

# Neonatal Intensive Care Outcomes

## Section 1. Basic Measure Information

### 1.A. Measure Name

Neonatal Intensive Care Outcomes

### 1.B. Measure Number

0209

### 1.C. Measure Description

**Please provide a non-technical description of the measure that conveys what it measures to a broad audience.**

The Neonatal Intensive Care Outcomes metric assess the hospital- or State-level outcomes of neonatal intensive care unit (NICU) hospitalizations. The optimal measure will adjust for differences in risk for infants of different birthweights and/or gestational ages and maternal sociodemographic factors. When maternal data are available, the risk-adjustment model may also be expanded to include maternal antepartum/peripartum complications, such as diabetes and hypertension.

### 1.D. Measure Owner

The Children's Hospital of Philadelphia (CHOP).

### 1.E. National Quality Forum (NQF) ID (if applicable)

Not applicable.

### 1.F. Measure Hierarchy

**Please note here if the measure is part of a measure hierarchy or is part of a measure group or composite measure. The following definitions are used by AHRQ:**

- 1. Please identify the name of the collection of measures to which the measure belongs (if applicable). A collection is the highest possible level of the measure hierarchy. A collection may contain one or more sets, subsets, composites, and/or individual measures.**

Not applicable.

- 2. Please identify the name of the measure set to which the measure belongs (if applicable). A set is the second level of the hierarchy. A set may include one or more subsets, composites, and/or individual measures.**

Not applicable.

- 3. Please identify the name of the subset to which the measure belongs (if applicable). A subset is the third level of the hierarchy. A subset may include one or more composites, and/or individual measures.**

Not applicable.

- 4. Please identify the name of the composite measure to which the measure belongs (if applicable). A composite is a measure with a score that is an aggregate of scores from other measures. A composite may include one or more other composites and/or individual measures. Composites may comprise component measures that can or cannot be used on their own.**

Not applicable.

## **1.G. Numerator Statement**

For each outcome, the numerator is the number of infants with gestational age between 23-34 weeks who had evidence of the outcome during their NICU hospitalization.

## **1.H. Numerator Exclusions**

Infants missing gestational age or with a specified congenital anomaly as described in Table 1 (see Supporting Documents).

## **1.I. Denominator Statement**

Number of eligible newborns discharged from the NICU.

## **1.J. Denominator Exclusions**

Infants missing gestational age or with a specified anomaly as described in Table 1 (see Supporting Documents).

## **1.K. Data Sources**

**Check all the data sources for which the measure is specified and tested.**

Administrative data (e.g., claims data).

**If other, please list all other data sources in the field below.**

The use of hospital-level administrative data linked with vital statistics records allows for improved assessment of gestational age and/or birthweight information by patient.

## **Section 2: Detailed Measure Specifications**

**Provide sufficient detail to describe how a measure would be calculated from the recommended data sources, uploading a separate document (+ Upload attachment) or a link to a URL. Examples of detailed measure specifications can be found in the CHIPRA**

**Initial Core Set Technical Specifications Manual 2011 published by the Centers for Medicare & Medicaid Services. Although submission of formal programming code or algorithms that demonstrate how a measure would be calculated from a query of an appropriate electronic data source are not requested at this time, the availability of these resources may be a factor in determining whether a measure can be recommended for use.**

**Eligible population:** Newborns where gestational age is <35 weeks excluding those with a specified congenital anomaly, missing gestational age, or non-residents of the State.

**Numerator statement:** For each outcome, number of infants with gestational age between 23-34 weeks with evidence of the outcome during the NICU hospitalization.

**Denominator statement:** Number of eligible infants with gestational age between 23-34 weeks discharged from the NICU.

**Adjusted metric:** Adjusting for race, gender, education as a proxy for socioeconomic status, maternal medical conditions, gestational age, and insurance status. Note that these variables may not be available in all datasets. The adjusted results of the outcome rates using all of these variables are described as “Adjusted Model” with maternal medical data, which have the greatest face validity for practicing physicians, based on data that support the idea that each of these variables contributes in some way to a patient’s risk for an outcome. Also, if maternal medical data are not available, we present information on the validity and reliability of the risk-adjusted rates without these variables (Adjusted Model). See supplement for codes to identify NICU outcomes, as well as additional information in Tables 1-5 (see Supporting Documents).

## **Section 3. Importance of the Measure**

**In the following sections, provide brief descriptions of how the measure meets one or more of the following criteria for measure importance (general importance, importance to Medicaid and/or CHIP, complements or enhances an existing measure). Include references related to specific points made in your narrative (not a free-form listing of citations).**

### **3.A. Evidence for General Importance of the Measure**

**Provide evidence for all applicable aspects of general importance:**

- **Addresses a known or suspected quality gap and/or disparity in quality (e.g., addresses a socioeconomic disparity, a racial/ethnic disparity, a disparity for Children with Special Health Care Needs (CSHCN), a disparity for limited English proficient (LEP) populations).**
- **Potential for quality improvement (i.e., there are effective approaches to reducing the quality gap or disparity in quality).**
- **Prevalence of condition among children under age 21 and/or among pregnant women.**

- **Severity of condition and burden of condition on children, family, and society (unrelated to cost).**
- **Fiscal burden of measure focus (e.g., clinical condition) on patients, families, public and private payers, or society more generally, currently and over the life span of the child.**
- **Association of measure topic with children’s future health – for example, a measure addressing childhood obesity may have implications for the subsequent development of cardiovascular diseases.**
- **The extent to which the measure is applicable to changes across developmental stages (e.g., infancy, early childhood, middle childhood, adolescence, young adulthood).**

Preterm births account for 11-12 percent of all live births in the United States. Infants that experience one or more of the common complications of preterm birth are at higher risk for neurocognitive delay and, thus, an increased likelihood of having special health care needs (Klebermass-Schrehof, Czaba, Olischar, et al., 2012; Neubauer, Voss, Kattner, 2008; Schlapbach, Aebischer, Adams, et al., 2011; Schmidt, Asztalos, Roberts, et al., 2003; Schmidt, Roberts, Davis, et al., 2015; Schulzke, Deshpande, Patole, 2007; Shah, Meizen-Derr, Gratton, et al., 2012).

