Evaluation of the Surviving Sepsis Campaign (SSC) 3- Hour Sepsis Bundle Standards in a Level Three Emergency Department

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Abstract

Sepsis is a complex syndrome leading to increased hospital mortality and readmissions in the United States. Additionally, this syndrome causes significant financial strain on both micro and macro healthcare systems. Because sepsis and septic shock are leading causes of death worldwide, the international Surviving Sepsis Campaign (SSC) was forged as a joint initiative between the Society of Critical Care Medicine (SCCM) and the European Society of Intensive Care Medicine (ESICM) with a commitment to reduce morbidity and mortality from sepsis worldwide (SCCM, n.d.). In order to address the complexity of this disease process, the SSC created the sepsis guidelines to standardize care for septic patients in the emergency department. Improved patient outcomes with adherence to these guidelines has led the Centers for Medicare and Medicaid Services (CMS) to adopt the SSC measures as their core reimbursement metrics. While sepsis bundle adherence has shown to improve patient outcomes and allows for CMC reimbursement, many emergency departments (ED) fail to reach compliance. The aim of this quality improvement project was to evaluate the adherence to the SSC guidelines in a level III ED using the PDSA study model. If bundle compliance was not found to meet current benchmarks, it would be recommended future PDSA models be utilized to investigate and implement the use of a code sepsis (CS) or critical response team (CRT) to improve bundle adherence.

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Problem Statement

Sepsis is the body's systemic immunological response to an infective agent that, if left untreated, can lead to end-stage organ dysfunction and death (Gyawali et al., 2019). Due to the complex nature of this process, the SSC established guidelines for the identification and management of patients with sepsis, including severe sepsis or septic shock. Additionally, the SSC provides recommendations for successful application of these guidelines in clinical practice (Dellinger et al., 2017). The expectation in emergency department's (ED) nationwide is for caregivers to utilize the SSC guidelines to direct patient care. However, despite available guidelines, mortality rates from severe sepsis and septic shock remain high, with nearly 270,000 Americans dying as a result of sepsis annually (Center for Disease Control and Prevention [CDC], 2020). The goal of this DNP project was to evaluate the adherence to the SSC guidelines in a level three ED and determine if implementation if a code sepsis was merited.

Available Knowledge

Sepsis is one of the leading causes of hospital readmission and mortality in the United States (US) (Ferguson et al., 2019). At least 1.7 million adults develop sepsis in the US annually and eventually 270,000 eventually die of severe sepsis and septic shock every year (CDC, 2020). Additionally, sepsis causes significant financial strain on both micro and macro healthcare systems. While hospital related costs vary considerably, it remains one of the most expensive conditions treated in the inpatient setting with over $24 billion dollars spent annually (Whitfield et al., 2020).

The SSC sepsis guidelines, last updated in 2016, remain the standard of care for septic patients in the emergency department. Data consistently demonstrates sepsis bundle compliance, including rapid attainment of lactic acid and blood cultures, IV antibiotic administration, and weight based IV fluid bolus, is associated with decreased mortality and improved patient outcomes (Baghdadi et al., 2020; Levy et al., 2015; Milano et al., 2018). In one of the largest prospective cohort studies involving nearly 30,000 patients, compliance with the sepsis bundle was associated with a 25% relative risk reduction in mortality (Levy et al., 2015). Additionally, for every 10% increase in adherence there was a 4% decrease in intensive care unit (ICU) stay (Levy et al., 2015). Improved patient outcomes with adherence to these guidelines has led the Centers for Medicare and Medicaid Services (CMS) to adopt the SSC measures as their core reimbursement metrics, known as the early management bundle, severe sepsis/septic shock (SEP-1) (Ramsdell et al., 2017). As CMS continue to link reimbursement to sepsis quality metrics, achieving sepsis bundle compliance is essential for financial government support and improved patient outcomes (Delawder & Hulton, 2020). Still, adherence to the sepsis bundle remains variable. A recent retrospective analysis calculated the mean hospital SEP-1 bundle compliance in 50 participating emergency department was only 54% (Venkatesh et al., 2018).

