NATIONAL QUALITY FORUM

MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections.

To navigate the links in the worksheet: Ctrl + click link to go to the link; ALT + LEFT ARROW to return

Brief Measure Information

NQF #: 0480

Corresponding Measures: 0480e

De.2. Measure Title: PC-05 Exclusive Breast Milk Feeding

Co.1.1. Measure Steward: The Joint Commission

De.3. Brief Description of Measure: PC-05 assesses the rate of newborns exclusively fed breast milk during the newborn´s entire hospitalization. This measure is part of a set of four nationally implemented measures that address perinatal care (PC-01: Elective Delivery, ePC-01: Elective Delivery; PC-02: Cesarean Birth, ePC-02: Cesarean Birth will be added as an eCQM 1/1/2020; PC-05: Exclusive Breast Milk Feeding, ePC-05: Exclusive Breast Milk Feeding; PC-06 Unexpected Complications in Term Newborns was added 1/1/2019).

PC-05: Exclusive Breast Milk Feeding is one of three measures in this set that have been re-engineered as eCQMs (ePC-01 Elective Delivery, ePC-02 Cesarean Birth and ePC-05 Exclusive Breast Milk Feeding).

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.1. Developer Rationale: Exclusive breast milk feeding for the first 6 months of neonatal 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). ACOG has recently reiterated its position (ACOG, 2007). A recent Cochrane review substantiates the benefits (Kramer et al., 2002). Much evidence has now focused on the prenatal and intrapartum period as critical for the success of exclusive (or any) BF (Centers for Disease Control and Prevention [CDC], 2007; Petrova et al., 2007; Shealy et al., 2005; Taveras et al., 2004). Exclusive breast milk feeding rate during birth hospital stay has been calculated by the California Department of Public Health for the last several years

using newborn genetic disease testing data. Healthy People 2010 and the CDC have also been active in promoting this goal.

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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.

Sources

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- World Health Organization. (2007). Indicators for assessing infant and young child feeding practices. Washington, DC, USA: World Health Organization. Available at: http://apps.who.int/iris/bitstream/10665/43895/1/9789241596664_eng.pdf

S.4. Numerator Statement: Newborns that were fed breast milk only since birth

S.6. Denominator Statement: Single term liveborn newborns discharged alive from the hospital with ICD-10-CM Principal Diagnosis Code for single liveborn newborn as defined in Appendix A, Table 11.20.1.

Single term newborns discharged alive from the hospital

Liveborn newborns with ICD-10-CM Principal Diagnosis Code for single liveborn newborn as defined in Appendix A, Table 11.20.1

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

• ICD-10-CM Other Diagnosis Codes for galactosemia as defined in Appendix A, Table 11.21

• ICD-10-PCS Principal Procedure Code or ICD-10-PCS Other Procedure Codes for parenteral infusion as defined in Appendix A, Table 11.22

• Experienced death

• Length of Stay >120 days

• Patients transferred to another hospital

• Patients who are not term or with < 37 weeks gestation completed

De.1. Measure Type: Process

S.17. Data Source: Electronic Health Records, Other, Paper Medical Records

S.20. Level of Analysis: Facility, Other

IF Endorsement Maintenance – Original Endorsement Date: Oct 24, 2008 **Most Recent Endorsement Date:** Oct 25, 2016

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? Not Applicable

Preliminary Analysis: Maintenance of Endorsement

To maintain NQF endorsement endorsed measures are evaluated periodically to ensure that the measures still meets the NQF endorsement criteria (“maintenance”). The emphasis for maintaining endorsement is focused on how effective the measure is for promoting improvements in quality. Endorsed measures should have some experience from the field to inform the evaluation. The emphasis for maintaining endorsement is noted for each criterion.

Criteria 1: Importance to Measure and Report

1a. Evidence

Maintenance measures – less emphasis on evidence unless there is new information or change in evidence since the prior evaluation.

1a. Evidence. The evidence requirements for a *structure, process or intermediate outcome* measure is that it is based on a systematic review (SR) and grading of the body of empirical evidence where the specific focus of the evidence matches what is being measured. For measures derived from patient report, evidence also should demonstrate that the target population values the measured process or structure and finds it meaningful.

The developer provides the following evidence for this measure:

- **Systematic Review of the evidence specific to this measure?** ☒ **Yes** ☐ **No**
- **Quality, Quantity and Consistency of evidence provided?** ☒ **Yes** ☐ **No**
- **Evidence graded?** ☐ **Yes** ☒ **No**

Summary of prior review in 2016

The developer noted:

- A systematic review of the evidence supporting this measure resulted in a clinical protocol from the Academy of Breastfeeding Medicine (ABM); it also was based on recommendations from 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.
- The recommendation was a Level II (of three levels) recommendation of the ABM Protocol Committee.
- Previously, the Committee members noted concerns around patient choice and that an issue with this measure is that it puts pressure on patients to breastfeed when it may not be appropriate due to circumstances outside the control of the hospital (for example, work circumstances that do not allow pumping). Furthermore, the Committee also discussed the potential for a balancing measure.

Changes to evidence from last review

☐ **The developer attests that there have been no changes in the evidence since the measure was last evaluated.**

☒ **The developer provided updated evidence for this measure:**

Updates:

- The developer provided a 2012 policy statement by the American Academy of Pediatrics (AAP), which conducted a systematic review of the evidence (95 studies) supporting exclusive breastfeeding and the use of human milk.
- The developer provides summaries of the benefits of exclusive breastfeeding from the studies included in the AAP review – those benefits being improvement of respiratory tract infections, gastrointestinal tract infections, mortality, inflammatory bowel disease, obesity, diabetes, and other infant outcomes.
- However, neither the evidence nor recommendations were graded.
- It is not clear why this 2012 AAP document was not cited in the 2016 submission.

Exception to evidence

- The developer did not list any exceptions to Evidence.

Question for the Committee:

If the developer provided updated evidence for this measure:

- *The updated evidence is directionally similar to the previous submission. Does the Committee wish to discuss and/or revote on Evidence?*

Guidance from the Evidence Algorithm

Outcome measure: NO → (Box 3) Process measure based on guideline or systematic review and graded body of evidence: NO → (Box 7) Evidence submitted without grading: YES → (Box 8) Summarized evidence includes all studies: YES → (Box 9) High certainty that evidence indicates benefits outweigh any risks: YES → MODERATE

Preliminary rating for evidence: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

1b. Gap in Care/Opportunity for Improvement and 1b. Disparities

Maintenance measures – increased emphasis on gap and variation

1b. Performance Gap. The performance gap requirements include demonstrating quality problems and opportunity for improvement.

For the 2020 submission, the developer reported (1,950 hospitals; 885,234 patients):

- Mean performance rate of 49.3% (SD 18.1%)
- The interquartile range (IQR) was 24.7%.
- Deciles (0,10,20,30,40,50,60,70,80,90,100) were: 1.2%, 24.6%, 34.1%, 40.2%, 45.1%, 49.7%, 54.3%, 59.2%, 65.0%, 72.7%, 98.7

The developer noted that a goal of 70% should be achievable based on its analysis of the data.

Disparities

The developer provided the performance rates of exclusive in hospital breastfeeding for CY2018, by baby gender, ethnicity, and race.

Baby gender

Gender	Rate (%)
Female	51.6
Male	51.1
Unknown	39.4

Baby Hispanic ethnicity

Hispanic Ethnicity	Rate (%)
No	53.2
Yes	40.8

Baby Race

Race	Rate (%)
White	56.4
African American	31.5
American Indian	47.0
Asian	48.5
Pacific Islander	46.4
Unable to Determine	49.2

Question for the Committee:

- *Is there a gap in care and/or disparities that warrant a national performance measure?*

Preliminary rating for opportunity for improvement: ☒ High ☐ Moderate ☐ Low ☐ Insufficient

Committee Pre-evaluation Comments:
Criteria 1: Importance to Measure and Report (including 1a, 1b, 1c)

1a. Importance to Measure and Report

Comments:

** evidence applies directly, process reached desired outcome, only additional information would be to add COVID and breastfeeding from CDC since H1N1 is included

** There is good evidence to support this measure.

** Evidence is directly related to the measure and desired outcomes. New evidence was submitted.

** No one is disputing the benefits of breastfeeding, however the developers haven't addressed concerns about patient autonomy and choice. There is literature around this, and this has not been addressed.

1b. Performance Gap

Comments:

** yes, data was provided, gap demonstrated and supported encouraging the adoption with improved outcomes in those implementing

** There are still significant gaps in care and this measure is still warranted.

** There continues to be a performance gap and warrants a national measure.

** Yes, demonstrates gaps in care

1b. Disparities

Comments:

** Yes, data included, disparities and outcomes highlighted

** Significant disparities exist between population groups and a national performance measure is still indicated.

** Disparities are noted regionally and with race and ethnicity.

** Yes, differences by infant race and ethnicity

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability: Specifications and Testing

2b. Validity: Testing; Exclusions; Risk-Adjustment; Meaningful Differences; Comparability; Missing Data

2c. For composite measures: empirical analysis support composite approach

Reliability

2a1. Specifications requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented. For maintenance measures – no change in emphasis – specifications should be evaluated the same as with new measures.

2a2. Reliability testing demonstrates if the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise enough to distinguish differences in performance across providers. For maintenance measures – less emphasis if no new testing data provided.

Validity

2b2. Validity testing should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For maintenance measures – less emphasis if no new testing data provided.

2b2-2b6. Potential threats to validity should be assessed/addressed.

Complex measure evaluated by Scientific Methods Panel? ☐ **Yes** ☒ **No**

Evaluators:

- Not applicable

Methods Panel Evaluation Summary:

- Not applicable

Question for the Committee regarding reliability:

- *Do you have any concerns that the measure can be consistently implemented (i.e., are measure specifications adequate)?*

Question for the Committee regarding validity:

- *Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?*

Preliminary rating for reliability:	☒ **High**	☐ **Moderate**	☐ **Low**	☐ **Insufficient**
Preliminary rating for validity:	☒ **High**	☐ **Moderate**	☐ **Low**	☐ **Insufficient**

Scientific Acceptability: Preliminary Analysis Form

Measure Number: 0480

Measure Title: PC-05 Exclusive Breast Milk Feeding

Type of measure:

☒ **Process** ☐ **Process: Appropriate Use** ☐ **Structure** ☐ **Efficiency** ☐ **Cost/Resource Use**

☐ **Outcome** ☐ **Outcome: PRO-PM** ☐ **Outcome: Intermediate Clinical Outcome** ☐ **Composite**

Data Source:

☐ **Claims** ☐ **Electronic Health Data** ☒ **Electronic Health Records** ☐ **Management Data**
☐ **Assessment Data** ☒ **Paper Medical Records** ☐ **Instrument-Based Data** ☐ **Registry Data**
☐ **Enrollment Data** ☐ **Other**

Level of Analysis:

☐ **Clinician: Group/Practice** ☐ **Clinician: Individual** ☒ **Facility** ☐ **Health Plan**
☐ **Population: Community, County or City** ☐ **Population: Regional and State**
☐ **Integrated Delivery System** ☐ **Other**

Measure is:

☐ **New** ☒ **Previously endorsed (**NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.)

RELIABILITY: SPECIFICATIONS

1. **Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented?** ☒ **Yes** ☐ **No**

   Submission document: "MIF_0480" document, items S.1-S.22

   NOTE*: NQF staff will conduct a separate, more technical, check of eCQM specifications, value sets, logic, and feasibility, so no need to consider these in your evaluation.*

2. **Briefly summarize any concerns about the measure specifications.**

   No concerns

RELIABILITY: TESTING

Submission document: "MIF_0480" document for specifications, testing attachment questions 1.1-1.4 and section 2a2

3. **Reliability testing level** ☒ **Measure score** ☐ **Data element** ☐ **Neither**
4. **Reliability testing was conducted with the data source and level of analysis indicated for this measure** ☒ **Yes** ☐ **No**
5. If score-level and/or data element reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical VALIDITY testing** of patient-level data conducted?

   ☐ **Yes** ☐ **No**

6. **Assess the method(s) used for reliability testing**

   Submission document: Testing attachment, section 2a2

   - The developer provided score-level reliability for the measure using the beta-binomial model (signal to noise) on a 2018 data set of 1,950 hospitals with a median number of deliveries of 1,034; the median number of denominator cases was 329. Per Adams (2009), reliability scores range from 0.0 to 1.0. A score of zero implies that all variation is attributed to measurement error (i.e., noise), whereas a reliability of 1.0 implies that all variation is caused by a real difference in performance (across hospitals).
   - Because of the switch from ICD-9 to ICD-10 codes, the developer also examined reliability by comparing results from the 2017 data submission that utilized ICD-9 codes to the results from the 2018 data submission that utilized ICD-10 codes. Summary statistics for the number of

numerator cases, number of denominator cases, and observed rates are presented. Hospital data were also matched by each year in each of the three attributes and a paired t-test was used to determine statistical significance for each attribute.

7. A**ssess the results of reliability testing**

   Submission document: Testing attachment, section 2a2

   For the 2020 submission, the developer reports the following signal to noise reliability statistics:
   - Average: 0.97
   - Median: 0.98
   - 10^{th}-90^{th} percentile across hospitals: 0.95-0.99

   The developer noted that average score 0.76 is acceptable reliability for most of the hospitals. (As noted by the developer, in general, a score of 0.7 or higher suggests the measure has adequate reliability.)

		N	Mean	Std. Dev.	Min	Q1	Median	Q3	Max	Pairwise Difference	P-Value
Numerator	ICD-9	2022	57.1909	82.2855	0	20	36	60	1064	-0.3546	0.5365
	ICD-10	1947	24.8598	83.45	0	20	37	61	1031		
Denominator	ICD-9	2022	112.997	137.374	1	46	82	109	1729	-1.1089	0.2225
	ICD-10	1947	113.84	138.737	1	47	81	110	1572		
Rate	ICD-9	2022	0.48639	0.19364	0	0.35088	0.5	0.62264	1	0.00241	0.3095
	ICD-10	1947	0.48904	0.19107	0	0.36145	0.48864	0.62	1		

The developer reported that pairwise comparisons were not statistically significant for the number of numerator cases, the number of denominator cases, and the observed rates between matched hospitals between 2017 data (ICD-9) and 2018 data (ICD-10) with p-values greater than 0.05. The developer concluded this suggests there are no differences in reliability of the measure using the previous ICD-9 coding and the current ICD-10 coding.

