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Evaluating the Impact of an Early Alert Team Implementation on Sepsis Mortality Rates

Shelley Ann Hyndman
Walden University

Walden University

College of Health Sciences

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Shelley Hyndman

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Review Committee
Dr. Suzanne Richins, Committee Chairperson, Health Sciences Faculty
Dr. Melissa Green, Committee Member, Health Sciences Faculty
Dr. Rabeh Hijazi, University Reviewer, Health Sciences Faculty

Chief Academic Officer and Provost
Sue Subocz, Ph.D.

Walden University
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Abstract

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MSN, Walden University, 2014

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Doctoral Study Submitted in Partial Fulfillment

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Abstract

Sepsis is ranked as one of the leading causes of death among hospitalized patients in the United States. Early identification and treatment of sepsis according to time-sensitive evidence-based protocols is essential to improve outcomes. Existing sepsis research focused on fostering consensus on sepsis definitions and evidence-based treatment protocols; yet, the literature lacks prescriptive evidence regarding organizational structures that reduce patient mortality. The purpose of this quantitative study was to understand how a change in organizational infrastructure could influence the delivery of sepsis-focused care. Using Donabedian's theoretical framework, the research questions for this study focused on an implementation of an Early Alert Team and the effect it had on sepsis-related mortality, time to antibiotic treatment, and compliance with sepsis bundles at the study site. The retrospective quantitative study was based on a secondary data analysis from a large community teaching hospital in Pennsylvania from May 2016 to December 2018. A total of 6,228 adult patients met sepsis inclusion criteria. Statistical analysis using chi-square revealed a statistically significant reduction in sepsis-related mortality and improved compliance with sepsis bundles; however, there was not a significant improvement in median time to antibiotic treatment. The study provided evidence regarding the affect sepsis has on patients' lives the importance of standardizing treatment protocols and cultivating an innovative process that results in improved patient outcomes.

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Dedication

This study is dedicated to my husband Vernon, and our children Zach (& Lindsay), Lauren, Kaitlin, and Elijah. I am truly blessed to have such a loving and supportive family that allowed me to pursue my dream while encouraging me each step of the way. I am forever grateful for your sacrifices and loving support.

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Section 1: Foundation of the Study and Literature Review

Introduction

Sepsis-related mortality is a major challenge in hospitals across the United States. According to the Centers for Disease Control (CDC, 2016) nearly 1.7 million U.S. adults develop sepsis annually, and approximately 270,000 of those individuals die. Sepsis is recognized as a life-threatening condition triggering mortality rates that are significantly worse than those associated with heart attacks, strokes, and trauma (CDC, 2018a). Previously, the ability to identify patients who were in the early stages of sepsis was challenging because the symptomatology was similar to other serious illnesses (Jones et al., 2016). Healthcare researchers continued to refine the definition of *sepsis* and proposed treatment algorithms based on the severity of an infection (Levy, Evans, & Rhodes, 2018).

Hospital leaders are accountable for developing structures that facilitate the delivery of high-quality care by the healthcare team (American College of Healthcare Executives [ACHE], 2017. The American Hospital Association (AHA, 2011) related that hospital mortality is a major public concern and any quality improvements strengthen the local community's confidence in the healthcare organization. Hospital leaders can influence quality and safety outcomes through targeted goals and process improvement initiatives (Taylor, Clay-Williams, Hogden, Braithwaite, & Groene, 2015).

Problem Statement

Sepsis is a life-threatening medical condition that is recognized as one of the leading causes of death among hospitalized patients (Rhee et al., 2019). Early recognition

and classification of the stage of sepsis is essential for prompt treatment and to reduce the incidence of avoidable deaths (Flynn Makic & Bridges, 2018). Targeted clinical interventions that comprise the sepsis bundle include lactate level measurement, acquisition of blood cultures before administration of broad-spectrum antibiotics, aggressive fluid resuscitation, and initiation of vasopressors if hypotension is detected (Levy et al., 2018). For every hour that sepsis treatment is delayed, there is a 4% increased risk of death (Seymour et al., 2017). Healthcare leaders routinely struggle with sepsis-related mortality rates within their organizations and, as a result, executives must establish an infrastructure to produce positive quality and safety outcomes. From a regulatory standpoint, The Joint Commission (TJC, 2019) conveyed healthcare leader accountability in ensuring patients receive safe, high-quality care. Thus, healthcare leader collaboration with the care team is necessary to drive organizational quality improvement efforts, reinforce evidence-based clinical protocols, and reduce sepsis related mortality (ACHE, 2017; Doerfler et al., 2015).

The Surviving Sepsis Campaign's (SSC) development of sepsis clinical definitions and treatment bundles aid in early identification of the disease and promote the use of targeted treatment protocols across the nation (CDC, 2016; Grek et al., 2017; Rhodes et al., 2015). Despite advancements in sepsis care, high rates of sepsis-related mortality exist among adult hospitalized patients (Armen et al., 2016). The Hospital & Healthsystem Association of Pennsylvania (HAP, 2018) in collaboration with the Hospital Improvement Innovation Network (HIIN) require acute care hospitals to achieve a 20% reduction (from baseline) in severe sepsis and sepsis mortality (AHA, 2018). To

meet the state mandated quality improvement requirement, executive leaders at a HAP-participating hospital re-evaluated existing sepsis care within the organization and found inconsistent compliance with sepsis bundle implementation. The hospital's sepsis-related mortality results indicated that a new organizational structure was required for early identification and standardized treatment of sepsis (Pennsylvania Health Care Cost Containment Council, 2017; Premier 2018).

The specific problem that I addressed in this study is that sepsis bundle clinical recommendations were not consistently implemented in a timely manner across the healthcare organization and, as a result, sepsis-related mortality rates in the acute care setting remain high (HAP, 2018; Premier, 2018). TJC's (2019) leadership standards highlight healthcare leaders' accountability for developing a reliable infrastructure and processes that improve patient safety and clinical outcomes in the organization. Although the SSC incorporated clinical research regarding sepsis definitions and treatment bundles, there is a lack of recommendations regarding organizational structures that improve timeliness of the clinical team's sepsis bundle implementation (Levy, 2018). Based on a gap in the literature, it is not clearly understood how the implementation of an Early Alert Team (*pseudonym) could facilitate improved diagnosis to treatment times and the clinical team's adherence to sepsis bundles. Notwithstanding clinical best practice recommendations and interventions that support early detection and treatment of sepsis, variation still exists in translating evidence to clinical practice within healthcare organizations (Damiani et al., 2015).

Purpose of the Study

My purpose in this study was to understand how a change in organizational infrastructure, through the implementation of a new sepsis surveillance team, influences the delivery of care to the patient and positively affects clinical outcomes. Specifically, the implementation of an Early Alert Team, which includes electronic health record (EHR) sepsis surveillance, and the effects that this structure has on sepsis diagnosis, initiation of sepsis bundle, time to treatment, and overall sepsis mortality rates for adult patients in an acute care setting. The retrospective quantitative methodology allowed me to focus on analysis of data from a healthcare organization in Pennsylvania that recently implemented an Early Alert Team model. The relationship between key variables in sepsis care will be explored. Furthermore, the analysis may provide insight as to whether using the Early Alert Team as a standardized approach to sepsis care will positively affect patient mortality rates. From a healthcare executive viewpoint, in this study, I encompassed quality and performance improvement aspects, as well as the prospect of leveraging healthcare technology to influence the delivery of clinical care (ACHE, 2017).

Research Question(s) and Hypotheses

RQ1: To what extent does implementation of an Early Alert Team affect sepsis related mortality among adult hospitalized patients?

H_0 (null hypothesis): There is no difference in sepsis mortality rates when comparing pre and post implementation of the Early Alert Team ($p > .05$).

H_a(alternative hypothesis): There is a statistically significant relationship between implementation of an early alert team and decreased mortality rates ($p < .05$).

