

NATIONAL QUALITY FORUM

Measure Evaluation 4.1 December 2009

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

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

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

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

Evaluation ratings of the extent to which the criteria are met

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

(for NQF staff use) NQF Review #: 1493 NQF Project: Cardiovascular Endorsement Maintenance 2010	
MEASURE DESCRIPTIVE INFORMATION	
De.1 Measure Title:	Aspirin at discharge for patients with Percutaneous Coronary Intervention (PCI)
De.2 Brief description of measure:	Proportion of adult patients (age 18 or older) who undergo a percutaneous coronary intervention (PCI) and are prescribed aspirin at discharge.
1.1-2 Type of Measure:	Process
De.3 If included in a composite or paired with another measure, please identify composite or paired measure	N/A
De.4 National Priority Partners Priority Area:	
De.5 IOM Quality Domain:	Effectiveness, Safety, Timeliness
De.6 Consumer Care Need:	Getting better, Living with illness

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	NQF Staff
<p>A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. <i>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.</i></p> <p>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</p> <p>A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):</p> <p>A.3 Measure Steward Agreement: Agreement will be signed and submitted prior to or at the time of measure submission</p> <p>A.4 Measure Steward Agreement attached: NQF - signed-634238762359539272.pdf</p>	A Y <input checked="" type="checkbox"/> N <input type="checkbox"/>
B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and	B

update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	Y <input checked="" type="checkbox"/> N <input type="checkbox"/>
C. The intended use of the measure includes both public reporting and quality improvement. ► Purpose: Public reporting, Internal quality improvement Accountability, Payment incentive, Accreditation	C Y <input checked="" type="checkbox"/> N <input type="checkbox"/>
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1 Testing: Yes, fully developed and tested D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures? Yes	D Y <input checked="" type="checkbox"/> N <input type="checkbox"/>
(for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward (if submission returned):	Met Y <input checked="" type="checkbox"/> N <input type="checkbox"/>
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 quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. <i>Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.</i> (evaluation criteria) 1a. High Impact _____	Eval Ratin g
(for NQF staff use) Specific NPP goal:	
1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Severity of illness 1a.2 1a.3 Summary of Evidence of High Impact: Cardiovascular disease is the single most common cause of death in the U.S. There are an estimated 64 million people with cardiovascular disease with direct costs totaling over 226 billion dollars in 2004. Estimates of direct costs due to cardiovascular disease are projected to be 503.2 billion dollars in 2010. In 2002, approximately 864,480 deaths were attributable to cardiovascular disease, or 1 in 2.9 deaths in the US. Approximately 1 million PCI procedures are performed annually. 6.1 million hospital discharges listed cardiovascular disease as the primary diagnosis in 2006. In 2004 coronary 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.	1a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
1a.4 Citations for Evidence of High Impact: American Heart Association. Heart disease and stroke statistics- 2010 update: A report of the American Heart Association. Available at: http://circ.ahajournals.org/cgi/content/full/103/24/3019. Accessed October 13, 2010.	
1b. Opportunity for Improvement _____	1b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/>
1b.1 Benefits (improvements in quality) envisioned by use of this measure: Aspirin therapy reduces the risk of ischemic events following PCI. This measure will encourage improvement in rates of aspirin	

