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PRE AND POST IMPLEMENTATION EVALUATION OF AN EMERGENCY
DEPARTMENT SEVERE SEPSIS ALERT AND PRACTICE PROTOCOL

by

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A thesis submitted in partial fulfillment of the requirements
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ABSTRACT

Severe sepsis kills an estimated 1,400 people worldwide every day. This often fatal infectious process accounts for an estimated 215,000 deaths in the United States (US) annually.

The main goal of this project was to evaluate the impact of the Emergency Department Severe Sepsis Alert and Practice Protocol (EDSSAPP) post implementation, on time to first antibiotic administration, length of stay, and mortality in patients admitted via the ORMC ED with severe sepsis.

This study evaluated the time to first antibiotic administration, total ED and hospital length of stay (LOS) and mortality of severe sepsis patients either with a severe sepsis alert (SSA) activated or no alert activated that were admitted to the hospital through the ED. A retrospective review of the electronic medical record (EMR) was conducted to gather the required data across three time cohorts: base line/time zero (T0), six months prior to the implementation of EDSSAPP; Time one (T1) the first six months following initial EDSSAPP implementation; and Time two (T2), six months following reinstatement of the corporate sepsis committee.

The most significant finding of this study was the increased number of Severe Sepsis Alerts activated in time cohort T2 (n=113) compared to T1 (n=19). Another important finding was the decreased mortality in T2 (16.4%) compared to T0 (22.7%) and T1 (33%). Overall, the number of ED patients with severe sepsis who received antibiotics within the EDSSAPP required 60 minutes did not consistently improve across the three time cohorts, T0 (81.8%), T1 (71.7%) and T2 (80.6%).

The hospital LOS of stay was increased by almost 1.5 days between those patients with a severe sepsis alert activated in T1 (9.00 days) compared to time T2 (10.48 days). There was no

significant decrease in the ED LOS across time cohorts and between groups of patients who had a SSA activated versus no alert activated. However, there was a 1 hour and 28 minute decrease in ED LOS in patients who had a severe sepsis alert activated in T1 compared to T0. In addition, there was a 1 hour and 52 minutes decrease in ED LOS between patients who had a SSA activated compared to those who had no alert activated in T2.

While EDSSAPP data does not demonstrate the statistically significant results that was expected, the challenges related to adherence by providers to EDSSAPP is as it is seen in the literature. Increased awareness via consistent communication of on-going audit results to ED personnel will heighten their awareness for severe sepsis and EDSSAPP. Improved collaborative efforts with the interdisciplinary team are needed to refocus everyone's efforts to increase early recognition that is followed by appropriate treatment interventions and documentation is essential. Lastly, the development of a formal process to follow up with individual providers as close to real time as possible following a SSA that includes accountability for care provided and related documentation would also contribute to both awareness and adherence.

“If you don't know where you're going, any road will get you there”
~ Cheshire Cat, Alice In Wonderland.

Without a doubt the road to completing my doctoral education has been a challenge. Having a goal in mind is only half the battle, it is also important to know the right road to take to get there. It is clear to me that you must be willing make turns in order to stay on the right path and more importantly, this is a road **NOT** traveled alone.

I wish to dedicate this thesis to my family, first and foremost my husband Larry, for without his loving support coordinating our busy home and life activities, I would have not been able to concentrate on my thesis. Next, I would like to thank our children and all of our wonderful grandchildren who amaze and inspire me every day.

I would also like to thank our very special friends Dannie and Tancy Stanbery, “River Time” is the BEST!!

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It is also important for me to recognize my Co-Investigator Katrin Breault BSN, RN, CEN and our sub-investigators Meredith Mahar BSN, RN and Jennifer Donovan ASN, RN, CEN for without their help the review of all those EMR's would have been incredibly more tedious. Katrin's and my very special "Sepsis Sundays" will always hold a dear place in my heart.

I would also like to express my very heartfelt thank you to the Emergency Department Leadership Team and Staff: RN's, Paramedics, Advanced Clinical Technicians, Unit Secretary's and Guest Services, Physicians and Residents, your hard work and dedication to our patients and their families is unequalled.

Last but certainly not least I have a very special thank you for Patty Geddie MS, CNS, AOCNS my friend, my CNS colleague and fellow doctoral student. I appreciate your help, support, and encouragement not to mention the many HOURS of data entry, review, confirmation and analysis. You are amazing and I am proud to be your friend and colleague.

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CHAPTER ONE: INTRODUCTION

Background/Scope of the Problem

Severe sepsis, commonly known as blood poisoning, is a serious health threat killing an estimated 1,400 people worldwide each day (<http://ssc.sccm.org/background/worldsoldestkiller> retrieved 7/4/12). Sepsis is the 10th leading cause of death in industrialized countries, killing as many people each year as does acute myocardial infarctions (Marshall, 2008). In addition, it is suspected that 80% of patients who died from major injuries actually succumbed from severe sepsis (<http://ssc.sccm.org/background/worldsoldestkiller>). Despite substantial research and significant advances in technology and treatment, severe sepsis continues to be deadly, with mortality rates ranging from 30 to 50% (Shorr, Micek, Jackson & Kollef, 2007). This fatal infectious process accounts for an estimated 215,000 deaths in the United States (US) annually (Rezende et al., 2008). From 1999 to 2005 approximately 6% of all US deaths were related to severe sepsis; however, it is important to note that secondary to documentation and reporting variances, the National Center for Health Statistics believes that this number may be grossly underestimated (Melamed & Sorvillo, 2009). Data from 2009 demonstrate that in the US alone, the economic and social burdens to society resulting from the direct costs of caring for the severe sepsis patient population is approximately \$17 billion (Silva & Araujo, 2009). The indirect costs to society are thought to be somewhere between \$34 and \$51 billion annually. As the US population continues to age, deaths from severe sepsis are only expected to increase (Melamed & Sorvillo, 2009). Severe sepsis was the leading cause of death for hospitalized patients in the US between 2003 and 2007 with the number of in-patient deaths increasing an alarming 35% and associated hospital costs increasing an estimated 57% (Lagu et al., 2012).

The History and Definition of Severe Sepsis

As early as 400 BC, Hippocrates described sepsis by saying that living tissue could be broken down in the body by one of two very different ways (Marshall, 2008). The first he called Pepsis; this was a healthy process, one that resulted in digestion of food and in nature caused the fermentation of grapes into wine. The second process he called Sepsis, where flesh becomes rotten and wounds festered. Hippocrates considered sepsis an evil process producing disease in man. In nature sepsis was thought to be responsible for the stench in swamps. These beliefs, as expressed by Hippocrates stood as one basis for understanding diseases for two thousand years. Another contribution to the understanding of sepsis was described by Galen of Pergamon (130 – 200 AD). Galen named the “cardinal signs of inflammation: rubor, calor, dolor and tumor” (p. 471). Red, hot, and painful are today still considered the signs of an infectious process. A fifth symptom of inflammation, loss of function, was later added by Celsius. Hippocrates, Galen and Celsius’s conclusions remain foundational concepts regarding how diseases inflicted humans and caused life threatening physiological changes until the late 1800’s when the Pasteur Institute of France began the tedious task of exploring and understanding the complex microbial pathophysiology of infections.

Despite the medical community’s growing knowledge of infectious diseases, there continues to be challenges encountered when caring for septic patients. Rather than addressing each patient’s unique immune response to the infectious process, the treatment for this patient population has continued to focus on ways to identify and kill the invading organisms. According to Warren (2010) “it isn’t the replication of bacteria in animals or humans that kills us, but rather the consequences related to the inflammatory response” (p.14). He goes on to describe the septic patient’s response to this process as a delicate balance between the patient not

responding with enough inflammation to fight the invading microbes as in the immune-compromised patient or in patients with a chronic infectious process. In contrast, Warren noted that the patient who experiences an excessive inflammatory response may rapidly advance into severe sepsis. Therefore, health is not only the lack of disease, but also regulation of the body's inflammatory response to the presence of foreign organisms. The patient's symptoms of sepsis are not initially caused by any injury or damage directly from the invading organisms, but rather the physiological response to the presence of organisms in the body. This conclusion supports the concept that, at least initially, the patient's symptoms are a result of the invasion, and not widespread cellular damage from the offender. This new perspective increases the opportunities for innovative treatment possibilities (Marshall, 2008). While the patient's actual inflammatory response is responsible for symptoms of severe sepsis, identifying the exact initial cause or any contributing immune system compromise leading to the rapid advancement of the illness may not be easily identified.

The Symptoms and Treatment of Severe Sepsis

It is important to note that there is no one single organism responsible for severe sepsis. These infections may be caused by bacteria, viruses or fungi (Martin, Mannino, Eaton & Moss, 2003). The symptoms of severe sepsis such as an altered mental status, tachycardia, fever, and hypotension are also seen in many other medical conditions; therefore caution must be taken in order to avoid misdiagnosis. Treating these patients by choosing the most effective antimicrobial medication to counteract the suspected cause of the illness is not a simple decision. Healthcare providers must, like a puzzle, analyze the symptoms and maintain a high index of suspicion for sepsis. The healthcare provider is also obligated to consider many additional treatment options

and choose the interventions that they believe will achieve a positive outcome. On occasion, there are legitimate concerns that treatment decisions are made based on traditional approaches, rather than current evidence (Kollef & Micek, 2010). Treatment can be focused on reducing the patient's systemic inflammatory response or may be aimed at killing the identified invading organism (Bone et al., 1992), or both. In 2005, the American Thoracic Society and the Infectious Disease Society of America collaborated to identify the most appropriate antimicrobial therapy for the treatment of nosocomial pneumonia. While choosing the appropriate antimicrobial may appear to be a simple concept, the recommending group believed there was clear evidence to the contrary based on evidence of poor patient outcomes. In addition to choosing the most appropriate antimicrobial agent, the timing of this treatment has also been determined to be an important key to the patient's chance for survival. Every hour that passes without the administration of the appropriate antimicrobial medication the patient's chance of survival decreases 7.6%.

Severe sepsis creates a wide variety of symptoms which can mimic many other medical conditions, making a definitive diagnosis and initiating treatment an ongoing challenge (Raghavan & Marik, 2006). In addition, each individual patient's response to the invading microbes is also influenced by many contributing factors such as the patient's age, the status of the immune system, and the presence of any pre-existing co-morbidities. There is however, no question that severe sepsis can lead to single or multiple organ dysfunction, multisystem organ failure, and death, and the number of lives lost secondary to sepsis can be reduced using the Surviving Sepsis Campaign (SSC) guidelines. A worldwide campaign was launched to provide education and improve compliance with these guidelines for the treatment of sepsis.

The Surviving Sepsis Campaign

The established signs of inflammation, along with the understanding of microbes as causes of sickness, have remained basic fundamental theories of infections until the Barcelona Declaration in 2002. This conference resulted in increased attention to severe sepsis and spurred new interest and an increased the sense of urgency to learn more and find answers (Marshall, 2008). At this international meeting of intensive care specialists, members of three of the world's leading professional medical organizations – the European Society of Intensive Care Medicine, the Society of Critical Care Medicine (SCCM), and the International Sepsis Forum joined forces to work together to improve both the recognition and the treatment of severe sepsis. This united group of healthcare professionals acknowledged the costs to the world's society were high both in the number of human lives lost and the corresponding societal financial burden. This group agreed that increased awareness by healthcare providers was an absolute necessity to achieve an early and accurate diagnosis of severe sepsis followed by the appropriate and timely treatment. The Barcelona Declaration had one simple yet ambitious primary objective: improve severe sepsis patient survival by 25% worldwide by 2009 (Rivers & Ahrens, 2008). The SSC was developed and the group elected to move forward in four phases.

Phase one began in October of 2002 following the Barcelona Declaration. After both discussion and debate the group agreed that the universal definition of severe sepsis was the body's systemic response to an overwhelming infection resulting in hypo-perfusion that can rapidly cause organ failure and death (Bone et al., 1992). The phase one goal was to globally communicate and educate by publishing the SSC components related to the importance of early recognition and treatment of severe sepsis.

The SSC second phase began in 2003 when selected international experts in critical care and infectious disease collaborated to develop and publish severe sepsis treatment guidelines (<http://www.survivingsepsis.org/guidelines/Pages/default.aspx>). In early 2004 these guidelines were completed and recommended for adoption and implementation into clinical practice for this patient population. The guidelines were up-dated in 2008 and a summary of these guidelines are presented in Appendix A. While the SSC guidelines were again updated and released in the Spring of 2013 it is the 2008 guidelines that will be used for this study as these were the guidelines available during the inception and implementation of Emergency Department Severe Sepsis Alert and Practice Protocol (EDSSAPP) in the participating facility.

The main objective of phase three was for the consortium promoting SSC to collaborate with the Institute for Healthcare Improvement (IHI), a not-for-profit independent organization whose main focus is helping leaders and healthcare providers worldwide to find ways to change the delivery of care in order to provide both safe and quality care to all who access the healthcare system (<http://www.ihl.org/explore/Sepsis/Pages/default.aspx>). Through this strategic partnership, sepsis bundles were developed using the evidence-based guidelines previously introduced in the SSC. A bundle consists of a group of evidence-based interventions that when implemented together can improve the patient's outcomes. Bundles have become an important tool for health care providers. One important goal in developing the sepsis bundle was to make it user friendly and easy for providers to implement into their daily practice. The concept of Early Goal Directed Therapy (EGDT) was first described for the treatment severe sepsis and septic shock patients by Rivers et al. in 2001. Jones, Shapiro & Roshon, (2007) identified the unique challenges faced by ED's in both community and academic medical facilities in implementing EGDT. This study noted that severe sepsis and septic shock had high mortality rates along with

significant facility resource utilization. In addition, they concluded that early recognition combined with EGDT improved patient outcomes. EGDT in severe sepsis and septic shock is an important tool to improve patient outcomes and saves lives. The key to implementation of EGDT is dependent on the clinician's ability to recognize the patient as having severe sepsis or septic shock. Part of this recognition includes evaluating the patient for specific criteria as defined in the SSC guidelines, such as a serum lactate greater than four, a systolic blood pressure less than 90 mm Hg and a change in level of consciousness. According to Dellinger et al. (2008) early goal-directed resuscitation improves survival for emergency department patients presenting with septic shock.

In addition, a central data collection process was developed by the SSC program (<http://www.survivingsepsis.org/Data-Collection>) so that participating facilities worldwide could enter information and results to determine if the SSC was making a difference and improving the care of severe sepsis patients. Tools were developed as a resource for users to produce graphs of their facilities' data to help demonstrate their improvements (<http://www.survivingsepsis.org/Resources/Pages/default.aspx>). SSC guidelines and bundles were reviewed, revised and updated along with links provided on the websites where the most current sepsis information can be obtained. One link provided on the site is to the *Advances in Sepsis* (<http://www.advancesinsepsis.com/>) web site that has many of the current international leading medical experts as contributing authors.

Phase four includes continuing to update the SSC program based on new evidence, as well as continuing the efforts to educate healthcare providers worldwide. In addition, an analysis of the data entered into the SSC website from 15,000 severe sepsis patient records was conducted and published: *The Surviving Sepsis Campaign: Results of an international guideline-based*

performance improvement program targeting severe sepsis (Levy et al., 2010). This analysis validated results that patient outcomes were improved when SSC bundles were implemented.

The Role of Evidence-Based Practice in the Treatment of Severe Sepsis

Providing safe and quality patient care is a foundational principle for healthcare today and one important way to accomplish this is through the use of evidence-based practice (EBP). This term was first discussed in 1972 by the English medical researcher, Dr. Archie Cochran (Melnyk & Fineout-Overholt, 2011). Dr. Cochran strongly believed the best empirical evidence to support appropriate care came from randomized clinical trials. He further contended that there should be systematic and rigorous reviews of research in order to find the most effective treatments. It is important for healthcare providers today to combine EBP with sound clinical judgment and collaboration with the patient (Dontje, 2007). While there are still some healthcare providers who continue to feel that EBP is a “cookie cutter approach,” professional healthcare organizations have embraced it, issuing best practice guidelines based upon EBP principles.

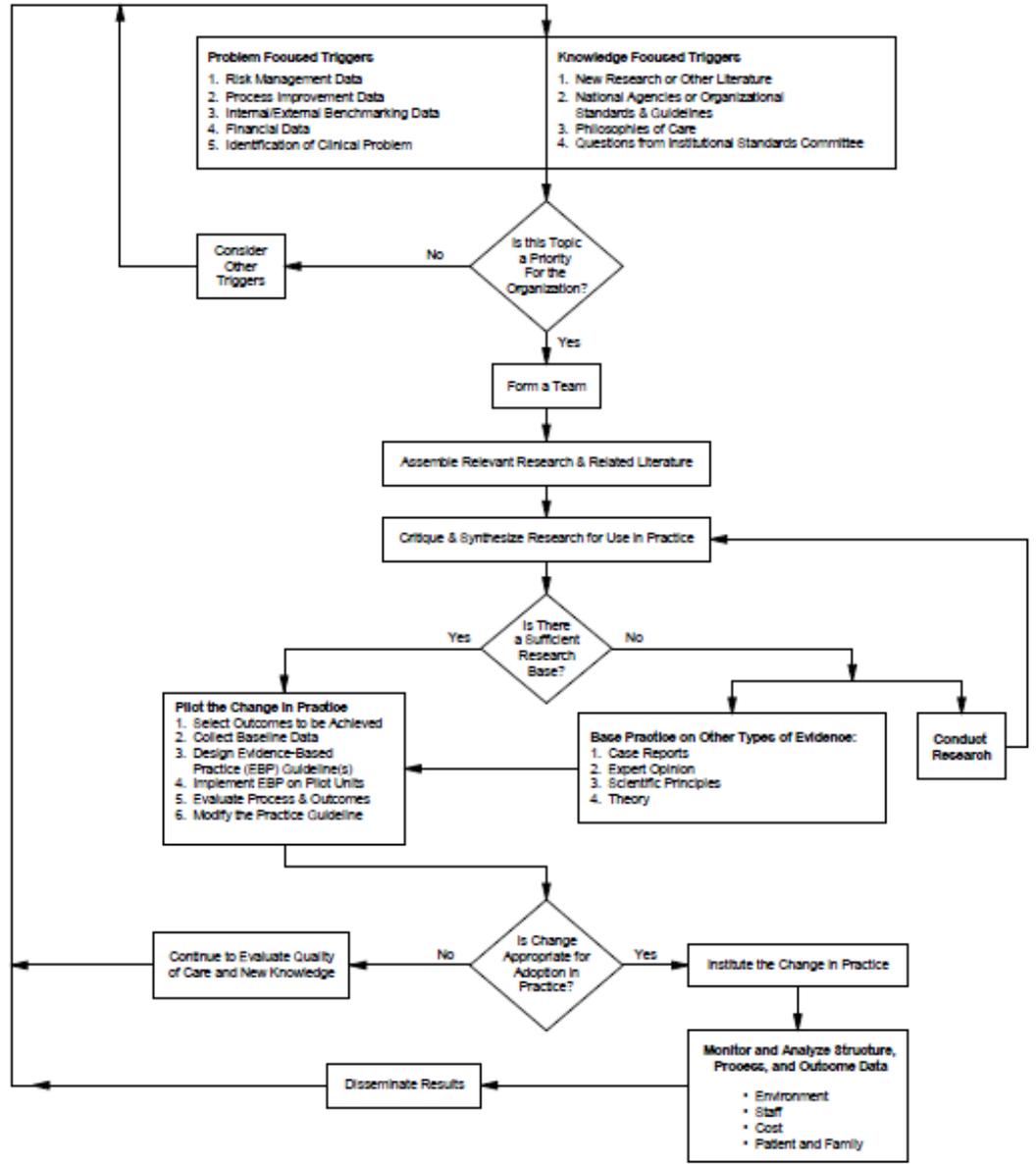
In addition, EBP has become an accreditation standard and incorporated into accreditation review by agencies such as The Joint Commission (TJC). As an example, TJC establishes National Patient Safety Goals based on merit, cost and effectiveness. These goals are promoted as an accreditation standard and enforced through the accreditation review process.

