UTILIZING A MULTI-FACETED APPROACH TO IMPROVE 6-HOUR BUNDLE COMPLIANCE OF PATIENTS WITH SEVERE SEPSIS AND SEPTIC SHOCK

by

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ABSTRACT

ERIKA GABBARD. Utilizing a multi-faceted approach to improve 6-hour bundle compliance of patients with severe sepsis and septic shock.
(Under the direction of DR. DAVID LANGFORD)

Purpose: The purpose of this DNP Scholarly Project was to evaluate the impact of Virtual Critical Care (VCC) and Sepsis Program Coordinators on 6 hour bundle compliance (divided into 3 time frames: first 3 hour, second 3 hour, and total 6 hour) for patients with severe sepsis and septic shock following the Society of Critical Care Medicine's Surviving Sepsis Campaign Guidelines. Background: Severe sepsis and septic shock is defined as a systemic infection leading to massive widespread vasodilation and poor tissue perfusion resulting in organ dysfunction and death. While cases have tripled in the last twenty years, mortality among this patient population remains approximately 25%. Through the use of the Surviving Sepsis Guidelines, a bundled approach to care for this population focuses on timely antibiotics, intravenous volume replacement, and invasive hemodynamic monitoring. Methods: This is a pre and post measure of an intervention designed to improve adherence to the standard of care for the patient with severe sepsis and septic shock, defined as Code Sepsis. Data was collected from December 1st 2013 to December 31st 2014 on Code Sepsis patients admitted to the intensive care unit at nine different hospitals. A total of 1806 patients met the inclusion criteria. Results: Results demonstrated a statistically significant improvement in first 3 hour bundle compliance (6.4%, 95% CI 1.6-11.3%), p-value = 0.01., second 3 hour bundle compliance (6.2%, 95% CI 2.7-9.7%), p-value = 0.001 and total 6 hour bundle compliance (4.2%, 95% CI 1.5-6.9%), p-value=0.003.

Approximately 45 readmissions were prevented with a cost avoidance of $290,619, and among the survivors, it was demonstrated that the intervention group avoided 1,011 hospital days for a cost avoidance of $374,088. In addition, there was a reported reduction in mortality by 8.3% (95% CI 4.5% to 12.2%) p-value < .0001, which demonstrated a total of 80 lives saved. Implications for Practice: This supports current literature that a coordinated, systematic approach improves bundle compliance and reduces hospital length of stay, readmission, and mortality.

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CHAPTER 1: INTRODUCTION

1.1 Background

Severe sepsis cases have tripled in the last 30 years, with primary diagnoses of sepsis doubling over the last decade (NCHS, 2011). Epidemiologic data shows that the annual number of sepsis cases presenting and admitted through emergency departments in the US is over 750,000 (Wang, 2007). In 2009, septicemia was the sixth most common reason for hospitalization, costing approximately 15.4 billion dollars and accounting for 4.3% of hospital costs (Elixhauser, Friedman, & Stranges, 2011). Torio and Andrews (2011) reported that septicemia was the most expensive condition treated with an estimate of 20.3 billion dollars spent, accounting for 5.2% of hospital costs. They also reported that septicemia was ranked in the top four most costly hospital conditions for Medicare, Medicaid, private insurance, and uninsured patients. The average length of stay for patients hospitalized with sepsis is 8.4 days which is 75% longer than those hospitalized for other conditions (NCHS, 2011). Most important to report is the mortality rate for patients with severe sepsis or septic shock, which can range 17% to 25% (Elixhauser, et al., 2011; Dellinger, Levy, Rhodes, Annane, Gerlach, & Opal et al., 2012). Patients who are hospitalized with sepsis are more than eight times more likely to die before hospital discharge compared to other diagnoses (Hall, Williams, DeFrances, & Golosinskiy, 2011).

Sepsis is a systemic illness in response to infection that has various degrees of severity. Sepsis is usually diagnosed when infection is paired with systemic clinical

indications such as: fever or hypothermia, tachycardia, tachypnea, altered mental status, hypotension, decreased urine output, peripheral edema, elevated or decreased white blood cell count, hyperbilirubinemia, hyperglycemia, increased C-reactive protein, procalcitonin or creatinine, coagulation abnormalities, increased cardiac output or decreased venous oxygen saturation (Roberts & Todd, 2012; Dellinger et al., 2012). Severe sepsis is defined as sepsis with end-organ failure or poor tissue perfusion. Septic shock, which is the worst case, is defined as sepsis-induced hypotension that is unresponsive to fluid resuscitation. The tissue hypoperfusion related to the sepsis is further defined by "infection-induced hypotension, elevated lactate, or oliguria" (Dellinger et al. 2012. p. 583).

Due to the severity and frequency of sepsis cases, Dellinger et al. (2012) created international guidelines that established a standardized, evidence-based management of patients with sepsis-induced tissue hypoperfusion. This is defined as sepsis with hypotension despite fluid resuscitation or a serum lactate that is ≥ 4 mmol/L. There are seven components, referred to as a bundle, which are to be completed within six hours of recognition of hypoperfusion to optimize the patient's chance for survival. Within the 6 hour time frame there are a total of two time components: the first 3 hour and the second 3 hour. Within the first 3 hours clinicians should: measure serum lactate levels, obtain blood cultures, administer appropriate antibiotics after obtaining blood cultures, and ensure the patient has received a minimum of 30mL/kg of intravenous fluid. The second 3 hours should include administering vasopressors for hypotension that does not respond to initial fluid resuscitation, inserting a central venous catheter and administer appropriate therapies to achieve a central venous pressure (CVP) of 8 to 12 mmHg, a venous

oxygenation ($ScvO_2$) of >70%, and remeasure a lactate if initial lactate was elevated. For patients who are identified in the emergency department, some of the initial therapies will be accomplished there while the remaining bundle components are achieved after the patient arrives to the Intensive Care Unit. Cannon et al. (2013) found that by utilizing early intervention strategies, one life can be saved for every seven treated.

Telemedicine was a new strategy being utilized at the project setting, which is a large healthcare system in the Southeast United States. Within this organization, there are over 26 facilities that have intensive care units (ICUs) with approximately 552 critical care beds. The Virtual Critical Care (VCC) Command Center a state-of-the-art two-way audio/video connectivity to providers in the ICU, plus clinical monitoring such as blood pressure, heart rate, respirations, oxygen saturation as well as advanced invasive line monitoring. Their function is to assist with implementing the standards of care and coordinate critical care management for patients in the ICU. Experienced critical care nurses and board-certified Intensivists staff the VCC 24 hours a day. VCC assists to ensure best practices by:

- Assuring adherence to evidence-based standards of care.
- Allowing earlier recognition of subtle changes in a patient's condition.
- Ensuring immediate response by specialists to urgent and emergent situations.
- Leveraging expertise of a limited number of intensivists.
- Increasing collaboration among caregivers.
- Facilitating quality data collection, reporting and benchmarking.

