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 #:** 0074 **NQF Project:** Cardiovascular Endorsement Maintenance 2010
MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** Chronic Stable Coronary Artery Disease: Lipid Control
De.2 **Brief description of measure**: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who have a LDL-C result <100 mg/dL OR patients who have a LDL-C result >=100 mg/dL and have a documented plan of care to achieve LDL-C <100mg/dL, including at a minimum the prescription of a statin
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**
De.4 **National Priority Partners Priority Area:** Population health De.5 **IOM Quality Domain**: Effectiveness, Equity De.6 **Consumer Care Need:** Living with illness

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

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

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. *Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.* (evaluation criteria) **1a. High Impact**	**Eval Rating**
(for NQF staff use) **Specific NPP goal**:	
1a.1 **Demonstrated High Impact Aspect of Healthcare:** Affects large numbers, Leading cause of morbidity/mortality, High resource use 1a.2 1a.3 **Summary of Evidence of High Impact:** •16.3 million Americans are living with coronary heart disease – of that 16.3 million, 54% are men and 46% are women. (1) •Coronary heart disease makes up more than half of all cardiovascular events in men and women less than 75 years of age. (1) •The lifetime risk of developing coronary heart disease after age 40 is 49% for men and 32% for women. (1) •The incidence of coronary heart disease in women lags behind men by 10 years for total coronary heart disease and by 20 years for more serious clinical events such as myocardial infarction and death.(1) •Coronary heart disease caused approximately 1 of every 6 deaths in the United States in 2007. (1) •While death rates have fallen from 1968 to the present, coronary heart disease is the largest killer of men and women in the United States. (1) It has been estimated that approximately 47% of this decrease is attributed to treatments (medical and surgical), while approximately 44% is attributed to changes in risk	**1a** C☐ P☐ M☐ N☐

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

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

factors. (1)

•In 2007, the estimated direct and indirect cost for coronary heart disease in the United States is $177.5 billion. (1)

•In 2006, coronary artery disease was the most expensive condition treated in US hospitals at a cost of $52.6 billion (2) and accounted for 5% of total hospitalization costs.(3)

•Thirty percent of Medicare's total expenditures are applied to cardiovascular disease.(4)

•In 2007, $5.2 billion was spent on outpatient visits related to chronic ischemic heart disease.(5)

1a.4 Citations for Evidence of High Impact: (1) Roger VL, Go AS, Lloyd-Jones DM, et al; on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2011 update: a report from the American Heart Association. Circulation. 2011;123:e000–e000. Available at: http://circ.ahajournals.org/cgi/reprint/CIR.0b013e3182009701v1
(2) Andrews RM. The national hospital bill: the most expensive conditions by payer, 2006. Agency for Healthcare Research and Quality, Statistical Brief #59. 2008. Available at: http://www.hcup-us.ahrq.gov/reports/ statbriefs/ sb59.pdf.
(3) Agency for Healthcare Research and Quality. HCUP Facts and Figures, 2006: Statistics on Hospital-based Care in the United State. Available at: http://www.hcup-us.ahrq.gov/reports/factsandfigures/facts_figures_2006. jsp#ex4_2b.
(4) Centers for Medicare and Medicaid Services. Health Care Financing Review: Medicare & Medicaid Statistical Supplement. Table 10.4: Hospital Outpatient bills, covered charges, and program payments under medicare by selected reasons for the visit: calendar year 2007. Baltimore, MD: Centers for Medicare and Medicaid Services; 2008. Available at"
http://www.cms.gov.MedicareMedicaidStatSupp/downloads/2008Table10.4.pdf
(5) Trogdon JG, Finkelstein EA, Nwaise IA, Tangka FK, Orenstein D. The economic burden of chronic cardiovascular disease for major insurers. Health Promotion Practice. 2007;8(3):234-242

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: Improvement of lipid management and the number of patients on a statin as first line therapy.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
Performance relating to the National Committee for Quality Assurance measure of cholesterol management for patients with cardiovascular conditions shows the following for 2007 (1):

Measure
Percentage of patients 18 to 75 years of age who were discharged for acute myocardial infarction, coronary artery bypass or percutaneous transluminal coronary angioplasty, or who had a diagnosis of ischemic vascular disease who received an LDD-C screening or whose LDL-C level was controlled to <100 mg/dL.

