



TO: Consensus Standards Approval Committee

FR: Helen Burstin, MD, MPH

SU: Letters of Appeal on Perinatal Measures

DA: May 4, 2012

A letter of appeal was submitted regarding measure *0480 Exclusive Breast Milk*Feeding endorsed in the *Perinatal and Reproductive Healthcare Endorsement*Maintenance project report. The letter was submitted by the Executive Vice

President for the International Formula Council (ICF). In accordance with the NQF

CDP, this measure was evaluated and recommended by the NQF Perinatal and

Reproductive Healthcare Measures Steering Committee and released for member and public comment. The committee recommendations and member voting results were reviewed by the CSAC. The CSAC recommended the measures for endorsement and the Board of Directors endorsed the set of measures on March 30, 2012.

The following materials are attached for your reference:

- Appendix A: 0480 Exclusive breast milk feeding measure specifications;
- Appendix B: Letter of Appeal (from the International Formula Council)
- Appendix C: Response from the measure developer (the Joint Commission);
- Appendix D: Prior CSAC memo on the measure, including voting results.

The NQF Consensus Development Process version 1.8 includes an appeal process and states that "anyone may register a request for reconsideration of an endorsed voluntary consensus standard by notifying the NQF in writing within 30 days of public notification that the voluntary consensus standard had been approved by the CSAC. For an appeal to be considered, the notification letter to the NQF must include information clearly demonstrating that the appellant has interests that are directly and materially affected by the NQF-endorsed voluntary consensus standard(s), and that the NQF decision has had (or will have) an adverse effect on those interests. Appeals will be reviewed by NQF staff and management, who may consult with the project's technical advisors, Steering Committee, and/or other sources, as appropriate, before a recommendation is provided to the CSAC and BoD. Following consultation with the CSAC, the BoD shall act on an appeal within seven

calendar days of the CSAC's recommendation to BoD regarding the appeal. The result of this BoD action shall be promulgated in the same manner as the original decision. NQF will maintain a record of all appeals, as well as post them on the web site."

#### **Subject of the Appeals**

An appeal from the International Formula Council was received regarding the following measure:

#### 0480 PC-05 Exclusive Breast Milk Feeding (the Joint Commission)

This measure assesses the number of newborns exclusively fed breast milk feeding during the newborn's entire hospitalization. This measure is a part of a set of five nationally implemented measures that address perinatal care (PC-01: Elective Delivery, PC-02: Cesarean Section, PC-03: Antenatal Steroids, PC-04: Health Care-Associated Bloodstream Infections in Newborns).

IFC requested reconsideration of the endorsement of the measure. The appellant's primary objection to the measure is that it does not include a mother's choice not to breastfeed as an exclusion. They had raised similar concerns about the measure previously and these concerns were discussed throughout the evaluation process.

The appeal letter and the measure developer's response are attached (Appendices B and C). Please refer to the letters for a complete discussion. Portions of the appeal letter are excerpted below.

- We believe that families' right to choose and be supported in their infant feeding decisions is not being upheld or protected.
- As we previously noted, a mother's choice not to breastfeed is <u>not</u> recognized as reason for exclusion from the The Joint Commission's (TJC) Perinatal Measure of Exclusive Breastfeeding and the NQF's endorsement of the measure. We continue to be concerned that by excluding this option, the measure may be interpreted to mean that a mother's choice is not a valid reason for not exclusively feeding breast milk, and that such measures may be used to discourage hospitals and health care professionals from recognizing, supporting, or respecting mothers who chose not to exclusively breastfeed their infants.
- This approach conflicts with the recommendations of health authorities. The World Health Organization's (WHO) *Global Strategy for Infant and Young Child*

Feeding<sup>1</sup> states moms should be supported in their feeding decision. Additionally, in the recent *Call to Action to Support Breastfeeding*, both the Surgeon General and the Health and Human Services Secretary advocate no mother should be made to feel guilty if she cannot or chooses not to breastfeed.<sup>2</sup>

• We would also support a complementary measurement strategy as suggested by another NQF Steering Committee member who said, "a complementary measurement strategy would assure we're not overly coercive... once this is implemented." The member suggested "a consumer assessment health plan survey" asking "...did you get the support you need? Was your choice respected?" Unfortunately, this suggestion also was not implemented.

#### Response

Evaluation of Measures During the Consensus Development Process

#### 0480 PC-05 Exclusive Breast Milk Feeding

Maintenance Measure

**Description:** This measure assesses the number of newborns exclusively fed breast milk feeding during the newborn's entire hospitalization. This measure is a part of a set of five nationally implemented measures that address perinatal care (PC-01: Elective Delivery, PC-02: Cesarean Section, PC-03: Antenatal Steroids, PC-04: Health Care-Associated Bloodstream Infections in Newborns).

Numerator Statement: Newborns that were fed breast milk only since birth

**Denominator Statement:** Single term liveborn newborns discharged from the hospital with ICD-9-CM Principal Diagnosis Code or ICD-9-CM Other Diagnosis Codes for single liveborn newborn as defined in Appendix A, Table 11.20.1available at: http://manual.jointcommission.org

#### **Exclusions:**

- Admitted to the Neonatal Intensive Care Unit (NICU) at this hospital during the hospitalization
- ICD-9-CM Principal Diagnosis Code or ICD-9-CM Other Diagnosis Codes for galactosemia as defined in Appendix A, Table 11.21
- ICD-9-CM Principal Procedure Code or ICD-9-CM Other Procedure Codes for parenteral infusion as defined in Appendix A, Table 11.22
- Experienced death
- Length of Stay >120 days
- Enrolled in clinical trials
- Documented Reason for Not Exclusively Feeding Breast Milk
- Patients transferred to another hospital
- ICD-9-CM Principal Diagnosis Code or ICD-9-CM Other Diagnosis Codes for premature newborns as defined in

Appendix A, Table 11.23

Adjustment/Stratification: No risk adjustment or risk stratification Not Applicable

Level of Analysis: Facility, Population: National

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Paper Records

Measure Steward: The Joint Commission

#### STEERING COMMITTEE MEETING 11/29-30/2011

Importance to Measure and Report: Y-21; N-3

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

Workgroup ratings of the sub-criteria:

1a. Impact: H-4; M-1; L-0; I-0; 1b. Performance Gap: H-4; M-1; L-0; I-0

#### 0480 PC-05 Exclusive Breast Milk Feeding

1c. Evidence Quantity: H-4; M-1; L-0; I-0; Quality: H-5; M-0; L-0; I-0; Consistency: H-5; M-0; L-0; I-0 Rationale:

- Documented medical benefits to baby; some issues with intent and implementation of "exclusive"
- Exclusive breastfeeding during hospitalization and at discharge increases longer term breastfeeding
- Current performance = 41%
- Data presented on racial and ethnic disparities- large disparities; very susceptible to values of the patient population
- Large nursing component a systems issue of the hospital environment
- Goal is not 100% -- Healthy People 2010 set a 75% target

#### 2. Scientific Acceptability of Measure Properties: Y-22; N-2

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

Workgroup ratings of the subcriteria:

2a. Reliability: H-3; M-2; L-0; I-0 2b. Validity: H-5; M-0; L-0; I-0

#### Rationale:

- A Committee member noted that if the measure is "risk-adjusted" for race and educational level, 40% of the variance is removed
- Measure is not stratified for disparities developers note lack of reliability in the data element for race needed for stratification. Some Committee members argued that "rules now exist" to assign race.
- Exclusions for NICU, HIV, multiple births, transfers, mom taking drugs or medications
- Sampling is allowed

#### 3. Usability: H-16; M-6; L-2; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

Workgroup ratings of the subcriteria:

3a. Public Reporting: H-5; M-0; L-0; I-0

3b. QI: H-4; M-1; L-0; I-0

#### Rationale:

- Would also be good as a population –level measure communities can facilitate change in attitudes and cultural values
- Health benefits for the child and the mother
- The bar may be too high for some users consider intermediate process measures to facilitate adoption.

#### 4. Feasibility: H-9; M-12; L-3; I-0

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Workgroup ratings of the subcriteria:

- 4a. Byproduct of Care Processes: H-4; M-1; L-0; I-0
- 4b. Electronic data sources: H-5; M-0; L-0; I-0
- 4c. Suscep inaccuracies, consequences: H-2; M-2; L-0; I-0
- 4d. Data collection strategy: H-3; M-2; L-0; I-0

#### Rationale:

- Possible encroachment on patient autonomy overzealous insistence on breastfeeding can alienate mothers.
- Labor intensive to collect data unless data collection (feeding) forms are designed well
- An important measure for Medicaid

#### Steering Committee Recommendation for Endorsement: Y-20; N-4

**Rationale:** Breast milk feeding confers many health benefits to mother and child. Current rates of breast milk feeding are low with much room for improvement. Supporting breast milk feeding requires strong systems support and significant nursing

#### 0480 PC-05 Exclusive Breast Milk Feeding

involvement.

#### **Public & Member Comment**

#### Comments included:

- Ten comments noting the benefits of breastfeeding, but raising concerns about "mandated breastfeeding".
   Commenters were also concerned about a woman's right to choose whether or not to breastfeed, and whether the measure would prevent women who chose not to breastfeed from receiving proper education and information on alternatives.
- Measure also received eight supportive comments, stating that the health reasons for breastfeeding are well
  documented, that the measure would not mandate breastfeeding for all babies, and that performance for this measure
  is not expected to be at 100%.

#### **Steering Committee:**

The Committee underscored the significant health benefits for newborns (reduction in otitis media, respiratory tract infections, atopic dermatitis, gastroenteritis, type 2 diabetes, sudden infant death syndrome, and obesity) and mother (decreased risk for type 2 diabetes, ovarian cancer, and breast cancer) conferred by breastfeeding and support all efforts to optimize maternal education, encouragement, and support to enable women to make the healthiest choices for herself and her child. The Committee agreed that improving support for mothers who wish to breastfeed does not equal removing a choice. The Committee acknowledged that the target for this measure is not 100% and that the potential unintended consequences of "inappropriate coercion" should be monitored.

The Committee noted that current performance is quite low at 40% with much room for improvement. Both the Committee and the developer agreed that the purpose of the measure is to eliminate impediments to breastfeeding. According to the CDC, <a href="http://www.cdc.gov/breastfeeding/data/reportcard.htm">(http://www.cdc.gov/breastfeeding/data/reportcard.htm</a>) "less than 5% of U.S. infants are born in Baby-Friendly hospitals, a global designation that indicates best practices in maternity care to support breastfeeding mothers. The hospital period is critical for mothers and babies to learn to breastfeed, and hospitals need to do more to support them. Birth facility policies and practices significantly impact whether a woman chooses to start breastfeeding and how long she continues to breastfeed." The Committee recommends additional process measures to assist facilities in improving support for breastfeeding.

The Committee agreed to maintain their recommendation of the measure.

#### **NQF** Member Voting

The 30-day voting period for the Perinatal and Reproductive Healthcare Endorsement Maintenance project closed on February 27, 2012.

Measure #0480 PC-05 Exclusive					
Breast Milk Feeding					
				Total	%
Measure Council	Yes	No	Abstain	Votes	Approval*
Consumer	4	0	0	4	100%
Health Plan	5	0	0	5	100%
Health Professional	3	0	1	4	100%

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Provider Organizations	3	1	0	4	75%
Public/Community Health Agency	0	0	0	0	
Purchaser	7	0	0	7	100%
QMRI	2	0	0	2	100%
Supplier/Industry	0	0	0	0	
All Councils	24	1	1	26	96%
Percentage of councils approving					
(>50%)					100%
Average council percentage approval					96%
*equation: Yes/ (Total - Abstain)					

#### **Discussion**

The intent of this measure is to encourage and support mothers in making the healthiest choice for themselves and their baby. Education and support for breastfeeding should begin during pregnancy so that mothers are prepared to feed their newborn. This requires collaboration and coordination between the practitioners and the hospital.

In March, 2012, the American Academy of Pediatrics released an update of their breast feeding policy statement:

Breastfeeding and human milk are the normative standards for infant feeding and nutrition. Given the documented short- and long-term medical and neurodevelopment advantages of breastfeeding, infant nutrition should be considered a public health issue and not only a lifestyle choice. The American Academy of Pediatrics reaffirms its recommendation of exclusive breastfeeding for about 6 months, followed by continued breastfeeding as complementary foods are introduced, with continuation of breastfeeding for 1 year or longer as mutually desired by mother and infant. Medical contraindications to breastfeeding are rare. <sup>1</sup>

During the Perinatal project, the Steering Committee recommended development of additional measures around breastfeeding, including measures to support hospitals in making progress toward better performance on measure 480: Exclusive Breast Milk Feeding, such as measures of rates of exclusive breastfeeding stratified by maternal

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<sup>&</sup>lt;sup>1</sup> Breastfeeding and the Use of Human Milk SECTION ON BREASTFEEDING *Pediatrics* 2012;129;e827; originally published online February 27, 2012; DOI: 10.1542/peds.2011-3552

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intention to breastfeed; and measures of rates of breastfeeding for infants cared for in NICUs stratified by weight groups and gestational age.

The Joint Commission, in their May 4, 2012 response, has indicated that they intend "to modify this measure in an upcoming version of our specifications manual such that the original measure will be retained as currently specified. However, an additional stratified rate will be computed which will exclude those newborns whose maternal choice was to not breastfeed. Details of the specifications for the stratified rate are still being worked out, but it is hoped that this addition will provide clarification behind the exclusive breast milk feeding measure rate."

Overall, the issues raised in the appeal have been considered during the Consensus Development Process. The additional stratified rate planned by the Joint Commission addresses the concerns raised by the appellant and the Steering Committee's recommendation for monitoring of unintended consequences during implementation of the measure.

## 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 #: 0480 NQF Project: Perinatal and Reproductive Health Project

(for Endorsement Maintenance Review)

Original Endorsement Date: Oct 24, 2008 Most Recent Endorsement Date: Mar 30, 2012 Last

Updated Date: Apr 25, 2012

#### **BRIEF MEASURE INFORMATION**

De.1 Measure Title: PC-05 Exclusive Breast Milk Feeding

Co.1.1 Measure Steward: The Joint Commission

**De.2 Brief Description of Measure:** This measure assesses the number of newborns exclusively fed breast milk feeding during the newborn's entire hospitalization. This measure is a part of a set of five nationally implemented measures that address perinatal care (PC-01: Elective Delivery, PC-02: Cesarean Section, PC-03: Antenatal Steroids, PC-04: Health Care-Associated Bloodstream Infections in Newborns).

2a1.1 Numerator Statement: Newborns that were fed breast milk only since birth

**2a1.4 Denominator Statement:** Single term liveborn newborns discharged from the hospital with ICD-9-CM Principal Diagnosis Code or ICD-9-CM Other Diagnosis Codes for single liveborn newborn as defined in Appendix A, Table 11.20.1available at: http://manual.jointcommission.org

**2a1.8 Denominator Exclusions:** • Admitted to the Neonatal Intensive Care Unit (NICU) at this hospital during the hospitalization

- ICD-9-CM Principal Diagnosis Code or ICD-9-CM Other Diagnosis Codes for galactosemia as defined in Appendix A, Table 11.21
- ICD-9-CM Principal Procedure Code or ICD-9-CM Other Procedure Codes for parenteral infusion as defined in Appendix A, Table 11.22
- Experienced death
- Length of Stay >120 days
- Enrolled in clinical trials
- Documented Reason for Not Exclusively Feeding Breast Milk
- Patients transferred to another hospital
- ICD-9-CM Principal Diagnosis Code or ICD-9-CM Other Diagnosis Codes for premature newborns as defined in Appendix A, Table 11.23
- 1.1 Measure Type: Process

2a1. 25-26 Data Source: Administrative claims, Electronic Clinical Data, Paper Medical Records

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

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:**

Is the measure untested? Yes No If untested, explain how it meets criteria for consideration for time-limited endorsement:

- 1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (check De.5):
- **5. Similar/related** endorsed or submitted measures (*check 5.1*): Other Criteria:

**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: HO MO LO I O

(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 and Reproductive Health **De.5 Cross Cutting Areas** (Check all the areas that apply): Patient and Family Engagement
- **1a.1 Demonstrated High Impact Aspect of Healthcare:** Affects large numbers, Patient/societal consequences of poor quality
- 1a.2 If "Other," please describe:
- 1a.3 Summary of Evidence of High Impact (Provide epidemiologic or resource use data):

Exclusive breast milk feeding for the first 6 months of neonatal life has long been the expressed goal of World Health Organization (WHO), US Department of Health and Human Services (DHHS), American Academy of Pediatrics (AAP) and American College of Obstetricians and Gynecologists (ACOG). ACOG reiterated its position in a Committee Opinion on breastfeeding (ACOG, 2007). Additionally, a Cochrane review of two randomized control trials and 18 other studies substantiates the benefits of exclusive breast milk feeding for the first six months of life (Kramer et al., 2002).

Breastfeeding is associated with decreased risk for many early-life diseases and conditions, including otitis media, respiratory tract infections, atopic dermatitis, gastroenteritis, type 2 diabetes, sudden infant death syndrome, and obesity. Breastfeeding also is associated with health benefits to women, including decreased risk for type 2 diabetes, ovarian cancer, and breast cancer (Ip et al., 2007). Exclusive breastfeeding is defined as a newborn receiving only breast milk and no other liquids or solids except for drops or syrups consisting of vitamins, minerals, or medicines (WHO, 1991).

In 2007, Healthy People 2010 objectives for breastfeeding initiation and duration included two new objectives on exclusive breastfeeding to increase the proportion of mothers who exclusively breastfeed their infants through age 3 months to 60% and through age 6 months to 25% [objectives 16-19d and 16-19e] (DHHS, 2000). The Healthy People 2020 objectives for exclusive breastfeeding were continued through age 3 months with a goal of 46.2% and age 6 months with a goal of 25.5% [objectives MICH-21.4 and MICH-21.5]. Also included is the related objective MICH-24: increase the proportion of live births that occur in facilities that provide recommended care for lactating mothers and their babies (DHHS, 2010).

The Centers for Disease Control and Prevention (CDC) developed a Guide to Breastfeeding Interventions in 2005 for the promotion and support of breastfeeding based on detailed input from the spectrum of

breastfeeding experts which can be used to help hospitals achieve the Healthy People 2020 objective MICH-24. Institutional changes i.e., attaining Baby Friendly Hospital Initiative status, individual interventions including increased rooming-in of mothers and newborns, early skin to skin contact and discontinuing policies that are not evidence based have been shown to increase breastfeeding initiation and duration rates as well (Shealy et al., 2007). According to the CDC (2011), mothers who want to breastfeed who do not receive hospital support will stop early. The CDC encourages hospitals to partner with Baby-Friendly hospitals to learn how to improve maternity care, use the CDC's Maternity Practice in Infant Nutrition and Care (mPINC) survey data to prioritize changes to improve maternity care practices and stop distributing formula samples and give-aways to breastfeeding mothers.

- **1a.4 Citations for Evidence of High Impact cited in 1a.3:** American College of Obstetricians and Gynecologists (ACOG). (Feb. 2007). Committee on Obstetric Practice and Committee on Health Care for Underserved Women. Breastfeeding: Maternal and Infant Aspects. ACOG Committee Opinion 361.
- Centers for Disease Control and Prevention (CDC). (2011). Hospital support for breastfeeding: Preventing obesity begins in hospitals. CDC Vital Signs, Retrieved September 26, 2011 at: http://www.cdc.gov/VitalSigns/pdf/2011-08-vitalsigns.pdf
- Ip S, Chung M, Raman G, et al. Breastfeeding and maternal and infant health outcomes in developed countries. Rockville, MD: US Department of Health and Human Services; 2007. Retrieved on September 27, 2011 at: http://www.ahrq.gov/downloads/pub/evidence/pdf/brfout/brfout.pdf.
- Kramer, M.S. & Kakuma, R. (2002). Optimal duration of exclusive breastfeeding. [107 refs] Cochrane Database of Systematic Reviews. (1):CD003517.
- Shealy, K.R., Li, R., Benton-Davis, S., & Grummer-Strawn, L.M. (2005). The CDC guide to breastfeeding interventions. Atlanta, GA: US Department of Health and Human Services, CDC. Available at: http://www.cdc.gov/breastfeeding/pdf/breastfeeding\_interventions.pdf
- US Department of Health and Human Services (DHHS). (2000). Healthy People 2010. Washington, DC. Retrieved on Setember 26, 2011 at: http://www.healthypeople.gov/2010
- US Department of Health and Human Services (DHHS). (2010). Healthy People 2020. Washington, DC. Retrieved on September 26, 2011 at: http://www.healthypeople.gov/2020
- World Health Organization (WHO). Indicators for assessing breastfeeding practices. Geneva, Switzerland: World Health Organization; 1991. Retrieved on September 27, 2011 at: http://www.who.int/child-adolescent-health/new publications/nutrition/who cdd ser 91.14.pdf.

#### 1b. Opportunity for Improvement: HO MO LO I O

(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: Increasing the number of newborns who are exclusively fed breast milk for the first six months of life remains a major goal of the WHO, DHHS, AAP and ACOG. Guidelines for the promotion of breast milk feeding are available from the CDC to assist hospitals in establishing successful interventions to improve exclusive breast milk feeding rates in newborns. Breast milk feeding results in numerous health benefits for both mother and newborn. Breastfeeding is associated with decreased risk for many early-life diseases and conditions, including otitis media, respiratory tract infections, atopic dermatitis, gastroenteritis, type 2 diabetes, sudden infant death syndrome, and obesity. Breastfeeding also is associated with health benefits to women, including decreased risk for type 2 diabetes, ovarian cancer, and breast cancer. The measure will assist health care organizations (HCOs) to track evidence of an increase in the number of newborns who were exclusively fed breast milk during the birth hospitalization.
- **1b.2 Summary of Data Demonstrating Performance Gap** (Variation or overall less than optimal performance across providers): [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 2007, the CDC analyzed data from the National Immunization Survey (NIS). The report indicated that even though rates for breastfeeding initiation and duration increased among infants born during 2000-2004, rates for exclusive breastfeeding through ages 3 months and 6 months among infants born in 2004 were 30.5% and 11.3%, respectively, below targets set by Healthy People 2010 (CDC, 2007). These rates are

still below the new targets set by Healthy People 2020 (DHHS, 2010).

Based on 4 quarters of data reported to The Joint Commission, PC-05 has an aggregate performance rate of 41.5 %, indicating a potential performance gap of 33.5% based on the Healthy People 2010 goal of 75% of mothers breastfeeding at hospital discharge.

