Compliance of Sepsis Bundle Completion in Persons Who Use Drugs

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NURS 703B: DNP Project Planning

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Submitted to: Dr. Diana Clapp - Chair

This paper is submitted in partial fulfillment of the requirements for

the Doctor of Nursing Practice degree.

Abstract

Sepsis is a life-threatening condition caused by an infectious agent that is responsible for significant mortality world-wide (Dolin et al., 2019; Evans et al., 2021). In order to standardize sepsis-related care, the Centers for Medicare and Medicaid Services (CMS) Hospital Quality Initiatives have incorporated evidence-based guidelines set forth by the Surviving Sepsis Campaign in the format of SEP-1 bundle (Alexander et al., 2022). People who use drugs (PWUD) are at higher risk for developing sepsis and septic shock (Neviere, 2022). Thus, the aim of this project was to determine if the SEP-1 bundle set forth by CMS is met for PWUD with comparable compliance to patients who do not use drugs at a regional medical center. Specific bundle components were also tracked for their contribution to either bundle compliance or failure. Inadequate administration of antibiotics or 30 ml/kg of crystalloid calculated for ideal body weight were the most common reasons for bundle failure. Results were not significant for PWUD receiving care that was less bundle-compliant than people who do not use drugs ($p = 0.5648$); however, these results are limited by the small sample size included in this retrospective chart review. A more extensive chart review with a larger sample size is needed to determine if care is equitable for PWUD. This QI project offers a starting point for developing interventions to increase bundle compliance through targeting the most often-failed bundle components.

Problem Description

Sepsis is a life-threatening condition in which an infected host has a dysregulated response to the offending pathogen (Evans et al., 2021). Bacteria are the most commonly identified cause; however, viruses and fungi may also initiate this host response (Dolin et al., 2019). World-wide, it is estimated that one out of every three to six people that develop sepsis are killed (Evans et al., 2021). In the United States, there are approximately 1.7 million cases of sepsis per year (Rhee et al., 2019). In order to standardize sepsis-related care and reduce its associated mortality, the Surviving Sepsis Campaign was founded in 2004 and periodically publishes updated guidelines supported by the latest evidence, the most recent of which was in 2021 (Dellinger et al., 2023).

Persons who use drugs (PWUD), especially intravenously, are at higher risk for serious bacterial infections, including skin/soft tissue infections, osteomyelitis, bacteremia, and endocarditis (Capizzi et al, 2020). Because of this higher risk, especially in the case of bacteremia, these patients are also at higher risk for developing sepsis and septic shock (Neviere, 2022). In a nation-wide retrospective cohort study, the rate of sepsis hospitalizations related to opioid use were found to have risen by 77% from January 2008 to September 2015 (Alrewashdeh et al., 2021). This trend has also been demonstrated among intravenous (IV) drug users specifically; in Oregon from 2008 to 2018, hospitalizations for bacteremia/sepsis rose 18-fold among this population (Capizzi et al., 2020).

Available Knowledge

The current Surviving Sepsis Campaign (SSC) guidelines recommend beginning antimicrobial therapy within one hour of identifying patients who are at high risk for sepsis or septic shock. Additionally, for patients with sepsis-induced hypoperfusion, the guidelines recommend beginning fluid resuscitation within three hours (Evans et al., 2021). Delays in receiving these treatments have been associated with higher mortality in patients with sepsis (Gregorowicz et al., 2020). SSC guidelines have been incorporated into the Centers for Medicare and Medicaid Services (CMS) Hospital Quality Initiatives

(HQI) since 2015, which aim to ensure the delivery of quality healthcare in facilities that receive Medicare payments (Alexander et al., 2022).

