Evaluation of an Interprofessional Emergency Department Sepsis Quality Improvement Initiative

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A Scholarly Practice Project presented to the Graduate Faculty of the University of Virginia in Candidacy for the Degree of Doctor of Nursing Practice

School of Nursing

University of Virginia
May 2018

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Acknowledgements

I would like to thank Karen Braden, RN, CPNP and Dr. Debra Perina, MD, FACEP for their mentorship during completion of this quality improvement project.

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Abstract

Purpose: Utilizing the 2016 Surviving Sepsis Campaign guidelines to frame appropriate interventions, the purpose of this scholarly practice project is to evaluate the outcomes of an interprofessional sepsis quality improvement initiative in the ED.

Project Question: Does the implementation of an interprofessional ED sepsis quality improvement initiative increase 3-hour bundle compliance and decrease all-cause in-hospital mortality for ED patients with a sepsis alert activated?

Setting and sample: The project was conducted at a rural, academic, safety-net, level 1 trauma center with approximately 60,000 ED visits per year. The sample included 525 patients, aged 18 years and older, between July and December 2017 who had a sepsis alert activated.

Measures: Adherence to the 3-hour bundle elements of care and all-cause in-hospital mortality.

Method: A prospective, descriptive project evaluating the effect of the sepsis quality improvement initiative over six months.

Procedures: The interprofessional, ED quality improvement team consisted of 11 professionals, who collaborated through 6 formal meetings in a 6-month period. Collected data included demographics, throughput metrics, 3-hour bundle components and mortality.

Results: Over the project period, the mean door to sepsis alert time decreased by 37 minutes. Adherence improved to 3 of the 4 major elements of the 3-hour sepsis management bundle. Month-to-month analysis of mortality data did not demonstrate any significant changes during the project period.

Nursing implications: This quality improvement initiative empowered nursing staff to screen patients for sepsis, activate sepsis alerts, and initiate bundled care as appropriate.

Evaluation of an Emergency Department Sepsis Quality Improvement Program

Sepsis is a complex clinical syndrome in which a combination of host and pathogen factors results in physiologic, pathologic and chemical derangements (Singer et al., 2016). Nationally, according to death certificates between 1999 and 2014 over 2.4 million or 6% of all deaths were sepsis-related (Epstein, Dantes, Magill, & Fiore, 2016). Dellinger (2015) reported that in the United States between 2000 and 2008 sepsis-related diagnoses doubled. Furthermore, the Hospital Care and Utilization Project (HCUP) determined that, among inpatient visits in 2013, sepsis was the most common reason for admission and the costliest diagnosis accounting for 23.7 billion dollars spent (Torio & Moore, 2016).

Historically, the first definitions and clinical criteria of sepsis, severe sepsis, and septic shock were developed in 1991 (Bone et al., 1992). These definitions focused on the body's inflammatory response, known as the systemic inflammatory response syndrome (SIRS) (Singer et al., 2016). The SIRS criteria include: 1) a white blood cell count < 4,000 cells/mm3 or > 12,000 cells/mm3 or 10% immature bands, 2) a heart rate greater than 90 beats per minute, 3) a respiratory rate greater than 20 breaths per minute or a $PaCO_2$ < 32mmHg, and 4) a temperature < 36 or > 38 degrees Celsius (Bone et al., 1992). Patients with a source of infection and two of these four criteria were considered to be septic. Severe sepsis was defined as sepsis complicated by end "organ dysfunction, hypoperfusion, or hypotension" (Bone et al., 1992, p. 1646). Septic shock was defined as sepsis with refractory hypotension despite adequate fluid resuscitation and organ dysfunction (Bone et al., 1992) (Singer et al., 2016). Over time, some practitioners became critical of SIRS as the clinical criteria to detect and diagnose sepsis because it lacks specificity and overly focuses on the inflammatory component of sepsis (Singer et al., 2016). Critics argued that infected patients might benefit from the inflammatory response, leading to

greater debate about the prognostic ability of the SIRS criteria in detecting and diagnosing sepsis (Singer et al., 2016).

In 2016, a task force of 19 professionals published "The Third International Consensus Definitions of Sepsis and Septic Shock (SEP-3)" (Singer et al., 2016). Definitions were revised to reflect the current knowledge of sepsis. The revision simplified the terms while eliminating the phrase "severe sepsis." Sepsis is now defined as "life-threatening organ dysfunction caused by a dysregulated host response to infection" (Singer et al., 2016, p 804). Septic shock is now "defined as a subset of sepsis in which particularly profound circulatory, cellular and metabolic abnormalities are associated with a greater risk of mortality than sepsis alone" (Singer et al., 2016, p 801). Rather than focusing on the controversial SIRS criteria, the new definitions focus primarily on organ damage (Singer et al., 2016).

Following the release of the new definitions, Seymour et al., (2016) conducted a retrospective cohort study that assessed over 1.3 million patient encounters to refine and evaluate a newer clinical criterion to identify sepsis. The study recommended the use of the Sequential Organ Failure Assessment (SOFA) in the ICU setting and quick Sepsis-related Sequential Organ Failure Assessment (qSOFA) outside the ICU setting to detect sepsis and predict illness severity. SOFA is designed to assess for the presence of sepsis in critically ill patients using a combination of clinical symptoms and biomarkers to diagnose organ dysfunction (Seymour et al., 2016). In patients outside the ICU setting, clinicians frequently do not have access to the necessary laboratory values to calculate a SOFA score. Another score, designated qSOFA, was designed to be more practical for the bedside clinician to easily assess the patient (Seymour et al., 2016) (Singer et al., 2016). The qSOFA score is calculated using three components: 1) systolic blood pressure < 100mmHg, 2) altered mental status and 3) respiratory rate greater than or equal to 22

breaths per minute (Seymour et al., 2016) (Singer et al., 2016). If present, each component is worth 1 point, and a total score greater than or equal to 2 is predictive of a prolonged ICU stay and/or increased mortality risk (Seymour et al., 2016).

In March of 2017 the "Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock: 2016" were published updating the 2012 guidelines (Rhodes et al., 2017). These guidelines endorse the use of the new SEP-3 definitions however; they do not endorse the use of specific clinical criteria to detect and diagnosis sepsis (Rhodes et al., 2017). Serious challenges exist in identifying sepsis, as there is no gold standard for diagnosis (Seymour et al., 2016) (Singer et al., 2016). These guidelines focus on the management of sepsis with attention to early identification, fluid resuscitation, source control, lactate measurement, and antimicrobial therapy within one hour of recognition. The guidelines also recommend sepsis screening and performance improvement programs. Previous research concluded that PI initiatives led to increased compliance with bundled sepsis care and reductions in morbidity and mortality (Rhodes et al., 2017).

Currently, gaps in knowledge and practice exist regarding the implementation of the new SEP-3 definitions, clinical criteria, and the 2016 Surviving Sepsis Campaign Guidelines. Further complicating the gaps is a lack of congruent expectations between research, professional organizations and regulatory agencies. Multiple professional stakeholders are invested in promoting better sepsis care. The Joint Commission (TJC), The National Quality Forum (NQF), The Centers for Medicare and Medicaid (CMS), the Institute for Healthcare Improvement (IHI) and the Surviving Sepsis Campaign (SSC) are just a few examples of organizations that have advocated for research, quality improvement, and better outcomes for septic patients (Institute for Healthcare Improvement, 2016; National Quality Forum, 2017; The Joint Commission for

Transforming Healthcare, n.d.; SSC, 2017). Despite their advocacy, many of these professional organizations continue to utilize outdated guidelines and the former definitions of sepsis, severe sepsis and septic shock for their initiatives.

CMS developed the SEP-1 guidelines in 2015 for hospitals participating in Medicare and Medicaid. (Appendix A) (Dellinger, 2015) (Quality Net, 2015) (The Joint Commission, 2017). This benchmarking tool dictates reportable metrics surrounding severe sepsis and septic shock care. It is similar to the NQF #0500 quality improvement initiative created at the Henry Ford Institute to improve compliance with sepsis bundles (Dellinger, 2015) (NQF, 2017). The SEP-1 guidelines have not been updated to reflect current sepsis research. The SEP-1 guideline requires hospitals to intervene within 3 hours of the recognition of severe sepsis (Appendix A) (The Joint Commission, 2017). These interventions include 1) lactate measurement, 2) blood culture collection and 3) administration of broad-spectrum antibiotics. If a patient is diagnosed with severe sepsis and their initial lactate is elevated, the bundle requires repeat lactate measurement within 6 hours of presentation. If a patient is diagnosed with septic shock, the following interventions are required within 3 hours of presentation: 1) lactate measurement, 2) blood culture collection, 3) administration of broad-spectrum antibiotics, and 4) administration a 30ml/kg bolus of crystalloid fluids. If a patient diagnosed with septic shock remains hypotensive after initial fluid resuscitation, it is required to start vasopressors within 6 hours of the patient's presentation. If the patient is hypotensive after initial fluid resuscitation or the initial lactate was >4 mmol/L, it is required to complete and document a volume status and tissue perfusion assessment within 6 hours of the patient's presentation (The Joint Commission, 2017). In order to be adherent with the SEP-1 bundle, it is required that all elements of the bundle are adhered to (Santistevan, 2016).

While the SEP-1 guidelines focus on the time of recognition, the SSC endorses an alternate time stamp for sepsis-related interventions. The SSC published a position statement identifying "time zero" as the time of Emergency Department triage and the basis for timely interventions (SSC Leadership, n.d.). Assessing intervention adherence from the time of ED triage emphasizes the importance of early sepsis recognition and intervention.

The 2012 version of the SSC guidelines focused on early goal-directed therapy (EGDT) (Dellinger et al., 2013). The recommendation of EGDT was removed from the SSC bundle in 2015 after the publication of the ProCESS, ProMISe and ARISE trials (SSC Executive Committee, 2015). These trials demonstrated that early intervention was superior to achieving the clinical goals established by EGDT (Mouncey et al., 2015) (The ARISE Investigators and the ANZICS Clinical Trials Group, 2014) (The ProCESS Investigators, 2014) (SSC Executive Committee, 2017). Currently, the SSC bundle is similar to the CMS bundle however; it does not delineate intervention by diagnosis. The SSC endorses a 3-hour bundle and a 6-hour bundle. The elements of the 3-hour bundle are 1) lactate measurement, 2) blood culture collection prior to antibiotic administration, 3) broad-spectrum antibiotic administration and 4) 30ml/kg crystalloid bolus for hypotension or lactate > 4mmol/L (SSC, 2015). The elements of the 6-hour bundle are: 1) vasopressor administration to maintain a MAP > 65mmhg for patients not responsive to initial fluid resuscitation, 2) assess and document volume status and tissue perfusion for patients with hypotension refractory to initial fluid resuscitation or an initial lactate measurement >4 mmol/L, 3) re-measure the lactate if the initial lactate was elevated (SSC, 2015). To date, these bundles have not yet been updated by the SSC to reflect the 2016 SSC guidelines.

The 2016 SSC guidelines endorse multiple modifications to the care of septic patients. While these guidelines eliminate EGDT, they continue to emphasize early recognition and intervention. The guidelines make the following recommendations concerning the elements that are currently bundled by the SSC. Lactate should be measured and trended to guide resuscitation. Blood cultures should be collected prior to antibiotic administration without causing delays in care. Broad-spectrum antibiotics should be administered within 1 hour of the recognition of sepsis and septic shock. Within 3 hours, a 30ml/kg bolus of crystalloid fluids is recommended for all patients experiencing sepsis-induced-hypo-perfusion. Sepsis-induced hypo-perfusion is defined as organ dysfunction and/or hypotension and elevated lactate levels (Rhodes et al., 2017). Continuous dynamic re-assessment of hemodynamic status is recommended. For patients diagnosed with septic shock, vasopressors such as norepinephrine and vasopressin should be administered to maintain a MAP > 65mmhg (Rhodes et al., 2017). In summary, the application of the 2016 SSC guidelines to the previous SSC bundle results in major differences with regards to antibiotic administration and fluid resuscitation.

Purpose

The Emergency Department, which served as the quality improvement project practice site, had not fully adopted the 2016 SSC guidelines into their clinical practice. Yet, the management team desired to optimize the care of septic patients in the ED. A cohort of leaders determined that a quality improvement initiative was an appropriate method to improve ED sepsis care. The SSC guidelines, professional organizations, and research endorse the use of performance improvement to improve sepsis care. Important components of effective sepsis Performance Improvement (PI) programs include interprofessional collaboration, establishing and implementing protocols, bundled care, data collection with the comparison to benchmark

metrics, and continuous feedback (Rhodes et al., 2017). Quality Improvement (QI), a variation of PI, examines patient care and system-level processes with the intention of improving patient outcomes (Hickey & Brosnan, 2017). Utilizing the 2016 SSC guidelines to frame appropriate interventions and outcomes, the purpose of this scholarly practice project is to evaluate the implementation of an interprofessional sepsis quality improvement initiative in the ED.

Research Question

Does the implementation of an interprofessional ED sepsis quality improvement initiative increase 3-hr bundle compliance and decrease all-cause in-hospital mortality for patients with an ED sepsis alert activated?

Literature Review

The "Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock: 2016" addresses the importance of performance improvement (PI) initiatives to improve the clinical care for septic patients (Rhodes et al., 2017). Multiple studies reinforce this recommendation by concluding PI and QI can significantly decrease mortality from sepsis (Rhodes et al., 2017). Given the multiple components associated with sepsis care and quality improvement, this review of literature focuses on the clinical criteria to detect and diagnose sepsis and interprofessional quality improvement initiatives.

Clinical Criteria

Currently, no gold standard exists to detect or diagnose sepsis (Singer et al., 2016) (Seymour et al., 2016). A variety of clinical criteria are used in clinical practice to aid in the identification of septic patients. When each clinical criterion was developed, it reflected the scientific knowledge that existed about sepsis. Over time, the clinical criteria have progressed into more specific and less sensitive ways of detecting sepsis. Sepsis is a complex clinical

syndrome that requires astute clinicians to understand and interpret a variety of clinical criteria to ensure optimal patient outcomes. This portion of the review of literature focuses on the clinical criteria used to detect and diagnose sepsis.