RQ2: To what extent does sepsis surveillance by the Early Alert Team affect the time elapsed from sepsis detection to initiation of treatment (antibiotic administration)?

H_0 (null hypothesis): There is no difference in time from sepsis detection to treatment (antibiotic administration) when comparing pre and post implementation of the Early Alert Team ($p > .05$).

H_a (alternative hypothesis): There is a statistically significant relationship between implementation of the Early Alert Team and reduced time from sepsis detection to treatment (antibiotic administration) of sepsis ($p < .05$).

RQ3: To what extent does implementation of the Early Alert Team affect compliance with the SEP-1 sepsis treatment bundle?

H_0 (null hypothesis): There is no change in compliance with the SEP-1 sepsis treatment bundle when comparing preimplementation and postimplementation of the Early Alert Team ($p > .05$).

H_a(alternative hypothesis): There is a statistically significant relationship between implementation of the Early Alert Team and compliance with the SEP-1 sepsis treatment bundle ($p < .05$)

Theoretical Foundation for the Study

The theoretical basis for this study was Donabedian's Quality Framework, which incorporates the triad components of structure, process, and outcome as the gauge for quality healthcare (Ayanian & Markel, 2016). Donabedian's quality improvement framework is used extensively by the Agency for Healthcare Research and Quality (AHRQ, n.d.) and served as the conceptual springboard for the Institute of Medicine's

Crossing the Quality Chasm report (Hurtado, Swift, & Corrigan, 2001). I used Donabedian's (2005) model to evaluate the complexity of the relationship between structure and process, as well as the combined effects that these elements have on sepsis-related patient mortality. According to Donabedian's theory, improvements in structure should result in improved clinical processes, which will positively affect patient outcomes (AHRQ, n.d.).

In this study, structure represents the capacity within the healthcare organization to provide high-quality sepsis care. Structure encompasses elements such as the competence of the clinical providers, the role of the Early Alert Team, and the function of the EHR to access key clinical indicators (Guirgis et al., 2017; Hayden et al., 2016). The clinical process measures are evaluated based on two criteria: the time involved to diagnose the patient on the sepsis spectrum and adherence to the evidence-based sepsis bundles once sepsis is identified (Levy et al., 2018). The outcome measure is reflected in the structure components' effects on clinical processes, which should result in earlier identification of patients with sepsis and treatment according to the sepsis best practices. These are measured by decreased mortality rate.

Nature of the Study

I conducted a retrospective quantitative study using the secondary data in the EHR system related to sepsis cases, Early Alert Team data, and mortality outcomes for sepsis patients. Variables of interest included cases that triggered sepsis, time-to-treatment according to sepsis bundles, whether there was Early Alert Team involvement, and sepsis-related mortality rates. I conducted analysis using chi-square test to determine

statistical significance in sepsis-related mortality, postimplementation of the Early Alert Team initiative. I completed the statistical analysis using IBM SPSS (Statistical Package for the Social Sciences) software (Wagner, 2016).

Significance

Healthcare leaders play a vital role in system redesign and advancing processes that contribute to societal well-being (Berwick, Feeley, & Loehrer, 2015). Positive social change within the healthcare environment implies a transformation in organizational processes that result in positive outcomes for patients, providers, and the organization. A reduction in sepsis-related mortality will affect the lives of thousands of community members, demonstrate cost savings for the healthcare organization, and provide financial benefit for all payers (Danna, 2018). The implementation of an Early Alert Team contributes to positive social change within the healthcare environment by decreasing untoward outcomes; the Early Alert Team advances a new patient care philosophy surrounding sepsis care that was previously considered insurmountable, standardizes treatment protocols, and cultivates an innovative process that results in saved patient lives. The development of a specially trained Early Alert Team in conjunction with discrete data leveraged through technological advances within the EHR empowers the healthcare team to positively affect patient outcomes (Pruinelli et al., 2016). The new organizational structure facilitates improved collaboration among the healthcare team and a collective effort to transform how sepsis care is provided, which, in turn, makes healthcare safer and stimulates positive social change. The implications for positive social change include knowledge useful for healthcare administrators who are searching

for a structure that changes how clinical teams and processes are established to reduce sepsis-related mortality among the adult patient population. Moreover, this study may contribute to the understanding that sepsis-related mortality is a preventable outcome, which may prompt additional research that shifts the focus from time-sensitive diagnosis and treatment to sepsis prevention efforts. The challenge for today's healthcare leader is to shift the culture within a healthcare organization from historical practices and embrace a more proactive and innovative approach to longstanding problems. Similarly, social change within healthcare organizations evolves with time and can have long-term benefits for society (Stephan, Patterson, Kelly, & Mair, 2016).

Definition of Key Terms

I have defined the following terms to provide further clarification as they relate to this study:

Consensus conference: The 1991 collaboration between the American College of Chest Physicians (ACCP), the Society of Critical Care Medicine (SCCM), the European Society of Intensive Care Medicine (ESICM), the American Thoracic Society (ATS), and the Surgical Infection Society (SIS) to establish expert driven sepsis definitions (Levy et al., 2003).

Diagnosis related group (*DRG*): Patient classification system that provides a means for coding the type of patients a hospital treats and associated costs. DRGs are based upon the patient's principal diagnosis, procedures performed, and the presence of complications or comorbidities (CMS, 2017).

Early Alert Team: A team that is composed of registered nurses with an extensive background in critical care, as well designated physician champions for the various patient care areas within the hospital. The primary function of an Early Alert Team is 24-hour-per day, 7-day per week clinical surveillance and evaluation of EHR sepsis alerts for adult patients being treated in the emergency department and inpatient units. When a sepsis EHR alert is identified and validated, the Early Alert Team collaborates with bedside providers to discuss clinical findings and ensure that the sepsis bundle is implemented according to time-based protocols.

Organ dysfunction: Acute dysfunction or low blood flow in one or more of the major body organs. This clinical finding is the threshold that elevates uncomplicated infection to sepsis. The method to assess for organ dysfunction is Sequential (Sepsis-Related) Organ Failure Assessment (SOFA).

Quick SOFA (*qSOFA*): An assessment tool that helps physicians identify key warning signs in patients: altered mental status, a decrease in patient's systolic blood pressure to less than 100mm Hg, respiratory rate greater than 22 breaths per minute.

Rapid response team (*RRT*)*:* A team of healthcare providers with critical care expertise that respond to the bedside of hospitalized patients when the early signs of deterioration are triggered. RRTs facilitate clinical interventions to stabilize patients or assist with transition to a higher level of care.

SEP-1: Sepsis CMS core measure for the hospital inpatient quality reporting (IQR) program. Aligns with SIRS criteria for prognostication rather than Sepsis-3 (Faust & Weingart, 2017; Shankar-Hari et al., 2016).

Sepsis: A life-threatening condition that involves organ dysfunction due to a dysregulated host response to infection (Society of Critical Care Medicine, 2018).

Sepsis bundle: Key elements of care concerning the diagnosis and timely treatment of patients with septic shock. The sepsis treatment bundle evolved from the 6-hour bundle (Sepsis-1) and 3 hour bundle (Sepsis-2), to the most recent hour-1 bundle (SCC 2016 guidelines). The bundle's targeted treatment components assist clinicians to translate complex guidelines into meaningful changes in behavior (Jozwiak, Monnet, & Teboul, 2016) .

Septicemia: A historic term used to describe the invasion of bacteria into the blood stream. Also, was referred to as *blood poisoning* in layman's terms. Terminology first used circa 1860. (Merriam-Webster Dictionary).

Septic shock: Part of the sepsis cascade characterized by profound circulatory, cellular, and metabolic abnormalities that substantially increase mortality (SCCM, 2018). Septic shock differs from sepsis in that the complications are more severe and the risk of patient death is greater. Clinical findings include persistent hypotension requiring vasopressors to maintain mean arterial pressure (MAP) ≥65 mm Hg, blood lactate level >2 mmol/L despite adequate volume resuscitation.

