

Timely Fluid Bolus for Children with Severe Sepsis or Septic Shock

Section 1. Basic Measure Information

1.A. Measure Name

Timely Fluid Bolus for Children with Severe Sepsis or Septic Shock

1.B. Measure Number

0231

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 with severe sepsis or septic shock who received a fluid bolus within 60 minutes of meeting diagnostic criteria for this 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 (Odetola, Gebremariam, Freed, 2007; Watson, Carcillo, Linde-Zwirble, et al., 2003). Also, annual hospital treatment costs are significant, at nearly \$2 billion (Watson, et al., 2003). Clinical practice parameters and clinical 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 to 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 prompt initiation of fluid resuscitation in order to restore circulation, thus decreasing the risk of organ failure (Rivers, Ahrens, 2008). Fluid boluses should be started within the first hour of recognition of severe sepsis or septic shock (Brierley, Carcillo, Choong, et al., 2009). Research has shown that early and sufficient amounts of fluid administered within the first hour following the recognition of severe sepsis and septic shock have been associated with decreased mortality by attenuating the inflammatory response characteristic of sepsis and restoring the circulation and organ perfusion (Oliveira, Nogueira de Sa, Oliveria, et al., 2008).

This measure uses medical record data to calculate the proportion of eligible children who received a fluid bolus within 60 minutes of being diagnosed with severe sepsis or septic shock.

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 severe sepsis or septic shock who received a fluid bolus within 60 minutes of meeting diagnostic criteria for these conditions. Eligible children are all those admitted to the hospital, including the emergency department (ED). Severe sepsis and septic shock are defined in Table 1 (see Supporting Documents).

Codes to identify potential severe sepsis and septic shock cases using administrative data to identify medical records for review are documented in Table 2 (see Supporting Documents). Fluid bolus is defined as $\geq 20\text{mL/kg}$ of intravenous or intraosseous fluid administered over ≤ 15 minutes.

1.H. Numerator Exclusions

1. All children in the neonatal intensive care unit (NICU).
2. Children with chronic renal failure as defined by any mention of chronic renal failure or end-stage renal disease.
3. Children with congestive heart failure as defined by any mention of congestive heart failure.
4. Children who died within 60 minutes of meeting diagnostic criteria for severe sepsis or septic shock.
5. Patients with advanced directives for comfort care.
6. 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 severe sepsis or septic shock. Eligible children are all those admitted to the hospital, including the ED. Severe sepsis and septic shock are defined in Table 1 (see Supporting Documents). Codes to identify potential severe sepsis and septic shock 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 in the NICU.
2. Children with chronic renal failure as defined by any mention of chronic renal failure or end-stage renal disease.
3. Children with congestive heart failure as defined by any mention of congestive heart failure.
4. Children who died within 60 minutes of meeting diagnostic criteria for severe sepsis or septic shock.
5. Patients with advanced directives for comfort care.
6. 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 Medical Record.

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.

Please see Supporting Documents for Detailed Measure 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 invasion by 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). 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 occurring during infancy as reported by Angus, Linde-Zwirble, Lidicker, et al. (2001) at 5.3/1,000 infants and Watson, et al. (2003) at 5.16/1,000 infants. Odetola and colleagues (2007) 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.

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, 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 are also reports of age-specific differences in mortality from pediatric sepsis. Higher mortality rates 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 children (Oliveira, et al., 2008). Also, older pediatric patients have been sick longer than younger patients and may also have experienced more hospital admissions and treatments, such as transplantation or chemotherapy, making them more vulnerable to sepsis syndrome (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 as high as 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. 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 38.5°C [hyperthermia] or less than 36°C [hypothermia]); abnormal leukocyte count (elevated or depressed); accelerated heart rate (tachycardia); or accelerated respiratory rate (tachypnea) (Goldstein, et al., 2005). 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 dysfunction (respiratory, renal, neurologic, hematologic, or hepatic) (Goldstein, et al., 2005). 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 Timely Fluid Resuscitation

Early recognition of sepsis syndrome and prompt treatment in the ED are essential to achieving successful outcomes (Dellinger, et al., 2013; 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 then to promptly initiate appropriate treatment to hinder or reverse progression to the later stages of severe sepsis and septic shock (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 prior to escalation to severe sepsis or septic shock (Rivers, Ahrens, 2008).

The current management strategy for treatment is goal-directed 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 the circulation and perfusion to vital organs (Khilnani, Deopujari, Carcillo, 2008). The components of early goal-directed therapy include prompt resuscitation of poor perfusion through the administration of intravenous fluids; 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).

