SECTION I.
BASIC MEASURE INFORMATION

I.A. Measure Name

Timely Fluid Bolus for Children with Severe Sepsis or Septic Shock

I.B. Measure Citation Information

Odetola FO, Freed GL, Madden BW, Shevrin CA, McCormick J, Dombkowski KJ for the Quality Measurement, Evaluation, Testing, Review, and Implementation Consortium. Timely fluid bolus for children with severe sepsis or septic shock. National Quality Measures Clearinghouse (NQMC). Rockville (MD): Agency for Healthcare Research and Quality (AHRQ). Published June 8, 2015.

I.C. Measure Description

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% of hospitalized children with sepsis in the United States die (Watson et al., 2003; Odetola et al., 2007). 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 (Dellinger et al., 2013; Carcillo et al., 2002). Improved survival has been associated with adherence to guidelines that emphasize time-sensitive resuscitation of children with sepsis syndrome (Han 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 and Ahrens, 2008). Fluid boluses should be started within the first hour of recognition of severe sepsis or septic shock (Brierley 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 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.

I.D. Measure Owner

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

I.E. National Quality Forum (NQF) ID (if applicable)

Not applicable

I.F. Measure Hierarchy

Please use this section to note 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's National Quality Measures Clearinghouse and are available at http://www.qualitymeasures.ahrq.gov/about/hierarchy.aspx:

I.F.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.

I.F.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

I.F.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

I.F.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

I.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. Severe sepsis and septic shock are defined in Table 1.

Codes to identify potential severe sepsis and septic shock cases using administrative data to identify medical records for review are documented in Table 2. Fluid bolus is defined as ≥20mL/kg of intravenous or intraosseous fluid administered over ≤15 minutes.

I.H. Numerator Exclusions (as appropriate)

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.

I.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 emergency department. Severe sepsis and septic shock are defined in Table 1. Codes to identify potential severe sepsis and septic shock cases using administrative data to identify medical records for review are documented in Table 2.

I.J. Denominator Exclusions (as appropriate)

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.

Table 1: Definition of Severe Sepsis and Septic Shock

Term	Definition
Severe sepsis	Sepsis plus one of the following: cardiovascular organ dysfunction OR acute respiratory distress syndrome OR two or more other organ dysfunctions.
Sepsis	Systemic Inflammatory Response Syndrome (SIRS) in the presence of, or as a result of, suspected or proven infection
SIRS	The presence of at least two of the following four criteria, one of which must be abnormal temperature or leukocyte count: • Core temperature of > 38.5°C or < 36°C. • Tachycardia, defined as a mean heart rate > 2 SD above normal for age in the absence of external stimulus, chronic drugs, or painful stimuli; or otherwise unexplained persistent elevation over a 0.5-to 4-hr time period **OR** for children <1 yr old: bradycardia, defined as a mean heart rate <10th percentile for age in the absence of external vagal stimulus, β-blocker drugs, or congenital heart disease; or otherwise unexplained persistent depression over a 0.5-hr time period. • Mean respiratory rate > 2 SD above normal for age or mechanical ventilation for an acute process not related to underlying neuromuscular disease or the receipt of general anesthesia. • Leukocyte count elevated or depressed for age (not secondary to chemotherapy-induced leukopenia) or > 10% immature neutrophils.
Infection	A suspected or proven (by positive culture, tissue stain, or polymerase chain reaction test) infection caused by any pathogen OR a clinical syndrome associated with a high probability of infection. Evidence of infection includes positive findings on clinical exam, imaging, or laboratory tests (e.g., white blood cells in a normally sterile body fluid, perforated viscus, chest radiograph consistent with pneumonia, petechial or purpuric rash, or purpura fulminans).

Suspected infection	Infection is suspected when one of the following is documented:
	• Orders for antibiotics OR
	• Antibiotics administered OR
	• Orders for urine, blood or spinal culture OR
	• Urine, blood or spinal culture drawn OR
	• Chart notation of:
	  • "Rule out infection" OR
	  • "Suspected infection" OR
	  • "Rule out sepsis" OR
	  • "Suspected sepsis"