Severe sepsis: This term is included from a historical perspective but is no longer included in consensus definitions due to the fact sepsis has a mortality rate of 10 percent or higher, making the condition already severe (SCCM, 2018).

Surviving sepsis campaign (*SSC*): A global initiative created in 2002 by the Society of Critical Care Medicine (SCCM) and the European Society of Intensive Care

Medicine (ESICM) to address sepsis care. In 2003, the SSC partnered with the Institute for Healthcare Improvement (IHI) and endorsed the 3 and 6-hour sepsis bundles. In 2016, the 1-hour sepsis treatment bundle (Sepsis-3) was published as the result of updated research. The SSC mission is to increase sepsis awareness, educate healthcare professionals, and leverage research outcomes to improve the treatment of sepsis and reduce sepsis mortality.

Systemic inflammatory response syndrome (*SIRS*): A serious condition defined as an inflammatory response throughout the body, which is manifested by temperature, tachycardia, tachypnea, and leukocytosis (Balk, 2013). Sensitive indicator for infection that can lead to sepsis and organ failure, but also noted in response to trauma and pancreatitis.

Assumptions

I based my research study on several assumptions. First, the fact that I used a quantitative approach indicates a basic philosophical assumption that will affect the study. Researchers have asserted that a quantitative approach is used to test theories by examining the relationship between variables (Creswell, 2013). I made the following assumptions regarding this study:

1. The sepsis mortality data available through the Premier data base is accurate and reliable.
2. The coding team collecting and submitting the data aligned with sepsis treatment guidelines.

3. The data in the EHR regarding Early Alert Team involvement accurately reflect team processes.
4. The implementation of the Early Alert Team was facilitated by the organization's executive leaders.
5. The presence of other organizational initiatives was accurately accounted for during the pre and post Early Alert Team implementation data timeframe.

Scope and Delimitations

My scope in this this study was to analyze the implementation of an Early Alert Team and to determine whether there was a relationship to sepsis-related hospital mortality rates. The study delimitations are adult patients ≥ 18 years old who were diagnosed with sepsis at a large community teaching hospital in Pennsylvania.

Literature Search Strategy

In my search strategy, I looked for comprehensive literature reviews that included key words, concepts, central issues, and trends related to sepsis. The scope of the literature review focused on peer-reviewed studies published within the last 5 years. In addition, foundational literature prior to this period is included to provide context. I queried the Walden University library databases CINAHL, MEDLINE, ProQuest Health using key terms and Boolean operators (and, or, not). In addition, I used the Google Scholar search engine and authoritative healthcare industry sites to expand the literature search. Search terms include sepsis, sepsis bundles, sepsis mortality, sepsis surveillance,

remote monitoring and sepsis, rapid response teams and sepsis, early alert teams and sepsis, hospital processes and sepsis, EHR alerts and sepsis.

Literature Review Related to Key Variables and Concepts

My purpose in this research study was to examine the relationship between the implementation of an Early Alert Team and sepsis-related hospital mortality. Although significant advancements in sepsis care occurred during the last decade, a gap exists between clinical best practice recommendations and interventions that support early detection and treatment. Moreover, healthcare improvement efforts may lack alignment between hospital leaders and clinical providers, which can lead to ineffectual outcomes. Further research is needed regarding additional interventions and organizational structures that improve outcomes for patients with sepsis. In my literature review, I provide a comprehensive appraisal of the current evidence surrounding sepsis care and highlight the gaps in the literature that may affect sepsis-related hospital mortality.

Sepsis

Extant literature provides numerous studies regarding the origin and treatment of sepsis. Sepsis is described as one of medicine's oldest problems that continues to negatively impact clinical outcomes (Vincent & Abraham, 2006). The concept of sepsis, and its link to inevitable death, has existed for centuries. Groundbreaking discoveries in the 19th century by Louis Pasteur (1859), Joseph Lister (1865), and William Osler (1892) contributed to understanding sepsis and paved the way for continued research regarding the body's response to infection (Baron, Baron, & Perrella, 2006). White (1899) described *early experimentation* with blood cultures as a means of sepsis diagnosis;

however, confirmation of "septicemia" carried a very unfavorable prognosis. Notwithstanding ongoing research and technological advances over the last century, sepsis-related mortality remains unacceptably high (Levy et al., 2015).

One of the most significant challenges surrounding sepsis is the complexity of the disease process. Disease complexity, coupled with evolving definitions, create concern for clinicians who must ensure early detection, while avoiding overdiagnosis and unnecessary care. Research demonstrates that early detection and treatment are key objectives to inhibit infection. Delayed detection results in a cascading sequence of tissue damage, organ failure, and death (CDC, 2016). The foundational elements required to reduce sepsis-related mortality are infection prevention, early recognition of the signs of sepsis, and timely treatment (CDC, 2016; Levy et al., 2018). Although the understanding of sepsis continues to evolve, researchers and physicians have demonstrated divergent perspectives regarding diagnosis and treatment guidelines (Choi & McCarthy, 2018).

In 1991, the consensus conference developed systemic inflammatory response syndrome (SIRS) and sepsis (Sepsis-1) definitions to provide the medical community with a shared understanding of diagnosis and treatment requirements (Levy et al., 2003). Sepsis definitions (Sepsis-2: sepsis, severe sepsis, and septic shock) were expanded in 2001 to include assessment for organ damage (Levy et al., 2003). In 2016, the SCCM completely revised sepsis (Sepsis-3) definitions, which included updated diagnostic criteria and the directive of less reliance on SIRS as a reliable indicator of sepsis (Rhodes et al., 2017). The Society of Critical Care Medicine's (2018) recent communication

underscored the fact that sepsis is a life-threatening emergency and early treatment is key to reducing mortality.

The evolution of *sepsis* definitions based on scientific research is a key element in ensuring accurate diagnosis and treatment. In 2001, Rivers et al. confirmed mortality benefit related to early goal direct treatment (EGDT) in patients with severe sepsis and septic shock. Just over a decade later, the international research trials ProCESS, ARISE, and ProMISE concluded that there was no long-term survival benefit from EGDT versus standard resuscitation (Yealy et al., 2014; Peake et al., 2014; Mouncey et al., 2015; Osborn, 2017). The overarching focus for improving sepsis outcomes remains on early detection and treatment of sepsis. However, accurate sepsis detection and compliance with SSC treatment bundles is still lacking in many healthcare organizations (Armen et al., 2016; Chan, Peake, Bellomo, & Jones, 2016). To further complicate the situation, updates in hospital discharge codes related to sepsis definitions and historical coding practices that are geared towards reimbursement can contribute to conflicting sepsis surveillance data (Klompas & Rhee, 2016).

As hospital leaders struggle to create structures that facilitate accurate sepsis detection and compliance with sepsis bundles, regulatory pressure was introduced by the Centers for Medicare & Medicaid Services (CMS, 2016) as part of their quality reporting requirements for severe sepsis and septic shock (SEP-1). Currently, the SSC recommendations (Sepsis-3) and CMS (SEP-1) reporting metrics are not aligned, which creates confusion surrounding performance improvement efforts. Based on Donabedian's

theory, healthcare leaders should assess where gaps within an organization's care "structure" exist and identify processes to improve outcomes.