The HQI associated with sepsis, titled "Early Management Bundle, Severe Sepsis/Septic Shock Measure", is more commonly known as SEP-1 (Alexander et al., 2022). Compliance with this measure has been associated with improved patient outcomes in multiple studies. Specifically, Townsend et al. 2022 analyzed patient-level data reported to Medicare from 3,241 hospitals and found that in patients whose care was compliant with SEP-1, 30-day mortality was significantly reduced. Levy et al. (2018) found that compliance was associated with reduced hospital length of stay and in-hospital mortality; all bundle components except vasopressor administration were individually associated with reduced in-hospital mortality. While SEP-1 has not been updated with the most recent SSC guidelines, the Hour-1 bundle recommended by SSC has not been significantly associated with improved in-hospital or 28-day mortality, nor delayed rates of septic shock in various studies (Ko et al., 2021; Prachanukool et al., 2021).

Rationale

The Institute of Medicine (IOM)'s Model for Improvement (MFI) was chosen as a framework to guide the process of quality improvement. An important question that this model asks is, "What are we trying to accomplish?", which aids in targeting the specific needs a project is attempting to address (Provost et al., 2020). In the case of this project, multiple studies have demonstrated the negative experiences that PWUD associate with seeking medical care, including delays in treatment (Alrewashdeh et al., 2021; Capizzi et al., 2020; Mayer et al., 2023). This quality improvement project aimed to identify if these findings impact the care of PWUD at a non-profit regional medical center. This model was chosen for its universally applicable structure and its emphasis on continuous improvement (Provost et al., 2020). Additionally, the findings of this retrospective review may be used to guide the development of Plan-Do-Study-Act (PDSA) cycles. PDSA cycles are central to the MFI's structure and may be used to implement and evaluate change while providing an accessible path for improvement in the future.

Specific Aims

PWUD are known to be at higher risk of sepsis. The aim of this QI project is to determine if the SEP-1 bundle set forth by CMS is met for PWUD with comparable compliance to patients who do not use drugs at a regional medical center. The results of this project will help guide process improvement interventions to ensure that all patient care meets standard guidelines.

Methods

Context

The regional medical center where this project took place holds 465 licensed inpatient beds and 133 ED beds. In 2021, there were an estimated 99,000 ED visits making it one of the busiest on the West Coast. As of 2020, this facility serves two Oregon counties with an estimated population of 433,000 (United States Census Bureau, 2021). This facility utilizes the sepsis bundle algorithm set forth in the SEP-1 bundle algorithm to drive process improvement and monitor compliance (Appendix C). Reimbursement from CMS is determined by SEP-1 bundle compliance, whose development is closely aligned with SSC recommendations (Wang et al., 2020).

In Oregon, hospitalizations of people who inject drugs related to bacteremia/sepsis have seen a significant increase since 2008 (Capizzi et al., 2021). While there does not appear to be a current population estimate of people who inject drugs in Oregon, a meta-analysis conducted by Bradley et al. (2023) estimated that the national prevalence of people who inject drugs is approximately 1.5%. In 2021, approximately 21% of Oregonians aged 12 years or greater have used illicit drugs; furthermore, Oregon is ranked second in the nation for deaths due to drug use (HHS, 2022; Lenahan et al., 2023). Based on these figures, this regional medical center would likely see thousands of PWUD per year.

Interventions

This QI project utilized a retrospective chart review to determine the rate that this regional medical center met the SEP-1 bundle for all patients from October through December of 2022, and

examined if bundle compliance in PWUD varied significantly from patients who do not use drugs. Patients were included in this review if they had been diagnosed with severe sepsis or septic shock upon admission and were 18 years of age or older. PWUD were identified by a positive drug screen for illicit substances or a documented history of illicit drug use. Illicit drugs were defined as amphetamines, opiates, benzodiazepines, cocaine, and barbiturates for which the patient did not have a prescription. Patients were excluded if they developed sepsis after admission to the hospital.

Measures

The outcome measure for this project was the proportion of patients for which the sepsis bundle algorithm set forth by CMS was met; this also included a comparative analysis between the proportion of cases for which the bundle was met between those who used and did not use illicit drugs.

For all patients for whom the bundle was not met, process measures examined each portion of the bundle to determine if there was a specific factor that could be implicated in causing bundle failure at the regional medical facility using a Pareto chart (Appendix D).