Four full-time Sepsis Program Coordinators were hired to work at 6 of the hospitals to assist with this sepsis initiative. The Sepsis Program Coordinators chosen

were highly skilled RNs with critical care backgrounds and who demonstrated the ability to lead and influence change. The Sepsis Program Coordinator is a multifaceted position designed to give the individual facilities ownership over their Code Sepsis program. A patient is activated as a Code Sepsis when they have suspected infection and hypotension despite fluid resuscitation or a serum lactate ≥ 4 mmol/L. The Sepsis Program Coordinators provide several key roles to their individual hospitals:

- Provide in-depth education to all staff, including physicians and nurses, on the identification, activation and implementation of the Code Sepsis process.
- Provide real time reviews for each Code Sepsis activation and offer feedback on areas of strengths and opportunities for improvement.
- Work with existing electronic medical records and information technology processes to develop an Early Warning System to identify potential patients who may exhibit signs and symptoms of severe sepsis or septic shock.
- To share data related to mortality, length of stay (LOS), and bundle compliance which will be used to evaluate the care of these critically ill patients.
- To be the point of contact for Code Sepsis as the facility strives to provide high quality sepsis care throughout the hospital.

1.2 Problem Statement

Implementing the Surviving Sepsis Guidelines (Dellinger et al., 2012) in the first six hours of recognition of severe sepsis or septic shock is the goal to improving the patient's outcome. Bundle compliance varies among hospitals with reported low levels of compliance. Levy et al. (2010), reported a linear improvement in bundle compliance from 10.9% to 31.3% in two years following a dedicated campaign to improve bundle

compliance among 15,022 patients at 165 hospitals. There are also numerous barriers to achieving this goal: lack of knowledge regarding the physiology of sepsis, lack of resources and staff to appropriately and adequately implement the bundle, and differences in opinion of the evidence. The evidence demonstrates that when bundle compliance increases, patient mortality decreases (Levy et al., 2010).

1.3 Purpose of the Project

The purpose of this DNP Scholarly Project was to evaluate the impact of VCC and Sepsis Program Coordinators on 6 hour bundle compliance for Code Sepsis patients following the Society of Critical Care Medicine's Surviving Sepsis Campaign Guidelines (Dellinger et al., 2012). The first strategy to improve bundle compliance was to utilize VCC to interact with bedside critical care staff following an algorithmic approach to ensure bundle completion within the six hour time frame once the patient was transferred to the ICU (Appendix A).

The algorithm is broken down into two different time frames, to mirror the bundle components in the Surviving Sepsis Guidelines. The first part is to be done within three hours and the second part is to be completed within six hours. The first part includes: measuring serum lactate, obtain blood cultures, administering appropriate antibiotics and ensuring the patient receives at least 30mL/kg of intravenous fluids. The second part includes: inserting a central venous catheter, obtaining at least one measurement of central venous pressure of ≥8 mmHg and a venous oxygenation sample ($ScvO_2$) of ≥70 percent. The intention was to support the bedside staff in completing the bundle elements when needed. In doing that, bedside staff were given two hours to complete the first 3 hour bundle and 4 hours to complete the second 3 hour bundle. If a bundle element was

not completed prior to the directed time period, the hospital staff was contacted by the VCC staff to see what actions were needed to ensure that the element was completed. The second strategy to improve compliance with the bundle was to utilize the Sepsis Program Coordinators to provide education to nurses, physicians, pharmacists, and administration, perform real-time auditing, and disseminate case review feedback to the clinicians that were involved in the Code Sepsis case.

1.4 Clinical Question

The following clinical question was used to guide the design of this project. In adult patients (18 years of age or older) identified as Code Sepsis, would the addition of VCC and Sepsis Program Coordinators, increase adherence to the Surviving Sepsis Bundle standard of care and improve outcomes?

1.5 Project Objectives

Specific objectives are;

- Objective 1: Measure the percentage of patients receiving the first 3 hour bundle.
- Objective 2: Measure the percentage of patients receiving the second 3 hour bundle.
- Objective 3: Measure the percentage of patients receiving the total bundle in 6 hours.
- Objective 4: Determine ICU and overall hospital length of stay for patients identified as Code Sepsis.
- Objective 5: Determine 30-day sepsis-related readmission for patients identified as Code Sepsis.

- Objective 6: Determine in-hospital mortality for patients identified as Code Sepsis.

CHAPTER 2: LITERATURE REVIEW

2.1 Evolution of Current Sepsis Management

Early Goal Directed Therapy (EGDT) was introduced in a landmark study that evaluated the efficacy of a bundled approach to care for the patient with sepsis-induced hypoperfusion prior to admission to the ICU (Rivers, Nguyen, Havstad, Ressler, Muzzin, Knoblich, et al., 2001). EGDT consists of using intravenous fluids, vasopressors, packed red blood cells and inotropic agents to obtain and maintain certain hemodynamic values such as mean arterial pressure, CVP, and $Scv0_2$. Prior to Rivers' study, goal-directed therapy was only utilized in the ICU for severe sepsis and septic shock but not in the emergency department. By utilizing this approach upon arrival to the emergency department, Rivers demonstrated a 16% reduction in in-hospital mortality ($p = 0.009$) using EGDT. Kumar, Roberts, Wood, Light, Parrillo, Sharma, et al., (2006), found a positive relationship between delay in correct antibiotics and in-hospital mortality. They found finding that for each hour delay in administering antibiotics, there was a mean decrease in survival by 7.6%. Two other studies have found that antibiotic administration before shock recognition will lower hospital mortality when antibiotics are administered within one hour of onset of symptoms. (Puskarich, Trzeciak, Shapiro, Arnold, Horton, Studnek, et al., 2011; Ferrer, Artigas, Suarez, Palencia, Levy, Arenzana, et al., 2009).

Evaluating the outcomes of patients undergoing early sepsis resuscitation for cryptic shock (hyperlactatemia and normotension) compared with overt shock (hypotension), there was no difference in in-hospital mortality, length of stay or

complications between the two groups (Puskarich, Trzeciak, Shapiro, Heffner, Kline, & Jones, 2011). Mikkelsen, Miltiades, Gaieski, Goyal, Fuchs, Shah, et al. (2009) found a positive correlation with elevated serum lactate levels and mortality in severe sepsis that was independent of organ failure and shock.

