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 #:** 0068 **NQF Project:** Cardiovascular Endorsement Maintenance 2010
MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** Ischemic Vascular Disease (IVD): Use of Aspirin or another Antithrombotic
De.2 **Brief description of measure***:* The percentage of patients with ischemic vascular disease who currently report taking aspirin and the percentage of patients with ischemic vascular disease who were counseled about the risks and benefits of aspirin.
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 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*)**:** Proprietary measure 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	**B**

update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	Y☐ N☐
C. The intended use of the measure includes both public reporting and quality improvement. ►**Purpose:** Public reporting, Internal quality improvement	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 1a.2 1a.3 **Summary of Evidence of High Impact:** Coronary Heart Disease (CHD) was an underlying or contributing cause of death for 451,300 people that accounted for 1 of every 5 deaths in the United States in 2004. AMI was as an underlying or contributing cause of death for 156,000 people (AHA, 2008). In addition, the prevalence of CHD for both sexes in 2005 is nearly 16 million people or 7.3% of the American population (AHA, 2008) The cost of cardiovascular diseases and stroke in the United States for 2008 is estimated at $448.5 billion (AHA, 2008). This figure includes health expenditures (direct costs such as the cost of physicians and healthcare practitioners, hospital and nursing home services, medications, home health care and other medical durables) and lost productivity resulting from morbidity and mortality (indirect costs). Acute Myocardial Infarction (AMI) represents 18% of hospital discharges and 28% of deaths due to heart disease (NHLBI, 2000). Research has shown that costs associated with cardiovascular disease for hospitals are easily $156 billion (AHA, 2008). From 1979 to 2003, the percentage of discharges of patients with discharges from short-stay hospitals with CHD as the main diagnosis rose by 31%. Evidence has shown that age is a strong demographic factor for CHD. The average life expectancy has risen after 10 years by about 2 years since 1965, it is projected by 2030, 1 in 5 Americans will be aged 65 or older. The need for CHD management is essential (Berra, 2006). Aspirin	1a C☐ P☐ M☐ N☐

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).

treatments reduce MI in men (127 events per 100,000 person-years) and women (17 events per 100,000 person-years) (Grieving, 2008).
While studies have shown warfarin to be more effective, aspirin is a safer, more convenient, and less expensive form of therapy (Patrono, 2004). Aspirin therapy has been shown to directly reduce 14% of the odds of cardiovascular events among men and 12% of the odds for women (Berger, 2006). Aspirin use reduced the number of strokes by 20%, MI by 30%, and other vascular events by 30% (Weisman, 2002).
Also, aspirin treatments have been shown to prevent 1 cardiovascular event over an average follow-up of 6.4 years. This means that on average in a 6.4 year time period the use of aspirin therapy results in a benefit of 3 cardiovascular events prevented per 1000 women and 4 events prevented per 1000 men (Berger, 2006). Even for patients with peripheral arterial disease, aspirin has been shown to reduce CHD in people (Kikano, 2007).

While people with diabetes aged 65 or greater and aged 50-64 with CVD risks such as currently smoking, diagnosed hypertension, and diagnosed hypercholesterolemia use aspirin (74% and 78% respectively), only 60% of the age group of 35-49 with CVD risks uses aspirin. In addition, by stratifying by sex, research also shows that while 83% of men with CVD risk uses aspirin, only 65% of women with CVD risks take aspirin (Persell, 2004).
It was found that a secondary prevention portfolio with the inclusion of aspirin holds great promise for reducing the burden of cardiovascular disease in the highest risk patients for those with coronary heart disease (CHD) or stroke. (Robinson, 2005).
In addition to the benefits of aspirin, the adherence to the medication is high. It was found in a study that aspirin compliance was excellent in the secondary prevention of ischemic stroke. Even if the patients who failed to show up for laboratory testing are regarded as noncompliants, at least 90% of all patients were compliant in taking the aspirin (Lago, 2006).
Lastly, by calculating cost effectiveness and clinically preventable burden, the National Commission on Prevention Priorities (NCPP) determined aspirin use was the top most effective clinical preventable service (Maciosek, 2006).

