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EARLY ANTIBIOTIC INTERVENTION FOR SEPSIS

A DNP Project Submitted to the Graduate Faculty of Jacksonville State University in Partial Fulfillment of the Requirements for the Degree of Doctor of Nursing Practice

By

JOSEPH SCOTT HOOKS

Jacksonville, Alabama

June 28, 2021

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ABSTRACT

Sepsis is a life-threatening organ dysfunction caused by the body's response to an infection causing systemic inflammation. Timely intervention with broad-spectrum antibiotics is linked to improved outcomes, reversal of organ failure, and decreased hospital length of stay. Studies show that the incidence of sepsis is increasing, while mortality related to sepsis has declined over the past several decades. Effective treatment of the source of infection is key to improving sepsis recovery and preventing septic shock. Epidemiologic studies are showing startling increases in sepsis cases with falling mortality rates. Sepsis awareness is a primary focus of quality improvement initiatives in hospitals worldwide. This project focused on Sepsis education and awareness. If successful, the facility will see a decrease in failures to meet sepsis bundle criteria, focusing on appropriate antibiotic administration within the facility's allotted three-hour time frame.

Keywords: sepsis, sepsis management, sepsis antibiotics, sepsis-related costs, sepsis criteria, sepsis core measures, sepsis bundle, sepsis protocol, qSOFA, early antibiotic administration for sepsis, sepsis empiric antibiotics

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Early Antibiotic Intervention for Sepsis

Introduction

Sepsis is a life-threatening organ dysfunction related to the body's response to a microbial infection-causing systemic inflammation (SCCM). Timely intervention with broad-spectrum antibiotics within one hour of arrival to the Emergency Department (ED) is linked to improved outcomes, including in-hospital survival, the reversal of organ failure, and decreased hospital length of stay (Rhodes et al., 2017).

Background

Effective treatment of the source of infection is key to improving sepsis recovery and preventing septic shock. One of the essential elements of sepsis management is obtaining blood cultures and the early administration of broad-spectrum antibiotics with delayed administration of appropriate antibiotic therapy leading to worsening organ dysfunction or organ recovery reduction. A 2016 study by the Surviving Sepsis Campaign (SSC) showed that early antibiotic administration also decreases the risk of complications and decreases the hospital length of stay, lowering the costs associated with medical care (Rhodes et al., 2017b). For every hour delay in antibiotics for patients with septic shock, there is a 7.5% increase in mortality (Singer, 2017). To administer empiric antibiotic therapy, practitioners must know locally prevalent pathogens and their resistance. Once culture and sensitivity results are complete, treatment targets specific pathogens (Rhodes et al., 2017b).

According to the Journal of Thoracic Disease, numerous studies show that the incidence of sepsis is increasing, while mortality related to sepsis has declined over the past several decades. Coding practices and changes in diagnosis guidelines have made

trends assessment challenging. More patients are being diagnosed with sepsis because of administrators, clinicians, and policymakers who have worked to increase sepsis awareness. These conditions have led to a potential perception of increased total cases and decreased mortality in sepsis cases. An alternative method of measuring sepsis incidence and outcomes is to use objective clinical criteria routinely found in electronic health records (EHR) such as blood cultures, the use of vasopressors, and mechanical ventilation to measure acute organ dysfunction. Using this objective method has shown in recent studies that incidence and mortality have been stable during the past ten years (Rhee & Klompas, 2020).

According to the Centers for Medicare and Medicaid Services (CMS), sepsis core measures focus on adults 18 years of age and older diagnosed with severe sepsis or septic shock ("Core Measure", 2020). The core measure consists of several elements: lactate measurement, blood cultures, volume status, fluid resuscitation, broad-spectrum antibiotics, reflex lactic, and reassessment of volume status and tissue perfusion. These measures should be performed within one hour of sepsis diagnosis. The evidence for the components of this core measure is related to a reduction of hospital mortality, decreases in mortality, length of stay, and costs of care ("Core Measure," 2020).

Efforts to promote sepsis bundles of care have been associated with improved compliance with guidelines and decreased hospital mortality rates. Mortality reductions of 4% to 6% have been found in facilities with less than 30% compliance rates. When compliance rates reach 52% or higher, mortality rates improve over 20% showing a direct correlation between sepsis bundle compliance and decreased mortality rates ("Core Measure," 2020) CMS states that without continuous quality improvement (CQI), these

compliance rates will decrease over time. Studies show that standard order sets, increased bedside monitoring, and CQI feedback can modify provider behavior and reduce hospital mortality rates.