	Commercial	Medicare	Medicaid
Cholesterol Screening Rate	88.2	87.9	76.3
Cholesterol Control Rate	58.7	55.9	38.3

HealthPartners reported performance results in 2006 on their LDL screening and control measures, which are part of an optimal coronary artery disease care composite measure. 37.5% of members had all of their CAD risk factors optimally managed (LDL <100, blood pressure <140/90mmHg, daily aspirin, and documented non-tobacco use). 100% performance is not expected for this measure. HealthPartners has set a goal of 55% as excellent performance and 60% as superior performance. Individual rates by risk factor are also reported out separately. 83.4% of members with CAD had LDL screening in the measurement year and 59.6% of member s had an LDL <100 mg/dL. (2)

1b.3 Citations for data on performance gap:
(1) The State of Healthcare Quality 2008. National Committee for Quality Assurance. Washington, DC. Available at: http://www.ncqa.org/tabid/836/Default.aspx.

1b
C ☐
P ☐
M ☐
N ☐

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

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

(2) HealthPartners. 2007 Clinical Indicators Report—220/2007 Results. Minneapolis, MN. 2007.

1b.4 Summary of Data on disparities by population group:
We are not aware of any publications/evidence outlining disparities in this area.

1b.5 Citations for data on Disparities:

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*)**:** Managing LDL-C to less than 100 mg/dL through use of statins significantly reduces risk of cardiovascular events.

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

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

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

1c.6 Method for rating evidence:

1c.7 Summary of Controversy/Contradictory Evidence:

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

1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number***):**
Recommended lipid management includes assessment of a fasting lipid profile (Class I Recommendation, Level A Evidence). (ACC/AHA, 200723)
a. LDL-C should be less than 100 mg/dL (Class I Recommendation, Level A Evidence) and
b. Reduction of LDL-C to less than 70 mg/dL or high-dose statin therapy is reasonable (Class IIa Recommendation, Level A Evidence).
c. If baseline LDL-C is greater than or equal to 100 mg/dL, LDL-lowering medications are used in high-risk or moderately high-risk persons, it is recommended that intensity of the therapy be sufficient to achieve a 30% to 40% reduction in LDL-C levels (Class I Recommendation, Level A Evidence).
d. If on-treatment LDL-C is greater than or equal to 100 mg/dL, LDL-lowering therapy should be intensified (Class I Recommendation, Level A Evidence).
e. If baseline LDL-C is 70 to 100 mg/dL, it is reasonable to treat LDL-C to less than 70 mg/dL (Class IIa Recommendation, Level B Evidence).

Statins should be considered as first-line drugs when LDL-lowering drugs are indicated to achieve LDL treatment goals. (The Third Report of the National Cholesterol Education Program [NCEP] Adult Treatment Panel III [ATPII], 2002)

1c.10 Clinical Practice Guideline Citation: Fraker JD, Fihn SD, writing on behalf of the 2002 Chronic Stable Angina Writing Committee. 2007 chronic angina focused update of the ACC/AHA 2002 Guidelines for the Management of Patients with Chronic Stable Angina: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines Writing Group to Develop the Focused Update of the 2002 Guidelines for the Management of Patients with Chronic Stable Angina. J Am Coll Cardiol. 2007;50:2264-2274.

National Cholesterol Education Program, National Heart, Lung, and Blood Institute, National Institutes of Health. Third report of the National Cholesterol Education Program (NCEP) Expert Panel on detection, evaluation, and treatment of high blood cholesterol in adults (Adult Treatment Panel II). NIH Publication No. 02-5212. September 2002.

