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Early Intervention In Suspected Sepsis Patients

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Early Intervention in Suspected Sepsis Patients

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Objectives: Inform the development and implementation of an early response algorithm for suspected sepsis patients via a rapid response team.

Background: Recent literature supports the need for early recognition and intervention of suspected sepsis patients, potentially reducing morbidity and mortality.

Methods: A clinically and professionally reviewed algorithm was developed to execute early, sepsis-specific intervention. The algorithm design was carried out in 3 steps: (1) The establishment of recognition criteria based on evidence; (2) The validation of the algorithm by a panel of clinical experts; and (3) The development of a plan to initiate inclusion of the criteria into a rapid response team.

Results: Experts rated three of five domains described in the literature (Sepsis/Mortality, Early intervention/treatment, Code SMARRT Algorithm) as having greater than 90% agreement related to relevance and importance.

Conclusions: The implementation of the Code SMARRT algorithm has the potential to reduce unnecessary deaths related to sepsis and septic shock.

Keywords: Sepsis, Septic Shock, qSOFA, Early recognition, Rapid-response, Code SMARRT Algorithm

Introduction

Sepsis and septic-related conditions are currently the tenth-leading cause of death in the United States, producing a 20-50% mortality rate.[1] The Surviving Sepsis Campaign: International guidelines for the management of severe sepsis and septic shock 2012, describes the need to identify and treat sepsis in advance through the use of early, goal-directed therapy.[2] Recently, a taskforce convened to revise the definition of sepsis. The new international consensus definition for sepsis is a "life–threatening organ dysfunction caused by a dysregulated host response to infection."[3] The definition of septic shock was also changed to "a subset of sepsis in which particularly profound circulatory, cellular, and metabolic abnormalities are associated with a greater risk of mortality than with

sepsis alone."[3] In the United States, the incidence of sepsis continues to increase despite continued efforts to combat the disease.[4] This article seeks to promote rapid response to sepsis by identifying criteria for early recognition through the development of an algorithm and addresses the need for early intervention, which allows rapid response nurses to execute a pre-prescribed battery of tests to determine if a patient is potentially septic. Recent literature supports the need for early recognition and intervention of sepsis signs and symptoms to reduce morbidity and mortality.[4]

The Problem and Background - Clinical Deterioration

Severe sepsis affects over 1 million Americans, of this number, 28%-50% die from the disease.[5, 6] A 2003 landmark study reported 450,000 cases of sepsis per year and more than 100,000 yearly deaths related to sepsis.[1] Sepsis cases and number of deaths has increased from 1979 through 2000. Sepsis is particularly common in the elderly and is likely to continue to increase as the U.S. population ages. Although the mortality rate continues to decline in severe sepsis cases, the opposite is true within the septic shock population.[1] In their study, Angus et al., further discuss the challenges and characteristics associated with this disease process, such as the inability to follow prescribed guidelines and recognize signs and symptoms early.[7]

Clinical deterioration refers to a complication or issue in the condition of the patient that, if not promptly addressed, could cause an adverse event or increased mortality.[8] Buist & Stevens state:

> "If one accepts that the final common pathway for clinical deterioration will in some way manifest as an abnormal observation, then the ultimate defense for harm from patient adverse events needs to be the monitoring and acting upon such abnormalities."[9]

Early intervention in suspected sepsis patients is improved by the ability of nurses to recognize clinical deterioration and activate rapid response. A root-cause analysis in the patterns of unexpected in-hospital deaths demonstrates the flawed system of late detection, which further delays recognition and treatment of the deteriorating patient.[10] In essence, if patients often demonstrate physiological or clinical deterioration hours, if not days, prior to an adverse event, nurses should recognize these early signs and symptoms; this is especially true in septic patients, whose symptoms often are not detected early enough. Lack of ability to identify early key signs and symptoms, such as sepsis-related organ failure assessment (qSOFA), may permit the patient to progress to sepsis and serving as a missed opportunity to identify and employ early goal-directed therapy.

The Agency for Healthcare Research and Quality (AHRQ) estimates the cost of sepsis surpassing $20 billion as of 2013.[11] Amongst the aforementioned statistics; this expensive and deadly disease requires attention and timely treatment.