Implementation of EBP requires interdisciplinary collaboration between healthcare professionals. It is integral to patient care management and impacts patient outcomes. Almost 70% of patient adverse events occur due to lack of collaboration and communication between providers (Fewster-Thuente & Velsor-Friedrich, 2008). Collaboration and communication are

improved with the use of standardized, evidence-based guidelines developed through an organized process.

Multiple frameworks have been provided intended to organize process of developing evidence-based guidelines. Examples include those proposed by Melynk and Fineout-Overholt (2011), Rosswurm and Larrabee (1999), Stetler (2001), and Johns Hopkins Hospitals and Clinics (Newhouse, Dearholt & Poe, 2005). The Iowa Model (Figure 1) is representative of the processes discussed in these models. This model is used/reprinted with permission from the University of Iowa Hospitals and Clinics and Marita G. Titler PhD, RN, FAAN, copyright 1998 (Appendix B). It offers the healthcare provider a logical sequential flow to follow in an easy to read algorithm. In 2010 the Advanced Practice Nursing department at Orlando Health adopted the Iowa model as the preferred process to follow when considering the implementation of EBP process changes at this system. It is important to note that the Iowa model was not used during the development of EDSSAPP as this process was initiated in 2009 prior to the model's selection by this healthcare system.

**The Iowa Model of
Evidence-Based Practice to Promote Quality Care**



◊ = a decision point

Reference
 Tifler, M.G., Kleiber, C., Steelman, V.J., Rakei, B.A., Budreau, G., Everett, L.Q., Buckwalter, K.C., Tripp-Reimer, T., & Goode C. (2001). The Iowa Model of Evidence-Based Practice to Promote Quality Care. *Critical Care Nursing Clinics of North America*, 13(4), 407-500.

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Figure 1: The Iowa model of evidence-based practice to promote quality care

The following discussion is a comparison of the EDSSAPP process development with the steps of the Iowa model. This review was conducted in order to determine if the EDSSAPP process development correlated with EBP implementation guidelines as seen in the Iowa model. This evaluation demonstrated that the steps followed in EDSSAPP evolution mirrored the Iowa model up to the point of evaluation and dissemination of results.

The Iowa Model process begins with the identification of a trigger or clinical problem. In this case Orlando Health, using the SSC materials began looking at ways to improve the early identification of severe sepsis and combine this with timely and appropriate treatment. Organizational data confirmed suspicions that severe sepsis was indeed a threat to patients in this hospital system just as discussed in the international literature. The next step, following this model, was to determine the relevance of this severe sepsis project to the healthcare organization's mission and strategic plan. The significance of severe sepsis at this organization had previously been acknowledged in 2006 prior to the SCCM's presentation of the SSC so the problem or trigger had previously been identified as pertinent and continues to be in line with the organization's goal to decrease mortality.

Next, the Iowa Model algorithm calls for the formation of a team to gather and review evidence related to the identified problem. A multidisciplinary team was formed to develop this process in the Orlando Regional Medical Center (ORMC) Emergency Department (ED). Once the literature was evaluated, synthesized and ranked, the team determined what if any practice changes were necessary. Once this foundational work had been completed, the team agreed on the desired outcomes and corresponding EBP guidelines and an order set was developed. This ED's multidisciplinary team carefully reviewed and discussed the SSC's initial resuscitation bundle (Appendix C) addressing the first six hours of care and from these developed EDSSAPP.

Care was taken to ensure each component of the SSC bundle was reviewed, addressed and adapted as appropriate in both the treatment protocol and order set developed for implementation in our ED setting.

The Iowa Model states that the team may determine if it is best to first pilot the proposed process changes prior to full implementation. A pilot allows for the team to evaluate the process and to receive feedback from the frontline healthcare providers prior to full implementation. The ED team determined that the EDSSAPP process being introduced followed similar existing processes already used in the trauma and cardiac populations; therefore a trial or pilot was not needed. The next step post implementation is to carefully evaluate if this new process has changed practice and improved patient outcomes. As there was no pilot of EDSSAPP the next step for this team was to develop a formal process to continually monitor and evaluate EDSSAPP data and implement changes as necessary.

The Iowa model's last step is to recognize and address any identified challenges related to the changes made or EBP processes implemented. When EDSSAPP was first implemented a process was put into place to gather data on each of the ED patients that had a Severe Sepsis Alert (SSA) activated. Despite the collection of SSA patient's data there has not been any formal evaluation conducted related to this EDSSAPP data. This study is an objective evaluation of EDSSAPP and its impact on the severe sepsis patient population in this ED. According to the Iowa Model it is important for key members of the team to actively, continually and closely monitor the process and associated data that demonstrate the healthcare team's adherence to following the process and determining if any changes are necessary to sustain the evidence based practice changes. It is essential to communicate the ongoing data results with the entire healthcare team in order to encourage adherence and move forward to a sustained culture

change. It is this step in the Iowa Model that this severe sepsis study will complete, an evaluation and dissemination of the data at different time intervals since its original implementation to determine the impact it has had on this patient population's morbidity and mortality in this healthcare system.

Severe Sepsis Challenges in Emergency Departments

As established, the appropriate treatment of sepsis is time sensitive. Studies conducted by the SCCM and others have demonstrated the importance of early interventions with standard practice protocols and guidelines in order to improve outcomes for septic patients. One excellent example of successful implementation of the SSC program was in 2010 at the Catholic Healthcare West healthcare system (Rauber, 2010). This facility reported that three years after implementing the SSC guidelines a reduction of inpatient death rates by 33%, as well as a decrease on healthcare costs by \$36.5 million. Unfortunately, the Emergency Department (ED) is especially challenged to implement time-sensitive protocols.

Since 1990 the number of hospital-based emergency departments in the U.S. has declined by 27% while the number of patient visits has increased by 30% (Hsia, Kellermann & Shen, 2011). Between 1998 and 2008 there were more than 123 million visits to our nation's ED's. As the world's economy continues to struggle, there are increasing numbers of uninsured and underinsured individuals seeking healthcare in ED's. The Emergency Medical Treatment and Active Labor Act (EMTALA), a federal anti-dumping law passed in 1986 requires ED's to do a medical screening exam on all patients seeking emergency medical care, regardless of their ability to pay. These challenging economic conditions make the nations' ED's a "safety net" for the entire healthcare system. As ED patient volumes and acuities continue to increase, so do

delays in treatments and department overcrowding. It is not uncommon for ED's to care for admitted patients for extended periods of time while waiting for inpatient beds to become available. These throughput challenges can potentially contribute to the quality of care provided to patients seeking care in the ED. Clark and Normile (2007) noted in a 2003 Government Accounting Office report that the most common cause of delayed admission to the hospital was holding admitted patients in the ED due to a lack of critical care bed availability. The ED is simply not designed or staffed to care for patients over extended periods of time, especially critically ill or injured patients (Chalfin et al., 2007).

The Orlando Health Project

In response to the call for increased awareness and action, in October 2006 the SCCM presented the SSC to a select gathering of clinical leaders at Orlando Health. Following this introduction, corporate-wide teams were formed to develop a system-wide educational program based on the SSC materials. The primary educational goal was to teach clinical personnel to "Recognize, Respond and Rescue" septic patients at all the facilities in the Orlando Health system (Orlando Health Computer Assisted Instruction Program, 2007).

Once the educational process was in place and clinical provider education underway the next step was to establish teams to evaluate clinical areas for potential process changes that would include the SSC guidelines. Pertinent to the prominent role of the ED in early detection of sepsis, in February 2008 the ORMC ED/Level One Trauma Center sepsis team was formed. This multidisciplinary group included the following ED personnel: clinical pharmacist, phlebotomist, staff Registered Nurse (RN), Clinical Nurse Specialist (CNS), attending physician, and resident

physician. In addition, a representative from the hospital data/quality department also periodically participated.

In September 2009 the finalized Emergency Department Severe Sepsis Alert and Practice protocol (EDSSAPP) along with an order set based on the SSC guidelines were implemented in the ED (Appendix D). As recommended by the SSC the multi-disciplinary group that developed the EDSSAPP guidelines included an algorithm to increase early recognition of severe sepsis patients and initiation of EGDT. In addition, components of this protocol are intended to expedite the patient admission process.

Since the implementation of EDSSAPP there has been no formal evaluation of this process to determine the impact of this EBP-driven project on patient outcomes. For this reason a snap-shot audit data review was performed in 2010. Data were collected through a retrospective electronic medical record (EMR) audit of all Severe Sepsis Alerts called from the date of implementation: September 2009 to August 2010. For comparison purposes baseline data were also obtained from a retrospective EMR audit for the six months prior to the implementation of EDSSAPP. The data items collected at pre and post EDSSAPP implementation are noted in Table 1.

Table 1: Pre and post alert audit data items

Pre Alert	Post Alert
The shift of arrival	The shift of arrival
Gender	Gender
Time of arrival to time of first antibiotic given	Time of arrival to time of first antibiotic given
Average hospital length of stay	Average hospital length of stay

In order to ensure inter-rater reliability, all data were collected by the ED CNS and one ED staff nurse who volunteered to assist with the EDSSAPP project.

Early EDSSAPP Findings

As noted in the Table 2, between March and September of 2009 there were 37 patients admitted through the ED to a monitored unit at this facility with the diagnosis of severe sepsis or septic shock. For the first six months post implementation of EDSSAPP (from September 2009 to March 2010) there were 49 patients admitted to a monitored unit with the diagnosis of severe sepsis or septic shock and of these there were only 19 SSA's called. These data suggest that the EDSSAPP process was only being utilized approximately 38.7% of the time.

Table 2: Pre and post implementation audit data

Variables	Pre Implementation Data	Post Implementation Data
Time frame and number totals.	3/09 – 9/09: 37 patients admitted with diagnosis of severe sepsis/septic shock	9/09 – 3/10: 49 patients admitted with diagnosis of severe sepsis/septic shock 30 (61.2%) patients met severe sepsis/septic shock criteria and had NO ALERT called. 19 (38.7%) met severe sepsis/septic shock criteria and HAD ALERTS called.
Shift of arrival	7a – 7p: 73% 7p - 7a: 27%	7a – 7p: 55% 7p - 7a: 45%
Gender	27% Female 73% Male	32% Female 68% Male
Time of arrival to time of first antibiotic given	1 hour or less: 0% 1-2 hours: 9% 2-3 hours: 4.5% 3-4 hours: 3.2% Greater than 4 hours: 83.3%	1 hour or less: 73% 1-2 hours: 14% 2-3 hours: 4% 3-4 hours: 9% Greater than 4 hours: 0%
Average hospital length of stay	10.5 days	7.9 days

Discussion of EDSSAPP Audit Findings

Despite the fact that Severe Sepsis Alerts were not being initiated on all patients who met the criteria, there was improvement in processes related to treating severely septic patients. The one component that had the most significant change was the time to first antibiotic administration. The goal was to administer the antibiotic within one hour of the patient's arrival to the ED. The audit data demonstrated the numbers went from 0% antibiotics administered within one hour to 73% of ED severe sepsis patients receiving their initial antibiotics within in one hour of arrival to the ED. In addition, the data also showed the hospital had an overall decrease in length of stay for this population from 10.5 to 7.9 days during this time frame. These audit results were presented in a poster at the annual Emergency Nurses Association's Scientific Assembly in 2010 (Appendix E) and inspired the development of this study, ED staff involved in EDSSAPP determined it was time to have a formal evaluation of this process and decide if any changes are needed to improve the care of this patient population.

Doctor of Nursing Practice (DNP) Study Purpose

Despite worldwide educational efforts and advances in care, mortality in the sepsis patient population continues to remain high. While the snap shot audit data presented here indicates an improvement in the care provided to these patients, a more thorough assessment of data will assist in determining what, if any changes need to be made to the current educational programs or to the EDSSAPP process itself. Monitoring and evaluating EDSSAPP process using the Iowa Model as an organizing construct as discussed earlier will assist in determining the impact of this process change on patient and organizational outcomes. It is the purpose of this

thesis to conduct a retrospective analysis of data associated with the SSC campaign in the ED at ORMC in order to advise the organization and contribute to the profession.

The primary purpose of this study was to assess the effect of EDSSAPP implementation (alert-activated versus no alert- activated) on the time to first antibiotic administration, ED and hospital LOS, and mortality in severe sepsis patients admitted to the hospital through the ORMC ED across three time cohorts: 1) base line time zero (T0): six months prior to EDSSAPP implementation, 2) time one (T1): the first six months following the initial EDSSAPP implementation, and 3) time two (T2): six months following the reinstatement of the corporate sepsis committee.

CHAPTER TWO: LITERATURE REVIEW

Introduction

The foundations for the literature related to the assessment and treatment of severe sepsis and septic shock are derived from the 1991 collaborative work of the American College of Chest Physicians and the Society of Critical Care Medicine. In 1992 their work was added to a global initiative including efforts from the European Society of Intensive Care Medicine and the International Sepsis Forum to begin the “Surviving Sepsis Campaign” (Bone, et al., 1992). Research continues today to look for ways to diagnosis sepsis early and provide the most effective definitive treatment. As a result there is extensive literature available addressing severe sepsis and septic shock. Sepsis literature, specifically related to the unique challenges faced by emergency departments was also plentiful.

Orlando Health’s sepsis initiative did as the SSC recommended, implemented educational and process changes to “Recognize, Respond and Rescue” this vulnerable patient population. Information found throughout the literature mirrors the experiences at the ORMC ED during this process change. Now, following the Iowa model algorithm a study was conducted to determine if EDSSAPP has positively impacted patient outcomes.

The focus of this chapter is to discuss the review of literature addressing the barriers to and strategies for developing and implementing process change related to the care of severe sepsis patients in the ED, evaluate the currently available diagnostic laboratory testing for sepsis, and analyze post process change successes seen in the ED setting. Appendix F is the Literature Review Summary table.

Diagnostic Tools to Determine Severe Sepsis

Patients presenting with symptoms of severe sepsis or septic shock must not only have the history of their present illness determined, but their comprehensive medical history accurately obtained as well. One of the valuable tools available to the clinician to assist in determining the diagnosis of sepsis is laboratory testing. The following three serum tests-C-reactive protein (CRP), Lactate, and Procalcitonin (PCT) - are helpful in evaluating and determining if the patient is septic.

CRP is protein that is normally found in the blood and can be measured when inflammation is suspected. The challenge the clinician faces is that this level is also increased in other conditions: surgery, traumatic injuries, burns, or any inflammatory process. Therefore, CRP can increase the provider's suspicion for sepsis; however, it is not reliable as a definitive diagnostic test for sepsis (Lee et al., 2008).

Lactic acid (lactate) is the level of acid in the blood stream and was first measured in human serum in 1843 by Scherer while describing a patient in septic shock (Jansen et al 2009). Elevated lactate levels indicate anaerobic metabolism, a condition seen in patients with severe sepsis and septic shock. The clinician must use caution, however, when using lactate as an indication of sepsis as elevated levels may also be seen in patients following strenuous exercise, in patients with liver disease, kidney disease or heart failure. In 2009 Arnold et al. looked at lactate levels and found that the earlier a patient can normalize the lactate level, the higher the probability they would survive. The authors' conclusions were that following a patient's lactate levels and making efforts at lowering the value a priority for continued treatment are an important component of care in the septic patient population. However, Jansen et al. (also in 2009) conducted systematic review of the technology related to lactic acid measurements and its

reliability in assisting to make a diagnosis of sepsis and found this finding to be questionable. While this study questioned lactate levels' reliability in diagnosing severe sepsis, the authors did agree that this has a place in the assessment and treatment of septic patients and should be just one tool used to assist, but not replace the clinician's assessment or clinical judgment. Vanzant and Schmelzer (2011) also evaluated the use of lactate levels in diagnosing and treating septic patients and came to a similar conclusion. These authors stated that measuring serum lactate is a quick and easily obtained laboratory test in the ED and therefore should be included in the assessment process. While high lactate levels will alert the clinician that this patient is at a greater risk for mortality it is not specific enough to clearly identify the potential cause of the patient's condition. Shapiro et al (2005) noted that identifying sepsis in the ED is a challenge to clinicians as the signs and symptoms are subtle and currently there is no definitive diagnostic test available. Shapiro et al. did agree that high lactate levels were clearly associated with higher mortality in septic patients. In addition, they also found that 4.9% of patients in their study with sepsis who despite having normal lactate levels died. They concluded that lactate levels, while a valuable bio-marker in the assessment of these patients is not the reliable as a single diagnostic test for this patient population.