1c
C☐
P☐
M☐
N☐

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

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.11 National Guideline Clearinghouse or other URL:	
1c.12 Rating of strength of recommendation (*also provide narrative description of the rating and by whom***):**	
1c.13 Method for rating strength of recommendation (*If different from USPSTF system, also describe rating and how it relates to USPSTF)***:** ACC/AHA Classification of Recommendations and Levels of Evidence Classification of Recommendations Class I: Conditions for which there is evidence 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. Level of Evidence 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 NHLBI/ATP III - Not ranked	
1c.14 Rationale for using this guideline over others: It is the PCPI policy to use guidelines, which are evidence-based, applicable to physicians and other healthcare providers, and developed by a national specialty organization or government agency. In addition, the PCPI has now expanded what is acceptable as the evidence base for measures to included documented quality improvement (QI) initiatives or implementation projects that have demonstrated improvement in the quality of care.	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to Measure and Report?*	**1**
Steering Committee: Was the threshold criterion, *Importance to Measure and Report***, met?** **Rationale:**	**1** **Y☐** **N☐**
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	**Eval Rating**
2a. MEASURE SPECIFICATIONS	
S.1 Do you have a web page where current detailed measure specifications can be obtained? **S.2 If yes, provide web page URL:** **2a. Precisely Specified**	
2a.1 Numerator Statement (*Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):** Patients who have a LDL-C result <100 mg/dL OR Patients who have a LDL-C result >=100 mg/dL and have a documented plan of care1 to achieve LDL-C <100 mg/dL, including at a minimum the prescription of a statin within a 12 month period Definitions:	**2a-specs** **C☐** **P☐** **M☐** **N☐**

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

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

*Documented plan of care may also include: documentation of discussion of lifestyle modifications (diet, exercise); scheduled re-assessment of LDL-C

*Prescribed may include prescription given to the patient for a statin at one or more visits in the measurement period OR patient already taking a statin as documented in current medication list

Numerator Instructions:
The first numerator option can be reported for patients who have a documented LDL-C < 100 mg/dL at any time during the measurement period.

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

2a.3 Numerator Details (*All information required to collect/calculate the numerator, including all codes, logic, and definitions***):**
See attached for EHR Specifications.
For Claims/Administrative: Report CPT II Code Patients who have LDL-C <100 mg/dL 3048F Most recent LDL-C <100 mg/dL
OR
Patients who have LDL-C =100 mg/dL and have a documented plan of care to achieve LDL-C <100 mg/dL, including prescription of lipid-lowering therapy
• 3049F Most recent LDL-C 100-129 mg/dL
OR
• 3050F Most recent LDL-C greater than or equal to 130 mg/dL
AND
• 05XXF (code in development) Lipid lowering therapy plan of care documented
AND
• 4002F Statin therapy prescribed

2a.4 Denominator Statement (*Brief, text description of the denominator - target population being measured***):**
All patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period

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

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

2a.8 Denominator Details (*All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):**
See attached for EHR Specifications.
For Claims/Administrative: See coding tables attached for coding (ICD-9-CM, ICD-10-CM, CPT)

2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population***):**
Documentation of medical reason(s) for not prescribing a statin (eg, allergy, intolerance to statin medication(s), other medical reasons)

Documentation of patient reason(s) for not prescribing a statin (eg, patient declined, other patient reasons)

Documentation of system reason(s) for not prescribing a statin (eg, financial reasons, other system reasons)

2a.10 Denominator Exclusion Details (*All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**
See attached for EHR Specifications.
For Claims/Administrative:
Documentation of medical reason(s) for not prescribing a statin (eg, allergy, intolerance to statin

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.

medication(s), other medical reasons) • Append modifier to CPT II code 4XXXF-1P (in development) Documentation of patient reason(s) for not prescribing a statin (eg, patient declined, other patient reasons) • Append modifier to CPT II code 4XXXF-2P (in development) Documentation of system reason(s) for not a statin (eg, financial reasons, other system reasons) • Append modifier to CPT II code 4XXXF-3P (in development)
2a.11 Stratification Details/Variables (*All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
2a.12-13 Risk Adjustment Type: No risk adjustment necessary **2a.14 Risk Adjustment Methodology/Variables (***List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):** **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***):** See attached for calculation algorithm.
2a.22 Describe the method for discriminating performance *(e.g., significance testing)***:**
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)*:
2a.24 Data Source (*Check the source(s) for which the measure is specified and tested)***:** Electronic administrative data/claims, Electronic clinical data, Electronic Health/Medical Record, 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.***):** This measure, in its previous specifications, is currently being used in the ACCF PINNACLE registry for the outpatient office setting. **2a.26-28 Data source/data collection instrument reference web page URL or attachment:** URL www.pinnacleregistry.org **2a.29-31 Data dictionary/code table web page URL or attachment:** Attachment PCPI_CAD-2_LipidControl NQF 0074.pdf **2a.32-35 Level of Measurement/Analysis** (*Check the level(s) for which the measure is specified and tested)* Clinicians: Individual, Clinicians: Group **2a.36-37 Care Settings (***Check the setting(s) for which the measure is specified and tested)* Home, Ambulatory Care: Office, Ambulatory Care: Clinic, Nursing home (NH) /Skilled Nursing Facility (SNF), Ambulatory Care: Hospital Outpatient, Assisted Living, Group homes **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)*: Additional data is available in section 1 of the CAD measure testing summary.