Rapid Response

Rapid Response Teams (RRT) have been employed in hospitals throughout the world to expedite response to clinical patient deterioration; however, their effectiveness remains controversial in the healthcare field due to a lack of substantial, formal research.[12] However, Chan et.al. describe a reduction in hospital mortality rates post-RRT implementation.[13] The rapid response system concept was founded at the Liverpool Hospital in Sydney, Australia.[14] The goal was to create a team that would respond quickly in the event of cardiac arrest – or to identify early patient deterioration. Of primary importance is the need to identify situations of clinical deterioration outside of the intensive care unit. Jones, DeVita, and Bellomo discuss *failure to rescue* as a response to delayed or missed care that exposes the patient to increased risk.[15] RRTs generally operate independently, outside of the intensive care unit. They are different

than code teams in that they proactively look for "patients at higher risk" and intervene accordingly.[16] Mailey theorized that there would be a significant decrease in mortality in the septic patient population if septic patients were treated earlier.[16] However, Jäderling et.al., suggest that their study does not support the use of rapid response in identifying deteriorating ward patients.[17]

Early recognition and treatment for septic patient populations would require the creation of a rapid response system specifically for sepsis patients. Sebat, et. al., have created a model that incorporates an early sepsis recognition tool into the education of front-line nursing providers. Their study found that, over a five-year period, there was a significant reduction in the amount of time required to treat septic patients.[18]

Sepsis Guidelines

The Surviving Sepsis Campaign is a collaboration of internationally-acclaimed physicians who have formed a consensus committee to address current evidence-based practice guidelines and sepsis care.[19] A leading team of international experts release annual revisions through the Surviving Sepsis Campaign in order to provide best practice guidelines supported by the evidence.[20] This team specifically developed best practice guidelines for the management of severe sepsis and septic shock.[21] An important focus of the Surviving Sepsis Campaign collaborative is to address early identification of patients with sepsis by recognizing early clinical deterioration and deploying swift goal-directed therapy to reduce mortality.[20]

Early Intervention & Treatment

Early detection of signs and symptoms of sepsis is necessary to combat the condition. Rapid response teams are most effective in providing early assessment and intervention to cardiac arrest patients, possibly having a profound effect on the sepsis patient population. Furthermore, the largest contributor to the failure to rescue sepsis patients is

the inability to activate the rapid response team.[4] For these reasons, tools have been implemented to assist in detection of early warning signs. Clinical deterioration was the measure in which two screening tools were compared, side-by-side, by Wallgren, U.M. et al. This retrospective, cross-sectional study compared the Robson screening tool to the BAS 90-30-90 tool. The Robson screening tool includes temperature, heart rate, respiratory rate, altered mental status, plasma glucose, and a history suggestive of a new infection. The BAS 90-30-90 tool refers to the following vital signs: oxygen saturation, respiratory rate, and systolic blood pressure. The study further mentions the need for proper identification, as many septic patients go undiagnosed until further in the disease process.[22] Both tools are designed to be utilized in the pre-hospital setting. Although the above research is limited, the assumption that these tools are needed for diagnosis prior to arrival in the emergency room remains true. Emergency medical personnel need to be trained to recognize sepsis. Dr. Laura Andrews mentions a combination of advanced technologies, versus the "old school" mentality, when focusing on early identification.[23] To this point, Bassily-Marcus discussed overcoming the afferent arm (activation) by incorporating technology interaction via the electronic medical record.[4] However, this retrospective study speaks to early recognition of unexpected patient deterioration. Various additional tools include rapid care alerts as described in an observational cohort study addressing unexpected deaths related to a lack of treatment or failure to rescue.[24] Other facilities have deployed early warning systems as "vital sign values" that utilize color to determine range of deterioration, allowing providers to intervene at the appropriate point of care.[25] Automated electronic tools have been used to prompt bedside evaluation, and, in some cases, demonstrate statistical significance in promoting early warning and recognition of septic patients.[26, 27] While electronic tools and alerts are useful, they are best utilized in combination with expert nursing assessment. Physical

nursing assessment is vital in the ability to identify a clinically deteriorating patient. Recognizing sepsis earlier and knowing how to intervene, is necessary for early goal-directed treatment.

