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THE IMPACT OF EARLY GOAL DIRECTED SEPSIS BUNDLE SETS IN THE EMERGENCY DEPARTMENT AND THE IMPACT OF SEP-1 COMPLIANCE RATES

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By

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THE IMPACT OF EARLY GOAL DIRECTED SEPSIS BUNDLE SETS IN THE EMERGENCY DEPARTMENT AND THE IMPACT ON SEP-1 COMPLIANCE RATES

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ABSTRACT

THE IMPACT OF EARLY GOAL DIRECTED SEPSIS BUNDLE SETS IN THE EMERGENCY DEPARTMENT AND THE IMPACT ON SEP-1 COMPLIANCE RATES

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Sepsis is a medical emergency that is prevalent throughout hospitals everywhere. Due to the growing crisis, the Centers for Medicare and Medicaid Services (CMS) in collaboration with the Surviving Sepsis Campaign (SSC) adopted core measures for sepsis (SEP-1) which aim at improving overall compliance of evidence-based treatment standards for sepsis. The purpose of this Doctor of Nursing Practice (DNP) project was to determine if incorporating early goal directed sepsis bundles in a rural Midwestern ED was effective in increasing compliance with SEP-1 rates. The secondary purpose evaluated how nursing knowledge, awareness, and compliance with sepsis bundles affects SEP-1 compliance rates. A permutation *t* test was performed to compare SEP-1 compliance rates for 2019 before any sepsis protocol was implemented, which was 43.9%. A formal sepsis protocol started March 2, 2020, with data collection occurring from March 2020 to March 2021 and included 37 patients, showing an overall ED SEP-1 compliance of 64.9%. No significant findings were seen in nursing compliance with the sepsis bundle. Overall, these findings show that an organized approach and incorporating an early goal directed sepsis protocol to clinical practice guidelines did show an improvement in SEP-1 compliance scores.

DEDICATION

This Doctor of Nursing Practice project is dedicated to my husband, Tyson. Thank you for the unconditional love, support, and taking amazing care of our family every day, but especially throughout my doctoral program.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

CMS	Center for Medicare and Medicaid Services
DNP	Doctor of Nursing Practice
ED	Emergency Department
EGDT	Early Goal Directed Therapy
ICU	Intensive Care Unit
IHI	Institute for Healthcare Improvement
IRB	Institutional Review Board
MAP	Mean Arterial Pressure
SSC	Surviving Sepsis Campaign
TJC	The Joint Commission
QM	Quality Management

Chapter One

Introduction

Sepsis is defined as the body's systemic response to an infectious process (Gyawali, Ramakrishna, & Dhamoon, 2019). Sepsis is classified as a medical emergency, and despite significant advancements in understanding the pathophysiology of sepsis, it remains the leading cause of death in the adult intensive care unit (ICU) (Berg & Gerlach, 2018). Sepsis accounts for 1.3 million hospital stays per year in the United States (U.S), and the number and rate of hospitalizations has tripled over the last two decades (Leon et al., 2018). Nearly 1 in 3 patients die from sepsis-induced organ dysfunction or septic shock in the United States annually (Whitfield et al., 2019).

Formally, sepsis was understood to be a hyper-inflammatory response to an infection, accompanied by a cytokine storm (Berg & Gerlach, 2018). The current definition explains sepsis as a "life threatening organ dysfunction caused by a dysregulated host response to infection" (Berg & Gerlach, 2018, p. 4). The term severe sepsis involves peripheral organ dysfunction which is included in the newer definition of sepsis. Septic shock occurs when serum lactate levels are more than 2mmol/L, and when a mean blood pressure (MAP) of 65 mmHg can be reached only when vasopressors are utilized despite adequate fluid management (Berg & Gerlach, 2018).

Sepsis can be classified as community onset or hospital acquired, depending on its place of acquisition (Tsertsvadze et al., 2016). Differentiation of the type of sepsis is not always consistent, however it is suggested that cases of sepsis diagnosed on hospital admission or up to 48 hours thereafter were classified as community-acquired and cases diagnosed 48 hours after hospital admission were classified as hospital-acquired

(Westphal et al., 2019). The clinical manifestations of each may present similarly and may not need to be differentiated for appropriate management of sepsis.

Background and Significance

Sepsis bundles.

Sepsis bundles are a group of various therapies built around evidence-based guidelines that guide care to septic patients (Khan & Divatia, 2010). Often called sepsis care bundles or sepsis bundles, they are a small set of evidence-based interventions for a target population, aimed to improve patient outcomes (Institute for Healthcare Improvement, 2020). When specific therapies are implemented together, greater benefits are delivered having a significant impact on outcomes, as opposed to a singular therapy. Sepsis bundles can play a crucial role in uniformity of care, and consistent implementation of an evidence-based bundle is important for effective management and treatment of sepsis (Khan & Divatia, 2010). Specific sepsis bundles and straight forward elements are implemented to improve perfusion to vital organs. When applied appropriately, mortality rates can be reduced by up to 40% when all bundled elements are completed within six hours of sepsis presentation (Whitfield et al., 2019). In a 2019 study conducted by Whitefield et al. 450 participants were randomly placed in two groups with one group receiving sepsis bundles and the other group receiving current standardized care. The results indicated when sepsis bundles were applied appropriately, hospital mortality rates were reduced when all bundled elements are completed ($p = 0.011$) within six hours of sepsis presentation (Whitfield et al., 2019). In addition, a reduction in time to empiric antimicrobial therapy was noted when sepsis bundles were utilized.

Sepsis bundles were initially published in 2004 from the Surviving Sepsis Campaign (SSC) guidelines for the management of severe sepsis and septic shock (Society of Critical Care Medicine, 2021). The campaign consisted of 11 international societies to develop guidelines for managing severe sepsis and septic shock (Society of Critical Care Medicine, 2021). The campaign aimed at improving sepsis diagnosis, sepsis management, and survival of patients diagnosed with sepsis (Khan & Divatia, 2010). Clinical application of early sepsis bundles were first reported in a single-center study, and when compared with standard care, initiating early sepsis bundles decreased mortality in patients with septic shock from 56.8% to 42.3% (Rivers et al., 2001). SSC tested sepsis bundles from 2005 to 2010 to gather information on how a protocolized approach in the early phases of sepsis can lead to better patient outcomes (Berg & Gerlach, 2018). While sepsis guidelines have been revised as literature has been updated, what remains is the importance of hospitals having a performance improvement program for sepsis with adequate sepsis screening tools and guidelines established to influence and standardize sepsis care (Berg & Gerlach, 2018). Standardizing care can assist with better patient outcomes for sepsis and ensure care is consistent with current practice guidelines.

SEP-1.

In the effort to address the sepsis crisis, the Centers for Medicare and Medicaid Services (CMS), in collaboration with SSC, created the SEP-1 core measure. Core measures are national standards of care designed to reduce patient complications, improve patient care, and lead to better patient outcomes (Johns Hopkins Medicine, 2021). Hospitals must report their compliance ratings with various core measures,

including SEP-1, to governing agencies such as The Joint Commission (TJC), a health care accreditation organization, CMS, and other agencies affiliated with payment reimbursement.

Higher compliance ratings indicate a hospital is following certain steps to manage a specific condition. Patients can look up these ratings and compare hospitals, and ultimately choose where to receive care based on their compliance. CMS began requiring U.S. hospitals to report compliance rates with the SEP-1 core sepsis measure in October 2015 (Rhee et al., 2018). The SEP-1 core measure has prompted hospitals to implement improvement programs and processes to ensure compliance with these measures are met. In addition, if hospitals demonstrate decreased compliance, reimbursement from governmental and insurance companies may be affected resulting in increased health care costs for the consumer. Sepsis bundles are the result of the SEP-1 core measure. Chapter 2 will outline the sepsis bundle.

Early goal directed therapy.

Early goal directed therapy (EGDT) treatment of sepsis has been associated with improved outcomes for patients. The challenge of recognizing sepsis signs and symptoms early is essential for proper treatment to begin without delay. Signs and symptoms of sepsis include elevated heart rate, low blood pressure, confusion, pain or discomfort, shortness of breath, clammy or sweaty skin, fever, or feeling cold (Centers for Disease Control and Prevention, 2019). Recognition of sepsis can often be vague as the pathogenesis of sepsis is difficult to identify and is complex (Evans, 2018). Optimization of the management of sepsis in the emergency department (ED) is a public health priority (Viale et al., 2017).

Sepsis visits are prevalent in the U.S., estimating 850,000 ED visits annually (Wang, Jones, & Donnelly, 2017). The ED is the first contact within the healthcare system for patients with community-onset sepsis, ultimately making initial triage and assessment important. EGDT employs sepsis bundles in a systematic fashion in the critical golden hours when "definitive recognition and treatment provide maximal benefit in terms of outcome" (Rivers et al., 2001, p. 1368).

Hospital harms.

The Institute for Healthcare Improvement (IHI) defines hospital harms as an "unintended physical injury resulting from or contributed to by medical care (including the absence of indicated medical treatment) that requires additional monitoring, treatment, or hospitalization, or that results in death" (AHRQ, 2019, para. 3). Harms are classified as an adverse event, which can be preventable for patients. These types of preventable harms can also be defined as an "act of commission (doing something wrong) or omission (failing to do the right thing) leading to an undesirable outcome or significant potential for such an outcome" (Agency for Healthcare Research and Quality [AHRQ], 2019, para. 7). Recognizing that not all events are preventable is an important concept, as some events are ameliorable adverse events, where less harm could have occurred if care had been different.

Statement of Purpose

The purpose of this Doctor of Nursing Practice (DNP) project was to determine if incorporating early goal directed sepsis bundles in a rural Midwestern ED was effective in increasing compliance with SEP-1 rates. The secondary purpose evaluated how nursing knowledge, awareness, and compliance with

sepsis bundles affects SEP-1 compliance rates. By implementing an evidence-based sepsis bundle, EGDT for sepsis may be an effective option for sepsis management by incorporating bundled care and ultimately improving patient outcomes. No formalized bundled sepsis care was in clinical practice in the rural Midwestern ED before this DNP project was instituted.

For this DNP project, two research questions were identified:

1. Does implementation of an evidence-based early goal directed sepsis bundle set in a rural Midwestern ED increase SEP-1 compliance rates?
2. Did RN compliance with the sepsis bundle change over time?

