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Antibiotic Administration Time During a Code Sepsis

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Abstract

Problem: Sepsis is the leading cause of morbidity and mortality and antibiotic administration within 60-minutes is a priority. The purpose of this quality improvement project was to improve sepsis patient's outcomes by administering parenteral antibiotics within 60-minutes of a code sepsis (CS) activation.

Method: Observational descriptive design utilizing a retrospective medical record review over a three-month period in 2020 and 2021. A purposive sampling of adult patients from a Midwestern, metropolitan, Level II trauma and medical center emergency department (ED) were selected.

Results: The administration of parental antibiotics once a sepsis bundle was activated was essentially 28-minutes in 2020 and 2021 (t (416)=0.16, p=.874). This is well within the recommended 60-minutes by *Surviving Sepsis Campaign* (SSC). In addition, there was a weak relationship found between antibiotic administration time and LOS for 2020 (r=-0.01; CI [-0.13, 0.11]; p=.910), and also for 2021 (r=0.02; CI [-0.11, 0.16]; p=.745). Results of a Fisher exact test found home or self-care was significant (in 2020: 128 [100.81]; in 2021: 53 [80.19], p<.001). More patients were discharged to home in 2020 than in 2021.

Implications: Antibiotic administration times were less than 60-minutes in 2020 and 2021. The LOS and final disposition were essentially unchanged. The Covid-19 pandemic may influence these results. Regardless, sepsis remains a leading cause of death in adults and continuous quality improvement may drive better outcomes.

Keywords: sepsis, sepsis bundle, and door-to-antibiotic time for sepsis treatment

Antibiotic Administration Time During a Code Sepsis

A leading cause of critical illness and hospital mortality is sepsis. Sepsis is a life-threatening organ dysfunction condition caused by a dysregulated and inflammatory host response to an infection (Coopersmith et al., 2018). Essentially one person dies every two minutes from sepsis; hence, sepsis is a worldwide medical condition claiming the death of 258,000 people each year and is considered a medical emergency (Walters, 2018). In the United States, there are more than 1.5 million cases of sepsis annually (Seymour, Gesten, Prescott, & Friedrich, 2017). The Centers for Disease Control and Prevention (CDC) reported the most common source (80%) for contracting illness originates within the general community (CDC, 2016). A deceiving characteristic for early sepsis is a well- or tired-appearing person who usually arrives in the emergency department (ED) or to a primary care provider (PCP) for a general illness complaint. Early identification of sepsis is critical, especially when there is a change in the patient's condition. The restoration of tissue perfusion and organ function becomes a primary goal in re-establishing and maintaining hemodynamic stability from the inflammatory response (Makic & Bridges, 2018). Patient survival from sepsis and controlling the body's response can be challenging.

A "sepsis protocol" or "sepsis bundle" has evolved and is based on worldwide evidence for the identification and management of sepsis. Kim and Sunghoon (2019) reported the following symptoms as important identifiers for sepsis and are known as the systemic inflammatory response syndrome (SIRS) criteria: abnormally high or low temperature (T), elevated heart rate (HR), elevated respiratory rate (RR), low blood pressure (BP) or mean arterial pressure (MAP) less than 65 mmHg, and unexplained

altered mental status (AMS). Once identified, a sepsis bundle has been recommended to be initiated to include a serum lactic acid, set of blood cultures, antibiotic administration, crystalloids initiated parenterally at 30 mL/kg over one hour, and vasopressors if two or more consecutive BP readings are low (Systolic BP <90 mmHg, or MAP <65 mmHg (Kim and Sunghoon, 2019). While protocols and bundles may vary slightly, a Level II Trauma and Medical Center in a large Midwestern, metropolitan area developed an evidence-based protocol known as "code sepsis" (CS) to decrease mortality and improve health outcomes for patients being treated for sepsis. The CS was developed to identify and treat suspected sepsis and septic shock based on the Centers for Medicare and Medicaid Services (CMS) sepsis core measures and guidelines from the Surviving Sepsis Campaign (Coopersmith et al., 2018). The medical center has been utilizing CS to identify and treat patients suspected of infection within the first six-hour period of suspicion. A CS activation consists of a medical team at the organization responding to the early recognition, early management and if needed, resuscitation of sepsis. The CS team consists of a critical care registered nurse (CCRN), respiratory therapist (RT), pharmacist, and an ED physician. When a patient is admitted with clinical symptoms of two or more SIRS criteria, and suspected or documented infection, a CS is activated for prompt intervention. Despite the CS team and CS bundle efforts, the administration time of the initial dose of antibiotics has been identified as a consistent problem and as an opportunity for improvement.