Recommendations from the Surviving Sepsis Campaign include a six-hour treatment bundle consisting of the following: a measured lactate level, venous oxygenation, mean arterial pressure, central venous pressure; leading to an early intervention including blood cultures, broad-spectrum antibiotics, and fluids.[19]

The above literature-based recommendations include evidence that execution of recommended bundles or therapies reduces mortality. However, the literature is lacking with respect to compliance with treatment recommendations.[20] Despite the numerous treatment modalities available to physicians and nurses on the front lines of hospitals, failure to identify and rescue sepsis patients are recurring themes in the literature.[4,19,27,28] The idea of rapid administration of broad-spectrum antibiotics is also suggested. This is not the only factor, as Miano et. al., continues the discussion that recognition, resuscitation, and treatment are necessary in order to successfully combat this disease.[29]

Intervention via Protocol

As noted throughout the literature, early identification of septic patients has been a challenge due to a lack of protocols and structure. The staff at Wake Forest Baptist Medical Center, were one of the first to create a rapid response protocol and team aimed at reducing sepsis.[30] By providing an electronically generated Modified Early Warning Score (MEWS) and educating front-line nursing staff, patients with or at risk for sepsis, are identified early. The task was to create a similar model that gives providers guidance through evidence-based literature. A 2011 study mentions the possibility of creating a sepsis protocol that is collaborative and functions between departments.[31] Additionally, Christiana Care Health Services in Wilmington, Delaware boast a 49.4% reduction in

mortality rates after the implementation of a sepsis alert program.[32] Such examples demonstrate the effectiveness of a sepsis-specific protocol focused on early identification in sepsis care and treatment.

Recommended Algorithm

While significant strides have been made toward the management of sepsis care, the effective implementation of early identification of at-risk patients in daily practice could improve. The clinical signs and symptoms of pre-sepsis in patients can be subtle and variable, thus it is imperative that nurses identify the clinical triggers and have available resources to respond rapidly. Winters suggests that "the general staff concern about vital sign criteria is more severe in these patients (septic), and given the critical care expertise of the responding team, these very sick patients (nearly one-fifth of whom were septic) who would likely otherwise do poorly, do just as well as their less ill counterparts who are admitted to the ICU."[12]

The development and implementation that enhances early identification and execution of specific sepsis treatment is warranted. Hospitals and healthcare facilities have used algorithms to guide practice for years. The goal is to reduce mortality rates similar to those achieved by other hospitals that have implemented similar treatment protocols, such as Wake Forest Medical Center.[33] When a rapid response team arrives to assess a staff concern, or patient status change, either through a modified early warning score (MEWS) or nurse-generated notification, they would discern signs of sepsis via a quick sepsis-related organ failure assessment (qSOFA score) >1. The presence of 2 or more qSOFA points increases the likelihood of increased mortality by 3-14-fold.[3] If confirmed, the team would call a Code SMARRT (Sepsis Management Alert Rapid Response Team). Code SMARRT would generate a nurse-driven protocol of care consisting of labs, fluids and antibiotics (see Table 1). Without directing the early identification of sepsis patients

through the use of the rapid response team, mortality rates associated with the disease will continue to rise.[22, 34]