Procalcitonin (PCT) is another serum laboratory test that may be useful for the clinician when evaluating potentially septic patients. This is a fairly new inflammation bio-marker that can be helpful in determining the presence of a bacterial infection. A 2010 a study by de Kruif et al. conducted in 310 bed teaching hospital compared CRP results in febrile ED patients to the PCT levels in those same patients. Their findings demonstrated that PCT was more specific for bacterial infection while the CRP was more sensitive for the presence of inflammation. Used in combination, PCT and CRP would be valuable additions to the laboratory diagnostic tests for

patients with suspected sepsis. They did, however, note that common use of PCT as a biomarker has not yet been established as a standard component of care in the ED. A study by Lee et al. (2008) supported the de Kruif conclusions, noting that PCT can be a valuable laboratory test for the clinician who suspects sepsis when it is used in conjunction with assessment findings and clinical judgment.

The literature supports that while there is no single laboratory test currently available to reliably diagnosis sepsis, multiple tests combined with assessment findings and clinical judgment are the key in determining if the patient is septic.

Barriers to Implementation of Evidence Based Guidelines

In an effort to encourage use of the SSC guidelines, the 2008 International Guidelines for the Management of Severe Sepsis and Septic Shock (Dellinger et al.2008) carefully spelled out in detail the steps in recognizing sepsis. They evaluated the quality of the evidence used to support the guidelines and treatment options. These recommendations include antibiotic therapy, source control, intravenous fluid therapy, contemplation of vasopressors, inotropes and corticosteroids. Each section has a discussion and the rationale for each recommendation. The information in these guidelines provides the clinician with the necessary tools to understand the science behind the recommendations so appropriate informed treatment decisions can be made as expeditiously as possible.

Although the literature supports the utilization of the SSC guidelines to standardize care, many authors also agree that guidelines are not intended to take the place of the clinician's knowledge or experience (Dontje, 2007). The clinician should not ignore the individual patient's medical history or the clinician's assessment findings and clinical judgment. The challenges

faced in ED's are twofold, first how to recognize sepsis early and second, how to consistently initiate the SSC EGDT as the standard treatment.

EGDT through implementation of interdisciplinary order sets or patient care bundles has a positive impact on patient outcomes. Despite the knowledge that the utilization of these bundles results in positive patient outcomes, there continues to be inconsistent implementation and adherence to them worldwide (Weinert & Mann, 2008). According to Weinert and Mann, (2008) there is a new arm of research emerging to look at these delay issues. This implementation science, a new way to disseminate research is also called T2 or translational research. It is a way for healthcare providers looking to help discover why there are delays in getting research to the bedside and ways to get findings adopted into practice sooner.

Many barriers to implementation have been acknowledged. Weinert and Mann (2008) identified that "guideline development and implementation strategies have occasionally overshadowed the guidelines actual content" (pg. 463). Some additional reasons noted for the underutilization of guidelines were the perceived lack of consideration for the individual patient's history and co-morbidities, and the possibility of excessive influence or financial stake by authors or third party entities as the guidelines were being developed.

Related to ED adherence specifically, only 7% of emergency physicians from 30 academic tertiary care facilities reported that they used any EGDT when caring for their patients (Carlbon and Rubenfeld 2007). These authors also concluded the results of their study were consistent with other initiatives such as treatment for ventilator-associated pneumonia and hand washing. Carlbon and Rubenfeld acknowledged that there are many challenges in getting knowledge gained from research and applying it at the bedside.

The literature clearly supports that the treatment of severe sepsis and septic shock should be developed using the evidence based SSC EGDT guidelines. It also shows that the time it takes to initiate EGDT guidelines after the clinician recognizes severe sepsis or septic shock greatly influences the patient's outcomes (Dellinger et al., 2008). For every hour delayed in the administration of antibiotics in the severe sepsis patient the risk for a poor outcome increases by 7.6% (Zubert et al. 2010). Similarities of increased mortality secondary to the delay of time to treatment can also be found in the trauma population. In trauma care, the golden hour is the time immediately following injury, when survival is dependent on rapid assessments and appropriate resuscitative interventions (Advanced Trauma Life Support, 2012).

The reluctance of healthcare providers to accept EGDT and change care delivery has been compared to the same resistance seen when guidelines and protocols were developed to care for the cardiovascular, stroke, and trauma populations (Huang et al., 2007). Some of the barriers identified by administrators and clinicians are directly related to concerns that practice changes can result in increased costs secondary to a lack of facility resources. ED overcrowding, the absence of multidisciplinary education specific to sepsis patients, a general lack of understanding of the mortality benefits of EGDT, and the absence of organizational leadership support account for the lack of EGDT implementation.

The literature suggests that support for sepsis initiatives can be solicited from both healthcare providers and the organizational leadership by sharing with them successful implementation data from facilities that have already initiated established EBP protocols. The positive impact on patient outcomes, the decrease in patient's length of stays (LOS), and reduced costs associated with the improved patient outcomes can and should be convincing rationale for change. For example, it has been calculated that an ED that treats 91 severely septic or septic

shock patients annually and consistently practices EGDT would realize an estimated savings of approximately \$788,606 a year (Haung et al., 2007). In addition, facilities that are already centers for stroke, trauma, and cardiac patients would more than likely already have the necessary multidisciplinary healthcare providers, technology and protocols in place to positively impact the septic patient population without making extensive changes.

Program Implementation Efforts

In an effort to encourage adherence, a program called MUST (Multiple Urgent Sepsis Therapies) was developed at the Beth Israel Deaconess Medical Center in Boston. It included the rationale for each step of the protocol during its development. In addition, they creatively adapted their trauma patient flow sheet used for nursing documentation to be available specifically for septic patients (Jones, Shapiro & Roshon, 2007). As the format of this document was already familiar to the staff and easy to use, the authors expected adherence would be high. This same multidisciplinary group of clinicians also used a variety of educational techniques for all the different disciplines prior to the protocol's implementation. Post implementation, the team monitored adherence to the protocol and communicated with the individual healthcare providers after each septic patient was seen in the ED. The group's goal was to develop an expectation that there was accountability by all members of the team for the care they provided. Since its implementation, this protocol has been established as the standard of care for the ED. Despite the general acceptance of the new standard, this facility's team admits that they continue to encounter occasional challenges with compliance and hope that their consistent case reviews will demonstrate that this program is being sustained. In order to sustain positive changes strategies must include continued reviews and open communications with providers.

In a study conducted at a large university based hospital in Madrid, researchers evaluated their ED to determine if the physicians were using the sepsis bundle as implemented (de Miguel-Yanes et al., 2006). They found that during the two month long study the ED census totaled 31,238 patients. There were multiple missed septic patients and two patients who were thought to have sepsis but were later determined to not be septic. In response to the results of this evaluation the researchers concluded that the best way to improve the early recognition and treatment of septic patients was to create a multidisciplinary collaborative team and develop a comprehensive education program for the entire hospital staff. The strategy of multidisciplinary collaboration is seen throughout the literature as an important component for development, implementation, and sustaining positive changes.

In a comprehensive study by Nguyen et al. (2007) they describe a process of bundle development followed by extensive sepsis education of the ED personnel and finally implementation of the developed processes followed by an evaluation of the implementation itself. Despite their extensive and intensive efforts the researchers noted that it took two years post implementation to achieve a greater than 50% adherence to bundle use in the ED.

Several themes from the literature related to implementation of guidelines and protocols have been identified. Multidisciplinary collaboration, not only between physicians and nurses, but also different specialty areas within the facility, was a primary factor for success. This was closely followed by an organized and systematic approach to the literature review, protocol development, facility wide education and an evaluation program that included following up with the individual healthcare providers post case review.

Post Implementation Evaluations

Evaluating the impact of implementing any change in practice is an important component of the change process. As a way to assist facilities and evaluate improvements the SSC developed a performance improvement program and recruited 165 hospitals worldwide to participate resulting in 15,022 patients being entered into their data base (Levy et al., 2010). The purpose of this program was to determine the extent of practice changes and determine if use of the SSC guidelines improved patient outcomes. Hospital participation in this program was completely voluntary. Facilities were asked to enter data components related to the SSC guidelines from the first six hours resuscitation bundle and the second 24 hour management bundle into the secure data base. The data demonstrated overall good levels of compliance with the first three measures in the six hour bundle. Those measures were obtaining serum lactate levels, blood cultures prior to initial antibiotic administration, and administering appropriate broad-spectrum antibiotic. Early recognition of sepsis by lactate measurement was done 86% of the time. Obtaining blood cultures prior to antibiotic administration and initiation of appropriate antibiotic therapy was documented 78% of the time. Interestingly, these three components are most consistently performed in the ED. Although the outcomes of this performance improvement process are not the result of formal scientific research these results demonstrated a decrease in patient mortality when providers used the SSC guidelines. The authors did note, however, that some of the decrease in mortality might also be attributed to patients being less critically ill when enrolled as first thought.

Mikkelsen et al. (2010) looked specifically at the challenges one emergency department faced during implementation and if EGDT was being consistently utilized for patients experiencing severe sepsis and septic shock. The facility identified that utilization of the EGDT

guidelines had, over the two year evaluation time frame, 2005 to 2007, decreased from 61% to 40%. Their results demonstrated that mortality rates for patients who had EGDT started but not completed was at 36% while in patients who had EGDT initiated and completed mortality rate was decreased to 30%. In addition, the authors noted an interesting discrepancy related to the use of EGDT among the 33 ED physicians at this facility. When the treating ED physician was female, EGDT was implemented 48.5% of the time compared to 62.4% of the time for their male counterparts. The data also demonstrated that the younger physicians, with the least years of experience in practice utilized EGDT guidelines more frequently than their older and more experienced colleagues. The authors acknowledged their study's interesting age and gender findings related to implementation of EGDT and noted the need to investigate this further. In addition, they suggested that EGDT protocol adherence might be improved if a "consultation service" was created and became involved early in the patients care. The EDSSAPP audit findings discussed earlier showed that SSA's were only being activated 38.7% of the time; these results are in line with facilities as found in the literature. Further research is needed to help identify barriers to implementation of EGDT.

Looking back at the ORMC EDSSAPP process in light of information gained from this comprehensive literature review, there is one component that stands out as most likely a contributing factor to the perceived low numbers of SSA's being activated- the gathering and sharing of real time data with the healthcare team members.

Early Goal Directed Therapy/Safe and Cost Effective Care

Today's healthcare environment requires facilities to provide safe and quality care while continuously striving to maintain cost effectiveness. Shorr et al., (2007, pg 1257) cited that the

“costs of sepsis are staggering and total tens of billions of dollars annually” and implementation of evidenced-based sepsis protocols can result in substantial savings in both lives and costs of care. Studies by Jones, Troyer and Kline (2011) and Talmor, Greenberg, Howell, Lisbon, Novack and Shapiro (2008) looked at the cost effectiveness of implementing EGDT. In the Talmor et al study (2008), the authors noted that once EGDT was initiated there was an increase in both time and resources needed to care for septic patients. They also cited an increased LOS in the intensive care unit (ICU) and associated care costs. The Jones et al. study (2011) had similar results, concluding implementation of EGDT had indeed increased associated care costs. In both studies, while the direct costs calculated for caring for severe sepsis and septic shock increased after the implementation of EGDT, there were also corresponding increases in quality-adjusted life years (QALYs) of the patients who survived. A QALY is defined as an estimate of how many years of life that a reasonable person might gain secondary to medical treatment. There are several factors considered when measuring the quality of life as related to the individual’s health. These contributing factors include pain, and general ability to perform activities of daily living. While the authors all agreed the indirect life year’s savings made up for the rise in direct care costs for sepsis patients it is important to note that these were single center studies.

Lagu et al. (2011) used data collected by the Premier Healthcare Informatics in Charlotte North Carolina, from 309 hospitals that treated 166,931 septic patients from 2004 to 2006. Their goal was to determine if there was any association between the amount of money a hospital spent on the care of septic patients and improved survival rates for these patients. The authors carefully selected facilities and conducted complex statistical analyses to evaluate the outcomes. The study results demonstrated care of the septic patient varies widely across the US and there was

no obvious association between increased hospital spending on costs of direct care for the septic patient and improved patient survival rates.

Powell, Khare, Courtney and Feinglass (2010) also found results similar to Lagu et al. (2011) related to the variety of care provided to sepsis patients in hospitals across the US. Data for this study included 87,166 adult septic patients seen and treated in 551 US hospitals. The results demonstrated ED's experiencing higher volumes of septic patients were more likely to have better-quality care for this vulnerable population. Clark and Normile (2007) identified that holding admitted patients in the ED awaiting in house bed availability can contribute to increased patient mortality. They also noted that mortality was increased on weekend shifts versus weekday shifts. Despite the increased mortality for patients being held for admission Clark and Normile's data did show that septic patients who were seen and received initial treatment in the ED did receive their antibiotics, on average, one hour sooner than patients directly admitted to an inpatient bed.

The amount of literature available related to sepsis will continue to grow as the healthcare community searches for ways to identify sepsis early and researchers look for the most effective definitive treatment. In addition, it will not only be important for clinicians to stay abreast of the latest related evidence but to find ways to implement the necessary changes to improve patient outcomes and decrease mortality.

CHAPTER THREE: METHODS

Severe sepsis is a significant threat to patients worldwide. While the previously reviewed EDSSAPP audit snap-shot data demonstrated that this process had improved care for severely septic patients in this organization's ED, a more thorough evaluation of the process and its associated outcomes was needed. Implementation of EBP requires practice change(s), as was noted in the steps of the Iowa model. In addition, an analysis of the process changes and associated data with a continued evaluation of the quality of care being delivered is necessary to ensure improved patient outcomes. Another important step in this process is the dissemination of results, communicating to the healthcare community is an important component as this contributes to new knowledge and assists in demonstrating that translating research into practice can improve care at the bedside.

The main goal of this study was to evaluate the impact of EDSSAPP, pre and post implementation, on severe sepsis patients admitted via the ORMC ED. Specific components of the process were selected for review based on their importance in contributing to positive patient outcomes. Following the Iowa model process for implementation of evidence-based practice recommendations, monitoring this process change and associated outcomes along with disseminating the results is one way to contribute to sustaining the positive changes.

Research Aim

The primary aim of this study was to assess the outcomes of EDSSAPP on severe sepsis patients admitted via the ORMC ED across three time cohorts on:

- Alert activated versus no alert activated
- Time to first antibiotic administration

- Total ED and hospital LOS
- Mortality

Study Design

A retrospective review of data from the electronic medical record (EMR) was conducted to gather the required data for the following cohorts:

1. Base line/time zero (T0): six months prior to the implementation of EDSSAPP; the purpose of this data was for comparison with the other two time cohorts.
2. Time one (T1): the first six months following initial EDSSAPP implementation, to determine the immediate impact of EDSSAPP.
3. Time two (T2): six months following reinstatement of the corporate sepsis committee; these data were used for further comparisons to determine the impact of EDSSAPP.

Research Questions

All the data gathered for this study were analyzed to answer the following research questions.

- a. In ED patients with severe sepsis what was the effect of EDSSAPP on time to first antibiotic administration at three time cohorts, T0, T1, and T2?
 - a. In ED patients *with* a severe sepsis alert activated, what was the effect of EDSSAPP on time to first antibiotic administration *between* time cohorts T1 and T2?
 - b. In ED patients *without* a severe sepsis alert activated what was the effect of EDSSAPP on time to first antibiotic administration *between* time cohorts T0, T1, and T2?

- c. In ED patients *with* and *without* a severe sepsis alert activated, what was the effect of EDSSAPP on time to first antibiotic administration *within* groups at time cohort T1?
- d. In ED patients *with* and *without* a severe sepsis alert activated, what was the effect of EDSSAPP on time to first antibiotic administration *within* groups at time cohort T2?

2.1 In ED patients with severe sepsis, what was the effect of EDSSAPP on ED LOS across three time cohorts T0, T1 and T2?

- a. In ED patients with a severe sepsis alert activated, what was the effect of EDSSAPP on ED LOS between time cohorts T1 and T2?
- b. In ED patients without a severe sepsis alert activated, what was the effect of EDSSAPP on ED LOS between time cohorts T0, T1 and T2?
- c. In ED patients with and without a severe sepsis alert activated, what was the effect of EDSSAPP on ED LOS within groups at time cohort T1?
- d. In ED patients with and without a severe sepsis alert activated, what was the effect of EDSSAPP on ED LOS within groups at time cohort T2?

2.2 In ED patients with severe sepsis, what was the effect of EDSSAPP on hospital LOS across three time cohorts T0, T1 and T2?

- a. In ED patients with a severe sepsis alert activated, what was the effect of EDSSAPP on hospital LOS between time cohorts T1 and T2?
- b. In ED patients without a severe sepsis alert activated, what was the effect of EDSSAPP on hospital LOS between time cohorts T0, T1 and T2?
- c. In ED patients with and without a severe sepsis alert activated, what was the effect of EDSSAPP on hospital LOS within groups at time cohort T1?

- d. In ED patients with and without a severe sepsis alert activated, what was the effect of EDSSAPP on hospital LOS within groups at time cohort T2?
3. In ED severe sepsis patients, what was the effect of EDSSAPP on mortality between time cohorts T0, T1 and T2?
 4. In ED severe sepsis patients, what was the effect of EDSSAPP with reactivation of the corporate sepsis committee on the number of severe sepsis alerts activated between time cohorts T1 compared to T2?
 - a. In ED severe sepsis patients, what was the effect of EDSSAPP with reactivation of the corporate sepsis committee on the number of severe sepsis patients with a severe sepsis alert activated between time cohorts T1 compared to T2?
 - b. In ED severe sepsis patients, what was the effect of EDSSAPP with reactivation of the corporate sepsis committee on the number of severe sepsis patients without a severe sepsis alert activated between time cohorts T1 compared to T2?

Subject Sampling

The cohort data were obtained between 2009 and 2013 and a description of each cohort can be seen in Table 3. Subjects included in T0 were a convenience sample of 22 patients admitted to the hospital from the ORMC ED with any of the initial ICD 9 codes listed in Table 4 that did not have a SSA activated. Subjects without a SSA activated in T1(n = 26) and T2 (n = 21) were also a convenience sample consisting of all patients admitted to the hospital from the ORMC ED with any of the initial ICD 9 codes listed in Table 3. All SSA activated patients from T1 (n = 19) and T2 (n = 113) were obtained from the existing EDSSAPP log. The lists of subjects with no SSA activated that were admitted for all three time cohorts from the ORMC ED

were obtained following approval from the Orlando Health Nursing Research Council, the ORMC and UCF IRB with waiver of consent, and application process to the Corporate Office of Safety and Transformation, Clinical Analysis and Outcomes (CAO) at Orlando Health as required by the organization’s policy.