Timely antibiotic administration for patients suspected of infection is an essential factor to reducing complications and mortality from sepsis; and, is recommended to occur as soon as infection is identified or suspected (Kim and Sunghoon,2019). The purpose of

this quality improvement project was to provide parenteral antibiotics within 60-minutes of a CS activation. The aim of this project was to decrease antibiotic administration start time by 10% over three-months. The outcome measures of interest were 1) Time of CS activation, 2) Time antibiotic administration initiated, 3) Total length of hospital stay (LOS), and 4) Final disposition upon discharge (e.g., home, rehabilitation facility, morgue, etc). The question for study is: In hospitalized patients aged 18-years and older, what is the effect on hospital LOS and final disposition when antibiotics were administered within 60-minutes of a CS activation compared to antibiotic administration occurring over 60-minutes from CS activation?

Literature Review

The search engines used for this literature review were CINAHL, Cochrane Library, and PUBMED. The key search terms were sepsis, sepsis bundle, and door-to-antibiotic time for sepsis treatment using the Boolean operators AND and OR. Initially, 170 publications were retrieved; therefore, the search was further refined to include greater than 18-years old, established or strong suspicion of infection, and two or more SIRS criteria. Excluded were those less than 18-years old, no suspicion of infection, and less than two SIRS criteria. This refined search yielded 70 publications. Finally, an ancestry approach was used on select publications with a total of 13 publications ultimately selected for this review.

The definition of sepsis is the dysregulated host response to an infection with organ dysfunction resulting from an exaggerated inflammatory response (Kim & Sunghoon, 2019). Sepsis is diagnosed when an infection is present and at least two SIRS criteria are present: abnormal T, increased HR, low BP, and unexplained AMS (Kim &

Sunghoon, 2019). Early identification and treatment for sepsis is critical to recovery and survival; however, healthcare providers can be challenged when patients initially appear well and seek medical attention for an otherwise routine illness (Makic & Bridges, 2018; Coopersmith et al., 2018). Reduced mortality rates, hospital LOS, and hospital costs have been associated with early identification and treatment for sepsis (Coopersmith et al., 2018). An exaggerated inflammatory response to any type of infection can occur within hours, days, or weeks from the invading organism (e.g., viral, bacterial, fungal, or parasitic). The identification of infection may take hours to days, and serum, urine, or other body fluid cultures may be negative. Because of these potential delays, the identification of sepsis becomes challenging.

Sepsis is the body's response to an infection when the immune system is negatively affected when fighting against bacteria, viruses, fungi, and parasites. However, the pathophysiology of sepsis is a far more complex interaction between the infectious agent and host contributing to a sepsis condition. In the initial response to sepsis, the host responds to the activation of pathogens (macrophages, monocytes, neutrophils, and natural killer cells) through the binding of pathogen-associated molecular patterns (Gyawali, Ramakrishna, & Dhamoon, 2019). As a result, proinflammatory cytokines are released (TNF, IL-1, and IL-6) causing an activation and proliferation of leukocytes, upregulation of endothelial adhesion molecules and chemokines expression, tissue factor production, and the induction of hepatic acute phase reactants (Gyawali et al., 2019). The immune response becomes overwhelmed resulting in damage and death of the host cells and tissues.

