In-Hospital Quality-of-Care Measures for Pediatric Sepsis Syndrome

Folafoluwa O. Odetola, MD, MPH, Gary Freed, MD, MPH, Caroline Shevrin, MS, Brian Madden, MS, Julie McCormick, MA, Kevin Dombkowski, DrPh

abstract

BACKGROUND AND OBJECTIVES: Sepsis syndrome, comprising sepsis, severe sepsis, and septic shock, is a leading cause of child mortality and morbidity, for which the delivery of time-sensitive care leads to improved survival. We aimed to describe the development and testing of quality measures for in-hospital care of pediatric sepsis syndrome.

METHODS: Seven measures of quality of care for children hospitalized with sepsis syndrome were developed by using an iterative process including literature review, development of concepts and candidate measures, and selection of measures for feasibility and importance by 2 panels of experts. The measures were tested for reliability and validity among children 0 to 18 years of age hospitalized with sepsis syndrome from January 1, 2012, to June 30, 2013.

RESULTS: Of 27 hospitals, 59% had no protocol for the identification and treatment of pediatric sepsis syndrome. Blood culture was performed in only 70% of patients with pediatric sepsis syndrome. Antibiotics were administered within 1 hour of diagnosis in 70% of patients with pediatric severe sepsis or septic shock, and timely fluid resuscitation was performed in 50% of patients with severe sepsis or septic shock. Documentation of heart rate during fluid resuscitation of children with severe sepsis or septic shock was observed in 18% of cases. Two measures could not be rigorously tested for validity and reliability given the rarity of septic shock and were deemed infeasible.

CONCLUSIONS: This multisite study to develop and validate measures of the quality of hospital care of children with sepsis syndrome highlights the existence of important gaps in delivery of care.

Department of Pediatrics and Communicable Diseases, Child Health Evaluation and Research Center, University of Michigan Health System, Ann Arbor, Michigan

Dr Odetola participated in study conception and design, data acquisition and interpretation, drafting of the manuscript, and critical revision of the manuscript for important intellectual content; Dr Freed obtained funding for the study and participated in study conception and design, data acquisition and interpretation, drafting of the manuscript, and critical revision of the manuscript for important intellectual content; Ms Shevrin and Ms McCormick participated in study conception and design, interpretation of the data, and critical revision of the manuscript; Mr Madden participated in study conception and design, data management and analysis, and critical revision of the manuscript; Dr Dombkowski participated in study conception and design, analysis and interpretation of the data, and critically revised the manuscript for important intellectual content; and all authors approved the final manuscript as submitted.

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Address correspondence to Folafoluwa O. Odetola, MD, MPH, Department of Pediatrics and Communicable Diseases, University of Michigan, 6C07, 300 North Ingalls St, Ann Arbor, MI 48109. E-mail: fodetola@med.umich.edu

WHAT'S KNOWN ON THIS SUBJECT: Timely recognition and treatment of pediatric sepsis syndrome is critical to survival. The use of protocols for early diagnosis and treatment of pediatric sepsis is associated with a reduction in morbidity and hospital resource use.

WHAT THIS STUDY ADDS: This multisite study developed and validated 5 measures of the quality of hospital care of pediatric sepsis syndrome and highlighted important gaps in the delivery of resuscitative care and in the use of protocols to guide care.

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Sepsis syndrome, encompassing sepsis, severe sepsis, and septic shock, is a leading cause of death in children.[1] There are more than 75 000 cases of severe sepsis in the US pediatric population annually, with an associated annual cost burden of ~5 000 000 000 US dollars.[2] Treatment of pediatric sepsis syndrome requires early deployment of time-sensitive therapies such as fluid resuscitation and antibiotics, which have been reported to have significant positive impact on survival[3,4] and duration of hospitalization.[5]

Despite strong evidence for the positive impact of the aforementioned clinical practices on the outcomes for children with sepsis syndrome, there is significant variation in resuscitative care provided to hospitalized children with sepsis syndrome and in the hospital resource capacity available for definitive care among the most severely ill children.[6]

Carefully developed quality measures that target important areas related to the care of children with sepsis syndrome might identify areas where care can be improved and highlight variation in care provided across hospitals. Unfortunately, there are currently no quality-of-care measures pertaining to the diagnosis, assessment, or treatment of pediatric sepsis syndrome.

The study was conducted to develop measures to assess the quality of care provided to children hospitalized with sepsis syndrome and subsequently test the measures for reliability and validity.