- **1b.3 Citations for Data on Performance Gap:** [For <u>Maintenance</u> 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]
- Centers for Disease Control and Prevention (CDC). (2007). Breastfeeding trends and updated national health objectives for exclusive breastfeeding--United States, birth years 2000-2004. [Journal Article] MMWR Morbidity & Mortality Weekly Report. 56(30):760-3.
- The Joint Commission, unpublished data, 2011.
- US Department of Health and Human Services (DHHS). (2010). Healthy People 2020. Washington, DC. Retrieved on September 26, 2011 at: http://www.healthypeople.gov/2020
- **1b.4 Summary of Data on Disparities by Population Group:** [For <u>Maintenance</u> –Descriptive statistics for performance results <u>for this measure</u> by population group]

A study was conducted by Petrova et al. (2007) to identify the association between the in-hospital feeding pattern and the infant's post discharge feeding modality during the first month of life in a culturally diverse population of women. Demographic, clinical, and feeding practice data were collected from the medical charts and interviews of mothers conducted in the first month after singleton delivery of healthy term newborns. Among the 307 mothers who completed the study, exclusive in-hospital breast milk feeding was reported by 54.2% of white, 38.7% of black, 54.0% of asian, and 44.7% of hispanic (p = 0.063), and among these, only 55.6%, 50.0%, 58.9%, and 19.1%, respectively, maintained exclusive breast milk feeding during the first postpartum month (p < 0.02). The rate of exclusive breast milk feeding at the end of the first month was 10.5%, 15.8%, 20.7%, and 3.9%, respectively, for the white, black, asian, and hispanic mothers whose infants received partial or no breastfeeding in-hospital. Overall, the logistic regression analysis showed significant association between initiation of exclusive breast milk feeding in-hospital and exclusive breast milk feeding at the end of the first month (odds ratio 7.2 and 95% confidence interval 4.0, 12.6). In conclusion, it showed a larger decline in the continuation of exclusive breast milk feeding and the lowest rate of exclusive breast milk feeding at 1 month in the hispanic mothers. Irrespective of race/ethnicity, mothers who practice exclusive breast milk feeding in-hospital are more likely to exclusively fed breast milk throughout the neonatal period.

According to the CDC, from 2000-2004 the rates of exclusive breastfeeding were significantly lower among black infants (compared with white infants) and infants born to unmarried mothers (compared with married mothers). Additionally, older age, urban residence, higher education, and higher income of mothers all were positively associated with exclusive breast milk feeding (CDC, 2007).

- **1b.5 Citations for Data on Disparities Cited in 1b.4:** [For <u>Maintenance</u> 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 included]
- Centers for Disease Control and Prevention (CDC). (2007). Breastfeeding trends and updated national health objectives for exclusive breastfeeding-United States, birth years 2000-2004. [Journal Article] MMWR Morbidity & Mortality Weekly Report. 56(30):760-3.
- Petrova, A., Hegyi, T., Mehta, R. (2007). Maternal race/ethnicity and one-month exclusive breastfeeding in association with the in-hospital feeding modality. Breastfeeding Medicine: The Official Journal of the Academy of Breastfeeding Medicine. 2(2):92-8.
- **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 No If not a health outcome, rate the body of evidence.

Quantity	Quantity: HO MO LO IO Quality: HO MO LO IO Consistency: HO MO LO IO						
Quantit y	Qualit y	Consisten cy	Does the measure pass subcriterion1c?				
М-Н	М-Н	М-Н	Yes❶				
L	М-Н	М	Yes● IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No●				
М-Н	L	М-Н	Yes● IF potential benefits to patients clearly outweigh potential harms: otherwise No●				
L-M-H	L-M-H	L	No •				
<b>Health outcome</b> – rationale supports relationship to at least one healthcare structure, process, intervention, or service		Does the measure pass subcriterion1c? 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 focus of the measure is to increase the number of newborns who are exclusively fed breast milk during the birth hospitalization >> population determined >> population assessed >> newborns exclusively fed

breast milk while in the hospital >> reduced morbidity and mortality of for mother and newborn.

#### 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 central topic for the measure is promotion of exclusive breast milk feeding of the newborn during the entire birth hospitalization. The evidence shows numerous health benefits for both mothers and newborns. The target population for the performance measure is consistent with the body of evidence supporting the need for improving exclusive breast milk feeding rates.

- **1c.5 Quantity of Studies in the Body of Evidence** (*Total number of studies, not articles*): 1c.5. Quantity of Studies in the Body of Evidence (Total number of studies, not articles)
  The body of literature examining breast feeding with neonatal outcomes is very large with over 27,000 articles published since 1980. 900 studies examine outcomes from breast-feeding with reductions in asthma, diarrheal illness, and childhood obesity being the most important health benefits. Exclusive
- asthma, diarrheal illness, and childhood obesity being the most important health benefits. Exclusive breast-feeding in the first weeks was the single most important factor. Over 100 studies have examined initial breast feeding as a quality measure. A separate but related evidence base is the World Health Organization and United Nations Children's Fund (UNICEF) Baby-Friendly Hospital Initiative that specifies Ten Steps to Successful Breastfeeding which identifies hospital practices that impair exclusive breast-feeding (over 200 separate studies).
- **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): The quality of evidence supporting the promotion and support of exclusive breast milk feeding is quite high with studies published that have involved mother and newborn couplets. As noted numerous RCTs have been conducted over the past decades demonstrating improved

health benefits for both mother and newborn. Some of the improved health benefits for newborns include: otitis media risk reduction by 23% (95% CI 9% to 36%), respiratory tract infections risk reduction by 72% (95% CI 46% to 86%), atopic dermatitis risk reduction by 42% (95% CI 8% to 59%), gastroenteritis risk reduction by 64% (95% CI 26% to 82%), type 2 diabetes risk reduction by 39 percent (95% CI 15% to 56%), sudden infant death syndrome risk reduction by 36 percent (95% CI 19% to 49%), and obesity risk reduction in two studies by 7-24% (95% CI 14% to 33% and 95% CI 1% to 12%) No study design flaws were identified during the literature review.

- **1c.7 Consistency of Results across Studies** (Summarize the consistency of the magnitude and direction of the effect): Studies spanning the past five decades have consistently demonstrated the health benefits of breast milk feeding for both mother and newborn. Again, some of the improved health benefits for newborns include: otitis media risk reduction by 23% (95% CI 9% to 36%), respiratory tract infections risk reduction by 72% (95% CI 46% to 86%), atopic dermatitis risk reduction by 42% (95% CI 8% to 59%), gastroenteritis risk reduction by 64% (95% CI 26% to 82%), type 2 diabetes risk reduction by 39 percent (95% CI 15% to 56%), sudden infant death syndrome risk reduction by 36 percent (95% CI 19% to 49%), and obesity risk reduction in two studies by 7- 24% (95% CI 14% to 33% and 95% CI 1% to 12%)
- **1c.8 Net Benefit** (*Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit benefit over harms*):

As described before, there are no known harms to patients associated with exclusive breast milk feeding. There are numerous studies documenting health benefits to both newborn and mother; therefore, the benefits of this recommended practice outweigh the harms.

- 1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? No
- 1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:
- 1c.11 System Used for Grading the Body of Evidence: Other
- **1c.12** If other, identify and describe the grading scale with definitions: Although grading of the evidence was not determined during our systematic review, it was determined that the guideline developers accounted for a balanced representation of information, looked beyond one specialty group or discipline, and provided information that was accessible and met the requirements set out in this measure maintenance form.
- 1c.13 Grade Assigned to the Body of Evidence: Not Applicable
- **1c.14 Summary of Controversy/Contradictory Evidence:** There is no documented evidence regarding controversy about the benefits of exclusive breast milk feeding for mother and newborn.
- 1c.15 Citations for Evidence other than Guidelines (Guidelines addressed below):
- American College of Obstetricians and Gynecologists (ACOG). (Feb. 2007). Committee on Obstetric Practice and Committee on Health Care for Underserved Women. Breastfeeding: Maternal and Infant Aspects. ACOG Committee Opinion 361.
- Centers for Disease Control and Prevention (CDC). (2011). Hospital support for breastfeeding: Preventing obesity begins in hospitals. CDC Vital Signs, Retrieved September 26, 2011 at: http://www.cdc.gov/VitalSigns/pdf/2011-08-vitalsigns.pdf
- Ip S, Chung M, Raman G, et al. Breastfeeding and maternal and infant health outcomes in developed countries. Rockville, MD: US Department of Health and Human Services; 2007. Retrieved on September 27, 2011 at: http://www.ahrq.gov/downloads/pub/evidence/pdf/brfout/brfout.pdf.
- Kramer, M.S. & Kakuma, R. (2002). Optimal duration of exclusive breastfeeding. [107 refs] Cochrane Database of Systematic Reviews. (1):CD003517.

- Shealy, K.R., Li, R., Benton-Davis, S., & Grummer-Strawn, L.M. (2005). The CDC guide to breastfeeding interventions. Atlanta, GA: US Department of Health and Human Services, CDC. Available at: http://www.cdc.gov/breastfeeding/pdf/breastfeeding/interventions.pdf
- US Department of Health and Human Services (DHHS). (2000). Healthy People 2010. Washington, DC. Retrieved on Setember 26, 2011 at: http://www.healthypeople.gov/2010
- US Department of Health and Human Services (DHHS). (2010). Healthy People 2020. Washington, DC. Retrieved on September 26, 2011 at: http://www.healthypeople.gov/2020
- World Health Organization (WHO). Indicators for assessing breastfeeding practices. Geneva, Switzerland: World Health Organization; 1991. Retrieved on September 27, 2011 at: http://www.who.int/child-adolescent-health/new\_publications/nutrition/who\_cdd\_ser\_91.14.pdf.

# **1c.16 Quote verbatim,** the specific guideline recommendation (Including guideline # and/or page #): The following major recommendations are included in the Academy of Breastfeeding Medicine Protocol # 7on pages 173-177:

**Policy Statements** 

- 1. The "name of institution" staff will actively support breastfeeding as the preferred method of providing nutrition to infants. A multidisciplinary, culturally appropriate team comprising hospital administrators, physician and nursing staff, lactation consultants and specialists, nutrition staff, other appropriate staff, and parents shall be established and maintained to identify and eliminate institutional barriers to breastfeeding. On a yearly basis, this group will compile and evaluate data relevant to breastfeeding support services and formulate a plan of action to implement needed changes. (III)
- 2. A written breastfeeding policy will be developed and communicated to all health care staff. The "name of institution" breastfeeding policy will be reviewed and updated biannually using current research as an evidence-based guide. (III)
- 3. All pregnant women and their support people as appropriate will be provided with information on breastfeeding and counseled on the benefits of breastfeeding, contraindications to breastfeeding, and risk of formula feeding (Academy of Breastfeeding Medicine Protocol Committee, "Clinical protocol #19," 2009). (II-1, II-2, III)
- 4. The woman's desire to breastfeed will be documented in her medical record. (III)
- 5. Mothers will be encouraged to exclusively breastfeed unless medically contraindicated. The method of feeding will be documented in the medical record of every infant. (Exclusive breastfeeding is defined as providing breast milk as the sole source of nutrition.) Exclusively breastfed babies receive no other liquids or solids, with the exception of oral medications prescribed by a medical care provider for the infant.) (II-1, II-2, III)
- 6. At birth or soon thereafter all newborns, if baby and mother are stable, will be placed skin-to-skin with the mother. Skin-to-skin contact involves placing the naked baby prone on the mother's bare chest. The infant and mother can then be dried and remain together in this position with warm blankets covering them as appropriate. Mother—infant couples will be given the opportunity to initiate breastfeeding within 1 hour of birth. Post-cesarean-birth babies will be encouraged to breastfeed as soon as possible, potentially in the operating room or recovery area (see Table 1 in the original guideline document). The administration of vitamin K and prophylactic antibiotics to prevent ophthalmia neonatorum should be delayed for the first hour after birth to allow uninterrupted mother—infant contact and breastfeeding (Academy of Breastfeeding Medicine Protocol Committee, "ABM clinical protocol #3," 2009; Mikiel-Kostyra, Mazur, & Boltruszko, 2002; Righard & Alade, 1990). (II-1)
- 7. Breastfeeding mother–infant couples will be encouraged to remain together throughout their hospital stay, including at night (rooming-in). Skin-to-skin contact will be encouraged as much as possible. (II-1)
- 8. Breastfeeding assessment, teaching, and documentation will be done on each shift and whenever possible with each staff contact with the mother. Each feeding will be documented, including latch, position, and any problems encountered, in the infant's medical record. For feedings not directly observed, maternal report may be used. Every shift, a direct observation of the baby's position and latch-on during feeding will be performed and documented. (II-1, II-2, III)
- 9. Mothers will be encouraged to utilize available breastfeeding resources including classes, written materials, and video presentations, as appropriate. If clinically indicated, the healthcare professional or

nurse will make a referral to a lactation consultant or specialist for additional education or assistance. (II-1, II-2, III)

- 10. Breastfeeding mothers will be instructed about:
- a. Proper positioning and latch on
- b. Nutritive suckling and swallowing
- c. Milk production and release
- d. Frequency of feeding/feeding cues
- e. Hand expression of breast milk and use of a pump if indicated
- f. How to assess if infant is adequately nourished
- g. Reasons for contacting the healthcare professional

These skills will be taught to primiparous and multiparous women, provided in written form (Eidelman, Hoffmann, & Kaitz, 1993), and reviewed before the mother goes home. (II-1, II-2, III)

- 11. Parents will be taught that breastfeeding infants, including cesarean-birth babies, should be put to breast at least 8 to 12 times each 24 hours, with some infants needing to be fed more frequently. Infant feeding cues (e.g., increased alertness or activity, mouthing, or rooting) will be used as indicators of the baby's readiness for feeding. Breastfeeding babies will be breastfed at night. (II-1, II-2, III)
- 12. Time limits for breastfeeding on each side will be avoided. Infants can be offered both breasts at each feeding but may be interested in feeding only on one side at a feeding during the early days. (II-1, II-2, III)
- 13. No supplemental water, glucose water, or formula will be given unless specifically ordered by a healthcare professional (e.g., physician, certified nurse midwife, or nurse practitioner) or by the mother's documented and informed request. Prior to non-medically indicated supplementation, mothers will be informed of the risks of supplementing. The supplement should be fed to the baby by cup if possible and will be no more than 10 to 15 mL (per feeding) in a term baby (during the first 1 to 2 days of life). Alternative feeding methods such as syringe or spoon feeding may also be used; however, these methods have not been shown to be effective in preserving breastfeeding. Bottles will not be placed in a breastfeeding infant's bassinet (Howard et al., 2003; Howard et al., 1999; Marinelli, Burke, & Dodd, 2001). (II-1, II-2)
- 14. This institution does not give group instruction in the use of formula. Those parents who, after appropriate counseling, choose to formula feed their infants will be provided individual instruction.
- 15. Pacifiers will not be given to normal full-term breastfeeding infants. The pacifier guidelines at "name of institution" state that preterm infants in the Neonatal Intensive Care or Special Care Unit or infants with specific medical conditions (e.g., neonatal abstinence syndrome) may be given pacifiers for non-nutritive sucking. Newborns undergoing painful procedures (e.g., circumcision) may be given a pacifier as a method of pain management during the procedure. The infant will not return to the mother with the pacifier. "Name of institution" encourages "pain-free newborn care," which may include breastfeeding during the heel stick procedure for the newborn metabolic screening tests (Gray et al., 2002). (I)
- 16. Routine blood glucose monitoring of full-term healthy appropriate-for-gestational age infants is not indicated. Assessment for clinical signs of hypoglycemia and dehydration will be ongoing (Wight, Marinelli, & Academy of Breastfeeding Medicine Clinical Protocol Committee, 2006). (I)
- 17. Antilactation drugs will not be given to any postpartum mother. (I)
- 18. Routine use of nipple creams, ointments, or other topical preparations will be avoided unless such therapy has been indicated for a dermatologic problem. Mothers with sore nipples will be observed for latch-on techniques and will be instructed to apply expressed colostrum or breast milk to the areola/nipple after each feeding. (III)
- 19. Nipple shields or bottle nipples will not be routinely used to cover a mother's nipples, to treat latchon problems, or to prevent or manage sore or cracked nipples or used when a mother has flat or inverted nipples. Nipple shields will be used only in conjunction with a lactation consultation and after other attempts to correct the difficulty have failed. (III)
- 20. After 24 hours of life, if the infant has not latched on or fed effectively, the mother will be instructed to begin to massage her breasts and hand express colostrum into the baby's mouth during feeding attempts. Skin-to-skin contact will be encouraged. Parents will be instructed to watch closely for feeding cues and whenever these are observed to awaken and feed the infant. If the baby continues to feed poorly, hand expression by the mother or a double set-up electric breast pump will be initiated and maintained

approximately every 3 hours or a minimum of eight times per day. Any expressed colostrum or mother's milk will be fed to the baby by an alternative method. The mother will be reminded that she may not obtain much milk or even any milk the first few times she expresses her breasts. Until the mother's milk is available, a collaborative decision should be made among the mother, nurse, and healthcare professional (e.g., physician/nurse practitioner/certified nurse midwife) regarding the need to supplement the baby. Each day the responsible healthcare professional will be consulted regarding the volume and type of the supplement. Pacifiers will be avoided. In cases of problem feeding, the lactation consultant or specialist will be consulted (Academy of Breastfeeding Medicine Protocol Committee, "ABM clinical protocol #3," 2009). (I, III)

- 21. If the baby is still not latching on well or feeding well when discharged to home, the feeding/expression/supplementing plan will be reviewed in addition to routine breastfeeding instructions. A follow-up visit or contact will be scheduled within 24 hours. Depending on the clinical situation it may be appropriate to delay discharge of the couplet to provide further breastfeeding intervention, support, and education. (III)
- 22. All babies should be seen for follow-up within the first few days postpartum. This visit should be with a physician (pediatrician or family physician) or other qualified health care practitioner for a formal evaluation of breastfeeding performance, a weight check, assessment of jaundice and age appropriate elimination: (a) for infants discharged at less than 2 days of age (<48 hours), follow-up at 2 to 4 days of age; (b) for infants discharged between 48 and 72 hours, follow-up at 4 to 5 days of age. Infants discharged after 5 to 6 days may be seen 1 week later.
- 23. Mothers who are separated from their sick or premature infants will be
- a. Instructed on how to use skilled hand expression or the double set up electric breast pump. Instructions will include expression at least eight times per day or approximately every 3 hours for 15 minutes (or until milk flow stops, whichever is greater) around the clock and the importance of not missing an expression session during the night (III)
- b. Encouraged to breastfeed on demand as soon as the infant's condition permits (III)
- c. Taught proper storage and labeling of human milk (III)
- d. Assisted in learning skilled hand expression or obtaining a double set-up electric breast pump prior to going home (III)
- 24. Before leaving the hospital (Academy of Breastfeeding Medicine Clinical Protocol Committee, 2007), breastfeeding mothers should be able to:
- a. Position the baby correctly at the breast with no pain during the feeding
- b. Latch the baby to breast properly
- c. State when the baby is swallowing milk
- d. State that the baby should be nursed a minimum of eight to 12 times a day until satiety, with some infants needing to be fed more frequently
- e. State age-appropriate elimination patterns (at least six urinations per day and three to four stools per day by the fourth day of life)
- f. List indications for calling a healthcare professional
- g. Manually express milk from their breasts (III)
- 25. Prior to going home, mothers will be given the names and telephone numbers of community resources to contact for help with breastfeeding, including (the support group or resource recommended by "name of institution").
- 26. "Name of institution" does not accept free formula or free breast milk substitutes. Nursery or Neonatal Intensive Care Unit discharge bags offered to all mothers will not contain infant formula, coupons for formula, logos of formula companies, or literature with formula company logos.
- 27. "Name of institution" health professionals will attend educational sessions on lactation management and breastfeeding promotion to ensure that correct, current, and consistent information is provided to all mothers wishing to breastfeed (American Academy of Pediatrics, American Academy of Obstetricians and Gynecologists, 2006).

**Contraindications:** 

Breastfeeding is contraindicated in the following situations:

Mothers who are human immunodeficiency virus (HIV)-positive in locations where artificial feeding is

acceptable, feasible, affordable, sustainable, and safe (I)

- Mothers currently using illicit drugs (e.g., cocaine, heroin) unless specifically approved by the infant's healthcare provider on a case-by-case basis (I)
- Mothers taking certain medications. Most prescribed and over-the-counter drugs are safe for the breastfeeding infant. Some medications may make it necessary to interrupt breastfeeding, such as radioactive isotopes, antimetabolites, cancer chemotherapy, some psychotropic medications and a small number of other medications. (III)
- Mothers with active, untreated tuberculosis. A mother can express her milk until she is no longer contagious. (I)
- Infants with galactosemia (I)
- Mothers with active herpetic lesions on her breast(s). Breastfeeding can be recommended on the unaffected breast. (The Infectious Disease Service will be consulted for problematic infectious disease issues.) (I)
- Mothers with onset of varicella within 5 days before or up to 48 hours after delivery, until they are no longer infectious (I)
- Mothers with human T-cell lymphotropic virus type I or type II (I)
- **1c.17 Clinical Practice Guideline Citation:** Philipp BL, Academy of Breastfeeding Medicine Protocol Committee. ABM clinical protocol #7: model breastfeeding policy (revision 2010). Breastfeed Med 2010 Aug;5(4):173-7.
- 1c.18 National Guideline Clearinghouse or other URL:

http://www.guideline.gov/content.aspx?id=24013&search=breastfeeding+policy

- 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: Academy of Breastfeeding Medicine Protocol Committee
- 1c.21 System Used for Grading the Strength of Guideline Recommendation: Other
- **1c.22** If other, identify and describe the grading scale with definitions: The system for categorizing recommendations in this guideline is as follows:

#### Levels of Evidence

- I Evidence obtained from at least one properly randomized controlled trial
- II-1 Evidence obtained from well-designed controlled trials without randomization
- II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies and case reports; or reports of expert committees
- 1c.23 Grade Assigned to the Recommendation: Grading varies from I to III
- **1c.24** Rationale for Using this Guideline Over Others: This policy is based on recommendations from the most recent breastfeeding policy statements published by the Office on Women's Health of the U.S. Department of Health and Human Services, the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the American Academy of Family Physicians, the World Health Organization (WHO), the Academy of Breastfeeding Medicine, and the UNICEF/WHO evidence-based "Ten

Steps to Successful Breastfeeding."

The recommendations were based primarily on a comprehensive review of the existing literature. In cases where the literature does not appear conclusive, recommendations were based on the consensus opinion of the group of experts.

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

1c.28 Attach evidence submission form:

1c.29 Attach appendix for supplemental materials:

Was the threshold criterion, *Importance to Measure and Report*, met? (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, <u>as specified</u>, 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
- S.2 If yes, provide web page URL: http://manual.jointcommission.org
- 2a. RELIABILITY. Precise Specifications and Reliability Testing: HO MO LO I O
- 2a1. Precise Measure Specifications. (The measure specifications precise and unambiguous.)
- **2a1.1 Numerator Statement** (Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome):

Newborns that were fed breast milk only since birth

**2a1.2 Numerator Time Window** (The time period in which the target process, condition, event, or outcome is eligible for inclusion):

Episode of care

**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:

One data element is used to calculate the numerator:

1. Exclusive Breast Milk Feeding - Documentation that the newborn was exclusively fed breast milk during the entire hospitalization. Allowable Values: Yes or No/UTD. Cases are eligible for the numerator when allowable value = yes.