2.2 Bundle Methodology to Direct Sepsis Management

Four studies have demonstrated a decrease in mortality and improved risk reduction in relation to 6-hour bundle compliance (Shiraszmizo, 2011; Shapiro et al., 2006; Nguyen, Corbett, Steele, Banta, Clark, Hayes, et al., 2007; Gao, Melody, Daniels, Giles, & Fox, 2005). Barochia, Xizhong, Vitberg, Suffredini, O'Grady, Banks, et al. (2010) performed a meta-analysis of 8 unblinded trials to assess the effects that goal-directed therapy had on mortality. The authors reported a positive correlation between the odds of surviving (OR, 1.91; 95% CI, 1.49 – 2.45; $p < 0.0001$) and receiving appropriate antibiotics (OR, 3.06; 95% CI, 1.69 – 5.53; $p = 0.0002$) with bundled care. Castellanos-Ortego, Suberviola, Garcia-Astudillo, Holanda, Ortiz, Llorca, et al. (2010) reported a positive correlation between survival and the number of bundle elements completed and that compliance with 6 or more bundle elements was an independent predictor of survival.

A meta-analysis was published in an attempt to analyze if early intervention with goal-directed therapy was more beneficial than later initiation (Gao, Wang, Bakker, Tang, & Liu, 2005). A total of thirteen randomized-controlled trials were included for a sum of 2,525 patients. The authors found that goal-directed therapy was associated with a 17% relative risk reduction on overall mortality for patients with sepsis within the first

6 hours of admission. The mortality benefit was not associated with trials where the goal-directed therapy was initiated late or undetermined.

Most recently, two randomized controlled trials have reported no significant difference in mortality utilizing early goal directed therapy versus protocolized care or usual care. The first of these two trials randomized three groups of patients with severe sepsis and septic shock (Yealy, Kellum, Juang, et al., 2014). Yealy et al. compared three arms: strict early goal-directed therapy, evidence-based protocolized care, and usual care. The authors found no statistical difference in 28-day mortality between these three groups. However, upon further review of the study, a few key components should be noted. Approximately 70% of the hospitals enrolled had prior established sepsis protocols with approximately 60% of all patients receiving central lines. Notably, all groups in the study started fluid and antibiotic treatment prior to randomization.

In October of 2014, the ARISE trial was published, also noting no statistical difference in 28-day mortality utilizing their two arms in the study (Peake, Delaney, Bailey, Bellomo, Cameron, Cooper, et al., 2014). The two arms consisted of a total of 1600 patients who received protocolized early-goal-directed therapy or standard usual care. It should be noted that prior to the implementation of the study, all facilities involved had no prior protocolized standard of care for this patient population. In this study, the exclusion criteria included patients with a life expectancy of less than 90 days or death that appeared to be imminent or inevitable. At baseline, both patient groups received significant amounts of intravenous fluids prior to randomization with on average of 34.6mL/kg in the EGDT group and 34.7mL/kg in the usual-care group. Once randomized the two groups received an additional, on average, 26.8mL/kg and

23.2mL/kg respectively within the first 6 hours. As noted previously, the Surviving Sepsis Guidelines states that patients should receive 30mL/kg of intravenous fluids, meaning that both arms received the minimum amount of fluid prior to randomization, not including the additional fluid they received after randomization. It should also be noted that both groups received antibiotics prior to randomization.

2.3 Telemedicine

The evidence supports the use of virtual telemedicine. Several studies have evaluated the impact that telemedicine has on mortality, length of stay, and complications. Young, Chan, Lu, Nallamothu, Sasson, & Cram (2011) performed a systematic review and meta-analysis evaluating the impact of telemedicine on patient outcomes. They found a positive correlation with lower ICU mortality and lower ICU length of stay but no correlation in hospital mortality or length of stay. In 2012, Wilcox and Adhikari did another systematic review and meta-analysis to evaluate the impact of telemedicine on patients outcomes. They reported a lower ICU and hospital mortality and a reduction in ICU and hospital length of stay. Lilly, Smyrnios, Heard, Hemeon, Emhoff, Bagley, et al., (2013) evaluated 118, 990 adult patients from 56 ICUs at 32 different hospitals. Hospital and ICU mortality was significantly lower in the intervention arm. The adjusted ICU length of stay was reduced by 1.1 days for those patients in the ICU for greater than 7 days. For those patients in the ICU for longer than 14 days, the adjusted ICU length of stay was reduced by 2.5 days and in the group of patients whose ICU stay was longer than 30 days, the adjusted ICU length of stay was reduced by 4.5 days. Four elements were identified as having the most effect on lowering mortality and ICU length of stay: intensivist review within one hour of

admission, appropriate use of performance data, adherence to evidenced-based standards of care, and faster alert response times.

To date, only one study has been performed utilizing a tele-ICU approach to standardize sepsis screening and management. Rincon, Bourke, and Seiver (2011) evaluated the feasibility of a tele-ICU nurse driven approach to improve early identification and treatment process. Over a two-year period, they were able to demonstrate a statistical significance in the compliance of antibiotic administration, serum lactate measurement, initial fluid bolus, and central line placement as compared to historical data.

2.4 Theoretical Framework

E.M. Rogers' Diffusion of Innovation Theory (1962) was the theoretical framework guiding this project (Appendix B). It discusses how over time a project will gain momentum, diffuse, and be adopted throughout an organization. This framework incorporates how people will choose, or not choose, to adopt an innovative change. Rogers describes that there are four main elements to the Diffusion of Innovation: innovation, communication channels, time, and the social system. The innovation is where an "idea, practice, or object is perceived as new by an individual or unit" (Rogers, 1962. p 11). The idea behind this is perception. Historically at this healthcare system, the patient with severe sepsis or septic shock was not considered as critically ill as patients with other disease processes such as an acute myocardial infarction. Because of this, there was a lack of urgency for the need to provide swift treatment or the belief that the patient did not require the full treatment bundle.

The second component to Rogers' theory, communication channels, deals with how parties receive information. Rogers states that individuals will receive information more effectively when they receive it from others that are like them, in characteristics, meaning, and language. This applies to the Code Sepsis population as common groups were identified between the key stakeholders: nurses, physicians, data analysts, administration, quality, and pharmacists. Instead of having one individual disseminate all of the information to everyone, multiple champions are designated to ensure that the message can be well received. The challenge that comes is getting that information to people who are not engaged. During the communication channel process, an individual will go through five stages: knowledge, persuasion, decision, implementation, and confirmation. Knowledge refers to when an individual receives and understands the information. Persuasion happens when the individual forms an opinion or attitude towards the innovation. Decision is when the individual chooses to adopt or reject the innovation. Implementation occurs when the individual participates in the innovation and confirmation occurs when they seek reinforcement for their decision of the innovation.

The third component is time. Rogers states that time is involved in a variety of ways. The first includes how long an individual will take to receive the information the first time and decides whether to accept or reject it. The second is how quickly or late they choose to adopt the innovation. The final piece to time is the rate of adoption for the system. In the healthcare system's Code Sepsis initiative, this has been seen in a variety of ways at the different hospitals, where one group of stakeholders will accept the initiative, such as the nurses, while the physicians will not, or where one hospital will reject the change while another facility will readily accept it in its entirety.