International guidelines recommend that fluid resuscitation for children begin as soon as possible, ideally within the first hour following recognition of severe sepsis or septic shock (Brierley, et al., 2009; Carcillo, et al., 2002; Dellinger, et al., 2013). Children at these stages of sepsis syndrome are experiencing severe fluid loss (hypovolemia) due to mechanisms such as capillary leakage, excessive sweating, and increased respiration. This loss of fluid renders the heart unable to pump

enough blood through the body, precipitating organ dysfunction. Fluid therapy addresses this problem by increasing systemic blood flow and oxygen delivery, thus potentially avoiding further clinical deterioration and improving outcomes. However, delay in initiating fluid resuscitation can contribute to peripheral vascular failure and irreversible defects in oxygen delivery, culminating in failure of vital organs (Dünser, Festic, Dondorp, et al, 2012; Khilnani, et al., 2008).

A limited window of opportunity exists for treating underlying injury once shock is present. Odds of mortality have been shown to double with each passing hour of persistent shock, and each hour of delay in resuscitation has been associated with a 50 percent increase in odds of mortality (Han, et al., 2003). To address this issue, Larsen and colleagues studied the effects of implementing a septic shock protocol for children, designed to increase compliance with key interventions such as fluid resuscitation and timely antibiotic therapy (Larsen, et al., 2011). Use of the protocol was associated with a significant decrease in length of stay in the hospital and a trend toward decreased mortality in children who received initial fluid resuscitation of at least 20 mL/kg (normal saline [NS]) within an hour, as well as antibiotics within 3 hours of admission to the ED coupled with assessment of serum lactate (Larsen, et al., 2011).

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 delay in the recognition and treatment of pediatric shock (Cruz, Perry, Williams, et al., 2011). These barriers include varying levels of experience among ED 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 (Cruz, et al., 2011). Similarly, Oliveria and colleagues suggested reasons for delay may include inaccuracy in assessing the severity of a child's state of shock, shortage of health care providers, fatigue among medical teams, and difficulty in establishing adequate intravascular access (Oliveira, et al., 2008).

Treatment of septic shock cannot start at arrival at the intensive care unit; it must begin when patients present to the ED (Larsen, et al., 2011). Early recognition and treatment of septic shock right from presentation to the ED benefits all patients because it leads to more meticulous patient assessment (Larsen, et al., 2011). The development of ED shock protocols for pediatric patients with sepsis syndrome standardizes and facilitates care by providing explicit instructions regarding interventions and timeframes (Cruz, et al., 2011). This will allow earlier intervention and harness resources for very ill children. To mitigate delay in the recognition of sepsis, a triage tool could aid improved recognition of abnormal vital signs and lead to more timely identification and treatment of patients at risk (Cruz, et al., 2011).

Another possible performance barrier has to do with hospital type and location. Many children live far from medical facilities that offer specialized pediatric care. For those presenting with septic shock to remote community hospitals, resuscitation efforts made by attending physicians are crucial to their survival and should be prioritized. Delay in resuscitation while waiting to transfer patients to a more advanced pediatric medical facility is unwise (Han, et al., 2003). In a 9-year retrospective study, Han and colleagues reported 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 (Han, et al., 2003). In a separate report, Odetola and colleagues (2007) reported that pediatric patients with sepsis who were transferred incurred higher charges than those whose care did not entail transfer.

As clinical guidelines for the treatment of sepsis were developed at pediatric academic centers without accounting for use at community hospitals, barriers to use may exist (Han, et al., 2003). For example, some community physicians may lack the specialized technical skills necessary for treating children with severe sepsis or septic shock. Educational barriers regarding the guidelines themselves may curtail implementation if physicians are unaware of or lack the necessary support to execute stepwise, goal-directed interventions in a timely manner. However, most of the procedures detailed in current guidelines are easily within the scope of a community-based practice (Han, et al., 2003). Continued efforts to increase knowledge and comfort with sepsis guidelines among community physicians will likely improve outcomes. Odetola and colleagues also noted an urgent need for concerted clinical and educational efforts within the clinical care setting designed to limit the progression of sepsis severity, as multiple organ dysfunction portends poor outcomes including death (Odetola, et al., 2007).