- **2a1.4 Denominator Statement** (*Brief, narrative description of the target population being measured*): Single term liveborn newborns discharged from the hospital with ICD-9-CM Principal Diagnosis Code or ICD-9-CM Other Diagnosis Codes for single liveborn newborn as defined in Appendix A, Table 11.20.1available at: http://manual.jointcommission.org
- **2a1.5 Target Population Category** (Check all the populations for which the measure is specified and tested if any): Maternal Health
- **2a1.6 Denominator Time Window** (*The time period in which cases are eligible for inclusion*): Episode of care
- **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):

Thirteen data elements are used to calculate the denominator:

- 1. Admission Date The month, day and year of admission to acute inpatient care.
- 2. Admission Type- The code indicating priority/type of admission.
- 3. Admission to NICU Documentation that the newborn was admitted to the Neonatal Intensive Care Unit (NICU) at this hospital any time during the hospitalization. Allowable values: Yes or No/UTD
- 4. Birthdate The month, day and year the patient was born.
- 5. Clinical Trial Documentation that during this hospital stay the patient was enrolled in a clinical trial in which patients who are newborns were being studied. Allowable values: Yes or No/UTD
- 6. Discharge Date The month day and year the patient was discharged from acute care, left against medical advice or expired during the stay.
- 7. Discharge Status The place or setting to which the patient was discharged.
- 8. ICD-9-CM Other Diagnosis Codes The International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes associated with the secondary diagnoses for this hospitalization.
- 9. ICD-9-CM Other Procedure Codes The International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) code that identifies significant procedures performed other than the principal procedure during this hospitalization.
- 10. ICD-9-CM Principal Diagnosis Code The International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) code associated with the diagnosis established after study to be chiefly responsible for occasioning the admission of the patient for this hospitalization.
- 11. ICD-9-CM Principal Procedure Code The International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) code that identifies the principal procedure performed during this hospitalization. The principal procedure is the procedure performed for definitive treatment rather than diagnostic or exploratory purposes, or which is necessary to take care of a complication.
- 12. Point of Origin for Admission or Visit- The code indicating the point of patient origin for this admission.
- 13. Reason for Not Exclusively Feeding Breast Milk Reasons for not exclusively feeding breast milk during the entire hospitalization are clearly documented in the medical record. These reasons are due to a maternal medical condition for which feeding breast milk should be avoided. Allowable Values: Yes or No/UTD.

#### **2a1.8 Denominator Exclusions** (Brief narrative description of exclusions from the target population):

- Admitted to the Neonatal Intensive Care Unit (NICU) at this hospital during the hospitalization
- ICD-9-CM Principal Diagnosis Code or ICD-9-CM Other Diagnosis Codes for galactosemia as defined in Appendix A, Table 11.21
- ICD-9-CM Principal Procedure Code or ICD-9-CM Other Procedure Codes for parenteral infusion as defined in Appendix A, Table 11.22
- Experienced death
- Length of Stay >120 days
- Enrolled in clinical trials

- Documented Reason for Not Exclusively Feeding Breast Milk
- Patients transferred to another hospital
- ICD-9-CM Principal Diagnosis Code or ICD-9-CM Other Diagnosis Codes for premature newborns as defined in Appendix A, Table 11.23
- **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):
- The data element Admission to NICU is used to determine if the patient was admitted to the NICU.
- Patients with ICD-9-CM Principal Diagnosis Code or ICD-9-CM Other Diagnosis Codes for galactosemia are excluded.
- Patients with ICD-9-CM Principal Procedure Code or ICD-9-CM Other Procedure Codes for parenteral infusion are excluded.
- The data element Discharge Status is used to determine if the patient experienced death.
- Length of stay (LOS) in days is equal to the Discharge Date minus the Admission Date. If the LOS is greater than 120 days the patient is excluded.
- Patients are excluded if "Yes" is selected for Clinical Trial.
- The data element Reason for Not Exclusively Feeding Breast Milk is used to determine if the patient had a documented reason for not being exclusively fed breast milk.
- The data element Discharge Status is used to determine if the patient the patient was transferred to another hospital.
- Patients with ICD-9-CM Principal Diagnosis Code or ICD-9-CM Other Diagnosis Codes for premature newborns are excluded.
- **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):

Not Applicable

- **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.):
- **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.):

- 1. Start processing. Run cases that are included in the PC-Newborn Initial Patient Newborns with Breast Feeding and pass the edits defined in the Transmission Data Processing Flow: Clinical through this measure.
- 2. Check Admission Type
- a. If Admission Type equals 1, 2, 3, 5, 9, the case will proceed to a Measure Category Assignment of B and will not be in the measure population. Stop processing.
- b. If Admission Type equals 4, continue processing and proceed to Point of Origin for Admission or Visit.
- 3. Check Point of Origin for Admission or Visit
- a. If Point of Origin for Admission or Visit equals 6, the case will proceed to a Measure Category Assignment of B and will not be in the measure population. Stop processing.
- b. If Point of Origin for Admission or Visit equals 5, continue processing and proceed to Discharge Status.
- 4. Check Discharge Status
- a. If Discharge Status equals 02, 05, 20, the case will proceed to a Measure Category Assignment of B and will not be in the measure population. Stop processing.
- b. If Discharge Status equals 01, 03, 04, 06, 07, 21, 43, 50, 51, 61, 62, 63, 64, 65, 66, 70, continue processing and proceed to Clinical Trial.
- 5. Check Clinical Trial
- a. If Clinical Trial is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Stop processing.
- b. If Clinical Trial equals Yes, the case will proceed to a Measure Category Assignment of B and will not be in the measure population. Stop processing.
- c. If Clinical Trial equals No, continue processing and proceed to Admission to NICU.
- Check Admission to NICU
- a. If Admission to NICU is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Stop processing.
- b. If Admission to NICU equals Yes, the case will proceed to a Measure Category Assignment of B and will not be in the measure population. Stop processing.
- c. If Admission to NICU equals No, continue processing and proceed to Exclusive Breast Milk Feeding.
- 7. Check Exclusive Breast Milk Feeding
- a. If Exclusive Breast Milk Feeding is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Stop processing.
- d. If Exclusive Breast Milk Feeding equals Yes, the case will proceed to a Measure Category Assignment of E and will be in the Numerator Population. Stop processing.
- e. If Exclusive Breast Milk Feeding equals No, continue processing and proceed to Reason for Not Exclusively Feeding Breast Milk.
- 8. Check Reason for Not Exclusively Feeding Breast Milk
- a. If Reason for Not Exclusively Feeding Breast Milk is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Stop processing.
- b. If Reason for Not Exclusively Feeding Breast Milk equals Yes, the case will proceed to a Measure Category Assignment of B and will Not be in the measure population. Stop processing.
- c. If Reason for Not Exclusively Feeding Breast Milk equals No, the case will proceed to a Measure Category Assignment of D and will be in the measure population. Stop processing.

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

http:manual.jointcommission.org

**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):

The initial patient population includes patients with age at admission (Admission Date – Birthdate) = 2 days, Length of Stay (Discharge Date - Admission Date) = 120 days, an ICD-9-CM Principal or Other Diagnosis Code as defined in Appendix A, Table 11.20.1, NO ICD-9-CM Principal or Other Diagnosis Code as defined in Appendix A, Table 11.21, NO ICD-9-CM-Principal or Other Procedure Code as defined in Appendix A, Table 11.22 and NO ICD-9-CM Principal or Other Diagnosis Code as defined in Appendix A, Table 11.23 are included in this subpopulation and are eligible to be sampled. The sample is taken randomly as follows for a monthly sample:

- Average monthly Initial Patient Population >= 181 results in a minimum random sample size of 37.
- Average monthly Initial Patient Population 46 180 results in a minimum random sample size of 20% of the population size.
- Average monthly Initial Patient Population 9 45 results in a minimum random sample size of 9.
- Average monthly Initial Patient Population <9 results in no sampling; 100% Initial Patient Population required

**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, Paper Medical 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.): Each data element in the data dictionary includes suggested data sources. The data are collected using contracted Performance Measurement Systems (vendors) that develop data collection tools based on the measure specifications. The tools are verified and tested by Joint Commission staff to confirm the accuracy and conformance of the data collection tool with the measure specifications. The vendor may not offer the measure set to hospitals until verification as been passed.

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment:

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

**URL** 

http://manual.jointcommission.org

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

**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 PC measure set has been in national use since the 2nd quarter of 2010. It is a requirement of participation in the ORYX initiative that data on all measures in the set are collected. (ORYX is the term used by The Joint Commission to describe the component of the hospital accreditation program which

requires data collection and reporting on standardized national performance measures.) Demographics of organizations collecting and reporting data on these measures are as follows:

163 health care organizations representing various types, locations and sizes:

10 For Profit, 91 Not for Profit, 46 Military Facilities, 9 County, 2 State, 5 Other

15 >=500 beds; 29 250-499 beds; 50 100-249 beds; 69 <100 beds

Located in: AE, AK, AL, AP, AR, AZ, CA, DO, DC, FL, GA, HI, ID, IL, IN, KS, KY, LA, MA, MD, MI, MN, MO, MS, MT, NC, NE, NV, NY, OH, OK, PA, PR, RI, SC, TN, TX, VA, WA, WI, WV 26 performance measurement systems

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

This measure was adapted from NQF-endorsed measure 0480 Exclusive Breastfeeding During Birth Hospitalization. As such, reliability was addressed during the original endorsement. The Joint Commission will be conducting further reliability studies on this measure as well as the entire PC measure set beginning in October 2011.

Currently, these hospitals are supported in their data collection and reporting efforts by 26 contracted performance measurement system (PMS) vendors. It is a contractual requirement of Joint Commission listed vendors that the quality and reliability of data submitted to them by contracted health care organizations must be monitored on a quarterly basis. In addition, The Joint Commission analyzes these data by running 17 quality tests on the data submitted into ORYX. (ORYX is the term used by The Joint Commission to describe the component of the hospital accreditation program which requires data collection and reporting on standardized national performance measures). The following is a list of the major tests done on the submitted ORYX data, taken from the 2011 ORYX Performance Measurement System Requirements manual.

- Transmission of complete data
- Usage of individual core measure data received: To understand if the HCO provides the relevant service to treat the relevant population
- Investigation of aberrant data points
- Verification of patient population and sample size
- Identification of missing data elements
- Validation of the accuracy of target outliers
- Data integrity
- Data corrections

#### **Data Element Agreement Rate:**

Inter-rater reliability testing methodology utilized by contracted performance measure system vendors as outlined in the contract is as follows:

- All clinical data elements and all editable demographic elements are scored.
- All measure data are reabstracted with originally abstracted data having been blinded so that the reabstraction is not biased.
- Reabstracted data are compared with originally abstracted data on a data element by data element basis. A data element agreement rate is calculated. Clinical and demographic data are scored separately, and an overall agreement rate is computed.

# **2a2.3 Testing Results** (Reliability statistics, assessment of adequacy in the context of norms for the test conducted):

Validity (Measure evaluation criterion 2b)

Data element agreement rates were reported to The Joint Commission for 1Q11. This reflects the findings of 106 hospitals, comprising 26,302 records (100% sample). The following table delineates calculated agreement rates for individual data elements that are used to compute measure rates for PC-05.

Data Elements with a Mismatch - Newborn total n total d rate Admission Date 661 662 99.85%

Admission to NICU 571 576 99.13%

Admission Type 661 662 99.85%

Exclusive Breast Milk Feeding 513 526 97.53% Point of Origin for Admission or Visit 671 672 99.85%

Reason for Not Exclusively Feeding Breast Milk 334 342 97.66%

These agreement rates are considered to be well within acceptable levels.

#### 2b. VALIDITY. Validity, Testing, including all Threats to Validity: HO MO LO I O

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:

This measure focuses on the rate of newborns that were exclusively fed breast milk during the entire birth hospitalization. The literature supports the focus on healthy term newborns that were exclusively fed breast milk. This measure excludes patients diagnosed with galactosemia, receiving TPN, experienced death or requiring a higher level of care due to illness or prematurity resulting in an admission to the NICU or transfer to another hospital, since these are contraindications supported in the literature. Also excluded from the measure are patients with a length of stay greater than 120 days, and those enrolled in a clinical trial. These exclusions are not addressed in the literature, but are included for this measure in order to harmonize with other CMS/Joint Commission aligned measures.

- **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 PC measure set has been in national use since the 2nd quarter of 2010. Demographics of organizations collecting and reporting data on these measures are as follows:

163 health care organizations representing various types, locations and sizes:

10 For Profit, 91 Not for Profit, 46 Military Facilities, 9 County, 2 State, 5 Other

15 >=500 beds; 29 250-499 beds; 50 100-249 beds; 69 <100 beds

Located in: AE, AK, AL, AP, AR, AZ, CA, DO, DC, FL, GA, HI, ID, IL, IN, KS, KY, LA, MA, MD, MI, MN, MO, MS, MT, NC, NE, NV, NY, OH, OK, PA, PR, RI, SC, TN, TX, VA, WA, WI, WV 26 performance measurement systems

**2b2.2 Analytic Method** (Describe method of validity testing and rationale; if face validity, describe systematic assessment):

Since the measure has been in national use, continued face validity of the measure has been determined through analysis of feedback from measure users. The Joint Commission provides a web-based application with which measure users can provide feedback regarding appropriateness of measure specifications, request clarification of specifications, and/or provide other comments pertinent to the measure. This feedback is systematically continually reviewed in order to identify trends and to identify areas of the measure specifications that require clarification or revision. Additionally, Joint Commission staff continually monitors the national literature and environment in order to assess continued validity of this measure.

In addition, The Joint Commission will begin reliability site visits this year. During the site visits, Joint Commission staff will conduct focus group interviews with hospital staff working with the PC measures to obtain feedback regarding the validity of the measures and suggestions for further refinement of the specifications.

**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):

Analysis of feedback obtained via our automated feedback system reveals slightly more than 130 submissions regarding specifications for this measure since its implementation in 2010. Predominant themes of these submissions involved questions regarding clarification of the data elements Exclusive

Breast Milk Feeding regarding the definition and Reason for Not exclusively Feeding Breast Milk as to why additional newborn conditions were not considered exclusions. Also the data element Discharge from NICU was changed to Admission to NICU based on feedback that some hospitals sent newborns to a step-down unit from the NICU prior to discharge. Additional notes for abstractors were added to the data elements for clarification. Other notes for abstractors were added to the data element admission date to clarify the date of delivery is used as the admission date and not the date of the order written to admit. The denominator statement and algorithm were changed to single term newborns discharged from the hospital to capture healthy newborns. In addition, the denominator excluded population and algorithm were revised to capture premature newborns with an additional ICD-9-CM diagnosis code table and newborns transferred to another hospital.

**POTENTIAL THREATS TO VALIDITY**. (<u>All</u> 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 PC measure set has been in national use since the 2nd quarter of 2010. Demographics of organizations collecting and reporting data on these measures are as follows:

163 health care organizations representing various types, locations and sizes:

10 For Profit, 91 Not for Profit, 46 Military Facilities, 9 County, 2 State, 5 Other

15 >=500 beds; 29 250-499 beds; 50 100-249 beds; 69 <100 beds

Located in: AE, AK, AL, AP, AR, AZ, CA, DO, DC, FL, GA, HI, ID, IL, IN, KS, KY, LA, MA, MD, MI, MN, MO, MS, MT, NC, NE, NV, NY, OH, OK, PA, PR, RI, SC, TN, TX, VA, WA, WI, WV 26 performance measurement systems

**2b3.2 Analytic Method** (Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference):

Measure exclusions that were not derived directly from the evidence are presented below. Please note that these are population exclusions that are necessary to ensure consistency in all measures in this 5 measure set.

These exclusions were analyzed for frequency of occurrence. An issue that is of great concern to users of this measure is that due to the presence of exceptions to the measure, attainment of a 100% measure rate is not possible. Because of the role of this measure in the current Joint Commission accreditation process, this is especially troubling to measure users. This concern is the basis for a number of the non-evidence-based exclusions to these measures. Additional reasons for these population exclusions are enumerated in our response to section 2b1.1 above. The following measure exclusions that were not derived directly from the evidence are as follows:

- 1. Patients with LOS <120 days
- 2. Patients enrolled in clinical trials

**2b3.3 Results** (Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses):

N=353,671

- 1. Patients who have a length of stay (LOS) greater than 120 days =0%
- 2. Patients enrolled in clinical trials =0%

**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):

Not Applicable

**2b4.2 Analytic Method** (Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables):

Not Applicable

**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):

Not Applicable

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: Not Applicable

**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 sample, characteristics of the entities included):

As previously noted the PC measure set has been in national use since the 2nd guarter of 2010.

Demographics of organizations collecting and reporting data on these measures are as follows:

163 health care organizations representing various types, locations and sizes:

10 For Profit, 91 Not for Profit, 46 Military Facilities, 9 County, 2 State, 5 Other

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Located in: AE, AK, AL, AP, AR, AZ, CA, DO, DC, FL, GA, HI, ID, IL, IN, KS, KY, LA, MA, MD, MI, MN, MO, MS, MT, NC, NE, NV, NY, OH, OK, PA, PR, RI, SC, TN, TX, VA, WA, WI, WV 26 performance measurement systems

**2b5.2 Analytic Method** (Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance):

The method used to analyze meaningful differences in performance at The Joint Commission is Target Analysis. The object of target analysis is to compare a health care organizations (HCO) data against a comparative norm for the purpose of evaluating performance improvement opportunities. When an organization's performance level is statistically significantly different from a comparative norm, it is considered a statistical deviation. A statistical deviation may be desirable or undesirable depending on the "direction of improvement" of the measure.

There are two components to the target analysis methodology used at The Joint Commission. Given the national average for a performance measure, a target range is constructed. Using generalized linear mixed models methodology (also known as hierarchical models), a predicted estimate of an HCO's performance, with a corresponding 95% confidence interval, is generated. This confidence interval is compared to the target range, to determine the HCOs' rating. The estimate of the organization's true performance is based on both the data from that organization and on data from the entire set of reporting organizations.

**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):*PC-05 Distribution of Outliers

2011 1st Quarter Data:

Scores on this measure: N=161, Mean 48.33%, SD 0.23493

10th Percentile= 19.23% 25th Percentile= 31.88%

50th Percentile= 50%

75th Percentile= 63.6%

90th Percentile= 78.95%

- 4 (2.48%) Favorable results statistically significantly higher than the national rate 119 (73.91%) Neutral results not significantly different from target range 38 (23.6%) Undesirable –results statistically significantly lower than the national rate
- **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): Multiple data sources are not used for this measure.
- **2b6.2 Analytic Method** (Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure):

  Not Applicable
- **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):

  Not Applicable
- **2c. Disparities in Care: HO MO LO I O NAO** (*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): The measure is not stratified for disparities.
- 2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:

Although rates of exclusive breastfeeding were significantly lower among black infants (compared with white infants) and infants born to unmarried mothers (compared with married mothers, this measure is not stratified for these elements. The Joint Commission does not currently capture date elements for race or ethnicity because these data elements have not been shown to be reliably collectable due to the fact that no national standardized definitions exist for these data elements. Also, not all hospitals collect race and ethnicity. In the future, it may be feasible for The Joint Commission to explore how race and ethnicity and other relevant disparity data might be collected reliably in the future.

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

#### 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)

C.1 Intended Actual/Planned Use (Check all the planned 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), Regulatory and Accreditation Programs

- **3.1 Current Use** (Check all that apply; for any that are checked, provide the specific program information in the following questions): Public Reporting, Regulatory and Accreditation Programs, Quality Improvement with Benchmarking (external benchmarking to multiple organizations), Quality Improvement (Internal to the specific organization)
- 3a. Usefulness for Public Reporting: HO MO LO IO

(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)). If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: **[For Maintenance** – 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 Joint Commission has a longstanding commitment to providing meaningful information about the comparative performance of accredited organizations to the public. The Quality Check® Web site, www.qualitycheck.org, launched in 1996, fulfills this commitment. Among other things, Quality Check allows consumers to view or download free hospital performance measure results. Measure rates for PC-05 (and all the PC measures) will be included in the hospital performance measure results beginning in 2012 once reliability testing has been completed.

**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: All measure specifications (e.g., numerator, denominator, exclusions, data elements and measure calculation algorithms) are standardized in order to produce consistent measure results. Specifications are updated biannually based on feedback from vendors, and hospitals, as well as technical advisory member recommendations and updated clinical practice guidelines. Data are collected using data collection tools that have been verified by The Joint Commission to accurately collect measure data elements and compute measure assignment categories according to the measure specifications. Quarterly data reported to The Joint Commission are subject to a number of data quality tests to ensure the accuracy of the data. The measure rate is computed using a standardized measure calculation algorithm.

The Joint Commission provides an opportunity for abstractors to submit questions and feedback about the measure specifications via an on-line website. As discussed previously, this information is used to evaluate the need for revisions and provide abstractors with a database of frequently asked questions. Measure updates and issues about the measures are presented and discussed at an annual performance measurement system vendor conference. These activities support the Joint Commission's effort to provide results that are useable, understandable and useful for public reporting.

- **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 Joint Commission is a national (and international) accreditor of hospitals and other healthcare organizations. This measure set is one of 10 available measure sets from which hospitals can select to meet The Joint Commission's ORYX accreditation program requirement for data collection and reporting. Additional information located at: http://www.jointcommission.org/facts\_about\_oryx\_for\_hospitals/
- **3b.** Usefulness for Quality Improvement: HO MO LO IO (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].

While The Joint Commission developed this measure for and uses results from this measure in its accreditation activities, the measure is also intended for use in internal quality improvement by accredited organizations.

**3b.2.** Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated (e.g., QI initiative), describe the data, method and results:

From an accreditation perspective, measure results have proven useful in that they are used in the Priority Focus Process, which helps to focus accreditation survey activities toward areas of greatest need. From the hospital quality improvement perspective, measure rates are included in the Joint Commission's Strategic Surveillance System (S3) product, which is made available, at no additional cost to accredited organizations and is used by them to identify gaps in the care they provide relative to other measure users. Aggregate measure results have improved over time, indicating that they are being used by hospitals to identify and address areas in need of improvement. Since this measure was introduced nationally in 2010, aggregate performance has improved. PC-05 began with 2010 Quarter 2 reporting data at 39.7 % or a performance gap of 60.3 %, There has been consistent improvement in aggregate performance rates for the following consecutive four quarters, with the most recent 2011 Quarter 1 reportable performance at 42.9%.

Overall, to what extent was the criterion, *Usability*, met? HO MO LO I O 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: HO MO LO I O
- **4a.1-2** How are the data elements needed to compute measure scores generated? (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: HO MO LO I O
- **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
- 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: The Joint Commission is in the process of preparing for conversion to eMeasure specification beginning in the 4th quarter 2011 for the PC measure set.
- 4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: HO MO LO I O
- 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:

The initial patient population algorithm for PC-05 was revised because premature newborns and multiple gestations were not excluded from the measure. The measure algorithm was also revised because outborn newborns and newborns transferred to another hospital were not excluded from the measure. In response, the ICD-9-CM diagnosis tables were updated and new tables were added to identify those patients. Additionally, the data element Discharged from NICU was changed to Admission to NICU. Since implementation, the Notes for Abstraction section of the data elements has been updated to clarify issues that have been identified after review of the feedback received from measure users.

- 4d. Data Collection Strategy/Implementation: HO MO LO I O
- 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):

At the present time, hospitals using this performance measure generally collect measure data via manual review of the paper medical record, the EMR or a combination of both. Collected data are submitted to The Joint Commission on a quarterly basis, by way of contracted performance measurement system vendors, as described previously. Specifications for this measure are freely available to anyone who wishes to use the measure. Feedback from hospitals using this measure indicates that required data elements are generally available in the medical record, and measure specifications are robust and easy to understand. As described above, as feedback from measure users has indicated the need for clarification or revision of measure specifications, this has taken place.