Table 3: EDSSAPP patient cohorts

Baseline: Pre-EDSSAPP Implementation T0	Cohort 1: Post-EDSSAPP Implementation T1	Cohort 2: Post-Reinstatement of Corporate Sepsis Committee T2
4/1/09 to 9/28/09	9/29/09 to 3/31/10	8/14/12 to 2/14/13
Patients with Severe Sepsis (n=22) Severe sepsis/septic shock patients meeting inclusion criteria for the six months prior to implementation of EDSSAPP.	Patients with Severe Sepsis Alert Activated (n=19) Severe sepsis/septic shock patients for the first six months post implementation of EDSSAPP meeting inclusion criteria that had a severe sepsis alert paged.	Patients with Severe Sepsis Alert Activated (n=113) Severe sepsis/septic shock patients for six months post reinstatement of corporate Sepsis committee activity meeting inclusion criteria that had a severe sepsis alert paged.
	Patients without Severe Sepsis Alert Activated (n=26) Severe sepsis/septic shock patients for the first six months post implementation of EDSSAPP who met inclusion criteria and did NOT have a severe sepsis alert paged.	Patients without Severe Sepsis Alert Activated (n=21) Severe sepsis/septic shock patients for six months post reinstatement of corporate Sepsis committee activity meeting inclusion criteria and did NOT have a severe sepsis alert paged.

Inclusion criteria consist of all ORMC ED patients who were:

- 18 years or older
- Admitted to the hospital through this ED during the assigned time cohorts
- Diagnosed with any of the ICD-9 codes listed in Table 4 with or without a SSA activated

Exclusion Criteria consists of all ORMC ED patients who were:

- Younger than 18 years
- Admitted to the hospital through the ORMC ED without an initial ICD-9 code as listed in Table 4
- Expired in the ED, or were not admitted to this facility
- All patients that were transferred to a nursing home, skilled nursing facility, or hospice outside the Orlando Health system from the ED

Setting

The Orlando Regional Medical Center (ORMC) ED is a 58 bed, state-certified, level one trauma center. The average daily census is 200 patients with 30% to 37% of these patients being admitted to the hospital. ORMC is a Joint Commission-accredited facility, and the ED is staffed by board-certified emergency physicians and emergency medicine residents. The ED's nursing staff has a wide range of experience from one year to thirty years with approximately 20% of the nursing staff holding the national certification- Certified Emergency Nurse (CEN). In addition, the ED is staffed by state certified paramedics, licensed clinical social workers, licensed respiratory therapists, radiology technicians, certified phlebotomists and advanced clinical technicians. Standardized evidence-based guidelines are currently implemented for the trauma, cardiac and stroke patient populations.

Protection of Human Subjects

As this was a retrospective EMR review, the only direct risk to subjects selected for this study is the possible breach of confidentiality. In addition, there are no direct or indirect benefits to these subjects. This study was presented to the Nursing Research Council and following their

approval was submitted to the Institutional Review Boards at both the University of Central Florida and Orlando Health, approval letters are provided in Appendices G, H, I. Consent was obtained from Orlando Health to use the EDSSAPP process for this study (Appendix J).

Confidentiality

The data protection plan for this study includes ensuring that all data were de-identified, entered into the secured electronic spread sheets and kept on a password protected computer and encrypted flash drive locked in the Clinical Nurse Specialist’s office.

Data Collection

Initial electronic lists of ED patients hospitalized for the three cohorts were obtained from the hospital’s CAO Department. Once these lists were screened for inclusion criteria, the specific approved variables were collected through a comprehensive retrospective EMR review by the study team. The study data obtained included the approved descriptive, independent, and dependent variables for all the groups in each of the three time cohorts and can be seen in Table 4 along with the statistical test planned to analyze the data. A sample of the spreadsheet that was used for data entry can be seen in Appendix K.

Table 4: Descriptive variables and data analysis plan

Descriptive Variables			
Variable	Level of Measurement	Coding	Statistical Test
Day of the week	Nominal	1= Monday 2= Tuesday 3= Wednesday 4= Thursday 5= Friday	Frequencies, percent

Descriptive Variables			
Variable	Level of Measurement	Coding	Statistical Test
		6= Saturday 7= Sunday	
Time of arrival	Scale	Clocked military time	Will be used to calculate time to initial antibiotic
Mode of arrival	Nominal	1= Private car 2= EMS	Frequencies, percent
Gender	Nominal	0= Male 1= Female	Frequencies, percent
Age	Scale	Age in years.	Frequencies, percent; Mean, Mode, Median, Standard Deviation
Race	Nominal	1= Caucasian 2= Hispanic 3= African American 4= Asian 5= Other	Frequencies, percent
ICD-9 codes	Nominal	1. 38.0 Strep sepsis 2. 38.11 MRSA Sepsis 3. 38.12 Methicillin-resistant Staphylococcus aureus (MRSA) septicemia 4.38.19 Staphylococci septicemia NEC 5. 38.40 Gram-neg septicemia (NOS) 6. 38.42 Ecoli sepsis 7. 38.43 Pseudomonas septicemia 8. 38.44 Serratia septicemia 9. 38.49 Gram-neg septicemia NEC 10. 38.9 Septicemia NOS 11. 670.04 Major puerp infection NOS-p/p 12. 728.86 Necrotizing Fasciitis 13. 785.52 Septic Shock 14. 995.91 Sepsis 15. 995.92 Severe Sepsis 16. 999.31 Infection due to central venous catheter	Frequencies, percent
Presenting complaint	Nominal	Open category	Frequencies, percent

Descriptive Variables			
Variable	Level of Measurement	Coding	Statistical Test
Initial ED lactate level	Scale	Number mEq/L	Frequencies, percent; Mean, Mode, Median, Standard Deviation
Initial ED lactate serum source	Nominal	1= Venous 2= Arterial	Frequencies, percent
Initial ED White Blood Cell Count	Scale	Number (cells per mcL)	Frequencies, percent; Mean, Mode, Median, Percent, Standard Deviation
Time from order to First Antibiotic Administration	Scale	Calculated from the time of EDMD order to the time of EDRN initiation of administration.	Frequencies, percent; Mean, Mode, Median, Percent, Standard Deviation
Time of discharge from ED	Scale	Military Time	Used to calculate ED LOS (minutes?)
ED LOS	Scale	Calculated from the time of arrival to the ED to the time departed from the ED to in-patient bed.	Frequencies, percent; Mean, Mode, Median, Percent, Standard Deviation
Hospital LOS	Scale	Time of arrival to ED to time of discharge from the hospital or death.	Frequencies, percent; Mean, Mode, Median, Percent, Standard Deviation
Mortality	Nominal	1=Discharged 2=Expired	Frequencies, percent
Number of Severe Sepsis patients admitted to the hospital from the ED during the noted time frames	Scale	Number of severe sepsis patients admitted from the ED.	Frequencies, percent; Mean, Mode, Median, Percent, Standard Deviation

The ICD-9 codes were used as a part of the inclusion criteria with 16 initial codes related to sepsis approved for this study can be seen in Table 5. At the beginning of data gathering the PI and Co-PI elected to gather only one initial admission and principal ICD-9 code on each of the EMR's as these patients had multiple ICD-9 codes, some had as many as 20 per patient record.

Table 5: Initial ICD-9 codes

ICD-9 Code	Definition
38.0	Strep sepsis
38.11	MRSA Sepsis
38.12	Methicillin-resistant Staphylococcus aureus (MRSA) septicemia
38.19	Staphylococci septicemia NEC
38.40	Gram-neg septicemia (NOS)
38.42	Ecoli sepsis
38.43	Pseudomonas septicemia
38.44	Serratia septicemia
38.49	Gram-neg septicemia NEC
38.9	Septicemia NOS
670.04	Major puerp infection NOS-p/p
728.86	Necrotizing Fasciitis
785.52	Septic Shock
995.91	Sepsis
995.92	Severe Sepsis
999.31	Infection due to central venous catheter

The most complex variables to measure were the patient’s initial/presenting complaints. The Principal Investigator (PI) and statistician collaborated to categorize this variable in order to have a meaningful way to calculate the data. The patients initial/presenting complaints were grouped by systems and a summary of these groupings and their associated percentage per cohort are listed in Table 9 in Chapter 4.

Inter-Rater Reliability

Inter rater reliability was established by the PI prior to any data gathering by the research team. As a part of the CNS’s practice, EMR’s are regularly reviewed for audits and process improvement projects; this activity supports CNS as the PI’s expertise in EMR review. The CNS chose five severe sepsis charts and gathered the required data. Next, the team of co-investigator

and sub-investigators were given the same five charts independently to abstract the required data points. The inter-rater reliability data sheets were reviewed and scored for accuracy against the CNS completed data sheet. A 100% matching was obtained and accurate inter-rater reliability achieved. None of the investigators failed to meet the required standard and no remediation or reevaluation was needed.

Statistics and Data Analysis

Data were entered into the approved SPSS (v 21) spread sheets followed by a thorough review to ensure accuracy by the PI and statistician. Descriptive and inferential statistics were run as appropriate to the research questions as seen in Table 6. The data related to the ED and hospital LOS were not normally distributed, therefore non-parametric statistics were run.

Table 6: Data analysis plan by research questions

Research Questions	Variable	Level of Measurement	Coding	Statistical Test
RQ 1. In ED patients with severe sepsis what was the effect of EDSSAPP on time to first antibiotic administration at three time cohorts, T0, T1, and T2?				
a. In ED patients <i>with</i> a SSA activated, what was the effect of EDSSAPP on time to first antibiotic administration <i>between</i> time cohorts T1 and T2?	IV: EDSSAPP DV: Total antibiotic time (from initial antibiotic order to time of antibiotic administration)	Nominal Nominal	0=No 1=Yes 1= ≤60 minutes 2= > 60 minutes	Chi Square
b. In ED patients <i>without</i> a SSA activated, what was the effect of EDSSAPP on time to first antibiotic administration <i>between</i> time cohorts T0, T1, and T2?	IV: EDSSAPP DV: Total antibiotic time (from initial antibiotic order to time of antibiotic administration)	Nominal Nominal	0=No 1=Yes 1= <60 minutes 2= > 60 minutes	Chi Square
c. In ED patients <i>with</i> and <i>without</i> a SSA activated what was the effect of EDSSAPP on time to first antibiotic administration <i>within</i> time cohort T1?	IV: EDSSAPP DV: Total antibiotic time (from initial antibiotic order to time of antibiotic administration)	Nominal Nominal	0=No 1=Yes 1= <60 minutes 2= > 60 minutes	Chi Square
d. In ED patients <i>with</i> and <i>without</i> a SSA activated what was the effect of EDSSAPP on time to first antibiotic administration <i>within</i> time cohort T2?	IV: EDSSAPP DV: Total antibiotic time (from	Nominal Nominal	0=No 1=Yes 1= ≤ 60 minutes	Chi Square

Research Questions	Variable	Level of Measurement	Coding	Statistical Test
	initial antibiotic order to time of antibiotic administration)		2= > 60 minutes	
RQ 2.1. In ED patients with severe sepsis what was the effect of EDSSAPP on ED LOS across three time cohorts T0, T1 and T2?				
a. In ED patients <i>with</i> a SSA activated what was the effect of EDSSAPP on ED LOS <i>between</i> time cohorts T1 and T2?	IV: EDSSAPP DV: ED LOS	Nominal Ratio	0=No 1=Yes Number of minutes	Mann-Whitney U
b. In ED patients <i>without</i> a SSA activated what was the effect of EDSSAPP on ED LOS <i>between</i> time cohorts T0, T1 and T2?	IV: EDSSAPP DV: ED LOS	Nominal Ratio	0=No 1=Yes Number of minutes	Kruskal Wallis test
c. In ED patients <i>with</i> and <i>without</i> a SSA activated, what was the effect of EDSSAPP on ED LOS <i>within</i> time cohorts at T1?	IV: EDSSAPP DV: ED LOS	Nominal Ratio	0=No 1=Yes Number of minutes	Mann-Whitney U
d. In ED patients <i>with</i> and <i>without</i> a SSA activated, what was the effect of EDSSAPP on ED LOS <i>within</i> time cohorts at T2?	IV: EDSSAPP DV: ED LOS	Nominal Ratio	0=No 1=Yes Number of minutes	Mann-Whitney U
RQ 2.2. In ED patients with severe sepsis what was the effect of EDSSAPP on hospital LOS across three time cohorts T0, T1 and T2?				
a. In ED patients <i>with</i> a SSA activated what was the effect of EDSSAPP on hospital LOS <i>between</i> time cohorts T1 and T2?	IV: EDSSAPP	Nominal	0=No 1=Yes	Mann-Whitney U

Research Questions	Variable	Level of Measurement	Coding	Statistical Test
	DV: hospital LOS	Ratio	Number of days	
b. In ED patients <i>without</i> a SSA activated what was the effect of EDSSAPP on hospital LOS <i>between</i> time cohorts T0, T1 and T2?	IV: EDSSAPP DV: hospital LOS	Nominal Ratio	0=No 1=Yes Number of days	Kruskal Wallis test
c. In ED patients <i>with</i> and <i>without</i> a SSA activated, what was the effect of EDSSAPP on hospital LOS <i>within</i> time cohorts at T1?	IV: EDSSAPP DV: hospital LOS	Nominal Ratio	0=No 1=Yes Number of days	Mann-Whitney U
d. In ED patients <i>with</i> and <i>without</i> a SSA activated, what was the effect of EDSSAPP on hospital LOS <i>within</i> time cohorts at T2?	IV: EDSSAPP DV: hospital LOS	Nominal Ratio	0=No 1=Yes Number of days	Mann-Whitney U
RQ 3. In ED severe sepsis patients, what was the effect of EDSSAPP on mortality between time cohorts T0, T1 and T2?				
RQ 3. In ED severe sepsis patients, what was the effect of EDSSAPP on mortality <i>between</i> time cohorts T0, T1 and T2?	IV: EDSSAPP DV: Mortality	Nominal Nominal	0= No 1= Yes 0=No 1= Yes	Chi Square
RQ 4. In ED severe sepsis patients, what was the effect of EDSSAPP with reactivation of the corporate sepsis committee on the number of severe sepsis patients with and without a severe sepsis alert activated between time cohorts T1 compared to T2?				
RQ 4. In ED severe sepsis patients, what was the effect of EDSSAPP with reactivation of the corporate sepsis committee on the number of	IV: EDSSAPP with reactivation of corporate sepsis committee	Nominal	0= No 1= Yes	Chi Square

Research Questions	Variable	Level of Measurement	Coding	Statistical Test
severe sepsis patients <i>with</i> and <i>without</i> a severe sepsis alert activated <i>between</i> time cohorts T1 compared to T2?	DV: Number of SSAs and SSNAs	Nominal	0= No 1=Yes	
a. In ED severe sepsis patients, what was the effect of EDSSAPP with reactivation of the corporate sepsis committee on the number of severe sepsis patients <i>with</i> a severe sepsis alert activated <i>between</i> time cohorts T1 compared to T2?	IV: EDSSAPP with reactivation of corporate sepsis committee DV: Number of SSAs	Nominal Nominal	0= No 1= Yes 0= No 1=Yes	Chi Square
b. In ED severe sepsis patients, what was the effect of EDSSAPP with reactivation of the corporate sepsis committee on the number of severe sepsis patients <i>without</i> a severe sepsis alert activated <i>between</i> time cohorts T1 compared to T2?	IV: EDSSAPP with reactivation of corporate sepsis committee DV: Number of SOSAs	Nominal Nominal	0= No 1= Yes 0= No 1=Yes	Chi Square

CHAPTER FOUR: RESULTS

In this chapter the results of the data analyses are presented followed by the findings as related to each of the study questions. Data were examined for missing values, outliers and normality as appropriate. Descriptive statistics, frequencies, Chi Square, Mann- Whitney U, and Kruskal Wallis tests were used for this study. Data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 21.

Raw data were obtained following the approved process and the data were received in an Excel spread sheet via secure hospital email. A total of 2,330 patients were included in the initial raw data requested. Once the data were screened using the inclusion and exclusion criteria, a total of 201 patients were included. Table 7 is a summary of the total number of patients that populated each of the study cohorts. A table of the entire EDSSAPP demographic data is shown in Appendix L.

Table 7: Sample size per time cohort

Cohort	No Alert Activated	Alert Activated	Total
TIME 0	22	0	22
TIME 1	26	19	45
TIME 2	21	113	134
Total	69	132	201

Time 0 = Pre EDSSAPP, Time 1 = First 6 months post EDSSAPP implementation, Time 2 = EDSSAPP following the reactivation of corporate sepsis committee.

Sample Characteristics

The demographic data were for each of the cohorts individually and for the total study population as a whole. Demographic data and baseline characteristics for this study are summarized in Table 8.

Table 8: EDSSAPP demographic data

		Time Cohorts					
		All Time Cohorts	Time 0	Time 1		Time 2	
			No Alert	Alert	No Alert	Alert	No Alert
			(n = 22)	(n = 19)	(n = 26)	(n = 113)	(n = 21)
Size		201 (100%)	22 (10.94%)	19 (9.45%)	26 (12.93%)	113 (56.21%)	21 (10.44%)
Characteristic	Age Mean (sd)	62.42 (18.47)	59.86 (18.31)	62.37 (20.78)	53.62 (21.53)	64.95 (16.66)	62.43 (19.82)
	Median (range)	64.0 (19-102)	63.5 (23-90)	68.0 (23-93)	52.0 (19-88)	67.0 (19-95)	62.0 (29-102)
	Gender Mean (%)						
	Male	103 (51.2)	9 (40.9)	14 (73.7)	17 (65.4)	57 (50.4)	6 (28.6)
	Female	98 (48.8)	13 (59.1)	5 (26.3)	9 (34.6)	56 (49.6)	15 (71.4)
	Race Mean (%)						10 (47.6)
	Caucasian	116 (57.7)	14 (63.6)	13 (68.4)	14 (53.8)	65 (57.5)	6 (28.6)
	Black	60 (29.9)	4 (18.2)	6 (31.6)	8 (30.8)	36 (31.9)	4 (19.0)
	Hispanic	21 (10.4)	3 (13.6)	0 (0.0)	4 (15.4)	10 (8.8)	1 (4.8)
	Asian	4 (2.0)	1 (4.5)	0 (0.0)	0 (0.0)	2 (1.8)	
	Alert Status Mean (%)						
	Alert	132 (65.7)	0 (0.0)	19 (100)	0 (0.0)	113 (100)	0 (0.0)
	No Alert	69 (34.4)	22 (100)	0 (0.0)	26 (100)	0 (0.0)	21 (100)

Of the 201 patients, the mean age for the total sample was 62.42 years (range 19-102 years, SD 18.47 years). Most were white (57.7%) with an even gender distribution of male (51.2%) and female (48.8%). The majority had a severe sepsis alert activated (65.7%).