Regarding fluid resuscitation at community hospitals, Han and colleagues found that practice tended to be conservative. Community physicians administered similar median volumes of fluid therapy (20 mL/kg) to pediatric patients with persistent shock and those in whom shock was reversed (Han, et al., 2003). This finding suggests that community physicians tended not to administer additional fluid boluses to patients who remained in persistent shock after providing an initial fluid bolus. When faced with persistent septic shock, community physicians tended to escalate preferentially to inotropic/vasopressor support, rather than additional fluid therapy. While children in septic shock require inotropic/vasopressor support, the hemodynamic impact of catecholamine infusions may be undermined by inadequate fluid resuscitation. This practice may suggest unfamiliarity with clinical guidelines (Han, et al., 2003).

Oliveira and colleagues noted that while the importance of time- and fluid-sensitive treatment for patients with severe sepsis or septic shock is well known, the lack of local clinical protocols and treatment goals limited the behavior of health care providers (Oliveira, et al., 2008). These researchers found that while physicians were aware of existing guidelines, nurses were less familiar with them. Nurses often did not know why a patient was receiving a particular treatment, which might explain the failure noted by Oliveira and colleagues (2008) to consistently observe achievement of at least a 40-mL/kg dose of fluid resuscitation in the first hour of treatment of septic shock. Special attention should be given to nursing education, these researchers say, emphasizing the critical role of good vascular access and the importance of teamwork.

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 children with Medicaid/CHIP can have a diagnosis of sepsis. Likewise, hospitals that treat children for sepsis are likely to encounter patients with Medicaid/CHIP coverage. Sepsis is one of the top 10 most expensive diseases managed by hospitals, accounting for 2.8 percent (\$24.8 billion) of the national hospital bill in 2005. Of these charges, approximately \$19.5 billion was 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 currently are no known quality measures related to timely fluid bolus for pediatric patients with severe sepsis or septic shock. 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, 2017). The regulations in New York exemplify an 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?

- Care Setting – ambulatory: No.**
- 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 special health care needs/chronic 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:** No.
- m. **Measure Topic other (please specify):** No.
- 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 19 years of age).
- 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 for children diagnosed with severe sepsis or septic shock (receiving a fluid bolus within 60 minutes of meeting diagnostic criteria) that, if followed, results in a desirable outcome (reduced mortality). Expert consensus has identified recognition of sepsis syndrome and aggressive treatment of its symptoms 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 prompt initiation of fluid resuscitation in order to maintain or restore circulation, thus decreasing the risk of organ failure and mortality. Table 3 (see Supporting Documents) summarizes several key sources of evidence for this measure, using the U.S. Preventive Services Task Force (USPSTF) rankings (criteria denoted as a note to Table 3, see Supporting Documents).

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 if they cannot be aroused. Other clinical signs of septic shock in children with a suspected infection include: (1) hypothermia or hyperthermia; (2) signs of inadequate tissue perfusion, including any of the following: prolonged capillary refill greater than 2 seconds, diminished pulses, mottled cool extremities, flash capillary refill, bounding peripheral pulses, or wide pulse pressure; and (3) decreased urine output less than 1 mL/kg/h. Because children often maintain their blood pressure until they are severely ill, systemic hypotension is not a requirement for diagnosis of septic shock in children; in fact, shock may occur long before blood pressure collapses (Goldstein, et al., 2005). While hypotension is not necessary for the clinical diagnosis of septic shock, its presence in a child with clinical suspicion of infection is confirmatory (Brierley, et al., 2009).

The current management strategy for septic shock focuses on antimicrobial and hemodynamic goal-directed therapies. All interventions are directed at killing the offending microorganism and restoring normal perfusion to vital organs and restoring the circulation (Saladino, 2004). Goals for the first hour of resuscitation 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 of resuscitation 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, normal ionized calcium concentration (Brierley, et al., 2009; Dellinger, et al., 2013), decreased lactate, and decreased base deficit and mixed venous oxygen saturation of greater than 70 percent (Dellinger, et al., 2013).

Age is an important determinant of risk of bacterial infection, whether related to maturation of the immune system or exposure to microbes common to an environment or peer group (Saladino,

2004). 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 meningitidis*, 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 influenzae* type B, *S. pneumoniae*, and *N. meningitidis* has changed the epidemiology of severe sepsis in children (Rooney, Nadel, 2009). Those who are chronically ill or immunocompromised make up a larger portion of the population with severe sepsis in children than in adults (Goldstein, et al., 2005).