Methods

This DNP project is a quality improvement (QI) initiative that took place in a rural Midwestern ED. Consecutive sampling technique was be used for all adult patients with severe sepsis/septic shock. Patients were identified initially by a triage RN on patient arrival. Once evaluated by the triage RN, the patient will be referred to an ED physician who will determine if the patient meets sepsis guidelines based on the patient's presentation and history. A detailed explanation of sepsis guidelines is further explained in Chapter 3, design paragraph. A retrospective pre-post design was used to compare ED compliance with SEP-1 rates from 2019 to 2020. Since the sepsis bundle started in March 2020, a full year of data was collected, therefore ending the study in March 2021. Interventions were implemented in March 2020. Data from 2019, 2020, and 2021 (January, February, and March) was collected retrospectively for all patients with the diagnosis of severe sepsis and/or septic shock.

Proposed interventions included revisions of sepsis orders in the ED electronic medical record (EMR), activation of an ED sepsis alert, and an *ED Sepsis Alert Checklist* (see Appendix A), which is a written communication tool to be used during the ED sepsis alert. The ED sepsis alert is initiated when the ED nurse and physician assess a patient over the age of 18 and determine a patient meets sepsis criteria. The hospital operator is then paged by the ED staff alerting them an ED sepsis alert has been initiated. The hospital operator is instructed to page the laboratory technician, the ICU nurse functioning as the SWAT nurse, hospital supervisor, and the pharmacy department. The SWAT nurse is an ICU RN assigned each shift to report to emergencies throughout the hospital. If staffing permits, all will respond to the patient's bedside in the ED. Otherwise, the sepsis bundle will reside in the ED with ED staff conducting interventions.

A secondary intervention includes nursing compliance with this bundle when sepsis criteria is met, and an ED sepsis alert has been activated. Nursing compliance was measured by a self-reported Likert style questionnaire issued at the beginning of the DNP project (called the Sepsis Protocol and Sepsis Alert Baseline survey) and at the end of data collection, called (Sepsis Protocol and Sepsis Alert Conclusion Survey) and will commonly be referred to as Sepsis Protocol and Sepsis Alert Survey throughout this DNP project, and designated as baseline or conclusion as needed (see Appendix B). A *Sepsis Alert Checklist* should be initiated for all sepsis alerts, which serves as a communication tool all staff members can use throughout the ED sepsis alert as well as a report tool during shift change or when patients are admitted. The *Sepsis Alert Checklist* incorporates the SEP-1 core measures to increase compliance with the sepsis bundle and

outlines when time sensitive sepsis interventions should be completed. The *Sepsis Alert Checklist* will be reviewed by ED management or the sepsis committee at the hospital on an as needed basis if any follow up or chart review is required during this study. The *Sepsis Alert Checklist* was created independently by the student researcher and was revised and approved by the sepsis committee. The sepsis committee comprises an ED physician, ED management, Quality Management (QM), ICU management, and senior management. Permission to implement the *Sepsis Alert Checklist* was granted by the sepsis committee (see Appendix C).

Introduction of Theoretical Framework

The focus of this DNP project is to improve sepsis compliance rates by incorporating early goal directed sepsis care when a patient is screened positive for sepsis in the ED. The nursing process discipline theory created by Ida Jean Orlando was used to plan, implement, and evaluate the introduction of sepsis bundles, and implement an ED sepsis alert in the ED. The model focuses on patient centered care and incorporates five concepts: (a) professional nursing function, (b) patient's presenting behavior, (c) immediate reaction, (d) deliberate nursing process, and (e) improvement (Alligood, 2013). Orlando's theory is a middle-range theory created as a reflective practice theory with the basis of discovering and resolving problematic situations (Alligood, 2013). With putting the patient as the focal point of nursing care and following the five interrelated concepts, Orlando's nursing process can be fulfilled.

The nursing process discipline theory focuses on understanding complex situations and problem solving by incorporating the nurse's past experience and clinical knowledge with their understanding of the immediate situation at hand (Alligood, 2013).

This allows the nurse to effectively produce a deliberate reaction, as the nurse explores to identify the problem further, as well as an appropriate solution. By incorporating Orlando's framework, the nurse is effectively able to meet the patient's immediate needs by addressing them directly, and/or calling for help from others. The goal is to help diminish any distress the patient may be experiencing or improve the patient's sense of adequacy or well-being (Alligood, 2013).

When implementing the nursing process discipline theory into nursing practice, the focus becomes on the interaction between nurse and patient, perception validation, and how the incorporation of the nursing process produces positive outcomes or patient improvement (Faust, 2002). Integrating this theory allows for interventions to be tailored specifically to the patient in distress, while empowering nursing to understand patient satisfaction and improvement which ultimately is the goal (Faust, 2002). The nurse uses the nursing process when synthesizing the nursing process discipline theory, which follows: assessment, diagnosis, planning, implementation, and evaluation (Petiprin, 2020). Orlando's theoretical framework explains that patients need help communicating their needs, and how important the nurse-patient relationship is for patients to have their needs met (Petiprin, 2020).

Chapter Two

Literature Review

Sepsis is a medical emergency with a complex pathophysiology. Sepsis remains one of the major causes of morbidity and mortality in critically ill patients in the United States, with up to 300 cases per 100,000 people (Gyawali et al., 2019). Worldwide, sepsis results in approximately 6 million deaths annually (Gyawali et al., 2019). Sepsis is caused by the body's response to infection, which is defined as a life-threatening organ dysfunction due to a dysregulated host response to infection (Marik & Taeb, 2017). It is one of the oldest themes in medicine dating back to Hippocrates, and despite advances in medicine and health care, remains one of the leading causes of death (Cawcutt & Peters, 2014). Sepsis is a life-threatening emergency and is the body's response when an infection is present (CDC, 2019). It is classified as a physiologic, pathologic, and biologic syndrome that is induced by infection (Singer et al., 2016). Without timely treatment, sepsis can cause tissue damage, organ failure, and death (CDC, 2019).

Older Criteria to Identify Sepsis

Sepsis represents the findings of systemic inflammatory response syndrome (SIRS) which is characterized by having two or more of the following as well as a documented or suspected infection: (a) body temperature greater than 38°C or less than 36°C, (b) heart rate greater than 90 beats per minute, (c) respiratory rate greater than 20 breaths per minute, and (d) white blood cell (WBC) count greater than 12,000/mm^3 or less than 4000/mm^3 or greater than 10% immature forms (Remick, 2007). In 1991, the original concept of SIRS was developed from An American College of Chest

Physicians/Society of Critical Care Medicine Consensus Conference which describes it as inflammatory excess (Bone et al., 1992). The validity of SIRS regarding sepsis pathophysiology has since been challenged. Sepsis is now known to have both pro and anti-inflammatory responses affecting pathways involving "cardiovascular, neuronal, autonomic, hormonal, bioenergetic, metabolic, and coagulation" (Singer et al., 2016, p. 5).

Newer Definitions to Identify Sepsis

Newer definitions defining clinical criteria of sepsis came out in 2016 from the European Society of Intensive Care Medicine and SSC consisting of a task force of 19 critical care, infectious disease, surgical, and pulmonary specialists (Singer et al., 2016). Updates included a scoring definition using a quick sequential organ failure assessment (qSOFA) scoring system to identify simultaneous organ dysfunction in sepsis (Gül, Arslantaş, Cinel, & Kumar, 2017). The most recent clinical criteria of sepsis include altered mental status, systolic blood pressure <100 mmHg, and a respiratory rate >22/min (Gül et al., 2017). If 2 of the 3 criteria were present, a qSOFA would be positive, identifying possible infection and ultimately high-risk for sepsis and increase in hospital mortality rates (Gül et al., 2017).

Symptoms of sepsis commonly include rapid breathing and heart rate, shortness of breath, confusion or disorientation, extreme pain or discomfort, fever, shivering or feeling cold, and clammy or sweaty skin (National Institute of Health, 2021). Severe sepsis is sepsis plus one of the following clinical problems: 1) cardiovascular system dysfunction, 2) acute respiratory distress syndrome (ARDS), or 3) dysfunction of 2 or more other organ systems (Atrain Education, 2020). Dysfunction of at least one organ

or organ system can include hypotension, oliguria, or metabolic acidosis, which can evolve into septic shock (Cawcutt & Peters, 2014). Septic shock presents as severe sepsis with persistent hypotension despite fluid resuscitation (Cawcutt & Peters, 2014).

Sepsis develops secondary to various medical conditions; therefore, early identification is crucial. Sepsis can result from either community-acquired or hospital-acquired infections, with the most common underlying causes being pneumonia, intra-abdominal infections, and urinary tract infections (Cawcutt & Peters, 2014). Clinical features of sepsis can vary, depending on the site and severity of infection. Time is the most critical factor in determining survival (Berdugo, 2020), which is why employing a best practice and evidence-based approach to manage sepsis is essential.

Implementation of Sepsis Bundles

Clinical practice guidelines, also known as sepsis bundles, were developed in 2004 by the SSC to better manage the provision of care for sepsis. Sepsis bundles are intended to provide guidance for the clinician caring for the patient with sepsis, and are best practice guidelines (Rhodes et al., 2017). The bundles aim at improving diagnosis, management, and survival for people with sepsis because they promote early interventions (Leon et al., 2018). Early interventions are vital to increase survival rate, improve morbidity, reduce healthcare cost, and decrease overall length of hospital stay (Leon et al., 2018). Sepsis bundles work best when incorporated in guiding care when they are simplified and consistent.

Sepsis bundles have been central to the implementation of the SSC and have been a cornerstone of sepsis quality improvement since 2005 (Levy, Evans, & Rhodes, 2018). The sepsis guidelines conclude that patients need urgent assessment and

treatment including initial fluid resuscitation, obtaining laboratory results, and precise measurements of hemodynamic status (Levy et al., 2018). Sepsis bundles incorporate timeframes for when recommended treatment should be completed. Revision of the SSC bundles occurred in 2018, which combined the 3-hour parameters into a 1-hour timeframe, with the priority of beginning fluid resuscitation and sepsis management immediately (Levy et al., 2018). Consistent terminology of the SSC bundles includes time zero or time of presentation which is defined as the triage time in the ED, or transfer arrival time from another location and when the earliest documentation occurs consistent with the elements of sepsis (Levy et al., 2018). While more than 1 hour may be required for fluid resuscitation to be completed, the sepsis bundle incorporates the initiation of fluid resuscitation and starting treatment such as obtaining blood for lactate level and blood cultures, starting antibiotics, and in the case of persistent hypotension, initiation of vasopressor therapy, which are all begun immediately (Levy et al., 2018).

