SEPSIS BUNDLE EVALUATION FOR
QUALITY IMPROVEMENT

by

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ABSTRACT

Sepsis is a common diagnosis in the acute care setting. Left untreated, sepsis can result in many long-term complications including permanent organ damage and death. Sepsis has become such a common diagnosis that the Centers for Medicare & Medicaid (CMS) have implemented core measures that are meant to aid in quickly diagnosing and treating septic patients. Because sepsis requires prompt treatment, these guidelines have been divided into three- and six-hour bundles to assure prompt treatment after diagnosis. If hospitals fail to follow these core measures, the institution is not reimbursed for the cost of medical care for that patient. Implementation of the three and six-hour bundles have been shown to improve patient outcomes, decreasing mortality associated with sepsis. Compliance rates with these core measures in a rural hospital in Northwest Montana, which will be called Hospital X, have been consistently below the goal of 80% compliance.

This quality-improvement project (QIP) utilized interventions to identify where non-compliance was occurring and interventions to improve overall institution compliance rates. Chart review and process flow observation were used to identify which parts of the bundle were not being implemented according to CMS guidelines. Use of a newly created sepsis handoff tool and implementing nurse education on the core measures were interventions used in an effort to increase overall institution compliance. Results: Overall compliance rates improved from 57% in May, 2018 to 87% in June, 2018 after implementation of interventions. For the months of June, 2018 – September, 2018, compliance rates remained >70%.

Conclusion: The two interventions that were implemented during the course of this project seemed to improve compliance based off a significant improvement in overall compliance rates during months where the interventions were implemented. There are many recommendations for future research and interventions based off the findings from this project.
CHAPTER ONE

INTRODUCTION

Background

In emergency departments (ED) and acute care settings across the nation, sepsis is one of the most common and fatal diagnoses, costing hospitals billions and patients their lives. Sepsis as a continuum is defined as “a syndrome of physiologic, pathologic, and biochemical abnormalities induced by infection” (Singer, Deutschman, Seymour, Shankar-Hari, Bauer … and Angus, 2016, pg. 802). Sepsis can lead to severe sepsis and septic shock, a process described as “a systemic, deleterious host response to infection leading to severe sepsis (acute organ dysfunction secondary to documented or suspected infection) and septic shock (severe sepsis plus hypotension not reversed with fluid resuscitation)” (Dellinger, Levy, Rhodes, Annane, Gerlach, Opal … and Machado, 2013, pg. 583). General diagnostic criteria for sepsis include presence of fever, hypothermia, tachycardia ( >90 beats per minute), tachypnea (>20 breaths per minute), altered mental status, positive fluid balance/edema, and hyperglycemia (>140 mg/dL) in non-diabetic patients (Dellinger et al., 2013). Criteria for systemic inflammatory response syndrome (SIRS) includes the above symptoms in addition to a white blood cell (WBC) count >12,000 or <4,000, lactate level >2 mmol/L, elevated procalcitonin, elevated C-reactive protein (CRP), mottling of skin or prolonged capillary refill, and other evidence of acute organ failure (Kaukonen, Bailey, Pilcher, Cooper, & Bellomo 2015). Sepsis can be identified in acute care
settings by the presence of two or more SIRS criteria in addition to clinical interpretation of the presenting symptoms (Kaukonen et al., 2015). The presence of two or more SIRS criteria plus suspected infection is the model being utilized at a rural Montana hospital (Hospital X) for prompt identification of sepsis upon ED arrival.

The Surviving Sepsis Campaign (SSC) recognizes that sepsis, like many acute illnesses including myocardial infarction, stroke, and polytrauma, requires timely intervention to achieve the best possible outcome (Dellinger et al., 2013). The SSC originally presented guidelines (bundles) for early sepsis identification in 2003. Data from a 7.5-year span demonstrated a 25% decrease in relative risk of hospital mortality with compliance of these guidelines (Ramsdell, Smith, and Kerkhove, 2017). These guidelines were updated in 2015 and have been adopted by the National Quality Forum (NQF). The Centers for Medicare and Medicaid Services (CMS) has now adopted NQF sepsis bundles (order sets referred to as bundles) as a core measure known as the Early Management Bundle, Severe Sepsis/Septic Shock (SEP-1). The purpose of the SEP-1 is to help clinicians recognize sepsis early and rapidly initiate appropriate treatment (Ransdell, Smith, and Kerkhove 2017). There is a minimum of three and a maximum of seven components of this measure which are divided into three and six-hour bundles post SIRS identification. Failure to comply may result in decreased hospital reimbursement.

**Problem Statement**

Hospital X has adopted both the three and six-hour bundles with criteria meeting CMS guidelines. The three-hour bundle is the first tool used for early identification of
Sepsis. For this bundle, two or more SIRS criteria plus a suspected source of infection populates an order set with appropriate interventions. The three-hour bundle time starts when two or more SIRS criteria are identified with a suspected source of infection. Subsequently, specific actions are required to occur within three hours and include: blood cultures and lab work (including a lactate) prior to antibiotic administration, broad spectrum antibiotics administered within one hour of symptom onset, an IV fluid bolus (30cc/kg/hr) within one hour of symptoms onset, and use of pressors if hypotension is not corrected with intravenous (IV) fluid bolus (see Figure 1). If the patient presents with severe sepsis (two SIRS criteria with one or more signs of organ dysfunction) or septic shock (severe sepsis criteria with persistent hypotension, and/or a lactate >4), the 6-hour bundle is initiated. The CMS response actions required for the 6-hour bundle include: second lactate drawn within six hours of symptoms onset, repeat physician examination documented by the physician within six hours (vital signs, chest, cardiac, and skin examination, capillary refill and pulse assessment), and IV fluid, albumin, or blood to keep the mean arterial pressure (MAP) > 60 (see Figure 2). Note that all interventions in figures 1 and 2 highlighted in red for each bundle are required by CMS for hospital reimbursement.

Early sepsis is not being identified and treated according to CMS guidelines in the Hospital X emergency department (ED). The sepsis bundle was first launched at Hospital X two years ago. The goal compliance rate is 80% or higher. Data between October 2017 and January 2018 have demonstrated a significant drop in compliance (from 76% to 58%) (Pistorese, B., personal communication, 2018). Because the sepsis bundle is now
considered a core measure, there several consequences for failure to implement according
to guidelines. Patient outcomes have been shown to be largely affected by utilization (or
lack thereof) of a sepsis bundle. The International Multicentre Pravalence Study on
Sepsis (IMPreSS study) found that with three-hour sepsis bundle compliance there was a
40% reduction in hospital mortality and a 36% reduction with the six-hour bundle
(Ramsdell, Smith, and Kerkhove, 2017). Despite various interventions to improve
compliance including documentation tools in the EMR and nurse/physician education,
the compliance rate remains significantly less than the goal at Hospital X. The
identification and correction of barriers will improve patient outcomes and increase
hospital reimbursement rates if successfully implemented.

Project Purpose and Objectives

The purpose of this project was to identify barriers to successful implementation
of the Hospital X sepsis protocol in the ED and make appropriate recommendations for
corrective action based off these findings. The objectives for this project were as follows:

- Identify barriers to successful implementation of the sepsis protocol by review of
  charts and process flow observation
- Create recommendations specific to identified barriers
- Implement recommendations in the clinical setting
- Evaluate the effectiveness of the implementation of recommendations by tracking
  compliance rates
- Propose additional recommendations for increased compliance
• Improve patient outcomes

The long-term goal of proper implementation is to improve patient outcomes and increase hospital reimbursement rates.

**Significance**

**Prevalence and Cost of Sepsis**

As our population ages, prevalence of comorbidities and chronic illness contributes to the increasing number of septic patients in acute care areas. In 2011, costs associated with sepsis accounted for 5.2% of total United States (U.S.) hospital costs (over $20 billion), making it the single most expensive disease process in the US (Singer et al., 2016). More recent data suggests that sepsis affects more than 750,000 patients yearly with more than 200,000 cases resulting in death (Alverdy and Krezalek, 2016). Incidence of sepsis is increasing; one in five in the general population is being affected. Of these patients, one in four patients diagnosed with sepsis will die (Dellinger et al., 2013). Other sources suggest this number may be higher, with as many as one in two or one in three patients who die in acute care settings having a current diagnosis of sepsis (Clark, 2014). A review of the literature shows that sepsis and associated mortality rates are rising at an incredible rate (Alverdy and Krezalek, 2016). Severe sepsis is the leading cause of death in non-cardiac Intensive Care Units (ICU) with mortality rates between 30-50% and septic shock mortality rates between 50-60% (Kuo, Chang, Wu, Chen, Lin, Wen, and Jerng, 2012). As a result, the CMS is now including sepsis as a core measure, requiring standards for the timing of treatment (Healthcare Business Insights, 2016).
Hospital X has implemented CMS core measures by utilizing three and six-hour sepsis bundles (see figures 1, 2) that fulfill core measure interventions for patients who are possibly septic. When done correctly, these bundles satisfy all CMS recommendations resulting in improved patient outcomes and increased reimbursement rates for septic patients.

Three-Hour Bundle

The three-hour sepsis bundle is triggered for patients with suspected infection who demonstrate two or more of the following SIRS criteria: tachypnea (respiratory rate >20), tachycardia (heart rate >90), hyperthermia or hypothermia (temp >38°C or <36°C), elevated or low WBC count (WBC<4 or >12), and altered mental status. Once initiated, the nurse should collect blood for immediate analysis of infecting organisms (blood cultures), complete blood count (CBC) with differential, an initial lactic acid level, and a comprehensive metabolic panel (CMP). After blood has been collected, a broad-spectrum antibiotic or combination of broad-spectrum antibiotics should be administered along with a 30cc/kg fluid bolus of Normal Saline (NS) or Lactated Ringer’s (LR), calculated using ideal body weight. For persistent hypotension not responsive to fluid bolus, consider central line placement and use of vasopressors. If indicated, transfer to the ICU should be considered. Blood for analysis should be collected within three hours of documentation of suspected sepsis (i.e. two or more SIRS criteria). Antibiotic and fluid bolus administration should be completed within three hours after identification of symptoms. If these interventions are not performed and documented in the stated timeframe, CMS requirements have not been met and the case is considered a “fall out”.
The three-hour bundle has been outlined below in Figure 1 with all CMS required interventions highlighted in red.

