NATIONAL QUALITY FORUM

Measure Evaluation 4.1
December 2009

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

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

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

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

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

(for NQF staff use) NQF Review #: 1498 NQF Project: Cardiovascular Endorsement Maintenance 2010

MEASURE DESCRIPTIVE INFORMATION

De.1 Measure Title: Statins at discharge for patients with percutaneous coronary intervention (PCI)

De.2 Brief description of measure: Proportion of adult patients (age 18 or older) who undergo a percutaneous coronary intervention (PCI) and are prescribed a statin at discharge.

1.1-2 Type of Measure: Process

De.3 If included in a composite or paired with another measure, please identify composite or paired measure
N/A

De.4 National Priority Partners Priority Area:
De.5 IOM Quality Domain: Effectiveness, Timeliness
De.6 Consumer Care Need: Getting better, Staying healthy

CONDITIONS FOR CONSIDERATION BY NQF

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

A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.

A.1 Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?

Yes

A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):

A.3 Measure Steward Agreement: Agreement will be signed and submitted prior to or at the time of measure submission

A.4 Measure Steward Agreement attached: NQF - signed.pdf

B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and

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

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<td>Steering Committee Reviewer Name:</td>
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1. IMPORTANCE TO MEASURE AND REPORT

Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.

1a. High Impact:

(for NQF staff use) Specific NPP goal:

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Severity of illness

1a.2

1a.3 Summary of Evidence of High Impact: Cardiovascular disease is the single most common cause of death in the U.S. There are an estimated 64 million people with cardiovascular disease with direct costs totaling over 226 billion dollars in 2004. Estimates of direct costs due to cardiovascular disease are projected to be 503.2 billion dollars in 2010. In 2002, approximately 864,480 deaths were attributable to cardiovascular disease, or 1 in 2.9 deaths in the US. Approximately 1 million PCI procedures are performed annually. 6.1 million hospital discharges listed cardiovascular disease as the primary diagnosis in 2006. In 2004 coronary artherosclerosis attributed to 1.2 million hospital stays, with 44 billion in associated expenses. More than half of hospital stays were due to PCI or cardiac revascularization.


1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: Statin therapy reduces the...
1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:

Several prior studies have documented low treatment rates in patients with established coronary artery disease. A recent study of all patients in the National Registry of Myocardial Infarction (NRM1) found that statins were being prescribed only 82% of the time in patients hospitalized with AMI who were eligible for statin therapy. However, the hospitals included in this study were voluntary participants in a national quality improvement registry. Data from the NCDR CathPCI Registry also suggest room for improvement for this measure. Data from the NCDR CathPCI Registry for 1121 facilities (563,988 records) showed some variation in performance for this measure. Performance ranged from 72% at the 5th percentile to 98% at the 95th percentile. 50% of hospitals did not prescribe statins at discharge for 10% of its patients.

1b.3 Citations for data on performance gap:


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 89.5% with the lowest decile 77.9% and highest decile 96.3%. This is similar to that observed for non-Safety Net hospitals (median 87.6%, lowest decile 76.0%, highest decile 96.5%). Similarly, median hospital performance was similar across quartiles of proportion of white patients (quartile 1: 89.0%, quartile 2: 89.0%, quartile 3: 90.4%, quartile 4: 90.0%).

1b.5 Citations for data on Disparities:

Unpublished NCDR data, please see attached documentation.

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population): Statin therapy is used for secondary prevention to reduce the progression of coronary artery disease (CAD).

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

1c.4 Summary of Evidence (as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome):

The Atorvastatin Versus Revascularization Treatment (AVERT) trial (298) randomly assigned 314 patients

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

Comment [k4]: 1c. The measure focus is:

- an outcome (e.g., morbidity, mortality, function-health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed; OR
- if an intermediate outcome, process, structure, etc., there is evidence that supports the specific measure focus as follows:
  - Intermediate outcome – evidence that the measured intermediate outcome (e.g., blood pressure, HbA1c) leads to improved health/avoidance of harm or cost/benefit.
  - Process – evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
  - Structure – evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
  - Patient experience – evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of individuals/ the public.
- Access – evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
- Efficiency – demonstration of an association between the measured resource use and level of performance with respect to one or more of the other five IOM aims of quality.