A larger proportion of babies born to black mothers are premature, even after adjusting for income, education level, and socioeconomic status. Once born preterm, some of these complications, especially IVH, occur at higher frequency in infants of minority racial/ethnic status, particularly black infants (Shankaran, Lin, Maller-Kesselman, et al., 2014).

Preventing the occurrence of these common complications of preterm birth is an area of emphasis by insurers and public health professionals. Numerous studies including those presented in this report describe hospital-level variation in the rates of bronchopulmonary dysplasia (BPD), retinopathy of prematurity (ROP), necrotizing enterocolitis (NEC), intraventricular hemorrhage (IVH), and infection (Aziz, McMillan, Andrews, et al., 2005; Lapcharoensap, Gage, Kan, et al., 2015; Lee, McMillan, Ohlsson, et al., 2000; Profit, Gould, Bennett, et al., 2016). These measures are used in the benchmarking activities of such groups as the Vermont Oxford Network, a group of over 900 NICUs in the United States and 1,200 NICUs internationally, and the California Perinatal Quality Care Collaborative. Higher-than-expected rates of any of these complications may reflect lower care quality beginning at the delivery of the infant or during the initial hospital stay (Lorch, Baiocchi, Ahlberg, et al., 2012). For each outcome measure, there are potential processes or structures of care that may reduce the rates of these complications at the level of the individual patient or the hospital.

**BPD:** gentle ventilation strategies, including primary use of continuous positive airway pressure (CPAP); adequate nutrition; and receipt of antenatal corticosteroids (Biniwale, Ehrenkranz, 2006; Carlo, 2012; Crowley, 2006; Ho, Subramaniam, Davis, 2015; Peltoniemi, Kari, Hallman 2011; Roberts, Dalziel, 2006).

**ROP:** Appropriate ventilation strategies and avoidance of hyperoxia (Boost Collaborative Groups, et al., 2013; Nobile, Gnocchini, Pantanetti, et al., 2014; Poets, Roberts, Schmidt, et al., 2015; Saugstad, Aune, 2014; Schmidt, Whyte, Asztalos, et al., 2013; Sola, Golombek, Montes, et al., 2014; Vaucher, Peralta-Carcelen, Finer, et al., 2012).

**IVH:** Receipt of antenatal corticosteroids, midline head positioning during the first 7 days of age (Crowley, 2000; Malusky, Donze, 2011; Peltoniemi, et al., 2011; Roberts, Dalziel, 2006).

**Infections:** Hand washing, central line management, and protocols (Capretti, Sandri, Tridapalli, et al., 2008; Helder, Brug, van Goudoever, et al., 2014; Ng, Wong, Lyon, et al., 2004; Pessoa-Silva, Hugonnet, Pfister, et al., 2007; Schulman, Dimand, Lee, et al., 2015; Schulman, Stricof, Stevens, et al., 2009).

**NEC:** Feeding pathways, antenatal corticosteroids (Crowley, 2000; McCallie, Lee, Mayer, et al., 2011; Morgan, Young, McGuire, 2015; Patel, Trivedi, Bhandari, et al., 2014; Peltoniemi, et al., 2011; Roberts, Dalziel, 2006; Viswanathan, McNelis, Super, et al., 2015; Wiedmeier, Henry, Baer, et al., 2008).

The costs and stresses of an infant admitted to the NICU can have a profound effect on family well-being. Several studies have found elevated levels of hostility, anxiety, and/or depression among parents of NICU infants (Carter, Mulder, Bartram, et al., 2005; Doering, Moser, Dracup, 2000). These alterations in parental attitudes and family well-being can produce long-term effects on the development of the child and family. Caring for a premature infant also requires more maternal/family education (Bakewell-Sachs, Gennaro, 2004; Paul, Leeman, Hollenbeak, et al., 2006). The presence of these complications increases the risk of future readmissions (Ray 2013), emergency room visits (Wade, Lorch, Bakewell-Sachs, 2008), and neurocognitive impairment (Klebermass-Schrehof, et al., 2012; Neubauer, et al., 2008; Schlapbach, et al., 2011; Schmidt, et al., 2003; Schmidt, et al., 2015; Schulzke, et al., 2007; Shah, et al., 2012) that all result in financial and social stress to the family (McGrath-Morrow, Ryan, Riekert, et al., 2013).

Costs and resource utilization by preterm, low birthweight infants (those at the highest risk of readmission) are substantially higher (according to Gilbert and colleagues: \$224,000 at 500-600 g, vs. \$1,000 at 3000g or greater) (Gilbert, Nesbitt, Danielsen, 2003; Russell, Green, Steiner, et al., 2007). Total in-hospital costs are increased in infants with one of these complications (BPD, ROP, IVH, or NEC), with increased daily costs of care and prolonged length of stay associated with the management of these conditions and delayed achievement of the skills needed for discharge (Bakewell-Sachs, Medoff-Cooper, Escobar, et al., 2009; Johnson, Patel, Jegier, et al., 2013; Payne, Carpenter, Badger, et al., 2004). Premature infants and infants with morbidities have been shown to have a higher number of office visits (especially for higher cost non-well-child visits) and a greater number of prescriptions (Wade, et al., 2008). Estimated rates of outpatient visits for the very-low-birthweight infants range from more than five visits/month during the first 3 months post-discharge for infants born at a gestational age under 26 weeks, to an average of 1.5 visits/month overall for the first year after discharge for infants born at a gestational age under 32 weeks.