Overall, to what extent was the criterion, *Feasibility*, met? **HO MO LO I O** 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

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:
- 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?
- 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):** The Joint Commission, One Renaissance Blvd., Oakbrook Terrace, Illinois, 60181

Co.2 Point of Contact: Jerod M., Loeb, PhD, iloeb@jointcommission.org, 630-792-5920-

**Co.3 Measure Developer if different from Measure Steward:** The California Maternal Quality Care Collaborative, 750 Welch Rd., Suite 224, Palo Alto, California, 94304

Co.4 Point of Contact: Elliott., Main, MD, MainE@sutterhealth.org, 415-750-6003-

**Co.5 Submitter:** Ann, Watt, MBA, RHIA, awatt@jointcommission.org, 630-792-5944-, The Joint Commission

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

The California Maternal Quality Care Collaborative

Co.7 Public Contact: Celeste, Milton, MPH, BSN, RN, cmilton@jointcommission.org, 630-792-5925-, The Joint Commission

#### 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.

Michael Ross, MD, MPH (Chair) Harbor-UCLA Medical Center Torrance, CA

Wanda Barfield, MD, MPH Centers for Disease Control and Prevention Atlanta, GA

Kenneth E. Brown, MD, MBA, FACOG, FACHE Woman's Hospital Lafayette, LA

Martin McCaffrey, MD UNC North Carolina Children's Hospital Chapel Hill, NC

Cathy Collins-Fulea, MSN, CNM Henry Ford Hospital Detroit, MI Janet H. Muri, MBA National Perinatal Information Center/ Quality Analytic Services Providence, RI

Kathleen Simpson, PhD, RNC, FAAN St. John's Mercy Medical Center St. Louis, MO

Michael Socol, MD Northwestern University Medical School Chicago, IL

Rebecca Zimmermann, MPP America's Health Insurance Plans Washington, DC

The technical advisory panel (TAP) members determined priority areas that could be evaluated to improve care related to perinatal care during the development timeframe. After implementation, minor revisions, acknowledged by TAP representatives, were made to improve clarity. Hospital feedback will be reviewed during the reliability testing phase of the project to assist the TAP in making the final measure recommendations.

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: 0480 Exclusive Breastfeeding During Birth Hospitalization

The California Maternal Quality Care Collaborative (CMQCC) was the measure steward and original measure developer. The measure was recommended for inclusion by the PC TAP as one of five measures in the Joint Commission's Perinatal Care (PC) core measure set. The Joint Commission held a series of conference calls with CMQCC to discuss the measure specifications and proposed revisions and worked with the original measure developer for agreement on specifications revisions prior to national implementation. As work began to re-endorse the measure, The Joint Commission assumed stewardship of the measure.

#### **Measure Developer/Steward Updates and Ongoing Maintenance**

- Ad.3 Year the measure was first released: 2010
- Ad.4 Month and Year of most recent revision: 08, 2011
- Ad.5 What is your frequency for review/update of this measure? Biannual
- Ad.6 When is the next scheduled review/update for this measure? 02, 2012

**Ad.7 Copyright statement:** No royalty or use fee is required for copying or reprinting this manual, but the following are required as a condition of usage: 1) disclosure that the Specifications Manual is periodically updated, and that the version being copied or reprinted may not be up-to-date when used unless the copier or printer has verified the version to be up-to-date and affirms that, and 2) users participating in Joint Commission accreditation, including ORYX® vendors, are required to update their software and associated documentation based on the published manual production timelines.

#### Ad.8 Disclaimers:

#### Ad.9 Additional Information/Comments:

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



April 24, 2012

National Quality Forum Steering Committee and Staff 1030 15th St, NW Suite 800 Washington, D.C. 20005

Re: Perinatal and Reproductive Healthcare: Endorsement Maintenance 2011

Dear National Quality Forum Steering Committee and Staff,

The International Formula Council (IFC) is an association of manufacturers and marketers of formulated nutrition products, e.g., infant formulas and adult nutritionals, whose members are based predominantly in North America. We appreciate the opportunity to comment further on the National Quality Forum's (NFQ) Perinatal and Reproductive Healthcare: Endorsement Maintenance 2011. IFC initially submitted comments online on January 18, 2012 regarding this issue. Subsequently, the NQF Steering Committee, members, the Consensus Standards Approval Committee (CSAC), and the NQF Board all voted to endorse the measure.

As noted in our previous comments, the IFC agrees with the American Academy of Pediatrics and other health care professional organizations that breastfeeding is the ideal infant feeding method and that it offers specific infant and maternal health benefits. The IFC also believes that parents should be trusted to make the best feeding choices for their babies according to their life circumstances and the needs of their families, and should be supported in that decision. We believe that families' right to choose and be supported in their infant feeding decisions is not being upheld or protected.

As we previously noted, a mother's choice not to breastfeed is <u>not</u> recognized as reason for exclusion from the The Joint Commission's (TJC) Perinatal Measure of Exclusive Breastfeeding and the NQF's endorsement of the measure. We continue to be concerned that by excluding this option, the measure may be interpreted to mean that a mother's choice is not a valid reason for not exclusively feeding breast milk, and that such measures may be used to discourage hospitals and health care professionals from recognizing, supporting, or respecting mothers who chose not to exclusively breastfeed their infants.

This approach conflicts with the recommendations of health authorities. The World Health Organization's (WHO) *Global Strategy for Infant and Young Child Feeding*<sup>1</sup> states moms should be supported in their feeding decision. Additionally, in the recent *Call to Action to Support Breastfeeding*, both the Surgeon General and the Health and Human Services Secretary advocate no mother should be made to feel guilty if she cannot or chooses not to breastfeed.<sup>2</sup> We note that at the January 2010 California Breastfeeding Summit, a representative from The Joint Commission gave a presentation that stated (on slide 91), "The Joint Commission recognizes and supports the right of a woman to refuse breast milk feeding" and "A mother's

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<sup>\*</sup> IFC members are: Abbott Nutrition; Mead Johnson Nutrition; Nestlé Infant Nutrition; PBM Products, LLC, A Perrigo Company; and Pfizer Nutrition.

choice to breastfeed is a decision to be respected." However, without a *specific* exclusion that supports a mother's infant feeding choice, there is no validation of such a statement, and rather the accreditation measure seems a direct violation of a mother's personal infant feeding decision. We strongly agree with NQF that this measure may be an "encroachment on patient autonomy" as "overzealous insistence on breastfeeding may alienate mothers."

We believe it is important to note that NQF received 10 comments suggesting that this measure "inappropriately mandates that women breastfeed." Of particular relevance, several NQF steering committee members expressed concerns similar to ours during the February 1, 2012 conference call; their opinions follow:

- "...it's a little bit disingenuous to say...that this is all about just removing processes.
  ...there might be the coercion of mothers.... there's going to be competition between the hospitals... there's going to be payment decisions...pressure on the hospitals beyond simply... saying... we just want you to... do a better job at not handing out formula.... if you truly just wanted to improve the processes I guess we could just measure those processes."
- "...there happens to be no evidence to demonstrate that over a broad range of population types such as the United States that the hospitals can have a dramatic effect on permanent breastfeeding."
- "...this is a PC measure having very little to do with science and really promoting the coercion of mothers which does happen because... hospitals want to have a high score. They are being judged."

Previously, IFC strongly urged the NQF to add "mothers who chose not to exclusively breastfeed" to the list of exclusions. This was reiterated by a NQF Steering Committee member who said, "perhaps we could say that... if when they [mothers] enter the hospital if they identify it's [their infant feeding choice] formula feeding they shouldn't be a part of this cohort." We are disappointed to learn that this suggestion apparently was ignored.

Additionally, we recommend language acknowledging that mothers should be recognized, supported, and respected in their personal infant feeding decisions be added to the "4. Feasibility" section of the measurement description.

We would also support a complementary measurement strategy as suggested by another NQF Steering Committee member who said, "a complementary measurement strategy would assure we're not overly coercive... once this is implemented." The member suggested "a consumer assessment health plan survey" asking "...did you get the support you need? Was your choice respected?" Unfortunately, this suggestion also was not implemented.

We would welcome a discussion of the exclusive breast milk feeding measure. We agree that more can be done to support and encourage breastfeeding in hospitals; however we believe that accreditation measures should not be intentionally structured to supersede a mother's own infant feeding choice. Thank you again for the additional opportunity to comment. Please contact me if you have questions.

Sincerely,

Mardi K. Mountford, MPH Executive Vice President

#### References

- 1. World Health Organization; Global Strategy for Infant and Young Child Feeding. Available at: <a href="http://apps.who.int/gb/archive/pdf\_files/WHA54/ea547.pdf">http://apps.who.int/gb/archive/pdf\_files/WHA54/ea547.pdf</a>
- The Surgeon General's Call to Action to Support Breastfeeding; January 2011. Available
  at:
   http://www.surgeongeneral.gov/topics/breastfeeding/calltoactiontosupportbreastfeeding.p
- 3. Healthy People 2020; Maternal, Infant, and Child Health Objectives. Available at <a href="http://healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicid=26">http://healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicid=26</a>.

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#### APPENDIX C

#### Response from the measure developer, The Joint Commission

May 4, 2012 (via email)

The Joint Commission appreciates the view of the International Formula Council. The overall goal of PC-05: Exclusive Breast Milk Feeding is to improve exclusive breast milk feeding rates during birth hospitalization which are currently estimated to be as low as 30% in some parts of the country. Exclusive breast milk feeding for the first 6 months of newborn life has long been the expressed goal of World Health Organization (WHO), Department of Health and Human Services (DHHS), American Academy of Pediatrics (AAP) and American College of Obstetricians and Gynecologists (ACOG). A number of evidence-based studies show that establishing exclusive breast milk feeding during hospitalization results in greater success in continuing exclusive breast milk feeding for the first six months of life which is one of the goals for *Healthy People 2020*. A recent Cochrane review also confirms the numerous benefits of exclusive breast milk feeding for both the mother and newborn. The Joint Commission does not require a specific rate of performance for this measure, nor does it expect that the rate will be 100%. Improvement for this measure is denoted by an increase in the measure rate. The overall goal is to increase the number of healthy mothers who are exclusively breast milk feeding their newborns.

The Joint Commission recognizes and supports the right of a woman to refuse breast milk feeding; however, this has not been an exclusion for the purposes of the intent of the measure. While a mother's choice to breastfeed is a decision to be respected, there are a number of educational programs based on scientific evidence that have successfully been implemented by hospitals and can be used to increase the number of mothers that exclusively breast milk feed their newborns. The Joint Commission recognizes that cultural beliefs and values may influence the decision whether to exclusively breast milk feed or not. Because of this, we encourage health care providers to integrate culturally sensitive information when promoting exclusive breast milk feeding as an option.

The above notwithstanding, The Joint Commission does not wish to promote a measure which may produce adverse consequences. Therefore it is our intent to modify this measure in an upcoming version of our specifications manual such that the original measure will be retained as currently specified. However, an additional stratified rate will be computed which will exclude those newborns whose maternal choice was to not breastfeed. Details of the specifications for the stratified rate are still be worked out, but it is hoped that this addition will provide clarification behind the exclusive breast milk feeding measure rate.

TO: Consensus Standards Approval Committee (CSAC)

FR: Reva Winkler and Suzanne Theberge

RE: Result of Voting for *Perinatal and Reproductive Healthcare Endorsement Maintenance*, 2011

DA: February 29, 2012

The CSAC will review the recommendations from the project, *Perinatal and Reproductive Healthcare Measures Endorsement Maintenance* during the March 7, 2012, in-person meeting. This memo includes the list of recommended measures, summary information about the project, and the Member voting results. The individual measure evaluation summary tables from the draft report are in the Appendix. The complete voting draft report and detailed measure information are available on the project webpage.

# **CSAC ACTION REQUIRED**

Pursuant to the Consensus Development Process (CDP), the CSAC may consider approval of 14 candidate consensus standards:

#### **PROCESS**

This project followed the National Quality Forum's (NQF's) version 1.9 of the CDP. The Steering Committee met by conference call in November 2011 and then in person on November 29-30, 2011, to evaluate the measures. The Committee met via conference call on February 1, 2012, to address the comments received during the NQF member and public comment period.

# Perinatal and Reproductive Healthcare Endorsement Maintenance 2011

	MAINTENANCE	NEW	TOTAL
Measures under consideration	29	3*	32
Withdrawn from consideration	11		
Recommended	12	2	14
Not recommended	6	1	7
Reasons for Not Recommending	Importance – 3	Importance - 1	
	Scientific Acceptability - 1		
	Overall - 1		
	Competing measure – 1		

<sup>\*</sup>Includes one composite measure with 10 components.

The measures were evaluated against the 2011 measure evaluation criteria. The Steering Committee encountered several overarching issues during its discussions and evaluations of the measures. These issues were factored into the Committee's ratings and recommendations for multiple measures and are explained below.

# Long-term outcomes

Several measures assessed use of medications have been shown to benefit the infant (steroids, Group B Strep prophylaxis) or the mother (prophylactic antibiotics for Cesarean section) without evidence of adverse outcomes in the short term. However, emerging data raised concerns regarding potential changes in neonatal gut flora with C-section and antibiotics use. Data on long-term outcomes are not available; though, questions remain. The Committee suggested that population-health level measures that can follow children for many years may provide valuable information on potential long-term risks.

# Population-level companion measures

The Committee noted that several measures have significant regional and cultural influences, such as breast feeding rates. Companion population-level measures may be useful in changing the attitudes and values of a community for overall improved care for women and infants.

## Composite measures

The Committee generally supported the concept of composite measures for various aspects of prenatal, intra-partum, postpartum, and neonatal care. Although the Committee did not recommend the one safety-related composite measure submitted for consideration, they urged the developers to continue their work and offered suggestions to improve the measure. There were also multiple Committee suggestions for new composite measure development.

#### Use of vital statistics as a data source

Committee members noted that vital statistics data are underutilized for performance measurement. Many stakeholders such as states and Medicaid agencies do not have access to medical record data. Birth certificate data can provide additional clinical information not available in billing records. Measures that combine claims data and vital records data can be useful in the absence of chart data.

# Related and competing measures

The Committee evaluated four similar measures for health-care acquired neonatal infections and agreed it would prefer to recommend a single measure rather than multiple, overlapping measures. While the measure specifications are similar, the data sources for three of the four measures, however, are very different. One is built from hospital billing data, a second is based

on voluntary individual hospital submissions to The Joint Commission, and two are developed from data submitted to the Vermont Oxford Network by its member hospitals. Thus the variation and benchmark information each could generate is potentially quite different, and the various current users understandably do not want to lose that capacity. However, states and private purchasers do not readily have access to the registry-base measures. In the absence of head-to-head comparisons of the measures the Committee cannot make any judgments as to differences in reliability and validity. Given these issues, the Committee recommended retaining three of the measures for the present time.

#### Harmonization

Harmonization was not a significant issue in this project. One new measure was submitted fully harmonized with an endorsed measure. It is anticipated that clinician-level measures in development will be harmonized with these facility-level measures.

## COMMENTS ON THE DRAFT REPORT AND THEIR DISPOSITION

NQF received 149 comments from a variety of stakeholders, including 19 member organizations and 53 organizations and private citizens who did are not NQF members on measures both recommended and not recommended for endorsement as well as general comments on the draft report.

A table of complete comments submitted during the comment period, with the responses to each comment and the actions taken by the Steering Committee, is posted to the UPerinatal and Reproductive Health Endorsement Maintenance project page on the NQF website, along with the measure submission forms. The Steering Committee reviewed and responded to all comments received. They did not make any changes to the recommendations based on the comments received.

The Steering Committee reviewed the comments and focused its discussion on specific measures or topic areas with the most significant and recurring issues. Comments about specific measure specifications and rationale were forwarded to the measure developers, who were invited to respond.

#### **GENERAL COMMENTS**

# Additional areas for measure development

Many comments were submitted suggesting areas for additional measure development or echoed the areas identified in the draft report.

**ACTION TAKEN**: After review by the Committee, the report was updated to include many of these suggestions.

## **Electronic Health Records**

An EHR vendor submitted comments on all of the measures regarding the feasibility of each measure for a typical hospital or medical practice using an advanced EHR and the typical clinical users who will be recording the required information. They did not submit comments on the appropriateness, accuracy, or importance of the measures. They noted concerns or suggested minor modifications to the specifications for the following measures to improve the usability in EHRs.

**ACTION TAKEN:** Currently, none of the measures under consideration are specified for use in EHRs; thus, the issues raised have been provided to the developers for their consideration as they move toward an electronic environment.

# Level of analysis

Several commenters requested additional level of analysis for three measures:

- 0469: PC-01 Elective Delivery (requesting clinician, clinician group, ACO, health plan)
  - o Currently facility and population (national) level
- 0470: Incidence of Episiotomy (requesting clinician, clinician group, ACO, health plan)
  - o Currently facility level
- 0471: PC-02 Cesarean Section (requesting clinician, clinician group, ACO, health plan)
  - o Currently facility and population (national) level

**ACTION TAKEN:** The Committee noted that it is difficult to "just bring measures down to the clinician level" and that methodologic challenges (small sample size and attribution) result in unstable results at the clinician level. These measures would need testing at the clinician-level prior to specifying that level of analysis. The developers have responded that clinician-level measures are not the focus of their measure development program.

# Mandatory hospital reporting

Several comments noted the low numbers of participants by hospitals for the Joint Commission (TJC) core set and urged mandatory reporting be required to provide stakeholders more information about the quality of maternity care.

**ACTION TAKEN:** Reporting on and implementation of measures are not within the purview of the NQF endorsement process. However, the NQF-convened National Priorities Partnership Maternity Action Team is seeking mandatory reporting as a priority

action for 2012. The Committee also noted that LeapFrog is also encouraging public reporting.

# **Target values**

A commenter noted that it is hard to know how to interpret a hospital's episiotomy rates (#0470) or NTSV cesarean section rates (#0471). The interpretation of these measures and the manner in which they are used can greatly affect their validity for accountability and/or quality improvement purposes. For example, if a low risk woman arrives in labor with a herpetic lesion she should have a cesarean section. Regions with higher rates of babies with macrosomia might also have more cesarean sections. Additionally, "routine" episiotomies should be avoided, but clinically indicated cases (albeit not in large numbers) are necessary.

ACTION TAKEN: The Committee stated that "de-contextualized, arbitrary targets are problematic" and that target rates are very context-driven. Committee members agreed that current rates are too high in many institutions on these measures and that until more data is available to fully describe current performance and relationships to outcomes and identify what improvement is possible, specific targets are not feasible. They noted that trends, or comparisons with other institutions, are a more useful measurement than a specific target value. The Committee requested that the developers consider developing benchmarks based on data collected from using the measure, and presenting that when the measures undergo maintenance review.

#### MEASURE SPECIFIC COMMENTS

# 0480: Exclusive Breast Milk Feeding

#### Measure evaluation form

This measure received 18 comments. While ten commenters acknowledged the health benefits of breastfeeding, they were primarily concerned with "mandated breastfeeding" and suggested that it was a woman's right to choose whether or not to breastfeed, and the measure would prevent women who chose not to breastfeed from receiving proper education and information on alternatives. However, eight commenters supported the measure, stating that the health reasons for breastfeeding are well documented, that the measure would not mandate breastfeeding for all babies, and that performance for this measure is not expected to be at 100%.

**ACTION TAKEN:** The Committee underscored the significant health benefits for newborns (reduction in otitis media, respiratory tract infections, atopic dermatitis, gastroenteritis, type 2 diabetes, sudden infant death syndrome, and obesity) and mother (decreased risk for type 2 diabetes, ovarian cancer, and breast cancer) conferred by breastfeeding and support all efforts to optimize maternal education, encouragement, and

support to enable women to make the healthiest choices for herself and her child. The Committee agreed that improving support for mothers who wish to breastfeed does not equal removing a choice. The Committee acknowledged that the target for this measure is not 100% and that the potential unintended consequences of "inappropriate coercion" should be monitored.

The Committee noted that current performance is quite low at 40% with much room for improvement. Both the Committee and the developer agreed that the purpose of the measure is to eliminate impediments to breastfeeding. According to the CDC, (<a href="http://www.cdc.gov/breastfeeding/data/reportcard.htm">http://www.cdc.gov/breastfeeding/data/reportcard.htm</a>) "less than 5% of U.S. infants are born in Baby-Friendly hospitals, a global designation that indicates best practices in maternity care to support breastfeeding mothers. The hospital period is critical for mothers and babies to learn to breastfeed, and hospitals need to do more to support them. Birth facility policies and practices significantly impact whether a woman chooses to start breastfeeding and how long she continues to breastfeed." The Committee recommends additional process measures to assist facilities in improving support for breastfeeding. The Committee agreed to maintain their recommendation of the measure.

# Health care acquired infection measures

- 0304: Late sepsis or meningitis in Very Low Birth Weight (VLBW) neonates (riskadjusted) Measure evaluation form
- 0478: Neonatal Blood Stream Infection Rate (NQI #3) Measure evaluation form
- 1731: Health Care-Associated Bloodstream Infections in Newborns Measure evaluation form

Three commenters raised concerns about having three separate measures on hospital acquired/late onset infections and requested that the measures be harmonized. While some of the comments agreed that the measures use different reporting streams, they suggested having three separate measures would cause confusion. One commenter agreed that there was a need for three separate measures and supported all three. A commenter noted that measures 0478 and 1731 would identify infants with late-onset sepsis, and that the population of infants that develop late onset meningitis is unique and general measures would not be efficacious for this population. Additionally, all three measures received comments and questions on the specifications, which were sent to the developers.

**ACTION TAKEN:** The Committee agreed that measure 304 was a related HAI measure but is quite distinct in that it 1) focuses on a very-high risk population—VLBW infants with a infection rate of 15% (VLBW represents only 1.5% of all births); 2) the measure only applies to hospitals with NICUs (approximately 800-900 hospitals in the US); and 3)

uses clinical data for the Vermont Oxford Network registry that captures 80% of VLBW infants in the US.

Measure 1731 was created by TJC when it selected five NQF-endorsed measures, including measure 478, for its Perinatal Core Set. Measures 478 and 1731 are fully harmonized measures within the limits of their data sources and measure 1731 is also harmonized with the other four measures in TJC Perinatal Core Set (0469 Elective Delivery < 39 weeks; 0471 Cesarean section; 0476 Antenatal Steroids; and 0480 Exclusive Breast Milk Feeding) for use in TJC's performance measurement programs. Measures 478 and 1731 differ from related measure 304 in that they also capture larger babies who experience in-hospital death; operating room procedure; mechanical ventilation; or transfers in less than 2 days of age. Measure 478 is based on administrative data and is collected in the HCUP State Inpatient Databases that are widely used by states.

The Committee understood the concerns about multiple related measures, but in the absence of head-to-head comparisons of the measures the Committee could not make any judgments as to differences in reliability and validity. All three measures are widely used and each is useful to different user groups. After reviewing and discussing the comments, the Committee did not change its recommendation of all three measures.

# 0470: Incidence of Episiotomy

#### Measure evaluation form

A commenter suggested additional exclusions for shortening the second stage of labor; the developer responded that the suggested exclusions did not align with ACOG guidelines and that it would be too complicated to captured using current data collection methods. Two comments were submitted in support of this measure.

ACTION TAKEN: The developer responded that "the ACOG technical bulletin (number 71, 2006) states that "(e)ven the presumption that episiotomy shortens the second stage of labor has not been conclusively shown." Regardless, the goal of this measure is to reduce (not eliminate) the routine use of episiotomy at the facility level. We anticipate that there may be clinical scenarios wherein a provider may choose to perform an episiotomy. These indications and the one cited above are too complex to be captured using current methods of data capture and therefore cannot and should not be included in this measure." The Committee agreed with the developer response and did not change their recommendation.