8. Was the method described and appropriate for assessing the proportion of variability due to real differences among measured entities? NOTE: If multiple methods used, at least one must be appropriate.

   Submission document: Testing attachment, section 2a2.2 LINK

   ☒ **Yes**

   ☐ **No**

   ☐ **Not applicable** (score-level testing was not performed)

9. Was the method described and appropriate for assessing the reliability of ALL critical data elements?

   Submission document: Testing attachment, section 2a2.2LINK

   ☐ **Yes**

   ☐ **No**

   ☒ **Not applicable** (data element testing was not performed)

10. **OVERALL RATING OF RELIABILITY** (taking into account precision of specifications and all testing results):

    ☒ **High** (NOTE: Can be HIGH only if score-level testing has been conducted)

    ☐ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has not been conducted)

    ☐ **Low** (NOTE: Should rate LOW if you believe specifications are NOT precise, unambiguous, and complete or if testing methods/results are not adequate)

    ☐ **Insufficient** (NOTE: Should rate INSUFFICIENT if you believe you do not have the information you need to make a rating decision)

11. **Briefly explain rationale for the rating of OVERALL RATING OF RELIABILITY and any concerns you may have with the approach to demonstrating reliability.**
    - The developer provided a score-level reliability statistic indicating high reliability, as defined by Adams (2009).
    - The developer was thorough and demonstrated no difference in reliability from the switch from ICD-9 to ICD-10 codes.

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

12. **Please describe any concerns you have with measure exclusions.**

    Submission document: Testing attachment, section 2b2.

    - In the current submission, five exclusions (discharge disposition: acute care facility; discharge disposition: other healthcare facility; discharge disposition: expired; not a term newborn; admission to NICU) were empirically tested for impact on the denominator. The developer provided a rationale for each exclusion and the percentage lost to the exclusions, which are not mutually exclusive. The developer stated all exclusions are necessary to ensure the construct validity of the measure and all have a clinical rationale; in the specifications, these exclusions have been incorporated into the measure definition.
    - No concerns.
    - In its previous submission, the developer noted exclusions that were not derived directly from the evidence and the justification for them.

13. **Please describe any concerns you have regarding the ability to identify meaningful differences in performance.**

    Submission document: Testing attachment, section 2b4

    - To demonstrate meaningful differences in performance, the developer calculated a funnel plot for the annual hospital rates of the measure, where the observed measure is plotted against a measure of its precision, so that the control limits form a 'funnel' around the target outcome. It superimposes the 95 per cent (≈two standard deviation) and 99.8 per cent (≈three standard deviation) prediction limits over this plot around the overall measure rate; those rates lying outside the confidence limits are identified as outliers. (Spiegelhalter, DJ. Funnel plots for comparing institutional performance. *Statistics in Medicine*. 2005; 24:1185–1202.)
    - The developer reported that 816 hospitals were identified as outliers with rates beyond the two standard deviation lower limit, and 687 hospitals were identified as outliers with rates beyond the three standard deviation limit. A hospital with the median denominator size of 329 would be expected to fall in a 99.9% confidence interval of 43% to 60%.

- The developer stated that the results indicate significant differences in performance among hospitals and an appreciable number of hospitals are not within the expected level of variability and differ significantly from the mean overall rate.
- No concerns.

14. **Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified.**
Submission document: Testing attachment, section 2b5.

- Not applicable.

15. **Please describe any concerns you have regarding missing data.**

Submission document: Testing attachment, section 2b6.

- Hospitals transmitting data with missing data on any of the critical elements are not accepted; the measure has been collected since 2011.
- No concerns.

16. **Risk Adjustment**

16a. **Risk-adjustment method** ☒ **None** ☐ **Statistical model** ☐ **Stratification**

16b. **If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?**

☐ Yes ☐ No ☐ Not applicable

- The developer does not provide a conceptual rationale for the lack risk adjustment.

16c. **Social risk adjustment:**

16c.1 Are social risk factors included in risk model? ☐ Yes ☐ No ☒ Not applicable

16c.2 Conceptual rationale for social risk factors included? ☒ Yes ☐ No

- The developer does not adjust for social risk factors, and states that patient-level sociodemographic variables are not used, and none were available for analysis. The developer states there is no compelling evidence available supporting association between social risk factors and the measure.

16c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus? ☐ Yes ☐ No

16d.**Risk adjustment summary:**

- Not applicable

16d.1 All of the risk-adjustment variables present at the start of care? ☐ Yes ☐ No
16d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion? ☐ Yes ☐ No
16d.3 Is the risk adjustment approach appropriately developed and assessed? ☐ Yes ☐ No
16d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration) ☐ Yes ☐ No
16d.5.Appropriate risk-adjustment strategy included in the measure? ☐ Yes ☐ No

16e**. Assess the risk-adjustment approach**

- The measure is not risk adjusted; the developer did not provide a rational for this approach.
- The measure is not risk adjusted for social risk factors; the developer provided a rationale for this approach.
- The Committee may wish to discuss these approaches with the developer.

For cost/resource use measures ONLY:

17. **Are the specifications in alignment with the stated measure intent?**

    ☐ **Yes** ☐ **Somewhat** ☐ **No (If "Somewhat" or "No", please explain)**

18. **Describe any concerns of threats to validity related to attribution, the costing approach, carve outs, or truncation (approach to outliers):**

VALIDITY: TESTING

19. **Validity testing level:** ☒ **Measure score** ☐ **Data element** ☐ **Both**

20. **Method of establishing validity of the measure score:**

    ☐ **Face validity**

    ☒ **Empirical validity testing of the measure score**

    ☐ **N/A (score-level testing not conducted)**

21. **Assess the method(s) for establishing validity**

    Submission document: Testing attachment, section 2b2.

    - The developer used construct validity to calculate correlations of this measure with other measures of perinatal quality and with other measures of hospital quality.
        - For 0480, a higher rate is higher quality. The developer hypothesized that it would correlate positively to perinatal care measures where a high rate is desirable (e.g., ePC-05 Exclusive Breast Milk Feeding) and correlate negatively to perinatal care measures where a low rate is desirable (e.g., PC-01 Elective Delivery, PC-02 Cesarean Birth, and ePC-01).
        - For other measures of hospital quality, the developer used the Hospital Compare Five-Star rating system, which rates facilities on multiple quality measures. The developer hypothesized that rates for 0480 would be positively correlated with the Five-Star rating.
    - The developer stated a correlation of 0.1 to 0.3 was considered weak, 0.3 to 0.5 was considered moderate, and >0.5 was considered strong.

22. **Assess the results(s) for establishing validity**

    Submission document: Testing attachment, section 2b2.

    - The developer reported a correlation coefficient of -0.026 with PC-01 Elective Delivery, i.e., weakly negative correlation, but directionally as hypothesized. A correlation coefficient of -0.281 between this measure and PC-02 Cesarean Birth was reported, i.e., weakly negative, but directionally as hypothesized. The correlation between this measure and its e-measure version was strongly positive (0.748).
    - With respect to the correlation analysis of this measure and Hospital Five-Star, the developer reported a moderate correlation between the score for this measure (0480 Exclusive Breast Milk Feeding) and the overall quality rating ($\rho = 0.364$, $p < .0001$). The developer noted this suggests that facilities having a higher overall quality rating tend to have a higher score on this measure, indicating higher quality of newborn care.

23. **Was the method described and appropriate for assessing conceptually and theoretically sound hypothesized relationships?**

    Submission document: Testing attachment, section 2b1.

    ☒ **Yes**

    ☐ **No**

    ☐ **Not applicable** (score-level testing was not performed)

24. **Was the method described and appropriate for assessing the accuracy of ALL critical data elements?**
NOTE that data element validation from the literature is acceptable.

Submission document: *Testing attachment, section 2b1.*

☐ **Yes**

☐ **No**

☒ **Not applicable** (data element testing was not performed)

25. **OVERALL RATING OF VALIDITY taking into account the results and scope of all testing and analysis of potential threats.**

☒ **High** (NOTE: Can be HIGH only if score-level testing has been conducted)

☐ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has NOT been conducted)

☐ **Low** (NOTE: Should rate LOW if you believe that there are threats to validity and/or relevant threats to validity were not assessed OR if testing methods/results are not adequate)

☐ **Insufficient** (NOTE: For instrument-based measures and some composite measures, testing at both the score level and the data element level is required; if not conducted, should rate as INSUFFICIENT.)

26. **Briefly explain rationale for rating of OVERALL RATING OF VALIDITY and any concerns you may have with the developers' approach to demonstrating validity.**

- No concerns.
  - The developer provided empirical data related to exclusions and previously a rationale for those for which it did not have data, as well as data on meaningful differences. Missing data are not an issue.
  - The developer's construct validity testing against CMS's global Five-Star system is a strong approach.

ADDITIONAL RECOMMENDATIONS

27. **If you have listed any concerns in this form, do you believe these concerns warrant further discussion by the multi-stakeholder Standing Committee? If so, please list those concerns below.**

- No additional concerns or questions.

Committee Pre-evaluation Comments:
Criteria 2: Scientific Acceptability of Measure Properties (including all 2a, 2b, and 2c)

2a1. Reliability – Specifications

Comments:

** reliability is good, no concerns it can be consistently implemented

** No concerns.

** High reliability and no concerns with being implemented.

** no concerns

2a2. Reliability – Testing

Comments:

** no

** No concerns

** no

** No concerns

2b1. Validity –Testing

Comments:

** no

** No concerns.

** no

** no concerns

2b2-3. Exclusions/Risk Adjustment

Comments:

** 2b2no 2b3 appropriate risk adjustment strategy is included

** The developer states that "there is no compelling evidence available supporting association between social risk factors and the measure."

** Exclusions are consistent with the evidence. The measure is not risk-adjusted.

** because of the variety of factors that go into exclusive breastfeeding and again, considering patient choice/autonomy, risk-adjustment could be helpful

2b4-7. Threats to Validity/Meaningful Differences/Comparability of Performance Scores/Missing Data

Comments:

** 2b-7no.2b4-yes 2b5yes2b6-no

** No concerns.

** This measure does indicate there are differences regarding the quality of care of newborns. Missing data are not an issue.

** no concerns

Criterion 3. Feasibility

Maintenance measures – no change in emphasis – implementation issues may be more prominent

3. Feasibility is the extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

- The developer reported that data are generated by and used by healthcare personnel during the provision of care, coded by someone other than the person obtaining the original information, and/or abstracted from a record by someone other than the person obtaining the original information.
- The developer reported that data collection occurs using a mixture of electronic health records and paper medical records to allow for data capture of unstructured data fields.
- The developer also noted that while the data for this specific measure used manual data collection, facilities interested in electronic data collection can deploy NQF 480e, the corollary eCQM.
- The developer noted that facilities using this measure collect data through manual review of EMR, data derived from vital records reports from state or local public health departments, delivery logs, or clinical information systems or a combination. Collected data are submitted to the Joint Commission on a quarterly basis.

Questions for the Committee:

- *Are the required data elements routinely generated and used during care delivery?*
- *Are the required data elements available in electronic form, e.g., EHR or other electronic sources?*

Preliminary rating for feasibility: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 3: Feasibility

Comments:

** no concerns of data collection

** No concerns.

** With manual chart abstractions, this can be difficult to obtain the data. Sampling does help with the feasibility.

** Relatively straightforward for those who have EHRs, though still may be inconsistently captured

Criterion 4: Usability and Use

Maintenance measures – increased emphasis – much greater focus on measure use and usefulness, including both impact/improvement and unintended consequences

4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

4a. Use evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

Current uses of the measure

Publicly reported? ☒ **Yes** ☐ **No**

Current use in an accountability program? ☒ **Yes** ☐ **No** ☐ **UNCLEAR**

OR

Planned use in an accountability program? ☐ **Yes** ☐ **No**

Accountability program details

The developer reported the measure is publicly reported, as follows:

- Quality Check® - Publicly available website with performance data on 3,300 Joint Commission-accredited hospitals http://www.qualitycheck.org/consumer/searchQCR.aspx

The developer reported the measure is part of the following accountability program:

- The Joint Commission Hospital Accreditation Program - An accreditation program that recognizes hospitals that meet standard requirements to provide safe and effective patient care http://jointcommission.org

4a.2. Feedback on the measure by those being measured or others. Three criteria demonstrate feedback: 1) those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; 2) those being measured and other users have been given an opportunity to provide feedback on the measure performance or implementation; 3) this feedback has been considered when changes are incorporated into the measure

Feedback on the measure by those being measured or others

The developer reported:

- Feedback reports are provided on a quarterly and/or annual basis to partnering organizations. The Continuous Customer Engagement (CCE) dashboard with embedded quality improvement tools are also used to improve the quality of performance measures internally.
- The developer analyzes aggregate performance for each measure in the perinatal set and identifies the measures for which the greatest opportunities for improvement exist among accredited hospitals. Based on those findings, an educational webinar series that address the high-opportunity topics is developed; all participating facilities have access to the webinars.
- The Joint Commission utilizes an automated feedback system with access available to the measured entities and the vendors contracted by measured entities. A clinical lead is responsible for each individual measure set. The system is monitored daily and response is provided typically within eight business hours. If queries cannot be managed via written response, arrangements are made to address any issues or concerns via phone. All feedback is tracked and considered. If upon analysis there are trends noted giving cause for updates, this is reviewed by the measure work-group to confirm the need for revision.
- The developer indicated that questions on the measures are most likely to come through the clinical and data receipt mailboxes provided on all communications. In addition, the developer has advisory committees for the Hospital Accreditation Program, which meet on a quarterly basis, and have the opportunity to provide feedback on the measures being collected.
- The developer indicated that statistical questions on this measure related to how it is to be publicly reported in 2020 and that "queries submitted via the automated feedback system have decreased significantly for the PC-05 measure in the past three years."