Comment [k5]: 4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., mammography) or measures for multiple care processes that affect a single outcome.
with stable CAD, normal LV function, and class I and/or II angina to PTCA or medical therapy with 80 mg of atorvastatin daily (mean low-density lipoprotein cholesterol equals 77 mg per dL). At 18 months of follow-up, 13% of the medically treated group had ischemic events compared with 21% of the PTCA group (P equals 0.048). Angina relief was greater in those treated with PTCA. Although not statistically different when adjusted for interim analysis, these data suggest that in low-risk patients with stable CAD, aggressive lipid lowering therapy can be as effective as PTCA in reducing ischemic events.

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

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

1c.7 Summary of Controversy/Contradictory Evidence: N/A


1c.9 Quote the Specific guideline recommendation (including guideline number and/or page number):

1. Starting dietary therapy is recommended. Reduce intake of saturated fats (to less than 7% of total calories), trans fatty acids, and cholesterol (to less than 200 mg per day). A fasting lipid profile should be assessed in all patients and within 24 hours of hospitalization for those with an acute cardiovascular or coronary event. For hospitalized patients, initiation of lipid lowering medication is indicated as recommended below before discharge according to the following schedule:
- LDL-C should be less than 100 mg per dL. Further reduction of LDL-C to less than 70 mg per dL is reasonable.
- If baseline LDL-C is greater than or equal to 100 mg per dL, LDL-lowering drug therapy should be initiated.

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ACC/AHA NSTEMI Guideline 2007:
CLASS I
b. Hydroxymethyl glutaryl-coenzyme A reductase inhibitors (statins), in the absence of contraindications, regardless of baseline LDL-C and diet modification, should be given to post-UA/ NSTEMI patients, including postrevascularization patients. (Level of Evidence: A)
c. For hospitalized patients, lipid-lowering medications should be initiated before discharge. (Level of Evidence: A)
d. For UA/NSTEMI patients with elevated LDL-C (greater than or equal to 100 mg per dL), cholesterol-lowering therapy should be initiated or intensified to achieve an LDL-C of less than 100 mg per dL. (Level of Evidence: A) Further titration to less than 70 mg per dL is reasonable. (Class Ila, Level of Evidence: A)
e. Therapeutic options to reduce non-HDL-C are recommended, including more intense LDL-C-lowering therapy. (Level of Evidence: B)

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ACC/AHA STEMI Guideline 2004:

Class Ila
1. It is reasonable to prescribe drug therapy at hospital discharge to patients with non-HDL-C greater than or equal to 130 mg/dL, with a goal of reducing non-HDL-C to substantially less than 130 mg/dL. (Level of
2. It is reasonable to prescribe drugs such as niacin or fibrate therapy to raise HDL-C levels in patients with LDL-C less than 100 mg/dL and non-HDL-C less than 130 mg/dL but HDL-C less than 40 mg/dL despite dietary and other nonpharmacological therapy. Dietary-supplement niacin must not be used as a substitute for prescription niacin, and over-the-counter niacin should be used only if approved and monitored by a physician. (Level of Evidence: B)

3. It is reasonable to add drug therapy with either niacin or a fibrate to diet regardless of LDL and HDL levels when triglyceride levels are greater than 500 mg/dL. In this setting, non-HDL-C (goal substantially less than 130 mg/dL) should be the cholesterol target rather than LDL-C. Dietary-supplement niacin must not be used as a substitute for prescription niacin, and over-the-counter niacin should be used only if approved and monitored by a physician. (Level of Evidence: B)


1c.11 National Guideline Clearinghouse or other URL: http://circ.ahajournals.org/cgi/content/full/113/1/156

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

1c.13 Method for rating strength of recommendation (if different from USPSTF system, also describe rating and how it relates to USPSTF):
ACC/AHA Taskforce on Practice Guidelines Method: Indications are categorized as class I, II, or III on the basis of a multifactorial assessment of risk and expected efficacy viewed in the context of current knowledge and the relative strength of this knowledge. These classes summarize the recommendations for procedures or treatments as follows:
Class I: Conditions for which there is evidence for and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.
Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.
Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.
Class IIb: Usefulness/efficacy is less well established by evidence/opinion.
Class III: Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful.

1c.14 Rationale for using this guideline over others:
These guidelines are the most widely recognized professional guideline in the US for cardiovascular medicine in the area of percutaneous coronary intervention care.