1a.4 **Citations for Evidence of High Impact:** American Diabetes Association. Standards of Medical Care in Diabetes – 2008. Diabetes Care 31:S12-S54, 2008.

American Heart Association. Heart Disease and Stroke Statistics — 2008 Update. http://www.americanheart.org/downloadable/heart/1200082005246HS_Stats%202008.final.pdfAccessed: Accessed 15 Jul 2008.

Berger, JS. Roncaglioni MC, Avanzini F. Aspirin for the primary prevention of cardiovascular events in women and men: a sex-specific meta-analysis of randomized controlled trials. JAMA 2006;296(4):306-314.

Berra K, Miller NH, Fair JM. Cardiovascular disease prevention and disease management: A critical role for nursing. J Cardiopulm Rehabil 2006;26(4):197-206.

Grieving, JP, Buskens E, Koffijberg H, Algra A. Cost-effectiveness of aspirin treatment in the primary prevention of cardiovascular disease events in subgroups based on age, gender, and varying cardiovascular risk. Circulation 2008;117:2875-2883.

Kikano GE, Brown MT. Antiplatelet therapy for atherothrombotic disease: an update for the primary care physician. Mayo Clin Proc. May 2007;82(5):583-593.

Lago A, Tembl JI, Pareja A, Ponz A, Ferrer JM, Vallés J, Santos MT: Adherence to Aspirin in Secondary Prevention of Ischemic Stroke. Cerebrovasc Dis 2006;21:353-356.

Maciosek MV, Coffield AB, Edwards NM, Flottemesch TJ, Goodman MJ, Solberg LI. Priorities among effective clinical preventive services: results of a systematic review and analysis. Am J Prev Med 2006;31 (1): 52-61.

National Institutes of Health, National Heart, Lung, and Blood Institute. Morbidity and Mortality: 2000 Chart Book on Cardiovascular, Lung, and Blood Diseases. http://www.nhlbi.nih.gov/resources/docs/cht-book.htm

Patrono C, Coller B, FitzGerald GA, Hirsh J, Roth G. Platelet-Active Drugs: The relationships among dose, effectiveness, and side effects: the seventh ACCP Conference on antithrombotic and thrombolytic therapy. Chest 2004;126:234-264.

Persell SD, Baker DW. Aspirin use among adults with diabetes: recent trends and emerging sex disparities. Arch Intern Med 2004;164(22):2492-2499.

Robinson JG, Maheshwari N. A "poly-portfolio" for secondary prevention: a strategy to reduce subsequent events by up to 97% over five years. Am J Cardiol. 2005 Feb 1;95(3):373-8.

Weisman SM, Graham DY. Evaluation of the benefits and risks of low-dose aspirin in the secondary prevention of cardiovascular and cerebrovascular events. Arch Intern Med. Oct 28 2002;162(19):2197-2202.

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: Aspirin is the safer, more convenient and least expensive form of therapy in reducing caridovascular events amoung men and women; reducing the number of strokes, MI, and other vascular events considerably.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
[Data from physician applications to Heart/Stroke Recognition Program]

Year	N (physicians)	N (patients)	Avg Rate	P10	P25	P50	P75	P90
2005	51	1415	86.55	64.0	80.0	92.0	100.0	100.0
2006	561	21510	91.04	80.0	88.0	92.0	100.0	100.0
2007	821	25577	89.28	76.0	84.0	92.0	97.1	100.0
2008	671	23643	88.13	74.3	84.0	92.0	96.0	100.0
2009	208	6062	92.06	80.0	88.0	96.0	97.1	100.0

1b.3 Citations for data on performance gap:
None

1b.4 Summary of Data on disparities by population group:
NOne

1b.5 Citations for data on Disparities:
None

1b
C☐
P☐
M☐
N☐

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*)**:** Aspirin therapy has been shown to directly reduce 14% of the odds of cardiovascular events among men and 12% of the odds for women (Berger, 2006). Aspirin use reduced the number of strokes by 20%, MI by 30%, and other vascular events by 30% (Weisman, 2002). In addition, aspirin is a safer, more convenient, and less expensive form of therapy than warfarin(Patrono, 2004).

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

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

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

1c
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.