The fourth component to Roger's Diffusion of Innovation Theory, the social system, relates to "a set of interrelated units that are engaged in joint problem solving to accomplish a common goal" (Rogers, 1962. p 24). If there are barriers to accepting the change, what are the individual parties doing to collaborate and adopt? This has been an issue with central line placement for the Code Sepsis patient. Some facilities have the resources to place a central line but do not believe that all of these patients require one. There are other facilities that would like to place central lines in each of these patients but do not have the resources or manpower to do so. Some of the facilities have chosen to reject the central line placement while others have overcome the obstacles and provided additional training or an on-call schedule to ensure that all patients are getting each component to therapy.

Rogers created a distribution curve to show the occurrence of adoption to an innovation. It follows a bell-shaped curved and has normal distribution. It is divided into five categories: innovators, early adopters, early majority, late majority, and laggards. Innovators, only 2.5% of the group, are the people that are keen to new ideas and innovations but can make risky decisions. 13.5% of the group are considered the early adopters, who have the biggest influence on the group when others are looking for more information about the innovation. The early majority group will accept the innovation just prior to the rest of the system but not participate in a leadership role. The late majority are considered to be the skeptics and will adopt late in the stage and usually only after receiving organizational pressure. The laggards are the last to adopt the innovation and very resistant to change.

As briefly discussed in the above paragraphs, there are a number of barriers to change for this initiative. They include: belief of the science, sense of urgency for the bundle treatment, belief that each component to the bundle must be met, resistance to conform to a guideline and orderset. This Scholarly Project approached these barriers from two directions. The Sepsis Program Coordinator role was designed to establish a relationship with the facility and improve communication channels. Through this relationship, they enhanced education of the staff, followed-up with opportunities for improvement, and ensured the throughput of the patient from initiation to the end of the six-hour window. The VCC staff assisted with monitoring these patients when the bedside staff may not have had time to go through the chart and verify each bundle element was completed. If orders were needed for intravenous fluids or vasopressors, the VCC staff were able to input those orders in. If a central line had not been placed and was needed, the VCC physician would be able to have a one-on-one conversation with the bedside physician to discuss and strategize on how to accomplish this within the time frame allotted.

CHAPTER 3: METHODS

3.1 Project Design

This was a pre and post measure of an intervention designed to improve adherence to the standard of care and improve outcomes for the patient identified as Code Sepsis. The pre-intervention data was obtained from December 2013 through May 2014, prior to the implementation of the coordinators and VCC. This data was compared to the post-intervention period from June 2014 through December 31st 2014. Demographic characteristics were collected without patient identifiers, so anonymity was maintained. There was no direct contact with patients during this time and the data was retrieved from the electronic medical record and encrypted and stored on a secured database. IRB approval was received from the institution (APPENDIX C). Consent was waived for the patients involved in this project as this was a uniform system-wide change based on a standardized approach to clinical care.

3.2 Methodology

Participants

A patient met criteria for Code Sepsis when they were identified as having suspected infection and either a systolic blood pressure of less than 90 mmHg after fluid resuscitation or a serum lactate marker greater than 4mmol/L. All adult participants, aged 18 or older who met Code Sepsis Criteria at one of the 9 included facilities, were activated as a Code Sepsis via the Physician Connection Line (PCL) and admitted to an Intensive Care Unit were included in this project.

Setting

Nine hospitals participated in this project: one Level 1 Trauma center, four tertiary hospitals, and four community hospitals. Of the 9 hospitals, 4 received the services of the Sepsis Program Coordinators and VCC, 2 only had the coordinators, and the other 3 only had VCC.

Tools/Measures

The bundle compliance elements for Objectives 1, 2, and 3 were extracted from the electronic medical record using the patient account and medical record number. Objectives 4, 5, and 6 (length of stay, readmission, and mortality) were obtained through the administrative database called Premier. ICU length of stay observed-to-expected (O/E) data was obtained through the Philips database that is used for VCC. O/E ratio is a measure comparing what was observed for a specific patient population to what was expected for that same patient population and is presented here as a ratio. If the ratio is equal to 1.0, then the number of observed events, or time for LOS, equals that of expected events or time. If the number is less than 1.0, then there are a lower number of events than is expected and if the number is greater than 1.0, there are a higher number of events than is expected. The general formula for O/E is sum(observed values/events)/sum(expected values or events). Code Sepsis activation data was obtained through the Physician Connection Line (PCL) log. The PCL is the method used by facilities to activate a Code Sepsis at their respective facility. The PCL log data includes patient account number, medical record number, patient location at the time of Code Sepsis activation, time of code sepsis activation, and whether or not Code Sepsis was activated by VCC. SAS Enterprise Guide was used to calculate the statistical tests for

study outcomes that included t-test and Chi-squared test. The logic for computing bundle component compliance was built in SAS Enterprise Guide using the data output from Power Insight Explorer merged with the Code Sepsis log provided by the PCL.

The sample size computation was based on a desire to show an improvement of 10% in overall bundle compliance with the assumption that current compliance with the total treatment bundle was at 20%. The goal of improvement was determined based on the healthcare system's goal. A total sample size of N= 582 (pre-intervention n= 291 and post-intervention n= 291), was determined to be sufficient to detect a meaningful difference of 10% between the 2 groups using a 2 tailed z-test of proportions between the 2 groups with an 80% power and a 5% level of significance. This 10% difference would represent the 20% compliance pre intervention and 30% compliance with the intervention proposed.

The outcome objectives measured in each of the pre and post-intervention periods are described below:

(1) Objective 1 (p_3); defined as the percentage of patients receiving the first 3 hour bundle, defined as (i) initial lactate, (ii) blood cultures, (iii) antibiotics, and (iv) IVF bolus of at least 30mL/kg measured in each the pre and post-intervention groups

(2) Objective 2 (p_6); defined as the percentage of patients receiving the second 3 hour bundle, defined as (i) central venous pressure goal met (at least 1 measurement >8mmHg), and (ii) central venous oxygenation goal met (at least 1 measurement >70%); measured in each the pre and post-intervention groups

(3) Objective 3 (p_{all}); defined as the percentage of patients receiving the total bundle in 6 hours, defined by all six of the treatment components; measured in each of the pre and post-intervention groups.