Methods which improve prompt sepsis identification and bundle compliance have the potential to improve patient mortality and reduce the economic burden of sepsis in the United States. For patients in the emergency department meeting sepsis criteria, the activation of a code sepsis (CS) or a critical response team (CRT) has been shown to decrease patient's overall length of stay (LOS) and mortality (Boter et al., 2019). Although various methods of CS or CRT exist, the general principles for all processes include early recognition and intervention by optimizing resources and escalating care (Kang et al., 2019). A current retrospective cohort study indicated

induction of a CS in the ED increased SEP-1 perfect score attainment (PSA) from 30.7% to 71.3% and reduced patient mortality (Whitfield et al., 2020). Further studies are ongoing to evaluate the effectiveness of CS and CRT's in the emergency department, and preliminary data shows significant evidence in favor of their utilization.

Rationale

Most US hospitals participate in the federal government's Medicare/Medicaid health insurance program directed by CMS because it accounts for the largest single payer reimbursement in the US—approximately 63% of all inpatient medical cost (Wang et al., 2021). CMS utilizes a progressive program that incentivizes hospital compliance with SEP-1 bundles, beginning with participation in their Hospital Inpatient Quality Reporting Program (IQRP) and leading to promotion of performance measures in the Value Based Purchasing (VBP) program from which hospital reimbursement is calculated (Barbash et al., 2019; Wang et al., 2021).

SEP-1 is an "all-or-nothing" compensation approach and, while 100% bundle compliance is ambitious, it is infrequently achieved (Rhee et al., 2018). The goal of compliance outlined by the level three emergency department participating in this quality improvement study was 100% bundle adherence; however, current bundle compliance has not been specifically evaluated. The initiation of a CS or CRT have been proposed to achieve sepsis bundle goals under the assumption such responses would elicit urgency and timely care for these patients; however, comprehensive data collection prior to utilizing this intervention is incomplete. It is sensible to think such teams would be beneficial in critical patient scenarios, such as sepsis, but organized data collection is still warranted.

The Plan–Do–Study–Act (PDSA) model was chosen to guide this quality improvement (QI) project because it effectively establishes a relationship between process changes

implemented in dynamic systems, such as the emergency department (Speroff & O'Connor, 2004). Using the PDSA method as both a model and framework for this QI project allowed a systematic approach for data collection and evaluation. Furthermore, it permitted cyclical learning and development providing a framework for future studies and implementations if warranted.

In this PDSA driven project proposal, SEP-1 bundle compliance was evaluated in a level III ED (*plan)* by completing a comprehensive retrospective review (*do)*. These results were then evaluated *(study)* and utilization of a code sepsis or critical response team were assessed for implementation (*act)*. If warranted, implementation of a CS or CRT could then be applied and assessed using another PDSA model. The Standards for Quality Improvement Reporting Excellence (SQUIRE) 2.0 guidelines was utilized for reporting this project's aims, methods, and findings.

Specific Aim

The purpose of this project was to determine SEP-1 bundle adherence in a level III ED at Providence Milwaukie hospital and compare this data with set hospital benchmark goals to establish if there was a need for adherence improvement by utilizing evidenced based interventions, specifically implementation of a CS and CRT.

Methods

Context

Providence Milwaukie Hospital (PMH) is a 77-bed acute care community hospital in Milwaukie Oregon with over six hundred employees that exists to meet the health needs of Milwaukie and outside region's needs. The emergency department itself is a 21-bed unit that is staffed by board-certified emergency department physicians, nurses, technicians, social workers,

and additional clinical and ancillary staff. Staffing ratios vary throughout the day, fluctuating based on typical patient census patterns. There are generally one to three providers, four to nine nurses, and two to three ED technicians on the unit at any given time. Annual 2019 patient census data recorded Providence Milwaukie had 29,941 emergency department visits and 2,812 hospital admissions, mirroring the CDC's 2019 national average ratio (CDC, 2021; Providence Health Services, 2019). The number of severe sepsis and septic shock patients seen at PMH ED fluctuates monthly, with highest prevalence seen in fall and winter; however, the most recent Covid-19 health pandemic altered the standard sepsis patterns and ratios.

As a level III community hospital, PMH is restricted in its ability to admit certain critically ill patient populations, as the hospital lacks access to resources such as neurosurgery, cardiothoracic surgery, interventional radiology, renal dialysis, angiography, extracorporeal membrane oxygenation (ECMO), or prone positioning capabilities. Patients presenting to the ED in extremis potentially requiring these resources are inevitably transferred to higher capability hospitals. Still, all of these critically ill patients are evaluated, treated, and stabilized in the PMH ED before further throughput. In recent years, clinical staff have affirmed not only an increase in patient acuity, but an increase in length of boarding patients due to limited inpatient hospital availability. This manifests as ED medical staff having to identify, initiate, and monitor therapies that would ideally be managed in an intensive care unit setting.