Additional Feedback:

- Not reviewed by the Measure Applications Partnership

***Question for the Committee**:*

- *Can the performance results be used to further the goal of high-quality, efficient healthcare?*

Preliminary rating for Use: ☒ **Pass** ☐ **No Pass**

4b. Usability (4a1. Improvement; 4a2. Benefits of measure)

4b. Usability evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4b.1 Improvement. Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

Improvement results:

- The developer reported aggregate rates of exclusive breast milk feeding from 2015-2018, showing no change over time:
    - 2015-51.8%

    - 2016-52.9%
    - 2017-51.6%
    - 2018-51.5%
- NQF staff review of the 2016 material noted the following
    - 2Q 2010 (165 hospitals): 40.9% national aggregate rate
    - CY 2011 (166 hospitals): 45.9% national aggregate rate
    - CY 2012 (170 hospitals): 51.1% national aggregate rate
    - CY 2013 (197 hospitals): 53.6% national aggregate rate
    - CY 2014 (1,286 hospitals): 49.4% national aggregate rate

4b2. Benefits vs. harms. Benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Unexpected findings (positive or negative) during implementation

The developer reported three unintended consequences and the mitigating actions it took:

- Data abstractions for the mother's initial feeding plan for a separate sub-measure did not follow normal workflow patterns and greatly increased the burden of data abstraction for hospitals.
    - Mitigating action: Retire the sub-measure Exclusive Breast Milk Feeding Considering Mother's Initial Feeding Plan
- Late preterm newborns were not being routinely excluded from the denominator population via diagnosis codes for premature newborns.
    - Mitigating action: Add a new denominator data element, Term Newborn, so that now only newborns who were term or =>37 weeks gestation completed were included.
- Reviewing medical records for maternal medical conditions as reasons for not exclusively feeding breast milk was greatly increasing the burden of data abstraction based on feedback from hospitals.
    - Mitigating action: The denominator data element Reason For Not Exclusively Feeding Breast Milk was removed from the denominator excluded population in order to simplify data abstraction.

Potential harms

- None identified by the developer other than the unexpected findings, above

Additional Feedback: This measure was not brought to MAP.

***Question for the Committee**:*

- *Can the performance results be used to further the goal of high-quality, efficient healthcare?*
- *Do the benefits of the measure outweigh any potential unintended consequences?*

Preliminary rating for Usability and use: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 4: Usability and Use

4a1-2. Use - Accountability and Transparency/Feedback

Comments:

** yes

** Results are publicly reported and currently used in an accountability program.

** The measure is publicly reported through TJC and is part of their accountability program. Those being measured are given the opportunity to provide feedback on the measure.

** no concerns- appears to be incorporating feedback reasonably

4b1. Usability – Improvement/ Benefits vs. harms/ Transparency

Comments:

** 4b1 goal reinforces current recommendations, 4b2 unintended consequence may be unknowing recommending breastfeeding in those medically unable to do so, the chemo patient, active infected mother with a communicable disease

** The developer explained unexpected findings and actions taken to mitigate burdens. No new unintended impacts on patients were recorded. Low breastfeeding rates is a systemic problem and I believe this measure should be maintained.

** Nationally the performance has had relatively little improvement over time. There needs to be more of an emphasis on this from both the OB and the Peds community. No unintended consequences identified.

** Unclear that this is leading to improvement, and again, may warrant a balancing measure to reflect patient choice/autonomy, or infant need

Criterion 5: Related and Competing Measures

Related or competing measures

- The developer did not list any corresponding related measures, despite acknowledging they did exist.
- NQF staff are aware of 0480e, the eCQM version of this measure, as noted also by the developer elsewhere.

Harmonization

- The developer states that the measure specifications completely harmonized to the extent possible, given the fact that the data source for #0480e is the electronic clinical quality measure record.
- The developer does not identify differences, a rationale for the differences, nor the impact of the differences on interpretability and data collection burden.

***Questions for the Committee**:*

- *Does the Committee wish to query the developer as to what NQF measures specifically are related or competing?*
- *Does the Committee wish to discuss with the developer the impact of the specification differences on interpretability?*

Committee Pre-evaluation Comments: Criterion 5: Related and Competing Measures

Comments:

** na

** No concerns.

** No competing measures.

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of June 15, 2020

- No comments received
- **Of the 0 NQF members who have submitted a support/non-support choice:**
  - 0 support the measure
  - 0 do not support the measure

Developer Submission

Additional evaluations and submission materials attachments…

1. Evidence and Performance Gap – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. ***Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria.***

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form

2020_nqf_evidence_attachment_PC05_0480.docx

1a.1 For Maintenance of Endorsement: Is there new evidence about the measure since the last update/submission?

Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence.

1a. Evidence (subcriterion 1a)

Measure Number (*if previously endorsed*)**:** 0480

Measure Title: PC-05 Exclusive Breast Milk Feeding

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

Date of Submission: April 8, 2020

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

☐ Outcome: Click here to name the health outcome

☐ Patient-reported outcome (PRO): Click here to name the PRO

PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health- related behaviors. (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

☐ Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

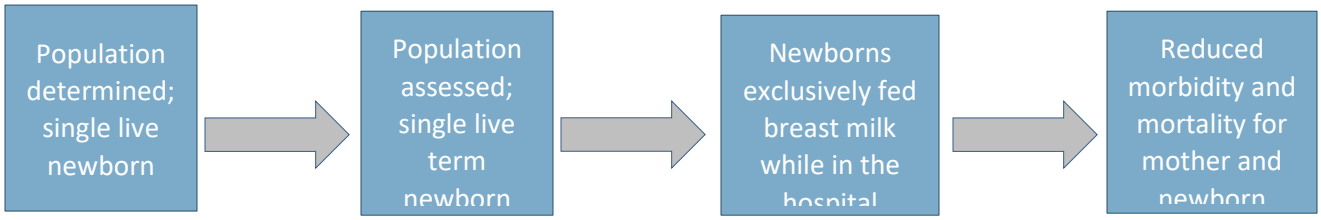
☐ Process: Exclusive breast milk feeding during the newborn's entire hospitalization ☐

Appropriate use measure: Click here to name what is being measured

☐ Structure: Click here to name the structure

☐ Composite: Click here to name what is being measured

1a.2 LOGIC MODEL Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.



The intent of the measure is to increase the number of single live term newborns who are exclusively fed breast milk during the birth hospitalization >> population determined; single live newborn >> population assessed; single live newborn >> 1 newborns exclusively fed breast milk while in the hospital >> 2 reduced morbidity and mortality of for mother and newborn.

1a.3 Value and Meaningfulness: If this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

Not applicable

****RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) ****

1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.

Not Applicable

1a.3. SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the evidence is not based on a systematic review go to section

1a.4) If you wish to include more than one systematic review, add additional tables.

What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)

☐Clinical Practice Guideline recommendation (with evidence review) (publication in the table)

☐US Preventive Services Task Force Recommendation

☐Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐Other see 1a.4

2020 Submission

Source: • Title • Author • Date • Citation, including page number • URL	**Title:** Breastfeeding and the use of human milk. **Author:** American Academy of Pediatrics **Date:** 2012 **Citation:** American Academy of Pediatrics. Policy Statement. Breastfeeding and the use of human milk. 2012 Mar; 129 (3): e827-841. **URL:** https://pediatrics.aappublications.org/content/pediatrics/129/3/e827.full.pdf
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	**From the guideline abstract:** Breastfeeding and human milk are the normative standards for infant feeding and nutrition. Given the documented short- and long-term medical and neurodevelopmental 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. This policy statement is an update from a previous policy statement by the American Academy of Pediatrics. Updated research and systematic reviews have reinforced the conclusion that breastfeeding and human milk are the reference normative standards for infant feeding and nutrition. The current statement updates the evidence for this conclusion and serves as a basis for AAP publications that detail breastfeeding management and infant nutrition, including the AAP Breastfeeding Handbook for Physicians, AAP Sample Hospital Breastfeeding Policy for Newborns, AAP Breastfeeding Residency Curriculum, and the AAP Safe and Healthy Beginnings Toolkit. The AAP 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.

Grade assigned to the evidence associated with the recommendation with the definition of the grade	No grades of evidence were assigned to the recommendations.
Provide all other grades and definitions from the evidence grading system	Not applicable
Grade assigned to the recommendation with definition of the grade	Not applicable
Provide all other grades and definitions from the recommendation grading system	Not applicable
Body of evidence: • Quantity – how many studies? • Quality – what type of studies?	**Quantity:** The literature examining exclusive breast milk feeding and neonatal outcomes has 95 US breastfeeding studies published. Of those studies, there were prospective cohort studies (19), retrospective cohort studies (11), observational studies (14), systematic reviews (10), population-based (6), ESCALE study (1), panel study (1), cross-sectional studies (1), multi-variate regression studies (5), randomized-control studies (5), meta-analysis (7), comparative study (1), longitudinal study (1), large randomized trials (7), surveys and policies (6). **Quality:** Information on the overall quality of evidence across the studies is not provided; although, this policy statement discusses the evidence exclusive breastfeeding. Breastfed children have at least a **six times greater chance of survival** in the early months than non-breastfed children. Breastfeeding drastically reduces deaths from acute respiratory infection and diarrhea, two major child killers, as well as from other infectious diseases (WHO-Lancet 2000). Related evidence by The World Health Organization (WHO) and United Nations Children´s Fund (UNICEF) recommendations on breastfeeding are as follows: initiation of breastfeeding within the first hour after the birth; exclusive breastfeeding for the first six months; and continued breastfeeding for two years or more, together with safe, nutritionally adequate, age appropriate, responsive complementary feeding starting in the sixth month. https://www.unicef.org/nutrition/index_24763.html. According to the American Academy of Pediatrics, research and practice have reinforced the conclusion that breastfeeding, and the use of human milk confer the unique nutritional and non-nutritional values to the

	infant and mother and, in turn, optimize infant, child and adult health as well as child growth and development. Recently, published evidence-based studies have confirmed and quantitated the risks of not breastfeeding. Thus, infant feeding should not be considered as a lifestyle choice but rather as a basic health issue. As such, the pediatrician's role in advocating and supporting proper breastfeeding practices is essential and vital for the achievement of this preferred public health goal. There is no documented evidence regarding controversy related to the exclusivity of breast milk feeding.
Estimates of benefit and consistency across studies	Estimates of benefit and consistency across the studies are not provided; although, this committee opinion discusses the evidence supporting exclusive breastfeeding. **Infant Outcomes:** 1. Respiratory Tract Infections and Otitis Media Risk of hospitalization for lower respiratory tract infections in the first year is reduced 72% if infants breastfed exclusively for more than 4 months. Infants who exclusively breastfed for 4 to 6 months had a fourfold increase in the risk of pneumonia compared with infants who exclusively breastfed for more than 6 months. Any breastfeeding compared with exclusive commercial infant formula feeding will reduce the incidence of otitis media (OM) by 23%. Exclusive breastfeeding for more than 3 months reduces the risk of otitis media by 50%. Serious colds and ear and throat infections were reduced by 63% in infants who exclusively breastfed for 6 months. 2. Gastrointestinal Tract Infections Any breastfeeding is associated with a 64% reduction in the incidence of nonspecific gastrointestinal tract infections, and this effect lasts for 2 months after cessation of breastfeeding. 3. Necrotizing Enterocolitis A more recent study of preterm infants fed an exclusive human milk diet compared with those fed human milk supplemented with cow-milk-based infant formula products noted a 77% reduction in NEC. One case of NEC could be prevented if 10 infants received an exclusive human milk diet, and 1 case of NEC requiring surgery or

	resulting in death could be prevented if 8 infants received an exclusive human milk diet. 4. Sudden Infant Death Syndrome and Infant Mortality Meta-analyses with a clear definition of degree of breastfeeding and adjusted for confounders and other known risks for sudden infant death syndrome (SIDS) note that breastfeeding is associated with a 36% reduced risk of SIDS. It has been calculated that more than 900 infant lives per year may be saved in the United States if 90% of mothers exclusively breastfed for 6 months. In the 42 developing countries in which 90% of the world's childhood deaths occur, exclusive breastfeeding for 6 months and weaning after 1 year is the most effective intervention, with the potential of preventing more than 1 million infant deaths per year, equal to preventing 13% of the world's childhood mortality. 5. Allergic Disease There is a protective effect of exclusive breastfeeding for 3 to 4 months in reducing the incidence of clinical asthma, atopic dermatitis, and eczema by 27% in a low-risk population and up to 42% in infants with positive family history. 6. Celiac Disease There is a reduction of 52% in the risk of developing celiac disease in infants who were breastfed at the time of gluten exposure. Overall, there is an association between increased duration of breastfeeding and reduced risk of celiac disease when measured as the presence of celiac antibodies. Gluten-containing foods should be introduced while the infant is receiving only breast milk and not infant formula or other bovine milk products. 7. Inflammatory Bowel Disease Breastfeeding is associated with a 31% reduction in the risk of childhood inflammatory bowel disease. Different patterns of intestinal colonization in breastfed versus commercial infant formula–fed infants may add to the preventive effect of human milk. 8. Obesity Because rates of obesity are significantly lower in breastfed infants, national campaigns to prevent obesity begin with breastfeeding support. There is a 15% to 30% reduction in adolescent and adult obesity rates if any breastfeeding occurred in infancy compared with no breastfeeding. The duration of breastfeeding also is inversely related to the risk of overweight; each month of breastfeeding being associated with a 4% reduction in risk. Breastfed infants self-regulate intake volume

	irrespective of maneuvers that increase available milk volume, and the early programming of self-regulation, in turn, affects adult weight gain. 9. Diabetes Up to a 30% reduction in the incidence of type 1 diabetes mellitus is reported for infants who exclusively breastfed for at least 3 months, thus avoiding exposure to cow milk protein. It has been postulated that the putative mechanism in the development of type 1 diabetes mellitus is the infant's exposure to cow milk β-lactoglobulin, which stimulates an immune-mediated process cross reacting with pancreatic β cells. A reduction of 40% in the incidence of type 2 diabetes mellitus is reported, possibly reflecting the long-term positive effect of breastfeeding on weight control and feeding self-regulation. 10. Childhood Leukemia and Lymphoma There is a reduction of 20% in the risk of acute lymphocytic leukemia and 15% in the risk of acute myeloid leukemia in infants breastfed for 6 months or longer. Breastfeeding for less than 6 months is protective but of less magnitude (approximately 12% and 10%, respectively). 11. Neurodevelopmental Outcomes Consistent differences in neurodevelopmental outcome between breastfed and commercial infant formula–fed infants have been reported, but the outcomes are confounded by differences in parental education, intelligence, home environment, and socioeconomic status. Higher intelligence scores are noted in infants who exclusively breastfed for 3 months or longer, and higher teacher ratings were observed if exclusive breastfeeding was practiced for 3 months or longer. 12. Preterm Infants Lower rates of sepsis and NEC indicate that human milk contributes to the development of the preterm infant's immature host defense. Extremely preterm infants receiving the greatest proportion of human milk in the NICU had significantly greater scores for mental, motor, and behavior ratings at ages 18 months and 30 months. Long-term studies of preterm infants also suggest that human milk feeding is associated with lower rates of metabolic syndrome, and in adolescents, it is associated with lower blood pressures and low-density lipoprotein concentrations and improved leptin and insulin metabolism. Recommendations on Breastfeeding Management for Preterm Infants 1. All preterm infants should receive human milk.