METHODS

Measure Development Process

Overview

After definition of the scope of the study (Supplemental Information), measures of the quality of care for children hospitalized with sepsis syndrome were developed by using an iterative process including literature review, development of concepts and candidate measures, and selection of measures for importance and feasibility by expert panels (Fig 1).

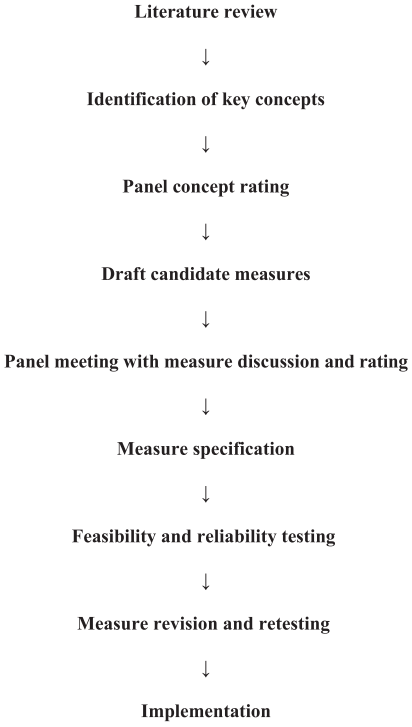

FIGURE 1
Iterative process of measure development.

Literature Review, Concept Development, and Expert Input

An in-depth systematic review of the literature within PubMed, Cumulative Index to Nursing and Allied Health Literature, Google Scholar, Scopus, and the Agency for Healthcare Research and Quality National Guidelines Clearinghouse was conducted on pediatric sepsis syndrome with inclusion of all guidelines, recommendations, and expert reviews. All information was restricted to the English language with relevance to the US population. Five hundred seventy-three articles were screened, resulting in a final list of 124 articles (Fig 2). After review of the literature, concept areas for quality assessment were developed by using a systematic framework built on a scientific rationale for sepsis quality measure development, emphasizing the time sensitivity of documented care.

Two panels of experts were established: a representative panel to review the evidence-based concepts and candidate measures and a feasibility panel to review the candidate measures alone. The 9-member representative panel had experts in pediatric specialties, including critical care medicine, nursing, neonatology, hematology-oncology, hospital medicine (academic and community hospital settings), general surgery, emergency medicine, and infectious disease. The parent of a child survivor of sepsis syndrome was included in the panel. The 6-member feasibility panel included the medical officer of a multi-institutional health system, a pediatrician and informatician, a manager of a multi-institutional relational health care database, a medical records data and billing coder, an executive of a commercial health insurance plan, and a state director of Medicaid. All panelists were national experts other than the parent representative and the Medicaid director from Michigan.

Thirty-one evidence-based concepts were developed by the study team and sent via e-mail to the representative panel to vote on importance and feasibility (Supplemental Information). Voting was conducted online and involved scoring each concept from 1 (low) through 9 (high). The scores were averaged across all panelists, with calculation of the mean score both as a raw value and then after removal of the highest and lowest scores. A threshold score of 7 was chosen by the study team for further consideration of a concept as a source for measure development. This score represented a value in which there was clear separation in the rankings compared with other concepts.