With the release of the SEP-3 definitions in 2016, it became critical to identify a method of establishing clinical criteria that corresponded to the new definitions. Seymour et al., 2016 completed a research study that reviewed 1.3 million patient encounters and identified 148,907 patients with suspected infection to construct the clinical criteria for the SEP-3 definitions. Through the retrospective analysis of a prospective cohort Seymour et al., randomized these patients into a derivation and validation cohort. The study evaluated the "primary outcome of in-hospital mortality and the secondary outcome of in-hospital mortality or Intensive Care Unit (ICU) length of stay (LOS) greater than three days" (Seymour et al., 2016, p 762). Within the ICU setting the study evaluated the predictive validity of the SIRS, Logistic Organ Dysfunction Scale (LODS) and SOFA criteria. The research concluded that between the LODS and SOFA criteria there was not a statistically significant difference at predicting inpatient mortality; however, both criteria were statistically better than the SIRS criteria (Seymour et al., 2016).

The qSOFA score was generated using the multiple logistic regression and was validated in four external data sets that contained 706,399 patients from 165 hospitals that included patients from the pre-hospital setting, the inpatient setting and one German hospital (Seymour et al., 2016). The study concluded that SOFA should be used in the ICU setting and qSOFA should be utilized outside the ICU setting to assess patients. Additionally, the study concluded that while SOFA is designed to detect and diagnose sepsis, qSOFA is designed to predict prolonged ICU hospitalization or in-hospital mortality (Seymour et al., 2016).

A review of the literature evaluating the clinical criteria of qSOFA was completed using the electronic databases CINAHL, PubMed and Cochrane (Appendix B). Studies published before July 2017 were included. CINHAL was searched using the key terms "emergency department" and "qSOFA or quick sepsis-related organ failure assessment" and resulted in the identification of 15 studies. The key terms “emergency department,” “qSOFA,” and “sepsis” were used to search PubMed and Cochrane, resulting in the identification of 15 and 3 studies respectively. Studies were then reviewed by title, abstract, and full text. Inclusion criteria were 1) any study that compared qSOFA to other sepsis screening tools. Exclusion criteria were: 1) any article that was not published in the English language, 2) any article that was not published in full text, 3) studies that used SIRS criteria to define their study population 4) any study that evaluated a specific infectious process, such as pneumonia, rather than all infectious processes and 5) any studies in the pre-hospital setting. Studies were included if they were randomized control trials or non- randomized comparison cohort studies. Case studies, editorials, and pre/post studies were excluded.

Three studies, composed of populations admitted to the ICU, evaluated the prognostic accuracy of SIRS and qSOFA (April et al., 2016; Finkelsztein et al., 2016; Raith et al., 2017). The research by Finkelsztein et al., (2016) concluded that qSOFA was significantly better at predicting all-cause in-hospital mortality when compared to the SIRS criteria, $p = .03$. Over a three-year period, April et al., (2016) identified 214 septic ICU patients and concluded that in-hospital mortality was predicted similarly between SIRS and qSOFA. One limitation of this study is that 61 patients with advanced directives were excluded from the study (April et al., 2016). The exclusion of patients with advanced directives may have skewed the mortality data. Raith et al., 2017 evaluated qSOFA, SOFA, and SIRS across a sample of 184,875 patients from

182 different ICUs. This study contained over 15 years of data and found statistically significant differences between the criteria, $p < .001$. In-hospital mortality was best determined by SOFA, followed by qSOFA and then SIRS criteria (Raith et al., 2017). A limitation of these 3 studies is that the sample was already admitted to the ICU, making it difficult to determine the practicality of using the clinical criteria to identify sepsis in the ED. Finally, this research does not account for septic ED patients who were admitted to lower acuity locations in the hospital.

Henning et al. compared qSOFA to the SIRS criteria in 7,637 patients admitted to the hospital from the ED and concluded that qSOFA was less sensitive but more specific at predicting in-hospital mortality when compared to the SIRS criteria. qSOFA scores greater than or equal to 2 were 52% sensitive and 86% specific at predicting mortality. In contrast, SIRS and a suspected infection was 83% sensitive and 50% specific at predicting mortality (Henning et al., 2017). The challenge for emergency medicine clinicians to utilize clinical criterion that balance sensitivity and specificity is addressed explicitly in the authors' discussion (Henning et al., 2017).

Williams et al., 2016 evaluated 8,871 ED patients in an Australian hospital over 4 years with suspected infection and concluded that there was no statistically significant difference between SIRS and qSOFA in detecting organ dysfunction (AUROC, .72 - .73; difference .01; 95% CI [0.0, 0.03]). The study reinforced that qSOFA scores greater than or equal to 2 had high specificity but poor sensitivity (96.1% specific, 29.9% sensitivity). Meanwhile, SIRS criteria were 61.1% specific and 72.3% sensitive at predicting in-hospital mortality (Williams et al., 2017).

Wang, Chen, Guo Mei & Yang, 2016 compared the validity of qSOFA, SOFA, APACHE II and the Mortality in the Emergency Department Sepsis Score (MEDSS) scores in an ED located in Beijing, China (Appendix A). The study's inclusion criteria included patients with

clinically diagnosed infections, for example, pneumonia or intra-abdominal infections. Ninety-two percent of the study sample had greater than 2 qSOFA variables present, leading the reader to believe the study sample was more severely ill. The study determined that the Area Under the Receiver Operating Curve (AUROC) of the four tools was as follows: MEDSS (.751, 95% CI, [0.682, 0.782]); APACHE II (.732, 95% CI, [0.682, 0.782]); SOFA (.729, 95% CI [0.676, 0.782]) and qSOFA (.666, 95% CI, [0.609, 0.723]). The only statistically significant difference was between the qSOFA and MEDSS score, $p < .05$. It was also determined that the 28-day mortality of patients with a qSOFA score greater than or equal to 2 was significantly higher than patients with a qSOFA less than two (42.4% vs. 17.4%, $p < .001$) (Wang et al., 2016). A limitation is the inclusion of patients already diagnosed with an infection, ultimately undermining the screening aspect.

Many hospitals utilize early warning scores to detect illness severity and deterioration among their patients. Churpek et al. (2016) completed a retrospective analysis of 30,677 patients with suspected infection either in the ED or on the medical wards. Their research compared the early warning scores to the new and former clinical criteria of sepsis. qSOFA was compared to SIRS, the National Early Warning Score (NEWS), and the Modified Early Warning Score (MEWS). Statistically significant differences were found using the patient's highest calculated scores. NEWS was superior, followed by MEWS, qSOFA, and SIRS at predicting in-hospital mortality (Churpek et al., 2017).

Freund et al. (2017) completed a prospective four-week international study that evaluated the prognostic validity of qSOFA, SOFA, SIRS and severe sepsis definitions at 30 hospitals among 879 patients. Inclusion criteria was ED patients with suspected infection. Utilizing the AUROC the study calculated the highest for qSOFA (.80; 95% CI [0.74, 0.85]) followed by

SOFA (.77; 95% CI [0.71, 0.82]) compared with SIRS and severe sepsis both at (.65; 95% CI; [.59, .70]), $p < .001$. The strength of this study is the prospective design however it must be noted that the qSOFA score was calculated using the worst value for each variable during their entire ED length of stay (Freund et al., 2017).

Common themes are elicited by the research investigating the newly defined clinical criteria of qSOFA. Study limitations include retrospective analysis and small sample sizes. The research highlights that qSOFA is more specific at predicting inpatient mortality but less sensitive when compared to SIRS. The ability to predict in-hospital mortality or prolonged hospitalization is important. However, clinical practice in the ED focuses on the detection of sepsis. Clinicians must understand the clinical criteria and its intention, which then leads to a balancing act between detection and measures of illness severity (Angus et al., 2016). Further prospective studies are warranted using qSOFA to determine the clinical implications of this criterion in the Emergency Department setting.

Quality Improvement

A review of the literature was performed using the electronic databases CINAHL, PubMed and Cochrane (Appendix C). The key terms “sepsis” and “quality improvement” and “emergency department” were used to search CINAHL since 2007 and July 2017, with full English text and returned 11 results. Of these studies, 6 were included after title, abstract and full-text review. The key terms “sepsis” and “quality improvement” and “emergency department” were used to search PubMed within the last five years and returned 35 results. Of these studies, 5 were duplicates, 16 were removed after title review, 8 after abstract review and then 3 after full-text review. The same key terms were used to search Cochrane with four resulting studies; however, one was a duplicate, one was an abstract and two results were the

same. Four studies were identified through ancestry and included in the review of quality improvement literature. Inclusion criteria were any study that discussed quality improvement. Exclusion criteria were: 1) any article that specifically addressed the hematology, oncology, or pediatric patient population, 2) any article that was not published in full text or 3) any study addressing multiple quality indicators. No specific study design was required for this review of the literature. Multiple themes resulted from this literature review, to include initiatives that focused on interprofessional quality improvement, bundled care, and sepsis screening.

Interprofessional Quality Improvement Initiatives.

MacRedmond, et al., 2010 evaluated the impact of a quality improvement initiative that focused on early goal-directed therapy, achievement of resuscitation goals, antibiotic administration and hospital mortality. Over six months, data were collected for 37 patients who were admitted via the ED with the diagnosis of severe sepsis. The interprofessional team included physicians, nurse educators, and the quality utilization management team. They met bi-monthly over an eight-month period to address sepsis management and utilized lean thinking and the Plan-Do-Study-Act (PDSA) methods of assessing and modifying care to meet bundle benchmarks. The completed interventions included staff education, development of a sepsis algorithm and order set, and the provision of invasive hemodynamic monitoring equipment. Analysis revealed that their methods improved the time to antibiotic administration and early goal-directed therapy for their sample. Nurses also improved their ability to recognize sepsis after an educational intervention ($p = .002$), with improvements in sensitivity from 75% to 92.3% ($p < .001$). Their interventions also led to decreased time to antibiotic administration (1.4 hours vs. 2.7 hours, $p = .06$) and statistically significant improvements regarding the mean start time of EGDT (3.2 vs. 10.4 hours, $p = .001$). Furthermore, post-intervention 100% of patients had their

lactate measurements completed. The authors note they sustained their improvements for 1 year after the commencement of the initial project period (MacRedmond et al., 2010).

Seoane et al., 2013 examined the formation of an interprofessional sepsis steering committee in a large academic tertiary referral center that utilized rapid cycle changes PDSA to optimize their sepsis management. The project occurred from July 2008 to June 2012. The team completed case reviews of 1,105 patients admitted to the medical intensive care unit (MICU) for severe sepsis or septic shock. The interprofessional team included ED and Critical Care Physicians, a clinical pharmacist, hospital administrators, performance improvement and informatics staff. The first action of the committee was the creation of an order set based on the 2008 SSC guidelines. Median time to antibiotic administration significantly decreased from 140 minutes in 2008 to 72 minutes in 2011, $p < .001$. Additionally, for hospitalized patients, the median LOS decreased from 8 to 7 days, $p = .036$. Sustainability was the cornerstone of this intervention, as they continued to meet and optimize sepsis care four years after they began the sepsis steering committee (Seoane et al., 2013).

Using the SSC Guidelines, Grek, et al., 2016 utilized QI to focus on promoting early identification and interprofessional resuscitation for patients diagnosed with severe sepsis at a large, tertiary care center with 304 beds. The primary outcome was bundle compliance, and the secondary outcome was mortality. QI interventions included a detection tool (sepsis sniffer), visual aids in the ED, a multidisciplinary Sepsis and Shock Response Team (SSRT), a resuscitation flowsheet, and provider pocket cards. The project utilized the QI methods of Define, Measure, Analyze, Improve, Control (DMAIC), Failure Modes and Effects Analysis (FMEA), PDSA, as well as others. Data were prospectively collected from December 2011 to March 2012. Adherence to bundle measures was determined using both an individual and “all or

none" approach. Before the QI interventions bundle adherence was zero percent, however, post-implementation bundle adherence improved to 51%. Patients admitted through the ED with severe sepsis had a significant decrease in mortality; the mortality index decreased from 0.884 to 0.662, $p = .049$ (Grek et al., 2016).

Powell and Fowler, (2014) at Baylor Health Care System (BHCS) evaluated a quality improvement initiative to decrease mortality from sepsis. Their approach focused on performance improvement throughout the entire organization, at multiple sites, extending from hospital executives to bedside staff. They developed goals that emphasized screening and bundle compliance. Using an interprofessional approach, the Safe, Timely, Effective, Efficient, Equitable, and Patient-centered (STEEEP) framework, and PDSA they completed continuous quality improvement with a focus on transparency. They improved their median ED arrival to antibiotic time (122 minutes to 74), ED arrival to IV fluid bolus completion (119 minutes to 88), and adherence for ED arrival to antibiotic administration within 180 minutes (70% to 90%). From June 2011 to June 2012, their ED to ICU admit time decreased from 507 minutes to 281 minutes. Additionally, the institution used the Hospital Standard Mortality Ratio (HSMR) to calculate a total of 555 lives saved due to their QI initiatives (Powell & Fowler, 2014).

McColl et al., 2017 improved ED sepsis management through the implementation of multiple interventions using an interprofessional approach. They aimed to optimize staff knowledge, sepsis management, and decrease mortality. The completed interventions included a needs assessment, process mapping, triage enhancements, physician chart prompts, EHR alterations, sepsis protocols, and staff education. The study had a statistically significant lower 30-day all-cause hospital mortality rate post-intervention, $p = .0006$, (30.7% versus 17.3%, absolute difference 13.4%, 95% CI [9.8,17]) (McColl et al., 2017).

These quality improvement projects demonstrate the benefits of an interprofessional approach to the optimization of sepsis care. Limitations of these projects include that they were pre/post design constructs and that several were single site settings. It is also difficult to determine the presence of a Hawthorne effect and what factors were most responsible for increased compliance, given that most projects had more than one intervention. Finally, it is essential to consider that these projects were conducted-using the previous definitions and clinical criteria of sepsis; prior to the new 2016 guidelines.

Bundled Care Quality Improvement Initiatives.

Between June 2008 and December 2009, Wang, Xiong, Schorr, and Dellinger prospectively evaluated the implementation of SSC bundles in the ED. The primary outcome was in-hospital mortality. This project which took place in Beijing, China enrolled 195 patients who were diagnosed with severe sepsis and septic shock. Post-intervention adherence to all elements of the EGDT bundle improved significantly, $p < .05$. Mortality also decreased after implementation of the bundles from 44.8% to 31.6%, $p < .05$ (Wang, Xiong, Schorr, & Dellinger, 2013).

In a two-year project that started in 2003, Nguyen et al. implemented a quality improvement bundle that mirrored the IHI's recommendations. The primary and secondary outcomes measured were bundle compliance and mortality (Nguyen et al., 2007). Utilizing a staff survey, the principles of evidence to action; awareness, agreement, adoption, and adherence, and PDSA, the project sought to translate research into practice. The project had 3 phases; baseline, education, and operation that were subsequently followed by 5 QI quartiles. Comparing baseline to the last QI quartile demonstrated that bundle compliance for EGDT improved from zero percent to 51.2%. Mortality also decreased by 19% for patients who

received all elements of the bundle. Nguyen et al. (2007) believed an important factor in their success was the leadership of a physician champion.