# 0475: Hepatitis B Vaccine Coverage Among All Live Newborn Infants Prior to Hospital or Birthing Facility Discharge

# Measure evaluation form

This measure received three supportive comments and one comment noting concern with the exclusion of parental refusals, and requested that refusals be measured separately as a component of the numerator, consistent with NQF-endorsed immunization measures for influenza and pneumonia.

ACTION TAKEN: The developer replied that the original proposal for this measure encouraged such an approach—intending parental/guardian exclusions to be an optional adjustment to the denominator. Data obtained during field testing of the measure indicated that hospitals were not yet fully able to compute the amount of vaccination refusals. As use of ICD-10 codes is adopted (effective October 1, 2013), training hospital staff to appropriately document vaccinations refusals will occur and the measure will become more accurate. The Committee noted that coding for parental refusals will be standardized with ICD-10 and that should be incorporated into the next annual update. The Committee did not change their recommendation.

# 0476: Appropriate Use of Antenatal Steroids

## Measure evaluation form

A comment was submitted that supported the measure, but suggested that the specifications be altered to bring them in line with the new ACOG Committee Opinion (Feb 2011); the developer agreed that these specifications were being updated as of February 2012. A second comment requested clarification on the list of reasons for the exclusion criteria "documented reason for not administering antenatal steroid," noting that without a specified list, there will be inconsistency in measurement with facilities, who will provide their own coding reasons.

**ACTION TAKEN:** The Committee agreed with the updated specifications. The developer explained that the data analysis is done by trained abstractors who are able to assess whether or not the documented reasons meet the specifications. The Committee did not change their recommendation.

0477: Under 1500g infant Not Delivered at Appropriate Level of Care

Measure evaluation form

This measure received two comments requesting expansion of the exclusion criteria to include reasons outside of the health care system's control for failure to transport to a hospital with appropriate levels of care services (e.g., very late presentation in active labor, lack of safe transportation, distance to NICU in rural areas).

**ACTION TAKEN:** The developer noted that in their use of this measure, urban hospitals were less likely to perform well on this measure than rural ones and also noted that the performance on this measure is not intended to be zero. The measure data is collected from simple administrative data and does not require chart review. After review of the comments and developer response, the Committee did not change their recommendation on the measure.

# 0483: Proportion of infants 22 to 29 weeks gestation screened for retinopathy of prematurity.

## Measure evaluation form

A commenter raised concerns noting that their internal data (submitted for publication) does not support the burden of reporting this measure. Another commenter requested clarification on the exclusion criteria, stating that the exclusions "Outborn infants admitted to the reporting hospital more than 28 days after birth" and "Outborn infants who have been home prior to admission" do not appear aligned. This comment has been sent to the developer for a response.

ACTION TAKEN: The Committee agreed the data mentioned by the commenter should be reviewed after it is published, and that it should be taken into consideration during annual updates or maintenance review. The Committee also noted that some high-performing hospitals may have very little room for improvement but the Vermont Oxford Network (VON) data indicates that more than 23% percent of infants at 29 weeks gestation are not screened before hospital discharge. The developer clarified the exclusions, explaining that they pertain to VON's data collection criteria. The Committee did not change their recommendation of the measure.

# 1746: Intrapartum Antibiotic Prophylaxis for Group B Streptococcus (GBS)

# Measure evaluation form

Commenters submitted questions on the details of the specifications, and on the ability of EHRs to manage the many different data elements required to calculate this measure. The comments were sent to the developer for a response.

**ACTION TAKEN:** The developer responded that they kept the scope of the measure confined to the essentials for delivering care, and that they expect data collection will be easier as electronic systems are standardized. After reviewing the developer's response, the Committee had no additional comments and did not change their recommendation.

#### MEASURES NOT RECOMMENDED

Three measures not recommended by the Committee received comments in support of the measures:

0479: Birth dose of hepatitis B vaccine and hepatitis B immune globulin for newborns of hepatitis B surface antigen (HBsAg) positive mothers

# Measure evaluation form

The measure developer, supported by 31 comments from a range of stakeholders, requested reconsideration of measure 0479. Commenters raised concerns about the disparities in care for babies born to HBsAg positive mothers and the long-term implications of not measuring Hepatitis B immune globulin (HBIG) administration to prevent Hepatitis B infection (HBV). The Immunization Action Coalition submitted data noting that of the 24,000 infants born to mothers who are chronically infected, this measure could prevent an estimated 9,100 infants from developing chronic HBV, including preventing an estimated 2,300 from dying of liver failure or liver cancer as adults. Other commenters noted that the CDC estimates that 1,000 newborns a year are infected with the HBV. Multiple comments noted that this measure would help achieve one of the primary goals of the DHHS "Action Plan for the Prevention, Care and Treatment of Viral Hepatitis".

ACTION TAKEN: The Committee noted that this is a very regional issue, and with measure 0475: Hep B vaccine coverage among all live newborn infants prior to hospital or birthing facility discharge in place, the additional impact of this measure would be small and highly variable among states. This measure addresses only babies born to HBsAg positive mothers. In 2009 in California, the state with the largest number of maternal cases 2077 of 2138 infants, (97.1%) received the first dose of the hepatitis B vaccine and the HBIG within 24 hours of birth. The developer argued that since HBV is a preventable disease every effort should be made to reach 100% compliance. The Committee agreed with the importance of the issue but suggested that with a small gap in current performance a national quality measure may not be the right approach to capture the few babies that are being missed. The Committee pointed to CDC's funded state, local, and territorial Perinatal Hepatitis B Prevention Coordinators that focus on

preventing perinatal transmission of HBV. After reviewing the comments and listening to the measure developer, the Committee voted not to change their recommendation against endorsement of the measure.

# 0502: Pregnancy test for female abdominal pain patients

# Measure evaluation form

The developer requested that the Committee review and reconsider its recommendation against this measure, as it passed all of the four NQF evaluation criteria.

ACTION TAKEN: The Committee pointed to the number of medium to low ratings on the sub-criteria for Importance and Scientific Acceptability. The Committee agreed to reevaluate the measure after review of the transcript of the original Steering Committee and workgroup discussions. On re-evaluation, the Committee again decided not to recommend the measure. Although the Committee determined the measure passed the Importance criteria by a small majority, members voiced concerns over lack of data on ectopic disease burden; little data on current performance and gap; and specifically, no data on how many ectopic pregnancies are identified by routine urine pregnancy testing in the ER and impact on outcomes. Committee members noted that the ratings on reliability and validity and feasibility again had substantial numbers of medium or low votes citing concerns with the conflicting information presented on reliability and validity, and burden of data collection particularly for the exclusions.

## 0747: Admission to Neonatal Intensive Care Unit at Term

## Measure evaluation form

Two comments were submitted suggesting that this component of the composite Adverse Outcomes Index measure is an important measure and that it be endorsed on its own.. Supporters voiced concerns with potential overuse of NICU facilities and the need for a measure to monitor the quality and appropriateness of NICU admissions.

**ACTION TAKEN:** The developer is willing to support a stand-alone measure. The developer clarified that the measure captures only the highest NICU acuity, i.e., uniform billing code 174 Level IV, newborn intensive care. Committee members noted that staffing and utilization patterns for NICUs is highly variable and speculated that overuse might be more likely at lower levels of acuity, e.g., observation for possible sepsis or hypothermia or hypoglycemia. Committee members would want to review the literature and evidence for overutilization as part of the evaluation for a stand-alone measure.

Committee members asked how an NICU admission measure would relate to endorsed measure 0716 <u>Healthy Term Newborn</u> and noted that it would need to be harmonized if it was not directly competing. The Committee agreed the developer should pursue further development and testing, and bring the measure back to NQF for review in the future.

# **NQF MEMBER VOTING**

The 15-day voting period for the Perinatal and Reproductive Healthcare Endorsement Maintenance 2011 project concluded on February 27, 2012. 26 member organizations voted; no votes were received from the Public/Community Health Agency or Supplier/Industry councils. All 14 measures were approved with total approval ranging from 96% to 100%.

One Consumer Council voter, Childbirth Connection, submitted a voting comment on a measure not recommended, consistent with their submitted comments during the review period. No other comments were submitted during voting.

**Voting Comment:** Childbirth Connection is disappointed that the Steering Committee did not also recommend endorsement of 0479 Birth dose of hepatitis B vaccine and hepatitis B immune globulin for newborns of hepatitis B surface antigen (HBsAg) positive mothers. The report states that disparity measures are a high priority, and this measure would favorably impact disparity populations. We found the many comments about preventable morbidity and mortality to be compelling. We noted that mechanisms for awareness (e.g., CDC programs) make a difference in care practices as, we believe, would a nationally endorsed performance measure. We disagree that this is a regional concern, as immigrants from endemic areas are widely distributed throughout the country. We expect that upcoming NQF measure endorsement projects with relevant themes will provide the developers with an opportunity to resubmit this measure, and we hope the measure will be well received.

# **Voting Results**

Voting results for the 14 candidate consensus standards are provided below. (The full measure summary evaluation tables are in Appendix A.)

Measure #0304 Late Sepsis or Meningitis in Very Low Birth Weight (VLBW) Neonates (riskadjusted)

Measure Council	Yes	No	Abstain	<b>Total Votes</b>	% Approval*
Consumer	4	0	0	4	100%
Health Plan	5	0	0	5	100%

Health Professional	4	0	0	4	100%
Provider Organizations	4	0	0	4	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	7	0	0	7	100%
QMRI	2	0	0	2	100%
Supplier/Industry	0	0	0	0	
All Councils	26	0	0	26	100%
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

<sup>\*</sup>equation: Yes/ (Total - Abstain)

# Measure #0469 PC-01 Elective Delivery

Measure Council	Yes	No	Abstain	<b>Total Votes</b>	% Approval*
Consumer	4	0	0	4	100%
Health Plan	5	0	0	5	100%
Health Professional	3	0	1	4	100%
Provider Organizations	4	0	0	4	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	7	0	0	7	100%
QMRI	2	0	0	2	100%
Supplier/Industry	0	0	0	0	
All Councils	25	0	1	26	100%
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

<sup>\*</sup>equation: Yes/ (Total - Abstain)

# Measure #0470 Incidence of Episiotomy

Measure Council	Yes	No	Abstain	<b>Total Votes</b>	% Approval*
Consumer	4	0	0	4	100%
Health Plan	5	0	0	5	100%
Health Professional	3	0	1	4	100%
Provider Organizations	3	1	0	4	75%
Public/Community Health Agency	0	0	0	0	
Purchaser	7	0	0	7	100%
QMRI	2	0	0	2	100%
Supplier/Industry	0	0	0	0	
All Councils	24	1	1	26	96%
Percentage of councils approving (>50%)					100%
Average council percentage approval					96%

<sup>\*</sup>equation: Yes/ (Total - Abstain)

# Measure #0471 PC-02 Cesarean Section

Measure Council	Yes	No	Abstain	<b>Total Votes</b>	% Approval*
Consumer	4	0	0	4	100%
Health Plan	5	0	0	5	100%
Health Professional	3	0	1	4	100%
Provider Organizations	4	0	0	4	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	7	0	0	7	100%
QMRI	2	0	0	2	100%
Supplier/Industry	0	0	0	0	
All Councils	25	0	1	26	100%
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

<sup>\*</sup>equation: Yes/ (Total - Abstain)

# Measure #0472 Appropriate Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision- Cesarean Section

Measure Council	Yes	No	Abstain	<b>Total Votes</b>	% Approval*
Consumer	4	0	0	4	100%
Health Plan	5	0	0	5	100%
Health Professional	4	0	0	4	100%
Provider Organizations	4	0	0	4	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	7	0	0	7	100%
QMRI	2	0	0	2	100%
Supplier/Industry	0	0	0	0	
All Councils	26	0	0	26	100%
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

<sup>\*</sup>equation: Yes/ (Total - Abstain)

Measure #0473 Appropriate DVT Prophylaxis in Women Undergoing Cesarean Delivery

Measure #04/5 Appropriate DV 1 Frophyl	VVUII	nen Undergonig Cesarean Denvery			
Measure Council	Yes	No	Abstain	<b>Total Votes</b>	% Approval*
Consumer	4	0	0	4	100%
Health Plan	5	0	0	5	100%
Health Professional	3	0	1	4	100%
Provider Organizations	4	0	0	4	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	7	0	0	7	100%
QMRI	2	0	0	2	100%
Supplier/Industry	0	0	0	0	
All Councils	25	0	1	26	100%
Percentage of councils approving (>50%)					100%

Average council percentage approval 100%
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<sup>\*</sup>equation: Yes/ (Total - Abstain)

Measure #0475 Hepatitis B Vaccine Coverage Among All Live Newborn Infants Prior to Hospital or Birthing Facility Discharge

Measure Council	Yes	No	Abstain	<b>Total Votes</b>	% Approval*
Consumer	4	0	0	4	100%
Health Plan	5	0	0	5	100%
Health Professional	4	0	0	4	100%
Provider Organizations	4	0	0	4	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	7	0	0	7	100%
QMRI	2	0	0	2	100%
Supplier/Industry	0	0	0	0	
All Councils	26	0	0	26	100%
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

<sup>\*</sup>equation: Yes/ (Total - Abstain)

# Measure #0476 PC-03 Antenatal Steroids

Measure Council	Yes	No	Abstain	<b>Total Votes</b>	% Approval*
Consumer	4	0	0	4	100%
Health Plan	5	0	0	5	100%
Health Professional	3	0	1	4	100%
Provider Organizations	4	0	0	4	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	7	0	0	7	100%
QMRI	2	0	0	2	100%
Supplier/Industry	0	0	0	0	
All Councils	25	0	1	26	100%
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

<sup>\*</sup>equation: Yes/ (Total - Abstain)

Measure #0477 Under 1500g infant Not Delivered at Appropriate Level of Care

measure notification and insulative benefice at appropriate bever of care							
Measure Council	Yes	No	Abstain	<b>Total Votes</b>	% Approval*		
Consumer	4	0	0	4	100%		
Health Plan	5	0	0	5	100%		
Health Professional	3	0	1	4	100%		
Provider Organizations	4	0	0	4	100%		
Public/Community Health Agency	0	0	0	0			
Purchaser	7	0	0	7	100%		

QMRI	2	0	0	2	100%
Supplier/Industry	0	0	0	0	
All Councils	25	0	1	26	100%
Percentage of councils approving (>50%)				100%	
Average council percentage approval					100%

<sup>\*</sup>equation: Yes/ (Total - Abstain)

# Measure #0478 Neonatal Blood Stream Infection Rate (NQI #3)

Measure Council	Yes	No	Abstain	<b>Total Votes</b>	% Approval*
Consumer	4	0	0	4	100%
Health Plan	5	0	0	5	100%
Health Professional	4	0	0	4	100%
Provider Organizations	4	0	0	4	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	7	0	0	7	100%
QMRI	2	0	0	2	100%
Supplier/Industry	0	0	0	0	
All Councils	26	0	0	26	100%
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

<sup>\*</sup>equation: Yes/ (Total - Abstain)

# Measure #0480 PC-05 Exclusive Breast Milk Feeding

Measure Council	Yes	No	Abstain	<b>Total Votes</b>	% Approval*
Consumer	4	0	0	4	100%
Health Plan	5	0	0	5	100%
Health Professional	3	0	1	4	100%
Provider Organizations	3	1	0	4	75%
Public/Community Health Agency	0	0	0	0	
Purchaser	7	0	0	7	100%
QMRI	2	0	0	2	100%
Supplier/Industry	0	0	0	0	
All Councils	24	1	1	26	96%
Percentage of councils approving (>50%)					100%
Average council percentage approval					96%

<sup>\*</sup>equation: Yes/ (Total - Abstain)

# ${\bf Measure}~\#0483~{\bf Proportion}~{\bf of}~{\bf Infants}~{\bf 22}~{\bf to}~{\bf 29}~{\bf Weeks}~{\bf Gestation}~{\bf Screened}~{\bf for}~{\bf Retinopathy}~{\bf of}~{\bf Prematurity}$

Measure Council	Yes	No	Abstain	<b>Total Votes</b>	% Approval*
Consumer	4	0	0	4	100%
Health Plan	5	0	0	5	100%

Health Professional	3	0	1	4	100%
Provider Organizations	3	1	0	4	75%
Public/Community Health Agency	0	0	0	0	
Purchaser	7	0	0	7	100%
QMRI	2	0	0	2	100%
Supplier/Industry	0	0	0	0	
All Councils	24	1	1	26	96%
Percentage of councils approving (>50%)					100%
Average council percentage approval					96%

<sup>\*</sup>equation: Yes/ (Total - Abstain)

# **Measure #1731 Health Care-Associated Bloodstream Infections in Newborns**

Measure Council	Yes	No	Abstain	<b>Total Votes</b>	% Approval*
Consumer	4	0	0	4	100%
Health Plan	5	0	0	5	100%
Health Professional	4	0	0	4	100%
Provider Organizations	3	1	0	4	75%
Public/Community Health Agency	0	0	0	0	
Purchaser	7	0	0	7	100%
QMRI	2	0	0	2	100%
Supplier/Industry	0	0	0	0	
All Councils	25	1	0	26	96%
Percentage of councils approving (>50%)					100%
Average council percentage approval					96%

<sup>\*</sup>equation: Yes/ (Total - Abstain)

Measure #1746 Intrapartum Antibiotic Prophylaxis for Group B Streptococcus (GBS)

Measure Council	Yes	No	Abstain	<b>Total Votes</b>	% Approval*
Consumer	4	0	0	4	100%
Health Plan	5	0	0	5	100%
Health Professional	4	0	0	4	100%
Provider Organizations	4	0	0	4	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	7	0	0	7	100%
QMRI	2	0	0	2	100%
Supplier/Industry	0	0	0	0	
All Councils	26	0	0	26	100%
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

<sup>\*</sup>equation: Yes/ (Total - Abstain)

# MEASURES WITHDRAWN FROM CONSIDERATION

Nine measures previously endorsed by NQF have not been re-submitted or withdrawn from maintenance of endorsement. Two additional measures were withdrawn after initial submission. The following measures are being retired from endorsement:

Measure	Reason for retirement
0012: Prenatal Screening for Human	Will be superseded by measures currently in
Immunodeficiency Virus (HIV) (AMA/PCPI)	development.
0014: Prenatal Anti-D Immune Globulin	Will be superseded by measures currently in
(AMA/PCPI)	development.
0015: Prenatal Blood Groups (ABO), D (Rh)	Will be superseded by measures currently in
Type (AMA/PCPI)	development.
0016: Prenatal Blood Group Antibody Testing	Will be superseded by measures currently in
(AMA/PCPI)	development.
0333: Severity-Standardized ALOS -	Developer no longer maintains the measure.
Deliveries (Leapfrog Group)	
0474: Birth Trauma – Injury to Neonate (PSI	Withdrawn during Steering Committee
17) (AHRQ)	discussion.
0485: Neonatal Immunization (Child Health	Measure no longer aligns with APIC
Corporation of America)	guidelines
0606: Pregnant women that had HIV testing	Developer elected not to pursue maintenance
(Ingenix)	of endorsement.
0607: Pregnant women that had syphilis	Developer elected not to pursue maintenance
screening (Ingenix)	of endorsement.
0608: Pregnant women that had HBsAg testing	Developer elected not to pursue maintenance
(Ingenix)	of endorsement.
0484: Proportion of infants 22-29 weeks	Withdrawn due to changing evidence and
gestation treated with surfactant who are	practice.
treated within 2 hours of birth (VON)	

#### APPENDIX A: MEASURE EVALUATION SUMMARY TABLES

### 0469 PC-01 Elective Delivery

#### Maintenance Measure (previously time-limited endorsement)

**Description**: This measure assesses patients with elective vaginal deliveries or elective cesarean sections at >= 37 and < 39 weeks of gestation completed. This measure is a part of a set of five nationally implemented measures that address perinatal care (PC-02: Cesarean Section, PC-03: Antenatal Steroids, PC-04: Health Care-Associated Bloodstream Infections in Newborns, PC-05: Exclusive Breast Milk Feeding)

**Numerator Statement:** Patients with elective deliveries with ICD-9-CM Principal Procedure Code or ICD-9-CM Other Procedure Codes for one or more of the following:

- Medical induction of labor as defined in Appendix A, Table 11.05 available at: http://manual.jointcommission.org
- Cesarean section as defined in Appendix A, Table 11.06 while not in Active Labor or experiencing Spontaneous Rupture of Membranes available at: http://manual.iointcommission.org

**Denominator Statement:** Patients delivering newborns with >= 37 and < 39 weeks of gestation completed **Exclusions:** 

- ICD-9-CM Principal Diagnosis Code or ICD-9-CM Other Diagnosis Codes for conditions possibly justifying elective delivery prior to 39 weeks gestation as defined in Appendix A, Table 11.07
- Less than 8 years of age
- Greater than or equal to 65 years of age
- Length of Stay >120 days
- Enrolled in clinical trials

Adjustment/Stratification: No risk adjustment or risk stratification Not Applicable Not Applicable

Level of Analysis: Facility, Population: National

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Paper Records

Measure Steward: The Joint Commission

#### STEERING COMMITTEE MEETING 11/29-30/2011

### Importance to Measure and Report: Y-25; N-0

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

1a. Impact: H-7; M-0; L-1; I-0; 1b. Performance Gap: H-8; M-0; L-0; I-0

1c. Evidence Quantity: H-7; M-1; L-0; I-0; Quality: H-3; M-4; L-1; I-0; Consistency: H-7; M-0; L-1; I-0

#### Rationale:

- Significant opportunity for improvement Joint Commission data indicates current performance at 18%.
- Evidence is strong that elective delivery prior to 39 weeks impacts newborn adversely.
- The goal is not 0% because of unusual circumstances that will not be captured by the measure.

#### 2. Scientific Acceptability of Measure Properties: Y-24; N-1

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: H-5; M-2; L-0; I-1 2b. Validity: H-4; M-4; L-0; I-0

#### Rationale:

- Measure has generous exclusions, but two significant exclusions are left out prior Classical C-section and myomectomy –
  developer acknowledges that they are hearing this feedback repeatedly and are considering including, though the number of
  Classical C-sections and myomectomies is quite small.
- Some coding issues "active labor" not easily coded; ICD-10 has greater specificity but Classical C-section and myomectomy are not in the first iteration.
- Exclusions are generous but some "diagnosis creep" may be seen with increased use of allowable exclusions

## 3. Usability: H-9; M-15; L-1; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)
3a. Public Reporting: H-4; M-3; L-0; I-1

3b. QI: H-4: M-3: L-0: I-1

#### Rationale:

- Some limitations for use with Medicaid not all elements are readily captured in billing codes.
- Some chart review is needed after use of the codes.

#### 0469 PC-01 Elective Delivery

Adopted by the March of Dimes as a major campaign.

# 4. Feasibility: H-3; M-21; L-1; I-0

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

4a. Byproduct of Care Processes: H-7; M-0; L-1; I-0

4b. Electronic data sources: H-4; M-4; L-0; I-0

4c. Suscep inaccuracies, consequences: H-2; M-4; L-1; I-1

4d. Data collection strategy: H-6; M-2; L-0; I-0

# Rationale:

• Data intense but feasible.