The unbalanced hemostasis in sepsis initiates both the inflammatory and coagulation cascades suspected to be caused by the release of tissue factor from disrupted endothelial cells. When the tissue factor is activated, the production of thrombin, platelets, and the formation of platelet fibrin clots cause a decrease in local perfusion resulting in tissue hypoxia and organ dysfunction (Gyawali et al., 2019). The immune system of sepsis patients becomes powerless in fighting against secondary bacterial, viral, or fungal infections due to the decrease in T-cells and decreased response to inflammatory cytokines. Gyawali et al. (2019) reported a global depletion of CD4+ and CD8+ T-cells in intensive care unit (ICU) patients who have died from sepsis. There is an alteration in the body's hemodynamics from a decreased delivery of oxygen to the cells resulting in hypoperfusion (Gyawali et al., 2019). Hypoperfusion affects the body's organs in several ways. The inflammatory mediator prompts the dilations of the arterial and venous blood flow and decreases the venous return causing hypotension and shock in sepsis patients (Gyawali et al., 2019).

In the lungs, the alveolar-endothelial barrier is weakened and protein rich fluid accumulates in the interstitial lung spaces decreasing lung compliance leading to an acute respiratory distress syndrome (ARDS) (Gyawali et al., 2019). In the kidneys, an acute kidney injury occurs due to the reduced renal perfusion, acute tubular necrosis, and the deficiency in the microvasculature and tubules. For the gastrointestinal tract, the mucosal lining is compromised leading to the leakage of bacteria in circulation making the host susceptible to disease. In the liver, the bilirubin is decreased resulting in the production of cholestatis (Gyawali et al., 2019). Due to endothelial changes in the blood-brain barrier,

related to the entry of toxins, inflammatory cells, and cytokines, an altered mentation is likely in sepsis patients. (Gyawali et al., 2019).

Because of the complex nature of sepsis, the estimated healthcare cost for sepsis care is $27 billion per year with a one-year survival rate estimated to be less than 50% (Afrefian et al., 2017). Hospital-related costs were based on the type of sepsis and the population, but the treatment for any sepsis is consistently the most expensive syndrome in US hospitals (Afrefian et al., 2017). The total hospital stay in terms of cost per patient were between $13,292 and $75,015 (Paoli, 2017). The average length of stay for patients admitted with sepsis without organ function is eight days, 16 days for sepsis cases do not present on admission, and seven days for sepsis cases present on admission (Paoli, 2017). The mortality rate for sepsis without organ dysfunction is 5.6%, 13.8% (sepsis does not present on admission), and 4.5 % (sepsis cases present on admission) (Paoli, 2017).

A Surviving Sepsis Research Committee (the Committee), a consensus committee of 16 international experts, convened to develop a *Surviving Sepsis Campaign* (SSC, Coopersmith et al., 2018). The Committee addressed all aspects of sepsis (including mortality rates, diagnostics, treatments, hospital LOS, and costs) by developing research questions to determine the best evidence for reducing mortality from sepsis (Coopersmith et al, 2018). Coopersmith et al. (2018) concluded the immediate administration of parenteral antibiotics and in cases of an unknown pathogen, a combination of antibiotics, may decrease mortality in septic patients. An antibiotic combination therapy is thought to expedite the clearance of the offending pathogen and ensure at least one pathogen to be sensitive to the treatment (Coopersmith et al, 2018). However, Coopersmith et al. (2018) found no difference in the literature in administrating parenteral monotherapy vs

combination therapy in mortality or outcomes in patients with sepsis. Of note, their research on mono- or combination antibiotic therapy were of low quality and without randomized controlled trials (Coopersmith et al., 2018). Hence, the coverage of broad-spectrum antibiotic therapy was not included in the Committee practice guidelines on sepsis (Coopersmith et al, 2018). Regardless, immediate antibiotic therapy is advocated to assist the immune system and lessen the inflammatory response.