Readmission rates are elevated in infants with BPD, NEC, and IVH, and the extra care and attention required by a premature of NICU infant makes it more difficult for the parents to maintain a two-income household (Gennaro, 1996). As stated above, the risk of neurocognitive delay is increased for infants with any one of these conditions. Finally, increased risk of social and behavioral problems associated with prematurity can have lingering effects over the entire life of the child. Early pediatric interventions have been shown to reduce these risks.

The occurrence of these complications may have long-term effects through childhood and adulthood. For example, BPD has been associated with the development of asthma and reduced lung function in childhood and young adulthood (Choukroun, Feghali, Vautrat, et al., 2013; Islam, Keller, Aschner, et al., 2015; Skromme, Leversen, Eide, et al., 2015). Additionally, infants with these complications are at higher risk of neurocognitive delay that is frequently the direct result of the complications. Finally, ROP may result in visual impairment—in the worst case scenario, blindness—which, in conjunction with the neurocognitive delay that many of these infants experience, results in a high risk of school delay (Msall, Phelps, Hardy, et al., 2004).

Premature infants and infants with complications have been shown to have delayed achievement of physiologic milestones, such as respiration and feeding (Bakewell-Sachs, et al., 2009). In multiple studies, including multi-study reviews, of outcomes for babies born preterm versus term, preterm infants had significantly lower cognitive scores, educational ability, and need for medical interventions, as well as an increased relative risk of developing attention deficit hyperactivity disorder (ADHD) (Bhutta, Cleves, Casey, et al., 2002; Chapieski, Evankovich, 1997; McGowan, 2011). Rates of these adverse outcomes are increased in infants experiencing one or more of the complications outlined in this report. Several programs aimed at early intervention focused on reducing the developmental delay of preterm infants via parental education, family support, and pediatric follow-up have shown improved cognitive scores (Brooks-Gunn, Klebanov, Liaw, et al., 1993).

### **3.B. Evidence for Importance of the Measure to Medicaid and/or CHIP**

**Comment on any specific features of this measure important to Medicaid and/or CHIP that are in addition to the evidence of importance described above, including the following:**

- **The extent to which the measure is understood to be sensitive to changes in Medicaid or CHIP (e.g., policy changes, quality improvement strategies).**
- **Relevance to the Early and Periodic Screening, Diagnostic and Treatment benefit in Medicaid (EPSDT).**
- **Any other specific relevance to Medicaid/CHIP (please specify).**

As previous work has shown lower rates of these common complications at higher level, higher volume centers, Medicaid and Title V policies surrounding perinatal regionalization may result in lower rates of these complications.

Because of the slowed development and increased potential for health complications or behavioral problems among premature low birthweight infants, the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program will be integral in early identification and treatment of problems among these at-risk babies and children. Increased focus on regular

preventive care may reduce the number of unnecessary hospital readmissions and ensure improved overall quality of outpatient care received by the infants (D'Agostino, Passarella, Saynisch, et al., 2015).

### **3.C. Relationship to Other Measures (if any)**

**Describe, if known, how this measure complements or improves on an existing measure in this topic area for the child or adult population, or if it is intended to fill a specific gap in an existing measure category or topic. For example, the proposed measure may enhance an existing measure in the initial core set, it may lower the age range for an existing adult-focused measure, or it may fill a gap in measurement (e.g., for asthma care quality, inpatient care measures).**

This measure fills the gap of assessing NICU-specific inpatient care measures. The outcomes relevant to NICU hospitalizations are unique, as the patient population is highly specific and complicated. These outcomes are not generalizable to other patient populations.

## **Section 4. Measure Categories**

**CHIPRA legislation requires that measures in the initial and improved core set, taken together, cover all settings, services, and topics of health care relevant to children. Moreover, the legislation requires the core set to address the needs of children across all ages, including services to promote healthy birth. Regardless of the eventual use of the measure, we are interested in knowing all settings, services, measure topics, and populations that this measure addresses. These categories are not exclusive of one another, so please indicate "Yes" to all that apply.**

**Does the measure address this category?**

- a. **Care Setting – ambulatory:** No.
- b. **Care Setting – inpatient:** Yes.
- c. **Care Setting – other – please specify:** No.
- d. **Service – preventive health, including services to promote healthy birth:** No.
- e. **Service – care for acute conditions:** No.
- f. **Service – care for children with special health care needs/chronic conditions:** Yes.
- g. **Service – other (please specify):** No.
- h. **Measure Topic – duration of enrollment:** No.
- i. **Measure Topic – clinical quality:** No.
- j. **Measure Topic – patient safety:** No.
- k. **Measure Topic – family experience with care:** No.
- l. **Measure Topic – care in the most integrated setting:** Yes.
- m. **Measure Topic other (please specify):** No.
- n. **Population – pregnant women:** No.
- o. **Population – neonates (28 days after birth) (specify age range):** Yes; 0-28 days.
- p. **Population – infants (29 days to 1 year) (specify age range):** Yes; 29-244 days.
- q. **Population – pre-school age children (1 year through 5 years) (specify age range):**  
No.

- r. **Population – school-aged children (6 years through 10 years) (specify age range):** No.
- s. **Population – adolescents (11 years through 20 years) (specify age range):** Not applicable.
- t. **Population – other (specify age range):** No.
- u. **Other category (please specify):** Not applicable.