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

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

<p>prescribing at discharge following PCI and subsequently reduce rates of adverse outcomes after PCI by facilitating quality improvement in this area.</p> <p>1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers: A recent study of 352 nongovernment acute care hospitals demonstrated a performance gap in aspirin prescribing at discharge in 5490 Medicare beneficiaries following MI. 24% of patients were not prescribed aspirin at discharge. Data from the NCDR CathPCI Registry for 1121 facilities (566,305 records) showed some variation in performance for this measure. Performance ranged from 89% at the 5th percentile to 100% at the 95th percentile. 25% of hospitals did not prescribe aspirin at discharge for 5% of its patients.</p> <p>1b.3 Citations for data on performance gap: 1. Unpublished NCDR data. Please see documentation attached. 2. Krumholz HM, Radford MJ, Ellerbeck EF, et al. Aspirin for secondary prevention after acute myocardial infarction in the elderly: prescribed use and outcomes. <i>Ann Intern Med.</i> 1996;124:292-8.</p> <p>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 of proportion of patients of white race. Both sets of analyses suggested that the range of hospital performance is similar irrespective of the SES of the patients treated. Specifically, the median for Safety Net hospitals was 97.7% with the lowest decile 92.0% and highest decile 99.8%. This is similar to that observed for non-Safety Net hospitals (median 97.1%, lowest decile 91.0%, highest decile 99.5%). Similarly, median hospital performance was similar across quartiles of proportion of white patients (quartile 1: 97.0%, quartile 2: 97.7%, quartile 3: 98.2%, quartile 4: 98.2%).</p> <p>1b.5 Citations for data on Disparities: Unpublished NCDR data. Please see documentation attached.</p>	<p>N <input type="checkbox"/></p>
<p>1c. Outcome or Evidence to Support Measure Focus</p> <p>1c.1 Relationship to Outcomes (For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population): Aspirin reduces the frequency of ischemic complications after PCI, including MI and stroke.</p> <p>1c.2-3. Type of Evidence: Evidence-based guideline, Randomized controlled trial</p> <p>1c.4 Summary of Evidence (as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome): On the basis of 12 randomized trials in 18,788 patients with prior infarction, the Antiplatelet Trialists' Collaboration reported a 25% reduction in the risk of recurrent infarction, stroke, or vascular death in patients receiving prolonged antiplatelet therapy (36 fewer events for every 1000 patients treated). No antiplatelet therapy has proved superior to aspirin in this population, and daily doses of aspirin between 80 and 325 mg appear to be effective. These compelling data suggest that all patients recovering from STEMI should, in the absence of contraindications, continue taking aspirin for an indefinite period.</p> <p>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)</p> <p>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.</p> <p>1c.7 Summary of Controversy/Contradictory Evidence:</p>	<p>1c <input type="checkbox"/> C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

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

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

Comment [k5]: 4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status - patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a ... [2]

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

1c.8 Citations for Evidence (other than guidelines): Antithrombotic Trialists' Collaboration. Collaborative meta-analysis of randomised trials of antiplatelet therapy for prevention of death, myocardial infarction, and stroke in high-risk patients. *BMJ* 2002;324:71-86.

Gutstein DE, Fuster V. Pathophysiologic bases for adjunctive therapies in the treatment and secondary prevention of acute myocardial infarction. *Clin Cardiol* 1998;21:161-8.

Hennekens CH, Dyken ML, Fuster V. Aspirin as a therapeutic agent in cardiovascular disease: a statement for healthcare professionals from the American Heart Association. *Circulation* 1997;96:2751-3.

1c.9 Quote the Specific guideline recommendation (including guideline number and/or page number): *AHA/ACC PCI Guidelines, Focused Update 2007:*

3. After PCI, in patients without allergy or increased risk of bleeding, aspirin 162 mg to 325 mg daily should be given for at least 1 month after BMS implantation, 3 months after sirolimus-eluting stent implantation, and 6 months after paclitaxel-eluting stent implantation, after which daily long-term aspirin use should be continued indefinitely at a dose of 75 mg to 162 mg. (Level of Evidence: B)

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ACC/AHA NSTEMI Guidelines 2007:

CLASS I

1. For UA/NSTEMI patients treated medically without stenting, aspirin (75 to 162 mg per day) should be prescribed indefinitely (Level of Evidence: A); clopidogrel (75 mg per day) should be prescribed for at least 1 month (Level of Evidence: A) and ideally for up to 1 year. (Level of Evidence: B)

2. For UA/NSTEMI patients treated with bare-metal stents, aspirin 162 to 325 mg per day should be prescribed for at least 1 month (Level of Evidence: B), then continued indefinitely at a dose of 75 to 162 mg per day (Level of Evidence: A); clopidogrel should be prescribed at a dose of 75 mg per day for a minimum of 1 month and ideally for up to 1 year (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks). (Level of Evidence: B)

3. For UA/NSTEMI patients treated with DES, aspirin 162 to 325 mg per day should be prescribed for at least 3 months after sirolimus-eluting stent implantation and 6 months after paclitaxel-eluting stent implantation then continued indefinitely at a dose of 75 to 162 mg per day. (Level of Evidence: B) Clopidogrel 75 mg daily should be given for at least 12 months to all post-PCI patients receiving DES. (Level of Evidence: B)