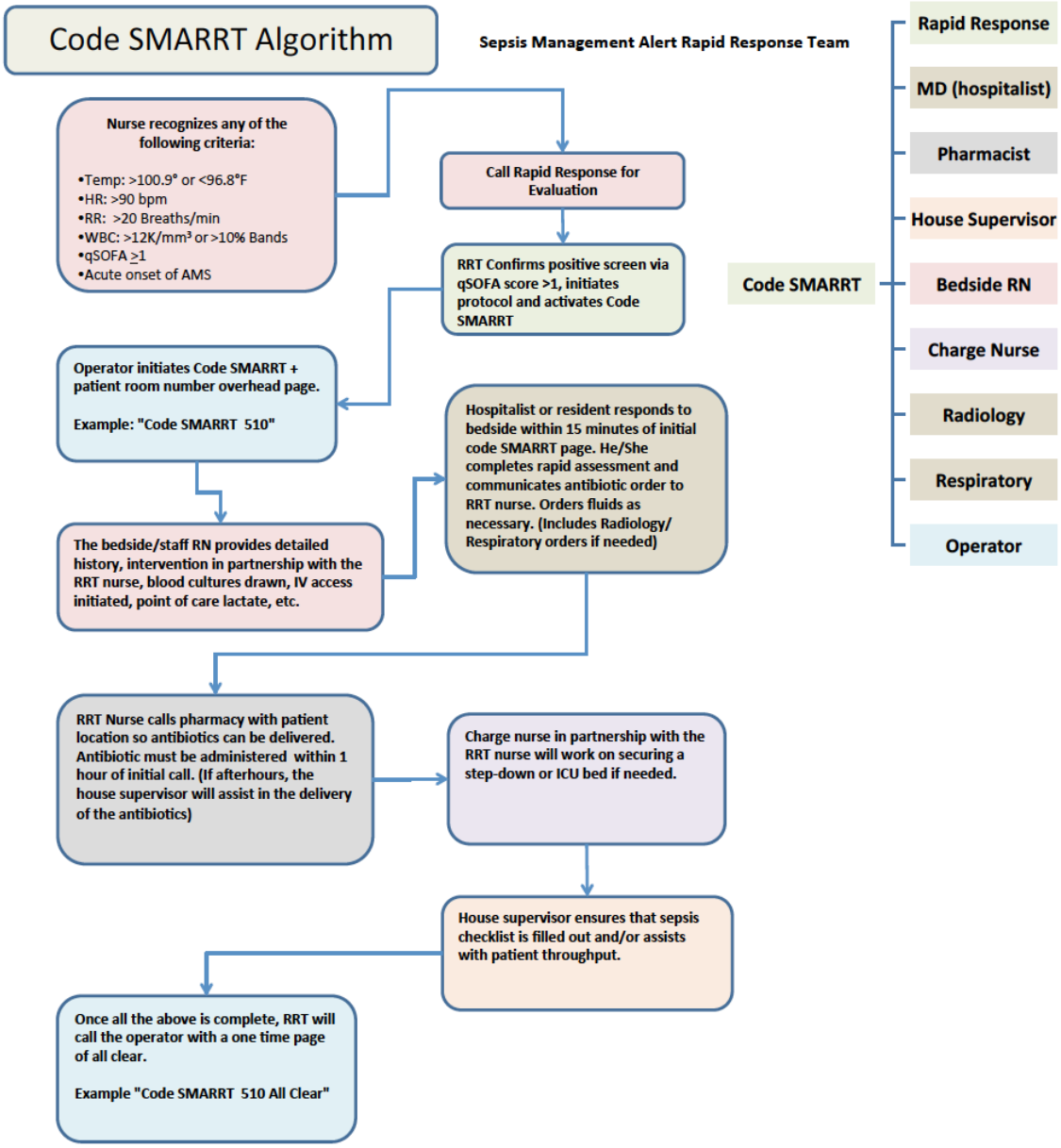

Table 1. Code SMARRT Algorithm

***Numerical data provided by the Surviving Sepsis Campaign, Subject matter experts, and critical care recommendations.**

Methods

The design of the Code SMARRT algorithm was conducted from October 20, 2014 to July 29, 2016. The investigation was carried out in three steps: (1) The establishment of

the criteria for sepsis recognition based on the evidence; (2) The validation of the Code SMARRT algorithm by a panel of clinical content experts; and (3) The development of an action plan to initiate inclusion of the criteria into a rapid response team.

The first step involved a comprehensive, systematic literature review, which revealed 45 articles that describing various medical standards and applied definitions related to sepsis. Criteria related to recognition/signs and symptoms of systemic inflammatory response syndrome, sepsis, severe sepsis, and septic shock, as well as the new Sepsis-3 definition, were examined and content was incorporated into a new Code SMARRT algorithm. A literature review matrix assisted in categorizing the level of evidence, themes, and content supportive of identification of sepsis and septic-related conditions. Literature and data were gathered from four primary databases. Pub med/Medline, CINAHL, The Cochrane Library, and the Trip Database produced current best practice on early identification. The terminology and keyword phrases used to glean a robust literature review are as follows: sepsis, septic shock, systemic inflammatory response syndrome, bacteremia, septicemia, infection, mortality, Community Hospital, multiple organ failure, organ dysfunction, inpatient hospital, and adult population. Exclusion criteria addressed the provision of non-direct evidence that the sepsis bundle reduces morbidity and/or mortality, as well as text that did not support early intervention and treatment in the sepsis population. Additional resources utilized included the Yale University library system, American College of Chest Physicians, International guidelines for the management of severe sepsis and septic shock: (2012), and voluntary collaboration with professional peers and colleagues.