**Figure 1. 3-Hour Sepsis Bundle**

**Sepsis Protocol (3 hour bundle)**

2 or more of SIRS criteria met plus a suspected infection
1. RR > 20
2. HR > 90
3. Temp $>$ 38.0 or $<$ 36.0 C
4. WBC $>$ 12 or $<$ 4, 10% bands
5. Altered mental status

- Obtain cultures and lab work
  - CBC with differential
  - Lactic acid #1
  - CMP (evaluates organ)

- Highlighted in RED - CMS required

- Establish sepsis severity
  - **Severe sepsis**: 2 or more SIRS criteria and 1 or more organ dysfunction
  - **Septic shock**: severe sepsis and persistent hypoperfusion after initial fluid boluses

- Administer IVF and Antibiotics (within 1st hour)
  - NS or LR at 30cc/kg/hr (4-6 liters/2hr)
  - Broad spectrum antibiotic, organ specific coverage

- Highlighted RED - CMS required

- Stabilize patient and consider:
  - Intubation
  - Central line especially if pressors are in use
  - Start pressors only if hypotension is not corrected by IVF boluses
  - X-ray/CT/US as indicated
  - Aim for MAP $>$ 60

- Transfer to ICU (optimal in 2 hours or less)
Six-Hour Bundle

The first step in the six-hour bundle is determining the severity of sepsis. Severe sepsis is defined as the presence of two or more SIRS criteria with one or more symptom(s) of organ dysfunction. Symptoms of organ dysfunction include lactic acid >4, persistent hypotension, creatinine level >2, urine output less than 0.5cc/kg/hour for two hours or more, platelet level under 100,000, international normalized ratio (INR) >1.5, and a partial thromboplastin time (PTT) >60. Septic shock is defined as criteria met for severe sepsis plus either an elevated lactic acid (>4) and/or persistent hypotension (mean arterial pressure <65, systolic blood pressure <90, or a 40-point drop in baseline systolic blood pressure consistent in two or more readings). If a patient has progressed to severe sepsis or septic shock, the six-hour bundle is initiated. The six-hour bundle includes drawing a second lactic acid level, repeat focused exam by physician, and continuation/completion of fluid resuscitation (30cc/kg) within six hours of symptom onset. The repeat focused exam must include vital signs, chest and cardiac examination, capillary refill time, skin assessment (mottling), and pulse strength. Other considerations include use of vasoactive medications for persistent hypotension, ventilation, deep vein thrombosis (DVT) prophylaxis, gastrointestinal (GI) prophylaxis, assessment of neurological status with sedation holidays if the patient is sedated, and continued antibiotic administration. The six-hour bundle is outlined in Figure 2, with CMS required interventions being highlighted in red.
Figure 2. 6-Hour Sepsis Bundle

**Sepsis Protocol (6 hour bundle)**

**Severe sepsis**
- 2 or more SIRS criteria
- 1 or more signs of organ dysfunction
  - Lactic acid > 4
  - Hypotension
  - Creatinine > 2.0
  - Urine output < 0.5 ml/kg/hr \( \times 2 \text{ hrs} \)
  - PLT < 100,000
  - INR > 1.5
  - aPTT > 60

**Septic shock** - present when both are met
- Pt has met severe sepsis criteria
- 1 or more of the following
  - Lactic acid level > 4
  - Persistent hypotension
    - MAP < 65, SBP < 90, or 40-point drop in baseline BP by 2 or more constant readings

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**Highlighted RED-CMS required**

- Draw lactic acid #2 (within 6 hours of presentation)
- Consider repeat of other labs

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- Repeat focused examination within 6 hours/Physician documentation
  - VS
  - Chest examination
  - Cardiac examination
  - Capillary refill
  - Skin examination
  - Pulses

---

**IV Fluid**
- NS or LR (consider albumin or blood)
- 30 ml/kg/hr
- Limit pressors-use IVF boluses to keep MAP > 60

---

**Medical management**
- Ventilation (low volume)
- DVT prophylaxis
- GI prophylaxis
- Sedation schedule-sedation holiday
- Continue and reassess antibiotics

---

Highlighted in RED-CMS required
Definition of Terms

- Systemic inflammatory response syndrome (SIRS) is defined by the National Cancer Institute as an inflammatory state throughout the body that may be caused by severe bacterial infection. It is identified by the following symptoms: fast heart rate, low blood pressure, low or high body temperature, and low or high white blood cell count (cancer.gov, 2018).

- Sepsis is defined as the presence of harmful bacteria and their toxins in the bloodstream, typically from an existing infection such as cellulitis, urinary tract infection, or wound infection (Dellinger et al., 2013).

- Severe sepsis is defined as the presence of two or more SIRS criteria with one or more signs of organ dysfunction diagnosed by laboratory findings and physical examination (Dellinger et al., 2013).

- Septic shock is defined as severe sepsis criteria with an elevated Lactic Acid Level or persistent hypotension (Dellinger et al., 2013).

- Mean arterial pressure (MAP) is defined as the average pressure in the patient’s arteries during one cardiac cycle. It is calculated using the Systolic and Diastolic pressures (MAP = (SBP + 2(DBP))/3. The MAP is used as a priority indicator of perfusion to vital organs. Per the Surviving Sepsis Campaign, the goal MAP for septic patients should be >65 to achieve adequate perfusion (SSC, 2018).

- Centers for Medicare & Medicaid Services (CMS) is a federal agency within the Department of Health and Human Services (HHS) that is responsible for
administration of Medicare and Medicaid including hospital reimbursement (Healthcare Business Insights, 2016).

- Blood culture is a serum lab test identifying the presence of bacteria in the bloodstream. It is key in identifying sepsis and for adjusting antibiotic treatment (SSC, 2018).

- Complete blood count with differential (CBC with diff) is a blood test that provides information about the cells in the patient’s blood. It can be used to detect conditions such as infection, which would demonstrate an elevated white blood cell count (SSC, 2018).

- Lactic acid level is a blood test that detects elevated lactate levels in the blood, which can result in a metabolic acidosis (commonly seen in Septic patients due to hypoperfusion). A lactate level >4 is used as a diagnostic criteria for septic shock (SSC, 2018)

- Comprehensive metabolic panel (CMP) is a blood test used to check kidney and liver function as well as electrolytes and fluid balance. It is helpful in diagnosing organ dysfunction in severe sepsis and septic shock (SSC, 2018).

- Creatinine level is included on the CMP. Elevated levels are indicative of renal dysfunction, making this test useful in determining organ dysfunction in severe sepsis and septic shock (SSC, 2018).

- International normalized ratio (INR) uses the Prothrombin Time (PT) to calculate the coagulopathy of the patient’s blood. Normal range is 0.8-1.2. Levels may be elevated in septic patients, increasing their risk for bleeding (SSC, 2018).
Partial thromboplastin time (PTT) is a blood test used to detect abnormalities in blood clotting and for treatment effects of Heparin. Normal PTT is between 30-50, and may be elevated in patients with sepsis (SSC, 2018).

Vasopressors are drugs that increase blood pressure by causing constriction of the blood vessels. Patients requiring vasopressors will most likely require central line placement due to the necrotizing effects of the medication in tissues (Singer et al., 2016).

Central Lines are venous access catheters placed in the larger veins of the arms, neck, or groin that allow for medication administration, blood draws, administration of vasoactive medications, and central venous monitoring (Singer et al., 2016).

Assumptions

1) Patients diagnosed with sepsis have an accurate diagnosis.

2) Presence of two or more SIRS criteria is in fact caused by sepsis and is not due to other comorbidities or diagnoses.

3) Compliance rates are tracked using inclusion and exclusion criteria that are consistent and objective.

4) The reasons for non-compliance and “fall outs” have not been identified in Hospital X.

5) Nurses and physicians will be open to implementing interventions based on project findings for noncompliance.
Summary

Sepsis continues to be a costly and fatal health issue throughout the U.S.. Sepsis bundles have been developed by various entities to decrease mortality, improve patient outcomes, and decrease hospital costs associated with sepsis. Hospital X recently adopted a three and six-hour sepsis bundle in accordance with CMS core measures. The compliance rates, however, have been consistently below the goal (80% compliance) for the past five months. This project was designed to identify barriers that interfere with successful implementation of the sepsis bundles and provide recommendations and interventions for corrective action.
CHAPTER TWO

REVIEW OF LITERATURE

Description of Search Methods

A thorough search of the literature was performed. Databases utilized were CINAHL, Cochrane Library, Medline, and PubMed. Search terms utilized were sepsis, bundle, CMS, guidelines, outcomes, mortality, morbidity, and protocol. In addition to relevant articles found in this manner, a number of recent peer-reviewed literature sources used to formulate the protocol were provided by a physician at Hospital X.

Literature Findings

Bundle Development

The prevalence of sepsis is on the rise, with 1,000,000 cases per year reported in patients older than or equal to 65 years of age and approximately 350,000 deaths (Leisman, Doerfler, Ward, Masick, Wie, Gribbin … and D’Amore 2016). Early development of the sepsis bundle began in 2001 when Rivers and colleagues (2001) published an article on early goal-directed therapy (EGDT) for the treatment of sepsis. EGDT consists of specific laboratory work, IV fluids, central venous monitoring, early antibiotics, and directed vasopressor therapy. The original study assigned patients with sepsis to receive either six hours of EGDT or the standard therapy. In both groups, hospital mortality, end points with respect to resuscitation, and APACHE II scores were obtained serially for 72 hours to measure outcome. A total of 263 patients were enrolled,
with 130 patients in the EGDT group and 133 patients in the control group (standard therapy). There was no significant difference in the patients’ baseline condition. The results demonstrated a significant survival benefit (30.5% mortality in EGDT vs. 46.5% in standard therapy group) in patients with severe sepsis or septic shock. In addition to survival benefits, patients in the EGDT group also had a significantly higher central venous oxygen saturation, lower lactate concentration, lower base deficit, lower APACHE II scores, and higher pH than the control group. This study has served as a baseline model for sepsis bundle implementation.

These results have been validated by many current research studies. One example includes a prospective, multisite, observational study following three sequential independent cohorts in the U.S. healthcare system. Patients being treated in tertiary, community, and academic hospitals were separated into two groups: one in which a three-hour sepsis bundle was properly implemented and one in which standard treatment was implemented. The three-hour sepsis bundle included the following elements: 1) blood cultures drawn before antibiotics; 2) parenteral antibiotics administered at most 180 minutes and a lactate ordered at most 60 minutes from identification of at least two identified SIRS criteria; 3) lactate results available at most 90 minutes post-order; and 4) 30 mL/kg of intravenous fluids (IVF) bolus started from the time the patient walks in the door (time zero). Cohort 1 had a total of 5,819 patients of which 1,050 (18%) demonstrating bundle compliance. Mortality rates were significantly lower in the bundle-compliant group compared to the non-bundle compliant group (22.6% vs. 26.5%). Cohort 2 consisted of 1,697 patients with 739 demonstrating bundle compliance. Mortality was
significantly lower in the bundle group (13.4%) vs. the non-bundle group (17.8%).

Cohort 3 had a total of 7,239 patients with 2,115 demonstrating bundle compliance.

Mortality rates were 18.1% and 21% respectively. For all cohorts, initiation of the 3-hour sepsis bundle resulted in a significant decrease in both patient mortality and associated costs (Leisman et al., 2016). Many of the patients in the control groups most likely received many portions of the bundle, however failure to provide interventions in the short time period defined above and failure to implement even one of the above interventions automatically placed patients in the control group.

There are potential limitations to the Leisman study. For instance, many compliant groups had lower frequency of comorbidities and organ dysfunction with higher lactate levels and increased hypotension frequency. These patients may have been easier to identify, and therefore more likely to receive appropriate initial care. Because these patients may have increased mortality rate due to increased illness, observed benefits of bundle compliance may be understated. The authors did attempt to use multivariable regression to account for these discrepancies. The study design was successful in given the large sample sizes, multi-site approach, and strict compliance definitions, the results of this study to demonstrate a decrease in mortality and cost associated with implementation of the three-hour sepsis bundle (Leisman et al., 2016).

New York State hospitals were required to follow protocols (initiation of sepsis bundles) for early identification and treatment of sepsis in 2013. Upon initiation of these changes, Seymour and colleagues (2017) performed a retrospective study with patients diagnosed with sepsis and septic shock reported to the New York State Department of
Health from April 1, 2014 to June 30, 2016. For these patients, a sepsis protocol was initiated within 6 hours following ED arrival, and had all items on a 3-hour sepsis bundle completed (blood cultures before antibiotics, broad-spectrum antibiotics, and lactate measurements) within 12 hours. Fluid bolus administration was only performed if the patient had an elevated lactate (>/=4mmol/L) or hypotension (SBP < 90 mm Hg). The authors used multilevel models to assess associations between time until completion of the three-hour sepsis bundle and risk-adjusted mortality. This study included 49,331 patients at 149 hospitals. Inclusion criteria were age greater than 17, diagnosis of severe sepsis or septic shock as defined by the International Sepsis Definitions Conference (Sepsis-2), and patients who had a sepsis protocol initiated in the ER within 6 hours of arrival. Patients who had the 3-hour bundle completed in greater than 12 hours after initiation of the protocol were removed. Other exclusion criteria included patients whom bundled care was clinically contraindicated, patients with limited code status, patients who declined interventions, and patients already enrolled in a clinical trial.