Early identification of sepsis can increase the initiation of treatment and ultimately patient outcomes. Seymour et al. (2017) reviewed data from the New York State Department of Health (NYSDOH) from April 1, 2014 to June 30, 2016. In this retrospective study conducted from 185 hospitals within the NYSDOH jurisdiction requiring all hospitals to report patients with sepsis and septic shock, an electronic case report form consisting of data on demographic characteristics, coexisting conditions, characteristics of sepsis and septic shock, illness severity, and outcomes were evaluated (Seymour et al., 2017). The time and date of the sepsis protocol initiation of a three-hour bundle and six-hour bundle for patients were compared. They found the delay in completing a three-or the six-hour bundle and the administration of a broad-spectrum antibiotics was associated with higher risk adjustment in hospital mortality (Seymour et al., 2017). The authors offered three explanations to support early diagnosis and treatment. First, rapid administration of antibiotics decreased the burden of the pathogen on the body, reduced the host inflammatory response, and resulted in a reduction in organ dysfunction (Seymour et al., 2017). Second, the serum lactate level provided a quick measurement for clinicians in identifying otherwise unrecognized shock and prepared for an improved delivery of sepsis treatment (Seymour et al., 2017). Finally, providers who could swiftly

suspect infection and worsening organ dysfunction reflected an enhanced delivery of sepsis treatment and outcomes (Seymour et al, 2017). The limitations of this study included non-randomization, broad-spectrum antibiotics being limited with the antibiotics only being measurable with positive cultures, and hospitals may have differed in common pathogens and antimicrobial resistance (Seymour et al., 2017). Improved outcomes were consistently reported when certain serum diagnostics, such as lactic acid and antibiotic therapy was evaluated and initiated sooner than later.

In a study conducted within the United Kingdom (UK), McGregor (2014) evaluated completion of a "sepsis six" bundle of six essential items identified to be of benefit if completed within an hour: 1) Blood cultures, 2) Full blood count and lactic acid, 3) Parenteral fluid administration, 4) Parenteral antibiotic administration, 5) Monitoring urine output, and 6) Application of oxygen. After several Plan Do-Study-Act (PDSA) cycles including education, implementation, and public display of results regarding the sepsis care pathway, they found a decrease from six-hours to 1.4 hours for antibiotic administration. Reportedly, there is an 8% increased mortality for every hour of antibiotic administration delay (Kumar et al. [2006], cited in McGregor, 2014). Thus, reducing the door-to-drug time for antibiotic administration in septic patients may be significantly reduced with a concentrated effort to enhance the timely completion of a sepsis bundle.

Donabedian's model of structure, process, and outcomes were used in this project to bring awareness of early recognition in patterns and nature of sepsis patients quickly and improve efficiency in treating sepsis (Yankovsky, Gajewski, & Dunton 2016). The compliance of utilizing the CS bundle (structure) will guide healthcare providers or staff

to improve the practice of administering antibiotics within the first hour of suspicion of infection to sepsis patients. The model will guide the advancement of knowledge and developing skills to engage and build confidence in healthcare providers or staff in promptly completing all the components in the CS bundle (process). The goal is to decrease patient morality and organ dysfunction (outcomes) caused by sepsis (Yankovsky et al., 2016).

Method

Design

An observational, descriptive design utilizing a retrospective medical record review from February 1, 2020 through April 30, 2020 was conducted for baseline information regarding CS antibiotic administration time. A PDSA cycle included CS education and data reporting on the CS bundle was completed for the staff in February 2021. From February 1, 2021 through April 30, 2021, the same data was collected and compared to the 2020 data.

Setting

A Midwestern, metropolitan, Level II trauma and medical center emergency department (ED). The medical center serves a population of over three million residents; however, the area has over a dozen hospitals serving the same population. There are approximately 460 inpatient beds, consisting of 36 intensive care unit (ICU) beds, 26 transitional care unit (TCU) and 398 general medicine or surgery beds for adult patients.

Sample

A purposive sampling of adult patients with an admitting or final diagnosis of sepsis. Inclusion criteria were those 18-years and older who were hospitalized and had a CS activation. Exclusion criteria were participants younger than 18-years of age, not hospitalized, or without a CS activation.