The second step included the validation of content related to the code SMARRT algorithm using a panel of experts (see Table 2). The early intervention algorithm was reviewed by this panel of experts based on the methodology developed by the Doctor of

Nursing Practice (DNP) faculty at Yale School of Nursing. The following steps were implemented to ensure the expert panel objective is one of rigor and accuracy: 1) Identification of relevant content through comprehensive review of evidence; 2) Aggregation and development of elements; 3) Categorization of elements into common themes; 4) Establishment of rating scales and domains based on relevance and importance; 5) Inclusion standard of .78 (78%) affirmative response and .90 (90%) total response; 6) An expert review rating phase; 7) Creation of a structured form; 8) Identification of experts in sepsis care; 9) Rating by five experts and continued independent analysis of results; and, 10) A discussion and description of the final product. The panel included five experts in the fields of research, surgery, medicine, critical care, and nursing.

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Table 2. Expert Panel Members

The third and final step included the development of an action plan to ensure inclusion of the criteria into a rapid response team algorithm for early intervention of sepsis. Utilizing the Code SMARRT algorithm, active surveillance, and early warning systems, the early identification of sepsis in patients will potentially reduce mortality. Code SMARRT is

directed and championed by the rapid response nurse. The following members are part of a team that executes the early intervention and goal-directed therapy needed by the sepsis-positive patient population (see Table 3).

Role	Response	Duties
Bedside Nurse (RN)	Bedside nurse provides detailed history, medication reconciliation, treatments and details of hospital stay.	To assist RRT Nurse
Rapid Response Nurse (RN)	Rapid response nurse confirms positive qSOFA >1, initiates protocol and activates Code SMARRT	Champions Code SMARRT initiative
Responding Provider (MD/DO/NP/PA)	Arrives to bedside once Code SMARRT is called: He/She completes rapid assessment and communicates antibiotic order to RRT nurse. Orders fluids as necessary.	Assessment, Orders
Patient Care Coordinator (RN)	Floor PCC in partnership with the RRT nurse will work on securing a step-down or ICU bed if needed.	Patient care upgrade/throughput
Pharmacist (PharmD)	RRT Nurse calls pharmacy with details of location so antibiotics can be delivered. Antibiotic must be administered within 1 hour of initial call. (If afterhours, the house supervisor will assist in the delivery of the antibiotics)	Provide antibiotics per order from bedside Licensed Independent Provider (LIP) responder within 1 hour
House Supervisor (RN)	House supervisor ensures that sepsis checklist is filled out and/ or assists with patient throughput.	Available for needs
Hospital Operator	Operator initiates Code SMARRT by paging room number, floor and location	Initiates page throughout facility and all clear page once complete

Table 3. Code SMARRT Team Members - Response / Duties

Implementation / Continued Education

The rapid response team should consist of at least five fulltime registered nurses. These experienced critical care nurses, should also demonstrate annual competencies in the area of basic life support, advanced cardiac life support, and National Institutes of Health (NIH) stroke assessments, along with other nursing modules and training. Continuing education for nursing staff throughout the hospital should be conducted (quarterly), to

promote rapid response to deteriorating patients. Code SMARRT should also be introduced to new nurses during onboarding sessions.

Results

An expert panel rating tool was developed to guide the evaluation of the relevance and importance of the Code SMARRT algorithm. The Yale School of Nursing guidelines for evaluation of content validity were utilized to evaluate the responses of the experts. Each category identified a topical domain (e.g. Sepsis and Mortality) with sub-domain (e.g. Clinical Deterioration) to follow. The domains were informed by the evidence and validated by the expert panel with a focus on the Code SMARRT algorithm. A letter of explanation was sent to the experts in sepsis or septic-related conditions. The experts reviewed the algorithm for relevance and importance using the tool (see Table 4). The counts in the subdomains repeat the number of panel experts rating each item on the numeric scale provided. With this information, the percent of agreement was calculated. Responses to the presented categories of greater than 78% agreement were considered as meeting the defined criteria of evidence-based. No internal review board approval is necessary for this project, as it is meant to establish criteria by a panel of experts and inform the development and implementation of a team to respond when clinical criteria of suspected or confirmed criteria is met.

