# NATIONAL QUALITY FORUM

**Measure Evaluation 4.1**
**December 2009**

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the evaluation criteria are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

**TAP/Workgroup** (if utilized)**:** Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: *If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).*

**Steering Committee:** Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met
C = Completely (unquestionably demonstrated to meet the criterion)
P = Partially (demonstrated to partially meet the criterion)
M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)
N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)
NA = Not applicable (only an option for a few subcriteria as indicated)

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| (for NQF staff use) **NQF Review #:** OT3-031-10 **NQF Project:** Patient Outcomes Measures: Child Health and Mental Health (Phase III) |
| **MEASURE DESCRIPTIVE INFORMATION** |
| **De.1 Measure Title:** Healthy Term Newborn |
| **De.2 Brief description of measure***:* Percent of term singleton livebirths (excluding those with diagnoses originating in the fetal period) who DO NOT have significant complications during birth or the nursery care. |
| **1.1-2 Type of Measure:** Outcome<br>**De.3 If included in a composite or paired with another measure, please identify composite or paired measure** |
| **De.4 National Priority Partners Priority Area:** Safety<br>**De.5 IOM Quality Domain**: Safety<br>**De.6 Consumer Care Need:** |

| **CONDITIONS FOR CONSIDERATION BY NQF** | |
|---|---|
| Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards: | **NQF Staff** |
| **A.** The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.*<br>**A.1 Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes<br>**A.2 Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:**<br>**A.3 Measure Steward Agreement:** Agreement will be signed and submitted prior to or at the time of measure submission<br>**A.4 Measure Steward Agreement attached:** | **A**<br>**Y☐**<br>**N☐** |
| **B.** The measure owner/steward verifies there is an identified responsible entity and process to maintain and | **B** |

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|---|---|
| update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section | Y☐ N☐ |
| **C.** The intended use of the measure includes both public reporting and quality improvement.<br>►**Purpose:** Public reporting, Internal quality improvement | C<br>Y☐<br>N☐ |
| **D.** The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement.<br>D.1**Testing:** Yes, fully developed and tested<br>D.2 **Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?** Yes | D<br>Y☐<br>N☐ |
| (for NQF staff use**)** **Have all conditions for consideration been met?**<br>**Staff Notes to Steward** (*if submission returned*)**:** | **Met**<br>Y☐<br>N☐ |
| **Staff Notes to Reviewers** (*issues or questions regarding any criteria*)**:** | |
| **Staff Reviewer Name(s):** | |

| | |
|---|---|
| **TAP/Workgroup Reviewer Name:** | |
| **Steering Committee Reviewer Name:** | |
| **1. IMPORTANCE TO MEASURE AND REPORT** | |
| Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. *Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.* (evaluation criteria)<br>**1a. High Impact** | Eval Rating |
| (for NQF staff use) Specific NPP goal: | |
| 1a.1 **Demonstrated High Impact Aspect of Healthcare:** Patient/societal consequences of poor quality, Affects large numbers, Frequently performed procedure, High resource use<br>1a.2<br><br>1a.3 **Summary of Evidence of High Impact:** Over 4 million births occur in the US each year with over 3 million meeting our measure denominator criteria. In this population there is a very high rate of procedures that brought the child into the world, e.g. 33% are born via cesarean births and 11% by forceps and vacuum. That adds up to over 1.5 million procedures. Unless there has been a prenatal diagnosis, the expectations for birth are high--perfection is a common parental objective. This measure is the first to address the question of how commonly we do reach this goal. Here we have defined a normal newborn as NOT having any serious morbidities or procedures that would involve NICU care. We also include physical separation (prolonged LOS or transfers to another hospital as a significant morbidity.<br><br>1a.4 **Citations for Evidence of High Impact:** Hamilton BE, Martin JA, Ventura SJ. Births: Preliminary data for 2007. National vital statistics reports, Web release; vol 57 no 12. Hyattsville, MD: National Center for Health Statistics. Released March 18, 2009.<br><br>Gregory KD, Fridman M, Shah S, Korst LM. Global measures of quality- and patient safety-related childbirth outcomes: should we monitor adverse or ideal rates? Am J Obstet Gynecol. 2009 Jun;200(6):681.e1-7. | **1a**<br>C☐<br>P☐<br>M☐<br>N☐ |
| **1b. Opportunity for Improvement** | **1b** |

C☐
P☐
M☐
N☐

**1b.1 Benefits (improvements in quality) envisioned by use of this measure:** THis measure is important from several perspectives. It captures the normal outcome for the most common procedure(s) in the US-childbirth and nursery care. It stresses the normal outcome for this normal process. On the other hand there are many opportunities for improvement in the maternity and nursery care for normal term infants that can lead to morbidities. THis measure also serves to balance other measures that foucs on maternal process measures that could impact the child.

**1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:**
We have significant opportunities to improve care for otherwise healthy term infants. Labor and birth management (oxytocin, other practices, delivery types) can lead to birth injuries, trauma and hypoxia/asphyxia events and in some infants neurologic complications. Elective delivery between 37 and 39 weeks can lead to respiratory disorders and long NICU care in some infants. Many authors have shown that there may be limited benefit for a floor cesarean rate of 15-20%, there is no advantage to the fetus/newborn of higher rates, Indeed, we and multiple authors have shown that when looking at outcome codes, such as used in this measure, neonatal outcomes actually decline significantly. Others have found that rates of PS17 (AHRQ Birth injury/trauma) have high preventability rates and that was looking at a very limited set of codes. We have expanded that code set significantly by examining procedure codes as well as diagnoses.

