

POST-SEPSIS SYNDROME:
IMPROVING MORBIDITY & MORTALITY
FOLLOWING HOSPITALIZATION

by

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ABSTRACT

Sepsis is the life-threatening organ dysfunction caused by a dysregulated host response to infection. Globally, statistics are grim with 19 million cases diagnosed annually. Each year in the United States (US) there are over 1.6 million people diagnosed with sepsis; over 250,000 of these will not survive. Currently, it is a leading cause of morbidity, mortality, and hospital readmissions in the US. The population of focus was those residing within the north-central Montana region. The purpose of this project was to explore the topic of post-sepsis syndrome (PSS) and its occurrence following a primary diagnosis of sepsis. The goal of this project was the development of a quality improvement initiative focused on establishing a care-management program for patients diagnosed with sepsis. Ultimately, maximizing patient health and healthcare organization outcomes. An interprofessional team was convened to develop an evidence-based quality-improvement plan to decrease the human and financial costs of sepsis and PSS. The purposed evaluation of the quality-improvement project includes monthly PDSA cycles with project goals reviewed bi-annually.

INTRODUCTION

Sepsis is the life-threatening organ dysfunction caused by a dysregulated host response to infection (Singer et al., 2016). Globally, statistics are grim with 19 million cases diagnosed annually. Each year in the United States (US) there are over 1.6 million people diagnosed with sepsis; over 250,000 of these will not survive. Currently, it is a leading cause of morbidity, mortality, and hospital readmissions. A contributing factor of these statistics is delayed diagnosis, creating a missed opportunity to provide critical early intervention. For those surviving, significant morbidity and mortality challenges are common. One-half of those surviving the original episode will develop some form of post-sepsis syndrome (PSS) with one-sixth having severe chronic impairment characterized by life-altering morbidities. Risk factors for patients most likely to develop PSS include those with comorbidities, longer duration of delirium while hospitalized, inadequate pain control, decreased early mobility, and lack of a strong support system. The likelihood of developing PSS is directly correlated with the severity of sepsis during the initial hospitalization.

Healthcare professionals and organizations are challenged with increasing readmission rates following an initial hospitalization of severe sepsis, with up to 32% of these patients being readmitted within 30 days of discharge. Further, 40% will be readmitted within 90 days and 63% within the next 12 months (Mostel et al., 2020).

Healthcare professionals often do not fully understand PSS. In particular, limited knowledge regarding the lasting effects of PSS and identifying patients who are at risk are problematic. For patients, families, and healthcare professionals, high-quality care coordination is needed. For healthcare organizations, action needs to be taken to decrease morbidity and subsequent readmission. This process can only begin when more awareness of PSS is spotlighted (De Backer & Dorman, 2017; Sepsis Alliance, 2020).

Problem Statement

Post-sepsis syndrome is a relatively new diagnosis for patients who have survived severe sepsis or septic shock. Healthcare professional's knowledge of PSS creates gaps in the quality of care necessitating an innovative approach to care management.

Background and Need

Sepsis is the life-threatening organ dysfunction caused by a dysregulated host response to infection (Singer et al., 2016). The pathophysiologic process of sepsis is complex and multifaceted with diverse pathologic etiologies. The complicated etiology results in diverse patient presentations contributing to the difficulty of timely and accurate diagnoses. Delayed diagnosis directly contributes both to increased morbidity and mortality during and following the initial episode (Bahn et al., 2016).

Recent advancements have improved timely diagnosis and treatment; however, decreases in mortality have not been achieved. As a result, regulatory bodies such as Centers for Medicare and Medicaid Services (CMS) now require mandatory reporting on sepsis care within inpatient settings. The CMS actions are focused on the timely diagnosis and treatment for both severe sepsis and septic shock. These measures will greatly impact the level of hospital reimbursement.

Purpose of Study

The purpose of this study is to develop a care-management program for sepsis and to maximize patient health and healthcare organization outcomes.

