

NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)

Measure Number (if previously endorsed): 0268

Measure Title: Perioperative Care: Selection of Prophylactic Antibiotic-First OR Second Generation Cephalosporin

IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here: [Click here to enter composite measure #/ title](#)

Date of Submission: [3/17/2014](#)

Instructions

- For composite performance measures:
 - A separate evidence form is required for each component measure unless several components were studied together.
 - If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.
- Respond to all questions as instructed with answers immediately following the question. All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of supplemental materials may be submitted, but there is no guarantee it will be reviewed.
- If you are unable to check a box, please highlight or shade the box for your response.
- Maximum of 10 pages (includes questions/instructions; minimum font size 11 pt; do not change margins). **Contact NQF staff if more pages are needed.**
- Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](#).

Note: The information provided in this form is intended to aid the Steering Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF's evaluation criteria.

1a. Evidence to Support the Measure Focus

The measure focus is evidence-based, demonstrated as follows:

- **Health outcome:** ³ a rationale supports the relationship of the health outcome to processes or structures of care. Applies to patient-reported outcomes (PRO), including health-related quality of life/functional status, symptom/symptom burden, experience with care, health-related behavior.
- **Intermediate clinical outcome:** a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured intermediate clinical outcome leads to a desired health outcome.
- **Process:** ⁵ a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured process leads to a desired health outcome.
- **Structure:** a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured structure leads to a desired health outcome.
- **Efficiency:** ⁶ evidence not required for the resource use component.

Notes

3. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.
4. The preferred systems for grading the evidence are the U.S. Preventive Services Task Force (USPSTF) [grading definitions](#) and [methods](#), or Grading of Recommendations, Assessment, Development and Evaluation ([GRADE](#)) [guidelines](#).
5. 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 multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.

6. Measures of efficiency combine the concepts of resource use and quality (see NQF's [Measurement Framework: Evaluating Efficiency Across Episodes of Care](#); [AQA Principles of Efficiency Measures](#)).

1a.1. This is a measure of: *(should be consistent with type of measure entered in De.1)*

Outcome

- ☐ Health outcome: Click here to name the health outcome
- ☐ Patient-reported outcome (PRO): Click here to name the PRO
PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors
- ☐ Intermediate clinical outcome (e.g., lab value): Click here to name the intermediate outcome
- ☒ Process: [Selection of Prophylactic Antibiotic—First OR Second Generation Cephalosporin](#)
- ☐ Structure: Click here to name the structure
- ☐ Other: Click here to name what is being measured

HEALTH OUTCOME/PRO PERFORMANCE MEASURE *If not a health outcome or PRO, skip to 1a.3*

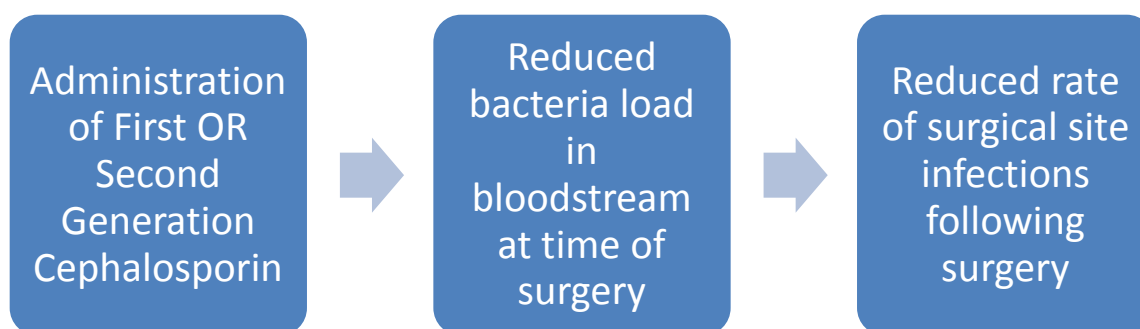
1a.2. Briefly state or diagram the path between the health outcome (or PRO) and the healthcare structures, processes, interventions, or services that influence it.

1a.2.1. State the rationale supporting the relationship between the health outcome (or PRO) to at least one healthcare structure, process, intervention, or service (*i.e., influence on outcome/PRO*).

Note: For health outcome/PRO performance measures, no further information is required; however, you may provide evidence for any of the structures, processes, interventions, or service identified above.

INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURE

1a.3. Briefly state or diagram the path between structure, process, intermediate outcome, and health outcomes. Include all the steps between the measure focus and the health outcome.



1a.3.1. What is the source of the systematic review of the body of evidence that supports the performance measure?

- ☒ Clinical Practice Guideline recommendation – **complete sections [1a.4](#), and [1a.7](#)**
- ☐ US Preventive Services Task Force Recommendation – **complete sections [1a.5](#) and [1a.7](#)**
- ☐ Other systematic review and grading of the body of evidence (e.g., *Cochrane Collaboration*, *AHRQ Evidence Practice Center*) – **complete sections [1a.6](#) and [1a.7](#)**
- ☐ Other – **complete section [1a.8](#)**

Please complete the sections indicated above for the source of evidence. You may skip the sections that do not apply.

1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

1a.4.1. Guideline citation (including date) and URL for guideline (if available online):

Bratzler DW, Dellinger EP, Olsen KM, et al. Clinical practice guidelines for antimicrobial prophylaxis in surgery. *Am J Health-Syst Pharm*. 2013;70:195-283.

<http://www.ashp.org/DocLibrary/BestPractices/TGSurgery.aspx>

1a.4.2. Identify guideline recommendation number and/or page number and quote verbatim, the specific guideline recommendation.

Page 590. “For most procedures, cefazolin is the drug of choice for prophylaxis because it is the most widely studied antimicrobial agent, with proven efficacy.”

1a.4.3. Grade assigned to the quoted recommendation with definition of the grade:

The guideline recommendations are given different grades, according to strength of evidence for each different procedure type. The grades vary from Level A to Level C for various procedures. See attachment A1 for grades assigned to specific procedure types.

Evidence supporting the recommendations for the use of antimicrobial therapy were classified as follows:

Level I: evidence from large, well-conducted, randomized, controlled clinical trials or a meta-analysis

Level II: evidence from small, well-conducted, randomized, controlled clinical trials

Level III: evidence from well-conducted cohort studies

Level IV: evidence from well-conducted case-control studies

Level V: evidence from uncontrolled studies that were not well conducted

Level VI: conflicting evidence that tends to favor the recommendation

Level VII: expert opinion or data extrapolated from evidence for general principles or other procedures

Recommendations are then categorized based on strength of evidence as follows:

Category A: Levels I through III evidence

Category B: Levels IV through VI evidence

Category C: Level VII evidence

The recommendations for the various procedure types were categorized as follows:

Category A: 28 procedure types

Category B: 4 procedure types

Category C: 9 procedure types

1a.4.4. Provide all other grades and associated definitions for recommendations in the grading system. (Note: If separate grades for the strength of the evidence, report them in section 1a.7.)

See 1a.4.3

1a.4.5. Citation and URL for methodology for grading recommendations (if different from 1a.4.1):
Dotson LR, Witmer DR. Development of ASHP therapeutic guidelines. *Am J Health-Syst Pharm.* 1995; 52:254-255.

1a.4.6. If guideline is evidence-based (rather than expert opinion), are the details of the quantity, quality, and consistency of the body of evidence available (e.g., evidence tables)?

☐ Yes → complete section 1a.7

☒ No → report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7

1a.5. UNITED STATES PREVENTIVE SERVICES TASK FORCE RECOMMENDATION

1a.5.1. Recommendation citation (including date) and **URL** for recommendation (if available online):

1a.5.2. Identify recommendation number and/or page number and **quote verbatim**, the specific recommendation.

1a.5.3. Grade assigned to the quoted recommendation with definition of the grade:

1a.5.4. Provide all other grades and associated definitions for recommendations in the grading system. (Note: the grading system for the evidence should be reported in section 1a.7.)

1a.5.5. Citation and URL for methodology for grading recommendations (if different from 1a.5.1):

Complete section 1a.7

1a.6. OTHER SYSTEMATIC REVIEW OF THE BODY OF EVIDENCE

1a.6.1. Citation (including date) and **URL** (if available online):

1a.6.2. Citation and URL for methodology for evidence review and grading (if different from 1a.6.1):

Complete section 1a.7

1a.7. FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE

If more than one systematic review of the evidence is identified above, you may choose to summarize the one (or more) for which the best information is available to provide a summary of the quantity, quality, and consistency of the body of evidence. Be sure to identify which review is the basis of the responses in this section and if more than one, provide a separate response for each review.