**1b.3 Citations for data on performance gap:**
Bailit JL, Garrett JM, Miller WC, McMahon MJ, Cefalo RC. Hospital primary cesarean delivery rates and the risk of poor neonatal outcomes. Am J Obstet Gynecol. 2002 Sep;187(3):721-7.

Bailit JL, Love TE, Dawson NV. Quality of obstetric care and risk-adjusted primary cesarean delivery rates. Am J Obstet Gynecol. 2006 Feb;194(2):402-7.

Clark SL, Miller DD, Belfort MA, Dildy GA, Frye DK, Meyers JA. Neonatal and maternal outcomes associated with elective term delivery. Am J Obstet Gynecol. 2009 Feb;200(2):156.e1-4. Epub 2008 Dec 25

Clark SL, Simpson KR, Knox GE, Garite TJ. Oxytocin: new perspectives on an old drug. Am J Obstet Gynecol. 2009 Jan;200(1):35.e1-6. Epub 2008 Jul 29

Dunne C, Da Silva O, Schmidt G, Natale R. Outcomes of elective labour induction and elective caesarean section in low-risk pregnancies between 37 and 41 weeks' gestation. J Obstet Gynaecol Can. 2009 Dec;31(12):1124-30.

Gould JB, Danielsen B, Korst LM, Phibbs R, Chance K, Main E, Wirtschafter DD, Stevenson DK. Cesarean delivery rates and neonatal morbidity in a low-risk population. Obstet Gynecol. 2004 Jul;104(1):11-9.

Robertson CM, Finer NN. Long-term follow-up of term neonates with perinatal asphyxia. Clin Perinatol. 1993 Jun;20(2):483-500.
.
Russo CA, Andrews RM. Potentially Avoidable Injuries to Mothers and Newborns During Childbirth, 2006. HCUP Statistical Brief #74. June 2009. Agency for Healthcare Research and Quality, Rockville, MD. http://www.hcup-us.ahrq.gov/reports/statbriefs/sb74.pdf.

Tita ATN, Landon MB, Spong CY, et al. Timing of Elective Repeat Cesarean Delivery at Term and Neonatal Outcomes. New Engl J Med 360:111, 2009

van Handel M, Swaab H, de Vries LS, Jongmans MJ. Long-term cognitive and behavioral consequences of neonatal encephalopathy following perinatal asphyxia: a review. Eur J Pediatr. 2007 Jul;166(7):645-54. Epub 2007 Apr 11.

**1b.4 Summary of Data on disparities by population group:**

we do not yet have data for this measure on racial disparities. We anticipate that it will be of significant interest and will be performing that research shortly.

**1b.5 Citations for data on Disparities:**
n/a

**1c. Outcome or Evidence to Support Measure Focus**

**1c.1 Relationship to Outcomes** (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** In the panel of maternal and child health measures, we are missing one that covers the largest population that of healthy term newborns. There is also the need to have balancing measures for other maternal and neonatal measures (if you increase one does that affect another?). For example many modern obstetric practices are done in the name of improving baby outcomes without having a proper measure to document that. In fact, many of these interventions, when formally studied actually lead to a diminution of newborn health.

**1c.2-3. Type of Evidence:** Observational study, Systematic synthesis of research, Expert opinion, Evidence-based guideline

**1c.4 Summary of Evidence** (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
There is a large body of evidence that term neonatal outcomes vary extensively from hospital to hospital. Cesarean rates, induction rates and other indicators of elective births (e.g. induction before 39 weeks) have all been linked to neonatal outcomes. Recent intervention programs in the State of Utah and at Magee Women's Hospital have shown direct neonatal improvements with reductions in elective deliveries before 39 weeks. THe State of Ohio also has promising early results for a a similar intervention project. There also has been concern about large variations in both the approaches and the outcomes of neonatal sepsis (CPQCC). What is missing from child health surveillance programs is a quality measure of normal term newborns.

**1c.5 Rating of strength/quality of evidence (***also provide narrative description of the rating and by whom***):**

**1c.6 Method for rating evidence:**

**1c.7 Summary of Controversy/Contradictory Evidence:** An area of controversy is how much certain diagnoses are under the control of medical care. We have tried to exclude all the important diagnoses that start before admission to the hospital for birth. Birth injuries such as fractured clavicle and brachial plexus injuries are an example of controversy as to how much is preventable. THe NQF #0474 measure of birth injury fell into this concern and excluded them. This measure takes the position that there is large variation in these specific codes and they are very concerning to parents and should take an infant out of the category of "healthy". THis is one advantage of defining the measure as health rather than specific diseases.

**1c.8 Citations for Evidence (***other than guidelines***):** Bailit JL, Garrett JM, Miller WC, McMahon MJ, Cefalo RC. Hospital primary cesarean delivery rates and the risk of poor neonatal outcomes. Am J Obstet Gynecol. 2002 Sep;187(3):721-7.