Significance to the Field

Despite a focus on early intervention, sepsis continues to challenge patients, providers, and healthcare organizations. Currently, each year in the US, 800,000 patients suffer life-altering complications following a diagnosis of sepsis. The resulting physical and cognitive impairments not only affect these patient's quality of life, but they also generate significant healthcare costs through increased use of both acute- and primary-care services. As a result, there is a disproportionate financial burden for Medicaid and Medicare as patients insured through these entities are more likely to be diagnosed with sepsis (Iwashyna et al., 2010). Sepsis has been recognized as a major public-health concern, accounting for more than \$24 billion (13%) of total US hospital costs in 2013

(Paoli et al., 2018). The underlying cause is uncertain; however, this fact is well established. In this project, we will introduce sepsis, PSS, and suggest an intervention to improve health outcomes.

Definitions

The following definitions are presented for use in this study and intended to assist the reader.

1. Centers for Medicare and Medicaid Services: The federal agency that runs the Medicare program. In addition, CMS works with the States to run the Medicaid program. CMS works to make sure that the beneficiaries of these programs are able to get high-quality health care (CMS, 2006).
2. Septic Shock: Subset of sepsis in which the underlying circulatory and cellular metabolism abnormalities are profound enough to substantially increase mortality (Singer et al., 2016).
3. Sepsis: The life-threatening organ dysfunction caused by a dysregulated host response to infection (Singer et al., 2016).
4. Systemic Inflammatory Response Syndrome Criteria (SIRS): Screening algorithm to streamline the early recognition and management of severe sepsis (Singer et al., 2016).
5. Safe, Timely, Effective, Efficient, Patient-centered Care (STEEP): Institute of Medicine's patient safety and quality-improvement principles (Agency for Healthcare Research and Quality, 2018).

6. Activities of Daily Living: Functional activities such as bathing, dressing, toileting, transferring, continence, and feeding (Correll, 2019).
7. Quality of Life (QoL): The degree to which a person or group is healthy, comfortable, and able to enjoy the activities of daily living (Merriam-Webster, n.d.).
8. Post Intensive Care Syndrome (PICS): A collection of physical, mental, and emotional symptoms that continue to persist after a patient leaves the intensive care unit (Cleveland Clinic, 2019).
9. North-central Montana: Made up of 11 counties and three American Indian reservations. Has an area over 31,000 square miles and is larger than ten other states. Population of approximately 148,000 and a predominance of older adults substantiating the needs (Opportunity Link, n.d.).
10. Clinical Nurse Leader: Member of an interprofessional team that can oversee the lateral integration of care for a distinct group of patients and may actively provide direct patient care in complex situations (American Association of Colleges of Nursing, n.d.).
11. Primary Care: Health care provided by a medical professional (such as a general practitioner, pediatrician, or nurse) with whom a patient has initial contact and by whom the patient may be referred to a specialist (Merriam-Webster, n.d.).

12. Care Coordinator: An interprofessional team member that focuses on patient- and family-centered care, assessing and meeting the needs of patients while helping them navigate effectively and efficiently through the healthcare system (Agency for Healthcare Research and Quality, 2014).

Limitations

Potential limitations for this project have been identified. Current research and best practices continue to be revised as new information becomes available. For this reason, an iterative process will be required for meaningful improvement. Limited healthcare provider knowledge and acceptance of current best practices may create unnecessary barriers. Further, data collection on the basis of age alone limits the scope of this project. The majority of data collected within the published literature is specific to ages 65 and over, consistent with the Medicare population.

Ethical Considerations

Beneficence is one of the fundamental ethics in healthcare. Thus, all healthcare professionals have a foundational moral imperative to provide the highest quality of care possible. The ethical principle of social justice is specific to ensuring that policies and practices are developed that ensure that all have an equal opportunity to health and healthcare.

