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 #:** 1530 **NQF Project:** Cardiovascular Endorsement Maintenance 2010
MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** Prophylactic Antibiotics prior to ICD (lead or implant) procedure
De.2 **Brief description of measure***:* Proportion of patients that receive an ICD implant or lead procedure that receive antibiotics within 1 hour (if fluoroquinolone or vancomycin, two hours) prior to procedure.
1.1-2 **Type of Measure:** Process De.3 **If included in a composite or paired with another measure, please identify composite or paired measure** N/A
De.4 **National Priority Partners Priority Area:** Safety De.5 **IOM Quality Domain**: Effectiveness, Safety, Timeliness De.6 **Consumer Care Need:** Getting better, Staying healthy, 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:** NQF - signed-634272262006493898.pdf	**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 Accountability, Payment incentive, Accreditation	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:** No, testing will be completed within 12 months 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, Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Severity of illness 1a.2 1a.3 **Summary of Evidence of High Impact:** In 2006, 114,000 inpatient defibrillator implantations were performed. The mean hospital charge for ICD procedures was $115,763. While ICDs are very effective in reducing cardiac death, complications including infection may occur during implantation that may lead to morbidity and mortality as well as increased hospital length of stay. The incidence of infection following device implantation is estimated between 0.68 and 3.28%. 1a.4 **Citations for Evidence of High Impact:** 1. American Heart Association. Heart disease and stroke statistics- 2010 update: A report of the American Heart Association. Available at: http://circ.ahajournals.org/cgi/content/abstract/CIRCULATIONAHA.109.192667v1. Accessed December 3, 2010. 2. Klug D, Balde M, Pavin D, et al. Risk factors related to infections of implanted pacemakers and cardioverter-defibrillators. Results of a large prospective study. Circulation. 2007;116:1349-1355. 3. Maytin M, Epstein LM. Proof positive: Efficacy of antibiotic prophylaxis in device implantation. Circ Arrhythmia Electrophysiol. 2009;2:4-5.	**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).

4. de Oliveira JC, Martinelli M, D´Orio Nishioka SA, et al. Efficacy of antibiotic prophylaxis prior to the implantation of pacemakers and cardioverter-defibrillators: Results of a large, prospective, randomized, double-blinded, placebo-controlled trial. Circ Arrhythmia Electrophysiol. 2009;2:29-34.

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: Prophylactic antibiotics prior to surgical procedures prevent infection related to the procedure. Several studies have established the efficacy of antibiotics in preventing surgical infection for many surgical procedures. The incidence of infection from ICD implant procedures is estimated at 0.68-3.28%. Hiven the potential complications associated with ICD-associated infections, pre-procedural antibiotic administration is integral to ensuring patient safety following ICD implantation.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
Data will be available from the NCDR ICD Registry Version 2 in 2011.

1b.3 Citations for data on performance gap:

1b.4 Summary of Data on disparities by population group:
Data will be available from the NCDR ICD Registry Version 2 in 2011.

1b.5 Citations for data on Disparities:

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*)**:** Prophylactic antibiotics prior to surgical procedures prevent infection related to the procedure. Several studies have established the efficacy of antibiotics in preventing surgical infection, including for ICD procedures.