Approval Processes

Approval for the quality improvement PDSA cycle to improve timely antibiotic administration times was obtained from the medical center administration. Additional approvals were obtained from the Doctor of Nursing practice (DNP) clinical scholarship committee and graduate school from the university. Finally, approvals were obtained by the organization's institutional review board (IRB) and the university IRB.

There were no anticipated risks to patients as this was a retrospective medical record review. A benefit to this study included observed patient outcomes related to antibiotic administration times.

Data Collection/Analysis

Data was collected from a medical record review in the electronic medical record (EMR). The baseline data was from those patients with a CS activation between February 1, 2020 through April 30, 2020. The second data set included those patients with a CS activation between February 1, 2021 through April 30, 2021. The data collected included the number of CS activations; demographic information (i.e., age, gender, race/ethnicity); time of parenteral antibiotic administration (time initiated); hospital LOS; and final disposition (i.e., home, rehabilitation facility, morgue, or other). All data will be de-identified as 20-1, 20-2, 20-3 and so on for the 2020 cohort, and 21-1, 21-2, 21-3, and so

on for the 2021 cohort. Data analysis included descriptive statistics, Fisher's Exact test, Pearson's Correlation and Two-Tailed Independent Sample *t* -Test.

Procedures

A team of key stakeholders was already in progress when the primary investigator (PI) for this quality improvement effort joined the team. A pharmacy representative was also a member of the quality improvement team. The team identified timely antibiotic administration as an opportunity for improvement. Based on the antibiotic administration data, the plan was to provide additional education on CS team activation and the CS bundle, past and current data reflected on posters posted in staff areas, and a reevaluation of antibiotic administration times. A *Sepsis Implementation and Compliance Campaign* (SICC) was developed to include relevant data on posters and other educational opportunities for staff to bring awareness of the importance of antibiotic administration times in patients with sepsis. The process began when a CS was activated and its order set was selected. The order set had a sepsis identifier to generate a message in the EMR which then sent a page to the pharmacist alerting the pharmacist about the CS. The orders were to be reviewed expeditiously by the pharmacist to ensure appropriate dosing, antibiotic coverage, and prompt delivery of an intravenous broad-spectrum antibiotic to the nurse caring for the patient.

Results

The total number medical records reviewed for the year 2020 and 2021 was 474 (*N*=474). In 2020 there were 264 (*n*=264) and 2021 there were 210 (*n*=210). Ages ranged from 18-99 years, and in 2020, the mean age was 63.25 years (*SD*=17.82); in 2021, the mean age was 65.07 years (*SD*=17.49). For gender, in 2020, there were 146 females

(*n*=146, 55%) and 118 males (*n*=118, 45%). In 2021, there were 105 females (*n*=105, 50%) and 105 males (*n*=105, 50%). For Race/Ethnicity in 2020, there were 129 Caucasians *(n*=129, 49%); 126 African Americans (*n*=126, 48%); six Asians (*n*=6, 2%); two Multiracial (*n*=2, 1%) and one Russian (*n*=1, 0%). In 2021, Race/Ethnicity revealed 111 African Americans (*n*=111, 53%), 99 Caucasian (*n*=99, 47%), zero Multiracial (*n*=0, 0%), zero Asian (*n*=0, 0%), and zero Russian (*n*=0, 0%).

The mean antibiotic administration time once a sepsis bundle was activated was 28.20 minutes (*SD*=14.19) for 2020, and the mean for 2021 was 27.98 minutes (*SD*=13.91). A two-tailed independent samples *t*-test was conducted between the two means. The difference was not significant based on an alpha value of 0.05

(*t* (416)=0.16, *p*=.874). Essentially antibiotic administration times were the same for both years.

Next, the mean hospital length of stay for the year 2020 was 7.55 days (*SD*=6.78) and for 2021 it was 7.42 days (*SD*=6.77). A Pearson correlation between the time of antibiotic administration and LOS revealed a weak relationship for 2020 (*r*=-0.01; CI [-0.13, 0.11]; *p*=.910), and also for 2021 (*r*=0.02; CI [-0.11, 0.16]; *p*=.745). The hospital LOS was essential not dependent on antibiotic administration times.