	• Human milk should be fortified, with protein, minerals, and vitamins to ensure optimal nutrient intake for infants weighing <1500gm at birth. • Pasteurized donor human milk, appropriately fortified, should be used if mother's own milk is unavailable or its use is contraindicated. 2. Methods and training protocols for manual and mechanical milk expression must be available to mothers. 3. Neonatal intensive care units should possess evidence-based protocols for collection, storage, and labeling of human milk. 4. Neonatal intensive care units should prevent the misadministration of human milk (http://www.cdc.gov/breastfeeding/recommendations/other_mothers_milk.htm). 5. There are no data to support routinely culturing human milk for bacterial or other organisms. **Maternal Outcomes** 1. Mothers have decreased postpartum blood loss and more rapid involution of the uterus. Continued breastfeeding leads to increased child spacing secondary to lactational amenorrhea. 2. In a covariate-adjusted study of more than 14 000 women postpartum, mothers who exclusively breastfed for longer than 6 months weighed 1.38 kg less than those who did not breastfeed. In mothers without a history of gestational diabetes, breastfeeding duration was associated with a decreased risk of type 2 diabetes mellitus; for each year of breastfeeding, there was a decreased risk of 4% to 12%. 3. An inverse relationship between the cumulative lifetime duration of breastfeeding and the development of rheumatoid arthritis has been noted. Women with a cumulative lactation history of 12 to 23 months had a significant reduction in hypertension (OR: 0.89; 95% CI: 0.84–0.93), hyperlipidemia (OR: 0.81; 95% **CI: 0.76–** 0.87), cardiovascular disease (OR: 0.90; 95% CI: 0.85–0.96), and diabetes (OR: 0.74; 95% CI: 0.65–0.84). 4. Cumulative duration of breastfeeding of longer than 12 months is associated with a 28% decrease in breast cancer (OR: 0.72; 95% CI: 0.65–0.8) and ovarian cancer (OR: 0.72; 95% CI: 0.54–0.97). **Duration of Exclusive Breastfeeding**

	1. The AAP recommends exclusive breastfeeding for about 6 months, with continuation of breastfeeding for 1 year or longer as mutually desired by mother and infant, a recommendation concurred to by the WHO and the Institute of Medicine. The AAP is cognizant that for some infants, because of family and medical history, individual developmental status, and/or social and cultural dynamics, complementary feeding, including gluten containing grains, begins earlier than 6 months of age. **Contraindications to Breastfeeding** 1. There are a limited number of medical conditions in which breastfeeding is contraindicated, including an infant with the metabolic disorder of classic galactosemia. 2. Mothers who are positive for human T-cell lymphotropic virus type I or II or untreated brucellosis should not breastfeed nor provide expressed milk to their infants Breastfeeding should not occur if the mother has active (infectious) untreated tuberculosis or has active herpes simplex lesions on her breast; however, expressed milk can be used because there is no concern about these infectious organisms passing through the milk. 3. Breastfeeding can be resumed when a mother with tuberculosis is treated for a minimum of 2 weeks and is documented that she is no longer infectious. 4. The CDC recommended that mothers acutely infected with H1N1 influenza should temporarily be isolated from their infants until they are afebrile, but they can provide expressed milk for feeding. 5. In the developing world, where mortality is increased in non-breastfeeding infants from a combination of malnutrition and infectious diseases, breastfeeding may outweigh the risk of the acquiring HIV infection from human milk. Infants in areas with endemic HIV who are exclusively breastfed for the first 3 months are at a lower risk of acquiring HIV infection than are those who received a mixed diet of human milk and other foods and/or commercial infant formula. 6. There is no contraindication to breastfeeding for a full-term infant whose mother is seropositive for cytomegalovirus (CMV). There is a possibility that CMV acquired from mother's milk may be associated with a late-onset sepsis-like syndrome in the extremely low birth weight (birth weight <1500 gm) preterm infant.

	7. Maternal substance abuse is not a categorical contraindication to breastfeeding. Adequately nourished narcotic dependent mothers can be encouraged to breastfeed if they are enrolled in a supervised methadone maintenance program and have negative screening for HIV and illicit drugs. **Maternal Diet** 1. Well-nourished lactating mothers have an increased daily energy need of 450 to 500 kcal/day that can be met by a modest increase in a normally balanced varied diet The mother's diet should include an average daily intake of 200 to 300 mg of the ω-3 long-chain polyunsaturated fatty acids (docosahexaenoic acid [DHA]) to guarantee a sufficient concentration of preformed DHA in the milk. Consumption of 1 to 2 portions of fish (e.g., herring, canned light tuna, salmon) per week will meet this need. The concern regarding the possible risk from intake of excessive mercury or other contaminants is offset by the neurobehavioral benefits of an adequate DHA intake and can be minimized by avoiding the intake of predatory fish (e.g., pike, marlin, mackerel, tile fish, swordfish). **Maternal Medications** 1. A forthcoming AAP policy statement on the transfer of drugs and other chemicals into human milk will provide additional recommendations, with focus on psychotropic drugs, herbal products, galactagogues, narcotics, and pain medications. In general, breastfeeding is not recommended when mothers are receiving medication from the following classes of drugs: amphetamines, chemotherapy agents, ergotamine's, and statins. Among the agents considered to be least problematic were the tricyclic antidepressants amitriptyline and clomipramine and the selective serotonin-reuptake inhibitors paroxetine and sertraline. **Hospital Routines** 1. The Sections on Breastfeeding and Perinatal Pediatrics have published the Sample Hospital Breastfeeding Policy that is available from the AAP Safe and Healthy Beginnings Web site. This sample hospital policy is based on the detailed recommendations of the previous AAP policy statement "Breastfeeding and the Use of Human Milk" as well as the principles of the 1991 WHO/UNICEF publication "Tens Steps to Successful Breastfeeding" and provides a template for developing a uniform hospital policy for support of breastfeeding. Emphasis is placed on the need to revise or discontinue disruptive hospital

	policies that interfere with early skin to-skin contact, that provide water, glucose water, or commercial infant formula without a medical indication, that restrict the amount of time the infant can be with the mother, that limit feeding duration, or that provide unlimited pacifier use. **WHO/UNICEF Ten Steps to Successful Breastfeeding** 1. Have a written breastfeeding policy that is routinely communicated to all health care staff. 2. Train all health care staff in the skills necessary to implement this policy. 3. Inform all pregnant women about the benefits and management of breastfeeding. 4. Help mothers initiate breastfeeding within the first hour of birth. 5. Show mothers how to breastfeed and how to maintain lactation even if they are separated from their infants. 6. Give newborn infants no food or drink other than breast milk, unless medically indicated. 7. Practice rooming-in (allow mothers and infants to remain together) 24 h a day. 8. Encourage breastfeeding on demand. 9. Give no artificial nipples or pacifiers to breastfeeding infants. 10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from hospital. 2. There is a need for a major conceptual change in the organization of the hospital services for the mother and infant dyad. This requires that medical and nursing routines and practices adjust to the principle that breastfeeding should begin within the first hour after birth (even for Cesarean deliveries) and that infants must be continuously accessible to the mother by rooming-in arrangements that facilitate around the-clock, on-demand feeding for the healthy infant. Formal staff training should not only focus on updating knowledge and techniques for breastfeeding support but also should acknowledge the need to change attitudes and eradicate unsubstantiated beliefs about the supposed equivalency of breastfeeding and commercial infant formula feeding. **Economic Benefits**

	According to the American Academy of Pediatrics, a detailed pediatric cost analysis based on the AHRQ 2007 report concluded that if 90% of US mothers would comply with the recommendation to breastfeed exclusively for 6 months, there would be a savings of $13 billion per year. Strategies that increase the number of mothers who breastfeed exclusively for about 6 months would be of great economic benefit on a national level.
What harms were identified?	There have been no harms identified as a result of implementation of the exclusive breast milk feeding measure.
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	As a result of the literature search there have been no new studies conducted since this publication that would change the conclusions from the referenced Systematic Review.

2016 submission

Source of Systematic Review: • Title • Author • Date • Citation, including page number • URL	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. http://www.guideline.gov/content.aspx?id=24013&search=breastfeeding+policy 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.
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	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. Anti-lactation 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 latch-on 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)
Grade assigned to the **evidence** associated with the recommendation with the definition of the grade	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.
Provide all other grades and definitions from the evidence grading system	USPSTF 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. 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.
Grade assigned to the **recommendation** with definition of the grade	Yes Level II Academy of Breastfeeding Medicine Protocol Committee Grading varies from I to III
Provide all other grades and definitions from the recommendation grading system	Not applicable
Body of evidence: • Quantity – how many studies? • Quality – what type of studies?	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. **Quantity:** 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 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). **Quality:** 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%) There is no documented evidence regarding controversy about the benefits of exclusive breast milk feeding for mother and newborn. **Quantity:** High **Quality:** High **Consistency:** High
Estimates of benefit and consistency across studies	**Consistency:** 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%) **Benefits:** 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.
What harms were identified?	Not applicable
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	Not applicable

1a.4 OTHER SOURCE OF EVIDENCE

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

Not applicable

1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure. A list of references without a summary is not acceptable.

Not applicable

1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure. A list of references without a summary is not acceptable.

Not applicable

1a.4.2 What process was used to identify the evidence?

Not applicable

1a.4.3. Provide the citation(s) for the evidence.

Not applicable

From previous submission: Citations from Evidence Other Than Guidelines

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- 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.
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- 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. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- Disparities in care across population groups.

1b.1. Briefly explain the rationale for this measure *(e.g., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure)*

<u>If a COMPOSITE</u> (e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.

Exclusive breast milk feeding for the first 6 months of neonatal 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). ACOG has recently reiterated its position (ACOG, 2007). A recent Cochrane review substantiates the benefits (Kramer et al., 2002). Much evidence has now focused on the prenatal and intrapartum period as critical for the success of exclusive (or any) BF (Centers for Disease Control and Prevention [CDC], 2007; Petrova et al., 2007; Shealy et al., 2005; Taveras et al., 2004). Exclusive breast milk feeding rate during birth hospital stay has been calculated by the California Department of Public Health for the last several years using newborn genetic disease testing data. Healthy People 2010 and the CDC have also been active in promoting this goal.

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.

Sources

- American Academy of Pediatrics. (2005). Section on Breastfeeding. Policy Statement: Breastfeeding and the Use of Human Milk. Pediatrics.115:496— 506.
- American College of Obstetricians and Gynecologists. (Feb. 2007). Committee on Obstetric Practice and Committee on Health Care for Underserved Women. Breastfeeding: Maternal and Infant Aspects. ACOG Committee Opinion 361.
- California Department of Public Health. (2017). Division of Maternal, Child and Adolescent Health, Breastfeeding Initiative, In-Hospital Breastfeeding Initiation Data, Hospital of Occurrence: Available at: https://www.cdph.ca.gov/Programs/CFH/DMCAH/Breastfeeding/Pages/In-Hospital-Breastfeeding-Initiation-Data.aspx

- Centers for Disease Control and Prevention. (Aug 3, 2007). Breastfeeding trends and updated national health objectives for exclusive breastfeeding--United States birth years 2000-2004. MMWR - Morbidity & Mortality Weekly Report. 56(30):760-3.
- Centers for Disease Control and Prevention. (2017). Division of Nutrition, Physical Activity and Obesity. Breastfeeding Report Card. Available at: https://www.cdc.gov/breastfeeding/data/reportcard.htm
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- Kramer, M.S. & Kakuma, R. (2002).Optimal duration of exclusive breastfeeding. [107 refs] Cochrane Database of Systematic Reviews. (1):CD003517.
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- 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.
- Taveras, E.M., Li, R., Grummer-Strawn, L., Richardson, M., Marshall, R., Rego, V.H., Miroshnik, I., & Lieu, T.A. (2004). Opinions and practices of clinicians associated with continuation of exclusive breastfeeding. Pediatrics. 113(4):e283-90.
- US Department of Health and Human Services. (2007). Healthy People 2010 Midcourse Review. Washington, DC: US Department of Health and Human Services. Available at: https://www.healthypeople.gov/2010/data/midcourse/html/default.htm?visit=1
- World Health Organization. (2007). Indicators for assessing infant and young child feeding practices. Washington, DC, USA: World Health Organization. Available at: http://apps.who.int/iris/bitstream/10665/43895/1/9789241596664_eng.pdf

1b.2. Provide performance scores on the measure as specified (<u>current and over time</u>) at the specified level of analysis. *(<u>This is required for maintenance of endorsement</u>. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.*

2020 Submission

CY2018: Reported rates of exclusive breast milk feeding continue to show considerable variability, with the following statistics and percentiles:

CY 2018 Statistics:

Number of hospitals: 1950

Total Number of Patients: 885,234

Mean (SD): 49.3% (18.1%)

IQR: 24.7%

Deciles (0,10,20,30,40,50,60,70,80,90,100): 1.2%, 24.6%, 34.1%, 40.2%, 45.1%, 49.7%, 54.3%, 59.2%, 65.0%, 72.7%, 98.7

Correction

The trend for this measure shows a flat rate with no change from 2015-2018. Reported rates of exclusive breast milk feeding continue to show considerable variability and a continued opportunity for improvement.

2015-51.8%

2016-52.9%

2017-51.6%

2018-51.5%

2016 Submission

Rates for exclusive breast milk feeding remain below 50% for over half of the hospitals reporting data. A goal of 70% should be achievable based on the Joint Commission's analysis of the data. The Perinatal Care (PC) core measures were added as a new core measure set in 2010 for hospitals to select in order to meet their ORYX performance measurement requirement for Joint Commission accreditation purposes at that time, approximately 165 hospitals reported the data with an average measure rate of 40.9% (n=54,630 patients). In January 2014, The Joint Commission required mandatory reporting of the PC measure set for all accredited hospitals with 1100 births or more annually. 1386 hospitals reported the data with an average rate of 49.4% (n=728,157 patients). It is important to note that a performance gap of 48% existed for the 10th percentile of hospitals performing at 22.0% (if 70% is considered goal performance) and that the aggregate rate dropped by 4.2% from the 2013 rate of 53.6%. Only the 90th percentile hospitals (74.3%) are performing above the goal of 70%. The threshold for mandatory reporting was lowered to 300 births annually effective January 2016. The reporting requirement will captures approximately 80% of all accredited birthing hospitals. As a result, the rates may decrease with the addition of approximately 821 more hospitals reporting data. Below is the specified level of analysis for PC-01 beginning with discharges April 1, 2010 through December 31, 2014.