(4) Objective 4; Length of Stay

   a. ICU length of stay: raw and risk-adjusted, with risk-adjusted outcomes determined using the Philips APACHE IV methodology

   b. Hospital length of stay: raw and risk-adjusted, with risk-adjusted outcomes determined using the Premier CareScience methodology

(5) Objective 5; Sepsis-related Readmission

   a. 30-day sepsis-related readmission rate: raw and risk-adjusted, with risk-adjusted outcomes determined using the Premier CareScience methodology

(6) Objective 6; Mortality

   a. Raw and risk-adjusted mortality, with risk-adjusted outcomes determined using the Premier CareScience methodology

Table 1: Database

The following data elements were collected for this project:

Data Element	
Process Measures	Number of Code Sepsis activations
	Central venous catheter placed within 6 hours of Time Zero • Percentage meeting goal and mean/median time to goal
	Length of stay • Days and O/E • Hospital (all) • ICU (O/E for VCC facilities only)
	30 Day Sepsis Readmission • Rate and O/E
	Extended length of stay
	Hospitalization after discharge from ICU >30 days
	Mortality • Rate and O/E
First 3 Hour	Lactate level result within 3 hours of Time Zero • Percentage meeting goal and mean/median time to goal
	Blood culture prior to antibiotic administration • Percentage meeting goal
	Antibiotics given • Percentage meeting goal and mean/median time to goal
	30mL/kg intravenous fluid administered within 3 hours of Time Zero • Percentage meeting goal and mean/median time to goal • Amount of fluid administered in 3 and 6 hours
Second 3 Hour	Central venous pressure goal met within 6 hours of Time Zero • Percentage meeting goal and mean/median time to goal
	Central venous oxygenation goal met within 6 hours of Time Zero • Percentage meeting goal and mean/median time to goal
Total 6 Hour	Entire treatment bundle completed within 6 hours of Time Zero • Percentage completing total bundle and average number of components complete

3.3 Project Analysis

Time Zero, marked as the start of the treatment bundle, was the time of Code Sepsis activation via the physician connection line (PCL). Compliance for the bundle and outcomes were measured for every patient activated through the PCL that was admitted to the ICU. For reporting of the first 3 hour, second 3 hour, and total 6 hour bundles, all elements must have been met in order to be considered compliant.

For (1), (2), and (3), a 2 tailed Z-test of proportions (Chi-square test) was used to compare $p_{3,\,pre}$ to $p_{3,\,post}$, where $p_{3,\,pre}$ and $p_{3,\,post}$ represented the percentage of patients who received the first 3 hour bundle in the pre and post-intervention periods respectively. The null hypothesis H_o was that $p_{3,\,pre} - p_{3,\,post} = 0$, the alternative hypothesis H_1 was that $p_{3,\,pre} - p_{3,\,post} \neq 0$. The same statistical test was used to evaluate $(p_{6,\,pre} - p_{6,\,post})$ and $(p_{all,pre} - p_{all,post})$.

Because the outcomes focused on the influence of the intervention on the *treatment of the patient*, comorbidities were not included in the analysis. Instead, the implementation of the initiatives focused on improving sepsis treatment as a single treatment effect, with an understanding that different aspects of the initiative may have had varying degrees of influence on the outcomes.

In an effort to provide timely data analysis, any patients with an ICU and/or hospital length of stay greater than 30 days were included in the raw data aggregate with a length of stay value of 30 days. These patients were removed from the risk-adjusted aggregate for both the pre and post intervention groups. Because the outcomes studied the influence of the treatment on the patient outcomes, the focus was placed on the risk-adjusted outcomes that allowed the ability to standardize across varying patient

populations to account for variation in pre and post-intervention patient acuity. This assisted in eliminating other explanatory variables that may have influenced a difference in outcomes across pre and post-intervention populations. ICU length of stay could only be measured at the hospitals monitored by VCC through their Philips database while hospital length of stay was reported for all nine hospitals.

CHAPTER 4: RESULTS

Project Findings

The purpose of this DNP Scholarly Project was to evaluate the 6-hour bundle compliance of Code Sepsis patients using VCC and Coordination. For the pre and post intervention, the total population for this project was 1806 patients, with 609 in the pre intervention group and 1197 in the post intervention group. Demographic data showed that 52.2% of patients were female and the mean age of the sample was 64 years with a median of 65 years and a range of 18 to 103 years.

For objective 1, defined as the percentage of patients receiving the first 3 hour bundle, the compliance increased from 47.8% in the pre-intervention group to 54.2% in the post-intervention group which represented an absolute difference of 6.4% (95% CI 1.6-11.3%, p-value = 0.01). For the first 3 hour bundle, intravenous fluid was the driving force that impacted overall increase in compliance. Lactate, antibiotics, and blood cultures reported no statistical difference from pre to post-intervention (94.7% vs 94%, 91.3% vs 91%, and 76.4% vs 76.5% respectively). Fluid, however, did increase 8.7% from 58.1% to 66.8% (95% CI 4.0% to 13.3%). This was statistically significant based on a chi-square difference of proportions test with a p-value = 0.0003.

For objective 2, defined as the percentage of patients receiving the second 3 hour bundle, the compliance increased from 10.8% in the pre-intervention group to 17% in the post-intervention group which represented an absolute difference of 6.2% (95% CI 2.7-9.7%, p-value = 0.001). For the second 3 hour bundle, $Scv0_2$ was the driving factor that

improved the overall increase in compliance. There was no significant difference in the CVP compliance for the patients from pre to post- intervention (36% to 33%, p=0.19). An improvement in the $ScvO_2$ goal, however was noted, with an increase from 14.0% to 24.3% ($p<0.0001$). It should also be noted that there was a reduction in CVC placement from 71.6% to 63.8% (p=0.0009). The marked increase in the $ScvO_2$ measure, despite the reduction in CVC placement, supported that $ScvO_2$ was the driver for the second 3 hour bundle compliance.

For objective 3, defined as the percentage of patients receiving the total bundle in 6 hours, the compliance increased from 5.8% in the pre-intervention group to 9.9% in the post-intervention group which represented an absolute difference of 4.24% (95% CI 1.5-6.9%, p-value = 0.003). With the noted improvement in the first and second 3 hour bundles, the total 6 hour bundle compliance almost doubled from the pre-intervention group.

There were several observations noted for objective 4, length of stay. ICU LOS could only be determined in the hospitals that received the services of VCC as they were able to use the Philips APACHE IV methodology. The raw ICU LOS decreased from 3.9 days in the pre-intervention group (n=315) to 3.6 days in the post-intervention group (n=708). This absolute difference of 0.29 days (95% CI -0.26-.85) was considered non-significant based on a t-test difference of means (p-value =0.30). The risk-adjusted results also showed no difference with an O/E of 0.78 in both the pre-intervention and post-intervention groups. When looking at just the survivors of the ICU LOS group, the raw ICU LOS decreased from 3.8 days in the pre-intervention group to 3.6 days in the post-intervention group. This absolute difference of 0.17 days (95% CI -0.44-.79) was

considered non-significant based on a t-test difference of means (p-value =0.58). The risk-adjusted results also showed no difference with an O/E of 0.79 in both the pre-intervention and post-intervention groups.