Bailit JL, Love TE, Dawson NV. Quality of obstetric care and risk-adjusted primary cesarean delivery rates. Am J Obstet Gynecol. 2006 Feb;194(2):402-7.

Clark SL, Miller DD, Belfort MA, Dildy GA, Frye DK, Meyers JA. Neonatal and maternal outcomes associated with elective term delivery. Am J Obstet Gynecol. 2009 Feb;200(2):156.e1-4. Epub 2008 Dec 25

Clark SL, Simpson KR, Knox GE, Garite TJ. Oxytocin: new perspectives on an old drug. Am J Obstet Gynecol. 2009 Jan;200(1):35.e1-6. Epub 2008 Jul 29

Dunne C, Da Silva O, Schmidt G, Natale R. Outcomes of elective labour induction and elective caesarean

**1c**
**C** ☐
**P** ☐
**M** ☐
**N** ☐

section in low-risk pregnancies between 37 and 41 weeks' gestation. J Obstet Gynaecol Can. 2009 Dec;31(12):1124-30.

Fisch JM, Labor induction process improvement: A patient quality-of-care initiative. Obset Gynecol 2009;113:797-803.

Gould JB, Danielsen B, Korst LM, Phibbs R, Chance K, Main E, Wirtschafter DD, Stevenson DK. Cesarean delivery rates and neonatal morbidity in a low-risk population. Obstet Gynecol. 2004 Jul;104(1):11-9.

Hansen AK, Wisborg K, Uldbjerg N, Henriksen TB. Elective caesarean section and respiratory morbidity in the term and near-term neonate. Acta Obstet Gynecol Scand 2007;86:389-94.

Hansen AK, Wisborg K, Uldbjerg N, Henriksen TB. Risk of respiratory morbidity in term infants delivered by elective caesarean section: cohort study. BMJ. 2008 336:85-7.

Oshiro BT, Henry E, Wilson J, et al. Decreasing elective deliveries before 39 weeks of gestation in an integrated health care system. Obstet Gynecol 2009;113:840-811.

Robertson CM, Finer NN. Long-term follow-up of term neonates with perinatal asphyxia. Clin Perinatol. 1993 Jun;20(2):483-500.
.
Russo CA, Andrews RM. Potentially Avoidable Injuries to Mothers and Newborns During Childbirth, 2006. HCUP Statistical Brief #74. June 2009. Agency for Healthcare Research and Quality, Rockville, MD. http://www.hcup-us.ahrq.gov/reports/statbriefs/sb74.pdf.

Tita ATN, Landon MB, Spong CY, et al. Timing of Elective Repeat Cesarean Delivery at Term and Neonatal Outcomes. New Engl J Med 360:111, 2009

**1c.9 Quote the Specific guideline recommendation (***including guideline number and/or page number***):**
There are a number of obstetric guidelines that direct elements of the care that in turn affect the newborn. An example is the ACOG Practice bulletin on labor induction (#107): which states that elective deliveries should not occur prior to 39 weeks. This is covered in NQF #0469, Elective delivery prior to 39 completed weeks gestation, but does not have a corresponding measure of neonatal outcomes.

**1c.10 Clinical Practice Guideline Citation:** ACOG. Induction of labor. ACOG Practice Bulletin No. 107. Obstet Gynecol 2009; 114: 386-97.
**1c.11 National Guideline Clearinghouse or other URL:** n/a

**1c.12 Rating of strength of recommendation (***also provide narrative description of the rating and by whom***):**
Studies rank in the USPHTF rankings: II-1, II-2, II-3

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

**1c.14 Rationale for using this guideline over others:**
n/a

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|---|---|
| **TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for** *Importance to Measure and Report?* | **1** |
| **Steering Committee: Was the threshold criterion,** *Importance to Measure and Report***, met?**<br>**Rationale:** | **1**<br>**Y☐**<br>**N☐** |
| **2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES** | |

| Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria) | Eval Rating |
|---|---|
| **2a. MEASURE SPECIFICATIONS** | |
| **S.1 Do you have a web page where current detailed measure specifications can be obtained?**<br>**S.2 If yes, provide web page URL:**<br><br>**2a. Precisely Specified** | |
| **2a.1 Numerator Statement (***Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):**<br>The absence of conditions or procedures reflecting morbidity that happened during birth and nursery care to an otherwise normal infant. The morbidities may or may not have clearly been the result of medical care.<br><br>**2a.2 Numerator Time Window (***The time period in which cases are eligible for inclusion in the numerator***):**<br>Initial neonatal birth hospitalization only.<br><br>**2a.3 Numerator Details (***All information required to collect/calculate the numerator, including all codes, logic, and definitions***):**<br>Birth trauma/injuries<br>Fetus or newborn affected by:<br>other complications of labor and delivery 763.0,1,2,3,4,5<br>Subdural/cerebral hemorrhage 767.0 (In NQF Birth Injury Measure)<br>Subgaleal hemorrhage 767.11 (In NQF Birth Injury Measure)<br>Clavicle fracture 767.2<br>Other skeletal injuries 767.3 (In NQF Birth Injury Measure)<br>Spine/spinal cord injuries 767.4 (In NQF Birth Injury Measure)<br>Facial nerve injury 767.5 (In NQF Birth Injury Measure)<br>Brachial plexus injury 767.6<br>Other cranial/peripheral nerves 767.7 (In NQF Birth Injury Measure)<br>Other specified birth trauma 767.8 (In NQF Birth Injury Measure)<br><br>Hypoxia/Asphyxia<br>Severe birth asphyxia with neurologic involvement 768.5<br>Mild or moderate birth asphyxia +/- neurologic involvement 768.6<br>HIE 768.7<br>Unspecified birth asphyxia 768.9<br>Congenital or infantile CP 343<br><br>Shock, Resuscitation and Complications<br>DIC 776.2<br>NEC 777.5<br>Shock, hypotension 785.5<br>Renal failure (ATN) 584.5 (Adult code but no applicable neonatal code)<br>--Procedures --<br>Arterial catheterization 38.91<br>Umbilical venous catheterization 38.92<br>TPN 99.15<br>Gastrostomy 43.1<br>Gavage feeding 96.35<br>Cardiopulmonary resuscitation 99.60<br><br>Respiratory<br>Pulmonary Hypertension 747.83<br>RDS 769 | **2a-specs**<br>**C☐**<br>**P☐**<br>**M☐**<br>**N☐** |