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

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
The Prospective Evaluation of Pacemaker Lead Endocarditis study is a multicenter, prospective survey of the incidence and risk factors of infectious complications after implantation of pacemakers and cardioverter-defibrillators. Among 5866 pacing systems implanted, 3789 included 2 and 117 had >2 leads; among 453 implantable cardioverter-defibrillators, 178 were dual-lead systems. Infections developed over 12 months in 42 patients, representing an incidence of 0.68 per 100 patients (95% CI, 0.47 to 0.89) or 2 per 105 patient-days (1.4 per 105 to 2.6 per 105). The incidence of infection was 0.56 per 100 patients (95% CI, 0.33 to 0.78) and 0.99 per 100 patients (95% CI, 0.54 to 1.45) after de novo implantation and non–de novo implantation, respectively. In this study, an inverse correlation was observed between the development of infections and antibiotic prophylaxis.
A double blinded of 1000 consecutive patients undergoing pacemaker or ICD implantation were randomized to prophylactic antibiotics or placebo. The primary end point was any evidence of infection at the surgical incision (pulse generator pocket), or systemic infection related to be procedure. The trial was discontinued after649 patients were enrolled due to a significant difference in favor of the antibiotic arm (group I: 2 of 314 infected patients—0.63%; group II: 11 of 335 to 3.28%; RR=0.19; P=0.016). The following risk factors were positively correlated with infection by univariate analysis: nonuse of preventive antibiotic (P=0.016); implant procedures (versus generator replacement: P=0.02); presence of postoperative hematoma (P=0.03) and procedure duration (P=0.009). Multivariable analysis identified nonuse of antibiotic (P=0.037) and postoperative hematoma (P=0.023) as independent predictors of infection.

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom*)**:**
• Level of Evidence A: Data derived from multiple randomized clinical trials or meta-analyses.

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

1c.7 Summary of Controversy/Contradictory Evidence:

1c.8 Citations for Evidence (*other than guidelines***):** 1.Klug D, Balde M, Pavin D, et al. Risk factors related to infections of implanted pacemakers and cardioverter-defibrillators. Results of a large prospective study. Circulation. 2007;116:1349-1355.

2. Maytin M, Epstein LM. Proof positive: Efficacy of antibiotic prophylaxis in device implantation. Circ Arrhythmia Electrophysiol. 2009;2:4-5.

3. de Oliveira JC, Martinelli M, D´Orio Nishioka SA, et al. Efficacy of antibiotic prophylaxis prior to the implantation of pacemakers and cardioverter-defibrillators: Results of a large, prospective, randomized, double-blinded, placebo-controlled trial. Circ Arrhythmia Electrophysiol. 2009;2:29-34.

1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number***):**
AHA Scientific Statement- Nonvalvular Cardiovascular Device- Related Infections
Primary prophylaxis
•Modeled after that used to prevent surgical site infection.
•Because of the low incidence of infection for many of the devices, evidence-based data have not been collected that prove efficacy.
•Routinely used for placement of electrophysiological cardiac devices, ventricular assist devices, total artificial hearts, ventriculoatrial shunts, cardiac suture line pledgets, vascular grafts, and arterial patches.
Secondary prophylaxis
•Antibiotic prophylaxis is not routinely recommended after device placement for patients who undergo dental, respiratory, gastrointestinal or genitourinary procedures.
•It is recommended for patients with these devices if they undergo incision and drainage of infection at other sites (eg, abscess) or replacement of an infected device.
•It is recommended for patients with residual leak after device placement for attempted closure of the leak associated with patent ductus arteriosus, atrial septal defect, or ventricular septal defect.

Surgical Infection Prevention Guidelines Writers Group Recommendations:
"On the basis of published evidence, the workgroup endorsed the national performance measure that infusion of the first antimicrobial dose should begin within 60 min before incision. However, when a fluoroquinolone or vancomycin is indicated, the infusion should begin within 120 min before incision to prevent antibiotic-associated reactions." (Page 1708)

"Cardiothoracic and vascular surgery. The recommended antimicrobials for cardiothoracic and vascular operations include cefazolin or cefuroxime [10–12, 14, 16]. For patients with serious allergy or adverse reaction to b-lactams, vancomycin is appropriate, and clindamycin may be an acceptable alternative." (Page 1711)