Analysis

The data set did not yield an appropriate sample size for use of the Chi-squared test for independence. Thus, the Fishers Exact test was used to test for significance ($p < 0.05$) and to determine the relationship between successful completion of the sepsis bundle algorithm and identification of the patient as a PWUD. The null hypothesis was that these variables were independent of each other; the alternative hypothesis was that they were not independent of each other and a PWUD would have significantly different rates of Hour-1 bundle completion when compared to patients who did not use drugs. Rates of bundle failure that can be contributed to a specific bundle component were analyzed using a Pareto chart to determine other influences on successful bundle completion and identify areas for process improvement.

Ethical Considerations

The stigma perceived by PWUD may cause negative healthcare experiences that deter them from seeking future care and cause feelings of distrust and frustration (Muncan et al., 2020). Thus, preserving their right to confidentiality is an especially important ethical issue to integrate in this project in order to maintain trust in the medical system. All patient identifiers were removed from the accumulated data and data was kept in a password-protected database.

The proposal for this project was submitted to both the OHSU and regional medical center's institutional review board and was approved without ethical concerns.

Results

In the time period designated for this project, 45 patients met the inclusion criteria. Of these 45 patients, three were identified as PWUD and 42 were identified as non-drug users. One third of PWUD (n=1) received care that was compliant with the SEP-1 bundle. Of the patients who were not PWUD, 59.5% (n=25) received care that was compliant with the bundle. Of the total sample size, 57.8% (n=26) received bundle compliant care. Because the small sample size of PWUD did not yield sufficient expected results to allow an accurate Chi-Square test for independence, the Fishers Exact test was used to calculate significance for SEP-1 compliance between the categories of PWUD and people who did not use drugs. The association between these two groups was not statistically significant ($p< 0.05$) between these two groups, with $p = 0.5648$.

A Pareto chart was created to analyze the impact that each bundle component had on patients in all categories whose care failed bundle compliance (Appendix D). This chart organizes failed bundle components in order of their frequency of failure, and provides a visual representation of data for quick identification of the most impactful bundle components. Administration of 30 ml/kg ideal body weight of crystalloid was the most frequently failed bundle component, at 12 failures. Antibiotic administration was the next most frequent cause of bundle failure (9 failures), followed by the drawing of blood cultures prior to antibiotic administration (7 failures), and drawing an initial lactic acid (2 failures). Of the

19 patients whose care failed the SEP-1 bundle, 6 cases failed in multiple bundle components. Of the two PWUD whose care failed the bundle, both were due receiving inadequate fluid resuscitation, the most common reason for bundle failure among all included patients.

Discussion

Summary

The specific aim of this project was to identify if PWUD benefit from SEP-1 bundle compliance compared to people who did not use drugs; results indicated that there was no significant difference in bundle compliance between these two populations. However, the sample size of PWUD was quite small with n=3, compared to the sample size of non-drug users, n=42. To further target future quality improvement methods, the failure of specific bundle components was measured amongst all patients; in both PWUD and people who did not, the component that contributed to bundle failure was most often the timely and accurate administration of 30ml/kg ideal body weight of fluid.

Interpretation

While the intervention did not yield a significant association between PWUD and a lower SEP-1 bundle compliance, it did provide beneficial information for the areas in which the bundle most frequently failed for the total population. Specifically, the largest two contributors to compliance failure in this project were administration of IV fluids (12 failures) and administration of antibiotics (9 failures) within the bundle parameters. In a much larger analysis examining 3,799 patient encounters, Bauer et al. (2020) found that IV fluid administration and antibiotic administration were failed most frequently; thus, the findings of this project align with other studys' findings. Of the 19 patients whose care failed the bundle, fluid administration contributed to 12 failures, indicating a significant consideration for where to target quality improvement in the future.

In a study examining nation-wide performance of the SEP-1 bundle, Barbash et al. (2020) found that mean overall bundle compliance among hospitals was 48.9%. Comparatively, the compliance rates

at this regional medical center are performing above the average; however, even at the rate of 57.5% compliance, this still leaves four out of ten patients receiving care that is not compliant with the SEP-1 bundle. Therefore, this leaves a large number of patients who are not receiving the SEP-1 bundle's evidence-supported benefits such as reduced 30-day mortality and median length of stay (Townsend et al., 2022).