Presenting/Chief Complaint

The initial presenting/chief complaints varied widely as the EMR documentation of the complaints were based on what the patient or family stated to the ED staff on arrival. To organize these complaints in a systematic way for statistical analysis the study's PI and statistician collaborated to group the presenting or chief complaints by placing them into medical system categories. A non-parametric test (Kruskal Wallis) was conducted comparing the ED chief complaints in each category across the three time cohorts. The only chief complaint category that was statistically significant was skin/wounds with a p value of .001, despite the total number of patients in this category being small ($n=9$). The list of the system categories and associated complaints, with numbers, percentages and p values are listed in Table 9.

Table 9: Initial/presenting complaint summary

System	Examples of Conditions	Total	T0	T1	T2	p values
		n (%)	n (%)	n (%)	n (%)	
Metabolic	Hypoglycemia Fever/chills Electrolyte imbalance Sepsis Hyperglycemia Flu like symptoms Septic shock	56 (27.9)	4 (18.2)	10 (22.2)	42(31.3)	.43
Neurologic	Altered mental status Un-responsive Seizures Near syncope Syncope	51 (25.4)	8 (36.4)	12 (26.6)	31(23.1)	.40
Respiratory	Pneumonia Shortness of breath Respiratory distress Difficulty breathing	31 (15.4)	5 (22.7)	7(15.5)	19(14.2)	.35

System	Examples of Conditions	Total	T0	T1	T2	<i>p</i> values
		n (%)	n (%)	n (%)	n (%)	
	Pleural Effusion Hemoptysis					
Gastro-intestinal	Abdominal pain Displaced peg tube Abdominal abscess Nausea and vomiting Diarrhea Rectal bleeding Liver failure Small bowel obstruction Vomiting and diarrhea Partial small bowel obstruction Rectal pain	18 (9.0)	1 (4.5)	3 (6.6)	14(10.4)	.15
Cardiac	Hypo-tension Chest pain Supra- ventricular tachycardia STEMI alert	12 (6.0)	3 (13.6)	2 (4.4)	7 (5.2)	.50
Skin-Wounds	Abscess Multiple wounds Gangrene Decubitus ulcer Infected dialysis catheter wound	9 (4.5)	0 (0.0)	6 (13.3)	3 (2.2)	.001
Genital-urinary	Urinary tract infection Need dialysis Hematuria Urinary retention Dysuria	3 (1.5)	0 (0.0)	0 (0.0)	3 (2.2)	.89
Other	Problem with central venous line Pain Weakness	21 (10.4)	1 (4.5)	5 (11.1)	15(11.2)	.35

System	Examples of Conditions	Total	T0	T1	T2	p values
		n (%)	n (%)	n (%)	n (%)	
	Displaced tube Pulled muscle General illness Failure to thrive					

Research Questions

Research Question 1: Antibiotic Administration

In ED patients with severe sepsis what was the effect of EDSSAPP on time to first antibiotic administration at three time cohorts T0, T1 and T2?

Antibiotic administration times were placed into two groups: those ≤ 60 minutes and those > 60 minutes for statistical analysis based on the EDSSAPP antibiotic administration time requirement. A Chi-Square test was conducted comparing antibiotic time (≤ 60 minutes versus > 60 minutes) in patients with severe sepsis (*with* and *without* a severe sepsis alert activated) in time cohorts T0, T1, and T2. No statistically significant differences in time of antibiotic administration was found between T0, T1, and T2 ($p = .38$), results are listed in Table 10.

Table 10: ED antibiotic administration times by time cohorts and groups

Characteristics	Time Cohorts					X ² p value
	T0 n = 22	T1 n = 45	T2 n = 134			
All Patients	n (%)	n (%)	n (%)			
Antibiotic Time ≤ 60 minutes						
Yes	18 (81.8)	32 (71.1)	108 (80.6)			.38
No	4 (18.2)	13 (28.9)	26 (19.4)			
Groups: Severe Sepsis Alert	No Alert n = 22	Alert n = 19	No Alert n = 26	Alert n = 113	No Alert n = 21	p value
Antibiotic Time ≤ 60 minutes	n (%)	n (%)	n (%)	n (%)	n (%)	
Yes	18 (81.8)	-	19 (73.1)	-	18 (85.7)	.74
No	4 (18.2)	-	7 (26.9)	-	3 (14.3)	
Yes	-	13 (68.4)	-	90 (79.6)	-	.52
No	-	6 (31.6)	-	23 (20.4)	-	
Yes	-	13(68.4)	19 (73.1)	-	-	.35
No	-	6 (31.6)	7 (26.9)	-	-	
Yes	-	-	-	90 (79.6)	18 (85.7)	.51
No	-	-	-	23 (20.4)	3 (14.3)	

Research Question 2.1: ED Length of Stay

In ED patients with severe sepsis, what was the effect of EDSSAPP on ED LOS across three time cohorts T0, T1 and T2?

A Kruskal Wallis test was conducted comparing the ED LOS of patients with severe sepsis at the three different time cohorts. Although the ED LOS was shorter in T1, there was no significant difference in ED LOS across the three time cohorts ($p = .14$).

- a. *In ED patients **with** a severe sepsis alert activated, what was the effect of EDSSAPP on ED LOS between time cohorts T1 and T2?*

A Mann-Whitney U test was conducted comparing the mean ED LOS in patients *with* a severe sepsis alert activated in T1 versus T2. There was a statistically significant lower ED LOS in patients *with* a severe sepsis alert activated in cohort T1 (365.32 minutes) compared to T2 (422.88 minutes) resulting in a p value of .05.

b. In ED patients without a severe sepsis alert activated, what was the effect of EDSSAPP on ED LOS between time cohorts T0, T1 and T2?

A Kruskal Wallis test was conducted comparing the ED LOS of patients *without* a severe sepsis alert activated at the three different time cohorts. Although the ED LOS was shorter for patients *without* a severe sepsis alert activated in T1, there was no overall significant difference in ED LOS across the three time cohorts ($p = .44$).

c. In ED patients with and without a severe sepsis alert activated, what was the effect of EDSSAPP on ED LOS at time cohort T1?

A Mann-Whitney U test was conducted comparing the ED LOS in patients *with* and *without* a severe sepsis alert activated in T1. Although there was a shorter ED LOS for patients that had a SSA activated there was no significant difference found between the groups ($p=.32$).

d. In ED patients with and without a severe sepsis alert activated, what was the effect of EDSSAPP on ED LOS at time cohort T2?

A Mann-Whitney U test was conducted comparing the mean ED LOS in patients *with* and *without* severe sepsis alert in T2. Although there was a shorter ED LOS for patients that had a SSA activated there was no significant difference was found between groups ($p=.37$).

Research Question 2.2: Hospital Length of Stay

In ED patients with severe sepsis, what was the effect of EDSSAPP on hospital LOS across three time cohorts T0, T1 and T2?

A series of non-parametric tests (Mann - Whitney U and Kruskal Wallis) were conducted comparing the hospital LOS in patients *with* and *without* a SSA activated in time cohorts T0, T1, and T2. The following changes occurred but were not statistically significant: overall the hospital LOS was shorter in T1 (mean rank 94.1) compared to T0 (mean rank 97.8) and T2 (mean rank 103.84) with a p value of .60.

a. In ED patients with a severe sepsis alert activated, what was the effect of EDSSAPP on hospital LOS between time cohorts T1 and T2?

A Mann-Whitney U test was conducted comparing mean hospital LOS in patients *with* a severe sepsis alert activated in T1 versus T2. There was no significant difference in hospital LOS in patients *with* a severe sepsis alert activated in cohorts T1 compared to T2 ($p = .51$).

b. In ED patients without a severe sepsis alert activated, what was the effect of EDSSAPP on hospital LOS between time cohorts T0, T1 and T2?

A Kruskal Wallis test was conducted comparing the hospital LOS of patients *without* a severe sepsis alert activated at the three different time cohorts. Although the hospital LOS was shorter in T1, there was no overall significant difference in hospital LOS across the three time cohorts ($p = .94$).

c. In ED patients with and without a severe sepsis alert activated, what was the effect of EDSSAPP on hospital LOS at time cohort T1?

A Mann-Whitney U test was conducted comparing hospital LOS in patients *with* and *without* a severe sepsis alert activated in T1. There was no significant difference in hospital LOS ($p = .75$).

d. In ED patients with and without a severe sepsis alert activated, what was the effect of EDSSAPP on hospital LOS at time cohort T2?

A Mann-Whitney U test was conducted comparing hospital LOS in patients *with* and *without* a severe sepsis alert activated in T2. There was no significant difference in hospital LOS ($p = .54$).

Table 11: ED and hospital length of stay by time cohorts and groups

Characteristics	Time Cohorts						p value
	T0		T1		T2		
ED Length of Stay ^a (range in minutes)	442.18 (163-881)		394.10 (67-807)		533.00 (54-1772)		.14
ED Length of Stay ^b (range in minutes)	-		394.10 (67-807)		533.00 (54-1772)		.05
Hospital Length of Stay ^a (range in days)	11.95 (1-60)		9.22 (1-43)		9.52 (1-91)		.60
Hospital Length of Stay ^b (range in days)	-		9.22 (1-43)		9.52 (1-91)		.33
Sepsis Alert Groups	Alert	No Alert	Alert	No Alert	Alert	No Alert	
ED Length of Stay ^a (range in minutes)	-	442.18 (163-881)	-	422.88 (67-807)	-	578.19 (173-1442)	.44
Hospital Length of Stay ^a (range in days)	-	11.95 (1-60)	-	9.00 (1-43)	-	8.57 (1-21)	.94
ED Length of Stay ^b (range in minutes)	-	-	365.32 (127-793)	-	487.81 (54-1772)	-	.05
Hospital Length of Stay ^b (range in days)	-	-	9.00 (1-43)	-	10.48 (1-91)	-	.51
ED Length of Stay ^b (range in minutes)	-	-	365.32 (127-793)	422.88 (67-807)	-	-	.32
Hospital Length of Stay ^b (range in days)	-	-	9.00 (1-43)	9.00 (1-43)	-	-	.75
ED Length of Stay ^b (range in minutes)	-	-	-	-	487.81 (54-1772)	578.19 (173-1442)	.37
Hospital Length of Stay ^b (range in days)	-	-	-	-	10.48 (1-91)	8.57 (1-21)	.54

^aKruskall Wallis; ^bMann-Whitney U

Research Question 3: Mortality

*In ED severe sepsis patients, what was the effect of EDSSAPP on mortality **between** time cohorts T0, T1 and T2?*

A Chi Square test was conducted comparing mortality (Yes versus No) in severe sepsis patients (*with* and *without* a severe sepsis alert activated) between time cohorts T1 and T2, in comparison to T0. A statistically significant decrease in mortality ($p = .04$) was found in T2, T0 ($n=5, 22\%$), T1 ($n=15, 33\%$) T2 ($n=22, 16\%$). (Table 12).

Research Question 4: Activation of Severe Sepsis Alert.

- a. In ED severe sepsis patients, what was the effect of EDSSAPP with reactivation of the corporate sepsis committee on the number of severe sepsis patients with a severe sepsis alert activated between time cohorts T1 compared to T2?*
- b. In ED severe sepsis patients, what was the effect of EDSSAPP with reactivation of the corporate sepsis committee on the number of severe sepsis patients without a severe sepsis alert activated between time cohorts T1 compared to T2?*

A Chi Square test was conducted comparing the number of severe sepsis patients *with* and *without* a severe sepsis alert activated (Yes versus No) between time cohorts T1 and T2. A statistically significant increase in the number of severe sepsis alerts activated was found between T1 ($n=19$) and T2 ($n=113$) resulting in a p value of $.001$). Although no statistically significant differences were found in number of severe sepsis patients that *did not* have a SSA activated between T1 ($n=26$) and T2 ($n=21$) with a p value of $.06$ this should be considered a clinical significance with more severe sepsis patients were recognized, alerted and treated.

Table 12: ED severe sepsis alerts activated and mortality by time cohorts

Characteristics	Time Cohorts			<i>p</i> value
	T0 n = 22	T1 n = 45	T2 n = 134	
All Patients	n (%)	n (%)	n (%)	
Sepsis Alert Activated	n (%)	n (%)	n (%)	
Yes	-	19 (42.2)	113 (84.3)	.001
No	-	26 (57.8)	21 (15.6)	
Mortality				
Yes	5 (22.72)	15 (33.33)	22 (16.42)	.04
No	17 (77.27)	30 (66.67)	112 (83.6)	

CHAPTER FIVE: DISCUSSION

This study evaluated the impact of EDSSAPP implementation on antibiotic administration times, length of stay (ED and Hospital), and mortality over two time cohorts (T1, T2) as compared to pre-implementation (T0). In addition, this study evaluated the impact of the corporate sepsis committee activity on the number of severe sepsis alerts activated versus not activated were compared during time cohorts T1 and T2.

Study findings provide preliminary support for implementation of EDSSAPP with the additional corporate sepsis committee activity on improving outcomes of ED patients with severe sepsis. Additional research is needed to evaluate the impact of other external factors that may influence these outcomes, such as patient characteristics, competing patient care priorities and the overall ED personnel's attitudes, perception and knowledge of the EDSSAPP process and goals.

Utilization of evidence-based guidelines to address severe sepsis in the ED is an ongoing challenge. Barriers to implementation of and adherence to evidence-based guidelines or protocols include physician concerns related to the perceived lack of consideration for individualization of patient treatment and the potential influence of outside third parties, such as pharmaceutical companies, on research outcomes. The reluctance to accept standardized sepsis guidelines are similar to the challenges experienced when other standardized guidelines for diseases, such as acute coronary syndrome, stroke, and trauma, were implemented (Huang et al., 2007). In a 2013 systematic literature review of adherence to guidelines and protocols in the pre-hospital and emergency care settings Ebben et. al. (2013) noted that adherence to either national or international guidelines ranged from 7.8% to 95%. No one single reason was identified for this issue, rather it was recommended that in order to ensure improvements in quality patient care

via the use of evidence-based guidelines and protocols strategies must be developed to increase healthcare providers' adherence. As with previous guideline acceptance, more time to gather and review data may be needed to demonstrate positive patient outcomes from guideline utilization in order to have a universal acceptance of standardized sepsis guidelines in the ED. In addition, the local EMS agencies have instituted their own Sepsis Alert process using the SSC criteria; increased collaboration with our pre-hospital partners related to their sepsis alert process is a good first step to improve coordination of care across the continuum.

Activation of Severe Sepsis Alert

The most significant finding of this study was the increased number ED patients who had severe sepsis alerts activated in time cohort T2. The number of severe sepsis alerts activated in T2 (n=113) compared to T1 (n=19) was significantly increased and was most likely the result of influence upon ED personnel by the re-activation of the corporate severe sepsis committee. Literature world-wide has consistently noted that despite the evidence showing improved patient outcomes following the use of the SSC patient care bundles there continues to be inconsistent utilization (Weinert & Mann, 2008). The re-activation of the corporate sepsis committee in T2 (8/2012 – 2/2013) resulted in focused directed activities including physician to physician communications and CNS clinical rounding in an effort to increase the ED personnel's awareness of severe sepsis and adherence to EDSSAPP. Though not statistically significant, the number of ED severe sepsis patients that did *not* have an alert activated decreased from T1 (n=26) to T2 (n=21). In a study by Nguyen et.al. (2007) they noted that despite their intensive and extensive efforts to educate personnel and increase utilization of their severe sepsis bundles it took over two years to finally reach greater than 50% compliance with their sepsis bundle use.

This study was conducted over 18 months and as seen in the literature it takes time to implement process changes and consistent efforts to sustain the changes. The CNS role is uniquely designed to both lead evidence-based change and support collaboration with multidisciplinary personnel to sustain the changes.

Mortality

Another important finding was that mortality significantly decreased at T2 (16.4%) compared to T0 (22.7%) and T1 (33%). The re-activation of the corporate sepsis committee and active involvement of the CNS with rounding and on-going continuous efforts to increase staff awareness of EDSSAPP may have influenced reducing mortality compared to the EDSSAPP intervention alone. However, despite the reduction of mortality in T2 compared to T0 and T1, the number of patients who received antibiotics in less than 60 minutes did not increase across the three time cohorts. T0 had 82% receive antibiotics within 60 minutes while T1 had 71% and T2 had 81%. This is a curious finding as the literature has shown that delays in antibiotic administration can contribute to increased mortality for severe sepsis patients (Zubert et al. 2010). It is possible that the EDSSAPP order set components were being implemented on all ED patients with severe sepsis, even when there was no alert being activated on the patient. While individual order set components initiations were not collected for this study, this could be contributing to the lower mortality rates. Other potential contributing factors to consider are possible decreased ED patient volumes, allowing the staff more time to care for each patient, decreased patient acuities, and increased in-patient bed availability resulting in the ED not holding patients for extended times.

Hospital and ED LOS

The hospital length of stay was significantly increased by almost 1.5 days between those patients with a severe sepsis alert activated in T1 (9.00 days) compared to time T2 (10.48 days). Also, there was no significant decrease in the ED LOS across time cohorts and between groups of patients who had a severe sepsis alert activated versus no alert activated. However, there was a 1 hour and 28 minute lower in ED LOS in patients who had a severe sepsis alert activated in T1 compared to T0. Also, there was a 1 hour and 52 minutes lower in ED LOS between patients who had a severe sepsis alert activated compared to those who had no alert activated in T2. One potential contributing factor to either the increased or decreased ED LOS when a SSA is called is the role of the hospital administrative supervisors (AS). The AS's receive the notification when a SSA is called. This allows them to evaluate all the patients currently waiting to be assigned in-patient beds. Using the information related to each patient's acuity level could potentially move the SSA patient to the top of the list thereby decreasing their ED LOS. The AS process and its contribution to ED LOS was not evaluated as a part of this study.

There are many unknown external factors that may have contributed to the increased hospital LOS in T2 that were not evaluated for this study such as, patient comorbidities, hospital acquired complications (falls, pressure ulcers, catheter associated urinary tract infections [CAUTI], central line associated blood stream infections [CLABSI], discharge placement, etc.). The Institute of Medicine brought attention to the need to improve patient care and safety by reducing/preventing medical errors in their 2000 *To Err is Human* report. This report estimates that the total costs of these errors include longer hospital stays and related medical treatment, loss of life, productivity and disability is potentially greater than \$29 billion every year in the US (IOM Report, 2000).

