## 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 NOF Four conditions must be met before proposed measures may be considered and evaluated for suitability as NOF voluntary consensus standards: 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 Α Y⊠ N∏ measure submission A.4 Measure Steward Agreement attached: NQF - signed-634238762228916780.pdf

NQF	#1495
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□
<ul> <li>C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement.</li> <li>Purpose: Public reporting, Internal quality improvement Accountability, Payment incentive, Accreditation</li> </ul>	C Y⊠ N□
<ul> <li>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.</li> <li>D.1Testing: Yes, fully developed and tested</li> <li>D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures? Yes</li> </ul>	D Y⊠ N□
(for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward ( <i>if submission returned</i> ):	Met Y⊠ N□
Staff Notes to Reviewers (issues or questions regarding any criteria):	
Staff Reviewer Name(s): Reva Winkler	

#### 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 guality (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. Eval Measures must be judged to be important to measure and report in order to be evaluated against the Ratin remaining criteria. (evaluation criteria) 1a. High Impact 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 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 M at:http://circ.ahajournals.org/cgi/content/full/103/24/3019. Accessed October 13, 2010. N 1b. Opportunity for Improvement 1b C P 1b.1 Benefits (improvements in quality) envisioned by use of this measure: P2Y12 inhibitors, including

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

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).

2

- Comment [KP1]: 1a. The measure focus addresses:

•a specific national health goal/priority identified by NQF's National Priorities Partners; OR

Partners; UR • 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).

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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.

# **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 hospitals 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% Cl 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

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	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:

olntermediate 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 multistep care process, it measures the step that has the greatest effect on improving the specified desired outcome(s). o<u>Structure</u> - 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.

o<u>Access</u> - evidence that an association exists between access to a health service and the outcomes of, or experience with, care. o<u>Efficiency</u> - 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  $\rightarrow$ identify problem/potential problem → choose/plan intervention (with patient input)  $\rightarrow$  provide intervention  $\rightarrow$  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.

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

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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 drugeluting stent [DES]) during PCI for ACS, clopidogrel 75 mg dailyt (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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Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable

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/method

s/benefit.htm). If the USPSTE grading system was not used, the grading system is explained including how it relates to the USPSTE 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. 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 STelevation 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

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

Comment [k7]: USPSTF grading system http://www.ahrq.gov/clinic/uspstf/grades.ht m: 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.

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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.	
<b>1c.14 Rationale for using this guideline over others:</b> 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 <i>Importance to Measure and Report?</i>	1
Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i> , met? Rationale:	1 Y□ N□
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, <u>as specified</u> , produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	Eval Ratin g
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	
<b>2a.1 Numerator Statement</b> ( <i>Brief, text description of the numerator - what is being measured about the</i>	
target population, e.g. target condition, event, or outcome): Count of patients with a PCI procedure with a P2Y12 inhibitor (Clopidogrel, Prasugrel or Ticlopidine)	
<ul> <li>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):</li> <li>Count of patients with a PCI procedure with a P2Y12 inhibitor (Clopidogrel, Prasugrel or Ticlopidine) prescribed at discharge.</li> <li>2a.2 Numerator Time Window (The time period in which cases are eligible for inclusion in the numerator): 1 year</li> </ul>	
<ul> <li>target population, e.g. target condition, event, or outcome):</li> <li>Count of patients with a PCI procedure with a P2Y12 inhibitor (Clopidogrel, Prasugrel or Ticlopidine)</li> <li>prescribed at discharge.</li> <li>2a.2 Numerator Time Window (The time period in which cases are eligible for inclusion in the numerator):</li> </ul>	2a- specs C P M N
<ul> <li>target population, e.g. target condition, event, or outcome):</li> <li>Count of patients with a PCI procedure with a P2Y12 inhibitor (Clopidogrel, Prasugrel or Ticlopidine)</li> <li>borescribed at discharge.</li> <li>2a.2 Numerator Time Window (<i>The time period in which cases are eligible for inclusion in the numerator</i>):</li> <li>1 year</li> <li>2a.3 Numerator Details (<i>All information required to collect/calculate the numerator, including all codes, logic, and definitions</i>):</li> <li>Element Name: Discharge Medications</li> <li>Discharge medication=clopidogrel, ticlopidine, or prasugrel.</li> <li>Coding Instructions: Indicate which of the following medications the patient was prescribed upon discharge.</li> <li>Note(s): Complete only for patients who had a PCI procedure attempted or performed during this episode of care.</li> </ul>	specs C P M