While there was not a significant relationship established between PWUD and non-users' SEP-1 bundle compliance, this must be considered in the context of the limited sample size as well as the current body of research. Qualitative research supports a perception that PWUD are treated differently in emergency rooms because of stigma related to their drug use (Alrewashdeh et al., 2021; Capizzi et al., 2020; Mayer et al., 2023). PWUD also report experiencing neglect in the emergency room and delays in receiving needed treatment (Mayer et al., 2023). Additionally, the negative perceptions of healthcare workers toward PWUD are supported by a systematic review conducted by van Boekel et al. (2013), which found that health professionals had generally negative views of patients with a substance use disorder and this subsequently impacted patients' feelings of empowerment and treatment outcomes. While results were not significant in this quality improvement project, the limited number of PWUD in this initial analysis warrant a timeline expansion of this project's review to determine if equitable care is being provided at this regional medical center in light of current research findings.

Limitations

A significant limitation to this project involved the limited sample size. Because of this, these findings should not be used to assume equitable care at this institution and instead should drive a project that examines a larger set of patients for more accurate and generalizable results.

Conclusion

This project offers an important starting point for improving the sepsis-related care at this regional medical center. By using this data to develop new strategies targeting the specific bundle

components of fluid and antibiotic administration, compliance for many more patients may be achieved regardless of their drug-use status. While results were not able to verify a correlative relationship between PWUD and lower SEP-1 bundle compliance, this could be due to the significant limitation of sample size as the trend of measured data shows that PWUD receive less compliant care. Thus, a larger sample size is needed to evaluate if this medical center truly provides equitable care that positively impacts the vulnerable populations it serves.

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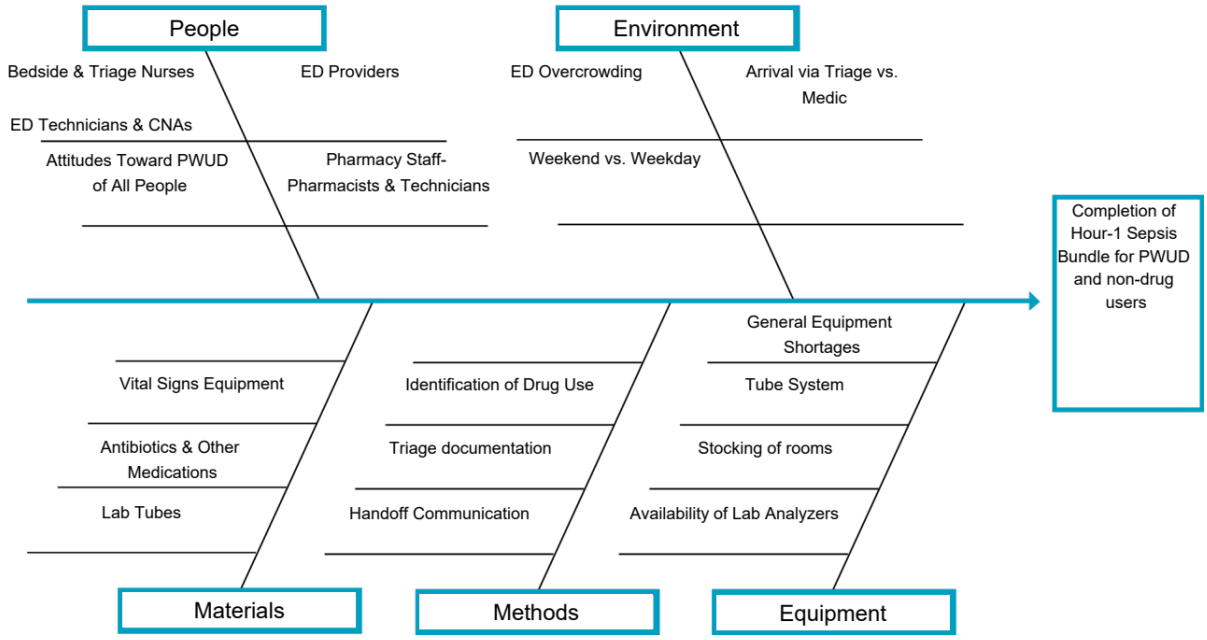
Appendix A