Term	Definition
Organ dysfunctions	**Cardiovascular** Despite administration of isotonic intravenous fluid bolus ≥ 40 mL/kg in 1 hour, • Decrease in BP (hypotension) < 5th percentile for age or systolic BP < 2 SD below normal for age **OR** • Need for vasoactive drug to maintain BP in normal range (dopamine > 5 µg/kg/min or dobutamine, epinephrine, or norepinephrine at any dose) OR **OR** • Two of the following: – Unexplained metabolic acidosis: base deficit > 5.0 mEq/L – Increased arterial lactate > 2 times upper limit of normal – Oliguria: urine output < 0.5 mL/kg/hr – Prolonged capillary refill: > 5 seconds – Core to peripheral temperature gap > 3°C **Respiratory** • PaO_2/FIO_2 < 300 in absence of cyanotic heart disease or preexisting lung disease **OR** • $PaCO_2$ > 65 torr or 20 mm Hg over baseline $PaCO_2$ **OR** • Proven need or > 50% FIO_2 to maintain saturation ≥ 92% **OR** • Need for non-elective invasive or noninvasive mechanical ventilation **Neurologic** • Glasgow Coma Score ≤ 11 **OR** • Acute change in mental status with a decrease in Glasgow Coma Score ≥ 3 points from abnormal baseline **Hematologic** • Platelet count < 80,000/mm^3 or a decline of 50% in platelet count from highest value recorded over the past 3 days (for chronic hematology/oncology patients) **OR** • International normalized ratio >2 **Renal** • Serum creatinine ≥ 2 times upper limit of normal for age or 2-fold increase in baseline creatinine **Hepatic** • Total bilirubin ≥ 4 mg/dL (not applicable for newborn) **OR** • ALT 2 times upper limit of normal for age
Septic Shock	Sepsis and cardiovascular organ dysfunction

Table 2: Codes to Identify Severe Sepsis and Septic Shock

Condition Name	ICD-9 Code(s)
Septicemia	038.xx
Streptococcal septicemia	038.0
Staphylococcal septicemia	038.1
Staphylococcal septicemia, unspecified	038.10
Methicillin susceptible Staphylococcus aureus septicemia	038.11
Methicillin resistant Staphylococcus aureus septicemia	038.12
Other staphylococcal septicemia	038.19
Pneumococcal septicemia [Streptococcus pneumoniae septicemia]	038.2
Septicemia due to anaerobes	038.3
Septicemia due to other gram-negative organisms	038.4

Condition Name	ICD-9 Code(s)
Septicemia due to gram-negative organism, unspecified	038.40
Septicemia due to Haemophilus influenzae [H. influenzae]	038.41
Septicemia due to escherichia coli [E. coli]	038.42
Septicemia due to pseudomonas	038.43
Septicemia due to serratia	038.44
Other septicemia due to gram-negative organisms	038.49
Other specified septicemias	038.8
Unspecified septicemia	038.9
Severe sepsis	995.92
Sepsis	995.91
Septicemia [sepsis] of newborn	771.81
Systemic inflammatory response syndrome due to non-infectious process with acute organ dysfunction	995.94
Bacteremia	790.7
Septic shock	785.52

I.K. Data Sources

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

Data Source	
1. Administrative Data (e.g., claims data)	
2. Paper Medical Record	
3. Survey – Health care professional report	
4. Survey – Parent/caregiver report	
5. Survey – Child report	
6. Electronic Medical Record	**X**
7. Other (If other, please list all other data sources in the field below.)	

References for Section I

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):666-688.

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):1365-1378.

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.

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):793-799.

Odetola FO, Gebremariam A, Freed GL. Patient and hospital correlates of clinical outcomes and resource utilization in severe pediatric sepsis. *Pediatrics* 2007; 119(3):487-494.

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 Advananced Life Support Guidelines in a pediatric intensive care unit in a developing world. *Pediatr Emerg Care* 2008; 24(12):810-815.

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-S47.

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.

SECTION II.
DETAILED MEASURE SPECIFICATIONS

Provide sufficient detail to describe how a measure would be calculated from the recommended data sources, either by uploading a separate document or by providing a link to a URL in the field below. 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.[1] 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 the measure specifications document, Q-METRIC Sepsis Measure 5, *Timely Fluid Bolus for Children with Severe Sepsis or Septic Shock*, at the end of this document. The sepsis codebook used for medical record data abstraction is also included as a separate file.

[1] Initial Core Set of Children's Health Care Quality Measures: Technical Specifications and Resource Manual for Federal Fiscal Year 2011 Reporting. Available at http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Quality-of-Care/Downloads/InitialCoreSetResourceManual.pdf and http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Quality-of-Care/CHIPRA-Initial-Core-Set-of-Childrens-Health-Care-Quality-Measures.html.

SECTION III.
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).

III.A. Evidence for General Importance of the Measure

Provide evidence for all applicable aspects of general importance, including but not limited to the following:

- Addresses a known or suspected quality gap or disparity in quality (e.g., addresses a socioeconomic disparity, a racial/ethnic disparity, a disparity for Children with Special Health Care Needs (CSHCN) and/or a disparity for limited English proficiency (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 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% in infants in 1966 to 9% 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 0.56/1000 children, with the highest prevalence in infancy at 5.6/1000 children; boys had a higher incidence compared with girls (0.6 vs. 0.52 per 1000 children) (Watson et al., 2003). Sepsis prevalence tends to have two peaks during childhood, corresponding to significant periods of time in the maturity of the immune system: first, during the neonatal stage, with an incidence of 4.3 per 1000 and second, at 2 years of age (Watson et al., 2003). Odetola et al. reported another age-specific peak in hospitalization rates: in 2003, children 15 to 19 years of age made up 18% of the pediatric population hospitalized nationally for sepsis (Odetola et al., 2007).

