# NATIONAL QUALITY FORUM

#### Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the submitting standards web page.

NQF #: 0472 NQF Project: Perinatal and Reproductive Health Project

(for Endorsement Maintenance Review)

Original Endorsement Date: Oct 24, 2008 Most Recent Endorsement Date: Oct 24, 2008

#### **BRIEF MEASURE INFORMATION**

De.1 Measure Title: Appropriate Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision – Cesarean section.

Co.1.1 Measure Steward: Massachusetts General Hospital/Partners Health Care System

**De.2 Brief Description of Measure:** Percentage of patients undergoing cesarean section who receive appropriate prophylactic antibiotics within 60 minutes of the start of the cesarean delivery, unless the patient is already receiving appropriate antibiotics

**2a1.1 Numerator Statement:** Percentage of women who receive recommended antibiotics within one hour before the start of cesarean section. This requires that (a) the antibiotic selection is consistent with current evidence and practice guidelines, and (b) that the antibiotics are given within an hour before delivery.

If the patient is already receiving appropriate antibiotics, for example for chorioamnionitis, additional dosing is not necessary.

**2a1.4 Denominator Statement:** All patients undergoing cesarean section without evidence of prior infection or already receiving prophylactic antibiotics for other reasons. Patients with significant allergies to penicillin and/or cephalosporins AND allegies to gentamicin and/or clindamycin are also excluded.

**2a1.8 Denominator Exclusions:** Women with evidence of prior infection or already receiving prophylactic antibiotics for other reasons; or with significant allergies to penicillin and/or cephalosporins AND allegies to gentamicin and/or clindamycin.

We do not exclude patients having emergency cesarean deliveries. We recognize that while in the case of most urgent and emergent cesarean deliveries administering timely antibiotic prophylaxis will be possible, very rarely clinical circumstances may not permit administration of antibiotic prophylaxis before skin incisions. Specifying these unusual circumstances, especially from readily abstracted medical record data, is not possible/feasible. Allowing a self-defined exclusion risks inappropriate definition. Instead we recognize that ideal performance on this measure may not be 100% given the small number of unusual emergencies and/or other circumstances. Providers/facilities should however target a 100% goal by, among other efforts, considering how antibiotic prophylaxis will be appropriately delivered even in the case of emergencies

1.1 Measure Type: Process

2a1. 25-26 Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Paper

Records

2a1.33 Level of Analysis: Facility, Population: State

1.2-1.4 Is this measure paired with another measure? No

De.3 If included in a composite, please identify the composite measure (title and NQF number if endorsed):

### **STAFF NOTES** (issues or questions regarding any criteria)

**Comments on Conditions for Consideration:** 

| Section.   |
|--|
| Is the measure untested? Yes No If untested, explain how it meets criteria for consideration for time-limited endorsement:   |
| <ul> <li>1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (check De.5):</li> <li>5. Similar/related endorsed or submitted measures (check 5.1):</li> <li>Other Criteria:</li> </ul>   |
| Staff Reviewer Name(s):  |
|  |
| 1. IMPACT, OPPORTUITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT   |
| Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See <u>guidance on evidence</u> .  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: H M L I (The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.)  |
| De.4 Subject/Topic Areas (Check all the areas that apply): Perinatal, Surgery: Perioperative De.5 Cross Cutting Areas (Check all the areas that apply): Safety: Healthcare Associated Infections   |
| 1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Frequently performed procedure  |
| 1a.2 If "Other," please describe:  |
| <b>1a.3 Summary of Evidence of High Impact</b> ( <i>Provide epidemiologic or resource use data</i> ):  Cesarean section is the most important risk factor for infectious complications of delivery. It is performed nation-wide > 1 million times a year and is being used at an increasing rate. At least 80 randomized trials have evaluated the use of perioperative antibiotics to prevent infection, finding a strong protective effect.  |
| 1a.4 Citations for Evidence of High Impact cited in 1a.3: Two good summaries are in the Cochrane Collaborative review and the ACOG recommendations   |
| Smail F, Hofmeyr GJ. Antibiotic prophlaxis for cesarean section. Cochrane Database of Systematic Reviews, 2002, Issue 3, Art. No. CD000933. DOI: 10.1002/14651858.CD000933.  |
| ACOG Committee on Obstetric Practice. Committee Opinion No. 465: antimicrobial prophylaxis for cesarean delivery: timing of administration. Obstet Gynecol 2010;116:791-2.   |
| 1b. Opportunity for Improvement: H M L I C (There is a demonstrated performance gap - variability or overall less than optimal performance)  |
| 1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:  Delivery of prophylactic antibiotics within an hour prior to incision time is a well-established quality and safety practice. It reduces the risk of morbidity to the mother and decreases the overall cost of care by avoiding the expense of treating postoperative infections.  |
| <b>1b.2 Summary of Data Demonstrating Performance Gap</b> ( <i>Variation or overall less than optimal performance across providers</i> ): [For <u>Maintenance</u> – Descriptive statistics for performance results <u>for this measure</u> - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.]  In Massachusetts, where the measure is in use in the MassHealth pay for performance program, state-wide rates of compliance with the overall measure (timing and selection) were 61% in FY 2008, 75% in RY 2009, and 77% in FY 2010. (The data for each fiscal year cited was drawn from the preceding calendar year.) In FY 2010, the first time MassHealth separately reported the components separately measure rates for timing were 79% and for antibiotic selection 88% |