Problem Statement

At least 1.7 million people develop sepsis in America each year, with roughly 270,000 dying (Centers for Disease Control and Prevention [CDC], 2020). The etiology for sepsis varies depending significantly on the area, hospital size, type of unit, and time of year. Although the pathogenic organism is identified in approximately half of sepsis cases, gram-positive and gram-negative bacteria are identified as the causative organism in roughly 90 percent of cases. In one epidemiologic study, sepsis is the fifth leading cause of years of productive life lost related to premature mortality making knowledge of risk factors significant. (Ahiawodzi, Kelly, Massengill, & Thompson, 2018). Risk factors include intensive care unit admission, bacteremia, advanced age, immunosuppression, chronic medical conditions, pneumonia, and health insurance status (Ahiawodzi, Kelly, Massengill, & Thompson, 2018). The purpose of this project is to reduce failures in Sepsis Core Measure guidelines with a focus an antibiotic administration. This project explores the following question: does provider education improve treatment time to appropriate broad-spectrum antibiotic administration within one hour of diagnosis compared to delayed administration after a sepsis diagnosis in an adult patient that presented to the Emergency Department prior to in-patient hospitalization?

Organizational Description of Project Site

Problems with sepsis diagnosis and intervention stem from the inadequate knowledge of sepsis criteria and the importance of early intervention at the project site

facility. The Society of Critical Care Medicine (SCCM) suggests that sepsis survival can be impacted by where a patient receives care, suggesting that lower-performing hospitals can improve sepsis outcomes (Hatfield et al., 2018). This project was implemented in a small, rural hospital in Southeastern United States, and was approved by the Chief Quality Officer to implement in the Emergency Department.

Review of the Literature

Sepsis is diagnosed in approximately 750,000 patients each year, killing roughly 210,000 people (Dugar, Choudhary, & Duggal, 2020). Sepsis is caused by the body's response to an infection that leads to life-threatening organ dysfunction. Epidemiologic studies show startling increases in sepsis cases with falling mortality rates (Rhee & Klompas, 2020). Increases in sepsis are believed to be caused by the aging population with predisposing comorbidities, increased immunosuppression, increased invasive procedures, and an array of multi-drug resistant pathogens. As a result, sepsis awareness is a primary focus of quality improvement initiatives in hospitals worldwide (Rhee & Klompas, 2020).

Understanding the physiology of sepsis is critical to diagnosis and management. Sepsis-related costs in the United States alone are more than \$20 billion per year (Dugar et al., 2020). Approximately 15% of patients diagnosed with sepsis progress to septic shock accounting for 10% of Intensive Care Unit (ICU) admissions and a mortality rate of 50%. In addition, delay of appropriate antibiotic administration is associated with a significant rise in mortality rates (Dugar et al., 2020). In May 2017, the World Health Organization (WHO) made sepsis a global health priority. They endorsed a resolution to

improve sepsis prevention, diagnosis, and management to improve patient outcomes (Kim & Park, 2019).

The SSC was created by a joint initiative between the SCCM and the European Society of Critical Care Medicine (ESICM) to reduce the morbidity and mortality from sepsis or septic shock. The SSC emphasizes routine screening of likely infected patients to improve identification and early treatment. They also recommend that hospitals have a quality improvement program that emphasizes early recognition and treatment (Society of Critical Care Medicine [SCCM], 2020).

There have been multiple sepsis definitions throughout the years, creating confusion in the criteria for a sepsis diagnosis. Sepsis was defined, in 1991, as a systemic inflammatory response syndrome (SIRS) related to infection requiring two of the following criteria: temperature below 36 degrees Celsius or above 38 degrees Celsius, heart rate higher than 90, a respiratory rate greater than 20, or white blood cell (WBC) count less than four or greater than 12 (Dugar et al., 2020). The definition of severe sepsis was the progression of sepsis to organ dysfunction, hypotension, and hypoperfusion of tissue. Septic shock is defined as hypotension and organ dysfunction that is persistent despite fluid volume resuscitation, vasopressor medications, and at least two SIRS criteria. In 2001, clinical and laboratory values were added to the definition. The definitions for sepsis were again updated in 2004 by the SSC and (CMS) to include serum lactate greater than two, and septic shock was defined as serum lactate greater than four and fluid resistant hypotension requiring vasoactive medications (Dellinger et al., 2004). The last classification was changed in 2016. Sepsis was then defined as a lifethreatening condition caused by a dysregulated host response to infection resulting in

organ dysfunction. Severe sepsis was removed from classification guidelines. Septic shock was classified as circulatory, cellular, and metabolic abnormalities in septic patients with fluid-resistant hypotension requiring vasopressors and associated tissue hypoperfusion with serum lactate greater than two (Dugar et al., 2020).