- 2Q 2010: 54,630 denominator cases; 22,346 numerator cases; 165 hospitals; 40.9% national aggregate rate; 0.46132 mean of hospital rates; 0.22274 standard deviation; 75.3% 90th percentile rate; 62.2% 75th percentile rate/upper quartile; 45.9% 50th percentile rate/median rate; 29.4% 25th percentile rate/lower quartile; and 15.5% 10th percentile rate.
- CY 2011: 69,613 denominator cases; 31,999 numerator cases; 166 hospitals; 45.9% national aggregate rate; 0.49335 mean of hospital rates; 0.21348 standard deviation; 76.2% 90th percentile rate; 62.8% 75th percentile rate/upper quartile; 50.6% 50th percentile rate/median rate; 34.8% 25th percentile rate/lower quartile; and 19.9% 10th percentile rate.
- CY 2012: 76,952 denominator cases; 39,337 numerator cases; 170 hospitals; 51.1% national aggregate rate; 0.55872 mean of hospital rates; 0.20359 standard deviation; 80.7% 90th percentile rate; 72.2% 75th percentile rate/upper quartile; 56.7% 50th percentile rate/median rate; 41.7% 25th percentile rate/lower quartile; and 27.1% 10th percentile rate.
- CY 2013: 91,011 denominator cases; 48,758 numerator cases; 197 hospitals; 53.6% national aggregate rate; 0.5632 mean of hospital rates; 0.19707 standard deviation; 79.3% 90th percentile rate; 72.1%% 75th

percentile rate/upper quartile; 57.3% 50th percentile rate/median rate; 42.3% 25th percentile rate/lower quartile; and 28.4% 10th percentile rate.

- CY 2014: 728,157 denominator cases; 359,633 numerator cases; 1386 hospitals; 49.4% national aggregate rate; 0.48724 mean of hospital rates; 0.19475 standard deviation; 74.3% 90th percentile rate; 62.4% 75th percentile rate/upper quartile; 49.1% 50th percentile rate/median rate; 35.1% 25th percentile rate/lower quartile; and 22.0% 10th percentile rate.

1b.3. If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.

Not Applicable

1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. *(This is required for maintenance of endorsement. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included.) For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.*

For 2018 discharges:

Measure rates by baby gender:

Gender	Rate (%)
Female	51.6
Male	51.1
Unknown	39.4

Measure rates by Hispanic Ethnicity:

Hispanic Ethnicity	Rate (%)
No	53.2
Yes	40.8

Measure rates by Race:

Race	Rate (%)
White	56.4
African American	31.5
American Indian	47.0
Asian	48.5
Pacific Islander	46.4
Unable to Determine	49.2

1b.5. If no or limited data on disparities from the measure as specified is reported in 1b.4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in 1b.4

2. Reliability and Validity—Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. ***Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.***

2a.1. Specifications The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. Subject/Topic Area *(check all the areas that apply):*

Perinatal Health, Perinatal Health : Newborn Care

De.6. Non-Condition Specific *(check all the areas that apply):*

Person-and Family-Centered Care

De.7. Target Population Category *(Check all the populations for which the measure is specified and tested if any):*

Women

S.1. Measure-specific Web Page *(Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)*

https://manual.jointcommission.org/releases/TJC2020A2/PerinatalCare.html

S.2a. If this is an eMeasure, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

This is not an eMeasure **Attachment:**

S.2b. Data Dictionary, Code Table, or Value Sets *(and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)*

Attachment **Attachment:** PC05AppendixATJCTablesv2020A2.xlsx

S.2c. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

No, this is not an instrument-based measure **Attachment:**

S.2d. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

Not an instrument-based measure

S.3.1. <u>For maintenance of endorsement:</u> Are there changes to the specifications since the last updates/submission. If yes, update the specifications for S1-2 and S4-22 and explain reasons for the changes in S3.2.

Yes

S.3.2. <u>For maintenance of endorsement,</u> please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.

On an annual basis, the chart abstracted measures maintained by The Joint Commission undergo an annual update to revise specifications based on updated research and clinical information or standards changes. The following changes have been made to the measure specifications:

- Appendix A - ICD-10 Code Tables: Revised to reflect the ICD-10 code updates for Fiscal Year (FY) 2019, effective for discharges October 1, 2018
- Appendix A - ICD-10 Code Tables: Revised to reflect the ICD-10 code updates for Fiscal Year (FY) 2020, effective for discharges October 1, 2019
- Use new allowable values for Term Newborn.
- Add new note for abstraction: To clarify that the use of dextrose or glucose 40% gel is considered a medication not a feeding.

S.4. Numerator Statement *(Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome) DO NOT include the rationale for the measure.*

<u>IF an OUTCOME MEASURE</u>, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

Newborns that were fed breast milk only since birth

S.5. 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, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)*

<u>IF an OUTCOME MEASURE,</u> describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

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.

S.6. Denominator Statement *(Brief, narrative description of the target population being measured)*

Single term liveborn newborns discharged alive from the hospital with ICD-10-CM Principal Diagnosis Code for single liveborn newborn as defined in Appendix A, Table 11.20.1.

Single term newborns discharged alive from the hospital

Liveborn newborns with ICD-10-CM Principal Diagnosis Code for single liveborn newborn as defined in Appendix A, Table 11.20.1

S.7. Denominator Details *(All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*

IF an OUTCOME MEASURE, describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

Ten data elements are used to calculate the denominator:

1. Admission Date – The month, day, and year of admission to acute inpatient care.

2. 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

3. Birthdate - The month, day, and year the patient was born.

4. Discharge Date – The month, day, and year the patient was discharged from acute care, left against medical advice, or expired during the stay.

5. Discharge Disposition - The place or setting to which the patient was discharged. (On the day of discharge)

6. ICD-10-CM Other Diagnosis Codes - The International Classification of Diseases, Tenth Revision, Clinical Modification codes associated with the other or secondary diagnoses for this hospitalization.

7. ICD-10-PCS Other Procedure Codes - The International Classification of Diseases, Tenth Revision, Procedure Coding System code that identifies significant procedures performed other than the principal procedure during this hospitalization.

8. ICD-10-CM Principal Diagnosis Code - The International Classification of Diseases, Tenth Revision, Clinical Modification code associated with the diagnosis that is primarily responsible for the admission of the patient to the hospital for care during this hospitalization.

9. ICD-10-CM Principal Procedure Code - The International Classification of Diseases, Tenth Revision, Procedure Coding System code that identifies the principal procedure performed for definitive treatment rather than diagnostic or exploratory purposes, or which is necessary to take care of a complication.

10. Term Newborn - Documentation that the newborn was at term or >= 37 completed weeks of gestation at the time of birth.

1. Yes, there is documentation that the newborn was at term or >= 37 completed weeks of gestation at the time of birth.

2. No, there is documentation that the newborn was not at term or >= 37 completed weeks of gestation at the time of birth.

3. UTD, unable to determine from medical record documentation.

S.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-10-CM Other Diagnosis Codes for galactosemia as defined in Appendix A, Table 11.21

• ICD-10-PCS Principal Procedure Code or ICD-10-PCS Other Procedure Codes for parenteral infusion as defined in Appendix A, Table 11.22

• Experienced death

• Length of Stay >120 days

• Patients transferred to another hospital

• Patients who are not term or with < 37 weeks gestation completed

S.9. Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*

• The data element Admission to NICU is used to determine if the patient was admitted to the NICU.

• Patients with ICD-10-CM Other Diagnosis Codes for galactosemia are excluded.

• Patients with ICD-10-PCS Principal Procedure Code or ICD-10-PMS Other Procedure Codes for parenteral infusion are excluded.

• 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.

• The data element Discharge Disposition is used to determine if the patient was transferred to another hospital or expired.

• The data element Term Newborn is used to determine if the patient was not term or < 37 completed weeks of gestation.

S.10. Stratification Information *(Provide all information required to stratify the measure results, if necessary, including the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b.)*

Not Applicable

S.11. Risk Adjustment Type (Select type. Provide specifications for risk stratification in measure testing attachment)

No risk adjustment or risk stratification

If other:

S.12. Type of score:

Rate/proportion

If other:

S.13. 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

S.14. Calculation Algorithm/Measure Logic (*Diagram or 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; time period for data, 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 Discharge Disposition

a) If Discharge Status is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Stop processing.

b) If Discharge Status equals 4,5, 6, the case will proceed to a Measure Category Assignment of B and will not be in the measure population. Stop processing.

c) If Discharge Status equals 1, 2, 3, 7, 8, continue processing and proceed to Term Newborn.

3. Check Term Newborn

a) If Term Newborn is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Stop processing.

b) If Term Newborn =1 the case will proceed to a Measure Category Assignment of E and will be in the Numerator population. Stop processing.

c) If Term Newborn =2 or 3, the case will proceed to a Measure Category Assignment of B and Not in the Measure Population. Stop processing.

4. 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.

5. 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.

b) 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.

c) If Exclusive Breast Milk Feeding equals No, the case will proceed to a Measure Category Assignment of D and will be in the Measure Population. Stop processing.

S.15. Sampling *(If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)*

IF an instrument-based performance measure (e.g., PRO-PM), identify whether (and how) proxy responses are allowed.

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-10-CM Principal or Other Diagnosis Code as defined in Appendix A, Table 11.20.1, NO ICD-10-CM Principal or Other Diagnosis Code as defined in Appendix A, Table 11.21 and NO ICD-10-PCS-Principal or Other Procedure Code as defined in Appendix A,

Table 11.22 and NO ICD-10-CM Principal or Other Diagnosis Code as defined in Appendix A 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

S.16. Survey/Patient-reported data *(If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.)*

Specify calculation of response rates to be reported with performance measure results.

Not Applicable

S.17. Data Source *(Check ONLY the sources for which the measure is SPECIFIED AND TESTED).*

If other, please describe in S.18.

Electronic Health Records, Other, Paper Medical Records

S.18. Data Source or Collection Instrument *(Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc., and describe how data are collected.)*

IF instrument-based, identify the specific instrument(s) and standard methods, modes, and languages of administration.

Starting in 2020, hospitals will use the Direct Data Submission Platform for submission of chart abstracted measures. Thus, in 2020, organizations have one place to submit both eCQM and chart abstracted data. The goal of the Direct Data Submission Platform is to ease the burden and expense of submission and empower organizations with data for quality improvement.

S.19. Data Source or Collection Instrument *(available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)*

No data collection instrument provided

S.20. Level of Analysis *(Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)*

Facility, Other

S.21. Care Setting *(Check ONLY the settings for which the measure is SPECIFIED AND TESTED)*

Inpatient/Hospital

If other:

S.22. COMPOSITE Performance Measure - Additional Specifications *(Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)*

Not Applicable

2. Validity – See attached Measure Testing Submission Form

2020_nqf_testing_attachment_PC05_0480_final-637227329986232316.docx

2.1 For maintenance of endorsement

Reliability testing: If testing of reliability of the measure score was not presented in prior submission(s), has reliability testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.2 For maintenance of endorsement

Has additional empirical validity testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.3 For maintenance of endorsement

Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes social risk factors is not prohibited at present. Please update sections 1.8, 2a2, 2b1,2b4.3 and 2b5 in the Testing attachment and S.140 and S.11 in the online submission form. NOTE: These sections must be updated even if social risk factors are not included in the risk-adjustment strategy. You MUST use the most current version of the Testing Attachment (v7.1) -- older versions of the form will not have all required questions.

No - This measure is not risk-adjusted

Measure Testing (subcriteria 2a2, 2b1-2b6)

Measure Number (*if previously endorsed*)**:** 0480

Measure Title: Exclusive Breast Milk Feeding

Date of Submission: January 3, 2020

Type of Measure:

□Outcome (*including PRO-PM*)	□Composite – ***STOP – use composite testing form***
☐Intermediate Clinical Outcome	□Cost/resource
□Process *(including Appropriate Use)*	□Efficiency
□Structure	

1. DATA/SAMPLE USED FOR ALL TESTING OF THIS MEASURE

Often the same data are used for all aspects of measure testing. In an effort to eliminate duplication, the first five questions apply to all measure testing. If there are differences by aspect of testing, (e.g., reliability vs. validity) be sure to indicate the specific differences in question 1.7.

1.1. What type of data was used for testing? (*Check all the sources of data identified in the measure*

specifications and data used for testing the measure. Testing must be provided for all the sources of data specified and intended for measure implementation. ***If different data sources are used for the numerator and denominator, indicate N [numerator] or D [denominator] after the checkbox.***)

Measure Specified to Use Data From: (*must be consistent with data sources entered in S.17*)	**Measure Tested with Data From:**
□abstracted from paper record	□abstracted from paper record
□claims	□claims
□registry	□registry
□abstracted from electronic health record	□abstracted from electronic health record
□eMeasure (HQMF) implemented in EHRs	□eMeasure (HQMF) implemented in EHRs
□ other: Click here to describe	□ other: Click here to describe

1.2. If an existing dataset was used, identify the specific dataset (*the dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry*). Not applicable

1.3. What are the dates of the data used in testing?

2020 Submission

Testing of measure score reliability and validity was performed using data from hospital discharges occurring in 2018.

2016 Submission

This submission included initial testing of measure score reliability and validity was performed using data from hospital discharges occurring in 1Q2011. Also, updates to validity and exclusions used 2015 data.

1.4. What levels of analysis were tested? (*testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan*)

Measure Specified to Measure Performance of: (*must be consistent with levels entered in item S.20*)	**Measure Tested at Level of:**
□individual clinician	□individual clinician
□group/practice	□group/practice
□hospital/facility/agency	□hospital/facility/agency
□health plan	□health plan
□ other: Click here to describe	□ other: Click here to describe

1.5. How many and which measured entities were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how*

entities were selected for inclusion in the sample)

2020 Submission

This measure assesses the proportion of newborns with exclusive breast milk feeding during the newborn's entire hospitalization. The intended use of the measure is to assess the quality of perinatal care in hospitals across the population.