In a project with 4,329 patients, Miller III et al., 2013 evaluated the utilization of a severe sepsis and septic shock bundle on mortality. The project evaluated patients admitted from the ED to the ICU between January 2004 and December 2010. Eleven hospitals, with 18 ICUs were included. The project took place in 3 phases over 7 years. A resuscitation and maintenance bundle were created using the 11 SSC guidelines. The comparison of baseline to 2010 revealed that "all or none" bundle compliance increased from 4.9% to 73.9% and mortality declined from 21.2% to 8.7%, $p < .0001$ (Miller III et al., 2013).

In a sample of 825 patients, Tromp et al., 2010 evaluated the effects of two interventions, one a nurse-led care bundle and the second a performance feedback tool on adherence to the SSC guidelines. The nurse led care bundle created by an interprofessional team and consisted of sepsis screening and a sepsis performance list. For ED patients, these interventions resulted in improved bundle adherence, demonstrated by 3.5% at baseline to 12.4% at the project conclusion (Tromp et al., 2010).

Screening Quality Improvement Initiatives.

After identifying a gap in practice, Kent & Fields (2012) developed a severe sepsis screening method for utilization in the ED. Prior to development, they identified barriers at their hospital that prevented the consistent implementation of sepsis management algorithms. The project took place in a 536-bed community hospital, with 60 ED beds, and approximately 80,000 annual visits. The screening instrument utilized the SIRS criteria, organ dysfunction criteria, infection (suspicion or current antibiotic administration), and Situation, Background, Assessment, Recommendation (SBAR) to facilitate the identification of severe sepsis and

interdisciplinary communication. Despite screening 406 patients, no definitive conclusions could be determined from this project given the small number that screened positive for severe sepsis. In the post-intervention period, 5 patients screened positive, and four had additional interventions completed after SBAR communication (Kent & Fields 2012). Future projects should incorporate larger cohorts of patients to assess this screening and communication style.

At the University of Washington Medical Center between May 2011 to June 2014, O'Keefe Gatewood, Wemple, Greco, Kritek, and Durvasula (2015) implemented an ED quality improvement project that focused on nurse sepsis screening in triage, computer-generated sepsis-alerts, and sepsis order sets. The screening instrument consisted of any "concern for infection" and two or more SIRS criteria (O'Keefe Gatewood, Wemple, Greco, Kritek and Durvasula, 2015, p 789). Following a positive screen, a nurse-led protocol started clinical intervention for the patient. A continuous feedback system was generated with a monthly dashboard that reviewed adherence to bundled sepsis care. Bundle compliance improved from 28% to 50% after the implementation of nurse sepsis screening in triage and role-specific order sets (O'Keefe Gatewood, Wemple, Greco, Kritek, & Durvasula, 2015). This project capitalized on the ED triage interaction, between patients and nurses, prior to examination by a LIP.

Research and Clinical Practice Gaps

Significant gaps in research, knowledge and clinical practice exist as a result of the novelty of sepsis research that endorses new definitions, clinical criteria, and management guidelines. To date, quality improvement research focuses on the former definitions of sepsis, severe sepsis, and septic shock. Additionally, the evidence does not adequately address the use of new clinical criteria during triage to screen patients for sepsis. Given the lack of available biomarkers to identify organ dysfunction during triage and prior to examination by a LIP,

clinical practice in the ED continues to rely upon the use of SIRS criteria to identify septic patients, anecdotally. ED sepsis screening with qSOFA is not appropriate given the lack of robust prospective studies validating this practice. Furthermore, qSOFA predicts prolonged ICU stay or mortality rather than detecting sepsis.

The current evidence is not specific about the most important aspect of a sepsis QI program. Given that most sepsis QI studies had more than one intervention, it is unclear where QI efforts should be focused. Further exacerbating the gaps is the continued use of older definitions and guidelines by regulatory agencies and professional organizations. Research analyzing the implementation of a quality improvement initiative that translates the new definitions, clinical criteria, and management guidelines to practice will be essential in the future.

Theoretical Framework

Donabedian's model (Donabedian, 1988) of Structure, Process and Outcomes was utilized as the theoretical framework for the interprofessional ED sepsis quality improvement process. This theoretical framework focuses on quality assessment through the three classifications of structure, process, and outcomes (Donabedian, 1988). This theoretical framework assumes that "a good structure increases the likelihood of good process, and good process increases the likelihood of a good outcome" (Donabedian, 1988, p 1745). Donabedian emphasizes the importance of understanding the intricacies of each classification prior to beginning a quality assessment and that each classification impacts the others (Donabedian, 1988). Structure refers to the setting, equipment, and personnel. The process focuses on the patient and provider, both individually and collectively. Outcomes are determined by the health of a patient or a patient population (Donabedian, 1988). Donabedian emphasizes the importance of measurable outcomes to prevent failed attempts at quality improvement. He describes implicit

and explicit measures; one focusing on more subjective analysis while the other focuses on more objective measurements of quality (Donabedian, 1988).

The setting for this QI project was an academic medical center. Consideration was given to the organizational culture, workload, and financial restrictions associated with this environment (Figure 1). The process of care for septic patients is critical and was the focus of the QI interventions. Established protocols were strengthened to swiftly and effectively deliver evidence-based care. Factors that influenced the timeliness of care included staff knowledge, the EMR, patient acuity, bed status, and ED throughput. Outcomes associated with the care of septic patients include bundle compliance, preventing the escalation of care, recovery, morbidity, and mortality. An explicit outcome measure associated with the clinical management of septic patients is adherence to the 3-hour bundle elements.

Scholarly Practice Project Question

Does the implementation of an interprofessional ED sepsis quality improvement initiative increase 3-hour bundle compliance and decrease all-cause in-hospital mortality for patients with an ED sepsis alert activated?

Methods

Sepsis

Sepsis is a complex clinical syndrome that requires expedited, sequenced, and evidence-based clinical interventions to decrease the risk of poor clinical outcomes and mortality. Prioritized clinical interventions are outlined by professional and regulatory agencies such as the CMS, NQF, and the SSC. These agencies utilize the former definitions of sepsis and promote the use of screening, bundled care, interprofessional teams, and performance improvement to achieve optimal clinical outcomes.

Purpose

Utilizing the 2016 SSC guidelines to frame appropriate interventions, the purpose of this scholarly practice project is to evaluate the outcomes of an interprofessional sepsis quality improvement initiative in the ED. As indices of patient and system level care, the primary outcomes of this quality improvement project were 3-hour bundle compliance and mortality.

Protection of Human Subjects

Approval for this project was granted from the Institutional Review Board (IRB) for Health Sciences Research (#20087). IRB submission was completed after the Scholarly Project was successfully proposed to the Scholarly Practice Project Team. The data was protected on the health system intranet, which contains a firewall to prevent privacy breaches. The most significant threat to human subjects was the potential breach of patient confidentiality. Only essential data elements were captured. Data was only accessed by individuals with Health Insurance Portability and Accountability Act (HIPAA) training.

Research Design

The quality improvement process was prospective and descriptive. Over a six-month period, the effect of the quality improvement intervention was evaluated. Quantitative data regarding sepsis identification, bundle adherence, and mortality was analyzed to determine the effect of the intervention over time.

Description of the Sample

The sample was the electronic medical records of ED patients, 18 years of age and older, who had a sepsis alert initiated between July and December 2017. Patients were excluded if they died within one hour of arrival to the ED.

Setting

The research setting was a rural, academic, Level I trauma care center in the Southeast U.S that serves a safety-net hospital. The hospital also serves as a National Cancer Institute (NCI) and transplant center. The hospital had 600 inpatient beds with an average daily census of 462 patients. The ED had 41 beds to evaluate patients, with the capacity to expand to 56 beds. The ED treated 62,998 patients in 2016. The ED is staffed by Attending Physicians, Resident Physicians, Registered Nurses, Patient Care Technicians, Hospital Unit Coordinators (HUCS) and one Nurse Practitioner.

Background.

By the calendar year, the ED had over 1,000 sepsis alerts in 2015, over 700 in 2016 and 1,070 in 2017. The ED procedure stated that once potentially septic patients were identified they would be sepsis alerted by either a physician or a nurse (Appendix D). This procedure cued staff to initiate an alert if a patient exhibited 3 out of 4 SIRS criteria. A sepsis alert was generated by telephoning the medical communications center. The medical communications center is responsible for creating and coordinating mass text pages. These text pages are sent to hospital staff as a means of communicating critical information. The sepsis alert procedure stated the following ED staff should be text paged to notify them of a potentially septic ED patient: Medical Director on-call, 2nd or 3rd-year Resident, Pharmacist, Charge Nurse, Inpatient Medical Emergency Team RN (MET RN), Bed Supervisor, and Quality Improvement Coordinator. Despite this written procedure, the ED Medical Director on-call, the Resident Physicians, the MET RN, and the Bed supervisor did not receive the text page notification due to informal requests that altered this practice.

Initial sepsis screening was completed through clinical judgment and best-practice-alerts (BPAs) in the electronic health record (EHR). The BPA notified staff when a patient exhibited 3

out of 4 SIRS criteria, with at least one criterion being an elevated white blood cell count or a fever. This BPA served as a fail-safe and did not automatically trigger a sepsis alert. It required the clinician to recognize the BPA and take action to escalate the patient's care. Often the BPA did not influence the triage nurse's care since the BPA was designed to alert the next time a provider re-opened the patient's EHR. However, if a triage nurse suspected a patient was septic, they had the autonomy and capability to initiate a sepsis alert from triage.

There was not a robust quality improvement program in place to monitor sepsis care. Standard practice was to provide feedback to staff on an individual basis when the standards of care were not met. Collected data were manually abstracted from the EHR and then entered into a database. With the assistance of the Quality Improvement Systems Administrator and Analyst, efforts were being made to generate automated reports to ease the burden of completing sepsis-related chart audits. Adherence to the standards of care was evaluated from the time of sepsis alert rather than the time of entry into the ED. The ED management desired to optimize sepsis management, and the literature supported the implementation of an interprofessional team supported by the literature.

Procedures

In the spring of 2017, an ED Sepsis Coalition was formed consisting of an Attending Physician, 3rd-year Resident, Quality Improvement Coordinator, Pharmacist, Quality Improvement Systems Administrator and Analyst, a performance improvement coach, a medical informaticist, 2 nursing informaticist, an RN, and a DNP student. The Sepsis Coalition met to address methods of optimizing sepsis clinical care in the Emergency Department.

The Interprofessional Quality Improvement Initiative.

Utilizing elements of lean methodology including an A3 format, the ED sepsis QI initiative aimed to improve the processes that impacted the clinical care delivered to septic patients. An A3 is a written format design for QI that structures the process and contains the following elements: the issue, the background/measurements, current condition, problem analysis, the targeted condition, countermeasures, the implementation plan, the test, and follow-up (Jimmerson, 2007). Between July and December 2017, the Sepsis Coalition met on 6 occasions. Each meeting was approximately one-hour long. Prior to each meeting, an agenda was distributed to the members of the Sepsis Coalition. While attendance varied from meeting to meeting, important decisions were not made unless key stakeholders were present.

In July, there were two meetings. The first meeting, July 13th, focused on the review of a subset of patients who were immunocompromised or had a diagnosis of liver failure. A previous meeting in June had determined that this subset of patients may not effectively trigger the BPA and subsequently may not be sepsis alerted. The Quality Improvement Systems Administrator and Analyst created an automated report that identified patients who were not diagnosed as septic in the ED but were potentially diagnosed as septic after admission. The members of the Sepsis Coalition reviewed this report. The discussion of these reviews led to important revelations about the criteria being used to detect and diagnose sepsis, screening, and communication.

Following this meeting, a change in the text paging process was implemented. In accordance with the sepsis procedure, the Attending and Resident Physicians on duty were added to the text page when a sepsis alert was initiated. This intervention was designed to improve communication and department situational awareness.

Prior to the 2nd meeting, a qualitative survey was created and distributed to the ED staff to assess their perceptions of the sepsis management. Based on the recipient's professional role, there were slight variations in the questions. The ED Attending and Resident Physician survey had 8 questions, the RN survey had 7 questions, and the Pharmacist survey had 6 questions. The Patient Care Technicians were not included in this qualitative assessment. Thirteen Attending physicians, 10 Resident Physicians, 45 Nurses and 6 Pharmacists completed the survey. The purpose of this qualitative assessment was to identify the strengths and weaknesses of sepsis management in the ED and to guide future quality improvement initiatives.

On July 27th, the group reconvened to discuss old business, sepsis screening, the sepsis order set, and the qualitative survey results. Examples of EHR sepsis screening utilized at other institutions were reviewed. The group concluded that more information was required to determine if the sepsis screening instruments were appropriate for the ED's workflow. During this meeting, the release of a new order set for sepsis management in the ED was finalized. The major change in the order set streamlined the antibiotics section, making it less cumbersome to navigate. During the open forum portion of the meeting, three additional topics were discussed, rectal temperatures, the timing of BPA, and communication. The rectal temperature discussion focused on the lack of equipment to complete the task and gaps in clinical practice. The coalition hypothesized that if each patient care area was standardized to have a rectal thermometer, there might be improvements in identifying sepsis. The BPA discussion focused on communication. It was determined that the physicians were not always aware that BPA had been triggered for their patient since it did not alert until the next time the physician opened the patient's chart. The question was then posed to the medical informaticist if notification could be placed on the EHR tracking board to alert the staff that the SIRS BPA had been triggered even if

the patient's chart was not open. The final element of discussion pertained to text paging the bedside nurses when their patient was sepsis alerted in an effort to improve communication and compliance with timely interventions.

Following the 2nd meeting, two significant events happened. The first event was a meeting to discuss the BPA. Topics of discussion included current and background BPAs and how to use the BPA to detect and diagnose sepsis. This discussion focused on moving from a detection BPA (3 of 4 SIRS criteria) to BPA that facilitated diagnosis (SIRS + SOFA variables). No conclusions were made determining the appropriate course of action. The second major event was an equipment assessment of the rectal temperature equipment in the ED. This assessment identified the need for 23 new thermometers and 55 rectal probes and holders. The results were shared with the ED management and steps were taken to purchase the equipment.