Most (82.5%) of the patients had the 3-hour bundle completed within the 3-hour time frame, with a median time of 1.3 hours. The median time from ED admission to antibiotic administration was .95 hours, and 2.56 hours for fluid bolus administration. Among the patients who had the three-hour bundle completed within 12 hours, the length of time it took to complete the bundle correlated directly with higher risk-adjusted in-hospital mortality. Each hour of time to completion of the three-hour bundle was associated with higher mortality odds (1.04 per hour). Patients receiving the completed bundle during hours 3-12 had 14% higher odds of in-hospital mortality than patients who
received the completed bundle within the first three hours. A similar correlation was found between time to IV antibiotic administration and in-hospital mortality. Patients who received antibiotics in the first 3 hours had a 14% lower mortality rate than those administered antibiotics during hours 3-12. Every aspect of the three-hour sepsis bundle was thought to decrease mortality with the exception of rapid administration of an initial IVF bolus. Patients requiring fluid bolus within 6 hours did not show a difference in mortality compared with patients who received it during hours 6-12 (Seymour et al., 2017).

Best Practice for Treatment of Sepsis

In 2015, the SSC recruited a consensus committee of 55 international experts from 25 international organizations to discuss a total of 93 statements on early management and resuscitation of patients with sepsis or septic shock and discuss validity of the current guidelines for management of sepsis. The guideline panel was separated into five sections including hemodynamics, infection, adjunctive therapies, metabolic, and ventilation. Questions from the latest version of the SSC guidelines were reviewed. Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) methodology was utilized in determining the validity of statements formulated through discussion of the panel. Following statement formulation, the panel members voted on whether or not they agreed or disagreed with the statement. Acceptance of a statement required a 75% vote of approval from all panel members with an additional 80% agreement threshold.
In regards to treatment of sepsis, a number of best practice statements (BPSs) were generated. In screening for sepsis and performance improvement, the following was considered a BPS: “We recommend that hospital systems have a high-performance improvement program for sepsis, including sepsis screening for acutely ill, high-risk patients” (Rhodes, Evens, Alhazzani, Levy, Antonelli, Ferrer … and Dellinger 2017, pg. 312). The rationale behind this statement is that performance improvement efforts for sepsis (i.e., sepsis bundles) have been associated with improved patient outcomes. Furthermore, successful programs should include protocol development and implementation, evaluation of targeted metrics, data collection, and continuous feedback to facilitate ongoing performance improvement. In regards to early identification and treatment of sepsis, feedback from the experts notes that “the implementation of a core set of recommendations (bundle) has been a cornerstone of sepsis performance improvement programs aimed at improving management,” (Rhodes et al., 2017, pg. 312). This statement is supported by a meta-analysis of 50 observational studies demonstrating that performance improvement programs are associated with increased compliance with SSC bundles and a significant reduction in mortality. Other BPSs support aspects of the 3 and 6-hour bundles including blood cultures prior to antibiotic administration, early lactate levels, IV fluid bolus for the hypotensive patient, and early broad-spectrum antibiotic administration (Rhodes et al., 2017).

In February of 2018, the SCC published additional updates on definitions of sepsis and guidelines for early recognition and prompt intervention of sepsis. Updated guidelines and interventions include:
• Early identification of patients with possible infection and sepsis
• Rapid and aggressive fluid resuscitation (at least 30mL/kg within three hours of sepsis-induced hypoperfusion)
• Frequent hemodynamic reassessment of patient response to fluids
• Administration of IV antibiotics within one hour of suspected sepsis or septic shock

(Sepsis Survival Campaign, 2018)

These additional guidelines are congruent with the three and six-hour sepsis bundles outlined by the SSC in 2016. Both the SSC and the CMS recommend early identification and treatment of patients with sepsis and septic shock. As a result, the SSC and the Institute for Healthcare Improvement have teamed up to developed three and six-hour sepsis bundles to decrease time between patient arrival in the ED and identification/treatment of sepsis and septic shock (Kuo, et al., 2012). It has been deemed by both entities and many randomized controlled trials (RCT) that use of sepsis bundles decreases time until intervention, improves patient outcomes, decreases cost, and ultimately is best practice.

Barriers to Implementation

There are a number of barriers that keep compliance levels of the three and six-hour sepsis bundles less than 100%. These barriers may range from a lack in documentation at appropriate times to the nurse not having time to hang the antibiotic within the one-hour window. In one study, Kuo et al. (2012) investigated compliance with a sepsis resuscitation bundle (SRB) by identifying barriers to implementation. The first part of this study involved review of medical records of patients admitted to the ICU
due to septic shock from January-June in 2007. Compliance rates with the six-part SRB were evaluated. The components of the SRB are identical to the sepsis bundle described in Figures 1 & 2. The second part of the study involved questionnaire-based interviews with medical residents and senior physicians to identify why compliance with the SRB was not achieved.

The study included a total of 40 patients with a diagnosis of sepsis or septic shock. The bundle of broad-spectrum antibiotics was achieved in 31 (77.5%) of patients. The components in the bundle with the lowest compliance were a ScvO2 of \( \geq 70\% \) and a CVP \( \geq 8 \) mm Hg (2.5% and 20% respectively). The overall compliance rate for the entire SCB was only 2.5%. For the second part of this study, 71 junior and 64 senior physicians were interviewed in order to identify barriers. The results demonstrated that many junior physicians were not as familiar with the SCB guidelines as the senior physicians, particularly regarding the use of ScvO2 and managing low ScvO2. Almost all of the physicians recognized the importance of central line placement, however the junior physicians were more reluctant to measure CVP and ScvO2, as they were less confident with central line placement. Other barriers include poor awareness and acceptance of the SCB, particularly measurement of the ScvO2 and prompt central line placement. The SRB components must be completed within 6 hours of diagnosis in order to be considered “compliant.” Other barriers may include delayed identification of sepsis/septic shock, and poor coordination in management of the septic patient. Recommendations included measures to increase confidence with central line placement and education on accurate implementation of the SCB (Kuo et al., 2012).
Limitations of this study include use of persistent hypotension as the starting point of initiation of the SCB, even though this may not be an accurate reflection of the actual scenario. There may be a time gap between the onset of sepsis/septic shock and the diagnosis of such, suggesting that the SCB perhaps should have been initiated sooner. Also, at the time of this study, there was no written protocol for the management of sepsis/septic shock during the study period. While evidence indicates that education programs/implementation of quality indicators are a basic requirement (and essential) to improve compliance with SRB’s, this study purely aimed to investigate potential barriers. Also, the sample size for this study was relatively low, however the results have been replicated by others, showing a low compliance rate in measuring/managing the ScvO2 of septic patients, making ScvO2 measurement a potential barrier (Levy, 2015; Ferrer, 2014; Kuo et al., 2012).

The Theoretical Domains Framework (TDF) was utilized to evaluate factors influencing implementation of the sepsis bundle. In this study, 34 health professionals were interviewed, with interviews being evaluated using TDF. Five general themes were identified as barriers to sepsis bundle implementation, including: 1) knowing what to do and why, 2) risks and benefits (there were specific concerns about harming patients through fluid overload), 3) working together (physician/nurse conflict), 4) empowerment and support (lack of confidence to challenge colleagues’ decision not to implement), and 5) staffing levels (lack of physicians at night preventing implementation). Both focus groups and individual interviews were used to generate data.
After gathering data on the barriers associated with proper implementation, six different Behavior Change Techniques (BCTs) were implemented in attempt to increase compliance. These include interventions such as a Sepsis Six education program for night coordinators, staff education sessions, and development of documents and materials. In addition to identifying potential barriers to implementation, this study also demonstrates the feasibility of using the TDF and BCT to modify implementation of interventions. This is a demonstration of a potential way to “bridge the gap” using behavioral theory to design interventions and commonly utilized approaches to quality improvement, such as the Plan-Do-Study-Act (PDSA) model. These two approaches could serve as a model for future quality improvement projects on existing protocols (Steinmo, Michie, Fuller, Stanley, Stapleton, & Stone 2016).

**Summary**

Prevalence of sepsis in increasing, and guidelines are continuously being updated in an attempt to improve patient outcomes and decrease costs. Sepsis bundles have been shown to decrease time from ER admission to treatment, improve patient outcomes, and decrease hospital costs. The SCC has outlined a 3 and 6-hour sepsis bundle that have been adopted by various entities including the CMS, and is now considered a core measure. SCC has helped define best practice by creating sepsis bundles, which have been adopted by many hospitals throughout the nation. There are many potential barriers to implementation, many of which have been identified in settings new to sepsis bundle implementation. The literature suggests that the speed at which interventions described in
the sepsis bundle are implemented is directly correlated with patient mortality and outcome.
CHAPTER THREE

METHODS

Introduction

The purpose of this project was to identify barriers to successful implementation of the Hospital X sepsis protocol and make appropriate recommendations for corrective action based off these findings. This project had three parts: identification of barriers to proper implementation, implementation of interventions to increase compliance, and evaluation of the effectiveness of those interventions. Barriers were identified by extensive chart review of 33 patients that were considered fall out cases and by observing the process flow of the treatment of septic patients in the emergency room setting. Once barriers were identified, interventions were implemented in the acute care setting in order to improve overall compliance. Those interventions included creating a sepsis handoff tool to be used for septic patients, holding monthly focused discussion groups, and implementing online education for nurses on the sepsis protocol. The sepsis handoff tool was used to keep track of all required interventions and included a list of interventions and what time they were performed (see Figure 3). The online education consisted of five questions pertaining to nurse’s knowledge of proper implementation of the protocol. These interventions were implemented effective June 1, 2018 and outcomes were evaluated by tracking overall compliance through the end of September, 2018.
Theoretical Framework

The framework that was utilized for this project was the *model for improvement*, which “provides an overarching framework for testing change ideas that are expected to make improvements” (Nelson, Batalden, & Godfrey, 2007). This is a two-part model. It starts by addressing three questions that are intended to focus on the intended improvement. These are as follows: 1) What are we trying to accomplish?, 2) How will we know that a change is an improvement?, and 3) What changes can we make that will result in an improvement? (Nelson et al., 2007). For the first question, a clear aim with measurable targets must be set. The second question utilizes qualitative and quantitative data to support the improvement. The third question involves creation of a statement that will explain what can be changed to influence improvement. The second part flows into the tests of change using the plan-do-study-act (PDSA) method. The model for improvement provides a guideline for testing ideas likely to lead to improvements that are successful. The answers to the first three questions result in approaches that are specific to the aim of the test, how the improvement will be identified, and the specifics of each change. Addressing these questions ensures that the organization does not start the change process without mindful planning that identifies the causal systems at work with ways to measure results. This model also offers a scientific approach for testing change and implementing improvements (PDSA method) (Nelson et al., 2007).

This model is designed to begin when the specific aim is well defined and change is ready to be tested. The PDSA model is used frequently in conducting tests of change in a rapid and disciplined fashion. It is a structured, continuous quality improvement method
that utilizes four steps to test changes repetitively. This is a straightforward process for testing new ideas, moving forward with new ideas to make improvements, and learning from current testing. The main focus of the PDSA model is determining if and what experimentations can produce superior results. Advantages of using this model include time (it can be completed quickly with minimal use of external resources and low risk), clarity (clear to all parties involved that the test is a pilot to be conducted in a small way over a short period of time), and increased knowledge (gives staff a new understanding of a different experience, enabling improvement teams to advance on the original change idea, increasing the likelihood of success) (Nelson et al., 2007).