4. Clopidogrel 75 mg daily (preferred) or ticlopidine (in the absence of contraindications) should be given to patients recovering from UA/NSTEMI when ASA is contraindicated or not tolerated because of hypersensitivity or gastrointestinal intolerance (but with gastroprotective agents such as proton-pump inhibitors). (Level of Evidence: A)

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ACC/AHA STEMI Guidelines 2004:

Class I

1. A daily dose of aspirin 75 to 162 mg orally should be given indefinitely to patients recovering from STEMI. (Level of Evidence: A)

2. If true aspirin allergy is present, preferably clopidogrel (75 mg orally per day) or, alternatively, ticlopidine (250 mg orally twice daily) should be substituted. (Level of Evidence: C)

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AHA/ACC guidelines for secondary prevention for patients with coronary and other atherosclerotic vascular disease:

Aspirin/Thienopyridines:

- Start aspirin 75 to 162 mg/d and continue indefinitely in all patients unless contraindicated. I (A)

For patients undergoing coronary artery bypass grafting, aspirin should be started within 48 hours after surgery to reduce saphenous vein graft closure. Dosing regimens ranging from 100 to 325mg/d appear to be efficacious. Doses higher than 162 mg/d can be continued for up to 1 year. I (B)

- Start and continue clopidogrel 75 mg/d in combination with aspirin for up to 12 months in patients after acute coronary syndrome or percutaneous coronary intervention with stent placement (>=1 month for bare

metal stent, >=3 months for sirolimus-eluting stent, and >=6 months for paclitaxel-eluting stent). I (B) Patients who have undergone percutaneous coronary intervention with stent placement should initially receive higher-dose aspirin at 325 mg/d for 1 month for bare metal stent, 3 months for sirolimus-eluting stent, and 6 months for paclitaxel-eluting stent. I (B)

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1c.10 Clinical Practice Guideline Citation: 1. King SB, III, Smith SC, Jr., Hirshfeld JW, Jr., et al. 2007 focused update of the ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention: a report of the American College of Cardiology/American Heart Association Task Force on Practice guidelines. J Am Coll Cardiol. 2008;51:172-209.

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

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

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

1c.11 National Guideline Clearinghouse or other URL:
<http://circ.ahajournals.org/cgi/content/full/117/2/261#TBL12188208>

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

Class I: Conditions for which there is evidence for and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.

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

ACC/AHA Taskforce on Practice Guidelines Method:

Indications are categorized as class I, II, or III on the basis of a multifactorial assessment of risk and expected efficacy viewed in the context of current knowledge and the relative strength of this knowledge. These classes summarize the recommendations for procedures or treatments as follows:

Class I: Conditions for which there is evidence for and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.

Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.

Class IIb: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful.

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

<p>1c.14 Rationale for using this guideline over others: This guideline is the most widely recognized professional guideline in the US for cardiovascular medicine in the area of percutaneous coronary intervention care.</p>	
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Importance to Measure and Report</i>?</p>	1
<p>Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i>, met? Rationale:</p>	1 Y <input type="checkbox"/> N <input type="checkbox"/>
<p>2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES</p>	
<p>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)</p>	Eval Rating
<p>2a. MEASURE SPECIFICATIONS</p>	
<p>S.1 Do you have a web page where current detailed measure specifications can be obtained? S.2 If yes, provide web page URL:</p>	
<p>2a. Precisely Specified _____</p>	
<p>2a.1 Numerator Statement (<i>Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome</i>): Count of patients with a PCI procedure with aspirin prescribed at discharge.</p> <p>2a.2 Numerator Time Window (<i>The time period in which cases are eligible for inclusion in the numerator</i>): 1 year</p> <p>2a.3 Numerator Details (<i>All information required to collect/calculate the numerator, including all codes, logic, and definitions</i>): Element Name: Discharge Medications Discharge Medications=aspirin (any) Coding Instructions: Indicate which of the following medications the patient was prescribed upon discharge. Note(s): Complete only for patients who had a PCI procedure attempted or performed during this episode of care. Discharge medications not required for patients who were discharged to "Other acute care hospital", "Hospice", or Left against medical advice (AMA)."</p> <p>Element Name: Medication Administered Medication Administered=Yes Coding Instructions: Indicates if the medication was administered, not administered, contraindicated or blinded. Selections: No- Medication was not administered or prescribed. Yes- Medication was administered or prescribed. Contraindicated- Medication was not administered because of a contraindication. (Contraindications must be documented explicitly by the physician, clearly evidenced within the medical record.) Blinded- Patient was in a research study or clinical trial and the administration of this specific medication or class of medications is unknown.</p>	
<p>2a.4 Denominator Statement (<i>Brief, text description of the denominator - target population being measured</i>): Count of patients with a PCI procedure</p>	2a-specs C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>

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) .