There is not systematically collected U.S. data available on compliance with perioperative antibiotics in c-section. We note that the experience of the SCIP program indicates that there are significant gaps in multiple surgical procedures nation-wide, without any apparent reason to expect that practice in c-section would be better than for other procedures already targeted for performance improvement. One recent Canadian study found compliance of < 25%. An international survey of eight centers in five countries (including the U.S.) reported that only two centers administered prophylaxis reliably. A Danish study found 8% of hospitals using prophylaxis in elective procedures, 52% for emergency procedures. 1b.3 Citations for Data on Performance Gap: [For Maintenance - Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included Griffiths J, Demainczuk N, Cordoviz M, Joffe AM. Surgical site infection following elective caesarean section: a case-control study of postdischarge surveillance. J Obstet Gynaecol Can 2005;27(4):340-44. Huskins WC, Ba-Thike K, Festin MR, et al. An international survey of practice variation in the use of antibiotic prophylaxis in cesarean section. Int J Gynecol Obstet 2001;73:141-5. Pedersen TK, Blaakaer J. Antibiotic prophylaxis in cesarean section. Acta Obstetrica et Gynecologica Scandinavica 1996;75:537-9. Personal communication from MassHealth Primary Provider Network, EOHHS, citing results of the December 16, 2010 Webcast to participants 1b.4 Summary of Data on Disparities by Population Group: [For Maintenance - Descriptive statistics for performance results for this measure by population group] It is unknown whether there are significant disparities in compliance with this measure by population group. 1b.5 Citations for Data on Disparities Cited in 1b.4: [For Maintenance – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included1 1c. Evidence (Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.) Is the measure focus a health outcome? Yes No If not a health outcome, rate the body of evidence. Quantity: H M L L I Quality: H M L I Consistency: H M L L I Quantity Quality Consistency Does the measure pass subcriterion1c? М-Н М-Н М-Н М-Н М Yes IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No М-Н М-Н Yes IF potential benefits to patients clearly outweigh potential harms: otherwise No L-M-H L L-M-H No 🗌 **Health outcome** – rationale supports relationship to at least Does the measure pass subcriterion1c? one healthcare structure, process, intervention, or service **Yes** IF rationale supports relationship 1c.1 Structure-Process-Outcome Relationship (Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process- health outcome; intermediate clinical outcome-health outcome): The measure focuses on the process of perioperative prophylactic antibiotics to prevent postoperative infections, with associated

morbidity and mortality.

#### 1c.2-3 Type of Evidence (Check all that apply):

Clinical Practice Guideline, Systematic review of body of evidence (other than within guideline development)

**1c.4 Directness of Evidence to the Specified Measure** (State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population):

The American College of Obstetricians and Gynecologists (ACOG) is the most authoritative body with guidelines. These directly address appropriate prophylactic antibiotic practice in elective and non-elective c-sections,

There are a few Cochrane Collaboration reviews and metaanalyses (listed below in references) directly covering the topic of antibiotic prophylaxis in cesarean section and component subtopics. These include Alfirevic 2010, Hopkins 2007, and Smail 2007.

Outside of the Cochrane metaanalyses and reviews, there are various independent reviews and meta-analyses. See in references below, for instance, Chelmow 2000, Constantine 2008, and Tita 2009.

- **1c.5 Quantity of Studies in the Body of Evidence** (*Total number of studies, not articles*): In the Cochrane analyses, Hopkins 2007 identified fifty-one trials published between 1979 and 1994. Alfirevic 2010 identified 29 studies, with 25 providing data. Small 2007 included eighty-one trials.
- **1c.6 Quality of Body of Evidence** (Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events): There are a large number of studies with varying methodology and quality, but including many strong ones.

Smail 2002 in the review of 81 trials comments, "The methodological quality of the trials was reasonably good." Smail 2010 notes that because many of the trials were older, there was not systematic information available to evaluate various possible biases; however, a number of sensitivity analyses found the conclusions unaltered after exclusion of subsets of trials.

- **1c.7 Consistency of Results across Studies** (Summarize the consistency of the magnitude and direction of the effect): Smail 2002 notes, "The women in these 81 trials varied greatly in their baseline risk of infection... The results of the trials included in this review are, however, remarkably consistent, both in direction of effect and effect size... Despite the large number of trials, different populations and different antibiotic regimens, there was no statistically significant heterogeneity for most outcomes."
- **1c.8 Net Benefit** (Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit benefit over harms):

Smail 2010 summarizes, "Endometritis was reduced by two thirds to three quarters and a decrease in wound infection was also identified. However, there was incomplete information collected about potential adverse effects, including the effect of antibiotics on the baby, making the assessment of overall benefits and harms complicated. Prophylactic antibiotics given to all women undergoing elective or non-elective cesarean section is clearly beneficial for women but there is uncertainty about the consequences for the baby."

- 1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? Yes
- 1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: The body of evidence is explicitly graded in in IDSA draft guidelines. The ACOG 2003 Practice Bulletin describes the evidence as "good amd consistent scientific evidence (Level A)."

The evidence is further implicitly graded in Cochrane reviews with language that closely resembles the definition of the highest available grade.

1c.11 System Used for Grading the Body of Evidence: Other

- **1c.12** If other, identify and describe the grading scale with definitions: The GRADE system definition of high quality evidence is, "Further research is very unlikely to change our confidence in the estimate of effect." The Smail 2010 Cochrane review provides an evaluation equivalent to this: "Further placebo controlled trials of the effectiveness of antibiotics with cesarean section are not ethically justified" because of the strength of the evidence showing reduction in adverse events, with little apparent risk.
- 1c.13 Grade Assigned to the Body of Evidence: Equivalent to GRADE "high."
- **1c.14 Summary of Controversy/Contradictory Evidence:** There is little controversy. However, the Cochrane 2010 review notes that there has not been systematic followup with infants: "However, studies did not assess potential adverse effects on the baby and the rates of oral thrush were not reported."