In the “plan” phase, the objectives are described in addition to the specific changes being tested. This step ensures that proper preparation is completed prior to the test being carried out, considering upstream and downstream impacts. The plan includes clarification of the problem that is being tested, the various roles of different healthcare providers, when the test will occur, any necessary education and training necessary before implementation, data collected to determine the success, who will collect the data, the length of time the test will be conducted, and what the overall expectations are. The “do” phase develops when the pilot test is launched based on the preparation in the planning phase. In this phase, collection of qualitative and quantitative data in addition to information that will inform the next PDSA cycle need to be obtained. This stage includes documentation of unexpected events, collecting feedback in regards to the pilot test, measuring results, and listening to feedback as the pilot is run. The “study” phase is used to analyze data, reflect on obtained results, and to debrief involved members of the
pilot test. Data should be collected in order to perform an adequate evaluation of what happened during the pilot trial. This is also a time where team members can identify any negative results and determine what can be improved during the next cycle. The “act” phase involves determining what changes or ideas should be modified/abandoned according to results from the last PDCA. This step involves determining the next best course of action. Improvements should be made in accordance to what is learned from previous cycles and the knowledge obtained from them. This aids in the development of the next PDCA cycle (Nelson et al., 2007).

Institutional Review Board

IRB approval was attained from Montana State University prior to data collection. The patient’s visit number was used as the primary source of identification. Because this project did not include direct contact with patients or any patient identifiers, the project was exempted from full review.

Sample and Setting

Hospital X is a 300-bed hospital located in rural Montana. It is one of the larger facilities in the area, offering a wide variety of services. Between the months of March, 2018 – September, 2018, there were a total of 307 patients with an initial diagnosis of sepsis. Of these cases, 177 patients were excluded from the sepsis population because of early resolved infection that did not progress to sepsis or misdiagnosis after further evaluation. Of the remaining sample (N=130) that met the criteria for sepsis and were
treated using the protocol, there were 33 septic patients that were not treated according to CMS guidelines and 97 patients that were treated according to guidelines (see Table 1). Hospital X has around 3,400 employees throughout over 100 departments. The areas of focus for this project were the emergency room, Intensive Care Unit, and medical floors.

Project Design

Identification of Barriers

The first part of this project was aimed at identifying barriers to proper implementation of the sepsis protocol. From March 2018 – September 2018, there were thirty-three cases identified in which criteria was not met for bundle compliance. These charts were reviewed using the patient’s visit number to determine what part(s) of the bundle were not in compliance. At the end of each of these months, a monthly meeting was held with emergency room physicians and nurse managers to discuss findings and areas for improvement. In addition to chart reviews, two sepsis patients were observed in the emergency room setting in order to follow the treatment process and identify any portions of the protocol that were missed and why in real time.

Interventions

After identifying potential barriers, interventions were implemented throughout the hospital in an attempt to increase compliance with the sepsis protocol. These interventions were introduced to the hospital on June 1, 2018. The first intervention was implementation of a Sepsis Handoff Tool (see Figure 3) developed by the DNP student. The tool was designed to cue nurses to which interventions needed to be completed and
when. The tool also was useful when patients were transferred from the emergency room to other floors, as it made it clear which interventions had been completed and which still needed to be completed and when. This tool was started at the time of diagnosis (time zero) and stayed with the patient’s chart throughout their stay. It was implemented by educating acute care nurses about the tool at staff meetings and was made available on all acute care floors starting June 1, 2018. The DNP student educated charge nurses on all acute care floors on what the tool was and how/when it should be used. Since this time, charge nurses on all floors have been encouraging use of the Sepsis Handoff Tool at the time of Sepsis diagnosis. As demonstrated in Figure 3, the handoff tool covered elements of both the three- and six-hour bundle sets and included a place for nurses to record times of interventions.
Figure 3. Code Sepsis Handoff Tool

**CODE SEPSIS HANDOFF TOOL**

<table>
<thead>
<tr>
<th>DATE:</th>
<th>TIME ZERO:</th>
</tr>
</thead>
</table>

*Time Zero: Identification of 2 or more SIRS criteria

### 3-HOUR BUNDLE ELEMENTS (To be completed within 3 hours of TIME ZERO)

<table>
<thead>
<tr>
<th>INITIAL LABS:</th>
<th>TIME COLLECTED:</th>
<th>WHY NOT PERFORMED:</th>
</tr>
</thead>
<tbody>
<tr>
<td>-Lactate</td>
<td>RESULTS:</td>
<td></td>
</tr>
<tr>
<td>-CBC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-CMP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(To be collected within 1 HOUR of time zero)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BLOOD CULTURES</th>
<th>TIME COLLECTED:</th>
<th>WHY NOT PERFORMED:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IV ANTIBIOTICS</th>
<th>ANTIBIOTIC START TIME:</th>
<th>WHY NOT ADMINISTERED:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Within 1 HOUR of time zero)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IV FLUID BOLUS</th>
<th>IVF GOAL: (Patient kg x 30 mL)</th>
<th>WHY NOT ADMINISTERED:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(30 ml/kg NS or LR initiated within 1 HOUR and complete within 2 HOURS of time zero)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
For patients with hypotension and/or evidence of organ system dysfunction

<table>
<thead>
<tr>
<th>TIME IVF STARTED:</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTAL IVF GIVEN IN ED:</td>
</tr>
</tbody>
</table>

6-HOUR BUNDLE ELEMENTS (To be completed within 6 hours of time zero)

<table>
<thead>
<tr>
<th>REPEAT LACTATE (To be performed within 6 hours of time zero)</th>
<th>TIME DRAWN:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RESULTS:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>VASOPRESSOR ADMINISTRATION (PRN)</th>
<th>TIME INITIATED (If appropriate):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>WHY NOT ADMINISTERED:</td>
</tr>
</tbody>
</table>

* Norepinephrine preferred

<table>
<thead>
<tr>
<th>REPEAT VOLUME STATUS AND TISSUE PERFUSION ASSESSMENT (Performed by MD)</th>
<th>EXAM TO INCLUDE:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>WHY NOT PERFORMED:</td>
</tr>
</tbody>
</table>

- VS
- Cardiopulmonary Exam
- Peripheral pulse evaluation
- Skin examination

OR ANY 2 OF THE FOLLOWING 4:
- CVP Measurement
- ScvO2 Measurement
- Bedside CV U/S
- Passive leg raise and/or Fluid Challenge
PATIENT MEETS CRITERIA FOR:

SEVERE SEPSIS:

SEPTIC SHOCK:

ED RN: ___________________________ ED MD: ___________________________

RN: ___________________________ MD: ___________________________

The second intervention required that nurses take a 7-item quiz to evaluate their knowledge of the sepsis protocol. This quiz was part of quarterly mandatory education for all nurses throughout the hospital, with 132 nurses total who took the quiz (N=132). The goal was to increase knowledge and awareness of the sepsis protocol amongst the nursing staff by asking specific questions about the aspects of the protocol that had been frequently missed (see Figure 6). House-wide, nurses were required to take and pass the test in order to fulfill mandatory education requirements. Nurses were allowed to re-take the quiz until a score of 100% was achieved. The questions asked and answers can be seen in Figure 4. The quiz was open to nurses June 1, 2018 and was required to be completed by July 1, 2018.
Figure 4. Sepsis Quiz Questions and Answers

SEPSIS QUIZ

Please answer the following questions:

1) **TRUE** or **FALSE**: IV antibiotics should be administered within one hour after blood cultures have been drawn and within 3 hours of bundle initiation.

2) **TRUE** or **FALSE**: For a SBP < 90, a 30 ml/kg fluid bolus should be started within three hours of sepsis bundle initiation.

3) **TRUE** or **FALSE**: A second lactate level should be drawn within 8 hours of the initiation of the sepsis bundle.

4) **TRUE** or **FALSE**: Early sepsis should be identified using 3 or more SIRS criteria for initiation of the three-hour bundle.

5) **TRUE** or **FALSE**: In addition to blood cultures, a CBC, lactate level, and a CMP should be drawn upon initiation of the 3-hour sepsis bundle.

6) **TRUE** or **FALSE**: The 6-hour sepsis bundle is initiated on all patients diagnosed with severe sepsis and septic shock.

7) Which of the following interventions are required by CMS to be in compliance with the sepsis bundles?
   
   a. Initiation of IV fluids within established time frame
   b. Obtaining a second lactate level within 6 hours of bundle initiation
   c. Insertion of central line
   d. Administration of IV antibiotics within established timeframe
   e. Transfer to Intensive Care Unit
   f. Use of vasopressors if blood pressure is not corrected with IV fluid boluses

1) TRUE
2) TRUE
3) FALSE
4) FALSE
5) TRUE
6) TRUE
7) A, B, D, F
Data on current barriers to proper sepsis bundle implementation was gathered in two ways. First, a retrospective chart review was conducted from March 2018 - September 2018. The documentation by both the nurse and the physician was reviewed for each case where the sepsis bundle was not implemented according to CMS guidelines. These charts were flagged by a Hospital X Quality Improvement RN, which the DNP student then reviewed to identify which aspects of the bundle were missing or implemented incorrectly. The DNP student kept track of which components of the sepsis bundle were not implemented correctly and identified the most common culprits for unsuccessful sepsis bundle compliance. To do this, a spreadsheet (see Tables 1 & 2) of the CMS required sepsis bundle interventions was created with which specific interventions were missed according to the chart reviews. This helped demonstrate which interventions were being missed most frequently. After collecting data on how many cases were missed and why, monthly discussion forums were held with ED physicians and nurse managers to further discuss why the cases were missed and what could be done differently in the future.

The second form of data collection occurred in the ED setting. The DNP student had monthly focused discussion groups from March, 2018 – September, 2018 to interview nurses and physicians on their perspective of why compliance with the sepsis bundle has been dropping after presenting data on which parts of the bundle were not being implemented. The DNP student
focused on topics such as timing (does the nurse feel there is not enough time to implement interventions in the given time frame?), miscommunication (between physician/nurse, nurse/lab, etc.), and the order set in Meditech (does it give the nurse all the tools s/he needs to properly implement the sepsis bundle?). The DNP student spoke with 10 ED physicians and 3 ED management nurses. In addition to themes identified in the chart review, feedback from staff was used to assess what changes needed to be made in order to support them and what the best way would be to implement these changes.

In addition to the monthly focused discussion groups, the DNP student observed the process flow for two septic patients on two separate occasions without intervening. On both of these occasions, the DNP student was called in to Hospital X to observe the treatment process when the diagnosis of sepsis was initially made. One of these cases was observed in May, 2018 and one in June, 2018. Without intervening or cueing nurses or physicians, the DNP student was able to watch the entire process of bundle implementation and observe which aspects of the bundle were within compliance and which were not performed properly. The DNP student was also able to further identify barriers to proper implementation through this process.

After barriers were identified, two interventions were implemented starting June 1, 2018. The first was introduction of the Sepsis Handoff Tool (see Figure 3) and nursing education through online mandatory education (see Figure 4). Compliance rates continued to be tracked through the end of September, 2018 to determine effectiveness of these interventions.
Analysis

There are a number of core interventions that are required by CMS. The ones evaluated in this project are as follows:

1) Obtain blood cultures and lab work (within 3 hours of arrival)
   a. CBC with differential
   b. Lactate #1
   c. Complete Metabolic Panel

2) Administer IVF and antibiotics within 3 hours of arrival
   a. Normal saline (NS) or lactated ringer’s (LR) at 30cc/kg/hr (4-6 liters 2/hr)
   b. Broad-spectrum antibiotic with organ specific coverage

3) Obtain lactate #2 (within 6 hours of presentation)

The total number of septic patients presenting to the ED were identified in Meditech for the months of March - September, 2018. Then, charts of patients who did not receive the sepsis bundle according to the protocol were analyzed to determine which of these elements was not performed correctly. The DNP student calculated the percentage of sepsis cases that were not implemented according to protocol and specified in which of the above categories the error was made. This provided information on which areas need the most work and guided recommendations.