## **Section 5. Evidence or Other Justification for the Focus of the Measure**

**The evidence base for the focus of the measures will be made explicit and transparent as part of the public release of CHIPRA deliberations; thus, it is critical for submitters to specify the scientific evidence or other basis for the focus of the measure in the following sections.**

### **5.A. Research Evidence**

**Research evidence should include a brief description of the evidence base for valid relationship(s) among the structure, process, and/or outcome of health care that is the focus of the measure. For example, evidence exists for the relationship between immunizing a child or adolescent (process of care) and improved outcomes for the child and the public. If sufficient evidence existed for the use of immunization registries in practice or at the State level and the provision of immunizations to children and adolescents, such evidence would support the focus of a measure on immunization registries (a structural measure).**

**Describe the nature of the evidence, including study design, and provide relevant citations for statements made. Evidence may include rigorous systematic reviews of research literature and high-quality research studies.**

The National Academy of Medicine (formerly the Institute of Medicine) has identified complications occurring during a hospitalization as a potential measure of quality. Similar to other hospitalized adults and children, common complications of preterm birth outlined here, including BPD, ROP, IVH, bacterial infection, and NEC, result in increased hospital costs and long-term adverse health outcomes for infants experiencing one or more of these conditions (Bakewell-Sacks, et al., 2009; Johnson, et al., 2013; Klebermass-Schrehof, et al., 2012; Neubauer, et al., 2008; Payne, et al., 2004; Schlapbach, et al., 2011; Schmidt, et al., 2003; Schmidt, et al., 2015; Schulzke, et al., 2007; Shah, et al., 2012).

There is ample evidence to suggest that higher-than-expected rates of these complications are associated to the quality of care provided by health care providers and hospitals. First, data suggest that rates of these complications vary widely between hospitals, and that lower rates are seen in higher level, higher volume hospitals that have lower mortality rates once adequate risk-adjustment is performed (Aziz, et al., 2005; Lapcharoensap, et al., 2015; Lee, et al., 2000; Lorch, et al., 2012; Profit, et al., 2016). Numerous randomized controlled trials and large cohort studies have demonstrated the association between specific processes of care and lower rates of these outcome measures. For example, feeding protocols, breast milk use, and antenatal corticosteroids



reduce the risk of NEC (Crowley, 2000; McCallie, et al., 2011; Morgan, et al., 2015; Patel, et al., 2014; Peltoniemi, et al., 2011; Roberts, Dalziel, 2006; Viswanathan, et al., 2015; Wiedmeier, et al., 2008); antenatal corticosteroids, gentle ventilation strategies, and prevention of hyperoxia are associated with lower rates of BPD and ROP (Biniwale, Ehrenkranz, 2006; BOOST, 2013; Carlo, 2012; Crowley, 2000; Ho, et al., 2015; Nobile, et al., 2014; Peltoniemi, et al., 2011; Poets, et al., 2015; Roberts, Dalziel, 2006; Saugstad, Aune, 2014; Schmidt, et al., 2013; Sola, et al., 2014; Vaucher, et al., 2012); antenatal corticosteroids and mid-line head positioning lower rates of IVH (Crowley, 2000; Malusky, Donze, 2011; Peltoniemi, et al., 2011; Roberts, Dalziel, 2006); and hand washing lowers the risk of infection (Capretti, et al., 2008; Helder, et al., 2014; Ng, et al., 2004; Pessoa-Silva, et al., 2007; Schulman, et al., 2009; Schulman, et al., 2015). Quality improvement strategies appear to reduce the rates of these complications at the individual hospital level, focusing on the specific process of care areas that may contribute to the development of these complications (Alshaikh, Kostecky, Blachly, et al., 2015; Lee, Kurtin, Wight, et al., 2012; Mola, Annibale, Wagner, et al., 2015; Patel, et al., 2014; Payne, Barry, Berg, et al., 2012; Pfister, Goldsmith, 2010; Wirtschafter, Powers, Pettit, et al., 2011).

Finally, there is significant public health interest in reducing the rates of these complications. Infants experiencing one or more complications have increased health care use in the first year after discharge from the NICU, with higher readmission rates (Ray 2013) and overall health care use (Wade, et al., 2008). Neurocognitive impairment is related to experiencing these complications (Klebermass-Schrehof, et al., 2012; Neubauer, et al., 2008; Schlapbach, et al., 2011; Schmidt, et al., 2003; Schmidt, et al., 2015; Schulzke, et al., 2007; Shah, et al., 2012). Therefore, there is substantial evidence supporting the use of these common complications of preterm birth as measures of the care provided in the inpatient setting.

## **5.B. Clinical or Other Rationale Supporting the Focus of the Measure (optional)**

**Provide documentation of the clinical or other rationale for the focus of this measure, including citations as appropriate and available.**

Not applicable.

## **Section 6. Scientific Soundness of the Measure**

**Explain the methods used to determine the scientific soundness of the measure itself. Include results of all tests of validity and reliability, including description(s) of the study sample(s) and methods used to arrive at the results. Note how characteristics of other data systems, data sources, or eligible populations may affect reliability and validity.**

### **6.A. Reliability**

**Reliability of the measure is the extent to which the measure results are reproducible when conditions remain the same. The method for establishing the reliability of a measure will depend on the type of measure, data source, and other factors.**

**Explain your rationale for selecting the methods you have chosen, show how you used the methods chosen, and provide information on the results (e.g., the Kappa statistic). Provide appropriate citations to justify methods.**

For the purposes of this report, we define the reliability of the metric as the ability to produce consistent as well as precise results under similar conditions. Specifically, we determined whether the outcome rates and the rankings based on these rates were consistent upon repeated sampling.

