**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** Click here to enter NQF number

**Measure Title**: Birthrisk Cesarean Birth Measure

**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**: 2/12/2016

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| **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 (*incudes 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](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **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**](#Note3) 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**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) 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**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) 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](http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm) and [methods](http://www.uspreventiveservicestaskforce.org/methods.htm), or Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/publications/index.htm).  **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](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

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

Outcome

Health outcome: Cesarean Birth

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: Click here to name the process

Structure: Click here to name the structure

Other: Click here to name what is being measured

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**HEALTH OUTCOME/PRO PERFORMANCE MEASURE**  *If not a health outcome or PRO, skip to* [*1a.3*](#Section1a3)

**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.**

The measure focus is the effect of the obstetrical care provider´s labor management strategies on a woman´s risk that labor will result in a cesarean birth. A woman’s risk that labor will result in a cesarean birth is significantly affected by her unique combination of physical characteristics and the size of her baby. Obstetrical care providers have attempted to assist women in labor by introducing labor management strategies. Measuring the effect of the obstetrical care provider’s labor management strategies on a woman’s inherent risk for cesarean birth will identify those strategies that can be used to decrease the number of cesarean births. A decrease in the number of cesarean births will decrease maternal morbidity and the cost of maternity care.

**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*).**

There are many different labor management strategies that have been used over the years to assist women who are in labor. Some of these strategies can decrease a woman’s inherent risk that labor will result in a cesarean birth and others can increase the risk. For example, the use of forceps can decrease a woman’s inherent risk for a cesarean birth whereas an impatient obstetrical care provider may increase a woman’s inherent risk.

*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.*

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**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***](#Section1a4)***, and*** [***1a.7***](#Section1a7)

US Preventive Services Task Force Recommendation – ***complete sections*** [***1a.5***](#Section1a5) ***and*** [***1a.7***](#Section1a7)

Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*) – ***complete sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)

Other – ***complete section*** [***1a.8***](#Section1a8)

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

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**1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION**

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

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

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

**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.*)

**1a.4.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.4.1*)**:**

**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***](#Section1a7)

No **→ *report on another systematic review of the evidence in sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)***; if another review does not exist, provide what is known from the guideline review of evidence in*** [***1a.7***](#Section1a7)

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**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***](#Section1a7)

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**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***](#Section1a7)

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**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?**

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

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

**1a.7.4.** **What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range**: Click here to enter date range

**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*)

**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*)

**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*)

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

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**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.*

In 1964 Dr. Edward H. Bishop published his landmark work titled "Pelvic Scoring for Elective Induction" as a practice guideline for the labor management strategy of elective induction of labor [1]. Countless studies and numerous guidelines regarding the results of labor management strategies have since been developed [2-20]. In 2000 the American College of Obstetrician and Gynecologist's task force on cesarean birth published an Evaluation of Cesarean Delivery which had 256 references [2]. In 2014 the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine published a consensus on the safe prevention of the primary cesarean delivery with 114 references [20]. These studies provide a tremendous body of evidence that not only do the labor management strategies of the obstetrical care provider significantly affect a woman's risk for cesarean birth but that each woman's risk that labor will result in a cesarean birth is significantly affected by her physical characteristics and the size of her baby. Maternal physical characteristics like parity, prepregnancy body mass index, age, height, gestational age, pregnancy weight gain as well as fetal birth weight and induction of labor have all been confirmed in numerous studies to significantly affect a woman's risk that labor will result in a cesarean birth. All of these factors must be taken into account in order to create an accurate measure of the effect of the obstetrical care provider's labor management strategies.

Even though the body of evidence consistently confirms that these factors significantly affect a woman’s risk that labor will result in a cesarean birth there is a study by Caceres et al. that has been recently referenced as providing evidence that a woman’s physical characteristics and the size of her baby can be ignored. The study states “One implication of this finding is that presenting hospital-specific cesarean rates for NTSV births might be appropriate without further case-mix adjustment” [21]. Critical review of the work by Caceres et al. reveals poorly selected risk factors, questionable quality of data collection, the work is not similar to the studies that were referenced and there is no attempt to explain the obvious contradiction between proving that risk factors significantly affect the risk of cesarean birth and then implying that they can be ignored when comparing outcome. In fact, one of the authors (Declercq E) of the Caceres study recently published the results of the effect of prepregnancy maternal body mass index on over two million women without a history of a prior cesarean birth who gave birth in 2012 to a single term (37-41 weeks) vertex baby [22]. The recent study by Declercq et al. concluded that “… prepregnancy obesity was found to represent an independent risk factor for primary cesareans, even after controlling for maternal demographic characteristics and medical risk factors.” The result of this larger more recent study contradicts the implication made by Caceres et al.

Data from millions of women who have given birth has recently become available [23]. Analysis of the data from over two million women who attempted labor in 2011 reveals that inducing labor in a five foot two inch 36 year old nulliparous woman with a starting weight of 175 lbs. who has gained 42 lbs. and is carrying a 4,000 gram baby has a cesarean birth rate of approximately 70%. Whereas a five foot four inch 18 year old nulliparous woman with a starting weight of 115 lbs. who has gained 30 lbs. carrying a 3,500 gram baby who arrives in spontaneous labor has a cesarean birth rate of approximately 7%. This tenfold difference in the rate of cesarean birth due to the physical characteristics of the mother and the size of her baby reveals that any attempt to use an unadjusted NTSV cesarean birth rate as a measure of the effect of the obstetrical care provider’s labor management strategies will be fatally flawed.