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

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

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

1c.6 Method for rating evidence: NA

1c.7 Summary of Controversy/Contradictory Evidence: NA

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

1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number***):**
ADA
Use aspirin therapy (75–162 mg/day) as a secondary prevention strategy in those with diabetes with a history of CVD. (Level A)

Level A: Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:
- Evidence from a well-conducted multicenter trial
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

Compelling non-experimental evidence, i.e., "all or none" rule developed by the Centre for Evidence-Based Medicine at Oxford Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including:
- Evidence from a well-conducted trial at one or more institutions

Evidence from a meta-analysis that incorporated quality ratings in the analysis

Use aspirin therapy (75–162 mg/day) as a primary prevention strategy in those with type 1 or 2 diabetes at increased cardiovascular risk, including those who are _40 years of age or who have additional risk factors (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria). (Level A)

AHA/ACC
Start aspirin 75 to 162 mg/d and continue indefinitely in all patients with coronary and other vascular disease unless contraindicated. Class I, Level A

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

ICSI
Aspirin should be prescribed to all patients with stable coronary disease. If a patient is aspirin intolerant, then use clopidogrel.
(Class A; Grade I)

Class A:
Randomized, controlled trial

Grade I :
The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

VA/DoD
Ensure that all patients with ischemic heart disease or angina symptoms receive antiplatelet therapy (aspirin 81-325 mg/day). For patients who require warfarin therapy, aspirin may be safely used at a dose of 80 mg/day.
If use of aspirin is contraindicated, clopidogrel (75 mg/day) may be used. (Quality of Evidence = I ;Strength of Recommendation = A)

Quality of Evidence = I Evidence is obtained from at least one properly randomized controlled trial (RCT).

Strength of Recommendation = A
A strong recommendation, based on evidence or general agreement, that a given procedure or treatment is

useful/effective, always acceptable, and usually indicated

AHA/ASA
The use of aspirin is recommended for cardiovascular (including but not specific to stroke) prophylaxis among persons whose risk is sufficiently high for the benefits to outweigh the risks associated with treatment (a 10-year risk of cardiovascular events of 6% to 10%). (Class I: Level A)

Class I, Level A:
Conditions for which there is evidence for and/or general agreement that the procedure or treatment is useful and effective.

Data derived from multiple randomized clinical trials.

ACCP
For long-term treatment after PCI, the guideline developers recommend aspirin, 75 to 162 mg/day. (Grade 1A)

For long-term treatment after PCI in patients who receive antithrombotic agents such as clopidogrel or warfarin, the guideline developers recommend lower-dose aspirin, 75 to 100 mg/day. (Grade 1C+)

For patients with ischemic stroke who are not receiving thrombolysis, the guideline developers recommend early aspirin therapy, 160 to 325 mg/day (Grade 1A)

Grade 1A: Randomized controlled trials (RCTs) without important limitations

Implications: Strong recommendation; can apply to most patients in most circumstances without reservation

Grade 1C+: No RCTs, but strong RCT results can be unequivocally extrapolated, or overwhelming evidence from observational studies

Implications: Strong recommendation; can apply to most patients in most circumstances

Grade 1A: Randomized controlled trials (RCTs) without important limitations

Implications: Strong recommendation; can apply to most patients in most circumstances without reservation

1c.10 Clinical Practice Guideline Citation: American Diabetes Association. Standards of Medical Care in Diabetes – 2008. Diabetes Care 31:S12-S54, 2008.
Pearson, TA et al. AHA Guidelines for Primary Prevention of Cardiovascular Disease and Stroke: 2002 Update: Consensus Panel Guide to Comprehensive Risk Reduction for Adult Patients Without Coronary or Other Atherosclerotic Vascular Diseases. American Heart Association Science Advisory and Coordinating Committee. Circulation. 2002 Jul 16;106(3):388-91.