The ED is the most common site where early sepsis is identified (Whitfield et al., 2019). Rivers, et al., (2001) performed a hallmark study focusing on EGDT before admission to the ICU from March 1997 through March 2000. The qualitative, double blinded study included 263 enrolled patients, in which 130 were randomly assigned to EGDT, and 133 were assigned to standard therapy (Rivers et al., 2001). Eligibility included patients who presented to the ED with severe sepsis, septic shock, or the sepsis syndrome. Patients had to fulfill two of the four SIRS criteria, have a systolic blood pressure (SBP) less than 90 mm Hg, and a blood lactate level of 4 mmol or more (Rivers et al., 2001). Rivers et al., (2001) attempted to evaluate the efficacy of EGDT before admission to the ICU, and if EGDT before admission to the ICU reduces the incidence of

multiorgan dysfunction, mortality, and the use of health care resources among patients with severe sepsis or septic shock (Rivers et al., 2001).

Treatment patients received a central venous catheter (CVC) and given a 500 ml crystalloid bolus to achieve a central venous pressure (CVP) of 8 to 12 mm Hg. If the mean arterial pressure (MAP) was less than 65 mm Hg, vasopressors were administered to achieve a MAP of at least 65 mm Hg. If central line oxygen saturation (SVO2) was less than 70%, red blood cells were transfused to reach a hematocrit of at least 30%, and if the SVO2 remained less than 70%, a vasopressor, Dobutamine, was started (Rivers et al., 2001). Differences between the two groups at baseline were tested with the use of the t-test, the chi-square test, or Wilcoxon's rank-sum test (Rivers et al., 2001).

Results of the study concluded EGDT provided during the early stages of severe sepsis and septic shock had significant short and long-term benefits. The hemodynamic goals for CVP, MAP, and urine output was achieved in 86.1% of the standard-therapy group, as compared with 99.2% of the early-therapy group ($p<0.001$) (Rivers et al., 2001). Regarding mortality, in-hospital mortality rates were significantly higher in the standard-therapy group than in the EGDT group ($p=0.009$), as was the mortality in the standard group at 28 days ($p=0.01$) and 60 days ($p=0.03$) (Rivers et al., 2001). Findings suggest the rate of in-hospital death due to sudden cardiovascular collapse was significantly higher in the standard-therapy group than in the early therapy group ($p=0.02$) but found the rate of death due to multiorgan failure was similar in the two groups ($p=0.27$), showing no significant results (Rivers et al., 2001). Rivers et al., (2001) found that patients in the EGDT group received more fluid in the first 6 hours compared to the standard group, ($p <0.001$), but the patients in the standard group

received more fluid during the period of 7 to 72 hours than those in the EGDT group (p=0.01) (Rivers et al., 2001). The findings of Rivers et al. (2001) were significant and found:

> The benefits of EGDT in terms of outcome are multifactorial. The incidence of death due to sudden cardiovascular collapse in the standard therapy group was approximately double that in the group assigned to early goal-directed therapy, suggesting that an abrupt transition to severe disease is an important cause of early death (p. 1375).

Early Identification

Another study by Zhang et al., (2017) addressed how early management of sepsis and initiation of SSC bundle may improve patient outcomes. Zhang et al., (2017) conducted a thorough literature review of original studies electronically using PubMed, yielding 13 randomized controlled trials (RCTs), 12 systematic reviews, and meta-analysis with the focus on patient outcomes, and their main findings identified that EGDT significantly improved mortality compared to standard care (Zhang et al., 2017). In addition, Zhang et al., (2017) found that the idea of EGDT may benefit ICU patients over ED patients because the diagnosis of sepsis to start of treatment was faster due to a better knowledge of time, and that EGDT provided in the earliest stages of severe sepsis and septic shock had significant short-term improvements (Zhang et al., 2017). The main findings showed the importance of early recognition of sepsis, and the inability to achieve early resuscitation goals was associated with increased 28-day mortality rate (Zhang et al., 2017). Lastly, the authors concluded that early awareness of sepsis and

prompt initiation of the SSC bundle remain crucial for improving the outcome of severely septic patients (Zhang et al., 2017).

Responding to sepsis like other emergency codes also aligns with EGDT. Sepsis core measures are found to improve the compliance rates of the treatment bundles (Whitfield et al., 2019). Whitfield et al., (2019) evaluated hospitals who implement a *code sepsis* to increase quality of care as well as adhere to timeliness to care. Using a retrospective, observational cohort design, this study took place in an ED between December 2016 to February 2018 and reviewed 450 adult patients with sepsis. Triage nurses were informed to notify the ED physician if two or more criteria were present: (a) temperature >100.4°F or <96.8° F, (b) heart rate (HR) >90 beats per minute, (c) respiratory rate >20, 4) SBP <90 mmHg, and (d) altered mental status in the presence of a suspected infection (Whitfield et al., 2019). If the physician felt a known infection was present, a code sepsis was activated to prioritize care consisting of an immediate intravenous (IV) access, sepsis blood work, IV fluids, and antibiotics readily available (Whitfield et al., 2019). This qualitative and quantitative study utilized a Shapiro-Wilk test to test for normality, a *Mann-Whitney U* test for continuous data and outcomes expressed as a median, and categorical data was assessed using a *chi-square or Fisher's exact test* (Whitfield et al., 2019).

Whitfield et al., (2019) determined that the implementation of an adult code sepsis protocol resulted in significant improvement in the rate of SEP-1 and various clinical outcomes for patients who presented to the ED with severe sepsis and septic shock (Whitfield et al., 2019). Compliance with each SEP-1 element was improved, time to treat with the appropriate and effective antimicrobial therapy was reduced, and

in-hospital mortality decreased (Whitfield et al., 2019). The authors discovered no significant results associated with length of stay, total cost per case, and readmission rates (Whitfield et al., 2019). Additionally, they found that the implementation of an interdisciplinary team approach to manage patients with severe sepsis and septic shock had a positive impact on compliance with SEP-1 bundle, as well as in-hospital mortality, and 30-day readmission (Whitfield et al., 2019).

Every year millions of patients suffer from injuries due to unsafe or adverse events from hospital care (World Health Organization, 2020). These harms can be attributed to unsafe care and/or care that fails to meet the standard of care. Sepsis is classified as one of the most common patient safety situations causing concern for patients (World Health Organization, 2020). Sepsis is considered to be a patient harm because it is "not diagnosed early enough to save a patient's life. Because these infections are often resistant to antibiotics, they can rapidly lead to deteriorating clinical conditions, affecting an estimated 31 million people worldwide, and causing over 5 million deaths per year" (World Health Organization, 2020, The burden of harm section, para. 9).

Compliance with the SEP-1 element can reduce sepsis harm rates as they provide an organized approach to clinical guidelines. Bundled approach has been proven to be effective in improving clinical outcomes (Borgert, Goossens, & Dongelmans, 2015). The management of sepsis became a CMS core measure as it is supported by "increasingly clear reproducible high-quality evidence from clinical trials that defines the timing of specific treatments and assessments for patients recognized as having sepsis" (Motzkus & Lilly, 2017, p. 955).

Sepsis Bundle

In order to be fully compliant with SEP-1 core measure, all elements of the bundle must be met. This rural Midwestern hospital tracks sepsis rates according to compliance with the bundle. The Quality Management (QM) department at this rural Midwestern hospital track sepsis compliance rates regularly to determine where bundle compliance is met, and when and where fallouts are occurring. The bundle includes:

> Severe sepsis requires lactate measurements, blood cultures, and broad-spectrum antibiotics within 3 hours of sepsis onset, with repeat lactate measurements within 6 hours if the initial lactate is >2.0mmol/L. The septic shock bundle also requires 30 cc/kg of intravenous fluids within 3 hours, vasopressors within 6 hours for persistent hypotension, and a repeat volume assessment exam within 6 hours (Rhee et al., 2018, p. 2).

Overall compliance with SEP-1 core measures can impact quality performance ratings of the hospital. These core measures have prompted healthcare facilities to implement quality improvement programs to ensure compliance. Utilization of early goal-directed protocols where screening triggers and goals are incorporated were associated with earlier recognition of sepsis and better compliance with bundle elements (Whitfield et al., 2019). Sepsis is associated with high morbidity and mortality; therefore, identification of sepsis prevention strategies is a public health priority. It is important that appropriate assessment and interventions taken for sepsis management are evidence-based to improve SEP-1 compliance and decrease sepsis harm rates. Early bedside intervention with a sepsis alert and sepsis team is found to improve compliance

with the SSC bundle, and therefore a positive impact on patient outcomes (Viale et al., 2017).

Fluid Resuscitation

Crystalloids are solutions of ions that are freely permeable through capillary membranes, with the most common being isotonic crystalloids (Semler & Rice, 2016). Isotonic saline is most commonly administered intravenously (IV) and is recommended as the first line fluid for sepsis resuscitation as patients with sepsis are frequently hypovolemic from decreased intake, fight against vascular resistance, venous capacitance, and vascular leaking resulting in decreased stroke volume and decreased cardiac output (Semler & Rice, 2016). The biggest threat becomes tissue hypoxia, anaerobic metabolism, and lactic acidosis (Semler & Rice, 2016). Rivers et al., (2001) evaluated 263 patients with sepsis, dividing 130 patients who were randomly assigned to receive EGDT versus 133 patients assigned to receive standard therapy. The EGDT patients received more IV fluid (5.0 versus 3.5 liters, $p<0.001$), red blood cell transfusion (64.1% versus 18.5%, $p<0.001$) and dobutamine (13.7 versus 0.8, $p<0.001$), and resulted with 16% lower in-hospital mortality compared to standard group therapy (46.5 versus 30.5, $p=0.009$) (Semler & Rice, 2016).

Vasopressors

Evidence of survival has been studied with utilizing fluid resuscitation to maintain better hemodynamics. When adequate resuscitation doesn't stabilize hemodynamics, vasopressors can be effective by increasing vasoconstriction, which can increase systemic vascular resistance (SVR), leading to an increase in the MAP, and ultimately improve perfusion to organs. (VanValkinburgh, Kerndt, & Hashmi, 2021).