For hospital length of stay, using the Premier CareScience methodology, the raw data demonstrated a reduction in LOS from 8.4 days in the pre-intervention group to 8.2 days in the post-intervention group. This absolute difference of 0.16 days (95% CI -0.64-.98) was considered non-significant (p-value = 0.69). The risk-adjusted results demonstrated a reduction in hospital LOS from 1.3 in the pre-intervention group to 1.2 in the post-intervention group. However, among the survivors group, the hospital length of stay was reduced from 9.3 days in the pre-intervention group to 8.8 days in the post-intervention group. The absolute difference noted was 0.59 days (95% CI -0.34-1.58) and considered non-significant based on a t-test difference of means (p-value =0.21). The risk adjusted hospital LOS O/E was reduced from 1.3 in the pre-intervention group to 1.1 in the post-intervention group. With an average reduction in hospital LOS of just over ½ hospital day among survivors, a total of 1,011 hospital days were prevented. This assumption was supported by a reduction in the risk adjusted hospital LOS. Based on the minimum average cost per non-ICU hospital day at this hospital system, which is $370.00, the reduction in risk adjusted hospital LOS equated to a cost avoidance of $393,407.23 among survivors in the intervention population.

Objective 5, defined as 30-day sepsis readmission rate, was determined using the Premier CareScience methodology as well. The raw readmission rate was decreased from 18.2% in the pre-intervention group to 13.9% in the post-intervention group. The absolute difference of 4.1% (95% CI 0.0 – 8.3) was considered significant based on a chi-

square difference of proportions (p-value =0.05). When observing the risk-adjusted sepsis readmission rate, a reduction in O/E was noted from 1.21 in the pre-intervention group to 0.89 in the post-intervention group. Based on the average cost of $6,417.00 for a sepsis readmission, the reduction in risk adjusted readmission equated to a cost avoidance of $290,619.79 among survivors in the intervention population.

Objective 6 was defined as in-hospital mortality. The raw in-hospital mortality rate decreased from 25.3% in the pre-intervention group to 17% in the post-intervention group. The absolute difference of 8.3% (95% CI 4.5% - 12.2%) was significant based on a chi-square difference of proportions (p-value = <0.0001). The risk-adjusted in-hospital mortality rate was also noted to have decreased. The O/E in the pre-intervention group decreased from 1.02 to 0.74 in the post-intervention group. Given the observed baseline of the pre-intervention group, the observed mortality percentage in the post-intervention group should have been 23.8% instead of the actual mortality rate of 17%. This reduction in risk-adjusted mortality equates to 80 lives saved.

CHAPTER 5: DISCUSSION

5.1 Discussion of Results

This project was designed to measure the effect of the Sepsis Program Coordinators in combination with the Code Sepsis management algorithm of the VCC on the 6 hour bundle compliance of patients activated as Code Sepsis. This project supports current literature that a coordinated, systematic approach improves bundle compliance, hospital length of stay, readmission, and mortality.

Of the 1806 patients in the study, 1293 were activated as Code Sepsis in the ED. When comparing the measures and outcomes of patients activated in the Emergency Department (ED), an overall increase was observed in the first 3 hour, second 3 hour, and total 6 hour bundle compliance for the ED Code Sepsis activations, versus the Code Sepsis activations from the in-patient (IP) setting. The first three hour bundle improved from 54.9% to 64.9% (10%; 95% CI 4.4% - 15.6%, p-value 0.0004), with intravenous fluid being the driving factor. The second three hour bundle improved from 10.8% to 14.9% (4.2%; 95% CI 0.26% to 8.1%, p-value 0.04) and the entire six hour bundle improved from 6.9% to 11.6% (4.7%; 95% CI 1.3% to 8.2%, p-value 0.008). Mortality in the ED Code Sepsis activation group decreased from 22.7% to 15.2% (15.2%; 95% CI 12.8% to 17.6%, p-value 0.001).

It should be noted that VCC can only affect the first 3 hour bundle compliance of an ED activated Code Sepsis if the patient is transferred to the ICU before the 3 hour time window is completed as VCC is only utilized in the ICU. If the patient remains in the ED

for the entire 3 hours, then VCC cannot provide that support for the first 3 hour bundle. Of the 513 IP activations, the only significant improvement in bundle completion that was observed was the second 3 hour bundle that pertained to CVP and $Scv0_2$ measurement. An improvement in the second 3 hour bundle was observed from 11.1% to 22.3% (11.2%; 95% CI 4.2% to 18.3%, p-value 0.002) with the $Scv0_2$ measurement being the driving factor. The Mortality, in the IP Code Sepsis activation group, was also noted to decrease from 32% to 21.4% (10.6%; 95% CI 2.7% to 18.5%, p-value 0.01). There was a difference noted in baseline and intervention mortality rates between the ED Code Sepsis Activations and the IP Code Sepsis Activations. This could be due to issues with co-morbidities, delay in activation, as well as the focus of education and training being targeted solely towards the ED activation group.

The question to consider for future implications is whether the entire 6 hour bundle is necessary, which includes managing a patient with vasopressors, inotropic agents and packed red blood cells, or should the main focus be placed on early identification, timely antibiotic administration, and aggressive fluid resuscitation. While the latest research has reported no mortality difference between EGDT and standard of care, the studies demonstrated that each arm gave early antibiotics and aggressive intravenous fluids, which are essential elements to the first 3 hour bundle (Yealy et al., & Peake et al., 2014). Standard care in today's medical world is not the same as when Rivers' performed his landmark study almost 15 years ago. While the Surviving Sepsis Guidelines have not yet been changed, many hospitals, including the ones involved in this project, do not insert central lines into every patient who is activated as a Code Sepsis. The rationale for this is that IV antibiotics and fluids can be given succinctly and

simultaneously if a patient has at least two large bore IV catheters. In order for a CVP and $Scv0_2$ to be measured, a central line is required. In this project, central line insertion decreased from 69% to 59.4%. That is approximately the insertion rate for both studies by Peake et al. and Yealy et al. At best, the highest compliance rate one could get for the 2^{nd} 3 hour bundle would be limited to the central line insertion rate.

5.2 Limitations

There are several limitations to be noted with this project. This was an evaluation of implementation of a guideline at nine hospitals in one healthcare system. This project was designed to measure the contribution of VCC and the Sepsis Program Coordinators on adherence to sepsis guidelines using data from six months prior to VCC and Coordinator implementation to six months after implementation. The individual impact each strategy had on the overall improvement in compliance and outcomes was not assessed.

The sample comprised of adult patients who were activated as a Code Sepsis and admitted to the ICU. All Code Sepsis activations should meet the listed criteria of suspected infection and either hypotension after fluid resuscitation or a serum lactate of greater than four. However activation was provider driven, variations in the number of providers and their clinical assessment may have included patients that did not meet the full criteria or were activated by mistake as in the case of a patient having an elevated lactate from a seizure rather than from an infection. By requiring the patient to be admitted to the ICU, this helps to limit the possibility that the activation was not a mistake. The bias could also mean that the sample is missing patients who met Code Sepsis criteria but were not actually activated as a Code Sepsis by the provider. This area

of concern has been minimized through extensive education, accountability measures and case review feedback.

