient identifiers and unique physician identifiers will be collected for each record submitted to the NCDR.

j. Data Confidentiality. Participant shall maintain appropriate procedures to safeguard data confidentiality in compliance with applicable law. Participant will be solely responsible for any and all of its acts or omissions regarding the privacy and security of the data it furnishes hereunder. Participant shall maintain appropriate liability insurance for its acts and omissions under this paragraph.

3. ACCF Responsibility.

a. Acceptance of Data. ACCF agrees to accept Participant's clinical data, subject to review by ACCF, except where the submitted data does not conform to this Agreement, including, without limitation, the data evaluation and acceptance process and standards established by NCDR, and as updated from time to time by ACCF. In such cases, ACCF reserves the right to either reject the data submission in its entirety, or to limit the use of such data, if it does not meet the required ACCF standards, both with respect to new data and as set forth in Section 2.g. Data may only be accepted if submitted using ACCF-approved software obtained from ACCF or a vendor approved by ACCF, under ACCF-approved formats and processes.

b. Reports. ACCF agrees to generate institutional reports for each Registry based on Participant's submitted data, and to distribute reports to Participants. Reports include aggregated demographic, general procedural information, and patient outcomes in a form made available by ACCF to Participants, and as updated by ACCF from time to time. Data Quality Reports will be distributed with each data submission within this Agreement and paid-through-relevant time period. Institution-specific and

national reports will be distributed both quarterly and annually within this Agreement and paid-through-relevant time period.

c. Use of ACCF Data Set. ACCF agrees to produce, disseminate, and periodically revise the data elements, definitions, and formats, and to certify software that allows Participants to directly transmit their patient data to NCDR.

d. Training. ACCF will provide documents and programs that serve as resources that guide Participant's data collection activities.

e. Data Accuracy. ACCF will analyze the Participant's submitted data records by means of electronic data checks, consistency checks, and range checks to review data accuracy and completeness and determine aggregate completion rates, and will return Data Quality Reports to Participant within thirty (30) days after submission. All reasonable efforts will be made by ACCF to communicate with Participant's Registry Site Manager to assist the Participant in providing the submitted data.

f. Data Assessment Audit. ACCF may, at its option, audit submitted patient data to review its accuracy and completeness. ACCF will notify Participant within forty-five (45) days of the completion of the audit process (completion and return of data from the auditor) of the results of the audit and any action that the Participant may need to take as a result of the audit, and may take any actions in response as provided in Section 2.g. of this Agreement.

g. Identifiers. ACCF will accept unique patient identifiers and unique physician identifiers for each record submitted to NCDR by Participant.

4. Privacy Laws; Security.

a. Compliance with Privacy Laws. The Parties agree to abide by all federal, state, and local laws pertaining to confidentiality and disclosure with regard to all information or records obtained and reviewed hereunder. ACCF acknowledges that it is a "Business Associate" as defined and referred to under HIPAA. Accordingly, ACCF shall take reasonable steps to comply with the requirements under HIPAA for Business Associates as set forth in Appendix A to this Agreement ("Business Associate Agreement"). ACCF will have all rights, as well as all responsibilities, set forth in Appendix A as if fully set forth herein.

b. Security. ACCF will take reasonable steps to maintain its security policies and procedures to protect Participant data as provided in Appendix A. If ACCF determines that a breach of security has occurred, ACCF will promptly notify Participant. ACCF will be responsible for its acts and omissions regarding the privacy and security of the data it maintains under this Agreement.

5. Use of Names and Logos.

   a. Use of ACCF Name. Without the express prior written consent of ACCF, Participant shall not make any announcements concerning the matters set forth in this Agreement, use the word or symbol ACCF, ACC, NCDR® or any trademarks or service marks of ACCF, ACC, and ACCF business partners, or make any reference to ACCF, ACC, and ACCF business partners in any advertising or promotional material, letterhead, symbol or logo, or other communication that is not strictly internal to participant, or in any other manner, including, without limitation, press releases or lists.

   b. Use of Participant's Logo/Trademarks. Without the express prior written consent of Participant, ACCF shall not use the logos, trademarks or service marks of Participant.

6. Data and Copyright Ownership.

   a. Individual Patient Data. The data for individual patients submitted by Participant shall be the exclusive property of Participant, subject to the rights, if any, of the Participant's patients in Individually Identifiable Health Information, and subject to the rights granted to ACCF in this Agreement and the Business Associate Agreement. Participant hereby agrees the return of that information is infeasible as it has been integrated into the Registries. Participant grants to ACCF a perpetual, enterprise-wide, royalty-free license, that is worldwide and in all forms and all media (including derivative works), to use the data of individual patients submitted by Participant in such manner that is consistent with this Agreement. To the extent ACCF develops de-identified or similar data that is not Individually Identifiable Health Information from the data submitted by Participant for individual patients, ACCF shall exclusively own such data, and any derivative works from it, as Intellectual Property Rights owned by ACCF.

   b. Intellectual Property; Aggregate Data. All Intellectual Property Rights and title to all proprietary information in and rights to any software, database, NCDR, Registries, any data submitted and accepted by ACCF for use in the NCDR program, aggregate data and the compilation of the same with any other data received in connection with the NCDR program, and any derivative works using the Registries, including, without limitation, any reports, calculations and models based thereon, and De-identified Data as described in Section 6.a., including, without limitation, all copyrights, patent rights, trademarks, trade secret rights, and any other rights and interest in any of the foregoing shall be and remain at all times for all purposes with ACCF. For purposes of this Agreement, "Intellectual Property Rights" means all, or any intermediate version or portion, of any formulas, processes, outlines, algorithms, ideas, inventions, know how, techniques, intangible, proprietary and industrial property rights and all intangible and derivative works thereof, including, without limitation, any and all now known or hereafter existing, in and to (i) trademarks, trade name, service marks, slogans, domain names, uniform resource locators or

logos; (ii) copyrights, moral rights, and other rights in works of authorship, including, but not limited to, compilations of data; (iii) patents and patent applications, patentable ideas, inventions and innovations; (iv) know-how and trade-secrets; and (v) registrations, applications, renewals, extensions, continuations, divisions or reissues of the foregoing. ACCF reserves the right to use De-identified Data and Protected Health Information ("PHI") in electronic or other format whether or not contained in a Limited Data Set as discussed more fully in Appendix A, including, without limitation, to support ongoing improvements and enhancements to NCDR. Once Participant data is accepted by ACCF into NCDR for analysis and reporting, this data becomes part of the NCDR aggregate data and it cannot be retracted from NCDR by Participant. Information to which ACCF has access or ownership under this Section 6 shall not be considered Confidential Information to be returned to Participant under Section 9.

c. Publication. If Participant desires to publish or otherwise distribute or use, in whole or in part, any aggregate data or reports provided by ACCF, or produced in connection with or derived from NCDR, with the exception of strictly internal use within the Participant as defined in Section 1, Participant must first obtain the prior express written consent of ACCF. To the extent Participant is permitted to publish aggregate data, such aggregate data and any related information published in connection with it must be reviewed and approved by ACCF prior to publication.

7. Participant Fees. Participant will pay ACCF an annual fee for each Registry to participate in that Registry. Payment of the annual fee includes quarterly submission of data, ACCF-supplied self-training documentation, and distribution of Data Quality Reports and Institution-specific Reports. From time to time, ACCF may develop other reports and products for an additional charge. Unless overnight delivery is requested by Participant, there will be no handling or shipping charges. The entire annual fee is non-refundable even if this Agreement is terminated prior to the end of the term.

8. Term, Enforcement and Termination. This Agreement shall be effective until December 31, 2010, then renew automatically for additional one (1) year terms unless the Participant provides ACCF with ninety (90) days' advance written notice of its desire to terminate the Agreement at the end of the then-current term. The Parties agree that this Agreement may be enforced or terminated with respect to any particular Registry, without initiating or impairing any Party's right to enforce any right with respect to any other Registry or this Agreement as a whole.

a. Termination for Breach. Either Party may terminate this Agreement upon the other Party's material breach of this Agreement by providing the non-breaching Party with thirty (30) days written notice of its intention to terminate for a material breach. The breaching Party shall have thirty (30) days from the date of such notice to cure the breach. If, after thirty (30) days of the date of such notification, the breach is not cured to the satisfaction of the non-breaching party, this Agreement will terminate automatically at the end of the foregoing thirty (30) day period. Notwithstanding the foregoing, the non-breaching party may determine, in its sole discretion, that the

breach cannot be reasonably cured within the foregoing thirty (30) day period and may extend the cure period by written notice to the breaching party.

b. Termination Without Cause. Either Party may terminate this Agreement without cause by providing the other with at least ninety (90) days written notice.

c. Termination for Failure to Meet Data Completeness and Consistency Requirements. ACCF reserves the right to immediately terminate this Agreement and Participant's participation in NCDR if it determines that any two (2) calendar quarters of Participant's data within a rolling twelve (12) calendar–month period are noncompliant with NCDR standards or otherwise unacceptable for inclusion in the NCDR national averages. ACCF may, in its sole discretion, provide the Participant with the opportunity to cure the inadequate data as stated in Section 2.g. without affecting the rights of ACCF to terminate this Agreement under this Section or otherwise.

d. Termination of Software Use. Upon termination of this Agreement, Participant agrees that it shall not use NCDR software or the NCDR dataset for collecting and reporting data, or any other purpose, without the express written consent of ACCF, except as necessary to wind down Participant's participation in a Registry or the NCDR as a whole. Furthermore, Participant agrees that ACCF may notify Participant's approved software vendor of the termination of this Agreement as to any Registry or in its entirety, and agrees that it will allow its approved software vendor under Section 2.b. to terminate any such software license to Participant without penalty to such vendor, and to prevent further use of the software, including its use for data entry by Participant into the NCDR dataset.

9. Confidentiality.

a. Confidentiality. For the purposes of this Agreement, "Confidential Information" means any software, material, data, or business, financial, operational, customer, vendor and other information disclosed by one Party to the other and not generally known by or disclosed to the public or known to the receiving Party solely by reason of the negotiation or performance of this Agreement, and shall include, without limitation, the terms of this Agreement. Each Party shall maintain all of the other Party's Confidential Information in strict confidence and will protect such information with the same degree of care that such Party exercises with its own Confidential Information, but in no event with less than a reasonable degree of care. Except as provided in this Agreement, a Party shall not use or disclose any Confidential Information of the other Party in any manner without the express prior written consent of such Party, with the exception that ACCF may share a Participant's identification number ("Participant ID") with that Participant's software vendor so long as such vendor is approved as provided in this Agreement. Access to and use of any Confidential Information shall be restricted to those employees and persons within a Party's organization with known discretion and with a need to use the information to perform such Party's

obligations under this Agreement. A Party's consultants, subcontractors, and business partners shall be included within the meaning of "persons within a Party's organization," provided that such consultants, subcontractors, and business partners have executed a non-disclosure or confidentiality agreement with provisions no less stringent than those applicable to such Party under this Agreement, and such Party shall make such signed agreements available to the other Party upon request. Notwithstanding anything herein to the contrary, Confidential Information shall not include information that is: (a) already known to or otherwise in the possession of a Party at the time of receipt from the other Party, and that was not known or received as the result of violation of any obligation of confidentiality; (b) publicly available or otherwise in the public domain prior to disclosure by a Party; (c) rightfully obtained by a Party from any third party having a right to disclose such information without restriction and without breach of any confidentiality obligation by such third party; (d) developed by a Party independent of any disclosure hereunder, as evidenced by detailed written records made in the normal course of Participant's business during the development process; or (e) disclosed pursuant to the order of a court or administrative body of competent jurisdiction or a government agency, provided that the Party receiving such order shall notify the other prior to such disclosure, and shall cooperate with the other Party in the event such Party elects to legally contest, request confidential treatment, or otherwise avoid such disclosure.

b. Return of Confidential Information. Except as otherwise provided herein, all of a Party's Confidential Information disclosed to the other Party, and all copies thereof, shall be and remain the property of the disclosing Party. All such Confidential Information, and any and all copies and reproductions thereof, shall, upon the expiration or termination of this Agreement for any reason, or within fifteen (15) days of written request by the disclosing Party, be promptly returned to it, or destroyed, at the disclosing Party's direction. In the event of such requested destruction, the Party receiving such request shall provide to the other Party written certification of compliance therewith within fifteen (15) days of such written request. Notwithstanding the provisions of this Section 9, any information governed by Section 6.a. or 6.b. or the provisions of the Business Associate Agreement shall be governed, respectively, by those Sections of this Agreement, as applicable.

10. Indemnification.

a. ACCF Indemnity. ACCF will indemnify, defend, and hold Participant harmless from any third-party claim, demand, cause of action, lawsuit, or proceeding brought against Participant based upon any gross negligence or willful misconduct on the part of ACCF, provided, however, that any such liability for any such indemnification shall be limited to and not exceed the amount of any fees paid by Participant in the year the liability arose. Such indemnification may include: (1) reasonable attorneys' fees and costs associated with defense of such claim; (2) damages and costs finally awarded; and (3) the cost of any settlement

entered into by ACCF. Such indemnification obligation is contingent on Participant: (i) notifying ACCF of any such claim within thirty (30) days of Participant's notice of such claim; (ii) providing ACCF with reasonable information, assistance, and cooperation in defending the lawsuit or proceeding (to the extent requested by ACCF); and (iii) giving ACCF full control and sole authority over the defense and settlement of such claim. ACCF will not enter into any settlement or compromise of any such claim without Participant's prior consent, which shall not be unreasonably withheld.

b. Participant's Indemnities. Participant will indemnify, defend, and hold ACCF and ACCF's employees, officers, directors, agents, contractors, and business partners (collectively as the "ACCF Indemnitees") harmless from any third-party claim, demand, cause of action lawsuit, or proceeding brought against one or more ACCF Indemnitees based upon: (1) any errors or inaccuracies contained in the data as delivered by Participant to ACCF; (2) any medical treatment, diagnosis or prescription rendered by Participant or its agents (including physicians and healthcare professionals); (3) Participant failing to have all rights in the data necessary to use NCDR and to disclose such information to ACCF; and (4) the use of Registry reports in connection with any quality assurance, peer review, or similar administrative or judicial proceeding; and (5) any claim that is based, in whole or in part, on a breach of any warranty, representation or covenant made by Participant under this Agreement, including, but not limited to, any third-party lawsuit or proceeding brought against ACCF or any of ACCF Indemnitees based upon a claim that any data submitted by Participant infringe any third-party rights. Participant's indemnification will include: (i) all attorneys' fees and costs associated with defense of such claim; (ii) all damages and costs finally awarded; and (iii) the full cost of any settlement entered into by Participant.

11. Limitation of Liability. The aggregate liability of ACCF Indemnitees under this Agreement for any and all claims and causes of action, including, without limitation, any action predicated on indemnification as set forth in Section 10.a. above, shall be limited to and not exceed the amount of any fees paid by Participant in the year the liability arose, regardless of whether ACCF has been advised of the possibility of such damages, or any remedy set forth herein fails of its essential purpose or otherwise. ACCF Indemnitees shall not be liable for any other damages or costs, including costs of procurement of substitutes, loss of profits, loss of activity data or other information, inability to access the services or software, interruption of business, or for any other special, consequential, or incidental damages, however caused, whether, without limitation, for breach of warranty, contract, tort, infringement, negligence, strict liability or otherwise. Participant acknowledges that the NCDR fees and business model reflect this allocation of risk. Participant agrees it will take no legal action against ACCF, ACCF subcontractors, ACCF business partners, software or other Participants.

12. Notices. All notices and demands of any kind or nature which either Party to this Agreement may be required or may desire to serve upon the other in connection with this Agreement shall be in writing, and may be served personally, by registered or certified United States

mail, or by overnight courier (e.g., Federal Express, DHL, or UPS) to the following addresses:

If to the Participant: _____
_____
_____
_____
_____
_____

With a copy to: _____
_____
_____
_____
_____
_____

If to ACCF: American College of Cardiology Foundation
2400 N Street NW
Washington, DC 20037
Attn: General Counsel

Service of such notice or demand so made shall be deemed complete on the day of actual delivery. Any Party hereto may, from time to time, by notice in writing served upon the other Party as aforesaid, designate a different mailing address or a different person to which all further notices or demands shall thereafter be addressed.

13 Headings. The headings of the various paragraphs hereof are intended solely for the convenience of reference and are not intended for any purpose whatsoever to explain, modify, or place any construction upon any of the provisions of this Agreement.

14 Assignment. Neither this Agreement nor either Parties' rights and obligations hereunder may be assigned to a third party without the prior written consent of the non-assigning Party; provided, however, that ACCF may assign this Agreement and its rights and obligations to a parent or an entity controlled by or under common control with ACCF, or a venture or entity in which ACCF has a majority ownership interest, or upon a change of control of ACCF, without the consent of the Participant.

15 Relationship of Parties. The relationship of the Parties to this Agreement is that of independent contractors and not that of master and servant, principal and agent, employer and employee, or partners or joint venturers.

16 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which taken together shall constitute one and the same instrument.

17 Waiver. A waiver by either Party to this Agreement of any of its items or conditions in any one instance shall not be deemed or construed to be a general waiver of such term or condition or a waiver of any subsequent breach.

18 Governing Law. This Agreement will be governed by and construed exclusively in accordance with the laws of the District of Columbia, without regard to any conflicts of law principles applied. The Parties agree that United Nations Convention on Contracts for the International Sale of Goods does not apply to this Agreement. Any suit or proceeding relating to this Agreement shall be brought only in the District of Columbia. Each Party consents to the exclusive personal jurisdiction and venue of the courts located in the District of Columbia.

19 Severability. All provisions of this Agreement are severable. If any provision or portion hereof is determined to be unenforceable by a court of competent jurisdiction, then the rest of the Agreement shall remain in full effect, provided that its general purposes remain reasonably capable of being effected.

20 Entire Agreement. This Agreement and the attached Appendices: (a) constitute the entire Agreement between the Parties with respect to the subject matter; (b) supersede and replace all prior agreements, oral or written, between the Parties relating to the subject matter; and (c) except as otherwise indicated, may not be modified or otherwise changed in any manner except by a written instrument executed by both Parties.

21 Survival. The following sections of this Agreement survive its termination as to any Registry or in its entirety, for any reason: Sections 4, 6, 8.d., 9, 10, 18 and the Business Associate Agreement.

22 No Third-Party Beneficiaries. The Parties agree there are no third-party beneficiaries, intended or otherwise, to this Agreement, including, without limitation, patients of any Participant.

IN WITNESS WHEREOF, each of the Parties hereto has caused this Agreement to be executed as of the Effective Date:

PARTICIPANT	**ACCF**
Signature: _____	Signature:_____
Name: _____	Name:_____
Title: _____	Title: _____
Date: _____	Date: _____

APPENDIX A
BUSINESS ASSOCIATE AGREEMENT

In the course of satisfying its contractual obligations to Participant pursuant to the Participant's engagement of ACCF through the Master Agreement, ACCF is performing a function or activity on behalf of Participant that constitutes ACCF a "Business Associate" of Participant within the meaning of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (45 C.F.R. Parts 160 and 164, as amended) ("HIPAA"). The purpose of this Appendix is to provide the Participant with satisfactory assurance that, as Participant's Business Associate, ACCF shall comply with the privacy and security requirements concerning Business Associates imposed by HIPAA and its implementing regulations as amended. Accordingly, ACCF and Participant agree as follows:

I. GENERAL PROVISIONS

Section 1. **Effect**. The terms and provisions of this Appendix shall supersede any other conflicting or inconsistent terms and provisions in the Master Agreement to which this Appendix is attached, including all exhibits or other attachments thereto and all documents incorporated therein by reference.

Section 2. **Amendment**. ACCF and Participant agree to amend this Appendix to the extent necessary to allow Participant or the ACCF to comply with the Standards for Privacy of Individually Identifiable Health Information (45 C.F.R. Parts 160 and 164, as amended) (hereinafter "Privacy Standards"), the Standards for Electronic Transactions (45 C.F.R. Parts 160 and 162), and the Security Standards (45 C.F.R. Parts 160, 162 and 164), all as modified or supplemented by the HITECH Act 42 U.S.C. §3000 et. seq., and implementing regulations and guidance (collectively, the "Standards") promulgated, or to be promulgated, by the Secretary or other authorized agencies. The ACCF agrees to develop amendments to this Appendix to incorporate any material provisions required by the Standards, and to distribute the same to Participant for adoption. Any amendment distributed by ACCF shall be deemed to be accepted by Participant unless ACCF is notified by Participant of any objections within thirty (30) days of its receipt of such amendment. Each Party is responsible for determining the adequacy of the amendment for its compliance with HIPAA.

Section 3. **Definitions**. Capitalized terms used herein without definition shall have the respective meanings assigned to such terms in the Agreement, or Part V of this Appendix.

II. OBLIGATIONS OF ACCF

Section 1. **Use and Disclosure of Protected Health Information**.

(a) ACCF may use and disclose Participant's PHI only as permitted under the Master Agreement and this Appendix A. ACCF shall use reasonable measures to ensure that its directors, officers, employees, subcontractors, business partners, and agents do not use or disclose Participant's PHI received from Participant in any manner that would constitute a violation of the Privacy Standards if done by Participant, except that ACCF may use and disclose Participant's PHI to ACCF's subcontractors and others: (i) for ACCF's proper management and administration if ACCF enters into a written agreement with a party to whom it releases Participant's PHI, and uses reasonable measures to require such party to hold such Participant's PHI confidentially, to further use or disclose it only as required by law or for the purpose for which it was disclosed, and to notify ACCF of any instances of which it becomes aware in which the confidentiality of the Participant's PHI is breached in a manner consistent with ACCF's obligations under this Appendix; (ii) to carry out ACCF's legal responsibilities hereunder, or as otherwise required by law or regulation; (iii) to provide Data Aggregation services relating to the health care operations of Participant and other hospitals or health systems with which ACCF contracts; (iv) to de-identify Participant's PHI it receives from Participant, if any, pursuant to 45 CFR § 164.514, which De-identified Data, and any derivative works from such data, shall be owned by ACCF, in all forms and media worldwide, and may be used by ACCF for any lawful purpose; or (v) to create and disclose a Limited Data Set, provided that the conditions set forth in Section 9 of this Appendix are satisfied.

(b) Effective not later than February 17, 2010, or such later date as may be specified pursuant to the HITECH Act, ACCF shall limit its uses and disclosures of Participant's PHI to uses and disclosures that comply with the Business Associate requirements of 45 CFR 164.504 (e) (2). The foregoing shall not be construed to limit the responsibility of the ACCF under the Master Agreement and this Appendix as in effect prior to February 17, 2010.

(c) Effective February 17, 2010, ACCF shall determine the Minimum Necessary Protected Health Information to be disclosed for uses, disclosures or requests of or for Participant's PHI, other that those that exempt from the Minimum Necessary requirement specified in 45 CFR 164.502(b)(2), in order to accomplish the intended purpose of the use, disclosure, or request, consistent with the terms of the Master Agreement. To the extent practicable and consistent with the terms of the Master Agreement, as determined by ACCF, the Minimum Necessary shall be the information contained in a Limited Data Set, as defined in 45 CFR 164.514(e)(2). At such time as the Secretary issues guidance on what constitutes the "Minimum Necessary" for purposes of the HIPAA Privacy Rule,

ACCF shall provide Participant with an amendment to this section which complies with the guidance, which shall replace this Section 1 (c) as of the effective date of the guidance.

(d) Effective not later than six (6) months after the date on which the Secretary publishes applicable final regulations, ACCF shall not, directly or indirectly, receive remuneration in exchange for Participant's PHI unless ACCF or the Participant has obtained to an authorization from the subject individual(s) which complies with all applicable requirements or unless an exception specified in Section 13405(d)(2) of the HITECH Act, 42 U.S.C. 17935(d)(2) or regulations published by the Secretary applies. ACCF shall not rely on any of the foregoing exceptions as to Participant's PHI without advance notice to all Participants which describes the types of circumstances and the applicable exceptions to be relied upon by the ACCF. Such notice may be made through notice published on the NCDR web site.

Section 2. **Safeguards Against Misuse of Information**. ACCF agrees that it shall use reasonable safeguards to prevent the use or disclosure of Participant's PHI except as otherwise provided for in this Appendix and the Master Agreement or as otherwise permitted by the Standards. Such safeguards shall include the implementation and maintenance of reasonable and appropriate administrative, technical, and physical safeguards to protect the security, integrity, confidentiality, and availability of Participant's PHI created, maintained, received, or transmitted by ACCF. ACCF shall further use reasonable measures to ensure that any agent to whom it provides Participant's PHI, including a subcontractor, agrees to implement reasonable and appropriate safeguards to protect such Participant's PHI. Effective not later than February 17, 2010, or such later date as may be specified pursuant to the HITECH Act, ACCF shall fulfill the foregoing responsibilities by being in compliance with the provisions of the HIPAA Standards for Privacy of Individually Identifiable Health Information set forth at 45 CFR 164.308 (Administrative Safeguards); 45 CFR 164.310 (Physical Safeguards); 45 CFR 164, 312 (Technical Safeguards) and 45 CFR 164.316 (Policies and Procedures and Documentation Requirements) (collectively, the "Security Requirements") in the same manner as the Security Requirements apply to a Covered Entity under HIPAA. ACCF shall also comply with additional or modified requirements set forth in any Annual Guidance as to the Security Requirements published by the Secretary and with the additional requirements of the HITECH Act that relate to security of Participant's PHI.

Section 3. **Reporting of Disclosures of Protected Health Information or Security Incidents**.

(a) ACCF shall maintain systems to monitor and detect a Breach of Unsecured Protected Health Information accessed, maintained, retained, modified, stored, destroyed or otherwise held or used in Unsecured form by ACCF, whether the Unsecured Protected Health Information is in paper or electronic form. ACCF shall provide to notice of a Breach involving Participant's PHI within five (_5___) business days of the first day the Breach is known, or reasonably should have been known, to the ACCF, including for this purpose any employee, officer, or other agent of the ACCF (other than the individual committing the Breach). The notice shall include the identification of each individual whose Unsecured Protected Health Information was, or is reasonably believed to have been, subject to the Breach and the circumstances of the Breach, as both are known to ACCF at that time. The notice shall be given via email to Participants Privacy Officer, as stated by Participant on the ncdr website. The Parties agree that notice in accordance with the foregoing satisfies the notice requirements of this Section 5. Following the notice, ACCF shall conduct such further investigation and analysis as is reasonably required, and shall promptly advise Participant of additional information pertinent to the Breach which ACCF obtains. ACCF shall cooperate with Participant to support the provision of required notices in a timely manner, including the determination of whether the use, access, or disclosure is one that "poses a significant risk of financial, reputational, or other harm to the individual", thereby requiring notice. Participant is responsible for the provision of notice in a timely manner, provided that Participant shall consult with ACCF in good faith regarding the details of the notice.

(b) ACCF shall also, promptly on becoming aware of it, report any Security Incident involving Participant's PHI to Participant, unless the Security Incident was the subject of a notice under Section 3 (a) .

Section 4. **Agreements with Third Parties**. ACCF shall obtain and maintain an agreement with each of the ACCF subcontractors or agents that has or shall have access to Participant's PHI, which is received from, or created or received by ACCF on behalf of Participant, pursuant to which agreement such subcontractor or agent agrees to be bound by restrictions, terms and conditions that are consistent with those applicable to ACCF pursuant to this Appendix and the Agreement with respect to such Participant's PHI, provided however that this Section shall not apply to disclosures by ACCF of a Limited Data Set, as such disclosures shall be governed by Section 9 of this Appendix.

Section 5. **Access to Information**. Within twenty (20) days of a request by Participant for access to Participant's PHI about an individual contained in a Designated Record Set so that it may respond to said individual's request for such information, ACCF shall

make available to Participant such Participant's PHI provided that such Participant's PHI constitutes a Designated Record Set, such determination to be made by ACCF. In the event any individual requests access to Participant's PHI directly from ACCF, ACCF shall within twenty (20) days forward such request to Participant. Any denials of access to the Participant's PHI requested shall be the responsibility of Participant.

Section 6. **Availability of Protected Health Information for Amendment**. Within twenty (20) days of receipt of a request from Participant for the amendment of an individual's Participant's PHI, or a record regarding an individual maintained by ACCF in a Designated Record Set, ACCF shall provide such information to Participant for amendment, and incorporate any such amendments in the Participant's PHI as required by 45 C.F.R. Part 164.526.

Section 7. **Accounting of Disclosures**.
(a) Within twenty (20) days of notice by Participant to ACCF that it has received a request from a patient for an accounting of disclosures of Participant's PHI, other than related to the treatment of the patient, the processing of payments related to such treatment, or the operation of Participant or its business associate, and not relating to disclosures made earlier than the later of six (6) years prior to the date on which the accounting was requested or April 14, 2003, the effective date of the Privacy Standards, ACCF shall make available to Participant such information as is in ACCF possession and that is required for Participant to make the accounting required by 45 C.F.R. Part 164.528. In the event the request for an accounting is delivered directly to ACCF, ACCF shall, within twenty (20) days, forward such request to Participant. ACCF hereby agrees to implement an appropriate record-keeping process to enable it to comply with the requirements of this Section.

(b) In addition, Participant shall advise ACCF in writing if Participant uses or maintains an Electronic Health Record(s) ("EHR") through which disclosures of Participant's PHI are made and of the effective date upon which the requirement to provide an Accounting for EHR disclosures for purposes of Treatment, Payment and Health Care Operations ("TPO Accounting") is effective as to Participant. Such notice shall be provided to the ACCF in writing at least thirty days (30) in advance of the date the requirements to provide a TPO Accounting are applicable to Participant ("TPO Notice Period"). ACCF shall capture and store information required for a TPO Accounting for EHR disclosures of Participant's PHI through or by ACCF for a minimum of a rolling three (3) year period beginning with the later of the date specified in the Participant's notice or the end of the TPO Notice Period, in accordance with the applicable regulations published by the Secretary. From and after the effective date specified in the Participant's notice, ACCF shall, as instructed by the Participant, either provide the TPO Accounting directly to the

individual making the request or provide the information required for the TPO Accounting to the Participant. In either case, the information required for the TPO Accounting shall be available to the individual or to the Participant, as appropriate, within twenty (20) days of ACCF's receipt of a request. To the extent not expressly prohibited by the HIPAA, the ACCF reserves the right to make a reasonable charge to Participant for each TPO Accounting provided to Participant or to an individual at Participant's request.

Section 8. **Availability of Books and Records**. ACCF hereby agrees to make its internal practices, books, and records relating to the use and disclosure of Participant's PHI received from, or created or received by ACCF on behalf of, Participant available to the Secretary for purposes of determining Participant's compliance with the Privacy Standards, as requested in writing by Participant.

Section 9. **Data Use Agreement**.

Section 9.1. **Activities**. The Parties agree that ACCF may use and disclose a Limited Data Set for purposes of cardiovascular research initiated by ACCF, or as otherwise permitted by the Privacy Standards or Required by Law. Such Limited Data Sets need not be for the use of the Participant but ACCF shall endeavor to make any resulting research studies, articles or similar results generally be made available to Participant through posting on the ACCF website or through publication. ACCF shall use reasonable measures to ensure that its directors, officers, employees, contractors, and agents do not use or disclose a Limited Data Set in any manner that would constitute a violation of the Privacy Standards if used or disclosed by Participant. ACCF agrees not to use a Limited Data Set in such a way as to identify any individual, and further agrees not to contact any individual. The activities referred to in Section 9.1. of this Appendix shall collectively be referred to as the "Activities."

Section 9.2. **Limited Data Set**. Participant agrees that ACCF may derive directly or through a subcontractor who is bound by terms and conditions consistent with ACCF's obligations under this Appendix a Limited Data Set from Participant's PHI otherwise provided to ACCF pursuant to the Master Agreement and use that Limited Data Set including in combination with other data in the performance of the Activities, provided, however, that no Limited Data Set created by ACCF shall include any direct identifiers set forth at 45 C.F.R. Part 164.514(e)(2).

Section 9.3. **Safeguards Against Misuse of Information**. ACCF shall use reasonable safeguards to prevent the use or disclosure of a Limited Data Set other than as permitted under this Agreement.

Section 9.4. **Reporting of Wrongful Disclosures**. ACCF shall, within twenty (20) days of becoming aware of any use or disclosure of a Limited Data Set in violation of the Agreement by ACCF, its officers, directors, employees, contractors, or agents, or by a third party to which ACCF disclosed a Limited Data Set, report any such disclosure to Participant.

Section 9.5. **Agreements with Third Parties**. ACCF shall obtain and maintain an agreement with each third party that has or will have access to a Limited Data Set, which satisfies the requirements for a Data Use Agreement, as set forth in 45 C.F.R. Part 164.514(e) (4), with respect to the Limited Data Set.

III. OBLIGATIONS OF PARTICIPANT

Section 1. Participant shall be responsible for assuring Participant's compliance with the HIPAA Standards.

Section 2. Participant shall provide ACCF with at least thirty (30) days advance written notice of any restrictions on uses and disclosures of Participant's PHI that it agrees to, pursuant to 45 C.F.R. Part 164.522, which will affect the uses and disclosures of Participant's PHI, which ACCF is permitted to make pursuant to the Master Agreement, including this Appendix A.

III. TERMINATION OF AGREEMENT

Section 1. **Termination Upon Breach of Provisions Applicable to Protected Health Information or Participant's Obligations**. Any other provision of this Appendix or the Master Agreement notwithstanding, the Master Agreement and this Appendix may be terminated by the Participant upon thirty (30) days written notice to ACCF in the event that ACCF breaches any provision contained in this Appendix, which notice shall describe the breach in reasonable detail. If such breach is not cured within such thirty (30) day period; provided, however, that in the event that termination of this Agreement is not feasible, in Participant's sole discretion, ACCF hereby acknowledges that Participant shall have the right to report the breach to the Secretary, notwithstanding any other provision of this Agreement to the contrary. Effective February 17, 2010, in the event that ACCF becomes aware of a pattern of activity or a practice of the Participant that constitutes a material violation of the obligations of Participant under its this Appendix, ACCF shall provide Participant with written notice describing the material violation in reasonable detail and a period of not less than thirty (30) days after receipt of such notice to cure the material violation. If such breach is not cured within such thirty

(30) day period, ACCF may terminate the Master Agreement and this Appendix on notice to Participant provided, however, that in the event that termination of the Master Agreement and this Appendix is not feasible, in ACCF's sole judgment, Participant hereby acknowledges that ACCF shall have the right to report the breach to the Secretary, notwithstanding any other provision of this Agreement to the contrary.

Section 2. **Return or Destruction of Protected Health Information Upon Termination**. Participant and ACCF have determined that return or destruction of Participant's PHI is not feasible upon termination of the Agreement. Therefore, ACCF shall have the applicable rights and shall comply with the applicable requirements of this Appendix for so long as Participant's PHI is held by ACCF. In the event that ACCF determines that it shall no longer maintain such Participant's PHI, it shall either return such Participant's PHI to Participant or destroy it (with certification of such destruction) at the sole option of ACCF. The terms and provisions of this Appendix shall survive termination of the Agreement, and such Participant's PHI shall be used or disclosed solely for such purpose or purposes which prevented the return or destruction of such Participant's PHI, and shall be maintained as confidential. Aggregate data, De-identified Data shall not be subject to this obligation. Participant's PHI contained in a Limited Data Set shall continue to be governed by the Data Use Agreement provisions of Section 9 of this Appendix.

V. DEFINITIONS FOR USE IN THIS APPENDIX

"Data Aggregation" shall mean, with respect to Participant's PHI created or received by ACCF in its capacity as the Business Associate of Participant, the combining of such Participant's PHI by ACCF with the Participant's PHI received by ACCF in its capacity as a Business Associate of another participant, to permit data analyses that relate to the health care operations of the respective participants.

"De-identified Data" shall have the meaning set forth in 45 C.F.R. Part 164.514 regarding de-identification of Participant's PHI.

"Designated Record Set" shall have the meaning set forth in 45 C.F.R. Part 164.501.

"Electronic Media" shall mean the mode of electronic transmissions. It includes the Internet, extranet (using Internet technology to link a business with information only accessible to collaborating parties), leased lines, dial-up lines, private networks, and those transmissions that are physically moved from one location to another using magnetic tape, disk, or compact disk media.

"Electronic Protected Health Information" or "EParticipant's PHI" shall have the same meaning as the term "electronic protected health information" at 45 C.F.R. 160.103.

"Health Care Operations" shall have the meaning set forth in 45 C.F.R. Part 164.501.

"HITECH Act" shall mean the provisions of Division A, Title XIII of the American Recovery and Reinvestment Act of 2009 ("ARRA"), known as The Health Information Technology for Economic and Clinical Health, Act 42 U.S.C. §3000 et. seq., and implementing regulations and guidance including all implementing regulations and other official guidance, set forth.

"Individually Identifiable Health Information" shall mean information that is a subset of health information Participant's PHI information collected from an individual, and:

(i) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(ii) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and (a) identifies the individual, or (b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

"Limited Data Set" shall have the meaning ascribed to it in 45 C.F.R. Part 164.514 (e) (1).

"Master Agreement" shall mean the NCDR Master Agreement between the Parties including any general policies, supplements or notices posted on the ncdr website (www.ncdr.com).

"Participant's PHI" shall mean the Protected Health Information of the Participant to which the Master Agreement and this Appendix applies.

"Privacy Standards" shall mean the Standard for Privacy of Individually Identifiable Health Information, 45 C.F.R. Parts 160 and 164.

"PHI", "Protected Health Information" or "Participant's PHI" shall mean Individually Identifiable Health Information that is: (i) transmitted by electronic media; (ii) maintained in any medium constituting Electronic Media; or (iii) transmitted or maintained in any other form or medium or Activity Data as that term is used in the

Agreement. Under no circumstances shall aggregate data or De-identified Data constitute "Protected Health Information" or "Participant's PHI". "Protected Health Information" or "Participant's PHI" shall not include: (i) education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. §1232g; and (ii) records described in 20 U.S.C.§1232g(a)(4)(B)(iv).

"Research" shall have the meaning set forth in 45 C.F.R. Part 164.501.

"Secretary" shall mean the Secretary of the Department of Health and Human Services or such other federal agency as is authorized to publish regulations or guidance pursuant to the HITECH Act.

"**Security Incident"** shall mean the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information, or interference with systems operations in an information system.

"Security Standards" shall mean the Health Insurance Reform Security Standards at 45 C.F.R. parts 160, 162, and 164.

All other defined terms in this Business Associate Agreement have the meaning assigned in the HITECH Act, unless otherwise defined in the HIPAA Privacy Rule or the HIPAA Security Rule.

CathPCI Registry® Addendum

ADDENDUM OF AGREEMENT BETWEEN
NCDR® PARTICIPANT AND
THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION

THIS ADDENDUM ("Addendum") is made this _____ day of _____ 20___ ("Effective Date"), between the American College of Cardiology Foundation ("ACCF"), a non-profit, tax-exempt organization with office located in Washington, DC, and _____ ("Participant") (collectively "Parties"). This Addendum adds certain terms, including participation in an additional ACCF Registry, to the Master Agreement relating to Participant's participation in the American College of Cardiology Foundation National Cardiovascular Data Registry ("NCDR®") dated the ___ of _____, 20___ (Master Agreement");

RECITALS:

WHEREAS, in accordance with Section 1.a. of the Master Agreement, the Parties wish to add an additional Registry to the Master Agreement and to document Participant's participation in the additional Registry on the terms and conditions of the Master Agreement, except to the extent additional or modified terms and conditions are specifically added by this Addendum.

WHEREAS, The Parties acknowledge that the NCDR® consists of four unique hospital based registries: the CathPCI Registry®, the ICD Registry™, the IMPACT Registry, the CARE Registry®, and the ACTION Registry®- GWTG™ as well as one office based registry, the PINNACLE Registry™;

WHEREAS, the additional Registry to which the Parties desire to extend the Master Agreement to is the CathPCI Registry® ("CathPCI Registry").

NOW, THEREFORE, in consideration of the mutual promises and agreements hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by ACCF and Participant,

IT IS AGREED:

1. The Parties agree that all of the Recitals are true and correct and are hereby incorporated by reference into this Agreement. All defined terms in the Master Agreement have the same meaning in this Addendum unless otherwise specifically stated.

2. The Parties recognize that all obligations detailed in the existing Agreement apply to participation in the CathPCI Registry.

CathPCI Registry® Addendum

3. The ACCF has developed a web-based data collection tool ("Tool") for submission of Participant's Clinical Data in the CathPCI Registry and this Tool, meets the requirements of ACCF approved software as outlined in paragraph 2b of the existing Agreement. Participant acknowledges that in order for Participant to elect use of tool Participant must indicate use of the Tool on the site profile.