The American College of Critical Care Medicine (ACCM) guidelines recommend a MAP of 60-65 Hg is required to adequately perfuse organs, and if appropriate fluid resuscitation does not reach that target range, vasopressors be initiated (VanValkinburgh et al., 2021). The SSC recommends norepinephrine as the initial vasopressor (Avni et al., 2015). Evidence and efficiency of vasopressors has been evaluated by Anvi et al., (2015) who searched electronic databases on sepsis and the outcome was mortality of sepsis patients at 28 days (Avni et al., 2015). This systematic review and meta-analysis included RCT and randomized crossover trials comparing different vasopressors for treatment of septic shock in adult patients (Avni et al., 2015). They reviewed 32 studies published from 1989-2012 and a Cochrane systematic review assessed the efficacy of vasopressors, as well as comparing vasopressors such as dopamine and norepinephrine (Avni et al., 2015).

Results showed an advantage of norepinephrine over dopamine, with a reduction in mortality of 11% in 28 days (Avni et al., 2015). Early administration of vasopressors can be beneficial to prevent fluid overload, and they can be beneficial to adequately restore MAP (Hamzaoui & Shi, 2020). A retrospective study of 213 patients evaluated the time to initiate norepinephrine was a major factor associated with mortality, showing later initiation had worse outcomes for patients and earlier initiation shortened the duration of hypotension, and the overall dose of norepinephrine was lower (Hamzaoui & Shi, 2020). The current recommendations by the SSC suggest vasopressors be administered after the initial fluid resuscitation of 30mL/kg of crystalloids is administered, and recent updates proposed a new 1-hour bundle indicating to start

vasopressors if the patient is hypotensive during or after fluid resuscitation to keep MAP ≥ 65 mmHg (Hamzaoui & Shi, 2020).

Summary

Based on the literature review, EGDT and bundled care can improve outcomes, by decreasing mortality rates, stabilizing hemodynamics, initiating timely antibiotic therapy, and increasing compliance with SEP-1 measures. Early identification and treatment for sepsis can be valuable for patients in the beginning stages of sepsis and in response have a significant impact on reduction of patient harms. Early recognition and prompt initiation with a structured treatment algorithm is incorporated into the SSC bundle and remain imperative for improving the fate of severely septic patients (Zhang et al., 2017) Therefore, the purpose of this Doctor of Nursing Practice (DNP) project was to determine if incorporating early goal directed sepsis bundles in a rural Midwestern ED was effective in increasing compliance with SEP-1 rates. The secondary purpose evaluated how nursing knowledge, awareness, and compliance with sepsis bundles affects SEP-1 compliance rates.

Theoretical Framework

Orlando's deliberative nursing process theory was used to assist this DNP project in the implementation of a formal bundle of interventions aimed to improve sepsis compliance rates. The theory of deliberative nursing process emphasizes the importance of communication between nurses and patients and is described in five concepts: (a) function of professional nursing, (b) presenting behavior, (c) immediate reaction, (d) nursing process discipline, and (e) improvement (Petiprin, 2016). The

concept of professional nursing is the first step and concentrates on the nurse assisting the patient with their immediate needs and providing direct assistance (Petiprin, 2016). This is done by focusing on the immediate situation and "avoiding, relieving, diminishing, or curing the sense of helplessness in the patient" (Petiprin, 2016, para3). This is an important concept that can be applied when a patient enters the ED with their chief complaint that correlates to signs and symptoms of sepsis and for nursing to act in a professional and timely fashion to triage the patient. It is crucial to obtain a thorough history of presenting illness (HPI) and obtain accurate vital signs to effectively triage to ensure all the information is current and reliable. The concept of presenting behavior, which is the second step, is achieved by recognizing that the patient has a problematic situation (Petiprin, 2016). An example of this can be tachycardia, hypotension, or a fever and requires the nurse to synthesize verbal and nonverbal cues and implement appropriate treatment. This is where the triage nurse must critically think if this is a true emergency or if this can be deferred. The nurse must act in accordance with hospital policy, while ensuring safety of the patient.

The third concept in Orlando's nursing process framework is immediate reaction. This concept requires assessing the patient's behavior, which can be done by a detailed assessment from a patient's verbal and nonverbal communication (Sheldon & Ellington, 2008). This response can really determine how the nurse-patient relationship is perceived and can impact the care that the patient receives. This concept can be applied to the actions the triage nurse has and the urgency associated with it. The patient may require immediate medical attention and the nurse may have to find a provider to examine that patient urgently, especially if an ED Sepsis Alert is suspected on the

associated symptoms the patient is presenting with. If the patient is hypotensive, their immediate reaction may be to insert an intravenous (IV) catheter as IV fluids may be required to stabilize their BP.

The fourth concept is nursing process discipline which requires the nurse to further investigate the patient's needs (Petiprin, 2020). This concept involves deeper assessment and exploration of the patient by employing meaningful communication between the nurse and patient. Understanding the patients' needs may involve supportive care if they are in a febrile state, such as a cold compress or a warm blanket if they have the chills. It involves the RN to involve the patient and family in their care so the patient receives patient centered care, and honors their personal beliefs and values.

Improvement is the final concept, which is resolution of the patient's situation. For example, improvement in the sepsis patient may be the patient was able to get out of bed into a chair and eat breakfast without feeling short of breath or experiencing fluctuations in their blood pressure during position changes, indicating normovolemia and no hypoxic events. How well the nurse and patient communicated throughout their interaction is important for these five concepts to be completed (Petiprin, 2016). Orlando emphasizes how dynamic the nurse-patient situation is, and to assist in the meaningfulness of the relationship, both need to maximize their interaction.

This concept was examined in an exploratory study of 60 nursing students and their responses to a simulated clients questionnaire based on Orlando's theory. Students' immediate responses to physical and mental problems of a patient in distress were classified into six main categories: physical caring, uncertainty, assuring, recommending, asking information, and explaining (Abdoli & Safavi, 2010). The study concluded that

nursing students responded to patients' needs automatically and were concerned with a patient's medical diagnosis, physical caring for patients, and assurance to the patient, but not aware of considering a patient's ability in decision making (Abdoli & Safavi, 2010). This shows that caring for a patient as a whole has been overlooked, and something that the nursing education system should be emphasizing in their curriculum to promote caring physically and mentally for the patient in distress (Abdoli & Safavi, 2010).

Incorporating Orlando's nursing process framework into this DNP project is applicable because it explains the importance of the nurse meeting the immediate needs of the patient. When a patient presents to the ED, the triage (RN) is often the first person to clinically assess a patient. The role of the triage RN is essential as their assessment can determine a patient's level of need for medical assistance and establish when they should receive it. How the triage RN reacts is important because it can guide interventions specific for patient care. There are several factors that may impact a nurse's response to a patient. These factors are:

1. Clinical factors – time, workload, peer support.
2. Nurse-patient factors – previous experiences together, relationship, duration.
3. Nurse factors – experience, personality, clinical experience, communication style, stress.
4. Patient factors – personality, diagnosis, prognosis, coping patterns, support system, verbal, and nonverbal communication (Sheldon & Ellington, 2008).

These factors are important to a patient who presents with sepsis as all of these steps can be an advantage or disadvantage to a patient's care. When clinical factors

are supported and a nurse has adequate time and support from their peers, patient care can often be expedited allowing for care to be implemented sooner. This can include initiating SEP-1 measures within the allotted timeframe. When evaluating nurse-patient and nurse factors in regard to the sepsis patient, the nurse's ability to communicate effectively with the patient and advocate for their needs, while maintaining good clinical judgement and reporting it to the provider is important. However, this type of time-management often comes with experience, and these concepts may be harder for less experienced nurses to multitask when a complex septic patient is involved, especially when patient factors (the last concept) impact a nurse's response to a patient, are challenging. These components can all build on each other and affect the care of the septic patient in the ED.

Chapter Three

Methods

Purpose and Sample

It is shown that early interventions such as prompt detection, fluid resuscitation, and antibiotic therapy contribute to a reduction in sepsis-related mortality (Westphal et al., 2019). Strategies to reduce sepsis associated complications and mortality require prompt diagnosis and treatment. Sepsis bundles provide a specific protocol for clinical staff to follow when patients present with symptoms of sepsis. The primary objective of this DNP project was to determine if incorporating early goal directed sepsis bundles in a rural Midwestern ED was effective in improving compliance with SEP-1 measures. The secondary objective was to assess RN compliance with sepsis protocols and knowledge among the nursing staff at baseline (or when implementation of the sepsis protocol began) and one year after the implementation of these newly developed sepsis protocols to determine if there is any correlation with RN compliance and SEP-1 rates. The sepsis protocols were developed by the student and the hospital sepsis committee utilizing evidence-based interventions for ED patients presenting with known or suspected sepsis.

The implementation of a bundled sepsis protocol was newly developed for this rural mid-western ED at the start of this DNP project. This protocol was created by utilizing evidence-based interventions when sepsis is suspected in a patient who presents to the ED. Consecutive sampling techniques were used by the QM department including all adult patients over 18 years old with sepsis and septic shock. Inclusion criteria included adult patients over 18 years old with a final diagnosis, or discharge diagnosis of

severe sepsis or septic shock, and those who met initial triage criteria for sepsis. Exclusion criteria included patients transferred from outlying institutions to the ED and patients with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) also referred to as COVID-19. A sample size calculator to determine the minimum number of patients needed for the study was not needed due to the length of time for pre and post-cohort. A retrospective pre-post design was used to compare ED compliance with SEP-1 rates from 2019 when no formal sepsis interventions were developed, to March 2020 through March 2021 when sepsis bundles were initiated. Nursing compliance rates with SEP-1 core measures were measured from the start of the DNP project compared to the end by the QM department electronically and provided to the student.

Project Approval Process

Institutional review board (IRB) approval was obtained from the hospital prior to any data collection for this DNP project (see Appendix D). IRB was not required through the university (see Appendix E). The university requires completion of Collaborative Institutional training Initiative (CITI) modules prior to the IRB approval process which was achieved (see Appendix F). Following data collection, all surveys will be kept in a locked device without any identifying information for seven years. After seven years, all data will be shredded and discarded.

Informed Consent and Quality Assurance

Patient identifiers were not attached to any data, therefore patient consent forms were not required for this study. Data was abstracted electronically by the QM department through nursing and physician documentation. All patient identifiers were removed prior to data review and ethical compliance was followed.

