

OUTCOMES OF A QUALITY IMPROVEMENT PROJECT:  
INTEGRATING SEPSIS BUNDLES IN THE RURAL  
EMERGENCY DEPARTMENT

by

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A scholarly project submitted in partial fulfillment  
of the requirements for the degree

of

Doctor of Nursing Practice

in

Family and Individual Health

MONTANA STATE UNIVERSITY  
Bozeman, Montana

July 2019

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## ACKNOWLEDGEMENTS

Thank you to the Beartooth Billings Clinic for accepting this project and being supporters throughout the entire process. Also, thank you to the quality department for accepting this process into the 2019 provider goals, as well as using the sepsis bundles as an emergency department quality measure for 2019.

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## GLOSSARY

**Surviving Sepsis Campaign Guidelines:** Guidelines that are set by the Surviving Sepsis Campaign that have shown improvement in care for the septic patient. Guidelines include interventions and recommended time goals. Bundles implemented should comply with the guidelines. There is no component of the guidelines requiring bundles to be implemented as a protocol.

**Sepsis Bundle:** Bundle that was implemented in the rural emergency department (Appendix G)

**Sepsis Order Guideline:** Guide that outlines the sepsis bundle that was used in the facility; sepsis bundle and sepsis order guideline will be interchangeable in this project

**Door-to-Antibiotic Administration Times:** Time, in minutes, from the o'clock time the patient's chart is generated to the o'clock time that antibiotic infusion was initiated

## ABSTRACT

**BACKGROUND:** Rural hospitals have a poor adherence to the Surviving Sepsis Campaign guidelines, which includes door-to-antibiotic administration times under 60 minutes leading to a higher risk of mortality (Mohr et al., 2018). The aim of this project was to improve door-to-antibiotic times through the implementation of a sepsis bundle, which would place all necessary orders together. The project was set in a rural emergency department in southwestern Montana. Participants included provider staff at the facility including family nurse practitioners, physician assistants, and medical doctors.

**METHODS:** The FADE (focus, analyze, develop, execute, and evaluate) method of quality improvement was used for this project. Baseline assessment included a review of patient medical records who met sepsis criteria from January–June 2017. Antibiotic administration times were reviewed using data collection from the patient charts. A literature review was conducted to identify appropriate sepsis bundle implementation interventions.

**INTERVENTIONS:** Sepsis bundles were introduced to the provider staff through education and meetings to aid in identifying the need for sepsis bundles in the emergency department. Baseline times were also presented to the staff to provide evidence that the current practices were not meeting goals. A sepsis bundle was chosen by the medical director and the Doctor of Nursing Practice (DNP) student that fit best with the resources available in the emergency department.

**RESULTS:** Three months after the implementation of sepsis bundles, a chart review was performed on all patients that met sepsis criteria. Again, door-to-antibiotic administration times was reviewed. Door-to-antibiotic administration times improved by 40.5 minutes, which is a 22 percent improvement.

**CONCLUSION:** The use of sepsis bundles in the care of the septic patient improved door-to-antibiotic administration times. Although improvement in the quality improvement measures was noted, additional work is needed to achieve Surviving Sepsis Campaign's goal of door-to-antibiotic times of under 60 minutes.

*Keywords:* sepsis, bundle, antibiotics, rural, emergency department

## CHAPTER ONE

## INTRODUCTION

IntroductionBackground Knowledge

Sepsis is defined as the presence of infection, which can be probable or confirmed, and is accompanied by systemic manifestations of infection (DeBacker & Dorman, 2017). Sepsis is prevalent in all genders, ages, and races and is a concern in the healthcare setting. The diagnosis of sepsis can include different levels of the process including sepsis, severe sepsis, and septic shock. According to the 2016 Surviving Sepsis Guidelines, “sepsis and sepsis shock are medical emergencies and we recommend that treatment and resuscitation begin immediately (best practice statement)” (Society of Critical Care Medicine [SCCM], 2016a, slide 30). Healthcare providers can improve care of the septic patient by initiating interventions early. The Society of Critical Care Medicine (2016a) reports that we could save 400,000 lives annually if healthcare providers treated half of the eligible patients.

Sepsis is the body’s life-threatening response to an infection, which can potentially lead to tissue damage, organ failure, and death (Sepsis Alliance, 2019a). Sepsis can be caused by any infection but is most commonly caused by urinary tract infections, pneumonia, and soft tissue infections (Sepsis Alliance, 2017). Sepsis occurs when the body’s response to the infection is abnormal (Mayo Clinic, 2019). The abnormal response leads to a decrease of oxygenation, which in turn increases lactic acid

in the body. Buildup of lactic acid causes significant damage to multiple organ systems (Mayo Clinic, 2019). Signs and symptoms of sepsis include hypotension, tachycardia, hypothermia, hyperthermia, tachypnea, and hypoxia (Mayo Clinic, 2019). The presence of these signs and symptoms in a patient with an infection qualify a patient to be diagnosed as septic (Jones, 2017).

There are varying degrees of sepsis. As sepsis progresses to severe sepsis, there are signs of organ dysfunction and failure. Examples of organ dysfunction/failure in a septic patient include but are not limited to anuria (lack of urine production), abnormal liver enzymes, and change in mental status (Sepsis Alliance, 2019a). The most severe form of sepsis is septic shock. Septic shock is diagnosed when a patient becomes hypotensive and needs vasopressors to keep blood pressures at normal levels (Sepsis Alliance, 2019a).

Sepsis is responsible for 20% of all in-hospital deaths annually in the United States (Gauer, 2013). Sepsis has been found to account for approximately 210,000 deaths annually (Gauer, 2013). The number of sepsis deaths is equivalent to the annual acute myocardial infarction deaths (Gauer, 2013). The mortality rate for severe sepsis is between 25% to 30%, and septic shock mortality rates remain between 40% to 70% (Gauer, 2013). According to Jones et al. (2008), early intervention as close as possible to the time of diagnosis in septic patients has been shown to reduce mortality rates from 64% to 39%.

Sepsis is one of the most expensive inpatient care costs in American hospitals, averaging more than \$18,000 per patient per hospital stay (Sepsis Alliance, 2019a). There

were over 1.5 billion hospital stays related to sepsis in the United States in 2014, equating to \$27 billion spent on sepsis care (Sepsis Alliance, 2019a). Early detection and treatment of sepsis in emergency departments can decrease hospital costs and increase survival rates (Paoli, Reynolds, Sinha, Gitlin, & Crouser, 2018).

### Surviving Sepsis Campaign

The International Sepsis Forum was developed in 1997 with the goal to develop a set of evidence-based guidelines for the management of septic shock (Marshall, Dellinger, & Levy, 2010). The International Sepsis Forum published its guidelines for the management of septic shock in 2001. Even with the development of the aforementioned guidelines, there were no guidelines to treat sepsis, only septic shock (SCCM, n.d.a). The Society of Critical Care Medicine, the European Society of Intensive Care Medicine, and the International Sepsis Forum joined forces in response to a survey of critical care practitioners identifying a need for better assessment and diagnosis of sepsis (Marshall et al., 2010). The campaign's objective was to increase provider knowledge of the diagnosis and treatment of sepsis, with an initial goal to reduce mortality from sepsis by 5% in five years (SCCM, n.d.b, para. 2). The initial activity of the Surviving Sepsis Campaign was to review, expand, and update the International Sepsis Forum's guidelines by focusing on guidelines that practitioners could follow for sepsis and septic shock (Marshall et al., 2010). The anticipated result was to improve outcomes of the septic patient through an increase of sepsis knowledge (Marshall et al., 2010). In September 2002, the Surviving Sepsis Campaign was adopted, and sepsis bundles were introduced to improve sepsis care (SCCM, n.d.a).

The Surviving Sepsis Campaign's executive committee was composed of five medical doctors (MDs) with emergency and intensive care experience, and one MD clinical director of critical care (Marshall et al., 2010). The steering committee was composed of six MDs, one professor of nursing, and one Doctor of Nursing Practice (DNP) acute care nurse practitioner (Marshall et al., 2010). The background of the executive committee served as expertise in the subject matter of sepsis. Surviving Sepsis Campaign bundles have been implemented in hospitals worldwide and have positively affected the care of septic patients (Marshall et al., 2010).

The Surviving Sepsis Campaign provided guidelines for care of septic patients. The 2016 guidelines recommended administration of broad-spectrum antimicrobials as soon as possible after recognition of sepsis signs and symptoms. The guidelines recommended initiation of antibiotics within one hour of patient presentation. To accomplish this recommendation, the guidelines helped to reduce the complexity of sepsis care. In addition to timely antibiotic administration, the guidelines recommended a bolus of at least 30 milliliters/kilogram (ml/kg) of intravenous crystalloid fluid given within the first three hours of presentation (SCCM, 2016b). The guidelines also suggested orders be placed in a bundle, which is the core of the Campaign's quality improvement efforts (SCCM, n.d.c).

Care of a septic patient has involved a complex process, including multiple blood tests, diagnostic imaging, and fluid resuscitation. Blood tests performed include a complete blood count, lactate, and blood cultures. A complete blood count is used to measure how many white blood cells are circulating throughout the body (Sepsis

Alliance, 2019b). White blood cells are elevated when a bacteria, virus, or other organisms are identified as foreign are in the body. White blood cell counts may be low or elevated in the septic patient. Lactate is produced in the body when organs are not receiving enough oxygen (Sepsis Alliance, 2019b). The suspicion for sepsis is elevated when lactate is elevated and there is a suspected infection. Blood cultures are drawn on a septic patient to identify what type of bacteria has caused the infection in the blood (Sepsis Alliance, 2019b). Blood cultures are analyzed in the lab for up to three days to identify the type of bacteria and which antibiotics the bacteria are sensitive to. In an attempt to streamline complex care associated with a sepsis patient, the Surviving Sepsis Campaign organized evidence-based sepsis interventions in a standardized order set or bundle.

### Bundles

Bundles are a selected set of interventions of care and, when implemented as a group, have a greater effect on patient outcomes than if the components were implemented separately (Haraden, 2017). Bundles have been shown to decrease in-hospital mortality, reduce hospital length of stay, reduce cost of care per patient, and improve patient's quality of life (Jozwiak, Monnet, & Teboul, 2016). Bundles have been effective in other aspects of care such as minimizing microbial contamination during catheter insertion and decreasing rates of ventilator-associated pneumonia (Marshall et al, 2010). According to Duzkaya, Bozkurt, Uysal, and Yakut (2016), catheter-associated urinary tract infections in the intensive care unit decreased from 5.8% to 1.5% per 1000 urinary catheter days. Timely treatment can be accomplished with a bundle of orders used

to simplify complex processes found in the care of patients with sepsis” (SCCM n.d.c, para. 1).

The Surviving Sepsis Campaign developed a three-hour and six-hour bundle. The three-hour bundle includes lactate level, blood cultures prior to antibiotics, broad-spectrum antibiotic, and 30 mL/kg fluid resuscitation. The six-hour bundle includes vasopressors as needed for hypotension and a re-measurement of lactate. The three-hour and six-hour bundles are to be initiated from the time the patient presents to triage in the emergency department or arrival from the ambulance and be completed within a designated time limit (SCCM, 2016b). Within the three-hour bundle, the goal for broad-spectrum antibiotic administration initiation is within one hour of presentation (McFeely, 2017). The bundle encourages healthcare staff to act quickly to obtain peripheral blood cultures, measure lactate, administer broad-spectrum antibiotics, and start fluid resuscitation in a timely manner as orders are placed at once, rather than being placed individually over time by the provider.

The bundle does not have to be implemented as a protocol, which is an intervention that can be initiated by a nurse as long as a patient meets the criteria defined. The bundle must have components to meet the Surviving Sepsis Campaign guidelines, which includes lactate, blood cultures, fluid resuscitation, and antibiotic administration (SCCM, n.d.d). Within the first eight years of implementation of sepsis-related bundles, a 20% reduction of relative risk of mortality was seen (SCCM, n.d.a).