Meconium aspiration w/respiratory symptoms 770.12
Clear AF aspiration w/respiratory symptoms 770.14
Pneumothorax 770.2
Pulmonary hemorrhage 770.3
Primary and other atelectasis 770.4,5
TTN 770.6
Other respiratory problems after birth 770.81,2,3,4,6,7,8,9 (Apnea, cyanosis, respiratory arrest or failure, hypoxemia, aspiration of stomach contents)
--Procedures--
Birth trauma/injuries
Fetus or newborn affected by:
other complications of labor and delivery 763.0,1,2,3,4,5
Subdural/cerebral hemorrhage 767.0 (In NQF Birth Injury Measure)
Subgaleal hemorrhage 767.11 (In NQF Birth Injury Measure)
Clavicle fracture 767.2
Other skeletal injuries 767.3 (In NQF Birth Injury Measure)
Spine/spinal cord injuries 767.4 (In NQF Birth Injury Measure)
Facial nerve injury 767.5 (In NQF Birth Injury Measure)
Brachial plexus injury 767.6
Other cranial/peripheral nerves 767.7 (In NQF Birth Injury Measure)
Other specified birth trauma 767.8 (In NQF Birth Injury Measure)

Hypoxia/Asphyxia
Severe birth asphyxia with neurologic involvement 768.5
Mild or moderate birth asphyxia +/- neurologic involvement 768.6
HIE 768.7
Unspecified birth asphyxia 768.9
Congenital or infantile CP 343

Shock, Resuscitation and Complications
DIC 776.2
NEC 777.5
Shock, hypotension 785.5
Renal failure (ATN) 584.5 (Adult code but no applicable neonatal code)
--Procedures --
Arterial catheterization 38.91
Umbilical venous catheterization 38.92
TPN 99.15
Gastrostomy 43.1
Gavage feeding 96.35
Cardiopulmonary resuscitation 99.60

Respiratory
Pulmonary Hypertension 747.83
RDS 769
Meconium aspiration w/respiratory symptoms 770.12
Clear AF aspiration w/respiratory symptoms 770.14
Pneumothorax 770.2
Pulmonary hemorrhage 770.3
Primary and other atelectasis 770.4,5
TTN 770.6
Other respiratory problems after birth 770.81,2,3,4,6,7,8,9 (Apnea, cyanosis, respiratory arrest or failure, hypoxemia, aspiration of stomach contents)
--Procedures--
Non-invasive mechanical ventilation
without (delivery through) endotracheal
tube or tracheostomy 93.90 (Bi-level airway pressure, BiPAP , CPAP, Mechanical ventilation NOS, Non-invasive positive pressure (NIPPV), Non-invasive PPV, NPPV, That delivered by non-

invasive interface: face mask, nasal mask, nasal pillow, oral mouthpiece, oronasal mask)
Other respiratory therapy 93.91,3,4,5,6,8,9 (Other non-invasive ventilation and oxygen therapy)
Mechanical ventilation delivered through endotracheal tube or tracheostomy (invasive interface) 96.70,1,2 (Includes: BiPAP, CPAP, Endotracheal respiratory assistance,,Invasive positive pressure ventilation [IPPV], Mechanical ventilation through invasive interface. 4th digit is for duration
Inhaled nitric oxide 00.12
Chest tube 34.04

Infection
Congenital pneumonia 770.0
Septicemia of newborn 771.81
Bacteremia of newborn 771.83
Severe sepsis 995.92

Neurologic Complications
Intraventricular hemorrhage 772.10,1,2,3,4 (5th digits 1-4 refer to grade of IVH, 0 = not known)
Subarachnoid hemorrhage 772.2
Seizures 779.0
345.3 (Adult code also given, used in some nurseries)
Other/unspecified cerebral irritability 779.1
Coma and cerebral depression 779.2
Periventricular leukomalacia 779.7
Cardiac arrest newborn 779.85
427.5 (Adult code also given, used in some nurseries)
Encephalopathy 348.3 (Adult code, used in some nurseries)
Cerebral edema 348.5 (Adult code, used in some nurseries)
--Procedures---
Computed tomography of head 87.03
Other tomography of head 87.04
MRI brain, brainstem 88.91
EEG 89.14