1a.7.1. What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review?

Antibiotic selection for antimicrobial prophylaxis

1a.7.2. Grade assigned for the quality of the quoted evidence with definition of the grade:

Evidence supporting the recommendations for the use of antimicrobial therapy were classified as follows:

Level I: evidence from large, well-conducted, randomized, controlled clinical trials or a meta-analysis

Level II: evidence from small, well-conducted, randomized, controlled clinical trials

Level III: evidence from well-conducted cohort studies

Level IV: evidence from well-conducted case-control studies

Level V: evidence from uncontrolled studies that were not well conducted

Level VI: conflicting evidence that tends to favor the recommendation

Level VII: expert opinion or data extrapolated from evidence for general principles or other procedures

Recommendations are then categorized based on strength of evidence as follows:

Category A: Levels I through III evidence

Category B: Levels IV through VI evidence

Category C: Level VII evidence

The level of evidence for different procedures was assigned as follows:

Category A: 28 procedure types

Category B: 4 procedure types

Category C: 9 procedure types

1a.7.3. Provide all other grades and associated definitions for strength of the evidence in the grading system.

See question 1a.7.2

1a.7.4. What is the time period covered by the body of evidence? (provide the date range, e.g., 1990-2010). Date range: [1959-2010](#)

QUANTITY AND QUALITY OF BODY OF EVIDENCE

1a.7.5. How many and what type of study designs are included in the body of evidence? (e.g., 3 randomized controlled trials and 1 observational study)

Evidence cited in support of the recommendations for selection of antimicrobial prophylaxis agent includes:

- 186 clinical trials
- 16 meta-analyses and systematic reviews

- 10 published guidelines
- 39 retrospective studies
- 13 consensus statements
- 63 observational studies
- 8 surveys

1a.7.6. What is the overall quality of evidence across studies in the body of evidence? (*discuss the certainty or confidence in the estimates of effect particularly in relation to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population*)

The guideline does not provide an overall estimate of the body of evidence across studies. However, the recommendations for antimicrobial prophylaxis are based on a large number of randomized, controlled, clinical trials as well as a significant number of meta-analyses and systematic reviews of the evidence. In reviewing the body of evidence, the guideline developers specifically considered the following characteristics for each study: validity, reliability, clinical applicability, flexibility, clarity, and multidisciplinary nature.

ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

1a.7.7. What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence? (*e.g., ranges of percentages or odds ratios for improvement/decline across studies, results of meta-analysis, and statistical significance*)

Because the recommendations for antimicrobial prophylaxis vary by procedure type, the guideline does not provide an overall quantitative estimate of the benefit for antimicrobial prophylaxis. However, the guideline does provide some estimates of benefit for specific procedure types. For example, antimicrobial prophylaxis for cardiac procedures has been shown to lower the occurrence of postoperative surgical site infection up to fivefold. For thoracic procedures, use of antimicrobial prophylaxis was associated with a 13% decrease in surgical site infections. For clean head and neck procedures, the odds of meningitis were reduced by half with the use of antimicrobial prophylaxis. Similarly, infection rates were reduced by half with antimicrobial prophylaxis for patients undergoing hysterectomy.

1a.7.8. What harms were studied and how do they affect the net benefit (benefits over harms)?

Potential harms discussed within the guideline include cost of treatment, allergic reactions, and effect of antimicrobial agents on the microbial flora of the patient or hospital. Each of these harms was included in the determination of the recommended antimicrobial agent for each procedure type. For each procedure type, a primary antimicrobial agent is recommended along with an alternative agent for patients with allergies. The potential benefits of antimicrobial prophylaxis (eg, reduced surgical site infection rate, reduced surgical site infection-related morbidity and mortality, reduced cost and length of stay) were felt to far outweigh the potential harms.

UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE

1a.7.9. If new studies have been conducted since the systematic review of the body of evidence, provide for each new study: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.

Recent studies in antimicrobial prophylaxis for surgery have been published. However, these studies have focused on current practice patterns and adherence to prophylaxis guidelines as well as the issue of antibiotic resistance in surgical site infections.

1a.8 OTHER SOURCE OF EVIDENCE

If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.

1a.8.1 What process was used to identify the evidence?

1a.8.2. Provide the citation and summary for each piece of evidence.