### Location Problem

Rural healthcare facilities are designed to improve access to healthcare for communities where distance causes a barrier for care (Rural Health Information Hub, 2019). The facility where this project occurred, is considered a critical access hospital (CAH) as designated by the Centers for Medicare and Medicaid Services (Rural Health Information Hub, 2019). To qualify for a CAH designation, a facility must have 25 or fewer acute care inpatient beds, be located more than 35 miles from another hospital, provide 24/7 emergency care services, and maintain an annual average length of stay for acute patients of 96 hours or less (Rural Health Information Hub, 2019). CAHs differ from community to community-based on the community's unique needs (Rural Health Information Hub, 2019).

An opportunity for improvement of the care of patients with sepsis was identified at a local hospital when a new physician joined the staff at the hospital. The opportunity was vetted through the director of nursing and the medical director. Upon recommendation of the director of nursing, observation of care of the septic patient was conducted in the emergency room. From this, a project was implemented to evaluate the current care of septic patients in the local hospital's emergency department.

Multiple studies were published on the implementation of sepsis bundles in urban settings, with improvement in door-to-antibiotic times (Kalich et al., 2016; Bruce et al., 2015; Barochia et al., 2010; Hayden et al., 2015; Guo et al., 2014). However, there is minimal published research that analyzes the implementation of sepsis bundles in rural settings (Greenwood-Ericksen et al., 2018). The lack of research makes it difficult for

rural facilities to pursue implementation of sepsis bundles. The rural setting for this project possesses multiple barriers for sepsis bundles including lack of education on bundles; high patient to nurse ratios (two nurses can be taking care of 10 inpatients as well as managing an emergency department); limited resources in facility during nights, weekends, and holidays; and providers that are not present in clinic until called in during nights, weekends, and holidays. Also, rural facilities usually do not have invasive monitoring systems or intensive care units for patients, which are essential to evaluate central hemodynamics, peripheral tissue perfusion, and oxygenation (Shoemaker, Wo, Yu, Farjam, & Thangathurai, 2000). The bundle needs to be individualized for the rural setting and the available resources for sepsis bundles to be effective. If sepsis bundles are not modified to meet individual settings and resources, complete compliance cannot be achieved (Kramer, Cooke, Liu, Miller, & Iwashyna, 2015).

#### Intended Improvement

The specific aim of this project was to decrease door-to-antibiotic administration times by implementation of sepsis bundles in a rural emergency department. The initiation of sepsis bundles in the emergency department has been shown to decrease door-to-antibiotic times, improving morbidity and mortality in septic patients (Kalich et al., 2016; Barochia et al., 2010; Tipler, Pamplin, Mysliwicz, Anderson, & Mount, 2013; Miguel-Yanes, Munoz-Gonzalez, Andueza-Lillo, Moyano-Villaseca, Gonzalez-Ramallo, & Bustamante-Fermosel, 2009).

## CHAPTER TWO

## REVIEW OF LITERATURE

Review of Literature

A literature review was performed focusing on sepsis bundles in the emergency department in both urban and rural settings. The following Medical Subject Headings MESH terms were used: sepsis, septic shock, bundles, implementation, antibiotic administration, clinical practice guidelines, Surviving Sepsis Campaign, protocol, compliance, rural, critical care hospitals, and quality improvement. Databases used in the search included but were not limited to PubMed, CINAHL, Web of Science, and Google Scholar. Inclusion criteria included a date range of 2008-2018, peer-reviewed journal articles, English, adult patients 18 years and older, and sepsis bundles in the emergency department. A total of 24 studies were identified.

Multiple researchers reported the effectiveness of sepsis bundles in urban emergency departments. Few studies were identified regarding the use of sepsis bundles in rural emergency departments with limited resources (Kalich et al., 2016; Bruce et al., 2015; Barochia et al., 2010; Hayden et al., 2015; Guo et al., 2014). The initiation of sepsis bundles in urban emergency departments resulted in improved care and outcomes for septic patients. One factor that is repeatedly identified as a key to improved sepsis care is early identification and administration of antibiotics (Kalich et al., 2016; Barochia et al., 2010; Tipler et al., 2013; Miguel-Yanes et al., 2009).

### Early Identification and Early Initiation of Treatment

Rivers, Nguyen, Havstad, Ressler, and Muzzin (2001) performed a prospective, randomized study analyzing early goal-directed therapy in the treatment of severe sepsis and septic shock. The authors reviewed multiple patient-related factors and trends in these factors as sepsis bundles were implemented. The authors assess factors such as temperature, heart rate, urine output, blood pressure, and central venous pressure, with and without initiation of sepsis bundles. With the early goal-directed therapy inherent in sepsis bundle implementation, in-hospital mortality was 30.5 percent for the group with sepsis bundles as compared to 46.5 percent in the standard therapy group, which did not receive care within a sepsis bundle ( $P=0.009$ ) (Rivers et al., 2001). Patients in the early goal-directed therapy group/sepsis bundles had lower lactate concentrations, higher mean central venous oxygen saturation, and less severe organ dysfunction as measured by the APACHE II score (13.0 vs 15.9) (Rivers et al., 2001). The APACHE II scoring system is the Acute Physiologic Assessment and Chronic Health Evaluation, which generates a point score ranging from 0–71 based on 12 physiologic variables, age, and overall health (Eachempati, 2019). As the score of the APACHE II increases, the rate of mortality has also been shown to increase.

Early identification of sepsis is necessary to decrease door-to-antibiotic times in the emergency department. A triage nurse most often has the first interaction with the patient. Hayden et al. (2015) focused on a triage sepsis alert to decrease the time from patient arrival to the administration of fluids and antibiotics in the emergency department. The triage alert was called sepsis workup and treatment protocol (SWAT ) and

emphasized rapid mobilization of resources, standardized order sets, early broad-spectrum antibiotic administration, and fluid resuscitation (Hayden et al., 2015). The triage sepsis alert process included the triage nurse notifying the provider that the patient met systemic inflammatory response syndrome (SIRS) criteria. The provider then initiated the SWAT bundle if they felt it was indicated. The SWAT process reduced door-to-antibiotic times by 58.8 minutes ( $p<0.01$ ) and door to fluid bolus times by 30.5 minutes ( $p<0.01$ ) (Hayden et al., 2015).

### Components of Sepsis Bundles

Sepsis care is a complex process, which requires multiple components to provide comprehensive patient care (Barochia et al., 2010; Kramer et al., 2015). Bundles have included blood draw for laboratory analysis, obtaining intravenous access, administration of fluid boluses, regular monitoring of vital signs, and antibiotic administration (Barochia et al., 2010). Sepsis bundles can be modified based on the resources available in the facility. For instance, some rural facilities may not have capabilities to provide physiologic monitoring such as central venous pressure monitoring let alone a patient care unit where invasive monitoring can occur, such as in an intensive care unit (SCCM, n.d.d). Despite variations in care capabilities, most rural facilities are able to administer antibiotics in a consistent manner. Barochia et al. (2010) suggested all bundles should have an antibiotic component. When bundles have an antibiotic component, antibiotic administration times significantly decreased by 34.8 minutes ( $p<0.0001$ ) compared to the sepsis bundles that did not have an antibiotic component (Barochia et al., 2010). In order

to have compliance with the Surviving Sepsis Campaign, broad-spectrum antibiotics must be a part of all sepsis bundles (SCCM, n.d.d).

### Implementation of Sepsis Bundles and Reduction of Door-to-Antibiotic Times

Implementation of sepsis bundles has been shown to reduce the delay in recognition of sepsis and improve door-to-antibiotic times (Tipler et al., 2013; Kalich et al., 2016). Once a patient is identified with sepsis, the bundle is initiated. Once a septic patient is identified, the goal is to administer antibiotics in less than 60 minutes from the time of patient arrival (Tipler et al., 2013). To meet the goal of antibiotic administration under 60 minutes, blood cultures must be obtained prior to the administration of a broad-spectrum antibiotic (Kalich et al., 2016). Kalich et al. (2016) showed with implementation of a sepsis bundle, 81% of patients had a complete set of blood cultures prior to antibiotic administration and a 61% relative improvement of door-to-antibiotic times ( $P=0.03$ ).

Tipler et al. (2013) analyzed the reduction in antibiotic times once a sepsis bundle was implemented and found antibiotic administration times decreased on average by 61 minutes. Miguel-Yanes et al. (2009) showed with the implementation of sepsis bundles in the emergency department, the median time to first antibiotic dosing was decreased from six hours to 3.8 hours ( $P=0.001$ ). Bruce, Maiden, Fedullo, and Kim (2015) showed that with nurse-initiated sepsis bundles, antibiotic administration was reduced from 135 minutes to 108 minutes ( $P=0.021$ ).

### Compliance of Surviving Sepsis Campaign

Compliance with the Surviving Sepsis Campaign guidelines by using a bundle can improve patient care (Giuliano, Licardo, & Staul, 2011; Guo et al., 2014). Giuliano et al. (2011) conducted a non-randomized pilot study investigating the effect of a protocol watch within the EHR, which displayed prompts on the bedside to ensure the provider was implementing the bundle. With the protocol watch, there was a statistically significant decrease in time of antibiotic administration times (69.5 minutes,  $P=0.006$ ) (Giuliano et al., 2011).

Compliance of sepsis bundles at six hours and at 24 hours from time of identification of sepsis has been shown to decrease hospital mortality and improve patient outcomes (Guo et al., 2014). Hospital mortality rates decreased from 44.3% to 29.2% when providers were compliant with implementation of the 24-hour bundle. When the Surviving Sepsis Campaign guidelines were met using a bundle, patients received more serum lactate monitoring (62.3% vs. 11.3%), more blood cultures (47.1% vs. 24.5%), more fluid resuscitation (63.2% vs. 26.4%), and more glucose control (51.9% vs. 6.6%) (Guo et al., 2014).

### Barriers

The top three barriers of implementing and maintaining compliance of sepsis bundles include delay in sepsis diagnosis by the provider, delay in the availability of intensive care beds and lack of recognition at triage (Burney et al., 2016). Barriers to maintaining compliance of sepsis bundles can be overcome by determining an effective method to implement the bundles within the facility. High compliance rates with the use

of bundles can be difficult. Health care facilities should consider factors specific to their own practice, such as knowledge of sepsis and present resources (Borgert, Goossens, & Dongelmans, 2015). The bundles studied in the meta-analysis had many different implementation routes, but the bundles implemented with education, followed by implementation, audit and then follow up had the highest compliance (Borgert et al., 2015).

### Rurality

A barrier to initiating sepsis bundles in the rural emergency department is the isolation of the setting. According to Douthit, Kiv, Dwolatzky, and Biswas (2015), barriers in access to health care significantly impact health outcomes of rural patients. Accessing health care is a challenge for rural patients because of limited human and financial resources, significant distances from healthcare providers, and poor public transportation (Seright & Winters, 2015). Urban emergency departments outperform rural emergency departments on components of the Surviving Sepsis Campaign bundle, including antibiotic administration (Greenwood-Ericksen et al., 2018). The rural facility can improve patient outcomes by aiming to improve the provisions of services based on available resources (Douthit et al., 2015; Seright & Winters, 2015).

### Recommendations Based on Current Evidence

Current evidence indicated early detection of sepsis is mandatory to improve patient outcomes and to decrease door-to-antibiotic times (Kim & Park, 2018). Even though rural facilities have limitations, provisions in care can improve patient outcomes

(Douthit et al., 2015; Seright & Winters, 2015). Provisions in care can entail implementing the sepsis bundle. Sepsis bundles can have different components, the bundles should be formatted to fit the resources in the facility but should always have an antibiotic component (Barochia et al., 2010). To improve compliance with sepsis bundles, barriers should be addressed, and bundles should be implemented with education, followed by implementation, audits, and follow up (Borgert et al., 2015; Burney et al., 2016).