Second, the DNP student used data collected from the focused discussion groups to identify common themes in feedback from nurses and physicians as to the barriers for proper implementation. This feedback was also incorporated into the recommendations. Lastly, the DNP student used information gathered from observing treatment of two
septic patients in real time in order to further improve understanding of what the barriers were. Following interventions aimed to improve outcomes, compliance rates were tracked for four months (June, 2018 – September, 2018) post intervention in order to evaluate effectiveness.

**Summary**

As noted, as appropriate and feasible, corrective actions were taken in response to the barriers to adherence identified. The success of these actions was done using chart review and tracking overall compliance post intervention. The total number of patients admitted with a diagnosis of sepsis were tracked over a set period of time. Patients who did not receive interventions according to the sepsis protocol were identified. A percentage of patients who received the sepsis bundle correctly and in totality was calculated for seven months, three months pre-intervention and 4 months post intervention. This percentage was compared to existing data collected over the course of the past year. The goal was be to be at or above 80% compliance after suggestions for improved compliance are made, resulting in improved hospital reimbursement and patient outcomes.
CHAPTER FOUR

RESULTS

Project Purpose

The purpose of this project was to identify barriers to successful implementation of the Hospital X sepsis protocol and make appropriate recommendations for corrective action based off these findings. Once barriers were identified, specific corrective actions were taken in correlation with findings.

Findings

Overall findings suggested that reasons for non-compliance with the sepsis protocol are complex and multifactorial. The total sample size for the months of March, 2018 – September, 2018 was \( N = 130 \). This sample included all patients who met the criteria for implementation of the sepsis bundle. Patients who were excluded from the measure included patients whose symptoms had resolved (i.e. infection never progressed to sepsis) and patients who met SIRS criteria but were diagnosed with something other than sepsis. Of this sample, 33 patients \((n=33)\) who met criteria for the sepsis bundle were not treated according to guidelines, while the remaining 97 patients were. During the months of March, 2018 – September, 2018, data were collected using chart review, observation of process flow, and feedback from staff in order to determine causative factors for non-compliance.
The two main causative factors identified in this process were miscommunication between transferring units when transferring a septic patient from the ED to other floors, and hesitancy to initiate fluid resuscitation in patients with compromised respiratory, renal, or cardiac status. In order to address these causative factors, interventions were implemented that directly addressed these two problems. Interventions including use of the Sepsis Handoff Tool and required nursing education were implemented on June 1, 2018. The Sepsis Handoff Tool was designed to simplify and streamline communication between units when transferring the patient out of the ED. This tool was used to keep track of which interventions were completed and when, and which interventions still needed to be done in order to comply. The second intervention focused on educating nurses on every aspect of the protocol, including fluid resuscitation. Nurses were required to review a power point on sepsis followed by a quiz to test knowledge. The main goal of nurse education was to create awareness around all aspects of the protocol including proper fluid resuscitation. This protocol is nurse driven in nature. Because nurses are responsible for implementing the interventions in the appropriate time frame, they were targeted for education.

Results demonstrated an overall increase in compliance post interventions. Compliance rates started out consistently below 80%, and trended up between June, 2018 – September, 2018 (see Figure 5, Table 1). The largest increase in compliance occurred between May, 2018 (compliance 57%) and June, 2018 (compliance 87%), which was also when interventions were implemented. This would suggest that the causative factors were identified correctly and that the corrective measures taken were effective. It is
difficult to determine which intervention was most effective, however rising compliance rates demonstrate that one or both were improving awareness and compliance with the bundle.

**Figure 5. Compliance Rates March, 2018-September, 2018**

![Graph showing compliance rates over time](image)

**Table 1. Compliance Rates March, 2018-September, 2018**

<table>
<thead>
<tr>
<th>Month</th>
<th>Total Inpatient Cases with Sepsis</th>
<th>Cases Excluded from Measure</th>
<th>Criteria for Measure Met and Passed</th>
<th>Criteria for Measure Met and Failed</th>
<th>Percent Compliance with Measure Bundle</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2018</td>
<td>45</td>
<td>24</td>
<td>16</td>
<td>5</td>
<td>69%</td>
</tr>
<tr>
<td>April 2018</td>
<td>40</td>
<td>21</td>
<td>14</td>
<td>5</td>
<td>74%</td>
</tr>
<tr>
<td>May 2018</td>
<td>39</td>
<td>25</td>
<td>8</td>
<td>6</td>
<td>57%</td>
</tr>
<tr>
<td>June 2018</td>
<td>51</td>
<td>28</td>
<td>20</td>
<td>3</td>
<td>87%</td>
</tr>
<tr>
<td>July 2018</td>
<td>52</td>
<td>25</td>
<td>19</td>
<td>8</td>
<td>70%</td>
</tr>
<tr>
<td>August 2018</td>
<td>38</td>
<td>24</td>
<td>11</td>
<td>4</td>
<td>73%</td>
</tr>
<tr>
<td>September 2018</td>
<td>42</td>
<td>31</td>
<td>9</td>
<td>2</td>
<td>82%</td>
</tr>
</tbody>
</table>
Chart Review

Extensive chart reviews were performed for all patients where criteria were met for the measure and failed between the months of March 2018 – September, 2018. Documentation on non-compliant cases was reviewed and the elements of the bundle that were not met were recorded and tracked (see Figure 6, Table 2). There were five reasons for non-compliance including: initial lactic acid level not drawn within 3 hours, follow up lactic acid level not drawn within 6 hours, fluid bolus not administered within 3 hours, antibiotics not given within 3 hours, and blood cultures not being drawn within three hours. Data indicated that non-administration of the 30cc/kg fluid bolus within the 3-hour window was the number one reason for non-compliance (33%) followed by antibiotics not being administered in time (26%). Other reasons included the second lactic acid level not being drawn within 6 hours (21%), blood cultures not drawn in time (13%), and initial lactate level not obtained (7%). This data was used to develop content for mandatory nursing education.

Figure 6. Reasons for Non-Compliance
Table 2. Monthly Breakdown of Incompleted Measures

<table>
<thead>
<tr>
<th>Month</th>
<th>Criteria for Measure Met and Failed</th>
<th>Initial Lactate not drawn within 3 hours</th>
<th>Broad Spectrum Antibiotics not given within 3 hours</th>
<th>Blood Cultures not drawn within 3 Hours</th>
<th>Repeat Lactate not drawn within 6 hours</th>
<th>Resuscitation with fluids not done within 3 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2018</td>
<td>5</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>April 2018</td>
<td>5</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>May 2018</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>June 2018</td>
<td>3</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>July 2018</td>
<td>8</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>August 2018</td>
<td>4</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>September 2018</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>TOTAL</td>
<td>33</td>
<td>4</td>
<td>9</td>
<td>4</td>
<td>6</td>
<td>10</td>
</tr>
</tbody>
</table>

Process Flow

In order to further understand and identify causative factors associated with non-compliance, patient flow for hospital admission of two septic patients were observed. The DNP student was called to the hospital for observation when a suspected sepsis case was to be brought in by ambulance with anticipated hospital admission. The first observation occurred in May, 2018. The ED nurse completed all the measures in the three-hour bundle within the three-hour window. Results from the initial lactate demonstrated elevated levels of lactic acid. The second lactic acid level was timed for three hours after the initial level had been drawn, which was within the six-hour window for the six-hour bundle. However, after a total of 2.5 hours in the ED, the patient was transferred to the Intermediate Care Unit (IMC). In listening to the report given to the IMC nurse from the ED nurse, there was no mention of a second lactic acid level needing to be drawn. By this time, the patient’s condition was improving, and the patient appeared to be stable. The
second lactic acid level was timed for an hour after the patient arrived on IMC. The nurse receiving the patient from the ED was unaware that a second lactic acid level was ordered and did not send the second sample. The lab called to notify the nurse that the sample had never been sent, but by this time more than six hours had passed and the test was cancelled. The result was a failed measure due to failure to draw the second lactate on a patient diagnosed with sepsis. Miscommunication between nurses appeared to be the primary reason for this particular fallout. Elements of the 6-hour bundle that still needed to be completed were not communicated to the IMC nurse from the emergency room nurse. Had they been communicated, the second sample may have been sent, which would have satisfied all elements of the three and six-hour bundles.

**Figure 7. Process Flow Patient #1**
The second patient was observed in June, 2018. This case ended up as a fallout because the fluid bolus was not administered on time. This patient presented to the emergency room with a primary diagnosis of sepsis-pneumonia. They also had many co-morbidities including congestive heart failure (CHF) with frequent hospitalizations. Because of these factors and the patient’s symptoms, cardiology was consulted early on in the process. After identification of three SIRS criteria with suspected pneumonia, the sepsis bundle was activated. All aspects of the three-hour bundle were completed except for the IVF bolus. This was not completed, and in fact was discouraged by cardiology with fear that the fluid would result in flash pulmonary edema due to compromised cardiovascular function. With the patient already being in respiratory distress, the cardiologist felt that a fluid bolus was inappropriate despite persistent hypotension. The patient ended up intubated with a central line in the ICU, at which time a fluid bolus was given but was well outside the three-hour window. This resulted in a failed measure because the fluid bolus was not given within the three-hour window. Unlike the first patient, this patient failed the measure because a physician felt it was inappropriate to complete the measure given the patients symptoms and condition. Despite the fact that the patient presented with symptomatic hypotension and the nurse pushed for intravenous fluid administration, ultimately this patient was not fluid resuscitated in time to be in compliance with the 3-hour bundle measures.
Staff Feedback

During the months of March, 2018 – September, 2018, meetings were held monthly to discuss the findings from chart reviews. Each sepsis case that was considered a fall out was discussed at these meetings. Attendees collectively included ten emergency room physicians and three nurses who shared managerial responsibilities. The DNP student guided the discussion by asking for feedback on what can be done to improve compliance given the reasons for missed measures revealed through chart review. As each case was discussed, two themes were identified through concerns generated by the group. The first was failed communication. Many people in the group felt that measures were being missed when the patient was transferred to other floors from the emergency...
department. Chart review supported this, as many missed measures were missed after the patient had been transferred out of the emergency department. All of the group members felt that a handoff tool would be helpful in making sure communication between floors was accurate and complete.

The second issue that consistently arose was a need for more nurse education. The physicians felt that nurses were not as aware of all aspects of the protocol as they could be, and that further education would be necessary in improving compliance. This was supported by both chart reviews and process flow for patient #1. The argument for more education stemmed from many cases where the nurse did not understand the importance or significance of one or more aspects of the bundle, and therefore did not complete certain measures. The top two areas for education that were identified by the group were administration of the fluid bolus and making sure the second lactic acid level was drawn, although group members vocalized that they thought education on all elements of the measure would be helpful. The combination of chart review, observation of process flow, and feedback from providers and nurses lead to the development of corrective interventions: the sepsis handoff tool and online nursing education.

**Sepsis Handoff Tool**

The Sepsis Handoff Tool was introduced to the ED, ICU, IMC, and medical floors in June, 2018. The tool was developed in order to improve compliance with core measures by guiding nurses in successful completion of the three and six-hour bundles. Content included all aspects of the three-hour bundle on the front of the page and elements of the six-hour bundle on the back of the page. In the left column core measures
were listed. In the middle column, there was room to document time each required measure was completed. The right column was used to document if and why certain measures were not completed (see Figure 3). This tool was developed specifically to improve communication between the ED nurse and the receiving floor nurse. In transferring the septic patient, it was meant to guide the nurse in what information to communicate and what measures were not yet completed. When feedback for this tool was requested from the ED manager, she stated that she felt it helped the nurse communicate valuable information to receiving floors. She also felt that it guided the nurse taking care of a septic patient in what to do next and when. The tool is currently being utilized in Hospital X for patients newly diagnosed with sepsis housewide.