Design and Procedures

When a patient presented to the ED, a triage nurse assessed the patient on arrival and documented the HPI including associated symptoms and current vital signs. If a nurse detected abnormal vital signs or specific sepsis triggers, the sepsis protocol was introduced. The abnormal vital signs that were agreed upon by the sepsis committee are: (a) temperature >100.9F or < 96.8 F, (b) respiratory rate >20, (c) heart rate ≥ 90, 4) pulse oximetry <90%, (d) SBP <100, and (e) GCS score of <15 indicating altered mental status. There must also be two abnormal vital signs present in a patient for the sepsis protocol to be initiated. Additionally, one risk factor must also be included when a patient presents to the ED to initiate the sepsis protocol. The risk factors include: (a) age >65, (b) immunocompromised or receiving chemotherapy, (c) current fever, rigor, or night sweats, (d) recent surgery or invasive procedure, (e) implanted device or indwelling urinary catheter, and (f) white blood cell count >12,000 or lactate >2.

While specific criteria are required to be met to initiate the sepsis protocol, the nurse does reserve the right to use discretion and clinical judgement to initiate the protocol if a patient doesn't meet criteria, but they feel the patient's presentation warrants. Once the patient met criteria or nurse discretion is exercised, the nurse directly alerts the ED provider and inform them that the patient meets criteria for sepsis protocol. An ED provider then conducts their patient interview and assessment within 10 minutes to determine if an *ED sepsis alert* should be initiated. The sepsis alert was initiated when the ED provider assesses a patient and determines if a patient meets sepsis criteria by evaluating the vital signs, risk factors, and patient's condition overall. If it is determined that a sepsis alert should be called, the hospital operator will be notified by an ED staff

member, and send a page to the SWAT nurse, phlebotomist, pharmacy, and hospital supervisor that an *ED sepsis alert* has been initiated. Implementation of a sepsis alert ensures valuable resources are incorporated early in the patient's care.

Incorporating a multidisciplinary team can offset some of the critical workload required to be completed in a timely manner for EGDT to be effectively completed. A *Sepsis Alert Checklist* will be initiated for all sepsis alerts, which serves as a communication tool and as a reference guide to help ensure time sensitive sepsis interventions are completed, leading to increased sepsis care compliance. It also serves as a communication tool for staff members during shift change and when the patient is admitted. The *Sepsis Alert Checklist* is reviewed by ED management on an as needed basis.

Planning for a hospital QI project on sepsis began January 2020 by focusing on core measures, creation and revision of electronic order sets, sepsis protocols, communication tools, and promoting provider and staff education. The focus of this DNP project remained in the ED, as the majority of sepsis fall-outs resided in the ED. Initial education for all ED staff and clinical staff throughout the hospital regarding sepsis protocols and sepsis harms began at a mandatory harms awareness day in February 2020. Revision of protocols and tools were completed in January and February 2020, and sufficient data was collected by the QM department in 2019 to determine compliance with the SEP-1 core measures.

Data obtained from the QM department indicated compliance with SEP-1 core measures were not consistently being followed at this rural Midwestern hospital. In 2019, compliance for SEP-1 was 38.18% for the inpatient population, and 43.9% in the

ED therefore, it was noted there was an urgent need for an evidence-based QI project to be implemented. This DNP project began as a result of the QI project, and officially started March 2, 2020. Evaluation of data and progress were reviewed at the sepsis meetings and continued one year post implementation of this DNP project.

The study formally concluded in March 2021, to allow for one full year of data. A questionnaire containing several Likert style questions entitled Sepsis Protocol and Sepsis Alert Survey (see Appendix B) was independently created by the student researcher and was approved by the hospital IRB. The survey was given to ED nursing staff in July 2020 to assess baseline compliance with sepsis protocols and knowledge. The same survey was distributed to ED nursing staff at the end of data collection to assess nurse compliance and knowledge one year after interventions were initiated and compare with the baseline survey results.

Statistical Analysis

Due to the length of time for pre and post cohort, anticipated sample size was determined to be adequate. A permutation t test was performed to compare compliance with SEP-1 for 2019 compared to sepsis compliance rates in 2020 for one year after the interventions were implemented. The Sepsis Protocol and Sepsis Alert Survey (see Appendix B) was distributed to all ED nurses to assess baseline compliance with sepsis protocols and knowledge. This was done at various nursing huddles on different shifts and days throughout July 2020. The same survey was anonymously distributed at ED unit huddles one year after initiation (June and July 2021) by the student researcher in the same manner as the baseline compliance survey. The results of the nurse survey were

evaluated and analyzed using median values and determining the interquartile range (IQR) for each question on the questionnaire.

Two research questions were identified at the start of this DNP project. The first question was "Does implementation of an evidence-based early goal directed sepsis bundle set in a rural Midwestern ED increase SEP-1 compliance rates?" This research question was evaluated by comparing SEP-1 compliance scores in the ED using a permutation *t* test. The secondary research question determined was "Did RN compliance with the sepsis bundle change over time?" This research question was evaluated by comparing scores provided at the start of this DNP project compared to the end of the project. Results will be discussed in the next chapter.

Chapter Four

Results

Sepsis bundles are intended to provide best practice guidelines for the patients with sepsis. Implementation of sepsis bundles and EGDT has been effective in decreasing mortality and demonstrates significant improvement in compliance rates with each SEP-1 bundle element (Whitfield et al., 2019). The purpose of this Doctor of Nursing Practice (DNP) project was to determine if incorporating early goal directed sepsis bundles in a rural Midwestern ED was effective in increasing compliance with SEP-1 rates. The secondary purpose evaluated how nursing knowledge, awareness, and compliance with sepsis bundles affects SEP-1 compliance rates. The research questions for this DNP project were:

1. Does implementation of an evidence-based early goal directed sepsis bundle set in a rural Midwestern ED increase SEP-1 compliance rates?

2. Did RN compliance with the sepsis bundle change over time?

Demographic Information

Data were obtained using consecutive sampling for all patients with a severe sepsis or septic shock diagnosis. SEP-1 compliance was divided into pre- and post-intervention. Pre-intervention consisted of 12 months of 2019 as well as January and February of 2020. The sepsis protocol was initiated March 2020, therefore post-intervention included March 2020 through February 2021, for a full year of data. The QM department uses five data element points for eligible patients: (a) ICD-10-CM Principal Code, (b) ICD-10-CM Other Diagnosis code, (c) admission date, (d) birthdate,

and (e) discharge date. The survey from nursing staff for pre- and post-intervention, included all ED RNs. The baseline survey accounted for 21 nurses, and the one year follow up survey included 17 responses. All surveys were submitted anonymously without any identification or demographics.

Data Analysis

The Sepsis Protocol and Sepsis Alert Survey (see Appendix B) included a 7-item Likert scale to measure knowledge of sepsis and compliance with utilization of the sepsis protocol. The Likert scale ranged from "*strongly disagree*" receiving 1 point, to "*strongly agree*" receiving 5 points. The questions of the survey remained the same for baseline and one year follow up, and read as follows:

Table 1

RN Response to Sepsis Protocol and Sepsis Alert Survey

1) I am familiar with vital signs associate with sepsis?				
Strongly Disagree *n=0* **n=1**	Disagree *n=0* **n=0**	Neither Agree or Disagree *n=0* **n=0**	Agree *n=2* **n=3**	Strongly Agree *n=19* **n=13**
2) I am familiar with risk factors associated with sepsis?				
n=0 **n=1**	*n=0* **n=0**	*n=1* **n=0**	*n=2* **n=4**	*n=18* **n=12**
3) I believe my nursing care can improve sepsis outcomes?				
n=0 **n=1**	*n=0* **n=0**	n=0 **n=0**	*n=4* **n=4**	*n=17* **n=12**
4) I believe that early sepsis bundles are beneficial for patients?				
n=0 **n=1**	*n=0* **n=0**	*n=0* **n=0**	*n=3* **n=2**	*n=18* **n=14**
5) I perform a sepsis screen on every patient intake/assessment?				
n=0 **n=1**	*n=0* **n=0**	*n=1* **n=0**	*n=1* **n=2**	*n=19* **n=14**
6) I use the *Sepsis Alert Checklist* for every patient activated with a sepsis alert?				
n=0	*n=2*	*n=2*	*n=5*	*n=12*

n=2	**n=1**	**n=1**	**n=3**	**n=10**
7) I'm aware that sepsis bundle compliance includes time sensitive interventions incorporating: a. Drawing blood cultures				
n=0 **n=1**	*n=0* **n=0**	*n=0* **n=0**	*n=1* **n=0**	*n=20* **n=16**
7b. Fluid resuscitation at 30ml/kg				
n=0 **n=1**	*n=0* **n=0**	*n=0* **n=0**	*n=1* **n=0**	*n=20* **n=16**
7c. Blood lactate draw				
n=0 **n=1**	*n=0* **n=0**	*n=0* **n=0**	*n=1* **n=0**	*n=20* **n=16**
7d. Starting antibiotics				
n=0 **n=1**	*n=0* **n=0**	*n=0* **n=0**	*n=1* **n=0**	*n=20* **n=16**

Note. Italicized items indicate baseline survey responses, bolded items indicate conclusion survey responses

Table 2

Median and IQR Nurse Compliance Survey

Time	Question 1	Question 2	Question 3	Question 4	Question 5
Initial (Mar. 2020)	5 (0)	5 (0)	5 (0)	5 (0)	5 (0)
Final (Mar. 2021)	5 (0)	5 (1)	5 (1)	5 (0)	5 (0)