## CHAPTER THREE

## METHODS

MethodsTheoretical Underpinning

FADE Model. FADE model is a four-step cycle that is utilized in the healthcare setting to determine the need and outcomes of quality improvement projects (Iowa Department of Public Health, n.d.). The FADE model (focus, analyze, develop, execute, and evaluate) was used for this quality improvement project (Khalighi, 2007). The *focus* was to decrease door-to-antibiotic times in the septic patient in a rural emergency department. *Analyzing* included auditing charts of patients that met sepsis criteria from January–June 2017, for baseline data. A sepsis bundle was *developed* based on the Surviving Sepsis Campaign guidelines, and education was presented to provider staff. *Execution* was when the sepsis bundle was implemented, leading to *evaluation* by auditing charts of patients that met sepsis criteria from May–December 2018 to determine if sepsis bundles decreased door-to-antibiotic times. The FADE model was the model used to plan this project as informed by the rural nursing theory.

Rural Nursing Theory. Rural nursing theory was used, along with the FADE model, as the foundation for this project. Rural nursing is multidimensional, with three concepts: health, isolation and distance, and self-reliance and informal healthcare (Winters, 2013).

The first concept of rural nursing theory is health, which is defined by rural patients as the ability to work and maintain his/her activities of daily living (Winters, 2013). The nurse needs to have this concept of health in mind when treating a rural patient because most of the time, the patients do not come in until they are so ill they cannot complete activities of daily living. Sepsis is time sensitive and since rural patients tend to not seek medical care until they cannot perform activities of daily living, the patient already has been septic for hours, which increases their rate of mortality and morbidity (Winters, 2013). Spleen, Lengerich, Camacho, and Vanderpool (2014) found that rural residents are 1.7 times more likely to admit avoidance of healthcare when compared to residents residing in urban areas. Rural patients are more likely to avoid medical care because of insurance status, workforce shortage, transportation, and lack of health literacy (Spleen et al., 2014). According to Casey, Call, and Klingner (2001), rural residents are significantly less likely to seek preventative care versus urban residents due to limited resources, cost of care, and cultural beliefs. Avoidance of healthcare until absolutely necessary is another reason that sepsis bundles are so important in rural emergency departments.

The second concept, isolation and distance, plays a large factor in why patients may not present to the emergency department for evaluation until they are ill. Isolation and distance impair patients' timely access to care for acute and chronic illnesses. Patients seeking care from rural areas may be sick for multiple days prior to seeking care but lacked the resources to seek care earlier. With this potential delay in care, the facility may be in a time sensitive situation based upon the severity of sepsis.

The third concept, self-reliance and use of informal healthcare, is exhibited in the patient's resilience and their culture (Winters, 2013). Rural patients tend to first seek alternative therapies that were passed on from generation to generation, leading to seeking care at later stages of illnesses (Douthit et al., 2015). With this, the main request was for healthcare workers to respect them during their stay and not judge the patient for waiting so long to be evaluated (Winters, 2013). Barriers in the rural setting come along with these concepts

Initial trust is a significant barrier that a rural nurse must overcome with patients (Winters, 2013). For this barrier to be removed, the nurse needs to listen to the rural patient and respect their wishes and understand why they did not present until they were very ill. Listening to the rural patient can reduce the initial trust barrier, but it may not guarantee that the patient will seek care earlier the next time they are ill (Winters, 2013). Interventions outside of the acute setting that may help remove this barrier are implementing community involvement from hospital leaders, changing cultural stigma to regarding being seen for an illness, and promoting the benefits of preventative care (Douthit et al., 2015).

Rural nursing theory is essential for this project because patients in the rural setting can have multiple reasons why they do not seek medical care in a timely manner such as travel, distance, isolation, and use of informal healthcare (Winters, 2013). The healthcare staff has to be cognizant of these reasons and realize that the patient may be in severe sepsis when he/she arrives, thus increasing the need for timely antibiotics to improve patient outcomes. Sepsis keeps progressing the longer a patient waits to be seen,

so providers need to be placing orders in a bundle so that all aspects of septic care can be completed. Since we are unable to change health-seeking behaviors of rural patients, we need to reduce the wait time in the rural emergency department for initiation of treatment.

### Project Design

A pretest-posttest design was used to assess the effect of sepsis bundles implementation on the time between patient registration to administration of antibiotics. The term door-to-antibiotic times will be used for the remainder of this document to designate the aforementioned time frame. A pretest-posttest design allowed for assessment of the effect of implementation of the sepsis bundle in the project hospital by evaluating a critical aspect of sepsis care—antibiotic administration. More specifically, the project sought to determine the effect of implementation of the sepsis bundle on door-to-antibiotic times. The initial impetus for implementation of the sepsis bundle was spearheaded by the director of nursing at the rural facility and a newly hired physician. The director of nursing and physician had a strong desire to assess and improve sepsis care in their facility.

### Ethical Issues

The proposed project received exempt status from Montana State University's Institutional Review Board as the project involved the use of educational tests with no harm to the human subjects unless the information was recorded in a manner that the human subjects can be identified (Appendix C). The project was also exempt because no deviations from standard care were being performed; the change involved standard of

care interventions implemented in a more efficient manner. Patient information collected during the project was de-identified. Project approval was also obtained from the facility's director of quality, emergency department chair, and the director of nursing (Appendix D).

### Sample and Setting

Implementing sepsis bundles took place at a rural CAH in southwestern Montana. The rural community has a population of 2,349 with a median age of 46.9 years of age and a 91:100 male to female ratio (United States Census Bureau, 2017). The sepsis bundle was implemented in the emergency department of the rural CAH. The project site was a six-bed facility with an adjoining inpatient setting consisting of 12 beds. The emergency department treats an estimated 2,000 patients a year. Approximately 200 patients annually are transported to a major medical facility 60 miles from the hospital for higher level care (Beartooth Billings Clinic, 2010). The rural setting serves many smaller communities. Smaller communities surround the CAH can be 45–60 miles away, making travel barriers significant for patients. An average of 40 septic patients have presented to the emergency department on an annual basis.

The population of interest for this project was the provider staff at the CAH. The provider staff was composed of five medical doctors, two physician assistants, and one nurse practitioner (N=8). Median age of the providers is 43.5 years. The majority of the CAH providers are male, 63% (N=5). The mean years of college education years was 8.6 years. All providers practiced in the emergency department as well as the clinic. All

providers were required and currently possessed certifications in Advanced Cardiac Life Support, Pediatric Advanced Life Support, and Advanced Trauma Life Support.

The emergency department staff on a typical day included two registered nurses, two certified nursing assistants, and a registration specialist. Additional staff also consisted of a laboratory technician and a radiology technologist. The laboratory technician and radiology technologist maintained a staffing schedule similar to that of the providers. The provider, either a physician assistant, nurse practitioner, or medical doctor, were in the facility Monday through Friday from 0800–1700. During hours that the provider was not in the facility, 1700–0759, he/she was on-call with a required response time of 20 minutes or less. If the provider was delayed, verbal orders could be given over the phone. Prior to initiation of the project, there were no protocol bundle order sets implemented within the organization for the nursing staff to follow.

### Project Procedures

Key stakeholders are essential for a successful project and are those whose interests are in the project and the outcomes (Terhaar et al., 2016). Key stakeholders in the project included the director of nursing, director of quality, nursing staff, providers at the rural emergency department, quality department, pharmacists, and nursing support staff at the facility. The director of nursing and medical director were involved in decision making for the project and what aspects of care could be improved. The plan was proposed to the Institutional Review Board at Montana State University. Once IRB exemption (Appendix C) was awarded, the chief executive officer and the director of quality at the CAH approved the project.

Eligible Patients: The outcome of measure for this project was determined to be the time between patient registration and administration of antibiotics for patients identified as meeting sepsis criteria. In order to track this outcome, patient information needed to be collected and analyzed to determine the effect of the implementation of sepsis bundles. Patients eligible for inclusion in the project included adult patients presenting to the project site emergency room with assessment criteria consistent with sepsis. The time frame for the project was from January 2017 to December 2018. Eligibility for meeting sepsis criteria was based on the SIRS criteria. Patients had to have at least two of the following criteria *and a suspected or identified source of infection*:

- Oral or rectal temperature <36 degrees Celsius or >38.3 degrees Celsius
- Heart rate > 90 beats per minute
- Respiratory rate > 20 breaths per minute
- White blood cell count < 4,000 per microliter or > 12,000 per microliter

(Neviere, 2018).

A list of possible diagnoses was created to rule out any missing patients with sepsis that were coded incorrectly. The list of diagnoses (Appendix E) increased the likelihood all sepsis patients were identified. The staff of the medical records department ran a report from January to June 2017 to identify patients with designated diagnoses. Retrospective chart audits were then performed to evaluate baseline data of septic patient care at the project site. Patient charts were audited to determine if SIRS criteria were met (Appendix A). If SIRS criteria were met and the patient was over 18 years of age, the patient information was included in the baseline data. After the patient list was

completed, charts were audited for additional data including assigned provider, nurse, chief complaint, date and time of arrival, vital signs (heart rate, respirations, temperature), o'clock time of lactic acid draw, o'clock time of blood culture draw, o'clock time of antibiotic order placement, o'clock time of intravenous insertion, o'clock time of antibiotic administration, and disposition placement (either another facility or inpatient at CAH) (Appendix F). Time of arrival was recorded as the actual o'clock time the patient was registered in the computer documentation system versus the time the patient walked through the emergency department door. Door-to-antibiotic administration times were calculated by subtracting the time of arrival from the time of antibiotic administration. All data were recorded in an Excel spreadsheet on a password protected computer by the DNP student.

#### Compilation of Sepsis Bundle

Emergency department staff, provider call schedule, lab capabilities and antibiotics available in the project site were considered as potential factors affecting the development of the sepsis bundle. The sepsis bundle, created by the DNP student and medical director, included assessment of patients for SIRS criteria and notification of the provider by phone if a patient met SIRS criteria. Once the patient was identified as having sepsis, intravenous access would be obtained and labs would be drawn including complete blood count (CBC) with differential, comprehensive metabolic panel, lactate, PT/INR, and two peripheral blood cultures. Optional labs were included based on patients' complaints, for instance, wound culture and urine cultures could also be included if necessary. Administration of fluid boluses for resuscitation would be initiated

once labs were drawn. The rate of fluid bolus was 30 mL/kg of an isotonic fluid. The sepsis bundle included an antibiotic component based on patient presentation and suspected or confirmed infection. All of the components were compliant with the Surviving Sepsis Campaign Guidelines (SCCM, n.d.d).

The antibiotic component of the sepsis bundle was based on current evidence and project site resources available by the medical director and the DNP student (Stanford Health, 2017) (Appendix G). Each infectious process had its own preferred regimen with the antibiotic listed with base additive, infusion rate and duration, frequency, and adjusted doses based on creatinine clearance. The sepsis bundle implemented at the project facility is presented in Appendix G.

The sepsis bundle created was then presented to the director of quality and director of nursing for approval. Once approval was obtained, the sepsis bundle was presented at a medical staff meeting. All practicing providers at the project facility were present to review the project goals and baseline data from the retrospective chart audits. During the meeting, the provider group decided the sepsis bundle initially be implemented as guidelines for sepsis care. After the guidelines had been in place for at least six months, they would be re-evaluated for adoption as a formal protocol. All providers agreed on the sepsis bundle as a guideline. The sepsis bundle guidelines would also serve as a resource for the providers and staff.

### Sepsis Bundle Implementation

Sepsis bundles were implemented after approval from the provider staff. The process included nurse notification of the provider when a patient met sepsis criteria

(Appendix A). After the provider was notified a patient met sepsis criteria, the provider would give a verbal order to initiate the sepsis bundle. An ideal sepsis patient flow was identified and is presented in Figure 1.