**Inter-year reliability** was calculated for each measure using one-way random effects ANOVA models for 1 year from our datasets (representing hospitals in California using vital statistics linked to administrative hospital data). Briefly, data for each health care unit (hospitals, States) for the specified timeframe were analyzed using one-way ANOVA, with the specific command in STATA version 14 of Loneway outcome rate.

The random effects model assumes that there is a set of observed outcome rates  $y_{ij}$ , measured for  $n$  time frames within  $k$  groups of hospitals or states, such that  $Y_{ij} = \mu + a_i + e_{ij}$ , where  $a_i$  and  $e_{ij}$  are independent zero-mean random variables with a measured variance for a given hospital or state  $i$  where  $I = 1, 2, \dots, k$ .  $a_i$  measures the difference between the “typical outcome rate” for hospital or State  $I$  from the mean outcome rate for the observed cohort, and  $e_{ij}$  represents the deviation for the  $j$ th observation at a specific timeframe for that hospital or State  $I$  from this “typical outcome rate.”

We can then calculate the overall variance of these variables, as  $s_a^2$  and  $s_e^2$ , and the reliability of the metric by first calculating the intraclass correlation, or  $ICC = s_a^2 / (s_a^2 + s_e^2)$ . The reliability is then:  $Reliability = (t \cdot ICC) / (1 + (t-1) \cdot ICC)$ , where  $t$  is the group size.

Additionally, we report the Spearman’s rank sum correlation between outcome rates for the year time period preceding the observed rates and the “current” rates, or year  $(t-1)$  to year  $t$ , where  $t$  is a specific year within the observation window. Reliable measures should have higher values for both metrics.

**Reproducibility** of the results was calculated using Spearman-Brown statistics. Briefly, a 50 percent random sample of patients was drawn from each health care unit (State, hospital), and risk-adjustment models were calculated. Then, a second 50 percent sample was chosen, and Spearman rank sum correlation coefficients were calculated. This metric assesses the influence of changes to the case mix of a hospital, where one assumes that the 50 percent sample provides an “alternative” insight into the measure outcome rates at each hospital or State.

Overall, the reliability of these measures is strong, with values above 0.7 for all measures except for the most severe grades of intraventricular hemorrhage, whose rarity makes the measure somewhat less reliable. Similar data are seen in the Spearman-Brown reproducibility statistics (see Tables 6 and 7 in the Supporting Documents).

## **6.B. Validity**

**Validity of the measure is the extent to which the measure meaningfully represents the concept being evaluated. The method for establishing the validity of a measure will depend on the type of measure, data source, and other factors.**

**Explain your rationale for selecting the methods you have chosen, show how you used the methods chosen, and provide information on the results (e.g., R2 for concurrent validity).**

### **Risk-Adjustment Using a Complete Dataset: California Linked Dataset**

In order to utilize NICU outcome measures to evaluate State or hospital performance, the measure must be effectively risk-adjusted. To explore what could be accomplished with a complete set of clinical data, we performed a risk adjustment on a cohort of infants born between 1995 and 2009 in California at a gestational age between 23 and 34 weeks. The department of health linked these infants' birth certificates to death certificates using name and date of birth and then de-identified the records. Then, over 98 percent of these records were linked to maternal and newborn hospital records using prior methods (Herrchen, Gould, Nesbitt, 1997; Phibbs, Baker, Caughey, et al., 2007). Over 80 percent of the unmatched live birth or fetal death certificate records were missing the delivery hospital, suggesting a birth at home or a birthing center. The unmatched records had similar gestational age and racial/ethnic distributions to the matched records. To ensure that there were enough patients per hospital to make reliable estimates of the outcome rates (Silber 2010), we limited the analyses to those hospitals that discharged over 50 eligible patients per year (N=154). For risk adjustment, we included characteristics of the infant that may increase the risk of adverse outcomes based on prior work: gestational age, birthweight, gender, and insurance status (Lorch, Baiocchi, Silber, et al., 2010; Lorch, et al., 2012; Ray, 2013). Gestational age and birthweight are specifically captured in birth certificate records. Gestational age, birthweight, and sociodemographic information were available in over 98 percent of records in the California State data and have been used in prior work from this dataset (Lorch, et al., 2012; Phibbs, et al., 2007).

## **Results**

### **Unadjusted Variation**

Among infants with a gestational age between 23 and 34 weeks, there was substantial variation in the unadjusted outcome rates among California hospitals, regardless of the outcome measure examined.

### **Adjusted Variation**

The large variation between hospitals persisted after adjusting for gestational age and sociodemographic factors. Data are similar when maternal complications are added to the risk-adjustment models (see Supporting Documents for Tables 8a-8g and 9a-9g).

### **Predictive Validity**

We examined the correlation between outcome rates and hospital volume. Correlation with volume was performed based on previous work suggesting a volume-outcome association with

other potential measures of NICU quality, such as mortality rates (Phibbs, et al., 2007; Rogowski, Horbar, Staiger, et al., 2004); thus, higher volumes are a structural measure of neonatal intensive care. This work parallels other work in the literature that suggests higher volume hospitals have improved outcomes, likely secondarily to seeing more patients and implementing processes of care to improve their outcomes. We hypothesize that there should be a larger association between hospital volume and outcome rates (Table 10, see Supporting Documents).

As with other studies, we found that units with higher volume had increasing rates of several complications, including infection (Lorch, et al., 2012) and BPD (Jensen, Lorch, 2015). However, we saw some modest correlation with mortality and between complications, but it does appear that hospitals that do well on one measure may not do well on another, which is consistent with the different process levers that may reduce the risk of a specific complication and supports the need to examine multiple different complications (Table 11, see Supporting Documents).