Guidelines for prevention of surgical site infection:
Four principles must be followed to maximize the benefits of AMP (Surgical antimicrobial prophylaxis):
- Use an AMP agent for all operations or classes of operations in which its use has been shown to reduce SSI rates based on evidence from clinical trials or for those operations after which incisional or organ/space SSI would represent a catastrophe.
- Use an AMP agent that is safe, inexpensive, and bactericidal with an in vitro spectrum that covers the most probable intraoperative contaminants for the operation.
- Time the infusion of the initial dose of antimicrobial agent so that a bactericidal concentration of the drug is established in serum and tissues by the time the skin is incised.
- Maintain therapeutic levels of the antimicrobial agent in both serum and tissues throughout the operation and until, at most, a few hours after the incision is closed in the operating room.179,266-268,282,284,286
Because clotted blood is present in all surgical wounds, therapeutic serum levels of AMP agents are logically

important in addition to therapeutic tissue levels. Fibrin-enmeshed bacteria may be resistant to phagocytosis or to contact with antimicrobial agents that diffuse from the wound space.

Table 4 summarizes typical SSI pathogens according to operation type and cites studies that establish AMP efficacy for these operations. A simple way to organize AMP indications is based on using the surgical wound classification scheme shown in Table 7, which employs descriptive case features to postoperatively grade the degree of intraoperative microbial contamination. A surgeon makes the decision to use AMP by anticipating preoperatively the surgical wound class for a given operation.
AMP is indicated for all operations that entail entry into a hollow viscus under controlled conditions.

1c.10 Clinical Practice Guideline Citation: 1.Bratzler DW, Houck PM, for the Surgical Infection Prevention Guidelines Writers Group. Antimicrobial prophylaxis for surgery: An advisory statement from the National Surgical Infection Prevention Project. CID. 2004:38(15 June):1706-1715.

2.Mangram AJ, Horan TC, Pearson ML, et al. Guidelines for prevention of surgical site infection, 1999. Infect Control Hosp Epidemiol. 1999;20:247-280.

3.Baddour LM, Bettmann MA, Bolger AF, et al. AHA Scientific Statement: Nonvalvular cardiovascular device-related infections. Circulation. 2003;108:2015-31.
1c.11 National Guideline Clearinghouse or other URL: http://www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards.aspx

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

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

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***):** Count of patients that receive antibiotics prior to the ICD implant or leads procedure. **2a.2 Numerator Time Window (***The time period in which cases are eligible for inclusion in the numerator***):** 1 year	**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.3 Numerator Details (*All information required to collect/calculate the numerator, including all codes, logic, and definitions***):**
Prophylactic Antibiotics w/in 1 Hr of Procedure Start Time=yes.

Supporting definitions:
Note(s):
1. An order (written order, verbal order, or standing order/protocol) for prophylactic antibiotics to be given within one hour of procedure start time (two hours if receiving vancomycin or fluoroquinolone).
OR
2. Prophylactic antibiotic administered within one hour (if fluoroquinolone or vancomycin, two hours) prior to procedure start time.
In the event that the procedure is delayed, as long as the patient is redosed (if clinically appropriate) the appropriate selection should be applied.

2a.4 Denominator Statement (*Brief, text description of the denominator - target population being measured***):**
Count of patients with an ICD implant or lead procedure

2a.5 Target population gender: Female, Male
2a.6 Target population age range: All Patients

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

2a.8 Denominator Details (*All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):**
Count of patients with arrival/discharge dates from data submissions that pass NCDR data inclusion thresholds

2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population***):** -Patients with a documented contraindication to receiving prophylactic antibiotics prior to the ICD implant
-Patients receiving continuous antibiotics >24 hours prior to the implant

2a.10 Denominator Exclusion Details (*All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**
Prophylactic Antibiotics w/in 1 Hr of Procedure Start Time= No – not given, medical reason documented, including:

-Patients with a documented contraindication to receiving prophylactic antibiotics prior to the ICD implant
-Patients receiving continuous antibiotics >24 hours prior to the implant

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

2a.12-13 Risk Adjustment Type:

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

2a.15-17 Detailed risk model available Web page URL or attachment:

2a.18-19 Type of Score: Rate/proportion
2a.20 Interpretation of Score: Better quality = Higher score
2a.21 Calculation Algorithm (*Describe the calculation of the measure as a flowchart or series of steps***):**
Denominator Calculation:
1. Count of patients with arrival/discharge dates from data submissions that pass NCDR data inclusion thresholds
3. Exclude patients with Prophylactic Antibiotics w/in 1 Hr of Procedure Start Time= No – not given, medical

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.

reason documented

Numerator Calculation:
4. From denominator population, count of patients with Prophylactic Antibiotics w/in 1 Hr of Procedure Start Time=yes.