4. Participant recognizes that use of the Tool will require Internet Explorer 6.0 or higher.

5. The ACCF has developed a training mechanism detailing the functionality of the Tool. The training mechanism is specifically the intellectual property of the ACCF under Section 7 b. of the Master Agreement. It is the responsibility of the Participant to review the provided training materials and use the Tool as detailed in the materials. The ACCF reserves the right to amend or update the training materials periodically. The ACCF will notify the Participant of amendment of the training material and will make the material available to the Participant.

6. The ACCF will provide support via telephone and e-mail during normal business hours Monday-Friday 9:00 am -5:00 pm eastern time. Support will not be offered on the weekend or federal holidays. The ACCF will provide technical support for the utilization of Tool only. It is the responsibility of the Participant to handle any issue related to hardware requirements required to utilize the Tool.

7. The ACCF shall use reasonable efforts to promptly resolve any failure of the Tool to perform which materially impairs the Participant's use of the Tool or any malfunction or defect of the Tool, including through updates or corrections.

8. The ACCF shall deliver corrections to the Tool in the form of updated versions or revisions to the Tool.

9. The Parties agree that all Electronically Protected Health Information submitted via the Tool to ACCF is covered and protected under Appendix A of the Master Agreement.

10. All other terms of the Master Agreement shall remain in force and unchanged.

WITNESS WHEREOF, each of the parties hereto has caused this Addendum to be executed by its duly authorized agents

PARTICIPANT	**ACCF**
Signature: _____	Signature: _____
Title: _____	Title: _____
Date: _____	Date: _____

NCDR™ National Cardiovascular Data Registry

CathPCI Registry®

INVOICE

Please choose one:	Description	CathPCI Registry® Participation Dues	CathPCI Registry Implementation Fee	Invoice Amount
	We are enrolling in the CathPCI Registry before June 30, 2010	$3,685	$1,000	**$4,685**
	We are enrolling in the CathPCI Registry after June 30, 2010	$1,845	$1,000	**$2,845**

Amount Enclosed $_____

Please make your check payable to the *American College of Cardiology Foundation*

Your Name *(please print clearly)* _____

Title _____

Department _____

Facility Name _____

Address _____

City _____ State _____ ZIP _____

INSTRUCTIONS

Please review, complete, and sign the following CathPCI Registry® enrollment materials:

- Participant Contact Information Form
- CathPCI Registry-Specific Addendum
- This invoice

Mail the three completed forms with your check to:

American College of Cardiology Foundation
Attn: 2009 NCDR CathPCI Registry Enrollment
P.O. Box 79231
Baltimore, MD 21279-0231

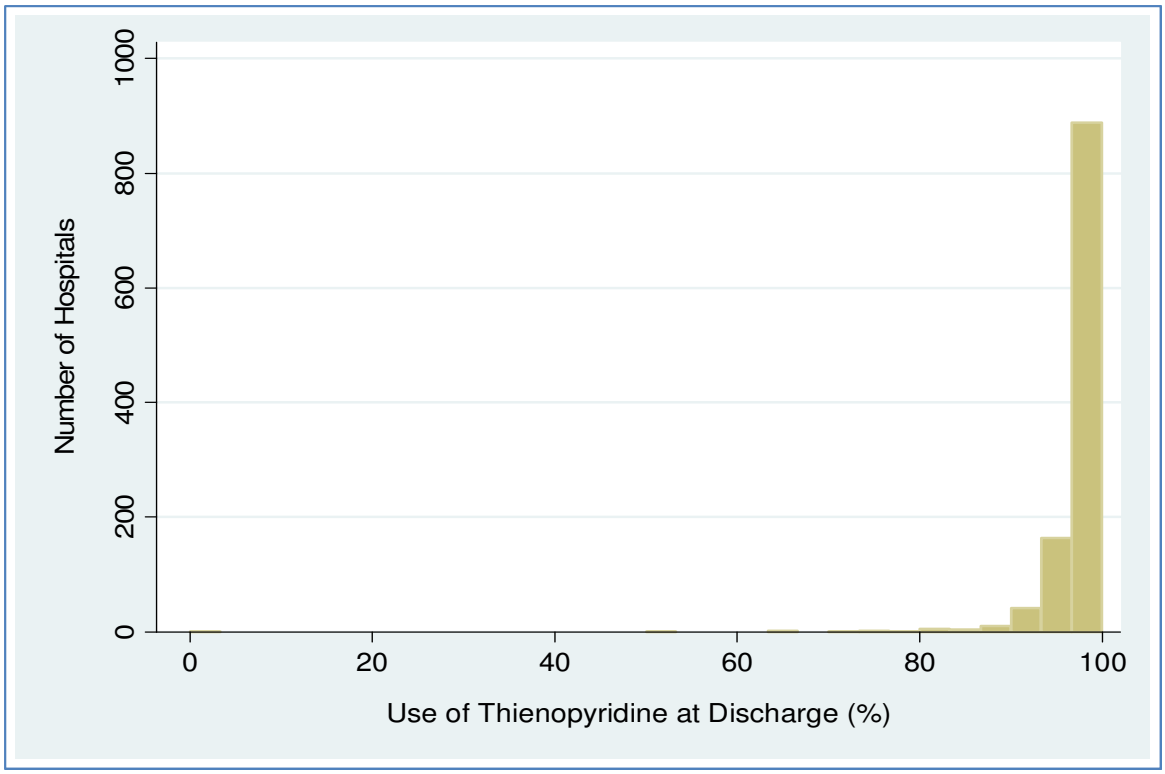
P2Y12 Inhibitor* Prescribed at Discharge- NCDR CathPCI® Registry Data, July 2009-June 2010

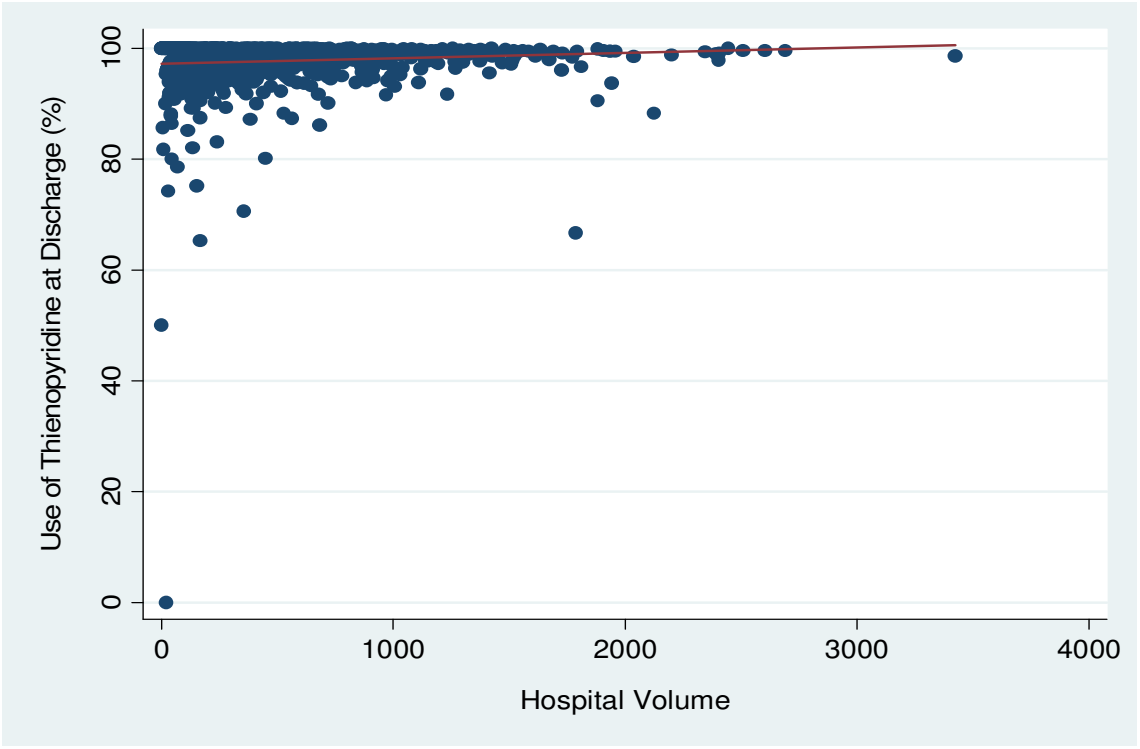
Exclusions	Hospital Stays		Patients		Facilities	
	#	%	#	%	#	%
Initial Sample	**1282945**	**100**	**1201850**	**100**	**1168**	**100**
Discharges not between July 2009 and Jane 2(	0	0.00	0	0.00	0	0.00
Remainging	**1282945**	**100.00**	**1201850**	**100.00**	**1168**	**100.00**
Without PCI with a stent implanted during the	748320	58.33	702978	58.49	46	3.94
Remainging	**534625**	**41.67**	**498872**	**41.51**	**1122**	**96.06**
Discharge Status: deceased	6280	1.17	6096	1.22	0	0.00
Remainging	**528345**	**98.83**	**492776**	**98.78**	**1122**	**100.00**
Discharge Location: Other acute care hospital	3022	0.57	2905	0.59	1	0.09
Remainging	**525323**	**99.43**	**489871**	**99.41**	**1121**	**99.91**
Discharge Location: Hospice	661	0.13	633	0.13	0	0.00
Remainging	**524662**	**99.87**	**489238**	**99.87**	**1121**	**100.00**
Discharge Location: Left against medical advi	1054	0.20	950	0.19	0	0.00
Remainging	**523608**	**99.80**	**488288**	**99.81**	**1121**	**100.00**
P2Y12 Inhibitor at discharge*: contraindicate	1991	0.38	1780	0.36	0	0.00
Study Sample	**521617**	**99.62**	**486508**	**99.64**	**1121**	**100.00**
Thienopyridine** at discharge	511310	98.02	477245	98.10	1120	99.91
Admissions with MI	**165385**	**31.71**	**163556**	**33.62**	**1116**	**99.55**
P2Y12 Inhibitor** at discharge	162105	98.02	160349	98.04	1115	99.91
Amdissions without MI	**356232**	**68.29**	**334709**	**68.80**	**1103**	**98.39**
P2Y12 Inhibitor** at discharge	349205	98.03	328327	98.09	1101	99.82

* Deifned all of the following: Clopidogrel at discharge -- unknown, contraindicated, or blinded; Ticlopidine at discharge -- unknown, contraindicated, or blinded; and Prasugrel at discharge -- unknown, contraindicated, or blinded.
** Deifned either of the following: Clopidogrel at discharge -- Yes; Ticlopidine at discharge -- Yes; or Prasugrel at discharge

Distribution of P2Y12 Inhibitor Prescription at Discharge

Description	**Volume**	**Rate**
N	1121	1121
Mean	465.31	0.9765
Std Deviation	426.42	0.0457
100% Max	3422	1.0000
99%	2036	1.0000
95%	1274	1.0000
90%	970	1.0000
75% Q3	629	0.9953
50% Median	361	0.9873
25% Q1	168	0.9721
10%	70	0.9464
5%	36	0.9268
1%	11	0.8195
0% Min	1	0.0000

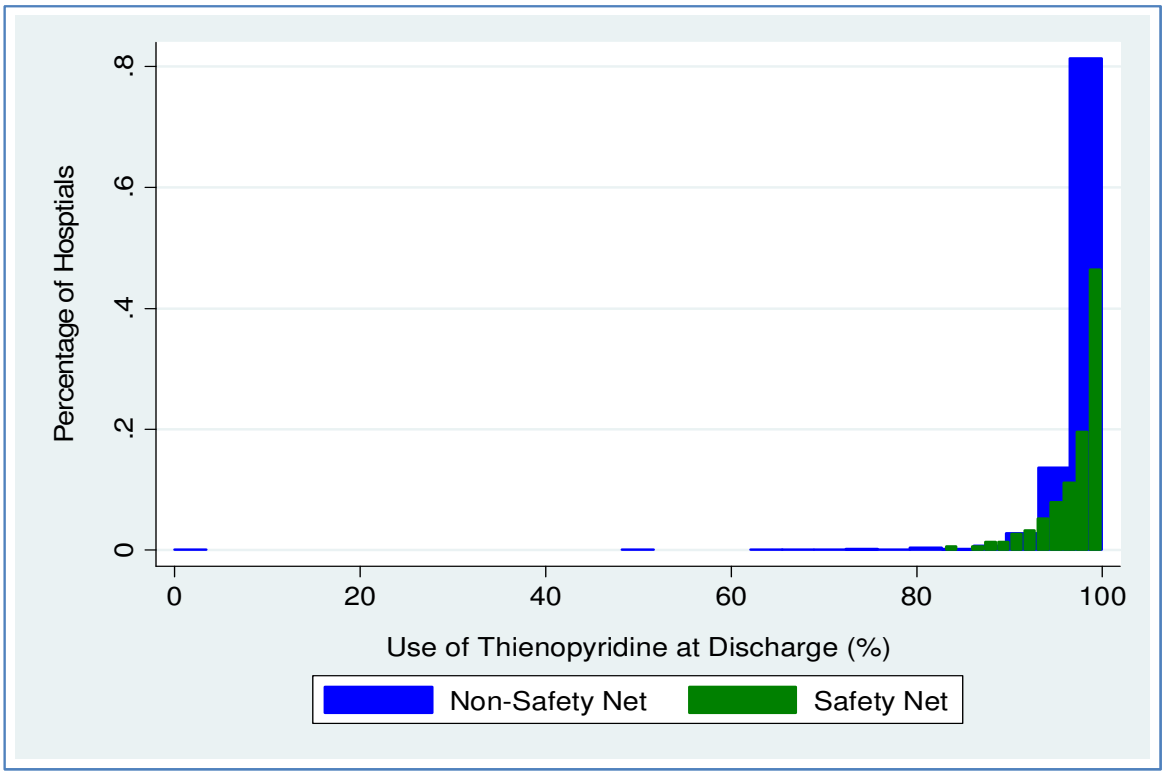

Number of Hospitals
0
200
400
600
800
1000
0
20
40
60
80
100
Use of Thienopyridine at Discharge (%)

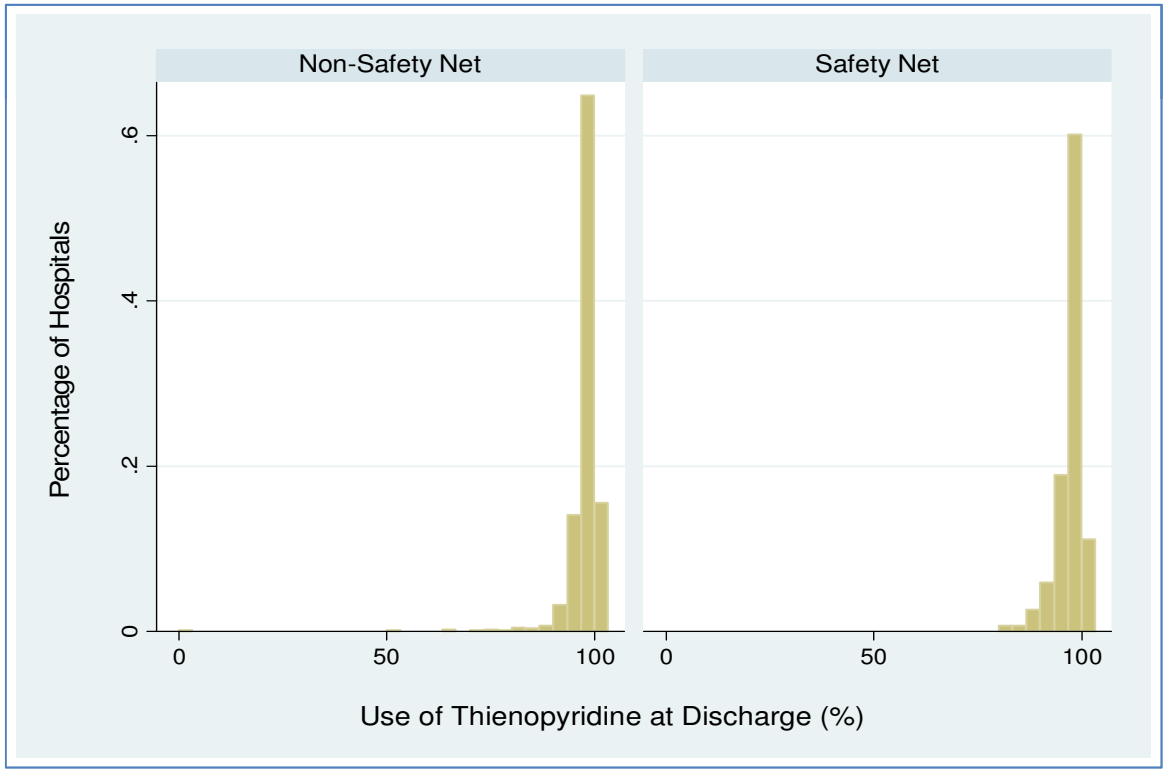

Use of Thienopyridine at Discharge (%)
0
20
40
60
80
100
0
1000
2000
3000
4000
Hospital Volume

Distribution of P2Y12 Inhibitor Prescription at Discharge Stratified by Safety Net Status

Description	Safety Net Status*			
	No		Yes	
	Volume	Rate	Volume	Rate
N	931	931	153	153
Mean	477.97	0.9770	417.58	0.9726
Std Deviation	437.32	0.0483	354.75	0.0308
100% Max	3422	1.0000	1943	1.0000
99%	2200	1.0000	1882	1.0000
95%	1324	1.0000	1111	1.0000
90%	993	1.0000	888	1.0000
75% Q3	639	0.9955	573	0.9944
50% Median	368	0.9875	322	0.9834
25% Q1	172	0.9738	167	0.9631
10%	70	0.9492	84	0.9367
5%	36	0.9303	37	0.9054
1%	11	0.8009	16	0.8607
0% Min	1	0.0000	4	0.8306

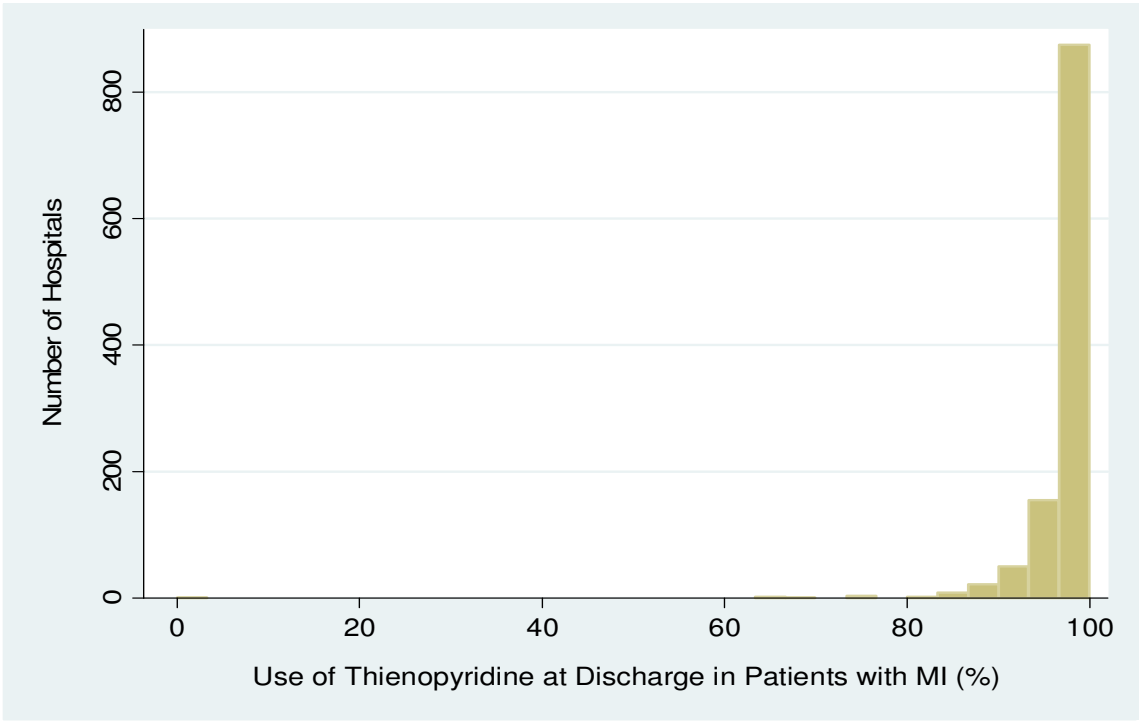
* Defined as government hospitals or non-government hosptials with high medicaid caseload using AHA 2008 Data.

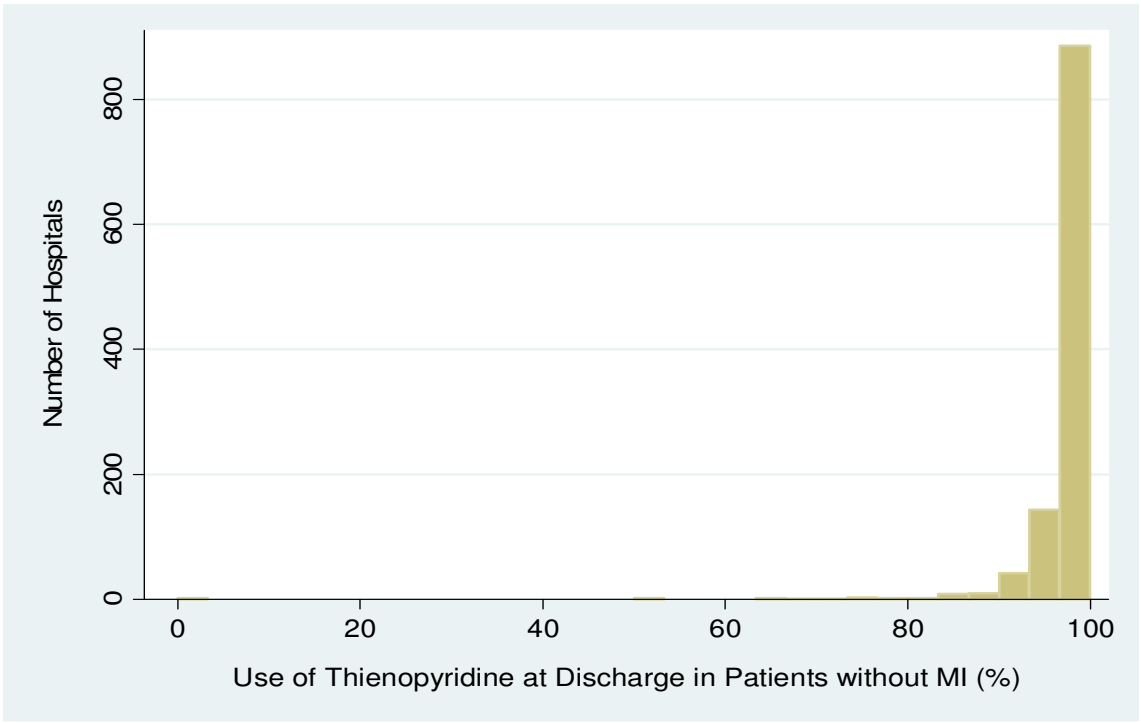

Percentage of Hospitals
0
.2
.4
.6
.8
0
20
40
60
80
100
Use of Thienopyridine at Discharge (%)
Non-Safety Net
Safety Net

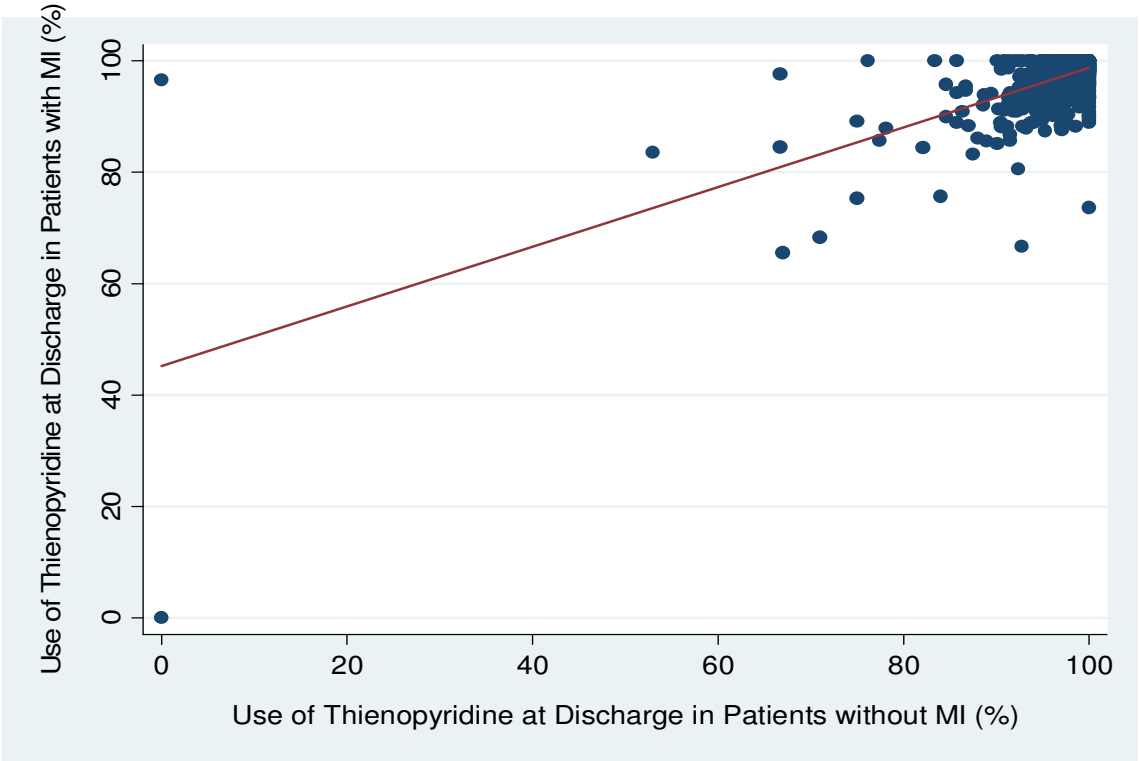

Non-Safety Net
Safety Net
Percentage of Hospitals
0
.2
.4
.6
0
50
100
0
50
100
Use of Thienopyridine at Discharge (%)

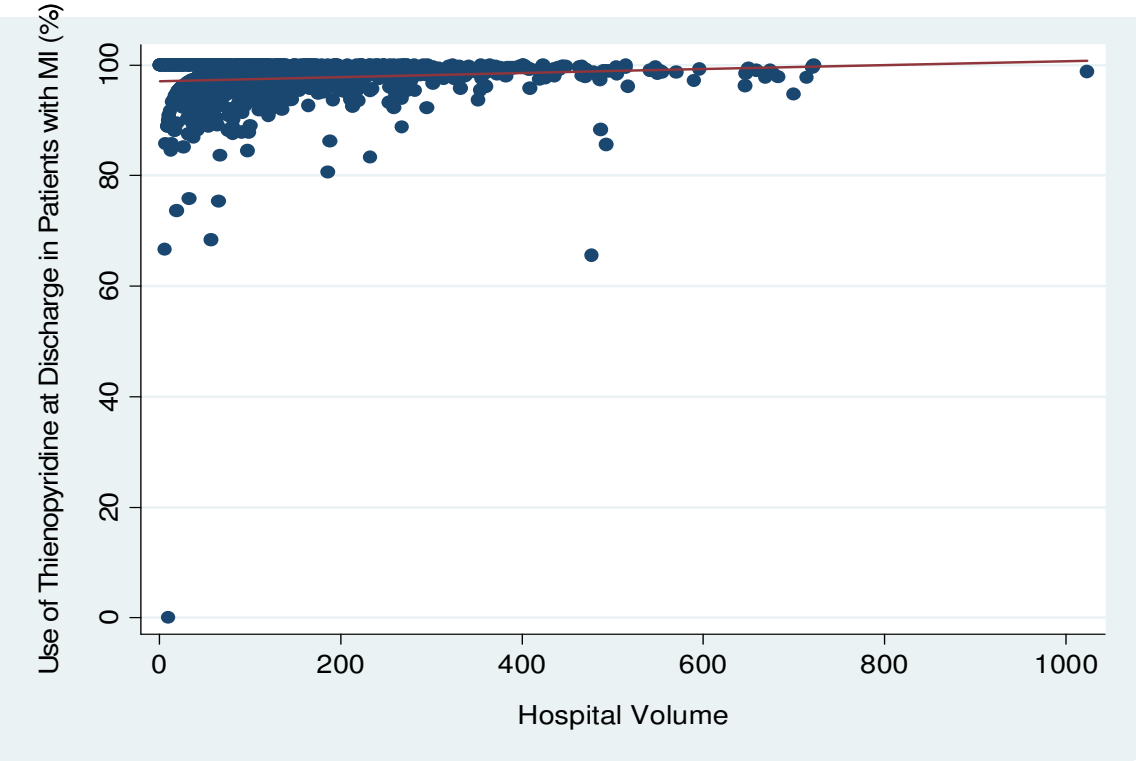
Distribution of P2Y12 Inhibitor Prescription at Discharge

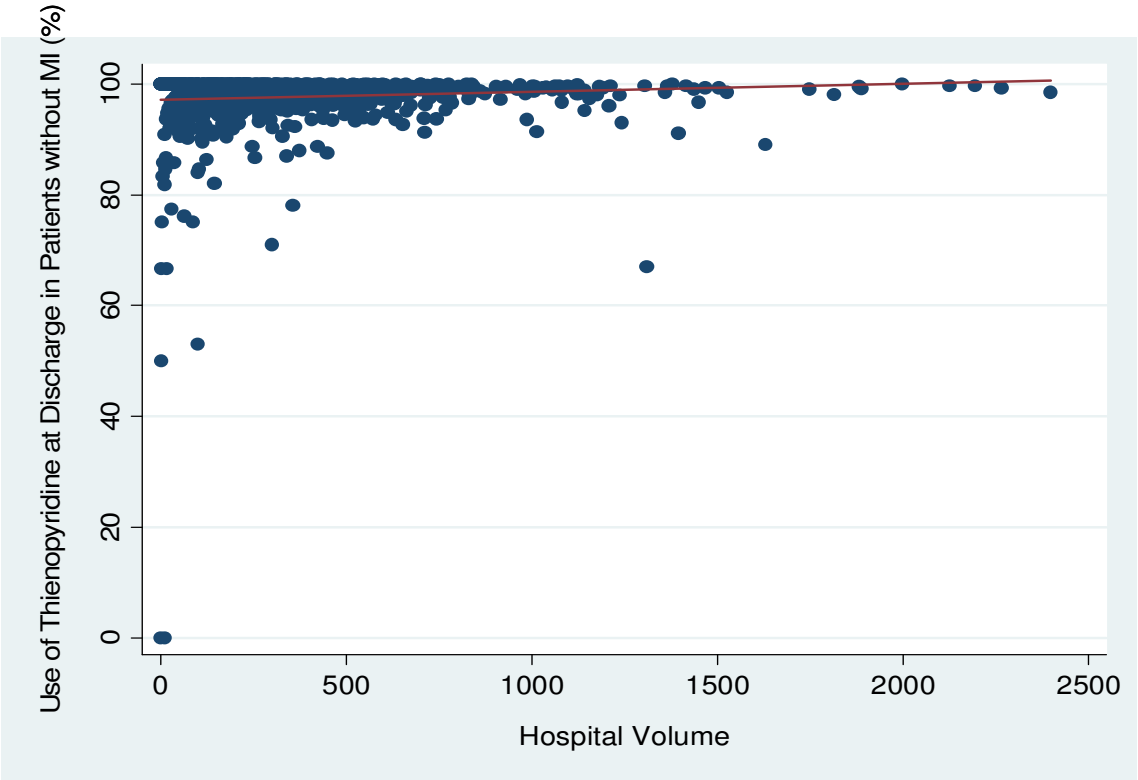
Description	In Admissions with MI			
	Yes		No	
	Volume	Rate	Volume	Rate
N	1116	1116	1103	1103
Mean	148.19	0.9762	322.97	0.9758
Std Deviation	129.09	0.0451	316.70	0.0577
100% Max	1023	1.0000	2399	1.0000
99%	647	1.0000	1505	1.0000
95%	419	1.0000	930	1.0000
90%	303	1.0000	703	1.0000
75% Q3	205	1.0000	424	0.9975
50% Median	115	0.9877	238	0.9892
25% Q1	57	0.9707	114	0.9726
10%	26	0.9403	43	0.9459
5%	14	0.9146	23	0.9227
1%	3	0.8462	3	0.7742
0% Min	1	0.0000	1	0.0000


Number of Hospitals
0
200
400
600
800
0
20
40
60
80
100
Use of Thienopyridine at Discharge in Patients with MI (%)


Number of Hospitals
0
200
400
600
800
0
20
40
60
80
100
Use of Thienopyridine at Discharge in Patients without MI (%)

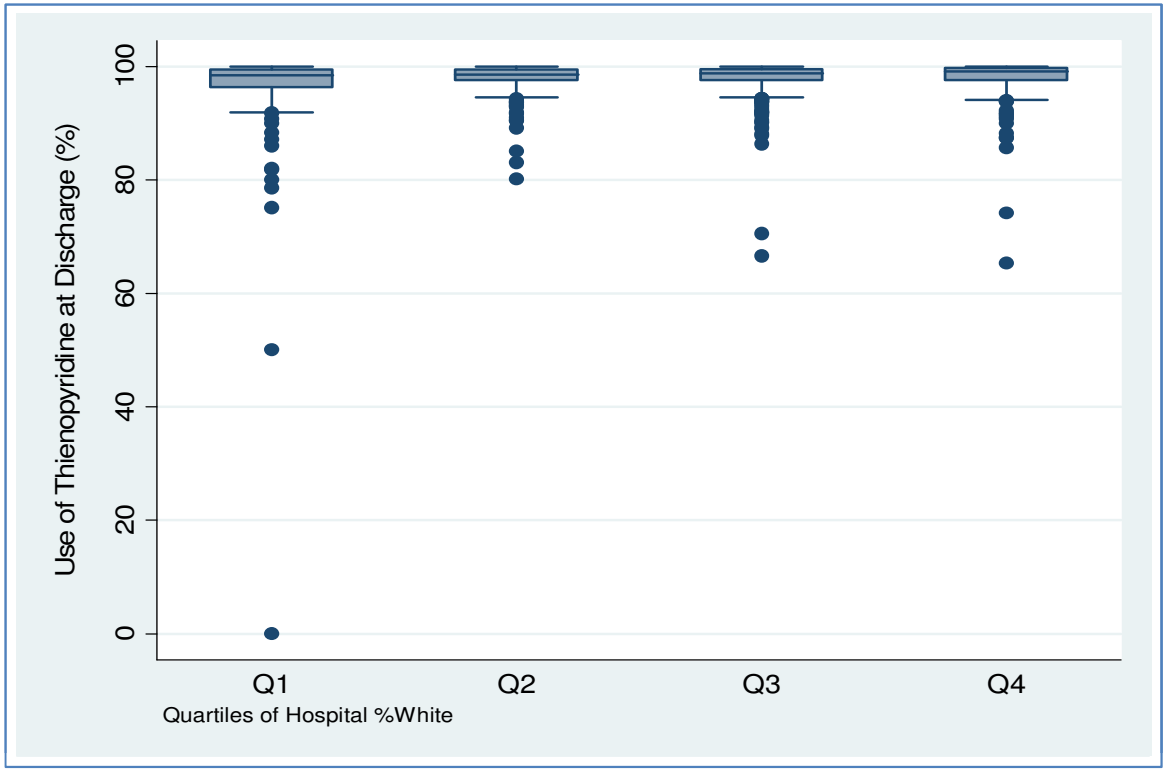

Use of Thienopyridine at Discharge in Patients with MI (%)
0
20
40
60
80
100
0
20
40
60
80
100
Use of Thienopyridine at Discharge in Patients without MI (%)


Use of Thienopyridine at Discharge in Patients with MI (%)
0
20
40
60
80
100
0
200
400
600
800
1000
Hospital Volume


Use of Thienopyridine at Discharge in Patients without MI (%)
0
20
40
60
80
100
0
500
1000
1500
2000
2500
Hospital Volume

Distribution of P2Y12 Inhibitor Prescription at Discharge Stratified by Hospital %White

Description	%White Q1 (0.00% to 84.20%)		Q2 (84.21% to 92.49%)		Q3 (92.50% to 96.85%)		Q4 (96.86% to 100.00%)	
	Volume	Rate	Volume	Rate	Volume	Rate	Volume	Rate
N	280	280	280	280	281	281	280	280
Mean	428.17	0.9687	503.69	0.9798	499.41	0.9774	429.87	0.9801
Std Deviatic	457.45	0.0732	407.01	0.0246	429.04	0.0347	406.21	0.0336
100% Max	3422	1.0000	2345	1.0000	2603	1.0000	2691	1.0000
99%	2405	1.0000	1936	1.0000	2407	1.0000	2036	1.0000
95%	1263	1.0000	1352	1.0000	1376	1.0000	1262	1.0000
90%	979	1.0000	1034	1.0000	961	1.0000	950	1.0000
75% Q3	567	0.9945	675	0.9946	640	0.9954	575	0.9975
50% Media	272	0.9852	416	0.9860	399	0.9874	337	0.9908
25% Q1	133	0.9640	205	0.9748	212	0.9749	138	0.9749
10%	59	0.9369	92	0.9568	104	0.9437	57	0.9518
5%	32	0.9189	44	0.9376	56	0.9200	24	0.9397
1%	2	0.7516	25	0.8509	22	0.8636	5	0.8571
0% Min	2	0.0000	16	0.8009	15	0.6665	1	0.6527


Use of Thienopyridine at Discharge (%)
0
20
40
60
80
100
Q1
Q2
Q3
Q4
Quartiles of Hospital %White

Testing Cohort

P2Y12 Prescribed at Discharge- Testing Cohort, July 2008-June 2009

Exclusions	Hospital Stays		Patients		Facilities	
	#	%	#	%	#	%
Initial Sample	**4594173**	**100**	**3931296**	**100**	**1089**	**100**
Discharges not between July 2008 and Jane 2009	3315964	72.18	2737465	69.63	38	3.49
Remainging	**1278209**	**27.82**	**1193831**	**30.37**	**1051**	**96.51**
Without PCI with a stent implanted during the admission	757116	59.23	708104	59.31	44	4.19
Remainging	**521093**	**40.77**	**485727**	**40.69**	**1007**	**95.81**
Discharge Status: deceased	5899	1.13	5719	1.18	0	0.00
Remainging	**515194**	**98.87**	**480008**	**98.82**	**1007**	**100.00**
Discharge Location: Other hospital	2763	0.54	2658	0.55	0	0.00
Remainging	**512431**	**99.46**	**477350**	**99.45**	**1007**	**100.00**
Thienopyridine at discharge*: contraindicated, or blinded	874	0.17	812	0.17	0	0.00
Study Sample	**511557**	**99.83**	**476538**	**99.83**	**1007**	**100.00**
Thienopyridine** at discharge	502902	98.31	468675	98.35	1007	100.00
Admissions with MI	**153076**	**29.92**	**151477**	**31.79**	**1001**	**99.40**
Thienopyridine** at discharge	150468	98.30	148921	98.31	1001	100.00
Amdissions without MI	**358481**	**70.08**	**336012**	**70.51**	**995**	**98.81**
Thienopyridine** at discharge	352434	98.31	330485	98.36	995	100.00

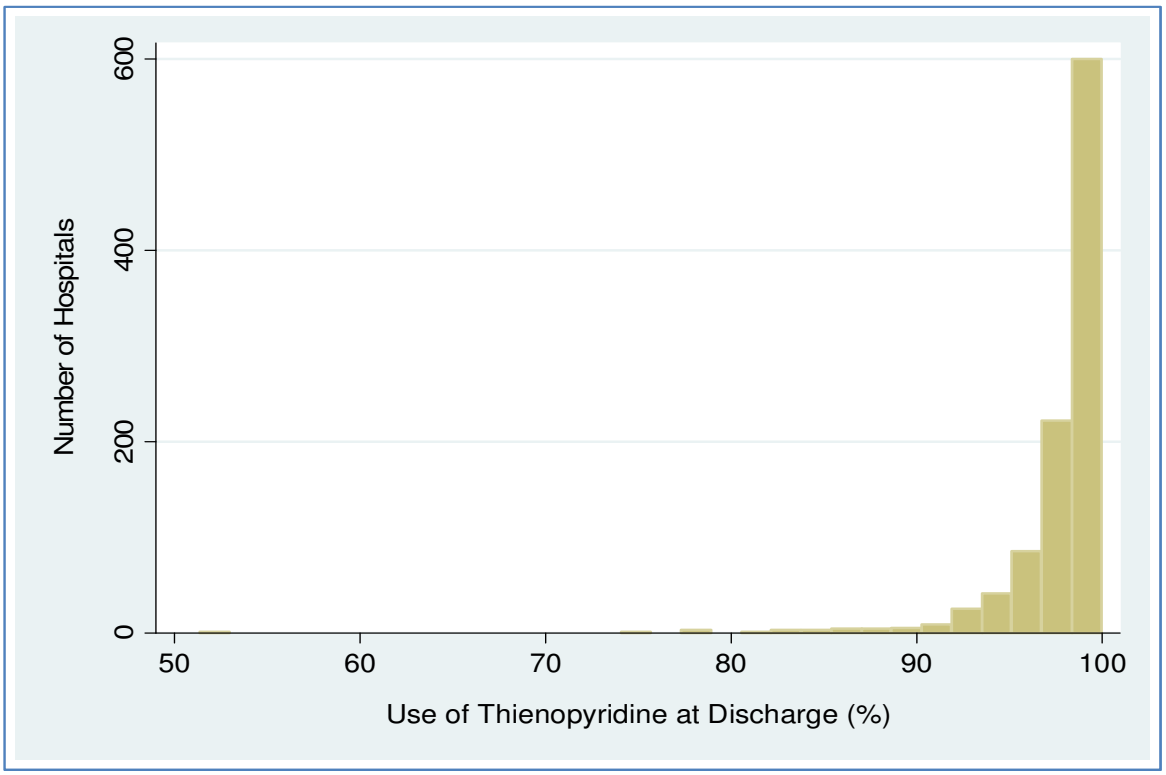
* Deifned all of the following: Clopidogrel at discharge -- unknown, contraindicated, or blinded; Ticlopidine at discharge --

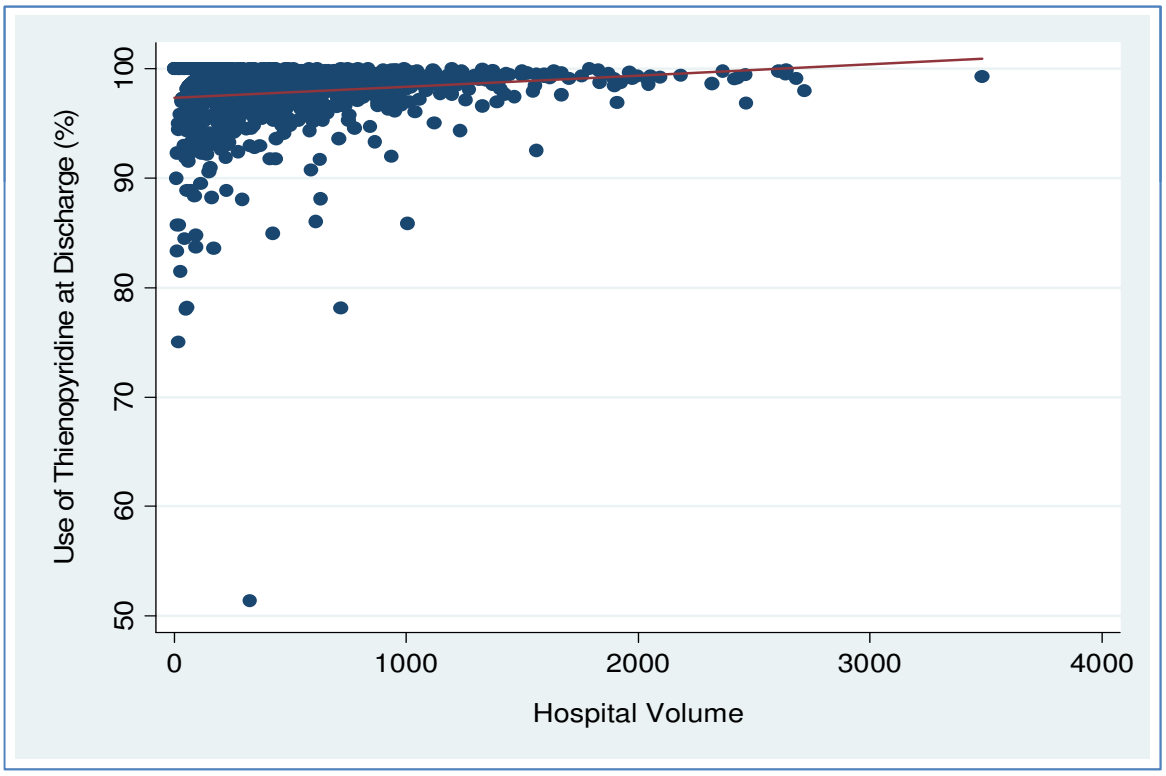
** Deifned either of the following: Clopidogrel at discharge -- Yes; Ticlopidine at discharge -- Yes.