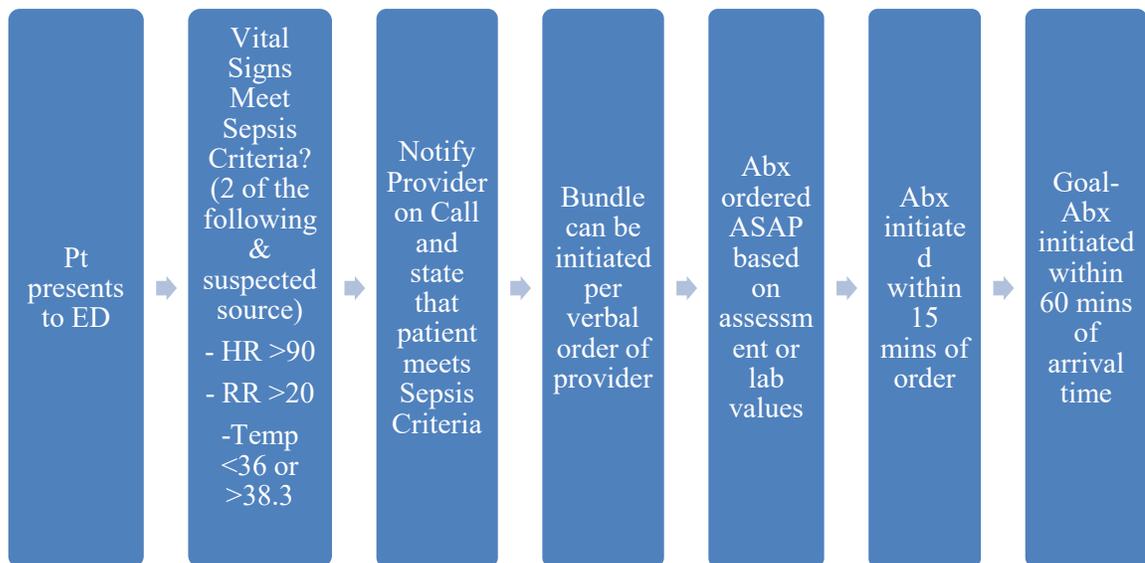


Figure 1: Ideal sepsis patient flowsheet.

### Post-Sepsis Bundle Implementation

Chart audits were performed post-sepsis bundle implementation. Post-sepsis bundle implementation chart audits occurred from May to December 2018. Patient charts identified by the director of medical records were audited to ensure all patients included met SIRS criteria and were over the age of 18. Once eligible patients were identified, each chart was reviewed, and the same data were gathered: provider, nurse, chief complaint, date, arrival time, vital signs (heart rate, respirations, temperature), o'clock time of lactic acid draw, o'clock time of blood culture draw, o'clock time of antibiotic

order placement, o'clock time of intravenous insertion, o'clock time of antibiotic administration, and disposition placement (Appendix F). Again, door-to-antibiotic administration times for each patient were calculated by subtracting the time of arrival from time of antibiotic administration.

### Measurements/Instruments

Multiple steps to ensure data quality by using electronic and manual processes were performed. The EHR program generated the reports of patients diagnosed with sepsis-related diagnoses (Appendix E). Charts were manually audited to ensure all patients that met sepsis criteria were in the data set.

The same data were collected (doctor, nurse, chief complaint, date, arrival time, vital signs (heart rate, respirations, temperature), time of lactic acid draw, time of blood culture draw, time of antibiotic order placement, time of intravenous insertion, time of antibiotic administration, and disposition placement) for each group and entered in the Excel spreadsheet. The statistical department of Montana State University was consulted and advised that there needed to be at least the same number of patients in the post-sepsis bundle implementation data as there were in the pre-sepsis bundle implementation data. Data were collected until a similar number of pre- and post-implementation charts were obtained.

### Analysis

To analyze data collected during the project, the DNP enlisted the assistance of a Lean Six Sigma professional. Per the Lean professional's recommendation, Minitab was

used as the quantitative statistical application to analyze the data of door-to-antibiotic times pre- and post- sepsis bundle implementation. The Excel spreadsheet was imported into the Minitab application, and statistical analysis was performed. The statistical analysis included the mean times, standard deviations, and P value, which determines if data is statistically significant. All data were kept on a password protected computer. Cohen's d formula was used to analyze the effect size. Cohen's d formula was calculated by the mean difference between the two groups and then divided by the pooled standard deviation.

## CHAPTER FOUR

## RESULTS

ResultsPre-Sepsis Bundle Results

Orders were not being ordered as a bundle and it was observed that at times, the blood cultures were not being ordered until after white blood cell count and lactic acid results were available, even though the patient met sepsis criteria (Appendix A). There were even circumstances when a lactic acid was not ordered until the complete blood count came back with an elevated white blood cell count, despite meeting sepsis criteria (Appendix A). Figure 2 presents the typical process for a septic patient in the emergency department.

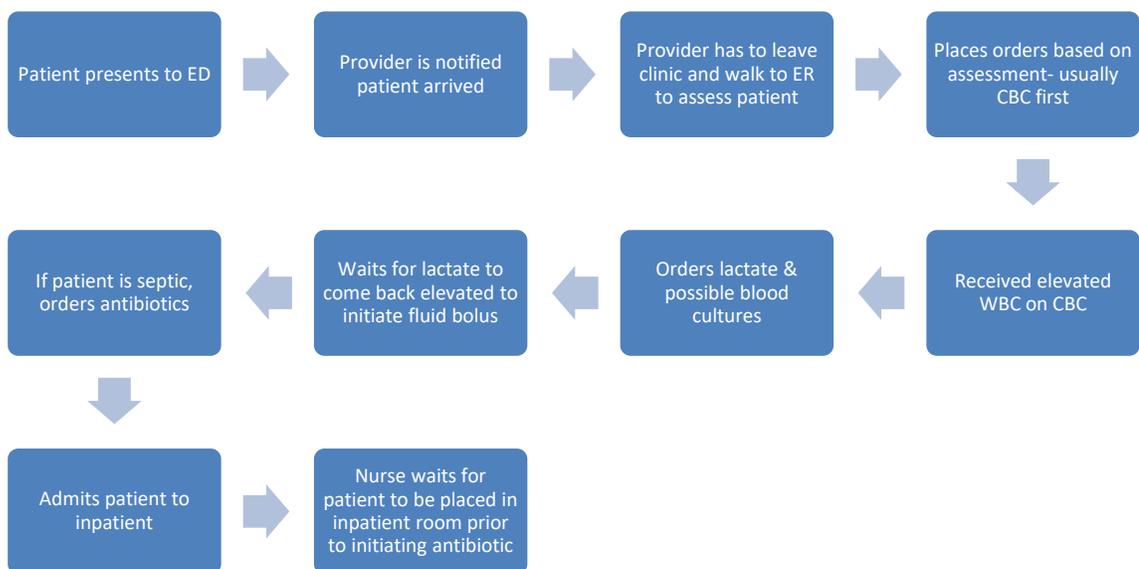


Figure 2: Pre-sepsis Bundle Process: Typical process of septic patient in the rural emergency department, pre-sepsis bundle implementation.

The DNP student performed a fishbone analysis after observation, which identified the root causes of not meeting the Surviving Sepsis Campaign goal of door-to-antibiotic times under 60 minutes. The fishbone analysis showed multiple issues that could be addressed but for the purpose of the project, orders were placed into a bundle to improve door-to-antibiotic times. The purpose of the project addressed issues including orders not being placed together, having to look up references regarding antibiotic mixture and rate, and waiting for antibiotics to be administered until present in the inpatient unit. Figure 3 presents the fishbone analysis, which identifies challenges and possible points of improvement for implementing sepsis bundles in this facility.

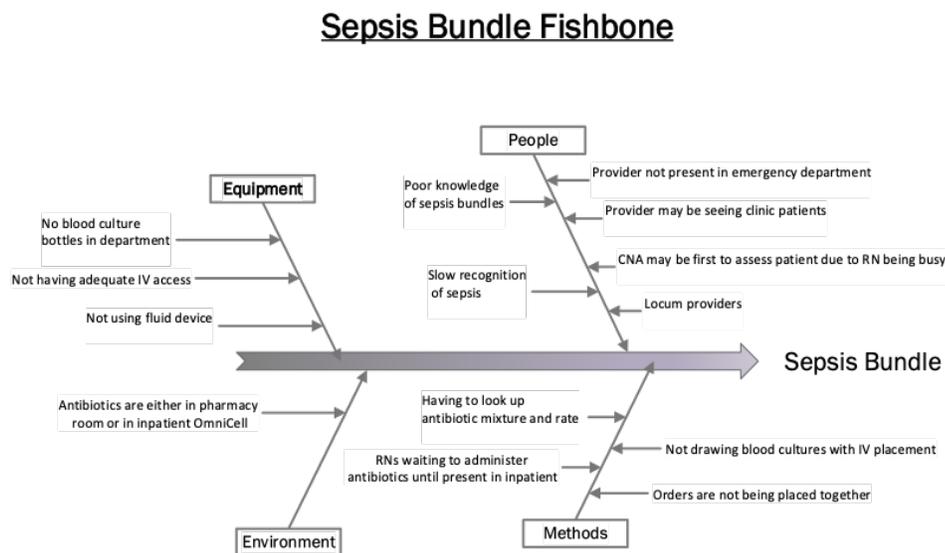


Figure 3: Fishbone diagram: The mechanism of which components had to be addressed in order for door-to-antibiotic times to be reduced by the implementation of the sepsis bundle.

Eleven patients met sepsis criteria prior to implementation of the sepsis bundle guide (Appendix A) between January 2017 and June 2017. Times from door-to-antibiotic

administration were recorded as the difference between the o'clock time of chart generation and the o'clock time of antibiotic administration. The mean door-to-antibiotic administration time was 181.5 minutes.

#### Door-to-Antibiotic Times

There was a statistically significant difference in door-to-antibiotic administration times pre- and post-sepsis bundle implementation. The mean time pre-sepsis bundle implementation was 181.5 minutes, and the mean time post-sepsis bundle implementation was 141.0 minutes post-sepsis bundle ( $P < 0.05$ ) (Figure 4). Figure 4 displays the pre-sepsis bundle mean door-to-antibiotic administration time compared the post-bundle mean door-to-antibiotic administration time. The post-sepsis bundle mean showed a decreased door-to-antibiotic administration time, which decreased the control limits. The narrowing of control limits indicated there is less variation of door-to-antibiotic administration times.

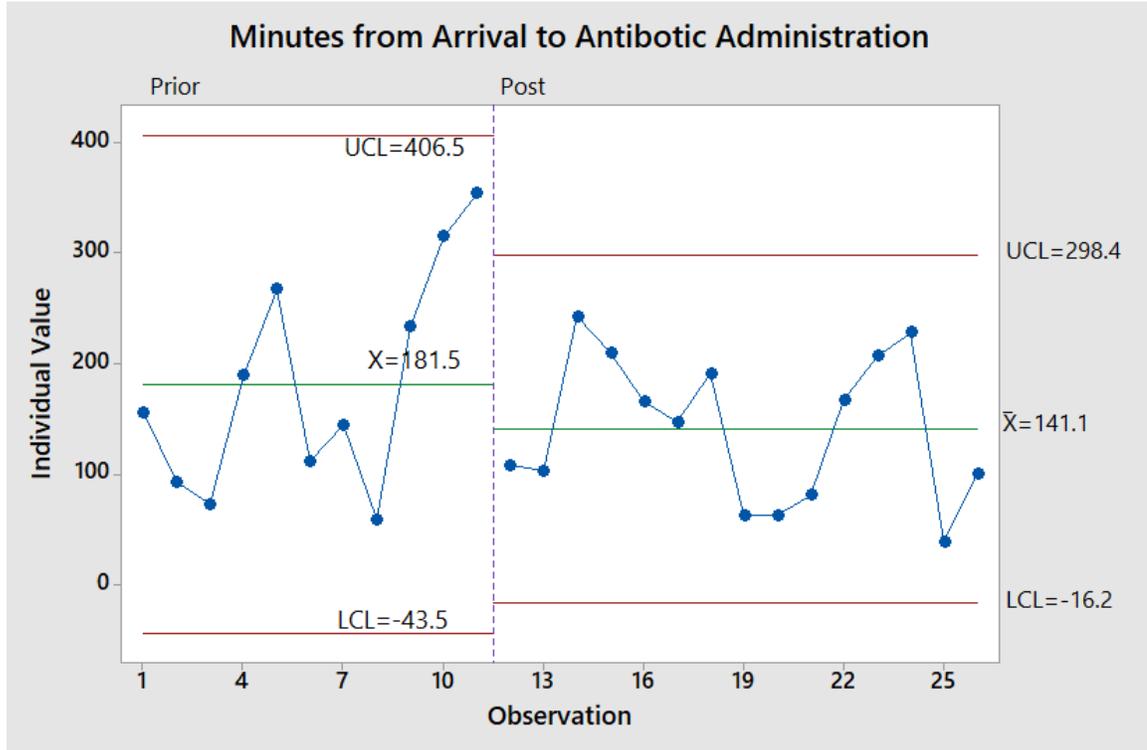


Figure 4: Door-to-Antibiotic Administration. The mean decreased from 181.5 minutes to 141.1 minutes. UCL shows the upper control limits, while LCL shows the lower control limits. The control limits are three sigmas from the mean time. The control limits narrowed which shows less variation post-sepsis bundle implementation.