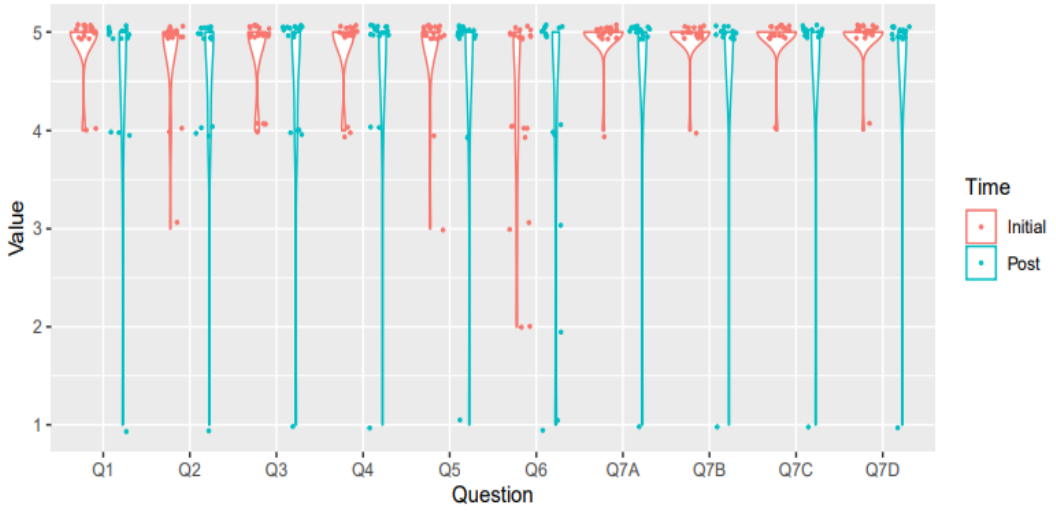
Time	Question 6	Question 7A	Question 7B	Question 7C	Question 7D
Initial (Mar. 2020)	5 (1)	5 (0)	5 (0)	5 (0)	5 (0)
Final (Mar. 2021)	5 (1)	5 (0)	5 (0)	5 (0)	5 (0)

The results of the responses to the *Sepsis Protocol and Sepsis Alert Survey* as seen in Table 2 show there is little to no variation in the data points. The medians for all the questions are five, and the IQR which is shown in the parentheses and refers to the middle 50%, are either 0 or 1 showing limited variation of response data. Due to the limited variation in responses, no further statistical tests were able to be calculated. Medians and IQR were used as the measurement tool as the distribution of survey responses are strongly skewed. There was one survey response that listed 1 for all the questions in the follow up group. It is possible to suspect that they inverted the 1-5 scale, given how consistently 5 was used as an answer amongst the other responses, however this is just an observation.

As seen in Table 3, when you compare the nurse responses from the *Sepsis Protocol and Sepsis Alert Survey*, results from the March 2020 (baseline) compared with the follow up survey (1 year post implementation of sepsis protocols), the most notable pattern seen are more non-5 answers in the follow up group, and this trend occurs in questions 2, 3, and 6, with question 6 showing the most variability in answers. The other questions show responses that are clustered to one value. It is possible these questions had the most variability due to fewer responses in the follow up survey, nursing staff not seeing the value or changes due to the sepsis protocol after being initiated one year previously or feeling like they cannot commit to every situation allowing the protocol to occur. Qualitative data from the "concerns/comments" section provided on the survey can infer some variability to responses. A summary of RN responses is included in Figure 1.

Table 3

Violin Plot Nurse Compliance Survey



Comments/Concerns from baseline *Sepsis Protocol and Sepsis Alert survey*
I wish the checklist was more basic- not WBC > than etc. more like symptom base
It was helpful when we had a STAT nurse for this process. Lab's response is super helpful
As far as the checklist goes, sometimes I am simply too busy to actually fill it out
Lab does not always respond to code sepsis calls. They are occasionally not needed, but when RN calls for lab assistance we are told "when someone is available". Sometimes this can delay cultures and other time sensitive labs on difficult sticks

Comments/Concerns from conclusion *Sepsis Protocol and Sepsis Alert survey*
Need to be aware of CHF, cardiac issues prior to ordering bolus
Additional "sepsis checklist" time consuming in ED with nurse/patient ratio, fluctuating acuity, etc. Easier to have built into existing documentation
Don't know about "checklist'
Staffing pool RN. Shifts are not consistent. Have to check what is all on the checklist.

Figure 1. Qualitative Responses from *Sepsis Protocol and Sepsis Alert Survey*: Nurses Statements

Sepsis compliance rates in the ED for 2019 were 43.9%. The sample size for the initial time frame was 14 months (2019 and January and February of 2020) and included 52 patients which shows ED SEP-1 compliance of 55.8%. The sample size for the post implementation time frame was 12 months (March 2020 to March 2021) and included 37 patients and an overall ED SEP-1 compliance of 64.9%. This shows that the mean compliance rates differ by less than 3% (table 4) with an increase in compliance after the sepsis protocol was implemented. The variability of each group is also similar showing little variability. Medians and IQR were used as measures of center and spread as the distribution of answers.

Table 4

Sep-1 Compliance Rates by Time Period

Time	Mean	SD	Median	IQR	Sample Size
Initial	58.3	38.9	66.7	72.9	14
Post	61.1	38.0	66.7	68.8	12

Table 5 breaks this down in months noting again 2019 ED SEP-1 compliance was 43.9% and 2019 plus January and February 2020 was 55.8%. For the actual timeframe of the protocol, March 2020-March 2021 (minus April 2020 as there was no data), ED SEP-1 compliance rate was 64.9%. This alternate analysis shows differentiates the data by time period, and not the mean monthly compliance rates (table 7). By looking at the data by time period, there is almost a 10% increase in compliance between the two groups. Running the permutation t-test gives a t-statistic of -0.861, with a p-value of 0.392.

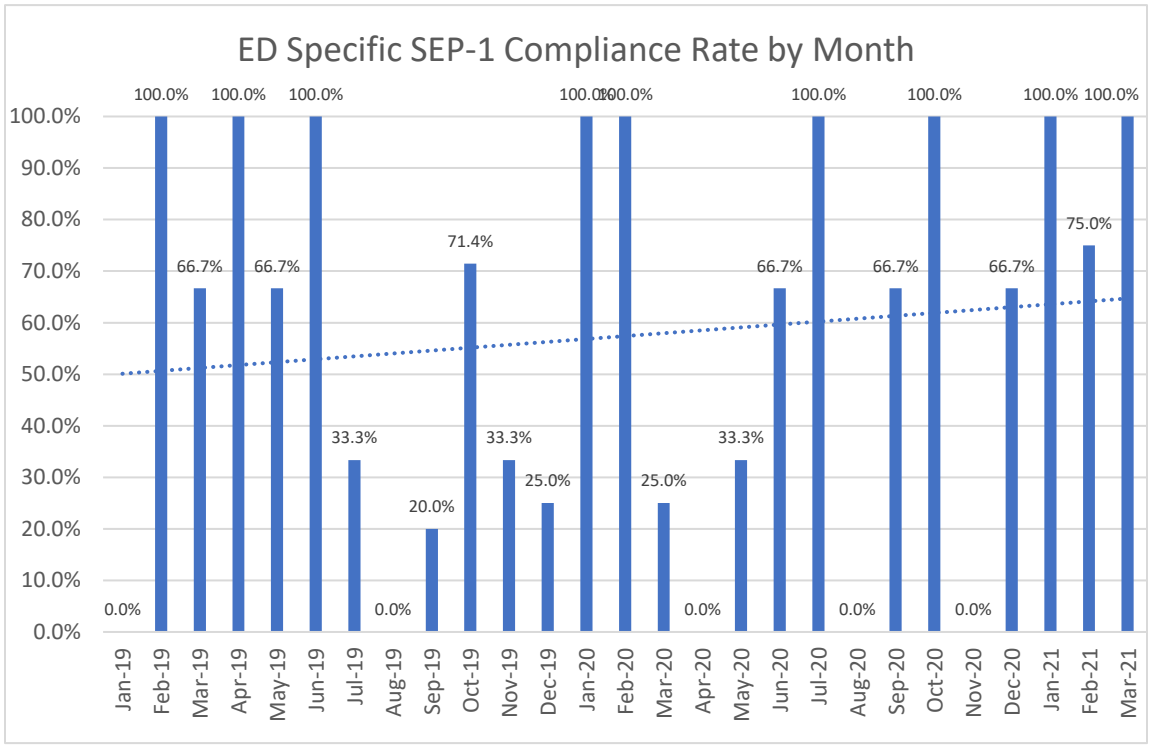
Given the relatively large *p*-value, there is a lack the evidence to reject the null hypothesis of no difference in compliance rates before and after implementation of the sepsis bundle. Again, there is a lack the evidence to claim that there is a difference in mean sepsis compliance rates before and after implementation of the sepsis bundle. Overall, even with the more powerful analysis to compare the sepsis compliance rates, there is still a lack the evidence to claim that the implementation of the sepsis bundle is associated with an increase in sepsis compliance rates. Given the fairly small sample sizes, this is not an entirely unexpected result, and the observed difference in compliance rates is encouraging.

Table 5

SEP-1 Compliance Rates by Month

Metrics in Sections	Value	Jan-19	Feb-19	Mar-19	Apr-19	May-19	Jun-19	Jul-19	Aug-19	Sep-19	Oct-19	Nov-19	Dec-19	Jan-20	Feb-20
ED Specific SEP-1 Compliance Rate	Num:	0	2	2	1	2	2	1	0	1	5	1	1	6	5
	Den:	4	2	3	1	3	2	3	4	5	7	3	4	6	5
	Value:	0.0%	100.0%	66.7%	100.0%	66.7%	100.0%	33.3%	0.0%	20.0%	71.4%	33.3%	25.0%	100.0%	100.0%

Mar-20	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21
1	0	1	4	1	0	2	1	0	2	4	3	5
4	0	3	6	1	2	3	1	1	3	4	4	5
25.0%	#N/A	33.3%	66.7%	100.0%	0.0%	66.7%	100.0%	0.0%	66.7%	100.0%	75.0%	100.0%



In the boxplot (table 6), both time periods are left skewed. With both time periods having similar distribution, there is little difference between compliance rates prior to implementation of the sepsis bundle (noted as initial), and after (noted as post). The null hypothesis is that there is no difference in mean sepsis compliance rates before and after implementation of the sepsis protocols (H_0: μ initial = μ Post) and an alternate hypothesis is there is a difference in mean sepsis compliance rates before and after implementation of sepsis protocol ($H_A: \mu\ initial \neq \mu\ Post$). A permutation *t*-test gives a *t*-statistic of -0.185, with a *p*-value of 0.4124. Given the relatively large *p*-value, there is a lack of evidence or failure to reject the null hypothesis of there being no difference in compliance rates before and after implementation of the sepsis protocol. Regarding the alternate hypothesis, there is also a lack of evidence to claim that there is a difference in the mean sepsis compliance before and after implementation of the sepsis bundle.