Sepsis Detection

Researchers clearly described the need for strategies that improve early recognition and timely response to patients at risk for sepsis (Chan, Peake, Bellomo, & Jones, 2016). Furthermore, hospitals leaders should establish guidelines for escalating the care of patients with sepsis (Doerfler et al., 2015). Healthcare executive leaders are responsible to establish structures that aid in early identification of sepsis and support evidence-based intervention to reduce sepsis-related mortality (Ferguson et al., 2019; Schorr et al., 2016). The international consensus of *sepsis* definitions is critical to aid in sepsis recognition and to standardize clinical care measures. Sepsis clinical presentation includes presence of altered mental status, tachycardia, arterial hypotension, respiratory symptoms such as dyspnea or tachypnea, temperature > 38.3°C or < 36°C, and decreased capillary refill, cyanosis or mottling that may signal shock (Singer et al., 2016). Researchers demonstrated that provider knowledge regarding sepsis bundles and the use of an effective screening tool can impact sepsis-related mortality (Stoneking et al., 2011).

Clinical tools that help providers screen for sepsis continue to evolve as new research is identified. The systemic inflammatory response syndrome (SIRS) score was initially viewed as the standard for assessing sepsis and mortality risk (Comstedt, Storgaard, & Lassen, 2009). As more evidence surfaced, the Sequential Organ Failure Assessment (SOFA) score was introduced and provided predictive mortality for sepsis. The addition of the quick Sequential Organ Failure Assessment (qSOFA) drastically

simplified the tool and supported prompt sepsis identification among patients outside of the intensive care unit setting. The National Early Warning Score (NEWS) is the newest measure implemented as an accurate predictor of 30-day mortality (Brink et al., 2019). According to the current evidence, qSOFA has better reliability than SIRS for patients in the emergency room, although SIRS is capable of providing positive results more quickly (Harimtepathip et al., 2018). Further research is needed to determine which assessment tool facilitates accurate time sensitive results for predicting sepsis mortality risk (Harimtepathip et al., 2018).

Numerous studies report the use of the EHRs to assist with identification of patients at risk for sepsis. These studies reported improved processes of care for patients identified with sepsis in regards to serum lactate levels and timeliness of antibiotic administration; however, there were no significant improvements in mortality outcomes (Hayden et al., 2016; Narayanan, Gross, Pintens, Fee, & MacDougall, 2016; MacMillan et al., 2018). Bansal et al. (2018) identified that a computerized early sepsis "sniffer" algorithm embedded in the EHR provided high sensitivity for detecting patients with sepsis, but did not replace human decision support to activate the sepsis and shock response team (SSRT) within the emergency department. The researchers further reinforced that automated early detection and communication with a dedicated sepsis response team improves sepsis care due to its change management aspects. Rothman et al. (2017) conveyed that the use of an effective screening tool and an EHR alert system assists with identification of at-risk patients and promotes implementation of the sepsis bundle, which can reduce mortality. Narayanan et al. (2016) found that the use of severe

sepsis best practice alerts via the EHR facilitated time to treatment and antibiotic administration, which resulted in reduced hospital length-of-stay (LOS) for patients with sepsis, but did not significantly affect sepsis related mortality. Chan, Peake, Bellomo, and Jones (2016) conveyed that enhanced recognition of sepsis through clinical informatics, as well as a process to escalate the care of patients diagnosed with sepsis is essential to help reduce the rate of in-hospital mortality.

Although EHR-based clinical triggers help determine a patient's risk for developing sepsis, Rincon, Manos, and Pierce (2017) expressed concern that EHR alerts may contribute to alarm fatigue for front line staff, which they begin to ignore, and as a result may impact data synthesis and timely intervention. Methods that reduce EHR alarm fatigue while still allowing the clinicians to respond to critical alerts are beneficial. Additionally, standardized tools, algorithms, and established communication pathways contribute to improved patient outcomes. Downey, Randell, Brown, and Jayne (2018) conducted a randomized controlled trial (RCT) focused on early detection of clinical deterioration via remote vital signs monitoring. The researchers conveyed that patients receiving continuous monitoring received antibiotics administration faster after evidence of sepsis was detected.

Sepsis Management

Early recognition of sepsis is key to improving patient outcomes. The SSC provides recommendations for time sensitive care bundles in order to improve sepsis outcomes (Levy et al., 2015). In the new Sepsis-3 1-hour bundle, the recommendation is to immediately measure lactate level, obtain blood cultures prior to antibiotic

administration, administer broad spectrum antibiotics, administer crystalloid if patient is hypotensive or lactate ≥ 4mmol/L, and administer vasopressors to maintain mean arterial pressure (MAP) ≥ 65 mmHg (Levy et al., 2018). In addition, the Sepsis-3 bundle incorporates a "time zero" element, which is the time-stamp of the first documentation in the EHR regarding the sepsis elements. The intent of the latest update is to begin aggressive resuscitation as soon as sepsis is detected. However, researchers clarified that it may not be possible to complete all bundle elements within the "hour," but all interventions are considered time sensitive (Levy et al., 2018).

Although the introduction of the sepsis bundles improved sepsis care and positively impacted mortality rates (McCoy & Das, 2017), bundles should not be used in the absence of sound clinical judgement (Lavallée et al., 2017). Researchers addressed process variation in sepsis treatment and concluded that the setting where patients receive care can impact their survival (Hatfield et al., 2018; Walkey & Wiener, 2014). Hospitals with lower volume of sepsis cases were found to experience higher mortality rates when compared to academic hospitals who have higher severe sepsis case volumes. As Acute Care Hospitals continue to experience high patient volumes and increasingly complex clinical cases, this scenario may contribute to delayed sepsis recognition and affect resource availability (Peltan et al., 2019). Researchers also addressed the importance of establishing a standardized approach to sepsis care that is supported through staff education and collaboration with the multidisciplinary team to effectively triage suspected diagnoses of sepsis and compliance with sepsis bundles (Doerfler et al., 2015; Maclay & Rephann, 2017). A retrospective study by Rush et al. (2018) found that

patients with a lower socioeconomic status who are diagnosed with sepsis were at higher risk of mortality than patients with a higher socioeconomic status. Similarly, careful attention must be provided to high-risk populations such as geriatric patients, and patients that present to the emergency department with symptomatology associated with urinary tract infection, pneumonia, post-surgical or abdominal complaints (CDC, 2016). The literature review identified increasing numbers of patients have sepsis upon presentation to the emergency department and that careful assessment can aid in early detection and diagnosis (Doerfler et al., 2015; Gatewood, Wemple, Greco, Kritek, & Durvsula, 2015). It is essential that providers remain cognizant of patient comorbidities, clinical trends, and reasons for hospitalization when implementing the sepsis bundle (Prasad et al., 2017).

Rapid Response Teams

Rapid response teams (RRTs) are widespread throughout the acute care setting. Historically, RRTs addressed inpatient medical emergencies but recently expanded their focus to include sepsis response in many organizations (Fernandez-Moure et al., 2019). Sepsis rapid response teams (SRRT) consist of critical care clinicians who are skilled at early recognition and treatment of sepsis. Researchers conveyed that SRRTs improved patient outcomes, improved compliance with protocols, and are instrumental in performance improvement initiatives (Ju, Al-Mashat, Rivas, & Sarani, 2018). Amland, Haley, and Lyons' (2016) retrospective study found that EHR-based clinical decision support (CDS) enabled electronic surveillance of patients and facilitated deployment of RRTs, which could possibly be leveraged to achieve earlier intervention among sepsis

patients. Fernando et al.'s (2018) research found that RRTs who triaged hospitalized patients according to the Sepsis-3 septic shock criteria aided in early detection of critically ill patients, and, thereby, helped to reduce in-hospital mortality. Similarly, Guirgis et al. (2017) conveyed that EHR alerts, RRT deployment, and adherence to standardized treatment protocols decreased sepsis-related patient mortality. Although EHR alerts facilitated earlier identification of sepsis, when the SRRT was part of the process it increased sepsis bundle compliance and reduced in-hospital mortality (Arabi et al., 2017).