Mortality among hospitalized children with severe sepsis has been reported to be between 4% and 10% (Watson et al., 2003; Odetola et al., 2007). Mortality is strongly associated with multiple organ dysfunction syndrome, occurring in 7% of children with one failing organ, increasing to 53% 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% in children with comorbid illness versus 2% 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 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. *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 et al., 2005; Melendez and 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 and 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 et al., 2011; Melendez and 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, 2008).

Outcomes of Timely Treatment, including Timely Fluid Resuscitation

Early recognition of sepsis syndrome and prompt treatment in the emergency department are essential to achieving successful outcomes (Dellinger et al., 2013; Melendez and 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 and 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, restore the circulation and perfusion to vital organs (Khilnani et al., 2008). The components of early goal-directed therapy include prompt resuscitation of 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 and 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 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% increased 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 emergency department 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 et al., 2011). They 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 (Cruz et al., 2011). Similarly, Oliveria et al. 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 emergency department (Larsen et al., 2011). 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). The development of emergency department 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). Han et al., in a 9-year retrospective study, reported that 29% 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 et al. (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 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 et al. 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 et al. 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.

III.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).[2]

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[2] The EPSDT is a comprehensive set of benefits available to children and youth under age 21 who are enrolled in Medicaid. For more information, see http://www.healthlaw.org/images/stories/epsdt/3-ESDPT08.pdf.

- 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% ($24.8 billion) of the national hospital bill in 2005. Of these charges, approximately $19.5 billion were charged to Medicare and Medicaid. AHRQ HCUP data show that the national cost of treating sepsis increased more (183%) than for other conditions between 1997 and 2005 (Rivers and Ahrens, 2008).

III.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 are currently 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 Title 10 (Health), sections 405.2 and 405.4). 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.

References for Section III

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):666-688.

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Dünser MW, Festic E, Dondorp A, et al. Recommendations for sepsis management in resource-limited settings. *Intensive Care Med* 2012; 38:557-574.

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Han YY, Carcillo JA, Dragotta MA, et al. Early reversal of pediatric-neonatal septic shock by community physicians is associated with improved outcomes. *Pediatrics* 2003; 112 (4):793-799.

Khilnani P, Deopujari S, Carcillo J. Recent advances in septic shock. *Indian J Pediatr* 2008; 75:821-830.

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-e1592.

Melendez E, Bachur R. Advances in the emergency management of pediatric sepsis. *Curr Opin Pediatr* 2006; 18:245-253.

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 405.2 – 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):487-494.

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):810-815.

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-S47.

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

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.

SECTION IV.
MEASURE CATEGORIES

CHIPRA legislation[3] 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,[4] 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.

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3 Children's Health Insurance Program Reauthorization Act of 2009. Public Law No. 111-3, 123 Stat. 8 (2009). Available at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_public_laws&docid=f:publ003.111.

4 Under Section 214 of CHIPRA, States may elect to cover the following groups under Medicaid only or under both Medicaid and CHIP: pregnant women and children up to age 19 for CHIP or up to age 21 for Medicaid.

	Does the measure address this category [Yes/No drop-down]	
a. Care Setting – ambulatory	**No**	
b. Care Setting – inpatient	**Yes**	
c. Care Setting – other—please specify	**No**	**[Add the following choices: home, school, other community and public health settings, long-term care, other---drop-down or radio buttons]**
d. Service – preventive health	**No**	
e. Service – care for acute conditions	**Yes**	
f. Service - care for children with special health care needs/chronic conditions	**No**	
g. Service – health promotion and services to promote healthy birth	**No**	
h. Service-other (please specify)	**No**	
i. Measure Topic -duration of enrollment	**No**	
j. Measure Topic – clinical quality	**Yes**	
k. Measure Topic – patient safety	**No**	
l. Measure Topic – family experience with care	**No**	
m. Measure Topic – care in the most integrated setting	**No**	
n. Measure Topic – other (please specify)	**No**	
o. Population – pregnant women	**No**	
p. Population – neonates (28 days after birth) (specify age range)	**Yes**	Birth-28 days
q. Population – infants (29 days to 1 year) (specify age range)	**Yes**	Ages 29 days -1 year
r. Population – pre-school age children (1 year through 5 years) (specify age range)	**Yes**	Ages 1- 5 years
s. Population – school-age children (6 years through 10 years) (specify age range)	**Yes**	Ages 6-10 years
t. Population – adolescents (11 years through 20 years) (specify age range)	**Yes**	Age 11-18 years (i.e., younger than 19 years old)

SECTION V.
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.