For the final disposition of the year 2020/2021, there were 128/53 discharged to home or self-care; 36/39 expired; 34/35 discharged to a Skilled Nursing Facility; 11/10 discharged to Custodial or Supportive Care; 4/3 discharged to Long-term Acute Care; 6/6 discharged to a Rehabilitation facility; 13/7 discharged to Nursing Facility: Medicaid; 5/5 discharged to Hospice: Medical Facility, 20/30 discharged to Home Health care Service, 2/8 discharged to Hospice: Home, 3/9 Left Against Medical Advice/ Discontinued care,

and 2/5other (psych unit, currently hospitalized, inpatient hospital [transfer to another hospital], LTAC, and other facility not defined elsewhere). Results of a Fisher exact test were significant based on an alpha value of 0.05, where only home or self-care was significant (in 2020: 128 [100.81]; in 2021: 53 [80.19], $p<.001$). More patients were discharged to home in 2020 than in 2021.

Discussion

The administration of parental antibiotics once a sepsis bundle was activated was essentially 28-minutes in 2020 and 2021.This is well within the recommended 60-minutes by SSC. In addition, there was no relationship found between antibiotic administration time and LOS or antibiotic administration time and final disposition. The SICC poster and badge buddies were introduced to ED staff to bring awareness in the gaps of knowledge on signs and symptoms of sepsis, however, this does appear to have resulted in improved times or disposition. Interestingly, more patients were discharged to home in 2020 than 2021. The cause for this was beyond the scope of this project.

A strength of this project was an adequate sample size evaluated during similar times for both years. A limitation was the Covid-19 pandemic was officially declared in March 2020. This may have influenced hospital LOS or final disposition as the cause for sepsis was evaluated. A recommendation for future study might be to assess the criteria for home discharge, or the study should be repeated after the pandemic.

Conclusion

The introduction of a SICC campaign did not influence antibiotic administration times, however, antibiotic administration times were less than 60-minutes before and after the SICC campaign was implemented. The LOS and final disposition were essentially

unchanged. Regardless, sepsis remains a leading cause of death in adults and continuous quality improvement may drive better outcomes.

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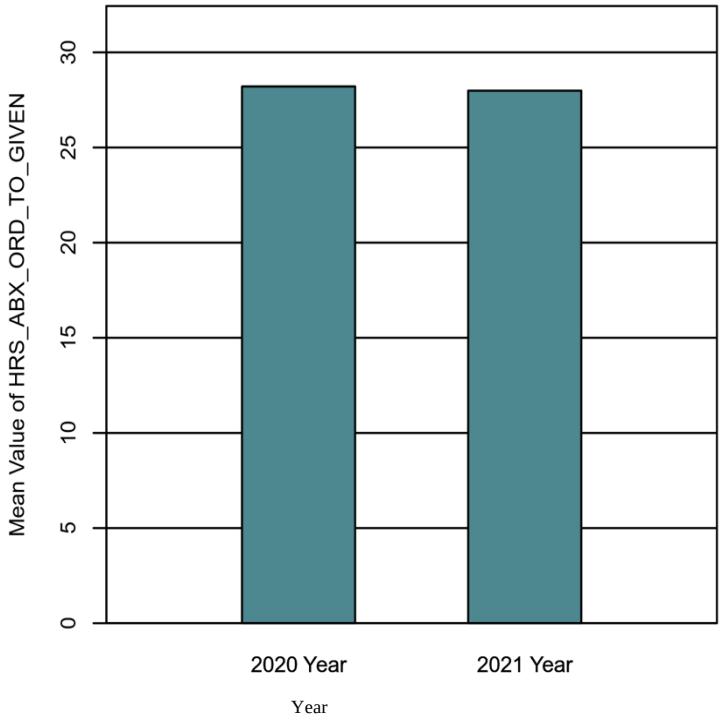
Appendix A