LITERATURE REVIEW

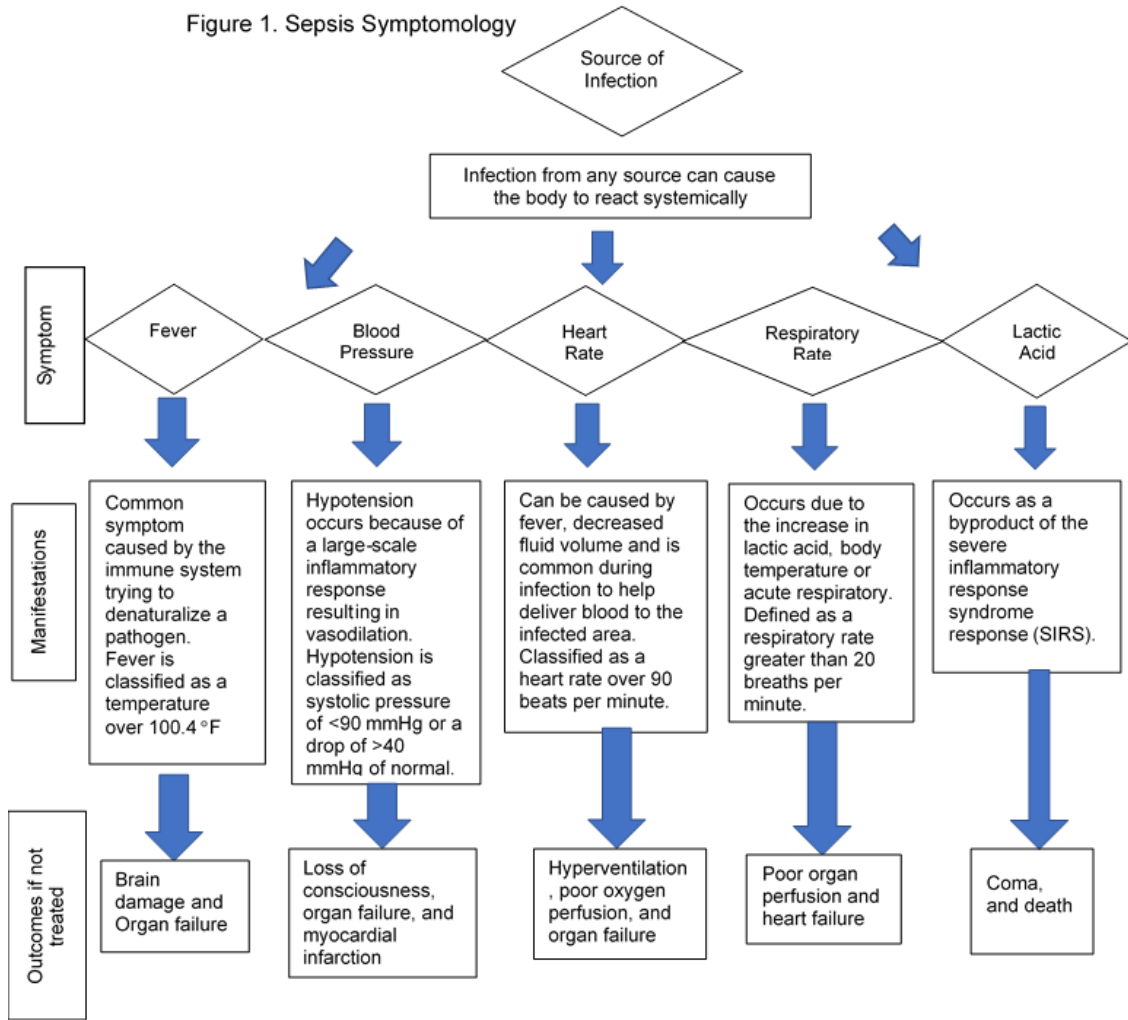
Introduction

Each year 1.6 million people are diagnosed with sepsis; of these, 250,000 will die as a result (Sepsis Alliance, 2020). Failure to identify sepsis early and initiate timely, effective treatment decreases the likelihood for survival. Care delivered to treat sepsis successfully requires a targeted approach (SEP-1 bundle) including continued treatment of the primary infection. Despite heroic efforts, those fortunate enough to survive may still sustain life-altering and costly complications (Iwashyna et al., 2010). Improving sepsis and post-sepsis outcomes will require an innovative approach to disease management.