### 1c.15 Citations for Evidence other than Guidelines (Guidelines addressed below):

- 1. ACOG Committee on Obstetric Practice. Committee Opinion No. 465: antimicrobial prophylaxis for cesarean delivery: timing of administration. Obstet Gynecol 2010;116:791-2.
- 2. ACOG Committee on Practice Bulletins--Gynecology. ACOG practice bulletin No. 104: antibiotic prophylaxis for gynecologic procedures. Obstet Gynecol 2009;113:1180-9.
- 3. ACOG Committee on Practice Bulletins--Obstetrics. ACOG Practice Bulletin No. 47: prophylactic antibiotics in labor and delivery. Obstet Gynecol 2003;102:875-82.
- 4. Alekwe LO, Kuti O, Orji EO, Ogunniyi SO. Comparison of ceftriaxone versus triple drug regimen in the prevention of cesarean section infectious morbidities. Journal of Maternal-Fetal & Neonatal Medicine 2008;21:638-42.
- 5. Alfirevic Z, Gyte GML, Dou L. Different classes of antibiotics given to women routinely for preventing infection at caesarean section. Cochrane Database of Systematic Reviews 2010:Art. No.: CD008426. DOI: 10.1002/14651858.CD008726.
- 6. American College of Obstetricians and Gynecologists. ACOG practice bulletin number 47, October 2003: Prophylactic Antibiotics in Labor and Delivery. Obstet Gynecol 2003;102:875-82.
- 7. Andrews WW, Hauth JC, Cliver SP, Savage K, Goldenberg RL. Randomized clinical trial of extended spectrum antibiotic prophylaxis with coverage for Ureaplasma urealyticum to reduce post-cesarean delivery endometritis. Obstet Gynecol 2003;101:1183-9.
- 8. Anonymous. Antimicrobial prophylaxis for surgery. Treatment Guidelines from The Medical Letter 2009;82:47-9.
- 9. Bagatree JS, Moodley J, Kleinschmidt I, Zawilski W. A randomised controlled trial of antibiotic prophylaxis in elective caesarean delivery. Br J Obstet Gynecol 2001;108:143-8.
- 10. Berghetta V, Baxter J, Chauhan S. Evidence-based surgery for cesarean delivery. Am J Obstet Gynecol 2005;2005:1607-17.
- 11. Bracero LA. Ampicillin/sulbactam versus cefotetan for the prevention of infection following cesarean delivery in high-risk patients: a randomized double-blind trial. Gynecol Obstet Invest 1997;44:21-5.
- 12. Bratzler DW, Houck PM, Surgical Infection Prevention Guidelines Writers W, et al. Antimicrobial prophylaxis for surgery: an advisory statement from the National Surgical Infection Prevention Project.[see comment]. Clin Infect Dis 2004;38:1706-15.
- 13. Briggs GG, Wan SR. Drug therapy during labor and delivery, part 1. Am J Health-Syst Pharm 2006;63:1038-47.
- 14. Chelmow D, Hennesy M, Evantash EG. Prophylactic antibiotics for non-laboring patients with intact membranes: an economic analysis. Am J Obstet Gynecol 2004;191:1661-5.
- 15. Chelmow D, Ruehli MS, Huang E. Prophylactic use of antibiotics for nonlaboring patients undergoing cesarean delivery with intact membranes: a meta-analysis. Am J Obstet Gynecol 2000;184:656-61.
- 16. Costantine MM, Rahman M, Ghulmiyah L, et al. Timing of perioperative antibiotics for cesarean delivery: a metaanalysis. Am J Obstet Gynecol 2008;199:301.e1-.e6.
- 17. Dellinger EP, Gross PA, Barrett TL, et al. Quality standard for antimicrobial prophylaxis in surgical procedures. Clin Infect Dis 1994;18:422-7.
- 18. Gonik B. Single- versus three-dose cefotaxime prophylaxis for cesarean section. Obstet Gynecol 1985;65:189-92.
- 19. Griffiths J, Demianczuk N, Cordovic M, Joffe AM. Surgical site infection following elective caesarean section: a case-control study of postdischarge surveillanc. J Obstet Gynaecol Can 2005;27:340-4.
- 20. Grugic Z, Popovic J, Bogavac M, Grujic I. Preoperative administration of cephalosporins for elective caesarean delivery. Srpski Arhiv Za Celokupno Lekarstvo 2010;138:600-3.
- 21. Hopkins L, Smaill FM. Antibiotic prophylaxis regimens and drugs for cesarean section. Cochrane Database of Systematic Reviews 1999:DE001136. DOI: 10.1002/14651858.CD001136.
- 22. Draft therapeutic guidelines on antimicrobial prophylaxis in surgery -- Section: cesarean delivery. 2011. (Accessed

September 28, 2011, 2011, at http://www.ashp.org/prophylaxis.)

- 23. Lamont RF, Stoebel JD, Kusanovic JP, et al. Current debate on the use of antibiotic prophylaxis for caesarean section. BJOG 2010:193-201.
- 24. Mitchell TF, Pearlman MD, Chapman RL, Bhatt-Mehta V, Faix RG. Maternal and transplacental pharmacokinetics of cefazolin. Obstet Gynecol 2001;98:1075-9.
- 25. Naylor CS, Steele L, Hsi R, Margolin M, Goldfinger D. Cefotetan-induced hemolysis associated with antibiotic prophylaxis for cesarean delivery. Am J Obstet Gynecol 2000;182:1427-8.
- 26. Noyes N, Berkeley AS, Freedman K, Ledger W. Incidence of postpartum endomyometritis following single-dose antibiotic prophylaxis with either ampicillin/sulbactam, cefazolin, or cefotetan in high-risk cesarean section patients. Infect Dis Obstet Gynecol 1998;6:220-3.
- 27. Robinson HE, Maxwell EL, Prince HM, O'Reilly MA, Jakobovits A. Cefotetan-induced life-threatening haemolysis. Med J Aust 2006;184:251.
- 28. Seve P, Ferry T, Vial T, Stankovic K, Bui-Xuan C, Broussolle C. [Very severe pregnancy hemolysis...]. Rev Med Interne 2004;25 Suppl 2:S290-1.
- 29. Shariatmadar S, Storry JR, Sausais L, Reid ME. Cefotetan-induced immune hemolytic anemia following prophylaxis for cesarean delivery. Immunohematology 2004;20:63-6.
- 30. Smaill FM, Hofmeyr GJ. Antibiotic prophylaxis for cesarean section. Cochrane Database of Systematic Reviews 2002;3:CD000933. DOI:1002/14651858.CD000933.
- 31. Spinnato JA, Youkilis B, Cook VD, Pietrantoni M, Clark AL, Gall SA. Antibiotic prophylaxis at cesarean delivery. J Matern Fetal Med 2000;9:348-50.
- 32. Sullivan SA, Smith T, Chang E, Hulsey T, Vandorsten JP, Soper DE. Administration of cefazolin prior to skin incision is superior to cefazolin at cord clamping in preventing postcesarean infectious morbidity: a randomized, controlled trial. Am J Obstet Gynecol 2007;196:455.e1-.e5.
- 33. Thigpen BD, Hood WA, Chauhan S, et al. Timing of prophylactic antibiotic administration in the uninfected laboring gravida: a randomized controlled trial. Am J Obstet Gynecol 2005;192:1864-71.
- Thurman AR, Anca Y, White CA, Soper DE. Post-cesarean delivery infectious morbidity: focus on preoperative antibiotics and methicillin-resistant Staphylococcus aureus. Am J Infect Control 2010;38:612-6.
- 35. Tita AT, Rouse DJ, Blackwell S, Saade GR, Spong CY, Andrews WW. Emerging concepts in antibiotic prophylaxis for cesarean delivery: a systematic review. Obstet Gynecol 2009;113:675-82.
- 36. Tita ATN, Hauth JC, Grimes A, Owen J, Stamm AM, Andrews WW. Decreasing incidence of postcesarean endometritis with extended-spectrum antibiotic prophylaxis. Obstet Gynecol 2008;2007:51-6.
- 37. Tita ATN, Owen J, Stamm AM, Grimes A, Hauth JC, Andrews WW. Impact of extended-spectrum antibiotic prophylaxis on incidence of postcesarean surgical wound infection. Am J Obstet Gynecol 2008;199:303.e1-.e3.
- 38. Pedersen TK, Blaakaer J. Antibiotic prophylaxis in cesarean section. Acta Obstetrica et Gynecologica Scandinavica 1996;75:537-9.
- 39. Huskins WC, Ba-Thike K, Festin MR, et al. An international survey of practice variation in the use of antibiotic prophylaxis in cesarean section. Int J Gynecol Obstet 2001;73:141-5.
- 40. Smaill FM, Gyte GML. Antibiotic prophylaxis versus no prophylaxis for preventing infection after cesarean section. Cochrane Database of Systematic Reviews 2010:Art. No.: CD007482. DOI: 10.1002/14651858.CD007482.pub2.