Treatment of Sepsis

The literature review provided strong evidence regarding compliance with sepsis bundles and its link to improved survival (Levy et al., 2018). Many studies conveyed the difficulty hospitals have in meeting sepsis treatment requirements. The publicly reported national average compliance rate for sepsis bundles is just 49% (Hospital Compare, 2018). Non-compliance is a complex issue, which is more than a simple failure to initiate the sepsis bundle (Berg, Vasquez, Hale, Nyberg, & Morgan, 2013). Structure elements such as clinician knowledge and sepsis focused training, as well as access to necessary resources is a critical component in time sensitive initiatives.

Summary

The incidence of sepsis and associated mortality rates is a key concern for healthcare leaders (CMS, 2016). The literature clearly describes the progression of sepsis identification and treatment over the last two decades. Key themes include early recognition and compliance with evidence-based treatment bundles (Levy et al., 2018).

Early recognition is facilitated through sepsis screening tools such as qSOFA that is administered by a provider, as well as sepsis alerts generated by the EHR, which are then validated by the clinical team. Lack of compliance with sepsis bundles range from lack of understanding of the SSC goals, to provider preference regarding individualizing sepsis care (Faust & Weingart, 2017). Healthcare organizations are increasingly using rapid response teams to support at risk populations, which may provide some benefit for sepsis patients (Arabi et al., 2017; Fernandez-Moure et al., 2019; Grek et al., 2017). However, there is limited evidence regarding organizational structures and processes that reliably reduce sepsis-related hospital mortality.

In my study, I assessed whether the implementation of a sepsis Early Alert Team structure has the potential to improve team compliance with evidence-based processes, which may improve sepsis outcomes. The knowledge gained from this research study will be instrumental to provide healthcare leaders a reliable method to implement hospital structures that improve team processes, which result in improved outcomes for adult patients diagnosed with sepsis.

In Section 2, the research design, rationale, and data collection methodology that guided this study are discussed. Section 3 comprises the presentation of the results and describes the research findings. The final section describes the application of the study's research findings to professional practice and the implications for social change.

Section 2: Research Design and Data Collection

Introduction

My purpose in this quantitative study was to understand how the implementation of a new organizational structure influences the delivery of care for sepsis patients and whether this structure affects sepsis-related mortality outcomes. Donabedian's (2005) theoretical framework served as the basis for the study and provide a lens to determine whether there was a relationship between key variables. Donabedian's triad includes the independent variables structure and process in relation to the dependent variable (outcome). The results garnered from this study may assist healthcare leaders in choosing a reliable structure and process that result in improved outcomes for adult patients diagnosed with sepsis in the acute care setting. This section contains the research design and rationale, methodology, as well as threats to validity.

Research Design and Rationale

The variables of interest for this study are the implementation of the Early Alert Team (independent) and sepsis-related mortality rates (dependent), sepsis surveillance by the Early Alert Team (independent) and time lapsed from sepsis detection to treatment time (dependent), as well as Early Alert Team involvement (independent) and staff compliance with sepsis bundle (dependent). A quantitative research design was used to determine whether a relationship exists between the independent and dependent variables. The focus of this design was to determine the extent of the relationship between two or more variables (Creswell, 2013). To clarify, the degree of correlation does not infer causation between the independent and dependent variables. The statistical

analysis helped determine whether implementation of the Early Alert Team affected time lapsed from EHR clinical trigger to diagnosis of sepsis (diagnosis time zero defined by antibiotic administration), team's compliance with sepsis bundles, and sepsis-related mortality rates.

My research design did not introduce significant time or resource constraints. I obtained the secondary data relatively quickly, and, therefore, this process facilitated timely analysis and interpretation of study results. There was no cost associated with access to the study data. Secondary data were available through Premier (DRG codes and mortality outcomes) and the organization's EHR reports (clinical elements, Early Alert Team time markers). The organization's research department required a letter of support from the service-line leader and an employee with research experience who served as the principal investigator (PI). Completion of the research ethics and compliance training module (Citiprogram, n.d.) was required by the study site before IRB application was permitted. The time involved for the training did not significantly impact key milestones for the study.

The design choice for this quantitative study is similar to research methodologies identified during the literature review regarding pre and post-intervention outcome analysis for sepsis patients (Amland, Haley, & Lyons, 2016; Arabi et al., 2017). The statistical analysis for the study provided further insight as to whether implementation of an Early Alert Team affects sepsis mortality outcomes. The study's results may advance knowledge for healthcare leaders to design structures and processes that improve sepsis patient mortality outcomes.

Methodology

The methodology includes the target population, sampling procedure for data collection, instrumentation, and operationalization of constructs. This retrospective study was based on the analysis of secondary data surrounding the May 2017 Early Alert Team sepsis initiative and, therefore, the study period will encompass preimplentation and postimplementation data May 2016 through December 2018. Numerator is all mortality outcome cases that expired in the hospital. Denominator exclusions are maternal deaths. Premier provides sepsis mortality rate benchmarking based on an O/E ratio (observed/expected), which is risk-adjusted. Risk adjustment accounts for the fact that not all sepsis mortality cases are preventable. The study site Premier cohort is hospitals with 400+ beds, Trauma Level 1 or Cardiac Care Unit.

Sampling

The sampling strategy I used for this quantitative study was a retrospective review of the study organization's administrative data. The raw data encompassed adult patients coded with a primary diagnosis of sepsis preimplementation and postimplementation of the Early Alert Team initiative. I deidentified all data for this study to ensure patients' anonymity. The sampling period for the data spans one-year pre-Early Alert Team implementation and 18-months postimplementation. Sepsis cases were identified in the Premier data base through report filters that facilitated case sampling based on primary diagnosis. Choice of the correct sample size was based on the standard formula $n = (2\sigma/E)2$ (Frankfort-Nachmias & Leon-Guerrero, 2015). A larger sample size ensured a smaller margin of error for a 95% confidence interval.

Permission was required to access the study data. I met this requirement through the Institutional Review Board (IRB) at the organization, as well as through Walden University IRB. I obtained the required leadership support permission letters from the study organization prior to the IRB application. Patient consent was not required for secondary research data analysis and, therefore, an exempt research application was submitted to the IRB.

Instrumentation and Operationalization of Constructs

I retrieved the historical data for this study from the Premier database, which spanned preimplementation and postimplementation of the Early Alert Team. Initial hospital encounter data capture included patient demographics, including age, sex, race, as well as detailed pharmacy data and microbiology laboratory result data (Premier, 2018). Hospital level data abstraction was done in accordance with the International Classification of Diseases (ICD) Diagnosis Codes, Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS). The Premier dataset was appropriate to determine whether the implementation of the Early Alert Team resulted in changes in time to treatment, bundle compliance, and sepsis-related hospital mortality. The data met ORYX® reporting requirements of TJC.

Operationalization of Constructs

A key element of this study was transition of the conceptual theory to specific variables that would explain the research phenomena. The theoretical structure for this study was Donabedian's Quality Improvement framework. The operational definition for Donabedian's *structure component* is the implementation of the Early Alert Team.

Implementation of the Early Alert Team is inclusive of the executive leadership and clinical leader collaboration to establish the quality improvement design, allocation of FTEs for the Early Alert Team model, sepsis education for team members, clinical tools such as the EHR alerts and use of the sepsis screening algorithm. The structure component was measured as Early Alert Team involvement and was designated in SPSS® as a categorical independent variable (Y or N). Donabedian's *process element* for this study included remote surveillance of the EHR by the Early Alert Team to identify sepsis patients, a method to validate sepsis alerts, and to ensure compliance with the sepsis bundles through concurrent communication with the clinical team that was caring for the patient. The process was measured by Early Alert Team involvement (categorical, independent variable) to treatment, which is defined by time (minutes) to antibiotic administration (dependent, continuous variable in SPSS®). One element included within the process element was the incorporation of a feedback mechanism to the team for sepsis performance metrics such as bundle compliance. The final element in Donabedian's model is outcome measurement. For this study, outcomes (numeric, dependent variables) were analyzed based on time to antibiotic administration, compliance rate with sepsis bundles, and sepsis mortality rate.