Sepsis

Sepsis is the life-threatening organ dysfunction caused by a dysregulated host response to infection (Singer et al., 2016). Timeliness of diagnosis is of the essence when it comes to surviving sepsis. Timeliness refers to early access to care, early diagnosis, and rapid implantation of appropriate treatment. Sepsis may result from any infection (even a simple infection) and ultimately affect virtually all body systems. As presented in Figure 1, multiple pathophysiologic alterations occur within the body. With absent or delayed treatment, acute organ failure and subsequent death are probable (Bennett, 2015).

Figure 1: Sepsis Symptomology



Unfortunately, sepsis can be difficult to diagnose, resulting in a delay of treatment. This delay is believed to be the primary factor placing individuals at risk for poor outcomes. In fact, undiagnosed or misdiagnosed sepsis is claimed to be the primary cause of death from infection (Vincent, 2016). The major challenge contributing to the misdiagnosis of sepsis is the lack of a definitive test or gold standard to guide practitioners. For example, sepsis does not have one

biologic marker, but rather has hundreds. As a result, sepsis presentation is diverse and complex.

Hallmarks have been identified, including fever, low blood pressure, high respiratory rate, increased white count, elevated lactic acid, and positive blood cultures, suggesting sepsis would be easy to diagnosis. However, the population most at risk (i.e., elderly) are often hypothermic and blood cultures may be negative. Further, these patients may have a low platelet count and no other symptoms. These deviations from expectations may result in practitioners' exclusion of sepsis on their list of differential diagnoses (Vincent, 2016).

Treatment

Sepsis treatment recommendations have undergone numerous revisions over the years as knowledge has expanded. Specifically, these changes occurred as our understanding of sepsis and the implications of treatment delays have become better understood. Organizations such as the Center for Medicare and Medicaid Services (CMS) have pioneered improvements in sepsis identification and treatment. For example, they have required the implantation of care modalities such as the severe sepsis and septic shock early management bundle (SEP-1).

The SEP-1 was the initial care bundle created and implemented in 2015 to combat the deadly nature of sepsis. The intended goals of this care bundle were to improve timely diagnosis and management of sepsis with a subsequent decrease in patient mortality. Inclusion criteria for patients under the SEP-1

bundle include meeting two of four elements of the systemic inflammatory response syndrome (SIRS) criteria (see Table 1), displaying at least one new organ dysfunction, and documentation of suspected infection present (Han et al., 2018). The SEP-1 bundle's effectiveness and efficacy has been ongoing since its inception.

Table 1. Systemic Inflammatory Response Syndrome (SIRS) Criteria

General Symptoms

- Heart rate > 90 bpm
- Tachypnea
- Core Body Temperature > 38° C or <36°C

Inflammatory Symptoms

- Leukocytosis
- Leukopenia
- Elevated C-reactive protein
- Elevated plasma procalcitonin

Hemodynamic Symptoms

- Hypotension (systolic blood pressure <90 mmHg; MAP <65 mmHg)

Organ Dysfunction Symptoms

- Coagulation abnormalities
- Hyperlactatemia
- Hyperbilirubinemia
- Thrombocytopenia
- Increase in Serum Creatinine
- Acute Oliguria
- Hypoxemia

Bennett, S. R. (2015). Sepsis in the intensive care unit. *Surgery*, 33(11), 565–571.