### Effect Size

Cohen's  $d$  formula was used to evaluate project design and the effect size to "quantify the size of the difference between the two groups" (Coe, 2002). A medium effect size ( $d=0.47$ ) was calculated with Cohen's  $d$ . The project design was effective in reducing door-to-antibiotic administration times.

### Project Timeline with Results

The project timeline, including results, are presented below in Figure 5

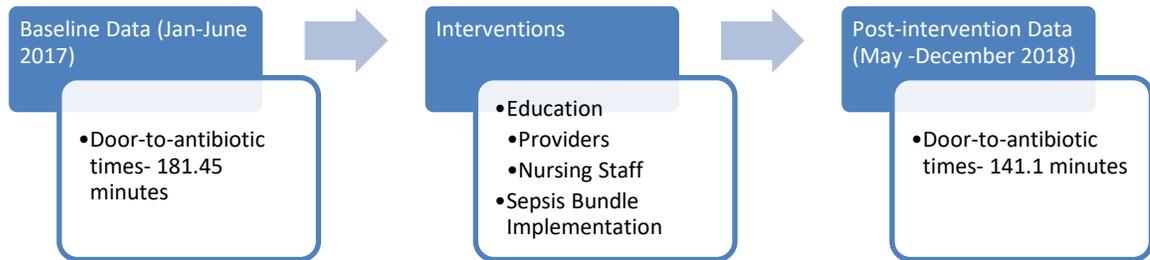


Figure 5. Flow chart of project timeline with results.

## CHAPTER FIVE

## DISCUSSION

DiscussionSummary of Findings

The project was a complex, invasive change of practice in a rural emergency department. Education and sepsis bundle guides affected the providers' care by improving the process of order placement, resulting in a decrease in the time lag between orders.

The most important finding of the project was the door-to-antibiotic times were statistically decreased. The decreased times can be associated with improved patient care and improved patient outcomes. Sepsis bundle implementation decreased door-to-antibiotic administration times by 40.5 minutes (181.5 minutes pre-sepsis bundle vs. 141.0 minutes post-sepsis bundle,  $P < 0.05$ ) in the project facility. Sepsis bundles decreased door-to-antibiotic administration times in this project and others in the literature (Kalich, 2016; Barochia et al., 2010; Tipler et al., 2013; Miguel-Yanes, 2009). The mean decrease of door-to-antibiotic administration times was 45.3 minutes when all of the studies were compared (Kalich, 2016; Barochia et al., 2010; Tipler et al., 2013; Miguel-Yanes, 2009).

The outcome from this project was very similar to the outcome from a Bruce et al. (2015) study in an urban emergency department, who found a reduction of door-to-

antibiotic administration of 27 minutes post-sepsis bundle implementation. Barochia et al. (2010) also found a reduction of door-to-antibiotic times by 34.8 minutes.

Burney et al. (2016) performed a study that addressed the barriers to implementing a sepsis bundle in the urban emergency department. Similar struggles were encountered during this project. These barriers included delay in sepsis diagnosis by the provider and lack of recognition at triage (Burney et al., 2016). In the rural emergency department, where this project was implemented, there is no triage because the patient population is not large enough to warrant a triage. There was a lack sepsis recognition when patients presented to the emergency department.

Borgert et al. (2015) found that the process of education, implementation, auditing, and then following up had the highest compliance with the sepsis bundle. This recommendation, as well as the FADE model, were used to help guide this project. The outcome of decreased door-to-antibiotic times correlated with the findings in the study by Borgert et al. (2015).

### Strengths and Limitations

Strengths of this project included pre- and post-intervention data showed a decrease in door-to-antibiotic administration times with the implementation of sepsis bundles and that it was one of the first quality improvement projects performed in the rural emergency department at this facility. The project aligned with the results from the Surviving Sepsis Campaign and was compliant with the campaign requirements. The benefit of the implementation of sepsis bundles in the rural emergency department

suggested a rural emergency department with limited resources could improve septic patient care and can reduce door-to-antibiotic times.

Limitations included a relatively small sample size; rural emergency departments do not have a plethora of patients daily preventing a large sample size. The sample size was comparable to other rural emergency departments, resulting in similarities that may encourage other rural emergency departments to adopt the sepsis bundle. Table 1 shows the characteristics of the eligible patients (pre and post-sepsis bundle implementation). A statistical analysis for equality was not performed, but upon visual review, groups appear to be equal in characteristics.

Characteristics of Patients			
	Pre-Bundle (N=11)	Post-Bundle (N=15)	Total (N=26)
Gender			
Male	72.8%	73.3%	73%
Female	27.2%	26.7%	27%
Age (Mean)	67.5 years	69.1 years	68.4 years
Diagnosis			
UTI	27.2%	26.7%	26.9%
CAP	54.5%	53.3%	53.8%
Cellulitis	18.3%	20.0%	19.3%

Table 1. Characteristics of sepsis patients in the emergency department pre-sepsis bundle, post-sepsis bundle, and total. Upon visual review, groups appear to be equal in characteristic, but the sample size is not big enough to perform a statistical analysis for equality.

There was a lack of education regarding sepsis prior to this project and pre-sepsis bundle knowledge assessment was not completed prior to the initiation of the project. Although education and sepsis bundle implementation were a major component of the project, it is possible other factors may have influenced the outcome measured. Other

potential factors that could have had an effect on the outcome measured were not identified or assessed.

Another limitation associated with the project was a change in provider staff while data were being collected. A locum tenens provider was present during post-sepsis bundle implementation. The provider had not participated in the education associated with sepsis bundle initiation.

A barrier to the project implementation included but was not limited to providers initially not accepting the bundle as a protocol. Instead, adjustments were made for the sepsis bundle to be implemented guideline. The providers were involved in developing the guideline but due to the extensive work to implement a protocol, they wanted to make sure the goal was sustainable before implementing the bundle as a protocol. Because the providers did not want to make the sepsis bundle a protocol until after the process was in place for some time, the nursing staff was advised on the appropriate communication to alert the provider that a patient met sepsis criteria (Appendix A). Providers did agree to give a verbal order if the patient met sepsis criteria so that the nurse could initiate the bundle prior to the provider's arrival.

In addition, the sepsis bundle was not included in the electronic health record (EHR) provider order entry system in time for the project initiation. The process to get an order set in the EHR required multiple committees to vet the sepsis bundle prior to inclusion in the EHR. To overcome this barrier, a paper order plan was placed in every trauma room in the emergency department. The paper order plan allowed the nurse to visualize sepsis criteria, and if the patient met sepsis criteria, they could use the order

plan to communicate the criteria to the provider. The ultimate goal was for the sepsis bundle order plan to be placed in the EHR for the providers; however, progress was made with the paper order plan. The implementation of the sepsis bundle order guide is expected to ease the transition for the providers to use the sepsis bundle within the EHR, increasing compliance with the sepsis bundle.

### Practice Implications

Implementation of sepsis bundles raised awareness and may encourage other rural emergency departments to adopt sepsis bundles through further outreach and education. The facility's quality department adopted the project and will continue reporting on outcomes quarterly as a quality improvement measure. The quality department decided to use this project as a measure for 2019; auditing will be performed by the quality department after Spring 2019. A staff nurse will take leadership of this project in the future, and the quality department will provide all needed resources and auditing tools in order to achieve door-to-antibiotic administration times of less than 60 minutes.

### Steps to Improve Future Projects

For future projects, facilities could evaluate multiple aspects of sepsis care including how the nurses' role affects door-to-antibiotic administration times, the barriers of rural healthcare on sepsis patients, and individual provider door-to-antibiotic administration times. Data collection over a longer period of time would improve future project. In rural facilities, there are fewer opportunities to evaluate sepsis patients due to

the decreased census in the emergency department compared to an urban facility seeing more patients daily, requiring longer study periods.

Also, length of stay pre-sepsis bundle and post-sepsis bundle could be tracked. If patients are usually transferred to a larger facility, it would be critical that length of stays could be obtained from the accepting facility for data collection. These data would allow future studies to analyze the decreased length of stay after the implementation of sepsis bundles compared to care without a sepsis bundle. Reducing length of stays of the sepsis patients could reduce the high level of costs in the healthcare setting.

Mortality and morbidity tracking could strengthen future studies. Mortality and morbidity must be specific to septic patients. The rural facilities that track mortality and morbidity would need to gather data from the accepting facility to which patients are transferred. Tracking mortality and morbidity, as well as length of stay, would strengthen future projects by providing increased data for better patient outcomes with the implementation of the sepsis bundle.

The components that could be addressed in future projects to decrease door-to-antibiotic times are identified by the red arrows in Figure 6.

### Sepsis Bundle Fishbone

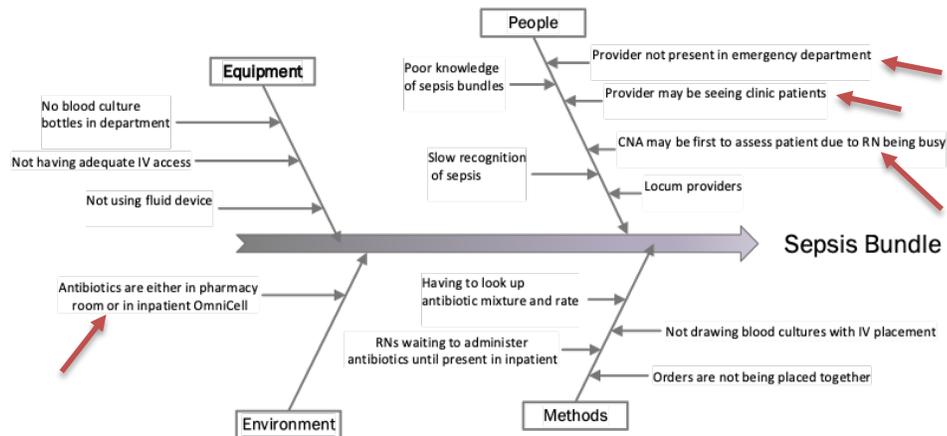


Figure 6: Fishbone diagram for future projects: The mechanism of which components had to be addressed in order for door-to-antibiotic times to be reduced by the implementation of the sepsis bundle. The red arrows indicate which components could be addressed in future projects to improve door-to-antibiotic times.

In future projects, it would be beneficial if providers understood and accepted sepsis bundle protocols. This would encourage nurses to initiate the bundle while another staff member called the provider, informing him/her that a septic patient was present.

### Financial Cost

The financial cost of implementing the sepsis bundle included materials and provider meeting times. The costs of the materials were covered through the facility. Materials included paper, laminating, and signs. The staff was paid during meetings,

which was also covered by the facility. Hourly wages were not available, so cost of meeting time could not be determined.