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Importance to Measure and Report? 1
Steering Committee: Was the threshold criterion, Importance to Measure and Report, met? 1
Rationale:

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

S.1 Do you have a web page where current detailed measure specifications can be obtained?
S.2 If yes, provide web page URL:

2a. Precisely Specified

2a.1 Numerator Statement (Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome):
Count of patients with a PCI procedure with statin prescribed at discharge

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

2a.3 Numerator Details (All information required to collect/calculate the numerator, including all codes, logic, and definitions):
Element Name: Discharge Medications
Discharge medications=statin (any)
Coding Instructions: Indicate which of the following medications the patient was prescribed upon discharge.
Note(s): Complete only for patients who had a PCI procedure attempted or performed during this episode of care.
Discharge medications not required for patients who were discharged to "Other acute care hospital", "Hospice", or "Left against medical advice (AMA)."

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

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

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

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

2a.8 Denominator Details (All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions):

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 NQI's Health Information Technology Expert Panel (HITEP).
Element name: PCI
PCI=Yes
Coding Instructions: Indicate if the patient had a percutaneous coronary intervention (PCI).
Selections: No/Yes
Supporting Definitions: PCI:A percutaneous coronary intervention (PCI) is the placement of an angioplasty guide wire, balloon, or other device (e.g. stent, atherectomy, brachytherapy, or thrombectomy catheter) into a native coronary artery or coronary artery bypass graft for the purpose of mechanical coronary revascularization.
Source: NCDR

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

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

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

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

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

2a.12-13 Risk Adjustment Type:

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

2a.15-17 Detailed risk model available Web page URL or attachment:
2a.18-19 Type of Score: Rate/proportion
2a.20 Interpretation of Score: Better quality = Higher score
2a.21 Calculation Algorithm (Describe the calculation of the measure as a flowchart or series of steps):
1. Count of patients with arrival/discharge dates from data submissions that pass NCDR data inclusion thresholds
2. Exclude patients with arrival/discharge dates without PCI during episode
3. Exclude patients with discharge status=deceased
4. Exclude patients with Discharge Location: Other acute care hospital
5. Exclude patients with Discharge Location: Left against medical advice
6. Exclude patients with Discharge Location: Hospice
7. Exclude patients with Statin at discharge: contraindicated or blinded
Numerator calculation:
8. From denominator population, count of patients with Discharge medication of statin=yes
Calculation of score:
9. Numerator count/Denominator count
2a.22 Describe the method for discriminating performance (e.g., significance testing):
Hospitals performance for this measure is benchmarked each quarter and annually against hospitals with similar procedural volume, as well as against the CathPCI Registry aggregate. These benchmarks identify superior performance and encourage poorer performers to improve. The methodology is a data-driven, peer-group performance feedback used to positively affect outcomes.
2a.23 Sampling (Survey) Methodology If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):
N/A
2a.24 Data Source (Check the source(s) for which the measure is specified and tested)
Registry data
2a.25 Data source/data collection instrument (identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.):
National Cardiovascular Data Registry (NCDR®) CathPCI Registry®
2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL
http://www.ncdr.com/WebNCDR/ELEMENTS.ASPX
2a.29-31 Data dictionary/code table web page URL or attachment: URL
http://www.ncdr.com/WebNCDR/ELEMENTS.ASPX
2a.32-35 Level of Measurement/Analysis (Check the level(s) for which the measure is specified and tested)
Facility/Agency
2a.36-37 Care Settings (Check the setting(s) for which the measure is specified and tested)
Hospital, Ambulatory Care: Hospital Outpatient
2a.38-41 Clinical Services (Healthcare services being measured, check all that apply)
Clinicians: PA/NP/Advanced Practice Nurse, Clinicians: Physicians (MD/DO)

TESTING/ANALYSIS

2b. Reliability testing
2b.1 Data/sample (description of data/sample and size): Reliability was established by validating the derivation cohort from version 4 CathPCI data with a testing cohort from version 3 CathPCI data. 555,023 patient records were analyzed from 1007 facilities between July 2008 and June 2009.
2b.2 Analytic Method (type of reliability & rationale, method for testing): Reliability was established by validating the derivation cohort from version 4 CathPCI data with a testing
cohort from version 3 CathPCI data.

2b.3 Testing Results (reliability statistics, assessment of adequacy in the context of norms for the test conducted):
Results were consistent among the derivation cohort and the testing cohort. Specifically, the median for hospitals in the derivation cohort was 89.3% with the lowest decile 77.2% and highest decile 96.4%. This is similar to that observed in the testing cohort (median 89.1%, lowest decile 76.3%, highest decile 96.2%).