Another area of concern for bias is patient acuity of the pre and post intervention sample. If the acuity was higher in the pre-intervention than the post-intervention, then the results that were reported may not be as significant. To address this, an additional analysis was performed that looked into the seven facilities that were monitored by VCC. Acute Physiology and Chronic Health Evaluation IV (APACHE IV) scores were collected to compare the acuities of the pre and post-intervention group. APACHE is a validated tool that utilizes patient physiological data to determine acuity and mortality risk using patient-based critical care clinical markers (Knaus, Zimmerman, Wagner, Draper, & Lawrence, 1981). There was no statistical difference between the two groups in acuity. The analysis demonstrated that the patient acuities in both groups were similar therefore eliminating the bias that one group was sicker than the other.

Time Zero in this study may not match what other facilities in the country are doing. Time Zero, in this project, is registered when Code Sepsis is activated, which should happen as soon as the provider recognizes that the patient meets the listed criteria. There are some hospitals that use a patient's triage time as Time Zero for ED Code Sepsis activations. This project used the actual time the Code Sepsis was notified to the PCL for both ED and IP activations. The point of activation was elected as Time Zero for both populations due to the involvement of the VCC. They are notified when a Code Sepsis is activated, however, they have no way to ascertain quickly and efficiently whether the patient was identified in the ED or as an IP. Having a consistent Time Zero for both ED and IP activations ensures that the time points are the same for all activations. While

there are patients who come to the ED and meet Code Sepsis criteria upon arrival, some may not meet criteria for several hours. This would make bundle compliance difficult as the team is not actively working to meet those specific parameters based on a patient's triage time. The advantage to using activation time as Time Zero helps to ensure that the patient benefits from the full 3 hour time frame for implementation of the first bundle.

Another limitation to the project is the VCC algorithm and the amount of fluid volume replacement. When the intervention was implemented in July, there was not a data point that allowed for abstraction of "30mL/kg" of intravenous fluid in the electronic medical record. The solution was to use a calculated estimate based on an average patient size which was determined to be eighty-three kilograms and would require all patients to receive a minimum of 2,490 mL of intravenous fluid within the first three hours. The algorithm was designed to ensure that the patient received a minimum of 2500 mL of fluid. The barrier to this approach is that there are patients who may need more or less based off their body weight. Prior to the completion of the intervention period, improved data analytics allowed the ability to accurately abstract "30mL/kg" which is the recommendation. Regardless of the method used, the measure was administration of fluids.

5.3 Significance

Severe sepsis and septic shock is defined as a systemic infection leading to massive widespread vasodilation and poor tissue perfusion resulting in organ dysfunction and death. Cases have doubled in the last decade and mortality among this patient population remains approximately 25%. Through the use of the Surviving Sepsis Guidelines (Dellinger et al. 2012), a bundled approach to care for this population focuses

on timely antibiotics, administration of intravenous volume replacement, and invasive hemodynamic monitoring and management.

Early goal directed therapy, in its entirely, is currently being debated (Peake et al., Yealy et al., 2014); however, it has been recognized that early identification, timely antibiotics and administration of intravenous fluids are mainstays of therapy. This project supports a large body of evidence that a systematic, coordinated approach to caring for critically ill septic patients can offer improvements in mortality, length of stay, and readmission. Not only do patients benefit from this coordinated approach, health care systems do as well. In six months, this project demonstrated approximately $664,707 in cost avoidance through decreasing length of stay and preventing sepsis-related readmissions. Such cost avoidance can assist in providing Sepsis Program Coordinator salaries, educational tools, and other resources implemented to improve care outcomes to this patient population to improve implementation of guidelines.

5.4 Recommendations

As the focused intervention demonstrates an avoidance of healthcare costs, additional funds should be dedicated to hiring more Sepsis Program Coordinators to include extensive facility and onsite education and interaction. They are essential in identifying current gaps and barriers to practice, establishing a consistent structure for identification and management of this critically ill patient population, and establishing the necessary reporting structure to provide real-time feedback on Code Sepsis reviews to the nurses and physicians that were involved in the case. Their clinical knowledge and interpersonal communication skills leverages them to interact with all teammates and assists to establish credibility among their colleagues and hospital administration.

As the IP Code Sepsis activations were small in comparison to the ED activations and have less of an impact on bundle compliance and primary outcomes, a targeted approach should occur with floor nurses and general providers in earlier identification of this high-risk population. The Sepsis Program Coordinators targeted their education and interaction towards the ED Code Sepsis activations, so more work should be focused on reaching out to this population. As this project has shown, VCC can provide more impact with the 2nd 3 hour bundle for ED and ICU Code Sepsis activations. Further investigation would need to occur to determine why VCC had no statistical significant effect on the first 3 hour bundle for IP Code Sepsis since patients are expected to be transferred to the ICU within the 3 hour time limit. A targeted approach with increased education and timely communication to providers and nurses that is focused on ensuring the first 3 hour bundle compliance in the ICU is recommended as it has been identified as not significantly improving.

Further recommendations include ensuring every hospital has a standardized screening mechanism for patients with potential sepsis and also ensuring that Sepsis screening is performed during Rapid Response Team (RRT) events. Floor nurses should be trained to identify early signs of infection as this allows for earlier medical intervention thereby potentially reducing the chance of further deterioration. Each hospital should have a dedicated RRT with skilled nurses that are trained to rapidly assess, identify, and manage potential patients who are at risk for or are clinically deteriorating. By having a standardized screening process for sepsis including standing orders that allow for interventions such as blood cultures, lactate measurement, and

intravenous fluids, the RRT nurse can assist in identifying patients who meet Code Sepsis criteria.

Expanding the interventions performed by VCC can assist in meeting the guidelines. While VCC is typically only utilized in the ICU, it does have the capabilities to perform mobile monitoring through a portable camera and computer. This would allow the VCC staff to physically assess the patient and provide recommendations and orders for the RRT and help facilitate a quick transfer to the ICU if the patient's condition warrants it. This earlier contact and intervention may help to improve bundle compliance for the IP Code Sepsis activation population as well as further improve other outcomes.

More research should be performed to delineate which components of Early Goal Directed Therapy are most beneficial to improving a patient's mortality rate including determining if there is a particular patient population that would benefit from having all elements versus only the first three-hour bundle. These recommendations to therapy should be considered in updating the Surviving Sepsis Guidelines using the literature that has been recently or soon to be published.

5.5 Summary

A pre and post intervention project was performed at nine hospitals to evaluate the effect that Sepsis Program Coordinators and VCC had on improving bundle compliance, hospital and ICU length of stay, sepsis-related readmissions, and in-hospital mortality. This project demonstrated a statistically significant improvement in first 3-hour bundle compliance, second 3-hour bundle compliance, and total 6-hour bundle compliance. Approximately 45 readmissions were prevented with a cost avoidance of $290,619. Among the survivors, it was demonstrated that the intervention group avoided

1,011 hospital days for a cost avoidance of $374,088. There was also a reported reduction in mortality by 8.3% which demonstrated a total of 80 lives saved. Intravenous fluid administration was identified as having the most significant impact on 3-hour bundle compliance for the ED activated Code Sepsis Patients. For IP Code Sepsis activations, the only significant improvement in bundle compliance was determined to be the 2nd 3-hour bundle. This project supports current literature that a coordinated, systematic approach improves bundle compliance, hospital length of stay, readmission, and mortality.