### Conclusion

Sepsis bundles and early identification of sepsis reduce door-to-antibiotic administration times when implemented in rural emergency departments (Rivers et al., 2001; Hayden et al., 2015; Tipler et al., 2013; Miguel-Yanes et al., 2009; Bruce et al., 2015). In this project, the implementation of sepsis bundles reduced door-to-antibiotic administration times by 40.5 minutes (181.5 minutes pre-sepsis bundle vs. 141.0 minutes post-sepsis bundle,  $P < 0.05$ ). Even though only one patient received their antibiotic under 60 minutes, which is the Surviving Sepsis Campaign goal, times were reduced by an average of over 40 minutes. The sepsis bundle will continue to be a process in the facility, with the continued goal of reducing door-to-antibiotic times.

All the components in the implemented sepsis bundle (Appendix G) comply with the Surviving Sepsis Campaign guidelines. This project provided evidence-based care to sepsis patients and may be of benefit for other rural facilities who had barriers to implementing a sepsis bundle.

The decrease of door-to-antibiotic administration times shows that the implementation of sepsis bundles in this rural emergency department was a useful intervention, despite the limited resources. Further integration of sepsis bundles in rural emergency departments may improve door-to-antibiotic times, thus improving the morbidity and mortality of septic patients.

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APPENDICES

APPENDIX A

SEPSIS CRITERIA (SIRS CRITERIA)

APPENDIX A

SEPSIS CRITERIA (SIRS CRITERIA)

At least two of the following and a suspected or identified source of infection:

- Oral or rectal temperature <36 degrees Celsius or >38.3 degrees Celsius
- Heart rate > 90 beats per minute
- Respiratory rate > 20 breaths per minute
- White blood cell count < 4,000 per microliter or > 12,000 per microliter

APPENDIX B

EVIDENCE TABLE

APPENDIX B

EVIDENCE TABLE

Citation: Author(s), Date of Publication & Title	Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables Studied and Their Definitions	Measureme nt of Major Variables	Data Analysis	Study Findings	Appraisal of Worth to Practice Strength of the Evidence (i.e., study of evidence + quality [study strengths and weaknesse s])
Kalich, B.A., Maguire, J.M., Campbell- Bright, S.L., Mehrotara, A., Caffey, T., Tulu, Z., Lin, F.C., & Carson, S.S. 2016. Impact of an Antibiotic- Specific Sepsis Bundle	None described	Before and after interventional study design. Gathered in a retrospective manner. Intervention was a sepsis bundle and abx specific bundle in ED	(n=124). 62 pts in before group and 62 pts in after sepsis bundle group.  Before group: 62 pts that were randomly selected that were similar to after group characteristics; between December 15,	ED sepsis bundle (Figure 2)  Abx times (time of diagnosis of severe sepsis to the correct abx administered)  Detailed abx selection and dosing based on presumed	Percentage compliance  Mins  Percentage of correct abx started in pts and	Descriptive stats for pt baseline characteristi cs  Fisher's exact test  Mann- Whitney <i>U</i> test  Analyses were	81% of pts had a complete set of blood cultures prior to abx  61% relative improvm ent in initiation of	<b>Inform practice-</b> performed in a single ED so cannot generalize; small sample size in before and after group. Would inform my practice on

<p>on Appropriate and Timely Antibiotic Administratio n for Severe Sepsis in the Emergency Department.</p>			<p>2011 &amp; March 15, 2012</p> <p>After group: 62 pts in ED with severe sepsis between Dec 15, 2012 &amp; March 15, 2013.</p> <p>Both groups had to meet severe sepsis criteria (Table 1), admitted to ED, did not receive abx at previous facility and were 18 years or older</p>	<p>infection source (time to correct abx)- 5 out of the 6 common abx used in bundle were in auto medication cabinet; after group had cefepime added to medication cabinet so 6 out of 6 were included in cabinet</p> <p>Education to nurses: information sessions, flyers in ED, quick reference cards</p> <p>Blood cultures before abx administration</p> <p>Inpatient mortality</p>	<p>in what time (mins)</p> <p>Compliance percentage</p> <p>Percentage</p> <p>Pts (percentage)</p>	<p>performed using SAS software</p> <p>Two tailed <math>\alpha</math> threshold of 0.05 for stat significance</p>	<p>appropriat e abx therapy with enhanced bundle</p> <p>No significan t difference between groups in terms of time to appropriat e abx</p>	<p>the importance of starting the appropriate abx first in the sequence to meet guidelines.</p> <p><b>Grade: B</b></p> <p>Appropriate abx times did not reach statistical significance</p> <p><b>Strengths:</b> In bundle, all sepsis and severe sepsis pts would receive abx in 60 mins -Can improve significantly in 3 months</p> <p><b>Weaknesse s:</b> Empiric abx therapy not listed in</p>
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								<p>bundle resulted in delay of care d/t getting from in hospital pharmacy and not being in the medication cabinet</p> <p>Improvement with compliance was not significant (may increase over time and with more education)</p> <p>-Many nurses not aware of starting a broad-spectrum, short-infusion first to meet guidelines</p> <p>-In a single ED</p> <p>-No physician order sets</p>
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<p>Burney, M., Underwood, J., McEvoy, S., Nelson, G., Dzierba, A., Kauari, V., &amp; Chong, D., (2012) Early detection and treatment of severe sepsis in the emergency department: identifying barriers to implementation of a protocol-based approach</p>	<p>None described</p>	<p>Cross-sectional, online survey with open-ended and closed-ended questions</p>	<p>Nurses and physicians in a major urban academic medical center, n=101 (57 ED staff nurses, 28 physicians and 16 resident physicians)</p>	<p>Baseline knowledge and self-reported confidence in identification of SIRS and sepsis</p> <p>Current practices in treatment</p> <p>Difficulties encountered in managing sepsis cases</p> <p>Perceived barriers to implementation of a clinical pathway based on early quantitative resuscitation goals</p> <p>To elicit suggestions for improvement of sepsis treatment within the department.</p>	<p>Percentages</p> <p>Percentages</p> <p>Percentages</p> <p>Percentages</p>	<p>PASW/SPSS version 18.0</p> <p>Descriptive statistics, Pearson <math>\chi^2</math> tests of independence, Statistical significance set at <math>P &lt; .05</math></p>	<p>Top 3 greatest perception in the ED for RN's: delay in diagnosis by MD (28.1%), delay in availability of ICU beds (19.3%), lack of recognition at triage (15.8%); MD's: delay in availability of ICU beds (20.5%), nursing delays (20.5%), lack of recognition at triage (18.2%), other (18.2%)</p> <p>Top 3 perceived</p>	<p><b>Strengths:</b> identified barriers to sepsis protocol</p> <p><b>Weaknesses:</b> survey voluntary; one institution, no validated survey tool. No risk of harm.</p> <p><b>Grade: I.</b> More information is needed to inform or change my practice. A valid tool was not used and the study was done in one institution.</p>
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							<p>barriers to implementation for RN's: physical space in ED (64.9%), lack of available nursing staff (45.6%), access to CVP/Scv O2 monitoring (40.4%); MD's: access to CVP/Scv O2 monitoring (79.5%), lack of available nursing staff (75.1%), physical space in the ED (59.1%)</p>	
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							Attending physicians were significantly more likely than residents to feel “not at all” competent ( $\chi^2=6.9$ , $p=.03$ ) when asked to self-assess their competence in performing a dynamic inferior vena cava ultrasound for fluid responsiveness.	
Bruce, H.R., Maiden, J., Fedullo, P. F. & Kim, S. March 2015. Impact of Nurse-	None described	Retrospective chart review and pre/post protocol data collection	n= 195; pts identified with severe sepsis or septic shock in ED	Nurse-initiated protocol: alert MD or charge nurse if two or more symptoms of SIRS present	Number of pts	Descriptive statistics $\chi^2$ - tests Mann-	Statistically significant improvement in compliance	<b>Inform practice</b> Single case control study- level 2

<p>Initiated ED Sepsis Protocol on Compliance with Sepsis Bundles, Time to Initial Antibiotic Administration and In-hospital Mortality</p>			<p>n=62 before protocol n=75 after protocol Population analyzed by chart review, no threat of attrition</p>	<p>Time to abx: admission to abx Compliance with bundle: compliance with 3 hour Surviving Sepsis Campaign bundle recommendations In-hospital mortality: pt death during hospitalization for sepsis</p>	<p>Mins Serum lactate measurement Blood cultures before abx Broad-spectrum abx Fluid administration 30mL/kg if hypotension or lactate &gt;4mmol/L Number of pts</p>	<p>Whitney tests</p>	<p>e with obtaining serum lactate levels (p=0.003) post protocol initiation. Median time to abx administration was reduced from 135 mins to 108 mins (p=0.021) Other major variables showed no statistically significant improvement</p>	<p><b>Grade: B Strengths:</b> - Statistically significant reduction in abx administration time was observed even in small sample size - Stated implication for further studies on interdisciplinary protocols to improve compliance <b>Weaknesses:</b> - Power analysis for sample size not conducted, with small sample size makes it difficult to generalize and detect</p>
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								<p>small changes</p> <ul style="list-style-type: none"> <li>-Nurses understanding of protocol not evaluated</li> <li>-Pre-protocol trends showed decline in antibiotic administration time</li> <li>-Number of patients without sepsis who had protocol triggered is unknown</li> </ul>
<p>Barochia, A.V., Cui, X., Vitberg, D., Suffredini, A.F., O’Grady, N.P., Banks, S.M., Minneci, P., Kern, S.J., Danner, R.L., Natanson, C. 2010.</p>	<p>None described</p>	<p>Meta-analysis of clinical trials</p>	<p>n= 8 articles met inclusion criteria out of 981 published articles using terms sepsis, septic shock, treatment, guidelines, protocols, early goal-directed therapy, &amp; bundles</p>	<p>Sepsis &amp; septic shock defined by American College of Chest Physicians</p> <p>Abx treatment: # of pts receiving abx w/in a specified time period; actual mean</p>	<p>Vital signs &amp; suspected source</p> <p>Hours, mins</p>	<p>R package metabin</p> <p>Brewslow-Day test</p> <p>Associated I<sup>2</sup> statistic</p> <p>Mantel-Haenszel test</p>	<p>The effect of bundled care on survival was consistent (I<sup>2</sup>=0%, p=.97)</p> <p>Statistically significant increase</p>	<p><b>Change:</b> Abx administration is the only component that is consistent and has the data to support the need for early</p>

<p>Bundled care for septic shock: an analysis of clinical trials.</p>			<p>n= 709 patients in control group</p> <p>n= 562 patients in bundle group</p> <p>Setting was care in the emergency department</p>	<p>time from presentation to abx administration; # of pts receiving appropriate abx based on culture results.</p> <p>Effect of bundled care</p>	<p>Survival rate</p>	<p>Weighted mean</p> <p>Jackknife sensitivity analysis</p>	<p>in odds of surviving with bundled care compared with controls (OR, 1.91; 95% CI, 1.49-2.45; <math>p&lt;.0001</math>).</p> <p>Time to abx significantly decreased (-.58 hrs; <math>p&lt;.0001</math>) with bundled care.</p>	<p>administration of appropriate abx. Enough evidence to change practice, bundles may be different per institution but all need to have an abx component</p> <p><b>Grade: A</b></p> <p><b>Strengths:</b> Meta-analysis, only appropriate abx met criteria, strong evidence for abx improvement with bundles</p> <p><b>Weaknesses:</b> Lack of methodologic rigor</p>
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								(lack of blinding, potential selection bias, duration of sepsis, use of unadjusted data), general care to usually improves over time
Hayden, G.E., Tuuri, R.E., Scott, R., Losek, J.D., Blackshaw, A.M., Schenling, A.J., Nietert, P.J., Hall, G.A. 2015. Triage sepsis alert and sepsis protocol lower times to fluids and antibiotics in the ED	None described	Retrospective, quasiexperimental	n=238 pt medical records that were suspected of having an infection and met criteria suggesting sepsis, severe sepsis, or septic shock.  n=108 medical records in the pre-SWAT  n=130 in the post-SWAT  Setting: single, urban, academic ED	SWAT: sepsis workup and treatment protocol emphasizing rapid mobilization of resources, standardized order sets, and early broad-spectrum abx and fluid resuscitation  Preintervention group:(dependent variable) no change  Post-intervention group:	Pt demographic data (age, sex, and race)  Vital signs  lab values (WBC & lactate level)  Door-to-bolus time  Door-to-antibiotic-time  Door-to-admit time  ED length of stay  Mortality	Door-to-bolus and door-to-abx given both had a P value of <.01. P values <.05 were considered to be statistically significant.  X <sup>2</sup> tests  sample t tests	The post-SWAT group demonstrated marked improvements in both the door-to-intravenous fluids and the door-to-abx time. the mean door-to-abx improved by 58.8 mins. The mean door-to-	<b>Inform:</b> This would be near the top of the hierarchy in the single non-randomized trial under single RCT. This study would inform my practice as it was only tested at one site.  <b>Grade: A</b>  <b>Strengths:</b> Door-to-fluids and