The overwhelming majority of the studies present in the body of evidence consistently confirm that the physical characteristics of the mother, the size of her baby and the labor management strategies used by the obstetrical care provider can all significantly affect a woman’s risk that labor will result in a cesarean birth. Discovering the labor management strategies that result in the appropriate cesarean birth rate for a population of women has a tremendous benefit for the women who are giving birth as well as to the overall cost of maternity care.

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

The developer of this measure is Gustavo San Román, MD, who is a board certified obstetrician gynecologist that has been managing laboring patients since 1986. In 2006, Dr. San Román began to collect data and review the literature in an attempt to create a better cesarean birth measure. Since 2006, a continuous review of the literature has been conducted with representative articles being listed below.

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

Each of the following references provide evidence that both the physical characteristics of the mother and her baby as well as the effect of the obstetrical care provider affect a woman’s risk for cesarean birth.

1. Bishop EH, Pelvic Scoring for Elective Induction. Obstet Gynecol 1964;24:166-8-7

2. American College of Obstetricians and Gynecologists Task Force on Cesarean Delivery.

Evaluation of cesarean delivery. Washington (DC): American College of Obstetricians and Gynecologists; 2000. p. 1-59

3. Kozhimannil KB, Law MR, Virnig BA. Cesarean Delivery Rates Vary 10-Fold Among US Hospitals; Reducing Variation May Address Quality, Cost Issues. Health affairs (Project Hope). 2013;32(3):527-535

4. Bailit JL, Love TE, Mercer B. Rising cesarean rates: are patients sicker? Am J Obstet Gynecol 2004;191:800-3.

5. Chen G, Uryasev S, Young T. On prediction of the cesarean delivery risk in a large private practice. Am J Obstet Gynecol 2004;191:617-25

6. Peregrine E, O’Brien P, Omar R, Jauniaux E. Clinical and Ultrasound Parameters to Predict the Risk of Cesarean Delivery After Induction of Labor. Obstet Gynecol 2006;107:227-33

7. Wilkes P, Wolf D, Kronbach D, Kunze M, Gibbs R. Risk Factors for Cesarean Delivery at Presentation of Nulliparous Patients in Labor. Obstet Gynecol 2003;102:1352-7

8. Bergholt T, Lim L, Jorgensen J, Robson M. Maternal body mass index in the first trimester and risk of cesarean delivery in nulliparous women in spontaneous labor. Am J Obstet Gynecol 2007;196(2):163.e1-5

9. Maslow A, Sweeny A. Elective Induction of Labor as a Risk Factor for Cesarean Delivery Among Low-Risk Women at Term. Obstet & Gynecol 2000;95:917-22

10. National Collaborating Centre for Women’s and Children’s Health. Induction of Labour – Clinical Guideline. 2nd ed. Regent’s Park, London: RCOG Press; 2008

11. Ehrenthal DB, Jiang X, Strobino DM. Labor Induction and the Risk of a Cesarean Delivery Among Nulliparous Women at Term. Obstet Gynecol 2010;116:35-42

12. Luthy DA, Malmgren JA, Zingheim RW, Leninger CJ. Physician contribution to a cesarean delivery risk model. Am J Obstet Gynecol 2003;188:1579-87.

13. Coonrod DV, Drachman D, Hobson P, et al. Nulliparous term singleton vertex cesarean delivery rates: institutional and individual level predictors. Am J Obstet Gynecol 2008;198:694.e1-694.e11

14. Barber EL, Lundsberg LS, Belanger K, Pettker CM, Funai EF, Illuzzi JL. Indications Contributing to the Increasing Cesarean Delivery Rate. Obstet Gynecol 2011;118:29-38

15. Main E, Moore D, Farrel B, Schimmel L, Altman R, Abrahams C, et al. Is there a useful cesarean birth measure? Assessment of the nulliparous term singleton vertex cesarean birth rate as a tool for obstetric quality improvement. Am J Obstet Gynecol 2006;194:1644-52

16. Robson MS. Classification of caesarean sections. Fetal and Maternal Medicine Review. 2001;12:23–39.

17. Goyert GL, Bottoms SF, Treadwell MC, Nehra PC. The Physician Factor in Cesarean Birth Rates. N. Engl J Med 1989; 320:706-9

18. Clark SL, Belfort MA, Hankins GDV, Meyers JA, Houser FM (2007) Variation in the rates of operative delivery in the United States. Am J Obstet Gynecol 196:526.e1–5

19. Brennan DJ, Robson MS, Murphy M, et al. Comparative analysis of international cesarean delivery rates using 10-group classification identifies significant variation in spontaneous labor. Am J Obstet Gynecol 2009;201:308.e1-8.

20. Caughey AB, Cahill AG, Guise JM, Rouse DJ. Safe Prevention of the Primary Cesarean Delivery. Obstet Gynecol 2014;123:693-711

21. Caceres IA, Arcaya M, Declercq E, Belanoff CM, Janakiraman V, et al. (2013) Hospital Differences in Cesarean Deliveries in Massachusetts (US) 2004–2006: The Case against Case-Mix Artifact. PLoS ONE 8(3): e57817

22. Declercq E, MacDorman M, Osterman M, Belanoff C, Iverson R. Prepregnancy Obesity and Primary Cesareans among Otherwise Low-Risk Mothers in 38 U.S. States in 2012. Birth 2015;42(4):309-18

23. Centers for Disease Control and Prevention. 2011 Birth Data Files. Available at http://www.cdc.gov/nchs/data\_access/Vitalstatsonline.htm. Retrieved December 22, 2015.