Testing Cohort

Distribution of Thienopyridine Prescription at Discharge

Description	**Volume**	**Rate**
N	1007	1007
Mean	508.00	0.9788
Std Deviation	463.56	0.0313
100% Max	3484	1.0000
99%	2365	1.0000
95%	1397	1.0000
90%	1080	1.0000
75% Q3	673	0.9947
50% Median	390	0.9875
25% Q1	194	0.9745
10%	76	0.9517
5%	42	0.9306
1%	13	0.8478
0% Min	1	0.5138


Number of Hospitals
0
200
400
600
50
60
70
80
90
100
Use of Thienopyridine at Discharge (%)

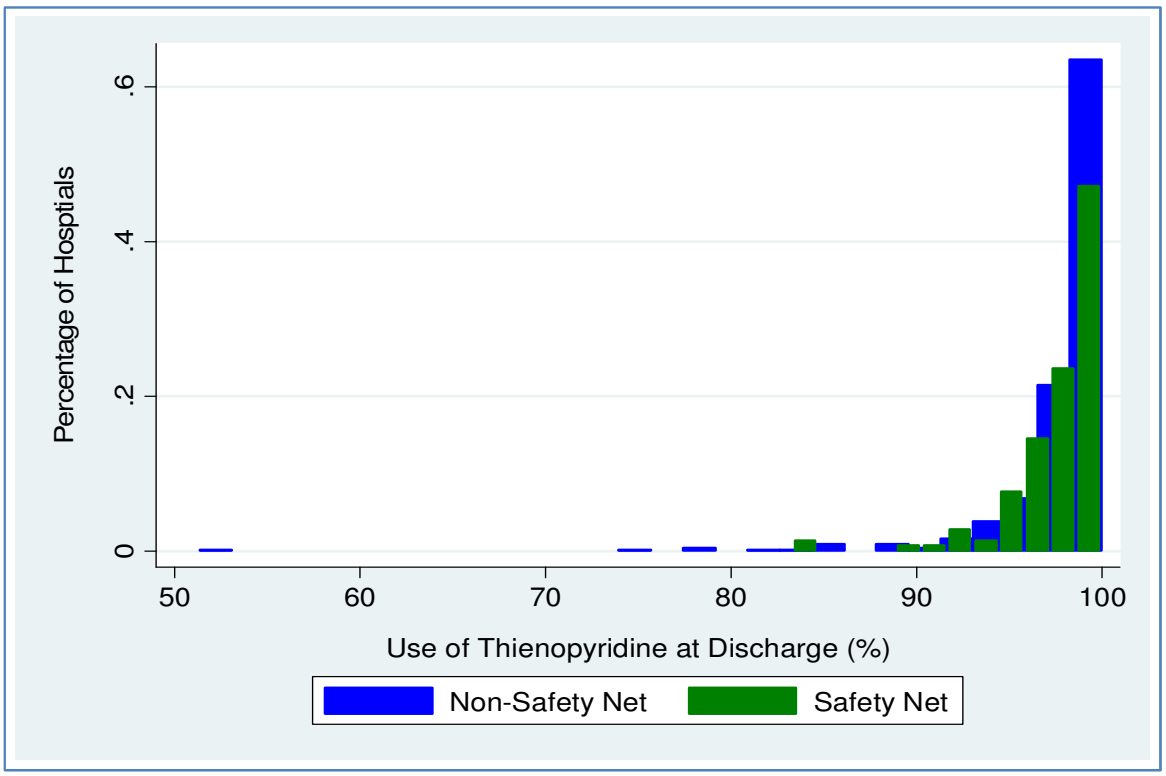

Use of Thienopyridine at Discharge (%)
50
60
70
80
90
100
0
1000
2000
3000
4000
Hospital Volume

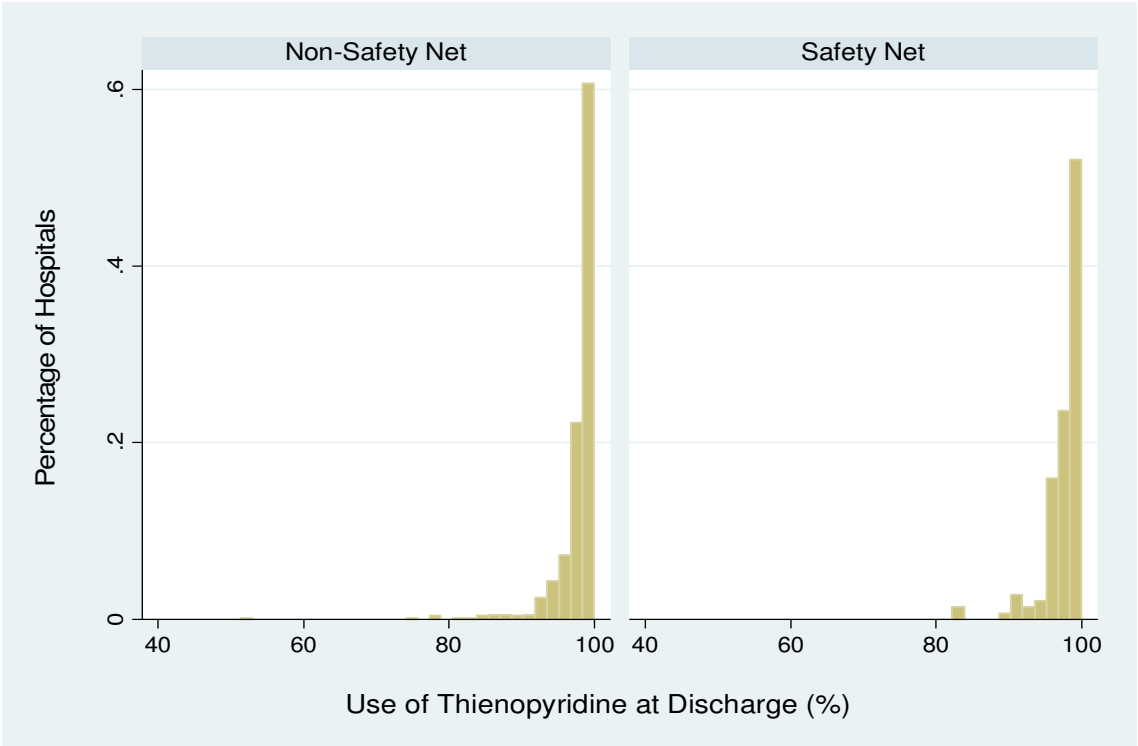
Testing Cohort

Distribution of Thienopyridine Prescription at Discharge Stratified by Safety Net Status

Description	Safety Net Status*			
	No		Yes	
	Volume	Rate	Volume	Rate
N	827	827	144	144
Mean	529.54	0.9792	430.17	0.9768
Std Deviation	477.98	0.0322	359.34	0.0261
100% Max	3484	1.0000	1834	1.0000
99%	2432	1.0000	1564	1.0000
95%	1416	1.0000	1081	1.0000
90%	1122	1.0000	937	1.0000
75% Q3	701	0.9949	583	0.9929
50% Median	404	0.9878	336.5	0.9846
25% Q1	202	0.9760	161	0.9687
10%	89	0.9528	77	0.9531
5%	49	0.9333	37	0.9252
1%	15	0.8478	10	0.8363
0% Min	1	0.5138	10	0.8333

* Defined as government hospitals or non-government hosptials with high medicaid caseload using AHA 2008 Data.

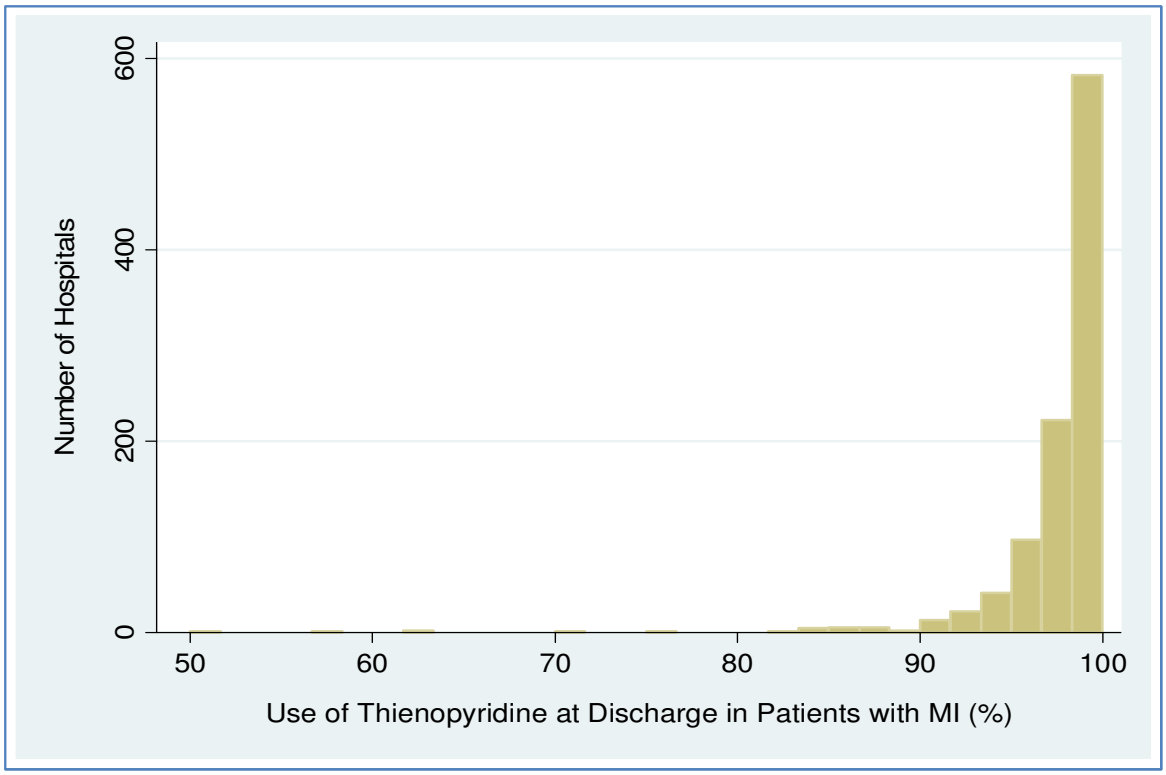

Percentage of Hosptials
0
.2
.4
.6
50
60
70
80
90
100
Use of Thienopyridine at Discharge (%)
Non-Safety Net
Safety Net

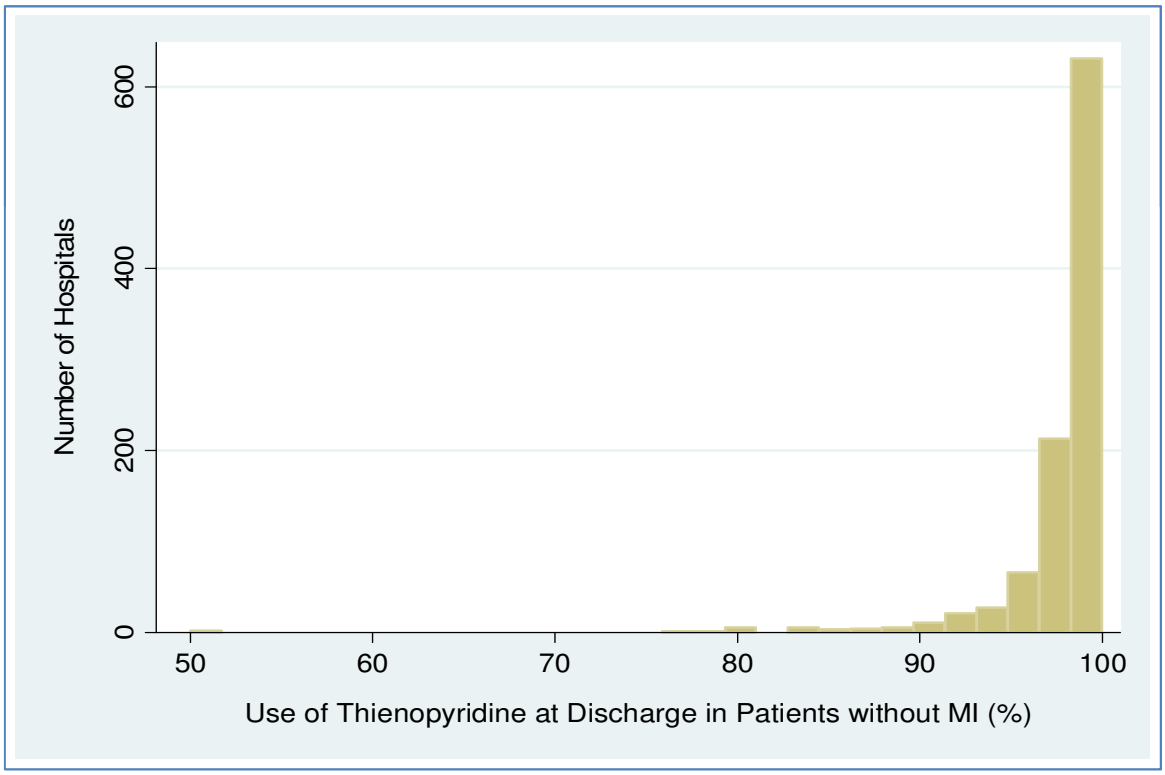

Non-Safety Net
Safety Net
Percentage of Hospitals
0
.2
.4
.6
40
60
80
100
Use of Thienopyridine at Discharge (%)

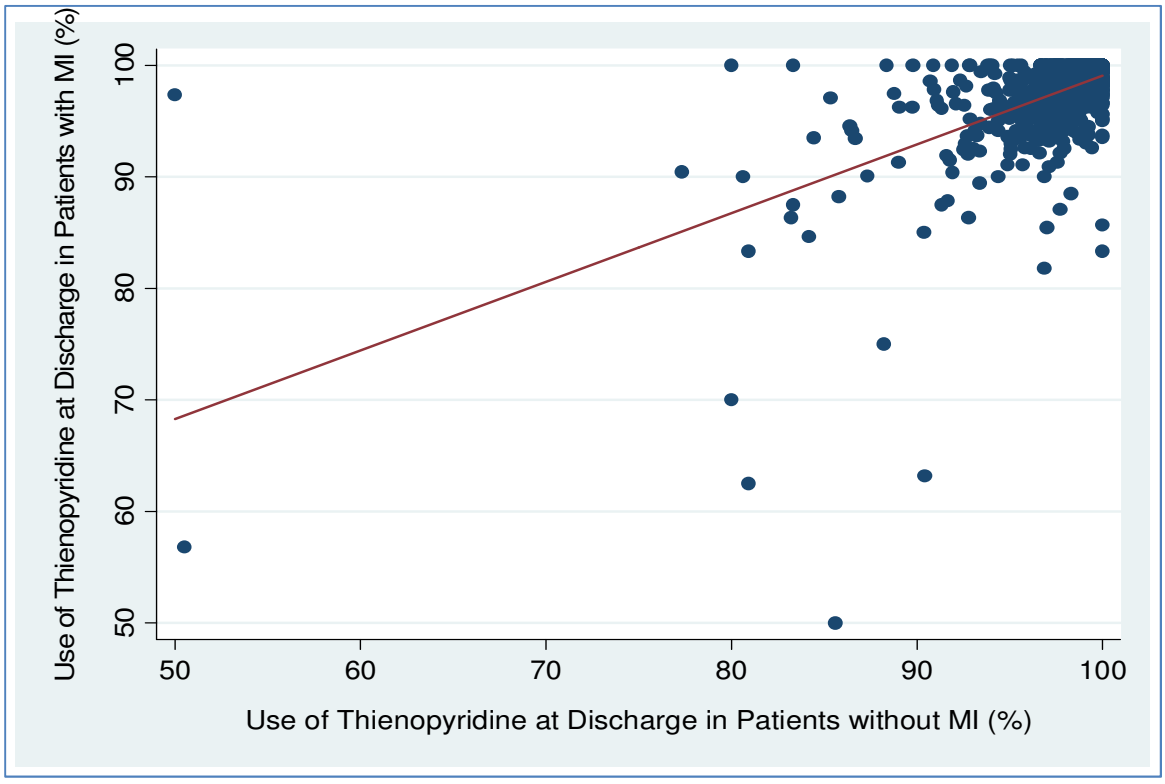
Testing Cohort

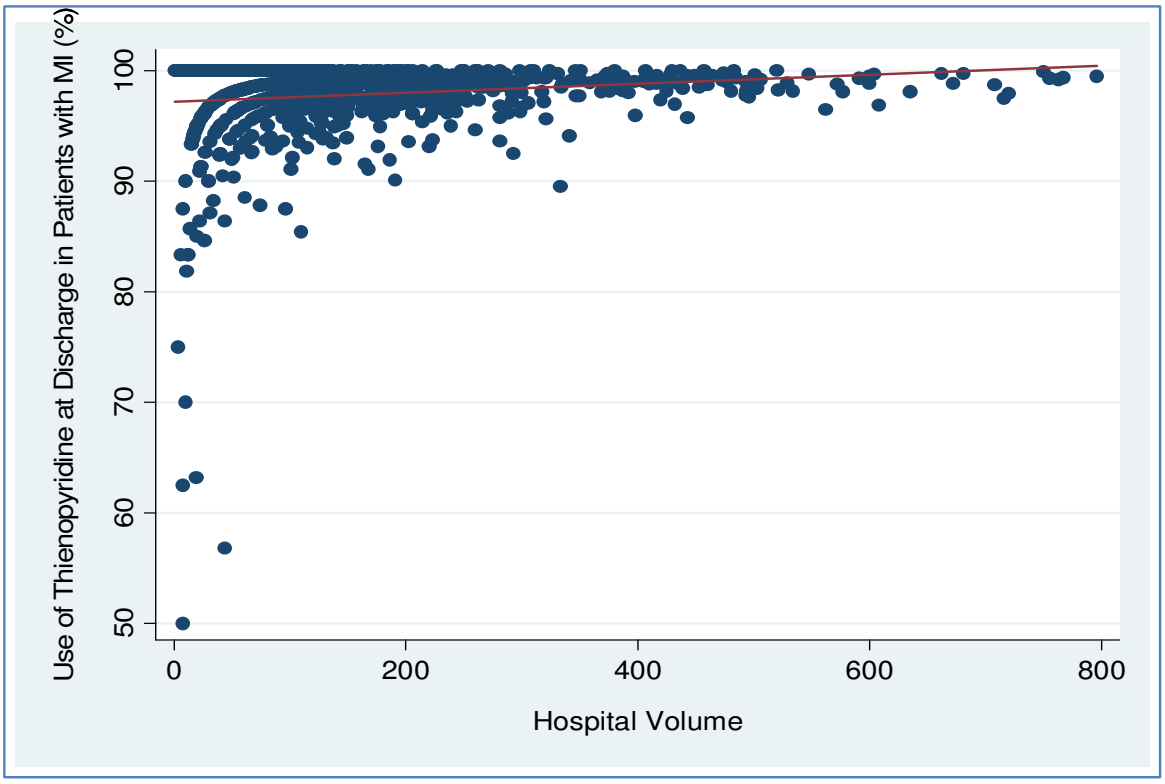
Distribution of Thienopyridine Prescription at Discharge

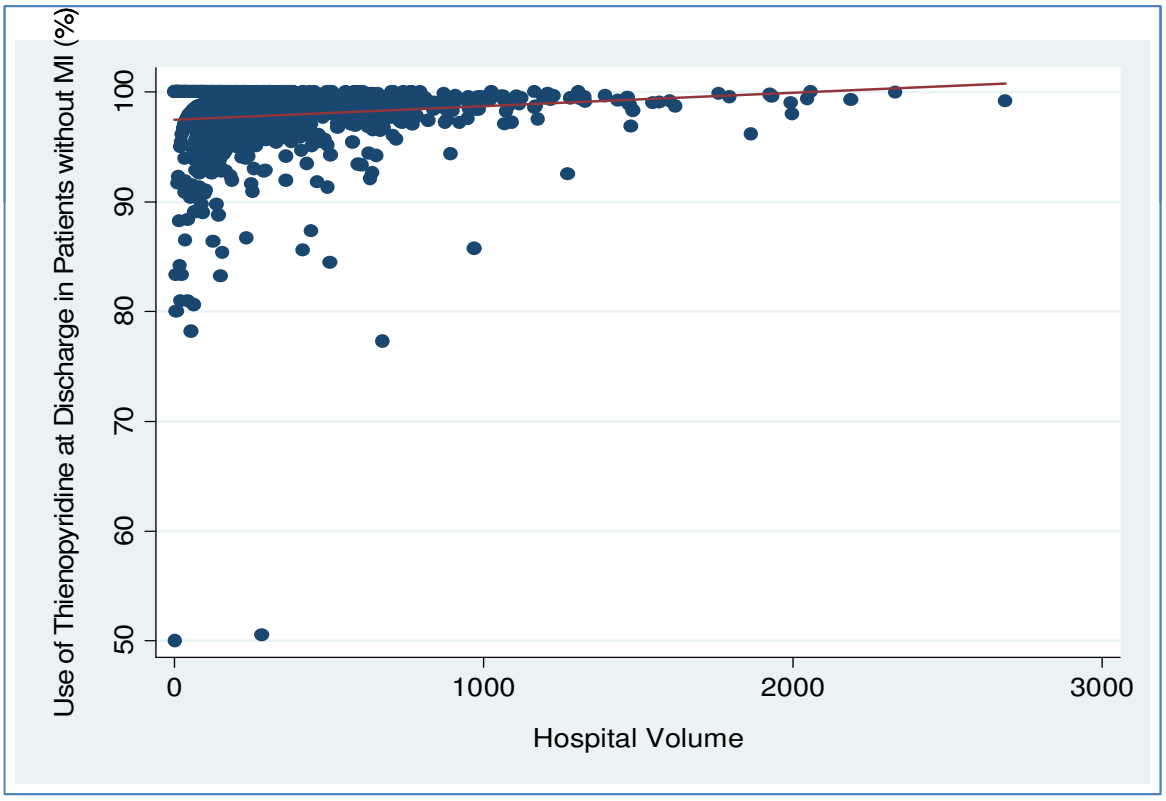
Description	In Admissions with MI: Yes		No	
	Volume	DTNPRD	Volume	DTNPRD
N	1001	1001	995	995
Mean	152.92	0.9781	360.28	0.9790
Std Deviation	135.15	0.0377	349.27	0.0361
100% Max	796	1.0000	2688	1.0000
99%	662	1.0000	1866	1.0000
95%	433	1.0000	1030	1.0000
90%	330	1.0000	760	1.0000
75% Q3	203	1.0000	467	0.9965
50% Median	116	0.9872	265	0.9890
25% Q1	55	0.9726	133	0.9750
10%	25	0.9500	47	0.9522
5%	15	0.9298	23	0.9259
1%	4	0.8462	5	0.8322
0% Min	1	0.5000	1	0.5000


Number of Hospitals
0
200
400
600
50
60
70
80
90
100
Use of Thienopyridine at Discharge in Patients with MI (%)


Number of Hospitals
0
200
400
600
50
60
70
80
90
100
Use of Thienopyridine at Discharge in Patients without MI (%)


Use of Thienopyridine at Discharge in Patients with MI (%)
50
60
70
80
90
100
Use of Thienopyridine at Discharge in Patients without MI (%)

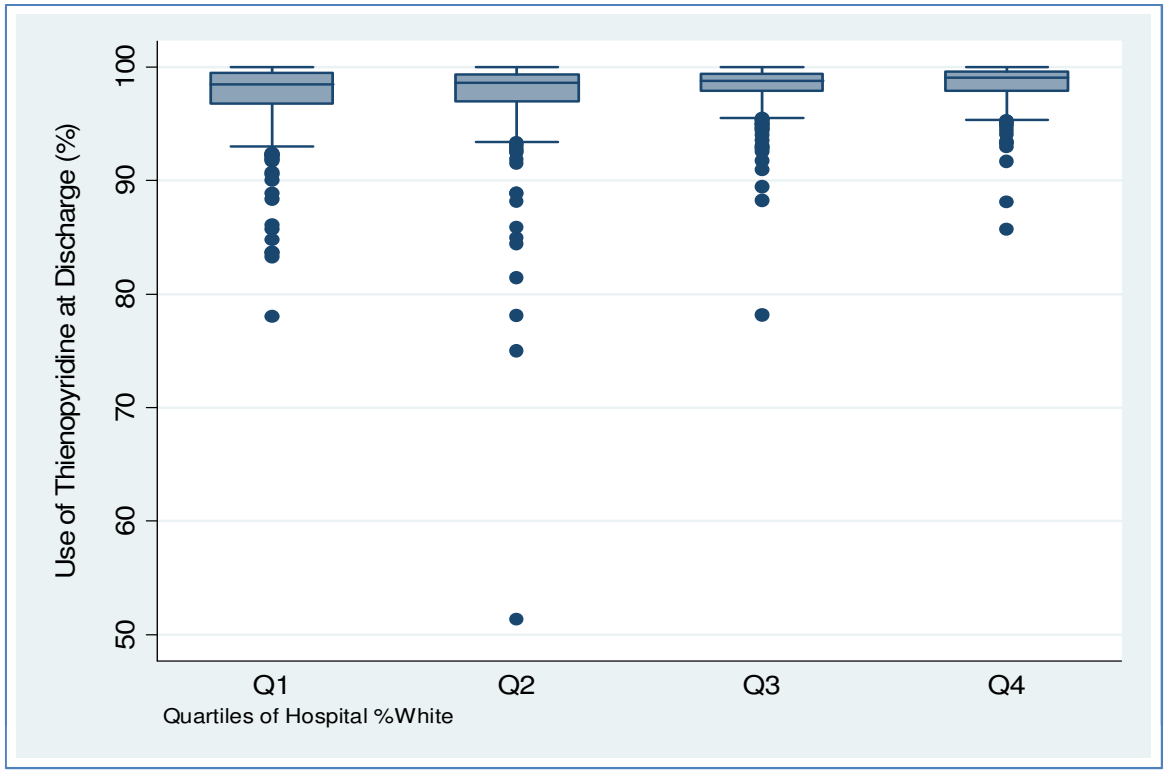

Use of Thienopyridine at Discharge in Patients with MI (%)
50
60
70
80
90
100
0
200
400
600
800
Hospital Volume


Use of Thienopyridine at Discharge in Patients without MI (%)
50
60
70
80
90
100
0
1000
2000
3000
Hospital Volume

Testing Cohort

Distribution of Thienopyridine Prescription at Discharge Stratified by Hospital %White

Description	%White	%White Q1 (0.00% to 84.20%)		Q2 (84.21% to 92.49%)		Q3 (92.50% to 96.85%)		Q4 (96.86% to 100.00%)	
		Volume	Rate	Volume	Rate	Volume	Rate	Volume	Rate
N	1007	251	251	252	252	252	252	252	252
Mean	0.7929	446.41	0.9747	551.04	0.9737	548.64	0.9819	485.66	0.9849
Std Deviation	0.2264	456.60	0.0328	472.86	0.0441	458.96	0.0223	459.96	0.0183
100% Max	1.0000	2718	1.0000	3484	1.0000	2432	1.0000	2682	1.0000
99%	1.0000	2635	1.0000	2464	1.0000	2184	1.0000	2365	1.0000
95%	0.9877	1329	1.0000	1397	1.0000	1404	1.0000	1416	1.0000
90%	0.9740	1017	1.0000	1045	1.0000	1126	1.0000	958	1.0000
75% Q3	0.9423	555	0.9951	746	0.9932	769.5	0.9941	631	0.9960
50% Median	0.8762	318	0.9847	447	0.9863	417.5	0.9880	373.5	0.9906
25% Q1	0.7292	158	0.9673	213.5	0.9693	207	0.9786	169	0.9788
10%	0.4985	57	0.9430	95	0.9412	105	0.9585	60	0.9651
5%	0.2703	34	0.9174	59	0.9252	55	0.9459	24	0.9524
1%	0.0000	10	0.8363	20	0.7810	20	0.8947	2	0.9172
0% Min	0.0000	8	0.7800	6	0.5138	15	0.7818	1	0.8571


Use of Thienopyridine at Discharge (%)
50
60
70
80
90
100
Q1
Q2
Q3
Q4
Quartiles of Hospital %White

NATIONAL QUALITY FORUM

Measure Evaluation 4.1
December 2009

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

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

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

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

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

(for NQF staff use) **NQF Review #:** 1493 **NQF Project:** Cardiovascular Endorsement Maintenance 2010
MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** Aspirin at discharge for patients with Percutaneous Coronary Intervention (PCI)
De.2 **Brief description of measure***:* Proportion of adult patients (age 18 or older) who undergo a percutaneous coronary intervention (PCI) and are prescribed aspirin at discharge.
1.1-2 **Type of Measure:** Process De.3 **If included in a composite or paired with another measure, please identify composite or paired measure** N/A
De.4 **National Priority Partners Priority Area:** De.5 **IOM Quality Domain**: Effectiveness, Safety, Timeliness De.6 **Consumer Care Need:** Getting better, Living with illness

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	**NQF Staff**
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.* A.1 **Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes A.2 **Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:** A.3 **Measure Steward Agreement:** Agreement will be signed and submitted prior to or at the time of measure submission A.4 **Measure Steward Agreement attached:** NQF - signed-634238762359539272.pdf	**A** Y☐ N☐
B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and	**B**

update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	Y☐ N☐
C. The intended use of the measure includes both public reporting and quality improvement. ►**Purpose:** Public reporting, Internal quality improvement Accountability, Payment incentive, Accreditation	C Y☐ N☐
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1**Testing:** Yes, fully developed and tested D.2 **Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?** Yes	D Y☐ N☐
(for NQF staff use**) Have all conditions for consideration been met?** **Staff Notes to Steward** (*if submission returned*)**:**	**Met** Y☐ N☐
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**	
Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. *Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.* (evaluation criteria) **1a. High Impact**	Eval Ratin g
(for NQF staff use) Specific NPP goal:	
1a.1 **Demonstrated High Impact Aspect of Healthcare:** Affects large numbers, Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Severity of illness 1a.2 1a.3 **Summary of Evidence of High Impact:** Cardiovascular disease is the single most common cause of death in the U.S. There are an estimated 64 million people with cardiovascular disease with direct costs totaling over 226 billion dollars in 2004. Estimates of direct costs due to cardiovascular disease are projected to be 503.2 billion dollars in 2010. In 2002, approximately 864,480 deaths were attributable to cardiovascular disease, or 1 in 2.9 deaths in the US. Approximately 1 million PCI procedures are performed annually. 6.1 million hospital discharges listed cardiovascular disease as the primary diagnosis in 2006. In 2004 coronary artherosclerosis attributed to 1.2 million hospital stays, with 44 billion in associated expenses. More than half of hospital stays were due to PCI or cardiac revascularization. 1a.4 **Citations for Evidence of High Impact:** American Heart Association. Heart disease and stroke statistics- 2010 update: A report of the American Heart Association. Available at:http://circ.ahajournals.org/cgi/content/full/103/24/3019. Accessed October 13, 2010.	1a C☐ P☐ M☐ N☐
1b. Opportunity for Improvement 1b.1 **Benefits (improvements in quality) envisioned by use of this measure:** Aspirin therapy reduces the risk of ischemic events following PCI. This measure will encourage improvement in rates of aspirin	1b C☐ P☐ M☐

Comment [KP1]: 1a. The measure focus addresses:
•a specific national health goal/priority identified by NQF's National Priorities Partners; OR
•a demonstrated high impact aspect of healthcare (e.g., affects large numbers, leading cause of morbidity/mortality, high resource use (current and/or future), severity of illness, and patient/societal consequences of poor quality).

Comment [KP2]: 1b. Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating considerable variation, or overall poor performance, in the quality of care across providers and/or population groups (disparities in care).

prescribing at discharge following PCI and subsequently reduce rates of adverse outcomes after PCI by facilitating quality improvement in this area.

N☐

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
A recent study of 352 nongovernment acute care hospitals demonstrated a performance gap in aspirin prescribing at discharge in 5490 Medicare beneficiaries following MI. 24% of patients were not prescribed aspirin at discharge. Data from the NCDR CathPCI Registry for 1121 facilities (566,305 records) showed some variation in performance for this measure. Performance ranged from 89% at the 5th percentile to 100% at the 95th percentile. 25% of hospitals did not prescribe aspirin at discharge for 5% of its patients.

1b.3 Citations for data on performance gap:
1. Unpublished NCDR data. Please see documentation attached.
2. Krumholz HM, Radford MJ, Ellerbeck EF, et al. Aspirin for secondary prevention after acute myocardial infarction in the elderly: prescribed use and outcomes. Ann Intern Med. 1996;124:292-8.

1b.4 Summary of Data on disparities by population group:
We conducted stratified analyses of hospital performance for this measure by (a) hospital safety net status (defined as government hospitals or non-government hosptials with high medicaid caseload using AHA 2008) and (b) quartiles of proportion of patients of white race. Both sets of analyses suggested that the range of hospital performance is similar irrespective of the SES of the patients treated. Specifically, the median for Safety Net hospitals was 97.7% with the lowest decile 92.0% and highest decile 99.8%. This is similar to that observed for non-Safety Net hospitals (median 97.1%, lowest decile 91.0%, highest decile 99.5%). Similarly, median hospital performance was similar across quartiles of proportion of white patients (quartile 1: 97.0%, quartile 2: 97.7%, quartile 3: 98.2%, quartile 4: 98.2%).

1b.5 Citations for data on Disparities:
Unpublished NCDR data. Please see documentation attached.

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** Aspirin reduces the frequency of ischemic complications after PCI, including MI and stroke.

1c.2-3. Type of Evidence: Evidence-based guideline, Randomized controlled trial

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
On the basis of 12 randomized trials in 18,788 patients with prior infarction, the Antiplatelet Trialists' Collaboration reported a 25% reduction in the risk of recurrent infarction, stroke, or vascular death in patients receiving prolonged antiplatelet therapy (36 fewer events for every 1000 patients treated). No antiplatelet therapy has proved superior to aspirin in this population, and daily doses of aspirin between 80 and 325 mg appear to be effective. These compelling data suggest that all patients recovering from STEMI should, in the absence of contraindications, continue taking aspirin for an indefinite period.

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom***):**
Level B: Data derived from a single randomized trial or nonrandomized studies (American College of Cardiology/ American Heart Association TaskForce on Practice Guidelines)

1c.6 Method for rating evidence: The weight of evidence in support of the recommendation is listed as follows:
• Level of Evidence A: Data derived from multiple randomized clinical trials or meta-analyses.
• Level of Evidence B: Data derived from a single randomized trial or nonrandomized studies.
• Level of Evidence C: Only consensus opinion of experts, case studies, or standard-of-care.

1c.7 Summary of Controversy/Contradictory Evidence:

1c
C☐
P☐
M☐
N☐

Comment [k3]: 1 Examples of data on opportunity for improvement include, but are not limited to: prior studies, epidemiologic data, measure data from pilot testing or implementation. If data are not available, the measure focus is systematically assessed (e.g., expert panel rating) and judged to be a quality problem.

Comment [k4]: 1c. The measure focus is:
•an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;
OR
•if an intermediate outcome, process, structure, etc., there is **evidence** that supports the specific measure focus as follows:
oIntermediate outcome – evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
oProcess – evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and
if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
oStructure – evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
oPatient experience – evidence that an association exists between the measure of patient experience of health care and th ... [1]

Comment [k5]: 4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a ... [2]

Comment [k6]: 3 The strength of the body of evidence for the specific measure focus should be systematically assessed and rated (e.g., USPSTF grading system http://www.ahrq.gov/clinic/uspstf07/methods/benefit.htm). If the USPSTF grading system was not used, the grading system is explained including how it relates to the USPSTF grades or why it does not. However, evidence is not limited to quantitative studies and the best type of evidence depends upon the question being studied (e.g., randomized controlled trials appropriate for studying drug efficacy are not well suited for complex system changes). When qualitative studies are used, appropriate qualitative research criteria are used to judge the strength of the evidence.