				<p>(independent variable) activation of the EHR by the triage nurse to the MD to go to bedside and then assess and decide whether or not to initiate a SWAT bundle</p> <p>SWAT A: hypotensive pts</p> <p>SWAT B; normotensive pts</p>	<p>A segmented regression modeling approach was used</p>		<p>bolus time improved by 30.5 mins. There were no significant differences between the pre-SWAT and post-SWAT groups in regard to age, sex, or race. compared to the pre-SWAT group (P=.04)</p>	<p>door-to-abx were improved by almost an hour. -No risk for harm to patients that are being recognized as potential sepsis pt, decision to proceed with SWAT activation was left to the discretion of the physician. <b>Weaknesses:</b> -single site -different methods used to identify pre- and post-intervention groups -it did not track the performance of the alert system at triage</p>
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								-semi-feasible to bring into practice, depends on which charting system is being used and if it will accommodate alerts -retrospective -false positives and false negatives are not known
Giuliano, K., Licardo, M. & Staul, L. 2011. Impact of Protocol Watch on compliance with the Surviving Sepsis Campaign	None described	Pre/post-intervention, non-randomized pilot study	Phase 1 n=65 Phase 2 n=70  18 years or older, admitted to ICU/ED with sepsis or developed sepsis during stay between March 1 2006 and August 5, 2008	<u>Protocol Watch</u> - a clinical decision support system application for bedside monitoring of pts to assist physicians in implementing SSC guideline; prompts displayed on monitor bedside	Percentage	Descriptive statistics  $\chi^2$ tests  t tests  nonparametric tests	Higher amount of resuscitation bundle completion after intervention  No significant difference in time to completion of	<b>Inform Practice Grade: B</b>  Single non-randomized trial, level II  <b>Strengths:</b> Designed to improve compliance with guidelines,

				<p><u>Compliance with resuscitation bundle</u>- serum lactate, blood cultures before abx, abx within 3 hours, fluid resuscitation and vasopressors if appropriate,</p> <p><u>Compliance with management bundle</u>- appropriate use of steroids, appropriate use/no use of Xigris, glucose control to target, appropriate management of IPP</p> <p><u>Time to completion of resuscitation bundle</u>-</p> <p><u>Time to completion of</u></p>	<p>Percentage</p> <p>Hours</p> <p>Hours</p> <p>Mins</p>		<p>resuscitation bundle, compliance with management bundle or time to completion of management bundle</p> <p>Statistically significant decrease in time to abx administration</p>	<p>large sample size</p> <p><b>Limitations:</b> Non-randomized, only 2 facilities, already had paper systems established to monitor guidelines</p>
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				<u>management bundle-</u>				
				<u>Time to antibiotic administration-identification of sepsis/septic shock to administration</u>				
Tipler, P.S., Pamplin, J., Mysliwicz, V., Anderson, D., & Mount, C.A. 2013. Use of a protocolized approach to the management of sepsis can improve time to first dose of antibiotic.	None described	Retrospective chart review	Pts with severe sepsis throughout Jan 2008-Dec 2010; 18 years or older seen in the ED  n=209 pts (n=71 prior to bundle; n=132 after bundle implementation)	Sepsis, septic shock and severe sepsis was defined by 2008 Surviving Sepsis Campaign  SIRS criteria  Antibiotic administration	Vital signs and source of infection  Type/dose/mins	2-sided t test  Mann-Whitney <i>U</i> test	Average time to delivery of ciprofloxacin decreased by 58 mins ( <i>P</i> =.462) and vancomycin decreased by 99 mins ( <i>P</i> =.02)  Average time to all abx evaluated decreased by 61 mins	<b>Change practice:</b> decreased all abx administration times by 61 mins, average. Significant decrease in first abx dose  <b>Grade: A</b>  <b>Strengths:</b> Large sample size; compared data after bundle was initiated for a length of time  <b>Weaknesses:</b> Did not

								design study that allowed detecting a difference in outcomes for patients.
Kramer, R.D., Cooke, C.R., Liu, V., Miller, R.R. & Iwashyna, T.J. 2015. Variation in the contents of sepsis bundles and quality measures: a systematic review	Promoting Action on Research Implementation in Health Services framework  Reach Effectiveness - Adoption Implementation Maintenance framework	Systematic Review on PubMed 2008-2015	n= 158 documents with n= 36 that were using an version of SSC bundle	Bundles- list of care elements derived from evidence-based recommendations for resuscitation and management of pts with sepsis up to 6 hrs after diagnosis  Metric- any measures proposed by an organization to assess bundle compliance or related outcomes	Included 6-10 elements	None mentioned	Only lactate collection and broad-spectrum abx were listed in all bundles	<b>Inform practice:</b> Bundles can have many different elements and needs to be adjusted to the resources we have available. Would like to see the results of each bundle and how they differ inpatient outcomes.  <b>Grade: B</b> <b>Strengths:</b> Reviewed many different bundles and how they work. Large sample for

								<p>systematic review</p> <p><b>Weaknesses:</b> Did not survey individual hospitals, not all organizations had chance to respond. Future work needs to evaluate the relationship of the reported documents and the actual clinical practices</p>
<p>Guo, Q., Li, H., Li, Y., Nong, L., Xu, Y., He, G., Liu, X., Jiang, M., Xiao, Z., &amp; Zhong, N. 2014. Compliance with severe sepsis bundles and</p>	None mentioned	Prospective Cohort Study	<p>Adult patient who met criteria for severe CAP n=106 patients (n=46 enrolled in bundle groups)</p> <p>RICU in Chinese affiliated</p>	<p>CAP= acute infiltrate on Chest x-ray with <math>\geq 2</math> symptoms (fever, hypothermia, rigors, sweats, new cough, change of color in resp secretions, dyspnea or</p>	Vital signs and Chest X-ray, sputum color, patient's report	<p>Statistical Package for Social Science for Windows version 13.0</p> <p>Chi-square test</p> <p>Independent-samples <i>t</i> test</p>	<p>Compliance with abx administration with 1 hr and administration of vasopressors were high in both groups</p>	<p><b>Inform practice-</b> Compliance in bundles did have better outcomes at 72 hours and a decrease in hospital mortality.</p>

its effect on patient outcomes of severe community-acquired pneumonia in a limited resources country.			tertiary hospital  Exclusion criteria- cardiac arrest, ESCD	chest discomfort).  Sepsis Shock= SAP < 90mmHg, MAP <60mmHg or reduction of SAP >40mmHg from baseline  6/24 hr severe sepsis bundles  Severity of Illness	Vital Signs  Compliance in percentages  Acute physiology and chronic health evaluation (APACHE) II scores and Sequential organ failure assessment (SOFA)	Univariate and multivariate logistic regression	Rates of total compliance with 6-hr, 24-hr and 6/24 hr bundles were 47.1%, 51.9%, and 42.5% in bundle group  Rates of total compliance in control group were 0.0% in all bundles	<b>Grade: B</b>  <b>Strengths:</b> Control group was present, had to be compliant in all bundle aspects, not just certain interventions  <b>Weaknesses:</b> Only followed CAP patients and not any other septic patients, no long-term follow up to see any differences in outcome with bundles.
Miguel-Yanes, J.M., Munoz-Gonzalez, J., Andueza-Lillo, J.A., Moyano-Villaseca, B.,	None mentioned	Observational study	Adult pts that had diagnosis of sepsis, severe sepsis or septic shock. n=50 cases within one month	Five items proposed by SSC	-Lactic level -Obtained blood cultures prior to abx -Abx administered within 3 hrs	Fisher exact test  X <sup>2</sup> test  Kolmogorov-Smirnov test	Lactate measured in 46% of cases (12% in 2005)	<b>Inform practice:</b> Bundle indicated higher amounts of fluids given, lesser time

<p>Gonzalez-Ramallo, V.J., &amp; Bustamante-Fermosel, A. 2009. Implementati on of a bundle of actions to improve adherence to the Surviving Sepsis Campaign guidelines at the ED.</p>			<p>Had to spend minimum of 6 hrs in ED.</p>		<p>-Fluid replacement at 20ml/kg -Vasopressors if in shock</p>	<p>Mann-Whitney  Kruskal-Wallis</p>	<p>Blood cultures obtained in 67% of cases (85% in 2005)  62% of pts received abx within 3 hrs.</p>	<p>before received initial abx dose.  <b>Grade: C</b>  <b>Strengths:</b> Compared this study to study in 2005 to evaluate difference, did stop study short due to noticing staff changes were occurring to make identical circumstances to previous study  <b>Weaknesses:</b> Staff did change so there could have been skewed data prior to</p>
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								stopping study
Borgert, M.J., Goossens, A., & Dongelmans, D.A. 2015. What are effective strategies for implementation of care bundles on ICUs: a systematic review.	None mentioned	Systematic review of care bundles in ICU setting	n=47 studies Studies had to implement bundles for either sepsis, Central Line, or ventilator  Exclusion- Non-English, protocols, abstracts, letters, commentaries or editorials	Quality  Strategies  AON measurement  Composite measurement  Item-by-item measurement  Lowest level of compliance	Downs & Black checklist  Taxonomy  Percentage of all indicated elements the pts have received  Ratio between care that was actually given by care that should have been given  Nominator and denominator of each bundle element separately  Lowest level of compliance to one of the elements is considered the total bundle compliance	Pearson's product-moment correlation  Kendall's rank correlation	Compliance of bundles is influenced by multiple factors  77% scored 'fair'  13% scored 'good'  11% scored 'poor'	<b>Inform practice:</b> Bundles are useful in implementing care but it is hard for high compliance-need to take in factors that are specific for your practice  <b>Grade: B</b>  <b>Strengths:</b> Studied different bundles and their compliance rate. Bundles had different implementation and shown that education, followed by implementation and then audit and

								<p>follow up is best</p> <p><b>Weaknesses:</b> Didn't get all bundles because some facilities don't use the term 'bundle' - no randomized designs included- publication bias</p>
<p>Liu, D., Su, L., Han, G., Yan, P., &amp; Xie, L. 2015. Prognostic value of procalcitonin in adult patients with sepsis: a systematic review and meta-analysis</p>	<p>None mentioned</p>	<p>Systematic Review</p> <p>Search terms included “procalcitonin, PCT, PCT clearance, PCT-c, PCT decrease, PCT kinetics” and “sepsis, septicemia”</p>	<p>n=16 studies, 3126 pts</p> <p>Exclusion- reviews, letters, commentaries, correspondences, case reports, conference abstracts, expert opinions, editorials and animal experiments</p>	<p>Information bias</p> <p>Selection bias</p> <p>Confusion bias</p> <p>Confounding bias</p>	<p>Representativeness of the study and diagnostic criteria for sepsis</p> <p>Recruitment of consecutive patients</p> <p>Blinding of professionals</p> <p>Exclusion of patients with comorbidities linked to PCT levels.</p>	<p>MIDAS module</p> <p>Relative risk</p> <p>Q-test</p> <p><math>I^2</math> test</p>	<p>PCT non-clearance could predict sepsis mortality</p>	<p><b>Inform practice-</b> The study cannot be applied to ED patients due to not assessing the diagnostic accuracy. I would do further studies to see if PCT should be implemented in our</p>