Multiple prognostic indicators assist in the diagnosis of sepsis. Those tools include but are not limited to The Acute Physiology and Chronic Health Evaluation (APACHE II, III, and IV) scores, the simplified Acute Physiology Score III, the Mortality Probability Models. While these models are calculated and valuable in the first 24 hours of admission, they cannot calculate longitudinal changes over several days during inpatient care. SOFA (sequential organ failure assessment) and qSOFA (quick sequential organ failure assessment) are prognostic tools used to diagnose sepsis using scores based on continuous evaluation for organ dysfunction after hospital admission. SOFA scores evaluate six organs to assess disease severity over time in septic patients (Nakashima, Miyamoto, & Shimokawa, 2018). qSOFA consists of only three components, each with a score of one point: respiratory rate higher than 22, a change in mental status, and a systolic blood pressure of less than 100. A score of two indicates organ dysfunction (Marik & Taeb, 2017). Antibiotic therapy, initially, should be broadspectrum, covering all likely pathogens. Considerations for infection source, local pathogen susceptibility, previous antibiotic use, and immunosuppression should be taken when choosing initial antibiotic therapy (Dugar et al., 2020). This literature review compares the various sepsis identification methods and educates providers about the importance of timely, appropriate antibiotic administration.

Evidence-Based Practice: Verification of Chosen Option

This evidence-based project was implemented using a continuous education, quality improvement project to educate providers on recognizing the beginning stages of sepsis and how to intervene. The project provided continuing education through a PowerPoint presentation and a one-page handout (see Appendix A and B) teaching sepsis bundles and treatment guidelines after a retrospective peer review of patient charts. After education is provided, a peer review was completed to assess the project's success to verify a change in practice.

Theoretical Framework/Evidence-Based Practice Model

The Advancing Research and Clinical Practice Through Close Collaboration (ARCC) Model was used to implement this evidenced-based quality improvement project (see appendix C). The ARCC Model is "a guide for system-wide implementation and sustainability of Evidenced-based practice (EBP) in healthcare organizations that focuses on assisting clinicians with EBP knowledge, beliefs, and skills-building to consistently implement evidence-based care and the building of EBP cultures to sustain best practices" (Melnyk & Finehout-Overholt, 2019, p. 516). The ARCC model aims to provide healthcare organizations with a framework for implementing EBP to improve quality improvement outcomes. EBP mentors are used as a critical strategy in the ARCC model. Mentors are the point of care clinicians that consistently use evidence-based practice. Mentors reinforce beliefs and implementation of EBP to intensify the perception of EPB in a healthcare organization. An EBP culture within an organization is critical to maintaining high-quality, evidence-based care. Implementing the ARCC model within an organization that believes in EBP can improve patient outcomes considerably (Melnyk & Finehout-Overholt, 2019).

This project aims to educate medical providers on recognizing early symptoms of sepsis to prevent delays in treatment. Early symptoms include tachypnea, altered mental status, and hypotension. Beginning broad-spectrum antibiotic therapy outside the goal window of one hour causes in-hospital mortality rates to increase significantly. The probability of death had a significant statistical increase in relation to the increased number of hours of delay to the first appropriate antibiotic administration (Seymour et al., 2017). Using the ARCC model can change the mentality of providers and their beliefs about EBP. This project proposes that provider belief in EBP can be strengthened through continuing education and quality improvement. If that is the case, this project can improve the number of patients that meet core sepsis measures and lead to improved mortality rates among adult sepsis patients being admitted through the Emergency Department. Mentors were utilized in the ICU and ED to study and develop the material needed to implement this project. These mentors are highly knowledgeable in evidenced-based sepsis treatment and using the core measures put forth by CMS and the SSC.

Goals, Objectives, and Expected Outcomes

The purpose of this project is to improve early recognition and appropriate, broadspectrum antibiotic administration within one hour of sepsis diagnosis in the Emergency Department to increase the percentage that appropriate antibiotics are administered within the recommended one-hour time frame through continuing education. The project education included a power-point presentation to teach Emergency Department staff the SSC and Centers for Disease Control and Prevention (CDC) guidelines for sepsis recognition and management.