<p>2a.5 Target population gender: Female, Male</p> <p>2a.6 Target population age range: All patients >= 18 years of age.</p> <p>2a.7 Denominator Time Window (<i>The time period in which cases are eligible for inclusion in the denominator</i>): 1 year</p> <p>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</p>
<p>2a.9 Denominator Exclusions (<i>Brief text description of exclusions from the target population</i>): -Aspirin coded as contraindicated or blinded -Discharge status of deceased -Discharge location of "other acute care hospital", "hospice" or "against medical advice".</p> <p>2a.10 Denominator Exclusion Details (<i>All information required to collect exclusions to the denominator, including all codes, logic, and definitions</i>): Element name: Discharge Status Discharge status=deceased Coding Instructions: Indicate whether the patient was alive or deceased at discharge. Selections: Alive/Deceased</p> <p>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.)</p> <p>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.</p>
<p>2a.11 Stratification Details/Variables (<i>All information required to stratify the measure including the stratification variables, all codes, logic, and definitions</i>): N/A</p>
<p>2a.12-13 Risk Adjustment Type: No risk adjustment necessary</p>

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

<p>2a.14 Risk Adjustment Methodology/Variables (<i>List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method</i>): N/A</p> <p>2a.15-17 Detailed risk model available Web page URL or attachment:</p>	
<p>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: 1. Count of patients with arrival/discharge dates from data submissions that pass NCDR data inclusion thresholds 2. Exclude patients with arrival/discharge dates without PCI during episode 3. Exclude patients with discharge status=deceased 4. Exclude patients with Discharge Location: Other acute care hospital 5. Exclude patients with Discharge Location: Left against medical advice 6. Exclude patients with Discharge Location: Hospice 7. Exclude patients with Aspirin at discharge: contraindicated or blinded Numerator calculation: 8. From denominator population, count of patients with Discharge medication of aspirin=yes Calculation of score: 9. Numerator count/Denominator count</p>	
<p>2a.22 Describe the method for discriminating performance (<i>e.g., 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.</p>	
<p>2a.23 Sampling (Survey) Methodology <i>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):</i> N/A</p>	
<p>2a.24 Data Source (<i>Check the source(s) for which the measure is specified and tested</i>) Registry data</p> <p>2a.25 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®</p> <p>2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL http://www.ncdr.com/WebNCDR/ELEMENTS.ASPX</p> <p>2a.29-31 Data dictionary/code table web page URL or attachment: URL http://www.ncdr.com/WebNCDR/ELEMENTS.ASPX</p> <p>2a.32-35 Level of Measurement/Analysis (<i>Check the level(s) for which the measure is specified and tested</i>) Facility/Agency</p> <p>2a.36-37 Care Settings (<i>Check the setting(s) for which the measure is specified and tested</i>) Hospital, Ambulatory Care: Hospital Outpatient</p> <p>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)</p>	
<p>TESTING/ANALYSIS</p>	
<p>2b. Reliability testing</p>	<p>2b</p>

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

2b.1 Data/sample (description of data/sample and size): 1. Joint Commission validation of "Aspirin at prescribed at discharge" can be used to support the reliability of this measure. Data were reabstracted from a random sample that included a balanced distribution of hospitals based on setting (rural or urban), size, and geographic region. 227 AMI records were abstracted.

2. Reliability was established by validating the derivation cohort from version 4 CathPCI data with a testing cohort from version 3 CathPCI data. 555,023 patient records were analyzed from 1007 facilities between July 2008 and June 2009.

2b.2 Analytic Method (type of reliability & rationale, method for testing):

1. Joint Commission validation of "Aspirin at prescribed at discharge" can be used to support the reliability of this measure. Reliability of individual data elements was assessed using percent agreement for continuous variable data elements and chance-corrected agreement using Cohen's kappa for binary elements.