Data Analysis Plan

I obtained the datasets from Premier and the EHR, and I exported the data to a Microsoft® Excel® file that was later uploaded to IBM® SPSS® for statistical analysis (Wagner, 2016). Prior to the analysis, the data was assessed and scrubbed for outliers or missing data elements. One of the main considerations for the statistical analysis design is

whether the data met the parametric assumptions for testing, or if a non-parametric approach needed to be used. The final decision for the data analysis was based on determinations about the variables of interest, assumptions, and consideration of other approaches that could be used to answer the research questions.

Research Questions

RQ1: To what extent does implementation of an Early Alert Team affect sepsis-related mortality among adult hospitalized patients?

H_0 (null hypothesis): There is no difference in sepsis mortality rates when comparing pre and post implementation of the Early Alert Team ($p > .05$).

H_a (alternative hypothesis): There is a statistically significant relationship between implementation of an Early Alert Team and decreased mortality rates ($p < .05$).

RQ2: To what extent does sepsis surveillance by the Early Alert Team affect the time elapsed from sepsis detection to initiation of treatment (antibiotic administration)?

H_0 (null hypothesis): There is no difference in time from sepsis detection to treatment (antibiotic administration) when comparing pre and post implementation of the Early Alert Team ($p > .05$).

H_a (alternative hypothesis): There is a statistically significant relationship between implementation of the Early Alert Team and reduced time from sepsis detection to treatment (antibiotic administration)of sepsis ($p < .05$).

RQ3: To what extent does implementation of the Early Alert Team affect compliance with the sepsis treatment bundle (SEP-1)?

H_0 (null hypothesis): There is no change in compliance with the sepsis treatment bundle (SEP-1) when comparing pre and post implementation of the Early Alert Team ($p > .05$).

H_a (alternative hypothesis): There is a statistically significant relationship between implementation of the Early Alert Team and compliance with the (SEP-1) sepsis treatment bundle ($p < .05$).

Statistical Tests

The statistical tests used to test the hypotheses were based on the number and types of variables that needed to be analyzed. Initially, descriptive statistics using SPSS® was conducted to assess the raw data and assess whether the data was normally distributed, the preimplementation and postimplementation groups were equally balanced, and to identify any outliers that may impact the analysis.

A chi-square test for independence was used to test the strength of the relationship between variables. To establish the sample size needed to show a reduction in mortality from preimplementation to post implementation of the Early Alert Team, it was determined that a medium effect size would show a 1-2% difference between the groups. By using a chi-square to compare a medium effect size it was determined that approximately 66 cases per group would be needed for a power of 80% and a significance level of 0.05.

During the analysis the data was found to be non-parametric, therefore the Mann-Whitney U test was employed (Creswell, 2013). While non-parametric data can be transformed by manipulating it in an ethical manner to create a normal distribution, this

approach tends to be less sensitive in determining correlation (Creswell, 2013). An important factor during the statistical interpretation is consideration of the null hypothesis in relation to type I or type II errors, which was incorporated in this study to ensure validity of results (Creswell, 2013).

Threats to Validity

A retrospective study using secondary data analysis contains inherent aspects that can be a threat to the validity. Although there is an assumption that the original data were coded according to standard procedure, it is uncertain whether there is variability in coding practices among team members or time periods. In addition, there is always the potential for missing or incomplete data in the data set. Another aspect that could affect the study results was the presence of concurrent quality improvement or organization initiatives that could potentially have downstream impact on sepsis outcomes.

During the study design, attempts were made to reduce the threats to validity and improve the reliability of the results through the identification of a reliable data set, statistical testing methodology, and results interpretation.

Ethical Procedures

Researchers must ensure ethical practices throughout the research process. This includes practices related to the study design, participant selection, and maintaining the confidentiality of the participants data (Creswell, 2013). There are no human participants. All data was from a secondary source and was de-identified before the analysis. Every effort was taken to ensure safe data handling practices so the information remained secure.

One ethical consideration that pertains to this study is the fact that the data is from my work environment. Although I am aware of the sepsis quality improvement initiative, there is no conflict of interest regarding the design or influence on outcomes. The organizational leaders connected to the project regard the design and implementation of the Early Alert Team as proprietary information, and therefore, the organization is not identified in this study.

Summary

In Section 2, I discussed the quantitative research design and methodology used to complete the study. Donabedian's Quality model was described in relation to the study and how it related to the research construct and operationalization of variables. Key considerations to ensure ethical aspects were discussed, as well as my approach to ensure validity of research results. The results of the study will be discussed in Section 3: Presentation of the Results and Findings.

Section 3: Presentation of the Results and Findings

Sepsis-related hospital mortality is a growing concern for healthcare leaders across the United States (CMS, 2016). My purpose in this study was to examine the relationship between implementation of an Early Alert Team and sepsis-related mortality outcomes at a large community teaching hospital in Pennsylvania. The hypotheses that I used to guide this research study was the supposition that implementation of a sepsis focused surveillance team could improve time to treatment, compliance with the sepsis bundle, and sepsis-related mortality outcomes.

The statistical model that I used to analyze the study hypothesis was chi-square test of independence. This methodology facilitated the comparison of categorical variable distributions, measure of relationship, and a reliable approach to assess statistical significance based on predetermined alpha level.

Data Collection of Secondary Data Sets

The time frame for data collection was 7 business days. The request for secondary data was submitted at the study organization after Institutional Review Board (IRB) approval received for both the study site (1483627-1) and Walden University (09-26-19-0297133). The data reports encompassed variables of interest for the study period May 2016 through December 2018. The initial data report from Premier included all patients with a primary diagnosis of sepsis during the study period. The second data report was based on a sample population for time to antibiotic administration and bundle compliance that was manually abstracted from the EHR during the study period. I merged the files via Microsoft Excel based on unique medical record identifiers to ensure exact alignment.

There were no discrepancies in the use of secondary data from the plan presented in Section 2.

Results

A total of 6,228 patients met sepsis inclusion criteria pre (n = 2090) and postimplementation (n = 4138) implementation of the Early Alert Team (Table 1.). I used Pearson's chi-square for all covariate comparisons except for length of stay (LOS), where a Mann Whitney *U* test *was used* based on nonparametric data and comparison of median LOS. Covariate categories showed that patients 18 to 59 years old represented the highest percentage of the population, 28.5% and 29.7%, respectively, whereas individuals older than 89 years comprised the smallest group throughout the study period. The percentage of males and females was relatively even between pregroups and postgroups. White patients represented the majority of cases at 88.1% preimplementation and 86.9% postimplementation, whereas Black patients represented the next largest group at 6.7% pre and 6.2% post. The Diagnosis Related Group (DRG) codes demonstrated that DRG 871- septicemia or severe sepsis without mv (mechanical ventilation) > 96 hours with mcc (major complication or comorbidity) was the largest proportion at 55.8% and 54.4% of the pre/post cases respectively. DRG 872 – septicemia or severe sepsis without mv >96 hours without mcc was coded in 25% of all cases. The population for DRG 872 are classified as individuals without major comorbidity or complications/ or an extended period of mechanical ventilation. Medicare was the largest payer for each group, whereas Medicaid/Self-pay had the smallest proportion of cases.