The third meeting, on August 22nd, discussed the qualitative survey findings, the rectal thermometer equipment assessment, text paging, BPAs and vital signs. Four members of the coalition attended this meeting. The qualitative survey discussion focused on common themes about communication, antibiotics, rectal temperatures, and intravenous access. Data regarding the July 2017 BPAs was brought to the meeting. It was identified that 8 unique BPAs existed that were based upon the SIRS criteria. Half of the BPAs only fired in the background as "test" BPAs, while the other half accounted for the same BPA divided by professional role. Some of the BPAs incorporated measures of SIRS and organ dysfunction, however, based upon the data they were not deemed clinically relevant at that time. The meeting concluded with a discussion about vital signs. The group brainstormed ways to ensure the clinical staff was capturing vital signs every 15 minutes (4 times) from the time of the alert. This led to further discussion about communication between professional roles in the ED.

Between the third and fourth meeting, an effort was made to increase awareness of the BPA firing to ED physicians. This request led to the addition of a BPA column on the ED EHR tracking board. Subsequently, further discussion determined it was necessary for the notification to be located on the "patient list" portion of the EHR, where it would be more visible to staff. Also, during this period, a new infectious disease screening was being created. This was considered an opportunity to request a sepsis screening instrument in triage be added to the triage screening questions. Initial efforts were made to combine the two; however, this was not possible as one was completely dependent upon fever and the other was not.

Ten people attended the 4th meeting on October 5th, 2017. The following topics were addressed at this meeting: July and August sepsis metrics, the addition of a BPA column for the clinicians, triage sepsis screening, and revision of the sepsis procedure. The metrics reviewed included: 1) the number of alerts, 2) median door to alert time, 3) blood cultures (#1 and #2) collected prior to antibiotic administration, 4) lactates resulted within 1 hour of alert, 5) antibiotics (#1 and #2) administered within 1 hour of alert, 6) the administration of a 30ml/kg bolus for hypotension or a lactate > 4mmol/L, and 7) documented vitals every 15 minutes from the time of arrival. These items were calculated into percentages to display departmental adherence. The coalition identified a solution to increase awareness that the SIRS BPA triggered for a patient. It was decided that the best option would be the addition of a column on the ED track board that also displayed on the clinician's patient's list. Discussion continued regarding the best way to incorporate the bedside nurse into the text paging process. Screening was determined to be a priority action, and future meetings were coordinated to develop a triage screening instrument. Finally, it was determined that the coalition needed to identify two metrics

to focus their initial QI efforts towards. Thus, a survey was created for the sepsis coalition to determine what initiative they would like prioritized.

Between the 4th and 5th meeting, 4 members of the sepsis coalition with nursing background met to discuss and create a triage sepsis screening instrument. The goal of utilizing a screening instrument during triage was to identify septic patients early and provide timely intervention. Examples of sepsis screening instruments were reviewed, and the nurses determined the priority key elements they desired in screening. The group reached a consensus that the screening instrument should not serve as an algorithm but rather an intentional moment of reflection. The goal of the intentional moment of reflection was to review the patients' history of present illness, past medical history, and current clinical status to determine if they were at risk of being septic. Cues to consider transplant and immunocompromised patients were included in the screening. This was particularly important due to cancer and transplant center services of the hospital. The screening instrument consisted of 4 yes/no questions and a fifth question to document the nursing action taken based on the answer to the four previous questions (Figure 2). The screening instrument incorporated both SIRS criteria and SOFA variables.

At the 5th meeting, on October 19th, the Sepsis Coalition discussed the following topics: sepsis metrics, rectal thermometer equipment, the addition of a BPA column in the EHR, survey results review, sepsis screening, and the sepsis procedure updates. The metrics for September were reviewed and compared to July and August. It was identified that the department still required 2 new thermometer units, 29 rectal probes, and 17 rectal probe holders. The coalition finalized the proposed addition of the BPA column in the patient tracking list. The survey results were compiled, reviewed, and discussed. As a next step, the coalition decided to focus QI efforts on improving the door to alert time and antibiotic administration within 1 hour of alert. The

proposed screening instrument was presented to the coalition and endorsed for production in the EHR (Figure 2). Finally, to update the sepsis procedure revisions were solicited from coalition members.

Between the 5th and 6th meeting multiple significant events happened. The sepsis screening instrument was built in the test environment of the EHR and underwent multiple revisions for aesthetics. The sepsis procedure was revised to reflect the current definitions and clinical criteria for diagnosing sepsis. A visual management board was created in the ED to reflect QI initiatives in the ED including sepsis management. The data regarding median door to alert time and antibiotic administration were displayed on this board and in the employee break room. An A3 was drafted for the ED sepsis QI project. A survey was sent to the ED Nurses and PCTs inquiring if they wanted to receive all text pages for Stroke, STEMI, Sepsis and Trauma Alerts. The results of the text paging survey were reviewed. Seventy-seven nurses and 27 PCTS responded. Seventy-two percent of nurses and PCTs said they would like to receive all pages. This information as shared with the ED Manager and a request to change the text paging system was made.

At the 6th meeting on November 8th, the following topics were discussed: the addition of the BPA column in the EHR, rectal thermometers, sepsis screening, the sepsis procedure, review of the A3, and text paging. The BPA column was in the EHR "test" environment, and further clarification was provided on moving it to the live EHR environment. The department only required one new thermometer unit, 18-20 rectal probes, and no rectal probe holders. The final built version of the sepsis screening instrument was reviewed and approved for final production, with a go-live date of November 27th. The coalition approved the sepsis procedure with the final revisions and sent to the ED Medical Director for signature (Appendix G). A new sepsis badge

card for clinical staff was proposed and approved. The badge card reinforced recognizing sepsis and how to intervene to optimize patient care.

Following the 6th meeting, education regarding sepsis screening was shared with the staff through one-on-one education, staff huddles, and presentations in the employee break-room. Sepsis Screening went live on November 27th. The BPA column was added on January 2nd, 2018. Sepsis badge cards were distributed in January to clinical staff reinforcing the importance of early recognition and timely, appropriate interventions.

In summary, the interprofessional sepsis coalition was able to complete the following interventions to improve sepsis care: improved text paging notification to physician staff, revision of the sepsis order set, the creation of a QI visual management system, revision of the ED sepsis procedure, the development and implementation of a sepsis screening instrument for triage, standardization of the thermometer equipment and revision of the EMR tracking board. Despite the achievements of the sepsis coalition, the following items remain actionable: revision of the BPA, improved text paging notification to the nursing staff, and an automated sepsis report. Given the quality improvement process is continuous, the potential still exists to complete additional interventions in the future.

Data Collection Procedures.

Retrospective data collection was completed for each sepsis alert starting in August. BPA data were gathered from an automated report created by the Quality Improvement and Assurance Systems Analyst. The medical record number (MRN) and time of alert were obtained from the database of Sepsis Alert pages that are received by the Quality Improvement Coordinator. The patient's MRN was entered into the "patient station" section of the EHR, and

the chart corresponding to the date of the sepsis alert was accessed. The ED encounter summary, orders, and flowsheets were reviewed to obtain data elements.

Data abstraction from each chart took approximately ten minutes. The data were collected and transcribed as date/time groups into a database. Conditional formatting and formulas permitted the analysis of adherence to timely interventions. An intervention must have been completed within the exact prescribed timeframe to be considered adherent to the standard. Vital sign documentation was the only exception to this standard, as 20 minutes were permitted to capture the data. Cumulatively, these data were entered into a spreadsheet and stored on the ED Quality Data Coordinator's Health System secure server. The data were compiled into monthly reports to reflect the departmental adherence to the standards.

Measures

Data elements were collected from the EHR to determine demographics, throughput information and bundle compliance (Appendix E). Any patient over the age of 86 was recoded to the age 86 for Health Insurance Portability and Accountability Act (HIPAA) purposes. Adherence to the sepsis bundle elements was analyzed from both the time of arrival and the time of the alert. To account for the lag between the time of arrival and time of alert a metric titled "door-to-alert" was created. Acknowledging that the SSC identifies time zero as the time of triage, the decision was made to identify time zero as the time of ED arrival. This accounts for the lag between ED arrival and triage, which can vary depending on the census, acuity level, and human factors. The median door to alert time was reported on a monthly basis to the sepsis coalition and ED department staff. The bundle indicators that were analyzed included: 1) blood culture collection prior to antibiotic administration, 2) antibiotic administration within 1 hour of alert, 3) lactate measurement, and 4) administration of a 30ml/kg crystalloid bolus for sepsis-

induced-hypo-perfusion. Due to limitations with data abstraction, the administration of a 30ml/kg crystalloid bolus was evaluated to determine if it was administered throughout the entire ED length of stay rather than in a 3-hour period. Adherence was achieved if the patient received within 100ml of the calculated 30ml/kg bolus. The patients documented actual body weight was utilized to calculate the required crystalloid bolus.

Data Analysis Plan

The measures were summarized into 6 monthly compliance reports. Descriptive statistics were used to compute the data reported to the sepsis coalition and ED staff. In addition to descriptive statistics, inferential statistics were used to calculate differences in performance on a monthly basis. To detect changes in performance month-to-month analysis was completed to provide continuous progress reports to the staff. A statistician provided assistance with inferential statistics. Finally, the analysis comparing month 1 to month 6 was completed to detect an overall difference in performance. IBM® SPSS® version 24 was used to analyze the data.

Strengths and Weaknesses

A major strength of this project was the perceived institutional momentum towards improving sepsis care. This permitted the successful implementation of an interprofessional ED sepsis quality improvement initiative. This quality improvement initiative had multiple weaknesses. One weakness was the QI effort was conducted at single site. The second weakness was the manual extraction of outcome data from the EHR by a single person. Data collection required a large sum of dedicated time. Human factors also played a role in limiting the effectiveness of the initiative; examples include shift work and team dynamics. Finally, given that the project had multiple interventions, it is difficult to determine the most impactful

intervention to improve the clinical care of septic patients. While there were multiple weaknesses, there were two significant strengths. The first was the interprofessional approach to improving the structure and processes surrounding sepsis management. The knowledge, perspectives, and skills of every profession contributed significantly to improving clinical processes and outcomes. The second strength pertains to data collection. The collection of data manually by one person from the EHR provided consistency. The quality improvement initiative thoroughly explored the process and impacted the care of septic patients.

Results

Demographics

Data were retrospectively collected on 525 patients who were sepsis alerted between July and December 2017. Analyzed demographic data included age, gender, Emergency Severity Index (ESI) level, disposition, ICU admissions, and mortality. Descriptive and inferential statistics were performed using IBM® SPSS® version 24. For demographic data, the month-to-month analysis included the following comparisons: 1) July to August 2) August to September 3) September to October 4) October to November 5) November to December.

Mean age and standard deviation were calculated and analyzed for each month (Table 1). Levene's test of homogeneity of variance was not significant, p=0.408. Results of ANOVA statistical testing indicate that the distribution of age was the same across the months, ($F(5, 519) = 1.747$, $p = .122$).

The initial analysis of gender was completed using descriptive statistics (Table 2). Gender was then evaluated using a Chi-Square statistical test. The results show that there were no statistically significant differences in the gender proportions from month-to-month (Table 3).

The ESI level for each patient was collected and recoded into 2 categories: 1) ESI level 1 and 2, and 2) ESI level 3 and 4 (Table 2). There were no patients in the sample triaged as ESI

level 5. Two patients did not have an ESI level documented and were treated as missing data. Chi-Square statistics established that there was no statistically significant difference in ESI levels from month-to-month (Table 3).

Disposition from the ED refers to either admission, discharge, left without being discharged (LWOBD), or deceased. In the entire sample, one patient LWOBD and one died in the ED. These two patients were excluded from analysis. Disposition was recoded into two categories, admission versus discharge (Table 2). In total, 490 patients were admitted to any location in the hospital, accounting for 93% of the patients. There were no statistically significant differences in patient disposition from month-to-month (Table 3).

ICU admissions include sepsis-alerted patients admitted directly to any in-house ICU from the ED (Table 2). In total, 91 patients were admitted directly to the ICU from the ED, accounting for 18.6% of all admissions. The most common location of admission was the Medical Intensive Care Unit (MICU). Chi-Square testing established that there was no statistically significant difference between ICU admissions from month-to-month (Table 3).

The incidence of mortality was completed through frequency counts (Table 2). Between July and December, 24 patients died during their hospital admission. One patient remained in the hospital from initial ED sepsis admission. A Fisher's Exact Chi-square test established that there were no statistically significant differences in mortality from month-to-month (Table 3).

Door-to-Alert Data

The variable door-to-alert accounts for the period between ED arrival and the sepsis alert calculated in minutes. Five patients were sepsis alerted prior to their arrival to the Emergency Department. These patients were assigned zero minutes as the calculated difference between time-of-arrival and time-of-alert. The door-to-alert data were analyzed similarly to the

demographic data. The month-to-month analysis included the following comparisons: 1) July to August 2) August to September 3) September to October 4) October to November 5) November to December and 6) July to December. The sixth comparison, July to December, was added to the initial month-to-month analysis.

The mean and median were calculated for each month (Figure 3). Levene's test of homogeneity of variances resulted in statistical significance, $p = .000$. As a result, a Kruskal-Wallis test was conducted to establish if the distribution of the door-to-alert data was the same across the categories of month. The results indicate that the distribution of the door-to-alert time was the same across the categories of month, $p = .225$.

The Bundle Elements

The bundle elements were further divided to determine adherence to the standards of care. An example of this is the blood culture collection element of the bundle, which was then divided into the collection of blood culture #1 and blood culture #2. The antibiotic administration element of the bundle was divided in a similar manner.

Blood Cultures.

This element was divided into two separate components, blood culture #1 and blood culture #2. After comparing the time of blood culture collection to the antibiotic administration time, a categorical variable (yes/no) was documented to reflect adherence to the standard. If blood cultures were not drawn at all, this was categorized as not meeting the standard. Adherence was evaluated using the same month-to-month analysis as the door-to-alert data (Figure 4). No statistically significant differences in blood culture collection were calculated between the months July to August, August to September, September to October, October to November, and November to December (Table 4). In July 81% of the patients had blood culture

#1 collected prior to antibiotic administration, compared to December when adherence was calculated as 96% (Figure 4). Chi-Square statistics comparing July and December established that there was a statistically significant difference in the collection of blood culture #1 prior to antibiotic administration, $\chi 2$ (1, n = 168) = 8.43, p = .004 (Table 4).