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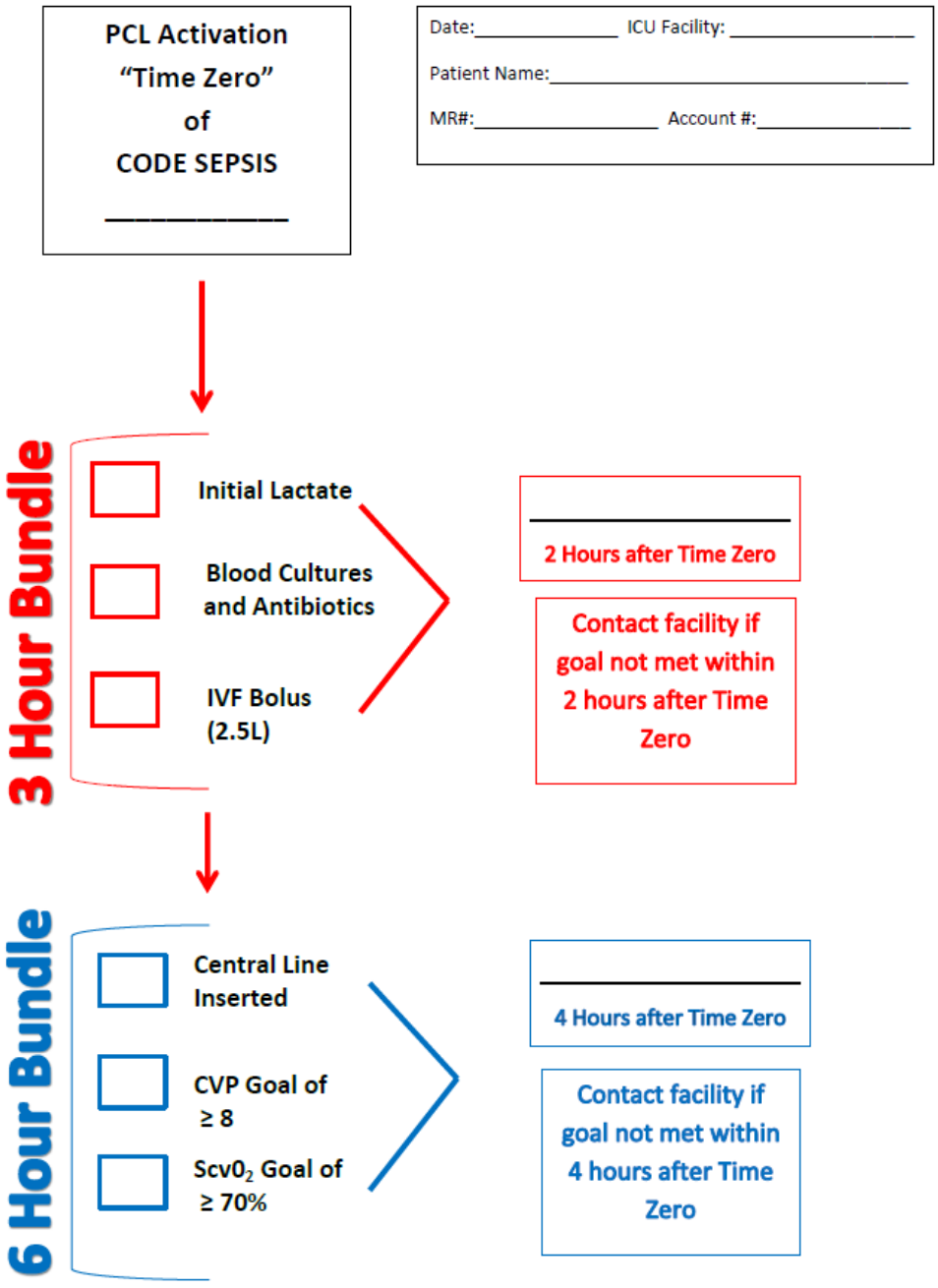
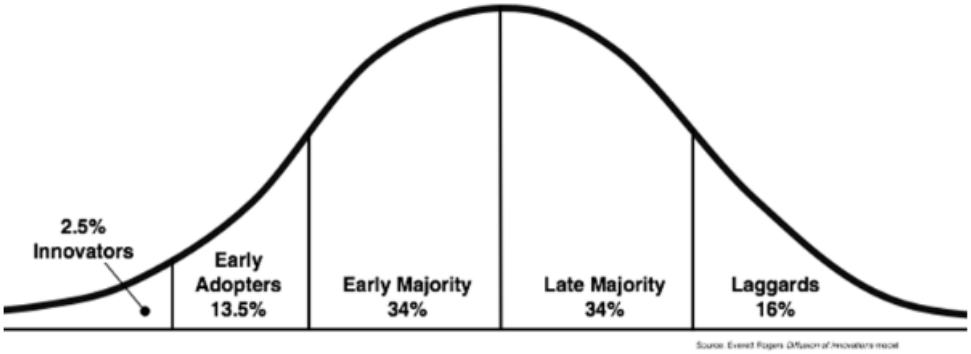
APPENDIX A: VCC ALGORITHM



APPENDIX B: EM ROGERS DIFFUSION OF INNOVATION MODEL



APPENDIX C: CAROLINAS HEALTHCARE SYSTEM IRB APPROVAL

Carolinas HealthCare System

June 18, 2014

Erika Gabbard, MSN, RN
CHS Critical Care Network
11532 Ardrey Crest Drive
Charlotte, NC 28227

RE: Improving 6-Hour Bundle Adherence of Patients with Severe Sepsis and Septic Shock

IRB File # 06-14-23EX

Dear Ms. Gabbard

I reviewed your proposal (dated original) and your flyer and determined your study meets the criteria for exempt status set forth in Code of Federal Regulations Title 45 Part 46 § 101(b), Categories # 2: Anonymous observations recorded in such a manner that the subjects cannot be identified directly or indirectly and # 4: Collection of data that will be recorded in a manner that the subjects cannot be identified directly or indirectly.

Any changes to the research study must be presented to the IRB for approval prior to implementation. If we can be of further assistance, feel free to contact the IRB Office, 704-355-3158.

Sincerely,

Sherry Laurent, PhD

Sherry Laurent, PhD
Chair, IRB

/cff

Note: The IRB complies with the requirements found in Part 56 of the 21 Code of Federal Regulations and Part 46 of the 45 Code of Federal Regulations. Federal-Wide Assurance # 00000387. The Registration Number is IORG 0000740. The Carolinas HealthCare System Institutional Review Board follows the ICH GCP guidelines with regard to the rights of human subjects.