V.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).

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 summarizes several key sources of evidence for this measure, using the US Preventive Services Task Force (USPSTF) rankings (criteria denoted as a note to Table 3).

Table 3: Evidence for Timely Fluid Bolus for Treatment of Children with Severe Sepsis or Septic Shock

Type of Evidence	Key Findings	Level of Evidence (USPSTF Ranking*)	Citations
Clinical guidelines	Pediatric considerations in severe sepsis: In the industrialized world with access to inotropes and mechanical ventilation, initial resuscitation of hypovolemic shock begins with infusion of isotonic crystalloids or albumin with boluses of up to 20 mL/kg crystalloids (or albumin equivalent) over 5-10 minutes, titrated to reversing hypotension, increasing urine output, and attaining normal capillary refill, peripheral pulses, and level of consciousness without inducing hepatomegaly or rales. If hepatomegaly or rales exist then inotropic support should be implemented, not fluid resuscitation. In non-hypotensive children with severe hemolytic anemia (severe malaria or sickle cell crises) transfusion is considered superior to crystalloid or albumin bolus. [p. 614]	III	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.
Clinical guidelines	ABCs for the first hour of resuscitation for pediatric septic shock: Goals include maintenance or restoration of circulation, defined as normal perfusion and blood pressure; maintenance or restoration of threshold heart rate. Fluid resuscitation should begin immediately unless hepatomegaly/rales are present. (Recall that rales may be heard in children with pneumonia as a cause of sepsis, so it does not always imply that the patient is fluid overloaded). If pneumonia is suspected or confirmed, fluid resuscitation should proceed with careful monitoring of the child's work of breathing and oxygen saturation. Rapid fluid boluses of 20 mL/kg (isotonic crystalloid or 5% albumin) can be administered by push or rapid infusion device (pressure bag) while observing for signs of fluid overload (i.e., the development of increased work of breathing, rales, gallop rhythm, or hepatomegaly). In the absence of these clinical findings, repeated fluid boluses can be administered to as much as 200 mL/kg in the first hour. Children commonly require 40 to 60 mL/kg in the first hour. Fluid can be pushed with the goal of attaining normal perfusion and blood pressure.	III	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):666-688

Type of Evidence	Key Findings	Level of Evidence (USPSTF Ranking*)	Citations
	Rapid fluid boluses of 20 mL/kg (isotonic saline or colloid) should be administered by push while observing for the development of rales, gallop rhythm, hepatomegaly, and increased work of breathing. In the absence of these clinical findings, fluid can be administered to as much as 200 mL/kg in the first hour. Fluid should be pushed with the goal of attaining normal perfusion and blood pressure. [p. 1371]		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):1365-1378
Clinical guidelines	The choice of fluid is less important than the volume of fluid administered, as the latter sustains cardiac preload, increases stroke volume, and improves oxygen delivery. [p. 247] There is no clearly defined end point in fluid resuscitation in the absence of a measurement of central venous pressure (CVP) or signs of fluid overload. Administration of 20 mL/kg of isotonic saline/lactated Ringer's as an initial bolus is recommended. This may be repeated twice more (total 60 mL/kg) over 15-30 minutes as clinically indicated by the hemodynamic status. Fluid refractory shock is defined as the persistence of signs of shock after administration of sufficient fluids to have achieved a CVP of 8-12 mmHg and/or signs of fluid overload. If the patient still shows signs of shock, additional therapy such as vasopressors should be administered while diagnostic and therapeutic interventions are being performed.	III	Melendez E, Bachur R. Advances in the emergency management of pediatric sepsis. *Curr Opin Pediatr* 2006; 18:245-253.
Clinical protocol	Once severe sepsis or septic shock has been identified, the highest management priorities are establishing vascular access and initiating fluid resuscitation to improve tissue perfusion. Maintenance of tissue perfusion is critical, because global tissue hypoxia is a key step toward multiple organ failure [p.s18]	III	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-S47.
Retrospective multicenter study	An analysis of mortality rates for children with severe sepsis and septic shock in relation to time-sensitive fluid resuscitation demonstrated the impact of early fluid resuscitation on shock reversal. Early volume replacement was associated with improved outcome. Greater amount of fluid received in the first hour was associated with decreased mortality, suggesting that restoration of adequate intravascular volume to improve tissue oxygen delivery can attenuate the inflammatory response and	III	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