Disposition/LOS
Neonatal death Disposition On the discharge diagnosis record
Neonatal transfer out Disposition On the discharge diagnosis record

LOS > 5d Discharge date – birth date LOS is assessed on a sub-population that has none of the above complications or procedures. In this set of "no inclusions in the numerator and LOS>5 days", further exclude the codes below:
773.1 Hemolytic disease due to ABO isoimmunization
99.83 Phototherapy of the newborn
V60.0,1,2,3,4,6,8,9 Housing, household and economic circumstances
V61.05 Family disruption due to child in welfare custody
V61.06 Family disruption due to child in foster care or in the care of non-parental family member

**2a.4 Denominator Statement (***Brief, text description of the denominator - target population being measured***):**
The denominator is composed of singleton, term (>=37 weeks), inborn, livebirths in their birth admission. The denominator further has eliminated fetal conditions likely to be present before labor. Maternal and obstetrical conditions (e.g. hypertension, prior cesarean, malpresentation) are not excluded unless evidence of fetal effect prior to labor (e.g. IUGR/SGA).

**2a.5 Target population gender:** Female, Male
**2a.6 Target population age range:** Newborns

**2a.7 Denominator Time Window (***The time period in which cases are eligible for inclusion in the denominator***):**
Initial neonatal birth hospitalization only during the time period of measurement (e.g. 6 months or a year).

**2a.8 Denominator Details (***All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):**
Denominator criteria uses ICD9 codes to identify singleton inborns (code of V30.00 or V30.01), or alternatively term (765.29 = 37+ weeks). Date of admission needs to equal the date of birth.

**2a.9 Denominator Exclusions (***Brief text description of exclusions from the target population***):**
Denominator exclusions: multiple gestations, preterm, congenital anomalies or fetuses affected by selected maternal conditions.

**2a.10 Denominator Exclusion Details (***All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**

| Exclusions | ICD9 Codes | Comments |
|---|---|---|
| Multiple gestation | 761.5 | |
| Preterm | 765.0,1 | |
| CONGENITAL ANOMALIES | 740.0,1,2 | (Anencephalus and similar anomalies) |
| | 741.0,9 | (Spina bifida) |
| | 742.0,1,2,3,4,5,8,9 | (Other congenital anomalies of nervous system) |
| | 743.0,1,2,3,4,5,6,8,9 | (Congenital anomalies of eye) |
| | 745.0,1,2,3,4,5,6,7,8,9 | (Congenital anomalies of the cardiac septum) |
| | 746.0,1,2,3,4,5,6,7,8,9 | (Other congenital anomalies of heart) |
| | 747.0,1,2,3,4 | (Other congenital anomalies of circulatory system--but not single umbilical artery) |
| | 748.0,1,2,3,4,5,6,8,9 | (Congenital anomalies of the respiratory system) |
| | 749.0,1,2 | (Cleft palate and cleft lip) |
| | 750.3,4,5,6,7,8,9 | (Congenital anomalies of the upper alimentary tract) |
| | 751.0,1,2,3,4,5,6,7,8,9 | (Other congenital anomalies of the digestive system) |
| | 753.0,1,2,3,5,6,8,9 | (Congenital anomalies of the urinary system) |
| | 754.0,1,2,3,4,5,6,7,8 | (Certain congenital musculoskeletal deformities) |
| | 757.1 | (Ichthyosis congenital) |
| | 758.0,1,2,3,5,6,8,9 | (Chromosomal anomalies--but not balanced translocations and Klinefelters syndrome) |
| | 759.5 | (Tuberous Sclerosis) |
| | 759.6 | (Other hamartoses) |
| | 759.7 | (Multiple congenital anomalies) |
| | 759.81,2,3,9 | (Other specified anomalies) |
| | 255.2 | (Adrenogenital disorders) |
| Fetus or newborn affected by placenta previa | 762.0 | |
| Fetus or newborn affected by abruptions | 762.1 | |
| Fetus or newborn affected by umbilical cord complications | 762.6 | (Umbilical thromboses, Vaso previa) |
| Impaired fetal growth, “light for dates” | 764.0,1,9 | (IUGR, SGA) |
| Hemolytic disease due to Rh or other isoimmunization | 773.0,2 | |
| Hydrops due to isoimmunization | 773.3 | |
| Idiopathic hydrops | 778.0 | |
| Drug withdrawal | 779.5 | |
| Laryngeal stenosis | 478.74 | |

**2a.11 Stratification Details/Variables (***All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
Stratification is done by birthing unit size: based on the collected denominator after exclusions. The denominator as so calculated represents approximately 75% of any given hospital's birth numbers. We

stratify many other maternity quality assessments at 1,000 and 3,000 births/year, so the denominator cuts would be at 750 and 2,250 (25% less).

**2a.12-13 Risk Adjustment Type:** No risk adjustment necessary

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

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

**2a.18-19 Type of Score:** Rate/proportion
**2a.20 Interpretation of Score:**
**2a.21 Calculation Algorithm (***Describe the calculation of the measure as a flowchart or series of steps***):**
Denominator Set: first identify term singleton infants, then exclude congenital anomalies, fetuses affected by maternal conditions and a few other selected conditions. THis set is "D".