Upon completion of this project, the Emergency Department staff will be able to:

- 1. Demonstrate the ability to recognize sepsis symptoms based on current guidelines and sepsis criteria.
- 2. Understand treatment guidelines, including laboratory and blood culture specimens, quantity and type of fluid administration needed for initial resuscitation, appropriate vasopressor medications if required, and appropriate antibiotic therapy with initial broad-spectrum coverage.
- 3. Show an improvement of initial appropriate, broad-spectrum antibiotic administration within the one-hour time frame recommended by the SSC.

Expected outcomes for this project are for emergency department staff to identify sepsis-related symptoms and begin SSC guidelines for treatment within the one-hour time frame set forth by SSC to decrease the length of stay and costs associated with treatment. Sepsis affects approximately 750,000 patients each year (Dugar et al., 2020). Studies also show that sepsis cases are increasing while mortality falls due to the aging population with predisposing comorbidities, increases in invasive procedures, and a multitude of drugresistant pathogens (Rhee & Klompas, 2020). According to the Chief Quality Officer, this project's facility has stated that there has been an increase in failures to meet the SSC sepsis bundle and expressed a need for quality improvement in this area. This project will decrease the number of cases that sepsis has been diagnosed with failure to meet guidelines that the SSC recommends, such as timely antibiotic administration, laboratory specimens, and blood cultures.

Project Design

The Quality Improvement (QI) project consisted of educational PowerPoints using quantitative research to evaluate education's success. The project aims to improve sepsis recognition and diagnosis to implement early treatment with appropriate broadspectrum antibiotics within one hour of the diagnosis. The project focused on the Emergency Department (ED) provider staff, including but not limited to physicians, nurses, and multi-skilled technicians. There have been many definitions for sepsis that have led to confusion in recognizing and diagnosing it. Sepsis is a life-threatening condition that must be identified and treated early (Dugar et al., 2020). This project consisted of educational PowerPoints to educate ED staff on the importance of meeting sepsis guidelines concentrating on early antibiotic administration within one hour of diagnosis. Sepsis, on average, affects approximately 750,000 patients each year and is the leading cause of death in critically ill patients, which is why early recognition and treatment are vitally important (Dugar et al., 2020). The PowerPoint education provided the information needed to recognize and treat per current SSC guidelines. The QI project was distributed to the Chief Quality Officer (CQO) and ED physicians at the implementation facility. Upon successful implementation, the aim is to improve sepsis recognition early and reduce the length of stay, mortality, and treatment cost involved with sepsis and septic shock.

Data Analysis included quantitative data obtained from chart reviews focusing on antibiotic administration times after sepsis diagnosis. Data analysis provided the basis for assessing and diagnosing sepsis before it leads to septic shock and end-organ failure. The education provided taught current guidelines of early sepsis management, according to the CDC and SSC.

Project Site and Population

The QI project gathered data for adult patients in the emergency department in a rural hospital in the Southeastern United States. According to the United States Census Bureau, the city had an approximate population of 35,000. The community is 58.3% Caucasian and 36.2% African American, with 27% approximately living at or below the poverty level (*Quick Facts*, 2019).

This project's resources and stakeholders include the Chief Quality Officer, Critical Care physicians, Critical Care nurse practitioners, Critical Care Doctor of Pharmacy, ED physicians, and Nurse Practitioners. The ED was chosen as the project site in conjunction with the CQO at the facility based on an increase in sepsis guidelines not being met. One of the only constraints involved in this QI project is time and scheduling. The hospital expects to have this project completed as soon as possible to increase sepsis core measure improvements in the ED. The project schedule goal is to implement in early 2021. The budget is not a concern or constraint, but the project design has been built to maximize the minimum budget.

Implementation Plan/Procedures

The project was discussed, and permission was obtained from the facility's CQO. The project's purpose and goals were communicated to all stakeholders. They clearly understand the project's purpose and objectives which will gain support for the project. Upper administration and management personnel were kept informed of each step of the project to support the project's value. Clinical and research data were gathered from December 2020 to early January 2021 through practicum hours with the project mentor, Dr. Megan Moore-Critical Care, DNP. Implementation was in late March 2021. It was delayed due to the Covid-19 pandemic. Data collected did not include any patient

identifiers, and files will be submitted to the facility and deleted from the lead investigator's password and biometric protected computer.