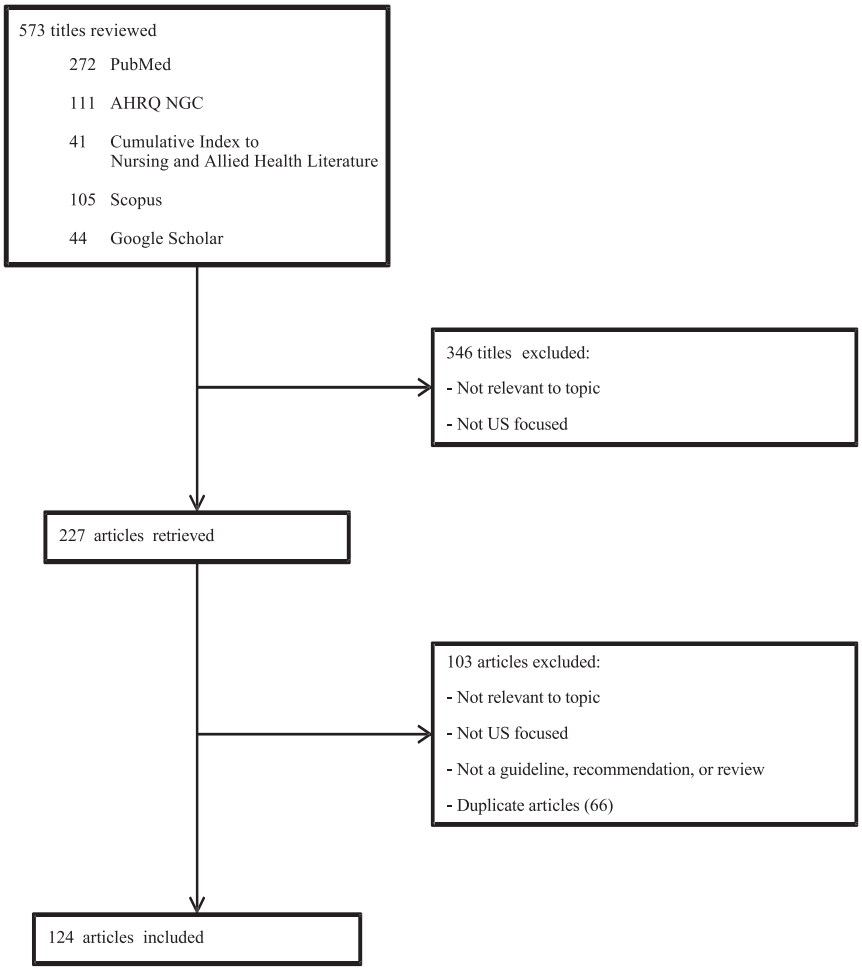

FIGURE 2
Search for literature on the prevention, assessment, and treatment of pediatric sepsis syndrome. AHRQ, Agency for Healthcare Research and Quality; NGC, National Guideline Clearinghouse.

Eighteen concepts with scores greater than the threshold were selected by the study team for measure development, with rigorous specification of the numerator and denominator populations and inclusion and exclusion criteria. These candidate measures were then subjected to extensive review by the 2 expert panels during a 2-day in-person meeting. The meeting addressed issues important to measure development, including the time-sensitive nature of the care of the child with sepsis syndrome and the documentation of such data within medical records. Thereafter, structured data abstraction instruments were created for the training of nurse data abstractors who subsequently performed detailed medical chart abstraction for the testing of developed measures. Both panels voted on the importance and feasibility of each candidate measure. Measures were scored from 1 through 9, and the scores were averaged across all panelists, with calculation of the mean score both as a raw score and after removal of the highest and lowest scores. A score of 7 for both importance and feasibility was established as the cutoff threshold by the study team. At the end of the process, 7 of the 18 candidate measures were selected for testing of their feasibility, reliability, and validity. As depicted in the list below, the first measure assessed the existence of a protocol for the identification and treatment of pediatric sepsis syndrome within the emergency department (ED), whereas all the other measures addressed the care provided after making the diagnosis of sepsis syndrome. The measures included the following:

Measure 1: Protocol for sepsis syndrome in the ED

- The proportion of hospitals with a specific written protocol to identify and treat children with sepsis syndrome in the ED

Measure 2: Transfer of septic shock patients to any ICU

- The proportion of hospitalized children with septic shock who were transferred from the ward or ED to any ICU

Measure 3: Timely blood culture for children with sepsis syndrome

- The proportion of hospitalized children with sepsis syndrome who had blood culture drawn within 4 hours of meeting diagnostic criteria for sepsis syndrome

Measure 4: Timely antibiotics for children with severe sepsis or septic shock

- The proportion of hospitalized children with severe sepsis or septic shock who received parenteral antibiotics within 60 minutes of meeting diagnostic criteria for severe sepsis or septic shock

Measure 5: Timely fluid bolus for children with severe sepsis or septic shock

- 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

Measure 6: Documentation of heart rate in children with severe sepsis or septic shock

- The proportion of hospitalized children with severe sepsis

or septic shock who had documentation of heart rate at least every 15 minutes for the first hour of intravenous or intraosseous fluid resuscitation and then hourly

Measure 7: Measurement of hemodynamics in children with catecholamine-resistant septic shock

- Hemodynamics are measured at least once during the resuscitation of hospitalized children with catecholamine-resistant shock

Testing of Measures for Feasibility, Reliability, and Validity

Measures were defined in terms of feasibility, reliability, and validity. The feasibility of a measure was defined as the extent to which required data were readily available or the collection would not create undue burden, and the degree to which a measure was susceptible to inaccuracies, errors, or unintended consequences. The reliability of a measure was defined as the extent to which a measure produced consistent results to allow for comparability and was assessed by the degree to which data for the measure were unbiased and free from random error, with the need for consistency of definitions, data sources, and documentation of information. Measure validity was defined as the degree to which measure specifications captured the event being measured and the extent to which a measure provided for fair comparisons across health care providers, facilities, health plans, and other potential end users of the measure. Measure validity was assessed by face validity, as determined by ranking of their importance and clinical relevance by the expert panels.