Numerator Set:
Step 1: Identify (using ICD9 codes: birth trauma/injuries, hypoxia/asphyxia, shock/resuscitation/complications, respiratory disorders, infections, and neurologic disorders. This is kept as Set "A".
Step 2: In the population without these codes, the disposition field is scanned to identify neonatal deaths and neonatal transports to another institution. these are kept as Set "B".
Step 3: In the group that did not die or was transfered, examine for LOS (Discharge date-delivery date). If >5 days then examine for exclusions for social and hyperbilirubinemia codes. THose without exclusions are kept as Set "C".
Step 4: Set N is calculated as the union of sets A+B+C
Step 5: Numerator is calculated as: (D-N)/D x100

**2a.22 Describe the method for discriminating performance** *(e.g., significance testing)***:**
We have used both top and bottom quintiles and 95%tile cutoffs for discriminating performance.

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

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

**2a.25 Data source/data collection instrument (***Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
n/a

**2a.26-28 Data source/data collection instrument reference web page URL or attachment:**

**2a.29-31 Data dictionary/code table web page URL or attachment:**

**2a.32-35 Level of Measurement/Analysis** (*Check the level(s) for which the measure is specified and tested)*
Clinicians: Group, Facility/Agency, Multi-site/corporate chain, Can be measured at all levels

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

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

## TESTING/ANALYSIS

**2b. Reliability testing** — **2b C☐**

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| **2b.1 Data/sample** *(description of data/sample and size)*: This measure has been tested on California discharge data sets for several years (2004 to 2007) with ~560,000 births per year. We also examined these codes on the HCUP data set that comprised over 8 million births.<br><br>**2b.2 Analytic Method** *(type of reliability & rationale, method for testing)*:<br>We examined intra-hospital consistency year over year (in the absence of intervention efforts) and found them very similar. This does not imply accuracy (same coding errors could be repeated) but does imply consistency of the measure.<br><br>**2b.3 Testing Results** *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:<br>There is concern for under-reporting of several of these diagnoses codes (especially those for hypoxia/asphyxia) which is why we went to the procedure codes for thoroughness of ascertainment. This is well supported by our earlier studies looking at Cesarean rates and neonatal outcomes (Gould, 2006). | P☐<br>M☐<br>N☐ |
| **2c. Validity testing**<br><br>**2c.1 Data/sample** *(description of data/sample and size)*: see below<br><br>**2c.2 Analytic Method** *(type of validity & rationale, method for testing)*:<br>Data correlations of the entire measure to other measures of have not been done. Comparisons of components codes to establish linkages to quality of care have been done by us and others (Gould, 1996; Gregory, 2009, among many others)<br><br>**2c.3 Testing Results** *(statistical results, assessment of adequacy in the context of norms for the test conducted)*:<br>Face validity was tested by discussions with both patient groups (see above) and with physician groups. THe later have long sought a way to measure healthy babies rather than just the more rare damaged infants. The inclusions were also seen by groups of obstetricians and neonatologists as fair and appropriate. | **2c**<br>C☐<br>P☐<br>M☐<br>N☐ |
| **2d. Exclusions Justified**<br><br>**2d.1 Summary of Evidence supporting exclusion(s):**<br>THe categories of exclusions will be discussed one by one:<br>Twins have very different issues than singletons and are often delivered for very different reasons and different times so they are are hard to group together with healthy singletons. THey comprise 1.5% of all births and only 0.5% of births over 37 weeks.<br>Preterm infants have very strong rates of morbidity and would overwhelm measures of term baby morbidity. Much of their is not preventable postnatally. There exists a NQF measure for administration of antenatal steroids for this population. Preterm births account for 12-13% of US births.<br>Congenital anomalies are an important source of neonatal morbidity but there is little to be done by the medical system for prevention. Many are prenatally diagnosed and so the family goes into the birth process knowing not to expect a "normal term newborn". Major congenital anomalies account for 1-2% of term births.<br>Likewise, Small for dates infants and infants with isoimmunization and drug withdrawal all have conditions acquired in utero and not in the birth process.<br><br>**2d.2 Citations for Evidence:**<br>these are textbook level exclusions.<br><br>**2d.3 Data/sample** *(description of data/sample and size)*: n/a<br><br>**2d.4 Analytic Method** *(type analysis & rationale)*:<br>n/a<br><br>**2d.5 Testing Results** *(e.g., frequency, variability, sensitivity analyses)*:<br>n/a | **2d**<br>C☐<br>P☐<br>M☐<br>N☐<br>NA☐ |