## **Section 7. Identification of Disparities**

**CHIPRA requires that quality measures be able to identify disparities by race, ethnicity, socioeconomic status, and special health care needs. Thus, we strongly encourage nominators to have tested measures in diverse populations. Such testing provides evidence for assessing measure’s performance for disparities identification. In the sections below, describe the results of efforts to demonstrate the capacity of this measure to produce results that can be stratified by the characteristics noted and retain the scientific soundness (reliability and validity) within and across the relevant subgroups.**

### **7.A. Race/Ethnicity**

#### **Methods**

For these analyses, race and ethnicity were determined based on the race/ethnicity variable reported in the data and classified based on Office of Management and Budget guidelines. White was defined as white, not of Hispanic origin; black was defined as black, not of Hispanic origin. For Hispanic, we combined children reported as “Hispanic or Latino” and “Hispanic or Latino and one or more races.” Other included American Indian, Alaska Native, Asian, Pacific Islander, and children with missing race/ethnicity information. We stratified the outcome metrics by enrollee race/ethnicity. Minority patients had higher rates of several complications in these data, including higher rates of BPD and NEC. Results are presented in Table 12 (see Supporting Documents).

### **7.B. Special Health Care Needs**

Analysis was limited to the birth hospitalizations, therefore definition of special health care needs above and beyond those included in risk adjustment were not assessed post-hospitalization. Thus, we were unable to pursue these analyses.

## 7.C. Socioeconomic Status

Maternal education level is included in the data, and we performed analyses using these data. As noted in the methods, these analyses were performed for the purposes of demonstrating feasibility and not for the purposes of assessing the significance of the associations. There was no substantive difference in rates of these outcome measures between women of different educational achievements (Table 13, see Supporting Documents).

## 7.D. Rurality/Urbanicity

A crosswalk was performed between the data using the 2010 Census urban and rural classification (<http://www.census.gov/geo/www/ua/2010Urbanruralclass.html>). There are two types of urban areas: urbanized areas have 50,000 or more people residing in an area; urban clusters have at least 2,500 and fewer than 50,000 residents. Rural encompasses all populations, housing, and territory not included within an urban area.

Urban patients had higher rates of many outcomes, including BDP, ROP, and infection, which may reflect differences in hospitals and differences in patient characteristics, including race/ethnicity (Table 14, see Supporting Documents).

## 7.E. Limited English Proficiency (LEP) Populations

LEP data are not included in the dataset; thus, we were unable to pursue these analyses.

# Section 8. Feasibility

**Feasibility is the extent to which the data required for the measure are readily available, retrievable without undue burden, and can be implemented for performance measurement. Using the following sections, explain the methods used to determine the feasibility of implementing the measure.**

## 8.A. Data Availability

### 1. What is the availability of data in existing data systems? How readily are the data available?

The NICU Outcomes measure is designed to be used with administrative datasets (if sufficient data are available to identify the at-risk population, such as birthweight or gestational age as specific fields in the administrative dataset); birth records linked to administrative datasets, which has been used to generate this metric in this report; or electronic health record (EHR) data. CPT codes allow for the identification of all inpatient admissions, whether to the NICU or to the general pediatrics floors.

Most States also already collect birth records. An example of State administrative data with linked birth records is presented using the State of California. Here, gestational age and birthweight variables are available on all State birth certificates. State hospital administrative records identify inpatient admissions both during the birth hospitalization and after discharge. EHR data collection is improving, but is not uniform across hospitals or States.

No attempts have been made to use EHR data for such a project. To do this would require either (1) population-based datasets from all payers and providers, similar to the all-payer datasets seen in such States as Massachusetts, Maine, New Hampshire, and Colorado; or (2) better communication and documentation of such health care encounters within the EHR by providers, to document an inpatient visit or an emergency department visit and the reasons for such a visit.

**2. If data are not available in existing data systems or would be better collected from future data systems, what is the potential for modifying current data systems or creating new data systems to enhance the feasibility of the measure and facilitate implementation?**

The primary mechanism to facilitate the use of this measure is to link vital statistics data to either hospital administrative data, as outlined in this report, or to insurance data. Such routine linkage will provide complementary, but necessary, data unavailable in either administrative or insurance data (such as Medicaid data) currently used by State agencies. Such linkages are being performed currently in several States.

Appropriate risk adjustment by gestational age and/or birthweight is extremely important to achieve a meaningful NICU outcomes measure. Gestational age was required for the California State data utilized. Therefore, it is not possible to report rates of missing data.

In short, use of State-level existing datasets will require improved clinical data collection and the linkage of data across State lines for States with extensive numbers of patients who cross from one State to another to receive care, to allow for appropriate assessment of the readmission metric.

## **8.B. Lessons from Use of the Measure**

**1. Describe the extent to which the measure has been used or is in use, including the types of settings in which it has been used, and purposes for which it has been used.**

This is a new measure that has not been used.

**2. If the measure has been used or is in use, what methods, if any, have already been used to collect data for this measure?**

This is a new measure that has not been used.

**3. What lessons are available from the current or prior use of the measure?**

This is a new measure that has not been used.

## **Section 9. Levels of Aggregation**

**CHIPRA states that data used in quality measures must be collected and reported in a standard format that permits comparison (at minimum) at State, health plan, and provider levels. Use the following table to provide information about this measure's use for reporting at the levels of aggregation in the table.**

**For the purpose of this section, please refer to the definitions for provider, practice site, medical group, and network in the Glossary of Terms.**

**If there is no information about whether the measure could be meaningfully reported at a specific level of aggregation, please write "Not available" in the text field before progressing to the next section.**

***Level of aggregation (Unit) for reporting on the quality of care for children covered by Medicaid/ CHIP†:***

***State level\* Can compare States***

***Intended use: Is measure intended to support meaningful comparisons at this level? (Yes/No)***

Yes.