Measure 1

This measure was tested by conducting a cross-sectional assessment of the existence, not content, of a written protocol for the identification and treatment of pediatric sepsis syndrome within the ED of a random sample of 50 hospitals in Michigan (38) and Ohio (12), which were selected after an online search of all nonfederal, short-term, acute care hospitals in the 2 states.[7,8] Measure feasibility was determined as the degree to which hospitals reported having a protocol for the identification and treatment of pediatric sepsis syndrome in the ED. Using a structured script (Supplemental Information), an investigator (F.O.O.) conducted phone interviews of the physician director or nurse manager of EDs at the 50 hospitals between November 2013 and February 2014. Respondents were asked for the existence of a specific written protocol to identify and treat children with sepsis syndrome in their ED. Data collected included the hospital's name, whether a protocol existed, and the official position of the respondent within the ED. The validity of the data regarding the existence of a protocol was ascertained by asking for copies of the protocol from hospitals that reported their existence.

Measures 2 to 7

These 6 measures were tested by cross-sectional analysis of medical records data for 100 children 0 to 18 years of age who were admitted to 1 of 3 large academic medical centers in Michigan between January 1, 2012 and June 30, 2013. The medical centers included 3 children's hospitals: a freestanding children's hospital, a children's hospital within a large community hospital, and a large children's hospital within a university-based health system. Diagnoses of sepsis, severe sepsis, and septic shock were ascertained by using the *International Classification of Diseases, Ninth Revision, Clinical Modification* diagnosis codes. All diagnoses were cross-checked for accuracy by ensuring they matched internationally accepted definitions for pediatric sepsis syndrome.[9]

Medical record data were abstracted by 3 trained nurse abstractors, and the reliability of abstracted data was determined through reabstraction of 5% (15 of 300 unique patient records) of the data by a second abstractor to calculate the interrater reliability (IRR) between abstractors (the extent to which the abstracted information was collected in a consistent manner). Records were selected on the basis of strict eligibility criteria for each measure, which were tested for reliability across the study sites. IRR was measured at all 3 study sites at the beginning of data abstraction and at 2 separate meetings thereafter at each site, with review of the multiple sepsis measures that were being evaluated. Two abstractors reviewed the same medical records; findings from these abstractions were then compared, and a list of discrepancies was created. When discrepancies 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, consensus was obtained and inconsistent records were corrected for the final data set. When consistent differences were noted between the abstractors, clarification was provided and the abstraction tool was modified, when appropriate. IRR was determined by calculating both percent agreement and Kappa (κ) statistics. κ values range from 0 (poor agreement) to 1 (perfect agreement), with values <0 indicating less than chance agreement.[10] The institutional review boards of the 3 study sites approved the study.

RESULTS

Field Testing of Measures

Measure 1

Of 50 hospitals contacted to ascertain the presence of a protocol for identification and treatment of pediatric sepsis syndrome in the

ED, the physician director or nurse manager at 27 hospitals responded after several calls (range of 1–6, based on response). Sixteen of these respondents (59%) reported there was no specific written protocol for identification and treatment of pediatric sepsis syndrome in their ED.

Measures 2 and 7

Two candidate measures could not be rigorously tested for validity and reliability given the rarity of cases of pediatric septic shock at the participating hospitals during the study period: measure 2 (the transfer of children in septic shock to an ICU) and measure 7 (the measurement of hemodynamics during catecholamine-resistant septic shock). They were therefore deemed infeasible measures of the quality of in-hospital care of pediatric sepsis syndrome.

Measures 3 to 6

For measure 3, overall, blood culture was performed in 70% (range of 60%–77%) of patients with pediatric sepsis syndrome within 4 hours after diagnosis (Table 1).

For measure 4, antibiotics were administered within 1 hour of diagnosis in 70% (range of 57%–83%) of patients with pediatric severe sepsis or septic shock (Table 2).

For measure 5, appropriate fluid resuscitation was documented to occur within 1 hour of diagnosis in 50% (range of 29%–67%) of patients with pediatric severe sepsis or septic shock (Table 3).

For measure 6, documentation of heart rate during fluid resuscitation of children with severe sepsis or septic shock was observed in only 18% of children (Table 4).