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| **2e. Risk Adjustment for Outcomes/ Resource Use Measures**<br><br>2e.1 **Data/sample** *(description of data/sample and size)*: n/a<br><br>2e.2 **Analytic Method** *(type of risk adjustment, analysis, & rationale)*:<br>n/a<br><br>2e.3 **Testing Results** *(risk model performance metrics)*:<br>n/a<br><br>2e.4 **If outcome or resource use measure is not risk adjusted, provide rationale:** Risk adjustment is not done as with the exclusions above we feel that we have a homogenious enough population not to disadvantage a particular type of hospital. We do intend to test and potentially stratify hospitals by size as noted above. | **2e**<br>C☐<br>P☐<br>M☐<br>N☐<br>NA☐ |
| **2f. Identification of Meaningful Differences in Performance**<br><br>2f.1 **Data/sample from Testing or Current Use** *(description of data/sample and size)*: Using California data (Patient Discharge Diagnosis sets) with >560,000 newborns reported each year, wer identied that this this measure falls into a reasonable bell shaped curve of hospital results.<br><br>2f.2 **Methods to identify statistically significant and practically/meaningfully differences in performance** *(type of analysis & rationale)*:<br>We have used both 95%tile at both ends and quintiles. It is not yet clear which will be superior for such needs as public reporting or benchmarking.<br><br>2f.3 **Provide Measure Scores from Testing or Current Use** *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:<br>We have used both 95%tile at both ends and quintiles. It is not yet clear which will be superior for such needs as public reporting or benchmarking. | **2f**<br>C☐<br>P☐<br>M☐<br>N☐ |
| **2g. Comparability of Multiple Data Sources/Methods**<br><br>2g.1 **Data/sample** *(description of data/sample and size)*: n/a<br><br>2g.2 **Analytic Method** *(type of analysis & rationale)*:<br>n/a<br><br>2g.3 **Testing Results** *(e.g., correlation statistics, comparison of rankings)*:<br>n/a | **2g**<br>C☐<br>P☐<br>M☐<br>N☐<br>NA☐ |
| **2h. Disparities in Care**<br><br>2h.**1 If measure is stratified, provide stratified results** *(scores by stratified categories/cohorts)*: We have not yet systematically analyzed this measure for race and and ethnicity. THis is planned for 2010 and will be added to the project as needed.<br><br>2h.2 **If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:**<br>n/a | **2h**<br>C☐<br>P☐<br>M☐<br>N☐<br>NA☐ |
| **TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for** *Scientific Acceptability of Measure Properties*? | **2** |
| **Steering Committee: Overall, to what extent was the criterion,** *Scientific Acceptability of Measure Properties*, **met?**<br>**Rationale:** | *2*<br>C☐<br>P☐<br>M☐<br>N☐ |
| **3. USABILITY** | |

| Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria) | Eval Rating |
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| **3a. Meaningful, Understandable, and Useful Information**<br><br>3a.1 **Current Use:** Not in use but testing completed<br><br>3a.2 **Use in a public reporting initiative (disclosure of performance results to the public at large)** (*If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years*)**:**<br>We plan to use this measure for public reporting within the next 1-2 years. California has well developed public reporting system (CHART) that we work with extensively with and they are very interested.<br><br>3a.3 **If used in other programs/initiatives (***If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years***):**<br>We will be using this measure in several current projects in California over the next 2 years. Several large health systems have expressed major interest in usig it as part of their QI including SUtter Health (40,000 annual births) and Southern California Kaiser-Permanente (34,000 annual births). It is designed to be a balancing measure for maternal measures already in place (Low-risk age adjusted Cesarean birth rate in first births, episiotomy rates, elective births in 37-39 week pregnancies).<br><br>**Testing of Interpretability** (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*)<br>3a.4 **Data/sample** *(description of data/sample and size)***:** 5 groups averaging 15 women each representing a cross section of racial and ethnic groups in San Francisco.<br><br>3a.5 **Methods** *(e.g., focus group, survey, QI project)***:**<br>Focus groups of pregnant women during childbirth education classes.<br><br>3a.6 **Results** *(qualitative and/or quantitative results and conclusions)***:**<br>We have done informal focus groups of several of current maternity QI measures and the premise of this one is the easily the best understood: "If i come to the hospital with a normal pregnancy, what is my chance of leaving the hospital with a heathy newborn-- no major complications, no NICU admission or major procedures done." Their responses confirmed the literature that a normal baby is their most desired and important outcome. | **3a**<br>**C**☐<br>**P**☐<br>**M**☐<br>**N**☐ |
| **3b/3c. Relation to other NQF-endorsed measures**<br><br>3b.1 **NQF # and Title of similar or related measures:**<br>#0474 Birth trauma | |
| (for NQF staff use) **Notes on similar/related** endorsed **or submitted measures:** | |
| **3b. Harmonization**<br>If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population):<br>3b.2 **Are the measure specifications harmonized? If not, why?**<br>#0474 Birth trauma includes a small number of birth injury codes and has a very low incidence (<3/1,000 births). Healthy Term Newborn measure includes all of the codes in #0474 and many more providing an incidence of 20-50/1,000 births. As the current measure is much more inclusive of a variety of neonatal morbidities (and inlcudes more birth injuries than #0474). this is because it has a different philosphy: #0474 required that all the neonatal codes be well established that thery were casued by provider actions. The current proposed mesure is lookinng at health and does not require that causation is established for every morbidity. | **3b**<br>**C**☐<br>**P**☐<br>**M**☐<br>**N**☐<br>**NA**☐ |
| **3c. Distinctive or Additive Value**<br>3c.1 **Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:**<br>#0474 provides a very limited window into term and near term infant morbidities from a single perspective | **3c**<br>**C**☐<br>**P**☐<br>**M**☐ |