Institute for Clinical Systems Improvement (ICSI). Stable coronary artery disease. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2009 Apr. 41
Smith SC, et al. Guidelines for Secondary Prevention for Patients with Coronary and Other Atherosclerotic Vascular Disease: 2006 Update: Endorsed by the National Heart, Lung, and Blood Institute Circulation 2006;113;2363-2372

Veterans Health Administration, Department of Defense. VA/DoD clinical practice guideline for the management of ischemic heart disease. Washington (DC): Veterans Health Administration, Department of Defense; 2003 Nov. Various

Goldstein LB, et al, American Heart Association, American Stroke Association Stroke Council. Primary prevention of ischemic stroke: a guideline from the American Heart Association/American Stroke Association Stroke Council [trunc]. Circulation 2006 Jun 20;113(24):e873-923.

Albers GW, Amarenco P, Easton JD, Sacco RL, Teal P. Antithrombotic and thrombolytic therapy for ischemic stroke: the Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy. Chest 2004 Sep;126 (3 Suppl):483S-512S **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***):** See above **1c.13 Method for rating strength of recommendation** (*If different from USPSTF system, also describe rating and how it relates to USPSTF)***:** **1c.14 Rationale for using this guideline over others:**	
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***):** Current aspirin use. The percentage of members in the denominator who are currently taking aspirin. The number of patients who have documentation of use of aspirin or another antithrombotic during the 12-month measurement period. Documentation in the medical record must include, at a minimum, a note indicating the date on which aspirin or another antithrombotic was prescribed or documentation of prescription from another treating physician. **2a.2 Numerator Time Window (***The time period in which cases are eligible for inclusion in the numerator***):** 12 months **2a.3 Numerator Details (***All information required to collect/calculate the numerator, including all codes, logic, and definitions***):** Table IVD-D: Codes to Identify Prescribed Oral Anti-Platelet Therapy Description CPT Category II ICD-9-CM Diagnosis Oral anti-platelet therapy prescribed 4011F V58.63, V58.66 Table IVD-E: Oral Anti-Platelet Therapies Description Prescription Oral anti-platelet therapies • aspirin • clopidogrel • aspirin-dipyridamole • prasugrel • ticlopidine	**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) .

2a.4 Denominator Statement (*Brief, text description of the denominator - target population being measured***):**
Age 18 years or older as of December 31 of the measurement year.
Patient inclusion criteria Health plan. Continuous medical benefit enrollment for the measurement year, with no more than one gap in continuous enrollment of up to 45 days during the measurement year. To determine continuous enrollment for a Medicaid beneficiary for whom enrollment is verified monthly, there may not be more than a 1-month gap in coverage during each year of continuous enrollment. The patient must be enrolled as of December 31 of the measurement year.
Non-health plan. Any enrollment, claim or encounter transaction any time during the measurement year.
Event/ diagnosis Event. Discharged alive for AMI, CABG or PCI on or between January 1 and November 1 of the year prior to the measurement year. Use the codes listed in Table IVD-A to identify AMI, PCI and CABG. AMI and CABG cases should be from inpatient claims only. All cases of PCI should be included, regardless of setting (e.g., inpatient, outpatient, ED).
Diagnosis. Identify patients as having IVD who met at least one of the two criteria below, during both the measurement year and the year prior to the measurement year. Criteria need not be the same across both years.
•At least one outpatient visit (Table IVD-C) with an IVD diagnosis (Table IVD-B), or
•At least one acute inpatient visit (Table IVD-C) with an IVD diagnosis (Table IVD-B)Medical record data
Documentation of IVD in the medical record includes:
•IVD
•Ischemic heart disease
•Angina
•Coronary atherosclerosis
•Coronary artery occlusion
•Cardiovascular disease
•Occlusion or stenosis of precerebral arteries (including basilar, carotid and vertebral arteries)
•Atherosclerosis of renal artery
•Atherosclerosis of native arteries of the extremities
•Chronic total occlusion of artery of the extremities
•Arterial embolism and thrombosis
•Atheroembolism.
Note: Use paper logs, patient registries or EMRs to identify the denominator, then use the medical record to confirm patient eligibility.
Exclusions None.

Table IVD-A: Codes to Identify AMI, PCI and CABG

Description	CPT	HCPCS	ICD-9-CM Diagnosis	ICD-9-CM Procedure
AMI (inpatient only)			410.x1	
CABG (inpatient only)	33510-33514, 33516-33519, 33521-33523, 33533-33536		S2205-S2209	36.1, 36.2
PCI	92980, 92982, 92995	G0290		00.66, 36.06, 36.07

Table IVD-B: Codes to Identify IVD

Description	ICD-9-CM Diagnosis
IVD	411, 413, 414.0, 414.2, 414.8, 414.9, 429.2, 433, 434, 440.1, 440.2, 440.4, 444, 445

Source: Table CMC-B in Cholesterol Management for Patients With Cardiovascular Conditions.

