Appropriateness of Red Cell Transfusions in the Pediatric Intensive Care Unit

Section 1. Basic Measure Information

1.A. Measure Name

Appropriateness of Red Cell Transfusions

1.B. Measure Number

0200

1.C. Measure Description

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

Percentage of transfusions in pediatric intensive care unit (PICU) patients who have a hemoglobin of less than or equal to 7 grams/deciliter (rounding down for 7.5 g/dL or less).

1.D. Measure Owner

Pediatric Measurement Center of Excellence (PMCoE)

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.**

   Pediatric Intensive Care Unit Measure Set.

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

Number of transfusions in PICU patients who have a hemoglobin of less than or equal to 7 grams/deciliter (rounding down for 7.5 g/dL or less).

Definition: one transfusion = one blood bank transfusion record.

1.H. Numerator Exclusions

None.

1.I. Denominator Statement

Number of transfusions performed in the PICU during the reporting period.

1.J. Denominator Exclusions

- All patients with cyanotic heart disease.
- All patients with unstable shock.*
- All patients who are actively bleeding or have acute hemolysis.
- All patients who are on extracorporeal membrane oxygenation (ECMO).
- All patients with sickle cell disease.

*The addition of or an increase in a continuous infusion of any cardioactive drug within the last 24 hours.

1.K. Data Sources

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

Paper medical record; electronic health record (EHR).

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

Not applicable.

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.

For Construction using Manual Chart Abstraction

To construct this measure using manual chart abstraction, a research nurse or other trained medical professional will perform chart reviews and manually abstract each element of the measure. For example, in addition to basic demographic elements, for this measure, elements such as PICU admission date (mm/dd/yyyy), PICU admission time (hh:mm, military), PICU discharge or transfer date (mm/dd/yyyy), PICU discharge or transfer time (hh:mm, military), and evidence of blood transfusion (yes/no) will be abstracted and used to identify the denominator population. Similarly, date of transfusion (mm/dd/yyyy), time of transfusion (hh:mm, military), hemoglobin lab value prior to transfusion (integer in 0-5 g/dl), date of hemoglobin lab value (mm/dd/yyyy), and time of hemoglobin lab value (hh:mm, military) will be abstracted from patient charts and used to identify which patients meet the numerator criteria. Additionally, diagnosis of cyanotic heart disease (yes/no), diagnosis of unstable shock (yes/no), evidence of active bleeding or diagnosis of acute hemolysis (yes/no), evidence of the patient on ECMO (yes/no), and a diagnosis of sickle cell (yes/no) will also be abstracted as exclusion criteria.

Please see Supporting Documents (Section 2) for Technical Specifications and the Chart Abstraction Tool for this measure.

For Construction as an eMeasure in the Electronic Health Record

To construct this measure as an eMeasure in the Electronic Health Record (EHR), each of the measure elements must exist in structured queriable fields. The eMeasure will be implemented in the EHR using the eMeasure specifications and an electronic algorithm that will compute the measure automatically and generate a performance report that indicates whether patients met the measure. Please see Section 2 in the Supporting Documents for eMeasure specifications.

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).**

Potential for Quality Improvement

Despite the mounting evidence that red blood cell transfusions may be associated with more harm than benefit, current transfusion practices vary within and between PICUs (Nahum, Ben-Ari, Schonfeld, 2004). The results from a case-based survey administered by Nahum and colleagues showed significant variation among pediatric intensivists in the hemoglobin level that would trigger an order for transfusion of red blood cells. Most transfusions occurred at hemoglobin values that were higher than recommended guidelines (Nahum, et al., 2004). Another frequently stated reason for red blood cell transfusion relates to the perceived improvement in oxygen delivery. Other factors influencing decisions to transfuse include: hemoglobin < 9.5 g/dL during the PICU stay, an admission diagnosis of cardiac disease, an admission PRISM (Pediatric Risk of Mortality) of >10, the presence of multiple organ dysfunction syndrome during the PICU stay, hypoxemia, young age, active gastric bleeding, and emergency surgery (Armano, Gauvin, Ducruet, et al., 2005; Demaret, Tucci, Ducruet, et al., 2013).

A pediatric critical care study on transfusion practices found a striking variation in practice patterns among pediatric critical care practitioners (Laverdiere, Gauvin, Hebert, et al., 2002). The threshold Hgb concentration chosen by pediatric intensivists for typical cases ranged at least from 7 to 13 g/dL. Also, the volume of red blood cells (RBCs) given was not related to the threshold Hgb concentration, suggesting that RBC transfusions are not optimally utilized (Laverdiere, et al., 2002).

Prevalence

The transfusion of red blood cells to PICU patients is a common routine. It is estimated that 40-50 percent of patients admitted to the PICU are anemic at admission or become anemic during the time in the PICU. Several landmark studies have found that transfusions of red blood cells are associated with higher mortality and morbidity, even when leukocyte-reduced product is used; that patients assigned to a restrictive transfusion strategy (hemoglobin < 7) do not have worse outcomes than those assigned to a liberal transfusion strategy (hemoglobin < 9); that pediatric intensivists incorporate a variety of data to guide decisions for transfusing patients; and that practices vary widely across the country (Slonim, Joseph, Turenne, et al., 2008). In the absence of data to suggest that transfusion actually achieves the desired goals of transfusion and plentiful data regarding the morbidity and cost associated with transfusion, overutilization of transfusions in PICUs likely contributes to morbidity and mortality in PICUs. According to a study using Pediatric Health Information System (PHIS) data, from 2001 to 2003, 4.8 percent (n=51,720) pediatric patients received blood product transfusions. The transfusion of red blood cells (RBCs) was the most frequently transfused product (n = 44,632, 60.2 percent) (Slonim, et al., 2008). According to a 6-month observational study of 30 PICUs, 33 percent of PICU patients are anemic on PICU admission, and another 41 percent become anemic during their PICU stay. Also, 49 percent of PICU patients are transfused during their PICU stay, with low Hgb cited as the most common reason for a transfusion. In this study, the overall average pre-transfusion Hgb was 9.7 ± 2.7 g/dL (Bateman, Boven, Forbes, et al., 2008).

Severity of Condition/Morbidity

According to Slonim, et al. (2008), of patients who expired, 30.1 percent were transfused compared to 4.5 percent of patients who survived ($p = < 0.001$).). Of those patients who received transfusions, 492 (0.95 percent) experienced a complication from the administered blood product. This accounted for a complication rate of 10.7 per 1,000 units transfused.

Patients admitted with an extreme severity level had a considerably higher likelihood of receiving a transfusion than those admitted with a minor severity level ($p < 0.001$). Patients admitted with a high severity level had a higher likelihood of also experiencing a transfusion reaction than those admitted with a minor severity level ($p < 0.001$) (5). There are many infectious transfusion risks, including: viral infections (such as cytomegalovirus [CMV], hepatitis B and C, HIV, West Nile Virus, Human Herpes Virus 8); bacterial infection; Prions (e.g., Creutzfeldt-Jakob disease); Parasites (e.g., malaria, babesiosis) (Istaphanous, Wheeler, Lisco, et al., 2011). Additional transfusion risks continue to emerge, including such pathogens as the Zika virus (Marano, Pupella, Vaglio, et al., 2016; Musso, Nhan, Robin, et al., 2014).

Non-infectious transfusion risks include: hemolysis, volume overload, transfusion-related immunomodulation, febrile nonhemolytic transfusion reaction, transfusion-related lung injury

(TRALI), coagulation defects, necrotizing enterocolitis in neonates, multiple organ dysfunction, metabolic abnormalities, and transfusion-related graft-versus-host disease (Istaphanous, et al., 2011).

New data indicate that using a hemoglobin transfusion threshold of >7 g/dL does not yield improved outcomes. Furthermore, smaller studies have suggested that PICU patients may be at an increased risk for morbidity and mortality when undergoing transfusion (Tyrell, Bateman, 2012).

Fiscal Burden

Resource use in terms of length of stay (LOS) and costs was higher in patients who received transfusion (Slonim, et al., 2008). The higher severity of illness was likely responsible for the increase in utilization, as manifested by increased LOS and costs for children who received transfusions. Pediatric RBC transfusions increase resource utilization. In a retrospective cohort analysis for 1996-1999, children with Hgb = 9 gm/dL were enrolled across five PICUs. The outcome variables examined were hospital mortality, resource use, days of oxygen use, days of mechanical ventilation, days of vasoactive infusions, and PICU and hospital lengths of stay (Goodman, Pollack, Patel, et al., 2003). See Tables 3.A.1 and 3.A.2 in the Supporting Documents for results. The study concluded that, consistent with data from hospitalized adult patients, RBC transfusions are associated with an increase in resource utilization in critically ill children.

Pediatric RBC transfusions also increase costs. Shander, et al., constructed an activity-based costing (ABC) model to determine the cost of blood transfusions in the surgical population of four hospitals (two U.S. hospitals and two European hospitals) (Shander, Hofmann, Ozawa, et al., 2010). Tasks and resource consumption related to blood administration were identified prospectively, and process frequency (i.e., usage) data were captured retrospectively from each hospital and used to populate the ABC model. Direct overhead costs (e.g., blood bank, lab, nursing staff, and pathologist) were found to account for 3-5 percent of costs at U.S. hospitals and was a small percentage for the European hospitals because their blood bank services were outsourced. Indirect overhead costs (e.g., building and asset depreciation, employee benefits, laundry and housekeeping, central supply, nursing administration, information technology, telecommunications, and purchasing) consistently contributed a higher proportion of the costs, accounting for 40-41 percent of costs at U.S. hospitals and 32 percent of the costs in European hospitals.

Across all four participating hospitals, a total estimated blood transfusion cost of $760.82 ± $293.74, the ABC model confirmed that (1) blood costs had been underestimated previously, (2) there are geographic variations in cost, and (3) opportunities for cost containment exist. Across all four hospitals, the two U.S. hospitals had an average cost of $1,182.32 and $726.05 per unit transfused, and the European hospitals had a per unit cost of $611.44 and $522.45. Additionally, blood product acquisition costs contributed to only 21-32 percent of total blood transfusion expenditures, with 21 and 28 percent in the U.S. hospitals and 29 percent and 32 percent in the European hospitals.

Applicable to Changes Across Developmental Stages

Children of all ages are at risk for RBC transfusion in PICUs and thereby transfusion-related event risks. The necessity of correctly identifying the threshold hemoglobin concentration that should trigger an order for transfusion of red blood cells applies to all developmental stages and age groups. While approximately 7.6 percent of transfusions were given to neonates, with older age groups having considerably lower rates, the older children were considerably more likely to experience a transfusion reaction than neonates (1 month-2 years; >2 years; both $p < 0.001$) (Slonim, et a., 2008).

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).**

In addition to the evidence of general importance described above, this measure is relevant and important to Medicaid and/or CHIP because the medically complex patients who are treated in the PICU often fall disproportionately into the Medicaid population. Children from poorer families are more likely to become critically ill, either because their access to care is not optimal or they have chronic conditions and do not receive the ongoing care needed to keep them out of the PICU.

The PICU is the "canary in the coal mine" for pediatric inpatient care; it is the intended placement location for the sickest children in the institution, where risk is high, teamwork is required, and resource utilization is elevated. The PICU is where lapses or gaps in safety or quality potentially are the most devastating, but it can also be the location where early improvement might be most noticeable if the correct measurements are completed, analyzed, and acted upon.

Existing pediatric critical care quality measures are limited and simply do not capture the clinical relevance needed for measuring, reporting, and improving quality. Continued progress in measurement science has been shown to be effective in engaging clinicians and promoting the dissemination of best practices across many stakeholders to close quality gaps and produce true improvement in PICU care. Among the benefits to Medicaid/CHIP are cost savings, improved patient outcomes, more efficient staffing, more effective use of resources, and more efficient procedures.

From 15 percent to 49 percent of PICU patients receive at least one RBC transfusion during their intensive care unit admission, and 62 percent of children who are transfused receive more than one transfusion (Armano, et al., 2005). Low hemoglobin is the most common reason provided for transfusion, with the median hemoglobin or transfusion ranging from 8.2 g/dL in adolescents

to 12.5 g/dL in neonates and an overall median pre-transfusion hemoglobin of 9.2 g/dL. The aim of this measure is to decrease the number of transfusions in PICUs and thereby decrease transfusion-related event risks. Other potential outcomes include decreased use of donor blood, which is a limited resource, and decreased costs associated with a PICU admission.

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).

No PICU-related measures are currently included in the Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set), yet the PICU is where a hospital's sickest and most vulnerable children are treated. In addition to closing gaps in safety and/or quality, implementation of appropriate measurements in the PICU could mitigate much of the elevated risk and costs associated with pediatric critical care.

Early in its process, the PMCoE PICU Expert Workgroup conducted an extensive review of existing measures related to pediatric critical care. Clinical experts and family representatives weighed in on a wide range of possible new measures to be proposed for the PICU. Once the appropriateness of red cell transfusions in PICU patients emerged as a concern among the Expert Workgroup members, it was soon determined that no such measure existed. Measure Champions were assigned to lead the development of a proposed new measure on this topic. The Measure Champions noted in their research that there is significant variation in practice patterns among pediatric critical care practitioners when it comes to identifying the threshold hemoglobin concentration that should trigger an order for transfusion of red blood cells. Evidence-based guidelines have standardized the practice and allowed better data collection in comparing outcomes; however, the most widely recognized clinical recommendation is not specific to pediatrics. The American Association of Blood Banks (AABB) recommends adhering to a restrictive transfusion strategy—that is, in adult and pediatric ICU patients, transfusion should be considered at hemoglobin concentrations of 7g/dL or less (Carson, Grossman, Kleinman, et al., 2012).

Based on feedback received through the Public Comment period, the Measure Champions replaced their primary citation of the AABB recommendation with the findings from a 2007 pediatric-specific study: in stable, critically ill children a hemoglobin threshold of 7 grams per deciliter for red cell transfusion can decrease transfusion requirements without increasing adverse outcomes (Lacroix, Herbert, Hutchinson, et al., 2007; Controlled-trials.com number, ISRCTN37246456 [controlledtrials.com].)

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:** Yes.
f. **Service – care for children with acute conditions:** Yes.
g. **Service – other (please specify):** No.
h. **Measure Topic – duration of enrollment:** No.
i. **Measure Topic – clinical quality:** Yes.
j. **Measure Topic – patient safety:** Yes.
k. **Measure Topic – family experience with care:** No.
l. **Measure Topic – care in the most integrated setting:** No.
m. **Measure Topic other (please specify):** No.
n. **Population – pregnant women:** No.
o. **Population – neonates (28 days after birth) (specify age range):** No.
p. **Population – infants (29 days to 1 year) (specify age range):** Yes; infants 29-364 days.
q. **Population – pre-school age children (1 year through 5 years) (specify age range):** Yes; 1-5 years.
r. **Population – school-aged children (6 years through 10 years) (specify age range):** Yes; 6-10 years.
s. **Population – adolescents (11 years through 20 years) (specify age range):** Yes; 11-20 years.
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.

Theoretically, transfusion of packed red blood cells (PRBCs) will increase oxygen delivery, which is oxygen content x cardiac output = [Hgb x SaO2 x 1.34 + (.003 x PaO2)] x CO. However, contradictory data exist suggesting that simply increasing global O2 delivery by RBC transfusion does not necessarily translate into increased tissue oxygen utilization. According to a 2011 review of published literature on transfusion medicine and outcomes of RBC transfusion in critically ill children, the authors concluded that the available evidence did not support the extensive use of RBC transfusions in these patients (Istaphanous, et al., 2011). Specific findings from this review included:

- 2,3-diphosphoglycerate is depleted in stored blood and not repleted until 24 hours post-transfusion.

- ATP is depleted during the storage process leading to altered RBC membrane deformability and integrity resulting in untimely destruction of the RBCs.

- The small quantity of free Hgb always present in banked RBC units quickly binds endogenously produced nitric oxide, resulting in vasoconstriction of small vessels and ultimately decreasing local O2 delivery at the tissue level.

Data from adult populations have also supported a lowered threshold for RBC transfusions in critically ill patients. Published in 1999, a multicenter, randomized, controlled clinical trial of transfusion requirements in critical care conducted by Hebert, et al., enrolled patients who were admitted to one of 25 ICUs in Canada between November 1994 and November 1997 (Hebert, Wells, Blajchman, et al., 1999). Patients were included if they met the following criteria: euvolemic, Hgb < 9.0g/dL, within 72 hours of ICU admission. Patients were excluded for any of the following: age < 16 years, chronic anemia, pregnancy, brain death, possibility of care withdrawal, routine admission after cardiac surgical procedure, unable to receive blood products, active blood loss at enrollment, an ongoing blood loss defined as 3 units of PRBCs or Hgb drop of 3g/dL in < 12 hours. Enrolled patients were randomly assigned to two treatment groups with no significant differences in baseline characteristics of the two groups; 81.9 percent were receiving mechanical ventilation, and 26.5 percent had an infection as a primary or secondary diagnosis. The restrictive transfusion strategy group included 418 patients, with a transfusion threshold Hgb < 7.0 g/dL and Hgb concentrations maintained between 7.0 and 9.0 g/dL; 420 patients were in the liberal transfusion strategy group, with a transfusion threshold Hgb < 10.0

g/dL and Hgb concentrations maintained between 10.0 and 12.0 g/dL. The average daily Hgb in the restrictive strategy group was 8.5±0.7 g/dL, and average daily Hgb in the liberal strategy group was 10.7±0.7 g/dL. Outcomes examined included 30-day mortality, 60-day mortality, and the mortality rate during the entire stay in the ICU; refer to Table 5.A.1 (see Supporting Documents) for results. The study concluded that a restrictive adult transfusion threshold of Hgb of 7.0g/dL combined with maintenance Hgb range of 7-9 g/dL is at least as effective and possibly superior to a liberal transfusion strategy with a Hgb transfusion trigger below 10 g/dL and maintenance of Hgb range between 10-12 g/dL.

A later study provided support for pediatric transfusion thresholds. A randomized pediatric trial conducted by Lacroix, et al. (2007), enrolled patients ranging in age from 3 days to 14 years who were admitted to one of 19 PICUs in four countries with Hgb < 9.5 g/dL. Patients were excluded if they were hypotensive, required an increase in vasoactive medications, or had acute blood loss or hemolysis. Enrolled patients were randomly assigned to either a restrictive-strategy group or a liberal-strategy group, and PRBCs were transfused within 12 hours of reaching the threshold; in both groups, the protocol was applied for 28 days. In the restrictive strategy group, the transfusion threshold was Hgb < 7g/dL, with a target range after transfusion of 8.5-9.5 g/dL. In the liberal-strategy group, the transfusion threshold was Hgb <9.5 g/dL, with a target range after transfusion of 11-12 g/dL. The primary outcomes examined included 28-day mortality after randomization, presence of MODS (multiple-organ-dysfunction-syndrome, defined as dysfunction of two or more organ systems; progression of MODS); refer to Table 5.A.2 (see Supporting Documents) for results. Secondary outcomes examined included sepsis, transfusion reactions, nosocomial respiratory infections, catheter-related infections, adverse events, ICU and hospital LOS, mortality, and daily Pediatric Logistic Organ Dysfunction (PELOD) assessment; refer to Table 5.A.3 (see Supporting Documents) for results. The study concluded that a restrictive transfusion strategy in stable PICU patients is as safe as a liberal transfusion strategy. The restrictive transfusion strategy can decrease the rate of exposure to red cells and decrease the total number of transfusions in critically ill children.

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.

Anemia in critically ill children is common. Anemia and transfusion with RBCs are common occurrences in critically ill and injured children. Traditional teaching states that transfusing critically ill patients will augment oxygen carrying capacity and oxygen delivery, resulting in benefit to the patient. Severe anemia is associated with morbidity and mortality; however, minimal data actually exist to support that blood transfusion administration to patients with hemoglobin less than 7g/dL achieves any benefit. Blood transfusions are associated with risks such as hospital-associated infection, gut ischemia, transfusion reactions, stimulation of the inflammatory response, and other events, which are well documented.

In 2013, the Children's Hospital Association (CHA) sponsored a research study that was conducted at six different sites in the United States, all of which were PICUs in children's hospitals. One of our Measure Champions, Dr. Vicki L. Montgomery, MD, Kosair Children's

Hospital/University of Louisville Health Sciences Center, is the Principal Investigator of this study, not yet published, entitled, "Standardized Implementation of Evidence Based Guidelines for Blood Transfusions in Critically Ill and Injured Children to Decrease Transfusions in Pediatric Intensive Care Units: The ASK Trial." The object of the study was to evaluate relevant data to establish a baseline related to the ordering of RBC transfusions in each unit and subsequently introduce a standardized implementation plan. This plan utilized the same guidelines as set forth in the proposed measure: a restrictive transfusion strategy with an initial threshold set at Hgb < 7g/dL.

Enrolled sites were advised of the existing data that encourage a restrictive transfusion strategy. The study guidance emphasized that intensivists, surgeons, oncologists, nurse practitioners, nurses, and blood bank personnel must all work together as a team to decide if a transfusion is necessary. While transfusions pose a risk to each patient and should not be taken lightly, it was stressed that transfusions are sometimes necessary despite higher Hgb. These situations may include acute blood loss, severe shock, and various unstable disease states. The point made was that each transfusion should be scrutinized so patients are transfused at the right time and for the right reason. Data collection has been completed, and analysis is in progress. Finally, the proposed measure is unique in that it is physician-specific and capable of measuring quality based on an individual physician's performance.

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.

Construction of the eMeasure and Manual Chart Abstraction of the Measures

Testing Sites

Testing for this measure was intended to occur at three hospitals of the Chicago Pediatric Quality and Safety Consortium (CPQSC): Lutheran General Children's Hospital, Christ Hope Children's Hospital, and Anne and Robert H. Lurie Children's Hospital. See description of the CPQSC participating hospitals in the Supporting Documents (Section 6.A). As Lutheran General Children's Hospital and Christ Hope Children's Hospital have structured fields for the denominator exceptions in the EHR but fail to use them regularly, these sites are unable to obtain

reliable electronic output for this measure. As a result, they did not participate in parallel forms testing. Similarly, due to limited resources, they also were unable to perform chart reviews for this measure.

Methods

Lurie Children's Hospital performed parallel forms reliability testing where a computed assessment of the measure was compared against manual chart reviews. The patient sample was identified using a reporting period of 01 January – 31 March 2015. Using an electronic algorithm, charts were identified that met the denominator criteria; the charts were stratified by age group (0 - < 6 years, 6 – < 12 years, 12 – < 18 years) and then randomly selected for abstraction within each age strata.

This measure was then implemented in the site's EHR using an electronic algorithm, which computed the measure automatically and generated a performance report on the selected sample of patients. At the same time, a trained chart abstracter performed manual chart reviews on the same patients. Manual chart abstraction was then compared to the automated data abstraction to determine how reliably the overall measure and individual measure elements were calculated.

To complete the manual chart abstraction, the following algorithm was followed:

1. Evaluate the charts in the patient sample to see whether the patients met the denominator criteria: all patients admitted to the PICU who received a transfusion. Patient records might contain more than one red cell transfusion so each transfusion was considered a measurement event.

2. Collect demographics and elements for equity assessment: age, gender, race/ethnicity, language preference, and insurance status/type.

3. Consider the exclusion criteria: all patients with cyanotic heart disease, unstable shock (addition of or increase in a continuous infusion of any cardioactive drug within the last 24 hours), patients who were actively bleeding or had acute hemolysis, patients on ECMO, and patients with sickle cell disease, and note whether the patient record met these criteria. If so, stop chart abstraction. The patient did not meet the denominator criteria for the measure;

4. Review patient chart and document measure elements in the chart abstraction tool, including both denominator and numerator measure elements.

5. Note relevant comments.

Analysis

Data analysis included construction of the measure and assessment of agreement across chart abstractions and electronic eMeasure output. The intent of the analysis was to test the ability to construct this measure as both an eMeasure and a manual chart review measure and to test the reliability and validity of the measure construction to provide a basis for its use as a measure of performance for public reporting and quality improvement. The results were analyzed to assess the level of agreement between the chart abstraction and the electronic eMeasure output and for the overall clinical performance of the measure.

Results

Lurie Children's Hospital was able to assess this eMeasure electronically, providing electronic output for 33 unique patients representing 181 transfusions. Please see Section 7 of this report for information regarding race/ethnicity, socioeconomic status, and language preference for this patient sample.

eMeasure Performance Results

Overall (N=181), the clinical performance of this eMeasure was fairly high, with 91 percent of transfusions meeting the numerator criteria of a transfusion occurring in PICU patients with a hemoglobin of less than or equal to 7 grams/deciliter (rounding down for 7.5 or less). When looking at the patient level, 82 percent of patients met the measure. The clinical performance of this measure was comparable across age groups: 0 - <6, 13 - <19, and 19 and older with performance scores of 96 percent, 92 percent, and 100 percent, respectively. The clinical performance was much lower in the 6 - <13 age group, receiving a performance score of 69 percent. This is likely due to the fact that the patients in this age bracket who had a transfusion without documentation of a low hemoglobin score (N=3) had a larger than expected number of transfusions (N=10).

Chart Review Performance Results

Five chart abstractions were performed at Lurie Children's Hospital. Of these five patients, 80 percent (N=4) met the measure criteria. Similarly, 80 percent (N=8) of unique transfusions met the measure criteria.

Reliability Testing

Chart abstractions were performed for five patient charts for patient-level data included in the electronic output. Agreement for parallel forms reliability testing was 100 percent for the measure elements: race, ethnicity, and payer. During the chart review process, the chart abstractor found that one patient was noted to have two transfusions in the electronic report; however, one of the orders was cancelled and only noted as such in the patient chart. As a result, the agreement for the denominator criteria was 90 percent. Aside from this discrepancy, overall agreement was 100 percent. As agreement was high with little to no variability, kappa statistics could not be computed.

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).

The PMCoE used the American Medical Association's Physician Consortium for Performance Improvement (AMA-PCPI) Wheel Methodology, which has been used extensively in the adult setting, to develop clinically relevant quality measures for pediatric critical care, including this measure, which is aimed at decreasing the number of transfusions in PICUs and thereby

decreasing transfusion-related event risks, decreasing utilization of donor blood—a limited resource—and decreasing costs associated with a PICU admission.

This measure was assessed for content validity by looking for agreement among subject matter experts, specifically by the panel of stakeholder representatives serving as members of the Pediatric Intensive Care Unit (PICU) Expert Workgroup during the development process (See Supporting Documents, Section 6.B). This multidisciplinary, national panel comprised physicians, nurses, parent/family representatives, and measure methodologists.

Additionally, input on the content validity of draft measures was obtained through a 21-day public comment period. The Expert Workgroup reviewed all comments received and modified the measures as needed (see Supporting Documents, Section 6.B).

Finally, the Expert Workgroup considered the following questions during the content validity assessment of this measure:

1. How strong is the scientific evidence supporting the validity of this measure as a quality measure?
100 percent of respondents indicated "Very Strong (55 percent)" or "Somewhat Strong (45 percent)."

2. Are all individuals in the denominator equally eligible for inclusion in the numerator?
All but one respondent (91 percent) answered, "Yes." Comment: "Not all patients receiving transfusions will be anemic, e.g., exchange transfusion; this should be noise though; it mainly aligns."

3. Is the measure a result under control of those whom the measure evaluates?
100 percent of respondents answered "Yes."

4. How well do the measure specifications capture the event that is the subject of the measure?
100 percent of respondents indicated "Very Well (64 percent)" or "Somewhat Well (36 percent)." Comments included:
- Having a complementary measure of "rate" would address issues of improvement.
- I support the proposed change to "rate" rather than "percentage."
- Caveat as discussed on the call: a rate might be a good complementary measure.
- No exclusion for severe ARDS (acute respiratory distress syndrome) or severe pulmonary hypertension – two populations in which patients are transfused above the 7 threshold – many of these patients are on vasoactive infusions.

5. Does the measure provide for fair comparisons of the performance of providers, facilities, health plans, or geographic areas?
100 percent of respondents answered "Yes." Comment: "A rate vs. percentage as discussed would be advantageous for the calculation."

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

The PMCoE PICU Expert Workgroup and Measure Champions were focused from the outset on the incorporation of specified elements to assess equity/disparities, particularly race/ethnicity, payer status (socioeconomic status inferred), and language preference. Additionally, performance of this measure was assessed by gender. Attention to equity/disparities assessment was incorporated into each stage of the measure development and testing process.

According to Slonim et al., (2008), significant differences have been found in transfusions and complications from transfusions related to race:

- Asian individuals were nearly twice as likely to receive a transfusion as white individuals ($p < 0.001$) and twice as likely to experience a transfusion complication as whites ($p = 0.23$) (Haque, Faysel, Khan, 2010).

- American Indians were 40 percent less likely to receive a transfusion compared with whites ($p < 0.001$) (Haque, et al., 2010).

In a study that investigated racial disparities in the utilization of commonly performed medical procedures in U.S. hospitals, including blood transfusion, Haque, et al., (2010), found that for whites vs. blacks, whites were 1.6 times less likely to receive blood transfusion ($p<0.001$); Hispanics were 38 percent more likely to receive blood transfusion than their white counterparts; Asians and Pacific Islanders were 48 percent more likely than whites to receive blood transfusion ($p<0.001$), and American Indians were about 22 percent more likely than whites to receive blood transfusion procedure ($p<0.05$) (Haque, et al., 2010).

The authors acknowledged that blood transfusion is widely used to treat sickle cell patients, and whites are significantly less likely to receive this procedure compared to other races. Although sickle cell anemia is mostly diagnosed in blacks, Hispanics are also diagnosed with this disease; however, the study also showed that Asians and Pacific Islanders were significantly more likely than whites to receive this procedure, which would not appear to be related to sickle cell anemia.

We recognize the value of testing in a diverse population so that the measure might be capable of producing stratified results to identify any disparities in the measure's performance. In specifying this measure, the Supplemental Data Elements included:

- Patient Characteristic Race using the "Race CDCREC Value Set."

- Patient Characteristic Ethnicity using the "Ethnicity CDCREC Value Set."

Testing

This measure was tested in Lurie Children's Hospital (N=33), where approximately 46 percent (N=15) of the sample was white, 21 percent (N=7) was black, 18 percent (N=6) was Hispanic, and 15 percent (N=5) was other. Patients who had a transfusion were more likely to meet the numerator criteria if they were black (100 percent), white (91 percent), or other (89 percent) than if they were Hispanic (72 percent). Transfusions were more likely to meet the measure if they were performed on black patients (100 percent, N=37), white patients (91 percent, N=82), and other/unknown (89 percent, N=44) than Hispanic patients (72 percent, N=18). This was statistically significant (p=0.01).

7.B. Special Health Care Needs

The performance of this measure was not assessed for children with special health care needs.

7.C. Socioeconomic Status

According to Slonim et al., (2008), significant differences have been found in - Patient Characteristic Payer using the "Payer SOP Value Set"

Testing

At Lurie Children's, approximately, 73 percent (N=24) of patients in this sample who received a transfusion used private insurance and 27 percent (N=9) used Medicaid. Similarly, considering all transfusions, 80 percent (N=145) were performed on patients using private insurance, and 20 percent (N=36) were performed on patients using Medicaid. The clinical performance of this measure was higher in the private insurance subsample, with 95 percent of transfusions meeting the measure as compared to 72 percent of transfusions performed in the Medicaid group. This difference is statistically significant (p<.0001).

Transfusions and Complications from Transfusions Related to Payer (Socioeconomic) Status

Percentage of patients receiving blood product transfusions, by payer type:

1. Private 5.1 percent (<0.001).

2. Other 4.3 percent (<0.001).

3. Government 5.3 percent.

In a study that investigated disparity based on race and payer status in the utilization of commonly performed medical procedures in U.S. hospitals, including blood transfusion, Haque, et al. (2010) found that:

- Among Medicaid recipients, blacks were 1.5 times and Hispanics and Asians and Pacific Islanders were 1.3 times as likely as whites to receive blood transfusion (p< 0.05).

- Among Medicare recipients, whites were less likely to receive blood transfusion compared to blacks, Hispanics and Asians and Pacific Islanders (p<0.05).

- Among private insurance holders, blacks, Hispanics and Asians and Pacific Islanders were between 1.3 and 1.4 times as likely as whites to receive blood transfusion (p<0.05).

- Among self-paid patients, blacks, Hispanics, and Asians and Pacific Islanders were between 1.3 and 1.5 times as likely as whites to receive blood transfusion (p<0.001).

We recognize the value of testing in a diverse population so that the measure might be capable of producing stratified results to identify any disparities in the measure's performance.

7.D. Rurality/Urbanicity

According to Slonim et al., (2008), differences have been found in transfusions and complications from transfusions related to geographic region and other hospital characteristics, e.g., staffed beds, mean daily census). For example:

- The rate of transfusions for children discharged from hospitals sited in Northeastern States was lower compared to those in other geographic locations, but the rate of transfusion reactions was higher compared to those other geographic locations (Slonim, et al., 2008). See Section 7, Table 7.D.1 in the Supporting Documents.

- The rate of transfusions and transfusion reactions differed by both the number of staffed hospital beds and the mean daily census of the participating institutions (Slonim, et al., 2008). See Section 7, Table 7.D.2 in the Supporting Documents.

Testing

All testing sites are located in the Chicagoland area; therefore, the performance of this measure was not assessed by rurality/urbanicity.

7.E. Limited English Proficiency (LEP) Populations

We recognize the value of testing in a diverse population so that the measure might be capable of producing stratified results to identify any disparities in the measure's performance. In specifying this measure, we assessed for language preference.

Testing

At Lurie Children's, English was the preferred language for 85 percent (N=28) of the patient sample, while 12 percent (N=4) preferred Spanish, and 3 percent (N=1) preferred a different language. Considering each transfusion, 92 percent (N=167) were performed on patients who preferred English as compared to 7 percent (N=12) on patients who preferred Spanish, and 1 percent (N=2) on patients who preferred a different language. This clinical performance was higher in English-speaking patients than in Spanish-speaking patients, with 86 percent of the English subgroup meeting the measure as compared to 50 percent of the Spanish subgroup. The patient who preferred a different language met the measure. Almost all (95 percent) of transfusions performed on English-speaking patients met the measure, whereas only 33 percent

of transfusions performed on Spanish-speaking patients met the measure. This difference was statistically significant (p<0.0001).

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 feasibility of the construction of this measure was assessed in the Chicago Pediatric Quality and Safety Consortium (CPQSC), which includes Advocate Children's Hospital – Park Ridge, Advocate Children's Hospital – Oak Lawn, John H. Stroger Hospital, and Lurie Children's Hospital. The EHR vendor systems used across these institutions included Epic and Cerner. Please see the Supporting Documents, Section 8, for the Data Element Table (DET) tool used in feasibility testing.

Based on the site informaticists' assessments and further validation of responses by the Northwestern PhD-level bioinformaticist, this measure was determined to be "technically feasible, can do today" at three testing sites, Advocate Children's Hospital – Park Ridge, Advocate Children's Hospital – Oak Lawn, and Lurie Children's Hospital. The results for John H. Stroger Jr Hospital of Cook County were "technically feasible with workflow modifications or changes to the EHR." This measure had implementation feasibility, "can do today" at only one site, Lurie Children's Hospital. The other testing sites were designated "feasible with workflow modifications or changes to the EHR." Please see Supporting Documents, Section 8, for feasibility testing results.

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?

There were two reasons that this measure was determined to be "technically feasible with workflow modifications or changes to the EHR" at John H. Stroger Jr Hospital. First, the informaticist was unable to determine the variable type for two denominator elements, occurrence of a blood transfusion and the associated date. Second, some denominator exceptions, including unstable shock and patients on ECMO, were captured only in free text fields, if at all. One recommendation to facilitate implementation would be to create discrete fields for the denominator exceptions and the occurrence of a blood transfusion so that this data can be stored in queriable fields as opposed to free text.

The reason for three sites being designated as "feasible with workflow modifications or changes to the EHR" for this measure had to do with the way denominator exceptions are currently

captured. For example at both Advocate Children's Hospital sites, structured fields for the exceptions are not always utilized when they are available. This makes it difficult to identify patients with the denominator criteria. One way to increase feasibility of this measure at these sites is to change the workflow such that structured fields, when available, are used for these measure elements.

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.

In 2013, the Children's Hospital Association (CHA) sponsored a research study that was conducted at six different sites in the United States – all PICUs in children's hospitals. The goal of the study was to evaluate relevant data to establish a baseline related to the ordering of red blood cell transfusions in each unit and subsequently introduce a standardized implementation plan. This plan utilized the same guidelines as set forth in the proposed measure: a restrictive transfusion strategy with an initial threshold set at Hgb < 7g/dL.

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?

The methods used to collect data in the CHA study involved a combination of reviewing logs from the blood bank, a form completed by the attending physician, and a chart review if necessary to fill in gaps.

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

In instances where a patient was transfused above the threshold of 7g/dL, the research team found it challenging to identify, based on the documentation, the factors contributing to the physician's decision to transfuse above the restrictive guideline. However, given opportunities to discuss the decision with the physician, the rationale became clear.

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?**
Not 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?**
There are no unintended consequences for reporting this measure if the data are accurate.

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?**
Not 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?**
There are no unintended consequences for reporting this measure if the data are accurate.

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?**
Not 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?**
There are no unintended consequences for reporting this measure if the data are accurate.

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?**
Not 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?**
There are no unintended consequences for reporting this measure if the data are accurate.

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 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?**
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?**
Not 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?**
There are no unintended consequences for reporting this measure if the data are accurate.

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?**
Not 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?**
There are no unintended consequences for reporting this measure if the data are accurate.

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).

During late summer 2014, together with four other draft PICU measures, this measure was widely disseminated during a 21-day period of Public Comment. The objective was two-fold: (1) to provide stakeholders with an opportunity to review the draft measures and advise PMCoE on appropriate changes in content, based on their respective areas of expertise; and (2) to assess the public's perception of the draft measures' usefulness and understandability.

In the case of this measure, Appropriateness of Red Cell Transfusions, we were able to enhance the usefulness and understandability by making the following changes directly indicated from Public Comment:

- Replaced as the primary evidence citation the 2012 recommendation from AABB, which is more adult-medicine focused and did not address all of the exclusions determined to be important in pediatrics, with the findings from the pediatric-specific study conducted by Lacroix, et al, in 2007:

  In stable, critically ill children a hemoglobin threshold of 7 grams per deciliter for red cell transfusion can decrease transfusion requirements without increasing adverse outcomes (10). (Controlled-trials.com number, ISRCTN37246456 [controlledtrials.com].)

- Added another exclusion, "patients who have acute hemolysis."

Additionally, the Measure Champions considered one comment suggesting that the measure description might not be clear enough in conveying that a high hemoglobin percentage is good; at the time, the Measure Champions believed that no modification was warranted. However, following specification and testing, they recognized that the measure's understandability might be enhanced, and it could potentially be more informative if a rate was reported. This issue is discussed further in Section 12 of this report.

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.

Health IT could be helpful in resolving a few issues with the construction of this measure in the EHR. For example, at one site the informaticist was unable to determine the variable type for two denominator elements, the occurrence of a blood transfusion and the associated date. Health IT could enhance the use of this measure by creating discrete, queriable fields for these elements so that the data can be stored in structured fields as opposed to free text. Similarly, denominator exceptions were often stored in free text fields as well. By creating structured fields for the denominator exceptions, Health IT could increase the implementation of this measure by providing a means to exclude patients who do not meet the denominator population.

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?

Feasibility testing for construction of this eMeasure was conducted in four sites in the CPQSC; in three of the sites, it was determined to be technically feasible to construct the measure. The feasibility of the measure was assessed using Cerner and Epic EHR systems. Of the three sites using Cerner, this measure was technically feasible at two of them and feasible with modifications to the EHR at one of them. Workflow changes were required in order to implement the measure at all three sites. This measure was feasible and implementable in the EHR of the site using Epic. Further details are provided in Section 8 of this report.

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 two of the testing sites, Lutheran General Children's Hospital and Christ Hope Children's Hospital, this measure could not be implemented. While the EHR included structured fields for the denominator exceptions, the structured fields were not always utilized when available. This makes it difficult to identify patients meeting the denominator criteria. One way to increase feasibility of this measure at these sites is to change the workflow such that structured fields, when available, are used for these measure elements.

Currently, many ICD-9 or ICD-10 codes and other variables are used to identify denominator exclusions in the EHR; if a simple checkbox could be used to identify patients with cyanotic heart disease, unstable shock, or sickle cell disease, as well as patients on ECMO, these data would be much easier to extract from the EHR. The boxes could easily be checked during clinical rounds.

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 criteria (see healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__standards_ifr/1195)?

No.

If yes, please describe.

Not applicable.

11.E. Health IT Calculation

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

The majority of data elements were identifiable and encoded as structured data in the EHR systems of each of our test sites, and we are confident that these elements will exist as structured data in the majority of EHR systems. The biggest concern regarding the calculation of these measures is that sites may not utilize existing structured fields for the exclusion criteria. If this is the case, patients that meet the exclusion criteria might be included in the denominator population. This might lead to patients being considered in this measure when, due to a diagnosis or other circumstances, they should not be in the denominator population. We recommend that sites utilize the structured fields present in their current EHR system to prevent this problem.

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?

Not applicable.

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).

Calculation of the Metric

Following the specification and testing of this measure, members of our Expert Workgroup expressed concern about the way in which the measure is calculated. As it is currently written, the clinical performance on the measure could appear to worsen even though the unit is improving, if with the improvement, the total number of transfusions in the unit decreases. To illustrate, consider this example:

Time point 1: 40 transfusions with Hgb 7 or less, 100 transfusions = 40 percent. Time point 2: 20 transfusions with Hgb 7 or less, 50 transfusions = 40 percent. It looks like no improvement when in reality, by using a more restrictive strategy, 50 fewer transfusions happened - which is a significant improvement.

On its last call, the Expert Workgroup considered whether potentially it might be more informative to instead report this measure as a rate. However, the experts noted that a calculation in this manner could introduce other confounders that might drive the rate up or down. Ultimately, the Expert Workgroup recommended that, if the current measure is accepted, a complementary measure might be considered in the future – the new one or complementary measure (requiring specification and testing) would be calculated as a rate. For example:

- Measure Description: Number of RBC transfusions in patients in the PICU with Hgb more than 7 g/dL per 100 PICU admissions during the time period (the more compliant the unit is to the measure, the lower the rate).

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- Numerator Statement: Number of RBC transfusions in patients in the PICU with Hgb more than 7 g/dL (7.5 g/dL rounded down).

- Denominator Statement: Number of PICU admissions during the time period.

eMeasure Limitations

The primary limitation of this measure as an eMeasure is that the exclusion criteria may be captured in free text fields or coded using multiple ICD-9 codes such that the exclusions are not easily specified.

Chart Review Limitations

The main limitation of this measure as a chart review measure is that the exclusion criteria might be difficult to find in the record if they are included in free text or in scanned documents. Additionally, chart review measures can be time consuming, and institutions may not have the resources to complete them. Additionally, most State Medicaid and CHIP programs find chart review as a method for quality assessment too challenging and burdensome, and therefore, they do not use measures specified for manual chart abstraction.

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.

Rationale for Selection

Importance

Between 15 and 49 percent of patients receive at least one red blood cell (RBC) transfusion during their pediatric intensive care unit (PICU) admission, and 62 percent of children who are transfused received more than one transfusion (Armano, et al., 2005). Current transfusion practices vary widely – both within and between PICUs (Nahum, et al., 2004). The results from a case-based survey showed significant variation among pediatric intensivists in the hemoglobin (Hgb) that would trigger an order for transfusion of RBCs. Most transfusions occurred at Hgb values that were higher than recommended guidelines (Nahum, et al., 2004).

Growing evidence has shown that RBC transfusions may be associated with more harm than benefit, with the most recent data indicating that using an Hgb transfusion threshold of >7 g/dL does not yield improved outcomes. One study reported a rate of complications of 10.7 per 1,000 units transfused (Slonim, et al., 2008). Other studies have suggested that PICU patients may be at an increased risk for morbidity and mortality when undergoing transfusion (Tyrell, Bateman, 2012). Blood transfusions are also well-documented to be associated with other risks, such as

hospital-associated infection, gut ischemia, transfusion reactions, and stimulation of the inflammatory response.

Pediatric RBC transfusions increase resource utilization and costs. Resource use in terms of length of stay (LOS) and costs were higher in patients who received transfusion (Slonim, et al., 2008). A study by Shander and colleagues in 2010 calculated that the cost per unit of RBCs transfused at two U.S. hospitals averaged $1,182.32 and $726.05 per unit transfused. Additionally, blood product acquisition costs contributed to only 21-32 percent of total blood transfusion expenditures, with direct and indirect overhead costs accounting for roughly double that percentage at U.S. hospitals (Shander, et al., 2010).

Desirable Attributes and Limitations

The aim of this measure is to safely decrease the number of transfusions in PICUs and thereby decrease transfusion-related events. Other outcomes include improved utilization of donor blood (a limited resource) and decreased costs associated with a PICU admission. The measure also captures important exclusion criteria that are necessary to factor in when considering a pediatric critical care population. Ironically, the exclusion criteria also represent a limitation. As an eMeasure, the exclusion criteria may be captured in free text fields or coded using multiple ICD-9 codes such that the exclusions are not easily specified. As a chart review measure, the exclusion criteria may be difficult to find in the record if they are included in free text or in scanned documents.

Another limitation is the way in which the measure is calculated and reported; as it is currently written, the percent could worsen even though the unit is doing better. This could occur if the total number of transfusions decreases. This led the Expert Workgroup to wonder whether it might potentially be more informative to report the measure as a rate, although that would have different drawbacks. It could be that a pair of complementary measures would be the most ideal solution – one measure (as submitted here) providing a percent and a new, additional measure that would be calculated as a rate.

Advantages

No PICU-related measures are currently included in the Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set), yet the PICU is where a hospital's sickest and most vulnerable children are treated. Implementation of this measure in the PICU could mitigate much of the elevated risks and costs associated with pediatric critical care.

The proposed measure is unique in that it is physician-specific and capable of measuring quality based on an individual physician's performance.

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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.