Intervention(s)

The primary intervention for this quality improvement project was the sepsis CMS core (SEP-1) measure, derived from the surviving sepsis campaign's newly updated 2016 sepsis bundle guidelines. Adherence to this SEP-1, or SSC 3-hour bundle, is considered goal standard evidenced based care currently, and 100% adherence has been the goal of PMH ED since its last

update in 2016. Although this intervention has been deemed the standard of care for septic and septic shock patient's presenting to PMH ED, bundle guideline compliance is still variable (Venkatesh et al., 2018).

In the PMH ED sepsis or severe sepsis is typically first identified during triage using the systemic inflammatory response syndrome (SIRS) criteria, although sepsis can develop at any point during a patient stay. SIRS is the occurrence of at least two of the following criteria: fever >38.0°C or hypothermia <36.0°C, tachycardia >90 beats/minute, tachypnea >20 breaths/minute, leukocytosis $>12*10^9$/l or leucopoenia $<4*10^9$ (Appendix A) (Comstedt et al., 2009; Levy et al., 2015; Santistevan, 2016). Severe sepsis is identified by the presence of sepsis plus one or more variables of organ dysfunction including the following: systolic blood pressure (SBP) < 90, mean arterial pressure (MAP) < 70, 40 point decrease from baseline SBP, creatinine > 2.0, urine output (UOP) < 0.5 ml/kg/hour for greater than two hours, bilirubin > 2.0, platelets < 100,000, INR > 1.5 or PTT > 60 seconds, altered mental status, or a lactate level > 2.0. (Appendix B) (Comstedt et al., 2009; Santistevan, 2016). Septic shock is defined by CMC as hypoperfusion despite adequate fluid resuscitation, or lactate > 4 (Appendix B) (Levy et al., 2015; Santistevan, 2016).

To be compliant with the CMC SEP-1, providers and nurses need to meet bundle measures within three hours for patients presenting with severe sepsis. This includes obtaining a serum lactate and blood cultures, then administering antibiotics. For patients with septic shock, a 30 mL/kg crystalloid fluid resuscitation must also be completed, followed by repeat volume status and tissue perfusion assessments. Volume status reassessment can be accomplished via a focused physical exam (e.g. capillary refill, vital signs, skin exam) or any two of the following controls: central venous pressure (CVP), central venous oxygen, bedside cardiovascular

ultrasound, or fluid challenge (Appendix C) (Santistevan, 2016). If hypotension persists despite adequate fluid resuscitation, vasopressor pharmacotherapy must be administered (Levy et al., 2015; Santistevan, 2016).

Study of the Intervention(s)

A single-center, retrospective chart review for quality improvement was performed at Providence Milwaukie emergency department between May 1, 2019 to May 31, 2021. ED records were searched by International Classification of Disease 10th revision (ICD-10) diagnosis code of sepsis, severe sepsis, or septic shock. Inclusion criteria for chart selection was adult patients over the age of 18 patients meeting severe sepsis or septic shock clinical measures within the ED setting (Appendix D). Exclusion criteria included patients with a directive for comfort care or palliative care within three hours of presentation of severe sepsis. Patients meeting study criteria underwent further chart review to determine sepsis-bundle adherence.

Measures

Data was extracted from the emergency department database using sepsis diagnosis chart tracers and recorded. Patient assessment data including heart rate, respiratory rate, blood pressure, temperature, oxygen saturations, and mental status were assessed for SIRS criteria. Clinical information pertaining to SEP-1 bundle elements were recorded—blood cultures, lactic acid, antibiotic, and IV fluid administration. These measurements met compliance if they were obtained within the 3-hour bundle time limit; failure to reach compliance any of these fields was recorded (Appendix E).

Analysis

Data was recorded in an electronic spreadsheet and evaluated via the 2016 SSC guidelines for determination of severe sepsis and septic shock. Time sensitive bundle elements including lactic acid, blood cultures, antibiotic administration, and fluid resuscitation were recorded. Unadjusted, raw analysis of sepsis patient's data was evaluated and compared to national SEP-1 standards. Evaluation of bundle compliance was calculated via an "all or nothing bundle compliance" method, ascertaining what percentage of sepsis patients at Providence Milwaukie ER met sepsis bundle compliance between May 1, 2019 to May 31, 2021.