2. Reliability was established by validating the derivation cohort from version 4 CathPCI data with a testing cohort from version 3 CathPCI data.

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

1. Joint Commission "Aspirin prescribed at discharge" measure validation results:

- Aspirin prescribed at discharge: Kappa=0.52
- Contraindication to aspirin at discharge: Kappa=0.53
- Discharge status: 94.2% agreement

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

The Data Quality Report (DQR) program has been developed to ensure data are valid and complete. The DQR is a process for submitting data files to the NCDR®. Participants use their data collection tool software to create a submission file which is uploaded to the NCDR website. After uploading, the data in the file is automatically checked for errors and completeness. Passing the DQR ensures well-formed data and a statistically significant submission. Types of errors detected by the DQR include:

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

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

2. Results were consistent among the derivation cohort and the testing cohort. Specifically, the median for hospitals in the derivation cohort was 97.7% with the lowest decile 91.8% and highest decile 99.8%. This is similar to that observed in the testing cohort (median 97.3%, lowest decile 91.7%, highest decile 99.5%).

2c. Validity testing

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

2c.2 Analytic Method (type of validity & rationale, method for testing):

C
P
M
N

2c
C
P
M
N

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

Comment [k12]: 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.

<p>Face/content validity was established to ensure this measure represented an important aspect of cardiovascular care for which improvement is needed.</p> <p>2c.3 Testing Results (<i>statistical results, assessment of adequacy in the context of norms for the test conducted</i>): 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.</p>	
<p>2d. Exclusions Justified</p> <p>2d.1 Summary of Evidence supporting exclusion(s): This measure exclude patients with evidence-based contraindications, or patients who are participating in a blinded research study and out of necessity the hospital is not aware of the prescribed discharge medications. This measure also excludes patients discharged to hospice, against medical advice, to another acute care hospital, or who expired prior to discharge as discharge medications to not apply to these patients. No evidence is necessary or available for these exclusions.</p> <p>2d.2 Citations for Evidence: N/A</p> <p>2d.3 Data/sample (<i>description of data/sample and size</i>): 1,282,945 patient records from the CathPCI Registry between July 2009 and June 2010 were analyzed from 1162 CathPCI Registry participants.</p> <p>2d.4 Analytic Method (<i>type analysis & rationale</i>): Frequency of exclusion coding.</p> <p>2d.5 Testing Results (<i>e.g., frequency, variability, sensitivity analyses</i>): Rates of exclusion coding: -Discharged to other acute care hospital: 3,931 (0.7%) -Discharged to hospice: 798 (0.14%) -Discharged against medical advice: 1,232 (0.20%) -Aspirin contraindicated or blinded: 6,682 (1.12%) -Discharge status of deceased: 8,027 (1.42%)</p>	<p>2d C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>2e. Risk Adjustment for Outcomes/ Resource Use Measures</p> <p>2e.1 Data/sample (<i>description of data/sample and size</i>): N/A</p> <p>2e.2 Analytic Method (<i>type of risk adjustment, analysis, & rationale</i>): N/A</p> <p>2e.3 Testing Results (<i>risk model performance metrics</i>): N/A</p> <p>2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: N/A</p>	<p>2e C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>2f. Identification of Meaningful Differences in Performance</p> <p>2f.1 Data/sample from Testing or Current Use (<i>description of data/sample and size</i>): 1121 facilities in the CathPCI Registry, 566,305 patient records between July 2009 and June 2010.</p> <p>2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance (<i>type of analysis & rationale</i>): Distribution of aspirin prescription at discharge.</p> <p>2f.3 Provide Measure Scores from Testing or Current Use (<i>description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance</i>): Performance ranged from 89% at the 5th percentile to 100% at the 95th percentile. 25% of hospitals did not prescribe aspirin at discharge for 5% of its patients. Please see documentation provided in Ad.11 for</p>	<p>2f C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

Comment [KP14]: 2d. Clinically necessary measure exclusions are identified and must be:
 •supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;
 AND
 •a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;
 AND
 •precisely defined and specified:
 –if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);
 if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category ... [3])