Table 1

Demographic Characteristics of Patients Pregroups (*N* = 2090) *and Postgroups* (*N* = 4138) *Groups: Total Sepsis Cases* (*N* = 6228)

	n (Pre)	%	*n* (Post)	%	*p value*
Age (years)					.49
18-59	596	28.5	1230	29.7	
60-69	470	22.5	906	21.9	
70-79	465	22.3	961	23.2	
80-88	367	17.6	706	17.1	
89+	191	9.1	335	8.1	
Gender					.067
Female	1027	49.1	2135	51.6	
Male	1063	50.9	2003	48.4	
Race					.171
American Indian	6	0.3	10	0.2	
Asian	6	0.3	14	0.3	
Black	139	6.7	257	6.2	
Other	83	4.0	207	5.0	
Pacific Islander	1	0.0	5	0.1	
Not Identified	14	0.7	51	1.2	
White	1841	88.1	3594	86.9	
Other	38	1.8	65	1.6	
					.453
DRG					
Infectious	314	15.0	676	16.3	
870, Septicemia or Severe Sepsis	51	2.4	85	2.1	
871, Septicemia/SEVR Sepsis/WMCC	1166	55.8	2253	54.4	
872, Septicemia/SEVR Sepsis/W/OMCC	521	24.9	1059	25.6	
Payer					.040*
Commercial	300	14.7	697	17.3*	
Medicaid/Self-Pay	223	11.0	435	10.8	
Medicare	1511	74.3	2898	71.9	
Length of Stay (LOS days), Mdn		5		5	.871

Note. Pearson's chi-square was used for all comparisons except LOS in which a Mann-Whitney *U* test was used.

Table 2

Percentage Mortality Based on Patient Demographics

	n (Pre)	%	*n* (Post)	%
Age (years)				
18-59	42	14.2	64	13.2
60-69	75	25.4	97	20.0
70-79	82	27.8	147	30.4
80-88	61	20.7	110	22.7
89+	35	11.9	66	13.6
Gender				
Female	149	50.5	274	56.6
Male	146	49.5	210	43.4
Race				
American Indian	0	0.0	2	0.4
Asian	0	0.0	2	0.4
Black	16	5.4	24	5.0
Other	10	3.4	15	3.1
Pacific Islander	0	0.0	1	0.2
Not Identified	7	2.4	11	2.3
White	262	88.8	429	88.6
Other	8	2.7	10	2.1
DRG				
Infectious	52	17.9	100	20.7
870, Septicemia or Severe Sepsis	19	6.4	24	5.0
871, Septicemia/SEVR Sepsis/WMCC	204	69.2	334	69.0
872, Septicemia/SEVR Sepsis/W/OMCC	12	4.1	16	3.3
Payer				
Commercial	24	8.4	54	11.3
Medicaid/Self-Pay	25	8.7	42	8.8
Medicare	237	82.9	384	80.0

Pre and post Early Alert Team implementation mortality statistics are illustrated in Table 2. Mortality is delineated according to patient age group, gender, race, DRG and payer. Individuals 70-79 years old represented the highest mortality rates in both the pre

(27.8%) and post groups (30.4%). Females experienced higher mortality rates than males. Whites represented 88.8%-88.6% of patient deaths. The majority of cases (69.2%-69.0%) were coded as DRG 871, which indicates septicemia/severe sepsis/with major complications and/or comorbidities. The number of patient deaths coded as DRG 870 and 872 would benefit from further evaluation based on the fact severe sepsis was present but patient population did not have major complications or comorbid conditions. This outcome may reflect preventable deaths.

In Table 3, I used cross-tabulations and chi-square test of independence to analyze mortality outcomes between the pre and post group. The pre group observed mortality rate is 295/2090 = 14.1% and the post group observed mortality rate is 484/4138 = 11.7%. Statistical significance was observed with a 2.4% (p = .006) decrease in mortality for the post implementation group. The mortality outcome data reported in Table 3 is not risk-adjusted. Furthermore, CMS SEP-1 accounts for patients placed on comfort care within 6 hours as one of the exclusion criteria for outcomes reporting. In this study, all sepsis-related mortality and comfort care/transfer to hospice is included.

Table 3

Percentage Mortality Pre and Post Implementation of Early Alert Team

	n	%	*p*
Grouping			.006*
Pre	295	14.1	
Post	484	11.7	

Note. Pearson's chi-square was used for the analysis of categorical variables.

The median time to antibiotic administration was calculated based on sample population data collected by the organization during the study period (Table 4). The

Mann-Whitney U test was used for the analysis based on the data being non-parametric. The median time to antibiotic for the pre group was 21 minutes, and the post group median time was 14 minutes. There was a 7 minute decrease in median time post Early Alert Team implementation, however, this outcome was not found to be statistically significant $p = .430$. Consideration regarding clinical significance should be further explored.

Table 4

Sample Population: Comparison of Median Time From Sepsis Trigger to Antibiotic Administration

	n (pre)	Median	*n* (post)	Median	*p*
Time, hh:mm	309	00:21	166	00:14	0.430

Note. Mann-Whitney *U* test was used based on non-parametric data.

In Table 5, the SEP-1 bundle compliance is reported pre and post Early Alert Team implementation. Data analysis was based on a sample population that was collected by the study site. SEP-1 criteria compliance is calculated as a composite measure. The SEP-1 bundle is comprised of the following requirements: initial lactate measurement, blood cultures before antibiotic administered, and fluid resuscitation (septic shock) within first three hours of presentation of sepsis, AND vasopressors if hypotensive, follow-up lactate level within 6 hours. The post implementation compliance was 65.9% as compared to the national average compliance rate of 49% (Hospital Compare, 2018)

Table 5

Sample Population: Percentage SEP-1Bundle Compliance Preimplementation and Postimplementation of Early Alert Team

	N	%	*p*
Grouping			<.001*
Pre	147	41.5	
Post	114	65.9	

Note. Significance determined using chi-square test.

Summary

The focus of this retrospective quantitative study was to determine whether implementation of an Early Alert Team impacted sepsis processes and outcomes in a large community teaching hospital in Pennsylvania. The research questions as stated in Section 1 and statistical analysis results are as follows:

RQ1: To what extent does implementation of an Early Alert Team affect sepsis-related mortality among adult hospitalized patients?

H_0 (null hypothesis): there is no difference in sepsis mortality rates when comparing pre and post implementation of the Early Alert Team ($p > .05$). There is evidence to reject the null hypothesis ($p = .006$).

H_a (alternative hypothesis): there is a statistically significant relationship between implementation of an Early Alert Team and decreased mortality rates ($p < .05$). The alternative hypothesis is supported based on a 2.4% ($p = .006$) decrease in mortality when comparing pre/post mortality rates.

RQ2: To what extent does sepsis surveillance by the Early Alert Team affect the time elapsed from sepsis detection to initiation of treatment (antibiotic administration)?

H_0 (null hypothesis): There is no difference in time from sepsis detection to treatment (antibiotic administration) when comparing pre and post implementation of the Early Alert Team ($p > .05$). There is not enough evidence to support claim, therefore, the null hypothesis is not rejected ($p = .430$).

H_a (alternative hypothesis): There is a statistically significant relationship between implementation of the Early Alert Team and reduced time from sepsis detection to treatment (antibiotic administration) of sepsis ($p < .05$). The median time to antibiotic administration was decreased by 7 minutes post implementation, which may be clinically beneficial but not statistically significant.

RQ3: To what extent does implementation of the Early Alert Team affect compliance with the sepsis treatment bundle (SEP-1)?

H_0 (null hypothesis): There is no change in compliance with the sepsis treatment bundle (SEP-1) when comparing pre and post implementation of the Early Alert Team ($p > .05$). There is evidence to reject the null hypothesis ($p < .001$).

H_a (alternative hypothesis): There is a statistically significant relationship between implementation of the Early Alert Team and compliance with the (SEP-1) sepsis treatment bundle ($p < .05$). The alternative hypothesis is supported based on a 24.4% increase ($p < .001$) in bundle compliance post implementation of the Early Alert Team.

The results from the data analysis are beneficial to assess the impact of Early Alert Team implementation on sepsis outcomes at the study site. The research hypothesis RQ1 was supported with a 2.4% decrease in sepsis-related hospital mortality, which demonstrated there was a statistically significant relationship ($p = .006$) between the

variables. RQ2 null hypothesis was not rejected based on a 7 minute decrease (p = .430) in median time to antibiotic administration. The null hypothesis for RQ3 was rejected based on a 24.4% improvement (p = <.001) in team compliance with sepsis bundle (SEP-1). In Section 4, the application to professional practice and implications for social change is presented.