Cause and Effect Diagram



Appendix B

Project Timeline

	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec-Mar
Finalize project design and approach (703A)	X	X						
Complete IRB determination or approval (703A)			X					
Data collection via retrospective review (703B)			X	X	X			
Final data analysis (703B)					X			
Write sections 13-17 of final paper (703B)						X	X	
Prepare for project dissemination (703B)								X

Appendix C

Sepsis Bundle Algorithms 07-01-2022 (3Q22) through 12-31-2022(4Q22) per the Center for Medicare and Medicaid Services (2022)

SEP-1: Early Management Bundle, Severe Sepsis/Septic Shock (Composite Measure)

Within three hours of presentation of severe sepsis:

- Initial lactate level measurement
- Broad spectrum or other antibiotics administered
- Blood cultures drawn prior to antibiotics

AND received within six hours of presentation of severe sepsis. ONLY if the initial lactate is elevated:

- Repeat lactate level measurement

AND within three hours of initial hypotension:

- Resuscitation with 30 mL/kg crystalloid fluids

OR within three hours of septic shock:

- Resuscitation with 30 mL/kg crystalloid fluids

AND within six hours of septic shock presentation, ONLY if hypotension persists after fluid administration:

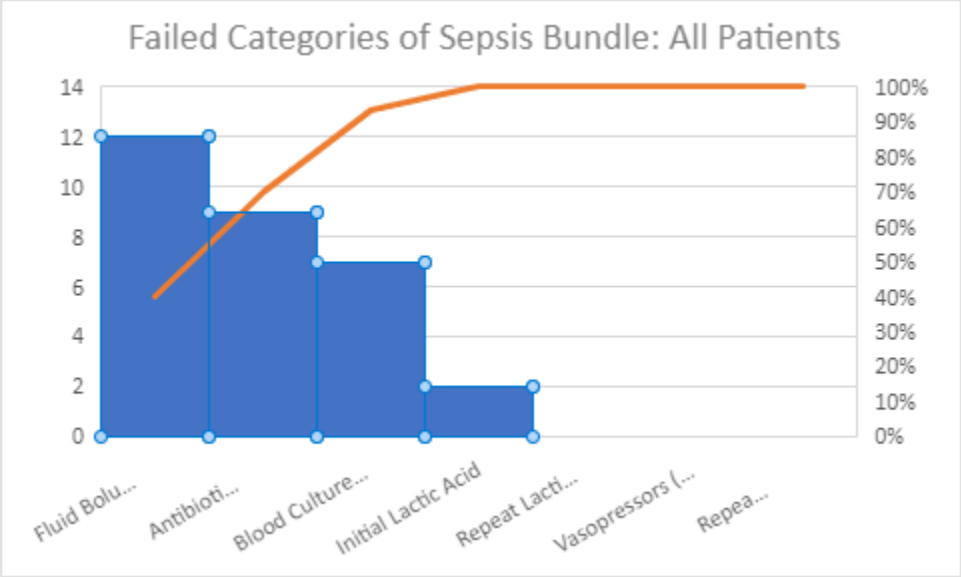
- Vasopressors are administered

AND within six hours of septic shock presentation, if hypotension persists after fluid administration or initial lactate >= 4 mmol/L:

- Repeat volume status and tissue perfusion assessment is performed

Appendix D

Pareto Chart: Failed Categories of SEP-1 Bundle: All Patients



This Pareto chart is a visual depiction of the SEP-1 categories that are most frequently failed, in order from highest to lowest frequency. The orange line reflects the cumulative frequencies of failed components.