**Nurse Education**

Nursing education was provided via online material developed by the DNP student that was focused on frequently missed core measures. Education was followed by a quiz to evaluate knowledge of all core measures (see Figure 4). This intervention was made available to nurses June 1, 2018 with completion required by July 1, 2018. All acute care nurses were required to take the quiz as part of mandatory education, with a total of 132 nurses completing the quiz. Content covered by this quiz included timing of intravenous antibiotic administration, when to administer the fluid bolus, when to draw the second lactic acid, how to identify early sepsis, which labs should be drawn within 3 hours, when to initiate the 6-hour bundle, and identification of mandatory measures in order to meet compliance with core measures. The goal of education was to raise awareness of what the bundle is and why it is important for patient outcomes. The content
of the quiz was shaped using information from chart reviews on why measures were failing, process flow observation, and feedback from providers and nurses during focused discussion groups. The questions were reviewed and approved by the group. After approval, questions were sent to the director of nursing education and made available on HealthStream (online continuing education program) for all nurses housewide. A score of 100% was required to pass the quiz, with nurses able to see which questions they got wrong after taking the test once. The nurses were able to take the quiz as many times as they needed. Of the total number of nurses that took the quiz, 47 nurses took it only one time (35.6%), and 85 nurses had to take it twice (64.4%) to achieve a score of 100%. Feedback from the emergency room nurse manager who was also required to take the quiz consisted of this being an effective way to increase awareness of the existence of the bundle in addition to how it is properly implemented.

Summary

Overall compliance rates significantly improved from June, 2018 – September, 2018. Average compliance rates have been consistently above 70% and have improved when compared with data collected pre-interventions. Reviewing patient charts revealed which aspects of the bundle were not being completed and why. Discussion of these cases in focused discussion groups revealed two main barriers to compliance: impaired communication during patient transfer and the need for more education for nurses. Observation of process flow supported that these barriers were in fact problematic, as the missed measure for patient #1 was a direct result of impaired communication and lack of
knowledge by the receiving nurse. After identifying these barriers, the Sepsis Handoff Tool was created to improve communication and compliance with core measures and mandatory online education on the sepsis protocol was initiated in June, 2018. After implementing these interventions, compliance rates drastically improved between the months of May, 2018 – June, 2018. This appears to have been in direct correlation with the implementation of corrective measures, suggesting that barriers were correctly identified and effective corrective action was taken.
CHAPTER FIVE

DISCUSSION

This quality improvement project was guided by the American Association of Colleges of Nursing (AACN) DNP Essentials. The AACN (2004) defines advanced nursing practice as

> any form of nursing intervention that influences health care outcomes for individuals or populations, including the direct care of individual patients, management of care for individuals and populations, administration of nursing and health care organizations, and the development and implementation of health policy. (pg. 4).

One of the objectives of this project was to improve patient outcomes through implementation of quality improvement initiatives, which still has many implications for future work and research beyond the scope of this project. Through careful identification of barriers to successful implementation and initiation of interventions that directly address these barriers, this project aimed to improve compliance, resulting in improved patient outcomes and financial benefits for Hospital X.

The AACN DNP Essential II is labeled “Organizational and Systems Leadership for Quality Improvement and Systems Thinking” (AACN, 2006, pg. 10). Under this Essential, the DNP graduate

> “must be able to assess the impact of practice policies and procedures on meeting the health needs of patient populations with whom they practice. DNP graduates must be proficient in quality improvement strategies and in creating and sustaining changes at the organizational and policy levels” (AACN, 2006, pg. 10).
This project is an example of quality improvement at the institutional level. By addressing barriers and implementing interventions, results demonstrated improvement in association with implementation. Improvement strategies were identified through chart review, observation of process flow, and staff feedback. The nursing education and creation/utilization of the sepsis handoff tool were attempts at creating sustainable change through tangible interventions at the institutional level. The ultimate goal was to improve compliance rates, lending to the ongoing improvement of health outcomes for this population. Because change is a dynamic process, there are many implications for future recommendations and research in an attempt to continue to improve compliance.

AACN DNP Essential III is labeled “Clinical Scholarship and Analytical Methods for Evidence-Based Practice (AACN, 2006, pg. 11). Application of this Essential involves “the translation of research into practice and the dissemination and integration of new knowledge, which are key activities of DNP graduates” (AACN, 2006, pg. 11). Through careful review of literature and current guidelines for evidence-based practice, this project was able to integrate current research into practice. Current CMS guidelines for treatment of sepsis were developed using current evidence, and are not only recommended but required. Consistent implementation of these guidelines has been difficult for Hospital X, and although compliance rates are rising, consistent interventions aimed towards increasing compliance will need to be continuously implemented in order to keep compliance rates high. The PDSA cycle used in guiding this project will need to be performed continuously in order to continue to improve compliance and outcomes.
AACN DNP Essential V (Health Care Policy for Advocacy in Health Care), reads that the DNP graduate will “demonstrate leadership in the development and implementation of institutional, local, state, federal, and/or international health policy” and “influence policy makers through active participation on committees, boards, or task forces at the institutional level to improve health care delivery and outcomes” (AACN, 2006, pg. 14). Another aspect of this Essential involves educating others regarding health policy and patient care outcomes. This project required the DNP graduate to demonstrate leadership in the implementation of the sepsis protocol by active participation in development of nursing education and interaction with key policy makers. This project required that the DNP student participate in active communication between key stakeholders through monthly focused discussion groups. Policy makers were influenced by data generated from extensive chart review for all cases where the measure(s) were missed. Nurses were educated in accordance with findings from these meetings with key stakeholders, and education was tailored to the most frequently missed measures.

Lastly, the AACN DNP Essential VI (Interprofessional Collaboration for Improving Patient and Population Health Outcomes) was implemented during the course of this project. This Essential focuses on the importance of interdisciplinary teams working together in order to provide safe, timely, effective, efficient, equitable, and patient centered-care (AACN, 2006, pg. 14). The DNP student acted as a leader in the implementation of this project. Many team members from many disciplines had to be brought together by the DNP student in order to initiate change. These team members included nurses, physicians, nurse managers, policy makers, and other members of the
healthcare team directly involved in patient care. The sepsis handoff tool is a specific example of the DNP student providing a tool to team members in order to improve communication, thus improving compliance and patient outcomes. Another example included the DNP student leading focused discussion groups with interdisciplinary team members on how to improve compliance. These monthly meetings were hugely helpful in the development of barrier specific interventions and areas for improvement. These meetings also encouraged team members to work together towards a common goal. Through collaboration and leadership, the DNP student was able to identify barriers and implement corrective measures which did appear to improve overall compliance.

**Summary of Results: Chart Review**

Chart reviews were performed from the months of March, 2018 – September, 2018 in order to gather data on which aspects of the sepsis bundle were being missed. There were five key elements of the CMS core measure that were missed for the 33 fall out cases:

- Initial lactate not drawn within 3 hours (7%)
- Repeat lactate not drawn within 6 hours (21%)
- Broad spectrum antibiotics not given within 3 hours (26%)
- Blood cultures not drawn within 3 hours (13%)
- Fluid resuscitation not done within 3 hours (33%)

This information was helpful in the development of nursing education. It was also helpful in guiding conversation during the focused discussion groups. Prior to the chart reviews,
information suggested delayed second lactate would be the primary deviation, however data demonstrated that fluid resuscitation was an even larger issue for compliance. The three main reasons for fall outs for fluid resuscitation were that the bolus was started but not completed within the three-hour window, the bolus was started after the three-hour mark, or the bolus was not started at all. There are many reasons why nurses and physicians may hesitate to give large volumes of fluid to patients who have compromised cardiovascular and/or pulmonary function, as this can lead to fluid overload and respiratory distress. However, several studies (e.g., Leisman et al., 2016, Radigan, 2017) demonstrate that the 30cc/kg is associated with improved patient outcomes in patients diagnosed with sepsis.

Current evidence-based practice supports the use of fluid resuscitation in septic patients even if they have co-morbid conditions such as cardiovascular or renal impairment. As an example, Leisman, Goldman, & Doerfler (2017) conducted a consecutive-sample, observational cohort trial over nine U.S. hospitals from October, 2014 – March, 2016. Adult patients with two or more SIRS criteria, suspected infection, and one or more organ dysfunction criteria were separated into three groups: patients who received crystalloid initiation in 30 minutes or less, patients who received crystalloid initiation in 30-120 minutes, and patients who received crystalloid initiation after 120 minutes. Out of 11,182 patients, fluid resuscitation was slower for patients with heart and/or renal failure. A total of 5,336 patients had the bolus started within 30 minutes, 2,388 patients 30-120 minutes, and 3,458 patients >120 minutes. Mortality was significantly lower for patients resuscitated earlier. The time to fluid resuscitation was
associated with 1.09 times greater odds of mortality per hour increase (Leisman, Goldman, and Doerfler, 2017). Surprisingly, earlier fluid resuscitation was also associated with lower rates of mechanical ventilation, ICU admission, and shorter length of stay. Despite comorbidities and severity of illness, more timely crystalloid initiation was directly associated with decreased mortality.

This is one example of many studies (Leisman et al., 2016, Radigan, 2017, Seymour et al., 2017, and SSC, 2018) supporting early use of fluid resuscitation in septic patients, even those who are compromised due to heart or renal failure. Hesitancy to resuscitate these patients is a common theme in many hospitals. This is why nursing education was tailored specifically to address this issue. Regardless of co-morbidities, early fluid resuscitation has been associated with decreased mortality and improved patient outcomes; it is arguably one of the more important core measures, and yet one of the most frequently missed interventions at Hospital X. After holding conversations in focused discussion groups, it was decided that nurse education around this issue could be helpful in earlier fluid administration for septic patients.

Failure to draw the second lactate within the six-hour window was the second most frequently missed component of the bundle. Chart review revealed that the most common reason for this was that when septic patients were transferred to other floors, the second lactate was either getting cancelled or was being drawn late due to lack of communication between nurses and laboratory technicians. The transferring nurse was not communicating to the floor nurse when the first lactate was drawn and when the second one was due. The Sepsis Handoff Tool was meant to improve communication due
to findings suggesting that improved communication was necessary for proper implementation of the bundle.

Other aspects of the bundle that were not followed according to protocol seemed to be due to nurses not being aware of time constraints. Many of the interventions were actually completed, but fell out of the three and six-hour time requirements. To address this issue, timing of interventions was one topic that was included in the required nurse education. The charts demonstrated that further education was necessary to emphasize the importance of the completion of the bundles within the allotted time. Overall, the chart reviews were extremely helpful in the identification of barriers and development of tools to help with compliance.

Summary of Results: Process Flow

The two instances where a septic patient was observed through their emergency room stay until after hospital admission were helpful in the identification of barriers associated with sepsis bundle compliance. The first patient did not meet core measures because the second lactic acid level was not drawn. By the time the receiving nurse was told about the second sample by the lab, more than six hours had passed. Had she been notified of the need to send the sample by the emergency room nurse, she may have sent the sample in time. This particular case seemed to simply be a lack of communication. Working together was identified as a common theme essential to proper implementation of the sepsis bundle in the Steinmo et al. (2016) study identifying barriers to successful implementation. Specifically, nurse-physician communication was identified as a theme
that was essential in order to implement the correct interventions in the allotted time frame. However, communication between all staff members is important for proper implementation, as is demonstrated in this case. Also, the nurse felt that by the time the lab notified her, the test was unnecessary due to improving patient condition. There was some unawareness of all aspects of the protocol needing to be completed in order to be in compliance with core measures. Thus, observation of this patient helped in the creation of the sepsis handoff tool and helped guide the topics for nurse education. It was helpful to see the process in action and visualize where the measure was failing.