Post-Sepsis Syndrome

Post-sepsis syndrome was first recognized as a unique complication of sepsis 20 years ago (Mostel et al., 2020; Sepsis Alliance, 2020). Practitioners caring for survivors of sepsis found they had new or worsening medical conditions that were believed to be separate from their sepsis experience. Over time, evidence came forth that cognitive and physical changes often developed in patients who had recently been diagnosed with sepsis. This led to the understanding that these symptoms may be directly related to the body's systemic response to infection. Data indicate, of those surviving sepsis, one-third die within 12 months; one-sixth have at least one severe chronic impairment (Sepsis Alliance, 2020). These chronic impairments can present as neurophysiologic or physical in nature (see Table 2).

Table 2. Effects of Post Sepsis Syndrome

System	Symptoms	Occurrence Percentage (%)
Physical	<ul style="list-style-type: none"> • Muscle or Joint Pain • Loss of ability to complete ADLs • Cardiovascular disease 	<ul style="list-style-type: none"> • Unknown* • Unknown* • 13-fold increase in risk for development (Mostel et al., 2020)

Table 2. Effects of Post Sepsis Syndrome Continued

System	Symptoms	Occurrence Percentage (%)
Neurological	<ul style="list-style-type: none"> • Decreased cognitive function • Short- and long-term memory loss • Dementia 	<ul style="list-style-type: none"> • 25–50% of survivors will experience one or more of these symptoms (Mostel et al., 2020)
Psychological	<ul style="list-style-type: none"> • Post-Traumatic Stress Disorder (PTSD) • Depression • Anxiety/Panic Attacks • Hallucinations • Nightmares • Decrease in self-esteem 	<ul style="list-style-type: none"> • 32% Anxiety within 2–3 months (Nikayin et al., 2016) • 29% Depression within 2–3 months (Rabiee et al., 2016) • 44% PTSD within 1–6 months (Parker et al., 2015)

* Information not available

Neurophysiologic

The decline in cognitive function post sepsis was first identified by Iwashyna (2010). Cognitive decline is believed to be multifaceted and a direct result of complicated and abnormal pathophysiology. Dysregulation of uremia and glycemia are theorized to be the leading factors contributing to cognitive decline. Further, cognitive changes are attributed to a systemic inflammatory response. Due to the body's dysregulated host immune response, permanent neurological damage may occur. The most common symptoms with these patients are changes in visual and psychological status, decreased motor speed, and alterations in ability to process information. While some symptoms may

improve with rehabilitation, others are chronic in nature (Calsavara et al., 2018; Iwashyna et al., 2010).

One factor contributing to the delay in the identification of PSS was post-intensive-care-unit syndrome (PICS). PICS is a collection of physical, mental, and emotional symptoms persisting after a patient leaves the intensive care unit, regardless of the reason for admission. Similarities between PICS and PSS are cognitive and psychological decline.

Over time, it has been identified that sepsis survivors have a greatly increased risk for hospital readmission. In fact, it is now known that PSS is the leading cause of readmission in the US (Sepsis Alliance, 2020). Patients may be readmitted with new deficits or an exacerbation of a pre-existing comorbidity. The increased need for PSS-related care adds to the financial burden experienced by patients and the healthcare system (Calsavara et al., 2018). Specific reasons for readmission vary widely and include systemic infection, redevelopment of sepsis, and exacerbation of previous chronic illness (Mostel et al., 2020).

At this time, data to describe readmission from patients with PSS are submitted to CMS but are not yet benchmarked or published. In the near future, this measure will be included as a value-based purchasing measure. With financial consequences looming, healthcare facilities are starting to invest in innovative solutions for long-term disease management. Historically, reeducation of staff has been found to have limited effect on quality improvement. The greatest success for this type of quality improvement project has been through

the utilization of specific disease-process care coordinators (i.e., heart disease, stroke, and diabetes) (Weaver et al., 2018).

Three appropriate care interventions capable of minimizing the occurrence or potential severity of PSS post-discharge have been identified: (1) early sepsis diagnosis and intervention, (2) management of pain, agitation, and delirium, and (3) early mobilization (Mostel et al., 2020; Prescott & Angus, 2018). When instituted and managed appropriately, survivors are optimally positioned for improved functionality and quality of life (QoL) following the acute episode (Mostel et al., 2020; Prescott & Angus, 2018).