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| of birth trauma. There are many other morbidities in term infants that are much more common and more important. The proposed measure covers all of them that were not related to diseases that the baby did not have upon walking into the hospital. Again our current measure has a very different focus: "If i come to the hospital with a normal pregnancy, what is my chance of leaving the hospital with a heathy newborn-- no major complications, no NICU admission or major procedures done."<br><br>5.1 **If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:**<br>The proposed measure is much broader and focuses on normal outcome than #0474. There are number of current large scale QI projects that will make use of the proposed measure to judge neonatal outcomes. THe larger incidence allows for much better statistical analysis and discrimination. | **N☐ NA☐** |
| **TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for** *Usability?* | **3** |
| **Steering Committee: Overall, to what extent was the criterion,** *Usability*, **met?**<br>**Rationale:** | **3**<br>**C☐ P☐ M☐ N☐** |
| **4. FEASIBILITY** | |
| Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria) | Eval Rating |
| **4a. Data Generated as a Byproduct of Care Processes**<br><br>4a.1-2 **How are the data elements that are needed to compute measure scores generated?**<br>Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry) | **4a**<br>**C☐ P☐ M☐ N☐** |
| **4b. Electronic Sources**<br><br>4b.1 **Are all the data elements available electronically?** (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*)<br>No<br><br>4b.2 **If not, specify the near-term path to achieve electronic capture by most providers.** | **4b**<br>**C☐ P☐ M☐ N☐** |
| **4c. Exclusions**<br><br>4c.1 **Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?**<br>No<br><br>4c.2 **If yes, provide justification.** | **4c**<br>**C☐ P☐ M☐ N☐ NA☐** |
| **4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences**<br><br>4d.1 **Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.**<br>As a hedge against incomplete coding we are using both diagnosis codes and procedure codes. The later are more faithfully recorded as they drive payment, Nonetheless, this is an opportunity to teach and improve coding (coding does not improve until it is used for something meaningful. As a back-up within this measure we are also identifying and counting babies with long NICU stays even if their diagnosis codes are not robust. No formal audits have been done. | **4d**<br>**C☐ P☐ M☐ N☐** |
| **4e. Data Collection Strategy/Implementation** | **4e**<br>**C☐** |

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| **4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:**<br>data collection has not been as issue as this is completely collectible using administrative data sets.<br><br>**4e.2 Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:**<br>no additional costs for collection. Some costs for QI activities around this topic. There are no fees for this measure.<br><br>**4e.3 Evidence for costs:**<br><br>**4e.4 Business case documentation:** | **P☐ M☐ N☐** |
| **TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for** *Feasibility*? | **4** |
| **Steering Committee: Overall, to what extent was the criterion,** *Feasibility*, **met?**<br>**Rationale:** | **4**<br>**C☐ P☐ M☐ N☐** |
| **RECOMMENDATION** | |
| (for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.** | **Time-limited ☐** |
| **Steering Committee: Do you recommend for endorsement?**<br>**Comments:** | **Y☐ N☐ A☐** |
| **CONTACT INFORMATION** | |
| **Co.1 Measure Steward (Intellectual Property Owner)**<br>**Co.1 Organization**<br>California Maternal Quality Care Collaborative (CMQCC), Medical School Office Building, 251 Campus Drive, MS 5415 , Stanford, California, 94305<br><br>**Co.2 Point of Contact**<br>Elliott, Main, MD, main@cmqcc.org, 415-992-2252- | |
| **Measure Developer If different from Measure Steward**<br>**Co.3 Organization**<br>California Maternal Quality Care Collaborative (CMQCC), Medical School Office Building, 251 Campus Drive, MS 5415 , Stanford, California, 94305<br><br>**Co.4 Point of Contact**<br>Elliott, Main, MD, main@cmqcc.org, 415-992-2252- | |
| **Co.5 Submitter If different from Measure Steward POC**<br>Elliott, Main, MD, main@cmqcc.org, 415-992-2252-, California Maternal Quality Care Collaborative (CMQCC) | |
| **Co.6 Additional organizations that sponsored/participated in measure development** | |
| **ADDITIONAL INFORMATION** | |
| **Workgroup/Expert Panel involved in measure development**<br>**Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.** | |

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| CPQCC members: Terri Slagle, MD and Richard Powers, MD (both Neonatologists long active in QI research)<br>MQI members: Kimberly Gregory, M.D., MPH; Lisa Korst, MD PhD; Moshe Freedman, PhD; Sona Shah, MPH; Michael Lu, MD MPH.<br>CMQCC members: Elliott Main, MD; Debra Bingham RN DrPH; Kathryn Melsop, MS<br>THe entire team reviewed and discussed the concepts and ICD9 codes. MQI did the first pass of the data analysis, CMQCC did subsequent. Testing with focus groups and with other organizations was done by CMQCC. |
| **Ad.2 If adapted, provide name of original measure:** n/a<br>**Ad.3-5 If adapted, provide original specifications URL or attachment** |
| **Measure Developer/Steward Updates and Ongoing Maintenance**<br>**Ad.6 Year the measure was first released:** 2009<br>**Ad.7 Month and Year of most recent revision:** 01, 2010<br>**Ad.8 What is your frequency for review/update of this measure?** every 2 years<br>**Ad.9 When is the next scheduled review/update for this measure?** 01, 2012 |
| **Ad.10 Copyright statement/disclaimers:** THis will be in the public domain. |
| **Ad.11 -13 Additional Information web page URL or attachment:** |
| **Date of Submission** (*MM/DD/YY*)**:** 02/06/2010 |