Entities in reliability and validity testing: Results were calculated from Joint Commission data that included 1950 hospitals submitting the measure using 2018 discharges and had greater than or equal to 30 denominator cases, the minimum sample size required for public reporting. The hospitals were geographically diverse and varied in size.

1950 health care organizations representing various types, locations and sizes:

370 For Profit, 1325 Not for Profit, 255 Government

628>=300 beds; 903 100-300 beds; 419 <100 beds

414 Rural; 1536 Urban

193 Major Teaching; 919 Minor Teaching; 838 Non-Teaching

2016 Submission

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

1.6. How many and which patients were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis); if a sample was used, describe how patients were selected for inclusion in the sample*)

2020 Submission

Patients in reliability and validity testing: Data are summarized at the hospital level. Below is a description of the sample. It includes number of hospitals included in Joint Commission data, the median initial population size, and the median denominator size for the measure across hospitals.

Median denominator size for the Exclusive Breast Milk Feeding measure, 2018 deliveries (Number of Patients = 14,184)

Number of Hospitals	Median number of deliveries	Median number of denominator cases
1950	1034	329

1.7. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing reported below.

2020 Submission

No differences in the data used for reliability and validity testing.

1.8 What were the social risk factors that were available and analyzed? For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

2020 Submission

No patient-level sociodemographic variables are used in the measure and none were available for analysis. There is no compelling evidence available supporting association between social risk factors and this measure.

2a2. RELIABILITY TESTING

***Note**: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a2.1 check critical data element; in 2a2.2 enter "see section 2b2 for validity testing of data elements"; and skip 2a2.3 and 2a2.4.*

2a2.1. What level of reliability testing was conducted? (*may be one or both levels*)

☐ **Critical data elements used in the measure** (*e.g., inter-abstractor reliability; data element reliability must address ALL critical data elements*)

☐ **Performance measure score** (e.g., *signal-to-noise analysis*)

2a2.2. For each level checked above, describe the method of reliability testing and what it tests (*describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used*)

2020 Submission

Reliability testing of performance measure score

We utilized the Beta-binomial model (Adams 2009) to assess how well one can distinguish the performance of one hospital from another. Conceptually, the Beta-binomial model measures the ratio of signal to noise. The signal is the proportion of the variability in the measured performance that can be explained by real differences in performance. The Beta-binomial model is an appropriate model when estimating the reliability of simple pass/fail rate measures as is the case with most Joint Commission measures. Reliability scores range from 0.0 to 1.0. A score of zero implies that all variation is attributed to measurement error (i.e., noise), whereas a reliability of 1.0 implies that all variation is caused by a real difference in performance (across hospitals).

Adams, J.L. The Reliability of Provider Profiling: A Tutorial. Santa Monica, California: RAND Corporation. TR-653-NCQA, 2009

Comparison of ICD-9 to ICD-10 codes

Reliability was measured by comparing results from the 2017 data submission that utilized ICD-9 codes to the results from the 2018 data submission that utilized ICD-10 codes. Summary statistics for the number of numerator cases, number of denominator cases, and observed rates are presented. Hospitals data were also matched by each year in each of the three attributes and a paired t-test was used to determine statistical significance for each attribute.

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 re-abstracted with originally abstracted data having been blinded so that the re-abstraction is not biased.
- Re-abstracted 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. For each level of testing checked above, what were the statistical results from reliability testing? (e.*g., percent agreement and kappa for the critical data elements; distribution of reliability statistics from a signal-to-noise analysis*)

Validity (Measure evaluation criterion 2b)

2020 Submission

Reliability testing of performance measure score

Reliability statistic for the measure: newborns with exclusive breast milk feeding during the newborn's entire hospitalization:

Average: 0.97

Median: 0.98

10^{th}-90^{th} percentile across hospitals: 0.95 – 0.99

Comparison of ICD-9 to ICD-10 codes

Comparison between the ICD-9 and ICD-10 number of numerator cases, denominator cases, and observed rates

		N	Mean	Std. Dev.	Min	Q1	Median	Q3	Max	Pairwise Difference	P-Value
Numerator	ICD-9	2022	57.1909	82.2855	0	20	36	60	1064	-0.3546	0.5365
	ICD-10	1947	24.8598	83.45	0	20	37	61	1031		

Denominator	ICD-9	2022	112.997	137.374	1	46	82	109	1729	-1.1089	0.2225
	ICD-10	1947	113.84	138.737	1	47	81	110	1572		
Rate	ICD-9	2022	0.48639	0.19364	0	0.35088	0.5	0.62264	1	0.00241	0.3095
	ICD-10	1947	0.48904	0.19107	0	0.36145	0.48864	0.62	1		

Data element agreement rates were reported to The Joint Commission for 1Q11. This reflects the findings of106 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 Numerator	Total Denominator	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 Breast Feeding	334	342	97.66%

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

2a2.4 What is your interpretation of the results in terms of demonstrating reliability? (i.*e., what do the results mean and what are the norms for the test conducted?*)

2020 Submission

In general, a score of 0.7 or higher suggests the measure has adequate reliability. The results suggest the measure has high reliability for most of the hospitals.

Pairwise comparisons were not statistically significant for the number of numerator cases, the number of denominator cases, and the observed rates between matched hospitals between 2017 data (ICD-9) and 2018 data (ICD-10) with p-values greater than 0.05. This suggests that there are no differences in reliability of the measure using the previous ICD-9 coding and the current ICD-10 coding.

2b1. VALIDITY TESTING-new

2b1.1. What level of validity testing was conducted? (*may be one or both levels*)

☐ **Critical data elements** (*data element validity must address ALL critical data elements*)

☐ **Performance measure score**

- ☐ **Empirical validity testing**
- ☐ **Systematic assessment of face validity of performance measure score as an indicator** of quality or resource use (*i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance*) **NOTE**: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.

2b1.2. For each level of testing checked above, describe the method of validity testing and what it tests (*describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used)*

2020 Submission

Correlations of the measure with other measures of perinatal care quality. Since a high measure rate for PC-05 is desirable, this measure is hypothesized to correlate positively to other perinatal care measures where a high rate is desirable (ePC-05) and negatively correlated to perinatal care measures where a low rate is desirable (PC-02, PC-01, ePC-01).

A correlation of 0.1 - 0.3 was considered weak, 0.3 - 0.5 was considered moderate, and over 0.5 was considered strong.

Correlation with other measures of hospital facility quality. Hospital Compare uses a five-star rating system to rate facilities based on multiple quality measures, including an overall rating. We performed a correlational analysis to see if facility scores for this measure were related to the facility's overall five-star rating. PC-05 rates would be hypothesized to correlate positively with the five-star rating.

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.

ICD-9 to ICD-10 Conversion Process:

The goal was to convert ICD-9 to ICD-10 equivalent codes, consistent with the clinical intent of the original measure specifications. The Joint Commission worked with a certified coding expert throughout the conversion process. The 3M Coding Conversion Tool was utilized, including forward mapping of ICD-9 codes to ICD-10 codes as well as reverse mapping from ICD-10 to ICD-9 to ensure appropriateness. MSDRGs and instructions in the tabular index were also examined to ensure appropriate code mapping. Crosswalks comprising ICD-9 codes mapped to ICD-10 codes were created and reviewed by members of the Technical Advisory Panel, CMS subcontractors, and performance measurement system vendors prior to being posted for a 12 month public comment period. Feedback from the field indicated that the crosswalks generally were mapped correctly. Minor modifications to the code tables were made as needed. Final code tables were published in early 2015, well in advance of the mandated date of October 1, 2015.

Newborns with Exclusive Breast Feeding - Patient Age at admission (Admission Date – Birthdate) ≤ 2 days, Length of Stay (Discharge Date - Admission Date) ≤ 120 days, an ICD-9-CM Principal as defined in Appendix A, Table 11.20.1, NO ICD-9-CM Other Diagnosis Codes 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 Other Diagnosis Codes as defined in Appendix A, Table 11.23 are included in this subpopulation and are eligible to be sampled.

PC-05 measure belongs to this sub population

The data used to measure the validity of the PC measure are comprised of data from the third and fourth quarters of 2014, and the first and second quarters of 2015. 1,345 hospitals submitted 2,695,467 inpatient records for all the elected PC measures. The hospitals included in the analysis reported one year of data and had 30 or more denominator cases in the analysis period.

Measure convergent validity for PC-05 was assessed using hospitals patient level data from The Joint Commission warehouse. Measure specifications, including population identification, numerator and denominator statements, exclusions, and data elements and their definitions were found to be understandable, retrievable, and relevant in previous validity testing.

2b1.3. What were the statistical results from validity testing? (*e.g., correlation; t-test*)

2020 Submission

Correlations with other measures of perinatal care quality

Table of Correlations

Measure	PC-01	PC-02	PC-05	ePC-01	ePC-05
PC-01-Elective Delivery	1				

PC-02-Cesarean Birth	0.133192	1			
PC-05-Exclusive Breast Milk Feeding	-0.02553	-0.28103	1		
ePC-01-Elective Delivery	0.008936	0.108322	0.022812		
ePC-05-Exclusive Breast Milk Feeding	0.040365	-0.17522	0.748033	-0.45737	1

Correlation with other measures of hospital facility quality.

A moderate correlation was found between the facility-level PC-05 measure score and the overall quality rating ($\rho = 0.360$, $p < .0001$). This result suggests that facilities having a higher overall quality rating tends to have a higher PC-05 score, indicating a higher quality of newborn care.

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.

N=1,352 hospitals

n= 775,909 records submitted

Analysis of hospitals' rate in conjunction with PC-05 measure

PC-05

Percentile 10%: 23%

Percentile 25%: 37%

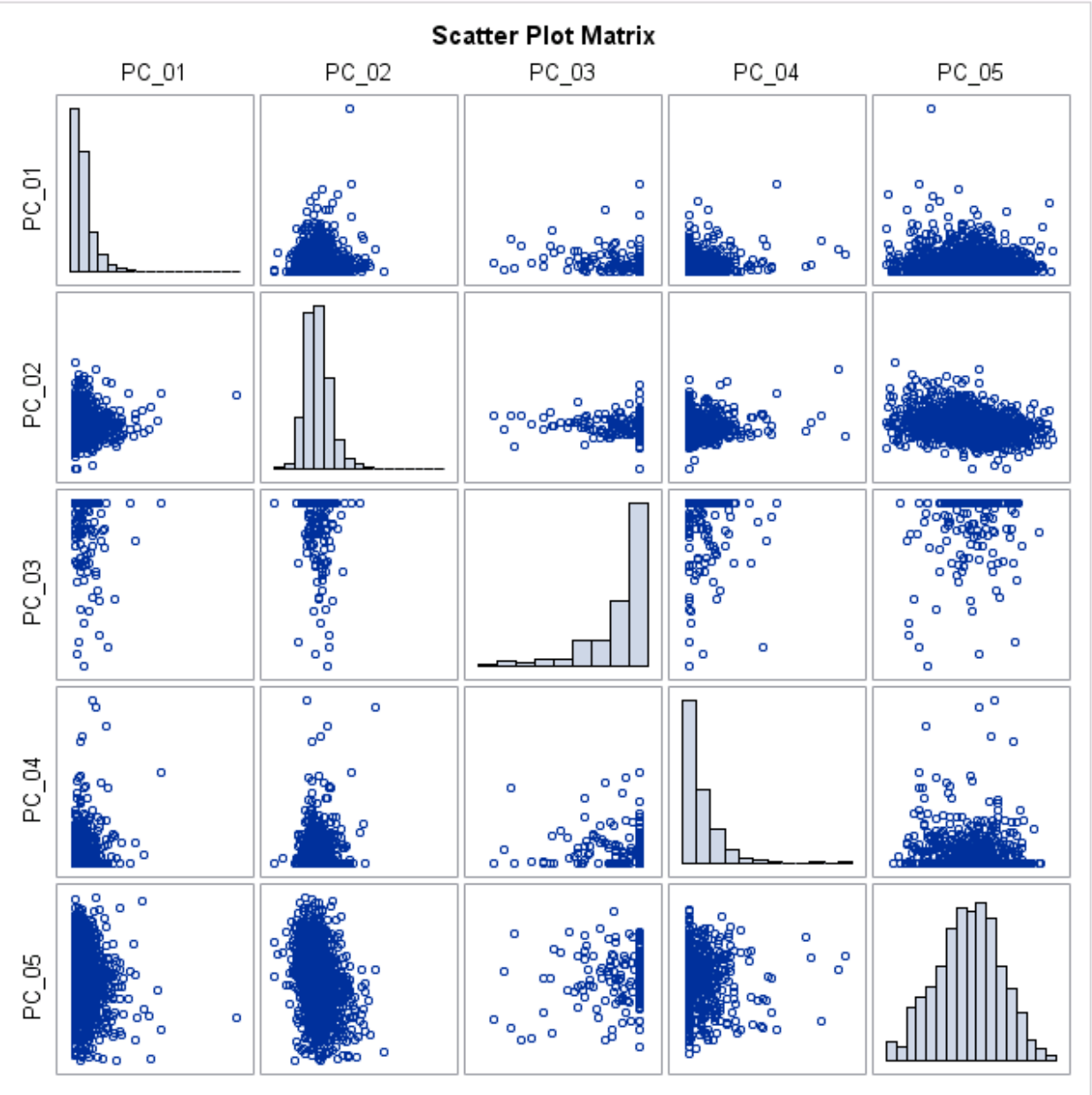
Median: 50%

Percentile 75%: 63%

Percentile 90%: 75%

Simple Statistics						
Variable	N	Mean	Std Dev	Median	Minimum	Maximum
PC_01	1237	0.02753	0.03803	0.01734	0	0.51240
PC_02	1345	0.26287	0.07974	0.25410	0	1.00000
PC_03	162	0.97762	0.03311	0.99425	0.84615	1.00000
PC_04	523	0.05267	0.08432	0.02203	0	0.66129
PC_05	1352	0.49198	0.19284	0.50190	0.00317	1.00000

Spearman Correlation Coefficients Prob > |r| under H0: Rho=0 Number of Observations					
	PC_01	PC_02	PC_03	PC_04	PC_05
PC_01	1.00000 1237	0.06843 0.0163 1231	-0.26960 0.0006 159	0.10724 0.0169 496	-0.03538 0.2137 1237
PC_02	0.06843 0.0163 1231	1.00000 1345	-0.18318 0.0196 162	0.02807 0.5218 523	-0.32009 <.0001 1343
PC_03	-0.26960 0.0006 159	-0.18318 0.0196 162	1.00000 162	-0.03117 0.7030 152	0.07729 0.3283 162
PC_04	0.10724 0.0169 496	0.02807 0.5218 523	-0.03117 0.7030 152	1.00000 523	-0.03560 0.4165 523
PC_05	-0.03538 0.2137 1237	-0.32009 <.0001 1343	0.07729 0.3283 162	-0.03560 0.4165 523	1.00000 1352



The Spearman rank-order correlation is a nonparametric measure of association based on the ranks of the data values by measure PC-05 and hospitals. We used this methodology because of the skewness of the distribution of the measure rates.