Type of Evidence	Key Findings	Level of Evidence (USPSTF Ranking*)	Citations
	enhance outcomes. [p. 813]		intensive care unit in a developing world. *Pediatr Emerg Care* 2008; 24(12):810-815
Clinical protocol	Patients with sepsis and tissue hypoperfusion appear to benefit from a rapid bolus of intravenous crystalloid solution of at least 20 mL/kg. Further fluid resuscitation should be guided by the response to fluid loading. A positive response can be considered as one of the following: >10% increase of systolic/mean arterial blood pressure; >10% reduction of heart rate; and/or improvement of mental state, peripheral perfusion, and/or urine output. Fluid amounts as high as 110 mL/kg may be required in children with septic shock during early resuscitation. In children with profound anemia and severe sepsis, fluid boluses must be administered cautiously, and blood transfusions should be considered. Fluid resuscitation should be stopped or interrupted when no improvement of tissue perfusion occurs in response to volume loading. Development of crepitations (rales) or hepatomegaly in children indicates fluid overload or impaired cardiac function. Since aggressive fluid resuscitation can lead to respiratory impairment, additional fluid resuscitation following the initial fluid boluses should be performed carefully if no mechanical ventilator is available. [p. 559-560] Fluid administration in patients with sepsis should be accomplished via the intravenous or intra-osseous route.	III	Dünser MW, Festic E, Dondorp A, et al. Recommendations for sepsis management in resource-limited settings. *Intensive Care Med* 2012; 38:557-574.

Note: *USPSTF criteria for assessing evidence at the individual study level are as follows: I) Properly powered and conducted randomized controlled trial (RCT); well-conducted systematic review or meta-analysis of homogeneous RCTs. II) Well-designed cohort or case-control analytic study. III) Opinions of respected authorities, based on clinical experience; descriptive studies or case reports; reports of expert committees.*

V.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; 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, decreased base deficit and mixed venous oxygen saturation of greater than 70% (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 and 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 and 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 and 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 and Nadel, 2009). Fungi account for approximately 5% of all cases of sepsis syndrome (Bochud et al., 2004). Most cases of fungal sepsis are caused by *Candida* species, which is associated with the highest mortality (40%) 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 and Nadel, 2009).

Sepsis is a complex series of interactions between the invading pathogen and the different host systems in the body (Rooney and 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 and 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 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).

References for Section V

Bochud P-Y, Bonten M, Marchetti O, Calandra T. 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):666-688.

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.

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.

Khilnani P, Deopujari S, Carcillo J. Recent advances in septic shock. *Indian J Pediatr* 2008; 75:821-830.

Rooney Z, Nadel S. Optimizing intensive care management in paediatric sepsis. *Curr Opin Infect Dis* 2009; 22:264-271.

Saladino RA. Management of septic shock in the pedatric emergency department in 2004. *Clin Ped Emerg Med* 2004; 5:20-27.

SECTION VI.
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.

VI.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. 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% 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%) 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%) 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%) were assessed for IRR across the three testing sites. For severe sepsis and septic shock, 15 of 300 unique patient records (5%) from the abstraction process were assessed for IRR across the three testing sites.

Table 4 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% and the Kappa was 0.38. The overall agreement for being in the NICU, having renal failure or having congestive heart failure was 100% with corresponding Kappa statistics of 1.00. The overall agreement for severe sepsis and septic shock diagnosis criteria were both 87%, 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 and Garrett, 2005).

Table 4: Percent Agreement and Kappa Statistics for Sepsis for Inter-Rater Reliability at Three Study Sites

Site	Eligibility Criteria/ Measure Numerator	Number of Records Reviewed	N Agreed (%)	Kappa Statistic
Hospital #1	Timely fluid bolus	3	100%	1.00
	In the NICU	3	100%	1.00
	Having renal failure	3	100%	1.00
	Having congestive heart failure	3	100%	1.00
	Severe sepsis	7	86%	0.72
	Septic shock	7	86%	0.70
Hospital #2	Timely fluid bolus	3	67%	0.00
	In the NICU	4	100%	1.00
	Having renal failure	3	100%	1.00
	Having congestive heart failure	3	100%	1.00
	Severe sepsis	4	75%	0.00
	Septic shock	4	75%	0.00
Hospital #3	Timely fluid bolus	4	75%	0.50
	In the NICU	4	100%	1.00
	Having renal failure	4	100%	1.00
	Having congestive heart failure	4	100%	1.00
	Severe sepsis	4	100%	1.00
	Septic shock	4	100%	1.00
All Sites	Timely fluid bolus	10	80%	0.38
	In the NICU	11	100%	1.00
	Having renal failure	10	100%	1.00
	Having congestive heart failure	10	100%	1.00
	Severe sepsis	15	87%	0.72
	Septic shock	15	87%	0.58

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% 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.