1c.8 Citations for Evidence (*other than guidelines*): Antithrombotic Trialists' Collaboration. Collaborative meta-analysis of randomised trials of antiplatelet therapy for prevention of death, myocardial infarction, and stroke in high-risk patients. BMJ 2002;324:71-86.

Gutstein DE, Fuster V. Pathophysiologic bases for adjunctive therapies in the treatment and secondary prevention of acute myocardial infarction. Clin Cardiol 1998;21:161-8.

Hennekens CH, Dyken ML, Fuster V. Aspirin as a therapeutic agent in cardiovascular disease: a statement for healthcare professionals from the American Heart Association. Circulation 1997;96:2751-3.

1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number*):
AHA/ACC PCI Guidelines, Focused Update 2007:
3. After PCI, in patients without allergy or increased risk of bleeding, aspirin 162 mg to 325 mg daily should be given for at least 1 month after BMS implantation, 3 months after sirolimus-eluting stent implantation, and 6 months after paclitaxel-eluting stent implantation, after which daily long-term aspirin use should be continued indefinitely at a dose of 75 mg to 162 mg. (Level of Evidence: B)

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ACC/AHA NSTEMI Guidelines 2007:
CLASS I
1. For UA/NSTEMI patients treated medically without stenting, aspirin (75 to 162 mg per day) should be prescribed indefinitely (Level of Evidence: A); clopidogrel (75 mg per day) should be prescribed for at least 1 month (Level of Evidence: A) and ideally for up to 1 year. (Level of Evidence: B)\
2. For UA/NSTEMI patients treated with bare-metal stents, aspirin 162 to 325 mg per day should be prescribed for at least 1 month (Level of Evidence: B), then continued indefinitely at a dose of 75 to 162 mg per day (Level of Evidence: A); clopidogrel should be prescribed at a dose of 75 mg per day for a minimum of 1 month and ideally for up to 1 year (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks). (Level of Evidence: B)
3. For UA/NSTEMI patients treated with DES, aspirin 162 to 325 mg per day should be prescribed for at least 3 months after sirolimuseluting stent implantation and 6 months after paclitaxel-eluting stent implantation then continued indefinitely at a dose of 75 to 162 mg per day. (Level of Evidence: B) Clopidogrel 75 mg daily should be given for at least 12 months to all post-PCI patients receiving DES. (Level of Evidence: B)
4. Clopidogrel 75 mg daily (preferred) or ticlopidine (in the absence of contraindications) should be given to patients recovering from UA/NSTEMI when ASA is contraindicated or not tolerated because of hypersensitivity or gastrointestinal intolerance (but with gastroprotective agents such as proton-pump inhibitors). (Level of Evidence: A)

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ACC/AHA STEMI Guidelines 2004:
Class I
1. A daily dose of aspirin 75 to 162 mg orally should be given indefinitely to patients recovering from STEMI. (Level of Evidence: A)
2. If true aspirin allergy is present, preferably clopidogrel (75 mg orally per day) or, alternatively, ticlopidine (250 mg orally twice daily) should be substituted. (Level of Evidence: C)

Page: e144

AHA/ACC guidelines for secondary prevention for patients with coronary and other atherosclerotic vascular disease:
Aspirin/Thienopyridines:
• Start aspirin 75 to 162 mg/d and continue indefinitely in all patients unless contraindicated. I (A)
For patients undergoing coronary artery bypass grafting, aspirin should be started within 48 hours after surgery to reduce saphenous vein graft closure. Dosing regimens ranging from 100 to 325mg/d appear to be efficacious. Doses higher than 162 mg/d can be continued for up to 1 year. I (B)
• Start and continue clopidogrel 75 mg/d in combination with aspirin for up to 12 months in patients after acute coronary syndrome or percutaneous coronary intervention with stent placement (>=1 month for bare

metal stent, >=3 months for sirolimus-eluting stent, and >=6 months for paclitaxel-eluting stent). I (B) Patients who have undergone percutaneous coronary intervention with stent placement should initially receive higher-dose aspirin at 325 mg/d for 1 month for bare metal stent, 3 months for sirolimus-eluting stent, and 6 months for paclitaxel-eluting stent. I (B

Page: 2132

1c.10 Clinical Practice Guideline Citation: 1. King SB, III, Smith SC, Jr., Hirshfeld JW, Jr., 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. J Am Coll Cardiol. 2008;51:172-209.

2. Anderson JL, Adams CD, Antman EM, et al. ACC/AHA 2007 guidelines for the management of patients with unstable angina/non-ST-Elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 2002 Guidelines for the Management of Patients With Unstable Angina/Non-ST-Elevation Myocardial Infarction) developed in collaboration with the American College of Emergency Physicians, the Society for Cardiovascular Angiography and Interventions, and the Society of Thoracic Surgeons endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation and the Society for Academic Emergency Medicine. J Am Coll Cardiol. 2007;50:e1-e157.

3. Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Management of Patients with Acute Myocardial Infarction). Circulation. 2004;110:e82-292.

4. Smith SC, Jr., Allen J, Blair SN, et al. AHA/ACC guidelines for secondary prevention for patients with coronary and other atherosclerotic vascular disease: 2006 update endorsed by the National Heart, Lung, and Blood Institute. J Am Coll Cardiol. 2006;47:2130-9.

1c.11 National Guideline Clearinghouse or other URL:
http://circ.ahajournals.org/cgi/content/full/117/2/261#TBL12188208

1c.12 Rating of strength of recommendation (*also provide narrative description of the rating and by whom***):**
Class I: Conditions for which there is evidence for and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.

1c.13 Method for rating strength of recommendation (*If different from* USPSTF system*, also describe rating and how it relates to USPSTF)***:**
ACC/AHA Taskforce on Practice Guidelines Method:

Indications are categorized as class I, II, or III on the basis of a multifactorial assessment of risk and expected efficacy viewed in the context of current knowledge and the relative strength of this knowledge. These classes summarize the recommendations for procedures or treatments as follows:

Class I: Conditions for which there is evidence for and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.

Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.

Class IIb: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful.

Comment [k7]: USPSTF grading system **http://www.ahrq.gov/clinic/uspstf/grades.htm**: **A -** The USPSTF recommends the service. There is high certainty that the net benefit is substantial. **B -** The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. **C -** The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small. Offer or provide this service only if other considerations support the offering or providing the service in an individual patient. **D -** The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. **I -** The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

1c.14 **Rationale for using this guideline over others:** This guideline is the most widely recognized professional guideline in the US for cardiovascular medicine in the area of percutaneous coronary intervention care.	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to Measure and Report?*	**1**
Steering Committee: Was the threshold criterion, *Importance to Measure and Report*, **met?** **Rationale:**	**1** **Y☐** **N☐**
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	Eval Rating
2a. MEASURE SPECIFICATIONS	
S.1 **Do you have a web page where current detailed measure specifications can be obtained?** S.2 **If yes, provide web page URL:** **2a. Precisely Specified**	
2a.1 **Numerator Statement (***Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):** Count of patients with a PCI procedure with aspirin prescribed at discharge. 2a.2 **Numerator Time Window (***The time period in which cases are eligible for inclusion in the numerator***):** 1 year 2a.3 **Numerator Details (***All information required to collect/calculate the numerator, including all codes, logic, and definitions***):** Element Name: Discharge Medications Discharge Medications=aspirin (any) Coding Instructions: Indicate which of the following medications the patient was prescribed upon discharge. Note(s): Complete only for patients who had a PCI procedure attempted or performed during this episode of care. Discharge medications not required for patients who were discharged to "Other acute care hospital","Hospice", or Left against medical advice (AMA)." Element Name: Medication Administered Medication Administered=Yes Coding Instructions: Indicates if the medication was administered, not administered, contraindicated or blinded. Selections: No- Medication was not administered or prescribed. Yes- Medication was administered or prescribed. Contraindicated- Medication was not administered because of a contraindication. (Contraindications must be documented explicitly by the physician, clearly evidenced within the medical record.) Blinded- Patient was in a research study or clinical trial and the administration of this specific medication or class of medications is unknown.	**2a-specs** **C☐** **P☐** **M☐** **N☐**
2a.4 **Denominator Statement (***Brief, text description of the denominator - target population being measured***):** Count of patients with a PCI procedure	

Comment [KP8]: **2a.** The measure is well defined and precisely specified so that it can be implemented consistently within and across organizations and allow for comparability. The required data elements are of high quality as defined by NQF's Health Information Technology Expert Panel (HITEP) .

2a.5 Target population gender: Female, Male
2a.6 Target population age range: All patients >= 18 years of age.

2a.7 Denominator Time Window (*The time period in which cases are eligible for inclusion in the denominator***):**
1 year

2a.8 Denominator Details (*All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):**
Element name: PCI
PCI=Yes
Coding Instructions: Indicate if the patient had a percutaneous coronary intervention (PCI).
Selections: No/Yes
Supporting Definitions: PCI:A percutaneous coronary intervention (PCI) is the placement of an angioplasty guide wire, balloon, or other device (e.g. stent, atherectomy, brachytherapy, or thrombectomy catheter) into a native coronary artery or coronary artery bypass graft for the purpose of mechanical coronary revascularization.Source: NCDR

2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population***):** -Aspirin coded as contraindicated or blinded
-Discharge status of deceased
-Discharge location of “other acute care hospital”, “hospice” or “against medical advice”.

2a.10 Denominator Exclusion Details (*All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**
Element name: Discharge Status
Discharge status=deceased
Coding Instructions: Indicate whether the patient was alive or deceased at discharge.
Selections: Alive/Deceased

Element name: Discharge Location
Discharge location="other acute hospital","hospice", or "left against medical advice"
Coding Instructions: Indicate the location to which the patient was discharged.
Selections:
-Home
-Extended care/TCU/rehabilitation
-Other acute care hospital
-Nursing home
-Hospice
-Other
Left against medical advice (The patient was discharged or eloped against medical advice.)

Medication Administered=contraindicated or blinded
Name: Medication Administered
Coding Instructions: Indicates if the medication was administered, not administered, contraindicated or blinded.
Selections:
No- Medication was not administered or prescribed.
Yes- Medication was administered or prescribed.
Contraindicated- Medication was not administered because of a contraindication.
(Contraindications must be documented explicitly by the physician, or
clearly evidenced within the medical record.)
Blinded- Patient was in a research study or clinical trial and the administration of this specific medication or class of medications is unknown.

2a.11 Stratification Details/Variables (*All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
N/A

2a.12-13 Risk Adjustment Type: No risk adjustment necessary

Comment [k9]: 11 Risk factors that influence outcomes should not be specified as exclusions.
12 Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

2a.14 Risk Adjustment Methodology/Variables (*List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**
N/A

2a.15-17 Detailed risk model available Web page URL or attachment:

2a.18-19 Type of Score: Rate/proportion
2a.20 Interpretation of Score: Better quality = Higher score
2a.21 Calculation Algorithm (*Describe the calculation of the measure as a flowchart or series of steps***):**
Denominator calculation:
1. Count of patients with arrival/discharge dates from data submissions that pass NCDR data inclusion thresholds
2. Exclude patients with arrival/discharge dates without PCI during episode
3. Exclude patients with discharge status=deceased
4. Exclude patients with Discharge Location: Other acute care hospital
5. Exclude patients with Discharge Location: Left against medical advice
6. Exclude patients with Discharge Location: Hospice
7. Exclude patients with Aspirin at discharge: contraindicated or blinded
Numerator calculation:
8. From denominator population, count of patients with Discharge medication of aspirin=yes

Calculation of score:
9. Numerator count/Denominator count

2a.22 Describe the method for discriminating performance *(e.g., significance testing)***:**
Hospitals performance for this measure is benchmarked each quarter and annually against hospitals with similar procedural volume, as well as against the CathPCI Registry aggregate. These benchmarks identify superior performance and encourage poorer performers to improve. The methodology is a data-driven, peer-group performance feedback used to positively affect outcomes.

2a.23 Sampling (Survey) Methodology *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)*:
N/A

2a.24 Data Source (*Check the source(s) for which the measure is specified and tested)*
Registry data

2a.25 Data source/data collection instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
National Cardiovascular Data Registry (NCDR®) CathPCI Registry®

2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL
http://www.ncdr.com/WebNCDR/ELEMENTS.ASPX

2a.29-31 Data dictionary/code table web page URL or attachment: URL
http://www.ncdr.com/WebNCDR/ELEMENTS.ASPX

2a.32-35 Level of Measurement/Analysis (*Check the level(s) for which the measure is specified and tested)*
Facility/Agency

2a.36-37 Care Settings (*Check the setting(s) for which the measure is specified and tested)*
Hospital, Ambulatory Care: Hospital Outpatient

2a.38-41 Clinical Services (*Healthcare services being measured, check all that apply*)
Clinicians: PA/NP/Advanced Practice Nurse, Clinicians: Physicians (MD/DO)

TESTING/ANALYSIS

2b. Reliability testing **2b**

Comment [KP10]: 2b. Reliability testing demonstrates the measure results are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period.

2b.1 Data/sample *(description of data/sample and size)*: 1. Joint Commission validation of "Aspirin at prescribed at discharge" can be used to support the reliability of this measure. Data were reabstracted from a random sample that included a balanced distribution of hospitals based on setting (rural or urban), size, and geographic region. 227 AMI records were abstracted.

2. Reliability was established by validating the derivation cohort from version 4 CathPCI data with a testing cohort from version 3 CathPCI data. 555,023 patient records were analyzed from 1007 facilities between July 2008 and June 2009.

2b.2 Analytic Method *(type of reliability & rationale, method for testing)*:
1. Joint Commission validation of "Aspirin at prescribed at discharge" can be used to support the reliability of this measure. Reliability of individual data elements was assessed using percent agreement for continuous variable data elements and chance-corrected agreement using Cohen´s kappa for binary elements.

2. Reliability was established by validating the derivation cohort from version 4 CathPCI data with a testing cohort from version 3 CathPCI data.

2b.3 Testing Results *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
1. Joint Commission "Aspirin prescribed at discharge" measure validation results:
-Aspirin prescribed at discharge: Kappa=0.52
-Contraindication to aspirin at discharge: Kappa=0.53
-Discharge status: 94.2% agreement

2. Elements included in this measure will be included in the CathPCI registry audit program in the future. Reliability is ensured through the Data Quality Report (DQR), clearly defined and specified data elements, and through the vendor certification process to ensure data submission vendors collect data elements reliably.

The Data Quality Report (DQR) program has been developed to ensure data are valid and complete. The DQR is a process for submitting data files to the NCDR®. Participants use their data collection tool software to create a submission file which is uploaded to the NCDR website. After uploading, the data in the file is automatically checked for errors and completeness. Passing the DQR ensures well-formed data and a statistically significant submission. Types of errors detected by the DQR include:
Schema:Structure doesn't match NCDR requirements
Dates: Inconsistent dates
Selection: Missing or mismatched data; Can be a parent/child errors where a field requests more data.
Outlier: Anomalies or exceptions; Data exceeds the possible limits. For example: 1,000mm length lesion.
Counter: errors deal with Closure Methods, Lesions, and Intracoronary Devices. Each one has a counter, when more than one is used
List: Missing data in the Medications or either Device lists

Reliability of the element "PCI" is strengthened because submitters to the CathPCI registry are required to complete this element. In addition, submitters cannot enter any of the elements in the "PCI Procedure" section if they do not answer "yes" to this element. In addition, the "discharge status" (alive or deceased" element is a required element.

2. Results were consistent among the derivation cohort and the testing cohort. Specifically, the median for hospitals in the derivation cohort was 97.7% with the lowest decile 91.8% and highest decile 99.8%. This is similar to that observed in the testing cohort (median 97.3%, lowest decile 91.7%, highest decile 99.5%).

C☐ P☐ M☐ N☐

2c. Validity testing

2c.1 Data/sample *(description of data/sample and size)*: Face/content validity: review of relevant evidence and guidelines and expert panel consensus process.

2c.2 Analytic Method *(type of validity & rationale, method for testing)*:

2c C☐ P☐ M☐ N☐

Comment [k11]: 8 Examples of reliability testing include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing may address the data items or final measure score.

Comment [KP12]: 2c. Validity testing demonstrates that the measure reflects the quality of care provided, adequately distinguishing good and poor quality. If face validity is the only validity addressed, it is systematically assessed.

Comment [k13]: 9 Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP < 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed (e.g., ratings by relevant stakeholders) and the measure is judged to represent quality care for the specific topic and that the measure focus is the most important aspect of quality for the specific topic.

Face/content validity was established to ensure this measure represented an important aspect of cardiovascular care for which improvement is needed.

2c.3 **Testing Results** *(statistical results, assessment of adequacy in the context of norms for the test conducted)*:
A review of the relevant evidence and guidelines and expert panel consensus process resulted in the conclusion that this is a valid measure of quality of cardiovascular care for patients with PCI.

2d. Exclusions Justified

2d.1 **Summary of Evidence supporting exclusion(s):**
This measure exclude patients with evidence-based contraindications, or patients who are participating in a blinded research study and out of necessity the hospital is not aware of the prescribed discharge medications. This measure also excludes patients discharged to hospice, against medical advice, to another acute care hospital, or who expired prior to discharge as discharge medications to not apply to these patients. No evidence is necessary or available for these exclusions.

2d.2 **Citations for Evidence:**
N/A

2d.3 **Data/sample** *(description of data/sample and size)*: 1,282,945 patient records from the CathPCI Registry between July 2009 and June 2010 were analyzed from 1162 CathPCI Registry participants.

2d.4 **Analytic Method** *(type analysis & rationale)*:
Frequency of exclusion coding.

2d.5 **Testing Results** *(e.g., frequency, variability, sensitivity analyses)*:
Rates of exclusion coding:
-Discharged to other acute care hospital: 3,931 (0.7%)
-Discharged to hospice: 798 (0.14%)
-Discharged against medical advice: 1,232 (0.20%)
-Aspirin contraindicated or blinded: 6,682 (1.12%)
-Discharge status of deceased: 8,027 (1.42%)

2d
C☐
P☐
M☐
N☐
NA☐

2e. Risk Adjustment for Outcomes/ Resource Use Measures

2e.1 **Data/sample** *(description of data/sample and size)*: N/A

2e.2 **Analytic Method** *(type of risk adjustment, analysis, & rationale)*:
N/A

2e.3 **Testing Results** *(risk model performance metrics)*:
N/A

2e.4 **If outcome or resource use measure is not risk adjusted, provide rationale:** N/A

2e
C☐
P☐
M☐
N☐
NA☐

2f. Identification of Meaningful Differences in Performance

2f.1 **Data/sample from Testing or Current Use** *(description of data/sample and size)*: 1121 facilities in the CathPCI Registry, 566,305 patient records between July 2009 and June 2010.

2f.2 **Methods to identify statistically significant and practically/meaningfully differences in performance** *(type of analysis & rationale)*:
Distribution of aspirin prescription at discharge.

2f.3 **Provide Measure Scores from Testing or Current Use** *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:
Performance ranged from 89% at the 5th percentile to 100% at the 95th percentile. 25% of hospitals did not prescribe aspirin at discharge for 5% of its patients. Please see documentation provided in Ad.11 for

2f
C☐
P☐
M☐
N☐

Comment [KP14]: 2d. Clinically necessary measure exclusions are identified and must be:
•supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;
AND
•a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;
AND
•precisely defined and specified:
–if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);
if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category ... [3]

Comment [k15]: 10 Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, sensitivity analyses with and without the exclusion, and variability of exclusions across providers.

Comment [KP16]: 2e. For outcome measures and other measures (e.g., resource use) when indicated:
•an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified and is based on patient clinical factors that influence the measured outcome (but not disparities in care) and are present at start of care;[Error! Bookmark not defined.] OR rationale/data support no risk adjustment.

Comment [k17]: 13 Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender (e.g., poorer treatment outcomes of African American men with prostate cancer, inequalities in treatment for CVD risk factors between men and women). It is preferable to stratify measures by race and socioeconomic status rather than adjusting out differences.

Comment [KP18]: 2f. Data analysis demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful differences in performance.

Comment [k19]: 14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% v. 75%) is clinically meaningful; or whether a statistically significant difference of $25 in cost for a ... [4]

detailed analyses.

2g. Comparability of Multiple Data Sources/Methods

2g.1 Data/sample *(description of data/sample and size)*: N/A

2g.2 Analytic Method *(type of analysis & rationale)*:
N/A

2g.3 Testing Results *(e.g., correlation statistics, comparison of rankings)*:
N/A

2g
C☐
P☐
M☐
N☐
NA☐

Comment [KP20]: 2g. If multiple data sources/methods are allowed, there is demonstration they produce comparable results.

2h. Disparities in Care

2h.1 If measure is stratified, provide stratified results *(scores by stratified categories/cohorts)*: We conducted stratified analyses of hospital performance for this measure by (a) hospital safety net status (defined as government hospitals or non-government hosptials with high medicaid caseload using AHA 2008) and (b) quartiles of proportion of patients of white race. Both sets of analyses suggested that the range of hospital performance is similar irrespective of the SES of the patients treated. Specifically, the median for Safety Net hospitals was 97.7% with the lowest decile 92.0% and highest decile 99.8%. This is similar to that observed for non-Safety Net hospitals (median 97.1%, lowest decile 91.0%, highest decile 99.5%). Similarly, median hospital performance was similar across quartiles of proportion of white patients (quartile 1: 97.0%, quartile 2: 97.7%, quartile 3: 98.2%, quartile 4: 98.2%). Based on these analyses, we do not believe that a stratified measure is necessary.

2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:

2h
C☐
P☐
M☐
N☐
NA☐

Comment [KP21]: 2h. If disparities in care have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results (e.g., by race, ethnicity, socioeconomic status, gender);OR rationale/data justifies why stratification is not necessary or not feasible.

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Scientific Acceptability of Measure Properties?*

2

Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties*, **met?**
Rationale:

2
C☐
P☐
M☐
N☐

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)

Eval Rating

3a. Meaningful, Understandable, and Useful Information

3a.1 Current Use: In use

3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (*If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years*):
ACCF plans to begin voluntary public reporting of NCDR measures, including this measure, by 2012. ACCF is currently evaluating public reporting options and finalizing decisions related to location and display of information to be reported as well as communication plans.

This measure is currently used by United Healthcare Services in their UnitedHealth Premium Cardiac Specialty Center designation program.

3a.3 If used in other programs/initiatives (*If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years***):**
Used for QI by NCDR CathPCI Registry participating institutions. For Q2 of 2010, 1174 institutions submitted

3a
C☐
P☐
M☐
N☐

Comment [KP22]: 3a. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audience(s) for both public reporting (e.g., focus group, cognitive testing) and informing quality improvement (e.g., quality improvement initiatives). An important outcome that may not have an identified improvement strategy still can be useful for informing quality improvement by identifying the need for and stimulating new approaches to improvement.

data.

Participating institutions receive an institutional outcomes report each quarter with their hospital´s data. Over 2000 metrics are included in each hospital´s outcomes report. 26 metrics are highlighted in the report executive summary. These metrics are selected by an NCDR panel of experts as presenting the greatest opportunity for care improvement. CathPCI "metrics", including this measure, appear in the executive summary of the outcomes report. Hospitals receive their measure score, as well as the rates for all hospitals in the CathPCI registry, and all hospitals in the same comparison group (based on volume), and the rate for the 90th percentile. A box and whisker plot is displayed for each metric to show hospitals how they compare to all hospitals in the CathPCI registry.

This measure is also provided to the Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2) and Hospital Corporation of America (HCA) for incorporation in their QI program efforts.

Testing of Interpretability (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*)
3a.4 Data/sample *(description of data/sample and size)*: 1. 61 NCDR CathPCI Registry participants, Fall 2009.
2. Beta testing for version 4 of the CathPCI registry institutional outcomes report, 80 sites

3a.5 Methods *(e.g., focus group, survey, QI project)*:
1. Survey
2. Sites provided feedback through an excel template

3a.6 Results *(qualitative and/or quantitative results and conclusions)*:
1. 92.9% responded yes to the question "Will this measure provide important information to you?"
2. Sites provided feedback on the institutional outcomes report that was used to modify the report. Sites provided feedback on invalid data and aspects of the report that were unclear.

3b/3c. Relation to other NQF-endorsed measures

3b.1 NQF # and Title of similar or related measures:
0237 Anti-platelet medication on discharge, # 0325 Discharged on anti-platelet therapy, #0142 Aspirin prescribed at discharge for AMI

(for NQF staff use) **Notes on similar/related** endorsed **or submitted measures:**

3b. Harmonization
If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population):
3b.2 Are the measure specifications harmonized? If not, why?
Yes, measure specifications are harmonized wherever possible to endorsed measures.

3b
C☐
P☐
M☐
N☐
NA☐

3c. Distinctive or Additive Value
3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:
This measure is distinct from #0142 Aspirin prescribed at discharge for AMI (CMS) in that it applies to all PCI patients and is not isolated to MI patients. In addition, the data source for this measure is different from #142. This measure uses registry data as a data source and the CMS measure uses claims and medical record data.

5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:

3c
C☐
P☐
M☐
N☐
NA☐

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Usability*?

3

Steering Committee: Overall, to what extent was the criterion, *Usability*, **met?**
Rationale:

3
C☐
P☐

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable

Comment [KP23]: 3b. The measure specifications are harmonized with other measures, and are applicable to multiple levels and settings.

Comment [k24]: 16 Measure harmonization refers to the standardization of specifications for similar measures on the same topic (e.g., *influenza immunization* of patients in hospitals or nursing homes), or related measures for the same target population (e.g., eye exam and HbA1c for *patients with diabetes*), or definitions applicable to many measures (e.g., age designation for children) so that they are uniform or compatible, unless differences are dictated by the evidence. The dimensions of harmonization can include numerator, denominator, exclusions, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.

Comment [KP25]: 3c. Review of existing endorsed measures and measure sets demonstrates that the measure provides a distinctive or additive value to existing NQF-endorsed measures (e.g., provides a more complete picture of quality for a particular condition or aspect of healthcare, is a more valid or efficient way to measure).

	M☐ N☐
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	Eval Rating
4a. Data Generated as a Byproduct of Care Processes 4a.1-2 **How are the data elements that are needed to compute measure scores generated?** Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)	**4a** C☐ P☐ M☐ N☐
4b. Electronic Sources 4b.1 **Are all the data elements available electronically?** (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*) Yes 4b.2 **If not, specify the near-term path to achieve electronic capture by most providers.**	**4b** C☐ P☐ M☐ N☐
4c. Exclusions 4c.1 **Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?** No 4c.2 **If yes, provide justification.**	**4c** C☐ P☐ M☐ N☐ NA☐
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences 4d.1 **Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.** The NCDR program takes a number of steps to minimize any potential for inaccuracies or errors in data used to report on performance back to hospitals. The process begins with support provided to data abstractors, including webinars, meetings, resource guides on the website, and clinical quality consultants available via e-mail or toll free phone number, to ensure consistent data collection. The NCDR establishes a unified electronic platform for data capture and submission that includes a certification process of the technical data collection tool selected by the hospital (either a commercially available software vendor product, the NCDR's own web base data collection tool, or a hospital's customized electronic medical record system) that must occur prior to any data submissions. The certification process provides edit checks of data elements within data collection tool to ensure high quality data submission. The NCDR data submission process includes a Data Quality Report (DQR) process that checks for validity in submissions based upon predetermined thresholds for element and composite completeness. The NCDR is putting in place a new strategy to systematically review the DQR results. The NCDR on-site audit program has been developed to assess reliability of data abstraction. This annual process reviews key elements at a select number of patient reports at the select number of sites and provides feedback scores to the hospitals. Any elements not currently included in the on-site audit process and deemed critical to capture for this measure will be added upon NQF endorsement.	**4d** C☐ P☐ M☐ N☐
4e. Data Collection Strategy/Implementation 4e.1 **Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation**	**4e** C☐ P☐ M☐ N☐

Comment [KP26]: 4a. For clinical measures, required data elements are routinely generated concurrent with and as a byproduct of care processes during care delivery. (e.g., BP recorded in the electronic record, not abstracted from the record later by other personnel; patient self-assessment tools, e.g., depression scale; lab values, meds, etc.)

Comment [KP27]: 4b. The required data elements are available in electronic sources. If the required data are not in existing electronic sources, a credible, near-term path to electronic collection by most providers is specified and clinical data elements are specified for transition to the electronic health record.

Comment [KP28]: 4c. Exclusions should not require additional data sources beyond what is required for scoring the measure (e.g., numerator and denominator) unless justified as supporting measure validity.

Comment [KP29]: 4d. Susceptibility to inaccuracies, errors, or unintended consequences and the ability to audit the data items to detect such problems are identified.

Comment [KP30]: 4e. Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, etc.) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use).

issues:
Beta testing with a set of registry participants takes place with each new registry version to identify errors in the data collection tool. In addition, modifications are made to metrics based on feedback during a public comment period.

The Data Quality Report (DQR) program has been developed to ensure data are valid and complete. The DQR is a process for submitting data files to the NCDR®. Participants use their data collection tool software to create a submission file which is uploaded to the NCDR website. After uploading, the data in the file is automatically checked for errors and completeness. Passing the DQR ensures well-formed data and a statistically significant submission. Types of errors detected by the DQR include:
Schema:Structure doesn't match NCDR requirements
Dates: Inconsistent dates
Selection: Missing or mismatched data; Can be a parent/child errors where a field requests more data.
Outlier: Anomalies or exceptions; Data exceeds the possible limits. For example: 1,000mm length lesion.
Counter: errors deal with Closure Methods, Lesions, and Intracoronary Devices. Each one has a counter, when more than one is used
List: Missing data in the Medications or either Device lists.

4e.2 **Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:**
CathPCI participants pay a fee of $3,800/year to enroll in the registry. Staff resources are needed for data collection and submission at the participating institution. Registry site managers/data collectors undergo (non-mandatory) training offered by the NCDR.

4e.3 **Evidence for costs:**
http://www.ncdr.com/WebNCDR/ncdrdocuments/B08352N%20CathPCI%20Registry%20Enrollment%20Packet%20Complete.pdf

4e.4 **Business case documentation:**

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility*?

4

Steering Committee: Overall, to what extent was the criterion, *Feasibility*, **met?**
Rationale:

4
C☐
P☐
M☐
N☐

RECOMMENDATION

(for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.**

Time-limited ☐

Steering Committee: Do you recommend for endorsement?
Comments:

Y☐
N☐
A☐

CONTACT INFORMATION

Co.1 **Measure Steward (Intellectual Property Owner)**
Co.1 **Organization**
American College of Cardiology Foundation, 2400 N Street NW, Washington, District Of Columbia, 20037

Co.2 **Point of Contact**
Kristyne, McGuinn, MHS, kmcguinn@acc.org, 202-375-6529-

Measure Developer If different from Measure Steward
Co.3 **Organization**
American College of Cardiology Foundation, 2400 N Street NW, Washington, District Of Columbia, 20037

Co.4 Point of Contact
Kristyne, McGuinn, MHS, kmcguinn@acc.org, 202-375-6529-

Co.5 Submitter If different from Measure Steward POC
Kristyne, McGuinn, MHS, kmcguinn@acc.org, 202-375-6529-, American College of Cardiology Foundation

Co.6 Additional organizations that sponsored/participated in measure development
Society for Cardiovascular Angiography and Interventions (SCAI)

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.
The CathPCI Steering Committee developed the initial metrics used for quality improvement in the CathPCI outcomes reports. The measures were selected for appropriateness for public reporting by the NCDR public reporting workgroup.

CathPCI Steering Committee:
Douglas Weaver, MD, FACC
Ronald Krone, MD, FACC
Gregory Dehmer, MD, FSCAI
John Messenger, MD, FACC
Lloyd Klein, MD, FACC
John Rumsfeld, MD, PhD, FACC
John Carroll, MD, FACC
Mauro Moscucci, MD, FACC
Jeffrey Popma, MD, FACC
Issam Moussa, MD, FSCAI
Kirk Garratt, MD, FSCAI
David Malenka, MD, FACC

Public Reporting Workgroup:
Fred Masoudi, MD, MSPH, FACC, FAHA, FACP
H. Vernon Anderson,MD, FACC, FSCAI
David Malenka, MD, FACC
Matt Roe, MD, FACC
Steve Hammill, MD, FHRS, FACC
Jeptha Curtis, MD, FACC
Paul Heidenreich, MD, MS, FACC
Brahmajee Nallamothu, MD, MPH, FACC
Mark Kremers, MD, FACC
Christopher White MD, FACC
Carl Tommaso, MD, FACC, FAHA, FSCAI
Sunil Rao, MD, FACC, FSCAI
Andrea Russo, MD, FACC, FHRS
Debabrata Mukherjee MD, FACC

Ad.2 If adapted, provide name of original measure: N/A
Ad.3-5 If adapted, provide original specifications URL or attachment

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.6 Year the measure was first released: 2005
Ad.7 Month and Year of most recent revision: 07, 2009
Ad.8 What is your frequency for review/update of this measure? Every 3-4 years or if guideline updates warrant more frequent update, or with new dataset version.
Ad.9 When is the next scheduled review/update for this measure? 06, 2011

Ad.10 Copyright statement/disclaimers:

Ad.11 -13 Additional Information web page URL or attachment: Attachment DASA Finalpdf.pdf

Date of Submission (*MM/DD/YY*)**:** 10/28/2010

Page 3: [1] Comment [k4] **Karen Pace** **10/5/2009 8:59:00 AM**

1c. The measure focus is:

- an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;

OR

- if an intermediate outcome, process, structure, etc., there is **evidence** that supports the specific measure focus as follows:
  - Intermediate outcome – evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
  - Process – evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and
    if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
  - Structure – evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
  - Patient experience – evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of individuals/ the public.
  - Access – evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
  - Efficiency – demonstration of an association between the measured resource use and level of performance with respect to one or more of the other five IOM aims of quality.

Page 3: [2] Comment [k5] **Karen Pace** **10/5/2009 8:59:00 AM**

4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., mammography) or measures for multiple care processes that affect a single outcome.

Page 10: [3] Comment [KP14] **Karen Pace** **10/5/2009 8:59:00 AM**

2d. Clinically necessary measure exclusions are identified and must be:

- supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;

AND

- a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;

AND

- precisely defined and specified:
  - if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);

if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

Page 10: [4] Comment [k19] **Karen Pace** **10/5/2009 8:59:00 AM**

14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% v. 75%) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v. $5,025) is practically meaningful. Measures with overall poor performance may not demonstrate much variability across providers.

NCDR™ National Cardiovascular Data Registry

CathPCI Registry®

ENROLLMENT INSTRUCTIONS

Thank you for your interest in the NCDR® CathPCI Registry®. Enrolling is as easy as 1-2-3:

1. The first step in completing the enrollment process is for you to review the following documents:

- **Participant Contact Information Form:** This form provides the CathPCI Registry account management team with appropriate contact information for your hospital.
- **NCDR Master Agreement:** This 22-page agreement details the obligations of NCDR and the obligations of the hospital entity as they relate to general registry operations.
- **CathPCI Registry-Specific Addendum:** This 3-page document details the obligations of both parties that are unique to the CathPCI Registry.
- **An invoice for 2010 participation dues and implementation fee** based on your date of enrollment.

2. Next, fill out the contact information form, sign and date the master agreement and addendum, and include the completed documents with your check made payable to the *American College of Cardiology Foundation*. Annual participation dues are prorated as outlined in the chart below:

Date of Enrollment	Participation Dues	Implementation Fee	Total Due
January 1, 2010 – June 30, 2010	$3,685	$1,000	**$4,685**
July 1, 2010 – December 31, 2010	$1,845	$1,000	**$2,845**

3. Send your completed enrollment packet: 1) the Participant Contact Information form, 2) the NCDR Master Agreement, 3) the CathPCI Registry-Specific Addendum, 4) your invoice, and 5) your check for your participation dues and implementation fee to:

American College of Cardiology Foundation
Attn: 2009 NCDR CathPCI Registry Enrollment
P.O. Box 79231
Baltimore, MD 21279-0231

As soon as we receive and process your documents and check (please allow 10 business days for processing of your enrollment materials), we'll send you an email with your NCDR Participant ID Number and your User ID and Password for the CathPCI Registry User Website.

NCDR offers a Web-based data entry tool as a benefit of participation in the CathPCI Registry. We have also contracted with several commercial vendors that offer a wide range of certified software packages. We encourage you to explore all of your options for data collection by visiting **www.ncdr.com**. After enrollment, you'll be asked to select either the Web-based data entry tool or one of the vendor software packages.

If you have any questions about the enrollment process, please call a CathPCI Registry Support Specialist at **800-257-4737.**

On behalf of NCDR, we look forward to your participation in the CathPCI Registry.

Sincerely,

The NCDR CathPCI Registry Account Management Team

The CathPCI Registry is an initiative of the American College of Cardiology Foundation, with partnering support from the Society for Cardiovascular Angiography and Interventions.

B08352N-P

NCDR™ National Cardiovascular Data Registry

CathPCI Registry®

PARTICIPANT CONTACT INFORMATION

Please complete the information requested below and include this document when you return your enrollment materials. *Only completed forms with valid email addresses will be processed.*

NOTE: Health systems must complete one form for each hospital enrolling.

HOSPITAL (please print clearly and legibly)

Health System (if applicable)	
Hospital Name	
Address 1	
Address 2	
City/State/ZIP Code	

REGISTRY SITE MANAGER (please print clearly and legibly)

Contact (First Name, Last Name)	
Title	
Address 1	
Address 2	
City/State/ZIP Code	
Telephone	( )
Fax	( )
Email	@

CONTRACT MANAGER (please print clearly and legibly)

Contact (First Name, Last Name)	
Title	
Address 1	
Address 2	
City/State/ZIP Code	
Telephone	( )
Fax	( )
Email	@

CARDIOSOURCE® SETUP (please print clearly and legibly): Registry participation also includes free access to Cardiosource, our educational Website that includes over 1,000 clinical trials, all ACC evidence-based practice guidelines, study guides, and more.

Technical Contact (First Name, Last Name)	
Email	@
IP Address Range*	

IP addresses may be obtained from your Information Technology network staff. Please advise them we need the network source address block(s) for your NAT range or any proxy servers which provide your users with access to the internet. These are the IP range(s) from which we would see them as originating. For example, if you own the following 25.254..* network range but your users only originate from a smaller subnet range (ex. 25.254.5.*), please submit that subnet range. We are only interested in network addresses, not subnet masks (ex. 255.255.255.0). If you have multiple addresses, please separate by a semicolon (ex. 155.246.*.*; 129.35.2.*). For additional information, please contact technical support at csinst@acc.org.

2010 MASTER AGREEMENT

NCDR® AGREEMENT BY AND BETWEEN
THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION
AND

_____

THIS AGREEMENT is made this ____ day of _____, 20___ ("Effective Date"), between the American College of Cardiology Foundation ("ACCF"), a non-profit, tax–exempt District of Columbia corporation located at 2400 N Street NW, Washington, DC 20037 and _____ ("Participant"), located at _____ (city/state). ACCF and Participant shall be referred to herein collectively as the "Parties" and individually as a "Party."

WHEREAS, ACCF has developed the National Cardiovascular Data Registry Program ("NCDR") to collect and report on standardized, national, clinical cardiovascular data in connection with different cardiovascular procedures, in which Participant desires to participate;

WHEREAS, NCDR permits comparisons of Participant data with national or regional summary data to aid Participants in their data completeness and consistency programs and other efforts to improve patient care;

WHEREAS, NCDR now consists of five unique hospital-based registries: the CathPCI Registry®, the ICD Registry™, the CARE Registry®, and the ACTION Registry®–GWTG™, and the IMPACT Registry™, as well as one office-based registry, the PINNACLE Registry™; (individually a "Registry" or collectively as the "Registries");

WHEREAS, Participant desires to participate in NCDR in one or more of the Registries to improve the quality of cardiovascular care;

WHEREAS, the Parties understand that the provision by ACCF of benchmarking and data aggregation services to Participant qualifies ACCF as a "Business Associate" with respect to Participant pursuant to the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (45 C.F.R. Parts 160 and 164, as amended) ("HIPAA"); and

NOW, THEREFORE, in consideration of the mutual promises and Agreements set forth, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by ACCF and Participant:

IT IS AGREED:

1. Participation in NCDR. Participant hereby agrees to participate in NCDR, and ACCF hereby agrees to permit Participant to participate in one or more of the Registries as provided herein. For purposes of this Agreement, a Participant is defined as a single facility or practice located in a discrete geographic area that is enrolled in NCDR through a Participant Agreement, and is eligible to submit relevant cardiovascular data to one of the Registries.

a. Additional Registries. If NCDR elects to establish an additional Registry, Participant may elect whether to participate in it.