The second case was more complex in nature and there were legitimate concerns with administering the 30cc/kg fluid bolus. This patient had frequent hospitalizations with known congestive heart failure (CHF). Because of this, cardiology was consulted early in the admission process, even with a primary diagnosis of sepsis. The patient was experiencing hypotension in the emergency room; however, it was not low enough to warrant fluid bolus administration per the cardiologist. There was concern of fluid overloading the patient. Every other aspect of the bundle was completed; however, the patient was not resuscitated with fluids until they were transferred to the ICU in critical condition, well after the three-hour window. The main issue here is that the provider was worried about doing harm to this patient by fluid overloading them, placing them at risk for flash pulmonary edema. However, the patient did end up intubated and on vasopressors, and in the end still received multiple fluid boluses that would have satisfied the volume requirements if done on time. This particular case was brought up at the June focused discussion group, with mixed feedback from providers. Some felt that the course
of action was appropriate given the patient’s past medical history, while other providers felt that the fluid should have been administered immediately.

This is a common barrier to proper implementation that has been an ongoing issue in other institutions besides Hospital X, and identified as a barrier in the study by Steimno, Muchie, Fuller, Stapelton, & Stone (2016). This study identified barriers to successful implementation, with a common theme of concerns about risks vs. benefits and fluid overloading patients being identified. As discussed above, current literature encourages early administration of fluids regardless of compromised cardiovascular or renal function. This case was useful in determining that further education was needed to ensure that fluid bolus administration occurred early for septic patients with co-morbidities. It also became clear that in addition to nurse education, it may have been helpful to educate physicians on this matter. In this particular instance, the reason for the missed measure was a physician order to not administer the fluids. Housewide physician education on this issue may have prevented this particular fallout.

Summary of Results: Sepsis Handoff Tool

The sepsis handoff tool was introduced house wide in June, 2018. This is also when the compliance rates increased from 57% in May, 2018 to 87% in June, 2018. The tool was meant to increase communication between staff members on which aspects of the bundle had been completed and which still needed to be completed in order to prevent fall outs. The information on the sheet was to be communicated from the ED nurse to the admitting nurse, and the sheet was to be transferred with the patient. It is difficult to
determine how frequently the tool was used (what percent of patients with sepsis had this intervention implemented) and how effective it was in improving communication. This tool remains available is is encouraged by nurse managers in the emergency room setting. This intervention was created not only to improve communication, but to remind nurses what all elements of the bundle were and when they needed to be completed. It included all aspects of the bundle that had been missed per chart review.

**Summary of Results: Nurse Education**

All acute care nurses at Hospital X were required to complete online education on how to accurately complete both the three and six-hour sepsis bundles. This education was created in attempt to increase awareness and knowledge of the bundles. The questions were created using data pulled from the chart reviews on which aspects of the bundle were not being implemented according to CMS core measures. The questions were written to emphasize which interventions need to be completed and when they need to be completed. The questions were delivered in an online program called HealthStream that is used for mandatory nursing education. All of the nurses that practice in acute care areas were required to take and pass the quiz with 100%. If the quiz was not passed the first time, nurses were allowed to take the quiz as many times as needed until they answered all of the questions correctly. After taking the quiz, the program would alert the nurse as to which questions they did or did not answer correctly, allowing them to see where mistakes were made. After completion of this module, a certificate was given to each nurse demonstrating that the module had been completed with no errors. More than
half of the nurses who participated in taking the quiz (64.4%) had to take the quiz twice in order to obtain a score of 100%. This implies that over half of the nurses were not familiar enough with the protocol to answer all of the questions correctly the first time, validating a need for education.

One aspect to consider is the fact that nurses were shown which questions they got wrong after taking the test initially in addition to the correct answer to the question. This could be why no nurse had to take the quiz more than twice. Although exposure to the correct answer may have increased awareness around different aspects of the protocol, it may have been better not to show the correct answers after the first time taking the quiz and instead have the nurse review the material in the power point provided in order to answer all questions correctly.

**Study Limitations and Barriers**

Limitations of this project include single site location, small sample size, and subjective interpretation of compliance. The sample is small and non-generalizable, making it difficult to apply findings to other institutions. This project was conducted over seven months, which made data collection limited by time. Population selection must only include patients with a diagnosis of sepsis, as SIRS criteria can be present in other diagnoses that are not Sepsis. Other limitations include data collection over a relatively short period of time, inability to evaluate utility of the Sepsis Handoff Tool, and difficulty assessing how effective nurse specific education was at increasing awareness and
knowledge. Although overall compliance rates did increase, it is difficult to determine which interventions specifically were helpful in producing this increase.

Because the Sepsis Handoff Tool and nurse education were implemented house wide, the data used to evaluate the effectiveness of these interventions was qualitative feedback from physicians and nurse managers along with data on overall sepsis bundle compliance. The inclusion criteria resulted in the exclusion of many patients from the total sample. Patients who were included had to have two or more SIRS criteria with confirmed infection. Patients who initially presented with SIRS criteria without an active infection and patients who did not require all aspects of the bundle were excluded from the overall sample (N=130). Furthermore, the number of patients who were not treated according to CMS core measures were also small (n=33). Data was collected over a relatively short period of time (7 months), making the long-lasting effects of the interventions difficult to evaluate.

One of the barriers of this project was an inability to separate which interventions were effective at improving compliance rates due to the fact that both interventions were introduced at the same time. Had the project not been limited by time, it would have been ideal to introduce one intervention at a time while tracking compliance rates to see which were most effective. Other activities that may have been effective in increasing compliance include raising awareness of reasons for fall outs during monthly focused discussion groups and having the DNP student available to analyze this data for discussion. These interventions were temporary in nature and limited by the duration of this project; this may affect future compliance rates. Also, there were some cases that
were excluded because of early recognition and treatment of infection that did not progress to sepsis. Only patients with a true diagnosis of sepsis were included in the sample. More data is needed on how frequently the sepsis handoff tool is being utilized and how effective the tool is at improving communication and compliance. In order to continue to improve compliance rates, there will need to be continued interventions to instill change such as education of new nurses on the protocol and continued use of the handoff tool on all floors.

**Implications for Future Research and Practice**

Because this is a quality improvement project, continued change and improvements will be necessary to keep compliance rates high. Recommendations for future research include:

- Evaluating effectiveness of online education by determining if compliance was better on units whose nursing staff scored higher on the first attempt or by comparing compliance among units who did and did not receive training
- Evaluating use of the Sepsis Handoff Tool by surveying nurses to see how frequently the tool is being used for septic patients
- Evaluate the effectiveness of the Sepsis Handoff Tool by asking acute care nurses if they feel this tool increases effectiveness of communication
- Continue to track compliance rates in order to evaluate the effectiveness and longevity of the interventions that have been implemented
Assess cost aspects and patient outcomes associated with deviations from CMS core measures

These recommendations will help to assure that barriers to proper implementation of the bundles continue to be identified and addressed accordingly. Future research should also include continued review of fall out charts in order to further track which interventions are not being performed according to CMS guidelines and to identify whether or not it was a nurse or physician error and track accordingly.

**Recommendations**

The number one recommendation is to continue to identify barriers to proper implementation and create interventions to directly address these barriers, just as this project has done. Barriers to implementation may evolve as different interventions are utilized in the acute care setting. Because of the changing barriers, interventions may need to be changed as well in future compliance improvement. Because compliance rates did go up after implementation of the above interventions, recommendations would include continued use and encouraged use of the Sepsis Handoff Tool in addition to education for all new nurse hires and continued education for existing staff members. In order to ensure its use, the Sepsis Handoff Tool should be an educational topic at acute care staff meetings, and charge nurses should continue to encourage use at the time of sepsis diagnosis. Another recommendation would include looking at which nurse and physician were assuming care of the patient during fall outs and directly communicating with that person in order to directly identify barriers. This feedback would provide
information on why the core measure was not met and allow the researcher to identify specific themes for fall out cases. After research has been performed on whether or not the fall out was due to nurse or physician error, education can be targeted appropriately. Researching which fall outs were due to nurse error and which were due to physician error may be helpful in guiding future educational interventions. Perhaps including physicians in future education may help improve compliance rates. The DNP student would also encourage the continuation of focused discussion groups for this topic in order to accurately identify barriers and brainstorm ideas for future interventions.

Different teams are alerted when patients are admitted with specific diagnoses. For example, when a stroke patient is being brought by ambulance, the stroke team is notified and all members act in order to ensure thorough and fast care. A similar process occurs for patients with acute myocardial infarction. Both of these diagnoses are time sensitive and require prompt intervention. Sepsis is similar in that there exists a protocol for rapid treatment (3 and 6-hour bundles) and treatment is time sensitive. Patients not treated quickly can progress to severe sepsis or septic shock, which increases length of stay, morbidity, and mortality. Current literature demonstrates a correlation in improved outcomes for septic patients and utilization of sepsis teams in the emergency room setting. One hospital created a multidisciplinary team that consisted of critical care and medical leadership personnel, critical care and medical-surgical nurses, a clinical nurse specialist, a pulmonologist, a quality management nurse, and a hospitalist physician. Use of this team was associated with a significant increase in compliance with CMS core measures and a significant decrease in mortality (Maclay & Rephann, 2017). Hospital X
has current employees in all of these positions, and could recruit these people to create a team that specializes in prompt identification and treatment of sepsis. On patient arrival, the team would be notified and ready to treat the patient on arrival. This may increase compliance by ensuring that the patient is being treated by sepsis experts who are aware of all CMS core measures.

Conclusion

This quality improvement project was the start of many improvements that can be made to increase compliance rates with the core measures required by CMS in attempt to improve patient outcomes and increase hospital reimbursement. Increasing awareness and knowledge base for nurses and physicians on all aspects of the three and six-hour bundles will be an important part of ensuring that compliance rates continue to improve. The two interventions that were implemented during the course of this project seemed to improve compliance based off a significant improvement in overall compliance rates during months where the interventions were implemented. There are many recommendations for future research and interventions based off the findings from this project. As with any quality improvement project, continuous evaluation and updated interventions will be necessary to ensure that the driving forces outweigh resisting forces, and change continues to move in a positive direction that improves patient outcomes. This project was the start of this process, and Hospital X will continue to evaluate outcomes and strive to improve compliance through similar processes.
REFERENCES CITED


APPENDICES
APPENDIX A:

IRB EXEMPTION
INSTITUTIONAL REVIEW BOARD
For the Protection of Human Subjects
FWA 00000165

Montana State University

MEMORANDUM

TO: Christine O'Connor and Susan Luparel
FROM: Mark Quinn, Chair, Institutional Review Board for the Protection of Human Subjects
DATE: April 8, 2018

RE: “Separate Bundle Evaluation for Quality improvement” [CO040618-EX]

The above research, described in your submission of April 6, 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) Tests and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed, or 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 B:

3-HOUR BUNDLE
**Sepsis Protocol (3 hour bundle)**

2 or more of SIRS criteria met plus a suspected infection
1. RR > 20
2. HR > 90
3. Temp > 38.0 or < 36.0°C
4. WBC > 12 or < 4, 10% bands
5. Altered mental status

---

**Obtain cultures and lab work**

* (STAT)
  - CBC with differential
  - Lactic acid #1
  - CMP (evaluates organ)

---

**Establish sepsis severity**

- *Severe sepsis:* 2 or more SIRS criteria and 1 or more organ dysfunction
- *Septic shock:* severe sepsis and persistent hypoperfusion after initial fluid boluses