2b.2 **Analytic Method** *(type of reliability & rationale, method for testing)*:
Additional data is available in section 1 of the CAD measure testing summary.

2b.3 **Testing Results** *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
Additional data is available in section 1 of the CAD measure testing summary.

2b
C☐
P☐
M☐
N☐

2c. Validity testing

2c.1 **Data/sample** *(description of data/sample and size)*:

2c.2 **Analytic Method** *(type of validity & rationale, method for testing)*:
All PCPI performance measures are assessed for content validity by expert work group members during the development process. Additional input on the content validity of draft measures is obtained through a 30-day public comment period and by also soliciting comments from a panel of consumer, purchaser, and patient representatives convened by the PCPI specifically for this purpose. All comments received are reviewed by the expert work group and the measures are adjusted as needed. Other external review groups (eg, focus groups) may be convened if there are any remaining concerns related to the content validity of the measures.

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

2c
C☐
P☐
M☐
N☐

2d. Exclusions Justified

2d.1 **Summary of Evidence supporting exclusion(s):**
Additional data is available in section 5 of the CAD measure testing summary.

2d.2 **Citations for Evidence:**
Additional data is available in section 5 of the CAD measure testing summary.

2d.3 **Data/sample** *(description of data/sample and size)*: Additional data is available in section 5 of the CAD measure testing summary.

2d.4 **Analytic Method** *(type analysis & rationale)*:
Additional data is available in section 5 of the CAD measure testing summary.

2d.5 **Testing Results** *(e.g., frequency, variability, sensitivity analyses)*:
Additional data is available in section 5 of the CAD measure testing summary.

2d
C☐
P☐
M☐
N☐
NA☐

2e. Risk Adjustment for Outcomes/ Resource Use Measures

2e.1 **Data/sample** *(description of data/sample and size)*: This measure does not employ the use of risk adjustment.

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

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

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

2e
C☐
P☐
M☐
N☐
NA☐

2f. Identification of Meaningful Differences in Performance

2f

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

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

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

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

Comment [k13]: 9 Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP < 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed (e.g., ratings by relevant stakeholders) and the measure is judged to represent quality care for the specific topic and that the measure ... [2]

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 ... [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 outc ... [4]

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 trea ... [5]

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.

2f.1 Data/sample from Testing or Current Use *(description of data/sample and size)*: Additional data is available in section 1 of the CAD measure testing summary. **2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance** *(type of analysis & rationale)*: Additional data is available in section 1 of the CAD measure testing summary. **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)*: Additional data is available in section 1 of the CAD measure testing summary.	C☐ P☐ M☐ N☐
2g. Comparability of Multiple Data Sources/Methods **2g.1 Data/sample** *(description of data/sample and size)*: Additional data is available in section 6 of the CAD measure testing summary. **2g.2 Analytic Method** *(type of analysis & rationale)*: Additional data is available in section 6 of the CAD measure testing summary. **2g.3 Testing Results** *(e.g., correlation statistics, comparison of rankings)*: Additional data is available in section 6 of the CAD measure testing summary.	**2g** C☐ P☐ M☐ N☐ NA☐
2h. Disparities in Care **2h.1 If measure is stratified, provide stratified results** *(scores by stratified categories/cohorts)*: The measure is not stratified by patient groups or cohorts that could potentially be affected by disparities in care, nor are we aware of any existing research identifying disparities in care that may be relevant to this measure. **2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:** We are not aware of any relevant disparities that have been identified.	**2h** C☐ P☐ M☐ N☐ NA☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Scientific Acceptability of Measure Properties?*	**2**
Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties*, **met?** **Rationale:**	*2* C☐ P☐ M☐ N☐
3. USABILITY	
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	**Eval Rating**
3a. Meaningful, Understandable, and Useful Information **3a.1 Current Use:** In use **3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large)** (*If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years*): This measure is not yet used in any public reporting initiative. The measure will, however, be eligible for inclusion in the CMS PQRS and other government programs in 2012 and would thus provide information about clinician participation to the public. The ACCF, AHA, and PCPI believe that the reporting of such participation information is a beneficial first step on a trajectory toward the public reporting of performance results, which is most appropriate after the measures are thoroughly tested and the reliability of the performance data has been validated. Continued NQF endorsement will facilitate our ongoing progress toward this public reporting objective.	**3a** C☐ P☐ M☐ N☐