## 1c.16 Quote verbatim, the specific guideline recommendation (Including guideline # and/or page #):

ACOG 2010 states, "The Committee on Obstetric Practice recommends antimicrobial prophylaxis for all cesaean deliveries unless the patient is already receiving appropriate antibiotics (eg, for chorioamnionitis) and tha prophylaxis should be administered within 60 minutes of the start of the cesarean delivery."

ACOG 2003 recommends, "For prophylaxis with desaeran delivery, narrow-spectrum antibiotics, such as a first-generation cephalosporin, should be used."

The current guidelines of the Infectious Disease Society of America (IDSA) and others for antimicrobial surgical prophylaxis do not include c-section. The IDSA and collaborators are scheduled to release revised guidelines in 2012. The Draft Therapeutic Guidelines on Antimicrobial Prophylaxis is Surgery section on cesarean delivery provides, "The recommended regimen for all women undergoing cesarean section is a single dose of cefazolin 1-2 g intravenously within 60 minutes prior to incision. (Strength of evidence for prophlaxis = A). For patients allergic to penicillins or cephalosporins alternative agents may include clindamycin 600 mg plus gentamicin 1.5 mg/kg, ciprofloxacin 400 mg, levofloxacin 400 mg or aztreonam 1g."

| <b>1c.17 Clinical Practice Guideline Citation:</b> ACOG Committee on Obstetric Practice. Antimicrobial prophylaxis for cesarean delivery: timing of administration. Obtet Gynecol 2010;116(2):791-2; also ACOG Committee on Practice Bulletins. ACOG practice bulletin No. 47: prophylactice antibiotics in labor and delivery. Obstet Gynecol 2003;102(4):875-82   |
|---|
| 1c.18 National Guideline Clearinghouse or other URL: http://www.ashp.org/prophylaxis (draft of IDSA and collaborators); ACOG professional guideline is available to qualified professionals   |
| 1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? Yes  |
| 1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: American College of Obstetricians and Gynecologists (ACOG)   |
| 1c.21 System Used for Grading the Strength of Guideline Recommendation: Other   |
| 1c.22 If other, identify and describe the grading scale with definitions: Not specified   |
| 1c.23 Grade Assigned to the Recommendation: Level A   |
| <b>1c.24 Rationale for Using this Guideline Over Others:</b> As of this date, ACOG has published the only final, authoritative guideline. The collaborative group of professional societies including the Infectious Disease Societies of America (IDSA) have another in draft, generally congruent with that of ACOG. When this revised guideline appears, the Measure Steward will review it and modify the current recommendations if and as appropriate.  |
| Based on the NQF descriptions for rating the evidence, what was the <u>developer's assessment</u> of the quantity, quality, and consistency of the body of evidence?  1c.25 Quantity: High 1c.26 Quality: High1c.27 Consistency: High   |
|   |
| Was the threshold criterion, <i>Importance to Measure and Report</i> , met? (1a & 1b must be rated moderate or high and 1c yes) Yes No Provide rationale based on specific subcriteria:   |
| (1a & 1b must be rated moderate or high and 1c yes) Yes No  |
| (1a & 1b must be rated moderate or high and 1c yes) Yes No Provide rationale based on specific subcriteria:   |
| (1a & 1b must be rated moderate or high and 1c yes) Yes No Provide rationale based on specific subcriteria:  For a new measure if the Committee votes NO, then STOP. For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for   |
| (1a & 1b must be rated moderate or high and 1c yes) Yes No Provide rationale based on specific subcriteria:  For a new measure if the Committee votes NO, then STOP. For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for   |
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| (1a & 1b must be rated moderate or high and 1c yes) Yes No Provide rationale based on specific subcriteria:  For a new measure if the Committee votes NO, then STOP. For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.  2. RELIABILITY & VALIDITY - 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)  Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See guidance on measure testing.  S.1 Measure Web Page (In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained). Do you have a web page where current detailed specifications for this measure can be obtained? Yes   |
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| (1a & 1b must be rated moderate or high and 1c yes) Yes No Provide rationale based on specific subcriteria:  For a new measure if the Committee votes NO, then STOP. For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.  2. RELIABILITY & VALIDITY - 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)  Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See guidance on measure testing.  S.1 Measure Web Page (In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained). Do you have a web page where current detailed specifications for this measure can be obtained? Yes   |
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Percentage of women who receive recommended antibiotics within one hour before the start of cesarean section. This requires that (a) the antibiotic selection is consistent with current evidence and practice guidelines, and (b) that the antibiotics are given within an hour before delivery.