Table 5. Inter-Rater Reliability of Assessment of Event within Specified Time Period

Site	Time	Total Records/Times Abstracted	Percent Agreement	Kappa Statistic
Hospital #1	Time of fluid bolus (within 60 minutes of diagnosis)	3	100%	1.00
Hospital #2	Time of fluid bolus (within 60 minutes of diagnosis)	3	67%	0.00
Hospital #3	Time of fluid bolus (within 60 minutes of diagnosis)	4	75%	0.50
All Sites	Time of fluid bolus (within 60 minutes of diagnosis)	10	80%	0.38

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 modified, where appropriate.

For the measure numerator, timely fluid bolus, 8 of 10 records agreed, resulting in an 80% agreement and a Kappa score of 0.38 (see Table 4). 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 that finding other documentation.

For both severe sepsis and septic shock diagnoses, 13 of 15 records agreed, resulting in an 87% 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 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 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.

VI.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., R^2 for concurrent validity). Provide appropriate citations to justify methods.

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). Overall, 50% 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%-67%).

Table 6: Timely Fluid Bolus for Children with Severe Sepsis or Septic Shock

Site	Numerator	Denominator	Rate
Hospital #1	9	17	53%
Hospital #2	2	7	29%
Hospital #3	4	6	67%
All Sites	15	30	50%

References for Section VI

Viera AJ, Garrett JM. Understanding interobserver agreement: the Kappa statistic. *Fam Med* 2005; 37(5):360-363.

SECTION VII.
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.

VII.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 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.

Table 7: Race/Ethnicity by Site for Children (Ages 0 through 18 years of age) with Sepsis Syndrome

Hospital	White				Black				Asian or Pacific Islander				Other or Unknown			
	Non-Hispanic	Hispanic	Unknown	Total	Non-Hispanic	Hispanic	Unknown	Total	Non-Hispanic	Hispanic	Unknown	Total	Non-Hispanic	Hispanic	Unknown	Total
Hospital 1 (N=100)	-	-	63%	63%	-	-	19%	19%	-	-	4%	4%	-	-	14%	14%
Hospital 2 (N=100)	-	-	59%	59%	-	-	35%	35%	-	-	-	0%	2%	4%	-	6%
Hospital 3 (N=100)	27%	5%	-	32%	52%	8%	-	60%	1%	-	-	1%	7%	-	-	7%

VII.B. Special Health Care Needs

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

VII.C. Socioeconomic Status

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

VII.D. Rurality/Urbanicity

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

VII.E. Limited English Proficiency (LEP) Populations

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

SECTION VIII.
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.[5] Using the following sections, explain the methods used to determine the feasibility of implementing the measure.

VIII.A. Data Availability

VIII.A.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%) 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%), 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 in 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, 2-4 nurse

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[5] The definition is adapted from: Centers for Medicare & Medicaid Services Quality Measurement and Health Assessment Group glossary, as part of the Measures Management System Measure Development Overview. Available at: http://www.cms.gov/MMS/19_MeasuresManagementSystemBlueprint.asp#TopOfPage. Accessed February 6, 2012.

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.

VIII.A.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 proposed measure was determined to be feasible by Q-METRIC using electronic medical record data at three large hospitals in Michigan.

VIII.B. Lessons from Use of the Measure

VIII.B.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.

VIII.B.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

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

Not applicable

SECTION IX.
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 Section XVI. 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. Table IX-1 shows the questions (in columns) about the measure's use at different levels of aggregation for quality reporting (in rows) included in the CHIPRA PQMP Candidate Measure Submission Form (CPCF).

Table IX-1 Questions about the measure's use at different levels of aggregation for quality reporting

Level of aggregation (Unit) for reporting on the quality of care for children covered by Medicaid/CHIP†	**Intended use: Is measure intended to support meaningful comparisons at this level? (Yes/No)**	**Data Sources: Are data sources available to support reporting at this level?**	**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?**	**In Use: Have measure results been reported at this level previously?**	**Reliability & Validity: Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?**	**Unintended consequences: What are the potential unintended consequences of reporting at this level of aggregation?**
State level*: Can compare States	☐Yes ☒No	No	Not applicable	No	No	Not applicable
Other geographic level: Can compare other geographic regions (e.g., MSA, HRR)	☐Yes ☒No	No	Not applicable	No	No	Not applicable
Medicaid or CHIP Payment model: Can compare payment models (e.g., managed care, primary care case management, FFS, and other models)	☐Yes ☒No	No	Not applicable	No	No	Not applicable
Health plan*: Can compare quality of care among health plans.	☐Yes ☒No	No	Not applicable	No	No	Not applicable
Provider-level* Individual practitioner: Can compare individual health care professionals	☒Yes ☐No	Yes.	This includes all hospitalized children with clinical documentation of severe sepsis or septic shock [see Table 1]	No	No	None identified
Hospital: Can compare hospitals	☐Yes ☒No	No	Not applicable	No	No	Not applicable
Practice, group, or facility:** Can compare: (i) practice sites; (ii) medical or other professional groups; or (iii) integrated or other delivery networks	☐Yes ☒No	No	Not applicable	No	No	Not applicable

† There could be other levels of reporting that could be of interest to Medicaid agencies such as markets and referral regions.