Viruses and fungi also cause sepsis, particularly in immunocompromised and very young or premature infants (Rooney, Nadel, 2009). Fungi account for approximately 5 percent of all cases of sepsis syndrome (Bochud, Bonten, Marchetti, et al., 2004). Most cases of fungal sepsis are caused by *Candida* species, which is associated with the highest mortality (40 percent) of all bloodstream pathogens. Between 1979 and 2000, the incidence of fungal sepsis increased threefold (Bochud, et al., 2004).

In decreasing order of frequency, the main sites of infection in patients with severe sepsis and septic shock are the lungs, bloodstream, abdomen, urinary tract, and skin and soft tissue (Bochud, et al., 2004). 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 the invading pathogen and the different host systems in the body (Rooney, Nadel, 2009). It is a dynamic condition 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 the pathogen in a manner that creates potentially harmful molecules, which, in turn, 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 the response to the pathogen, contributing to morbidity and mortality (Rooney, Nadel, 2009).

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 homeostasis 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).

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 here.

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. Among the three sites, 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 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, 10 of 300 unique patient records (3 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 must not meet specific exclusion criteria (in NICU, have renal failure, have congestive heart failure) in addition to meeting diagnostic criteria (severe sepsis and septic shock). Therefore, IRR was also assessed for these eligibility criteria. For identifying children in the NICU, 11 of 300 unique patient records (4 percent) were assessed for IRR across the three testing sites. For identifying children with renal failure or congestive heart failure, 10 of 300 unique patient records (3 percent) were assessed for IRR across the three testing sites. For severe sepsis and septic shock, 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 statistic for the numerator and the eligibility criteria of this measure for each site and across all sites. The overall agreement for timely fluid bolus was 80 percent, and the Kappa was 0.38. The overall agreement for being in the NICU, having renal failure, or having congestive heart failure was 100 percent with corresponding Kappa statistics of 1.00. The overall agreement for severe sepsis and for septic shock diagnosis criteria 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 the administration of a fluid bolus within 60 minutes of meeting diagnostic criteria for severe sepsis or septic shock. It was sometimes difficult for abstractors to identify the time at which events actually occurred. For example, a nurse's note might state that an event occurred at a given time, but the laboratory notes would indicate a different time. In addition, there were physician's notes that stated that an event occurred on a specific day, but the time of day was not recorded. Across the 10 medical records compared for IRR, 14 total times were abstracted for the numerator. Overall, 13 times were abstracted for the diagnoses of severe sepsis and septic shock.

Table 5 shows the percent agreement and Kappa statistic for assessing whether a fluid bolus was administered within 60 minutes of a severe sepsis or septic shock diagnosis for each site and across all sites. The overall agreement for administering a fluid bolus within 60 minutes of diagnosis was 80 percent with a Kappa statistic of 0.38. 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 severe sepsis diagnosis was made (± 15 minutes) was 33% and for

identifying the time of a septic shock diagnosis (± 15 minutes) was 73%. Note that a Kappa statistic cannot 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 electronic medical record 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 was modified, where appropriate.

For the measure numerator, timely fluid bolus, 8 of 10 records agreed, resulting in an 80 percent agreement and a Kappa score of 0.38 (see Table 4 in the Supporting Documents). When reviewing the two discrepancies, it was found that in one case, the first abstractor correctly recorded a fluid bolus, while the second abstractor indicated no fluid bolus. In the other instance, the second abstractor found evidence of a fluid bolus and the first did not. During review, it was determined that fluid boluses were given to both patients. There did not appear to be a clear reason that the documentation was missed; however, identifying the presence of a fluid bolus was reportedly more difficult than finding other documentation.

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 than 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 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 1,000 mL bolus was prepared, but later in the chart it was recorded that the dose administered was 0 mL. Therefore, it was unclear whether 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 may better locate and identify them in the future. Additionally, it was reiterated that the fluid bolus must 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 8.3 (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. This measure was tested among a total of 30 children younger than 19 years of age with severe sepsis or septic shock (Table 6, see Supporting Documents). Overall, 50 percent of children with severe sepsis or septic shock received a fluid bolus within 60 minutes of meeting diagnostic criteria for severe sepsis or septic shock (range: 29 to 67 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 information for 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 records data abstracted for this study did not include indicators of special health care needs.

7.C. Socioeconomic Status

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

7.D. Rurality/Urbanicity

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

7.E. Limited English Proficiency (LEP) Populations

The medical records data abstracted for this study did not include indicators of LEP.