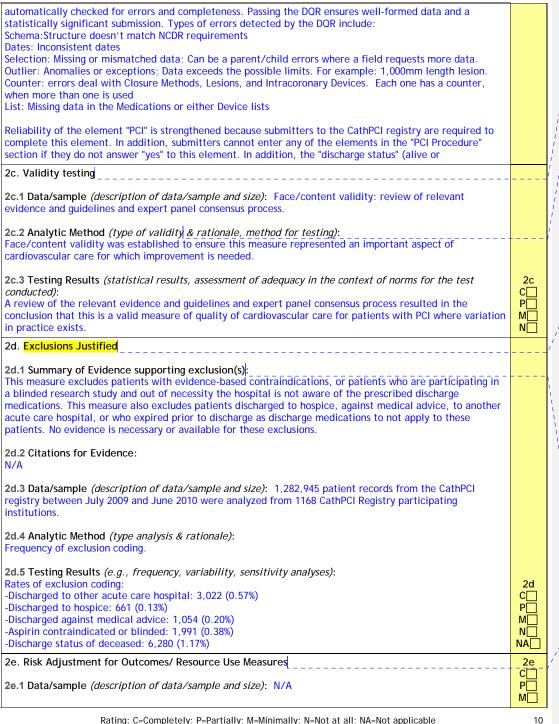
**Comment [KP8]:** 2a. The measure is well defined and precisely specified so that it can be implemented consistently within and across organizations and allow for comparability. The required data elements are of high quality as defined by NOF's Health Information Technology Expert Panel (HITEP).

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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 ( <i>Brief, text description of the denominator - target population being measured</i> ): 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.		
<b>2a.7 Denominator Time Window (</b> <i>The time period in which cases are eligible for inclusion in the denominator</i> <b>)</b> : 1 year		
2a.8 Denominator Details ( <i>All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions</i> ): 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.		
<ul> <li>2a.9 Denominator Exclusions (<i>Brief text description of exclusions from the target population</i>): -P2Y12 coded as contraindicated or blinded</li> <li>-Discharge status of expired</li> <li>-Discharge location of "other acute care hospital", "hospice" or "against medical advice".</li> <li>2a.10 Denominator Exclusion Details (<i>All information required to collect exclusions to the denominator, including all codes, logic, and definitions</i>):</li> </ul>		<ul> <li>Comment [k9]: 11 Risk factors that influence outcomes should not be specified as exclusions.</li> <li>12 Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.</li> </ul>
Element name: Discharge Status Discharge status= deceased Coding Instructions: Indicate whether the patient was alive or deceased at discharge.		

	NQF
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 class of medications is unknown.	ı or
<b>2a.11 Stratification Details/Variables</b> ( <i>AII information required to stratify the measure including the stratification variables, all codes, logic, and definitions</i> ): N/A	
2a.12-13 Risk Adjustment Type: No risk adjustment necessary	
<b>2a.14 Risk Adjustment Methodology/Variables (</b> <i>List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method</i> <b>)</b> : 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 ( <i>Describe the calculation of the measure as a flowchart or series of steps</i> ): Denominator calculation:	
<ol> <li>Count of patients with arrival/discharge dates from data submissions that pass NCDR data inclusion thresholds</li> <li>Exclude patients with arrival/discharge dates without PCI during episode</li> </ol>	
<ol> <li>Exclude patients with discharge status=deceased</li> <li>Exclude patients with Discharge Location: Other acute care hospital</li> <li>Exclude patients with Discharge Location: Left against medical advice</li> </ol>	
<ul> <li>6. Exclude patients with Discharge Location: Hospice</li> <li>7. Exclude patients with Statin at discharge: contraindicated or blinded</li> <li>8. Exclude patients with a stent.</li> </ul>	
Numerator calculation: 9. From denominator population, count of patients with Discharge medication of clopidogrel, ticlopidine, prasugrel=yes	or
Calculation of score: 10. Numerator count/Denominator count	

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

NQF	<sup>=</sup> #1495	
<b>2a.22 Describe the method for discriminating performance</b> ( <i>e.g.</i> , <i>significance testing</i> ): 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		
<b>2a.25</b> Data source/data collection instrument ( <i>Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.</i> ): 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		
<b>2a.36-37 Care Settings (</b> <i>Check the setting(s) for which the measure is specified and tested</i> <b>)</b> Hospital, Ambulatory Care: Hospital Outpatient		
2a.38-41 Clinical Services ( <i>Healthcare services being measured, check all that apply</i> ) Clinicians: PA/NP/Advanced Practice Nurse, Clinicians: Physicians (MD/DO)		
TESTING/ANALYSIS		
2b. Reliability testing		 Comment [KP10]: 2b. Reliability testing
<b>2b.1 Data/sample</b> <i>(description of data/sample and size)</i> : 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.		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.
<b>2b.2 Analytic Method</b> ( <i>type of reliability</i> & <i>rationale, method for testing</i> ): Reliability was established by validating the derivation cohort from version 4 CathPCI data with a testing cohort from version 3 CathPCI data.		 <b>Comment [k11]:</b> 8 Examples of reliability testing include, but are not limited to: inter- rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item
<b>2b.3 Testing Results</b> <i>(reliability statistics, assessment of adequacy in the context of norms for the test conducted):</i> 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%).		scales; test-retest for survey items. Reliabilit testing may address the data items or final measure score.
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.	2b	
The Data Quality Report (DQR) program has been developed to ensure data are valid and complete. The DQR	C P M	
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	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

