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)

<table>
<thead>
<tr>
<th>Measure Title: P2Y12 Inhibitor at discharge for patients with Percutaneous Coronary Intervention (PCI) (with stents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
<tr>
<td>Type of Measure: Process</td>
</tr>
<tr>
<td>If included in a composite or paired with another measure, please identify composite or paired measure N/A</td>
</tr>
<tr>
<td>National Priority Partners Priority Area:</td>
</tr>
<tr>
<td>IOM Quality Domain: Effectiveness, Safety, Timeliness</td>
</tr>
<tr>
<td>Consumer Care Need: Getting better, Staying healthy, Living with illness</td>
</tr>
</tbody>
</table>

Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:

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

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

C. The intended use of the measure includes both public reporting and quality improvement.

- Purpose: Public reporting, Internal quality improvement
- Accountability, Payment incentive, Accreditation

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

(for NQF staff use) Have all conditions for consideration been met?

Staff Notes to Steward (if submission returned):

Staff Notes to Reviewers (issues or questions regarding any criteria):

Staff Reviewer Name(s): Reva Winkler

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**1. IMPORTANCE TO MEASURE AND REPORT**

**1a. High Impact**

**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 atherosclerosis 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.


**1b. Opportunity for Improvement**

**1b.1 Benefits (improvements in quality) envisioned by use of this measure:** P2Y12 inhibitors, including
Steinhubl et al found 1 year, long-term clopidogrel therapy was associated with a 26.9% relative reduction 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 NCDS 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 NCDS 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 NCDS 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.4 Summary of Evidence: Evidence-based guideline, Randomized controlled trial, Expert opinion
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 treated 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 undergoing 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

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

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
•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 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.

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 is 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.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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Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
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 325 mg/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)

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.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, treatment is beneficial, and effective.

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

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.

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)

2a. MEASURE SPECIFICATIONS

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

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"

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).
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.
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.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)

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 98.9%, 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
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

<table>
<thead>
<tr>
<th>2c. Validity testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>2c.1 Data/sample (description of data/sample and size): Face/content validity: review of relevant evidence and guidelines and expert panel consensus process.</td>
</tr>
<tr>
<td>2c.2 Analytic Method (type of validity &amp; 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.</td>
</tr>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2d. Exclusions Justified</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
<tr>
<td>2d.2 Citations for Evidence: N/A</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>2d.4 Analytic Method (type analysis &amp; rationale): Frequency of exclusion coding.</td>
</tr>
<tr>
<td>2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses):</td>
</tr>
<tr>
<td>Rates of exclusion coding:</td>
</tr>
<tr>
<td>• Discharged to other acute care hospital: 3,022 (0.57%)</td>
</tr>
<tr>
<td>• Discharged to hospice: 661 (0.13%)</td>
</tr>
<tr>
<td>• Discharged against medical advice: 1,054 (0.20%)</td>
</tr>
<tr>
<td>• Aspirin contraindicated or blinded: 1,991 (0.38%)</td>
</tr>
<tr>
<td>• Discharge status of deceased: 6,280 (1.17%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2e. Risk Adjustment for Outcomes/ Resource Use Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>2e.1 Data/sample (description of data/sample and size): N/A</td>
</tr>
</tbody>
</table>

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

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 sufficient evidence; • a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus; • 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).
### 2e. 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

### 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):

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

### 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):

C

#### 2g.3 Testing Results (e.g., correlation statistics, comparison of rankings):

N/A

### 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.2 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:

N/A

---

**Comment [KP17]:** 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 [KP19]:** 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.
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 |

| Rationale: | 2 |

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 | 8 |

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):

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 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

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.

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:

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

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

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)

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)

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.
4c. Exclusions

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

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.

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.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?

| Rationale: Steering Committee: Overall, to what extent was the criterion, Feasibility, met? |
|---------------------------------|---------------------------------|
|                                  | 4                               |

RECOMMENDATION

(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.

<table>
<thead>
<tr>
<th>Steering Committee: Do you recommend for endorsement? Comments:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y N A</td>
</tr>
</tbody>
</table>

CONTACT INFORMATION

<table>
<thead>
<tr>
<th>Co.1 Measure Steward (Intellectual Property Owner)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co.1 Organization</td>
</tr>
<tr>
<td>Co.2 Point of Contact</td>
</tr>
</tbody>
</table>

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, kmcuinn@acc.org, 202-375-6529- |

Submitter if different from Measure Steward POC

<table>
<thead>
<tr>
<th>Co.5 Additional organizations that sponsored/participated in measure development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co.6 Society for Cardiovascular Angiography and Interventions (SCAI)</td>
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</table>

ADDITIONAL INFORMATION

<table>
<thead>
<tr>
<th>Workgroup/Expert Panel involved in measure development</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

CathPCI Steering Committee:

| Douglas Weaver, MD, FACC |

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
<table>
<thead>
<tr>
<th>Ronald Krone, MD, FACC</th>
</tr>
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<tbody>
<tr>
<td>Gregory Dehmer, MD, FSCAI</td>
</tr>
<tr>
<td>John Messenger, MD, FACC</td>
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<tr>
<td>Lloyd Klein, MD, FACC</td>
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<tr>
<td>John Rumsfeld, MD, PhD, FACC</td>
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<tr>
<td>John Carroll, MD, FACC</td>
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<tr>
<td>Mauro Moscucci, MD, FACC</td>
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<tr>
<td>Jeffrey Popma, MD, FACC</td>
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<tr>
<td>Issam Moussa, MD, FSCAI</td>
</tr>
<tr>
<td>Kirk Garratt, MD, FSCAI</td>
</tr>
<tr>
<td>David Malenka, MD, FACC</td>
</tr>
</tbody>
</table>

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: © 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