***Data Sources: Are data sources available to support reporting at this level?***

Yes.

***Sample Size: What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?***

This information is not yet available.

***In Use: Have measure results been reported at this level previously?***

No.

***Reliability & Validity: Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?***

No.

***Unintended consequences: What are the potential unintended consequences of reporting at this level of aggregation?***

This information is not yet available.

***Other geographic level: Can compare other geographic regions (e.g., MSA, HRR)***

***Intended use: Is measure intended to support meaningful comparisons at this level? (Yes/No)***

Yes.

***Data Sources: Are data sources available to support reporting at this level?***

Yes.

***Sample Size: What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?***

This information is not yet available.

***In Use:*** Have measure results been reported at this level previously?

No.

***Reliability & Validity:*** Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?

No.

***Unintended consequences:*** What are the potential unintended consequences of reporting at this level of aggregation?

This information is not yet available.

***Medicaid or CHIP Payment model:*** Can compare payment models (e.g., managed care, primary care case management, FFS, and other models)

***Intended use:*** Is measure intended to support meaningful comparisons at this level?

(Yes/No)

Yes.

***Data Sources:*** Are data sources available to support reporting at this level?

Yes.

***Sample Size:*** What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?

This information is not yet available.

***In Use:*** Have measure results been reported at this level previously?

No.

***Reliability & Validity:*** Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?

No.

***Unintended consequences:*** What are the potential unintended consequences of reporting at this level of aggregation?

This information is not yet available.

***Health plan\*:*** Can compare quality of care among health plans.

***Intended use:*** Is measure intended to support meaningful comparisons at this level?

(Yes/No)

Yes.

***Data Sources:*** Are data sources available to support reporting at this level?

Yes.



**Sample Size:** What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?

This information is not yet available.

**In Use:** Have measure results been reported at this level previously?

No.

**Reliability & Validity:** Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?

No.

**Unintended consequences:** What are the potential unintended consequences of reporting at this level of aggregation?

This information is not yet available.

**Provider Level**

**Individual practitioner:** Can compare individual health care professionals

**Intended use:** Is measure intended to support meaningful comparisons at this level?

(Yes/No)

No.

**Data Sources:** Are data sources available to support reporting at this level?

No.

**Sample Size:** What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?

Not applicable.

**In Use:** Have measure results been reported at this level previously?

No.

**Reliability & Validity:** Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?

No.

**Unintended consequences:** What are the potential unintended consequences of reporting at this level of aggregation?

Not applicable.

**Provider Level**

**Hospital:** Can compare hospitals

**Intended use:** Is measure intended to support meaningful comparisons at this level?

(Yes/No)

Yes.

**Data Sources:** Are data sources available to support reporting at this level?

Yes.

**Sample Size:** What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?

This information is not yet available.

**In Use:** Have measure results been reported at this level previously?

No.

**Reliability & Validity:** Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?

No.

**Unintended consequences:** What are the potential unintended consequences of reporting at this level of aggregation?

This information is not yet available.

**Provider Level**

**Practice, group, or facility:\*\* Can compare:** (i) practice sites; (ii) medical or other professional groups; or (iii) integrated or other delivery networks

**Intended use:** Is measure intended to support meaningful comparisons at this level?

(Yes/No)

Yes.

**Data Sources:** Are data sources available to support reporting at this level?

Yes.

**Sample Size:** What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?

This information is not yet available.

**In Use:** Have measure results been reported at this level previously?

No.

**Reliability & Validity:** Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?

No.

**Unintended consequences:** What are the potential unintended consequences of reporting at this level of aggregation?

This information is not yet available.

## **Section 10. Understandability**

**CHIPRA states that the core set should allow purchasers, families, and health care providers to understand the quality of care for children. Please describe the usefulness of this measure toward achieving this goal. Describe efforts to assess the understandability of this measure (e.g., focus group testing with stakeholders).**

To date, no efforts have been made to assess the understandability of this measure with an external group of stakeholders. In theory, this measure can be used by purchasers, families, and health care providers to determine rates of NICU outcomes and potentially identify areas to focus prevention efforts and improve quality of care for children.

## **Section 11. Health Information Technology**

**Please respond to the following questions in terms of any health information technology (health IT) that has been or could be incorporated into the measure calculation.**

### **11.A. Health IT Enhancement**

**Please describe how health IT may enhance the use of this measure.**

In order for a NICU outcomes metric to be maximally accurate, administrative datasets such as hospital discharge records should increasingly incorporate the data necessary to adjust the measure, such as gestational age and birthweight – either through linkage of data or by adding a field into the dataset. Currently, these variables can only be found in birth records and EHR data, which requires appropriate linkage of vital statistics data with either EHR data, hospital administrative data, or other population-based datasets. Such linkage typically will use probabilistic matching techniques given the limitations with either names (based on maternal last name for birth records, which may change afterwards) or social security numbers (not typically present in birth records). However, our work and the work of others suggest well over 98 percent linkage of such data using probabilistic techniques, including dates of service, birth dates, and address information.

### **11.B. Health IT Testing**

**Has the measure been tested as part of an electronic health record (EHR) or other health IT system?**

Yes.

**If so, in what health IT system was it tested and what were the results of testing?**

The measure has been tested using a dataset from the California Department of Health. These data were derived from hospital records linked to birth and death certificates. Because of the linkage with birth certificates, this dataset also contained valuable data for metric adjustments, such as gestational age.

### **11.C. Health IT Workflow**

**Please describe how the information needed to calculate the measure may be captured as part of routine clinical or administrative workflow.**

At this time, the information required to compute this measure is captured by States in administrative Medicaid and CHIP files that are also reported to the Centers for Medicare & Medicaid Services (CMS) on a quarterly basis. Hospitals, States, and insurance plans also collect birth record data, which can be very useful for adjusting the measure.