TABLE 1 Measure 3: Timely Blood Culture for Children With Sepsis Syndrome

Site	No. of Children With Timely Blood Culture	No. Children With Sepsis Syndrome	Rate, %
Hospital #1	64	89	72
Hospital #2	56	94	60
Hospital #3	71	92	77
All sites	191	275	70

TABLE 2 Measure 4: Timely Antibiotics for Children With Severe Sepsis or Septic Shock

Site	No. of Children With Timely Antibiotics	No. of Children With Severe Sepsis or Septic Shock	Rate, %
Hospital 1	9	13	69
Hospital 2	4	7	57
Hospital 3	5	6	83
All sites	18	26	70

TABLE 3 Measure 5: Timely Fluid Bolus for Children With Severe Sepsis or Septic Shock

Site	No. of Children With Timely Fluid Bolus	No. of Children With Severe Sepsis or Septic Shock	Rate, %
Hospital 1	9	17	53
Hospital 2	2	7	29
Hospital 3	4	6	67
All sites	15	30	50

TABLE 4 Measure 6: Documentation of Heart Rate for Children With Severe Sepsis or Septic Shock

Site	No. of Children With Documentation of Heart Rate	No. of Children With Severe Sepsis or Septic Shock	Rate, %
Hospital 1	3	11	27
Hospital 2	0	2	0
Hospital 3	0	4	0
All sites	3	17	18

Testing of Measures for Reliability and Validity

Measure 1

Validity of the data obtained through the telephone survey was assessed through verification of the existence of a protocol; hospitals indicating that they had a sepsis protocol were asked to submit the protocol to the study team. Although 11 of the 27 respondents reported having a written protocol for the identification and treatment of children who presented to their hospital ED with sepsis syndrome, only 2 protocols were received (18%) despite multiple contacts with the respondents. Of the remaining 9 respondents, 6 promised to send their protocol but did not, and 3 protocols could not be sent because they were embedded within the electronic health records of the hospitals.

Measures 3 to 6

Across all study sites, the overall percent agreement (κ statistics) for the diagnosis of sepsis, severe sepsis, and septic shock was 100% (1.00), 87% (0.72), and 87% (0.58), respectively.

Reliability and validity for measures 3 to 6 are displayed in Table 5.

Challenges During Measure Development and Testing

Timely recognition and treatment of pediatric sepsis syndrome is critical to survival; therefore, several of the measures required that treatment be provided within a specific time frame. To ensure that date and time restrictions of measures 3 to 6 were uniformly observed during the data abstraction process, abstractors received rigorous training. However, although there was a high level of agreement between

TABLE 5 List of Feasible Quality Measures for Sepsis Syndrome

Measure	Measure Text	Data Source	Records Reviewed	Face Validity Score[a]	Agreement, %	κ Statistic
1	The proportion of hospitals with a specific written protocol to identify and treat children with the sepsis syndrome in the ED	Phone survey	NA	7	N/A	N/A
3	The proportion of hospitalized children with sepsis syndrome who had blood culture drawn within 4 h of meeting diagnostic criteria for the sepsis syndrome	Medical records	15	7	87	−0.07
4	The proportion of hospitalized children with severe sepsis or septic shock who received parenteral antibiotics within 60 min of meeting diagnostic criteria for severe sepsis or septic shock	Medical records	9	8.7	89	0.00
5	The proportion of hospitalized children with severe sepsis or septic shock who received a fluid bolus within 60 min of meeting diagnostic criteria for severe sepsis or septic shock	Medical records	10	8.3	80	0.38
6	The proportion of hospitalized children with severe sepsis or septic shock who had documentation of heart rate at least every 15 min for the first hour of intravenous or intraosseous fluid resuscitation, and then hourly	Medical records	7	8.3	57	−0.24

N/A, not applicable.
[a] Range of 1–9.

abstractors in the diagnosis of each of the disease entities comprising sepsis syndrome, there was lower interobserver reliability during measure testing. It was sometimes difficult for abstractors to identify the time at which each event actually occurred. To illustrate, 8 out of 9 records reviewed for antibiotic administration within the first hour of diagnosis of severe sepsis or septic shock had perfect IRR; the only discrepancy was due to an abstractor not capturing the event in the ED whereas the other abstractor did. Eight of 10 records reviewed for fluid bolus administration within the first hour of diagnosis of severe sepsis or septic shock had perfect IRR; after review of the discrepancies, it was found that in 1 case, the first abstractor correctly recorded a fluid bolus, whereas 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.