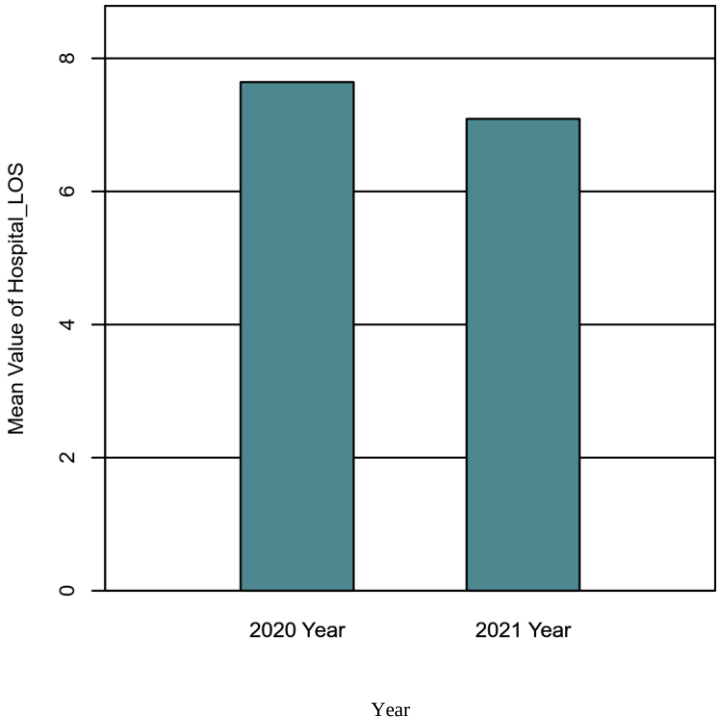
Figure 1. Antibiotic Administration Time after CS activation



Note. The mean antibiotic administration time once a sepsis bundle was activated was 28.20 minutes (*SD*=14.19) for 2020, and the mean for 2021 was 27.98 minutes (*SD*=13.91). A two-tailed independent samples *t*-test was conducted between the two means. The difference was not significant based on an alpha value of 0.05 (*t* (416)=0.16, *p*=.874). Essentially antibiotic administration times were the same for both years.

Appendix B

Figure 2. The Mean Hospital LOS



Note. The mean hospital length of stay for the year 2020 was 7.55 days (*SD*=6.78) and for 2021 it was 7.42 days (*SD*=6.77). A Pearson correlation between the time of antibiotic administration and LOS revealed a weak relationship for 2020 (*r*=-0.01; CI [-0.13, 0.11]; *p*=.910), and also for 2021 (*r*=0.02; CI [-0.11, 0.16]; *p*=.745). The hospital LOS was essential not dependent on antibiotic administration times.

Appendix C

Table 1. *Final Disposition for patients with the diagnosis of sepsis*

	Month				
Final Disposition Nominal	2020 Year	2021 Year	χ^2	df	p
Home or Self Care	128[100.81]	53[80.19]	37.42	1	<.001
Expired	36[41.77]	39[33.23]			
Skilled Nursing Facility	34[38.43]	35[30.57]			
Custodial or Supportive Care	11[11.70]	10[9.30]			
Long Term Acute Care	4[3.90]	3[3.10]			
Rehab: Inpatient	6[6.68]	6[5.32]			
Nursing Facility: Medicaid	13[11.14]	7[8.86]			
Hospice: Medical Facility	5[5.57]	5[4.43]			
other	2[3.90]	5[3.10]			
Home Health Care Svc	20[27.85]	30[22.15]			
Hospice: Home	2[5.57]	8[4.43]			
Left Against Medical Advice/Discontinued Care	3[6.68]	9[5.32]			

Note. Results of a Fisher exact test were significant based on an alpha value of 0.05, where only home or self-care was significant (in 2020: 128 [100.81]; in 2021: 53 [80.19], p<.001). More patients were discharged to home in 2020 than in 2021.