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

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

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

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

Comment [k19]: 14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% v. 75%) is clinically meaningful; or whether a statistically significant difference of \$25 in cost for a ... [4]

detailed analyses.	
2g. Comparability of Multiple Data Sources/Methods	
2g.1 Data/sample (description of data/sample and size): N/A	
2g.2 Analytic Method (type of analysis & rationale): N/A	2g C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
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 of proportion of patients of white race. Both sets of analyses suggested that the range of hospital performance is similar irrespective of the SES of the patients treated. Specifically, the median for Safety Net hospitals was 97.7% with the lowest decile 92.0% and highest decile 99.8%. This is similar to that observed for non-Safety Net hospitals (median 97.1%, lowest decile 91.0%, highest decile 99.5%). Similarly, median hospital performance was similar across quartiles of proportion of white patients (quartile 1: 97.0%, quartile 2: 97.7%, quartile 3: 98.2%, quartile 4: 98.2%). Based on these analyses, we do not believe that a stratified measure is necessary.	2h C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
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 <i>Scientific Acceptability of Measure Properties</i> ?	2
Steering Committee: Overall, to what extent was the criterion, <i>Scientific Acceptability of Measure Properties</i> , met? Rationale:	2 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
3. USABILITY	
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	Eval Ratin g
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.	3a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
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 Registry participating institutions. For Q2 of 2010, 1174 institutions submitted	

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.

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.

<p>data.</p> <p>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.</p> <p>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.</p> <p>Testing of Interpretability (<i>Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement</i>)</p> <p>3a.4 Data/sample (<i>description of data/sample and size</i>): 1. 61 NCDR CathPCI Registry participants, Fall 2009. 2. Beta testing for version 4 of the CathPCI registry institutional outcomes report, 80 sites</p> <p>3a.5 Methods (<i>e.g., focus group, survey, QI project</i>): 1. Survey 2. Sites provided feedback through an excel template</p> <p>3a.6 Results (<i>qualitative and/or quantitative results and conclusions</i>): 1. 92.9% responded yes to the question "Will this measure provide important information to you?" 2. Sites provided feedback on the institutional outcomes report that was used to modify the report. Sites provided feedback on invalid data and aspects of the report that were unclear.</p>	
<p>3b/3c. Relation to other NQF-endorsed measures</p> <p>3b.1 NQF # and Title of similar or related measures: # 0237 Anti-platelet medication on discharge, # 0325 Discharged on anti-platelet therapy, #0142 Aspirin prescribed at discharge for AMI</p>	
<p>(for NQF staff use) Notes on similar/related endorsed or submitted measures: multiple measures - consider harmonization around inclusions for aspirin vs anti-platelet</p>	
<p>3b. Harmonization</p> <p>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):</p> <p>3b.2 Are the measure specifications harmonized? If not, why? Yes, measure specifications are harmonized wherever possible to endorsed measures.</p>	<p>3b</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>
<p>3c. Distinctive or Additive Value</p> <p>3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures: This measure is distinct from #0142 Aspirin prescribed at discharge for AMI (CMS) in that it applies to all PCI patients and is not isolated to MI patients. In addition, the data source for this measure is different from #142. This measure uses registry data as a data source and the CMS measure uses claims and medical record data.</p> <p>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:</p>	<p>3c</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Usability?</p>	<p>3</p>
<p>Steering Committee: Overall, to what extent was the criterion, Usability, met? Rationale:</p>	<p>3</p> <p>C <input type="checkbox"/></p>

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

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

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

	P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	Eval Rating
4a. Data Generated as a Byproduct of Care Processes	4a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
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 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
4b.2 If not, specify the near-term path to achieve electronic capture by most providers.	
4c. Exclusions	4c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications? No	
4c.2 If yes, provide justification.	
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences	
4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results. The NCDR program takes a number of steps to minimize any potential for inaccuracies or errors in data used to report on performance back to hospitals. The process begins with support provided to data abstractors, including webinars, meetings, resource guides on the website, and clinical quality consultants available via e-mail or toll free phone number, to ensure consistent data collection. The NCDR establishes a unified electronic platform for data capture and submission that includes a certification process of the technical data collection tool selected by the hospital (either a commercially available software vendor product, the NCDR's own web base data collection tool, or a hospital's customized electronic medical record system) that must occur prior to any data submissions. The certification process provides edit checks of data elements within data collection tool to ensure high quality data submission. The NCDR data submission process includes a Data Quality Report (DQR) process that checks for validity in submissions based upon predetermined thresholds for element and composite completeness. The NCDR is putting in place a new strategy to systematically review the DQR results. The NCDR on-site audit program has been developed to assess reliability of data abstraction. This annual process reviews key elements at a select number of patient reports at the select number of sites and provides feedback scores to the hospitals. Any elements not currently included in the on-site audit process and deemed critical to capture for this measure will be added upon NQF endorsement.	4d C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
4e. Data Collection Strategy/Implementation	4e C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/>
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	