Table 6

Boxplot of Compliance Rates by Time Period

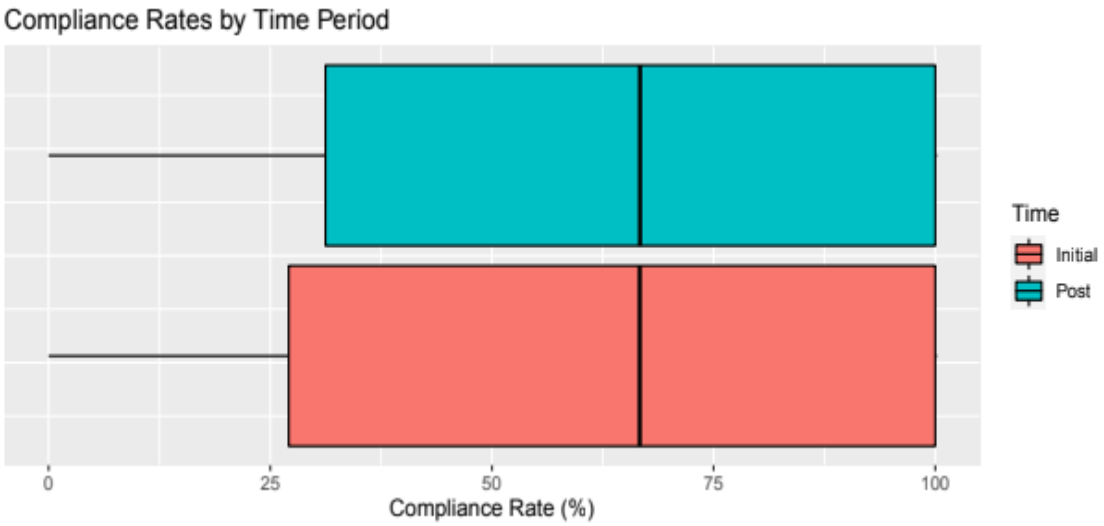


Table 5 breaks this down in months noting again 2019 ED SEP-1 compliance was 43.9% and 2019 plus January and February 2020 was 55.8%. For the actual timeframe of the protocol, March 2020-March 2021 (minus April 2020 as there was no data), ED SEP-1 compliance rate was 64.9%. This alternate analysis shows differentiates the data by time period, and not the mean monthly compliance rates (table 7).

Table 7

Compliance Rates Before and After Protocol Implementation

Time	Compliance %	Sample Size
Initial	55.8	52
Post	64.9	37

By looking at the data by time period, there is almost a 10% increase in compliance between the two groups. Running the permutation *t*-test gives a *t*-statistic of −0.861, with a *p*-value of 0.392. Given the relatively large *p*-value, there is a lack the evidence to reject the null hypothesis of no difference in compliance rates before and after implementation of the sepsis bundle. Again, there is a lack the evidence to claim that there is a difference in mean sepsis compliance rates before and after implementation of the sepsis bundle.

Overall, even with the more powerful analysis to compare the sepsis compliance rates, there is still a lack the evidence to claim that the implementation of the sepsis bundle is associated with an increase in sepsis compliance rates. Given the fairly small sample sizes, this is not an entirely unexpected result, and the observed difference

in compliance rates is encouraging.

Discussion

Previous literature review established that incorporating EGDT sepsis protocols in the ED setting can improve outcomes, by decreasing mortality rates, stabilizing hemodynamics, initiating timely antibiotic therapy, and increasing compliance with SEP-1 measures (Whitfield et al., 2019). Important key factors such as early identification of sepsis and a formal treatment protocol or sepsis pathway to guide care can be valuable for clinicians to ensure elements of the SEP-1 are met, and ultimately evidence-based practice is consistently followed. Lastly, based on the findings of this DNP project, an organized approach to clinical practice guidelines did show an improvement of less than 3% in overall compliance with the SEP-1 rates when looking at mean compliance scores, and 10% when looking at timeframe.

Two research questions were evaluated for this DNP project. The first question asked if implementation of an evidence-based early goal directed sepsis bundle set in a rural Midwestern ED increase SEP-1 compliance rates. The evidence gathered is lacking to claim that there was a change in compliance. When comparing the rates from prior to the implementation of the sepsis bundle to after, results were similar across the board, with the boxplots (Table 6) showing the same data. Sepsis compliance rates show that the mean compliance rates differ by less than 3%, with an increase in compliance after sepsis protocol was implemented. When statistically tested, there was little to no evidence to reject the null hypothesis and claim that there is a difference in compliance rates.

The second research question reviewed if there is an association with RN compliance with a sepsis bundle and sepsis compliance rates? Again, there is not enough evidence that nursing compliance increased after the sepsis protocol was introduced. Comparing median scores of the baseline from 1 year after implementation shows that median scores were equal (Table 2), with only a few survey responses showing any variable, and not enough to be conclusive.

This DNP project implemented Orlando's deliberative nursing process theory because understanding the dynamic between a nurse-patient, as well as how a nurse responds to a patient is a very important aspect of the patient's care. The importance of the nurse meeting the immediate needs of the patient is established early in a nurse-patient interaction, and often when a patient enters the ED and met with a triage RN. This theory emphasized that effective nursing practice is the "result of the nurses non-observable reaction (perception, thought and/or feeling) and then observable actions (activity) to the patients behavior" (Sheldon & Ellington, 2008, p. 390). This theory was included via education at the start of the DNP project at a mandatory harms awareness day in February 2020 for all nursing staff, where sepsis protocols and sepsis harms were outlined. ED nurses received updates on how to identify sepsis, SEP-1 core measures, compliance rates, and the updates with sepsis protocol that would be initiated started March 2, 2020.

Nurse participation and attitudes towards sepsis protocols were not factored into this study, however the several factors that may impact a nurse's response to a patient (patient factors, nurse factors, nurse-patient factors, and clinical factors) reviewed previously from this literature review contributed to the outcomes of this study and is discussed more in the limitations section.

Strengths and Limitations

Several limitations were identified in this DNP project. The first limitation was data collection from a single hospital. Incorporating another hospital ED would be useful in comparing QI initiatives and reviewing data. Having a longer time frame of data could also be beneficial to allow protocols to become more streamlined. With the median answer of the nursing surveys being 5, this shows that the data method may have been ineffective or not understood when answering.

The most obvious limitation was the COVID-19 pandemic that became a major concern to healthcare systems in mid-March 2020, shortly after this DNP project was initiated. This DNP project was initiated March 2, 2020 and the World Health Organization (WHO) declared COVID-19 a pandemic on March 11, 2020 (The American Journal of Managed Care Staff, 2021). The onset of a pandemic shortly after a process improvement change created a confounding variable in caring for patients in the ED. The surge in acuity and strain on hospital staff altered available staff throughout the hospital to report to the *ED sepsis alert* regularly such as lab personnel and the SWAT nurse. This lack of consistency posed inconsistencies in the sepsis protocol that was intended to be streamlined, due to COVID-19. Lastly, limited to no staff meetings were allowed to be conducted for several months due to concern of COVID-19 transmission, creating a barrier to follow up about progress with sepsis, feedback from staff, and education for new ED staff, which potentially limited the momentum behind a new protocol initiative.

Although the data shows a lack of evidence to claim there is a difference in SEP-1 compliance rates before and after implementation of a sepsis bundle, the main strength of this DNP project was the implementation of an evidence-based process that allowed for additional staff to help the ED RNs and ultimately improve timeframes to become compliant with SEP-1 bundle. An increase in sepsis awareness and increased sepsis education was also a strength of the project. Additionally, no formal sepsis process was followed prior to this DNP project. Streamlining protocols in the ED to provide continuity of care is a major strength and an outcome of this DNP project. The constraints of the pandemic eventually pulled the consistency of these resources, affecting the aid rendered in an *ED sepsis alert.*

Recommendations for Future Research

Initiating an *ED Sepsis alert* or type of code when a patient with sepsis presents to the ED can be beneficial to the clinical staff and ultimately the patient as SEP-1 measures can be implemented as the qualitative responses mentioned. Upon conclusion of this DNP project, it was found that incorporating a better tracking tool for time frame measurements would be recommended to see quantitative progress from initiating a sepsis bundle. This could include door to fluid administration, door to lactate blood draw, door to antibiotic infusion, etc.

Since compliance with the SEP-1 bundle is treated as all elements must be met to achieve compliance, this type of data can aid in progress and ultimately reported to other departments as their own QI metrics. Adding a formal hospital policy including the sepsis protocol and procedure could also improve future research as not having a policy in place allowed for inconsistencies in staff that reported to the *ED Sepsis Alert.*

Lastly, it could be beneficial to add an educational question the survey for nurses, questioning if the education provided at harms day, ED staff meetings and or huddles increased knowledge of SEP -1 bundles. This could aid in future research by assessing for educational gaps, and how to fill them in.

Clinical Implications for Practice and Conclusion

Identification of sepsis throughout the ED became more of an important topic due to this DNP project. Clinical staff and providers should continue to assess patients initially for sepsis and when identified, treating it as a true emergency. While the results of this study lack evidence to support the importance of EGDT for sepsis, previous literature review outlines the standard of care for sepsis requires prompt treatment and when identified early can have a significant impact on morbidity and mortality. Advanced practice registered nurses (APRNs) can play a major role in all aspects of sepsis education for the ED and hospital staff. APRNs possess advanced knowledge and skills with regards to leadership, organizational/institutional behavior, statistics, and educational techniques. All of these qualities will enhance the care of the sepsis patient leading to positive patient outcomes.