DISCUSSION

In this multisite study to develop and subsequently test measures of quality of care for children hospitalized with sepsis syndrome, we found notable gaps in the delivery of care for this time-sensitive condition within the study hospitals. More than half of the hospitals surveyed lacked a protocol for the identification and treatment of children with sepsis syndrome. In 1 in 3 cases of sepsis syndrome, no blood samples were sent for culture within 4 hours of diagnosis, whereas only in 70% of cases of pediatric severe sepsis or septic shock were antibiotics administered within the first hour of making the diagnosis. Timely fluid resuscitation was performed in only 50% of cases of severe sepsis or septic shock, whereas close documentation of heart rate during fluid resuscitation of children with severe sepsis or septic shock was observed in only 18% of cases.

Measurement of the quality of care provided to children hospitalized with sepsis syndrome might enhance the delivery of care and aid in the standardization of metrics used to assess care provided by health care personnel and hospitals. To illustrate, the use of protocols to standardize and facilitate care of pediatric sepsis by providing explicit instructions regarding interventions and time frames allows clinicians to intervene early and harness resources for the care of these ill children,[11] regardless of care setting. The use of protocols to streamline care of pediatric sepsis syndrome has been associated with improvement of the processes of care, including decreased time to antibiotic administration and fluid resuscitation,[11,12] shortened hospital stay,[12] and reduced occurrence of organ dysfunction.[13,14]

Prompt delivery of time-sensitive care, particularly fluid resuscitation and antibiotic administration, to children with severe sepsis and septic shock leads to improved outcomes.[3,4] It was therefore concerning that among cases of severe sepsis or septic shock reviewed, 50% did not receive appropriate fluid resuscitation and 30% did not receive antibiotics during the first hour after the diagnosis. This is an important deficiency in care that might be detrimental to outcomes for these critically ill children as revealed in previous reports, which revealed higher mortality with delayed shock reversal[3] or delayed antibiotic administration.[4,15–17] Future efforts at evaluating these new measures of quality of care will need to define acceptable thresholds for measure performance at the hospital level and associate such measure performance with outcomes of hospitalization for pediatric sepsis syndrome.

Close monitoring of children with severe sepsis or septic shock during fluid resuscitation is

important to ensure that clinical thresholds of restored perfusion and hemodynamics are met,[16] while avoiding the untoward consequences of overresuscitation such as pulmonary rales, hepatomegaly,[18,19] or fluid overload.[20] Importantly, such close assessment might also prevent underresuscitation of shock and its associated poor outcomes.[3] In the current study, however, only 18% of cases of severe sepsis or septic shock met the measure goal of documenting heart rate every 15 minutes during the first hour of resuscitation and hourly thereafter until resolution of severe sepsis or septic shock.

This study has limitations. Measure development and testing involved the use of diagnosis and procedure codes that could be subject to errors of attribution and ascertainment despite rigorous review of each record for accuracy of the diagnoses. As alluded to earlier, there were challenges during the development and testing of the measures. Timely recognition and treatment of pediatric sepsis syndrome is critical to survival; therefore, several of the measures required that treatment be provided within a specific time frame. There were, however, missing or discrepant event times which directly influenced the time-sensitive measures. This concern may be mitigated through future improvements to electronic health records to ensure accurate time is recorded for diagnosis of severe sepsis or septic shock and for the subsequent deployment of time-sensitive interventions. It is important to also note that the κ value is affected by the prevalence of the event being measured, so for rare findings, such as severe sepsis and septic shock, the low values of κ reported for some measures may not necessarily reflect low rates of overall agreement.[10]

Quality of care hinges on the intersection of process, structure, and outcomes.[21] The developed measures focus on the processes of care; therefore, future evaluation of the impact of these measures of quality of care will need to address their impact on outcomes of pediatric sepsis syndrome and determine thresholds of hospital performance that will be regarded as clinically important. Also, the measures are subject to refinement over time in tandem with scientific advancement and discovery of new evidentiary data to drive the care of children with sepsis syndrome.

CONCLUSIONS

Timely recognition and treatment of pediatric sepsis syndrome is critical to survival. Measures of the quality of in-hospital care of children with sepsis syndrome might enhance the ability to improve outcomes by reducing variation in care within and between hospitals. Gaps in the delivery of care for children with sepsis syndrome were identified in this multisite study, which have significant implications for child health outcomes.

ABBREVIATIONS

ED: emergency department
IRR: interrater reliability

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