Category *Subcategory*	Ratings			
	Relevance* % Agreement		Importance** % Agreement	
	1	2	1	2
Sepsis and Mortality				
Sepsis Defined		100%		100%
Epidemiology of Sepsis		100%	50%	50%
Signs & Symptoms of Sepsis		100%		100%
SIRS		100%	50%	50%
Sepsis		100%		100%
Severe Sepsis		100%		100%
Septic Shock		100%		100%
Clinical Deterioration		100%		100%
Sepsis Guidelines				
Surviving Sepsis Campaign		100%	20%	80%
Early Intervention and Treatment				
Early Detection of Sepsis		100%		100%
Screening Tools		100%		100%
6-Hour Treatment Bundle		100%	20%	80%
Early Goal Directed Therapy	20%	80%	40%	60%
Intervention via Protocol				
Rapid Response Teams		100%		100%
Modified Early Warning Score	20%	80%		100%
Code SMARRT Algorithm				
Team Members/Functions		100%		100%
Implementation	20%	80%		100%
Continued Education	20%	80%		100%
Call to Rapid Response	20%	80%		100%
Positive Sepsis Screening		100%		100%
Physician Consult		100%		100%
Pharmacy Consult		100%		100%
Level of Care Evaluation		100%		100%
Sepsis Checklist Completed		100%		100%
Sepsis Bundle Initiated		100%		100%
Patient Care Elevated		100%		100%
* 1=Low Relevance; 2=High Relevance ** 1=Low Importance; 2=High Importance				

Table 4. Expert Panel Rating Tool and Individual Responses

Evidence was extrapolated from meta-analysis, systematic reviews, randomized controlled trials, case studies, and expert opinions.

The literature revealed 5 total domains and 26 individual elements. The following domains were identified throughout the literature as major focus areas of sepsis: Sepsis

and Mortality, Sepsis Guidelines, Early Intervention and Treatment, Intervention via Protocol, and the Code SMARRT Algorithm. Four of the five domains represented disease information, guidelines, interventions and treatments. The 5th domain focused exclusively on the Code SMARRT algorithm and its components. The expert panel provided content validation via the content validity index. [35] The topical domains and elements of the Code SMARRT algorithm were inspected and scrutinized based on two dimensions – relevance and importance, providing a measured level of response ≥.78, or 78%, agreement with affirmative response and a total score of ≥.90, or 90%. The experts rated the following three domains as having greater than 90% agreement overall, related to relevance and importance: Sepsis and Mortality, Early intervention and treatment, and the Code SMARRT Algorithm. The Sepsis Guideline domain, which included only one element, the Surviving Sepsis Campaign, received a mean rating of 100% agreement of relevance, but only 80% of experts rated it as important. The intervention and protocol domain consisted of two subdomain elements: Rapid Response Teams and Modified Early Warning Score. The rapid response team element was rated with 100% agreement in relevance and importance, however only 80% and 100% of the experts agreed it was relevant and important, respectively. It is worth noting that two of the five experts did not complete a rating on the relevance and importance of the modified early warning score.

Discussion

The outcomes of this project can be used to further examine active and concurrent surveillance of clinical deterioration and sepsis across the inpatient population through the application of an independent rapid response team. The Code SMARRT Algorithm should guide current standards of practice with early intervention to improve clinical outcomes.

Other experts who did not participate in the expert survey provided suggestions. These suggestions include the following: “I personally think a 6-hour window is sufficient, but this does not necessarily mean wait until 6h if antibiotics can be given sooner.” Another physician suggested reducing the criteria to “only those of the qSOFA”. The new sepsis-3 definition works well in the ICU environment where critical care trained nurses are acutely aware of SOFA scores, however, the focus of the Code SMARRT Algorithm is on the early intervention of “suspected sepsis” patients on inpatient units. The overarching goal is to increase awareness of patient conditions, thus bringing a rapid response (critical-care-trained) nurse to the bedside for the evaluation portion (they will use the qSOFA for evaluation). By using the Code SMARRT Algorithm, the time to treatment of actual sepsis patients will be reduced through the earlier identification of symptoms in this patient population.

Conclusion

Based on recommendations from the Surviving Sepsis Campaign, subject matter expert responses, and thorough literature review of current evidence and best practice, this research has validated the need for early intervention in non-present-on-arrival sepsis patients. The cultivation and implementation of a rapid response algorithm specific to sepsis (Code SMARRT) has the potential to reduce unnecessary deaths related to sepsis and septic shock. This model can inform other facilities on how to leverage a freestanding rapid response team for surveillance and management of the suspected sepsis patient. The significance of this research addresses the literature for early identification and goal-directed therapy to reduce mortality related to unnecessary sepsis and septic shock deaths, with a focus on the inpatient population.

Disclosures

The authors have reported that no potential conflicts of interest exist with any companies or organizations whose product services may be discussed in this article. The authors further declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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