2a.22 Describe the method for discriminating performance *(e.g., significance testing)*:
Hospitals performance for this measure is benchmarked each quarter and annually against hospitals with similar procedural volume, as well as against the ICD Registry aggregate. These benchmarks identify superior performance and encourage poorer performers to improve. The methodology is a data-driven, peer-group performance feedback used to positively affect outcomes.

2a.23 Sampling (Survey) Methodology *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)*:
N/A

2a.24 Data Source (*Check the source(s) for which the measure is specified and tested)*
Registry data

2a.25 Data source/data collection instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
National Cardiovascular Data Registry (NCDR)® ICD RegistryTM

2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL
http://www.ncdr.com/WebNCDR/ICD/ELEMENTS.ASPX

2a.29-31 Data dictionary/code table web page URL or attachment: URL
http://www.ncdr.com/WebNCDR/ICD/ELEMENTS.ASPX

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

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

2a.38-41 Clinical Services (*Healthcare services being measured, check all that apply*)
Clinicians: PA/NP/Advanced Practice Nurse, Clinicians: Physicians (MD/DO)

TESTING/ANALYSIS

2b. Reliability testing

2b.1 Data/sample *(description of data/sample and size)*: Data will be available from the NCDR ICD Registry Version 2 in 2011.

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

2b.3 Testing Results *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
The Data Quality Report (DQR) program has been developed to ensure data are valid and complete. The DQR is a process for submitting data files to the NCDR®. Participants use their data collection tool software to create a submission file which is uploaded to the NCDR website. After uploading, the data in the file is automatically checked for errors and completeness. Passing the DQR ensures well-formed data and a statistically significant submission. Types of errors detected by the DQR include:
Schema:Structure doesn't match NCDR requirements
Dates: Inconsistent dates
Selection: Missing or mismatched data; Can be a parent/child errors where a field requests more data.
Outlier: Anomalies or exceptions; Data exceeds the possible limits. For example: 1,000mm length lesion.
Counter: errors deal with Closure Methods, Lesions, and Intracoronary Devices. Each one has a counter, when

2b
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.

more than one is used
List: Missing data in the Medications or either Device lists

2c. Validity testing

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

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

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

2c C☐ P☐ M☐ N☐

2d. Exclusions Justified

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

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

2d.3 **Data/sample** *(description of data/sample and size)*: Data will be available from the NCDR ICD Registry Version 2 in 2011.

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

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

2d C☐ P☐ M☐ N☐ NA☐

2e. Risk Adjustment for Outcomes/ Resource Use Measures

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

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

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

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

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)*: Data will be available from the NCDR ICD Registry Version 2 in 2011.

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

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)*:

2f C☐ P☐ M☐ N☐

2g. Comparability of Multiple Data Sources/Methods

2g

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 ... [4]

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 ... [5]

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 ... [6]

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 ... [7]

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 ... [8]