### **11.D. Health IT Standards**

**Are the data elements in this measure supported explicitly by the Office of the National Coordinator for Health IT Standards and Certification (ONC) criteria (see [healthit.hhs.gov/portal/server.pt/community/healthit\\_hhs\\_gov\\_standards\\_ifr/1195](http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_standards_ifr/1195))?**

Yes.

**If yes, please describe.**

Data elements in this measure are supported explicitly by the ONC criteria. The rules about electronically calculating all of the clinical and ambulatory quality measures specified by CMS for eligible hospitals and critical access hospitals will allow this measure to be validated. The rule about the ability to retrieve patient demographic data—including preferred language, gender, race, ethnicity, and date of birth—is essential for identifying disparities among various subgroups.

### **11.E. Health IT Calculation**

**Please assess the likelihood that missing or ambiguous information will lead to calculation errors.**

Not applicable.

### **11.F. Health IT Other Functions**

**If the measure is implemented in an EHR or other health IT system, how might implementation of other health IT functions (e.g., computerized decision support systems in an EHR) enhance performance characteristics on the measure?**

Because there are identified processes of care associated with lower risk of these complications, computerized decision support systems could improve performance on this metric by improving standardization of and adherence to specific protocols.

## **Section 12. Limitations of the Measure**

**Describe any limitations of the measure related to the attributes included in this CPCF (i.e., availability of measure specifications, importance of the measure, evidence for the focus of the measure, scientific soundness of the measure, identification of disparities, feasibility, levels of aggregation, understandability, health information technology).**

Our tests of the measure show a high degree of variation across States and hospitals, even after our attempts to adjust for differences in NICU case mix. However, that implementation may be difficult due to missing data from administrative datasets in use at the State and Federal levels.

Important adjusting variables, such as gestational age and birthweight, are not being consistently recorded in MAX or like datasets at this time; thus, accurate implementation of this metric will require new data collection, linkage with birth certificates, or more widespread and standardized use of EHRs for publicly reported measures.

An additional complication with the NICU outcomes measure, like any metric based on clinical outcomes, is that it is very difficult to identify preventable clinical outcomes from those that are unavoidable. There has not yet been a determination of the “optimal” level of outcomes in a State or hospital, so we cannot necessarily suggest that the lowest or highest observed rates are ideal or where they fall relative to what we “should” observe. Many established quality metrics, including those of the CHIPRA Initial Core Set, strive for a 0 percent or 100 percent performance rate. Identification of a baseline number of expected events is a much more difficult prospect, which complicates the identification of outliers or underperformers. Lastly, some variation due to severity may persist even after risk adjustment.

Another issue is censoring by mortality. Diagnosis of some of these measures, specifically BPD and ROP, can only be made at specific adjusted ages (adjusted age = gestational age at birth plus chronological age) later in a patient’s hospital course. BPD is diagnosed at 36 weeks adjusted age, while ROP is most commonly seen between 36 and 40 weeks adjusted age. Centers with higher-than-expected mortality rates may falsely decrease the observed and risk-adjusted rates of these complications if death occurs before these adjusted ages (Jensen, Lorch, 2015). All complication measures outlined in this report should be evaluated in context to other measures of quality, such as risk-adjusted mortality rates.

Finally, even if a target rate were to be identified, it is unclear how much scope there would be for policy action aimed at improving performance at a given level of measurement. Even with financial incentives, State policymakers may not have much ability to improve the overall rate of outcomes in their State without other quality improvement programs or State perinatal collaboratives.

## **Section 13. Summary Statement**

**Provide a summary rationale for why the measure should be selected for use, taking into account a balance among desirable attributes and limitations of the measure. Highlight specific advantages that this measure has over alternative measures on the same topic that were considered by the measure developer or specific advantages that this measure has over existing measures. If there is any information about this measure that is important for the review process but has not been addressed above, include it here.**

The National Academy of Medicine (formerly the Institute of Medicine) has identified complications occurring during a hospitalization as a potential measure of quality. Similar to complications in other hospitalized adults and children, common complications of preterm birth

outlined here—including bronchopulmonary dysplasia (BPD), retinopathy of prematurity (ROP), intraventricular hemorrhage (IVH), bacterial infection, and necrotizing enterocolitis (NEC)—result in increased hospital costs and long-term adverse health outcomes for infants experiencing one or more of these conditions.

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**The CHIPRA Pediatric Quality Measures Program (PQMP) Candidate Measure Submission Form (CPCF) was approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act.**

**The OMB Control Number is 0935-0205 and the Expiration Date is December 31, 2015.**

## **Public Disclosure Requirements**

**Each submission must include a written statement agreeing that, should U.S. Department of Health and Human Services accept the measure for the 2014 and/or 2015 Improved Core Measure Sets, full measure specifications for the accepted measure will be subject to public disclosure (e.g., on the Agency for Healthcare Research and Quality [AHRQ] and/or Centers for Medicare & Medicaid Services [CMS] websites), except that potential measure users will not be permitted to use the measure for commercial use. In addition, AHRQ expects that measures and full measure specifications will be made reasonably available to all interested parties. "Full measure specifications" is defined as all information that any potential measure implementer will need to use and analyze the measure, including use and analysis within an electronic health record or other health information technology. As used herein, "commercial use" refers to any sale, license or distribution of a measure for commercial gain, or incorporation of a measure into any product or service that is sold, licensed or distributed for commercial gain, even if there is no actual charge for inclusion of the measure. This statement must be signed by an individual authorized to act for any holder of copyright on each submitted measure or instrument. The authority of the signatory to provide such authorization should be described in the letter.**

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