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 #: NQF Project: Cardiovascular Endorsement Maintenance 2010

### MEASURE DESCRIPTIVE INFORMATION

<table>
<thead>
<tr>
<th>De.1 Measure Title</th>
<th>Prophylactic Antibiotics prior to ICD (lead or implant) procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>De.2 Brief description of measure</td>
<td>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.</td>
</tr>
<tr>
<td>De.3 Type of Measure</td>
<td>Process</td>
</tr>
<tr>
<td>De.4 National Priority Partners Priority Area</td>
<td>Safety</td>
</tr>
<tr>
<td>De.5 IOM Quality Domain</td>
<td>Effectiveness, Safety, Timeliness</td>
</tr>
<tr>
<td>De.6 Consumer Care Need</td>
<td>Getting better, Staying healthy, Living with illness</td>
</tr>
</tbody>
</table>

### CONDITIONS FOR CONSIDERATION BY NQF

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)?

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

B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and
update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section

C. The intended use of the measure includes both public reporting and quality improvement.

Purpose: Public reporting, Internal quality improvement

Accountability, Payment incentive, Accreditation

D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement.

D.1 Testing: 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

(for NQF staff use) Have all conditions for consideration been met?

Staff Notes to Steward (if submission returned):

Staff Notes to Reviewers (issues or questions regarding any criteria):

Staff Reviewer Name(s):

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

(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%.


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).
implantable cardioverter-defibrillators, 178 were dual-lead systems. Infections developed over 12 months in
The Prospective Evaluation of Pacemaker Lead Endocarditis study is a multicenter, prospective survey of the
healthcare services/care processes influence the outcome

procedure duration (P=0.009). Multivariable analysis identified nonuse of antibiotic (P=0.037) and
procedures (versus generator replacement: P=0.02); presence of postoperative hematoma (P=0.03) and
hemorrhage (P=0.01) were associated with increased risk of infection. The effect of infection on patient
outcome was not analyzed. The study was not designed to detect a difference in infection rate of 0.5%.

314 infected patients—0.63%; group II: 11 of 335 to 3.28%; RR=0.19; P=0.016). The following risk factors were
after 649 patients were enrolled due to a significant difference in favor of the antibiotic arm (group I: 2 of
incision (pulse generator pocket), or systemic infection related to the procedure. The trial was discontinued
before de novo implantation; 42 patients, representing an incidence of 0.68 per 100 patients (95% CI, 0.47 to 0.89) or 2 per 105 patient-
years (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
elderly patients (P=0.07). The number of patients older than 65 years of age was not reported.

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

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:

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 prophylactic 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
elderly patients (P=0.07). The number of patients older than 65 years of age was not reported.

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 the procedure. The trial was discontinued
after 649 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.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):

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 pledges, 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 β-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-embedded 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 stage 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.


1.11 National Guideline Clearinghouse or other URL: http://www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards.aspx

1.12 Rating of strength of recommendation (also provide narrative description of the rating and by whom):
N/A

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

1.14 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?

Steering Committee: Was the threshold criterion, Importance to Measure and Report, met? Rationale:

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)

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

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
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
2. Exclude patients with Prophylactic Antibiotics w/in 1 Hr of Procedure Start Time = No - not given, medical reason documented

**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.
### 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 Devices, Lesions, and Intracoronary Devices. Each one has a counter, where...
<table>
<thead>
<tr>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2c. Validity testing</strong></td>
</tr>
<tr>
<td><strong>2c.1 Data/sample (description of data/sample and size):</strong> Face/content validity: review of relevant evidence and guidelines and expert panel consensus process</td>
</tr>
<tr>
<td><strong>2c.2 Analytic Method (type of validity &amp; rationale, method for testing):</strong> Face/content validity was established to ensure this measure represented an important aspect of cardiovascular care for which improvement is needed.</td>
</tr>
<tr>
<td><strong>2c.3 Testing Results (statistical results, assessment of adequacy in the context of norms for the test conducted):</strong> 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.</td>
</tr>
</tbody>
</table>

### 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):**

### 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

### 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):**

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

- **2g.1 Compare 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):**

**Rating:** C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
2g.1 Data/sample (description of data/sample and size): N/A

2g.2 Analytic Method (type of analysis & rationale): N/A

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

2h. Disparities in Care

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

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

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Scientific Acceptability of Measure Properties?

Steering Committee: Overall, to what extent was the criterion, Scientific Acceptability of Measure Properties, met?

Rationale:

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)

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.

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

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:

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.

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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).

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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:
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)

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.

4c. Exclusions
4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?
No
4c.2 If yes, provide justification.

4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences
4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.
The NCDB 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 NCDB 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 NCDB’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 NCDB 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 NCDB is putting in place a new strategy to systematically review the DQR results.
The NCDB 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 NCDB endorsement.

4e. Data Collection Strategy/Implementation
4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/implementation issues:
Beta testing with a 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 NCDB. Participants use their data collection tool software to create a submission file which is uploaded to the NCDB website. After uploading, the data in the file are automatically checked for errors and completeness. Passing the DQR ensures well-formed data and a
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:

4e.4 Business case documentation:

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

**Rationale:**

**RECOMMENDATION**

(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.

**Steering Committee**: Do you recommend for endorsement? Comments:

**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, kmcgguinn@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, kmcgguinn@acc.org, 202-375-6529-

Co.5 Submitter If different from Measure Steward POC
Kristyne, McGuinn, MHS, kmcgguinn@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
- H. Vernon Anderson, MD, FACC, FSCAI
- David Malenka, MD, FACC
- Matt Roe, MD, FACC
- Steve Hammill, MD, FHRS, FACC
- Jeptha Curtis, MD, FACC
- Paul Heidenreich, MD, MS, FACC
- Brahmajee Nallamothu, MD, MPH, FACC
- Mark Kremers, MD, FACC
- Christopher White MD, FACC
- Carl Tommaso, MD, FACC, FAHA, FSCAI
- Sunil Rao, MD, FACC, FSCAI
- Andrea Russo, MD, FACC, FHRS
- Debabrata Mukherjee MD, FACC

**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.10** Copyright statement/disclaimers: © 2010 American College of Cardiology Foundation All Rights Reserved

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

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

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.

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.

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.

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).

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

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.

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.