The adherence blood culture #2 collection prior to antibiotic administration was determined in the same manner as blood culture #1. Chi-Square analysis found no statistically significant differences in the collection of blood culture #2 between July to August, August to September, September to October, October to November, and November to December (Table 4). Comparing July to December, an improvement was noted in blood culture #2 collection, rising from 66% to 84% (Figure 4). Chi-Square analysis compared July to December and determined that there was a statistically significant difference in blood culture #2 collection, $\chi 2$ (1, n = 168) = 7.23, p = .007.

Fluid Resuscitation.

This element of the bundle evaluated if a fluid bolus of 30 milliliters per kilogram was administered to patients with sepsis-induced hypo-perfusion. This analysis focused on 249 patients who either had any MAP < 65mmhg or initial lactate >2 during their ED stay (Figure 5). In order to be considered adherent to the standard, the amount of fluid administered had to be within 100 milliliters of the calculated fluid bolus. This data was recorded as a categorical variable, yes or no. Over the 6-month period, Chi-square analysis established there were no statistically significant differences in the adherence of fluid administration between the months (Table 4).

Intervention from Time-of –Alert

The two remaining elements of the 3-hour bundle were further divided to determine adherence. Considering the door-to-alert time, it was prioritized that the lactate should result within one hour of the sepsis alert. The time of the lactate result was compared to the alert time, and adherence was documented as yes or no. In July 76% of the patients had a lactate result within one hour, compared to 90% in December (Figure 6). Using Chi-Square statistics, it was determined there was no difference in lactate results within one hour of alert between July to August, August to September, September to October, October to November, and November to December (Table 4). When July and December were compared, it was determined there was a statistically significant difference in lactates resulted within one hour, $\chi 2$ (1, n = 168) = 5.52, p = .019.

The administration of antibiotics within one hour of alert was further divided to determine adherence to this bundle element better. The administration of the first and second antibiotic within one hour of the alert was analyzed. Any patient alerted who was then treated for viral illness, such as influenza, or any other non-infectious process was removed from the sample (n = 518). Over the six-month period, an improvement was apparent in the administration of the first antibiotic within one-hour alert. In July adherence was 81%, it peaked in October at 95%, and was 91% in December (Figure 7). Chi-Square statistics determined that there was no statistically significant difference in the administration of the first antibiotic within 1 hour of alert when evaluated from month-to-month (Table 4).

Adherence for the second antibiotic was calculated similarly as the first antibiotic, however, if a second antibiotic was not ordered, then that patient was removed from the total sample (n = 351). The administration of the second antibiotic was achieved 53% of the time in

July, peaked in October at 69%, and at the conclusion of the project in December was 68% (Figure 7). Chi-Square analysis determined there were no statistically significant differences in the administration of the second antibiotic within 1 hour of alert from month-to-month (Table 4).

Intervention from Time-Zero

Time zero was the time patient's ED arrival time. The first data point evaluated if the lactate resulted within 3-hours of time zero. In July 84% of the patients had a lactate resulted within 3 hours of time zero, compared to 96% in December (Figure 6). Chi-Square analysis established that there were statistically significant differences in the adherence to this standard when the months of July and December were compared, $\chi 2$ (1, n = 168) = 6.31, p = .012. Further month-to-month analysis did not reveal any statistically significant differences.

The administration of the first antibiotic within one hour of arrival was 36% adherence in July and increased to 51% in December (Figure 8). Month-to-month analysis did not reveal any statistically significant differences when using Chi-Square statistics; however, the comparison of July and December was approaching statistical significance, $\chi 2$ (1, n = 166) = 3.741, p = .053.

Over the 6-month period, the administration of the second antibiotic within one hour of arrival increased from 18% in July to 37% in December. This result was statistically significant when July and December were compared, $\chi 2$ (1, n = 115) = 4.88, p = .027 (Table 4) (Figure 8). Additional month-to-month comparisons did not result in any statistically significant differences in antibiotic #2 administration within 1 hour of time zero.

Discussion

Summary

The implementation of an interprofessional ED sepsis QI initiative improved adherence to 3 of the 4 major elements of the 3-hour sepsis management bundle. The 3 major elements that improved included lactate measurement, blood culture collection before antibiotic

administration, and the delivery of antibiotics within one hour, while the fluid resuscitation element was the only element that did not improve. The QI initiative did not change the incidence of all-cause in-hospital mortality for sepsis alerted patients over the course of the project period. This could be attributed to the seasonal variation of the project period. Future analysis of sepsis mortalities would be more meaningful if compared to the prior annual year.

The demographic variables that were collected and analyzed revealed a homogenous sample. This provided an excellent baseline to assess intervention adherence. In November, 110 patients were sepsis alerted. This was the highest of any month and may be related to influenza. As a result, many of the bundle elements demonstrated decreased adherence during this month when compared to the prior month. Potential factors that could have contributed to the decreased adherence are increased patient volume and clinician workload.

Early recognition of sepsis, a clinically essential action, provides an opportunity for clinicians to deliver time-sensitive interventions to septic patients swiftly. The interprofessional QI initiative built upon sepsis procedures that were already in place, including the "sepsis-alert" process. To capture the lag between ED arrival and the action of initiating a sepsis alert the door-to-sepsis-alert metric was created. Preferably, sepsis would be recognized during the first contact with a clinician to facilitate early intervention. In the ED, it is common practice that a nurse triages patients before contact with a LIP. Ideally, the door-to-sepsis-alert metric would be similar to the time between patient arrival to the ED and triage by an RN. This would demonstrate early recognition. Although not statistically significant, over the 6-month project period the decrease in the door-to-sepsis-alert metric was clinically significant. For example, the mean door-to-alert time decreased by 37 minutes over the 6-month period. The median decreased by 10 minutes over the project period (38 minutes to 28 minutes). Five patients in the

sample were sepsis-alerted by EMS during transport to the hospital. This notification, similar to S-T Elevation Myocardial Infarction and Stroke notifications, could eliminate delays in care for septic patients. Future QI work should consider including EMS personnel in the interprofessional team to further decrease the amount of time to sepsis-alert for patients transported by EMS.

Consistently throughout the project period, there was a focus on encouraging the practice of obtaining rectal temperatures in patients who had an altered mental status, an increased respiratory rate, unexplained persistent tachycardia, elevated oral temperatures that did not meet the threshold of febrile, rigors, or need for oxygen therapy. This educational focus, combined with the standardization of equipment in each exam room may have influenced earlier recognition of sepsis throughout the project period.

With the exception of fluid resuscitation, the analysis of the bundle elements revealed improved adherence to the guideline recommendations. Fluid resuscitation was a difficult data point to abstract in accordance with the 2016 SSC Guidelines, due to the assessment of multiple variables and time constraints. Challenges include the manual extraction of data from multiple locations in the EHR and inconsistent documentation practices. As a result, data were collected to reflect the ordered fluid resuscitation during the entire ED stay. Despite recommendations, adherence to fluid administration guidelines varied due to independent clinical decision-making. Anecdotally, confounding factors included hesitation when caring for patients with heart failure, end-stage renal disease, and pulmonary infections. It is also pertinent to consider that the QI process did not focus any specific efforts on adherence to this metric, as other metrics were prioritized during the QI process. Furthermore, the sepsis order set did not display fluid orders in

the format of 30ml/kg but instead had 2 separate liter volume orders that could be selected by the provider.

Although not all statistically significant, the administration of antibiotics within one hour had clinically significant improvements during the QI initiative. The delivery of antibiotics within one hour of sepsis alert peaked in October. The administration of antibiotic #1 within one hour of alert reached 95%, and it was hypothesized that any percentage above 95 would be difficult to achieve due to medically complex patients and medical decision-making. In November, decreased adherence could have been related to an increased patient volume, increased clinician workload or changes in the distribution of antibiotics within the hospital. Changes in the distribution of antibiotics within the hospital were the result of conservation efforts related to a large-scale natural disaster that occurred at the site of antibiotic production, thus leading to supply concerns regarding antibiotic availability.

The collection of lactates within one hour of alert or within 3 hours of time zero had statistically and clinically significant improvements in adherence. Future QI work should analyze the repetition of these lactates in accordance with guidelines.

The primary challenge with the ED sepsis QI initiative concerned data collection. Currently, the ED does not have an automated report that gathers information from the EHR. Each sepsis chart audit took approximately 10 minutes to complete. To remain a sustainable initiative, an automated report is required. At this time, sustainability, a desired achievement of this project, is not firmly established without an automated report. An automated report will provide the opportunity to generate progress reports to the clinicians taking care of these patients. With less time focused on data abstraction, more time will be available for interventions to address gaps in clinical practice and knowledge. It is recommended that

institutions consider creating sepsis visual management systems that readily display progress reports to staff members concerning guideline adherence.

Some limitations regarding the sample should be considered. The first limitation is it only includes patients who were sepsis-alerted in the ED. The ED sepsis alert process is not the same as being diagnosed with sepsis. The second consideration is that not all septic patients may have been sepsis alerted due to human factors and independent decision-making. The practice of treating a patient for sepsis and not initiating a sepsis-alert was strongly discouraged by the QI team throughout the project period but nevertheless occurred.

In summary, from July to December, the QI project demonstrated improved adherence to the 3-hour bundle in 8 of 9 established metrics. Five of these improvements were statistically significant. The improvement might be attributed to the interprofessional approach to ED sepsis optimization. This approach not only provided information regarding potential barriers to sepsis identification and management but also provided methods to address these obstacles.

Nursing Practice Implications

Adherence to evidence-based sepsis guidelines has the potential to reduce morbidity and mortality from sepsis. This quality improvement initiative empowered nursing staff to screen patients for sepsis, activate sepsis alerts and initiate bundled care as appropriate. The evaluation of the quality improvement process identified interventions that were successful at improving adherence to the standards. This information can lead to continuous QI as clinicians and administrators strive to improve the management of sepsis in their setting. The improved management of sepsis should lead to improved patient outcomes, which may have secondary and tertiary effects such as reduced ICU utilization and cost savings.

Considering the increased adherence to the 3-hour sepsis bundle in 3 out of 4 elements, this QI project demonstrates the value of a dedicated nurse to monitoring sepsis management. It is recommended that institutions consider developing a "Sepsis Coordinator" position. Advanced Practice Registered Nurses, such as Clinical Nurse Specialists, would be appropriate to hire into these positions. Sepsis Coordinators could assist with the collection of meaningful data, providing feedback to the staff, and translating new research into practice.

Products of the Scholarly Project

Products of this Scholarly Practice Project include the formation of an interprofessional sepsis coalition, a revised ED sepsis procedure, sepsis screening during triage, revised order sets, and improved text paging communication and a visual management system for QI. Additional products include the creation of a DNP Scholarly Project Report, an abstract, a manuscript for publication, a poster presentation, and a potential conference presentation.

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Table 1

Emergency department sepsis alert mean age by month, 2017 (n=525)

Month	N	Mean	Standard Deviation
July	80	56.4	17.9
August	84	56.4	16.9
September	79	62.4	18.7
October	84	61.0	18.5
November	110	58.5	17.4
December	88	61.2	16.2

Table 2

Emergency Department Sepsis Alert Demographic Information, 2017 (n = 525)

Characteristic	July n (%)	August n (%)	September n (%)	October n (%)	November n (%)	December n (%)
Number of Sepsis Alerts	80	84	79	84	110	88
Sex						
Male	33 (59)	40 (48)	44 (56)	39 (46)	63 (57)	51 (58)
Female	47 (41)	44 (52)	35 (44)	45 (54)	47 (43)	37 (42)
Emergency Severity Index						
Level 1 and 2	53 (66)	55 (66)	58 (73)	65 (77)	82 (75)	66 (75)
Level 3 and 4	27 (34)	29 (35)	20 (25)	19 (23)	27 (25)	22 (25)
Level Missing			1 (1.3)		1 (0.9)	
Hospital Admission	76 (95)	77 (92)	72 (91)	80 (95)	103 (94)	82 (93)
ICU Admission	18 (24)	12 (16)	15 (21)	15 (19)	21 (20.4)	10 (12)
Mortality	3	4	4	5	3[b]	5

Note: [a]Emergency Severity Index Level is a triage categorization provided by nursing staff to indicate the patient's acuity level, a level 1 patient is the most critically ill while a level 5 is the least critically ill. [b]One medically complex patient remained hospitalized in February 2018.

Table 3

Chi-Square statistics for demographic variables, July to December 2017[a] (n=525).

Characteristic	July to Aug		Aug to Sept		Sept to Oct		Oct to Nov		Nov to Dec	
	χ^2	*p*	χ^2	*p*	χ^2	*p*	χ^2	*p*	χ^2	*p*
Gender	0.673	.412	1.063	.302	1.399	.237	2.246	.134	0.009	.923
ESI Level[b]	0.11	.917	1.513	.219	0.202	.653	0.121	.728	0.001	.970
Disposition[c]	0.908	.341	0.146	.702	1.087	.297	0.228	.633	0.16	.898
ICU Admission[d]	1.592	.207	0.691	.406	0.104	.747	0.076	.782	2.197	.138
Mortality[e]		1.000		1.000		1.000		.243		.245

Note: [a]All degrees of freedom equal 1. [b]Compared groups are ESI Level 1 and 2 to ESI Level 3 and 4 patients, n = 523. [c]Compared admitted patients to discharged patients, n = 523. [d]Of admitted patients compares monthly ICU admissions, n = 490. [e]Mortality was analyzed using a Fisher's Exact Chi-Square test.