If the patient is already receiving appropriate antibiotics, for example for chorioamnionitis, additional dosing is not necessary.

- **2a1.2 Numerator Time Window** (The time period in which the target process, condition, event, or outcome is eligible for inclusion): One hour before incision time.
- **2a1.3 Numerator Details** (All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses: Patients receiving antibiotics within an hour before incision as recommended in major guidelines, specifically of the American College of Obstetricians and Gynecologists (ACOG). The ACOG guidelines currently call for a first-generation cephalosporin such as cefazolin as first-line therapy, and the combination of gentamicin and clindamycin for women with relevant allergies.

For the purposes of reporting, there may be one numerator of patients whose antibiotic selection is appropriate, and a second numerator of patients who receive antibiotics within one hour. While both components are necessary in the overall quality of care measure, separate reporting may help identify opportunities for improvement.

**2a1.4 Denominator Statement** (Brief, narrative description of the target population being measured):

All patients undergoing cesarean section without evidence of prior infection or already receiving prophylactic antibiotics for other reasons. Patients with significant allergies to penicillin and/or cephalosporins AND allegies to gentamicin and/or clindamycin are also excluded.

- 2a1.5 Target Population Category (Check all the populations for which the measure is specified and tested if any): Maternal Care
- **2a1.6 Denominator Time Window** (*The time period in which cases are eligible for inclusion*): Perioperative period.
- **2a1.7 Denominator Details** (All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses):

All patients undergoing cesarean section without evidence of prior infection or already receiving prophylactic antibiotics for other reasons; or with multiple significant drug allergies.

There may be various operational systems for identification of cesarean section, which is an unambiguous event. Most commonly hospital quality measurement systems rely on ICD-9 procedure codes (pending implementation of ICD-10). These may be found in Appendix A. Table 4.07 of the specifications for the National Hospital Quality Measures. Currently, they include

- o 74.0 Classical cesarean section
- o 74.1 Low cervical cesarean section
- o 74.2 Extraperitoneal cesarean section
- o 74.4 Cesarean section of other specified type
- o 74.99 Other cesarean section of unspecified type
- 2a1.8 Denominator Exclusions (Brief narrative description of exclusions from the target population):

Women with evidence of prior infection or already receiving prophylactic antibiotics for other reasons; or with significant allergies to penicillin and/or cephalosporins AND allegies to gentamicin and/or clindamycin.

We do not exclude patients having emergency cesarean deliveries. We recognize that while in the case of most urgent and emergent cesarean deliveries administering timely antibiotic prophylaxis will be possible, very rarely clinical circumstances may not permit administration of antibiotic prophylaxis before skin incisions. Specifying these unusual circumstances, especially from readily abstracted medical record data, is not possible/feasible. Allowing a self-defined exclusion risks inappropriate definition. Instead we recognize that ideal performance on this measure may not be 100% given the small number of unusual emergencies and/or other

circumstances. Providers/facilities should however target a 100% goal by, among other efforts, considering how antibiotic prophylaxis will be appropriately delivered even in the case of emergencies

**2a1.9 Denominator Exclusion Details** (All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses):

Patients who had a principal ICD-9 diagnosis code suggestive of preoperative infectious disease (as defined in Appendix A, Table 5.09 of the Specification Manual for National Hospital Quality Measures, Version 2.2, and future updates)

- Patients who were already receiving antibiotics within 24 hours prior to surgery except that prophylaxis with penicillin or ampicillin for Group B Streptococcus (GBS) is not a reason for exclusion.
- Patients with physician/advanced practice nurse/physician assistant/certified nurse midwife documented infection or prophylaxis for infection, except that prophylaxis for GBS is not a reason for exclusion.
- Patients who undergo other surgeries within 3 days before or after the cesarean section.
- **2a1.10 Stratification Details/Variables** (All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses):

The measure may electively be stratified by race, ethnicity, or other variables of interest. These additional variables would be identified and supplied by users according to local needs and interests.

- **2a1.11 Risk Adjustment Type** (Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13): No risk adjustment or risk stratification **2a1.12 If "Other," please describe:**
- **2a1.13 Statistical Risk Model and Variables** (Name the statistical method e.g., logistic regression and list all the risk factor variables. Note risk model development should be addressed in 2b4.):

  n/a
- 2a1.14-16 Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

2a1.17-18. Type of Score: Rate/proportion

- **2a1.19 Interpretation of Score** (Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score): Better quality = Higher score
- **2a1.20 Calculation Algorithm/Measure Logic**(Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.):

Rate = numerator of women receiving appropriate antibiotics within 1 hour prior to incision time divided by denominator of eligible women.

For submeasures, rate with appropriate timing = number of women receiving antibiotics within one hour before incision divided by denominator of eligible women. Rate with appropriate antibiotics selection = number of women receiving appropriate antibiotics before procedure divided by denominator of eligible women.

## 2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:

MassHealth has a published algorithm for local implementation -- as noted, other local implementations could vary slightly in details http://www.mass.gov/Eeohhs2/docs/masshealth/acutehosp/2012\_ry2012-eohhs-technical-sepcifications-manual-5-0-edit.pdf

**2a1.24 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):

We suggest that hospitals develop systems (anesthesia records, perioperative checklists) that would allow the measure to be evaluated in all patients.

Where such systems are not in place and resources are limited, it is suggested that the sampling criteria used for the National Hospital Quality Measures may provide a reasonable balance between the aim of maximum sample size and the aim of efficient use of chart review and IT resources.

As with with all measures, interpretation of the results should reflect adequacy of the size of the sample (or population), comparability of the underlying groups of patients, and how the results are to be used.