Care coordination is a multifaceted and evolving position within the interdisciplinary care team. The primary duties of this position may vary with the disease process being managed; however, core duties of the position remain constant. These core duties include the allocation of needed patient resources, monitoring patient progress, and facilitating communication within the interdisciplinary team (Weaver et al., 2018). Implementation of this form of quality, focused care delivery is known to improve patient outcomes and, subsequently, lower rates of readmissions, ultimately improving healthcare organization outcomes.

Rurality

Due to the rural nature of Montana, residents are at a considerably higher risk of morbidity and mortality following a diagnosis of sepsis. Rural populations are characterized by having higher levels of unemployment and

underemployment, limited access to transportation, and often limited access to healthcare resources, both at an acute and post-acute level (HRSA, 2019).

These disadvantages likely contribute to the readmission rate of greater than 30% of patients with a primary diagnosis of sepsis within 30 days.

METHODS

Introduction

As the number of individuals surviving sepsis continues to increase, the complex nature of PSS has drawn the attention of healthcare leaders, providers, and researchers alike. While the lived experience of sepsis survivorship is the primary concern of healthcare providers, the high cost of providing care services for this population has captured the attention of healthcare leaders and funding agencies. Though service delivery during the acute phase of sepsis has received much attention, guidelines for the provisions of aftercare for survivors and their families are limited. Unfortunately, little success has been achieved through traditional quality-improvement methodologies. For this reason, an innovative approach to address this crisis is presented.

A microsystem assessment was completed at the local regional tertiary referral center. Through this process, an opportunity to examine and develop a quality-improvement project to improve PSS outcomes was identified. Findings from this process correlate with state, regional, and national statistics. The completion of this microsystem assessment revealed a consistent problem with elevated 30-day readmission rates of those discharged with a primary diagnosis of sepsis.

Purpose

The purpose of this study was to develop a care-management program for PSS and to maximize patient health and healthcare organization outcomes.