								<p>practice bundle</p> <p><b>Grade: C</b></p> <p><b>Strengths:</b> Strict eligibility criteria so that not a lot of variables that were different</p> <p><b>Weaknesses:</b> Could not be applied to ED patients, could not do analyzes on different admission categories or sites of infection</p>
<p>Tang, B.M., Eslick, G.D., Craig, J.C., &amp; McLean, A.S. 2007. Accuracy of procalcitonin for sepsis diagnosis in critically ill</p>		<p>Systematic review</p> <p>Search in Medline, Embase, and Current Contents</p>	<p>n= 18 studies, 2092 pts</p> <p>Exclusion- pts did not have SIRS, too narrow spectrum of pts, duplicated studies,</p>	<p>Methodological quality</p>	<p>Cochrane Collaboration guidelines</p>	<p>Forest plots</p> <p>Cochran's Q-test</p> <p>Inverse variance method</p>	<p>Procalcitonin test cannot accurately distinguish sepsis from SIRS in critically</p>	<p><b>Inform practice:</b> Between the two studies that I have evaluated, I will have to do more research before PCT</p>

patients: systematic review and meta- analysis.			pediatric studies			Littenberg- Moses method  Egger's regression model	ill patients	is placed in a bundle at the facility  <b>Grade: C</b>  <b>Strengths:</b> A lot of information on PCT and why it can be used  <b>Weaknesse s:</b> Publication bias, tables were hard to interpret
Rivers, E., Nguyen, B., Havstad, S., Ressler, J., Muzzin ,A. 2001. Early goal- directed therapy in the treatment of severe sepsis and septic shock.	None mentioned	Prospective, randomized study	n=263 patients	In-hospital mortality  Resuscitation end points  Organ- dysfunction scores  Coagulation- related variables  Administered treatments	Kaplan-Meier  Vital signs  APACHE II score, SAPS II, and MODS  Platelet count PTT D-Dimer	Student's <i>t</i> test	Goal- directed therapy has significan t short- term and long-term benefits	<b>Change Practice-</b> Is considered the gold standard article for sepsis  <b>Grade: A</b>  <b>Strengths:</b> Measured multiple variables. Implemen ted the sepsis campaign

				Consumption of health care resources	Length of stay, mechanical ventilators			<b>Weaknesses:</b> Early study, greater than 10 years ago.
Douthit, N., Kiv, S., Dwolatzky, T., & Biswas. 2015. Exposing some important barriers to health care access in rural USA	None mentioned	Literature review	Rural healthcare	None	None	Disparities in rural healthcare compared to urban healthcare	To improve rural healthcare , ongoing program of improving the provision of services, promote recruitment, training and career development, increase health insurance and engage rural patients in health promotion	<b>Strengths:</b> Overview of rural healthcare barriers that need to be accounted for in implementation of sepsis bundles.

<p>Seright, T.J., Winters, C.A. 2015. Critical care in critical access hospitals</p>	<p>None</p>	<p>Qualitative</p>	<p>Critical access hospitals</p>	<p>None</p>	<p>None</p>	<p>Improving patient outcomes</p>	<p>Critical care nurses usually have the first interaction with the patient, so they can make a big difference . Relationships with other facilities can improve care of the patient.</p>	<p><b>Strengths:</b> Overview of how critical care access hospitals operate. Identified gaps in literature regarding critical access hospitals.</p>
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APPENDIX C

IRB FORM

APPENDIX C

## IRB FORM



**INSTITUTIONAL REVIEW BOARD**  
For the Protection of Human Subjects  
FWA 00000165

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**MEMORANDUM**

**TO:** Kierston Popp and Casey Cole  
**FROM:** Mark Quinn *Mark Quinn cy*  
Chair, Institutional Review Board for the Protection of Human Subjects  
**DATE:** February 8, 2018  
**RE:** "Sepsis Bundles in the Rural Emergency Department" [KP020818-EX]

The above research, described in your submission of February 7, 2018, is exempt from the requirement of review by the Institutional Review Board in accordance with the Code of Federal regulations, Part 46, section 101. The specific paragraph which applies to your research is:

- (b) (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (b) (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation.
- (b) (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (b) (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects.
- (b) (5) Research and demonstration projects, which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- (b) (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed, or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA, or approved by the EPA, or the Food Safety and Inspection Service of the USDA.

Although review by the Institutional Review Board is not required for the above research, the Committee will be glad to review it. If you wish a review and committee approval, please submit 3 copies of the usual application form and it will be processed by expedited review.

APPENDIX D

APPROVAL LETTER

APPENDIX D

APPROVAL LETTER

Cheryl,

Thank you for your follow up on this sepsis project plan. We are glad to have this opportunity to assist with research in this area and welcome this project to our facility. The project has the approval of our Chief Quality Officer, Emergency Department Chair and myself.

Thank you,

Bridgett J. Chartier  
Director of Nursing  
Beartooth Billings Clinic  
2525 North Broadway  
Red Lodge, MT 59068  
406-446-0514



APPENDIX E

POSSIBLE DIAGNOSES

APPENDIX E

## POSSIBLE DIAGNOSES

The list of diagnoses that were used to audit charts:

R78.81- Bacteremia  
R65.2- Severe Sepsis  
R65.21- Severe Sepsis with Septic Shock  
R65.1- Systemic inflammatory response syndrome of non-infectious origin  
R65.11- Systemic inflammatory response syndrome of non-infectious origin with acute organ dysfunction  
A40.0- Sepsis due to streptococcus, group A  
A40.1- Sepsis due to streptococcus, group B  
A40.9- Streptococcal sepsis, unspecified  
A41.2- Sepsis due to unspecified staphylococcus  
A41.0- Sepsis due to staphylococcus aureus  
A41.1- Sepsis due to other specified staphylococcus  
A40.3- Sepsis due to streptococcus pneumoniae  
A41.4- Sepsis due anaerobes  
A41.3- Sepsis due to Hemophilus influenza  
A41.5- Sepsis due to other Gram-negative organisms  
A41.51- Sepsis due to E.coli  
A41.52- Sepsis due to pseudomonas  
A41.59- Other Gram-negative sepsis  
A41.89- Other specified sepsis  
A41.9- Sepsis, unspecified organism  
J18.9- Pneumonia, unspecified organism  
L08.9- Local infection of the skin and subcutaneous tissue, unspecified  
R50.9- Fever, unspecified  
R00.0- Tachycardia  
N39.0- Urinary tract infection, site not specified  
T83.51- Infection and inflammatory reaction due to urinary catheter  
N10- Acute pyelonephritis  
N11.1- Chronic obstructive pyelonephritis  
A02.25- Salmonella pyelonephritis

APPENDIX F

DATA COLLECTION TOOL



APPENDIX G

SEPSIS BUNDLE GUIDE

APPENDIX G

## SEPSIS BUNDLE GUIDE

**Sepsis Orders****SIRS Criteria (at least 2 of the following and suspected source of infection)**

- Temp <36 or >38.3
- HR >90
- RR >20
- WBC <4,000 or >12,000
- Suspected source \_\_\_\_\_

	Time Called	Time Arrived
Call lab		
		Time Performed
Peripheral IV Access (>22g)		
Peripheral IV Access (>22g)		
Vital Signs q15 mins		

**Labs**

- CBC, Diff
- CMP
- Lactate
- PT/INR
- Cult Blood, Peripheral x2
- UA Routine Reflex Culture (Perform straight cath if >30mins)
- Wound Culture
- Chest X-Ray

**Fluid Resuscitation**

- Lactated Ringers
  - IV infusion, STAT, x1 dose Rate 500mL bolus

**Community-Acquired Pneumonia**

PREFERRED REGIMEN: Ceftriaxone and Azithromycin OR levofloxacin

- Ceftriaxone 2g in NS 100mL IVPB q 24hrs
  - Infuse over 60 mins
- Azithromycin 500mg in NS 250mL IVPB q24hrs
  - Infuse over 60 mins
- Levofloxacin 750mg IVPB q24hrs
  - Infuse over 90 mins
  - CrCl 20-49 (750mg q48hrs)
  - CrCl 10-19 (750mg initial then 500mg q48hrs)

Start Time

**Hospital Acquired Pneumonia**

*(Pneumonia that occurs 48 hours or more after admission and did not appear to be incubating at the time of admission)*

PREFERRED REGIMEN: Piperacillin/tazobactam OR Cefepime

- Piperacillin/tazobactam 4.5 g in NS 100mL IVPB q6hrs
  - Infuse over 60 mins
  - CrCl 20-40 (3.375g q6hrs)
  - CrCl <20 (2.25g q6hrs)
- Cefepime 2g in NS 100mL IVPB q8hrs
  - Infuse over 30 mins
  - CrCl 30-60 (2g q24hrs)
  - CrCl 11-29 (1g q24hrs)
  - CrCl <11 (500mg q24hrs)
- Vancomycin per pharmacy protocol (if MRSA risk factors: recent hospitalization, residence in long-term care facility, recent surgery, hemodialysis, prior antibiotic use, IV drug use, military service, sharing sports equipment, HIV infection, incarceration)

Start Time

**Urinary Tract Infection**

PREFERRED REGIMEN: Ceftriaxone OR Levofloxacin

- Ceftriaxone 1g in NS 100mL IVPB q24hrs
  - Infuse over 60 mins
- Levofloxacin 750mg IVPB q24hrs
  - Infuse over 60 mins
  - CrCl 20-49 (750mg q48hrs)
  - CrCl 10-19 (750mg initial dose then 500mg q48hrs)

Start Time

**Skin and Soft Tissue- Non-diabetic or no history of MRSA**

PREFERRED REGIMEN: Cefazolin OR Vancomycin

- Cefazolin 1g in NS 50mL IVPB q8hrs
  - Infuse over 30 mins
    - CrCl 11-34 (500mg q12hrs)
    - CrCl <10 (500mg q18-24hrs)
- Vancomycin per pharmacy protocol

Start Time

**Skin and Soft Tissue- Diabetic foot, abscess, or history of MRSA**

PREFERRED REGIMEN: Piperacillin/tazobactam and Vanco OR Metronidazole and Cefepime

- Piperacillin/tazobactam 4.5g in NS 100mL q6-8hrs
  - Infuse over 60 mins
- Vancomycin per pharmacy protocol
- Metronidazole 500mg q8hrs
- Cefepime 2g in NS 100mL q8hrs
  - Infuse over 30 mins
    - CrCl 30-60 (2g q24hrs)
    - CrCl 11-29 (1g q24hrs)
    - CrCl <11 (500mg q24hrs)

Start Time

**SEPSIS SHOCK**

**Respiratory Source**

PREFERRED REGIMEN: Piperacillin/tazobactam AND Levofloxacin AND Vancomycin

- Piperacillin/tazobactam 4.5g in NS 100mL IVPB q6-8hrs
  - Infuse over 60 mins
- Levofloxacin 750mg IVPB q24hrs
  - Infuse over 90 mins
    - CrCl 20-49 (750mg q48hrs)
    - CrCl 10-19 (750mg initial then 500mg q48hrs)
- Vancomycin per pharmacy protocol (Narrow)

Start Time

**Unknown Source**

PREFERRED REGIMEN: Piperacillin/tazobactam AND Vancomycin

- Piperacillin/tazobactam 4.5g in NS 100mL IVPB q6-8hrs
  - Infuse over 60 mins
- Vancomycin per pharmacy protocol (Narrow)

Start Time