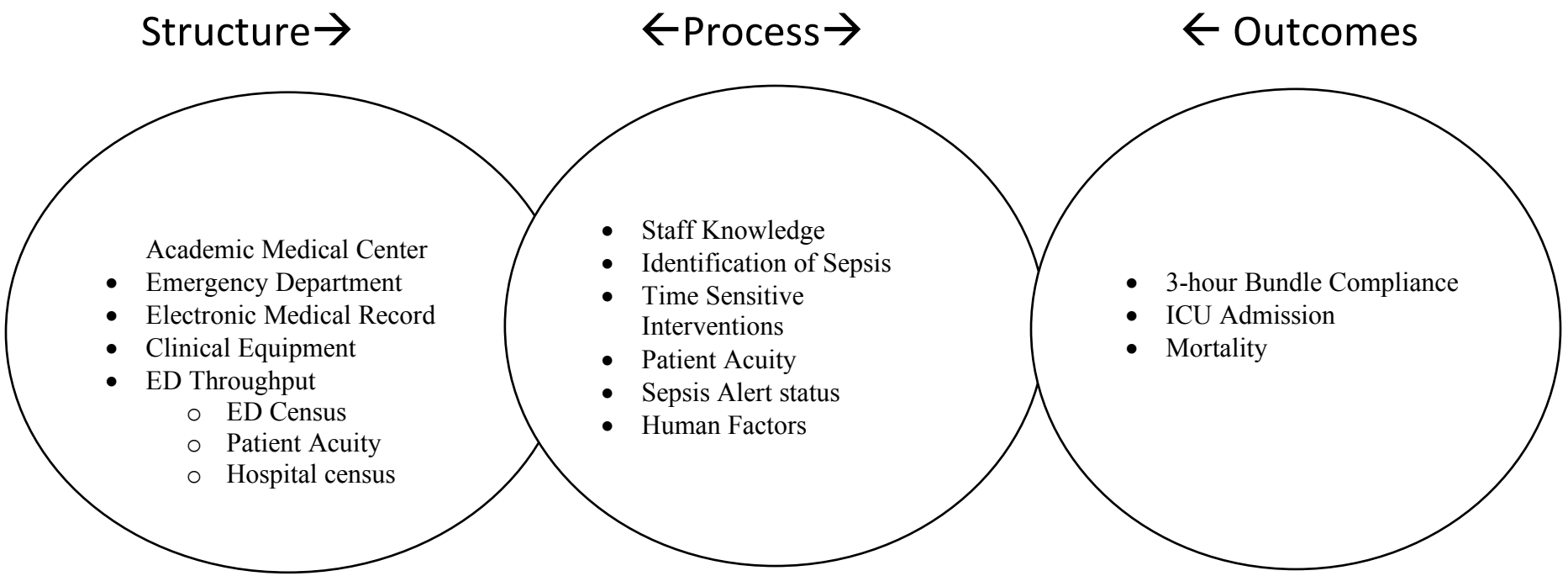
Table 4

Chi-Square statistics for interventions, July to December 2017[ab] (n = 525).

Characteristic	July to Aug		Aug to Sept		Sept to Oct		Oct to Nov		Nov to Dec		July to Dec	
	χ^2	*p*	χ^2	*p*	χ^2	*p*	χ^2	*p*	χ^2	*p*	χ^2	*p*
Blood Culture # 1	0.183	.669	0.160	.690	0.344	.558	2.583	.108	3.295	.070	8.429	.004
Blood Culture # 2	0.147	.702	0.65	.798	0.337	.561	2.698	.100	1.437	.231	7.230	.007
Fluid Resuscitation	0.695	.404	1.261	.262	0.529	.467	0.616	.433	0.008	.928	0.56	.814
From Time of Alert												
Lactate resulted in 1 hour	0.126	.722	1.055	.304	0.709	.400	1.507	.220	0.533	.465	5.517	.019
Antibiotic # 1 started	3.713	.054	0.433	.510	2.446	.118	3.646	.056	0.638	.424	3.099	.078
Antibiotic # 2 started	0.040	.841	0.127	.722	2.339	.126	0.151	.697	0.99	.753	2.934	.087
From Time Zero												
Lactate resulted in 3 hours	3.318	.069	0.043	.836	0.240	.624	0.075	.784	0.639	.424	6.312	.012
Antibiotic #1 started	1.932	.165	0.003	.955	0.161	.688	0.349	.555	0.454	.500	3.741	.053
Antibiotic #2 started	0.004	.949	1.981	.159	0.016	.901	0.011	.918	0.634	.426	4.882	.027

Note: [a]All degrees of freedom equal 1. [b]Statistical significance is $p < .05$.

Figure 1. Interpretation of theoretical framework: Donabedian's Structure, Process, Outcome.



Reference: (Donabedian, 1988).

Figure 2. Triage sepsis screening tool implemented November 27th, 2017.

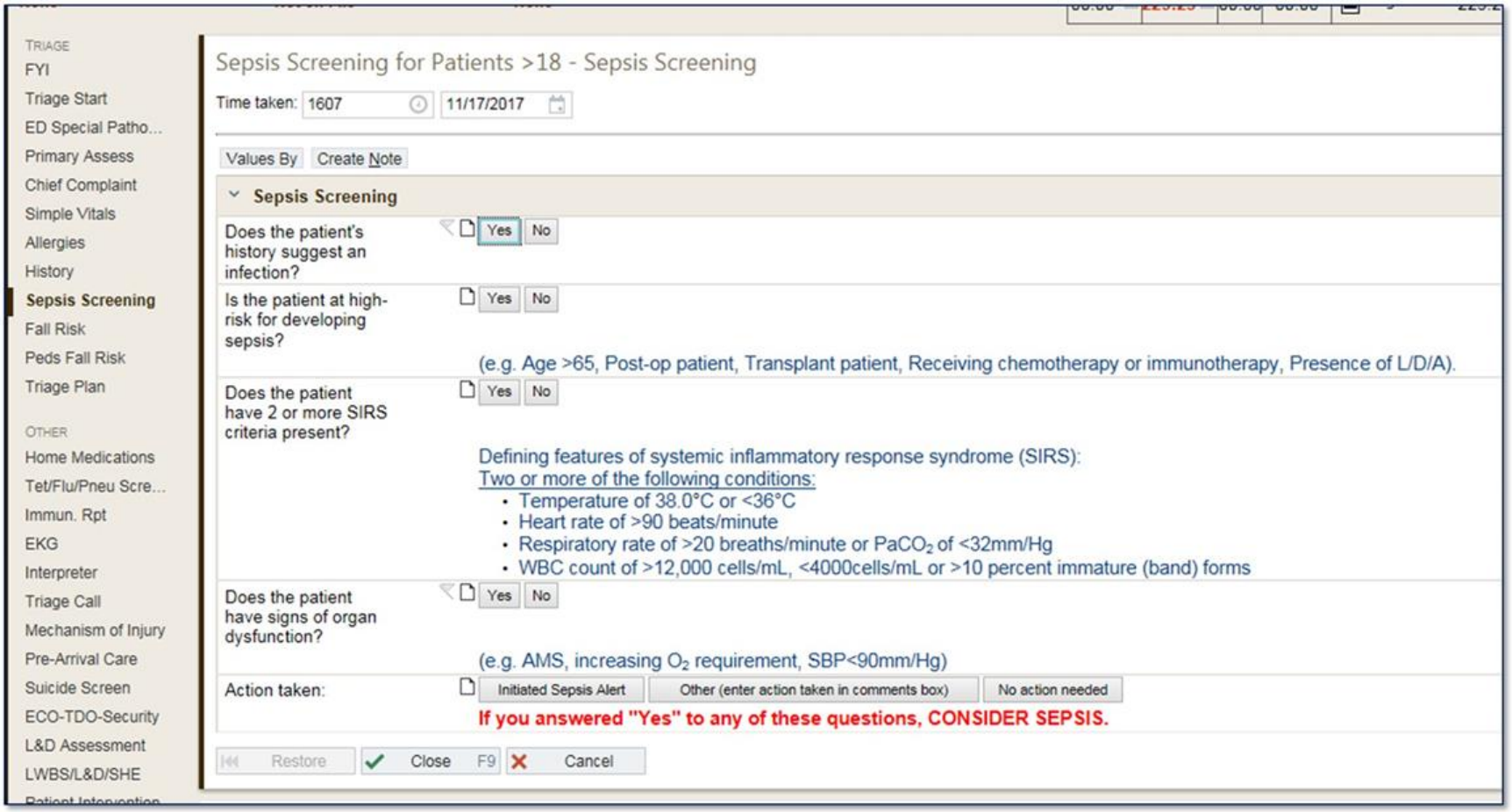
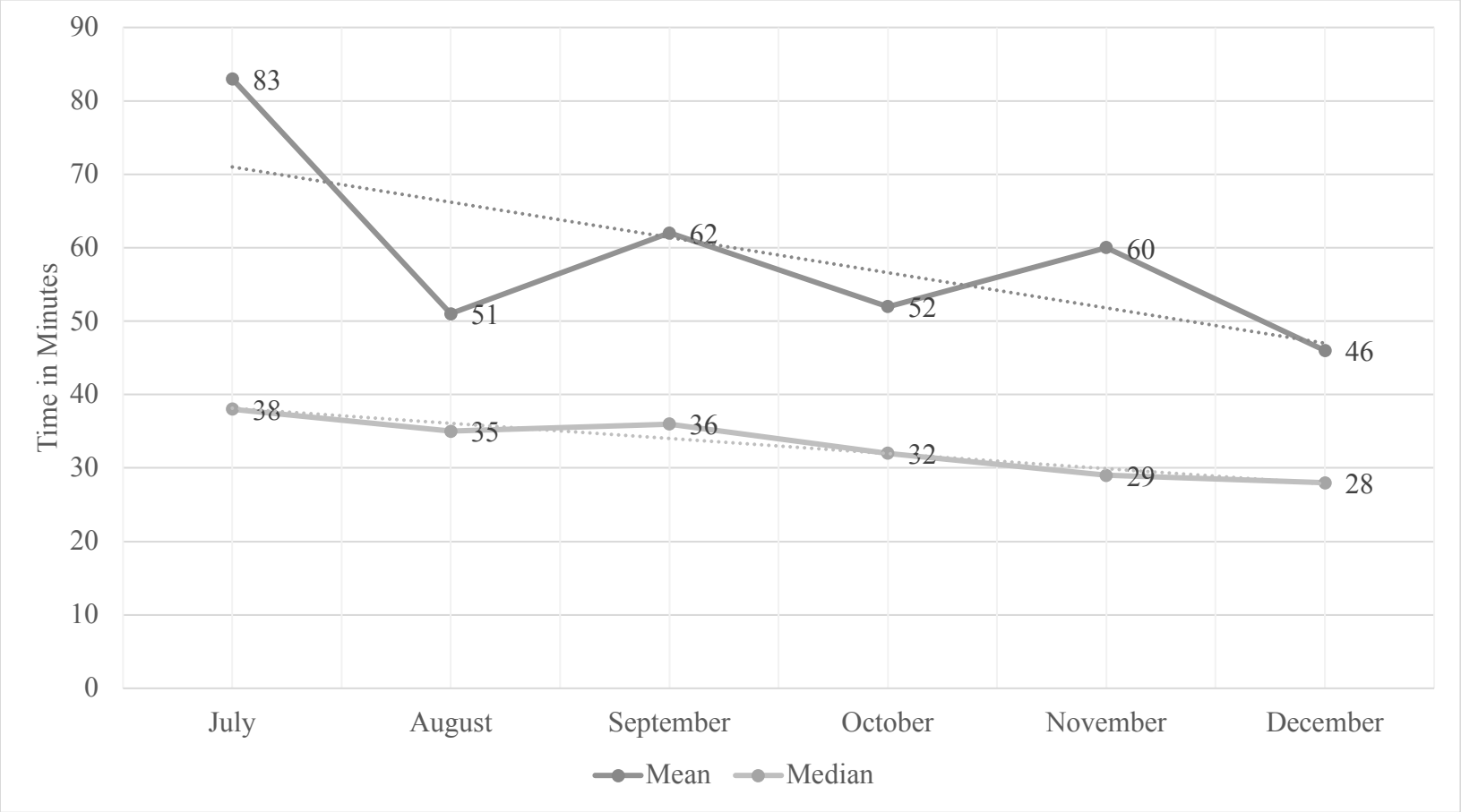
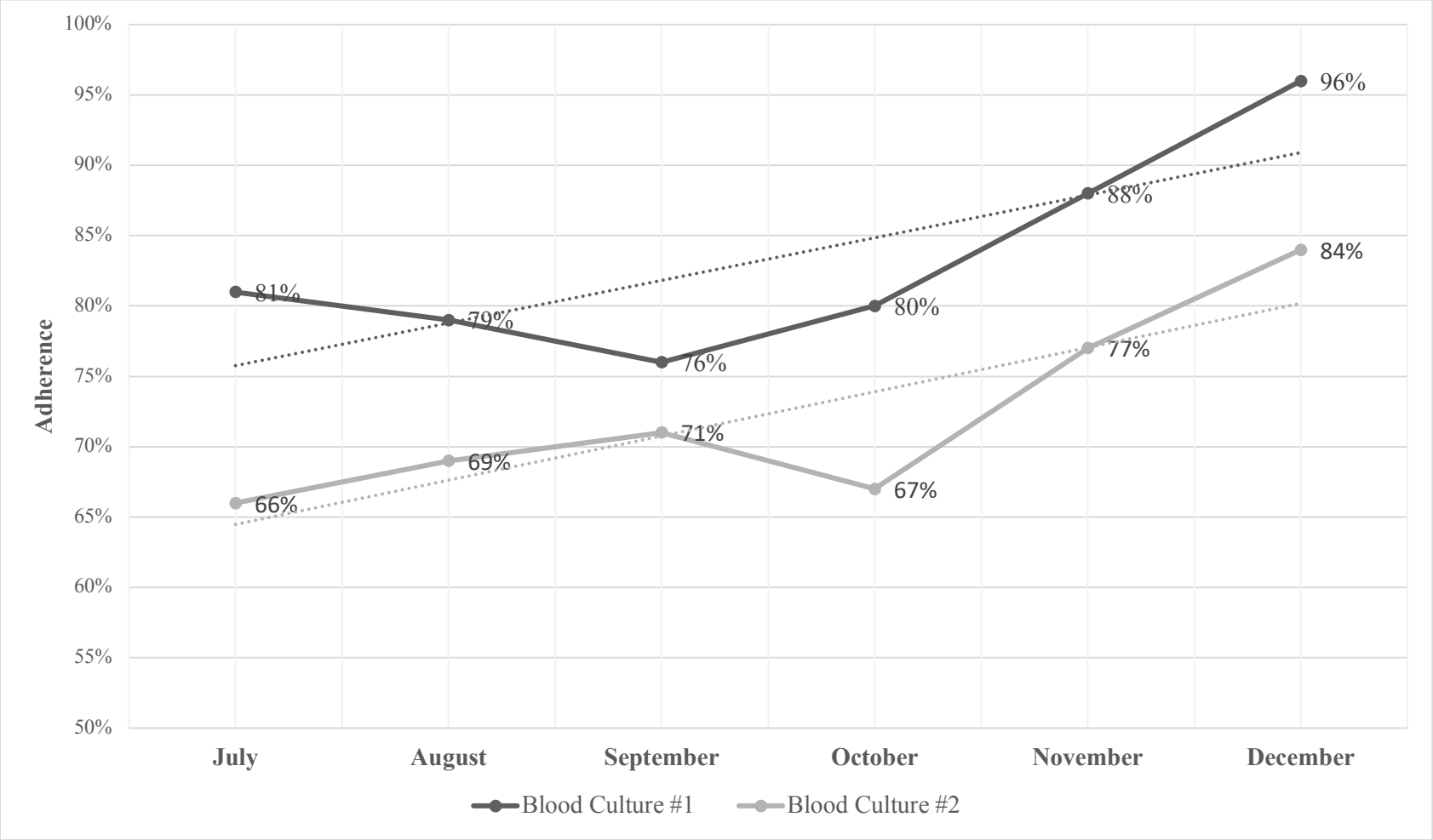


Figure 3. Door to Sepsis Alert Measures of Central Tendency, 2017[a] (n = 525).