Measurement Instruments

Data instruments planned for this project include patient charts and electronic medication records to assess the timeliness or delays in antibiotic administration after a sepsis diagnosis. Reports were submitted to the CQO to be forwarded to appropriate stakeholders. After project implementation, data was assessed by the CQO and the ED director to evaluate the project's success related to increases in meeting sepsis bundle core measures with a focus on timely antibiotic administration. A PowerPoint presentation was presented and included signs, symptoms, early intervention, and treatment, including the rationale for core measures to help participants understand the significance of meeting these metrics. The PowerPoint presentation was proceeded by data collection with chart reviews to assess and evaluate the project's success. The success was graded on the increase in early antibiotic administration, within one hour of sepsis diagnosis by the ED staff.

Data Collection Procedures

Data collection closely examined the results between times for antibiotic administration before the education and after. Data were collected to explore barriers to early antibiotic administration to allow the facility's quality team an opportunity to prepare for future projects to prevent those barriers. Upon project implementation, data from charts were gathered to assess the project's success. The project goal is to improve the percentage of providers recognizing sepsis and implementing early treatment, such as appropriate broad-spectrum antibiotics. Mentors for this project were chosen based on

access to patients with a sepsis diagnosis within the previous 12 months. Mentors assisted in gathering data during practicum hours while reviewing the chart for patients that have been diagnosed with sepsis or septic shock to evaluate if appropriate antibiotics have been administered within one hour of diagnosis. Mentors assisted in creating appropriate education for project implementation to ensure that proper education is provided to ED staff. The project was implemented in collaboration with the CQO and the ED medical director.

Data Analysis

Data Analysis included quantitative data obtained from chart reviews focusing on antibiotic administration times after sepsis diagnosis. This knowledge provides the basis for assessing and diagnosing sepsis before it leads to septic shock and end-organ failure. The education provided will teach current guidelines of early sepsis management, according to the CDC and SSC.

Cost-Benefit Analysis/Budget

This project's cost will be minimal, with time from the lead investigator being the primary consideration. Using a statistics expert for chart and graph building assistance for project presentation is approximated at \$200. The approximate total hours associated with this project will be 630 hours. The project preceptor and mentors donated their time and help at no cost to the project.

According to the United States Department of Health and Human Services (HHS), sepsis treatment cost Medicare in 2018 approximately \$41.5 billion dollars. HHS also estimates a 12% to 14% increase in the number of sepsis cases every two years (Health and Human Services [HHS], 2020). The average cost for U.S. hospitals caring for

patients with a primary sepsis diagnosis, according to CMS, is \$18,700 per patient. The average Medicare reimbursement for sepsis, with and without complications, is \$7,100 to \$12,000 per patient. The volume of sepsis patients has also doubled during the past decade, with inpatient mortality increasing by 20% (Wolters Kluwer, 2018).

Timeline

Project development began in 2019 with discussions between Dr. Douglas Stephens and myself to reduce sepsis bundle compliance failures in the ED for adult patients. The project was presented to the Chief Quality Officer (CQO) at the implementation facility during Spring 2020. As the IRB reviewed the project, it was determined that the focus should be narrowed to adult sepsis patients in the ED that received appropriate, broadspectrum antibiotics within one hour of sepsis diagnosis and if education helps improve this compliance goal.

Staff was provided educational material through a PowerPoint presentation and a one-page handout that taught pertinent information on the latest update to the sepsis bundle. During the time between presentation and implementation, the Covid-19 pandemic devastated our country and local facilities. The project was limited to chart reviews and discussing any issues and questions with project mentors. Due to the Covid-19 pandemic, the project was not able to be presented until March 2021. This delay has caused research results to be limited to approximately one month of data for April 2020. The facility, however, will continue to conduct monthly reports to reduce delays in antibiotic administration. (see Appendix C)

Ethical Considerations/Protection of Human Subjects

The Jacksonville State University Institutional Review Board (IRB) approval was obtained before initiating the DNP project (see Appendix D). The Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects all participants and patient health information privacy. According to hospital policy, the DNP lead investigator, all participants, and stakeholders carefully conducted this project by following all guidelines, protocols, and standards of care. No information obtained during this project contained private patient information, and no patient identifiers were included.

Project information was focused on quantitative data from hospital staff and did not include patient information. Benefits from early diagnoses and sepsis management include improved patient outcomes, reduced length of stay, and reduced costs for the facility. The project aims to increase the percentage of providers that meet CMS sepsis bundle measures focusing on appropriate broad-spectrum antibiotic administration within the first hour of diagnosis. An increase in meeting core measures will increase Medicare reimbursement for the facility and reduce the length of stay for patients, further assisting in cost-saving efforts (Zaccagnini & Pechacek, 2019).