ED's are challenged to rapidly identify severe sepsis patients as this illness creates a wide variety of symptoms which can mimic many other serious medical conditions. This makes the assessment process a complex endeavor while searching for a definitive diagnosis and initiating the appropriate treatment an ongoing challenge (Raghavan & Marik, 2006). The complexity of presenting signs and symptoms masking the actual cause of the patient's acute illness influences the patient's initial acuity prioritization (triage level) and ED bed assignment. In addition, it is important to consider that frequently multiple patients present at the same time for evaluation and treatment in the ED resulting in potential delays in ED bed availability. For the purposes of this study these influencing factors were not evaluated but should be considered for future studies. ED throughput or ED bed availability as well as in-patient bed availability also impacts the ED LOS and is a challenge worldwide. These throughput challenges can potentially contribute to the quality of care provided to patients seeking care in the ED. As Clark and Normile (2007) noted in a 2003 Government Accounting Office report the most common cause of delayed admission to the hospital was holding admitted patients in the ED due to a lack of critical care bed availability. The ED is simply not designed or staffed to care for patients over extended periods of time, especially critically ill or injured patients (Chalfin et al., 2007).

Antibiotic Administration

Overall, the number of ED patients with severe sepsis who received antibiotics within 60 minutes or less as required by EDSSAPP did not improve across the three time cohorts, T0 (81.8%), T1 (71.7%) and T2 (80.6%). There are several unknown external factors that may have contributed to the variability in the number of patients who received antibiotics as required by EDSSAPP, (competing patient acuity priorities, increased ED patient volumes, difficulty

obtaining venous access, etc.) that may have influenced the nurses' availability to administer the ordered antibiotics. Administering antibiotics within one hour in any busy emergency department is a formidable task as reflected in the literature and not successful until organized and systematic approaches are taken with consistent data review and follow up with providers (Zubert 2010).

In a study by Powell, Khare, Courtney and Feinglass (2007) they found that sepsis patients admitted through an ED having received an initial assessment and initiation of treatment had a lower mortality rate (17.1%) than sepsis patients who were made a direct admit to an in-patient bed not coming through the ED (19.7%). While this study provided mixed results and the ED continues to work towards more consistent adherence to EDSSAPP the care provided in the ED is a valuable contribution to improving outcomes for this patient population.

Implications

ED throughput is a challenge nationwide as noted in the literature. The longer patients are held in the ED awaiting placement to in-patient beds, the greater the chance for poor outcomes (Clark & Normile 2007). These poor patient outcomes are most likely secondary to the lack of ED staff and expertise to provide care for patients over prolonged periods of time; this is especially true of critically-ill or injured patients (Chalfin et al., 2007). The ORMC ED admits approximately 30% to 37% of its daily volume of patients. When the hospital has a high in-patient census, this can increase the time for notification that an in-patient bed is ready to receive an ED patient for admission. It may have been beneficial to review hospital census data at T0, T1 and T2 to determine its impact on admission delays. Increased ED LOS therefore could have a negative influence on the time to treatment initiation for one or more ED patients. Any decrease

in ED LOS could increase the ED's ability to potentially initiate treatment for other ED patients. The average daily census in this ED is 200 patients, which is approximately eight patients treated every hour. For every hour that a patient is held in the ED awaiting a ready in-patient bed, the ED could have initiated treatment for up to eight patients waiting for evaluation and treatment. In addition to the potential delay in care holding admitted patients can cause, there is also a possible loss of revenue for the hospital as patients frustrated with long waits leave the ED without being seen and treated.

One surprising result from this study was found in the evaluation of patient chief/presenting complaints. The number of patients with skin/wounds diagnosis increased from baseline ($p < .001$). Patients were assigned to this category based upon the following complaints: abscess, multiple wounds, gangrene, decubitus ulcers(s), infected dialysis catheters and general wounds. As seen in Chapter 4, this category had zero in T0, six in T1 and three in T2. The meaningfulness of this finding given the small number of patients assigned to this category is unclear and needs further investigation in future studies. However, from a clinical perspective communicating this finding to ED staff may increase awareness for possible sepsis in all patients presenting with existing wounds and other complaints as listed in this category.

Study Limitations

Several limitations should be considered when reviewing the EDSSAPP data results. The first being, that this study was conducted at one facility. While these results will be used to improve care provided in this ED they are not generalizable to other facilities. Following the analysis it was apparent that there were some data that were not included in EDSSAPP that might have enhanced this study. These include patient comorbidities, hospital acquired

infections/injuries and patient acuity levels. In addition, the individual components of the EDSSAPP order set and the ED and hospital census/capacity, during the different time cohorts were not evaluated. This study did not examine the hospital critical shortage of in-patient bed availability, also known “code green, yellow, red, and purple.” This is in part due to the hospital’s lack of a process to accurately track the in-patient bed availability status. This process was not taken into consideration for the purposes of this study, which is a limitation, but may be an explanation for the increased hospital LOS for both alerts and non-alerts in Time 2. While some findings were clinically significant, the sample size was small and not able to detect a statistical difference given the effect size of the outcome variable which may have been different with an increased sample size.

Recommendations for Practice

The results of this study will be used to help guide the ED CNS practice and be used while EDSSAPP is reviewed and revised. Continued participation on the current corporate sepsis committee will be an important part of the multidisciplinary collaboration needed to increase awareness of and adherence to using the evidenced- based severe sepsis order set by the attending physicians and residents. The committee is currently working on a program to track the order set usage. This is a necessary first step toward the development of policies that require and enforce individual provider accountability. On-going annual and periodic education will be coordinated with both corporate and unit based educators.

The CNS will also lead the refinement of the existing program to closely monitor the SSA data and communicate these results in as close to real time as possible to the providers involved in the care of the alerted patient. Select ED staff nurses have been provided special

EMR access and training in order to assist in gathering data on each SSA and placing this information into electronic spread sheet for calculations and results review. Increased communication of these results to ED team members will escalate their awareness for sepsis/severe sepsis and EDSSAPP, see ED Process Information Updates document Appendix M. Improved collaborative efforts with the interdisciplinary team are needed to refocus everyone's efforts to improve early recognition followed by appropriate treatment interventions and documentation is essential. In addition, a more formal team response to SSA's similar to that of Stroke or Trauma Alerts should be considered. Communication of the monthly audit results could be posted for providers to review. This could assist in not only maintaining the awareness of sepsis/severe sepsis but the potential need for improvement on crucial components of care for this patient population. Lastly, the development of a formal process to follow up with individual providers as close to real time as possible that includes accountability for care provided and related documentation would also contribute to awareness and adherence. This accountability for care provided following evidence-based guidelines and protocols is seen in other patient populations (cardiac, stroke and trauma) and is being scrutinized by both third party payers and regulatory agencies.

Recommendations for Future Research

As early recognition of sepsis is very important, it would be important to look at the time of arrival to the time that sepsis was suspected and interventions were initiated. Does early recognition of sepsis help to prevent patients from becoming severely septic and decrease mortality? Can readmissions for sepsis/severe sepsis from local skilled nursing facilities (SNF) be reduced by the implementation of a collaborative education effort between the hospital and

SNF's? In addition, the local EMS agencies have instituted their own Sepsis Alert process using the SSC criteria, collaborative research with our pre-hospital partners related to their sepsis alert process could improve coordination of care across the continuum.

Conclusions

The results of this study are consistent with what is seen in the literature with no new findings. In order to promote acceptance and utilization of guidelines, they need to be developed collaboratively with an interdisciplinary team, and once implemented, employed as intended to improve patient outcomes. Healthcare leaders should not assume that just because a protocol exists it will be used as intended. Protocols and guidelines must also be frequently reviewed with the most current literature and be revised as new evidence is uncovered. Protocols and guidelines are not intended to not replace the clinical judgment of the healthcare provider but rather to enhance the care provided (Dontje, 2007). Healthcare professionals need to be receptive to changing their practice, to using the most current evidence based guidelines even when this challenges their traditional ways of practicing (Huang et al., 2007). Moving forward with an organized, systematic and interdisciplinary approach has the best chance of succeeding in changing practice and improving outcomes.

APPENDIX A: SUMMARY OF 2008 SURVIVING SEPSIS CAMPAIGN

**Summary of the 2008
Guidelines for the Management of Severe Sepsis and Septic Shock**

SSC Guideline	Recommendations
1. Initial Resuscitation (first 6 hours) Resuscitation to begin STAT in patients with hypotension (SBP < 90), a change in Level of Consciousness or Glasgow Coma Score, or serum Lactate levels of 4 or greater.	Do NOT wait to begin care until the patient reaches in-house bed. Goals are to return patient to a hemodynamic stable status.
2. Diagnosis: obtain 2 or more blood cultures and cultures from other sites as clinically indicated. Preform diagnostic imaging as indicated by patient's assessment/condition.	If possible obtain all cultures prior to administration of antibiotics. However DO NOT delay administration of antibiotics if obtaining cultures is difficult or delayed.
3. Antibiotic Therapy to begin within one hour of recognizing severe sepsis/septic shock.	Use broad spectrum therapy chosen based on the suspected cause. May consider multiple or combination medications based on co-morbidities and or patient responses. STOP antibiotic therapy if cause found not to be bacterial or known to be susceptible to current medication.
4. Infectious source identification and control within 6 hours of arrival.	Remove all medical devices suspected or shown to be the cause or contributing to the cause of infection.
5. Fluid Therapy using crystalloids or colloids.	Rapid and large volumes may be necessary to stabilize hemodynamic status.
6. Vasopressors: should NOT be administered as an initial treatment for a hypotensive state.	If the patient does not positively respond to the administration of IV fluid then consider using norepinephrine or dopamine before any other pressors.
7. Inotropic Therapy to be considered cautiously in patients with known cardiac dysfunction.	Suggested medication for this patient population: dobutamine.
8. Steroids are to be considered in patients with hypotension not responsive to fluid therapy or vasopressors.	Steroidal therapy should only be used as long as absolutely necessary and patients must be weaned off this medication.
9. Blood Products: transfuse RBC's when Hgb is between 7-9 g/dL; administer platelets only after carefully evaluating the patient's levels using SSC guideline ranges.	Important to NOT use erythropoietin in an attempt to treat anemia in septic patients. Frequently monitor laboratory results and adjust care as indicated.
10. Mechanical ventilation may be necessary so close and continual evaluation of both airway and ventilatory efforts are important.	Interventions depend on patients' condition and responses to treatment, PEEP may be required in these patients.
11. Sedation should be used especially in mechanically ventilated patients.	Follow critical care sedation protocols, avoid paralytics and closely monitor patient.
12. Glucose control using frequent and accurate glucose measuring and intravenous insulin.	Caution with POCT as individual clinician technique can influence quality of results.
13. Renal replacement may be necessary/helpful in treating severe sepsis/septic shock.	Continuous veno- venous hemofiltration can be helpful in unstable septic/septic shock patients.
14. Bicarbonate therapy not recommended for treating severe sepsis/septic shock.	Improve acidotic state in these patients via infusion of fluids and correction of cellular acidosis.
15. Deep Vein prophylaxis using either low molecular weight heparin or a mechanical prophylactic device.	May consider using a combination of therapies depending the patients risk for DVT.
16. Stress Ulcer prophylaxis using H2 blockers or proton pump inhibitors.	Benefits of long term prevention of GI bleeding important to consider along with prevention of VAP.
17. Consideration for limitation of medical support based on realistic expected patient outcomes.	Living Will and HealthCare Surrogate designation should be completed prior to serious illness.

APPENDIX B: PERMISSION FOR USE OF THE IOWA MODEL FIGURE



Department of Nursing Services and Patient Care
Nursing Research, Evidence-Based Practice, Quality
200 Hawkins Drive, RM T100 GH
Iowa City, IA 52242
319-384-9098; 319-336-4348 (fax)
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February 9, 2015

Darleen A. Williams, MSN, CNS, CEN, CCNS, CNS-BC, EMT-P
DNP Student
University of Central Florida DNP Program
1732 Limewood Lane
Orlando, FL 32818



Dr. Williams:

As requested on August 5, 2011, you have permission to use a copy of the *1998 Iowa Model of Evidence-Based Practice to Promote Quality Care* in your student/paper assignment and presentation.

Copyright of the *Iowa Model of Evidence-Based Practice to Promote Quality Care* will be retained by the University of Iowa Hospitals and Clinics.

Please include the following statement with the figure: "Used/Reprinted with permission from the University of Iowa Hospitals and Clinics and Marita G. Titler, PhD, RN, FAAN, Copyright 1998. For permission to use or reproduce the model, please contact the University of Iowa Hospitals and Clinics at 319-384-9098 or uihcnursingresearchandebp@uiowa.edu." The reference for the Iowa Model is listed on the attached.

If you have any questions, please feel free to contact me at 319-384-9098 or kimberly-jordan@uiowa.edu. Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "Kimberly Jordan".

Kimberly Jordan
Administrative Services Coordinator

**APPENDIX C: SURVIVING SEPSIS CAMPAIGN INITIAL RESUSCITATION
BUNDLE**

2008 Six Hour Surviving Sepsis Campaign Resuscitation Bundle Summary

This six hour resuscitation bundle is a combination of evidence-based clinical goals that must be completed within 6 hours of identifying severe sepsis or septic shock.

1. Measure serum lactate.
2. Obtain blood cultures prior to antibiotic administration (if possible).
3. Administer broad-spectrum antibiotic within 3 hours of arrival to ED or within 1 hour of non-ED admission.
4. Treat hypotension and/or elevated lactate with intravenous fluids (initial minimum of 20 mL/kg of crystalloid).
5. Administer vasopressors for hypotension not responding to initial fluid resuscitation to maintain mean arterial pressure (MAP) >65 mmHg.
6. Administer vasopressors for hypotension not responding to initial fluid resuscitation to maintain mean arterial pressure (MAP) >65 mm Hg.
7. Maintain central venous pressure (CVP) of >8 mm Hg.
8. Achieve and maintain central venous oxygen saturation (ScvO₂) >70% or mixed venous oxygen saturation (SvO₂) >65%.

**APPENDIX D: EMERGENCY DEPARTMENT SEVERE SEPSIS ALERT AND
PRACTICE PROTOCOL**

**Orlando Regional Medical Center
Emergency Department
SEVERE SEPSIS ALERT GUIDELINES**

PLEASE NOTE: Nothing replaces professional CLINICAL JUDGEMENT when evaluating patients. If SEVERE SEPSIS IS SUSPECTED and the patient is not in an ED treatment bed yet INITIATE TREATMENT and notify the charge nurse STAT.

Pre-Hospital/ Emergency Medical Services Process

- When receiving an EMS radio report complete the Severe Sepsis screening section on the EMS report form. If positive notify the Charge nurse STAT.
- Patients presenting via EMS with *Suspected Severe Sepsis* will be seen immediately by the ED staff. If assigned to an ED treatment area the appropriate RN will follow the ED Severe Sepsis guidelines. If no ED treatment bed is immediately available the ED paramedic will notify the ED charge nurse STAT and follow the ED Severe Sepsis guidelines.

Emergency Department Process

- Patient arrives in ED: Assessment and Severe Sepsis screening are completed and triage category is assigned (suspected severe sepsis patients are triage category 1 or 2). All appropriate documentation in Sunrise will be completed.
- If the patient is not already in or assigned to a treatment bed notify the charge nurse **STAT** for bed assignment. The EDMD will be notified immediately that a suspected severe sepsis patient is in the department. Remember, the severe sepsis patient is a priority and treatment should begin immediately. Antibiotics should be given within **one hour** of being ordered. When available an ED phlebotomist will respond to assist with drawing blood and obtaining blood cultures.
- The EDMD will evaluate the patient promptly and if severe sepsis is suspected initiate a SEVERE SEPSIS ALERT and appropriate Severe Sepsis Order Set.
- When central line placement is initiated, every effort will be made to strictly adhere to hospital policies, including all necessary preparations and time out procedures.
- After initial resuscitation has been initiated consider obtaining other cultures as necessary ie: sputum or from existing wounds.

Patient Care Coordinator (PCC) process:

- All of the PCC's pagers will be activated when the "22" process for **SEVERE SEPSIS ALERT** is initiated.

- The PCC's office will call the ED "C" desk to acknowledge the **SEVERE SEPSIS ALERT** and get all necessary information from the ED regarding the patient's condition and type of bed needed for admission.

Respiratory Therapy process:

- Once the SEVERE SEPSIS ALERT page is received the ED respiratory therapist will respond to the ED bed where the patient is being treated to obtain, if ordered, STAT ABG's and perform POCT arterial lactate, if no ABG's are ordered the RT will run a STAT POCT venous lactate. RT will do an ETCO₂ evaluation and assist with any necessary respiratory support the patient may require.

Radiology process:

- Upon notification of a SEVERE SEPSIS ALERT the ED radiology technologist will respond to the ED bed where the patient is being treated to perform STAT any diagnostic radiology testing as required.