[a]All times rounded to the nearest minute.

Figure 4. Percentage of blood cultures collected prior to antibiotic administration, 2017[a]. (n = 525).



[a]All figures rounded to the nearest whole number. Statistically significant differences in adherence when July is compared to December for blood culture #1, $\chi 2$ (1, n = 168) = 8.43, p = .004, and blood culture #2, $\chi 2$ (1, n = 168) = 7.23, p = .007.

Figure 5. Fluid resuscitation of 30ml/kg for hypotension or lactate >2 received during entire ED length of stay.

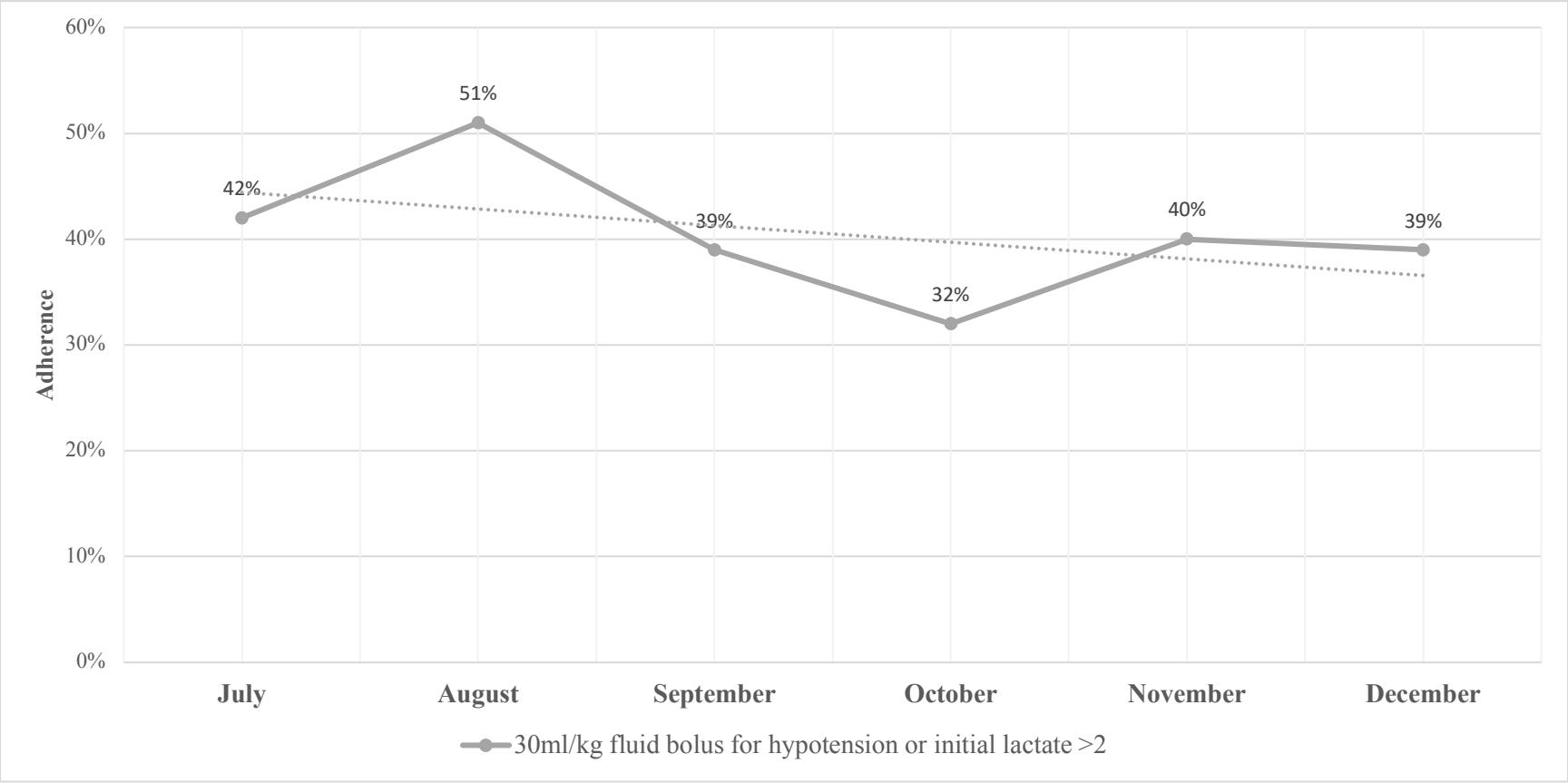
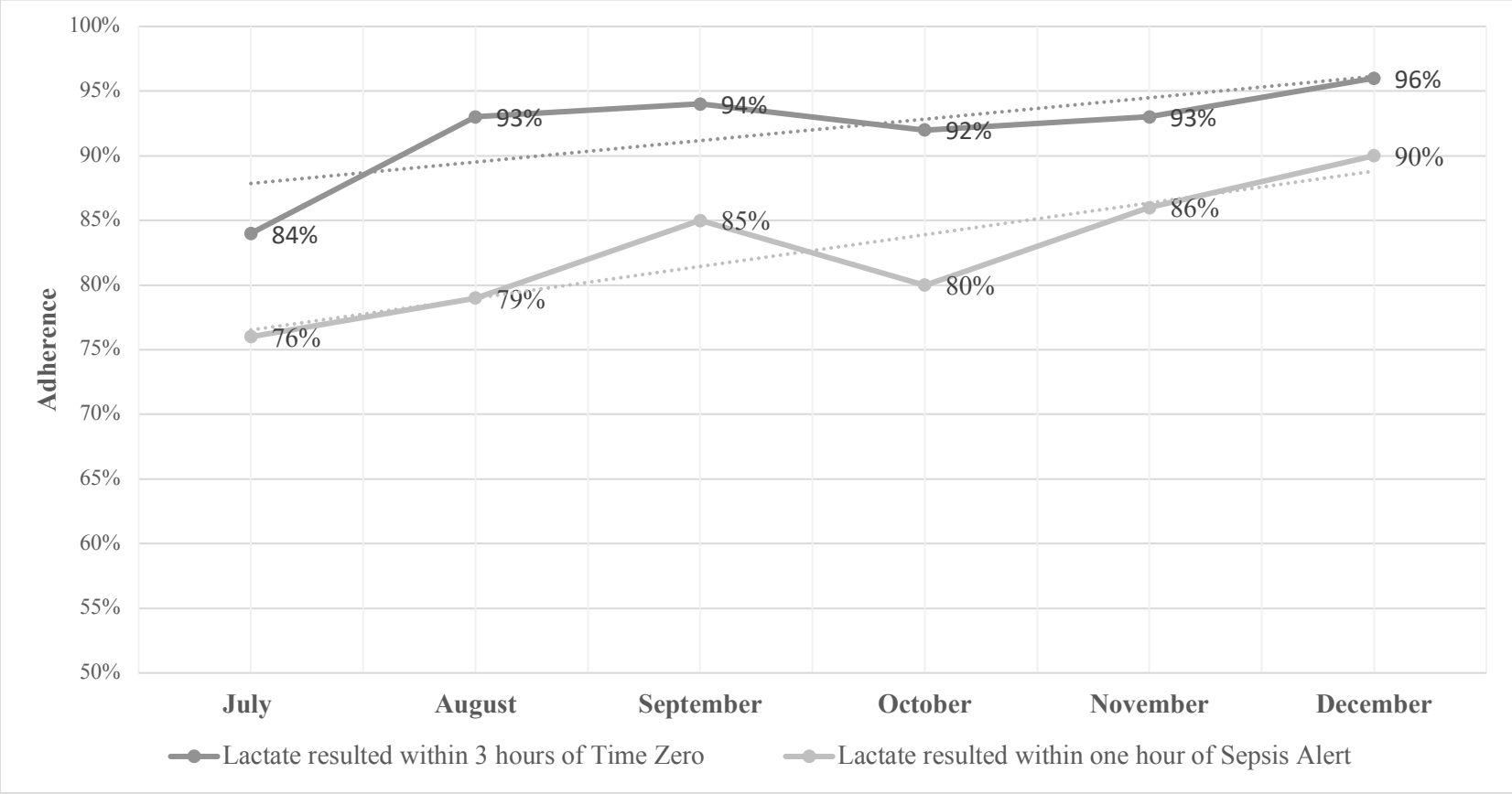
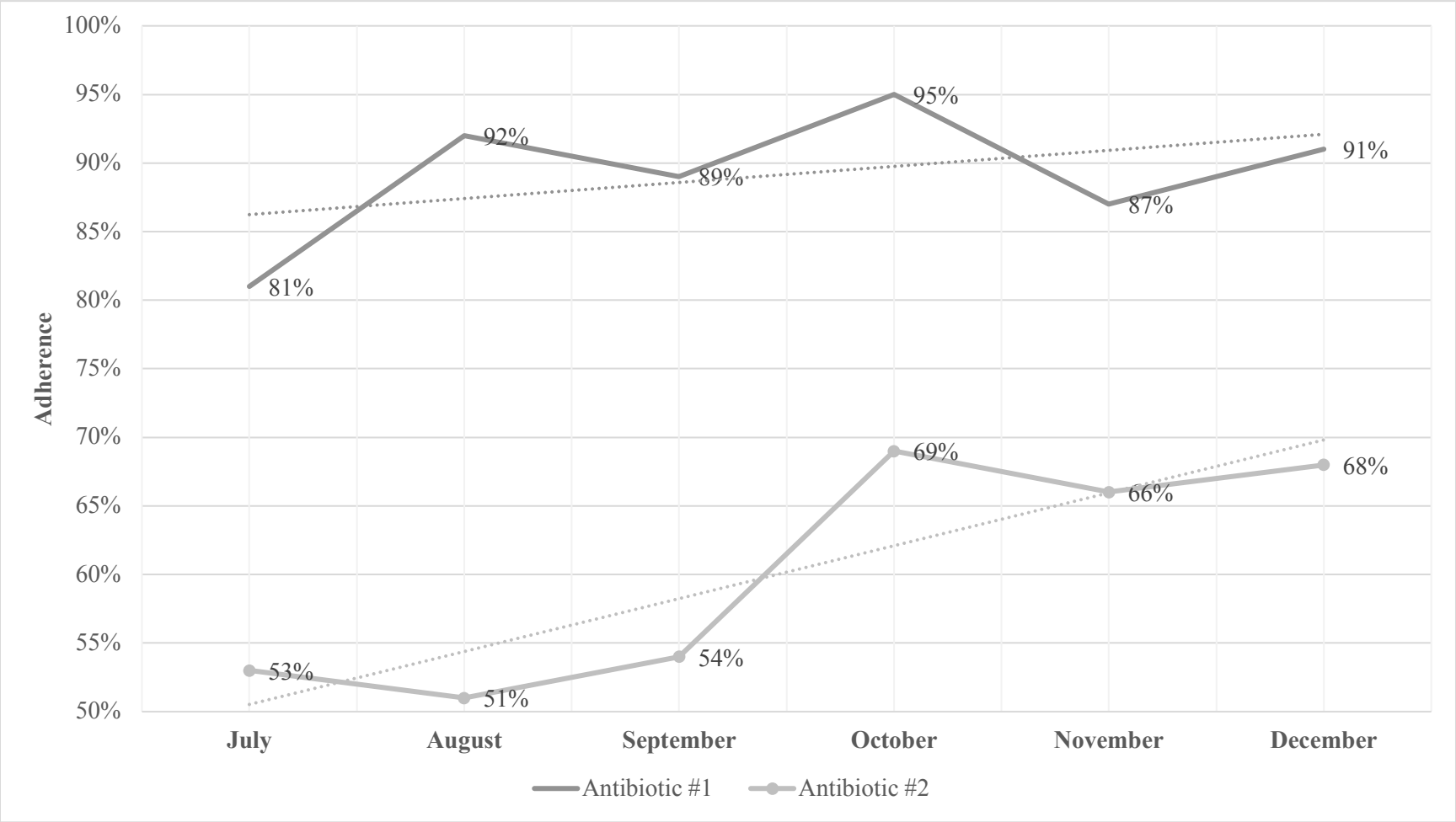


Figure 6. Percentage of lactates resulted by standard for Emergency Department sepsis alerts, 2017[a]. (n = 525).