2. Participant Responsibilities.

a. Submission of Clinical Data. Participant agrees to furnish clinical data in a manner consistent with this Agreement, relevant to the Registries in which it is participating, directly to NCDR in quarterly installments for at least a twelve (12) month period as provided under this Agreement.

i. Participant agrees that its data may be rejected by ACCF if Participant data is determined by ACCF to fail the NCDR data evaluation and acceptance process.

ii. Participant agrees to submit quarterly data within the "call for data period" as published by the ACCF.

iii. Participant agrees that submitted data will conform to Paragraphs 2.b., 2.d., 2.e., 2.f., and 2.h. of this Agreement.

b. Use of ACCF Data Set and ACCF-Approved Software. Participant will submit a data record on each patient who receives medical care and who is eligible for inclusion in the Registries in which Participant is participating under this Agreement. Participant agrees to use the Registry-specific data elements, definitions, and transmission format approved by ACCF and published in the NCDR Core Data Element Documentation ("ACCF Data Set") provided to Participant, and as amended by ACCF from time to time. Data must be submitted using ACCF-approved software from either ACCF or a vendor otherwise contracting with ACCF to provide such software, in formats that meet required transmission specifications as set forth in Section 2.c., or otherwise communicated to the Participant by ACCF from time to time. Participant agrees that Participant is solely responsible for selecting a software vendor from those vendors approved by ACCF, and that ACCF approval does not constitute an endorsement or guarantee of the performance of the selected vendor or the selected vendor's product.

c. Manner of Communication. Participant shall provide data to ACCF for purposes of the NCDR by secure website at www.ncdr.com. In addition, Participant shall designate a valid e-mail address that ACCF shall utilize to communicate with the Participant; such e-mail address shall only be accessible by the Participant's Registry Site Manager. Participant hereby acknowledges that ACCF will use such e-mail address to communicate pertinent information regarding Registry-specific issues. Participant shall submit data to ACCF for Registries electronically, utilizing methods determined by the ACCF. All submissions of data shall be submitted to ACCF utilizing ACCF-approved encryption software. Furthermore, the Participant shall maintain an updated institutional profile including ensuring that ACCF has a

valid e-mail address for the Registry Site Manager at all times in the form identified by ACCF.

d. Corroboration of Patient Data. Participant will furnish to NCDR independent corroboration, in a form satisfactory to ACCF in its sole, reasonable discretion, that all eligible patients' records have been submitted, based upon case volume counts or similar data from Participant's admitting/registration, cath lab log, billing, and/or medical records information or other hospital-based information system.

e. Data Collection Staff. Participant's data collection shall be performed by staff trained through the ACCF training program including Registry-specific offerings from ACCF promptly after any such training program is made available by ACCF to Participant. Participant agrees that its data collection staff shall adhere to the standards published in the current NCDR Core Data Element Documentation provided to Participant, and as updated from time to time. The current ACCF training program, included in the annual fee, consists of webinars, self-directed study using resources on the NCDR website as well as individualized clinical support. ACCF also offers additional and optional training, available for an additional charge at ACCF workshops which Participant shall encourage its staff to attend.

f. Registry Site Manager. Participant will designate a Registry Site Manager who will serve as the primary point of contact for each Registry and will supervise the data collection, confirm the accuracy of the data, receive the confidential reports, and act as direct liaison with ACCF. ACCF recommends that the Registry Site Manager be an experienced clinical professional such as the Clinical Service Line Director, a senior-level Registered Nurse, or a similarly trained and qualified representative of the quality improvement department; and if ACCF determines that any Registry Site Manager is not sufficiently trained or credentialed in this manner, Participant will identify an alternate individual to serve in that capacity. Participant also agrees to notify ACCF within ten (10) working days of any change in the Registry Site Manager. The Participant's Medical Director or his/her designee, identified to ACCF in writing as such, must approve all data submissions.

g. Data Evaluation and Acceptance Process. Participant agrees that its submitted patient data may be audited for accuracy and completeness by or on behalf of ACCF. In addition, all submissions are required to meet the NCDR inclusion threshold as defined in the current NCDR release provided to Participant, and as updated by ACCF from time to time, in order for Participant's data to be included in the national averages. Participant understands and agrees that auditing may include an onsite review of patient medical records and additional supporting documentation. The onsite audit process will consist of an audit of randomly selected charts and an evaluation of the process for data collection. In the event that a Participant is selected for an audit, the initial audit will be at the expense of ACCF, and Participant agrees to cooperate in such audit through making available documentation and access to Participant's staff. Participant agrees that if an audit

process or the application of threshold criteria find the data do not conform to ACCF standards, as a condition of continued participation in NCDR, the Participant shall submit within forty-five (45) days of notice of the audit an action plan, in a form acceptable to ACCF, to correct such data issues, as well as, in the sole discretion of ACCF, submit to an onsite audit conducted by a third-party auditor chosen by ACCF at the Participant's sole expense. Furthermore, the non-conforming data submitted by the Participant will be withheld from the ACCF database for national reporting purposes until such data is brought up to standard and re-submitted to ACCF by the Participant. Moreover, during any such correction period, while Participant may receive information comparing its data to general data from a Registry, ACCF makes no representation or warranty concerning the reliability of any such comparison or the conclusions Participant may draw from it.

h. Voluntary Audit Process. If Participant voluntarily chooses to have its data audited, Participant will fund the full cost of the audit, the results of which shall be available to both Parties. Only ACCF-approved auditors may perform the audit process. If such voluntary audit reveals data do not conform to ACCF standards or this Agreement, the process described in Section 2.g. shall be enforced.

i. Identifiers. Participant agrees that unique patient identifiers and unique physician identifiers will be collected for each record submitted to the NCDR.

j. Data Confidentiality. Participant shall maintain appropriate procedures to safeguard data confidentiality in compliance with applicable law. Participant will be solely responsible for any and all of its acts or omissions regarding the privacy and security of the data it furnishes hereunder. Participant shall maintain appropriate liability insurance for its acts and omissions under this paragraph.

3. ACCF Responsibility.

a. Acceptance of Data. ACCF agrees to accept Participant's clinical data, subject to review by ACCF, except where the submitted data does not conform to this Agreement, including, without limitation, the data evaluation and acceptance process and standards established by NCDR, and as updated from time to time by ACCF. In such cases, ACCF reserves the right to either reject the data submission in its entirety, or to limit the use of such data, if it does not meet the required ACCF standards, both with respect to new data and as set forth in Section 2.g. Data may only be accepted if submitted using ACCF-approved software obtained from ACCF or a vendor approved by ACCF, under ACCF-approved formats and processes.

b. Reports. ACCF agrees to generate institutional reports for each Registry based on Participant's submitted data, and to distribute reports to Participants. Reports include aggregated demographic, general procedural information, and patient outcomes in a form made available by ACCF to Participants, and as updated by ACCF from time to time. Data Quality Reports will be distributed with each data submission within this Agreement and paid-through-relevant time period. Institution-specific and

national reports will be distributed both quarterly and annually within this Agreement and paid-through-relevant time period.

c. Use of ACCF Data Set. ACCF agrees to produce, disseminate, and periodically revise the data elements, definitions, and formats, and to certify software that allows Participants to directly transmit their patient data to NCDR.

d. Training. ACCF will provide documents and programs that serve as resources that guide Participant's data collection activities.

e. Data Accuracy. ACCF will analyze the Participant's submitted data records by means of electronic data checks, consistency checks, and range checks to review data accuracy and completeness and determine aggregate completion rates, and will return Data Quality Reports to Participant within thirty (30) days after submission. All reasonable efforts will be made by ACCF to communicate with Participant's Registry Site Manager to assist the Participant in providing the submitted data.

f. Data Assessment Audit. ACCF may, at its option, audit submitted patient data to review its accuracy and completeness. ACCF will notify Participant within forty-five (45) days of the completion of the audit process (completion and return of data from the auditor) of the results of the audit and any action that the Participant may need to take as a result of the audit, and may take any actions in response as provided in Section 2.g. of this Agreement.

g. Identifiers. ACCF will accept unique patient identifiers and unique physician identifiers for each record submitted to NCDR by Participant.

4. Privacy Laws; Security.

a. Compliance with Privacy Laws. The Parties agree to abide by all federal, state, and local laws pertaining to confidentiality and disclosure with regard to all information or records obtained and reviewed hereunder. ACCF acknowledges that it is a "Business Associate" as defined and referred to under HIPAA. Accordingly, ACCF shall take reasonable steps to comply with the requirements under HIPAA for Business Associates as set forth in Appendix A to this Agreement ("Business Associate Agreement"). ACCF will have all rights, as well as all responsibilities, set forth in Appendix A as if fully set forth herein.

b. Security. ACCF will take reasonable steps to maintain its security policies and procedures to protect Participant data as provided in Appendix A. If ACCF determines that a breach of security has occurred, ACCF will promptly notify Participant. ACCF will be responsible for its acts and omissions regarding the privacy and security of the data it maintains under this Agreement.

5. Use of Names and Logos.

   a. Use of ACCF Name. Without the express prior written consent of ACCF, Participant shall not make any announcements concerning the matters set forth in this Agreement, use the word or symbol ACCF, ACC, NCDR® or any trademarks or service marks of ACCF, ACC, and ACCF business partners, or make any reference to ACCF, ACC, and ACCF business partners in any advertising or promotional material, letterhead, symbol or logo, or other communication that is not strictly internal to participant, or in any other manner, including, without limitation, press releases or lists.

   b. Use of Participant's Logo/Trademarks. Without the express prior written consent of Participant, ACCF shall not use the logos, trademarks or service marks of Participant.

6. Data and Copyright Ownership.

   a. Individual Patient Data. The data for individual patients submitted by Participant shall be the exclusive property of Participant, subject to the rights, if any, of the Participant's patients in Individually Identifiable Health Information, and subject to the rights granted to ACCF in this Agreement and the Business Associate Agreement. Participant hereby agrees the return of that information is infeasible as it has been integrated into the Registries. Participant grants to ACCF a perpetual, enterprise-wide, royalty-free license, that is worldwide and in all forms and all media (including derivative works), to use the data of individual patients submitted by Participant in such manner that is consistent with this Agreement. To the extent ACCF develops de-identified or similar data that is not Individually Identifiable Health Information from the data submitted by Participant for individual patients, ACCF shall exclusively own such data, and any derivative works from it, as Intellectual Property Rights owned by ACCF.

   b. Intellectual Property; Aggregate Data. All Intellectual Property Rights and title to all proprietary information in and rights to any software, database, NCDR, Registries, any data submitted and accepted by ACCF for use in the NCDR program, aggregate data and the compilation of the same with any other data received in connection with the NCDR program, and any derivative works using the Registries, including, without limitation, any reports, calculations and models based thereon, and De-identified Data as described in Section 6.a., including, without limitation, all copyrights, patent rights, trademarks, trade secret rights, and any other rights and interest in any of the foregoing shall be and remain at all times for all purposes with ACCF. For purposes of this Agreement, "Intellectual Property Rights" means all, or any intermediate version or portion, of any formulas, processes, outlines, algorithms, ideas, inventions, know how, techniques, intangible, proprietary and industrial property rights and all intangible and derivative works thereof, including, without limitation, any and all now known or hereafter existing, in and to (i) trademarks, trade name, service marks, slogans, domain names, uniform resource locators or

logos; (ii) copyrights, moral rights, and other rights in works of authorship, including, but not limited to, compilations of data; (iii) patents and patent applications, patentable ideas, inventions and innovations; (iv) know-how and trade-secrets; and (v) registrations, applications, renewals, extensions, continuations, divisions or reissues of the foregoing. ACCF reserves the right to use De-identified Data and Protected Health Information ("PHI") in electronic or other format whether or not contained in a Limited Data Set as discussed more fully in Appendix A, including, without limitation, to support ongoing improvements and enhancements to NCDR. Once Participant data is accepted by ACCF into NCDR for analysis and reporting, this data becomes part of the NCDR aggregate data and it cannot be retracted from NCDR by Participant. Information to which ACCF has access or ownership under this Section 6 shall not be considered Confidential Information to be returned to Participant under Section 9.

c. Publication. If Participant desires to publish or otherwise distribute or use, in whole or in part, any aggregate data or reports provided by ACCF, or produced in connection with or derived from NCDR, with the exception of strictly internal use within the Participant as defined in Section 1, Participant must first obtain the prior express written consent of ACCF. To the extent Participant is permitted to publish aggregate data, such aggregate data and any related information published in connection with it must be reviewed and approved by ACCF prior to publication.

7. Participant Fees. Participant will pay ACCF an annual fee for each Registry to participate in that Registry. Payment of the annual fee includes quarterly submission of data, ACCF-supplied self-training documentation, and distribution of Data Quality Reports and Institution-specific Reports. From time to time, ACCF may develop other reports and products for an additional charge. Unless overnight delivery is requested by Participant, there will be no handling or shipping charges. The entire annual fee is non-refundable even if this Agreement is terminated prior to the end of the term.

8. Term, Enforcement and Termination. This Agreement shall be effective until December 31, 2010, then renew automatically for additional one (1) year terms unless the Participant provides ACCF with ninety (90) days' advance written notice of its desire to terminate the Agreement at the end of the then-current term. The Parties agree that this Agreement may be enforced or terminated with respect to any particular Registry, without initiating or impairing any Party's right to enforce any right with respect to any other Registry or this Agreement as a whole.

a. Termination for Breach. Either Party may terminate this Agreement upon the other Party's material breach of this Agreement by providing the non-breaching Party with thirty (30) days written notice of its intention to terminate for a material breach. The breaching Party shall have thirty (30) days from the date of such notice to cure the breach. If, after thirty (30) days of the date of such notification, the breach is not cured to the satisfaction of the non-breaching party, this Agreement will terminate automatically at the end of the foregoing thirty (30) day period. Notwithstanding the foregoing, the non-breaching party may determine, in its sole discretion, that the

breach cannot be reasonably cured within the foregoing thirty (30) day period and may extend the cure period by written notice to the breaching party.

b. Termination Without Cause. Either Party may terminate this Agreement without cause by providing the other with at least ninety (90) days written notice.

c. Termination for Failure to Meet Data Completeness and Consistency Requirements. ACCF reserves the right to immediately terminate this Agreement and Participant's participation in NCDR if it determines that any two (2) calendar quarters of Participant's data within a rolling twelve (12) calendar–month period are noncompliant with NCDR standards or otherwise unacceptable for inclusion in the NCDR national averages. ACCF may, in its sole discretion, provide the Participant with the opportunity to cure the inadequate data as stated in Section 2.g. without affecting the rights of ACCF to terminate this Agreement under this Section or otherwise.

d. Termination of Software Use. Upon termination of this Agreement, Participant agrees that it shall not use NCDR software or the NCDR dataset for collecting and reporting data, or any other purpose, without the express written consent of ACCF, except as necessary to wind down Participant's participation in a Registry or the NCDR as a whole. Furthermore, Participant agrees that ACCF may notify Participant's approved software vendor of the termination of this Agreement as to any Registry or in its entirety, and agrees that it will allow its approved software vendor under Section 2.b. to terminate any such software license to Participant without penalty to such vendor, and to prevent further use of the software, including its use for data entry by Participant into the NCDR dataset.

9. Confidentiality.

a. Confidentiality. For the purposes of this Agreement, "Confidential Information" means any software, material, data, or business, financial, operational, customer, vendor and other information disclosed by one Party to the other and not generally known by or disclosed to the public or known to the receiving Party solely by reason of the negotiation or performance of this Agreement, and shall include, without limitation, the terms of this Agreement. Each Party shall maintain all of the other Party's Confidential Information in strict confidence and will protect such information with the same degree of care that such Party exercises with its own Confidential Information, but in no event with less than a reasonable degree of care. Except as provided in this Agreement, a Party shall not use or disclose any Confidential Information of the other Party in any manner without the express prior written consent of such Party, with the exception that ACCF may share a Participant's identification number ("Participant ID") with that Participant's software vendor so long as such vendor is approved as provided in this Agreement. Access to and use of any Confidential Information shall be restricted to those employees and persons within a Party's organization with known discretion and with a need to use the information to perform such Party's

obligations under this Agreement. A Party's consultants, subcontractors, and business partners shall be included within the meaning of "persons within a Party's organization," provided that such consultants, subcontractors, and business partners have executed a non-disclosure or confidentiality agreement with provisions no less stringent than those applicable to such Party under this Agreement, and such Party shall make such signed agreements available to the other Party upon request. Notwithstanding anything herein to the contrary, Confidential Information shall not include information that is: (a) already known to or otherwise in the possession of a Party at the time of receipt from the other Party, and that was not known or received as the result of violation of any obligation of confidentiality; (b) publicly available or otherwise in the public domain prior to disclosure by a Party; (c) rightfully obtained by a Party from any third party having a right to disclose such information without restriction and without breach of any confidentiality obligation by such third party; (d) developed by a Party independent of any disclosure hereunder, as evidenced by detailed written records made in the normal course of Participant's business during the development process; or (e) disclosed pursuant to the order of a court or administrative body of competent jurisdiction or a government agency, provided that the Party receiving such order shall notify the other prior to such disclosure, and shall cooperate with the other Party in the event such Party elects to legally contest, request confidential treatment, or otherwise avoid such disclosure.

b. Return of Confidential Information. Except as otherwise provided herein, all of a Party's Confidential Information disclosed to the other Party, and all copies thereof, shall be and remain the property of the disclosing Party. All such Confidential Information, and any and all copies and reproductions thereof, shall, upon the expiration or termination of this Agreement for any reason, or within fifteen (15) days of written request by the disclosing Party, be promptly returned to it, or destroyed, at the disclosing Party's direction. In the event of such requested destruction, the Party receiving such request shall provide to the other Party written certification of compliance therewith within fifteen (15) days of such written request. Notwithstanding the provisions of this Section 9, any information governed by Section 6.a. or 6.b. or the provisions of the Business Associate Agreement shall be governed, respectively, by those Sections of this Agreement, as applicable.

10. Indemnification.

a. ACCF Indemnity. ACCF will indemnify, defend, and hold Participant harmless from any third-party claim, demand, cause of action, lawsuit, or proceeding brought against Participant based upon any gross negligence or willful misconduct on the part of ACCF, provided, however, that any such liability for any such indemnification shall be limited to and not exceed the amount of any fees paid by Participant in the year the liability arose. Such indemnification may include: (1) reasonable attorneys' fees and costs associated with defense of such claim; (2) damages and costs finally awarded; and (3) the cost of any settlement

entered into by ACCF. Such indemnification obligation is contingent on Participant: (i) notifying ACCF of any such claim within thirty (30) days of Participant's notice of such claim; (ii) providing ACCF with reasonable information, assistance, and cooperation in defending the lawsuit or proceeding (to the extent requested by ACCF); and (iii) giving ACCF full control and sole authority over the defense and settlement of such claim. ACCF will not enter into any settlement or compromise of any such claim without Participant's prior consent, which shall not be unreasonably withheld.

b. Participant's Indemnities. Participant will indemnify, defend, and hold ACCF and ACCF's employees, officers, directors, agents, contractors, and business partners (collectively as the "ACCF Indemnitees") harmless from any third-party claim, demand, cause of action lawsuit, or proceeding brought against one or more ACCF Indemnitees based upon: (1) any errors or inaccuracies contained in the data as delivered by Participant to ACCF; (2) any medical treatment, diagnosis or prescription rendered by Participant or its agents (including physicians and healthcare professionals); (3) Participant failing to have all rights in the data necessary to use NCDR and to disclose such information to ACCF; and (4) the use of Registry reports in connection with any quality assurance, peer review, or similar administrative or judicial proceeding; and (5) any claim that is based, in whole or in part, on a breach of any warranty, representation or covenant made by Participant under this Agreement, including, but not limited to, any third-party lawsuit or proceeding brought against ACCF or any of ACCF Indemnitees based upon a claim that any data submitted by Participant infringe any third-party rights. Participant's indemnification will include: (i) all attorneys' fees and costs associated with defense of such claim; (ii) all damages and costs finally awarded; and (iii) the full cost of any settlement entered into by Participant.

11. Limitation of Liability. The aggregate liability of ACCF Indemnitees under this Agreement for any and all claims and causes of action, including, without limitation, any action predicated on indemnification as set forth in Section 10.a. above, shall be limited to and not exceed the amount of any fees paid by Participant in the year the liability arose, regardless of whether ACCF has been advised of the possibility of such damages, or any remedy set forth herein fails of its essential purpose or otherwise. ACCF Indemnitees shall not be liable for any other damages or costs, including costs of procurement of substitutes, loss of profits, loss of activity data or other information, inability to access the services or software, interruption of business, or for any other special, consequential, or incidental damages, however caused, whether, without limitation, for breach of warranty, contract, tort, infringement, negligence, strict liability or otherwise. Participant acknowledges that the NCDR fees and business model reflect this allocation of risk. Participant agrees it will take no legal action against ACCF, ACCF subcontractors, ACCF business partners, software or other Participants.

12. Notices. All notices and demands of any kind or nature which either Party to this Agreement may be required or may desire to serve upon the other in connection with this Agreement shall be in writing, and may be served personally, by registered or certified United States

mail, or by overnight courier (e.g., Federal Express, DHL, or UPS) to the following addresses:

If to the Participant: _____
_____
_____
_____
_____
_____

With a copy to: _____
_____
_____
_____
_____
_____

If to ACCF: American College of Cardiology Foundation
2400 N Street NW
Washington, DC 20037
Attn: General Counsel

Service of such notice or demand so made shall be deemed complete on the day of actual delivery. Any Party hereto may, from time to time, by notice in writing served upon the other Party as aforesaid, designate a different mailing address or a different person to which all further notices or demands shall thereafter be addressed.

13 Headings. The headings of the various paragraphs hereof are intended solely for the convenience of reference and are not intended for any purpose whatsoever to explain, modify, or place any construction upon any of the provisions of this Agreement.

14 Assignment. Neither this Agreement nor either Parties' rights and obligations hereunder may be assigned to a third party without the prior written consent of the non-assigning Party; provided, however, that ACCF may assign this Agreement and its rights and obligations to a parent or an entity controlled by or under common control with ACCF, or a venture or entity in which ACCF has a majority ownership interest, or upon a change of control of ACCF, without the consent of the Participant.

15 Relationship of Parties. The relationship of the Parties to this Agreement is that of independent contractors and not that of master and servant, principal and agent, employer and employee, or partners or joint venturers.

16 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which taken together shall constitute one and the same instrument.

17 Waiver. A waiver by either Party to this Agreement of any of its items or conditions in any one instance shall not be deemed or construed to be a general waiver of such term or condition or a waiver of any subsequent breach.

18 Governing Law. This Agreement will be governed by and construed exclusively in accordance with the laws of the District of Columbia, without regard to any conflicts of law principles applied. The Parties agree that United Nations Convention on Contracts for the International Sale of Goods does not apply to this Agreement. Any suit or proceeding relating to this Agreement shall be brought only in the District of Columbia. Each Party consents to the exclusive personal jurisdiction and venue of the courts located in the District of Columbia.

19 Severability. All provisions of this Agreement are severable. If any provision or portion hereof is determined to be unenforceable by a court of competent jurisdiction, then the rest of the Agreement shall remain in full effect, provided that its general purposes remain reasonably capable of being effected.

20 Entire Agreement. This Agreement and the attached Appendices: (a) constitute the entire Agreement between the Parties with respect to the subject matter; (b) supersede and replace all prior agreements, oral or written, between the Parties relating to the subject matter; and (c) except as otherwise indicated, may not be modified or otherwise changed in any manner except by a written instrument executed by both Parties.

21 Survival. The following sections of this Agreement survive its termination as to any Registry or in its entirety, for any reason: Sections 4, 6, 8.d., 9, 10, 18 and the Business Associate Agreement.

22 No Third-Party Beneficiaries. The Parties agree there are no third-party beneficiaries, intended or otherwise, to this Agreement, including, without limitation, patients of any Participant.

IN WITNESS WHEREOF, each of the Parties hereto has caused this Agreement to be executed as of the Effective Date:

PARTICIPANT	**ACCF**
Signature: _____	Signature:_____
Name: _____	Name:_____
Title: _____	Title: _____
Date: _____	Date: _____

APPENDIX A
BUSINESS ASSOCIATE AGREEMENT

In the course of satisfying its contractual obligations to Participant pursuant to the Participant's engagement of ACCF through the Master Agreement, ACCF is performing a function or activity on behalf of Participant that constitutes ACCF a "Business Associate" of Participant within the meaning of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (45 C.F.R. Parts 160 and 164, as amended) ("HIPAA"). The purpose of this Appendix is to provide the Participant with satisfactory assurance that, as Participant's Business Associate, ACCF shall comply with the privacy and security requirements concerning Business Associates imposed by HIPAA and its implementing regulations as amended. Accordingly, ACCF and Participant agree as follows:

I. GENERAL PROVISIONS

Section 1. **Effect**. The terms and provisions of this Appendix shall supersede any other conflicting or inconsistent terms and provisions in the Master Agreement to which this Appendix is attached, including all exhibits or other attachments thereto and all documents incorporated therein by reference.

Section 2. **Amendment**. ACCF and Participant agree to amend this Appendix to the extent necessary to allow Participant or the ACCF to comply with the Standards for Privacy of Individually Identifiable Health Information (45 C.F.R. Parts 160 and 164, as amended) (hereinafter "Privacy Standards"), the Standards for Electronic Transactions (45 C.F.R. Parts 160 and 162), and the Security Standards (45 C.F.R. Parts 160, 162 and 164), all as modified or supplemented by the HITECH Act 42 U.S.C. §3000 et. seq., and implementing regulations and guidance (collectively, the "Standards") promulgated, or to be promulgated, by the Secretary or other authorized agencies. The ACCF agrees to develop amendments to this Appendix to incorporate any material provisions required by the Standards, and to distribute the same to Participant for adoption. Any amendment distributed by ACCF shall be deemed to be accepted by Participant unless ACCF is notified by Participant of any objections within thirty (30) days of its receipt of such amendment. Each Party is responsible for determining the adequacy of the amendment for its compliance with HIPAA.

Section 3. **Definitions**. Capitalized terms used herein without definition shall have the respective meanings assigned to such terms in the Agreement, or Part V of this Appendix.

II. OBLIGATIONS OF ACCF

Section 1. **Use and Disclosure of Protected Health Information**.

(a) ACCF may use and disclose Participant's PHI only as permitted under the Master Agreement and this Appendix A. ACCF shall use reasonable measures to ensure that its directors, officers, employees, subcontractors, business partners, and agents do not use or disclose Participant's PHI received from Participant in any manner that would constitute a violation of the Privacy Standards if done by Participant, except that ACCF may use and disclose Participant's PHI to ACCF's subcontractors and others: (i) for ACCF's proper management and administration if ACCF enters into a written agreement with a party to whom it releases Participant's PHI, and uses reasonable measures to require such party to hold such Participant's PHI confidentially, to further use or disclose it only as required by law or for the purpose for which it was disclosed, and to notify ACCF of any instances of which it becomes aware in which the confidentiality of the Participant's PHI is breached in a manner consistent with ACCF's obligations under this Appendix; (ii) to carry out ACCF's legal responsibilities hereunder, or as otherwise required by law or regulation; (iii) to provide Data Aggregation services relating to the health care operations of Participant and other hospitals or health systems with which ACCF contracts; (iv) to de-identify Participant's PHI it receives from Participant, if any, pursuant to 45 CFR § 164.514, which De-identified Data, and any derivative works from such data, shall be owned by ACCF, in all forms and media worldwide, and may be used by ACCF for any lawful purpose; or (v) to create and disclose a Limited Data Set, provided that the conditions set forth in Section 9 of this Appendix are satisfied.

(b) Effective not later than February 17, 2010, or such later date as may be specified pursuant to the HITECH Act, ACCF shall limit its uses and disclosures of Participant's PHI to uses and disclosures that comply with the Business Associate requirements of 45 CFR 164.504 (e) (2). The foregoing shall not be construed to limit the responsibility of the ACCF under the Master Agreement and this Appendix as in effect prior to February 17, 2010.

(c) Effective February 17, 2010, ACCF shall determine the Minimum Necessary Protected Health Information to be disclosed for uses, disclosures or requests of or for Participant's PHI, other that those that exempt from the Minimum Necessary requirement specified in 45 CFR 164.502(b)(2), in order to accomplish the intended purpose of the use, disclosure, or request, consistent with the terms of the Master Agreement. To the extent practicable and consistent with the terms of the Master Agreement, as determined by ACCF, the Minimum Necessary shall be the information contained in a Limited Data Set, as defined in 45 CFR 164.514(e)(2). At such time as the Secretary issues guidance on what constitutes the "Minimum Necessary" for purposes of the HIPAA Privacy Rule,

ACCF shall provide Participant with an amendment to this section which complies with the guidance, which shall replace this Section 1 (c) as of the effective date of the guidance.

(d) Effective not later than six (6) months after the date on which the Secretary publishes applicable final regulations, ACCF shall not, directly or indirectly, receive remuneration in exchange for Participant's PHI unless ACCF or the Participant has obtained to an authorization from the subject individual(s) which complies with all applicable requirements or unless an exception specified in Section 13405(d)(2) of the HITECH Act, 42 U.S.C. 17935(d)(2) or regulations published by the Secretary applies. ACCF shall not rely on any of the foregoing exceptions as to Participant's PHI without advance notice to all Participants which describes the types of circumstances and the applicable exceptions to be relied upon by the ACCF. Such notice may be made through notice published on the NCDR web site.

Section 2. **Safeguards Against Misuse of Information**. ACCF agrees that it shall use reasonable safeguards to prevent the use or disclosure of Participant's PHI except as otherwise provided for in this Appendix and the Master Agreement or as otherwise permitted by the Standards. Such safeguards shall include the implementation and maintenance of reasonable and appropriate administrative, technical, and physical safeguards to protect the security, integrity, confidentiality, and availability of Participant's PHI created, maintained, received, or transmitted by ACCF. ACCF shall further use reasonable measures to ensure that any agent to whom it provides Participant's PHI, including a subcontractor, agrees to implement reasonable and appropriate safeguards to protect such Participant's PHI. Effective not later than February 17, 2010, or such later date as may be specified pursuant to the HITECH Act, ACCF shall fulfill the foregoing responsibilities by being in compliance with the provisions of the HIPAA Standards for Privacy of Individually Identifiable Health Information set forth at 45 CFR 164.308 (Administrative Safeguards); 45 CFR 164.310 (Physical Safeguards); 45 CFR 164, 312 (Technical Safeguards) and 45 CFR 164.316 (Policies and Procedures and Documentation Requirements) (collectively, the "Security Requirements") in the same manner as the Security Requirements apply to a Covered Entity under HIPAA. ACCF shall also comply with additional or modified requirements set forth in any Annual Guidance as to the Security Requirements published by the Secretary and with the additional requirements of the HITECH Act that relate to security of Participant's PHI.

Section 3. **Reporting of Disclosures of Protected Health Information or Security Incidents**.

(a) ACCF shall maintain systems to monitor and detect a Breach of Unsecured Protected Health Information accessed, maintained, retained, modified, stored, destroyed or otherwise held or used in Unsecured form by ACCF, whether the Unsecured Protected Health Information is in paper or electronic form. ACCF shall provide to notice of a Breach involving Participant's PHI within five (_5___) business days of the first day the Breach is known, or reasonably should have been known, to the ACCF, including for this purpose any employee, officer, or other agent of the ACCF (other than the individual committing the Breach). The notice shall include the identification of each individual whose Unsecured Protected Health Information was, or is reasonably believed to have been, subject to the Breach and the circumstances of the Breach, as both are known to ACCF at that time. The notice shall be given via email to Participants Privacy Officer, as stated by Participant on the ncdr website. The Parties agree that notice in accordance with the foregoing satisfies the notice requirements of this Section 5. Following the notice, ACCF shall conduct such further investigation and analysis as is reasonably required, and shall promptly advise Participant of additional information pertinent to the Breach which ACCF obtains. ACCF shall cooperate with Participant to support the provision of required notices in a timely manner, including the determination of whether the use, access, or disclosure is one that "poses a significant risk of financial, reputational, or other harm to the individual", thereby requiring notice. Participant is responsible for the provision of notice in a timely manner, provided that Participant shall consult with ACCF in good faith regarding the details of the notice.

(b) ACCF shall also, promptly on becoming aware of it, report any Security Incident involving Participant's PHI to Participant, unless the Security Incident was the subject of a notice under Section 3 (a) .

Section 4. **Agreements with Third Parties**. ACCF shall obtain and maintain an agreement with each of the ACCF subcontractors or agents that has or shall have access to Participant's PHI, which is received from, or created or received by ACCF on behalf of Participant, pursuant to which agreement such subcontractor or agent agrees to be bound by restrictions, terms and conditions that are consistent with those applicable to ACCF pursuant to this Appendix and the Agreement with respect to such Participant's PHI, provided however that this Section shall not apply to disclosures by ACCF of a Limited Data Set, as such disclosures shall be governed by Section 9 of this Appendix.

Section 5. **Access to Information**. Within twenty (20) days of a request by Participant for access to Participant's PHI about an individual contained in a Designated Record Set so that it may respond to said individual's request for such information, ACCF shall

make available to Participant such Participant's PHI provided that such Participant's PHI constitutes a Designated Record Set, such determination to be made by ACCF. In the event any individual requests access to Participant's PHI directly from ACCF, ACCF shall within twenty (20) days forward such request to Participant. Any denials of access to the Participant's PHI requested shall be the responsibility of Participant.

Section 6. **Availability of Protected Health Information for Amendment**. Within twenty (20) days of receipt of a request from Participant for the amendment of an individual's Participant's PHI, or a record regarding an individual maintained by ACCF in a Designated Record Set, ACCF shall provide such information to Participant for amendment, and incorporate any such amendments in the Participant's PHI as required by 45 C.F.R. Part 164.526.

Section 7. **Accounting of Disclosures**.
(a) Within twenty (20) days of notice by Participant to ACCF that it has received a request from a patient for an accounting of disclosures of Participant's PHI, other than related to the treatment of the patient, the processing of payments related to such treatment, or the operation of Participant or its business associate, and not relating to disclosures made earlier than the later of six (6) years prior to the date on which the accounting was requested or April 14, 2003, the effective date of the Privacy Standards, ACCF shall make available to Participant such information as is in ACCF possession and that is required for Participant to make the accounting required by 45 C.F.R. Part 164.528. In the event the request for an accounting is delivered directly to ACCF, ACCF shall, within twenty (20) days, forward such request to Participant. ACCF hereby agrees to implement an appropriate record-keeping process to enable it to comply with the requirements of this Section.

(b) In addition, Participant shall advise ACCF in writing if Participant uses or maintains an Electronic Health Record(s) ("EHR") through which disclosures of Participant's PHI are made and of the effective date upon which the requirement to provide an Accounting for EHR disclosures for purposes of Treatment, Payment and Health Care Operations ("TPO Accounting") is effective as to Participant. Such notice shall be provided to the ACCF in writing at least thirty days (30) in advance of the date the requirements to provide a TPO Accounting are applicable to Participant ("TPO Notice Period"). ACCF shall capture and store information required for a TPO Accounting for EHR disclosures of Participant's PHI through or by ACCF for a minimum of a rolling three (3) year period beginning with the later of the date specified in the Participant's notice or the end of the TPO Notice Period, in accordance with the applicable regulations published by the Secretary. From and after the effective date specified in the Participant's notice, ACCF shall, as instructed by the Participant, either provide the TPO Accounting directly to the

individual making the request or provide the information required for the TPO Accounting to the Participant. In either case, the information required for the TPO Accounting shall be available to the individual or to the Participant, as appropriate, within twenty (20) days of ACCF's receipt of a request. To the extent not expressly prohibited by the HIPAA, the ACCF reserves the right to make a reasonable charge to Participant for each TPO Accounting provided to Participant or to an individual at Participant's request.

Section 8. **Availability of Books and Records**. ACCF hereby agrees to make its internal practices, books, and records relating to the use and disclosure of Participant's PHI received from, or created or received by ACCF on behalf of, Participant available to the Secretary for purposes of determining Participant's compliance with the Privacy Standards, as requested in writing by Participant.

Section 9. **Data Use Agreement**.

Section 9.1. **Activities**. The Parties agree that ACCF may use and disclose a Limited Data Set for purposes of cardiovascular research initiated by ACCF, or as otherwise permitted by the Privacy Standards or Required by Law. Such Limited Data Sets need not be for the use of the Participant but ACCF shall endeavor to make any resulting research studies, articles or similar results generally be made available to Participant through posting on the ACCF website or through publication. ACCF shall use reasonable measures to ensure that its directors, officers, employees, contractors, and agents do not use or disclose a Limited Data Set in any manner that would constitute a violation of the Privacy Standards if used or disclosed by Participant. ACCF agrees not to use a Limited Data Set in such a way as to identify any individual, and further agrees not to contact any individual. The activities referred to in Section 9.1. of this Appendix shall collectively be referred to as the "Activities."

Section 9.2. **Limited Data Set**. Participant agrees that ACCF may derive directly or through a subcontractor who is bound by terms and conditions consistent with ACCF's obligations under this Appendix a Limited Data Set from Participant's PHI otherwise provided to ACCF pursuant to the Master Agreement and use that Limited Data Set including in combination with other data in the performance of the Activities, provided, however, that no Limited Data Set created by ACCF shall include any direct identifiers set forth at 45 C.F.R. Part 164.514(e)(2).

Section 9.3. **Safeguards Against Misuse of Information**. ACCF shall use reasonable safeguards to prevent the use or disclosure of a Limited Data Set other than as permitted under this Agreement.

Section 9.4. **Reporting of Wrongful Disclosures**. ACCF shall, within twenty (20) days of becoming aware of any use or disclosure of a Limited Data Set in violation of the Agreement by ACCF, its officers, directors, employees, contractors, or agents, or by a third party to which ACCF disclosed a Limited Data Set, report any such disclosure to Participant.

Section 9.5. **Agreements with Third Parties**. ACCF shall obtain and maintain an agreement with each third party that has or will have access to a Limited Data Set, which satisfies the requirements for a Data Use Agreement, as set forth in 45 C.F.R. Part 164.514(e) (4), with respect to the Limited Data Set.

III. OBLIGATIONS OF PARTICIPANT

Section 1. Participant shall be responsible for assuring Participant's compliance with the HIPAA Standards.

Section 2. Participant shall provide ACCF with at least thirty (30) days advance written notice of any restrictions on uses and disclosures of Participant's PHI that it agrees to, pursuant to 45 C.F.R. Part 164.522, which will affect the uses and disclosures of Participant's PHI, which ACCF is permitted to make pursuant to the Master Agreement, including this Appendix A.

III. TERMINATION OF AGREEMENT

Section 1. **Termination Upon Breach of Provisions Applicable to Protected Health Information or Participant's Obligations**. Any other provision of this Appendix or the Master Agreement notwithstanding, the Master Agreement and this Appendix may be terminated by the Participant upon thirty (30) days written notice to ACCF in the event that ACCF breaches any provision contained in this Appendix, which notice shall describe the breach in reasonable detail. If such breach is not cured within such thirty (30) day period; provided, however, that in the event that termination of this Agreement is not feasible, in Participant's sole discretion, ACCF hereby acknowledges that Participant shall have the right to report the breach to the Secretary, notwithstanding any other provision of this Agreement to the contrary. Effective February 17, 2010, in the event that ACCF becomes aware of a pattern of activity or a practice of the Participant that constitutes a material violation of the obligations of Participant under its this Appendix, ACCF shall provide Participant with written notice describing the material violation in reasonable detail and a period of not less than thirty (30) days after receipt of such notice to cure the material violation. If such breach is not cured within such thirty

(30) day period, ACCF may terminate the Master Agreement and this Appendix on notice to Participant provided, however, that in the event that termination of the Master Agreement and this Appendix is not feasible, in ACCF's sole judgment, Participant hereby acknowledges that ACCF shall have the right to report the breach to the Secretary, notwithstanding any other provision of this Agreement to the contrary.

Section 2. **Return or Destruction of Protected Health Information Upon Termination**. Participant and ACCF have determined that return or destruction of Participant's PHI is not feasible upon termination of the Agreement. Therefore, ACCF shall have the applicable rights and shall comply with the applicable requirements of this Appendix for so long as Participant's PHI is held by ACCF. In the event that ACCF determines that it shall no longer maintain such Participant's PHI, it shall either return such Participant's PHI to Participant or destroy it (with certification of such destruction) at the sole option of ACCF. The terms and provisions of this Appendix shall survive termination of the Agreement, and such Participant's PHI shall be used or disclosed solely for such purpose or purposes which prevented the return or destruction of such Participant's PHI, and shall be maintained as confidential. Aggregate data, De-identified Data shall not be subject to this obligation. Participant's PHI contained in a Limited Data Set shall continue to be governed by the Data Use Agreement provisions of Section 9 of this Appendix.