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

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

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

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.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***):**

All PCPI measures are suitable for use in quality improvement initiatives and are made freely available on the PCPI website and through the implementation efforts of medical specialty societies and other PCPI members. The PCPI strongly encourages the use of its measures in QI initiatives and seeks to provide information on such initiatives to PCPI members.

The American Heart Association's Get With The Guidelines®-Outpatient (GWTG-O) is a virtual performance improvement program that will improve adherence to evidence-based care in the outpatient setting, including specialist practices, general healthcare practices and health clinics. GWTG-Outpatient historically has had a long history of quality improvement for cardiovascular care. They have published 65 publications over the past 10 years. This program is designed to assist healthcare professionals in the outpatient setting to provide the best possible care to patients. This program collects a number of clinical measures for primary and secondary prevention. Clinical measure sets include those developed by American Heart Association, including those co-developed with other organizations, such as the American College of Cardiology Foundation and the American Medical Association, as well as other National Quality Forum endorsed measures.

Through this program, we collect data on clinical measures affecting a number of cardiovascular related conditions including, atrial fibrillation, coronary artery disease, heart failure, hypertension, diabetes, and preventative care. The primary analytical system used is Duke Clinical Research Institute. Get With The Guidelines®-Outpatient is a quality improvement program that can be utilized for Maintenance of Certification (MOC) with groups like American Board of Internal Medicine (ABIM) and American Board of Family Medicine (ABFM). ABIM has confirmed that the reports received from Get With The Guidelines-Outpatient can be utilized in completion of their Self-Directed Practice Improvement Module (PIM). The Self-Directed PIM provides one pathway for earning practice performance credit in ABIM's MOC program. This program includes several integral components: A preliminary Continuing Education (CE) course for the care team, data submission and reporting that is integrated with existing Electronic Health Records (EHRs)/health technology platforms, corresponding professional and provider education including webinars, online tools and resources, digital access to reference materials and videos through the Get With The Guidelines®-Outpatient website (http://outpatient.heart.org). The free continuing education activity titled, Outpatient Quality Improvement Focus, addresses the quality chasm and treatment gap, presents the benefits of quality improvement and identifies the steps necessary for implementation in the practice setting. This continuing education activity is certified for physicians, nurses and pharmacists.

The American College of Cardiology Foundation's Cardiology Practice Improvement Pathway (CPIP) uses clinical measure sets that are developed and specified by the American College of Cardiology Foundation with the American Heart Association and the American Medical Association's Physician Consortium for Performance Improvement for Hypertension, Stable Coronary Artery Disease, Heart Failure, and Atrial Fibrillation/Atrial Flutter. This program is intended as an approved quality improvement product that can be applied toward ABIM's Part IV practice performance requirement for Maintenance of Certification (ABIM AQI application submitted). They are in the process of creating a homepage on the Cardiosource.org homepage. The URL will be cardiosource.org/cpip. The web-based tool will be available after spring 2011. Through an online webinar hosted in November 2010, CPIP anticipates enrolling 50 - 100 practices during 2011 which will provide data from about 500-1,000 cardiologists. This ACCF initiative has contracted with the NY QIO: IPRO to analyze and scores based on thresholds. Of the 100 points needed to achieve recognition in the program, 70 come directly from clinical points such as the Heart Failure measures that are being submitted to NQF for consideration. IPRO will audit 5% of practices who submit their data for recognition evaluation.