Project Development

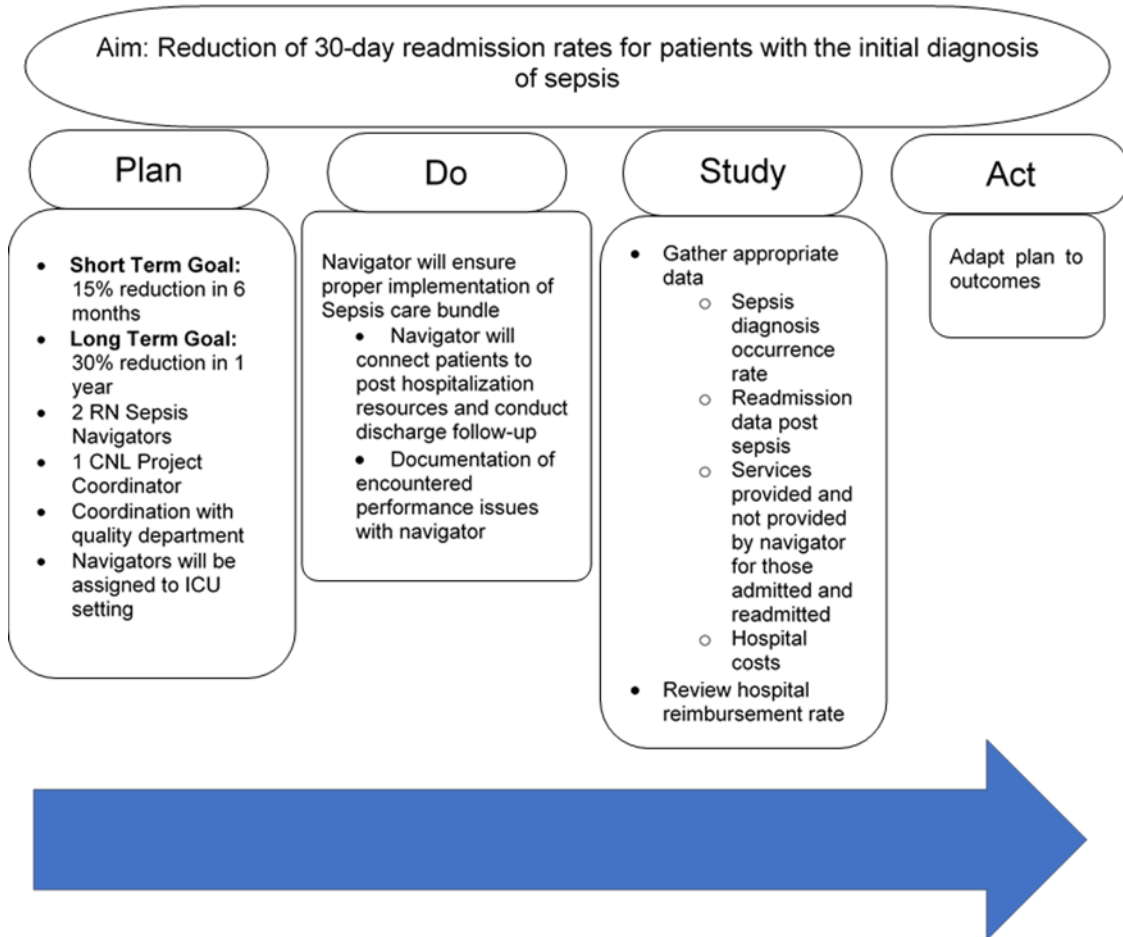
An interprofessional team was convened to develop an evidence-based quality-improvement project to decrease the human and financial costs of PSS. The proposed process for implementation is presented in Figure 2. Evaluation of the quality-improvement project will be conducted monthly with project goals evaluated biannually.

Target Sample Setting

Benefis Healthcare System, a level II trauma center, serves north-central Montana as the regional tertiary referral center serving approximately 164,000 residents across 13 rural counties (Benefis Health System, n.d.). Annually, Benefis provides care for over 800 individuals experiencing sepsis. The organization currently follows established national treatment guidelines for sepsis, using the SIRS. However, there are currently no practice guidelines for the identification and treatment of patients experiencing PSS. With the current trends in PSS prevalence and complications inherent in sepsis survivorship, the gap existing between patient-care needs and accessibility of services is detrimental to patients and costly to the healthcare system.

Figure 2. Proposed PDSA Plan

Figure 2. Proposed PDSA Plan



Instruments

Data collection tools utilized within this QI project will be focused on the collection of early identification and diagnostic success, and overall QI project function. The early sepsis identification and diagnostic tool will standardize the SIRS screening tool. The SIRS screening will be implemented and tracked monthly within the emergency and intensive care units (Appendix A). Data

collected from the SIRS screening tool will be monitored for improvements or declines in the success of early identification of sepsis monthly.

A Plan, Do, Study, Act (PDSA) (Institute for Healthcare Improvement, n.d.) evaluation cycle will be utilized to examine the continual evaluation of the QI project outcomes (successes and failures). Data will be reviewed monthly to identify project successes and/or failures, providing the opportunity for iterative, evidence-based changes. Appropriate improvements will be identified and implemented as determined by the QI project interprofessional team.

Proposed Analysis/Data Collected

Data collected will be entered into a data analysis system by the hospital quality analyst; additional data specific to this project will be extracted from Meditech and Nextgen as appropriate. Standard descriptive statistics will be used to describe patient and study outcomes. Group differences will be examined using standard psychometric methods.

CNL Roles

As leaders within the interprofessional team, Clinical Nurse Leaders (CNL) are in an ideal position to develop and monitor the efficacy of the plan of care. The CNL is educationally prepared to advocate for the complex healthcare needs of PSS patients. Through this leadership role, the CNL can readily assist other healthcare team members to understand, implement, and evaluate the plan of care, which can markedly improve patient and healthcare organization outcomes.