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

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2e.2 Analytic Method (type of risk adjustment, analysis, & rationale):         N/A         2e.3 Testing Results (risk model performance metrics):	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
N/A 2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: N/A		treatment outcomes of African American men with prostate cancer, inequalities in treatment for CVD risk factors between men and women).
2f. Identification of Meaningful Differences in Performance		It is preferable to stratify measures by race and socioeconomic status rather than adjusting out differences.
<ul> <li>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.</li> <li>2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance (type of analysis &amp; rationale):</li> </ul>		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.
Distribution by quartile, mean, median, SD. <b>2f.3 Provide Measure Scores from Testing or Current Use</b> (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% 02 629 0.9953 50% Median 361 0.9873		<b>Comment [k19]:</b> 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.
50% Methani       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	2f C P M 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	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 hospitals 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.	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.

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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*?

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

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)

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).* <u>If not publicly reported</u>, 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). <u>If not used for QI</u>, 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

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

**Comment [KP22]:** 3a. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audience(s) for <u>both</u> public reporting (e.g., focus group, cognitive testing) <u>and</u> 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	
<b>3b.1 NQF # and Title of similar or related measures:</b> #588: Stent drug-eluting clopidogrel, #465: Perioperative Anti-platelet Therapy for Patients undergoing Carotid Endarterectomy, #325: Discharged on Antiplatelet Therapy	
#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.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-	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.	3c C□ P□ M□
same target population), Describe why it is a more valid or efficient way to measure quality:	
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
Rationale:	C    P    M
Rationale:       4. FEASIBILITY         Extent to which the required data are readily available, retrievable without undue burden, and can be       1	C    P    M
Rationale:       4. FEASIBILITY         Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)       1.         4a. Data Generated as a Byproduct of Care Processes       1.	C P P M M N Eval Ratin g 4a
Rationale:       4. FEASIBILITY         Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)       1.         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?       1.         Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-       1.	C P M N Eval Ratin g
Rationale:       4. FEASIBILITY         Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)       1.         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?       2.         Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-       1.	C P P M N Eval Ratin g 4a C P P M
Rationale:       4. FEASIBILITY         Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)       1.         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?       2.         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)       4b. Electronic Sources       4b.1 Are all the data elements available electronically? (elements that are needed to compute measure	C PP M N Eval Ratin g 4a C P M

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 NQFendorsed 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.

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4c. Exclusions		 Comment [KP28]: 4c. Exclusions should not
4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications? No	4c C P M	require additional data sources beyond what is required for scoring the measure (e.g., numerator and denominator) unless justified as supporting measure validity.
4c.2 If yes, provide justification.	N NA	
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences		 <b>Comment [KP29]:</b> 4d. Susceptibility to inaccuracies, errors, or unintended
<b>4d.1</b> 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.		consequences and the ability to audit the data items to detect such problems are identified.
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		 <b>Comment [KP30]:</b> 4e. Demonstration that
<ul> <li>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:</li> <li>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</li> </ul>		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).
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 <sup>®</sup> . 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 C	
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.	P M N	

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4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary	
<i>measures</i> ): 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.	
<b>4e.3 Evidence for costs:</b> http://www.ncdr.com/WebNCDR/ncdrdocuments/B08352N%20CathPCI%20Registry%20EnrolIment%20Packet %20Complete.pdf	
4e.4 Business case documentation:	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Feasibility</i> ?	4
Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i> , 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 <u>Organization</u> 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 <u>Organization</u> 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	
<b>Co.6</b> 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	

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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.9 when is the next scheduled review/update for this measure? 06, 2011
Ad.10 Copyright statement/disclaimers: © 2010 American College of Cardiology Foundation All Rights Reserved
Ad.11 -13 Additional Information web page URL or attachment: Attachment DTNPRD Final.pdf
Date of Submission (MM/DD/YY): 10/28/2010