Table IVD-C: Codes to Identify Visit Type

Description	CPT	UB Revenue
Outpatient	99201-99205, 99211-99215, 99217-99220, 99241-99245, 99341-99345, 99347-99350, 99384-99387, 99394-99397, 99401-99404, 99411, 99412, 99420, 99429, 99455, 99456	051x, 0520-0523, 0526-0529, 057x-059x, 0982, 0983
Acute inpatient	99221-99223, 99231-99233, 99238, 99239, 99251-99255, 99261-99263, 99291	010x, 0110-0114, 0119, 0120-0124, 0129, 0130-0134, 0139, 0140-0144, 0149, 0150-0154, 0159, 016x, 020x-021x, 072x, 0987

2a.5 Target population gender:
2a.6 Target population age range: 18 older

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

2a.8 Denominator Details (*All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):**
Table IVD-F: Codes to Identify Visit Type

Description	CPT	UB Revenue
Outpatient	99201-99205, 99211-99215, 99217-99220, 99241-99245, 99341-99345, 99347-99350, 99384-99387, 99394-99397, 99401-99404, 99411, 99412, 99420, 99429, 99455, 99456	051x, 0520-0523 0526-0529 057x-059x, 077x, 0982,0983
Acute inpatient	99221-99223, 99231-99233, 99238, 99239, 99251-99255, 99261-99263, 99291	010x, 0110-0114, 0119, 0120-0124, 0129, 0130-0134, 0139, 0140-0144 0149,0150-0154, 0159 016x, 020x-022x, 072x, 0987

Codes to Identify AMI, PTCA, and CABG

Description	CPT	HCPCS	ICD-9-CM Diagnosis	ICD-9-CM Procedure
AMI (inpatient only)			410.x1	
CABG (inpatient only)	33510-33514, 33516-33519, 33521-33523, 33533-33536	S2205-S2209		36.1, 36.2
PTCA	33140, 92980, 92982, 92995			00.66, 36.06, 36.07, 36.09

Codes to Identify IVD

Description	ICD-9-CM Diagnosis
IVD	411, 413, 414.0, 414.2, 414.8, 414.9, 429.2, 433-434, 440.1, 440.2, 440.4, 444, 445

Medical record text: Coronary artery disease
Stable angina
Lower extremity arterial disease/peripheral artery disease
Ischemia
Stroke
Artheroembolism
Renal artery atherosclerosis

2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population***):** None

2a.10 Denominator Exclusion Details (*All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**
None

2a.11 Stratification Details/Variables (*All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
None

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***):**
NA

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.

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***):**
NA

2a.22 Describe the method for discriminating performance *(e.g., significance testing)***:**
After a measure is created, it will go through first-year analysis. This anaysis consists of a review of data completeness, national results, regional results, and eligible population and prevalence. The first-year results are compared by data collection methodology, health plan accreditation status and finally, are compared to the field test results.

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)*:
None

2a.24 Data Source (*Check the source(s) for which the measure is specified and tested)*
Paper medical record/flow-sheet, Electronic administrative data/claims, Electronic Health/Medical Record

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.***):**
NA

2a.26-28 Data source/data collection instrument reference web page URL or attachment:

2a.29-31 Data dictionary/code table web page URL or attachment:

2a.32-35 Level of Measurement/Analysis (*Check the level(s) for which the measure is specified and tested)*
Clinicians: Individual

2a.36-37 Care Settings (*Check the setting(s) for which the measure is specified and tested)*
Ambulatory Care: Clinic, All settings

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)***:** We are conducting analyses of reliability and will provide as soon as possible.