The American College of Cardiology Foundation's has an Performance Improvement program entitled "A New Era" which is an educational format approved for credit by the American Medical Association (AMA) and the American Nursing Credentialing Center. This continuing medical education program blends both quality improvement and educational methodologies to provide a high quality learning experience that impacts changes to practice. These activities are structured, long-term processes in which a healthcare professional learns about the heart failure specific performance metrics, uses metrics to retrospectively assess his

practice, applies these metrics prospectively over a useful interval, and reevaluates his performance. As part of this process, clinicians set goals for change and engage in structured learning activities to improve their performance. As of December 6th, 2010:
- 425 clinicians have enrolled in A New ERA
- The data is generated from all but four states (Montana, New Hampshire, South Dakota, and Wyoming)
- 82% are physicians
- 90% agreed or strongly agreed that performance metric data were valuable
- 80% agreed or strongly agreed that performance metric data review would help them improve their practice
- No one has finished the program, as it takes several months to do so

In 2008, the American College of Cardiology Foundation launched the PINNACLE program (formerly known as the Improving Continuous Cardiac Care or IC3). This was the first, national, prospective, outpatient based cardiac QI registry in the US. While participation is voluntary, this registry collects a variety of longituditional patient data at the point of service, including patients' symptoms, vital signs, medication, and recent hospitalizations. Jointly developed ACCF/AHA/PCPI measures for Coronary Artery Disease, Heart Failure, and Atrial Fibrillation. Data collection is achieved in 2 ways for the practices: paper forms or practice's electronic medical record data collection systems. The primary analytical system used is St. Luke's Mid America Heart Institute. The ACCF registry, PINNACLE, pulls data from outpatient facilities via paper flowsheets or 14 EHR vendors. As of December 10, 2010, there are 47 practices collecting data at 200 sites with 276,000 unique patients representing 1 million documented encounters.

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)*:

3a.5 **Methods** *(e.g., focus group, survey, QI project)*:

3a.6 **Results** *(qualitative and/or quantitative results and conclusions)*:

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

3b.1 **NQF # and Title of similar or related measures:**
Maintenance submission of NQF #0074: Drug Therapy for Lowering LDL-Cholesterol

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

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

3b
C ☐
P ☐
M ☐
N ☐
NA ☐

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

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

3c
C ☐
P ☐
M ☐
N ☐
NA ☐

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

3

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

3
C ☐
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).

	M☐ N☐
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	Eval Rating
4a. Data Generated as a Byproduct of Care Processes 4a.1-2 **How are the data elements that are needed to compute measure scores generated?** Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition), Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)	4a C☐ P☐ M☐ N☐
4b. Electronic Sources 4b.1 **Are all the data elements available electronically?** (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*) Yes 4b.2 **If not, specify the near-term path to achieve electronic capture by most providers.**	4b C☐ P☐ M☐ N☐
4c. Exclusions 4c.1 **Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?** No 4c.2 **If yes, provide justification.**	4c C☐ P☐ M☐ N☐ NA☐
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences 4d.1 **Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.** Although we are not currently aware of any unintended consequences related to this measure, we plan through an active redesign of the PCPI website to facilitate the collection of information on unintended consequences from the users of PCPI measures.	4d C☐ P☐ M☐ N☐
4e. Data Collection Strategy/Implementation 4e.1 **Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:** 4e.2 **Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:** Costs to implement the measure have not been calculated. 4e.3 **Evidence for costs:** 4e.4 **Business case documentation:**	4e C☐ P☐ M☐ N☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility*?	4
Steering Committee: Overall, to what extent was the criterion, *Feasibility*, **met?**	4

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).

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

CONTACT INFORMATION

Co.1 **Measure Steward (Intellectual Property Owner)**
Co.1 **Organization**
American Medical Association, 515 N. State St., Chicago, Illinois, 60654

Co.2 **Point of Contact**
Mark, Antman, DDS, MBA, mark.antman@ama-assn.org, 312-464-5056-

Measure Developer If different from Measure Steward
Co.3 **Organization**
American Medical Association, 515 N. State St., Chicago, Illinois, 60654

Co.4 **Point of Contact**
Mark, Antman, DDS, MBA, mark.antman@ama-assn.org, 312-464-5056-

Co.5 **Submitter If different from Measure Steward POC**
Mark, Antman, DDS, MBA, mark.antman@ama-assn.org, 312-464-5056-, American Medical Association

Co.6 **Additional organizations that sponsored/participated in measure development**
American College of Cardiology Foundation, American Heart Association