* Required in CHIPRA legislation.

** There is no implication that measures that are applicable at one level are automatically applicable at all three of the levels listed in this row.

SECTION X.
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 XI.
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 calculation of the measure.

XI.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.

XI.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.

XI.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 (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.

XI.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: http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__standards_ifr/1195)?

Yes

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 (Federal Register 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.

XI.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

XI.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 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% compliance with these measures, employing the same types of warnings to spur action before the time window has expired.

References for Section XI

Health information technology: Initial set of standards, implementation specifications, and certification criteria for electronic health record technology." Fed Regist **75**(8): 2013-2047.

SECTION XII.
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 XIII.
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% of children with severe sepsis or septic shock (range: 29%-67%).

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.

SECTION XIV.
IDENTIFYING INFORMATION FOR THE MEASURE SUBMITTER

Complete information about the person submitting the material, including the following:

a. Gary L. Freed, MD, MPH

b. Percy and Mary Murphy Professor of Pediatrics, School of Medicine; Professor of Health Management and Policy, School of Public Health

c. University of Michigan

d. 300 North Ingalls, Room 6E08, Ann Arbor, MI 48109

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g. Signed written statement guaranteeing that all aspects of the measure will be publicly available, as defined in the Public Disclosure Requirements.

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 (Section XIV: Identifying Information for the Measure Submitter).

This work was funded by the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare & Medicaid Services (CMS) under the CHIPRA Pediatric Quality Measures Program Centers of Excellence grant number U18 HS020516. AHRQ, in accordance to CHIPRA 42 U.S.C. Section 1139A(b), and consistent with AHRQ's mandate to disseminate research results, 42 U.S.C. Section 299c-3, has a worldwide irrevocable license to use and permit others to use products and materials from the grant for government purposes, which may include making the materials available for verification or replication by other researchers and making them available to the health care community and the public, if such distribution would significantly increase access to a product and thereby produce substantial or valuable public health benefits.

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Sepsis

Measure 5: Timely Fluid Bolus for Children with Severe Sepsis or Septic Shock

Description

The proportion of hospitalized children with severe sepsis or septic shock who received a fluid bolus within 60 minutes of meeting diagnostic criteria for severe sepsis or septic shock. A higher proportion indicates better performance.

Definitions

Intake period	January 1 through December 31 of the measurement year.
Hospitalized children	All children admitted to the hospital, including the Emergency Department.
Severe sepsis	Sepsis plus one of the following: cardiovascular organ dysfunction OR acute respiratory distress syndrome OR two or more other organ dysfunctions. ICD-9 code 995.92 (See Table 5-B).
Septic shock	Sepsis and cardiovascular organ dysfunction. ICD-9 code 785.52 (See Table 5-B).
Fluid bolus	≥20ml/kg of intravenous or intraosseous fluid administered over ≤15 minutes.

Table 5-A: Definition of Severe Sepsis and Septic Shock

Term	Definition
Severe sepsis	Sepsis plus one of the following: cardiovascular organ dysfunction OR acute respiratory distress syndrome OR two or more other organ dysfunctions.
Sepsis	Systemic Inflammatory Response Syndrome (SIRS) in the presence of, or as a result of, suspected or proven infection
SIRS	The presence of at least two of the following four criteria, one of which must be abnormal temperature or leukocyte count: • Core temperature of > 38.5°C or < 36°C. • Tachycardia, defined as a mean heart rate > 2 SD above normal for age in the absence of external stimulus, chronic drugs, or painful stimuli; or otherwise unexplained persistent elevation over a 0.5-to 4-hr time period **OR** for children <1 yr old: bradycardia, defined as a mean heart rate <10th percentile for age in the absence of external vagal stimulus, β-blocker drugs, or congenital heart disease; or otherwise unexplained persistent depression over a 0.5-hr time period. • Mean respiratory rate > 2 SD above normal for age or mechanical ventilation for an acute process not related to underlying neuromuscular disease or the receipt of general anesthesia. • Leukocyte count elevated or depressed for age (not secondary to chemotherapy-induced leukopenia) or > 10% immature neutrophils.
Infection	A suspected or proven (by positive culture, tissue stain, or polymerase chain reaction test) infection caused by any pathogen OR a clinical syndrome associated with a high probability of infection. Evidence of infection includes positive findings on clinical exam, imaging, or laboratory tests (e.g., white blood cells in a normally sterile body fluid, perforated viscus, chest radiograph consistent with pneumonia, petechial or purpuric rash, or purpura fulminans).

