Christina Siliciano
August 5, 2016

Assessing the Impact of a Triage Trigger Tool on the Quality of Sepsis Care in the Pediatric Emergency Department

Background

Overwhelming systemic infection leading to septic shock is a leading cause of morbidity and mortality in children. The American College of Critical Care Medicine and Pediatric Advanced Life Support combined guidelines provide widely accepted strategies for recognizing and managing septic chock in children. However, few systematic or quality improvement projects have been performed to evaluate best practices for children's hospitals. The Pediatric Septic Shock Collaborative is a multicenter quality collaborative sponsored by the American Academy of Pediatrics and the Children's Hospital Association aimed at improving the quality of care delivered to pediatric patients with septic shock in the emergency department setting. The Collaborative aims to use a dedicated triage trigger tool and intervention bundle to decrease relative mortality from pediatric sepsis at children's hospitals by 20% within one year. Other measures, including time to fluid resuscitation and time to antibiotics, will also be studied.

CHONY is a participating site in the Pediatric Septic Shock Collaborative (Columbia IRB-AAAM8208), and is developing an EMR-based triage trigger tool to help rapidly identify patients at risk for septic shock upon arrival to the Emergency Department.

Study Purpose

The purpose of this study is to utilize the EMR-based triage trigger tool to improve quality of care of pediatric septic shock in the CHONY emergency department. Specifically, the goal is to improve the percentage of patients with septic shock who receive antibiotics within 60 minutes. This endpoint has been selected because it is a guideline-based recommendation. In addition, we will consider mean time to antibiotics.

Study Design and Statistical Analysis

This is a time series study which will describe baseline data for antibiotic timeliness for septic shock patients in our Emergency Department and seek to compare these data to prospectively gathered data once the EMR-based triage trigger tool is in place.

The baseline data comprises 98 patients from May 2015 to May 2016, with 44% receiving antibiotics within 60 minutes. Using a chi-square test with an alpha of

0.05 and a power of 0.80, we will be able to detect an effect if the proportion of patient's receiving antibiotics increases to 65% or greater.

Additionally, longitudinal data will be displayed on a Statistical Process Control (SPC) run chart. The run chart will include baseline data, annotation to indicate implementation of the EMR-based triage trigger tool as well as other potential interventions (education, order sets, etc), and post implementation data. Non-random significant changes as defined by the Institute for Healthcare Improvement include any of the following; a shift (6 or more consecutive data points above or below the baseline), a trend (5 or more consecutive data points all increasing or decreasing), an astronomical point (a data point >3 standard deviations from baseline).

Study Subjects

Children age 0-18 who present to the CHONY Emergency Department who meet any of the following will be included:

1) Patients with 3 or more of the following clinical criteria:
    1) temperature abnormality (>38C or <36C)
    2) Hypotension
    3) Tachycardia
    4) Tachypnea
    5) Delayed capillary refill
    6) Altered mental status
    7) Pulse abnormality
    8) Skin abnorality

2) High-risk patients (defined below) who meet 2 or more of the above 8 clinical criteria. High-risk conditions defined as:
    1) Malignancy
    2) Asplenia
    3) Bone marrow transplant
    4) Central or indwelling line/catheter
    5) Solid organ transplant
    6) Severe MR/CP
    7) Immunodeficiency, immunocompromised, or immunosuppression

3) Patients for whom the following ICD codes are used: sepsis, septic shock, septicemia, hypotension, shock

4) Patients who receive antibiotics AND had blood cultures AND received at least 40 cc/kg fluid resuscitation while in the ED

Procedure
Monthly data discovery queries for all patients in the CHONY ED receiving diagnosis codes for sepsis, septicemia, shock, septic shock and hypotention will be utilized. The queries will provide MRN, date and time of ED visit for all qualifying patients. Each chart will then be reviewed for appropriateness of inclusion based on the above criteria. Patients with hypotension or shock unrelated to sepsis, and those who did not have sepsis in the Emergency Department but subsequently developed sepsis later in their stay will be excluded. Time to antibiotics for each patient will be calculated.

Confidentiality of Study Data
All PHI will be coded at the point of data entry with the exception of treatment date, which is an essential piece of data for our analysis. All data is stored on a password-protected computer and will be accessible only to study staff.

Location of Study
CHONY Emergency Department

Potential Risks
There are no potential clinical risks beyond those associated with standard care for patients with septic shock. There is a potential risk of loss of confidentiality, however, appropriate steps to maintain confidentiality will be undertaken (see above).

Potential Benefits
The potential benefit of this project is to improve adherence to evidence-based guidelines of pediatric septic shock care, with the eventual goal of improving outcomes for these patients in the future.

Consent
A waiver of consent is requested. This study utilizes evidence-based standard of care guidelines and thus involves no more than minimal risk to participants. No new therapies or treatments are being introduced. Furthermore, given the time-sensitive nature of treatment initiation in these potentially critically ill patients, obtaining informed consent would not be practical.

Sources

Dellinger RP et al. Surviving sepsis campaign: international guidelines for management of severe sepsis and septic shock: 2012. Crit Care Med. 2013 Feb;41(2):580-637.

Paul R et al. Adherence to PALS Sepsis Guidelines and Hospital Length of Stay. Pediatrics. 2012 Aug;130(2):e273-80.

Speroff T, O'connor GT. Study designs for PDSA Quality Improvement Research. Qual Manage Health Care. 13 (1);17-32.

Han YY, Carcillo JA, Dragotta MA, Billis DM, Watson RS, Westerman ME, Orr RA. Early reversal of pediatric-neonatal septic shock by community physicians is associated with improved outcome. Pediatrics. 2003 Oct; 112(4)793-9.

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