V. DEFINITIONS FOR USE IN THIS APPENDIX

"Data Aggregation" shall mean, with respect to Participant's PHI created or received by ACCF in its capacity as the Business Associate of Participant, the combining of such Participant's PHI by ACCF with the Participant's PHI received by ACCF in its capacity as a Business Associate of another participant, to permit data analyses that relate to the health care operations of the respective participants.

"De-identified Data" shall have the meaning set forth in 45 C.F.R. Part 164.514 regarding de-identification of Participant's PHI.

"Designated Record Set" shall have the meaning set forth in 45 C.F.R. Part 164.501.

"Electronic Media" shall mean the mode of electronic transmissions. It includes the Internet, extranet (using Internet technology to link a business with information only accessible to collaborating parties), leased lines, dial-up lines, private networks, and those transmissions that are physically moved from one location to another using magnetic tape, disk, or compact disk media.

"Electronic Protected Health Information" or "EParticipant's PHI" shall have the same meaning as the term "electronic protected health information" at 45 C.F.R. 160.103.

"Health Care Operations" shall have the meaning set forth in 45 C.F.R. Part 164.501.

"HITECH Act" shall mean the provisions of Division A, Title XIII of the American Recovery and Reinvestment Act of 2009 ("ARRA"), known as The Health Information Technology for Economic and Clinical Health, Act 42 U.S.C. §3000 et. seq., and implementing regulations and guidance including all implementing regulations and other official guidance, set forth.

"Individually Identifiable Health Information" shall mean information that is a subset of health information Participant's PHI information collected from an individual, and:

(i) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(ii) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and (a) identifies the individual, or (b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

"Limited Data Set" shall have the meaning ascribed to it in 45 C.F.R. Part 164.514 (e) (1).

"Master Agreement" shall mean the NCDR Master Agreement between the Parties including any general policies, supplements or notices posted on the ncdr website (www.ncdr.com).

"Participant's PHI" shall mean the Protected Health Information of the Participant to which the Master Agreement and this Appendix applies.

"Privacy Standards" shall mean the Standard for Privacy of Individually Identifiable Health Information, 45 C.F.R. Parts 160 and 164.

"PHI", "Protected Health Information" or "Participant's PHI" shall mean Individually Identifiable Health Information that is: (i) transmitted by electronic media; (ii) maintained in any medium constituting Electronic Media; or (iii) transmitted or maintained in any other form or medium or Activity Data as that term is used in the

Agreement. Under no circumstances shall aggregate data or De-identified Data constitute "Protected Health Information" or "Participant's PHI". "Protected Health Information" or "Participant's PHI" shall not include: (i) education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. §1232g; and (ii) records described in 20 U.S.C.§1232g(a)(4)(B)(iv).

"Research" shall have the meaning set forth in 45 C.F.R. Part 164.501.

"Secretary" shall mean the Secretary of the Department of Health and Human Services or such other federal agency as is authorized to publish regulations or guidance pursuant to the HITECH Act.

"**Security Incident"** shall mean the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information, or interference with systems operations in an information system.

"Security Standards" shall mean the Health Insurance Reform Security Standards at 45 C.F.R. parts 160, 162, and 164.

All other defined terms in this Business Associate Agreement have the meaning assigned in the HITECH Act, unless otherwise defined in the HIPAA Privacy Rule or the HIPAA Security Rule.

CathPCI Registry® Addendum

ADDENDUM OF AGREEMENT BETWEEN
NCDR® PARTICIPANT AND
THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION

THIS ADDENDUM ("Addendum") is made this _____ day of _____ 20___ ("Effective Date"), between the American College of Cardiology Foundation ("ACCF"), a non-profit, tax-exempt organization with office located in Washington, DC, and _____ ("Participant") (collectively "Parties"). This Addendum adds certain terms, including participation in an additional ACCF Registry, to the Master Agreement relating to Participant's participation in the American College of Cardiology Foundation National Cardiovascular Data Registry ("NCDR®") dated the ___ of _____, 20___ (Master Agreement");

RECITALS:

WHEREAS, in accordance with Section 1.a. of the Master Agreement, the Parties wish to add an additional Registry to the Master Agreement and to document Participant's participation in the additional Registry on the terms and conditions of the Master Agreement, except to the extent additional or modified terms and conditions are specifically added by this Addendum.

WHEREAS, The Parties acknowledge that the NCDR® consists of four unique hospital based registries: the CathPCI Registry®, the ICD Registry™, the IMPACT Registry, the CARE Registry®, and the ACTION Registry®- GWTG™ as well as one office based registry, the PINNACLE Registry™;

WHEREAS, the additional Registry to which the Parties desire to extend the Master Agreement to is the CathPCI Registry® ("CathPCI Registry").

NOW, THEREFORE, in consideration of the mutual promises and agreements hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by ACCF and Participant,

IT IS AGREED:

1. The Parties agree that all of the Recitals are true and correct and are hereby incorporated by reference into this Agreement. All defined terms in the Master Agreement have the same meaning in this Addendum unless otherwise specifically stated.

2. The Parties recognize that all obligations detailed in the existing Agreement apply to participation in the CathPCI Registry.

CathPCI Registry® Addendum

3. The ACCF has developed a web-based data collection tool ("Tool") for submission of Participant's Clinical Data in the CathPCI Registry and this Tool, meets the requirements of ACCF approved software as outlined in paragraph 2b of the existing Agreement. Participant acknowledges that in order for Participant to elect use of tool Participant must indicate use of the Tool on the site profile.

4. Participant recognizes that use of the Tool will require Internet Explorer 6.0 or higher.

5. The ACCF has developed a training mechanism detailing the functionality of the Tool. The training mechanism is specifically the intellectual property of the ACCF under Section 7 b. of the Master Agreement. It is the responsibility of the Participant to review the provided training materials and use the Tool as detailed in the materials. The ACCF reserves the right to amend or update the training materials periodically. The ACCF will notify the Participant of amendment of the training material and will make the material available to the Participant.

6. The ACCF will provide support via telephone and e-mail during normal business hours Monday-Friday 9:00 am -5:00 pm eastern time. Support will not be offered on the weekend or federal holidays. The ACCF will provide technical support for the utilization of Tool only. It is the responsibility of the Participant to handle any issue related to hardware requirements required to utilize the Tool.

7. The ACCF shall use reasonable efforts to promptly resolve any failure of the Tool to perform which materially impairs the Participant's use of the Tool or any malfunction or defect of the Tool, including through updates or corrections.

8. The ACCF shall deliver corrections to the Tool in the form of updated versions or revisions to the Tool.

9. The Parties agree that all Electronically Protected Health Information submitted via the Tool to ACCF is covered and protected under Appendix A of the Master Agreement.

10. All other terms of the Master Agreement shall remain in force and unchanged.

WITNESS WHEREOF, each of the parties hereto has caused this Addendum to be executed by its duly authorized agents

PARTICIPANT	**ACCF**
Signature: _____	Signature: _____
Title: _____	Title: _____
Date: _____	Date: _____

NCDR™ National Cardiovascular Data Registry

CathPCI Registry®

INVOICE

Please choose one:	Description	CathPCI Registry® Participation Dues	CathPCI Registry Implementation Fee	Invoice Amount
	We are enrolling in the CathPCI Registry before June 30, 2010	$3,685	$1,000	**$4,685**
	We are enrolling in the CathPCI Registry after June 30, 2010	$1,845	$1,000	**$2,845**

Amount Enclosed $_____

Please make your check payable to the *American College of Cardiology Foundation*

Your Name *(please print clearly)* _____

Title _____

Department _____

Facility Name _____

Address _____

City _____ State _____ ZIP _____

INSTRUCTIONS

Please review, complete, and sign the following CathPCI Registry® enrollment materials:

- Participant Contact Information Form
- CathPCI Registry-Specific Addendum
- This invoice

Mail the three completed forms with your check to:

American College of Cardiology Foundation
Attn: 2009 NCDR CathPCI Registry Enrollment
P.O. Box 79231
Baltimore, MD 21279-0231

NATIONAL QUALITY FORUM

Measure Evaluation 4.1
December 2009

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

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

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

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

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

(for NQF staff use) **NQF Review #:** 1498 **NQF Project:** Cardiovascular Endorsement Maintenance 2010
MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** Statins at discharge for patients with percutaneous coronary intervention (PCI)
De.2 **Brief description of measure***:* Proportion of adult patients (age 18 or older) who undergo a percutaneous coronary intervention (PCI) and are prescribed a statin at discharge.
1.1-2 **Type of Measure:** Process De.3 **If included in a composite or paired with another measure, please identify composite or paired measure** N/A
De.4 **National Priority Partners Priority Area:** De.5 **IOM Quality Domain**: Effectiveness, Timeliness De.6 **Consumer Care Need:** Getting better, Staying healthy

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	**NQF Staff**
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.* A.1 **Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes A.2 **Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:** A.3 **Measure Steward Agreement:** Agreement will be signed and submitted prior to or at the time of measure submission A.4 **Measure Steward Agreement attached:** NQF - signed.pdf	**A** **Y**☐ **N**☐
B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and	**B**

update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	Y☐ N☐
C. The intended use of the measure includes both public reporting and quality improvement. ►**Purpose:** Public reporting, Internal quality improvement Accountability, Payment incentive, Accreditation	C Y☐ N☐
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1**Testing:** Yes, fully developed and tested D.2 **Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?** Yes	D Y☐ N☐
(for NQF staff use) **Have all conditions for consideration been met?** **Staff Notes to Steward** (*if submission returned*)**:**	**Met** Y☐ N☐
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**	
Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. *Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.* (evaluation criteria) **1a. High Impact**	Eval Ratin g
(for NQF staff use) Specific NPP goal:	
1a.1 **Demonstrated High Impact Aspect of Healthcare:** Affects large numbers, Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Severity of illness 1a.2 1a.3 **Summary of Evidence of High Impact:** Cardiovascular disease is the single most common cause of death in the U.S. There are an estimated 64 million people with cardiovascular disease with direct costs totaling over 226 billion dollars in 2004. Estimates of direct costs due to cardiovascular disease are projected to be 503.2 billion dollars in 2010. In 2002, approximately 864,480 deaths were attributable to cardiovascular disease, or 1 in 2.9 deaths in the US. Approximately 1 million PCI procedures are performed annually. 6.1 million hospital discharges listed cardiovascular disease as the primary diagnosis in 2006. In 2004 coronary artherosclerosis attributed to 1.2 million hospital stays, with 44 billion in associated expenses. More than half of hospital stays were due to PCI or cardiac revascularization. 1a.4 **Citations for Evidence of High Impact:** American Heart Association. Heart disease and stroke statistics- 2010 update: A report of the American Heart Association. Available at:http://circ.ahajournals.org/cgi/content/full/103/24/3019. Accessed October 13, 2010.	**1a** C☐ P☐ M☐ N☐
1b. Opportunity for Improvement 1b.1 **Benefits (improvements in quality) envisioned by use of this measure:** Statin therapy reduces the	**1b** C☐ P☐

Comment [KP1]: 1a. The measure focus addresses:
•a specific national health goal/priority identified by NQF's National Priorities Partners; OR
•a demonstrated high impact aspect of healthcare (e.g., affects large numbers, leading cause of morbidity/mortality, high resource use (current and/or future), severity of illness, and patient/societal consequences of poor quality).

Comment [KP2]: 1b. Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating considerable variation, or overall poor performance, in the quality of care across providers and/or population groups (disparities in care).

risk of CAD following PCI. This measure will encourage improvement in rates of statin prescribing at discharge following PCI and subsequently reduce rates of adverse outcomes after PCI by facilitating quality improvement in this area.

M☐ N☐

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
Several prior studies have documented low treatment rates in patients with established coronary artery disease. Arecent study of all participants in the National Registry of Myocardial Infarction (NRMI) found that statins were being prescribed only 82% of the time in patients hospitalized with AMI who were eligible for statin therapy. However the hospitals included in this study were voluntary participants in a national quality improvement registry. Data from the NCDR CathPCI Registry also suggest room for improvement for this measure. Data from the NCDR CathPCI Registry for 1121 facilities (563,988 records) showed some variation in performance for this measure. Performance ranged from 72% at the 5th percentile to 98% at the 95th percentile. 50% of hospitals did not prescribe statins at discharge for 10% of its patients.

1b.3 Citations for data on performance gap:

• Fonarow GC, French WJ, Frederick PD. Trends in the use of lipid-lowering medications at discharge in patients with acute myocardial infarction: 1998 to 2006. American Heart Journal. 2009 Jan;157(1):185-194.e2.
• Frolkis JP, Zyzanski SJ, Schwartz JM, Suhan PS. Physician noncompliance with the 1993 National Cholesterol Education Program (NCEPATPII) guidelines. Circulation. 1998;98:851–5.
• Majumdar SR, Gurwitz JH, Soumerai SB. Undertreatment of hyperlipidemia in the secondary prevention of coronary artery disease. J Gen Intern Med. 1999;14:711–7.
• McBride P, Schrott HG, Plane MB, et al. Primary care practice adherence to National Cholesterol Education Program guidelines for patients with coronary heart disease. Arch Intern Med. 1998;158:1238–44.
• Miller M, Byington R, Hunninghake D, et al. Sex bias and underutilization of lipid-lowering therapy in patients with coronary artery disease at academic medical centers in the United States and Canada: Prospective Randomized Evaluation of the Vascular Effects of Norvasc Trial (PREVENT) Investigators. Arch Intern Med. 2000;160:343–7.
• Schrott HG, Bittner V, Vittinghoff E, et al. Adherence to National Cholesterol Education Program treatment goals in postmenopausal women with heart disease: the Heart and Estrogen/Progestin Replacement Study (HERS): the HERS Research Group. JAMA. 1997;277:1281– 6.
• Sueta CA, Chowdhury M, Boccuzzi SJ, et al. Analysis of the degree of undertreatment of hyperlipidemia and congestive heart failure secondary to coronary artery disease. Am J Cardiol. 1999;83:1303–7.

1b.4 Summary of Data on disparities by population group:
We conducted stratified analyses of hospital performance for this measure by (a) hospital safety net status (defined as government hospitals or non-government hosptials with high medicaid caseload using AHA 2008) and (b) quartiles of proportion of patients of white race. Both sets of analyses suggested that the range of hospital performance is similar irrespective of the SES of the patients treated. Specifically, the median for Safety Net hospitals was 89.5% with the lowest decile 77.9% and highest decile 96.3%. This is similar to that observed for non-Safety Net hospitals (median 87.6%, lowest decile 76.0%, highest decile 96.5%). Similarly, median hospital performance was similar across quartiles of proportion of white patients (quartile 1: 89.0%, quartile 2: 89.0%, quartile 3: 90.4%, quartile 4: 90.0%).

1b.5 Citations for data on Disparities:
Unpublished NCDR data, please see attached documentation.

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** Statin therapy is used for secondary prevention to reduce the progression of coronary artery disease (CAD).

1c.2-3. Type of Evidence: Evidence-based guideline, Randomized controlled trial, Expert opinion

1c C☐ P☐ M☐ N☐

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
The Atorvastatin Versus Revascularization Treatment (AVERT) trial (298) randomly assigned 341 patients

Comment [k3]: 1 Examples of data on opportunity for improvement include, but are not limited to: prior studies, epidemiologic data, measure data from pilot testing or implementation. If data are not available, the measure focus is systematically assessed (e.g., expert panel rating) and judged to be a quality problem.

Comment [k4]: 1c. The measure focus is:
•an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;
OR
•if an intermediate outcome, process, structure, etc., there is **evidence** that supports the specific measure focus as follows:
oIntermediate outcome – evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
oProcess – evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and
if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
oStructure – evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
oPatient experience – evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of individuals/ the public.
oAccess – evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
oEfficiency – demonstration of an association between the measured resource use and level of performance with respect to one or more of the other five IOM aims of quality.

Comment [k5]: 4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., mammography) or measures for multiple care processes that affect a single outcome.

with stable CAD, normal LV function, and class I and/or II angina to PTCA or medical therapy with 80 mg of atorvastatin daily (mean low-density lipoprotein cholesterol equals 77 mg per dL). At 18 months of follow-up, 13% of the medically treated group had ischemic events compared with 21% of the PTCA group (P equals 0.048). Angina relief was greater in those treated with PTCA. Although not statistically different when adjusted for interim analysis, these data suggest that in low-risk patients with stable CAD, aggressive lipid lowering therapy can be as effective as PTCA in reducing ischemic events.

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom***):**
Level B: Data derived from a single randomized trial or nonrandomized studies (American College of Cardiology/ American Heart Association TaskForce on Practice Guidelines)

1c.6 Method for rating evidence: The weight of evidence in support of the recommendation is listed as follows:
• Level of Evidence A: Data derived from multiple randomized clinical trials or meta-analyses.
• Level of Evidence B: Data derived from a single randomized trial or nonrandomized studies.
• Level of Evidence C: Only consensus opinion of experts, case studies, or standard-of-care.

1c.7 Summary of Controversy/Contradictory Evidence: N/A

1c.8 Citations for Evidence (*other than guidelines***):** Cannon CP, Braunwald E, McCabe CH, et al. Intensive versus moderate lipid lowering with statins after acute coronary syndromes. N Engl J Med 2004;350:1495-504.1c.9

1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number***):**
ACC/AHA PCI Guidelines (2007 Focused Update):
1. Starting dietary therapy is recommended. Reduce intake of saturated fats (to less than 7% of total calories), trans fatty acids, and cholesterol (to less than 200 mg per day).
A fasting lipid profile should be assessed in all patients and within 24 hours of hospitalization for those with an acute cardiovascular or coronary event. For hospitalized patients, initiation of lipid lowering medication is indicated as recommended below before discharge according to the following schedule:
-LDL-C should be less than 100 mg per dL. -Further reduction of LDL-C to less than 70 mg per dL is reasonable.
-If baseline LDL-C is greater than or equal to 100 mg per dL, LDL-lowering drug therapy should be initiated.

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ACC/AHA NSTEMI Guideline 2007:
CLASS I
b. Hydroxymethyl glutaryl-coenzyme A reductase inhibitors (statins), in the absence of contraindications, regardless of baseline LDL-C and diet modification, should be given to post-UA/ NSTEMI patients, including postrevascularization patients. (Level of Evidence: A)
c. For hospitalized patients, lipid-lowering medications should be initiated before discharge. (Level of Evidence: A)
d. For UA/NSTEMI patients with elevated LDL-C (greater than or equal to 100 mg per dL), cholesterol-lowering therapy should be initiated or intensified to achieve an LDL-C of less than 100 mg per dL. (Level of Evidence: A) Further titration to less than 70 mg per dL is reasonable. (Class IIa, Level of Evidence: A)
e. Therapeutic options to reduce non–HDL-C‡ are recommended, including more intense LDL-C–lowering therapy. (Level of Evidence: B)

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ACC/AHA STEMI Guideline 2004:

Class IIa
1. It is reasonable to prescribe drug therapy at hospital discharge to patients with non–HDL-C greater than or equal to 130 mg/dL, with a goal of reducing non–HDL-C to substantially less than 130 mg/dL. (Level of

Comment [k6]: 3 The strength of the body of evidence for the specific measure focus should be systematically assessed and rated (e.g., USPSTF grading system http://www.ahrq.gov/clinic/uspstf07/methods/benefit.htm). If the USPSTF grading system was not used, the grading system is explained including how it relates to the USPSTF grades or why it does not. However, evidence is not limited to quantitative studies and the best type of evidence depends upon the question being studied (e.g., randomized controlled trials appropriate for studying drug efficacy are not well suited for complex system changes). When qualitative studies are used, appropriate qualitative research criteria are used to judge the strength of the evidence.

Evidence: B)
2. It is reasonable to prescribe drugs such as niacin or fibrate therapy to raise HDL-C levels in patients with LDL-C less than 100 mg/dL and non–HDL-C less than 130 mg/dL but HDL-C less than 40 mg/dL despite dietary and other nonpharmacological therapy. Dietary-supplement niacin must not be used as a substitute for prescription niacin, and over-the-counter niacin should be used only if approved and monitored by a physician. (Level of Evidence: B)
3. It is reasonable to add drug therapy with either niacin or a fibrate to diet regardless of LDL and HDL levels when triglyceride levels are greater than 500 mg/dL. In this setting, non–HDL-C (goal substantially less than 130 mg/dL) should be the cholesterol target rather than LDL-C. Dietary-supplement niacin must not be used as a substitute for prescription niacin, and over-the-counter niacin should be used only if approved and monitored by a physician. (Level of Evidence: B)

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ACC/AHA Guidelines for secondary prevention for patients with coronary and other atherosclerotic vascular disease:
Statins:
For lipid management:
Assess fasting lipid profile in all patients, and within 24 hours of hospitalization for those with an acute cardiovascular or coronary event. For hospitalized patients, initiate lipid-lowering medication as recommended below before discharge according to the following schedule:
• LDL-C should be <100 mg/dL I (A), and
• Further reduction of LDL-C to <70 mg/dL is reasonable. IIa (A)
• If baseline LDL-C is >=100 mg/dL, initiate LDL-lowering drug therapy.§ I (A)
• If on-treatment LDL-C is >=100 mg/dL, intensify LDL-lowering drug therapy (may require LDL-lowering drug combination). I (A)
• If baseline LDL-C is 70 to 100 mg/dL, it is reasonable to treat to LDL-C <70 mg/dL. IIa (B)
• If triglycerides are 200 to 499 mg/dL, non-HDL-C should be <130 mg/dL. I (B), and
• Further reduction of non-HDL-C to <100 mg/dL is reasonable. IIa (B)
• Therapeutic options to reduce non-HDL-C are:
-More intense LDL-C–lowering therapy I (B), or
-Niacin (after LDL-C–lowering therapy) IIa (B), or
-Fibrate therapy# (after LDL-C–lowering therapy) IIa (B)
• If triglycerides are >=500 mg/dL#, therapeutic options to prevent pancreatitis are fibrate¶ or niacin before LDL-lowering therapy; and treat LDL-C to goal after triglyceride-lowering therapy. Achieve non-HDL-C <130 mg/dL if possible. I (C)

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NCEP Guideline:
In persons admitted to the hospital for a major coronary event, LDL cholesterol should be measured on admission or within 24 hours. This value can be used for treatment decisions. In general, persons hospitalized for a coronary event or procedure should be discharged on drug therapy if the LDL cholesterol is 130 mg/dL. If the LDL is 100–129 mg/dL, clinical judgment should be used in deciding whether to initiate drug treatment at discharge, recognizing that LDL cholesterol levels begin to decline in the first few hours after an event and are significantly decreased by 24-48 hours and may remain low for many weeks. Thus, the initial LDL cholesterol level obtained in the hospital may be substantially lower than is usual for the patient. Some authorities hold drug therapy should be initiated whenever a patient hospitalized for a CHD-related illness is found to have an LDL cholesterol >100 mg/dL. Initiation of drug therapy at the time of hospital discharge has two advantages. First, at that time patients are particularly motivated to undertake and adhere to risk-lowering interventions; and second, failure to initiate indicated therapy early is one of the causes of a large “treatment gap,” because outpatient followup is often less consistent and more fragmented.

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1c.10 Clinical Practice Guideline Citation: 1. PCI Focused Update 2007
King SB, III, Smith SC, Jr., Hirshfeld JW, Jr., 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. J Am Coll Cardiol. 2008;51:172-209.

2. Anderson JL, Adams CD, Antman EM, et al. ACC/AHA 2007 guidelines for the management of patients with unstable angina/non-ST-Elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 2002 Guidelines for the Management of Patients With Unstable Angina/Non-ST-Elevation Myocardial Infarction) developed in collaboration with the American College of Emergency Physicians, the Society for Cardiovascular Angiography and Interventions, and the Society of Thoracic Surgeons endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation and the Society for Academic Emergency Medicine. J Am Coll Cardiol. 2007;50:e1-e157.

3. Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Management of Patients with Acute Myocardial Infarction). Circulation. 2004;110:e82-292.

4. Smith SC, Jr., Allen J, Blair SN, et al. AHA/ACC guidelines for secondary prevention for patients with coronary and other atherosclerotic vascular disease: 2006 update endorsed by the National Heart, Lung, and Blood Institute. J Am Coll Cardiol. 2006;47:2130-9.

5. National Cholesterol Education Program. Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). NIH Pub. No. 02-5125. Bethesda, MD: National Heart, Lung, and Blood Institute, 2002;284 pages. Guidelines, Related Tools, and Patient Information available at http://www.nhlbi.nih.gov/guidelines/cholesterol/index.htm. Accessed May 15, 2003.

1c.11 National Guideline Clearinghouse or other URL:
http://circ.ahajournals.org/cgi/content/full/113/1/156

1c.12 Rating of strength of recommendation (*also provide narrative description of the rating and by whom***):**
Class I: Conditions for which there is evidence for and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.

1c.13 Method for rating strength of recommendation (*If different from* USPSTF system*, also describe rating and how it relates to USPSTF)***:**
ACC/AHA Taskforce on Practice Guidelines Method:
Indications are categorized as class I, II, or III on the basis of a multifactorial assessment of risk and expected efficacy viewed in the context of current knowledge and the relative strength of this knowledge. These classes summarize the recommendations for procedures or treatments as follows:

Class I: Conditions for which there is evidence for and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.
Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.
Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.
Class IIb: Usefulness/efficacy is less well established by evidence/opinion.
Class III: Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective
and in some cases may be harmful.

1c.14 Rationale for using this guideline over others:
These guidelines are the most widely recognized professional guideline in the US for cardiovascular medicine in the area of percutaneous coronary intervention care.

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to Measure and Report?*	**1**
Steering Committee: Was the threshold criterion, *Importance to Measure and Report***, met?**	**1**

Comment [k7]: USPSTF grading system **http://www.ahrq.gov/clinic/uspstf/grades.htm**: **A -** The USPSTF recommends the service. There is high certainty that the net benefit is substantial. **B -** The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. **C -** The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small. Offer or provide this service only if other considerations support the offering or providing the service in an individual patient. **D -** The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. **I -** The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

Rationale:	**Y☐ N☐**
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	Eval Rating
2a. MEASURE SPECIFICATIONS	
S.1 Do you have a web page where current detailed measure specifications can be obtained? **S.2 If yes, provide web page URL:** **2a. Precisely Specified**	
2a.1 Numerator Statement (*Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):** Count of patients with a PCI procedure with statin prescribed at discharge **2a.2 Numerator Time Window (***The time period in which cases are eligible for inclusion in the numerator***):** 1 year **2a.3 Numerator Details (***All information required to collect/calculate the numerator, including all codes, logic, and definitions***):** Element Name: Discharge Medications Discharge medications=statin (any) Coding Instructions: Indicate which of the following medications the patient was prescribed upon discharge. Note(s): Complete only for patients who had a PCI procedure attempted or performed during this episode of care. Discharge medications not required for patients who were discharged to "Other acute care hospital", "Hospice", or "Left against medical advice (AMA)." Element Name: Medication Administered Medication Administered= Yes Coding Instructions: Indicates if the medication was administered, not administered, contraindicated or blinded. Selections: No- Medication was not administered or prescribed. Yes- Medication was administered or prescribed. Contraindicated- Medication was not administered because of a contraindication. (Contraindications must be documented explicitly by the physician, or clearly evidenced within the medical record.) Blinded- Patient was in a research study or clinical trial and the administration of this specific medication or class of medications is unknown.	
2a.4 Denominator Statement (*Brief, text description of the denominator - target population being measured***):** Count of patients with a PCI procedure **2a.5 Target population gender:** Female, Male **2a.6 Target population age range:** Patients >=18 years of age **2a.7 Denominator Time Window (***The time period in which cases are eligible for inclusion in the denominator***):** 1 year **2a.8 Denominator Details (***All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):**	**2a-specs C☐ P☐ M☐ N☐**

Comment [KP8]: 2a. The measure is well defined and precisely specified so that it can be implemented consistently within and across organizations and allow for comparability. The required data elements are of high quality as defined by NQF's Health Information Technology Expert Panel (HITEP) .

Element name: PCI
PCI=Yes
Coding Instructions: Indicate if the patient had a percutaneous coronary intervention (PCI).
Selections: No/Yes
Supporting Definitions: PCI:A percutaneous coronary intervention (PCI) is the placement of an angioplasty guide wire, balloon, or other device (e.g. stent, atherectomy, brachytherapy, or thrombectomy catheter) into a native coronary artery or coronary
artery bypass graft for the purpose of mechanical coronary revascularization.
Source: NCDR

2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population***):** -Discharge status of deceased
-Discharge location of "other acute care hospital", "hospice" or "against medical advice".
-Statins coded as contraindicated or blinded

2a.10 Denominator Exclusion Details (*All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**
Element name: Discharge Status
Discharge status= deceased
Coding Instructions: Indicate whether the patient was alive or deceased at discharge.
Selections: Alive/Deceased

Element name: Discharge location
Discharge location="other acute hospital","hospice", or "left against medical advice"
Element name: Discharge Location
Coding instructions: Indicate the location to which the patient was discharged.
Selections:
-Home
-Extended care/TCU/rehabilitation
-Other acute care hospital
-Nursing home
-Hospice
-Other
Left against medical advice (The patient was discharged or eloped against medical advice.)

Element Name: Medication Administered
Medication Administered= contraindicated or blinded
Coding Instructions: Indicate if the medication was administered, not administered, contraindicated or blinded.
Selections:
No- Medication was not administered or prescribed.
Yes- Medication was administered or prescribed.
Contraindicated- Medication was not administered because of a contraindication.
(Contraindications must be documented explicitly by the physician, or
clearly evidenced within the medical record.)
Blinded- Patient was in a research study or clinical trial and the administration of this specific medication or class of medications is unknown.

2a.11 Stratification Details/Variables (*All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
N/A

2a.12-13 Risk Adjustment Type:

2a.14 Risk Adjustment Methodology/Variables (*List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**
N/A

2a.15-17 Detailed risk model available Web page URL or attachment:

Comment [k9]: 11 Risk factors that influence outcomes should not be specified as exclusions.
12 Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

2a.18-19 Type of Score: Rate/proportion
2a.20 Interpretation of Score: Better quality = Higher score
2a.21 Calculation Algorithm (*Describe the calculation of the measure as a flowchart or series of steps***):**
1. Count of patients with arrival/discharge dates from data submissions that pass NCDR data inclusion thresholds
2. Exclude patients with arrival/discharge dates without PCI during episode
3. Exclude patients with discharge status=deceased
4. Exclude patients with Discharge Location: Other acute care hospital
5. Exclude patients with Discharge Location: Left against medical advice
6. Exclude patients with Discharge Location: Hospice
7. Exclude patients with Statin at discharge: contraindicated or blinded

Numerator calculation:
8. From denominator population, count of patients with Discharge medication of statin=yes

Calculation of score:
9.Numerator count/Denominator count

2a.22 Describe the method for discriminating performance *(e.g., significance testing)***:**
Hospitals performance for this measure is benchmarked each quarter and annually against hospitals with similar procedural volume, as well as against the CathPCI Registry aggregate. These benchmarks identify superior performance and encourage poorer performers to improve. The methodology is a data-driven, peer-group performance feedback used to positively affect outcomes.

2a.23 Sampling (Survey) Methodology *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)*:
N/A

2a.24 Data Source (*Check the source(s) for which the measure is specified and tested)*
Registry data

2a.25 Data source/data collection instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
National Cardiovascular Data Registry (NCDR®) CathPCI Registry®

2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL
http://www.ncdr.com/WebNCDR/ELEMENTS.ASPX

2a.29-31 Data dictionary/code table web page URL or attachment: URL
http://www.ncdr.com/WebNCDR/ELEMENTS.ASPX

2a.32-35 Level of Measurement/Analysis (*Check the level(s) for which the measure is specified and tested)*
Facility/Agency

2a.36-37 Care Settings (*Check the setting(s) for which the measure is specified and tested)*
Hospital, Ambulatory Care: Hospital Outpatient

2a.38-41 Clinical Services (*Healthcare services being measured, check all that apply*)
Clinicians: PA/NP/Advanced Practice Nurse, Clinicians: Physicians (MD/DO)

TESTING/ANALYSIS

2b. Reliability testing

2b.1 Data/sample *(description of data/sample and size)***:** Reliability was established by validating the derivation cohort from version 4 CathPCI data with a testing cohort from version 3 CathPCI data. 555,023 patient records were analyzed from 1007 facilities between July 2008 and June 2009.

2b.2 Analytic Method *(type of reliability & rationale, method for testing)***:**
Reliability was established by validating the derivation cohort from version 4 CathPCI data with a testing

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Comment [KP10]: 2b. Reliability testing demonstrates the measure results are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period.

Comment [k11]: 8 Examples of reliability testing include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing may address the data items or final measure score.

cohort from version 3 CathPCI data.

2b.3 **Testing Results** *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
Results were consistent among the derivation cohort and the testing cohort. Specifically, the median for hospitals in the derivation cohort was 89.3% with the lowest decile 77.2% and highest decile 96.4%. This is similar to that observed in the testing cohort (median 89.1%, lowest decile 76.3%, highest decile 96.2%).

Elements included in this measure will be included in the CathPCI registry audit program in the future. Reliability is ensured through the Data Quality Report (DQR), clearly defined and specified data elements, and through the vendor certification process to ensure data submission vendors collect data elements reliably.

The Data Quality Report (DQR) program has been developed to ensure data are valid and complete. The DQR is a process for submitting data files to the NCDR®. Participants use their data collection tool software to create a submission file which is uploaded to the NCDR website. After uploading, the data in the file is automatically checked for errors and completeness. Passing the DQR ensures well-formed data and a statistically significant submission. Types of errors detected by the DQR include:
Schema:Structure doesn't match NCDR requirements
Dates: Inconsistent dates
Selection: Missing or mismatched data; Can be a parent/child errors where a field requests more data.
Outlier: Anomalies or exceptions; Data exceeds the possible limits. For example: 1,000mm length lesion.
Counter: errors deal with Closure Methods, Lesions, and Intracoronary Devices. Each one has a counter, when more than one is used
List: Missing data in the Medications or either Device lists

Reliability of the element "PCI" is strengthened because submitters to the CathPCI registry are required to complete this element. In addition, submitters cannot enter any of the elements in the "PCI Procedure" section if they do not answer "yes" to this element. In addition, the "discharge status" (alive or deceased) is a required element (100% threshold).

2c. Validity testing

2c.1 **Data/sample** *(description of data/sample and size)*: Face/content validity: review of relevant evidence and guidelines and expert panel consensus process.

2c.2 **Analytic Method** *(type of validity & rationale, method for testing)*:
Face/content validity was established to ensure this measure represented an important aspect of cardiovascular care for which improvement is needed.

2c.3 **Testing Results** *(statistical results, assessment of adequacy in the context of norms for the test conducted)*:
A review of the relevant evidence and guidelines and expert panel consensus process resulted in the conclusion that this is a valid measure of quality of cardiovascular care for patients with PCI.

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2d. Exclusions Justified

2d.1 **Summary of Evidence supporting exclusion(s)**:
These measures exclude patients with evidence-based contraindications, or patients who are participating in a blinded research study and out of necessity the hospital is not aware of the prescribed discharge medications. This measure also excludes patients discharged to hospice, against medical advice, to another acute care hospital, or who expired prior to discharge as discharge medications to not apply to these patients. No evidence is necessary or available for these exclusions.

2d.2 **Citations for Evidence:**
N/A

2d.3 **Data/sample** *(description of data/sample and size)*: 1,282,945 patient records from the CathPCI registry between July 2009 and June 2010 were analyzed from 1168 CathPCI Registry participants.

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Comment [KP12]: 2c. Validity testing demonstrates that the measure reflects the quality of care provided, adequately distinguishing good and poor quality. If face validity is the only validity addressed, it is systematically assessed.

Comment [k13]: 9 Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP < 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed (e.g., ratings by relevant stakeholders) and the measure is judged to represent quality care for the specific topic and that the measure focus is the most important aspect of quality for the specific topic.

Comment [KP14]: 2d. Clinically necessary measure exclusions are identified and must be:
•supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;
AND
•a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;
AND
•precisely defined and specified:
–if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);
if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

Comment [k15]: 10 Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, sensitivity analyses with and without the exclusion, and variability of exclusions across providers.

2d.4 Analytic Method *(type analysis & rationale)*:
Frequency of exclusion coding

2d.5 Testing Results *(e.g., frequency, variability, sensitivity analyses)*:
Rates of exclusion coding:
-Discharged to other acute care hospital: 3,931 (0.68%)
-Discharged to hospice: 798 (0.14%)
-Discharged against medical advice: 1232 (0.21%)
-Aspirin contraindicated or blinded: 8,999 (1.57%)
-Discharge status of deceased: 8,027 (1.37%)

2e. Risk Adjustment for Outcomes/ Resource Use Measures

2e.1 Data/sample *(description of data/sample and size)*: N/A

2e.2 Analytic Method *(type of risk adjustment, analysis, & rationale)*:
N/A

2e.3 Testing Results *(risk model performance metrics)*:
N/A

2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: N/A

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2f. Identification of Meaningful Differences in Performance

2f.1 Data/sample from Testing or Current Use *(description of data/sample and size)*: 563,988 patient records from 1121 hospitals in the CathPCI registry from July 2009 to June 2010.

2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance *(type of analysis & rationale)*:
Distribution of rates of statin prescribed on discharge.

2f.3 Provide Measure Scores from Testing or Current Use *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:
Performance ranged from 72% at the 5th percentile to 98% at the 95th percentile. 50% of hospitals did not prescribe statins at discharge for 10% of its patients. Please see documentation provided in Ad.11 for detailed analyses.

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2g. Comparability of Multiple Data Sources/Methods

2g.1 Data/sample *(description of data/sample and size)*: N/A

2g.2 Analytic Method *(type of analysis & rationale)*:
N/A

2g.3 Testing Results *(e.g., correlation statistics, comparison of rankings)*:
N/A

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2h. Disparities in Care

2h.1 If measure is stratified, provide stratified results *(scores by stratified categories/cohorts)*: We conducted stratified analyses of hospital performance for this measure by (a) hospital safety net status (defined as government hospitals or non-government hosptials with high medicaid caseload using AHA 2008) and (b) quartiles of proportion of patients of white race. Both sets of analyses suggested that the range of hospital performance is similar irrespective of the SES of the patients treated. Specifically, the median for Safety Net hospitals was 89.5% with the lowest decile 77.9% and highest decile 96.3%. This is similar to that observed for non-Safety Net hospitals (median 87.6%, lowest decile 76.0%, highest decile 96.5%). Similarly, median hospital performance was similar across quartiles of proportion of white patients (quartile 1: 89.0%,

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Comment [KP16]: 2e. For outcome measures and other measures (e.g., resource use) when indicated:
•an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified and is based on patient clinical factors that influence the measured outcome (but not disparities in care) and are present at start of care;[Error! Bookmark not defined.] OR rationale/data support no risk adjustment.

Comment [k17]: 13 Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender (e.g., poorer treatment outcomes of African American men with prostate cancer, inequalities in treatment for CVD risk factors between men and women). It is preferable to stratify measures by race and socioeconomic status rather than adjusting out differences.

Comment [KP18]: 2f. Data analysis demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful differences in performance.

Comment [k19]: 14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% v. 75%) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v. $5,025) is practically meaningful. Measures with overall poor performance may not demonstrate much variability across providers.

Comment [KP20]: 2g. If multiple data sources/methods are allowed, there is demonstration they produce comparable results.

Comment [KP21]: 2h. If disparities in care have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results (e.g., by race, ethnicity, socioeconomic status, gender);OR rationale/data justifies why stratification is not necessary or not feasible.

quartile 2: 89.0%, quartile 3: 90.4%, quartile 4: 90.0%). Based on these analyses, we do not believe that a stratified measure is necessary.

2h.2 **If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:**

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Scientific Acceptability of Measure Properties?* — **2**

Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties*, **met?** — *2* **C☐ P☐ M☐ N☐**

Rationale:

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria) — Eval Rating

3a. Meaningful, Understandable, and Useful Information

3a.1 **Current Use:** In use

3a.2 **Use in a public reporting initiative (disclosure of performance results to the public at large)** (*If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years*)**:**
ACCF plans to begin voluntary publicly report of NCDR measures, including this measure, by 2012. ACCF is currently evaluating public reporting options and finalizing decisions related to location and display of information to be reported as well as communication plans.