Suspected infection	Infection is suspected when one of the following is documented:
	• Orders for antibiotics OR
	• Antibiotics administered OR
	• Orders for urine, blood or spinal culture OR
	• Urine, blood or spinal culture drawn OR
	• Chart notation of:
	  • "Rule out infection" OR
	  • "Suspected infection" OR
	  • "Rule out sepsis" OR
	  • "Suspected sepsis"

Term	Definition
Organ dysfunctions	**Cardiovascular** Despite administration of isotonic intravenous fluid bolus ≥ 40 mL/kg in 1 hour, • Decrease in BP (hypotension) < 5th percentile for age or systolic BP < 2 SD below normal for age **OR** • Need for vasoactive drug to maintain BP in normal range (dopamine > 5 µg/kg/min or dobutamine, epinephrine, or norepinephrine at any dose) **OR** • Two of the following: – Unexplained metabolic acidosis: base deficit > 5.0 mEq/L – Increased arterial lactate > 2 times upper limit of normal – Oliguria: urine output < 0.5 mL/kg/hr – Prolonged capillary refill: > 5 seconds – Core to peripheral temperature gap > 3°C **Respiratory** • PaO_2/FIO_2 < 300 in absence of cyanotic heart disease or preexisting lung disease **OR** • $PaCO_2$ > 65 torr or 20 mm Hg over baseline $PaCO_2$ **OR** • Proven need or > 50% FIO_2 to maintain saturation ≥ 92% **OR** • Need for non-elective invasive or noninvasive mechanical ventilation **Neurologic** • Glasgow Coma Score ≤ 11 **OR** • Acute change in mental status with a decrease in Glasgow Coma Score ≥ 3 points from abnormal baseline **Hematologic** • Platelet count < 80,000/mm^3 or a decline of 50% in platelet count from highest value recorded over the past 3 days (for chronic hematology/oncology patients) **OR** • International normalized ratio >2 **Renal** • Serum creatinine ≥ 2 times upper limit of normal for age or 2-fold increase in baseline creatinine **Hepatic** • Total bilirubin ≥ 4 mg/dL (not applicable for newborn) **OR** • ALT 2 times upper limit of normal for age
Septic Shock	Sepsis and cardiovascular organ dysfunction

Table 5-B: Codes to Identify Severe Sepsis and Septic Shock

Condition Name	ICD-9 Code(s)
Septicemia	038.xx
Streptococcal septicemia	038.0
Staphylococcal septicemia	038.1
Staphylococcal septicemia, unspecified	038.10
Methicillin susceptible Staphylococcus aureus septicemia	038.11
Methicillin resistant Staphylococcus aureus septicemia	038.12
Other staphylococcal septicemia	038.19
Pneumococcal septicemia [Streptococcus pneumoniae septicemia]	038.2
Septicemia due to anaerobes	038.3
Septicemia due to other gram-negative organisms	038.4
Septicemia due to gram-negative organism, unspecified	038.40
Septicemia due to Haemophilus influenzae [H. influenzae]	038.41
Septicemia due to escherichia coli [E. coli]	038.42
Septicemia due to pseudomonas	038.43
Septicemia due to serratia	038.44
Other septicemia due to gram-negative organisms	038.49
Other specified septicemias	038.8
Unspecified septicemia	038.9
Severe sepsis	995.92
Sepsis	995.91
Septicemia [sepsis] of newborn	771.81
Systemic inflammatory response syndrome due to non-infectious process with acute organ dysfunction	995.94
Bacteremia	790.7
Septic shock	785.52

Eligible Population

The determination of eligible population for this measure requires medical record data.

Ages 0 to less than 19 years of age during measurement year

Event/Diagnosis Diagnosed with the severe sepsis or septic shock as documented in the medical record

Transfers For children with severe sepsis or septic shock who are transferred from another hospital, the proportion who receive a fluid bolus within 60 minutes of arrival.

Specification

Denominator All hospitalized children with severe sepsis or septic shock

Numerator Number of hospitalized children with severe sepsis or septic shock who received a fluid bolus within 60 minutes of meeting diagnostic criteria for severe sepsis or septic shock

Exclusions

- All children in the NICU.
- Children with chronic renal failure as defined by any mention of chronic renal failure or end stage renal disease.
- Children with congestive heart failure as defined by any mention of congestive heart failure.
- Children who died within 60 minutes of meeting diagnostic criteria for severe sepsis or septic shock.
- Patients with advanced directives for comfort care.
- Patient or surrogate decision maker declined or is unwilling to consent to therapies.