**2a1.25 Data Source** (Check all the sources for which the measure is specified and tested). If other, please describe: Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Paper Records

**2a1.26 Data Source/Data Collection Instrument** (*Identify the specific data source/data collection instrument*, e.g. name of database, clinical registry, collection instrument, etc.): A data abstraction form in current use is attached. We expect that there would be slight and routine modifications in this form from time to time, and note that the forms may have additions or adaptations to fit local needs.

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment: Attachment MAT-2 P4P abstraction form 2011-Q1.doc

# 2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:

**URL** 

The Massachusetts implementation is specified at the following url:

http://www.mass.gov/Eeohhs2/docs/masshealth/acutehosp/2012\_ry2012-eohhs-technical-sepcifications-manual-5-0-edit.pdf

2a1.33 Level of Analysis (Check the levels of analysis for which the measure is specified and tested): Facility, Population: State

2a1.34-35 Care Setting (Check all the settings for which the measure is specified and tested): Hospital/Acute Care Facility

**2a2**. **Reliability Testing.** (Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability.)

**2a2.1 Data/Sample** (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

The reliability of the measure is demonstrated extensively in the underlying clinical research, the analogous SCIP work, the Massachusetts experience, and studies by the Measure Steward.

Specifically, the developer conducted reliability studies comparing two independently sets of data for the same cases, finding a high level of concordance. These studies included comparisons of the use of different internal data systems for the same data element, e.g. paper and electronic charts.

The underlying science and clinical practice guidelines for perioperative antibiotic prophylaxis have an extensive history in the literature, with extensive track records in implementation in SCIP and other programs. The data elements involved -- occurrence of c-section, administration of antibiotics, times -- are unsubjective and widely accepted for use in quality measurement and research.

CMS comments as follows on SCIP reliablity and validity:

"This measure is currently in use in the Reporting Hospital Quality Data Annual Payment Update (RHQDAPU) program with data submitted by approximately 3500 hospitals.

This measure is reviewed bi-annually and revised as needed to ensure reliable specifications. An independent abstracting contractor is utilized by the RHQDAPU program to monitor validity of the measure specifications. Feedback from this contractor is incorporated into the proposed changes for each manual update."

from the National Quality Measures Clearinghouse http://qualitymeasures.ahrq.gov/content.aspx?id=27417

The current NQF-approved measure has been in use in Massachusetts Mediaid pay for performance for a few years. (The measure in use in this program has slight modifications to meet specific state requirements, such as the format for racial and ethnic data.) Each hospital's data abstraction is validated by a third party, just as for the National Hospital Quality Measures.

The Massachusetts Executive Office of Health and Human Services notes:

"Reliability Test Results. In RY08 a total of 94% of hospitals passed validation (n=61/65), in RY09 total of 98% hospitals passed validation (n=63/64) and in RY10 a total of 97% passed validation (n=62/64). The validation scores are based on sampling across all fourteen measure being collected under the MassHealth P4P program."

### 2a2.2 Analytic Method (Describe method of reliability testing & rationale):

In a reliablity study by the developer, two abstractors independently reviewed medical records of twenty cases. Key data elements of the abstractions, as well as the pass/fail results, were compared.

In the Massachusetts Medicaid pay for performance program, copies of medical records (including electronic elements) are sent to the contracted reviewer, here associated with the state Quality Improvement Organization recognized by CMS. Hospital abstraction is verified against the raw materials used. As with the NHQM validation, a score of 80% (for all sample charts in all measures) is required in order for the hospital to pass validation.

**2a2.3 Testing Results** (*Reliability statistics*, assessment of adequacy in the context of norms for the test conducted): For all 20 cases reviewed by the Measure Steward, the final results (pass/fail) was the same. For all 20 cases, the antibiotics administered were reported to be the same. For all times abstracted from the same clinical record system (e.g., anesthesia records, or nursing notes), the results of the two reviews were the same.

There were variations in timing of a few minutes when one record system was compared to another. These included differences between the graphic displays in the paper charts vs. the digital electronic records, and differences between anethesiologists' recorded times and OR nurses' times. The median difference was 3 minutes, principally due to rounding of the graphic displays to 5-minute marks.

| 2b. | VALIDITY. | <b>Validity</b> | Testing.   | including          | all Threats | to Validity: | H   | ] M | ] <b>L</b> 🗀 | I   |  |
|-----|-----------|-----------------|------------|--------------------|-------------|--------------|-----|-----|--------------|-----|--|
| LV. | **        | • • unaity      | , resurig, | , <u>including</u> | an incais   | to validity. | ••• |     |              | • • |  |

**2b1.1 Describe how the measure specifications** (measure focus, target population, and exclusions) are consistent with the evidence cited in support of the measure focus (criterion 1c) and identify any differences from the evidence:

The measure focus and exclusions have deliberately been made to match those of the SCIP program as far as possible. This measure addresses a procedure not included in SCIP, cesarean section. It is different in certain ways specific to this procedure. For example, antibiotics are to be given only in a single dose, so there is ordinarily no call to monitor discontinuation time to guard against overuse of antibiotics.

- 2b2. Validity Testing. (Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.)
- **2b2.1 Data/Sample** (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

The predictive validity of the measure may be considered as its ability to anticipate desirable outcomes on the basis of observation of unambiguous elements of clinical practice.

For this measure, the observation of the clinical practice of antibiotic administration for women undergoing surgical delivery may be observed with little doubt and with high reliability. The literature has demonstrated in extensive trials that these elements of clinical

practice tend to lead to desirable outcomes, i.e. the avoidance of subsequent infections.

- **2b2.2 Analytic Method** (Describe method of validity testing and rationale; if face validity, describe systematic assessment): The testing of the practice of antibiotic prophylaxis is extensive, described the the discussion of the literature.
- **2b2.3 Testing Results** (Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment):

Antibiotic prophylaxis is general is a universally accepted construct in health care. The large and continually updated literature on perioperative antibiotics, including specifically use in cesarean section, indicates that very strong face validity in review of medical records to establish what antibiotics are given at what times to women undergoing this procedure.

The Massachusetts Executive Office of Health and Human Services notes, "Hospital stakeholders continue to be actively engaged with MassHealth in providing input to refine maternity measure specifications consistent with evidence-based practice standards."