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

2g.1 Data/sample *(description of data/sample and size)*: N/A **2g.2 Analytic Method** *(type of analysis & rationale)*: N/A **2g.3 Testing Results** *(e.g., correlation statistics, comparison of rankings)*: N/A	C☐ P☐ M☐ N☐ NA☐
2h. Disparities in Care **2h.1 If measure is stratified, provide stratified results** *(scores by stratified categories/cohorts)*: **2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:**	**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*): ACCF plans to begin voluntary public reporting of NCDR measures, including this measure, by 2012. ACCF is currently evaluating public reporting options and finalizing decisions related to location and display of information to be reported as well as communication plans. **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*): This measure is used for QI by NCDR ICD Registry participating institutions. As of October 2010, 1582 institutions are enrolled in the ICD Registry. 78% submit data on all patients and 22% submit data on CMS patients only as part of a CMS mandate for submission of primary prevention data for all primary prevention ICD implant procedures. Participating institutions receive an institutional outcomes report each quarter with their hospital´s data. Over 1000 metrics are included in version 1 of each hospital´s outcomes report. 10 metrics are highlighted in the all patients report executive summary (16 for version 2 which will be released in early 2011). These metrics are selected by an NCDR panel of experts as presenting the greatest opportunity for care improvement. This measure has been selected as an executive summary metric for the ICD Registry Version 2 Outcomes Report, which will be released in 2011 (data are already being collected and submitted for this measure). Hospitals receive their measure score, as well as the rates for all hospitals in the ICD registry, and all hospitals in the same comparison group (based on volume), and the rate for the 90th and 50th percentiles. A box and whisker plot is displayed for each metric to show hospitals how they compare to all hospitals in the ICD registry.	**3a** C☐ P☐ M☐ N☐

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.

This measure is also provided to Hospital Corporation of America (HCA) for incorporation in their QI program efforts. The Centers for Medicare & Medicaid Services (CMS) mandates that all institutions submit data on ICD implant procedures for primary prevention in order to receive reimbursement for these procedures. CMS will use this data for assessment of the efficacy of ICD use for primary prevention. **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)*: 849 ICD registry participants, fall 2010. 3a.5 **Methods** *(e.g., focus group, survey, QI project)*: Online survey 3a.6 **Results** *(qualitative and/or quantitative results and conclusions)*: 74% of survey participants answered yes to the question "Will the following metrics provide information that will be valuable for quality improvement at your institution?"	
3b/3c. Relation to other NQF-endorsed measures 3b.1 **NQF # and Title of similar or related measures:** #126: Selection of Antibiotic Prophylaxis for Cardiac Surgery Patients, #472:Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision or at the Time of Delivery – Cesarean section., #527: Prophylactic antibiotic received within 1 hour prior to surgical incision SCIP-Inf-1, #528: Prophylactic antibiotic selection for surgical patients	
(for NQF staff use) **Notes on similar/related endorsed or submitted measures:**	
3b. Harmonization If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population): 3b.2 **Are the measure specifications harmonized? If not, why?** This measure is harmonized with the SCIP measure in terms of timing and selection of antibiotics. All exclusions in the SCIP measure can be captured under the "medical reason" exclusion for this measure.	**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:** This measure provides additive value to the NQF-endorsed measure set in that it applies to a procedure that is not currently addressed with endorsed measures, and uses a registry as a data source (while endorsed measures use medical record as a data source). 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☐ 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 Ratin g**
4a. Data Generated as a Byproduct of Care Processes	**4a** C☐

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).

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.)

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)

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☐

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.

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☐

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.

4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences

4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.
The NCDR program takes a number of steps to minimize any potential for inaccuracies or errors in data used to report on performance back to hospitals. The process begins with support to data abstractors, including webinars, meetings, resource guides on the website, and clinical quality consultants available via e-mail or toll free phone number, to ensure consistent data collection. The NCDR establishes a unified electronic platform for data capture and submission that includes a certification process of the technical data collection tool selected by the hospital (either a commercially available software vendor product, the NCDR´s own web-based data collection tool, or a hospital´s customized electronic medical record system) that must occur prior to any data submissions. The certification process provides edit checks of data elements within the data collection tool to ensure a high quality data submission.

The NCDR data submission process includes a Data Quality Report (DQR) process that checks for validity in submissions based upon predetermined thresholds for element and composite completeness. The NCDR is putting in place a new strategy to systematically review the DQR results.

The NCDR on-site audit program has been developed to assess the reliability of data abstraction. This annual process reviews key elements at a select number of patient reports at a select number of sites and provides feedback scores to the hospitals. Any elements not currently included in the on-site audit process and deemed critical to capture for this measure will be added upon NQF endorsement.