Orlando Regional Medical Center

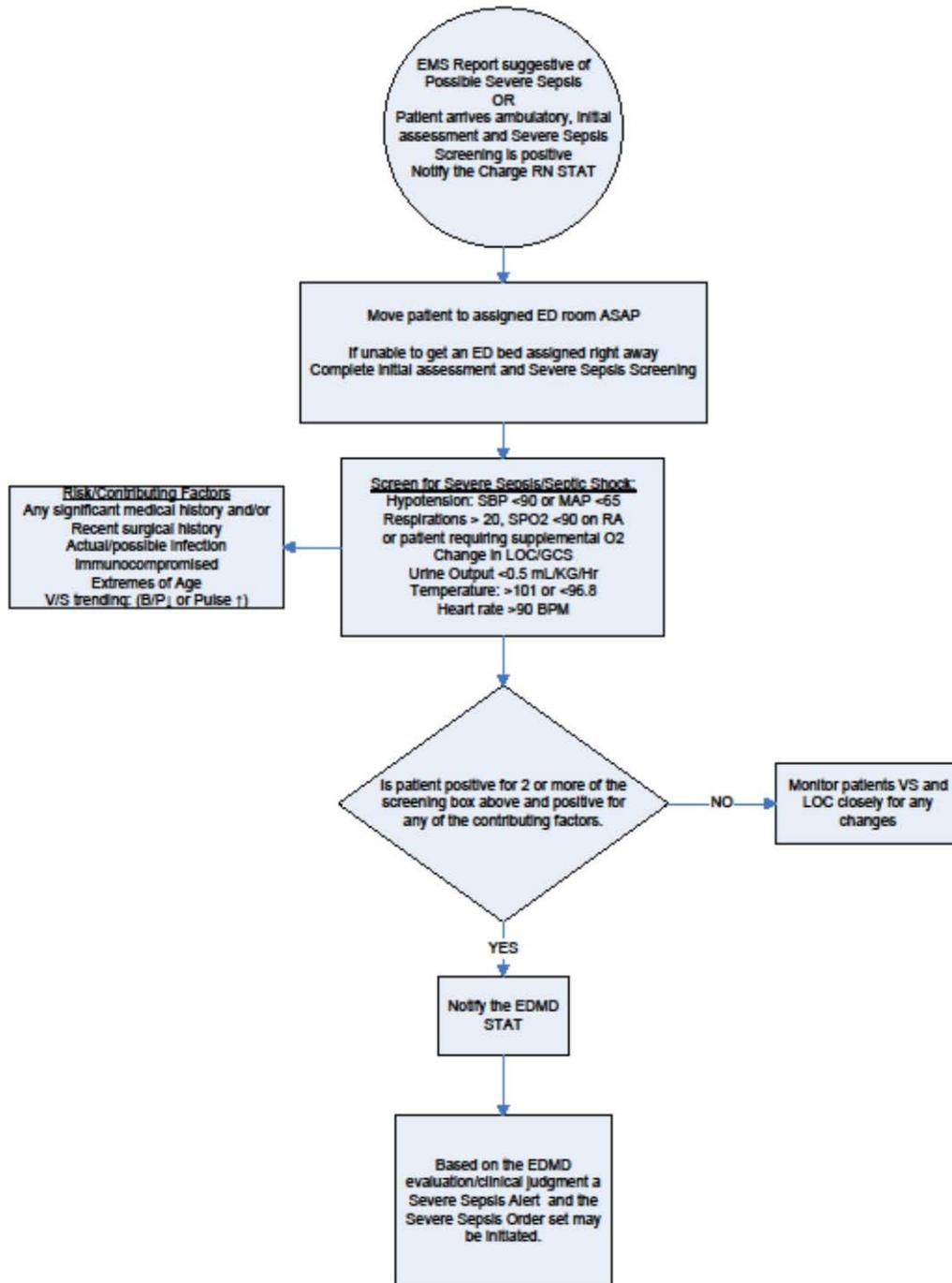
EMERGENCY DEPARTMENT “SEVERE SEPSIS ALERT” PAGER LIST

1. ED Respiratory Therapist
2. Patient Care Coordinator
3. ED staff nurse professional pager
4. ED Clinical Nurse Specialist
5. ED radiology
6. ED PharmD
7. ED phelbotomist

ED Secretary notifications:

1. Senior ED Resident on duty
2. Hospital Pharmacy

ORMC-ED Severe Sepsis Algorithm



PLACE STAT LABEL HERE

LINE UP PATIENT I.D. LABEL HERE

Allergies: _____

Nursing & Respiratory:

- STAT Establish intravenous access (at least one large bore) for IV fluid administration
- If, after IV bolus, MAP is still < 65 mmHg or SBP < 90 and or CVP < 8 mmHg notify managing physician
- FOR ED PATIENTS:**
 - STAT EKG. STAT portable CXR, ETCO2 evaluation.
 - ABG
 - If ABG is ordered by ED M.D. perform POCT arterial lactate. If no ABG is ordered RT will do POCT venous lactate.
 - Draw blood and send STAT:
 - CBC with differential, CMP, PT, PTT, type and screen, and blood cultures X 2 from different peripheral venipuncture sites. One set of blood cultures may be drawn from a pre-existing IV or central line **only if ordered by a physician.**
 - May obtain one set of the blood cultures from a pre-existing IV or central line
- Draw cultures prior to administering antibiotics unless this would delay giving antibiotics > 1 hour**
- FOR IN-PATIENTS:**
 - Draw blood and send to Laboratory Services for STAT:
 - Serum arterial lactate, ABG, and blood cultures X 2 from different peripheral venipuncture sites. One set of blood cultures may be drawn from a pre-existing IV or central line **only if ordered by a physician.**
 - May obtain one set of the blood cultures from a pre-existing IV or central line
- Draw cultures prior to administering antibiotics unless this would delay giving antibiotics > 1 hour**
- Serum random cortisol level
- STAT UA; R/O UTI
- If patient has an existing indwelling urinary catheter from transferring facility remove and insert a new indwelling urinary catheter BEFORE obtaining urine specimen.
- After initial resuscitation has been initiated consider obtaining other cultures ie: sputum or from existing wounds.
- If not present, prepare for the insertion of a central venous pressure catheter: include all necessary supplies and equipment for insertion at the bedside.

Monitoring:

- Continuous cardiac monitoring
- Pulse oximetry. Initiate oxygen therapy if oxygen saturation is < 94%
- If the patient gets intubated, monitor ETCO2 post intubation

Consultation:

- Consult
- Medical Critical Care for management of the patient
- Surgical Critical Care for placement of central venous access line
- _____ for placement of central venous access line

IV Fluids:

- 0.9% Normal Saline 2 liter bolus IV over 15-30 minutes
- Repeat _____ mL 0.9% Normal Saline IV bolus rapidly if SBP is < 90, MAP < 65 mmHg; HR >110 bpm.

_____, M.D. I.D.#: _____ Date: _____ Time: _____



ORLANDO HEALTH
1414 Kuhl Ave. • Orlando, FL 32806

**SEVERE SEPSIS INITIAL
RESUSCITATION ORDERS – ADULT
ED AND IN-PATIENT**

PLACE STAT LABEL HERE

LINE UP PATIENT I.D. LABEL HERE

Antibiotics/Antifungals:

Antimicrobials: (Pneumonia)

- Cefepime (Maxipime®) 2 Gm IV X 1 STAT [indication: severe sepsis] +
Tobramycin (Nebcin®) 200 mg IV X 1 STAT [indication: severe sepsis] +
Vancomycin (Vancocin®) 2 Gm IV X 1 STAT [indication: severe sepsis]
- Piperacillin/Tazobactam (Zosyn®) 4.5 Gm IV X 1 STAT [indication: severe sepsis] +
Tobramycin (Nebcin®) 200 mg IV X 1 STAT [indication: severe sepsis] +
Vancomycin (Vancocin®) 2 Gm IV X 1 STAT [indication: severe sepsis]
- Aztreonam (Azactam®) 2 Gm IV X 1 STAT [indication: severe sepsis] +
Tobramycin (Nebcin®) 200 mg IV X 1 STAT [indication: severe sepsis] +
Vancomycin (Vancocin®) 2 Gm IV X 1 STAT [indication: severe sepsis]

Antimicrobials (Intra-Abdominal)

- Piperacillin/Tazobactam (Zosyn®) 4.5 Gm IV X 1 STAT [indication: severe sepsis] +
Fluconazole (Diflucan®) 800 mg IV X 1 STAT [indication: severe sepsis]
- Ciprofloxacin (Cipro®) 400 mg IV X 1 STAT [indication: severe sepsis] +
Metronidazole (Flagyl®) 500 mg IV X 1 STAT [indication: severe sepsis] +
Fluconazole (Diflucan®) 800 mg IV X 1 STAT [indication: severe sepsis]
- Cefepime (Maxipime®) 2 Gm IV X 1 STAT [indication: severe sepsis] +
Metronidazole (Flagyl®) 500 mg IV X 1 STAT [indication: severe sepsis] +
Fluconazole (Diflucan®) 800 mg IV X 1 STAT [indication: severe sepsis]

Antimicrobials: (Urinary Tract Infection)

- Cefepime (Maxipime®) 2 Gm IV X 1 STAT [indication: severe sepsis]
- Ciprofloxacin (Cipro®) 400 mg IV X 1 STAT [indication: severe sepsis]

Vasopressor:

- Norepinephrine (Levophed®) 0.05 mcg/kg/min IV continuous infusion via central line preferred. Titrate to keep MAP > 65 mmHg. (Do not exceed 1 mcg/kg/min without notifying physician).

If after resuscitation the patient requires norepinephrine to maintain perfusion and/or mechanical ventilation, transfer to ICU and begin Severe Sepsis Maintenance Order Set

_____, M.D. I.D.#: _____ Date: _____ Time: _____

APPENDIX E: EDSSAPP POSTER



Emergency Department Implementation of a Severe Sepsis Alert & Practice Protocol

Darleen A. Williams, MSN, CNS, CEN, CCNS, CNS-BC & Katrin Breault, RN
Orlando Regional Medical Center Emergency Department, Orlando, Florida



PROBLEM STATEMENT

According to the Centers for Disease Control, sepsis is the 10th leading cause of death in the United States. Early recognition and time sensitive appropriate interventions are essential to patient survival. The Society of Critical Care Medicine's "Surviving Sepsis Campaign" acknowledges the important role that standard practice protocols and guidelines play in improving outcomes for septic patients (<http://www.survivingsepsis.com>).

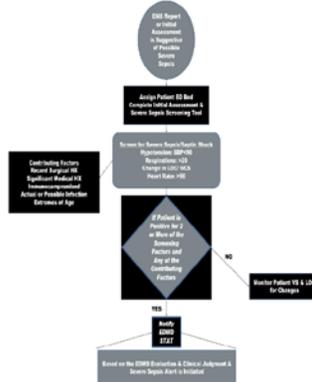
The primary objective of our Emergency Department Severe Sepsis Alert and Practice Protocol (EDSSAPP) is rapid recognition of septic patients followed by immediate initiation of early goal directed therapy including fluid resuscitation and antibiotic administration within one hour of arrival. In addition, EDSSAPP also expedites the admissions process.

METHODS

This was a process development and implementation project led by the ED's Clinical Nurse Specialist. An interdisciplinary team was formed and the 2008 Surviving Sepsis Campaign's international guidelines were used to help develop the process. In addition, current existing alert processes were also reviewed and components from them adapted for this project.

Data was collected through a retrospective electronic medical record review. In order to maintain inter-rater reliability all data was collected by the CNS and the ED staff nurse assisting on this project.

SEVERE SEPSIS ALERT ALGORITHM



DATA ANALYSIS

During the first 8 months post-implementation a total of 22 patients had the Severe Sepsis Alert and Practice Protocol initiated. For comparative analysis 22 patients diagnosed with severe sepsis in the pre-implementation phase were randomly selected for review. Overall, the majority of patients were male. Length of stay went from 10.5 days in the pre-implementation phase to 7.9 days post-implementation.

RESULTS

Comparison of Initial Antibiotic Administration Before and After a Severe Sepsis Alert and Protocol Implementation (N=44)

Administration Time	Before	After
Administered < 1 Hour	0%	73%
Administered 1 – 2 Hours	9%	14%
Administered 2 – 3 Hours	4.5%	4%
Administered 3 – 4 Hours	32%	9%
Administered > 6 Hours	54.5%	0%
Total	100%	100%

Source: 8 Month ED Chart Reviews 2008 – 2009 vs. 2009 – 2010

CONCLUSIONS & IMPLICATIONS

The literature supports that increased awareness of severe sepsis and early goal directed therapy improves patient outcomes. After implementation of the severe sepsis alert and practice protocol there was a marked decrease in the door to first antibiotic administration times in the ED and a reduction in patient's hospital length of stay was seen.

The positive results seen since the implementation of EDSSAPP has inspired the planning of a formal research study and greater staff involvement as our process is further refined.

APPENDIX F: LITERATURE REVIEW SUMMARY

Authors/Year	Discipline	Methods	Sample/Setting	Findings
<p>Arnold, R., Shapiro, N., Jones, A., Schorr, C., Pope, J., Casner, E., Parillo, J., Dellinger, R., Trzeciak, S.</p> <p>2008</p>	<p>Medicine</p>	<p>Using a standard data collection document analyzed consecutive ED patients diagnosed with severe sepsis between 2004-2007.</p>	<p>Patients 17 or older meeting consensus definitions for severe sepsis from a research collaborative of 3 urban hospitals.</p>	<p>A total of 166 subjects met criteria. Overall mortality was 23%. Mortality of the non-clearance lactate group was 60% and 19% in the lactate clearance group. An important contributing factor to survival is early lactate clearance.</p>
<p>Carlborn, D., Rubenfeld, G.</p> <p>2007</p>	<p>Medicine</p>	<p>National Telephone Survey with both quantitative and qualitative analysis</p>	<p>24 Emergency Medicine directors and 40 ED nursing managers from 25 of the US most densely populated areas.</p> <p>2 of the busiest teaching and 2 of the busiest non-teaching hospitals EDs.</p>	<p>Both the medical directors and nursing managers identified multiple barriers to implementing components of the SSC resuscitation bundles. One factor seen as critical is the nursing shortage. Also noted was challenged in recognition of sepsis. Only 7% of EDMDs acknowledged using EGDT.</p> <p>Study authors concluded there is an increased need for collaboration between critical care medicine and emergency medicine physicians. The ED is not the best place for extended</p>

Authors/Year	Discipline	Methods	Sample/Setting	Findings
				care for critical patients.
Clark, K., Brush, L. 2007	Nursing	Data were collected between 2001-2003 retrospectively from an ED computer tracking program, and the corresponding in-hospital program. An exploratory analysis of secondary data was conducted.	ED patients admitted to the ICU. (1,536) Large inner city, level one trauma center and tertiary care hospital.	The greater the time to first medication administration in the ED the longer the patients' hospital stay. Recognition of the patient's acuity and implementation of intervention's impacted both those who walked into the ED and those who arrived via ambulance. ED throughput and multidisciplinary collaboration are important contributing factors.
de Kruif, M., Limper M., Gerritsen, H., Speck, A., Brandjes, D., ten Cate, H., Bossuyt, M., Reitsma, P., van Gorp, E. 2010	Medicine	Observational study using multiple logistic regression analysis was performed to determine the diagnostic value of Procalcitonin (PCT) in diagnosing sepsis.	Patients 18 to 85 years old who presented to the ED with fever. 310 bed teaching hospital.	211 patients met criteria, 73 had positive blood cultures, 104 had infection likely via imaging and 34 had no infection identified. PCT can add value as a biomarker for sepsis when used in conjunction with c-reactive protein and clinician judgment.
Dellinger, P., Levy, M., Carlet, J., Bion, J., Parker, M., Jaeschke, R., Reinhart, K.,	Medicine	Using the Grades of Recommendation Assessment Development	N/A	International experts agree and evidence supports the guidelines. Rational is

Authors/Year	Discipline	Methods	Sample/Setting	Findings
Angus, D., Brun-Buisson, C., Beale, R., Calandra, T., Dhainaut, J., Gerlach, H., Harvey, M., Marini, J., Marshall, J., Ranieri, M., Ramsay, G., Sevransky, J., Thompson, T., Townsend, S., Vender, J., Zimmerman, J., Vincent J. 2008		Evaluation (GRADE) tool the SSC 2008 International guidelines for the management of severe sepsis and septic shock were systematically reviewed.		provided for each recommendation.
De-Miguel-Yanes, J., Andueza-Lilli, J., Gonzalez-Ramallo, V., Pastor, L., Munoz, J. 2006	Medicine	Observational study (only 2 months long)	A large university medical center ED (sees 515 patients/day) Physicians in study Internal Medicine NOT EDMDs	Compliance with EGDT guidelines poor, underestimated severe sepsis in 17 patients while overestimated in 2 patients.
Huang, D., Clermont, G., Dremsizov, T., Angus, D. 2007	Medicine	Determine the estimated effectiveness and resource use when implementing the SSC guidelines from the hospital perspective.	1000 Simulated adult septic patients. Simulation of the average US ED.	While there is financial investment in developing and implementing a process to initiate EGDT for sepsis patients the decreased length of stay and mortality rates can offset the initial costs.
Jansen, T., van Bommel, J., Bakker, J. 2009	Medicine	Systematic review of literature and Medical Database information.	N/A	Review determined that lactate plays a role in risk stratification for sepsis patients and

Authors/Year	Discipline	Methods	Sample/Setting	Findings
				suggested further, more rigorous study of its use.
Jones, A., Troyer, J., Kline, J. 2011	Medicine	Economic data analysis.	2 groups used the first one from 1 year before EGDT was implemented and the 2 nd from 2 years after. Single center study.	After very complex calculations it was determined that implementation EGDT is cost effective when calculating in the patient's life expectancy and quality adjusted life years (QALYs).
Jones, A., Shapiro, N., Roshon, M. 2007	Medicine	Sepsis process implementation with pre and post process evaluations.	Septic and septic shock patients admitted via the ED. 3 large urban hospitals ED's	Each facility encountered its own set of challenges and barriers. The authors concluded that only an estimated 50% of ED patients in the US receive the recommended EGDT care for sepsis as healthcare providers are slow to accept these standards. Common conclusions included that each facility needed to use resources and staffing appropriate for their individual needs, each facilities medical staff both ED and

Authors/Year	Discipline	Methods	Sample/Setting	Findings
				Intensive Care were slow to adopt EGDT, the introduction of new equipment required extensive training time and availability was not consistently reliable. The necessary follow up to sustain the programs used a lot of resources and time.
Lagu, T., Rothberg, M., Nathanson, B., Pekow, P., Steingrub, J., Lindenauer, P. 2011	Medicine	Analyzed the amount of money spent by the facility on sepsis and compared to the mortality of the population.	Between June 1, 2004 to June 30, 2006 reviewed 166,931 septic patients' records from 309 hospitals. The majority of hospitals were in urban locations, half were in the southern US.	The authors used complex data analysis and concluded there was NO relationship between spending more for sepsis care and improved patient outcomes.
Lee, Chien-Change, Chen, Shey-Ying, Tsai, Chu-Lin, Wu, Shwu-Chong, Chiang, Wen-Chu, Wange, Jiun-Ling, Sun, Hsin-Yun, Chen, Shyr-Chyr, Chen, Wen-Jone, Hsueh, Po-Ren 2008 Taiwan	Medicine	Prospective observational study looking at the prognostic value of Procalcitonin, C-Reactive protein and Mortality Scoring (MEDS) on septic ED patients.	Consecutive ED patients meeting SIRS criteria who were >14 years old. Emergency department at a university affiliated facility seeing >110,000 ED patients per year.	The MEDS scoring was a predictor of mortality and Procalcitonin is better in predicting mortality than C-Reactive Protein.
Levy, M., Dellinger, P., Townsend, S., Zwirble, W., Marshall, J., Bion,	Medicine	A performance improvement initiative to look at sites using the SSC guidelines and the	Any hospital worldwide participating in entering data into the SSC site.	Impression: there is improving compliance with EGDT bundles and decreased