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 the C.S. Mott Children's Hospital - UMHS. Data were abstracted from electronic health records (EHRs) 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; 30 records (10 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 with severe sepsis or septic shock who received a fluid bolus within 60 minutes of meeting diagnostic criteria for this condition (50 percent), calculated as measure numerator (15) divided by denominator (30) (See Table 6 in the Validity section).

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 8 minutes abstracting the data for this measure per eligible sepsis case, with time ranging from 1 to 20 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?

The measure was determined to be feasible by Q-METRIC using electronic medical record data at three large hospitals 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 currently 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?

Sample size includes all hospitalized children with clinical documentation of severe sepsis or septic shock.

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 means to assess how well basic levels of comprehensive care are being provided for children with severe sepsis or septic shock. 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 provided to children with severe sepsis or septic shock.

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, procedure codes, and times of services, 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 ED 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.

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) system. It will be captured by nurses, technicians, or physicians, depending on the workflow of the care setting (ED, 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 computerized provider order entry (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 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” and 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 hospitalized children younger than 19 years of age with severe sepsis or septic shock who received a fluid bolus within 60 minutes of meeting diagnostic criteria for this 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, which reflects timeliness of a fluid bolus being performed. Missing or discrepant times were observed and may be mitigated through future improvements to EHRs to ensure accurate time is recorded for a diagnosis of severe sepsis or septic shock and subsequent fluid bolus. Importantly, continuing advances in the development and implementation of EHRs may establish the feasibility of regularly implementing this measure with data supplied by electronic medical records.

In future implementation, there are considerations that may further 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 is the time to be collected, with this information being included in the measure specification.

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 Fluid Bolus for Children with Severe Sepsis or Septic Shock, assesses the proportion of hospitalized children younger than 19 years of age with severe sepsis or septic shock who received a fluid bolus within 60 minutes of meeting diagnostic criteria. A higher proportion indicates better performance, as reflected by appropriate treatment. This measure was tested using electronic medical record data. There are no existing quality measures for timely administration of a fluid bolus for children with severe sepsis or septic shock presenting to a hospital setting.

Sepsis is a potentially catastrophic condition that can escalate from infection to death within hours. Clinical practice parameters and clinical 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, including severe sepsis and septic shock. 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 prompt initiation of fluid resuscitation in order to maintain or restore circulation, thus decreasing the risk of organ failure. Research has shown that early and sufficient amounts of fluid administered within the first hour following the recognition of severe sepsis and septic shock have been associated with decreased mortality by attenuating the inflammatory response characteristic of sepsis. 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 30 eligible children younger than 19 years of age with severe sepsis or septic shock. Results showed that a fluid bolus was administered within 60 minutes of meeting diagnostic criteria for severe sepsis or septic shock for 50 percent of children with severe sepsis or septic shock (range: 29 to 67 percent).

This measure provides families, providers, and purchasers with a straightforward means of assessing how well basic levels of comprehensive care are being provided for children with severe sepsis or septic shock. The primary information needed for this measure includes basic demographics, dates and times of services, diagnostic codes, and procedure codes, all of which are widely available. Continuing advances in the development and implementation of health information technology 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.

Bochud P-Y, Bonten M, Marchetti O, et al. Antimicrobial therapy for patients with severe sepsis and septic shock: An evidence-based re view. *Crit Care Med* 2004; 32(11):S495-S512.

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, et al. 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.

Dünser MW, Festic E, Dondorp A, et al. Recommendations for sepsis management in resource-limited settings. *Intensive Care Med* 2012; 38:557-74.

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.

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. Effective May 17, 2017. Available at <http://w3.health.state.ny.us/dbspace/NYCRR10.nsf/56cf2e25d626f9f785256538006c3ed7/8525652c00680c3e8525652c006322b3?OpenDocument&Highlight=0,sepsis>; Accessed March 28, 2018.

New York Codes, Rules, and Regulations Title 10 (Health): Section 405.2 – medical staff. Effective May 17, 2017. Available at <http://w3.health.state.ny.us/dbspace/NYCRR10.nsf/56cf2e25d626f9f785256538006c3ed7/bc8961f6b14230318525677e00726457?OpenDocument&Highlight=0,sepsis>. Accessed March 28, 2018.

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 (ONC). Health information technology: Initial set of standards, implementation specifications, and certification criteria for electronic health record technology. Fed Regist 2010; 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; 24(3 Suppl):S1-47.

Rooney Z, Nadel S. Optimizing intensive care management in pediatric 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(1):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.

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.

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

Public Disclosure Requirements

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

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