Ethical Consideration

All patient data used in this retrospective study was deidentified to conserve confidentiality. All emergency department administrative staff was informed of the proposed study including the ED manager, assistant managers, and chief nursing officer. Further, the participating community emergency department gave their written and verbal consent for the initiation of the qualitative improvement project at this location. Finally, this project was submitted to both the OHSU and Providence IRB board for approval.

Results

Monthly sepsis compliance data was obtained from Providence Milwaukie Hospital and recorded in an Excel spread sheet (Appendix F). Data recorded included lactic acid, blood cultures, antibiotic administration, intravenous fluid administration, and total sepsis compliance. From May 2019 until May 2021 there were 162 sepsis patients meeting sepsis criteria for study evaluation. Full monthly sepsis compliance (defined as 100% compliance in all metrics) was attained 44% of the time (11 months). The remaining 14 months varied in sepsis bundle compliance, with the lowest measuring 33.3%. When evaluating individual bundle components,

compliance was highest obtaining lactic acids (95%) and IV fluid administration (75%). Compliance was lowest with obtaining blood cultures (58.3%) and antibiotic administration (62.5%). Contextual elements that could have affected the outcomes of meeting sepsis bundle benchmarks include the Covid-19 pandemic in which PPE was in short supply, patient acuity was higher, and staffing was not adequate for the acuity of patients seen.

Discussion

Interpretation

From this retrospective study, it is evident that SEP-1 compliance is deficient in this emergency department as 100% monthly compliance was obtained only 44% in the two years of its evaluation. Although mean hospital SEP-1 bundle compliance varies, this is still considerably lower than the 54% average ascertained in one study of 50 participating emergency departments (Venkatesh et al., 2018). Additionally, patient outcomes, although not recorded, were likely compromised as a result of delayed sepsis interventions, incurring additional physical, emotional and financial strains on patients and the hospital system as a whole. Overall, interpretation of this data shows poor SEP-1 compliance and the need for further interventions to increase sepsis bundle adherence.

Limitations

Several limitations exist in this study. First, data collected occurred during the Covid-19 pandemic and may not be accurately representative of typical sepsis bundle compliance patterns as all hospitals were experiencing supply chain disruptions, staffing and resources shortages, and higher patient acuity. Additionally, while chart review was completed by competent managerial staff, data collection is subject to human error, potentially skewing data results. Also, perfusion reassessment data was not recorded in retrospective chart review and was not provided for this

study. As this data was never recorded, it is not possible to verify compliance in this reassessment measure; therefore, compliance may be lower than the given results. Finally, as this is a small level three emergency department, it limits to the generalizability of the findings to larger institutions. To mitigate limitation effects, a single staff member participated in data collection and recording; however, due to the nature of this retrospective cohort study, few other adjustments could be made to address other limitations.

Conclusions

Based on the data, Providence Milwaukie met full monthly sepsis bundle compliance 44% of the time in a two-year period, under an estimated average of 54% and grossly below the hospitals SEP-1 compliance goal of 100%. Although study limitations exist, such as the Covid-19 pandemic and selection bias, the data still supports investing in processes that would increase SEP-1 compliance. A code sepsis has shown to improve perfect score attainment and reduce in patient mortality across various emergency departments and would be an appropriate intervention to use to increase sepsis bundle compliance (Whitfield et al., 2020). Future recommendations from this quality improvement project support another PDSA cycle be conducted to evaluate effectiveness of SEP-1 scores after the implementation of a code sepsis or critical response team in this PMH emergency department.

In summary, the data shows complete sepsis bundle compliance was only achieved 44 % from May 2019 until May 2021 suggesting a deficiency in this emergency department's participation with sepsis bundle standards and meeting SEP-1 benchmarks summarized by Surviving Sepsis Campaign and Centers for Medicare and Medicaid Services. These findings are relevant, as they support implementing and evaluating a future process to help bolster low compliance metrics in order to improve patient outcomes and increase federal reimbursement.

Funding

No outside funding supported the design, implementation, interpretation, or reporting of this work.