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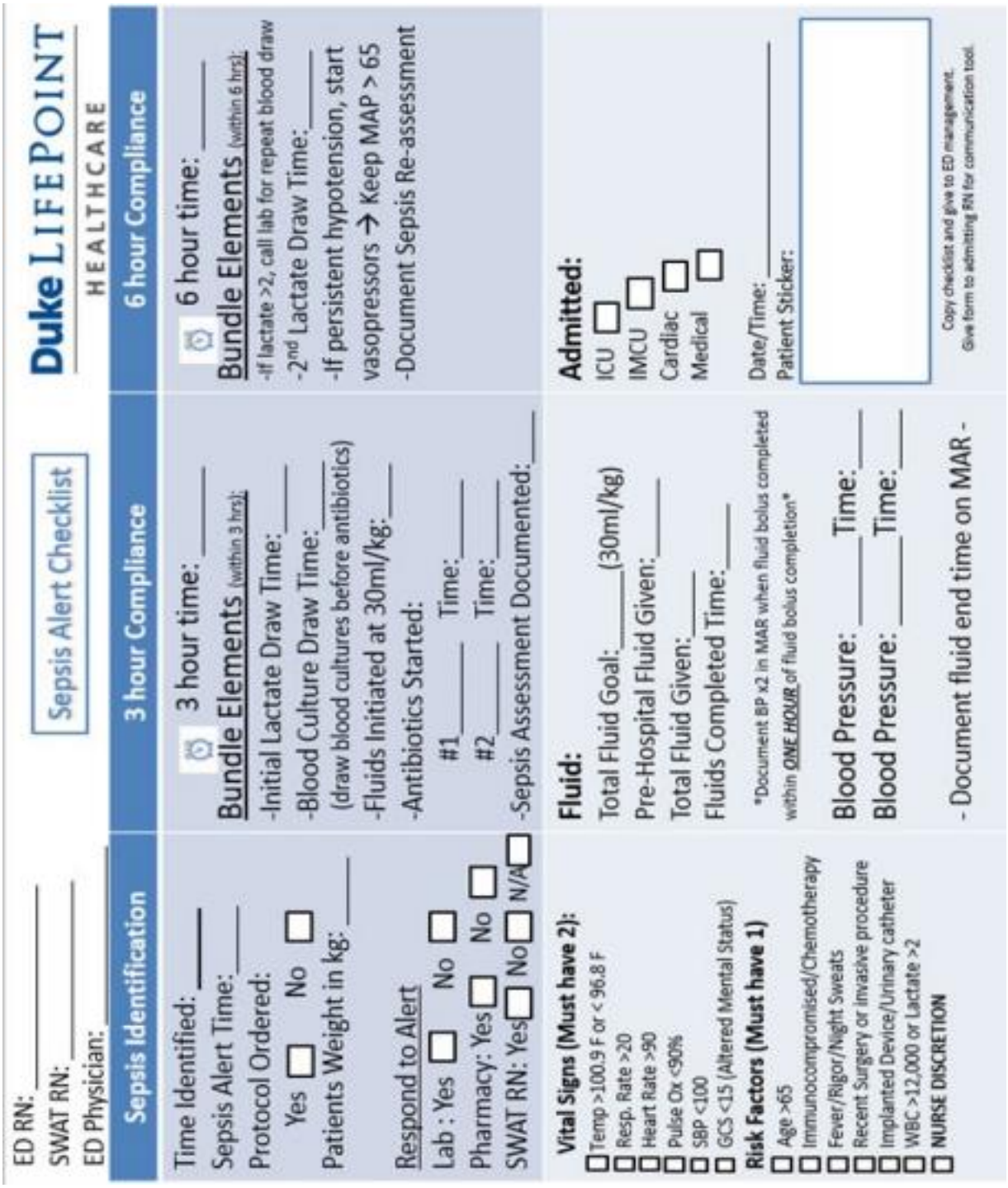
Appendix A

ED Sepsis Alert Checklist

Communication tool to aid all clinical staff throughout ED



Appendix B

Sepsis Protocol and Sepsis Alert Survey

Sepsis Protocol and Sepsis Alert Survey

Please answer the following questions regarding implementing the sepsis protocol and sepsis alert in the Emergency Department. This is an anonymous survey and any feedback is welcome. Thank you.

1- Strongly Disagree
2- Disagree
3- Neither Agree or Disagree
4- Agree
5- Strongly Agree

1. I am familiar with vital signs associated with sepsis?	1	2	3	4	5
2. I am familiar with risk factors associated with sepsis?	1	2	3	4	5
3. I believe my nursing care can improve sepsis outcomes?	1	2	3	4	5
4. I believe that early sepsis bundles are beneficial for patients?	1	2	3	4	5
5. I perform a sepsis screen on every patient intake/assessment?	1	2	3	4	5
6. I use the sepsis alert "checklist" for every patient activated with a sepsis alert?	1	2	3	4	5
7. I'm aware that sepsis bundle compliance includes time sensitive interventions incorporating:					
7a. Drawing Blood Cultures	1	2	3	4	5
7b. Fluid Resuscitation at 30ml/kg	1	2	3	4	5
7c. Blood Lactate draw	1	2	3	4	5
7d. Starting Antibiotics	1	2	3	4	5

Concern/Comments-

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_____

Appendix C

Permission from Sepsis Committee to Implement the *Sepsis Alert Checklist*

UPHS Marquette – Sepsis Committee

January 27, 2020

Attendance: Bryan Harkness, Mike Phillips, Dr. DickPerez, Val Prusi, Deb Jorae, Barb Marcotte, Kim Dunlap

Agenda	Discussion/Recommendation/Conclusion	Action Taken/Follow-up
Call to Order	The meeting was called to order by Deb Jorae. The last meeting had to be postponed due to Joint Commission arrival	
3 Good Things	• Cherlynn's first day at the new ICU Clinical Manager • DNP student Christie Ferrari has joined the committee • Good weekend	
Sepsis Guidance Card	Severe Sepsis / Septic Shock Management Bundle hard stock card was developed for the residence "ring of things". The card can be ordered from Smart Works	
Compliance	Barb reviewed sepsis compliance • November at 50% compliance • July and August were at 0% compliance (July with 3 patients and August with 8) • ED is the biggest contributor of fall outs with ICU close behind • Mike developed "Code Sepsis" since code stroke and code stemi work • Mike also working on algorithm (Christie to share algorithm she found during research) • Fluid resuscitation is number one reason for non-compliance (30ml per kg started withing 3 hours infused at more than 125 per hour) • Physicians struggle with the heart failure attributed with fluid overload, but patient's can be managed for fluid overload and die from sepsis • Christie made a nursing communication checklist and will update with Cherlynn	
Action Tracker Reviewed	The Sepsis Action Tracker was reviewed • Education for providers was completed by Barb M on 11/13/19 • The Gap Analysis was complete and sent to Elaine Long • RN screening tool still needs build in EDIS (things nurse could do before the MD) • Mike developed code sepsis • RN Assessment is EDIS is not being used as intended	
February HARMS Days	Hands on HARMS training to take place Feb 25, 26, 27, for all nursing staff. Cherlynn needs objects by Feb 18.	
Sepsis / Septic Shock Order Set reviewed	The Sepsis / Septic Shock Order Set was reviewed line by line • Amber and Cherlynn to work on plan of care for nursing • Change order – If central line present, continuous CVP monitoring • Delete – Measure central venous saturation in patients on Vasopressors • After STAT Lactic Acid, remove repeat every 4 hours because LACSEP repeats if 1st lab is elevated • Move blood cultures under Lactic Acid (the 2 tests together that are absolutely needed for Sepsis Bundle) • Remove blood cultures from central line – should be 2 from Peripheral • Add before Randon Cortisol – "Optional Labs based on patient presentation"	
Next Meeting	Next meeting Tuesday, February 4, at 11:00 in Conference Room 1A	

Recorded by: Janice Marchant

Appendix D

UP Health System Marquette IRB Letter

UP HEALTH SYSTEM
MARQUETTE
A Duke LifePoint Hospital

June 22, 2020

Ms. Christine Ferrari
370 CO RD KB
Marquette, MI 49855

RE: Implementation of an evidence-based early goal directed sepsis care bundle set in the Emergency Department to reduce sepsis HARM rates

UPHS-M IRB Study ID: 0928-2020
Category: Expedited (1,5,7)
IRB-of-Record: UPHS-M
Original IRB Approval Date: June 10, 2020
Study Expiration Date: June 10, 2021

Dear Ms.Ferrari:

Review of the above-referenced study by the UP Health-System Marquette's Institutional Review Board (IRB) was completed on June 10, 2020. I am pleased to advise you that the rights and welfare of the human subjects appear to be adequately protected and the IRB has approved this study for a period of one year. Documentation specifically reviewed was the following:

- PI Memo to the IRB
- Study Protocol
- UPHS-M Submission Worksheet
- Communication Tool for ED Sepsis Alert
- Sepsis Protocol and Sepsis Alert Baseline Survey
- Request for Waiver of Informed Consent

You are reminded that the next Board approval for this study will be set for one calendar year (date indicated above) or upon completion of the project-whichever comes first. If you plan to continue this project beyond one year, please make provisions for obtaining appropriate IRB approval prior to June 10, 2021. If this study is completed before one year, notification of completion and results need to be sent to the IRB for review. Prior to any publishing, approval from appropriate UPHS-M departments must be complete. Any changes in procedures involving human subjects must be reviewed by the IRB prior to initiation of the change. The IRB must also be notified promptly of any problems (unexpected side effects, complaints etc.) involving human subjects during the course of this study.

The IRB wishes you much success with your research and we look forward to hearing from you in-the-near future.

Sincerely,

Rudy Evonich, MD
Chairman UPHS-M IRB
OHRP IRB #00001757
RE/ssh

Appendix E

NMU IRB Approval Letter

Hi Derek,

Hope all is well. I have a question regarding if NMU IRB approval is needed for a particular DNP student. The student is collecting data from staff surveys and patient records however no identifying information is on the forms and patient consent is not required. Does the student need NMU IRB approval before collecting any data? The student already has UPHS-M IRB approval. Thanks so much.

Terry

Terry Durley, DNP, MPA, CRNA, FNP-C

Assistant Professor-School of Nursing

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1401 Presque Isle Ave

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Office: 906-227-2478

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Email: tdurley@nmu.edu

On Thu, Jun 25, 2020 at 5:55 PM Derek Anderson <dereande@nmu.edu> wrote: Hi Theresa,

If the student will not be using NMU as a vehicle for collecting data, then NO. If you still have questions, let's chat by phone tomorrow.

-Derek

Appendix F

CITI Program Certification

CITI PROGRAM

Completion Date 31-May-2019
Expiration Date 30-May-2022
Record ID 31834578

This is to certify that:

Christie Ferrari

Has completed the following CITI Program course:

Students (Curriculum Group)
Students using the internet for research (Course Learner Group)
1 - Basic Course (Stage)

Under requirements set by:

Northern Michigan University

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w8c6aef3f-8c1f-48a8-81ce-4dc5f659bd99-31834578