**POTENTIAL THREATS TO VALIDITY**. (All potential threats to validity were appropriately tested with adequate results.)

- **2b3. Measure Exclusions.** (Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.)
- **2b3.1 Data/Sample for analysis of exclusions** (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

The measure excludes, as far as it is possible to do this a priori, women for whom guideline therapies would plausibly be inappropriate. For example, those with multiple drug allergies make first-line therapies unsafe are excluded. Women who are already receiving antibiotics for other reasons, or who are undergoing significant procedures beside the surgical delivery, are apt to have clinical complexities that first-line therapies might or might not fit.

- **2b3.2 Analytic Method** (Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference):
- 2b3.3 Results (Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses):
- **2b4.** Risk Adjustment Strategy. (For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.)
- **2b4.1 Data/Sample** (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

  n/a
- **2b4.2 Analytic Method** (Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables):
- **2b4.3 Testing Results** (<u>Statistical risk model</u>: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. <u>Risk stratification</u>: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata):
- 2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment:
- **2b5. Identification of Meaningful Differences in Performance**. (The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.)
- 2b5.1 Data/Sample (Describe the data or sample including number of measured entities; number of patients; dates of data; if a

NQF #0472 Appropriate Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision - Cesarean sample, characteristics of the entities included): The current measure is in use across Massachusetts hospitals. As with other common rate-based measures, there is not a simply definable numeric difference representing a critical threshold. However, percentages are widely used, with audiences having some intuitive sense of what a "big" and a "little" difference is. **2b5.2 Analytic Method** (Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance): As with any common rate-based grading, the raw percentages provide a basis for understanding past performance. Where rates are based on small sample sizes, they are inherently approximate. If critical interpretation is important, the Measure Steward suggests reporting of the measure with confidence intervals or graphical techniques displaying the uncertainty of measurements. The Measure Steward does not suggest use of the simple performance scores alone to rank institutions, or to group institutions into tiers. 2b5.3 Results (Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance): 2b6. Comparability of Multiple Data Sources/Methods. (If specified for more than one data source, the various approaches result in comparable scores.) 2b6.1 Data/Sample (Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included): As discussed in the section on reliablity, the developer has compared paper-based and electronic record results. It is to be expected that institutions will have some differences in the format of their medical records. However, the underlying data elements -- administration of medications, times and dates, and occurrence of significant procedures -- are commonly compared across different settings. 2b6.2 Analytic Method (Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure): 2b6.3 Testing Results (Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted): **2c. Disparities in Care:** H M L L I NA (If applicable, the measure specifications allow identification of disparities.) 2c.1 If measure is stratified for disparities, provide stratified results (Scores by stratified categories/cohorts): It is currently unknown if there are disparities in the results of this measure. This reflects the relatively high performance of hospitals in available data, as well as the relative homogeneity of the populations -- there just has not been enough data to conduct meaningful comparisons. The developer believes further study would be very appropriate, once larger sample sizes accrue. 2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain: 2.1-2.3 Supplemental Testing Methodology Information: Steering Committee: Overall, was the criterion, Scientific Acceptability of Measure Properties, met?

(Reliability and Validity must be rated moderate or high) Yes No

Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

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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)

- **C.1 Intended Purpose/ Use** (Check all the purposes and/or uses for which the measure is intended): Public Reporting, Quality Improvement (Internal to the specific organization), Quality Improvement with Benchmarking (external benchmarking to multiple organizations)
- **3.1 Current Use** (Check all that apply; for any that are checked, provide the specific program information in the following questions): Payment Program, Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

| 3a. Usefulness for Public Reporting: | H | M | L |  |  |
|--------------------------------------|---|---|---|--|--|
|--------------------------------------|---|---|---|--|--|

(The measure is meaningful, understandable and useful for public reporting.)

**3a.1. Use in Public Reporting - disclosure of performance results to the public at large** (*If used in a public reporting program, provide name of program*(s), *locations, Web page URL*(s)). <u>If not publicly reported in a national or community program</u>, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: **[For <u>Maintenance</u>** – *If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.*]

The measure is in current use in the Massachusetts Medicaid pay for performance program, administered by the Executive Office of Health and Human Services (EOHHS). There is Internet public reporting of hospital quality in Massachusetts, which however by legislative mandate is performed by another arm of the state government. At this time, EOHHS does not have authorization to report the pay for performance results on the Internet, but there are discussions about how this might be done.

An additional wrinkle for Massachusetts Medicaid is that CMS is in the process of developing a national public reporting plan, as required under the Affordable Care Act.

Very similar results from SCIP are being widely and successfully reported to the public at large. The barriers to reporting the current measure are not intrinsic, but logistic, developmental, and to some extent political.

- 3a.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: The results are in use in funds distribution in Massachusetts pay for performance. Similar results from SCIP measures are widely reported and accepted.
- 3.2 Use for other Accountability Functions (payment, certification, accreditation). If used in a public accountability program, provide name of program(s), locations, Web page URL(s): The Massachusetts Medicaid programs uses a local implementation of the measure in its hospital pay-for-performance program.

http://massgex.ehs.state.ma.us/index

| 3b. | Usefulness | for Q | ualit | y Imp | rovem | ent: | H | M | L[ | <u> </u> |  |
|-----|------------|-------|-------|-------|-------|------|---|---|----|----------|--|
|     |            |       |       |       |       |      |   |   |    |          |  |

(The measure is meaningful, understandable and useful for quality improvement.)

**3b.1. Use in QI.** If used in quality improvement program, provide name of program(s), locations, Web page URL(s): **[For Maintenance –** If not used for QI, indicate the reasons and describe progress toward using performance results for improvement.

The overall measure is in current use in the Massachusetts Medicaid Pay for Performance program. As noted in the response to 1b.2 above, state-wide rates of compliance with the overall measure (timing and selection) were 61% in FY 2008, 75% in RY 2009, and 77% in FY 2010. (The data for each fiscal year cited was drawn from the preceding calendar year.) In FY 2010, the first time MassHealth separately reported the components separately, measure rates for timing were 79% and for antibiotic selection 88%.