Appendix E

IRB Determination

Salem Health
Hospitals & Clinics

Institutional Review Board
503-814-2811
irb@salemhealth.org
P.O. Box 14001
Salem, OR 97309

INSTITUTIONAL REVIEW BOARD
FWA #00009433

DATE: August 21, 2023

TO: Anna Adams, Principal Investigator

FROM: Deborah Muller, Salem Hospital IRB Coordinator

RE: **IRB # 9961 - Compliance of Sepsis Bundle Completion in Persons Who Use Drugs**

EXEMPT Determination

On August 23, 2023 the Salem Hospital IRB chair conducted a review of the above-referenced study request for exempt review and granted IRB Exemption per 45 CFR 46.104(d):

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

☐ (i) The identifiable private information or identifiable biospecimens are publicly available;

☐ (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

☒ (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

☐ (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501

This research does not involve children and this research is not FDA regulated.

The IRB also granted this study a waiver of HIPAA Authorization based on the criteria as stated at 45 CFR 160.164 (a, e). The IRB understands that this is a retrospective cohort study of patient data extracted from medical records, utilizing the following 4 criteria for minimizing risks to privacy:

- The research use of the health information does not represent more than a minimal risk to privacy
- That the research could not be done without the requested health information
- That it would not be practical to obtain signed authorizations from the research subjects
- That the specific elements of health information that are requested are not more than the minimum necessary to accomplish the goals of the study

The approved Exempt Review Request is attached for your files.

Annual IRB review is NOT required for this study, however, in accordance with Federal regulations, please immediately notify the IRB if you encounter any serious, disabling, life-threatening, or unanticipated events related to this study. Any new information or significant changes to the study must also be reported to the IRB.

The IRB asks that you notify us when your study has been completed, and submit a summary of the study activities and findings at the conclusion.

Please contact us if you have any questions, or if we may be of further service. You may reach Deborah Muller, IRB Coordinator, at (503) 814-2811 or by email

Appendix F

Letter of Support from Implementation Site

Letter of Support from Clinical Agency

Date: **08/10/2023**

Dear Anna Adams,

This letter confirms that I, Sierra Schneider, allow Anna Adams (OHSU Doctor of Nursing Practice Student) access to complete his/her DNP Final Project at our clinical site. The project will take place from approximately July 1, 2023 to April 30, 2024.

This letter summarizes the core elements of the project proposal, already reviewed by the DNP Project Preceptor and clinical liaison (if applicable):

Project Site(s):
Salem Health
890 Oak Street SE
Salem OR, 97301

Project Plan:
People who use drugs (PWUD) perceive delays in care related to stigma associated with their drug use. These patients are also at higher risk for sepsis. The Institute of Medicine (IOM)'s Model for Improvement (MFI) has been chosen as a framework to guide the process of quality improvement. This quality improvement project is aiming to identify if there is a measurable gap between the care that PWUD receive when experiencing sepsis as opposed to groups who do not. Using these findings, future Plan-Do-Study-Act Cycles can be implemented at Salem Health that introduce interventions that may close this potential gap. The aim of this QI project is to determine if sepsis guidelines, specifically the SEP-1 bundle, utilized by CMS is met for PWUD compared to other populations. Data will be collected retrospectively over a three-month period and analyzed using a chi-squared test for independence. For each failure of the SEP-1 bundle, the bundle component contributing to its failure will also be documented. Data will be de-identified and stored on password-protected devices. For the duration of this project, Salem Health agrees to allow access to patient data and a space to conduct activities.

During the project implementation and evaluation, Anna Adams will provide regular updates and communicate any necessary changes to the DNP Project Preceptor.

Our organization looks forward to working with this student to complete their DNP project. If we have any concerns related to this project, we will contact Anna Adams and Dr. Diana Clapp (DNP Project Chairperson).

Regards,

DNP Project Preceptor (Name, Job Title, Email, Phone):
G. Sierra Schneider, DVM, BSN, RN, CCRN, Sepsis Coordinator

Date Signed: August 10th, 2023.