• Possibility for overuse of "soft" exclusion criteria.

## Steering Committee Recommendation for Endorsement: Y-25; N-0

Rationale: Since endorsement in 2008 this measure has been adopted by many providers and the March of Dimes has launched a major campaign to prevent unnecessary prematurity. Data indicates significant opportunity for improvement and the evidence is strong that newborns are adversely affected by unnecessary early birth. The developers indicate a willingness to include two important exclusions – Classical C-section and myomectomy.

RECOMMENDATION: Strongly recommend additional exclusions for prior Classical C/S and myomectomy

#### **Public & Member Comment**

#### Comments included:

• Comments suggested that this be reported at the clinician level.

Developer response: provider level measures are not the focus of their measure development program.

Committee Response: The Committee noted that it is difficult to "just bring measures down to the clinician level" and that methodologic challenges (small sample size and attribution) result in unstable results at the clinician level. These measures would need testing at the clinician-level prior to specifying that level of analysis.

#### 0470 Incidence of Episiotomy

#### Maintenance Measure (previously time-limited endorsement)

**Description:** Percentage of vaginal deliveries (excluding those coded with shoulder dystocia) during which an episiotomy is performed. **Numerator Statement:** Number of episiotomy procedures (ICD-9 code 72.1, 72.21, 72.31, 72.71, 73.6; ICD-10

PCS:0W8NXZZ,0WQNXZZ,10D07Z3,10D07Z4,10D07Z5,10D07Z6) performed on women undergoing a vaginal delivery (excluding those with shoulder dystocia) during the analytic period- monthly, quarterly, yearly etc.

**Denominator Statement:** All vaginal deliveries during the analytic period- monthly, quarterly, yearly etc. excluding those coded with a shoulder dystocia.

**Exclusions:** Women who have a coded complication of shoulder dystocia. In the case of shoulder dystocia, an episiotomy is performed to free the shoulder and prevent/mitigate birth injury to the infant.

Adjustment/Stratification: No risk adjustment or risk stratification NA NA

Level of Analysis: Facility

Type of Measure: Outcome, Process

Data Source: Administrative claims, Paper Records Measure Steward: Christiana Care Health System

## STEERING COMMITTEE MEETING 11/29-30/2011

# Importance to Measure and Report: Y-19; N-0

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

1a. Impact: H-5; M-4; L-0; I-0; 1b. Performance Gap: H-6; M-3; L-0; I-0

1c. Evidence Quantity: H-6; M-2; L-0; I-1; Quality: H-4; M-4; L-0; I-1; Consistency: H-6; M-1; L-0; I-1

#### Rationale:

- Significant literature against episiotomy; evidence for increased risk of 3rd and 4th degree lacerations with episiotomy.
- ACOG supports restricted use of episiotomy.
- Wide variation in provider performance: in 2010 the National Perinatal Information Center reported a national rate of 16.2% with tremendous inter center variation (4.3% to 34.6%).
- Committee members report that when this measure is implemented, rapid improvement is seen.

## 2. Scientific Acceptability of Measure Properties: Y-19; N-0

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: H-8; M-1; L-0; I-0 2b. Validity: H-4; M-5; L-0; I-0

#### Rationale:

- Uses administrative data; CPT procedure codes are usually coded reliably.
- Developers' comparison with charts: some mismatch but random whether over coding or under coding.
- Only exclusion is shoulder dystocia an appropriate indication for episiotomy.
- Level of analysis at the facility level produces a stable result. Confidence intervals for individual clinicians is very unstable.

# 3. Usability: H-14; M-4; L-1; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)
3a. Public Reporting: H-5; M-1; L-3; I-0

3b. QI: H-5; M-4; L-0; I-0

# Rationale:

- Easily understood by multiple audiences.
- NPIC data shows wide variation in episiotomy incidence.
- Where measure has been used, rates of episiotomy are dropping.

# 4. Feasibility: H-15; M-5; L-0; I-0

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

4a. Byproduct of Care Processes: H-8; M-1; L-0; I-0

4b. Electronic data sources: H-8; M-1; L-0; I-0

4c. Suscep inaccuracies, consequences: H-8; M-0; L-1; I-0

4d. Data collection strategy: H-9; M-0; L-0; I-0

# Rationale:

- High fidelity in coding.
- Measures is easy to collect and useful for comparisons

# 0470 Incidence of Episiotomy

Steering Committee Recommendation for Endorsement: Y-19; N-1

**Rationale:** Current data indicates overuse of episiotomy and wide variation in performance. Evidence and ACOG guidelines support restricted use of episiotomy. When this measure is implemented, rapid performance improvement has been observed.

# Public & Member Comment

#### Comments included:

- Additional exclusions for shortening the second stage of labor;
- Report at the clinician level

#### Developer response:

- Suggested exclusions did not align with ACOG guidelines and it would be too complicated to capture using current data collection methods.
- Clinician level measures are not the focus of their measure development program.

Committee Response: The Committee agreed with the developer about the exclusions and noted that it is difficult to "just bring measures down to the clinician level" and that methodologic challenges (small sample size and attribution) result in unstable results at the clinician level. These measures would need testing at the clinician-level prior to specifying that level of analysis.

#### 0471 PC-02 Cesarean Section

#### Maintenance Measure

**Description**: This measure assesses the number of nulliparous women with a term, singleton baby in a vertex position delivered by cesarean section. This measure is part of a set of five nationally implemented measures that address perinatal care (PC-01: Elective Delivery, PC-03: Antenatal Steroids, PC-04: Health Care-Associated Bloodstream Infections in Newborns, PC-05: Exclusive Breast Milk Feeding).

**Numerator Statement:** Patients with cesarean sections with ICD-9-CM Principal Procedure Code or ICD-9-CM Other Procedure Codes for cesarean section as defined in Appendix A, Table 11.06 available at:

http://manual.jointcommission.org

**Denominator Statement:** Nulliparous patients delivered of a live term singleton newborn in vertex presentation

**Exclusions: •** ICD-9-CM Principal Diagnosis Code or ICD-9-CM Other Diagnosis Codes for contraindications to vaginal delivery as defined in Appendix A, Table 11.09

- Less than 8 years of age
- Greater than or equal to 65 years of age
- Length of Stay >120 days
- Enrolled in clinical trials

Adjustment/Stratification: Other Direct rate standardization to the distribution of the 2006 US population of nulliparous births. See attached spreadsheet for age bands used in the direct standardization. Not Applicable The Stratification Table used for direct standardization includes the Set Number, Stratified By, and the Age Stratum (Allowable Value). The Age Stratum refers to Patient Age which is calculated by the data element Admission Date minus the data element Birthdate. Each case will be stratified according to the patient age, after the Category Assignments (e.g., numerator, denominator, not in measure population) are completed and the overall rate is calculated.

Set Number Stratified By Age Stratum

PC-02a Overall Rate No allowable value exists for the overall rate. It includes all patients greater than or equal to 8 years and less than 65 years.

PC-02b Age 8 years through 14 years A Patient Age (Admission Date minus Birthdate) greater than or equal to 8 years and less than 15 years.

A Patient Age (Admission Date minus Birthdate) greater than or equal to 20 years and

A Patient Age (Admission Date minus Birthdate) greater than or equal to 25 years and

A Patient Age (Admission Date minus Birthdate) greater than or equal to 30 years and

A Patient Age (Admission Date minus Birthdate) greater than or equal to 35 years and

A Patient Age (Admission Date minus Birthdate) greater than or equal to 40 years and

A Patient Age (Admission Date minus Birthdate) greater than or equal to 45 years and

PC-02c Age 15 years through 19 years A Patient Age (Admission Date minus Birthdate) greater than or equal to 15 years and

less than 20 years.

PC-02d Age 20 years through 24 years less than 25 years.

PC-02e Age 25 years through 29 years

less than 30 years.

PC-02f Age 30 years through 34 years less than 35 years.

PC-02g Age 35 years through 40 years less than 40 years.

PC-02h Age 40 years through 44 years less than 45 years.

PC-02i Age 45 years through 64 years less than 65 years.

Level of Analysis: Facility, Population : National

Type of Measure: Outcome

Data Source: Administrative claims, Paper Records

Measure Steward: The Joint Commision

### STEERING COMMITTEE MEETING 11/29-30/2011

Importance to Measure and Report: Y-25; N-0

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

1a. Impact: H-7; M-0; L-0; I-0; 1b. Performance Gap: H-7; M-0; L-0; I-0

1c. Evidence Quantity: H-6; M-0; L-0; I-0; Quality: H-4; M-2; L-0; I-0; Consistency: H-5; M-1; L-0; I-0

#### Rationale:

- ACOG says this is the "optimal measure" for Cesarean section because it focuses on the first-time, uncomplicated pregnancy.
- Current performance 27.7% nationwide; rates are stable, not increasing.
- Measure looks at the outcome of the management of labor.
- The low-risk population is responsible for the large overall increase in C-section rates and shows the greatest variation.
- Large regional variations are observed.

#### 0471 PC-02 Cesarean Section

Measure results are related to induction rates; also parallels regional hysterectomy patterns.

# 2. Scientific Acceptability of Measure Properties: Y-25; N-0

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: H-6; M-1; L-0; I-0 2b. Validity: H-4; M-3; L-0; I-0

#### Rationale:

- Easily extractable from vital records.
- Good definitions.
- Stratification by age adjustment reflects linear rise in C/S rates from age 18 through 40 years (correlation coefficient = 98%).

## 3. Usability: H-23; M-2; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)
3a. Public Reporting: H-6; M-1; L-0; I-0

3b. QI: H-5; M-2; L-0; I-0

#### Rationale:

- Medicaid program core measure
- Greater incentives may be needed to see greater impact on results.
- Systems issues need to be addressed
- Initially a poorly understood measure significant learning curve as measure is more widely adopted.
- Improved performance on elective delivery < 39 weeks measure may reduce the C/S rate
- Another good measure for population assessment vital records are readily available

# 4. Feasibility: H-16; M-9; L-0; I-0

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

- 4a. Byproduct of Care Processes: H-5; M-2; L-0; I-0
- 4b. Electronic data sources: H-7; M-0; L-0; I-0
- 4c. Suscep inaccuracies, consequences: H-4; M-3; L-0; I-0
- 4d. Data collection strategy: H-7; M-0; L-0; I-0

## Rationale:

- States, Medicaid agencies and purchasers can do this measure.
- Vital records as an alternative data source.

# Steering Committee Recommendation for Endorsement: Y-25; N-0

**Rationale:** This is considered to be the "optimal measure" for primary Cesarean section. The measure assesses the outcome of the management of labor. Large regional variations are seen. The measure is readily constructed from several data sources.

# Public & Member Comment

#### Comments included:

Comments suggested that this be reported at the clinician level.

**Developer response**: Clinician level measures are not the focus of their measure development program.

Committee Response: The Committee noted that it is difficult to "just bring measures down to the clinician level" and that methodologic challenges (small sample size and attribution) result in unstable results at the clinician level. These measures would need testing at the clinician-level prior to specifying that level of analysis.

## 0472 Appropriate Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision- Cesarean Section.

#### Maintenance Measure

**Description:** 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

**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. **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.

**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

Adjustment/Stratification: No risk adjustment or risk stratification n/a 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.

Level of Analysis: Facility, Population: State

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Paper Records

Measure Steward: Massachusetts General Hospital/Partners Health Care System

## STEERING COMMITTEE MEETING 11/29-30/2011

# Importance to Measure and Report: Y-26; N-0

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

1a. Impact: H-7; M-1; L-0; I-0; 1b. Performance Gap: H-5; M-2; L-1; I-0

1c. Evidence Quantity: H-8; M-0; L-0; I-0; Quality: H-6; M-2; L-0; I-0; Consistency: H-8; M-0; L-0; I-0

#### Rationale:

- More than 1 million C-sections every year; high rates of surgical site infection.
- Clear evidence than antibiotic prophylaxis reduces surgical site infection.
- 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.
- Uncertain impact of antibiotic exposure to fetus; early data indicating change in fetal gut flora with C-section and antibiotic
  exposure; recent studies show changes in microbiological environment but not yet associated with health outcomes need
  longer-term studies to follow babies.

## 2. Scientific Acceptability of Measure Properties: Y-26; N-0

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: H-5; M-3; L-0; I-0 2b. Validity: H-6; M-2; L-0; I-0

#### Rationale:

- Good specifications.
- Well-tested; includes both timing and antibiotic selection.

#### 3. Usability: H-24; M-2; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)
3a. Public Reporting: H-7; M-1; L-0; I-0

3b. QI: H-8; M-0; L-0; I-0

#### Rationale:

- Used in Massachusetts with steady improvement in past three years.
- Hospitals already collect data for SCIP this is an additional surgical procedure.
- Harmonized with SCIP measures.

## 0472 Appropriate Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision- Cesarean Section.

#### 4. Feasibility: H-19; M-7; L-0; I-0

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

4a. Byproduct of Care Processes: H-7; M-0; L-1; I-0

4b. Electronic data sources: H-2; M-4; L-2; I-0

4c. Suscep inaccuracies, consequences: H-6; M-2; L-0; I-0

4d. Data collection strategy: H-7; M-1; L-0; I-0

#### Rationale:

• Can't do routine electronic data collection on all systems, but some do have the capability.

# Steering Committee Recommendation for Endorsement: Y-26; N-0

**Rationale:** This measure is harmonized with the SCIP measures, but covers a surgery that is excluded in the SCIP measures. Cesarean section is a high-frequency procedure with significant risk of surgical site infection. Current use in Massachusetts identifies opportunity for improvement and improvement over time when implemented.

# **Public & Member Comment**

#### Comments included:

• A commenter raised concerns on the ability of EHRs to handle the exclusion criteria.

**Developer response:** We have worked to use standard data elements as far as possible. We expect that, as with any process of care guideline, there will be individual cases with unusual circumstances. We are hopeful that most of the data collection can be done using common electronic data elements, and that over a period of time important additional factors can be incorporated into the systems.

**NQF response**: Currently, none of the measures under consideration are specified for use in EHRs; thus, the issues raised have been provided to the developers for their consideration as they move toward an electronic environment. NQF intends to require EHR specifications for all measure in the near future; additional details and guidance on those requirements are under consideration by the Consensus Standards Approval Committee.

Committee Response: The Committee appreciated the comments but agreed it was beyond the scope of their work at this time.

#### 0473 Appropriate DVT Prophylaxis in Women Undergoing Cesarean Delivery

# Maintenance measure (previously time-limited endorsement)

**Description:** Measure adherance to current ACOG, SMFM recommendations for use of DVT prophylaxis in women undergoing cesarean delivery. Current ACOG and SMFM recommendations call for the use of pneumatic compression devices in all women undergoing cesarean delivery who are not already receiving medical VTE prophylaxis. Numerator: Number of women undergoing cesarean delivery receiving either pneumatic compression device or medical prophylaxis prior to cesarean delivery. Denominator: All women undergoing cesarean delivery.

**Numerator Statement:** Number of women undergoing cesarean delivery who receive either fractionated or unfractionated heparin or heparinoid, or pneumatic compression devices prior to surgery

**Denominator Statement:** All women undergoing cesarean delivery.

**Exclusions**: Not receiving medical anticoagulation

Adjustment/Stratification: No risk adjustment or risk stratification N/A N/A

Level of Analysis: Facility Type of Measure: Process

Data Source: Electronic Clinical Data: Electronic Health Record, Electronic Clinical Data: Pharmacy, Paper Records

Measure Steward: Hospital Corporation of America

# STEERING COMMITTEE MEETING 11/29-30/2011

## Importance to Measure and Report: Y-20; N-3

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

1a. Impact: H-3; M-4; L-1; I-0; 1b. Performance Gap: H-1; M-4; L-3; I-0

1c. Evidence Quantity: H-1; M-4; L-3; I-0; Quality: H-1; M-4; L-3; I-0; Consistency: H-3; M-2; L-2; I-0 Rationale:

- Process to prevent an uncommon but catastrophic event pulmonary embolism accounts for 10% maternal deaths in US.
- VTE is the number 1 preventable cause of maternal death.
- Limited data on current performance as it is not in widespread use.
- Recent ACOG practice bulletin (September 2011) recommends DVT prophylaxis. Society of Maternal Fetal Medicine has similar guideline.
- Limited evidence in pregnant patients except for recent study from HCA; extrapolated from experience in other surgical patients. Data from HCA reported a reduction in fatal PE rate from 1.5/100,000 to 0.5/100,000 with use of prophylaxis.
- Cost-effectiveness data suggests low cost/easy to use.
- Does not address antepartum or post-partum DVT– intraoperative use only.
- 3/1000 incidence of DVT in pregnancy though some ascertainment issues; five-fold increase in DVT with C-section.

# 2. Scientific Acceptability of Measure Properties: Y-24; N-1

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: H-3; M-2; L-2; I-0 2b. Validity: H-3; M-4; L-0; I-0

#### Rationale:

- Data elements are straightforward
- Single exclusion of being on pharmacologic prophylaxis (small number of patients) eases data collection.

## 3. Usability: H-18; M-6; L-1; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)
3a. Public Reporting: H-3; M-4; L-0; I-0

3b. QI: H-4; M-2; L-1; I-0

# Rationale:

- Easy to understand
- Easy to drive practice change
- However, does not deal with the problem of continuing compliance through to hospital discharge and longer period of elevated risk.

#### 4. Feasibility: H-13; M-11; L-1; I-0

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

- 4a. Byproduct of Care Processes: H-6; M-1; L-1; I-0
- 4b. Electronic data sources: H-5; M-2; L-1; I-0

# 0473 Appropriate DVT Prophylaxis in Women Undergoing Cesarean Delivery

4c. Suscep inaccuracies, consequences: H-2; M-4; L-2; I-0

4d. Data collection strategy: H-6; M-2; L-0; I-0

# Rationale:

- Data field in some electronic records already
- Easy to document

# Steering Committee Recommendation for Endorsement: Y-21; N-2

• Rationale: Existing measures of VTE prophylaxis exclude pregnant women/C-section despite being at risk for catastrophic event (PE or death). Preventive measures have been shown to reduce mortality but are not widely used.

#### **Public & Member Comment**

## Comments included:

- Supportive comments.
- One commenter suggested that the developer create and test a paired measure for continued DVT prophylaxis, which may increase the benefit.

Steering Committee: The Committee agreed to add the suggested measure to the recommendations for future measure development.

## 0475 Hepatitis B Vaccine Coverage Among All Live Newborn Infants Prior to Hospital or Birthing Facility Discharge

Maintenance Measure (previously time-limited endorsement)

**Description:** Percent of live newborn infants that receive hepatitis B vaccination before discharge at each single hospital/birthing facility during given time period (one year).

**Numerator Statement:** The number of live newborn infants administered hepatitis B vaccine prior to discharge from the hospital/birthing facility ("birth dose" of hepatitis B vaccine).

**Denominator Statement:** The number of live newborn infants born at the hospital/birthing facility during the reporting window (one calendar year)

**Exclusions:** a. Optional recommended adjusted MEASURE denominator: determine number of live newborn infants born at the hospital/birthing facility whose parent/guardian refused hepatitis B birth dose and exclude from the denominator. ICD-10 code for this information might include the following (link: http://www.icd10data.com/ICD10CM/Codes/Z00-Z99/Z20-Z28/Z28-/#Z28):

i. Z28.03 Immunization not carried out because of immune compromised state of patient

ii. Z28.04 Immunization not carried out because of patient allergy to vaccine or component

iii. Z28.1 Immunization not carried out because of patient decision for reasons of belief or group pressure

iv. Z28.20 Immunization not carried out because of patient decision for unspecified reason

v. Z28.21 Immunization not carried out because of patient refusal

vi. Z28.29 Immunization not carried out because of patient decision for other reason

vii. Z28.82 Immunization not carried out because of caregiver refusal

The results of this measure should be reported as a separate MEASURE identifying that the coverage excludes infants whose parent(s)/guardian(s) refused hepatitis B vaccine for their infant before hospital or facility discharge (or by 1 month of age if during a prolonged stay).

Adjustment/Stratification: No risk adjustment or risk stratification N/A N/A

Level of Analysis: Clinician: Group/Practice, Clinician: Individual, Facility, Health Plan

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Electronic Clinical Data

: Pharmacy, Electronic Clinical Data: Registry

Measure Steward: Centers for Disease Control and Prevention

#### STEERING COMMITTEE MEETING 11/29-30/2011

#### Importance to Measure and Report: Y-22: N-2

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

1a. Impact: H-3; M-2; L-0; I-0; 1b. Performance Gap: H-3; M-2; L-0; I-0

1c. Evidence Quantity: H-3; M-2; L-0; I-0; Quality: H-1; M-4; L-0; I-0; Consistency: H-4; M-1; L-0; I-0

#### Rationale:

- Increasing number of pregnant women are found to be Hepatitis B Surface Antigen (HBsAg) positive (approximately 25,000/year)
- The 2010 National Immunization Study demonstrated that for 50 states and the District of Columbia, the calculated results for birth dose coverage were: median 66.7%; mean 65.7%; minimum 21.4%; maximum 83.3%. There is an APIC recommendation for neonatal immunization,
- Captures initial immunization in the series of three Hepatitis B vaccinations.
- Immunization prevents development of chronic hepatitis infection.

# 2. Scientific Acceptability of Measure Properties: Y-11; N-13 as written with optional exclusion for parent refusal; If exclusions are mandatory Y=22; N=3

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: H-3; M-2; L-0; I-0 2b. Validity: H-3; M-2; L-0; I-0

#### Rationale:

- Optional exclusions affect standardization and reduce comparability. Developer reports that exclusions are included if hospitals can collect the data.
- Including refusals is important for validity as a performance measure different perspective than for a public health surveillance measure.
- Developers report <3% refusal rate overall; some areas of 10-12% refusal.
- ICD-10 codes for parent refusal (none in ICD-9).

# 3. Usability: H-4; M-14 L-6; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

## 0475 Hepatitis B Vaccine Coverage Among All Live Newborn Infants Prior to Hospital or Birthing Facility Discharge

3a. Public Reporting: H-1; M-3; L-1; I-0

3b. QI: H-1; M-3; L-1; I-0

## Rationale:

- Not in use in public reporting
- Difficult to capture refusals until ICD-10

#### 4. Feasibility: H-3; M-19; L-3; I-0

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

4a. Byproduct of Care Processes: H-2; M-2; L-1; I-0

4b. Electronic data sources: H-1; M-3; L-1; I-0

4c. Suscep inaccuracies, consequences: H-0; M-3; L-1; I-1

4d. Data collection strategy: H-0; M-2; L-3; I-0

#### Rationale:

- Costly to review charts for refusals though numbers are small
- There is cost for initial programming for EHRs, but thereafter an advantage.

# Steering Committee Recommendation for Endorsement: Y-22; N-3 with mandatory exclusion for parent refusal

Rationale: This measure conforms to APIC recommendations for neonatal immunization and national rates demonstrate wide variation and opportunity for improvement. The developer agreed to remove the "optional" aspect of exclusions for parental refusal.

#### **Public & Member Comment**

#### Comments included:

- Three supportive comments
- Concerns with the exclusion of parental refusals, including a request that they be measured separately as a component of the numerator, as would be consistent with other NQF-endorsed immunization measures; and a concern that it may be difficult to capture reasons for refusal in EHRs.