The MassHealth Primary Provider Network of the Executive Office of Health and Human Services notes,

| "MAT-2: Perioperative Antibiotics for Cesarean Section. Measure rates for MAT 2 achieved statistically significant increases over the three years of the program. In RY08, measure rates were exceptionally low for this measure and had the greatest variability among hospitals. In RY09, MAT-2 rates improved significantly by 14% from RY08. From RY09 to RY10, 29 hospitals had an increase in measure rates out of which 8 hospitals showed a significant increase at the 5% significance level (p<.05). Measure rate failures continue to be primarily due to either: not adhering to guidelines for timing of antibiotic, and not administering an antibiotic for prophylaxis."  |
|--|
| (The scores for each rate year [RY] are based on hospital discharges for the earlier calendar year.]   |
| <b>3b.2.</b> Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated (e.g., Ql initiative), describe the data, method and results: As indicated above, the experience of the Massachusetts program, and the extensive experience of the comparable SCIP measures, provide a strong basis for confidence that the results are meaningful, understandable, and useful for quality improvement.  |
| Overall, to what extent was the criterion, <i>Usability</i> , met? H M L I D Provide rationale based on specific subcriteria:  |
|  |
| 4. FEASIBILITY   |
| Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)   |
| 4a. Data Generated as a Byproduct of Care Processes: H M L I   |
| <b>4a.1-2 How are the data elements needed to compute measure scores generated?</b> (Check all that apply). Data used in the measure are: generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition, Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims), Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)   |
| 4b. Electronic Sources: H M L I  |
| 4b.1 Are the data elements needed for the measure as specified available electronically (Elements that are needed to compute measure scores are in defined, computer-readable fields): Some data elements are in electronic sources  |
| <b>4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources:</b> In hospitals with advanced electronic systems, all or nearly all of the required data is available electronically. At MGH, the results are regularly reported from automated systems. It is typically good measurement practice to have a second level of human review for failures, since a trained and experienced clinician may identify circumstances that electronic data systems have missed, or simply captured incorrectly in the first place.   |
| Of course, not all hospitals have advanced electronic records. Those that rely on paper records to varying degrees will need to use those non-electronic sources.  |
| 4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H M M L I  |
| 4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results:  This measure, as all process measures, is susceptible to inadvertent gaps in documentation and to complex clinical circumstances beyond the intended scope of clinical guidelines. These have included legitimate use of unexpected antibiotics to cover for atypical pathogens (without explicit documentation). "Precipitous" deliveries may also present a challenge in measurement, since there is no agreed or simple standard for when there is "not enough" time for prophylactic antibiotics. |
| The difficulties for this measure are not greater than for other measures of the kind, and may be dealt with appropriately by avoiding   |

| overinterpretation of the raw scores.  |
|--|
| 4d. Data Collection Strategy/Implementation: H M L I   |
| A.2 Please check if either of the following apply (regarding proprietary measures): 4d.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 and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues (e.g., fees for use of proprietary measures): The measure has proved practical and has supplied good information for use in discussion of clinical practice differences and quality improvement. As with most clinical practice guidelines, there will be occasional patients for whom the first-line guideline treatment is not appropriate. |
| Overall, to what extent was the criterion, <i>Feasibility</i> , met? H M L I Provide rationale based on specific subcriteria:  |
| OVERALL SUITABILITY FOR ENDORSEMENT  |
| Does the measure meet all the NQF criteria for endorsement? Yes No Rationale:  |
| If the Committee votes No, STOP. If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.   |
| 5. COMPARISON TO RELATED AND COMPETING MEASURES  |
| J. COMPARISON TO RELATED AND COMPETING MEASURES  |
| If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made.  |
| 5.1 If there are related measures (either same measure focus or target population) or competing measures (both the same measure focus and same target population), list the NQF # and title of all related and/or competing measures:  0125 : Timing of Antibiotic Prophylaxis for Cardiac Surgery Patients 0126 : Selection of Antibiotic Prophylaxis for Cardiac Surgery Patients  |
| 5a. Harmonization  |
| 5a.1 If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):  Are the measure specifications completely harmonized? Yes  |
| 5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:  |
| 5b. Competing Measure(s)   |
| 5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible):  |

## **CONTACT INFORMATION**

**Co.1 Measure Steward (Intellectual Property Owner):** Massachusetts General Hospital/Partners Health Care System, 55 Fruit Street, Boston, Massachusetts, 02114

Co.2 Point of Contact: Paul, Nordberg, M.S., pnordberg@partners.org, 617-724-8269-

**Co.3 Measure Developer if different from Measure Steward:** Massachusetts General Hospital/Partners Health Care System, 55 Fruit Street, Boston, Massachusetts, 02114

Co.4 Point of Contact: Paul, Nordberg, M.S., pnordberg@partners.org, 617-724-8269-

**Co.5 Submitter:** Paul, Nordberg, M.S., pnordberg@partners.org, 617-724-8269-, Massachusetts General Hospital/Partners Health Care System

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

Jeffrey Ecker, M.D., clinical sponsor

Vincent Obstetrics Service

Massachusetts General Hospital

Paul Nordberg, administrative sponsor

Center for Quality and Safety

Massachusetts General Hospital

**Co.7 Public Contact:** Paul, Nordberg, M.S., pnordberg@partners.org, 617-724-8269-, Massachusetts General Hospital/Partners Health Care System

#### 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.

Jeffrey L. Ecker, M.D., of the Vincent Obstetrics Service of the Massachusetts General Hospital, supervised measure development. Dr. Ecker works with colleagues in the Partners Healthcare System in related efforts.

Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward:

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.3 Year the measure was first released: 2008

Ad.4 Month and Year of most recent revision: 10, 2011

Ad.5 What is your frequency for review/update of this measure? As significant clinical evidence and guidelines are released

Ad.6 When is the next scheduled review/update for this measure? 04, 2012

Ad.7 Copyright statement:

Ad.8 Disclaimers:

Ad.9 Additional Information/Comments:

Date of Submission (MM/DD/YY): 10/17/2011