Patient and healthcare professional education is another role for which the CNL is well prepared. The CNL can ensure patient education includes content specific to successfully recognizing complications of PSS and to develop realistic expectations of the recovery process. Healthcare professional education should include information about PSS to increase awareness and enhance their ability to better identify and implement early treatment (Sangan, 2019).

Finally, specific to this project is the role of care coordination to oversee the management of PSS. The CNL can help ensure that, within the acute-care setting, healthcare professionals are able to identify and provide early initiation of interprofessional interventions and treatment for PSS. Following discharge, the CNL can facilitate interprofessional discharge planning to ensure that patients have appropriate follow-up appointments, specialty referrals, and are monitored for complications and/or progression of PSS (Sangan, 2019).

These CNL roles and resulting care actions are consistent with the national agenda to improve health care through the STEEEP initiative. The CNL has the capacity to assist healthcare organizations in identifying, implementing, and evaluating a project such as this to improve patient and organization outcomes due to PSS. This unique ability has been developed through an educational process intended to provide the learner with the knowledge and skill to systematically identify areas in need of improvement, research best practices, and develop an evidence-based project to guide improvement efforts.

Barriers

Any change in practice is likely to be challenged due to healthcare provider current practice habits. Further, incorporating an additional healthcare professional into an established care team is likely to generate concerns regarding existing team roles and purpose (turf war). An additional barrier is the cost associated with adding a full-time employee. While the goal of the project is to improve organizational financial performance, upfront costs will likely be a concern within upper leadership. Due to variation in practice and challenges inherent in the “change process,” inconsistency in implementation of the care protocol may be a barrier for overall project success. For this reason, provider buy-in will be requisite. The primary strength of this project lies within its capacity to improve healthcare outcomes for patients, families, and healthcare organizations.

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APPENDICES

APPENDIX A

UNIVERSITY MEDICAL CENTER ADULT

ICU SEPSIS SCREENING TOOL

Place Patient Label Here

University Medical Center Adult ICU
Sepsis Screening Tool

Step 1:

Is the patient already being treated for sepsis? Yes No

If answer is yes, STOP.

If answer is no, CONTINUE to step 2

Step 2: (Two or more of the following)

A) Sepsis Criteria

- Temp > 100.9 or < 96.8 (in the last 24 hours)
- HR > 90 (in the last 24 hours)
- Respiratory Rate >20 or PaCO2 < 32 (in the last 24 hours)
- WBC >12000, < 4000, or > 10% Bands

B) Other possible indicators

- Acute change in Level of Consciousness
- Glucose > 120 in non-diabetic

If less than two items checked, STOP.

Step 3: Infection (Suspected or Confirmed)

Does this patient have a suspected or confirmed source of infection? Yes No

(Such as: Pneumonia, Invasive Catheter, UTI, Decubitis Ulcer, Acute Abdomen, Colitis, Meningitis, Pancreatitis, Cellulitis, Bone/Joint, or Wound)

If answer is NO, STOP.

If answer is YES, continue to step 4 and contact physician if necessary. The patient may have SEPSIS.

Step 4: Organ Dysfunction

- Acutely altered mental status
- Platelet count < 100,000
- SBP <90 or MAP <65
- Bilirubin >2mg/dl, AST>90, ALT >90
- SPO2 < 90%
- Lactate > 2mmol/L
- Creatinine > 2 mg/dl or urine output < 0.5 mg/kg/hr

If one or more items are checked the patient may have SEVERE SEPSIS.

Step 5. If patient screens positive for SEPSIS or SEVERE SEPSIS, CALL PHYSICIAN NOW (if not already aware).

- Early Goal Directed Therapy for Adult Sepsis orders were implemented
- Early Goal Directed Therapy for Adult Sepsis orders were NOT implemented

WHY _____

Date _____ Time _____