Conclusion

Sepsis is a life-threatening organ dysfunction related to the body's response to a microbial infection-causing systemic inflammation. This work concentrates on sepsis management with a primary focus on appropriate, broad-spectrum antibiotic administration within one hour of sepsis diagnosis. Timely intervention with broad-spectrum antibiotics within one hour of arrival to the Emergency Department is linked to improved outcomes, including in-hospital survival, the reversal of organ failure, and decreased hospital length of stay.

Primary data was obtained from the entire 2019 year, the first two quarters of 2020, and the first quarter of 2021. Statistical analysis using a Bayesian Poisson Regression Model working with rates per quarter counting the four quarters of 2019, the first two quarters of 2020, and the first quarter of 2021 revealed that it is unlikely to see 14 or more occurrences in the following quarters (see Appendix E).

Accurate conclusions of study results could not be determined due to multiple factors related to the Covid-19 pandemic. These factors include staffing-related issues such as temporary travel nurses, staffing shortages due to illness, and permanent staffing leaving to travel to areas that were devastated by Covid-19. Covid-19 also caused delays in implementation with the project's target facility not allowing outside vendors or students into the hospital to reduce exposure to the virus. Due to the delay in implementation, data could only be obtained from the first quarter of 2021. Data shows that occurrences or failures on antibiotic administration began to increase as Covid numbers increased. The fourteen events in 2021 directly correlate with a sharp increase in hospital Covid cases after the Christmas and New Year's holidays. The project was not implemented until the end of the first quarter, affecting data obtained. The facility will continue to track the benefits of the project as permanent staffing levels begin to normalize. Sepsis is a significant focus for the facility. The expectation is that the percentage of appropriate, broad-spectrum antibiotic administration within the recommended one hour from diagnosis will continue to improve.

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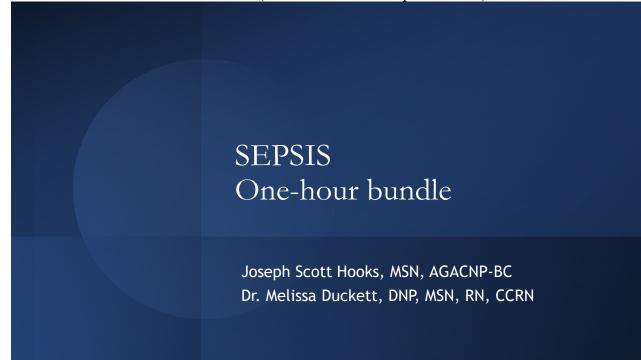
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APPENDIX A

PowerPoint Education (Double-click to view presentation)



Appendix B

2019 Sepsis Bundle

2019 Updated Surviving Sepsis Bundle

- 1. Measure Lactate Level
- 2. Obtain Blood Cultures before antibiotic administration.
- 3. Broad-spectrum antibiotic administration
- 4. Begin rapid administration of 20mL/kg crystalloid solution for hypotension or Lactate >4
- 5. Apply vasopressors if the patient is hypotensive after initial fluid administration to maintain MAP >65.

The primary goal of the 2019 1-hour bundle is to have each intervention *started* within 1 hour, including the *start* of broad-spectrum antibiotic administration.

The 1-hour clock begins at the earliest chart documentation of all elements consistent with sepsis.

qSOFA

- Respiratory rate >22 breaths per minute
- Altered mentation
- Systolic blood pressure <100
- A qSOFA score of 2 points indicates organ dysfunction and should lead to further investigation for sepsis severity.

Early identification

- Signs and symptoms of sepsis are non-specific but include:
- Symptoms related to infectious sources such as cough, dyspnea, purulent exudate.
- Hypotension
- Fever
- Tachycardia
- Tachypnea
- Signs of end-organ perfusion

Appendix C

Timeline

Table 1

Task	October 2020	November 2020	December 2020	January 2021	February 2021	March 2021	April 2021	May 2021
IRB submission	Х							
Recruitment of eligible participants		Х						
Project research		Х	Х					
Project planning				Х	Х			
Project Implementation						Х	Х	
Data-collection								Х

Appendix D

IRB approval

Figure 1



October 15, 2020

Dear Joseph Scott Hooks:

Your proposal submitted for review by the Human Participants Review Protocol for the project titled: "Early Antibiotic Intervention for Sepsis" has been approved as exempt. If the project is still in process one year from now, you are asked to provide the IRB with a renewal application and a report on the progress of the research project.

Sincerely, e U C

Joe Walsh Executive Secretary, IRB

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Appendix E

Statistical analysis