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

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

Reliability of the element "PCI" is strengthened because submitters to the CathPCI registry are required to complete this element. In addition, submitters cannot enter any of the elements in the "PCI Procedure" section if they do not answer "yes" to this element. In addition, the "discharge status" (alive or deceased) is a required element (100% threshold).

2c. Validity testing

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

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

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

2d. Exclusions Justified

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

2d.2 Citations for Evidence:
N/A

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

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
### 2d.4 Analytic Method (type analysis & rationale):

Frequency of exclusion coding

### 2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses):

Rates of exclusion coding:
- Discharged to other acute care hospital: 3,931 (0.68%)
- Discharged to hospice: 798 (0.14%)
- Discharged against medical advice: 1232 (0.21%)
- Aspirin contraindicated or blinded: 8,999 (1.57%)
- Discharge status of deceased: 8,027 (1.37%)

### 2e. Risk Adjustment for Outcomes/Resource Use Measures

#### 2e.1 Data/sample (description of data/sample and size):

N/A

#### 2e.2 Analytic Method (type of risk adjustment, analysis, & rationale):

N/A

#### 2e.3 Testing Results (risk model performance metrics):

N/A

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

### 2f. Identification of Meaningful Differences in Performance

#### 2f.1 Data/sample from Testing or Current Use (description of data/sample and size):

563,988 patient records from 1121 hospitals in the CathPCI registry from July 2009 to June 2010.

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

Distribution of rates of statin prescribed on discharge.

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

Performance ranged from 72% at the 5th percentile to 98% at the 95th percentile. 50% of hospitals did not prescribe statins at discharge for 10% of its patients. Please see documentation provided in Ad.11 for detailed analyses.

### 2g. Comparability of Multiple Data Sources/Methods

#### 2g.1 Data/sample (description of data/sample and size):

N/A

#### 2g.2 Analytic Method (type of analysis & rationale):

N/A

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

N/A

### 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 89.5% with the lowest decile 77.9% and highest decile 96.3%. This is similar to that observed for non-Safety Net hospitals (median 87.6%, lowest decile 76.0%, highest decile 96.5%). Similarly, median hospital performance was across quartiles of proportion of white patients (quartile 1: 89.0%, quartile 2: 88.1%, quartile 3: 87.6%, quartile 4: 86.3%).

### 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; 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 practicallyclinically meaningful differences in performance.

### Comment [K19]: 14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% v. 75%) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v. $5,025) is practically meaningful. Measures with overall poor performance may not demonstrate much variability across providers.

### Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
quartile 2: 89.0%, quartile 3: 90.4%, quartile 4: 90.0%). Based on these analyses, we do not believe that a stratified measure is necessary.

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

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<tr>
<th>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Scientific Acceptability of Measure Properties?</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Steering Committee: Overall, to what extent was the criterion, Scientific Acceptability of Measure Properties, met?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rationale:</td>
</tr>
<tr>
<td>C                                                                      P                                                                 M                                                                 N</td>
</tr>
</tbody>
</table>

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)

<table>
<thead>
<tr>
<th>3a. Meaningful, Understandable, and Useful Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>3a.1 Current Use: In use</td>
</tr>
</tbody>
</table>

3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years):

ACCF plans to begin voluntary publicly report of NCDR measures, including this measure, by 2012. ACCF is currently evaluating public reporting options and finalizing decisions related to location and display of information to be reported as well as communication plans.

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

3a.3 If used in other programs/initiatives (If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years):

Used for QI by NCDR CathPCI Registry participating institutions. For Q2 of 2010, 1174 institutions submitted data.

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

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

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

3a.4 Data/sample (description of data/sample and size): 1. 61 NCDR CathPCI Registry participants, Fall 2009.
2. Beta testing for version 4 of the CathPCI Registry institutional outcomes report, 80 sites

Comment [KP22]: 3a. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audience(s) for both public reporting (e.g., focus group, cognitive testing) and informing quality improvement (e.g., quality improvement initiatives). An important outcome that may not have an identified improvement strategy still can be useful for informing quality improvement by identifying the need for and stimulating new approaches to improvement.
3a.5 Methods (e.g., focus group, survey, QI project):
1. Survey
2. Sites provided feedback through an excel template

3a.6 Results (qualitative and/or quantitative results and conclusions):
1. 93.3% responded yes to the question “Will this measure provide important information to you?”
2. Sites provided feedback on the institutional outcomes report that was used to modify the report. Sites provided feedback on invalid data and aspects of the report that were unclear.