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 **Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.**
Bruce Abramowitz, MD, FACC (interventional cardiology; measure implementation)
Karen Alexander, MD (cardiology; geriatrics)
Craig T. Beam, CRE (patient representative)
Robert O. Bonow, MD, MACC, FAHA, FACP (cardiology)
Jill S. Burkiewicz, PharmD, BCPS (pharmacy)
Michael Crouch, MD, MSPH (family medicine)
David C. Goff, Jr., MD, PhD, FAHA, FACP (internal medicine)
Richard Hellman, MD, FACP, FACE (endocrinology)
Thomas James, III, FACP, FAAP (health plan representative)
Marjorie L. King, MD, FACC, MAACVPR (cardiology; cardiac rehabilitation)
Edison A. Machado, Jr., MD, MBA (measure implementation)
Eduardo Ortiz, MD, MPH (guideline development)
Michael O'Toole, MD (cardiology; electrophysiology; measure implementation)
Stephen D. Persell, MD, MPH (internal medicine; measure implementation)
Jesse M. Pines, MD, MBA, MSCE, FAAEM (emergency medicine)
Frank J. Rybicki, MD, PhD (radiology)
Lawrence B. Sadwin (patient representative)
Joanna D. Sikkema, MSN, ANP-BC, FAHA (cardiology)
Peter K. Smith, MD (thoracic surgery)
Patrick J. Torcson, MD, FACP, MMM (hospital medicine)
John B. Wong MD, FACP (internal medicine)

PCPI measures are developed through cross-specialty, multi-disciplinary work groups. All medical specialties and other health care professional disciplines participating in patient care for the clinical condition or topic under study must be equal contributors to the measure development process. In addition, the PCPI strives to include on its work groups individuals representing the perspectives of patients, consumers, private health plans, and employers. This broad-based approach to measure development ensures buy-in on the measures from all stakeholders and minimizes bias toward any individual specialty
or stakeholder group. All work groups have at least two co-chairs who have relevant clinical and/or measure development expertise and who are responsible for ensuring that consensus is achieved and that all perspectives are voiced.

Ad.2 **If adapted, provide name of original measure:** Maintenance submission of NQF #0074: Drug Therapy for Lowering LDL-Cholesterol
Ad.3-5 **If adapted, provide original specifications URL or attachment**

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.6 **Year the measure was first released:** 2003
Ad.7 **Month and Year of most recent revision:** 05, 2009
Ad.8 **What is your frequency for review/update of this measure?** Every 3 years or as new evidence becomes available that materially affects the measures
Ad.9 **When is the next scheduled review/update for this measure?** 05, 2012

Ad.10 **Copyright statement/disclaimers:** This Physician Performance Measurement Set (PPMS) and related data specifications were developed by the Physician Consortium for Performance Improvement (the Consortium) including the American College of Cardiology (ACC), the American Heart Association (AHA) and the American Medical Association (AMA) to facilitate quality improvement activities by physicians. The performance measures contained in this PPMS are not clinical guidelines and do not establish a standard of medical care, and have not been tested for all potential applications. This PPMS is intended to assist physicians to enhance quality of care and is not intended for comparing individual physicians to each other or for individual physician accountability by comparing physician performance against the measure or guideline.

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Limited proprietary coding is contained in the measure specifications for convenience. Users of the proprietary code sets should obtain all necessary licenses from the owners of these code sets. The AMA, the ACC, the AHA, the Consortium and its members disclaim all liability for use or accuracy of any Current Procedural Terminology (CPT®) or other coding contained in the specifications.

Ad.11 -13 **Additional Information web page URL or attachment:** Attachment Testing Summary CAD NQF Final_10_10-634238750084618705.pdf

Date of Submission (*MM/DD/YY*)**:** 01/20/2011

Page 4: [1] Comment [k4] **Karen Pace** **10/5/2009 8:59:00 AM**

1c. The measure focus is:

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

OR

- if an intermediate outcome, process, structure, etc., there is **evidence** that supports the specific measure focus as follows:
  - Intermediate outcome – evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
  - Process – evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and
    if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
  - Structure – evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
  - Patient experience – evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of individuals/ the public.
  - Access – evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
  - Efficiency – demonstration of an association between the measured resource use and level of performance with respect to one or more of the other five IOM aims of quality.

Page 8: [2] Comment [k13] **Karen Pace** **10/5/2009 8:59:00 AM**

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.

Page 8: [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 8: [4] Comment [KP16] **Karen Pace** **10/5/2009 8:59:00 AM**

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.

Page 8: [5] Comment [k17] **Karen Pace** **10/5/2009 8:59:00 AM**

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