This measure is currently used by United Healthcare Services in their UnitedHealth Premium Cardiac Specialty Center designation program. Wellpoint, Inc. currently uses this measure in its Quality-In-Sights: Hospital Incentive Program (Q-HIP).

3a.3 **If used in other programs/initiatives (***If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years***):**
Used for QI by NCDR CathPCI Registry participating institutions. For Q2 of 2010, 1174 institutions submitted data.

Participating institutions receive an institutional outcomes report each quarter with their hospital´s data. Over 2000 metrics are included in each hospital´s outcomes report. 26 metrics are highlighted in the report executive summary. These metrics are selected by an NCDR panel of experts as presenting the greatest opportunity for care improvement. CathPCI "metrics", including this measure, appear in the executive summary of the outcomes report. Hospitals receive their measure score, as well as the rates for all hospitals in the CathPCI registry, and all hospitals in the same comparison group (based on volume), and the rate for the 90th percentile. A box and whisker plot is displayed for each metric to show hospitals how they compare to all hospitals in the CathPCI registry.

This measure is also provided to the Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2) and Hospital Corporation of America (HCA) for incorporation in their QI program efforts.

Testing of Interpretability (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*)
3a.4 **Data/sample** *(description of data/sample and size)***:** 1. 61 NCDR CathPCI Registry participants, Fall 2009.
2. Beta testing for version 4 of the CathPCI Registry institutional outcomes report, 80 sites

3a **C☐ P☐ M☐ N☐**

Comment [KP22]: 3a. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audience(s) for both public reporting (e.g., focus group, cognitive testing) and informing quality improvement (e.g., quality improvement initiatives). An important outcome that may not have an identified improvement strategy still can be useful for informing quality improvement by identifying the need for and stimulating new approaches to improvement.

3a.5 Methods *(e.g., focus group, survey, QI project)*:
1. Survey
2. Sites provided feedback through an excel template

3a.6 Results *(qualitative and/or quantitative results and conclusions)*:
1. 93.3% responded yes to the question "Will this measure provide important information to you?"
2. Sites provided feedback on the institutional outcomes report that was used to modify the report. Sites provided feedback on invalid data and aspects of the report that were unclear.

3b/3c. Relation to other NQF-endorsed measures

3b.1 NQF # and Title of similar or related measures:
#543: Coronary Artery Disease and Medication Possession Ratio for Statin Therapy, #439: Discharged on Statin Medication (stroke patients), #639: Statin Prescribed at Discharge

(for NQF staff use) **Notes on similar/related** endorsed **or submitted measures:**

3b. Harmonization
If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population):
3b.2 Are the measure specifications harmonized? If not, why?
Yes, measure specifications are harmonized wherever possible to endorsed measures.

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3c. Distinctive or Additive Value
3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:
This measure is distinct from #639 Statin Prescribed at Discharge (CMS) in that it applies to all PCI patients and is not isolated to MI patients. In addition, the data source for this measure is different from #639. This measure uses registry data as a data source and the CMS measure uses claims and medical record data.

5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:

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TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Usability*?

3

Steering Committee: Overall, to what extent was the criterion, *Usability*, **met?**
Rationale:

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4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)

Eval Rating

4a. Data Generated as a Byproduct of Care Processes

4a.1-2 How are the data elements that are needed to compute measure scores generated?
Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)

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4b. Electronic Sources

4b.1 Are all the data elements available electronically? (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*)
Yes

4b.2 If not, specify the near-term path to achieve electronic capture by most providers.

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Comment [KP23]: 3b. The measure specifications are harmonized with other measures, and are applicable to multiple levels and settings.

Comment [k24]: 16 Measure harmonization refers to the standardization of specifications for similar measures on the same topic (e.g., *influenza immunization* of patients in hospitals or nursing homes), or related measures for the same target population (e.g., eye exam and HbA1c for *patients with diabetes*), or definitions applicable to many measures (e.g., age designation for children) so that they are uniform or compatible, unless differences are dictated by the evidence. The dimensions of harmonization can include numerator, denominator, exclusions, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.

Comment [KP25]: 3c. Review of existing endorsed measures and measure sets demonstrates that the measure provides a distinctive or additive value to existing NQF-endorsed measures (e.g., provides a more complete picture of quality for a particular condition or aspect of healthcare, is a more valid or efficient way to measure).

Comment [KP26]: 4a. For clinical measures, required data elements are routinely generated concurrent with and as a byproduct of care processes during care delivery. (e.g., BP recorded in the electronic record, not abstracted from the record later by other personnel; patient self-assessment tools, e.g., depression scale; lab values, meds, etc.)

Comment [KP27]: 4b. The required data elements are available in electronic sources. If the required data are not in existing electronic sources, a credible, near-term path to electronic collection by most providers is specified and clinical data elements are specified for transition to the electronic health record.

4c. Exclusions

4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?
No

4c.2 If yes, provide justification.

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Comment [KP28]: 4c. Exclusions should not require additional data sources beyond what is required for scoring the measure (e.g., numerator and denominator) unless justified as supporting measure validity.

4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences

4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.
The NCDR program takes a number of steps to minimize any potential for inaccuracies or errors in data used to report on performance back to hospitals. The process begins with support provided to data abstractors, including webinars, meetings, resource guides on the website, and clinical quality consultants available via e-mail or toll free phone number, to ensure consistent data collection. The NCDR establishes a unified electronic platform for data capture and submission that includes a certification process of the technical data collection tool selected by the hospital (either a commercially available software vendor product, the NCDR's own web base data collection tool, or a hospital's customized electronic medical record system) that must occur prior to any data submissions. The certification process provides edit checks of data elements within data collection tool to ensure high quality data submission.

The NCDR data submission process includes a Data Quality Report (DQR) process that checks for validity in submissions based upon predetermined thresholds for element and composite completeness. The NCDR is putting in place a new strategy to systematically review the DQR results.

The NCDR on-site audit program has been developed to assess reliability of data abstraction. This annual process reviews key elements at a select number of patient reports at the select number of sites and provides feedback scores to the hospitals. Any elements not currently included in the on-site audit process and deemed critical to capture for this measure will be added upon NQF endorsement.

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Comment [KP29]: 4d. Susceptibility to inaccuracies, errors, or unintended consequences and the ability to audit the data items to detect such problems are identified.

4e. Data Collection Strategy/Implementation

4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:
Beta testing with a set of registry participants takes place with each new registry version to identify errors in the data collection tool. In addition, modifications are made to metrics based on feedback during a public comment period.

The Data Quality Report (DQR) program has been developed to ensure data are valid and complete. The DQR is a process for submitting data files to the NCDR®. Participants use their data collection tool software to create a submission file which is uploaded to the NCDR website. After uploading, the data in the file is automatically checked for errors and completeness. Passing the DQR ensures well-formed data and a statistically significant submission. Types of errors detected by the DQR include:
Schema:Structure doesn't match NCDR requirements
Dates: Inconsistent dates
Selection: Missing or mismatched data; Can be a parent/child errors where a field requests more data.
Outlier: Anomalies or exceptions; Data exceeds the possible limits. For example: 1,000mm length lesion.
Counter: errors deal with Closure Methods, Lesions, and Intracoronary Devices. Each one has a counter, when more than one is used
List: Missing data in the Medications or either Device lists.

Data is submitted on a quarterly basis. If a submission does not pass the DQR process, the entire submission is excluded from benchmarking. Hospitals may resubmit to pass the DQR process.

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Comment [KP30]: 4e. Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, etc.) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use).

Data is submitted on a quarterly basis. If a submission does not pass the DQR process, the entire submission is excluded from benchmarking. Hospitals may resubmit to pass the DQR process. 4e.2 **Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:** CathPCI Registry participants pay a fee of $3,800/year to enroll in the registry. Staff resources are needed for data collection and submission at the participating institution. Registry site managers/data collectors undergo (non-mandatory) training offered by the NCDR. 4e.3 **Evidence for costs:** http://www.ncdr.com/WebNCDR/ncdrdocuments/B08352N%20CathPCI%20Registry%20Enrollment%20Packet%20Complete.pdf 4e.4 **Business case documentation:**	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility*?	**4**
Steering Committee: Overall, to what extent was the criterion, *Feasibility*, **met?** **Rationale:**	**4** **C☐** **P☐** **M☐** **N☐**
RECOMMENDATION	
(for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.**	**Time-limited ☐**
Steering Committee: Do you recommend for endorsement? **Comments:**	**Y☐** **N☐** **A☐**

CONTACT INFORMATION

Co.1 **Measure Steward (Intellectual Property Owner)**
Co.1 **Organization**
American College of Cardiology Foundation (ACCF), 2400 N Street NW, Washington, District Of Columbia, 20037

Co.2 **Point of Contact**
Kristyne, McGuinn, MHS, kmcguinn@acc.org, 202-375-6529-

Measure Developer If different from Measure Steward
Co.3 **Organization**
American College of Cardiology Foundation (ACCF), 2400 N Street NW, Washington, District Of Columbia, 20037

Co.4 **Point of Contact**
Kristyne, McGuinn, MHS, kmcguinn@acc.org, 202-375-6529-

Co.5 **Submitter If different from Measure Steward POC**
Kristyne, McGuinn, MHS, kmcguinn@acc.org, 202-375-6529-, American College of Cardiology Foundation (ACCF)

Co.6 **Additional organizations that sponsored/participated in measure development**
Society for Cardiovascular Angiography and Interventions (SCAI)

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 **Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.**
The CathPCI Steering Committee developed the initial metrics used for quality improvement in the CathPCI outcomes reports. The measures were selected for appropriateness for public reporting by the NCDR public reporting workgroup.

CathPCI Steering Committee:
Douglas Weaver, MD, FACC
Ronald Krone, MD, FACC
Gregory Dehmer, MD, FSCAI
John Messenger, MD, FACC
Lloyd Klein, MD, FACC
John Rumsfeld, MD, PhD, FACC
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Public Reporting Workgroup:
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Christopher White MD, FACC
Carl Tommaso, MD, FACC, FAHA, FSCAI
Sunil Rao, MD, FACC, FSCAI
Andrea Russo, MD, FACC, FHRS
Debabrata Mukherjee MD, FACC

Ad.2 **If adapted, provide name of original measure:** N/A
Ad.3-5 **If adapted, provide original specifications URL or attachment**

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.6 **Year the measure was first released:** 2005
Ad.7 **Month and Year of most recent revision:** 09, 2010
Ad.8 **What is your frequency for review/update of this measure?** Every 3-4 years or if guideline updates warrant more frequent update, or with new dataset version.
Ad.9 **When is the next scheduled review/update for this measure?** 06, 2011

Ad.10 **Copyright statement/disclaimers:**

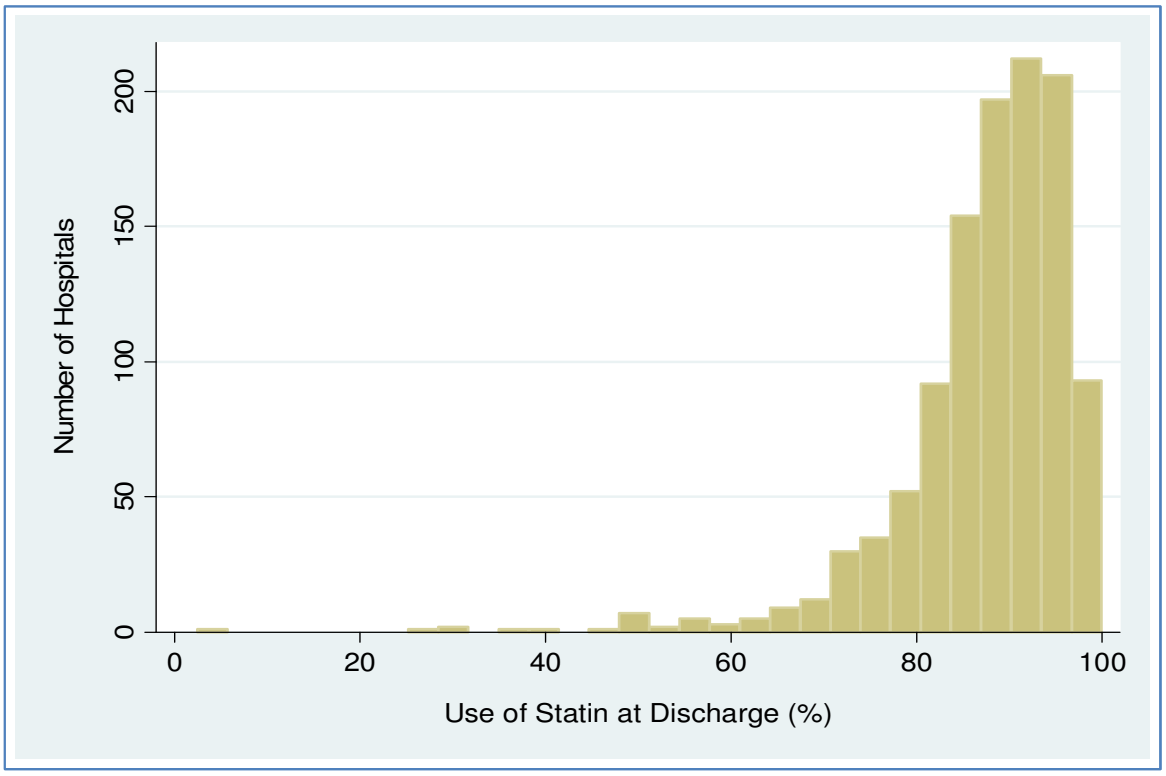
Ad.11 -13 **Additional Information web page URL or attachment:** Attachment DSTATIN Final.pdf

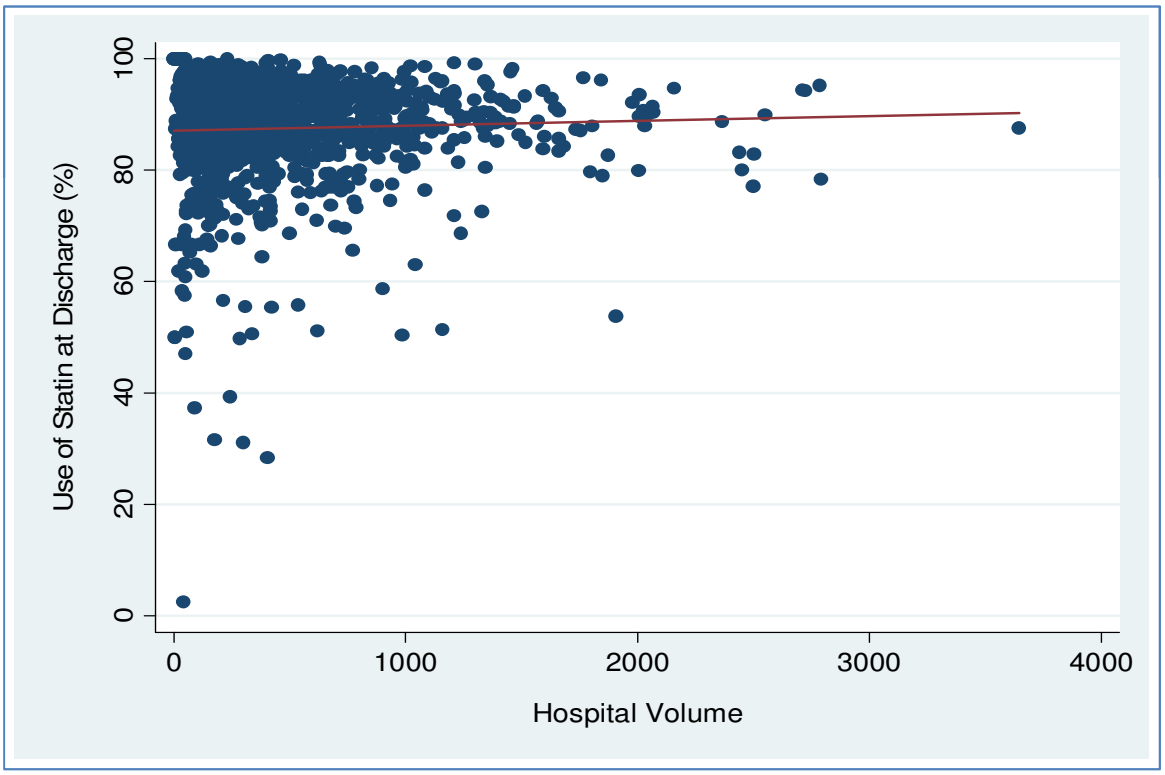
Date of Submission (*MM/DD/YY*)**:** 10/28/2010

Statin Prescribed at Discharge- NCDR CathPCI® Registry Data, July 2009-June 2010

Exclusions	Hospital Stays		Patients		Facilities	
	#	%	#	%	#	%
Initial Sample	**1282945**	**100**	**1201850**	**100**	**1168**	**100**
Discharges not between July 2009 and June 2010	0	0.00	0	0.00	0	0.00
Remainging	**1282945**	**100.00**	**1201850**	**100.00**	**1168**	**100.00**
Without PCI during the admission	695970	54.25	659146	54.84	46	3.94
Remainging	**586975**	**45.75**	**542704**	**45.16**	**1122**	**96.06**
Discharge Status: deceased	8027	1.37	7705	1.42	0	0.00
Remainging	**578948**	**98.63**	**534999**	**98.58**	**1122**	**100.00**
Discharge Location: Other acute care hospital	3931	0.68	3753	0.70	1	0.09
Remainging	**575017**	**99.32**	**531246**	**99.30**	**1121**	**99.91**
Discharge Location: Hospice	798	0.14	759	0.14	0	0.00
Remainging	**574219**	**99.86**	**530487**	**99.86**	**1121**	**100.00**
Discharge Location: Left against medical advice	1232	0.21	1070	0.20	0	0.00
Remainging	**572987**	**99.79**	**529417**	**99.80**	**1121**	**100.00**
Stent at discharge: contraindicated, or blinded	8999	1.57	7843	1.48	0	0.00
Study Sample	**563988**	**98.43**	**521574**	**98.52**	**1121**	**100.00**
Statin at discharge	496017	87.95	460407	88.27	1121	100.00
Admissions with MI	**179691**	**31.86**	**176975**	**33.93**	**1118**	**99.73**
Statin at discharge	164380	91.48	162043	91.56	1114	99.64
Amdissions without MI	**384297**	**68.14**	**358199**	**68.68**	**1103**	**98.39**
Statin at discharge	331637	86.30	310307	86.63	1102	99.91

Distribution of Statin Prescription at Discharge		
Description	**Volume**	**Rate**
N	1121	1121
Mean	503.11	0.8760
Std Deviation	457.11	0.0946
100% Max	3645	1.0000
99%	2158	1.0000
95%	1386	0.9777
90%	1041	0.9636
75% Q3	672	0.9369
50% Median	384	0.8930
25% Q1	183	0.8420
10%	77	0.7718
5%	41	0.7162
1%	14	0.5059
0% Min	1	0.0244

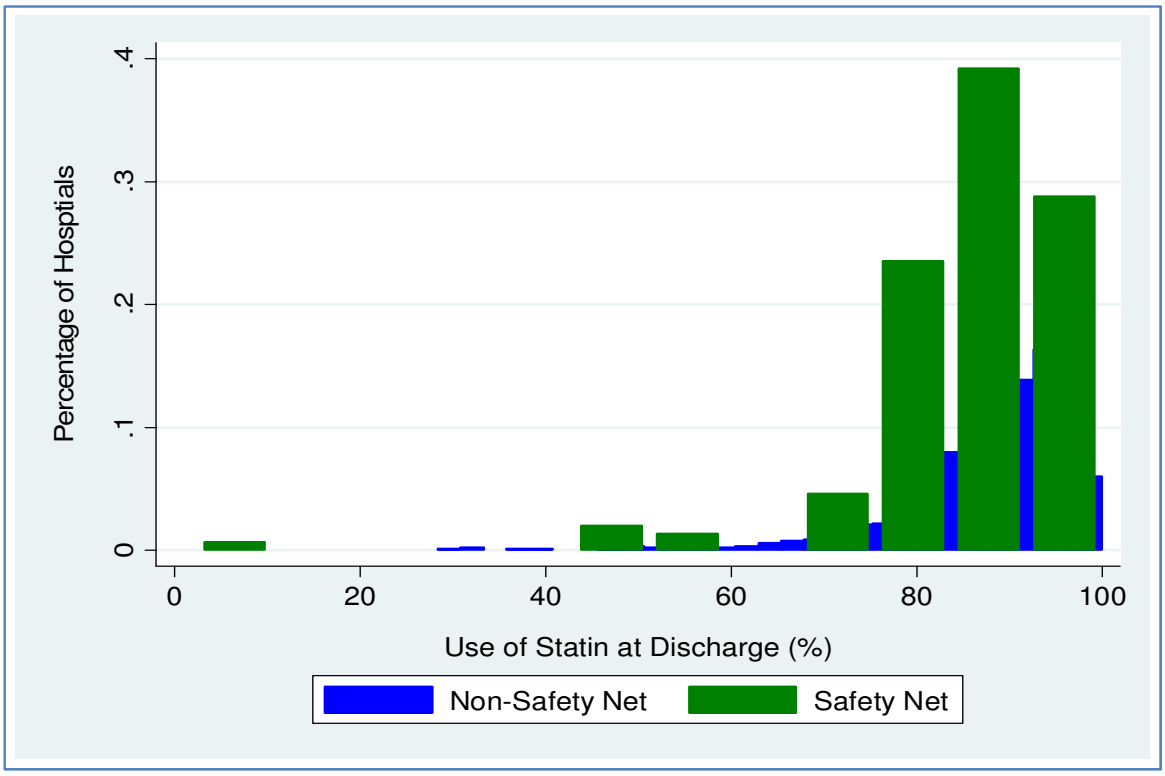

Number of Hospitals
0
50
100
150
200
0
20
40
60
80
100
Use of Statin at Discharge (%)

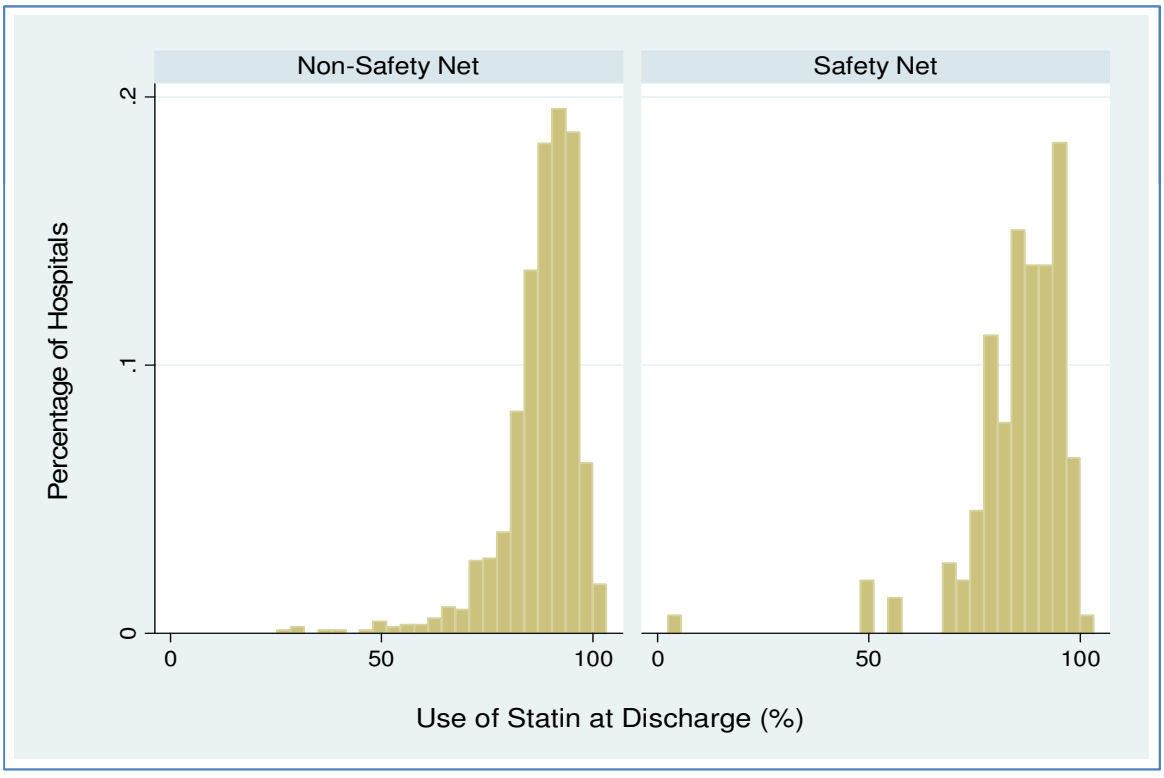

Use of Statin at Discharge (%)
0
20
40
60
80
100
0
1000
2000
3000
4000
Hospital Volume

Distribution of Statin Prescription at Discharge Stratified by Safety Net Status

Description	Safety Net Status*			
	No		Yes	
	Volume	Rate	Volume	Rate
N	931	931	153	153
Mean	516.72	0.8788	452.87	0.8555
Std Deviation	468.47	0.0907	383.59	0.1173
100% Max	3645	1.0000	2068	1.0000
99%	2441	1.0000	2004	0.9909
95%	1409	0.9769	1210	0.9770
90%	1071	0.9627	985	0.9647
75% Q3	687	0.9373	639	0.9356
50% Median	399	0.8947	341	0.8762
25% Q1	190	0.8475	180	0.8075
10%	80	0.7788	91	0.7600
5%	44	0.7209	42	0.6774
1%	14	0.5091	15	0.4982
0% Min	1	0.2840	4	0.0244

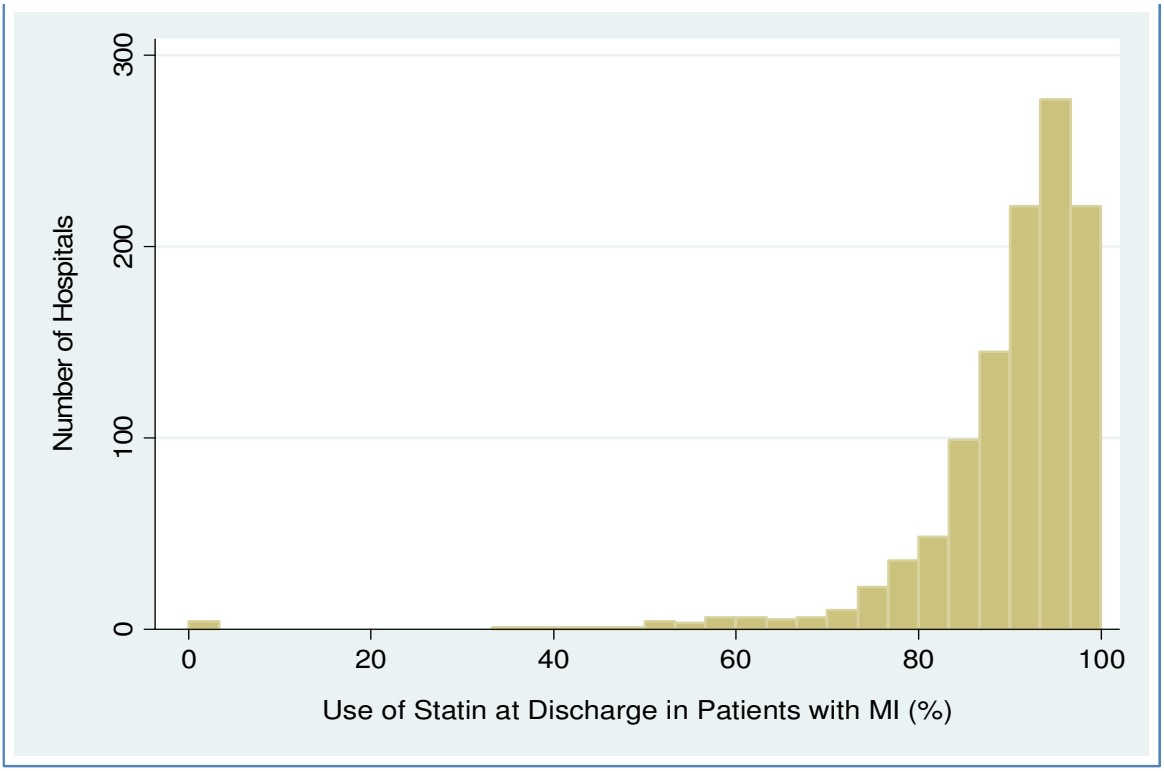
* Defined as government hospitals or non-government hosptials with high medicaid caseload using AHA 2008 Data.

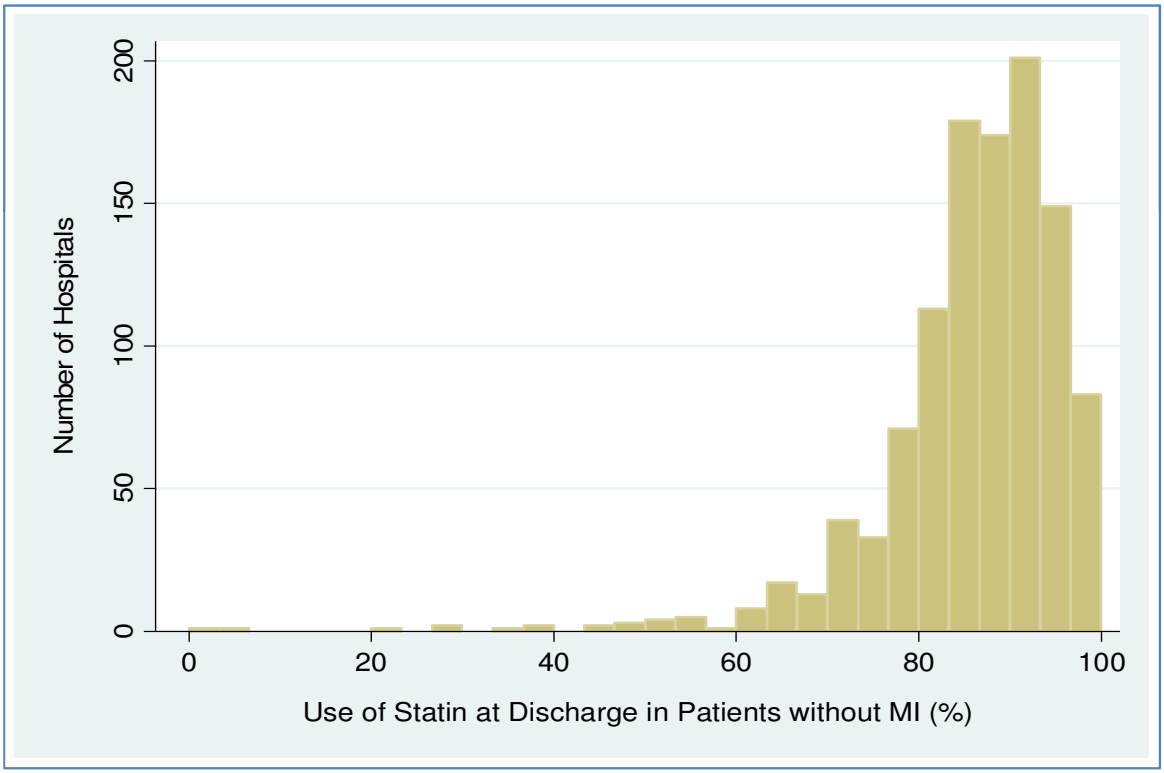

Percentage of Hospitals
0
.1
.2
.3
.4
0
20
40
60
80
100
Use of Statin at Discharge (%)
Non-Safety Net
Safety Net

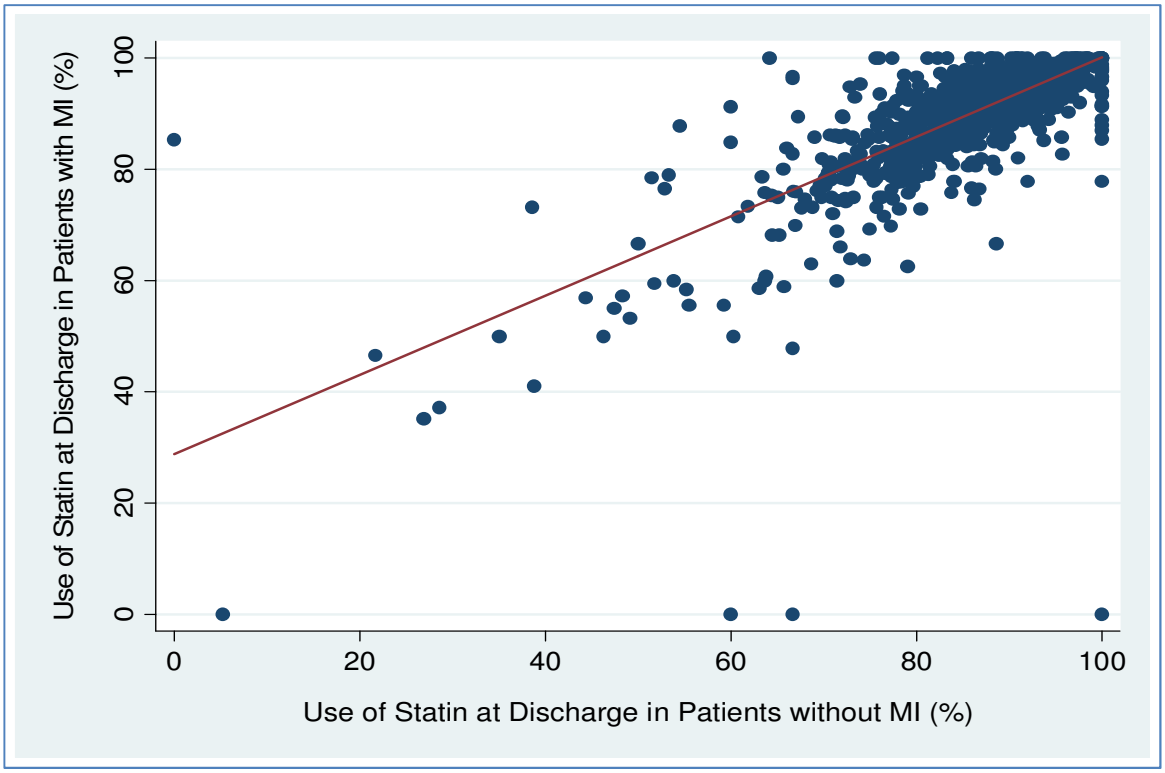

Non-Safety Net
Safety Net
Percentage of Hospitals
0
.1
.2
0
50
100
0
50
100
Use of Statin at Discharge (%)

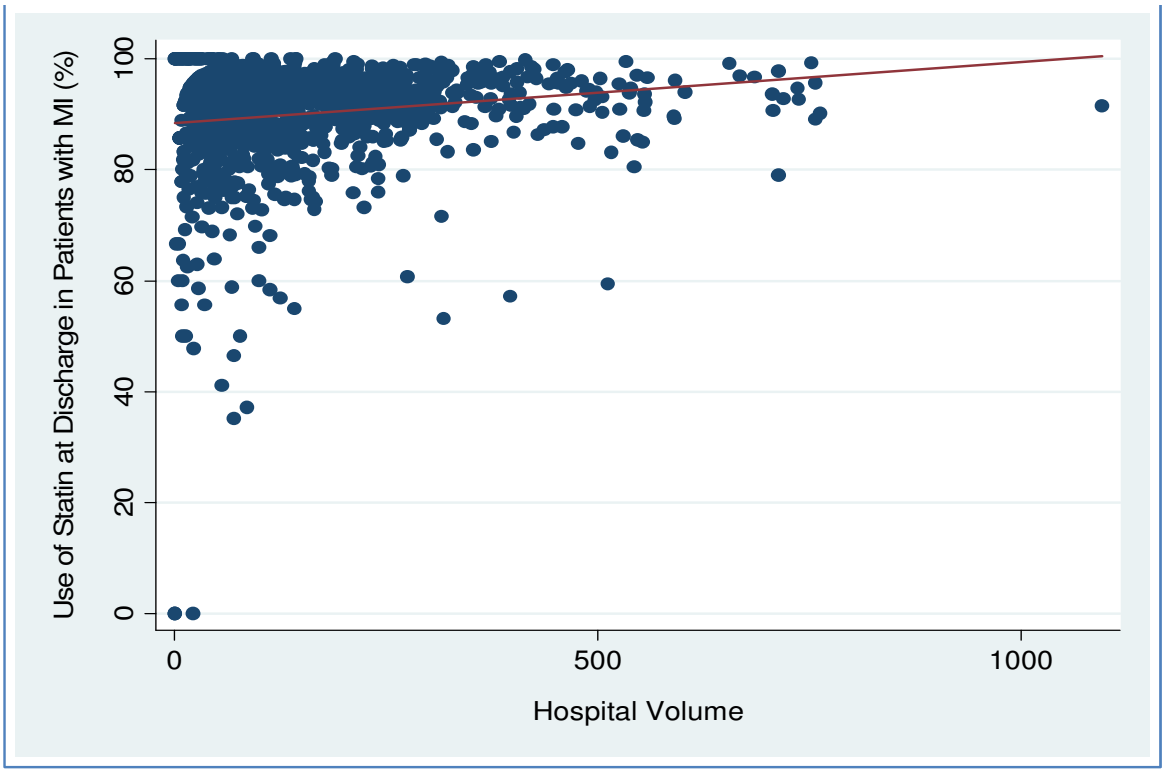
Distribution of Statin Prescription at Discharge

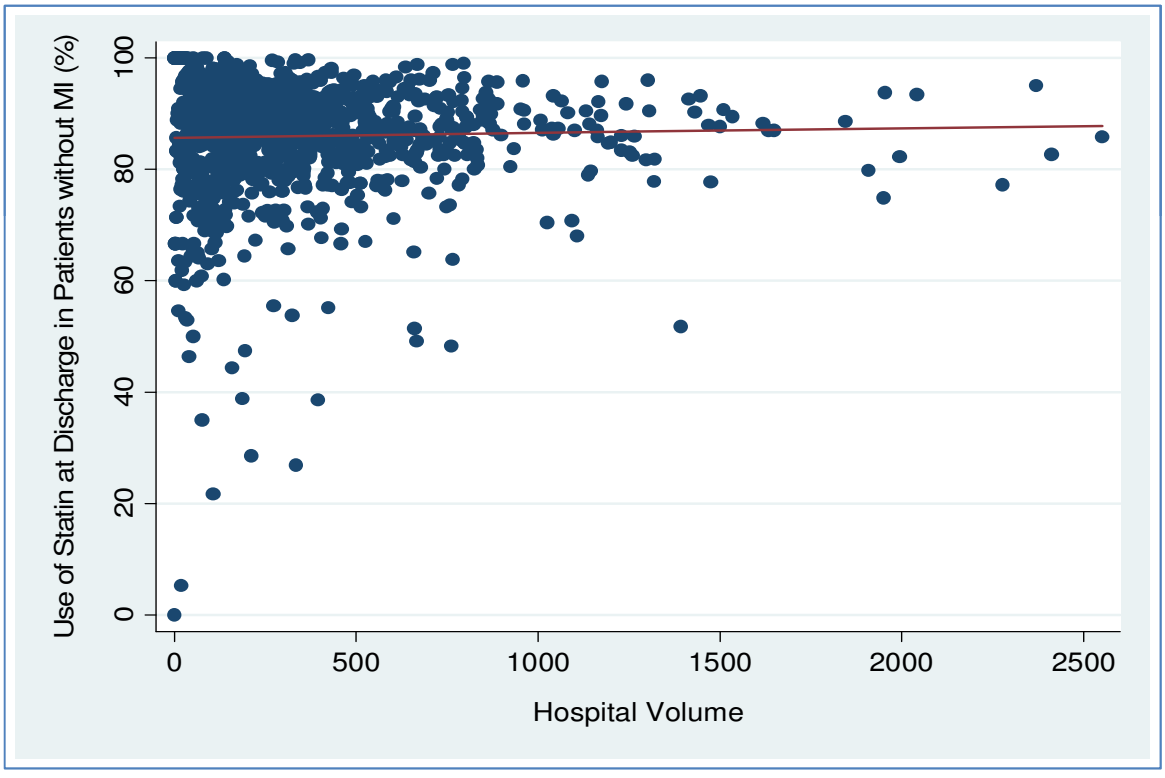
Description	In Admissions with MI			
	Yes		No	
	Volume	Rate	Volume	Rate
N	1118	1118	1103	1103
Mean	160.73	0.9016	348.41	0.8602
Std Deviation	138.97	0.1011	339.19	0.1033
100% Max	1095	1.0000	2550	1.0000
99%	706	1.0000	1633	1.0000
95%	448	1.0000	1007	0.9773
90%	332	0.9820	759	0.9599
75% Q3	220	0.9600	460	0.9264
50% Median	125	0.9254	257	0.8768
25% Q1	61	0.8771	124	0.8231
10%	27	0.8000	46	0.7500
5%	15	0.7500	25	0.6881
1%	4	0.5000	3	0.4829
0% Min	1	0.0000	1	0.0000