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

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

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

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

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

<p>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.</p> <p>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.</p> <p>4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary measures): CathPCI participants pay a fee of \$3,800/year to enroll in the registry. Staff resources are needed for data collection and submission at the participating institution. Registry site managers/data collectors undergo (non-mandatory) training offered by the NCDR.</p> <p>4e.3 Evidence for costs: http://www.ncdr.com/WebNCDR/ncdrdocuments/B08352N%20CathPCI%20Registry%20Enrollment%20Packet%20Complete.pdf</p> <p>4e.4 Business case documentation:</p>	<p>N <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Feasibility</i>?</p>	<p>4</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i>, met? Rationale:</p>	<p>4 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>RECOMMENDATION</p>	
<p>(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.</p>	<p>Time-limited <input type="checkbox"/></p>
<p>Steering Committee: Do you recommend for endorsement? Comments:</p>	<p>Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/></p>
<p>CONTACT INFORMATION</p>	
<p>Co.1 Measure Steward (Intellectual Property Owner) Co.1 Organization American College of Cardiology Foundation, 2400 N Street NW, Washington, District Of Columbia, 20037</p> <p>Co.2 Point of Contact Kristyne, McGuinn, MHS, kmcguinn@acc.org, 202-375-6529-</p>	
<p>Measure Developer If different from Measure Steward Co.3 Organization American College of Cardiology Foundation, 2400 N Street NW, Washington, District Of Columbia, 20037</p>	

<p>Co.4 Point of Contact Kristyne, McGuinn, MHS, kmcguinn@acc.org, 202-375-6529-</p>
<p>Co.5 Submitter If different from Measure Steward POC Kristyne, McGuinn, MHS, kmcguinn@acc.org, 202-375-6529-, American College of Cardiology Foundation</p>
<p>Co.6 Additional organizations that sponsored/participated in measure development Society for Cardiovascular Angiography and Interventions (SCAI)</p>
<p>ADDITIONAL INFORMATION</p>
<p>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.</p> <p>CathPCI Steering Committee: Douglas Weaver, MD, FACC Ronald Krone, MD, FACC Gregory Dehmer, MD, FSCAI John Messenger, MD, FACC Lloyd Klein, MD, FACC John Rumsfeld, MD, PhD, FACC John Carroll, MD, FACC Mauro Moscucci, MD, FACC Jeffrey Popma, MD, FACC Issam Moussa, MD, FSCAI Kirk Garratt, MD, FSCAI David Malenka, MD, FACC</p> <p>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 Jephtha 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</p>
<p>Ad.2 If adapted, provide name of original measure: N/A Ad.3-5 If adapted, provide original specifications URL or attachment</p>
<p>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</p>
<p>Ad.10 Copyright statement/disclaimers: © 2010 American College of Cardiology Foundation All Rights Reserved</p>
<p>Ad.11 -13 Additional Information web page URL or attachment: Attachment_DASA_Finalpdf.pdf</p>

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

Page 3: [1] Comment [k4] **Karen Pace** **10/5/2009 8:59:00 AM**

1c. The measure focus is:

- an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;

OR

- if an intermediate outcome, process, structure, etc., there is evidence that supports the specific measure focus as follows:
 - o Intermediate outcome - evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
 - o 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).
 - o 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.
 - o Patient experience - evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of individuals/ the public.
 - o Access - evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
 - o Efficiency - demonstration of an association between the measured resource use and level of performance with respect to one or more of the other five IOM aims of quality.

Page 3: [2] Comment [k5] **Karen Pace** **10/5/2009 8:59:00 AM**

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

Page 10: [3] Comment [KP14] **Karen Pace** **10/5/2009 8:59:00 AM**

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

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

AND

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

AND

- precisely defined and specified:

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

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

Page 10: [4] Comment [k19] **Karen Pace** **10/5/2009 8:59:00 AM**

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