Section 4: Application to Professional Practice and Implications for Social Change

Introduction

Each year, approximately 270,000 individuals succumb to sepsis in the acute care hospital setting (CDC, 2016). As a result, sepsis-related hospital mortality outcomes and quality improvement efforts to reduce mortality are key concerns for hospital leaders (HAP, 2018; Hospital Compare, 2018). My purpose in this retrospective quantitative study was to provide healthcare leaders an understanding of how a change in organizational infrastructure impacted sepsis-related mortality rates, time to treatment (antibiotic administration), and SEP-1 bundle compliance at a large community teaching hospital in Pennsylvania.

Interpretation of the Findings

The implementation of the Early Alert Team provided 24/7 clinical surveillance and a standardized approach to sepsis care within the organization, which resulted in a 2.4% ($p = .006$) decrease in sepsis mortality rates, decreased median time to antibiotic administration by 7 minutes ($p = .430$), and improved SEP-1 bundle compliance by 24.4% ($p < .001$).

The findings from this study align with key themes in sepsis research and support Donabedian's quality framework regarding structure, process, and outcome. Implementation of the Early Alert Team provided a 24/7 structure for EHR surveillance, including a standardized approach to sepsis care that encompassed staff training, team communication, screening tools, as well as executive level support. In this study,

executive leadership established sepsis care as an organization-wide priority and ensured adequate resources were in place to support the Early Alert Team sepsis quality initiative.

The data analysis denotes improvement for each of the study's research hypotheses post implementation of the Early Alert Team. Mortality outcomes and bundle compliance at the study site demonstrated improvement that was statistically significant. Overall sepsis mortality rates decreased from 14.1% preimplementation of the Early Alert Team to 11.7% postimplementation. Although median time to antibiotic administration improved, the improvement was not statistically significant but may be clinically significant in relation to overall mortality outcomes.

Evolving sepsis definitions and complex treatment bundles continue to present a challenge for both healthcare providers and healthcare administrators. The Federally regulated SEP-1 (CMS Early Management Bundle for Severe Sepsis/Septic Shock) focuses on acute care providers compliance with complex treatment bundles. However, some members of the medical community relay that SEP-1 is contradictory to the evidence-based SSC guidelines and does not allow for provider judgement. SEP-1 is mandated CMS core measure that requires compliance with specific process measures, which in theory should result in improved patient outcomes (measure of quality). SEP-1 also has well-defined inclusion and exclusion criteria for bundle compliance and mortality reporting. Prior non-compliance with sepsis bundles ranged from not fully understanding SSC parameters, as well as provider preference regarding individualized sepsis care, which may be considered contrary to SEP-1 compliance. This study's compliance rates are reported based on SEP-1 criteria which all acute care hospitals are

required to meet. Mortality rate reported for this study is non-risk adjusted and does not account for SEP-1 exclusions.

The literature underscores the importance of early sepsis recognition and timely treatment to improve patient outcomes. The Early Alert Team structure facilitates continuous surveillance of patients at risk for developing severe sepsis, as well as a method to validate EHR sepsis alerts without creating alarm fatigue for the frontline staff. The study organization's early sepsis recognition is facilitated through evidence-based sepsis screening tools that are administered by "sepsis aware" providers, as well as sepsis alerts generated by the EHR, which are then validated by the Early Alert Team. In summary, this study highlighted a new organizational structure and processes that demonstrated a statistically significant reduction in sepsis-related hospital mortality and improved bundle compliance during the study period.

Limitations of the Study

Although the study's outcome data demonstrated noteworthy results post Early Alert Team implementation, several important limitations were identified. First, the study was conducted at a single site in Pennsylvania, which may not be representative of patient populations or acute care hospitals across the nation. Second, I based this study on secondary data analysis which was limited by the number of cases correctly identified and coded as sepsis. Specifically, there was full access to all cases coded as sepsis to analyze mortality outcomes, however, antibiotic administration and bundle compliance data was based on a population sample that was manually abstracted by the study organization. The study site attributes lack of abstraction resources, and the time involved

for manual abstraction as a key factor regarding the number of cases available for analysis. Third, there is potential for errors in the coding data based on increased awareness regarding sepsis definitions and coding requirements throughout the study period. Fourth, the study site transitioned electronic health records from Cerner to Epic in October 2017, which may have changed the way data was recorded. Last, I could not account for the influence simultaneous quality improvement efforts at the study organization may have had on this study.

Recommendations

Further research is needed to validate the findings from this study and understand the characteristics of the Early Alert Team that effect sepsis outcomes. Although the findings from this study suggest an improvement in mortality outcomes, further research is needed to determine where organizational resources should be focused to optimize sepsis outcomes. As highlighted in the SEP-1 exclusion criteria, individuals who are medically complex/end-stage disease and request transition to comfort care may benefit from proper alignment of care/resources for patient/family support. The goal of sepsis focused quality improvement is best directed to preventable deaths and avoidable harm. Additional research is needed to understand the methodology executive leadership uses to establish organizational structures that improve clinical processes and sustain sepsis focused quality improvement efforts .

Implications for Professional Practice and Social change

Healthcare administrators have an overarching responsibility to design and advocate for structures and process within the healthcare organization that positively

affect patients, as well as the greater community. A key component of executive leadership is the ability to move a strategy into action. Effective healthcare operations and quality improvement efforts are quickly becoming the focus in the context of value-based purchasing initiatives. Given the SEP-1 mandate enforcing hospital compliance with core measures, it is estimated that this publicly reported measure will have financial implications for healthcare organizations in the future (Hospital Compare, 2018).

Social change within the healthcare environment occurs when a shift in organization culture occurs and healthcare leaders no longer accept sepsis-related hospital mortality as an unavoidable occurrence. Although some sepsis-related mortality is unavoidable based on patients end-stage comorbid conditions, greater awareness and continued education is needed regarding preventable harm. Healthcare leaders at the study site are broadly disseminating the results of the quality improvement initiative and communicate Early Alert Team outcomes as the number of "saved patient lives" based on a reduction in sepsis mortality.

The Early Alert Team initiative highlights one organization's focused effort to improve sepsis outcomes. Based on Donabedian's philosophy, there needs to be a strong focus on metrics and team engagement to improve outcomes. Clinical providers must recognize that organizational culture and the social systems in which they practice can greatly influence the quality of care provided (Donabedian, 2005). In this study, a collaborative partnership between executive leadership and the organization's clinical leaders resulted in an innovative structure for enhancing sepsis care. Significant time and resources were allocated for the development of the Early Alert Team and continued

quality improvement efforts continue. Ongoing executive leadership team support and communication regarding sepsis priorities have helped sustain the organization's sepsis care improvement efforts.

Conclusion

Sepsis is one of the leading causes of death for hospitalized patients. Although sepsis care has evolved over the last several decades, healthcare administrators and clinical leaders need to find innovative approaches to improve outcomes and reduce sepsis-related mortality. In this study, I provided evidence regarding the affect sepsis has on patients' lives and the gap that exists in standardized hospital structures needed to improve patient outcomes. Federal mandates targeting improved sepsis care and the potential for future value-based implications have prompted healthcare administrators to rethink their approach to identifying and treating sepsis. In this study, I provided evidence that implementation of an innovative care structure such as the Early Alert Team reduced sepsis-related mortality at the study organization. Healthcare leaders can leverage the sepsis care structure and processes discussed in this study to improve patient outcomes in their organization. As leaders, it is vital to disseminate quality improvement efforts and develop clinical best practice approaches to influence social change in the healthcare arena. As demonstrated by this study, leadership supported quality improvement efforts can result in saved patient lives

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