2b1.4. What is your interpretation of the results in terms of demonstrating validity? (i.*e., what do the results mean and what are the norms for the test conducted?*)

2020 Submission

Except for the correlation between PC-05 and ePC-01, the directions of the correlations were in the expected direction. The correlation of PC-05 and ePC-01, although expected to be in the negative direction, was not significantly greater than zero, nor was the correlation between PC-01 and PC-05. These measures (PC-05 vs PC-01 and ePC-01) evaluate two different populations, mothers and babies, and therefore two different aspects of perinatal care which are apparently not correlated. The perinatal care measures used in this analysis are measuring different components of perinatal care and would not be expected to be more than weakly correlated since perinatal care quality is a multidimensional quantity. The exception is the correlation between PC-05 and ePC-05 which would be expected to be positive and high as they are measuring the same quantity, which was in fact the case with the observed correlation.

These correlations support convergent validity.

The correlation of PC-05 with PC-02 is moderate and statistically significant. The other correlations with the other PC measures are relatively weak and not significant. Performance of hospitals on this measure varied widely, 90% of the hospital measure rates fall between 23 and 75%, indicating that there is much room for improvement on this measure.

2b2. EXCLUSIONS ANALYSIS

NA ☐no exclusions — *skip to section 2b3*

2b2.1. Describe the method of testing exclusions and what it tests (*describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used*)

2020 Submission

Our testing addresses exclusions, as shown in the table below.

Exclusion	Rationale	Measure Denominator lost due to exclusion
Discharge disposition: acute care facility	Newborns transferred to another hospital are excluded from the measure, since most of these newborns are NPO and are being transferred to a higher level of care due to medical conditions.	1.7%
Discharge disposition: other healthcare facility	Newborns transferred to another hospital are excluded from the measure, since most of these newborns are NPO and are being	0.2%

	transferred to a higher level of care due to medical conditions.	
Discharge disposition: expired	Patients who expire are not eligible to be in this measure.	0.2%
Not a term newborn	Newborns with prematurity, gestational age <37 weeks, are excluded from the measure, since term newborns are the population of interest.	6.5%
Admission to NICU	Newborns admitted to the NICU are excluded from the measure, since PC-05 only includes healthy term newborns.	4.9%

Note: The exclusions presented in this table are not mutually exclusive. For example, a discharge that falls under exclusions 1 and 4 would appear in both places in this table.

We tested whether the exclusions impacted the performance score denominator.

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

There were 775,909 admissions selected from the initial cohort. From among the 775,909 admissions in 1,352 hospitals, the descriptive statistics are given below.

The following exclusions were analyzed by subpopulation and measure for frequency and variability across providers:

Excluded Populations:

- Admitted to the Neonatal Intensive Care Unit (NICU) at this hospital during the hospitalization

- 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 Other Diagnosis Codes for premature newborns as defined in Appendix A Table 11.23

2b2.2. What were the statistical results from testing exclusions? (*include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores*)

2020 Submission

Exclusion	**Rationale**	**Measure Denominator lost due to exclusion**
Discharge disposition: acute care facility	Newborns transferred to another hospital are excluded from the measure, since most of these newborns are NPO and are being transferred to a higher level of care due to medical conditions.	1.7%
Discharge disposition: other healthcare facility	Newborns transferred to another hospital are excluded from the measure, since most of these newborns are NPO and are being transferred to a higher level of care due to medical conditions.	0.2%
Discharge disposition: expired	Patients who expire are not eligible to be in this measure.	0.2%
Not a term newborn	Newborns with prematurity, gestational age <37 weeks, are excluded from the measure, since term newborns are the population of interest.	6.5%

Admission to NICU	Newborns admitted to the NICU are excluded from the measure, since PC-05 only includes healthy term newborns.	4.9%

Number and percent of denominator remaining after exclusions

PC-05 Denominator

PC-05 denominator before exclusions	PC-05 denominator after exclusions	Percent after exclusions
1,035,466	902,717	87.2%

The percentiles for the hospital percent after exclusions had the following values for the 10th, 25th, 50th, 75th and 90th percentiles respectively: 80.3%, 84.8%, 88.9%, 92.1%, and 94.2%.

N=353,671

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

There were 775,909 admissions selected from the initial cohort. From among the 775,909 admissions in 1,352 hospitals, the descriptive statistics are given below.

Exclusion Subpopulation 3 - PC-05

Exclusion: Admitted to the Neonatal Intensive Care Unit (NICU) at this hospital during the hospitalization

Overall Number of Occurrences n = 40,754

Overall Occurrence Percentage: 5.25%

Minimum: 0 %

10th Percentile: 0%

Median: 4.25%

90th Percentile: 11.2%

Maximum: 69%

Exclusion: ICD-9-CM Other Diagnosis Codes for galactosemia as defined in Appendix A, Table 11.21

No observations noted

Exclusion: ICD-9-CM Principal Procedure Code or ICD-9-CM Other Procedure Codes for parenteral infusion as defined in Appendix A, Table 11.22

No observations noted

Exclusion: Patients who expire during the hospital stay
Overall Number of Occurrences n = 404
Overall Occurrence Percentage: 0.05%
Minimum: 0%
10th Percentile: 0%
Median: 0%
90th Percentile: 0.2%
Maximum: 1.9%

Exclusion: Length of Stay >120 days
No observations noted

Exclusion: Patients enrolled in clinical trials
Overall Number of Occurrences n = 248
Overall Occurrence Percentage: .03%
Minimum 0%
10th Percentile: 0%
Median: 0%
90th Percentile: 0%
Maximum: 32%

Exclusion: Documented Reason for Not Exclusively Feeding Breast Milk
Overall Number of Occurrences n = 7,282
Overall Occurrence Percentage: 0 .94%
Minimum 0%
10th Percentile: 0%
Median: 0.6%
90th Percentile: 2.3%
Maximum: 17.2%

Exclusion: Patients transferred to another hospital;
Overall Number of Occurrences n = 459
Overall Occurrence Percentage: 0.06%
Minimum 0%

10th Percentile: 0%

Median: 0%

90th Percentile: 0.2%

Maximum: 5.5%

Exclusion: ICD-9-CM Other Diagnosis Codes for premature newborns as defined in Appendix A, Table 11.23

No observations noted

2b2.3. What is your interpretation of the results in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results? (*i.e., the value outweighs the burden of increased data collection and analysis. Note: **If patient preference is an exclusion**, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion*)

2020 Submission

We tested several exclusions in order to understand the impact on the denominator. All exclusions are necessary to ensure the construct validity of the measure and all have a clinical rationale. In the specifications, these exclusions have been incorporated into the measure definition.

The overall frequency of exclusions is low for those in the measure denominator. The difference between the 10th and 90th percentiles of the distribution of exclusion rates is narrow indicating that the occurrence is random and likely would not bias performance results.

It is believed that all of the exclusions should be retained for the following reasons:

Exclusion: Admitted to the Neonatal Intensive Care Unit (NICU) at this hospital during the hospitalization

Rationale: Newborns admitted to the NICU are excluded from the measure, since PC-05 only includes healthy term newborns.

Exclusion: ICD-9-CM Other Diagnosis Codes for galactosemia as defined in Appendix A, Table 11.21

Rationale: Newborns diagnosed with galactosemia are excluded from the measure, since breast milk is contraindicated due to the newborn's inability to digest milk proteins.

Exclusion: ICD-9-CM Principal Procedure Code or ICD-9-CM Other Procedure Codes for parenteral infusion as defined in Appendix A, Table 11.22

Rationale: Newborns receiving parenteral infusions are excluded from the measure, since these newborns are NPO and no oral feedings would be given.

Exclusion: Patients who expired

Rationale: Patients who expire are not eligible to be in this measure

Exclusion: Length of Stay >120 days

Rationale: Included for this measure in order to harmonize with other CMS/Joint Commission aligned measures.

Exclusion: Patients enrolled in a Clinical Trial

Rationale: Newborns enrolled in clinical trials are excluded from the measure, since a clinical trial involves an intervention and control group which may impact the ability to provide breast milk feedings.

Exclusion: Documented Reason for Not Exclusively Feeding Breast Milk

Rationale: This data element has been removed effective with 10/1/15 discharges. Exclude cases when there were certain maternal medical reasons that the newborn could not be fed breast milk.

Exclusion: Patients transferred to another hospital

Rationale: Newborns transferred to another hospital are excluded from the measure, since most of these newborns are NPO and are being transferred to a higher level of care due to medical conditions

Exclusion: ICD-9-CM Other Diagnosis Codes for premature newborns as defined in Appendix A Table 11.23

Rationale: Newborns with prematurity codes are excluded from the measure, since these are not term newborns which is the population of interest. This was replaced with the new data element Term Newborn effective with 10/1/15 discharges in order to exclude pre-term newborns by gestational age <37 weeks and/or descriptors for pre-term.

2b3. RISK ADJUSTMENT/STRATIFICATION FOR OUTCOME OR RESOURCE USE MEASURES

If not an intermediate or health outcome, or PRO-PM, or resource use measure, skip to section 2b4.

2b3.1. What method of controlling for differences in case mix is used?

☐ **No risk adjustment or stratification**

☐ **Statistical risk model with** Click here to enter number of factors **risk factors**

☐ **Stratification by** Click here to enter number of categories **risk categories**

☐ **Other,** Click here to enter description

2b3.1.1 If using a statistical risk model, provide detailed risk model specifications, including the risk model method, risk factors, coefficients, equations, codes with descriptors, and definitions.

Not applicable

2b3.2. If an outcome or resource use component measure is not risk adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (case mix) is not needed to achieve fair comparisons across measured entities.

Not applicable

2b3.3a. Describe the conceptual/clinical and statistical methods and criteria used to select patient factors (clinical factors or social risk factors) used in the statistical risk model or for stratification by risk (*e.g., potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10; correlation of x or higher; patient factors should be present at the start of care*)

Also discuss any "ordering" of risk factor inclusion; for example, are social risk factors added after all clinical factors?

Not applicable

2b3.3b. How was the conceptual model of how social risk impacts this outcome developed? Please check all that apply:

- ☐ **Published literature**
- ☐ **Internal data analysis**
- ☐ **Other (please describe)**

Not applicable

2b3.4a. What were the statistical results of the analyses used to select risk factors?

Not applicable

2b3.4b. Describe the analyses and interpretation resulting in the decision to select social risk factors *(e.g. prevalence of the factor across measured entities, empirical association with the outcome, contribution of unique variation in the outcome, assessment of between-unit effects and within-unit effects.)* **Also describe the impact of adjusting for social risk (or not) on providers at high or low extremes of risk.**

Not applicable

2b3.5. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (*describe the steps—do not just name a method; what statistical analysis was used*)

Provide the statistical results from testing the approach to controlling for differences in patient characteristics (case mix) below.

If stratified, skip to 2b3.9

2b3.6. Statistical Risk Model Discrimination Statistics (*e.g., c-statistic, R-squared*)**:**

Not applicable

2b3.7. Statistical Risk Model Calibration Statistics (*e.g., Hosmer-Lemeshow statistic*):

Not applicable

2b3.8. Statistical Risk Model Calibration – Risk decile plots or calibration curves:

Not applicable

2b3.9. Results of Risk Stratification Analysis:

Not applicable

2b3.10. What is your interpretation of the results in terms of demonstrating adequacy of controlling for differences in patient characteristics (case mix)? (i.*e., what do the results mean and what are the norms for the test conducted*)

Not applicable

2b3.11. Optional Additional Testing for Risk Adjustment (*not required, but would provide additional support of adequacy of risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed*)

Not applicable

2b4. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE

2b4.1. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified

(*describe the steps—do not just name a method; what statistical analysis was used? Do not just repeat the information provided related to performance gap in 1b)*

2020 Submission

To demonstrate meaningful differences in performance, The Joint Commission calculates a funnel plot (Spiegelhalter 2004) for the annual hospital rates of the measure. In a funnel plot, the observed measure is plotted against a measure of its precision, so that the control limits form a 'funnel' around the target outcome. The 95 per cent (≈2 standard deviation) and 99.8 per cent (≈3 standard deviation) prediction limits are then superimposed over this plot around the overall measure rate. Those rates lying outside the confidence limits are identified as outliers.

Spiegelhalter, DJ. Funnel plots for comparing institutional performance. Statistics in Medicine 2005; 24:1185–1202.

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.

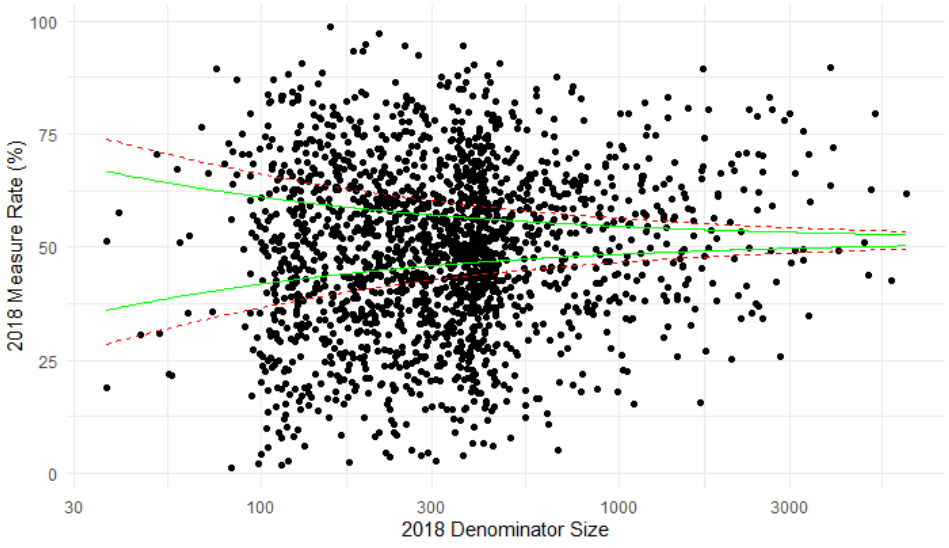
There are two components to the target analysis methodology used at The Joint Commission. Given the national average for a performance measure, a target range is constructed. Using generalized linear mixed models' methodology (also known as hierarchical models), a predicted estimate of an HCO's performance, 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.