#### Developer response:

- CDC agrees that ideally both measures (birth dose coverage including and excluding parent refusals) would be reported. A
  coverage assessment that includes parent refusals would be the most consistent with all other immunization coverage
  measures. As the ICD-10 codes are adopted and additional technology becomes available, accounting for parent refusals
  could add more granular way to evaluate coverage.
- From a health perspective, hospitals are perceived to have a joint responsibility with providers to educate families (even those wishing to refuse vaccination) on the importance of all childhood vaccinations, as well as on the hepatitis B vaccine as a means for preventing perinatal and household transmission of hepatitis B acquired from persons who may not even know they are infected.
- Failure to account for refusals would underestimate the true success of each hospital's compliance with the quality measure.

**Steering Committee:** The Committee noted that coding for parental refusals will be standardized with ICD-10 and that should be incorporated into annual updates. The Committee did not change their recommendation.

#### 0476 PC-03 Antenatal Steroids

#### Maintenance Measure (previously time-limited endorsement)

**Description:** This measure assesses patients at risk of preterm delivery at 24 0/7-32 0/7 weeks gestation receiving antenatal steroids prior to delivering preterm newborns. This measure is a part of a set of five nationally implemented measures that address perinatal care (PC-01: Elective Delivery, PC-02: Cesarean Section, PC-04: Health Care-Associated Bloodstream Infections in Newborns, PC-05: Exclusive Breast Milk Feeding).

**Numerator Statement:** Patients with a full course of antenatal steroids completed prior to delivering preterm newborns (refer to Appendix B, Table 11.0, antenatal steroid medications available at: <a href="http://manual.jointcommission.org">http://manual.jointcommission.org</a>)

**Denominator Statement:** Patients delivering live preterm newborns with 24 0/7-32 0/7 weeks gestation completed **Exclusions:** 

Less than 8 years of age

Greater than or equal to 65 years of age

Length of Stay >120 days

Enrolled in clinical trials

Documented Reason for Not Administering Antenatal Steroid

• ICD-9-CM Principal Diagnosis Code or ICD-9-CM Other Diagnosis Codes for fetal demise as defined in Appendix A, Table

11.09.1 available at: http://manual.jointcommission.org

Adjustment/Stratification: No risk adjustment or risk stratification Not Applicable Not applicable, the measure is not stratified.

Level of Analysis: Facility, Population: National

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data: Registry, Paper Records

Measure Steward: The Joint Commission

#### STEERING COMMITTEE MEETING 11/29-30/2011

#### Importance to Measure and Report: Y-24; N-0

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

1a. Impact: H-5; M-0; L-0; I-0; 1b. Performance Gap: H-5; M-0; L-0; I-0

1c. Evidence Quantity: H-5; M-0; L-0; I-0; Quality: H-5; M-0; L-0; I-0; Consistency: H-5; M-0; L-0; I-0

#### Rationale:

- Strong data demonstrating the benefit of steroid use; NIH and ACOG recommend use of steroids.
- Change from the original endorsed measure:
  - Requires full course of treatment; (if no time for full course to be administered, patient is excluded)
  - o 32-34 weeks with Premature Rupture of Membranes (PROM) not included
- There is no evidence or guidance for < 24 weeks
- From 2005-2007, data covering more than 90% of deliveries in California found that 23% of the more than 15,000 eligible infants did not receive antenatal steroids. Current Joint Commission data report 64.9% performance.
- Room for improvement; some improvement has been seen
- Another quality question might be whether steroids are overused in some patients. Need more information on the long-term impact of multiple steroid courses on the baby.

## 2. Scientific Acceptability of Measure Properties: Y-24; N-1

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-4: M-1: L-0: I-0 2b. Validity: H-5: M-0: L-0: I-0

#### Rationale:

- Testing indicates high reliability and moderate-high validity.
- The exclusion for patients who do not receive a complete course due to rapid delivery results in lack of credit to the provider for appropriate steroid therapy.

# 3. Usability: H-16; M-8; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)
3a. Public Reporting: H-5; M-0; L-0; I-0

3b. QI: H-5; M-0; L-0; I-0

#### Rationale:

This measure is on the recommended list of Medicaid core measures.

## 4. Feasibility: H-6; M-16; L-2; I-0

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c. Susceptibility to inaccuracies/ unintended consequences

#### 0476 PC-03 Antenatal Steroids

identified 4d. Data collection strategy can be implemented)

4a. Byproduct of Care Processes: H-3; M-2; L-0; I-0

4b. Electronic data sources: H-1; M-3; L-1; I-0

4c. Suscep inaccuracies, consequences: H-4; M-1; L-0; I-0

4d. Data collection strategy: H-4; M-0; L-1; I-0

Rationale:

Some chart review is needed

## Steering Committee Recommendation for Endorsement: Y-25; N-0

**Rationale:** There is significant room for improvement in performance for this evidence-based process of care that improves outcomes for premature infants. The measure is well-specified and demonstrates good reliability and validity.

#### **Public & Member Comment**

#### Comments included:

- Suggestion that specs be updated to bring them in line with the new ACOG Committee Opinion (Feb 2011)
- Clarification on the list of reasons for the exclusion criteria "documented reason for not administering antenatal steroid," noting that without a specified list, there will be inconsistency in measurement with facilities, who will provide their own coding reasons.

# Developer response:

- Agreed to update specs.
- Data analysis is done by trained abstractors who are able to assess whether or not the documented reasons meet the specifications

Steering Committee: The Committee agreed with the updated specifications and did not change their recommendation.

## 1746 Intrapartum Antibiotic Prophylaxis for Group B Streptococcus (GBS)

**New Measure** 

**Description**: Percentage of pregnant women who are eligible for and receive appropriate intrapartum antibiotic prophylaxis (IAP) for Group B Streptococcus (GBS)

Numerator Statement: All eligible patients who receive intrapartum antibiotic prophylaxis for GBS.

**Denominator Statement:** All women delivering live infants, except certain classes (described in response to 2a1.9 below) who are specifically deemed not to be at risk of vertical transmission of GBS.

Exclusions: Women not included in the denominator defined above, with specific exclusions as described below.

**Adjustment/Stratification**: No risk adjustment or risk stratification **Level of Analysis**: Facility, Integrated Delivery System, Population : State

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Paper Records

Measure Steward: Massachusetts General Hospital

## STEERING COMMITTEE MEETING 11/29-30/2011

### Importance to Measure and Report: Y-26; N-0

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

1a. Impact: H-5; M-0; L-0; I-0; 1b. Performance Gap: H-2; M-3; L-0; I-0

1c. Evidence Quantity: H-3; M-2; L-0; I-0; Quality: H-3; M-2; L-0; I-0; Consistency: H-2; M-3; L-0; I-0

#### Rationale:

- New data from Massachusetts suggests more opportunity for improvement that previously thought.
- In use in Massachusetts improved 71 to 87% over 3 years.
- CDC guidelines recommend prophylaxis for Group B Strep since it prevents lethal infection in newborns.

# 2. Scientific Acceptability of Measure Properties: Y-24; N-2

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: H-3; M-1; L-0; I-0 2b. Validity: H-3; M-1; L-0; I-0

#### Rationale:

- Intended to align with CDC guidelines; developer will clarify specifications especially for pre-term screening.
- Reliability and validity rated moderate-high.

# 3. Usability: H-14; M-11; L-1; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)
3a. Public Reporting: H-3; M-1; L-0; I-0

3b. QI: H-3; M-1; L-0; I-0

#### Rationale:

- In use in Massachusetts Medicaid program
- Unclear potential for unintended consequences: No data on long-term impact on children of exposure to antibiotics—. Though there is a not a clear relationship, gram negative infections have increased while GBS has declined.

#### 4. Feasibility: H-6; M-19; L-1; I-0

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

4a. Byproduct of Care Processes: H-4; M-0; L-0; I-0

4b. Electronic data sources: H-2; M-2; L-0; I-0

4c. Suscep inaccuracies, consequences: H-1; M-3; L-0; I-0

4d. Data collection strategy: H-3; M-1; L-0; I-0

#### Rationale:

Requires manual chart abstraction

## Steering Committee Recommendation for Endorsement: Y-26; N-0

Rationale: A measure of GBS prophylaxis was not recommended in the 2008 Perinatal project because data at that time indicated high performance. Newer data indicates that performance is not as high as previously thought. This measure aligns with evidence-based quidelines from CDC.

#### **Public & Member Comment**

# 1746 Intrapartum Antibiotic Prophylaxis for Group B Streptococcus (GBS)

# Comments included:

• Questions on details of the specifications and ability of EHRs to manage the many different data elements required to calculate the measure.

**Developer response**: The developer clarified the details for the commenters.

Steering Committee: The Committee had no additional comments and did not wish to change their recommendation.

## 0477 Under 1500g infant Not Delivered at Appropriate Level of Care

Maintenance Measure

**Description**: The number per 1,000 livebirths of <1500g infants delivered at hospitals not appropriate for that size infant.

Numerator Statement: Liveborn infants (<1500gms but over 24 weeks gestation) born at the given birth hospital Denominator Statement: All live births over 24 weeks gestation at the given birth hospital. NICU Level III status is defined by the State

Department of Health or similar body typically using American Academy of Pediatrics Criteria.

**Exclusions:** Stillbirths and livebirths <24weeks gestation.

Adjustment/Stratification: No risk adjustment or risk stratification n.a. none

Level of Analysis: Facility, Health Plan, Population: County or City, Population: National, Population: Regional, Population: State

Type of Measure: Outcome

Data Source: Electronic Clinical Data: Registry, Other

Measure Steward: California Maternal Quality Care Collaborative

## STEERING COMMITTEE MEETING 11/29-30/2011

# Importance to Measure and Report: Y-25; N-0

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

1a. Impact: H-5; M-0; L-0; I-0; 1b. Performance Gap: H-5; M-0; L-0; I-0

1c. Evidence Quantity: H-3; M-1; L-0; I-0; Quality: H-3; M-1; L-0; I-0; Consistency: H-4; M-0; L-0; I-0

#### Rationale:

- 2010 meta-analysis by CDC demonstrated a significant survival benefit for VLBW infants in Level 3 NICU (60% increase in mortality outside Level 3 NICU)
- Measure has been used at state-level for many years regionalization of care ongoing for 30+ years but lately seeing deregionalization due to economic factors
- In California (2008) the range of VLBW births in non-level III facilities was 0 to 15 per thousand with a mean of 4.8. The distribution is not evenly distributed.
- In California, developers found that failure to transfer is not common among rural hospitals but more frequent among urban hospitals where a Level 3 NICU is close by likely economic factors rather than medical factors determine transfer.
- All states have networks for transfers.

# 2. Scientific Acceptability of Measure Properties: Y-25; N-0

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: H-5; M-0; L-0; I-0 2b. Validity: H-4; M-1; L-0; I-0

# Rationale:

- This measure uses AAP definition of Level 3 NICU. States use various definitions.
- Specifications are precise
- Standard reporting under state vital statistics
- Excludes hospital with <50 deliveries a single event distorts the results</li>

#### 3. Usability: H-17; M-8; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

3a. Public Reporting: H-1: M-3: L-1: I-0

3b. QI: H-2; M-2; L-1; I-0

#### Rationale:

- EMTALA law concerns misinterpreted requires evaluation but does not preclude indicated transfer.
- This measure addresses system and administrative accountability for coordinating maternal transport.
- Need to involve EMS in quality improvement as transfer protocols typically require transport to nearest hospital rather than most appropriate hospital.
- Public reporting of this information likely to have big impact on local community and hospital trustees.

# 4. Feasibility: H-23; M-2; L-0; I-0

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

- 4a. Byproduct of Care Processes: H-5; M-0; L-0; I-0
- 4b. Electronic data sources: H-3; M-2; L-0; I-0
- 4c. Suscep inaccuracies, consequences: H-4; M-1; L-0; I-0
- 4d. Data collection strategy: H-5; M-0; L-0; I-0

## 0477 Under 1500g infant Not Delivered at Appropriate Level of Care

#### Rationale:

- Easy to report
- Collected in state birth data
- <1% missing data</p>

# Steering Committee Recommendation for Endorsement: Y-25; N-0

**Rationale:** This measure assesses appropriate transfer of VLBW babies to hospitals that greatly improve their chance of survival. In recent years, previously established regional transfer networks have been breaking down and transfer is not occurring, possibly due to economic rather than medical reasons. Current use of the measure in California indicates a large opportunity for improvement.

#### **Public & Member Comment**

#### Comments included:

 Request to expand the exclusion criteria to include reasons outside of the health care system's control for failure to transport to a hospital with appropriate levels of care services (e.g. very late presentation in active labor, lack of safe transportation, distance to NICU in rural areas).

#### Developer response:

• There are some cases in which it is out of the hospital/doctor's control that the mother delivers a baby at a lower level location. This is well understood and recognized by the developer. For this reason, the measure does not expect a zero rate, just a low rate not different from the normal distribution. When California hospitals were examined, a small group of hospitals with very high rates stood out from their peers. Interestingly these were not in distant rural areas but in urban areas where referral centers were close but the practice pattern was to transfer the baby after birth rather than the mother before birth. Currently this measure can easily be calculated using administrative data and setting up exclusions (requiring chart review for every case) would significantly increase the collection burden.

Steering Committee: The Committee did not change their recommendation on the measure.

#### 0478 Neonatal Blood Stream Infection Rate (NQI #3)

Maintenance Measure (previously time-limited endorsement)

Description: Percentage of high-risk newborn discharges with an ICD-9-CM diagnosis code of bloodstream infection

Numerator Statement: Discharges among cases meeting the inclusion and exclusion rules for the denominator with an ICD-9-CM code

for bloodstream infection in any secondary diagnosis field Denominator Statement: All newborns and outborns with

- 1) Birth weight 500 to 1499g OR
- 2) Gestational age between 24 and 30 weeks OR
- 3) Birth weight greater than or equal to 1500g AND
- in-hospital death OR
- operating room procedure OR
- mechanical ventilation OR
- age in days less than 2 AND transferred from another health care facility

**Exclusions**: Exclude cases:

- with principal diagnosis code of sepsis or secondary diagnosis code present on admission
- with birth weight less than 500 grams
- with length of stay less than 2 days
- with missing data for (SEX=missing), age (AGE=missing), quarter (DQTR=missing), year (YEAR=missing) or principal diagnosis (DX1=missing)

See Pediatric Quality Indicators Appendices:

• Appendix L – Low Birth Weight Categories

http://gualityindicators.ahrg.gov/Downloads/Software/SAS/V43/TechnicalSpecifications/PDI%20Appendices.pdf

Adjustment/Stratification: Statistical risk model The predicted value for each case is computed using a hierarchical model (logistic regression with hospital random effect) and covariates for gender, birthweight (500g groups), modified CMS DRG, congenital anomolies, transfer-in status and the availability of point of origin. The specific covariates retained in the model for this measure are listed below. The reference population used in the regression is the universe of discharges for states that participate in the HCUP State Inpatient Data (SID) for the years 2008, a database consisting of 43 states and approximately 6 million pediatric discharges. The expected rate is computed as the sum of the predicted value for each case divided by the number of cases for the unit of analysis of interest (i.e., hospital). The risk adjusted rate is computed using indirect standardization as the observed rate divided by the expected rate, multiplied by the reference population rate.

Specific covariates used for this measure:

Birth Weight 1000 to 2499 Birth Weight 750 to 999 Birth Weight <500 to 749

Modified DRG 1501 Neonates, died or transferred to another acute care

facility

Congenital anomalies category 1 Gastrointestinal Congenital anomalies category 5 Cardiovascular 8 Other

Congenital anomalies category

TRNSFER Transfer-in

NOPOUB04 UB-04 Point-of-Origin Data Not Available Not applicable

Level of Analysis: Facility Type of Measure: Outcome Data Source: Administrative claims

Measure Steward: Agency for Healthcare Research and Quality

#### STEERING COMMITTEE MEETING 11/29-30/2011

Importance to Measure and Report: Y-25; N-0

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

1a. Impact: H-5; M-0; L-0; I-0; 1b. Performance Gap: H-4; M-1; L-0; I-0

1c. Evidence Quantity: H-4; M-1; L-0; I-0; Quality: H-2; M-3; L-0; I-0; Consistency: H-2; M-2; L-0; I-1

Rationale:

- Important patient safety-related outcome measure.
- Increased incidence of infection in VLBW babies

## 2. Scientific Acceptability of Measure Properties: Y-23; N-2

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: H-2; M-3; L-0; I-0 2b. Validity: H-1; M-4; L-0; I-0

#### 0478 Neonatal Blood Stream Infection Rate (NQI #3)

#### Rationale:

- Uses discharge billing data
- No chart based validation; user feedback assessed.
- Risk model includes transfers into hospital. Some recent changes to the measure due to harmonization efforts AHRQ estimates has very little impact on mean rates or distribution
- Exclusions for specific bacteria only if present on admission
- ICD-9 to ICD-10 conversion in draft; ICD-10 has more specific codes for certain bacteria
- Includes larger babies who have certain characteristics as proxy for "likely to have been in NICU"
- Developer notes coding for mechanical ventilation is generally good as it is justification for longer length of stay

#### 3. Usability: H-13; M-11; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)
3a. Public Reporting: H-2; M-3; L-0; I-0

3b. QI: H-3; M-2; L-0; I-0

#### Rationale:

- Harmonized with new Joint Commission measure
- Transfers not a huge impact

#### 4. Feasibility: H-18; M-7; L-0; I-0

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

4a. Byproduct of Care Processes: H-4; M-1; L-0; I-0

4b. Electronic data sources: H-4; M-1; L-0; I-0

4c. Suscep inaccuracies, consequences: H-2; M-3; L-0; I-0

4d. Data collection strategy: H-4; M-1; L-0; I-0

#### Rationale:

Based on administrative data.

## Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-25; N-0

(All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures) <a href="Months:comments">Comments:</a>

- Uses discharge billing data
- Important patient safety-related outcome measure.

#### 5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures)

1731 Healthcare-associated bloodstream infections in newborns (Joint Commission)

303 Late sepsis or meningitis in neonates (risk-adjusted) (VON)

304 Late sepsis or meningitis in VLBW neonates (risk-adjusted) (VON)

#### Comments:

The different data streams are important for different users: states, Medicaid, and purchasers do not have access to chart data and rely on administrative data; Registry measures provide more clinical detail for the feedback/quality improvement program. The combined coding and chart review of the Joint Commission is important for accreditation purposes.

## Steering Committee Recommendation for Endorsement: Y-10; N-8 to recommend both 478 and 1731 as harmonized measures with different data streams

Steering Committee members acknowledged the added burden of multiple measures on hospitals and struggled with evaluating competing measures for hospital-acquired infections. The Committee noted that the variety of users with different data capabilities justify multiple, harmonized measures at this time.

## **Public & Member Comment**

## Comments included:

- Questions about the specifications
- Concerns about having three separate measures on hospital acquired infections and requests that the measures be harmonized.

#### 0478 Neonatal Blood Stream Infection Rate (NQI #3)

**Developer response:** The developer clarified the specifications.

Steering Committee: Measure 1731 was created by The Joint Commission (TJC) when it selected five NQF-endorsed measures, including measure 478, for its Perinatal Core Set. Measures 478 and 1731 are fully harmonized measures within the limits of their data sources and measure 1731 is also harmonized with the other four measures in TJC Perinatal Core Set (0469 Elective Delivery < 39 weeks; 0471 Cesarean section; 0476 Antenatal Steroids; and 0480 Exclusive Breast Milk Feeding) for use in TJC's performance measurement programs. Measures 478 and 1731 differ from related measure 304 in that they also capture larger babies who experience in-hospital death; operating room procedure; mechanical ventilation; or transfers in less than 2 days of age. Measure 478 is based on administrative data and is collected in the HCUP State Inpatient Databases that are widely used by states.

The Committee understands the concerns about multiple related measures, but in the absence of head-to-head comparisons of the measures the Committee cannot make any judgments as to differences in reliability and validity. All three measures are widely used and each is useful to different user groups. After reviewing and discussing the comments, the Committee did not change its recommendation of all three measures.

#### 1731 Health Care-Associated Bloodstream Infections in Newborns

#### **New Measure**

Description: This measure assesses the number of staphylococcal and gram negative septicemias or bacteremias in high-risk newborns. This measure is a part of a set of five nationally implemented measures that address perinatal care (PC-01: Elective Delivery, PC-02: Cesarean Section, PC-03: Antenatal Steroids, PC-05: Exclusive Breast Milk Feeding).

Numerator Statement: Newborns with septicemia or bacteremia with an ICD-9-CM Other Diagnosis Codes for septicemias as defined in Appendix A, Table 11.10.1 OR one or more ICD-9-CM Other Diagnosis Codes for newborn septicemia or bacteremia as defined in Appendix A, Table 11.10 and one diagnosis code for newborn bacteremia from Table 11.11 available at:

### http://manual.iointcommission.org

Denominator Statement: Liveborn newborns with an ICD-9-CM Other Diagnosis Codes for birth weight between 500 and 1499g as defined in Appendix A, Table 11.12, 11.13 or 11.14 OR Birth Weight between 500 and 1499g OR an ICD-9-CM Other Diagnosis Codes for birth weight = 1500g as defined in Appendix A, Table 11.15, 11.16 or 11.17 OR Birth Weight = 1500g who experienced one or more of the following:

- Experienced death
- 0 ICD-9-CM Principal Procedure Code or ICD-9-CM Other Procedure Codes for major surgery as defined in Appendix A, Table 11.18
- ICD-9-CM Principal Procedure Code or ICD-9-CM Other Procedure Codes for mechanical ventilation as defined in Appendix 0 A, Table 11.19
- Transferred in from another acute care hospital or health care setting within 2 days of birth.

#### **Exclusions:**

- ICD-9-CM Principal Diagnosis Code for sepsis as defined in Appendix A, Table 11.10.2
- ICD-9-CM Principal Diagnosis Code for liveborn newborn as defined in Appendix A, Table 11.10.3 AND ICD-9-CM Other Diagnosis Codes for newborn septicemia or bacteremia as defined in Appendix A, Table 11.10
- ICD-9-CM Other Diagnosis Codes for birth weight < 500g as defined in Appendix A, Table 11.20 OR Birth Weight < 500g
- Length of Stay < 2 days OR > 120 days
- Enrolled in clinical trials

Adjustment/Stratification: Statistical risk model Logistic regression

Model Risk Factors: Intercept Intercept

Birth Weight 1250g to 2499g Birth Weight 1000 to 1249g Birth Weight 500 to 999a

Modified DRG Newborn Transfers Out or Died Congenital Anomaly **Gastrointestinal Anomaly** Congenital Anomaly Cardiovascular Anomaly **Congenital Anomaly** Other Anomaly

Out-born Birth Newborns Transfers In Not applicable, the measure is not stratified.