4d
C☐ P☐ M☐ N☐

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

4e. Data Collection Strategy/Implementation

4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:
Beta testing with a sample of registry participants takes place with each new registry version to identify errors in the data collection tool. In addition, modifications are made to metrics based on feedback during a public comment period.

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

4e
C☐ P☐ M☐ N☐

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).

statistically significant submission. Types of errors detected by the DQR include: Schema: Structure doesn´t match NCDR requirements Dates: Inconsistent dates Selection: Missing or mismatched data; can be parent/child errors where a field requests more data Outlier: Anomalies or exceptions; data exceeds the possible limits. 4e.2 **Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:** ICD registry participants pay a fee of $3,480/year (as of 2010) to enroll in the registry. Staff resources are needed for data collection and submission at the participating institution. Registry site managers/data collectors undergo (non-mandatory) training offered by the NCDR. 4e.3 **Evidence for costs:** http://www.ncdr.com/WebNCDR/ncdrdocuments/B08352N%20ICD%20Registry%20Enrollment%20Packet%20Complete.pdf 4e.4 **Business case documentation:**	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility*?	**4**
Steering Committee: Overall, to what extent was the criterion, *Feasibility***, met?** **Rationale:**	**4** **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 College of Cardiology Foundation (ACCF), 2400 N Street NW, Washington, District Of Columbia, 20037 Co.2 **Point of Contact** Kristyne, McGuinn, MHS, kmcguinn@acc.org, 202-375-6529-
Measure Developer If different from Measure Steward Co.3 **Organization** American College of Cardiology Foundation (ACCF), 2400 N Street NW, Washington, District Of Columbia, 20037 Co.4 **Point of Contact** Kristyne, McGuinn, MHS, kmcguinn@acc.org, 202-375-6529-
Co.5 **Submitter If different from Measure Steward POC** Kristyne, McGuinn, MHS, kmcguinn@acc.org, 202-375-6529-, American College of Cardiology Foundation (ACCF)
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.
ICD Registry Steering Committee:
Mark S. Kremers, MD, FACC, FHRS Chair
Stephen C. Hammill, MD, FACC, FHRS Ex-Officio
Sana M. Al-Khatib, MD, FACC
Charles I. Berul, MD, FACC
Jeptha P. Curtis, MD, FACC
Paul A. Heidenreich, MD, FACC
Illeana L. Pina, MD, FACC
Matthew R. Reynolds, MD, FACC
Lynne Warner Stevenson, MD, FACC
Mary Norine Walsh, MD, FACC

Public Reporting Workgroup:
Fred Masoudi, MD, MSPH, FACC, FAHA, FACP
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David Malenka, MD, FACC
Matt Roe, MD, FACC
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Christopher White MD, FACC
Carl Tommaso, MD, FACC, FAHA, FSCAI
Sunil Rao, MD, FACC, FSCAI
Andrea Russo, MD, FACC, FHRS
Debabrata Mukherjee MD, FACC

Ad.2 If adapted, provide name of original measure: N/A
Ad.3-5 If adapted, provide original specifications URL or attachment

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.6 Year the measure was first released: 2006
Ad.7 Month and Year of most recent revision: 12, 2010
Ad.8 What is your frequency for review/update of this measure? Every 3-4 years or if guideline updates warrant more frequent update, or with new dataset version.
Ad.9 When is the next scheduled review/update for this measure? 06, 2011

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

Date of Submission (*MM/DD/YY*)**:** 12/14/2010

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

1c. The measure focus is:

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

OR

- if an intermediate outcome, process, structure, etc., there is **evidence** that supports the specific measure focus as follows:
  - 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 3: [2] Comment [k5] **Karen Pace** **10/5/2009 8:59:00 AM**

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

Page 3: [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 8: [4] 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: [5] 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

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: [6] 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: [7] 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 8: [8] 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.