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

3b.1 NQF # and Title of similar or related measures:
#543: Coronary Artery Disease and Medication Possession Ratio for Statin Therapy, #439: Discharged on Statin Medication (stroke patients), #639: Statin Prescribed at Discharge

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

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

3c. Distinctive or Additive Value
3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:
This measure is distinct from #639 Statin Prescribed at Discharge (CMS) in that it applies to all PCI patients and is not isolated to MI patients. In addition, the data source for this measure is different from #639. This measure uses registry data as a data source and the CMS measure uses claims and medical record data.

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

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.

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
### 4c. Exclusions

**4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?**

No

**4c.2 If yes, provide justification.**

### 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.

---

*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).*
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:

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<thead>
<tr>
<th>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Feasibility?</th>
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<tbody>
<tr>
<td>Steering Committee: Overall, to what extent was the criterion, Feasibility, met?</td>
</tr>
<tr>
<td>Rationale:</td>
</tr>
<tr>
<td>4</td>
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<table>
<thead>
<tr>
<th>RECOMMENDATION</th>
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<tbody>
<tr>
<td>(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.</td>
</tr>
<tr>
<td>Time-limited</td>
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<table>
<thead>
<tr>
<th>Steering Committee: Do you recommend for endorsement?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comments:</td>
</tr>
<tr>
<td>Y</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CONTACT INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co.1 Measure Steward (Intellectual Property Owner)</td>
</tr>
<tr>
<td>Co.1 Organization</td>
</tr>
<tr>
<td>American College of Cardiology Foundation (ACCF), 2400 N Street NW, Washington, District Of Columbia, 20037</td>
</tr>
<tr>
<td>Co.2 Point of Contact</td>
</tr>
<tr>
<td>Kristyne, McGuinn, MHS, <a href="mailto:kmcguinn@acc.org">kmcguinn@acc.org</a>, 202-375-6529-</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Measure Developer If different from Measure Steward</th>
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<tbody>
<tr>
<td>Co.3 Organization</td>
</tr>
<tr>
<td>American College of Cardiology Foundation (ACCF), 2400 N Street NW, Washington, District Of Columbia, 20037</td>
</tr>
<tr>
<td>Co.4 Point of Contact</td>
</tr>
<tr>
<td>Kristyne, McGuinn, MHS, <a href="mailto:kmcguinn@acc.org">kmcguinn@acc.org</a>, 202-375-6529-</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Co.5 Submitter If different from Measure Steward POC</th>
</tr>
</thead>
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</tr>
<tr>
<td>Kristyne, McGuinn, MHS, <a href="mailto:kmcguinn@acc.org">kmcguinn@acc.org</a>, 202-375-6529-, American College of Cardiology Foundation (ACCF)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Co.6 Additional organizations that sponsored/participated in measure development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Society for Cardiovascular Angiography and Interventions (SCAI)</td>
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<table>
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<tr>
<th>ADDITIONAL INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workgroup/Expert Panel involved in measure development</td>
</tr>
<tr>
<td>Ad.1 Provide a list of sponsoring organizations and workgroup/panel members’ names and organizations. Describe the members’ role in measure development.</td>
</tr>
<tr>
<td>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>
<tr>
<td>Measure Developer/Steward Updates and Ongoing Maintenance</td>
</tr>
<tr>
<td>----------------------------------------------------------</td>
</tr>
<tr>
<td>Ad.2 If adapted, provide name of original measure: N/A</td>
</tr>
<tr>
<td>Ad.3-5 If adapted, provide original specifications URL or attachment</td>
</tr>
<tr>
<td>Ad.6 The measure was first released: 2005</td>
</tr>
<tr>
<td>Ad.7 Month and Year of most recent revision: 09, 2010</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>Ad.9 When is the next scheduled review/update for this measure? 06, 2011</td>
</tr>
<tr>
<td>Ad.10 Copyright statement/disclaimers: © 2010 American College of Cardiology Foundation All Rights Reserved</td>
</tr>
<tr>
<td>Ad.11-13 Additional Information web page URL or attachment: Attachment DSTATIN Final.pdf</td>
</tr>
<tr>
<td>Date of Submission (MM/DD/YY): 10/28/2010</td>
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</table>