2b4.2. What were the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities? (e.g., *number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined*)

2020 Submission

Using the funnel plot, 816 hospitals were identified as low outliers (in an unfavorable direction) with rates below the 2 standard deviation lower limit and 687 hospitals were identified as low outliers with rates below the 3 standard deviation lower limit. A hospital with the median denominator size of 329 would be expected to fall in a 99.9% confidence interval of 43% to 60%.

Funnel Plot for PC-05:



PC-05 Distribution of Rates

2018 Yearly Data

Scores on this measure: N = 1950, Mean = 49.3%, SD = 18.1%

10th Percentile = 24.6%

25th Percentile = 37.2%

50th Percentile = 49.7%

75th Percentile = 61.9%

90th Percentile = 72.3%

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

2b4.3. What is your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities? (i.*e., what do the results mean in terms of statistical and meaningful differences?*)

2020 Submission

The results indicate a significant amount of hospital variability in rates and an appreciable number of hospitals that are not within the expected level of variability and vary significantly from the mean overall rate.

2b5. COMPARABILITY OF PERFORMANCE SCORES WHEN MORE THAN ONE SET OF SPECIFICATIONS
***If only one set of specifications, this section can be skipped*.**

Note: *This item is directed to measures that are risk-adjusted (with or without social risk factors)* ***OR*** *to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for*

claims or eMeasures). It does not apply to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator). ***Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.***

2020 Submission

This submission is for the chart-based measure version of the measure 0480e, which has been submitted as a separate measure.

2b5.1. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications (*describe the steps—do not just name a method; what statistical analysis was used*)

Not applicable

2b5.2. What were the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications? (*e.g., correlation, rank order*)

Not applicable

2b5.3. What is your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications? (i.*e., what do the results mean and what are the norms for the test conducted*)

Not applicable

2b6. MISSING DATA ANALYSIS AND MINIMIZING BIAS

2020 Submission

The measure has been collected since 2011 and hospitals transmitting data with missing data on any of the critical data elements are not accepted.

2b6.1. Describe the method of testing conducted to identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders) and how the specified handling of missing data minimizes bias (*describe the steps—do not just name a method; what statistical analysis was used*)

Not applicable

2b6.2. What is the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data? (*e.g., results of sensitivity analysis of the effect of various rules for missing data/nonresponse; if no empirical sensitivity analysis, identify the approaches for handling missing data that were considered and pros and cons of each*)

Not applicable

2b6.3. What is your interpretation of the results in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and non-responders) and how the specified handling of missing data minimizes bias**?** (i*.e., what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis, provide rationale for the selected approach for missing data*)

Not applicable

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

3a.1. Data Elements Generated as Byproduct of Care Processes.

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)

If other:

3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. To what extent are the specified data elements available electronically in defined fields (*i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields*) Update this field for **maintenance of endorsement**.

Some data elements are in defined fields in electronic sources

3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources. For **maintenance of endorsement**, if this measure is not an eMeasure (eCQM), please describe any efforts to develop an eMeasure (eCQM).

The Joint Commission recognizes that not all hospitals currently have the capacity to abstract the electronic version of this measure, so continues to offer this chart abstracted version which allows for data capture from

unstructured data fields. All data elements needed to compute the PC-05 performance measure score have been retooled for capture from electronic sources.

See corresponding measure NQF# 0480e

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL. Please also complete and attach the NQF Feasibility Score Card.

Attachment:

3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. <u>Required for maintenance of endorsement.</u> Describe difficulties (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.

<u>IF instrument-based,</u> consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

At the present time, hospitals using this performance measure generally collect measure data via manual review of the EMR, data derived from vital records reports received from state or local departments of public health, delivery logs or clinical information systems or a combination. Collected data are submitted to The Joint Commission on a quarterly basis, 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 feedback from measure users has indicated the need for clarification or revision of measure specifications, this has taken place.

3c.2. Describe any fees, licensing, or other requirements to use any aspect of the measure as specified *(e.g., value/code set, risk model, programming code, algorithm)*.

There are no fees or licensing requirements to use the Joint Commission performance measures, all of which are in the public domain.

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on

performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

4.1. Current and Planned Use

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.

Specific Plan for Use	Current Use (for current use provide URL)
	Public Reporting Quality Check® http://www.qualitycheck.org/consumer/searchQCR.aspx Quality Check® http://www.qualitycheck.org/consumer/searchQCR.aspx Regulatory and Accreditation Programs Hospital Accreditation Program http://jointcommission.org Hospital Accreditation Program http://jointcommission.org Quality Improvement (Internal to the specific organization) Perinatal Care Certification http://www.jointcommission.org/certification/perinatal_care_certification.aspx

4a1.1 For each CURRENT use, checked above (update for maintenance of endorsement), provide:

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included
- Level of measurement and setting

Name of program and sponsor: The Joint Commission Hospital Accreditation Program

- Purpose: An accreditation program that recognizes hospitals that meet standard requirements to provide safe and effective patient care.
- Geographic area and number and percentage of accountable entities and patients included: Nationwide; 2006 Joint Commission-accredited hospitals selected PC-05 to report in 2018 (67% of all Joint Commission-accredited hospitals), 1988 had one or more denominator cases (2018)

Name of program and sponsor: The Joint Commission Perspective's- The Official Newsletter of the Joint Commission. (2019). The joint commission recognizes 20 years of ORYX performance measure reporting; look back at the 20-year evolution of performance measure reporting and review the ORYX chart-abstracted measure results for 2017 and 2018, 39, 10.

- Purpose: The Perspective's article provides authoritative, accurate, and timely information about revisions and updates to Joint Commission standards, policies, and other requirements for all Joint Commission-accredited and -certified organizations and healthcare settings.

Name of program and sponsor: Quality Check®-The Joint Commission

- Purpose: A public website that allows consumers to: search for accredited and certified organizations by city and state, by name or by zip code (up to 250 miles); find organizations by type of service provided within a geographic area; download free hospital performance measure results; and, print a list of Joint Commission certified disease-specific care programs and health care staffing firms.
- Geographic area and number and percentage of accountable entities and patients included: Nationwide; 2006 Joint Commission-accredited hospitals selected PC-05 to report in 2018 (67% of all Joint Commission-accredited hospitals), 1988 had one or more denominator cases (2018)

Name of program and sponsor: Perinatal Care Certification-The Joint Commission

- Purpose: A certification program that recognizes hospitals that have achieved integrated, coordinated, patient-centered care for clinically uncomplicated pregnancies and births.
- Geographic area and number and percentage of accountable entities and patients included: Nationwide; 65 Joint Commission-accredited hospitals (2018)

4a1.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (*e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?*)

Not Applicable

4a1.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (*Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.*)

Not Applicable

4a2.1.1. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

How many and which types of measured entities and/or others were included? If only a sample of measured entities were included, describe the full population and how the sample was selected.

The Joint Commission provides accredited healthcare organizations feedback reports for the measures submitted. The results are shared with organizations on a quarterly and/or annual basis depending on the reporting cycle of the measure. In addition, the Joint Commission has launched a new program called Continuous Customer Engagement (CCE) to assist organization in improving the quality of the performance measures. CCE includes enhanced dashboards with QI tools embedded into the dashboard, as well as focused and targeted solutions to assist organizations with gaps in the performance of their measures. The initial outreach to organizations utilizes an email process for hospital contact related to their measure rates and analysis. Response is provided in a timely manner either by email or directly by phone. Additionally, the data is available publicly through The Joint Commission Quality Check website. Individual hospital data for each rolling yearly time period is viewable and can be downloaded from this website.

4a2.1.2. Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

The Joint Commission is committed to provided valuable and actionable feedback to accredited organizations submitted the performance measurement data. The Joint Commission aggregates the Patient level data is aggregated at the hospital level quarterly. The hospital Performance Measure Report and Quality Check

website are updated either quarterly or annually to reflect organization results, as well as National Benchmarks. A user guide to the Performance Measure Report is posted on the Joint Commission website. Quality Check includes yearly and quarterly hospital rates, state and national averages, and the top 10 percentile at the national and state level.

4a2.2.1. Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.

Describe how feedback was obtained.

The Joint Commission utilizes an automated feedback system with access available to the measured entities and the vendors contracted by measured entities. A clinical lead is responsible for each individual measure set. The system is monitored daily and response is provided typically within 8 business hours. If queries cannot be managed via written response, arrangements are made to address any issues or concerns via phone. In addition, the Joint Commission developed dashboards as part of an ongoing project to provide continuous customer engagement. The Joint Commission analyzes aggregate performance in each of measure and identifies the measures for which the greatest opportunities for improvement exist among accredited hospitals. Based on those findings, an educational webinar series that address the high-opportunity topics is developed. All accredited hospitals have access to the educational webinar series. Organizations with high opportunity for improvement are particularly encouraged to participate. The dashboard report—posted in the Resources and Tools section of an accredited hospital's secure Joint Commission Connect® extranet site—is representative of each organization's relative performance on each of the selected measures. For each measure, the dashboard shows that organization's performance compared to national, state, and Joint Commission–accredited organization averages. The dashboard is not a score-able element on survey, but rather, a tool to facilitate discussion about ongoing quality improvement work. For example, surveyors may ask an organization how it addresses the subset of performance measures in the report and what action(s) the organization is taking to improve processes.

4a2.2.2. Summarize the feedback obtained from those being measured.

The Joint Commission provides several venues for the organizations being measured to provide feedback. Questions on the measures are most likely to come through the clinical and data receipt mailboxes provided on all communications. In addition, the Joint Commission has advisory committees for the Hospital Accreditation Program, which meet on a quarterly basis, and have the opportunity to provide feedback on the measures being collected.

Most statistical questions on this measure were regarding how this measure was to be publicly reported in 2020. There was strong support for the public reporting of this measure from multiple stakeholders.

Queries submitted via the automated feedback system have decreased significantly for the early elective delivery measure in the past three years. This indicates that as these measures are used more frequently, there are fewer question about how the measure specifications. Note that these queries are unrelated to the measure rates, they are questions from the users of this measure about the interpretation of the measure and the measure specifications.

Correction

The statement "Queries submitted via the automated feedback system have decreased significantly for the measure in the past three years." does apply for PC-05.

4a2.2.3. Summarize the feedback obtained from other users

Same as above in 4a2.2.2.

4a2.3. Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

Note: All feedback is tracked and considered. If upon analysis there are trends noted giving cause for updates, this is reviewed by the measure workgroup to confirm the need for revision. Additionally, The Joint Commission engages a Technical Advisory Panel (TAP) for review and/or approval of updates which may require their additional subject matter expertise. All measure specifications are reviewed twice a year and updates are made as needed based on feedback from the measure users, input from the TAP, changes in the guidelines, or changes in clinical practice.

Minor modifications have been made to this measure based upon feedback received.

Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b1. Refer to data provided in 1b but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included.)

If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

Not Applicable

4b2. Unintended Consequences

The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

4b2.1. Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients.

Unintended Consequence: Data abstraction for the mother's initial feeding plan for PC-05a: Exclusive Breast Milk Feeding Considering Mother's Initial Feeding Plan did not follow normal workflow patterns and greatly increased the burden of data abstraction for hospitals. Numerous stakeholders also expressed concern that undecided mothers were often choosing both formula and breast milk, and it was perceived that these mothers were not receiving the same level of support as mothers who had chosen to feed breast milk only.

Mitigating Action: Retired the sub-measure PC-05a: Exclusive Breast Milk Feeding Considering Mother's Initial Feeding Plan.

Unintended Consequence: Late preterm newborns were not being routinely excluded from the denominator population via diagnosis codes for premature newborns on Table 11.23.

Mitigating Action: Table 11.23 was removed and a new denominator data element Term Newborn was added, so that now only newborns who were term or =>37 weeks gestation completed were included.

Unintended Consequence: Reviewing medical records for maternal medical conditions as reasons for not exclusively feeding breast milk was greatly increasing the burden of data abstraction based on feedback from hospitals.

Mitigating Action: The denominator data element Reason For Not Exclusively Feeding Breast Milk was removed from the denominator excluded population in order to simplify data abstraction.

4b2.2. Please explain any unexpected benefits from implementation of this measure.

Not applicable

5. Comparison to Related or 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.

5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

Yes

5.1a. List of related or competing measures (selected from NQF-endorsed measures)

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

Not applicable

5a. Harmonization of Related Measures

The measure specifications are harmonized with related measures;
OR
The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):
Are the measure specifications harmonized to the extent possible?

No

5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

Correction: The measures are completely harmonized to the extent possible, given the fact that the data source for #0480e is the electronic clinical quality measure record.

5b. Competing Measures

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);
OR

Multiple measures are justified.

5b.1. If this measure conceptually addresses 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.)
Not Applicable

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

Available at measure-specific web page URL identified in S.1 **Attachment:**

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): The Joint Commission

Co.2 Point of Contact: JohnMarc, Alban, jalban@jointcommission.org, 630-792-5304-

Co.3 Measure Developer if different from Measure Steward: The Joint Commission

Co.4 Point of Contact: Tricia, Elliott, Telliott2@jointcommission.org, 630-792-5643-

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development

Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

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Harbor-UCLA Medical Center

Torrance, CA

Martin McCaffrey, MD

UNC North Carolina Children's Hospital

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Debra Bingham PhD, RN, FAAN

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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.

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: 2010

Ad.3 Month and Year of most recent revision: 10, 2015

Ad.4 What is your frequency for review/update of this measure? Biannual

Ad.5 When is the next scheduled review/update for this measure? 01, 2020

Ad.6 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 vendors, are required to update their software and associated documentation based on the published manual production timelines.

Ad.7 Disclaimers:

Ad.8 Additional Information/Comments: