Timely Blood Culture for Children with Sepsis Syndrome

Section 1. Basic Measure Information

1.A. Measure Name

Timely Blood Culture for Children with Sepsis Syndrome

1.B. Measure Number

0229

1.C. Measure Description

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

This measure assesses the proportion of hospitalized children younger than 19 years of age identified as having sepsis syndrome who had a blood culture drawn within 4 hours of meeting diagnostic criteria for the condition. A higher proportion indicates better performance.

Sepsis is a potentially catastrophic condition that can escalate from infection to organ failure and death within hours. While mortality rates for pediatric sepsis have decreased over time, 4-10 percent of hospitalized children with sepsis in the United States die (Watson, Carcillo, Linde-Zwirble, 2003). Clinical practice parameters and guidelines for the treatment of children with sepsis syndrome emphasize the critical importance of early recognition and aggressive treatment for all suspected cases of pediatric sepsis syndrome (Carcillo, Fields, et al., 2002; Dellinger, Levy, Rhodes, et al., 2013); improved survival has been associated with adherence to guidelines that emphasize time-sensitive resuscitation of children with sepsis syndrome (Han, Carcillo, Dragotta, et al., 2003). Whether a child presents to an academic medical center or a community hospital, clinicians must be ready to rapidly deploy a set of time-sensitive, goal-directed, stepwise procedures to hinder or reverse the cascade of events in sepsis that lead to organ failure and death.

One essential element of timely and appropriate treatment is the blood culture. Promptly obtaining a blood culture to identify the invading pathogen helps clinicians determine an effective antimicrobial regimen. Because guidelines strongly recommend that children immediately receive a broad spectrum antibiotic, blood cultures should be drawn shortly after the patient presents to the hospital. However, administration of an antibiotic should not be unduly delayed to obtain the culture.

This measure uses medical record data to calculate the proportion of eligible children who had a blood culture drawn within 4 hours of being diagnosed with sepsis syndrome.

1.D. Measure Owner

The Quality Measurement, Evaluation, Testing, Review, and Implementation Consortium (Q-METRIC).

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.**

   This measure is part of the Q-METRIC Sepsis Measures Collection.

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

The eligible population for the numerator is the number of hospitalized children younger than 19 years of age with sepsis syndrome who had a blood culture drawn within 4 hours of meeting diagnostic criteria for this condition. Eligible children are all those admitted to the hospital, including the emergency department. Sepsis syndrome—which consists of sepsis, severe sepsis, and septic shock—is defined in Table 1 (see Supporting Documents). Codes to identify potential

sepsis syndrome cases using administrative data to identify medical records for review are documented in Table 2 (see Supporting Documents).

1.H. Numerator Exclusions

1. All children with sepsis syndrome who were transferred from another hospital, if the blood culture was performed at the referring hospital.
2. Children who died within 4 hours of meeting diagnostic criteria for sepsis syndrome.
3. Patients with advanced directives for comfort care.
4. Patient or surrogate decision-maker declined or is unwilling to consent to therapies.

1.I. Denominator Statement

The eligible population for the denominator is the number of hospitalized children younger than 19 years of age with sepsis syndrome. Eligible children are all those admitted to the hospital, including the emergency department. Sepsis syndrome, which consists of sepsis, severe sepsis, and septic shock, is defined in Table 1 (see Supporting Documents). Codes to identify potential sepsis syndrome cases using administrative data to identify medical records for review are documented in Table 2 (see Supporting Documents).

1.J. Denominator Exclusions

1. All children with sepsis syndrome who were transferred from another hospital, if the blood culture was performed at the referring hospital.
2. Children who died within 4 hours of meeting diagnostic criteria for sepsis syndrome.
3. Patients with advanced directives for comfort care.
4. Patient or surrogate decision-maker declined or is unwilling to consent to therapies.

1.K. Data Sources

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

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.

See Supporting Documents for technical 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).**

Importance

Sepsis is a complex, systemic response to the invasion of a pathogen that can progress to impaired blood flow and organ dysfunction (Skippen, Kisson, Waller, et al., 2008). Septic shock in children is a life-threatening illness that requires immediate recognition and rapid treatment (Han, et al., 2003).

Sepsis Prevalence and Incidence

While sepsis-associated mortality in children has declined in recent years, from 97 percent in infants in 1966 to 9 percent in the early 1990s, it remains a major cause of morbidity and mortality among children (Watson, et al., 2003). The incidence of pediatric sepsis was estimated in 1995 to be 0.56/1,000 children, with the highest prevalence in infancy at 5.6/1,000 children; boys had a higher incidence compared with girls (0.6 vs. 0.52 per 1,000 children) (Watson, et al., 2003). Sepsis prevalence tends to have two peaks during childhood. The first peak is during infancy, as reported by Angus, Linde-Zwirble, Lidicker, et al., in 2001 (5.3/1,000 infants) and by Watson and colleagues (5.16/1,000 infants) in 2003. Odetola and colleagues reported a second age-specific peak in hospitalization rates: in 2003, children 15 to 19 years of age made up 18 percent of the pediatric population hospitalized nationally for sepsis (Odetola, Gebremariam, Freed, 2007).

Mortality among hospitalized children with severe sepsis has been reported to be between 4 percent and 10 percent (Odetola, et al., 2007; Watson, et al., 2003). Mortality is strongly associated with multiple organ dysfunction syndrome, occurring in 7 percent of children with one failing organ, and increasing to 53 percent in those with at least four failing organs (Watson, et al., 2003). Comorbid illness is also associated with mortality from sepsis, with mortality rates of 8 percent in children with comorbid illness versus 2 percent among previously healthy children (Odetola, et al., 2007). There also are reports of age-specific differences in mortality from pediatric sepsis. Higher mortality rates from sepsis among children over the age of 2 years may be attributable to the presence of chronic and severe underlying disease and to improved survival of immune-compromised and immune-suppressed patients who also may have experienced more hospital admissions and treatments, such as transplantation or chemotherapy, making them more vulnerable to sepsis syndrome (Oliveira, Nogueira, Oliveira, et al., 2008).

Sepsis Cost

Estimated annual total cost of pediatric sepsis in the United States is $1.97 billion (Watson, et al., 2003). The average (mean) charge per hospitalization for sepsis is $47,126 (Odetola, et al., 2007). Children who died from sepsis had total hospital charges that were 2.5-fold higher compared with those who survived. Higher charges were also associated with higher severity of illness. Longer length of stay for children hospitalized with sepsis was associated with multiple comorbidities, multiple organ dysfunction, and higher illness severity (Odetola, et al., 2007).

Sepsis Pathology and Severity

Sepsis syndrome comprises three stages of illness:

1. Sepsis is defined as systemic inflammatory response syndrome (SIRS) occurring in the presence of a suspected or proven infection (bacterial, viral, fungal, or rickettsial) (Goldstein, Giroir, Randolph, et al., 2005; Melendez, Bachur, 2006). Diagnosis of SIRS requires at least two of the following criteria, one of which must be abnormal temperature or leukocyte count: abnormal temperature (greater than 38.5ºC [hyperthermia] or less than 36ºC [hypothermia]); abnormal leukocyte count (elevated or depressed); accelerated heart rate (tachycardia); or accelerated respiratory rate (tachypnea) (Goldstein, et al., 2005).

2. Severe sepsis includes sepsis plus one of the following clinical states: cardiovascular organ dysfunction (acute circulatory failure) or acute respiratory distress syndrome (ARDS); or two or more other organ systems with dysfunctions (respiratory, renal, neurologic, hematologic, or hepatic) (Goldstein, et al., 2005).
3. Septic shock is defined as sepsis and cardiovascular dysfunction (Goldstein, et al., 2005; Rivers, Ahrens, 2008). Unlike adults, the diagnosis of septic shock in children does not require the presence of low blood pressure (hypotension), as children often maintain normal blood pressure until the advanced stages of shock (Goldstein, et al., 2005; Larsen, Mecham, Greenberg, 2011; Melendez, Bachur, 2006; Skippen, et al., 2008). Shock occurs when the cardiovascular system is unable to provide energy resources (oxygen and glucose) to meet the needs of the tissues (Skippen, et al., 2008).

Outcomes of Timely Treatment, Including Blood Culture

Early recognition and prompt treatment of sepsis syndrome are essential for successful outcomes in the emergency department (Melendez, Bachur, 2006; Saladino, 2004). It is relatively simple to recognize the advanced conditions of severe sepsis and septic shock; the key for health care providers is to identify the abnormal physiologic symptoms indicative of incipient sepsis syndrome and initiate appropriate treatment to hinder or reverse progression to these later stages (Skippen, et al., 2008). Given the correlation between presenting physiologic characteristics and outcome, it is crucial that physicians promptly diagnose sepsis by collecting adequate and appropriate vital sign information before the escalation to severe sepsis or septic shock (Rivers, Ahrens, 2008).

The current management strategy for treatment of sepsis is goal-directed therapy, with institution of timely antimicrobial and hemodynamic (i.e., relating to the forces driving blood flow throughout the body) treatments. The point of all treatment is to kill the pathogen(s) triggering the sepsis and restore circulation and perfusion to vital organs (Khilnani, Deopujari, Carcillo, 2008). International guidelines prescribe that antibiotic therapy begin as soon as possible and within the first hour of recognition of septic shock and severe sepsis (Brierley, Carcillo, Choong, et al., 2009; Carcillo, et al., 2002). The components of early goal-directed therapy include prompt resuscitation of poor perfusion through the administration of intravenous fluids and appropriately targeted inotropic and/or vasopressor therapy, early empiric antimicrobial therapy, source control, appropriate and continuous monitoring of hemodynamic status, and additional supportive care as required (Melendez, Bachur, 2006). Efforts to diagnosis the source of infection should include obtaining a blood culture, followed by immediate administration of broad-spectrum antibiotics (ideally within 1 hour of presentation). When possible, blood cultures should be obtained before administering antibiotics, but this test should not delay administration of antibiotics (Dellinger, et al., 2013; Melendez, Bachur 2006). A study by Weinstein et al. shows that 99.3 percent of all sepsis occurrences are identified within the first two blood cultures (Weinstein, Reller, Murphy, et al. 1983).

In developed countries, each hour of delay in the administration of antibiotics is associated with an average 7.6 percent decrease in survival of septic shock (Kumar, Roberts, Wood, et al., 2006). The study also found that 50 percent of patients with septic shock did not receive effective antimicrobial therapy within 6 hours of documented hypotension (Kumar, et al., 2006). Also, odds of mortality double with each passing hour of persistent shock, and according to published guidelines, each hour of delay in resuscitation has been associated with a 50 percent increased

odds of mortality (Han, et al., 2003). Successful septic shock reversal depends upon the timeliness and appropriateness of therapies.

Performance Gap

Despite the availability of evidence-based guidelines for the care of children with sepsis, only a minority of children receive the standard of care. Process barriers are a common problem leading to delays in the recognition and treatment of pediatric shock (Cruz, Perry, Williams, et al, 2011). These barriers include varying levels of experience among emergency department staff performing initial evaluations, lack of adequate nursing staff for resource-intensive patients, difficulty in obtaining frequent vital signs, lack of standardization of empiric antibiotics and diagnostic tests, lack of prioritization of medications, and barriers to patient flow through the hospital. Shock protocols, which standardize and facilitate care by providing explicit instructions regarding interventions and timeframes, allow physicians to intervene earlier and harness resources for very ill children (Cruz, et al., 2011).

Many children live far from medical facilities that offer specialized pediatric care. For those presenting with septic shock to local hospitals, treatment efforts made by physicians will be critical to their survival and should be prioritized. Delay in care while waiting to transfer patients to a more advanced pediatric medical facility is unwise (Han, et al., 2003). The results of a 9-year retrospective study (Han, et al., 2003) indicated that 29 percent of infants and children who presented with septic shock at community hospitals and required transport to a larger medical center did not survive.

Because the clinical guidelines for the treatment of sepsis were developed at pediatric academic centers without accounting for their use at community hospitals, barriers to use may exist. For example, some community physicians may lack some of the specialized technical skills involved in managing sepsis in critically ill children. Others may be uncomfortable placing central venous catheters in critically ill children. Educational barriers regarding the guidelines themselves may curtail implementation if physicians are unaware or lack support to execute stepwise, goal-directed interventions, such as obtaining blood cultures and administering broad-spectrum antibiotics in a timely manner. However, most of the procedures detailed in the guidelines are easily within the scope of a community-based practice (Han, et al., 2003). Local physicians are as crucial to the treatment of pediatric sepsis as their counterparts at large academic medical centers; continued efforts to increase knowledge and comfort with sepsis guidelines will improve outcomes. Odetola and colleagues (2007) note an urgent need for concerted clinical and educational efforts within the clinical care setting, designed to limit the progression of sepsis severity. The association found between multiple organ dysfunction and death support such efforts as an important risk-reduction strategy (Odetola, et al., 2007).

Despite guideline recommendations for prompt initiation of antimicrobial therapy, delays in intravenous antibiotic therapy of 3.5 hours in survivors and 4 hours in patients who died have been observed (Oliveira, et al., 2008). Reasons for delay may include inaccuracy in assessing the severity of a child's state of shock and a shortage of health care providers. An overworked medical team will be less likely to conduct a timely evaluation and institute appropriate treatment in the first hour of response to septic shock (Oliveira, et al., 2008). Further, treatment of septic shock cannot start at arrival at the intensive care unit; it must begin when patients present to the emergency department. Early recognition and treatment of septic shock right from presentation to

the emergency department benefits all patients because it leads to more meticulous patient assessment (Larsen et al., 2011).

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).**

Sepsis and Medicaid/CHIP

This measure is relevant to Medicaid/CHIP because of the incidence of sepsis among young children and the substantial burden of this condition. Sepsis is one of the top 10 most expensive diseases managed by hospitals, accounting for 2.8 percent ($24.8 billion) of national hospital expenses in 2005. Of these charges, approximately $19.5 billion were charged to Medicare and Medicaid. Data from AHRQ's Healthcare Cost and Utilization Project (HCUP) show that the national cost of treating sepsis increased more (183 percent) than for other conditions between 1997 and 2005 (Rivers, Ahrens, 2008).

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).

There is a measure, developed by VHA, Inc., that assesses percentage of patients aged 16 years and older, with a diagnosis of severe sepsis/septic shock who had two sets of blood cultures collected within 24 hours following diagnosis (VHA, 2007). The Q-METRIC measure expands the VHA measure to include all children, not just those 16 years and older. The Q-METRIC measure, by focusing on a tighter timeframe (4 hours vs. 24), focuses more closely on the clinical imperative to address pediatric sepsis syndrome with an emphasis on early recognition and time-sensitive treatment.

New York State has enacted regulations to ensure that hospitals "have in place evidence-based protocols for the early recognition and treatment of patients with severe sepsis/septic shock that are based on generally accepted standards of care" (New York Codes, Rules, and Regulations Title 10 (Health), sections 405.2 and 405.4). The regulations in New York exemplify the interest and desire of health agencies for quality measures related to the care and treatment of pediatric sepsis syndrome.

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:** No.
g. **Service – other (please specify):** No.
h. **Measure Topic – duration of enrollment:** No.
i. **Measure Topic – clinical quality:** Yes.
j. **Measure Topic – patient safety:** No.
k. **Measure Topic – family experience with care:** No.
l. **Measure Topic – care in the most integrated setting:** Not applicable.
m. **Measure Topic other (please specify):** Not applicable.
n. **Population – pregnant women:** No.
o. **Population – neonates (28 days after birth) (specify age range):** Yes; birth to 28 days.
p. **Population – infants (29 days to 1 year) (specify age range):** Yes; ages 29 days to 1 year.
q. **Population – pre-school age children (1 year through 5 years) (specify age range):** Yes; ages 1-5 years.
r. **Population – school-aged children (6 years through 10 years) (specify age range):** Yes; ages 6-10 years.
s. **Population – adolescents (11 years through 20 years) (specify age range):** Yes; ages 11-18 years (younger than age 19 years).
t. **Population – other (specify age range):** Not applicable.
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.

This measure focuses on a clinical process (obtaining a blood culture for children with sepsis syndrome within 4 hours of their meeting diagnostic criteria) that, if followed, results in a desirable outcome (timely and accurate identification of the pathogen responsible for sepsis, leading to prompt prescription of specifically targeted antimicrobial agents). Expert consensus has identified recognition and aggressive treatment of sepsis syndrome as the bedrock of care for pediatric patients presenting with this potentially devastating condition. In particular, clinical guidelines have identified a series of goal-directed, stepwise interventions focused on hindering progression to shock or reversing it. An important step in this set of procedures is obtaining a blood culture shortly after diagnosis of sepsis syndrome and ideally before the initiation of broad spectrum antibiotics. Table 3 (see Supporting Documents) summarizes several key sources of evidence for this measure, using the U.S. Preventive Services Task Force (USPSTF) rankings.

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.

Children with infections often display the inflammatory triad of fever, tachycardia, and vasodilation (widening of the blood vessels) (Brierley, et al., 2009). Septic shock is suspected when children with these three symptoms display a change in mental status such as irritability, inappropriate crying, drowsiness, confusion, poor interaction with parents, lethargy, or an inability to be aroused. Clinical signs of septic shock in children with a suspected infection include hypothermia or hyperthermia; signs of inadequate tissue perfusion, including any of the following: prolonged capillary refill greater than 2 seconds, diminished pulses, mottled, cool extremities or flash capillary refill, bounding peripheral pulses, and wide pulse pressure; or decreased urine output less than 1 mL/kg/h. Hypotension is not necessary for the clinical diagnosis of septic shock; however, its presence in a child with clinical suspicion of infection is confirmatory (Brierley, et al., 2009).

Goals for the first hour of resuscitation in the emergency department are to maintain or restore the airway, oxygenation, and ventilation; maintain or restore circulation, defined as normal perfusion and blood pressure; and maintain or restore threshold heart rate (Brierley, et al., 2009).

Therapeutic endpoints include capillary refill of 2 seconds or less, normal pulses with no differential between the quality of peripheral and central pulses, warm extremities, urine output greater than 1 mL/kg/h, normal mental status, normal blood pressure for age, normal glucose concentration, and normal ionized calcium concentration (Brierley, et al., 2009).

The pathogens that cause severe sepsis vary with age and immunization status (Rooney, Nadel, 2009). Group B streptococci, *Escherichia coli*, *Listeria*, and herpes simplex virus commonly cause neonatal infections*; Streptococcus pneumoniae* and *Neisseria meningitides*, which tend to be community-acquired organisms, are seen more often in older children (Goldstein, et al., 2005; Rooney, Nadel, 2009). The introduction of conjugate vaccines given in infancy against *Haemophilus influenza* type B, *S. pneumoniae*, and *N. meningitidis* has changed the epidemiology of severe sepsis in children (Rooney, Nadel, 2009). Pediatric patients who are chronically ill or immunocompromised make up a larger proportion of the population with severe sepsis than adults (Goldstein, et al., 2005). Viruses and fungi also cause sepsis, particularly in immunocompromised and very young or premature infants. The pathophysiology of the disease is the same, however, irrespective of the precipitating pathogen (Rooney, Nadel, 2009).

Sepsis is a complex series of interactions between different host systems in the body and the invading pathogen (Rooney, Nadel, 2009). It is a dynamic phenomenon in which the roles of individual mediators may be transient and redundant, with many regulatory pathways activated. The process, however, ultimately leads to tissue damage and organ failure. In the early stages, immune cells react to a pathogen in a way that creates potentially harmful molecules that damage the endothelial cells. A cascade of inflammatory and coagulation responses leads to progressive organ impairment. Refractory vasodilation, fluid redistribution, and decreased myocardial function lead to shock. Severe sepsis becomes a self-perpetuating condition, as hypoxia and tissue ischemia exacerbate inflammatory and coagulation responses, resulting in further inflammation. A compensatory anti-inflammatory response syndrome develops, leading to relative immunosuppression, in which the host inflammatory cells are unable to respond to stimuli. The resulting immunoparalysis limits response to the pathogen, contributing to morbidity and mortality (Rooney, Nadel, 2009).

Because children often maintain their blood pressure until they are severely ill, systemic hypotension is not a requirement for diagnosis, and shock may occur long before hypotension appears in children (Goldstein, et al., 2005).

The treatment of septic shock in children is intended to optimize perfusion of critical vascular beds and prevent or correct metabolic abnormalities that result from cellular hypoperfusion (Khilnani, et al., 2008). The ultimate goals are to prevent or reverse defects in cellular substrate delivery and metabolism and to support the entire patient until homoeostasis is restored. For all forms of shock, treating the underlying cause is mandatory, and avoiding delay in treatment is essential. Delays in making the diagnosis and initiating treatment (fluid resuscitation and appropriate antibiotics), as well as suboptimal resuscitation, contribute to peripheral vascular failure and irreversible defects in oxygen supply, which can culminate in vital organ dysfunction (Khilnani, et al., 2008).

The initial therapeutic endpoints of resuscitation of septic shock are: capillary refill of 2 seconds or less; normal blood pressure for age; normal pulses with no differential between peripheral and central pulses; warm extremities; urine output greater than 1 mL/kg/h; normal mental status; decreased lactate; and mixed venous oxygen saturation of greater than 70 percent (Dellinger, et al., 2013).

A blood culture tests for infection in the blood by detecting the presence of bacteria or fungi. A bacterial infection in the blood can be serious because the blood can spread bacteria to any part of the body. To test for infection, blood is collected and placed in a cup (culture medium) with substances that allow bacteria or fungus to grow. If this occurs, the bacteria or fungi are checked visually by a microscope and chemically. Further sensitivity testing is conducted to determine the best antibiotic to use to kill the pathogen. Two or three samples may be taken from different venipuncture sites to make sure infection is not missed. If nothing grows, the blood culture is deemed negative (WebMD, 2012).

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.

This measure is based on medical record data. Reliability testing is described below.

Data and Methods

Measure testing involved an audit of medical records from three of the largest hospitals serving children in Michigan: Children's Hospital of Michigan (CHM, Detroit), Hurley Medical Center (Hurley, Flint), and C.S. Mott Children's Hospital-University of Michigan Health System (UMHS, Ann Arbor). Medical records for all children with sepsis syndrome meeting the measure specification criteria during the measurement year were abstracted at each site. Note that at the University of Michigan, an 18-month measurement period was used (January 1, 2012- June 30, 2013) to enable an adequate number of eligible records for review. Overall, 300 unique and valid records for children with sepsis syndrome were abstracted and reviewed to test this measure.

Reliability of medical record data was determined through re-abstraction of patient record data by a second abstractor to calculate the inter-rater reliability (IRR) between abstractors. Broadly, IRR is the extent to which the abstracted information is collected in a consistent manner. Low IRR may be a sign of poorly executed abstraction procedures, such as ambiguous wording in the data collection tool, inadequate abstractor training, or abstractor fatigue. For this measure, the medical record data collected by two nurse abstractors were compared.

Measuring IRR at the beginning of the abstraction process is imperative to identify and correct any misinterpretations early on. It is also important to assess IRR throughout the abstraction process to ensure that the collected data maintain high reliability standards. Therefore, IRR was evaluated at each site to address any reliability issues prior to completing data abstraction. Lessons learned were applied to work at the other sites.

IRR was determined by calculating both percent agreement and Kappa statistics. While abstraction was still being conducted at each site, IRR assessments were conducted for 5 percent of the total set of unique patient records that were abstracted. Two abstractors reviewed the same medical records; findings from these abstractions were then compared, and a list of discrepancies was created.

Three separate IRR meetings were conducted, one in the early stages of abstraction for each center. All of the meetings included a review of multiple sepsis measures that were being evaluated. Because of eligibility criteria, not all patient records were eligible for all measures. Therefore, records for IRR were not chosen completely at random; rather, records were selected to maximize the number of measures assessed for IRR at each site.

Results

For the measure numerator, 15 of 300 unique patient records (5 percent) from the abstraction process were assessed for IRR across the three testing sites. In order for a record to be abstracted for this measure, the patient had to meet a specific treatment criterion (lack of previous blood culture at a referring hospital) in addition to the diagnostic criteria (sepsis, severe sepsis, and septic shock). Therefore, IRR was also assessed for these eligibility criteria. For each of these, 15 of 300 unique patient records (5 percent) from the abstraction process were assessed for IRR across the three testing sites.

Table 4 (see Supporting Documents) shows the percent agreement and Kappa statistics for the numerator and the eligibility criteria of this measure for each site and across all sites. The overall agreement for blood culture performed elsewhere and sepsis syndrome were both 100 percent with a corresponding Kappa statistic of 1.00. The overall agreement for timely blood culture was 87 percent and the Kappa was -0.07. Likewise, the overall agreement for severe sepsis and septic shock were both 87 percent, with Kappa statistics of 0.72 and 0.58, respectively. Note that the Kappa value is affected by the prevalence of the finding under consideration, similar to positive predictive value being influenced by the prevalence of the condition. For rare findings, very low values of Kappa may not necessarily reflect low rates of overall agreement (Viera, Garrett, 2005).

This time-sensitive measure requires a blood culture to occur within 4 hours of the diagnosis of sepsis syndrome. It was sometimes difficult for abstractors to identify the time at which this

event actually occurred. For example, a nurse's note might state that a blood draw occurred at a given time, but the laboratory notes would indicate a different time. Across the 15 medical records compared for IRR, 13 total times were abstracted for the numerator. Overall, 51 total times were abstracted for the diagnosis of sepsis, and 13 times were abstracted for the diagnoses of severe sepsis and septic shock.

Table 5 (see Supporting Documents) shows the percent agreement and Kappa statistic for assessing whether a blood culture was conducted within 4 hours of a sepsis diagnosis for each site and across all sites. The overall agreement for conducting a blood culture within 4 hours of sepsis diagnosis was 80 percent with a Kappa statistic of 0.29. In addition, the reliability of determining the time at which key sepsis-related events took place was assessed. The overall agreement for identifying the time at which a sepsis diagnosis made (±15 minutes) was 40 percent. Similarly, the overall agreement for identifying the time at which severe sepsis diagnosis was made (±15 minutes) was 33 percent and for identifying the time of a septic shock diagnosis (±15 minutes) was 73 percent. Note that a Kappa statistic could not be calculated for the time of diagnoses measures, since disagreement of times could not be classified appropriately for statistical computation.

Discrepancies

When discrepancies between abstractors were found, the abstractors and a study team member reopened the EHR to review each abstractor's response and determine the correct answer. After discussion, a consensus result was obtained, and inconsistent records were corrected for the final dataset. When consistent differences were noted between the abstractors, clarification was provided and the abstraction tool modified, where appropriate.

For the measure numerator, timely blood culture, 13 of 15 records agreed, resulting in an 87 percent agreement and a Kappa score of -0.07 (see Table 4, in the Supporting Documents). This indicates that the two discrepancies were more than what was expected by chance. For one of the discrepancies, there actually was a blood culture done, and there did not appear to be a reason that one of the abstractors did not document it. In the other case, laboratory testing had been done, but a blood culture was not included. During the review and retraining, it was reiterated to ensure a blood culture was done, rather than just having general blood work.

For both severe sepsis and septic shock diagnoses, 13 of 15 records agreed, resulting in an 87 percent agreement and Kappa scores of 0.72 and 0.58, respectively. The Kappa statistic was lower for septic shock (0.58) because of a higher expected agreement.

For severe sepsis, one abstractor indicated that there was a low systolic blood pressure despite the administration of isotonic intravenous fluid bolus greater than or equal to 40 mL/kg in 1 hour, while the other abstractor did not. Upon review, it was discovered that there was a fluid bolus given but not at the rate required. For the second discrepancy, one abstractor indicated that there was mechanical ventilation indicating respiratory distress syndrome, while the other abstractor did not document any mechanical ventilation. During the review discussion, it was found that there was mechanical ventilation, which was missed by the second abstractor.

For septic shock, one discrepancy was the same as a discrepancy for the severe sepsis diagnosis; one abstractor indicated that there was a low systolic blood pressure despite the administration of an isotonic intravenous fluid bolus greater than or equal to 40 mL/kg in 1 hour. However the fluid bolus was not at the required rate. The other discrepancy was due to one abstractor recording a systolic blood pressure reading of 79, despite administration of a fluid bolus of at least 40 mL/kg in 1 hour. The other abstractor did not indicate that there was a fluid bolus at this rate. During review, it was found that the chart indicated that a 1000 mL bolus was prepared, but later in the chart it was recorded that the dose administered was 0 mL. Therefore, it was unclear whether or not the fluid was administered to the patient.

During the review and retraining, the locations for determining whether a bolus was administered and at what rate were reviewed so that abstractors would be able to better locate and identify them in the future. Additionally, it was reiterated that the fluid bolus had to be at the rate indicated by the measure specification and data abstraction tool.

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 validity of this measure was determined from two perspectives: face validity and validity of medical record data.

Face Validity

Face validity is the degree to which the measure construct characterizes the concept being assessed. The face validity of this measure was established by a national panel of experts and a parent representative for families of children with sepsis syndrome convened by Q-METRIC. The Q-METRIC panel included nationally recognized experts in the identification and treatment of pediatric sepsis syndrome, representing neonatology, hematology/oncology, infectious diseases, emergency medicine, nursing, pediatric surgery, and pediatric intensive care. In addition, measure validity was considered by experts in State Medicaid program operations, health plan quality measurement, health informatics, and health care quality measurement. In total, the Q-METRIC sepsis panel included 15 experts, providing a comprehensive perspective on sepsis syndrome care and the measurement of quality metrics for States and health plans.

The Q-METRIC expert panel concluded that this measure has a high degree of face validity through a detailed review of concepts and metrics considered to be essential to effective sepsis syndrome identification and treatment. Concepts and draft measures were rated by this group for their relative importance. This measure was highly rated, receiving an average score of 6.9 (with 9 as the highest possible score).

Validity of Abstracted Data

This measure was tested using medical record data. This source is considered the gold standard for clinical information; our findings indicate that these data have a high degree of face validity. This measure was tested among a total of 274 children younger than 19 years of age with sepsis syndrome (Table 6, see Supporting Documents). Overall, 70 percent of children with sepsis syndrome had a blood culture drawn within 4 hours of meeting diagnostic criteria for sepsis syndrome (range: 60 percent-77 percent).

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 documentation of race and ethnicity in the medical record varied across sites. As available in the medical record, race and ethnicity of the 300 children whose records were reviewed was obtained; Table 7 (see Supporting Documents) summarizes the distribution of race and ethnicity groups for each site. For the records reviewed, most cases eligible for review were for white children; however, at Hospital 3 the majority of cases reviewed were for black children.

7.B. Special Health Care Needs

The medical record data abstracted for this study did not include indicators of special health care needs.

7.C. Socioeconomic Status

The medical record data abstracted for this study did not include indicators of socioeconomic status.

7.D. Rurality/Urbanicity

The medical record data abstracted for this study did not include indicators of urban/rural residence.

7.E. Limited English Proficiency (LEP) Populations

The medical record data abstracted for this study did not include indicators of limited English proficiency.

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?

This measure is based on a review of medical record data. The medical chart audit included records from three of the largest hospitals serving children in Michigan: Children's Hospital of Michigan, Hurley Medical Center, and C.S. Mott Children's Hospital - UMHS. Data were abstracted from electronic health record (EHR) systems at all three sites.

Medical records for 100 children with sepsis syndrome meeting the measure specification criteria during the measurement period were abstracted at each site. In total, 300 unique and valid records were reviewed; 274 records (91 percent) met denominator criteria for this measure.

Based on the abstracted chart data, the rate was calculated as the proportion of children younger than 19 years of age identified as having sepsis syndrome who had a blood culture drawn within 4 hours of meeting diagnostic criteria for sepsis syndrome (70 percent), calculated as measure numerator (191) divided by denominator (274), as indicated in Table 6 (see Supporting Documents).

Medical record abstraction for this measure was accomplished with a data collection tool developed using LimeSurvey software (version 1.92, formerly PHPSurveyor). LimeSurvey is an open-source online application based in MySQL that enables users to develop and publish surveys, as well as collect responses. The tool was piloted to determine its usability and revised as necessary. The technical specification for this measure also underwent revisions following pilot testing.

Data abstraction was completed by experienced nurse abstractors who had undergone training for each medical record system used. Abstractors participated in onsite training during which the measure was discussed at length to include the description, calculation, definitions, eligible population specification, and exclusions. Following training, abstractors were provided with a coded list of potentially eligible cases from each of the sites. To abstract all pertinent data, two to four nurse abstractors, depending on the site, reviewed the electronic records. In addition to the specific data values required for this measure, key patient characteristics, such as date of birth and sex, were also collected.

Abstraction Times

In addition to calculating IRR, the study team assessed how burdensome it was to locate and record the information used to test this measure by having abstractors note the time it took to

complete each record. On average, the abstractors spent 11 minutes abstracting the data for this measure per eligible sepsis case, with time ranging from 1 to 45 minutes.

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?

This measure was deemed to be feasible by Q-METRIC using medical record data abstracted from EHR systems in three large hospitals serving children in Michigan.

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.

To our knowledge, this measure is not in use for children anywhere in the United States.

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?

Not applicable.

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

Not applicable.

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)**
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.

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)**
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.

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)**
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.

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

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
Individual practitioner: Can compare individual health care professionals

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?**
Includes all hospitalized children with sepsis syndrome (see Table 1 in the Supporting Documents).

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?**
None identified.

Provider Level
Hospital: Can compare hospitals

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
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)**
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.

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).

This measure provides families with a straightforward measure to assess how well basic levels of comprehensive care are being provided for children with sepsis syndrome. Low rates for the provision of care are easily understood to be unsatisfactory. The simplicity of the measure likewise makes it a straightforward guide for providers and purchasers to assess how well comprehensive care is being provided to children with sepsis syndrome.

This measure has not been assessed for comprehension. The primary information needed for this measure comes from medical record data and includes basic demographics, diagnostic codes, and procedure codes, all of which are widely available. The nurse abstractors testing the measure provided feedback to refine the abstraction tool and thus the specifications. These changes are reflected in the final documentation.

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 may enhance the use of this measure by providing the vehicle for ensuring timely completion of these activities and by providing queues for these activities that are aligned with roles. For example, when a patient arrives to an emergency department that has performed poorly on these measures, the source of poor performance may be related to waiting times. Health IT in the triage area could trigger different decision-making that allows these patients to be seen more quickly. Another source might be documentation of completed tasks, which can be either automated by health IT or augmented by systems such as mobile entry tools for nursing staff. In terms of queues, health IT can alert phlebotomists to draw blood for the studies, regardless of where the patient is and where the blood-drawing team is located.

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?

This measure was tested using medical record review conducted at three large hospitals in Michigan; medical records were abstracted using the EHR system at each participating site.

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.

This information is most typically captured in orders or in results within the EHR or computerized physician order entry (CPOE) systems. It will be captured by nurses, technicians, or physicians, depending on the workflow of the care setting (emergency department, ward, or intensive care unit). Although visit documentation may be helpful to ascertain if any of these activities was completed, this documentation may not be a useful source for these specific

measures since times may not be accurate in these notes. However, accuracy may vary across setting; for example, in some hospitals, medical records might be more accurate in the ICU setting.

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)?

Yes.

If yes, please describe.

The ONC's Health IT Standards explicitly address the receipt of laboratory results and other diagnostic tests into EHRs, which are directly relevant to this measure. In addition, these standards indicate the requirement for EHRs to track specific patient conditions, such as pediatric sepsis syndrome. The ONC standards include the following specific requirements in the Certification criteria (ONC, 2010) pertaining to Stage 2 Meaningful Use requirements:

Stage 2 (beginning in 2013): CMS has proposed that its goals for the Stage 2 meaningful use criteria expand upon the Stage 1 criteria to encourage the use of health IT for continuous quality improvement at the point of care. In addition, the exchange of information in the most structured format possible is encouraged. This can be accomplished through mechanisms such as the electronic transmission of orders entered using CPOE and the electronic transmission of diagnostic test results. Electronic transmission of diagnostic test results includes a broad array of data important to quality measurement, such as blood tests, microbiology, urinalysis, pathology tests, and radiology studies.

Incorporate clinical laboratory test results into EHR as structured data:

1. Electronically receive clinical laboratory test results in a structured format and display such results in human readable format.
2. Electronically display in human readable format any clinical laboratory tests that have been received with LOINC® codes.
3. Electronically display all the information for a test report specified at 42 CFR 493.1291(c) (1) through (7).

Generate lists of patients by specific conditions to use for quality improvement reduction of disparities outreach:

4. Enable a user to electronically update a patient's record based upon received laboratory test results. Enable a user to electronically select, sort, retrieve, and output a list of patients and patients' clinical information, based on user-defined demographic data, medication list, and specific conditions.

11.E. Health IT Calculation

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

Missing or ambiguous information in the following areas could lead to missing cases or calculation errors:

1. Child's date of birth.
2. ICD-9 codes selected to indicate sepsis syndrome (sepsis, severe sepsis, septic shock).
3. Date and time of treatment.
4. Type of tests performed.
5. Time of tests performed.
6. Care setting.

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?

Being able to show these measure results using health IT, especially to patients, might be transformative. Imagine, for example, an electronic white board in the room that describes "Our goals for your care" that has green, yellow, and red lights next to each of these measures. This system would be hypothesized to improve delivery of this care. Another approach that has been demonstrated to significantly improve quality is use of a process control system: health care administrators or leaders could monitor care to ensure 100 percent compliance with these measures, employing the same types of warnings to spur action before the time window has expired.

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).

This measure assesses the proportion of children younger than 19 years of age identified as having sepsis syndrome who had a blood culture drawn within 4 hours of meeting diagnostic criteria for the condition. A higher proportion indicates better performance, as reflected by appropriate treatment.

This measure was developed with the use of medical record data; the testing results reported here required the development of an abstraction tool and use of qualified nurse abstractors. Information needed for this measure includes date of birth, diagnosis codes, procedure codes, and

event dates and times. Our findings indicate that these data are generally available. However, we observed several limitations regarding event times that directly influence this measure, such as timeliness of a blood culture being performed. Missing or discrepant times were observed and may be mitigated through future improvements to EHR systems to ensure accurate and complete times are recorded for a sepsis diagnosis and subsequent blood culture. Note that continuing advances in the development and implementation of EHR systems may establish the feasibility of regularly implementing this measure with data supplied by electronic medical records.

In future implementation, some considerations may strengthen this measure and potentially ease the burden of data collection. Specific feedback from our medical record abstractors suggested that it may be helpful that for time-sensitive events, a specific hierarchy be developed *a priori* regarding the most reliable source of time or a determination made that the earliest time specified for any given event is the time to be recorded, with this information being included in the measure specification. It was noted that there were patients who had a blood culture drawn prior to meeting the required diagnostic criteria and that the specification should indicate if these individuals satisfy the numerator criteria.

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.

This measure, Timely Blood Culture for Children with Sepsis Syndrome, assesses the proportion of children younger than 19 years of age identified as having sepsis syndrome who had a blood culture drawn within 4 hours of meeting diagnostic criteria for sepsis. A higher proportion indicates better performance. This measure was tested using electronic medical record data. There are no existing quality measures for timely blood culture for children with sepsis syndrome presenting to a hospital setting.

Sepsis is a potentially catastrophic condition, one that can escalate from infection to organ failure and death within hours. The Surviving Sepsis Campaign clinical guidelines emphasize the critical importance of early recognition and aggressive treatment for all suspected cases of pediatric sepsis syndrome (Dellinger, et al., 2013). Clinicians must be ready to rapidly deploy a set of time-sensitive, goal-directed, stepwise procedures to hinder or reverse the cascade of events in sepsis that lead to organ failure. One essential element of timely and appropriate treatment is the blood culture. Promptly obtaining a blood culture to identify the invading pathogen helps clinicians determine an effective antimicrobial regimen. However, despite the availability of evidence-based guidelines for the care of children with sepsis, only a minority of children receive the standard of care for many reasons, including lack of experience, resources, and familiarity with clinical guidelines.

Q-METRIC tested this measure among a total of 275 eligible children younger than 19 years of age with sepsis syndrome. Results showed that a blood culture was drawn within 4 hours of meeting diagnostic criteria for 70 percent of children with sepsis syndrome (range: 60 percent-77 percent).

This measure provides families, clinicians, and purchasers with a straightforward means of assessing how well basic levels of comprehensive care are being provided for children with sepsis syndrome. The primary information needed for this measure includes basic demographics, dates, times, diagnostic codes, and procedure codes, all of which are widely available. Continuing advances in the development and implementation of health IT may establish the feasibility of regularly implementing this measure with data supplied by electronic medical records.

References

Angus DC, Linde-Zwirble WT, Lidicker J, et al. Epidemiology of severe sepsis in the United States: Analysis of incidence, outcome, and associated costs of care. Crit Care Med 2001; 29(7):1303-10.

Brierley J, Carcillo JA, Choong K, et al. Clinical practice parameters for hemodynamic support of pediatric and neonatal septic shock: 2007 update from the American College of Critical Care Medicine. Crit Care Med 2009; 37(2):666-88.

Carcillo JA, Fields AI, Task Force Committee Members. Clinical practice parameters for hemodynamic support of pediatric and neonatal patients in septic shock. Crit Care Med 2002; 30(6):1365- 78.

Cruz AT, Perry AM, Williams EA, et al. Implementation of goal-directed therapy for children with suspected sepsis in the emergency department. Pediatrics 2011; 127(3); e758-66.

Dellinger RP, Levy MM, Rhodes A, et al. Surviving Sepsis Campaign: International guidelines for management of severe sepsis and septic shock: 2012. Crit Care Med 2013; 41(2): 580-637. Update available at http://www.survivingsepsis.org/Guidelines/Pages/default.aspx. Accessed January 17, 2018.

Goldstein B, Giroir B, Randolph A, et al. International pediatric sepsis consensus conference: Definitions for sepsis and organ dysfunction in pediatrics. Pediatr Crit Care Med 2005; 6(1):2-8.

Han YY, Carcillo JA, Dragotta MA, et al. Early reversal of pediatric-neonatal septic shock by community physicians is associated with improved outcome. Pediatrics 2003; 112 (4):793-9.

Khilnani P, Deopujari S, Carcillo J. Recent advances in septic shock. Indian J Pediatr 2008; 75:821-30.

Kumar A, Roberts D, Wood KE, et al. Duration of hypotension before initiation of effective antimicrobial therapy is the critical determinant of survival in human septic shock. Crit Care Med 2006; 34(6):1589-96.

Larsen GY, Mecham N, Greenberg R. An emergency department septic shock protocol and care guideline for children initiated at triage. Pediatrics 2011; 127(6):e1585-92.

Melendez E, Bachur R. Advances in the emergency management of pediatric sepsis. Curr Opin Pediatr 2006; 18:245-53.

New York Codes, Rules, and Regulations Title 10 (Health): Section 405.2 – governing body. http://w3.health.state.ny.us/dbspace/NYCRR10.nsf/56cf2e25d626f9f785256538006c3ed7/8525652c00680c3e8525652c006322b3?OpenDocument&Highlight=0,sepsis; Accessed June 25, 2014.

New York Codes, Rules, and Regulations Title 10 (Health): Section 405.4 – medical staff. http://w3.health.state.ny.us/dbspace/NYCRR10.nsf/56cf2e25d626f9f785256538006c3ed7/bc8961f6b14230318525677e00726457?OpenDocument&Highlight=0,sepsis. Accessed June 25, 2014.

Odetola FO, Gebremariam A, Freed GL. Patient and hospital correlates of clinical outcomes and resource utilization in severe pediatric sepsis. Pediatrics 2007; 119(3):487-94.

Office of the National Coordinator for Health IT Standards and Certification (ONC). Health information technology: Initial set of standards, implementation specifications, and certification criteria for electronic health record technology." Fed Regist 75(8): 2013-47.

Oliveira CF, Nogueira de Sá FR, Oliveira DSF, et al. Time- and fluid-sensitive resuscitation for hemodynamic support of children in septic shock: Barriers to the implementation of the American College of Critical Care Medicine/Pediatric Advanced Life Support Guidelines in a pediatric intensive care unit in a developing world. Pediatr Emerg Care 2008; 24(12):810-5.

Rivers EP, Ahrens T. Improving outcomes for severe sepsis and septic shock: Tools for early identification of at-risk patients and treatment protocol implementation. Crit Care Clin 2008; S1-47.

Rooney Z, Nadel S. Optimizing intensive care management in paediatric sepsis. Curr Opin Infect Dis 2009; 22:264-71.

Saladino RA. Management of septic shock in the pediatric emergency department in 2004. Clin Pediatr Emerg Med 2004; 5:20-7.

Skippen P, Kisson N, Waller D, et al. Sepsis and septic shock: Progress and future considerations. Indian J Pediatr 2008; 75(6):599-607.

VHA, Inc. Sepsis: Percent of patients with severe sepsis/septic shock who had 2 sets of blood cultures collected within 24 hours following severe sepsis/septic shock identifications. National Quality Measures Clearinghouse. 2007 (currency reaffirmed 2011).

Viera AJ, Garrett JM. Understanding interobserver agreement: The Kappa statistic. Fam Med 2005; 37(5):360-3.

Watson RS, Carcillo JA, Linde-Zwirble WT, et al. The epidemiology of severe sepsis in children in the United States. Am J Respir Crit Care Med 2003; 167(5):695-701.

WebMD (Web resource). Information and resources: Blood culture. Available at https://www.webmd.com/a-to-z-guides/blood-culture#1. Accessed January 17, 2018.

Weinstein MP, Reller LB, Murphy JR, et al. The clinical significance of positive blood cultures: A comprehensive analysis of 500 episodes of bacteremia and fungemia in adults. I. Laboratory and epidemiologic observations. Rev Infect Dis 1983; 5(1):35-53.

Section 14: Identifying Information for the Measure Submitter

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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.

AHRQ Publication No. 18-P002-2-EF
February 2018