Number of Hospitals
0
100
200
300
0
20
40
60
80
100
Use of Statin at Discharge in Patients with MI (%)


Number of Hospitals
0
50
100
150
200
0
20
40
60
80
100
Use of Statin at Discharge in Patients without MI (%)

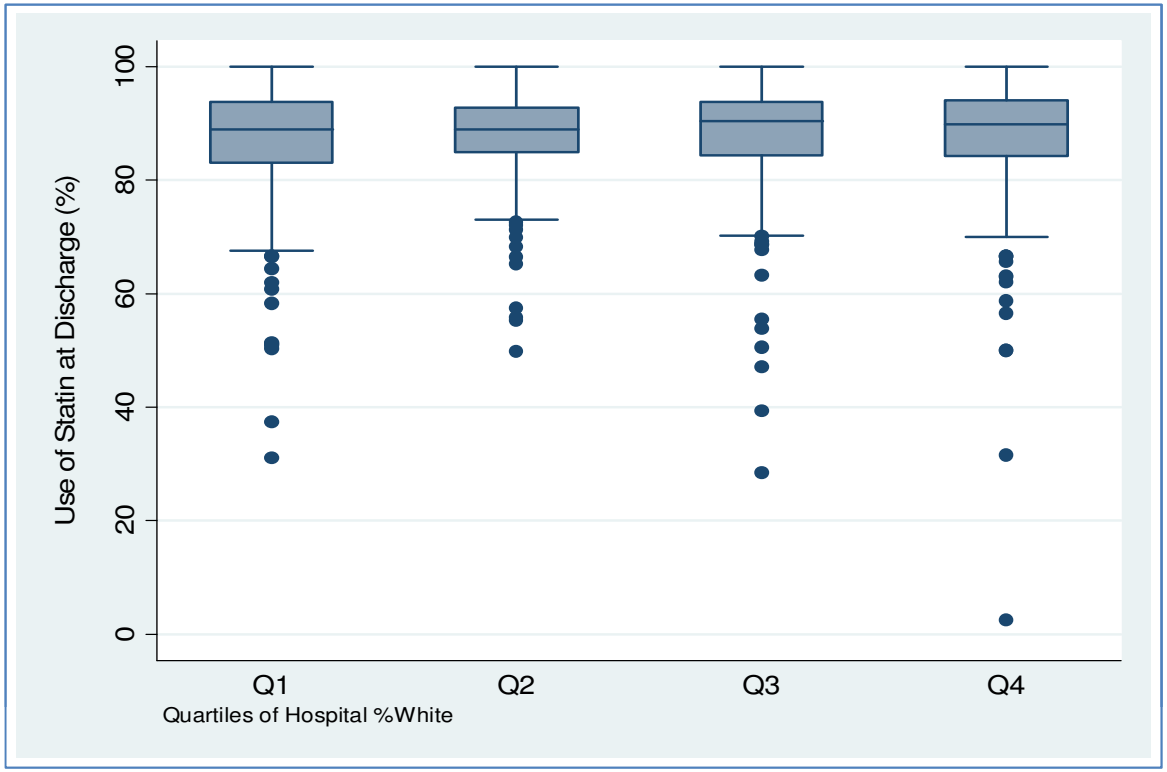

Use of Statin at Discharge in Patients with MI (%)
0
20
40
60
80
100
0
20
40
60
80
100
Use of Statin at Discharge in Patients without MI (%)


Use of Statin at Discharge in Patients with MI (%)
0
20
40
60
80
100
0
500
1000
Hospital Volume


Use of Statin at Discharge in Patients without MI (%)
0
20
40
60
80
100
0
500
1000
1500
2000
2500
Hospital Volume

Distribution of Statin Prescription at Discharge Stratified by Hospital %White

Description	%White							
	Q1 (3.33% to 84.72%)		Q2 (84.73% to 92.73%)		Q3 (92.74% to 96.95%)		Q4 (96.96% to 100.00%)	
	Volume	Rate	Volume	Rate	Volume	Rate	Volume	Rate
N	280	280	281	281	280	280	280	280
Mean	476.58	0.86846	531.26	0.87793	536.44	0.88079	468.06	0.87671
Std Deviatior	508.57	0.09977	418.88	0.07702	460.31	0.09383	433.94	0.10540
100% Max	3645	1.00000	2503	1.00000	2711	1.00000	2793	1.00000
99%	2725	1.00000	2008	1.00000	2441	1.00000	2158	1.00000
95%	1390.5	0.97638	1409	0.97271	1482.5	0.98052	1355.5	0.98512
90%	1117.5	0.96130	1071	0.96154	1084.5	0.96237	1019.5	0.96900
75% Q3	635.5	0.93781	714	0.92761	713	0.93819	634	0.94158
50% Median	302	0.88958	431	0.88942	413	0.90405	379	0.89809
25% Q1	147.5	0.82987	215	0.84779	231.5	0.84364	160.5	0.84237
10%	64	0.76056	96	0.77958	106.5	0.79013	61.5	0.77024
5%	35	0.68874	47	0.73669	61.5	0.72434	27	0.70518
1%	6	0.50407	25	0.55866	30	0.47059	6	0.50000
0% Min	2	0.31104	17	0.49825	15	0.28395	1	0.02439


Use of Statin at Discharge (%)
0
20
40
60
80
100
Q1
Q2
Q3
Q4
Quartiles of Hospital %White

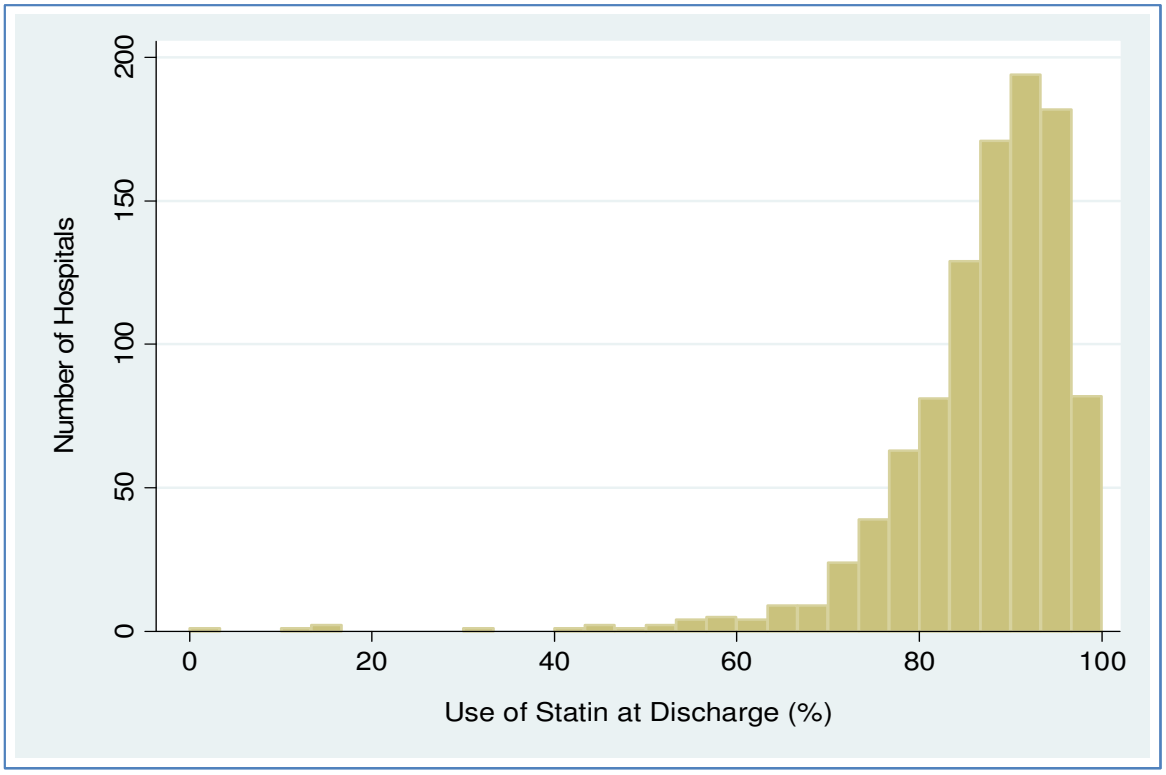
Testing Cohort

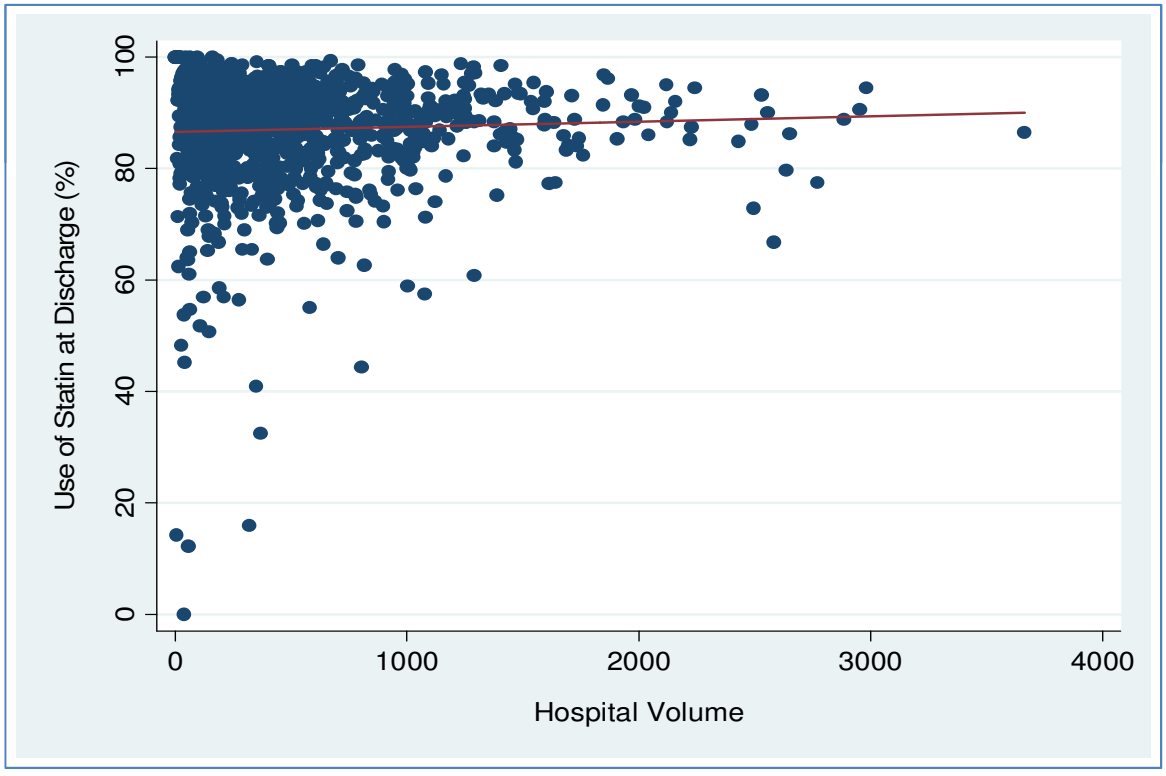
Statin Prescribed at Discharge- Testing Cohort, July 2008-June 2009

Exclusions	Hospital Stays		Patients		Facilities	
	#	%	#	%	#	%
Initial Sample	**4594173**	**100**	**3931296**	**100**	**1089**	**100**
Discharges not between July 2008 and Jane 2009	3315964	72.18	2737465	69.63	38	3.49
Remainging	**1278209**	**27.82**	**1193831**	**30.37**	**1051**	**96.51**
Without PCI during the admission	712139	55.71	670862	56.19	44	4.19
Remainging	**566070**	**44.29**	**522969**	**43.81**	**1007**	**95.81**
Discharge Status: deceased	7519	1.33	7237	1.38	0	0.00
Remainging	**558551**	**98.67**	**515732**	**98.62**	**1007**	**100.00**
Discharge Location: Other hospital	3528	0.63	3340	0.65	0	0.00
Remainging	**555023**	**99.37**	**512392**	**99.35**	**1007**	**100.00**
Stent at discharge: contraindicated, or blinded	7253	1.31	6328	1.23	0	0.00
Study Sample	**547770**	**98.69**	**506064**	**98.77**	**1007**	**100.00**
Statin at discharge	479397	87.52	444584	87.85	1006	99.90
Admissions with MI	**165400**	**30.20**	**162945**	**32.20**	**1001**	**99.40**
Statin at discharge	151156	91.39	149068	91.48	999	99.80
Amdissions without MI	**382370**	**69.80**	**355703**	**70.29**	**995**	**98.81**
Statin at discharge	328241	85.84	306483	86.16	994	99.90

Testing Cohort
Distribution of Statin Prescription at Discharge

Description	Volume	DSTATIN
N	1007	1007
Mean	543.96	0.8710
Std Deviation	493.71	0.0996
100% Max	3662	1.0000
99%	2496	1.0000
95%	1477	0.9756
90%	1158	0.9621
75% Q3	717	0.9355
50% Median	415	0.8912
25% Q1	207	0.8341
10%	82	0.7634
5%	45	0.7127
1%	13	0.5185
0% Min	1	0.0000


Number of Hospitals
0
50
100
150
200
0
20
40
60
80
100
Use of Statin at Discharge (%)

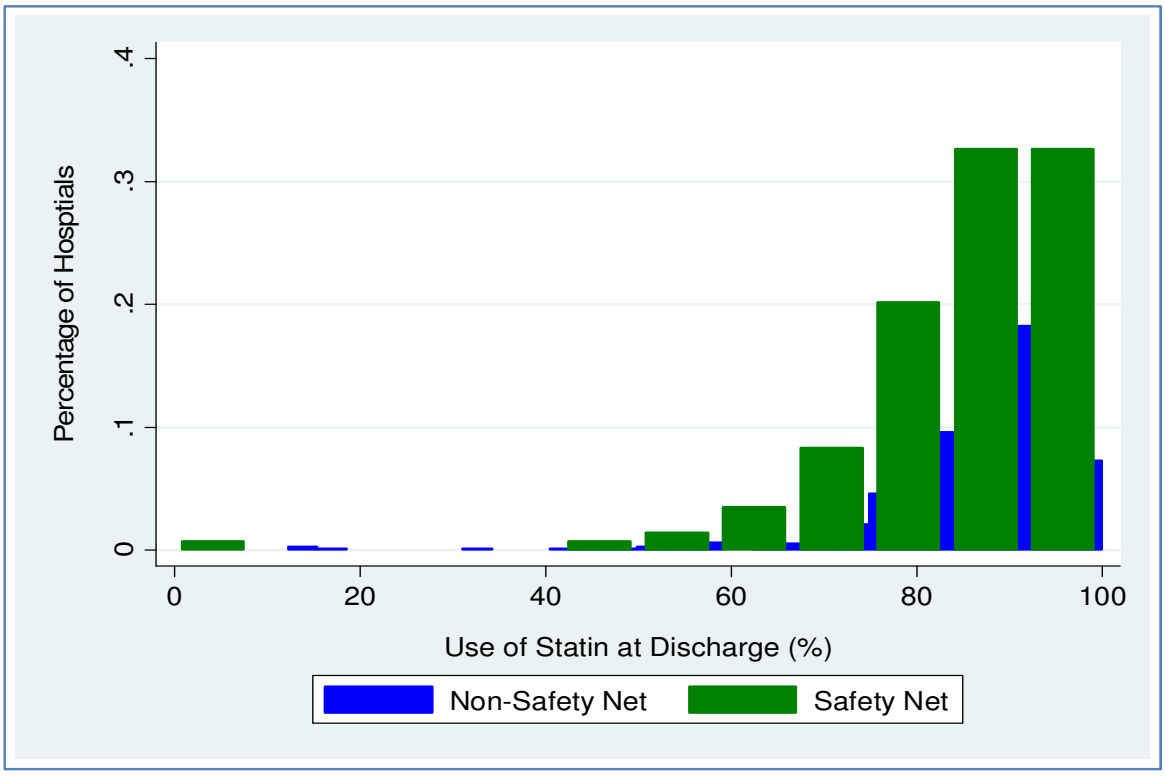

Use of Statin at Discharge (%)
0
20
40
60
80
100
0
1000
2000
3000
4000
Hospital Volume

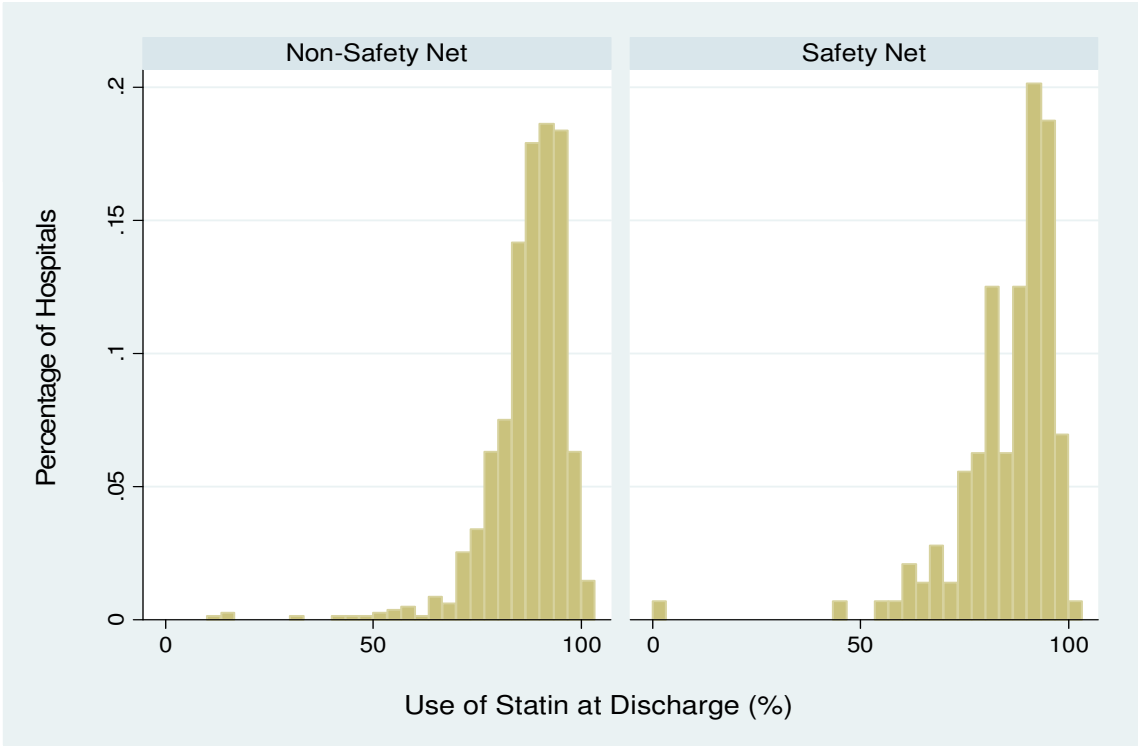
Testing Cohort

Distribution of Statin Prescription at Discharge Stratified by Safety Net Status

Description	Safety Net Status*			
	No		Yes	
	Volume	DSTATIN	Volume	DSTATIN
N	827	827	144	144
Mean	566.92	0.8726	461.12	0.8546
Std Deviation	508.75	0.0954	384.27	0.1243
100% Max	3662	1.0000	1932	1.0000
99%	2556	1.0000	1640	0.9915
95%	1535	0.9738	1150	0.9725
90%	1217	0.9593	998	0.9655
75% Q3	745	0.9349	642.5	0.9408
50% Median	430	0.8905	354.5	0.8916
25% Q1	221	0.8370	174	0.8066
10%	96	0.7692	81	0.7025
5%	53	0.7197	38	0.6400
1%	15	0.5185	11	0.4524
0% Min	1	0.1228	10	0.0000

* Defined as government hospitals or non-government hosptials with high medicaid caseload using AHA 2008 Data.

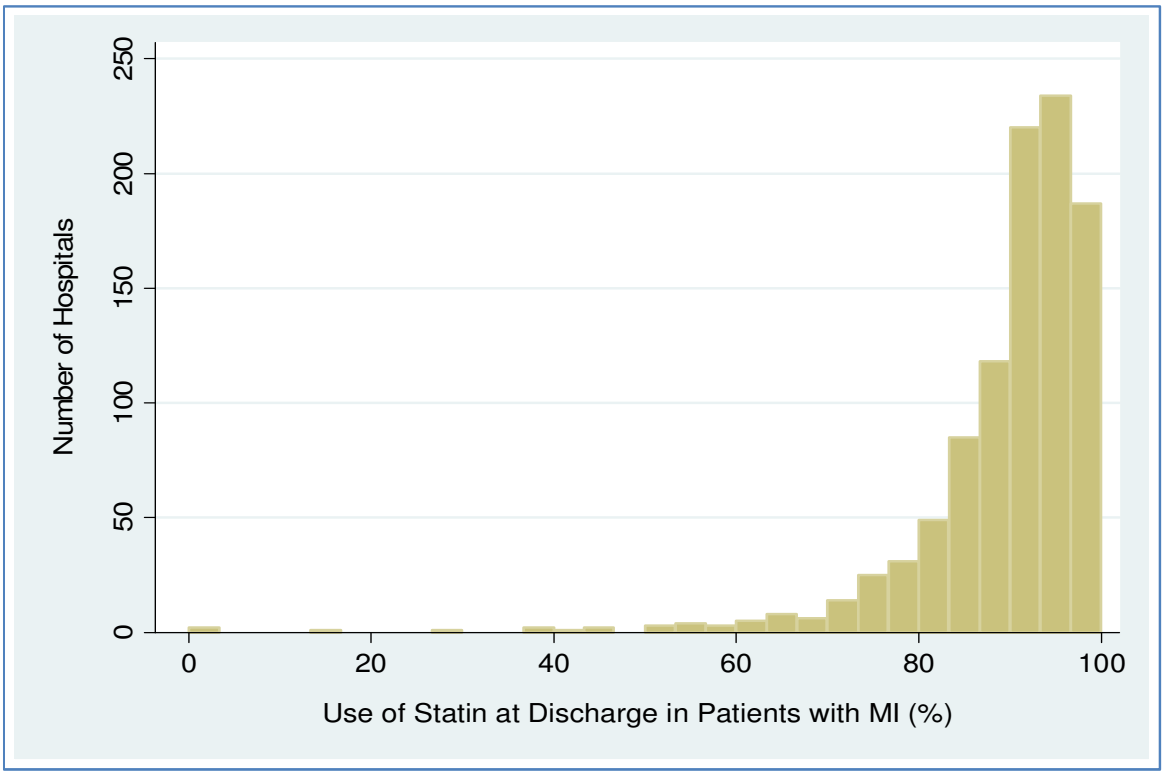

Percentage of Hospitals
0
.1
.2
.3
.4
0
20
40
60
80
100
Use of Statin at Discharge (%)
Non-Safety Net
Safety Net

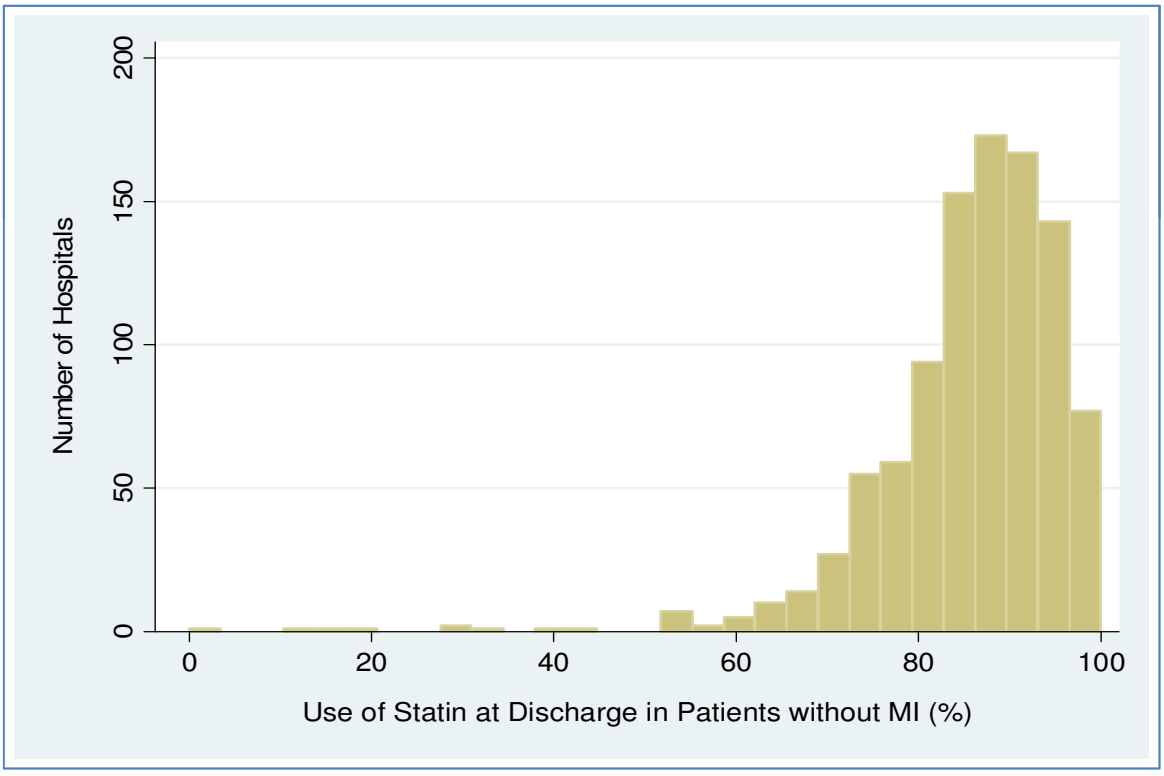

Non-Safety Net
Safety Net
Percentage of Hospitals
0
.05
.1
.15
.2
0
50
100
0
50
100
Use of Statin at Discharge (%)

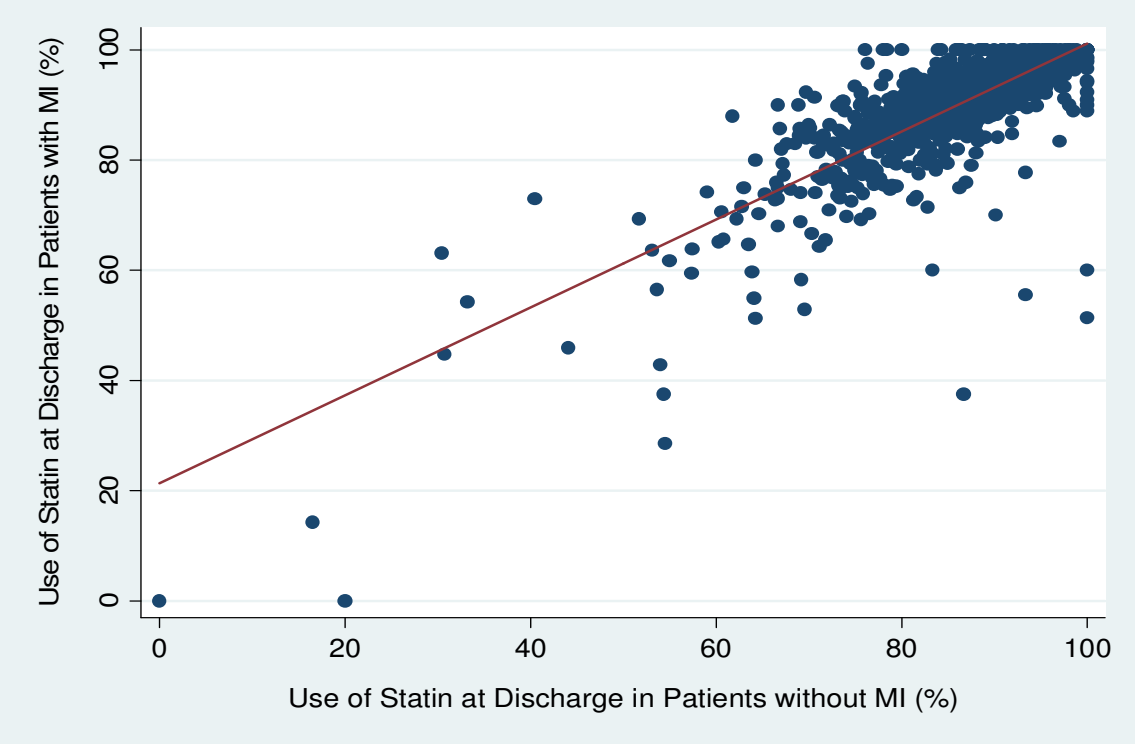
Testing Cohort

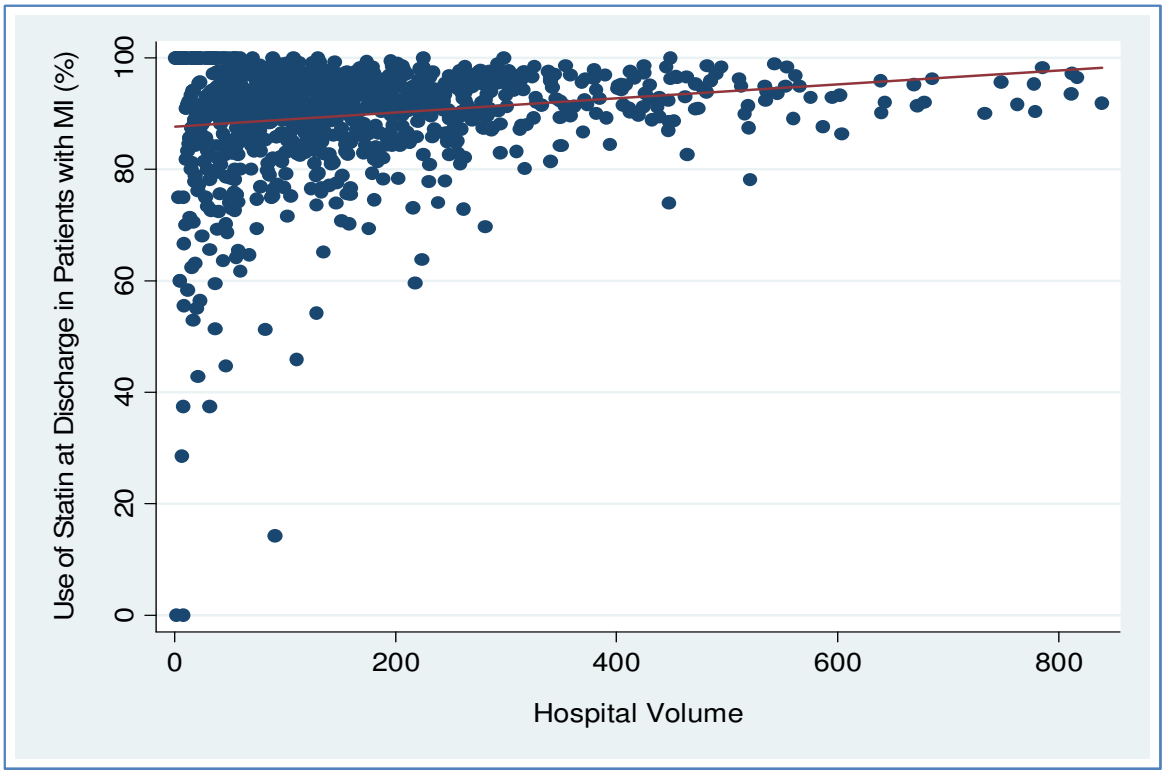
Distribution of Statin Prescription at Discharge

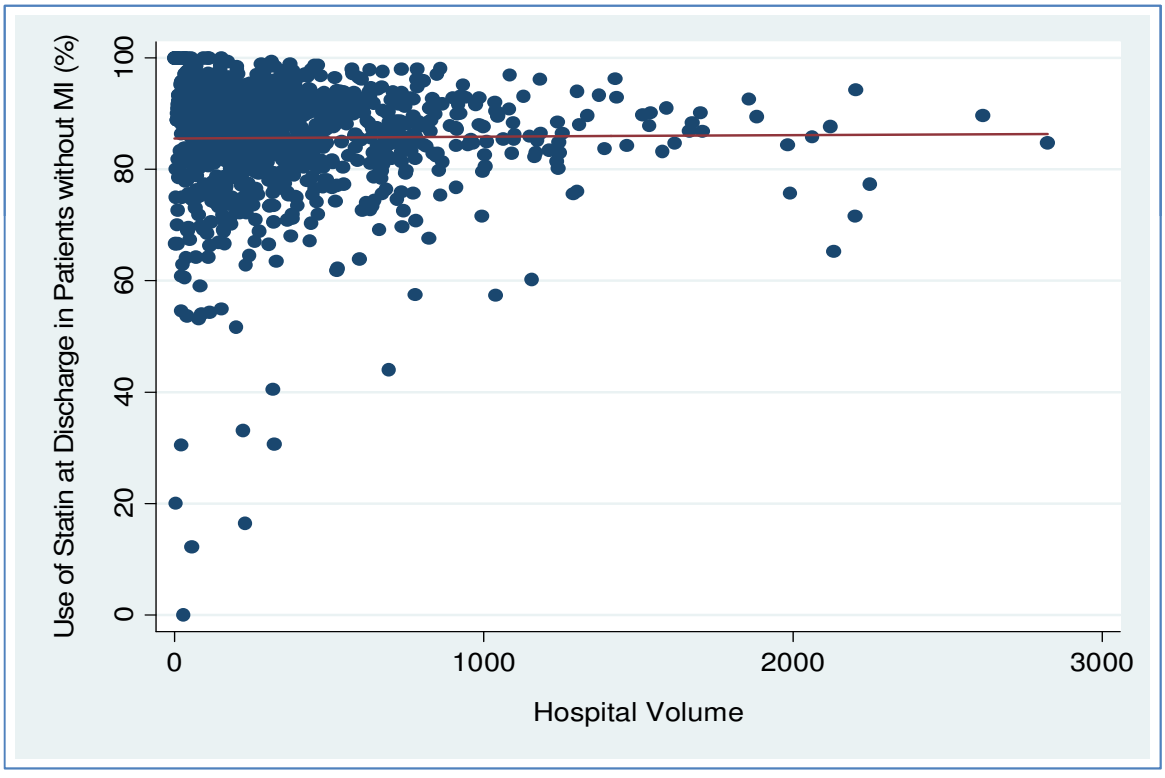
Description	In Admissions with MI: Yes		No	
	Volume	DSTATIN	Volume	DSTATIN
N	1001	1001	995	995
Mean	165.23	0.8980	384.29	0.8575
Std Deviation	144.72	0.1011	371.56	0.1030
100% Max	839	1.0000	2823	1.0000
99%	686	1.0000	1984	1.0000
95%	455	1.0000	1096	0.9762
90%	353	0.9820	820	0.9558
75% Q3	222	0.9590	505	0.9248
50% Median	127	0.9209	280	0.8750
25% Q1	60	0.8696	142	0.8168
10%	28	0.7907	49	0.7460
5%	16	0.7315	24	0.6913
1%	5	0.5135	5	0.5174
0% Min	1	0.0000	1	0.0000


Number of Hospitals
0
50
100
150
200
250
0
20
40
60
80
100
Use of Statin at Discharge in Patients with MI (%)


Number of Hospitals
0
50
100
150
200
0
20
40
60
80
100
Use of Statin at Discharge in Patients without MI (%)


Use of Statin at Discharge in Patients with MI (%)
0
20
40
60
80
100
0
20
40
60
80
100
Use of Statin at Discharge in Patients without MI (%)

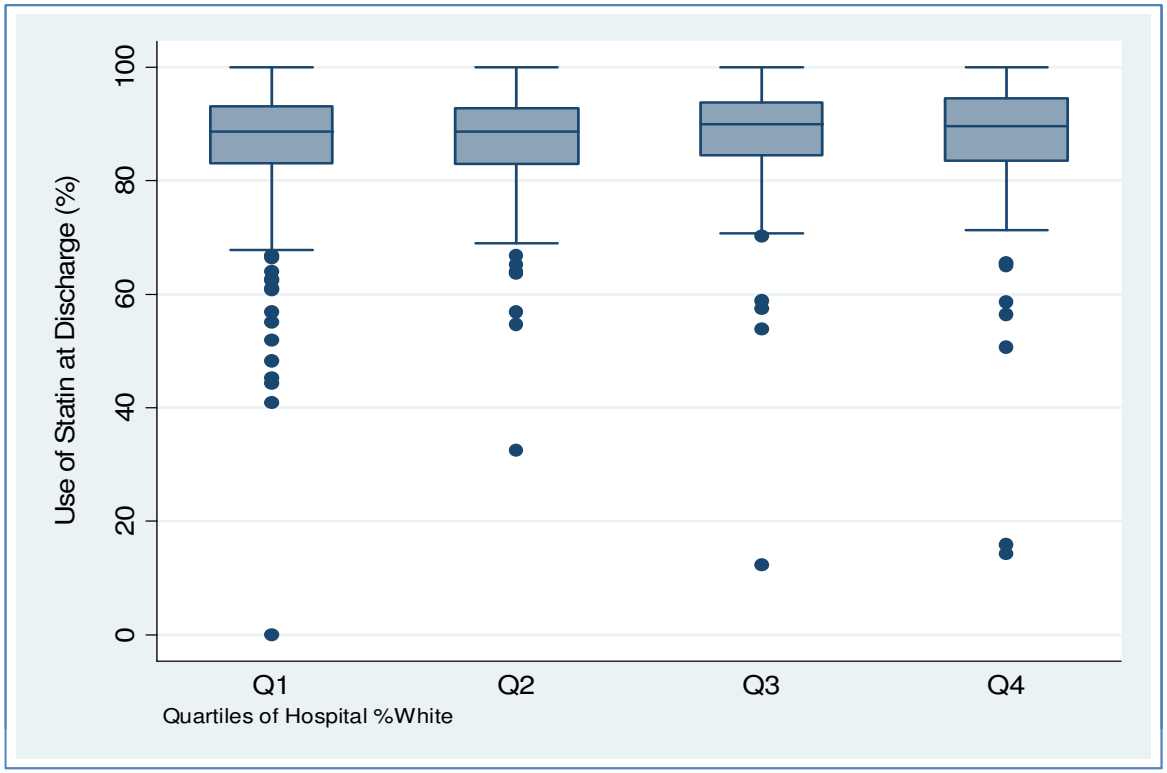

Use of Statin at Discharge in Patients with MI (%)
0
20
40
60
80
100
0
200
400
600
800
Hospital Volume


Use of Statin at Discharge in Patients without MI (%)
0
20
40
60
80
100
0
1000
2000
3000
Hospital Volume

Testing Cohort

Distribution of Statin Prescription at Discharge Stratified by Hospital %White

Description	%White	%White Q1		Q2		Q3		Q4	
		Volume	DASA	Volume	DASA	Volume	DASA	Volume	DASA
N	1007	251	251	252	252	252	252	252	252
Mean	0.7922	481.04	0.8600	584.96	0.8665	585.18	0.8813	524.42	0.8762
Std Deviation	0.2264	487.53	0.1158	504.27	0.0884	485.63	0.0878	492.27	0.1032
100% Max	1.0000	2981	1.0000	3662	1.0000	2556	1.0000	2771	1.0000
99%	1.0000	2649	1.0000	2581	0.9881	2431	1.0000	2528	1.0000
95%	0.9875	1430	0.9743	1480	0.9726	1470	0.9795	1535	0.9776
90%	0.9737	1060	0.9583	1158	0.9606	1208	0.9580	1056	0.9628
75% Q3	0.9418	604	0.9313	798.5	0.9282	803.5	0.9380	680	0.9449
50% Median	0.8717	346	0.8865	468	0.8864	457	0.8997	404	0.8967
25% Q1	0.7281	169	0.8294	225.5	0.8282	230.5	0.8451	184.5	0.8342
10%	0.5000	59	0.7350	106	0.7577	106	0.7860	64	0.7752
5%	0.2632	35	0.6400	64	0.7029	65	0.7571	24	0.7316
1%	0.0000	11	0.4435	23	0.5687	21	0.5743	2	0.5068
0% Min	0.0000	9	0.0000	15	0.3252	17	0.1228	1	0.1429


Use of Statin at Discharge (%)
0
20
40
60
80
100
Q1
Q2
Q3
Q4
Quartiles of Hospital %White