Appendices

Appendix A: SIRS sepsis criteria

- Fever >38.0°C
- Hypothermia <36.0°C
- Tachycardia >90 beats/minute
- Tachypnea >20 breaths/minute
- Leukocytosis $>12*10^9$/l or leucopoenia $<4*10^9$

Appendix B: Severe sepsis and septic shock as defined by CMS

Severe sepsis- Presence of sepsis + one or more variables of organ dysfunction

- Variables of organ dysfunction
    - systolic blood pressure (SBP) < 90
    - Mean arterial pressure (MAP) < 70
    - 40-point decrease from baseline SBP
    - Creatinine > 2.0
    - Urine output (UOP) < 0.5 ml/kg/hour for greater than two hours
    - Bilirubin > 2.0
    - Platelets < 100,000
    - INR > 1.5 or PTT > 60 seconds
    - Altered mental status
    - Lactate level > 2.0

Septic shock

- Hypoperfusion despite adequate fluid resuscitation or
- Lactate > 4

Appendix C: Repeat volume status and tissue perfusion assessments

- Focused physical exam
  - capillary refill
  - vital signs
  - skin exam
- Or any two controls
  - Central venous pressure (CVP)
  - Central venous oxygen
  - Bedside cardiovascular ultrasound
  - Fluid challenge

Appendix D: Sepsis Quality Improvement study criteria

Chart inclusion/ Exclusion criteria:

- Inclusion criteria
  - ICD-10 code sepsis, severe sepsis, or septic shock
  - 18 years of age and older
- Exclusion criteria
  - Comfort care within three hours of ED admission or less than 18 years of age

If the ED chart meets the above criteria the following SEP-1 Chart Audit tool will be applied to evaluate SEP-1 adherence.

Appendix E: SEP-1 Chart Audit Tool

1. ICD-10 Diagnostic code(s)
    a. Primary diagnosis
    b. Secondary diagnosis (s)
2. Is sepsis present (Appendix A)? If sepsis is present were the following measures obtained within 3 hours of onset?
    a. Blood cultures (yes or no)
    b. Serum lactate (yes or no)
    c. Administering antibiotic therapy (yes or no)
3. Does patient have severe sepsis?
    a. If yes was administration of 30 ml/kg bolus within three hours completed (yes or no)
4. Reperfusion assessment completed (yes no)
5. Septic shock refractory to IVF bolus (yes or no)
    a. If yes were vasopressors started (yes or no)

Appendix F

Month, Year of Date of Service	Distinct count of Sepsis	Sepsis Compliance	% Compliance LAC	% Compliance BC	% Compliance ABX	% Compliance IVF
May 2019	9	100.0%	100.0%	100.0%	100.0%	100.0%
June 2019	7	85.7%	85.7%	85.7%	85.7%	100.0%
July 2019	12	100.0%	100.0%	100.0%	100.0%	100.0%
August 2019	5	100.0%	100.0%	100.0%	100.0%	100.0%
September 2019	5	100.0%	100.0%	100.0%	100.0%	100.0%
October 2019	2	50.0%	100.0%	100.0%	50.0%	100.0%
November 2019	3	100.0%	100.0%	100.0%	100.0%	100.0%
December 2019	5	100.0%	100.0%	100.0%	100.0%	100.0%
January 2020	7	85.7%	100.0%	85.7%	100.0%	100.0%
February 2020	8	75.0%	100.0%	75.0%	87.5%	100.0%
March 2020	8	100.0%	100.0%	100.0%	100.0%	100.0%
April 2020	11	90.9%	100.0%	92.9%	100.0%	100.0%
May 2020	9	100.0%	100.0%	100.0%	100.0%	100.0%
June 2020	9	77.8%	100.0%	88.9%	88.9%	100.0%
July 2020	7	57.1%	100.0%	85.7%	85.7%	71.4%
August 2020	1	100.0%	100.0%	100.0%	100.0%	100.0%
September 2020	4	100.0%	100.0%	100.0%	100.0%	100.0%
October 2020	5	80.0%	100.0%	100.0%	80.0%	80.0%
November 2020	4	50.0%	100.0%	100.0%	75.0%	50.0%
December 2020	6	33.3%	100.0%	75.0%	100.0%	62.5%
January 2021	5	80.0%	100.0%	100.0%	80.0%	100.0%
February 2021	6	83.3%	100.0%	83.3%	100.0%	83.3%
March 2021	9	55.6%	100.0%	66.7%	88.9%	77.8%
April 2021	6	100.0%	100.0%	100.0%	100.0%	100.0%
May 2021	9	88.9%	100.0%	88.9%	100.0%	100.0%

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