---

**Administer IVF and Antibiotics (within 1st hour)**

- NS or LR at 30cc/kg/hr (4-6 liters/2hr)
- Broad spectrum antibiotic, organ specific coverage

---

**Stabilize patient and consider:**

- Intubation
- Central line especially if pressors are in use
- Start pressors only if hypotension is not corrected by IVF boluses
- X-ray/CT/US as indicated

---

**Transfer to ICU**

(optimal in 2 hours or less)

---

Highlighted in RED-CMS required

Highlighted RED-CMS required
APPENDIX C:

6-HOUR BUNDLE
**Sepsis Protocol (6 hour bundle)**

**Severe sepsis**
- 2 or more SIRS criteria
- 1 or more signs of organ dysfunction
  - Lactic acid > 4
  - Hypotension
  - Creatinine > 2.0
  - Urine output < 0.5 ml/kg/hr \( \times 2 \) hrs
  - PLT < 100,000
  - INR > 1.5
  - aPTT > 60

**Septic shock** - present when both are met
- Pt has met severe sepsis criteria
- 1 or more of the following
  - Lactic acid level > 4
  - Persistent hypotension
    (MAP < 65, SBP < 90, or 40-point drop in baseline BP by 2 or more constant readings)

---

**Highlighted RED-CMS required**

**Repeat focused examination within 6 hours/Physician documentation**
- VS
- Chest examination
- Cardiac examination
- Capillary refill
- Skin examination
- Pulses

---

**IV Fluid**
- NS or LR (consider albumin or blood)
- 30 ml/kg/hr
- Limit pressors-use IVF boluses to keep MAP > 60

**Medical management**
- Ventilation (low volume)
- DVT prophylaxis
- GI prophylaxis
- Sedation schedule-sedation holiday
- Continue and reassess antibiotics

---

**Highlighted in RED-CMS required**
APPENDIX D:

SEPSIS HANDOFF TOOL
**CODE SEPSIS HANDOFF TOOL**

<table>
<thead>
<tr>
<th>Date:</th>
<th>____________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time zero:</td>
<td>____________</td>
</tr>
</tbody>
</table>

*Time Zero: Identification of 2 or more SIRS criteria

### 3-HOUR BUNDLE ELEMENTS (To be completed within 3 hours of TIME ZERO)

<table>
<thead>
<tr>
<th><strong>Initial Labs:</strong></th>
<th><strong>Time Collected:</strong></th>
<th><strong>Why Not Performed:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>-Lactate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-CBC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-CMP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(To be collected within 1 HOUR of time zero)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Blood Cultures</strong></th>
<th><strong>Time Collected:</strong></th>
<th><strong>Why Not Performed:</strong></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>IV Antibiotics</strong></th>
<th><strong>Antibiotic Start Time:</strong></th>
<th><strong>Why Not Administered:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>(Within 1 HOUR of time zero)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>IV Fluid Bolus</strong></th>
<th><strong>IVF Goal:</strong></th>
<th><strong>Why Not Administered:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>(30 ml/kg NS or LR initiated within 1 HOUR and complete within 2 HOURS of time zero)</td>
<td>(Patient kg x 30 mL)</td>
<td></td>
</tr>
<tr>
<td>6-HOUR BUNDLE ELEMENTS (To be completed within 6 hours of time zero)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>REPEAT LACTATE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(To be performed within 6 hours of time zero)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TIME DRAWN:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>RESULTS:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>WHY NOT PERFORMED:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>VASPORESSOR ADMINISTRATION (PRN)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TIME INITIATED</strong> (If appropriate):</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>WHY NOT ADMINISTERED:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Norepinephrine preferred</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>REPEAT VOLUME STATUS AND TISSUE PERFUSION ASSESSMENT</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Performed by MD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>EXAM TO INCLUDE:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>OR ANY 2 OF THE FOLLOWING 4:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>WHY NOT PERFORMED:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PATIENT MEETS CRITERIA FOR:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SEVERE SEPSIS:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SEPTIC SHOCK:</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**ED RN:**

**ED MD:**
APPENDIX E:

SEPSIS QUIZ QUESTIONS & ANSWERS
SEPSIS QUIZ

Please answer the following questions:

1) **TRUE** or **FALSE**: IV antibiotics should be administered within one hour after blood cultures have been drawn and within 3 hours of bundle initiation.

2) **TRUE** or **FALSE**: For a SBP < 90, a 30 ml/kg fluid bolus should be started within three hours of sepsis bundle initiation.

3) **TRUE** or **FALSE**: A second lactate level should be drawn within 8 hours of the initiation of the sepsis bundle.

4) **TRUE** or **FALSE**: Early sepsis should be identified using 3 or more SIRS criteria for initiation of the three-hour bundle.

5) **TRUE** or **FALSE**: In addition to blood cultures, a CBC, lactate level, and a CMP should be drawn upon initiation of the 3-hour sepsis bundle.

6) **TRUE** or **FALSE**: The 6-hour sepsis bundle is initiated on all patients diagnosed with severe sepsis and septic shock.

7) Which of the following interventions are required by CMS to be in compliance with the sepsis bundles?

   a. Initiation of IV fluids within established time frame
   b. Obtaining a second lactate level within 6 hours of bundle initiation
   c. Insertion of central line
   d. Administration of IV antibiotics within established timeframe
   e. Transfer to Intensive Care Unit
   f. Use of vasopressors if blood pressure is not corrected with IV fluid boluses

8) **TRUE**
9) **TRUE**
10) **FALSE**
11) **FALSE**
12) **TRUE**
13) **TRUE**
14) A, B, D, F
APPENDIX F:

KRMC SEPSIS PROTOCOL, AGN107
Sepsis Protocol, AGN107

PURPOSE

To allow the registered nurse to properly screen and recognize the patient who is suspected to be septic. To allow the registered nurse to act promptly in initiating the sepsis protocol for quick treatment and better patient outcomes.

DEFINITIONS

1. **SIRS**: (Systemic Inflammatory Response Syndrome) is identified by two or more present of the following:
   
   A. Temp > 38.0 or <36.0
   
   B. HR >90
   
   C. RR>20
   
   D. WBC >12K or <4K or 10% bands
   
   E. Altered mental status

2. **SEVERE SEPSIS**: presence of two (2) or more SIRS criteria and one or more signs of organ dysfunction.

3. **SEPTIC SHOCK**: presence of severe sepsis and presence of either persistent hypotension or lactic acid level >4.
POLICY

1. Screen patient according to SIRS criteria.
2. Initiate monitoring: Nursing staff may initiate protocol when indicated – see attached
   A. VS and temp minimum of Q1 hour
   B. Keep O2 sat > 93%
   C. Insert IV 20 g or larger
   D. Draw labs for CBC with differential, CMP, lactic acid level, stat blood cultures to
      HOLD until the physician is notified. Note: After Labs ordered, IV antibiotic are to
      be given within one hour after blood cultures are drawn.
   E. If two consecutive SBP measurements are <90 (or a 40 point drop in patient
      baseline SBP), initiate a 30ml/kg fluid bolus.
3. Notify attending physician of suspected sepsis.
4. Staff will continue to monitor patient for any ongoing changes and report those changes
   to the attending physician.
5. Regardless if the patient’s condition does not improve after above interventions, access
   the CAT team and notify the attending physician for a potential ICU transfer.

APPENDIX G:

POWER POINT FOR ONLINE NURSING EDUCATION
SEPSIS

- Is characterized by a Systemic Inflammatory Response Syndrome (SIRS) to any infection
  - Estimated incidence >2% of ALL hospitalized patients
  - 6-30% of ALL Intensive Care patients
  - The single most expensive disease process in US hospital care, accounting for >$20 billion dollars annually
  - Up to ½ of hospital mortality may be attributable to sepsis
  - Mortality ranges from 30-50% and is known to be secondary to failed early recognition!
  - CMS has mandated core measures to improve early identification

KRH SEPSIS, 2017

- Preliminary data from 2017 all identified cases of sepsis:
  - 472 total cases of sepsis identified, 10% mortality
  - 362 cases identified first in ER, 8% mortality
  - 110 cases identified after admission, 16% mortality
SIRS

- SIRS criteria are nonspecific but sensitive and help us identify early sepsis
- Nursing staff plays an IMPERATIVE role in the early identification of sepsis
- SIRS criteria serve as an alert to the need for a protocol driven evaluation and intervention including:
  1. Blood work
  2. Cultures
  3. Antibiotics
  4. Fluids
- Early intervention is extremely time sensitive!
- Accurate documentation and communication are essential to the provision of best care.

Initiate Sepsis Protocol when:

2 or more of the following SIRS criteria are met in the proper clinical situation (nursing staff is asked to begin workup and confer with provider to expedite process):

- 1. RR > 20
- 2. HR > 90
- 3. Temperature > 38.0 or < 36.0 C
- 4. WBC > 12 or < 4, or 10% bands
- 5. Unexplained mental status changes
CMS Initial Requirements (The 3 hour bundle)

- 1. CBC with differential
- 2. Serum lactic acid (#1 and #2 by 6 hours)
- 3. CMP (evaluation of organ dysfunction)
- 4. Blood and other cultures as indicated
- 5. For BP < 90, begin IVF (NS or LR) to goal of 30cc/kg infused by four hours
- 6. After cultures, begin directed antibiotics within 1 hour
- 7. Accurately document timing of interventions on protocol tool

The Handoff:

- Accurate documentation of initiation of “3 hour bundle” requirements. The accurately timed documentation of all the core measures is a strict requirement of CMS for KRH to achieve compensation for care.
- Accurate and complete communication with the staff who will complete the documentation of the “6 hour bundle” (nursing and physician) which is also a CMS requirement.
- Use documentation tool (to follow) for handoff
APPENDIX H:

WRITTEN REPORT FOR AGENCY
Written Report for Agency

A project has been conducted in order to identify barriers to successful implementation of the current sepsis protocol at this facility and make appropriate recommendations for corrective action based off these findings. Once specific barriers were identified, specific corrective actions were taken in correlation with findings. Barriers to proper implementation were identified using three strategies:

- Extensive chart review of 33 patients that were considered fall out cases from March 2018-September 2018
- Process flow observations (2) of the treatment of septic patients in the ER setting
- Holding monthly focused discussion groups to get feedback from nurses and providers on how to improve compliance

Findings from the chart review revealed aspects of the bundle that were most commonly being missed. After identifying these interventions, two main causative factors were identified as the primary reasons for bundle non-compliance. The first was miscommunication between transferring units when transferring a septic patient from the ER to other floors. The second was hesitancy to implement certain aspects of the bundle for patient safety reasons (i.e. fluid bolus administration in patients with compromised respiratory, renal, or cardiac status). In order to address the causative factors, interventions were implemented that directly addressed these two problems and are as follows:

- Sepsis Handoff Tool was introduced to acute care floors June 1, 2018
- Mandatory Healthstream online education for all of nursing on core measures

Effectiveness of these interventions was evaluated by tracking overall compliance rates from March, 2018 – September, 2018. Results demonstrated a significant increase in compliance with implementation of these interventions (57% in May, 2018 – 87% compliance in June, 2018). Data since this time has demonstrated compliance rates consistently above 70%, a significant improvement from months prior. Recommendations for continued improvement in compliance with the sepsis core measures include:

- Continue to identify barriers to proper implementation and create interventions to directly address these barriers.
- Continue and encourage use of the Sepsis Handoff Tool and implement sepsis education to all new nurse hires.
- Present the Sepsis Handoff Tool as an educational topic at nursing staff meetings to ensure use.
- When a fallout occurs, identify which nurses/physicians were responsible for the patient during that time and ask them directly what the barriers were to proper implementation.
- Create sepsis education for physicians as well as nursing staff.

The above recommendations should be updated according to changing barriers and any changes to the current protocol. Thank you for your time and consideration of these recommendations.