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

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

2b
C☐
P☐
M☐
N☐

2c. Validity testing

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

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

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

2c
C☐
P☐
M☐
N☐

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 focus is the most important aspect of quality for the specific topic.

conducted):
NA

2d. Exclusions Justified

2d.1 **Summary of Evidence supporting exclusion(s):**
NA

2d.2 **Citations for Evidence:**
NA

2d.3 **Data/sample** *(description of data/sample and size)*: NA

2d.4 **Analytic Method** *(type analysis & rationale)*:
NA

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

2d
C☐
P☐
M☐
N☐
NA☐

2e. Risk Adjustment for Outcomes/ Resource Use Measures

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

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

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

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

2e
C☐
P☐
M☐
N☐
NA☐

2f. Identification of Meaningful Differences in Performance

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

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

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)*:
NA

2f
C☐
P☐
M☐
N☐

2g. Comparability of Multiple Data Sources/Methods

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

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

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

2g
C☐
P☐
M☐
N☐
NA☐

2h. Disparities in Care

2h.**1 If measure is stratified, provide stratified results** *(scores by stratified categories/cohorts)*: NA

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

2h
C☐
P☐
M☐
N☐
NA☐

Comment [KP14]: 2d. Clinically necessary measure exclusions are identified and must be:
•supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;
AND
•a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;
AND
•precisely defined and specified:
–if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);
if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about p ... [4]

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 ... [5]

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 w ... [6]

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

Comment [k19]: 14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation ... [7]

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.

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*)**:**
Healthcare Effectiveness Data and Information Set (HEDIS) - Health Plans and Physician Measurement

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***):**
Quality Compass: http://www.ncqa.org/tabid/177/Default.aspx
America´s Best Health Plans: http://www.ncqa.org/tabid/506/Default.aspx

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)***:** None

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

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

3a
C☐
P☐
M☐
N☐

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

3b.1 **NQF # and Title of similar or related measures:**
None

(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?**
NA

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:**
NA

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:**
NA

3c
C☐
P☐
M☐
N☐
NA☐

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Usability?*	**3**

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.

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).

Steering Committee: Overall, to what extent was the criterion, *Usability*, met? **Rationale:**	**3** **C☐** **P☐** **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)	**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.** NA	**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:** NA **4e.2 Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:** NA **4e.3 Evidence for costs:** NA **4e.4 Business case documentation:** NA	**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? **Rationale:**	**4** **C☐**

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

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

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

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

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

	P☐ 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**
National Committee for Quality Assurance, 1100 13th Street NW, Suite 1000, Washington, District Of Columbia, 20005

Co.2 **Point of Contact**
Greg, Pawlson, pawlson@ncqa.org, 202-955-5170-

Measure Developer If different from Measure Steward
Co.3 **Organization**
National Committee for Quality Assurance, 1100 13th Street NW, Suite 1000, Washington, District Of Columbia, 20005

Co.4 **Point of Contact**
Greg, Pawlson, pawlson@ncqa.org, 202-955-5170-

Co.5 **Submitter If different from Measure Steward POC**
Greg, Pawlson, pawlson@ncqa.org, 202-955-5170-, National Committee for Quality Assurance

Co.6 **Additional organizations that sponsored/participated in measure development**

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.**
NCQA follows a standard process to vet members for the measurement advisory panel for conflicts of interest.

Ad.2 **If adapted, provide name of original measure:**
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:**
Ad.7 **Month and Year of most recent revision:** 04, 2009
Ad.8 **What is your frequency for review/update of this measure?** Approximately every 3 years, sooner if the clinical guidelines have changed significantly
Ad.9 **When is the next scheduled review/update for this measure?**

Ad.10 **Copyright statement/disclaimers:**

Ad.11 -13 **Additional Information web page URL or attachment:**

Date of Submission (*MM/DD/YY*)**:** 12/31/2010

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 4: [2] Comment [k5] **Karen Pace** **10/5/2009 8:59:00 AM**

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

Page 4: [3] Comment [k6] **Karen Pace** **10/5/2009 8:59:00 AM**

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.

Page 11: [4] 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 11: [5] Comment [KP16] **Karen Pace** **10/5/2009 8:59:00 AM**

rationale/data support no risk adjustment.

Page 11: [6] 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 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.

Page 11: [7] Comment [k19]	Karen Pace	10/5/2009 8:59:00 AM

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