Level of Analysis: Facility, Population: National

Type of Measure: Outcome

Data Source: Administrative claims, Electronic Clinical Data, Paper Records

Measure Steward: The Joint Commission

## STEERING COMMITTEE MEETING 11/29-30/2011

#### Importance to Measure and Report: Y-20; N-4

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

1a. Impact: H-3: M-1: L-0: I-0: 1b. Performance Gap: H-3: M-1: L-0: I-0

1c. Evidence Quantity: H-1; M-2; L-0; I-0; Quality: H-2; M-1; L-0; I-0; Consistency: H-2; M-1; L-0; I-0

#### Rationale:

- Significant problem especially for VLBW infants
- Infections increase LOS and costs
- Variable rates reported: 6-33%
- Very similar to measure 478 harmonized within limits of data sources

## 2. Scientific Acceptability of Measure Properties: Y-21; N-0

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: H-1; M-3; L-0; I-0 2b. Validity: H-0; M-3; L-0; I-0

Rationale:

#### 1731 Health Care-Associated Bloodstream Infections in Newborns

- Risk-adjusted outcome measure not statistically significant results Committee noted that measure implementers could change the reporting strategy such as using a 90% confidence interval rather than 95%
- Moderate reliability and validity
- Some coding issues noted.

#### 3. Usability: H-9; M-12; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)
3a. Public Reporting: H-2; M-1; L-0; I-1

3b. QI: H-3; M-0; L-0; I-1

#### Rationale:

- Improvement seen with use of the measure.
- Several similar measures for healthcare-acquired infection in newborns. Measure is harmonized with claims-based measure 478.

#### 4. Feasibility: H-7: M-14: L-0: I-0

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

4a. Byproduct of Care Processes: H-3; M-1; L-0; I-0

4b. Electronic data sources: H-1; M-2; L-0; I-1

4c. Suscep inaccuracies, consequences: H-1; M-3; L-0; I-0

4d. Data collection strategy: H-4; M-0; L-0; I-0

#### Rationale:

Requires some chart abstraction

## Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-21; N-0

(All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures) Comments:

• This is an important, adverse outcome measure.

## 5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures)

478 Nosocomial blood stream infections in neonates (NQI #3) (AHRQ)

303 Late sepsis or meningitis in neonates (risk-adjusted) (VON)

304 Late sepsis or meningitis in VLBW neonates (risk-adjusted) (VON)

#### Comments:

- Committee had some difficulty comparing 478 and 1731 particularly for the exclusion of infection at the time of birth but once clarified were comfortable that the measure captured "health-care acquired" infections
- The different data streams are important for different users: states, Medicaid, and purchasers do not have access to chart data and rely on administrative data; Registry measures provide more clinical detail for the feedback/quality improvement program. The combined coding and chart review of the Joint Commission is important for accreditation purposes.

# Steering Committee Recommendation for Endorsement: Y-10; N-8 to recommend both 478 and 1731 due to harmonized measures with different data streams

#### Rationale:

Steering Committee members acknowledged the added burden of multiple measures on hospitals and struggled with evaluating competing measures for hospital-acquired infections. The Committee noted that the variety of users with different data capabilities justify multiple, harmonized measures at this time.

#### **Public & Member Comment**

#### Comments included:

- Questions about the specifications
- Concerns about having three separate measures on hospital acquired infections and requests that the measures be harmonized.

**Developer response:** The developer responded to the questions about the specifications.

**Steering Committee**: Measure 1731 was created by The Joint Commission (TJC) when it selected five NQF-endorsed measures, including measure 478, for its Perinatal Core Set. Measures 478 and 1731 are fully harmonized measures within the limits of their data

#### 1731 Health Care-Associated Bloodstream Infections in Newborns

sources and measure 1731 is also harmonized with the other four measures in TJC Perinatal Core Set (0469 Elective Delivery < 39 weeks; 0471 Cesarean section; 0476 Antenatal Steroids; and 0480 Exclusive Breast Milk Feeding) for use in TJC's performance measurement programs. Measures 478 and 1731 differ from related measure 304 in that they also capture larger babies who experience in-hospital death; operating room procedure; mechanical ventilation; or transfers in less than 2 days of age. Measure 478 is based on administrative data and is collected in the HCUP State Inpatient Databases that are widely used by states.

The Committee understands the concerns about multiple related measures, but in the absence of head-to-head comparisons of the measures the Committee cannot make any judgments as to differences in reliability and validity. All three measures are widely used and each is useful to different user groups. After reviewing and discussing the comments, the Committee did not change its recommendation of all three measures.

#### 0304 Late Sepsis or Meningitis in Very Low Birth Weight (VLBW) Neonates (risk-adjusted)

#### Maintenance Measure

**Description:** Standardized rate and standardized morbidity ratio for nosocomial bacterial infection after day 3 of life for very low birth weight infants, including infants with birth weights between 401 and 1500 grams and infants whose gestational age is between 22 and 29 weeks.

**Numerator Statement:** Eligible infants with one or more of the following criteria:

Criterion 1:

Bacterial Pathogen. A bacterial pathogen is recovered from a blood and/or cerebral spinal fluid culture obtained after Day 3 of life. OR

Criterion 2:

Coagulase Negative Staphylococcus. The infant has all 3 of the following:

- 1. Coagulase negative staphylococcus is recovered from a blood culture obtained from either a central line, or peripheral blood sample and/or is recovered from cerebrospinal fluid obtained by lumbar puncture, ventricular tap or ventricular drain.
- 2. One or more signs of generalized infection (such as apnea, temperature instability, feeding intolerance, worsening respiratory distress or hemodynamic instability).
- 3. Teatment with 5 or more days of intravenous antibiotics after the above cultures were obtained. If the infant died, was discharged, or transferred prior to the completion of 5 days of intravenous antibiotics, this condition would still be met if the intention were to treat for 5 or more days.

**Denominator Statement:** Eligible infants who are in the reporting hospital after day 3 of life.

**Exclusions:** Exclude patients who do not meet eligibility criteria for birth weight, gestational age or hospital admission, or if the infant is discharged home, is transferred or dies prior to day 3 of life.

Adjustment/Stratification: Statistical risk model The risk adjustment process begins by using logistic regression to model the infection measure on model covariates: gestational age and its squared term, small for gestational age (Yes/No), multiple gestation (Yes/No), APGAR score at 1 minute (0-10), infant gender (Female, Male), Maternal Race/Ethnicity (Black, Hispanic, White, Asian, Other), Vaginal Delivery (Yes/No), Major Birth Defect (Yes/No) and Birth Location (Inborn, Outborn).

An estimate is made of the "systematic variation" associated with the hospital standardized morbidity ratios (SMRs) using the method suggested by Martuzzi and Hills (Martuzzi M and Hills M, Estimating the degree of heterogeneity between event rates using likelihood, Am J of Epi, 1995, 141, 4, 369-374. This method assumes that the SMRs are distributed gamma, and that deviations from the gamma distribution are associated with random variation. The systematic variation is used to "shrink" center SMR values and their confidence limits based on the number of infants reported (see, e.g., Simpson J et al, Analysing differences in clinical outcomes between hospitals, Qual Saf Health Care, 2003, 12,

257-262. The values for centers with a smaller number of infants shrink more toward the mean of all centers than do centers with more infants. Values for estimates of the number of observed cases minus the number of expected cases (O-E) and control limits for O-E values are also shrunken using the systematic variation value.

The shrinkage method described above is the "gamma-Poisson" approach to filtering random variation associated with Nosocomial Bacterial Infection as a risk adjusted indicator of performance. This approach has been used in other settings for documenting hospital performance. N/A

Level of Analysis: Facility
Type of Measure: Outcome

Data Source: Electronic Clinical Data: Registry Measure Steward: Vermont Oxford Network (VON)

#### STEERING COMMITTEE MEETING 11/29-30/2011

Importance to Measure and Report: Y-26; N-0

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

1a. Impact: H-3; M-2; L-0; I-0; 1b. Performance Gap: H-4; M-1; L-0; I-0

1c. Evidence Quantity: H-2; M-1; L-0; I-1; Quality: H-2; M-2; L-0; I-0; Consistency: H-4; M-0; L-0; I-0 Rationale:

- VLBW infants at much higher risk for infection most vulnerable population
- Current performance 15% infection rate
- A different measure from 478 and 1731 because it focuses on the high-risk, VLBW babies who have higher infection rates. Measures 478 and 1731 address all newborns.

#### 0304 Late Sepsis or Meningitis in Very Low Birth Weight (VLBW) Neonates (risk-adjusted)

## 2. Scientific Acceptability of Measure Properties: Y-26; N-0

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: H-2; M-3; L-0; I-0 2b. Validity: H-1; M-4; L-0; I-0

#### Rationale:

Risk model slightly different for this population compared to the overall population in measure 303.

### 3. Usability: H-13; M-11; L-1; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)

3a. Public Reporting: H-2: M-2: L-1: I-0

3b. OI: H-4; M-1; L-0; I-0

#### Rationale:

- 80% of VLBW infants in US enrolled in VON
- A number of states have focused on this VLBW measure

#### 4. Feasibility: H-11; M-14; L-1; I-0

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

4a. Byproduct of Care Processes: H-5; M-0; L-0; I-0

4b. Electronic data sources: H-1; M-3; L-1; I-0

4c. Suscep inaccuracies, consequences: H-3; M-1; L-0; I-1

4d. Data collection strategy: H-3; M-1; L-0; I-1

#### Rationale:

80% of VLBW babies born in the US are currently reported to the VON registry. The data is already collected with benchmarking and feedback to the participants. VON data is not public reported.

#### Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-25; N-1

(All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures) Comments:

• VLBW infants are an important subgroup with very high risk of infection

#### 5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures)

478 Nosocomial blood stream infections in neonates (NQI #3) (AHRQ)

1731 Healthcare-associated bloodstream infections in newborns (Joint Commission)

303 Late sepsis or meningitis in neonates (risk-adjusted) (VON)

#### Comments:

- 80% of VLBW infants are in VON registry; hospitals will continue participation
- VLBW infants a special population not captured independently in 478 or 1371 with high infection rates around 15%

## Steering Committee Recommendation for Endorsement: Y-9; N-8

Rationale: The Committee agreed that this measure is addresses a special population not captured independently in 478 or 1731 with high infections rates (15%) but Committee members also note that VON data is not publicly available even though 80% of VLBW infants are included in the network.

#### **Public & Member Comment**

#### Comments included:

- Questions about the specifications
- Concerns about having three separate measures on hospital acquired infections and requests that the measures be harmonized.
- Concerns about the ability of EHRs to handle the measure.

#### Developer:

- VON measures are based on specific data items that require adherence to a clear definition of that item to ensure consistency
  across reporting centers and the interpretability of the measure across centers. As you mention, we believe these are critical
  to ensure the appropriateness, accuracy, and importance of the individual measures. Standard codes do not directly align
  with the VON measure definitions, and are also subject to data quality and reliability concerns.
- VON has been in discussions with various EHR providers, including Epic, regarding the feasibility of obtaining measures from

## 0304 Late Sepsis or Meningitis in Very Low Birth Weight (VLBW) Neonates (risk-adjusted)

electronic records. We welcome further discussions and are committed to working with EHR vendors to reduce the data collection burden while maintaining the quality of the data measures.

Steering Committee: The Committee agreed that measure 304 was a related HAI measure but is quite distinct in that it 1) focuses on a very-high risk population—VLBW infants with a infection rate of 15% (VLBW represents only 1.5% of all births); 2) the measure only applies to hospitals with NICUs (approximately 800-900 hospitals in the US); and uses clinical data for the Vermont Oxford Network registry that captures 80% of VLBW infants in the US.

The Committee understands the concerns about multiple related measures, but in the absence of head-to-head comparisons of the measures the Committee cannot make any judgments as to differences in reliability and validity. All three measures are widely used and each is useful to different user groups. After reviewing and discussing the comments, the Committee did not change its recommendation of all three measures.

#### 0480 PC-05 Exclusive Breast Milk Feeding

#### Maintenance Measure

Description: This measure assesses the number of newborns exclusively fed breast milk feeding during the newborn's entire hospitalization. This measure is a part of a set of five nationally implemented measures that address perinatal care (PC-01: Elective Delivery, PC-02: Cesarean Section, PC-03: Antenatal Steroids, PC-04: Health Care-Associated Bloodstream Infections in Newborns). Numerator Statement: Newborns that were fed breast milk only since birth

Denominator Statement: Single term liveborn newborns discharged from the hospital with ICD-9-CM Principal Diagnosis Code or ICD-9-CM Other Diagnosis Codes for single liveborn newborn as defined in Appendix A, Table 11.20.1available at: http://manual.iointcommission.org

#### **Exclusions:**

- Admitted to the Neonatal Intensive Care Unit (NICU) at this hospital during the hospitalization
- ICD-9-CM Principal Diagnosis Code or ICD-9-CM Other Diagnosis Codes for galactosemia as defined in Appendix A, Table 11.21
- ICD-9-CM Principal Procedure Code or ICD-9-CM Other Procedure Codes for parenteral infusion as defined in Appendix A, Table 11.22
- Experienced death
- Length of Stay >120 days
- Enrolled in clinical trials
- Documented Reason for Not Exclusively Feeding Breast Milk
- Patients transferred to another hospital
- ICD-9-CM Principal Diagnosis Code or ICD-9-CM Other Diagnosis Codes for premature newborns as defined in Appendix A,

#### Table 11.23

Adjustment/Stratification: No risk adjustment or risk stratification Not Applicable

Level of Analysis: Facility, Population: National

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Paper Records

Measure Steward: The Joint Commission

#### STEERING COMMITTEE MEETING 11/29-30/2011

## Importance to Measure and Report: Y-21: N-3

(1a. High Impact: 1b. Performance Gap. 1c. Evidence)

1a. Impact: H-4; M-1; L-0; I-0; 1b. Performance Gap: H-4; M-1; L-0; I-0

1c. Evidence Quantity: H-4; M-1; L-0; I-0; Quality: H-5; M-0; L-0; I-0; Consistency: H-5; M-0; L-0; I-0

#### Rationale:

- Documented medical benefits to baby; some issues with intent and implementation of "exclusive"
- Exclusive breastfeeding during hospitalization and at discharge increases longer term breastfeeding
- Current performance = 41%
- Data presented on racial and ethnic disparities- large disparities; very susceptible to values of the patient population
- Large nursing component a systems issue of the hospital environment
- Goal is not 100% -- Healthy People 2010 set a 75% target

#### 2. Scientific Acceptability of Measure Properties: Y-22; N-2

(2a. Reliability – precise specifications, testing: 2b. Validity – testing, threats to validity)

2a. Reliability: H-3; M-2; L-0; I-0 2b. Validity: H-5; M-0; L-0; I-0

## Rationale:

- A Committee member noted that if the measure is "risk-adjusted" for race and educational level, 40% of the variance is removed
- Measure is not stratified for disparities developers note lack of reliability in the data element for race needed for stratification. Some Committee members argued that "rules now exist" to assign race.
- Exclusions for NICU, HIV, multiple births, transfers, mom taking drugs or medications
- Sampling is allowed

#### 3. Usability: H-16; M-6; L-2; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement) 3a. Public Reporting: H-5; M-0; L-0; I-0

3b. QI: H-4; M-1; L-0; I-0

Rationale:

#### 0480 PC-05 Exclusive Breast Milk Feeding

- Would also be good as a population –level measure communities can facilitate change in attitudes and cultural values
- Health benefits for the child and the mother
- The bar may be too high for some users consider intermediate process measures to facilitate adoption

#### 4. Feasibility: H-9; M-12; L-3; I-0

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

4a. Byproduct of Care Processes: H-4; M-1; L-0; I-0

4b. Electronic data sources: H-5: M-0: L-0: I-0

4c. Suscep inaccuracies, consequences: H-2; M-2; L-0; I-0

4d. Data collection strategy: H-3; M-2; L-0; I-0

#### Rationale:

- Possible encroachment on patient autonomy overzealous insistence on breastfeeding can alienate mothers
- Labor intensive to collect data unless data collection (feeding) forms are designed well
- An important measure for Medicaid

#### Steering Committee Recommendation for Endorsement: Y-20; N-4

**Rationale:** Breast milk feeding confers many health benefits to mother and child. Current rates of breast milk feeding are low with much room for improvement. Supporting breast milk feeding requires strong systems support and significant nursing involvement.

## Public & Member Comment

#### Comments included:

- Many comments noting the benefits of breastfeeding, but raising concerns about "mandated breastfeeding". Commenters were also concerned about a woman's right to choose whether or not to breastfeed, and whether the measure would prevent women who chose not to breastfeed from receiving proper education and information on alternatives.
- Measure also received lots of supportive comments, stating that the health reasons for breastfeeding are well documented, that the measure would not mandate breastfeeding for all babies, and that performance for this measure is not expected to be at 100%.

#### **Steering Committee:**

The Committee underscored the significant health benefits for newborns (reduction in otitis media, respiratory tract infections, atopic dermatitis, gastroenteritis, type 2 diabetes, sudden infant death syndrome, and obesity) and mother (decreased risk for type 2 diabetes, ovarian cancer, and breast cancer) conferred by breastfeeding and support all efforts to optimize maternal education, encouragement, and support to enable women to make the healthiest choices for herself and her child. The Committee agreed that improving support for mothers who wish to breastfeed does not equal removing a choice. The Committee acknowledged that the target for this measure is not 100% and that the potential unintended consequences of "inappropriate coercion" should be monitored.

The Committee noted that current performance is quite low at 40% with much room for improvement. Both the Committee and the developer agreed that the purpose of the measure is to eliminate impediments to breastfeeding. According to the CDC, (<a href="http://www.cdc.gov/breastfeeding/data/reportcard.htm">http://www.cdc.gov/breastfeeding/data/reportcard.htm</a>) "less than 5% of U.S. infants are born in Baby-Friendly hospitals, a global designation that indicates best practices in maternity care to support breastfeeding mothers. The hospital period is critical for mothers and babies to learn to breastfeed, and hospitals need to do more to support them. Birth facility policies and practices significantly impact whether a woman chooses to start breastfeeding and how long she continues to breastfeed." The Committee recommends additional process measures to assist facilities in improving support for breastfeeding.

The Committee also noted that public policies impact support of breastfeeding. The Committee pointed to external barriers to breast feeding include the Family Leave Act providing mothers only with up to 12 weeks of unpaid, job-protected leave; health insurers may not cover the costs of breast pumps, donor human milk for at risk preterm infants, or a follow up nursing visit at home to facilitate breast feeding success; and most mothers are out of the hospital before breastfeeding is well established. While the hospital maternity stay is such a short, but critical, window of time, and hospital routine and culture may undermine women's ability to breast feed, this is also a major social issue that has long-term health care implications. The Committee strongly encourages additional public policies to encourage and support women's ability to breast feed.

The Committee agreed to maintain their recommendation of the measure.

#### 0483 Proportion of Infants 22 to 29 Weeks Gestation Screened for Retinopathy of Prematurity.

#### Maintenance Measure

**Description**: Proportion of infants 22 to 29 weeks gestation who were in the reporting hospital at the postnatal age recommended for retinopathy of prematurity (ROP) screening by the American Academy of Pediatrics (AAP) and who received a retinal examination for ROP prior to discharge.

**Numerator Statement:** Number of infants 22 to 29 weeks gestation who were in the reporting hospital at the postnatal age recommended for ROP screening by the AAP and who received a retinal exam for ROP prior to discharge.

**Denominator Statement:** All eligible infants 22 to 29 weeks gestation who were in the reporting hospital at the postnatal age recommended for ROP screening by the AAP.

**Exclusions:** 1. Infants outside the gestational age range of 22 to 29 weeks.

- 2. Outborn infants admitted to the reporting hospital more than 28 days after hirth
- 3. Outborn infants who have been home prior to admission.
- 4. Infants who die in the delivery room or initial resuscitation area prior to admission to the neonatal intensive care unit.
- 5. Infants not in the reporting hospital at the postnatal age recommended for ROP screening by the AAP.

**Adjustment/Stratification:** Stratification by risk category/subgroup N/A Reports are stratified by gestational age, birth location and birth weight category.

Level of Analysis: Facility Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data: Electronic Health Record, Electronic Clinical Data: Registry, Paper

Records

Measure Steward: Vermont Oxford Network

#### STEERING COMMITTEE MEETING 11/29-30/2011

#### Importance to Measure and Report: Y-21; N-4

(1a. High Impact: 1b. Performance Gap, 1c. Evidence)

1a. Impact: H-4; M-1; L-0; I-0; 1b. Performance Gap: H-0; M-4; L-1; I-0

1c. Evidence Quantity: H-4; M-0; L-0; I-1; Quality: H-2; M-2; L-1; I-0; Consistency: H-3; M-2; L-0; I-0

#### Rationale:

- Screening recommended by AAP and AAO
- VON data moderate opportunity for improvement (not published data); 79% performance at the 10th percentile.
- APP recommendation up to 30 6/7 weeks but VON eligibility criteria limits measure to 29 6/7 weeks
- Larger babies are often discharged or transferred prior to appropriate time of screening and may be lost to follow-up; < 29
  weeks targets babies who are still in hospital when screening should occur</li>
- Risk is higher at lower gestational ages

#### 2. Scientific Acceptability of Measure Properties: Y-23; N-2

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: H-4; M-1; L-0; I-0 2b. Validity: H-5; M-0; L-0; I-0

#### Rationale:

- Exclusion rate 21-24%: unknown how big the 30-32 weeks group recommended for screening that is not captured
- There are a small number of babies that are too sick to be screened at the appropriate time
- Credit is given for screening at whatever gestational age not necessarily when recommended by AAP
- Excludes outborn infants >28 days due to VON eligibility criteria

#### 3. Usability: H-11: M-13: L-1: I-0

(*Meaningful*, understandable, and useful to the intended audiences for 3a. Public Reporting/Accountability and 3b. Quality Improvement)
3a. Public Reporting: H-2; M-3; L-0; I-0

3b. QI: H-4; M-1; L-0; I-0

#### Rationale:

- Mainly used for internal QI. Hospital may share their VON data at their discretion.
- The measure is used in California Perinatal Quality Care Collaborative and is reported to the state.
- Questions regarding transition of this measure from registry to wider use limited by registry criteria
- No public reporting known

#### 0483 Proportion of Infants 22 to 29 Weeks Gestation Screened for Retinopathy of Prematurity.

Does not address whether appropriate follow-up was done after screening.

#### 4. Feasibility: H-15; M-9; L-1; I-0

(4a. Clinical data generated during care delivery; 4b. Electronic sources; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

4a. Byproduct of Care Processes: H-5; M-0; L-0; I-0

4b. Electronic data sources: H-4; M-1; L-0; I-0

4c. Suscep inaccuracies, consequences: H-3; M-2; L-0; I-0

4d. Data collection strategy: H-5; M-0; L-0; I-0

Rationale:

• Currently used by VON registry participants. Clinical data is submitted to the registry.

## Steering Committee Recommendation for Endorsement: Y-23; N-2

**Rationale:** Appropriate screening for retinopathy allows intervention to optimize vision. Although the data is not publicly available, the majority of hospitals with Level 3 NICUs participate in the VON registry.

#### **Public & Member Comment**

#### Comments included:

- A commenter raised concerns noting that their internal data (submitted for publication) does not support the added measurement burden.
- Another commenter requested clarification on the exclusion criteria, stating that the exclusions "Outborn infants admitted to the reporting hospital more than 28 days after birth" and "Outborn infants who have been home prior to admission" do not appear aligned

Steering Committee: The Committee agreed the data mentioned by the commenter should be reviewed after it is published, and that it should be taken into consideration during annual updates or maintenance review. The Committee also noted that some high-performing hospitals may have very little room for improvement but the Vermont Oxford Network (VON) data indicates that more than 23% percent of infants at 29 weeks gestation are not screened before hospital discharge. The developer clarified the exclusions, explaining that they pertain to VON's data collection criteria. The Committee did not change their recommendation of the measure.