Authors/Year	Discipline	Methods	Sample/Setting	Findings
J., Schorr, C., Artigas, A., Ramsay, G., Beale, R., Parker, M., Gerlach, H., Reinhart, K., Silva, E., Harvey, M., Regan, S., Angus, D. 2010		facility mortality. Partnered with the Institute of Healthcare Improvement to develop bundles.	165 hospitals in 30 countries participated with a total of 15,022 patients data included.	mortality in septic patients. Reviewers stated this improvement may be secondary to the patients data entered into the site were not as seriously ill as protocol called for.
Mikkelsen, M., Gaeski, D., Goyal, M., Miltiades, A., Munson, J., Pines, J., Fuchs, B., Shah, C., Bellamy, S., Christie, J. 2010	Medicine	Retrospective cohort study of EGDT eligible patients via EMR review. 2005 - 2007	ED severe sepsis/septic shock patients in a University Based Hospital ED.	EGDT was underutilized despite the documentation it improves patient outcomes. Analysis of EDMD's showed that EGDT was less likely to be initiated when the MD was female and had practiced for years. EGDT not started 42% of the time and not completed 43% of the time.
Nguyen, B. H., Corbett, S., Steele, R., Banta, J., Clark, R., Hayes, S., Edwards, J., Cho, T., Wittlake, W. 2007	Medicine	2 year Prospective observational study.	Academic medical center ED patients meeting severe sepsis/septic shock.	A peer review forum used with the ED medical director sending letters to individual MD's who did not complete the required EGDT bundle on eligible patients. It took 2 years to reach 50% of implementation compliance.
Powell, E., Khare,	Medicine	Cross-sectional	National data	The greater the

Authors/Year	Discipline	Methods	Sample/Setting	Findings
R., Courtney, M., Feinglass J. 2010		analysis of 2007 national in-patient data. Healthcare Research and Quality Agency: healthcare cost utilization project.	87,166 adult ED patients who were sepsis admits. From 551 US mainly urban hospitals.	volume of sepsis the better the care the population received. Authors concluded increased volume equals improved quality of care secondary to experience.
Shorr, A., Micek, S., Jackson, W., Kollef, M. 2007	Medicine	Retrospective analysis of before and after a sepsis protocol implementation to determine the financial impact.	120 ED patients with severe sepsis or septic shock, half before and half after sepsis protocol implementation. Academic hospital emergency department.	The median cost per patient before the protocol was \$21,985 and post protocol cost was \$16,103. Use of the protocol not only saved lives but also decreased overall hospital costs.
Talmor, D., Greenberg, D., Howell, M., Lisbon, A., Novack, v., Shapiro, N. 2008	Medicine	Prospective cohort study looking at both clinical and economic patient outcomes.	Consecutive patients presenting in septic shock. Emergency Department and Intensive Care Units in an urban facility with a comprehensive sepsis protocol in place.	The mortality of the historical control group was 9.4% higher than the study group; however the costs associated to care for the study group was \$8,807 higher than the historical control group.
Vanzant, A., Schmelzer, M. 2011	Nursing	Discussion of Sepsis and review of literature related to recognition and treatment of sepsis in the emergency department.	N/A: Literature review and general discussion of sepsis.	General review of Sepsis and the challenges faced by Emergency Departments in dealing with this patient population. Suggestion by the authors for ED's to develop early recognition and treatment protocols.

Authors/Year	Discipline	Methods	Sample/Setting	Findings
Weinert, C., Mann, H. 2008	Medicine	Opinion Review	Purpose of review was to examine the lack of research being brought to the bedside.	New discipline called Implementation Science was developed using principles from sociology, mass communications, adult education, informatics, research psychology and management theory. A new way to look at the evidence, confirm its strength and find a systematic way to change practice at the bedside mainly in the intensive care unit.
Zubert, S., Funk, D., Kumar, A. 2010	Medicine	Editorial	Review of multiple studies looking at reducing mortality in septic patients using EGDT.	Time is an important factor in the care of critically ill or injured patients. In the sepsis population receiving the most appropriate antibiotic within one of becoming symptomatic decreases mortality. Accomplishing this in a busy ED is challenging without an organized and systematic approach.

APPENDIX G: NURSING RESEARCH COUNCIL APPROVAL LETTER



Orlando Health
Center for Nursing Research
1414 Kuhl Ave. MP 161
Orlando, FL 32806
321.841.8332
harriet.miller@orlandohealth.com
orlandohealth.com

August 21, 2013

Harry Wingfield, MFA, CIP
Manager
Orlando Regional Medical Center
Institutional Review Board

Dear Harry,

I am writing to let you know that Darleen Williams, MSN, CNS, CEN, CCNS, CNS-BC, EMT-P (PI) submitted her proposal for a research study at Orlando Health titled **Pre and Post Implementation Evaluation of an Emergency Department Severe Sepsis Alert and Practice Protocol (EDSSAPP)** to the Orlando Health Corporate Nursing Research Council for review.

The Nursing Research Council reviewed the proposal and they recommended changes prior to Institutional Review Board submission (IRB). This proposal is recommended for IRB submission and Darleen Williams, MSN, CNS, CEN, CCNS, CNS-BC, EMT-P (PI) will be forwarding the new proposal to you.

Thank you for allowing us to review this protocol.

Sincerely,

Harriet Miller, PhD, ARNP, CPN, CCRP

Harriet D. Miller., PhD, ARNP, CPN, CCRP
Chair, Nursing Research Council and
Nurse Scientist
Center for Nursing Research

APPENDIX H: UCF IRB APPROVAL LETTER



University of Central Florida Institutional Review Board
Office of Research & Commercialization
12201 Research Parkway, Suite 501
Orlando, Florida 32826-3246
Telephone: 407-823-2901, 407-882-2901 or 407-882-2276
www.research.ucf.edu/compliance/irb.html

Notice that UCF will Rely Upon Other IRB for Review and Approval

From : UCF Institutional Review Board
FWA00000351, IRB00001138

To : Darleen Williams

Date : August 27, 2013

IRB Number: SBE-13-09585

Study Title: **Pre and Post Implementation Evaluation of an Emergency Department Severe Sepsis Alert and Practice Protocol**

Dear Researcher:

The research protocol noted above was reviewed by the University of Central Florida IRB designated Reviewer on August 27, 2013. The UCF IRB accepts the Orlando Health's Institutional Review Board review and approval of this study for the protection of human subjects in research. **The expiration date will be the date assigned by the Orlando Health's Institutional Review Board.**

This project may move forward as described in the protocol. It is understood that the Orlando Health's IRB is the IRB of Record for this study, but local issues involving the UCF population should be brought to the attention of the UCF IRB as well for local oversight, if needed.

All data must be retained as specified in the protocol for a minimum of five years (six if HIPAA applies) past the completion of this research. Additional requirements may be imposed by your funding agency, your department, or other entities. Access to data is limited to authorized individuals listed as key study personnel.

Failure to provide a continuing review report for renewal of the study to the Orlando Health's IRB could lead to study suspension, a loss of funding and/or publication possibilities, or a report of noncompliance to sponsors or funding agencies. If this study is funded by any branch of the Department of Health and Human Services (DHHS), an Office for Human Research Protections (OHRP) IRB Authorization form must be signed by the signatory officials of both institutions, and a copy of the form must be kept on file at the IRB office of both institutions.

On behalf of Sophia Dziegielewska, Ph.D., L.C.S.W., UCF IRB Chair, this letter is signed by:

Signature applied by Patria Davis on 08/28/2013 10:32:10 AM EDT

IRB Coordinator

APPENDIX I: ORMC IRB APPROVAL LETTER



1414 Kuhl Ave.
Orlando, FL 32806
321.843.7000
orlandohealth.com

MDACCO/ORMC/APMC
FWA # 0000384

DATE: August 26, 2013
TO: Darleen Williams
FROM: Orlando Regional Medical Center (ORMC) IRB
PROJECT TITLE: [497068-1] PRE AND POST IMPLEMENTATION EVALUATION OF AN EMERGENCY DEPARTMENT SEVERE SEPSIS ALERT AND PRACTICE PROTOCOL
REFERENCE #: [REDACTED]
SUBMISSION TYPE: New Project
ACTION: DETERMINATION OF EXEMPT STATUS
DECISION DATE: August 26, 2013
REVIEW CATEGORY: Exemption category # 4

Thank you for your submission of New Project materials for this project. The Orlando Regional Medical Center (ORMC) IRB has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations.

The IRB has approved the HIPAA Waiver of Authorization, under 45 CFR 164.512(i)(1) (i), and the Waiver of Informed Consent, under 45 CFR 46.116 (d) and 45CFR 46.117(C)(2), as requested on the "Waiver of Consent, Documentation, or use of PHI" IRB form that was submitted for the aforementioned study.

We will retain a copy of this correspondence within our records.

If you have any questions, please contact Harry Wingfield at 321-841-2646 or harry.wingfield@orlandohealth.com. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Orlando Regional Medical Center (ORMC) IRB's records.

Orlando Health Facilities: • ARNOLD PALMER HOSPITAL FOR CHILDREN • SOUTH SEMINOLE HOSPITAL
• M. D. ANDERSON CANCER CENTER ORLANDO • WINNIE PALMER HOSPITAL FOR WOMEN & BABIES
• SOUTH LAKE HOSPITAL • DR. P. PHILLIPS HOSPITAL • ORLANDO REGIONAL MEDICAL CENTER

APPENDIX J: ORMC ADMINISTRATION EDSSAPP APPROVAL



1414 Kuhl Ave.
Orlando, FL 32806
321.841.5111
myormc.com

January 22, 2013

Darleen A. Williams MSN, CNS, CEN, CCNS, CNS-BC, EMT-P
DNP Student
University of Central Florida DNP Program
1732 Limewood Lane
Orlando, FL. 332818

Dear Ms. Williams,

Your request to use a modified version of the Emergency Department Severe Sepsis Alert and Practice Protocol (EDSSAPP) materials in your doctoral thesis has been approved by the following administrative personnel:

Ms. Jayne Willis MSN, RN, NEA-BC
Chief Nursing Officer
Orlando Regional Medical Center

Leslie Ann Line Anderson MSHA, RN, CEN, NE-BC
Patient Care Administrator
ORMC Emergency Services and Air Care Team

Sincerely,

Leslie Line Anderson
Patient Care Administrator
ORMC Emergency Services and Air Care Team



APPENDIX K: SAMPLE EDSSAPP SPREADSHEET

Spread sheet EDSSAPP - Microsoft Excel

File Home Insert Page Layout Formulas Data Review View

Clipboard Font Alignment Number Styles Cells Editing

Normal Bad Good Neutral Calculation Check Cell

AutoSum Fill Clear Sort & Filter Find & Select

A1 Subject Number

	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V
1	Mode of Arrival	Age	Gender	Race	Presenting C/O	Abx ordered	Abx Started	Total ABX time min	Lactate result	V or A	WBC	Time left ED	Total ED LOS	Total Hospital LOS	D/C status	ICD 9 Codes	Comments
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APPENDIX L: EDSSAPP DEMOGRAPHIC TABLE

Time Cohorts	All	Time 0	Time 1		Time 2	
Alert Status	All	Non-Alert	Alert	Non-Alert	Alert	Non-Alert
Variables	Number (%)					
Size	201 (100%)	22 (10.94%)	19 (9.45%)	26 (12.93%)	113 (56.21%)	21 (10.44%)
Age						
Range	19-102	23-90	23 – 93	19 – 88	19 – 95	29 – 102
Mean (sd)	62.42 (18.47)	59.86 (18.31)	62.37 (20.78)	53.62 (21.53)	64.95 (16.66)	62.43 (19.82)
Gender						
Male	103 (51.2)	9 (40.9)	14 (73.7)	17 (65.4)	57 (50.4)	6 (28.6)
Female	98 (48.8)	13 (59.1)	5 (26.3)	9 (34.6)	56 (49.6)	15 (71.4)
Race						
Caucasian	116 (57.7)	14 (63.6)	13 (68.4)	14 (53.8)	65 (57.5)	10 (47.6)
Black	60 (29.9)	4 (18.2)	6 (31.6)	8 (30.8)	36 (31.9)	6 (28.6)
Hispanic	21 (10.4)	3 (13.6)	0 (0.0)	4 (15.4)	10 (8.8)	4 (19.0)
Asian	4 (2.0)	1 (4.5)	0 (0.0)	0 (0.0)	2 (1.8)	1 (4.8)
Week Day						
Sunday	15 (7.5)	2 (9.1)	0 (0.0)	3 (11.5)	9 (8.0)	1 (4.8)
Monday	36 (17.9)	6 (27.3)	4 (21.1)	4 (15.4)	19 (16.8)	3 (14.3)
Tuesday	33 (16.4)	2 (9.1)	4 (21.1)	3 (11.5)	24 (21.2)	0 (0.0)
Wednesday	32 (15.9)	2 (9.1)	1 (5.3)	6 (23.1)	18 (15.9)	5 (23.8)
Thursday	32 (15.9)	2 (9.1)	6 (31.6)	5 (19.2)	14 (12.4)	5 (23.8)
Friday	25 (12.4)	7 (31.8)	1 (5.3)	1 (3.8)	12 (10.6)	4 (19.0)
Saturday	28 (13.9)	1 (4.5)	3 (15.8)	4 (15.4)	17 (15.0)	3 (14.3)
Mode of Arrival						
EMS	136 (67.7)	17 (77.3)	19 (100)	18 (69.2)	71 (62.8)	11 (52.4)
Private Car	65 (32.3)	5 (22.7)	0 (0.0)	8 (30.8)	42 (37.2)	10 (47.6)
Shift Arrival						
7a-7p	127 (63.2)	13 (59.1)	12 (63.2)	17 (65.4)	69 (61.1)	16 (76.2)
7p-7a	74 (36.8)	9 (40.9)	7 (36.8)	9 (34.6)	44 (38.9)	5 (23.8)
Alert Status						
Alert	132 (65.7)	0 (0.0)	19 (100)	0 (0.0)	113 (100)	0 (0.0)
Non-Alert	69 (34.4)	22 (100)	0 (0.0)	26 (100)	0 (0.0)	21 (100)
C/O Systems						
Metabolic	56 (27.9)	4 (18.2)	6 (31.6)	4 (15.4)	38 (33.6)	4 (19.0)
Neurologic	51 (25.4)	8 (36.4)	6 (31.6)	6 (23.1)	29 (25.7)	2 (9.5)
Respiratory	31 (15.4)	5 (22.7)	3 (15.8)	4 (15.4)	13 (11.5)	6 (28.6)
GI	18 (9.0)	1 (4.5)	0 (0.0)	3 (11.5)	11 (9.7)	3 (14.3)
Cardiac	12 (6.0)	3 (13.6)	0 (0.0)	2 (7.7)	7 (6.2)	0 (0.0)
	9 (4.5)	0 (0.0)	1 (5.3)	5 (19.2)	1 (0.9)	2 (9.5)
Skin/Wounds	3 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	1 (4.8)
GU	21 (10.4)	1 (4.5)	3 (15.8)	2 (7.7)	12 (10.6)	3 (14.3)

Other						
WBC						
Range	0.5 – 84.5	5.1 - 33.5	0.5 – 54.0	1.6 – 43.0	0.5 – 84.4	5.2 -25.9
Mean	15.21 (10.77)	15.84 (9.49)	13.92 (11.77)	15.66 (10.91)	15.53 (11.52)	13.46 (6.49)
Antibiotic						
Order	194 (96.5)	21 (95.5)	19 (100)	22 (84.6)	111 (98.2)	21 (100)
Yes	7(3.5)	1 (4.5)	0 (0.0)	4 (15.4)	2 (1.8)	0 (0.0)
No						
Lactate						
Venous	94 (46.8)	5 (22.7)	10 (52.6)	6 (23.1)	68 (60.2)	5 (23.8)
Arterial	69 (34.3)	10 (45.5)	8 (42.1)	10 (38.5)	38 (33.6)	3 (14.3)
Not Done	38 (18.9)	7 (31.8)	1 (5.3)	10 (38.5)	7 (6.2)	13 (61.9)
Lactate Level						
Range	0.0 – 48.0	0.0 - 8.4	0.0 – 8.9	0.0 - 15.0	0.0 – 48	0.0 - 6.2
Mean (sd)	2.81 (4.26)	2.09 (.75)	1.53 (0.61)	3.05 (4.45)	3.15 (4.93)	1.14 (1.71)
ED LOS						
Range	54 – 1772	163 – 881	127 – 793	67 – 807	54 – 1772	173 -1442
Mean (sd)	472.28 (261.24)	442.18 (182.70)	365.32 (196.498)	422.88 (202.92)	487.81 (280.38)	578.19 (304.56)
Hospital LOS						
Range	1 – 91	1 – 60	1 – 43	1 – 43	1 – 91	1 – 21
Mean (sd)	10.11 (11.19)	11.95 (15.02)	9.00 (9.27)	9.00 (9.18)	10.48 (11.82)	8.57 (6.49)
Discharge						
status	66 (32.8)	6 (27.3)	2 (10.5)	9 (34.6)	41 (36.3)	8 (38.1)
Home	61 (30.3)	7 (31.8)	10 (52.6)	4 (15.4)	33 (29.2)	7 (33.3)
SNF	42 (20.9)	5 (22.7)	6 (31.6)	9 (34.6)	21 (18.6)	1 (4.8)
Expired	14 (7.0)	2 (9.1)	0 (0.0)	0 (0.0)	11 (9.7)	1 (4.8)
Hospice	12 (6.0)	2 (9.1)	0 (0.0)	3 (11.5)	3 (2.7)	4 (19.0)
Home	3 (1.5)	0 (0.0)	1 (5.3)	0 (0.0)	2 (1.8)	0 (0.0)
Health	2 (1.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (0.9)	0 (0.0)
Rehab	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)
AMA						
Psych						

APPENDIX M: ED PROCESS INFORMATION UPDATES

SEVERE SEPSIS ALERTS

JANUARY 2015

Audit Data

Methods and Measurement:

Sepsis Significance:

Data Analysis Results:

Sepsis Team Members:

Improvement Challenges:

Evidence of Improvement:

Place graph or chart here

Future Steps:

ORMC ED INFORMATION

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