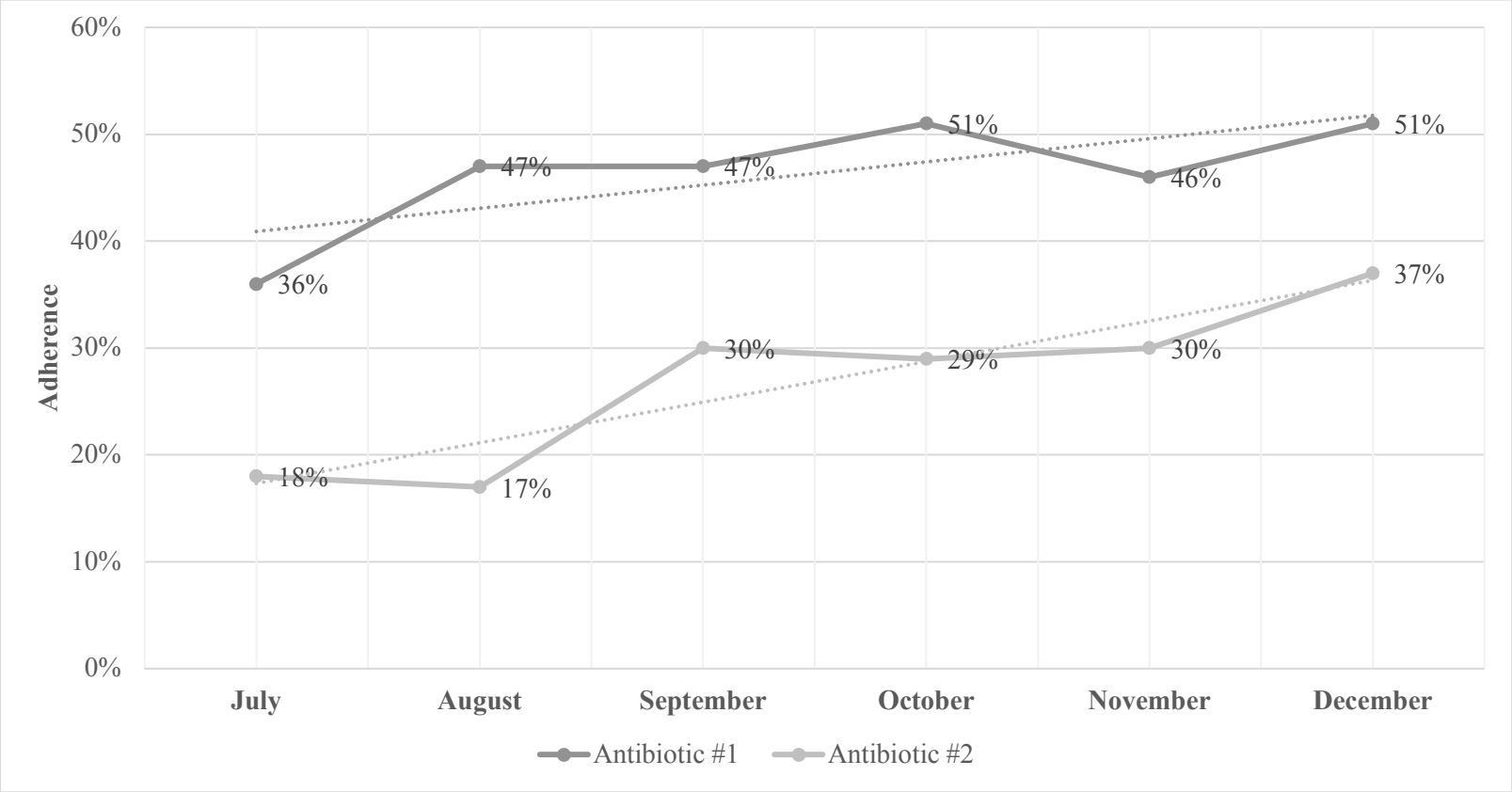
[a]All percentages rounded to the nearest whole number. The comparison of July to December established statistically significant differences in lactates resulted within one hour of sepsis alert, $\chi 2$ (1, n = 168) = 5.52, p = .019. The comparison of July to December established statistically significant differences in lactates resulted within 3 hours of sepsis alert, $\chi 2$ (1, n = 168) = 6.31, p = .012.

Figure 7. Percentage of antibiotics administered within one hour of Emergency Department Sepsis Alert, 2017[ab].



[a]Antibiotic #1 n = 518. [b]Antibiotic #2 n = 351.

Figure 8. Percentage of Emergency Department sepsis alerted patients given antibiotics within one hour of arrival, 2017[ab.]



[a]Antibiotic #1 n = 525. [b]Antibiotic #2 n = 351. The comparison of July to December was approaching statistically significant differences in antibiotic #1 administration within 1 hour of ED arrival, $\chi 2$ (1, n = 166) = 3.741, p = .053. The comparison of July to December established statistically significant differences in antibiotic #2 administration within 1 hour of ED arrival, $\chi 2$ (1, n = 115) = 4.88, p = .027.

Appendix A

Last Updated: Version 5.2

NQF-ENDORSED VOLUNTARY CONSENSUS STANDARDS FOR HOSPITAL CARE

Measure Information Form Collected For: CMS Only

Measure Set: Sepsis

Set Measure ID #: SEP-1

Performance Measure Name: Early Management Bundle, Severe Sepsis/Septic Shock

Description: This measure focuses on adults 18 years and older with a diagnosis of severe sepsis or septic shock. Consistent with Surviving Sepsis Campaign guidelines, it assesses measurement of lactate, obtaining blood cultures, administering broad spectrum antibiotics, fluid resuscitation, vasopressor administration, reassessment of volume status and tissue perfusion, and repeat lactate measurement. As reflected in the data elements and their definitions, the first three interventions should occur within 3 hours of presentation of severe sepsis, while the remaining interventions are expected to occur within 6 hours of presentation of septic shock.

Rationale: The evidence cited for all components of this measure is directly related to decreases in organ failure, overall reductions in hospital mortality, length of stay, and costs of care.

A principle of sepsis care is that clinicians must rapidly treat patients with an unknown causative organism and unknown antibiotic susceptibility. Since patients with severe sepsis have little margin for error regarding antimicrobial therapy, initial treatment should be broad spectrum to cover all likely pathogens. As soon as the causative organism is identified, based on subsequent culture and susceptibility testing, de- escalation is encouraged by selecting the most appropriate antimicrobial therapy to cover the identified pathogen, safely and cost effectively (Dellinger, 2012).

Multicenter efforts to promote bundles of care for severe sepsis and septic shock were associated with improved guideline compliance and lower hospital mortality (Ferrer, 2008 and Rhodes, 2015). Even with compliance rates of less than 30%, absolute reductions in mortality of 4-6% have been noted (Levy, 2010 and Ferrer, 2008). Absolute reductions in mortality of over 20% have been seen with compliance rates of 52% (Levy, 2010). Coba et al. has shown that when all bundle elements are completed and compared to patients who do not have bundle completion, the mortality difference is 14% (2011). Thus, there is a direct association between bundle compliance and improved mortality. Without a continuous quality initiative (CQI), even these compliance rates will not improve and will decrease over time (Ferrer, 2008). Multiple studies have shown that, for patients with severe sepsis, standardized order sets, enhanced bedside monitor display, telemedicine, and comprehensive CQI feedback is feasible, modifies

clinician behavior, and is associated with decreased hospital mortality (Thiel, 2009; Micek, 2006; Winterbottom, 2011; Schramm, 2011; Nguyen, 2007; Loyola, 2011).

Type of Measure: Process

Improvement Noted As: An increase in the rate

Numerator Statement: Patients who received ALL of the following:
Received 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:

- Repeat lactate level measurement only if initial lactate level is elevated AND ONLY if Septic Shock present:

Received within three hours of presentation of septic shock:

- Resuscitation with 30 ml/kg crystalloid fluids

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

- Vasopressors

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

- Repeat volume status and tissue perfusion assessment consisting of either
    - A focused exam including:
        - Vital signs, AND
        - Cardiopulmonary exam, AND
        - Capillary refill evaluation, AND
        - Peripheral pulse evaluation, AND
        - Skin examination

        OR
    - Any two of the following four:
        - Central venous pressure measurement
        - Central venous oxygen measurement
        - Bedside Cardiovascular Ultrasound
        - Passive Leg Raise or Fluid Challenge

Included Populations: As described above

Excluded Populations:
None

Data Elements:

- *Bedside Cardiovascular Ultrasound Date*
- *Bedside Cardiovascular Ultrasound Performed*
- *Bedside Cardiovascular Ultrasound Time*
- *Blood Culture Collection*
- *Blood Culture Collection Acceptable Delay*
- *Blood Culture Collection Date*

- *Blood Culture Collection Time*
- *Broad Spectrum or Other Antibiotic Administration*
- *Broad Spectrum or Other Antibiotic Administration Date*
- *Broad Spectrum or Other Antibiotic Administration Selection*
- *Broad Spectrum or Other Antibiotic Administration Time*
- *Capillary Refill Examination Date*
- *Capillary Refill Examination Performed*
- *Capillary Refill Examination Time*
- *Cardiopulmonary Evaluation Date*
- *Cardiopulmonary Evaluation Performed*
- *Cardiopulmonary Evaluation Time*
- *Central Venous Oxygen Measurement*
- *Central Venous Oxygen Measurement Date*
- *Central Venous Oxygen Measurement Time*
- *Central Venous Pressure Measurement*
- *Central Venous Pressure Measurement Date*
- *Central Venous Pressure Measurement Time*
- *Crystalloid Fluid Administration*
- *Crystalloid Fluid Administration Date*
- *Crystalloid Fluid Administration Time*
- *Documentation of Septic Shock*
- *Fluid Challenge Date*
- *Fluid Challenge Performed*
- *Fluid Challenge Time*
- *Initial Hypotension*
- *Initial Lactate Level Collection*
- *Initial Lactate Level Date*
- *Initial Lactate Level Result*
- *Initial Lactate Level Time*
- *Passive Leg Raise Exam Date*
- *Passive Leg Raise Exam Performed*
- *Passive Leg Raise Exam Time*
- *Peripheral Pulse Evaluation Date*
- *Peripheral Pulse Evaluation Performed*
- *Peripheral Pulse Evaluation Time*
- *Persistent Hypotension*
- *Repeat Lactate Level Collection*
- *Repeat Lactate Level Date*
- *Repeat Lactate Level Time*
- *Septic Shock Present*
- *Septic Shock Presentation Date*
- *Septic Shock Presentation Time*
- *Severe Sepsis Present*
- *Severe Sepsis Presentation Date*

- *Severe Sepsis Presentation Time*
- *Skin Examination Date*
- *Skin Examination Performed*
- *Skin Examination Time*
- *Vasopressor Administration*
- *Vasopressor Administration Date*
- *Vasopressor Administration Time*
- *Vital Signs Review Date*
- *Vital Signs Review Performed*
- *Vital Signs Review Time*

Denominator Statement: Inpatients age 18 and over with an *ICD-10-CM Principal or Other Diagnosis Code* of Sepsis, Severe Sepsis, or Septic Shock.

Included Populations: Discharges age 18 and over with an *ICD-10-CM Principal or Other Diagnosis Code* of Sepsis, Severe Sepsis, or Septic Shock as defined in Appendix A, Table 4.01.

Excluded Populations:

- Directive for Comfort Care or Palliative Care within 3 hours of presentation of severe sepsis
- Directive for Comfort Care or Palliative Care within 6 hours of presentation of septic shock
- Administrative contraindication to care within 6 hours of presentation of severe sepsis
- Administrative contraindication to care within 6 hours of presentation of septic shock
- Length of Stay >120 days
- Transfer in from another acute care facility
- Patients with severe sepsis who are discharged within 6 hours of presentation
- Patients with septic shock who are discharged within 6 hours of presentation
- Patients receiving IV antibiotics for more than 24 hours prior to presentation of severe sepsis.

Data Elements:

- *Administrative Contraindication to Care, Septic Shock*
- *Administrative Contraindication to Care, Severe Sepsis*
- *Admission Date*
- *Birthdate*
- *Directive for Comfort Care or Palliative Care, Septic Shock*
- *Directive for Comfort Care or Palliative Care, Severe Sepsis*
- *Discharge Date*
- *Discharge Disposition*
- *Discharge Time*
- *Transfer From Another Hospital or ASC*

Risk Adjustment: None

Data Collection Approach: Retrospective data sources for required data elements include administrative data and medical record documents. Some hospitals may prefer to gather data concurrently by identifying patients in the population of interest. This approach provides opportunity for improvement at the point of care/service. However, complete documentation includes the principal or other ICD-10-CM diagnosis and procedure codes, which require retrospective data entry.

Data Accuracy: Variation may exist in the assignment of ICD-10-CM codes; therefore, coding practices may require evaluation to ensure consistency**.**

Measure Analysis Suggestions: Hospitals may wish to aggregate the reasons for failure to meet this measure so that gaps in care may be identified and educationally addressed.

Sampling: Yes, please refer to the measure set specific sampling requirements and for additional information see the Population and Sampling Specifications.

Data Reported As: Aggregate rate generated from count data reported as a proportion

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(The Joint Commission, 2017)

Appendix B

Study	Subjects and Setting	Design	Intervention and Comparison Intervention	Outcomes
Seymour, et al., 2016	Primary Cohort- Encounters from 2010-2012 at 12 community and academic hospitals in the UPMC health care system. Of 1,309,025 records 148,907 encounters had suspected infection and were evaluated. Split the patients 50/50 to create a derivation and validation cohort. Four External Data Sets of 706,399 patients seen both pre-hospital and in-hospital were used to confirm the findings of the derivation and validation cohorts. These included patients at KPNC hospitals from 2009-2013; 130 U.S. VA hospitals from 2008-2010, 5 EMS agencies from King County, Washington between 2009-2010 and all patients from a German hospital enrolled in the hospital acquired infection prospective ALERTS system.	Retrospective Cohort Study	SOFA, qSOFA, SIRS, LODS	Construct validity assessed pairwise agreement. For predictive validity, the primary outcome was in hospital mortality. The Secondary outcome was in-hospital mortality or ICU LOS ≥ 3 days. Outside the ICU setting qSOFA was good for predicting in-hospital mortality (AUROC = 0.81; 95% CI, 0.80-0.82) compared to SOFA (AUROC = 0.79; 95% CI, 0.78-0.80; p<.001) and SIRS (AUROC=0.76; 95% CI, 0.75-0.77); p < .001). Findings were reported as similar in external data sets and for the secondary outcome. <u>Limitations:</u> Constructed using patients that already had an infection suspected. Is the original study determining the sepsis screening criteria? Included patients with suspected infection and did not compare to control arm.

Finkelsztein, et al., 2017	n=152 Subjects included those enrolled in The Weill Cornell Medicine Registry and Biobank of Critically Ill Patients. The cohort includes critically ill adults (>18 y.o.) admitted to the ICU at New York Presbyterian Hospital- Weill Cornell Medical Center.	Non-randomized comparison cohort study.	qSOFA and SIRS were measured within eight hours before admission to the ICU.	Primary outcome was all-cause in hospital mortality. Secondary outcomes included ICU-free days from ICU admission to day 28, ventilator free days from initiation of invasive mechanical ventilation to day 28 and organ dysfunction free days and renal dysfunction free days from ICU admission to day 14. qSOFA-positive patients experienced mortality at a rate of 27% compared to qSOFA-negative patients at 6% ($p<0.01$). Patients with 0, 1, 2, or 3, qSOFA criteria had in hospital mortality rates of 0%, 7%, 18%, and 45% respectively ($p<0.001$). "The discrimination of in-hospital mortality using qSOFA (AUC 0.74; 95% CI, 0.66-0.81) was significantly greater compared with SIRS criteria (AUC, 0.59; CI, 0.51-0.67; $p=0.03$)." qSOFA scores ≥ 2 had a 90% sensitivity and 42% specificity for in hospital mortality compared to 93% sensitivity and 12% specificity for SIRS ≥ 2. "ICU free days of qSOFA-positive patients were fewer than qSOFA negative patients [median, 20 days (IQR, 6-24) vs 24 days (IQR, 21-25); $p< 0.001$]. The discrimination of ICU-free days, 22 (i.e. <median of the entire cohort) using qSOFA (AUC, 0.65, 95% CI, 0.57-0.72) was significantly greater compared with SIRS criteria (AUC, 0.54; 95% CI, 0.45-0.62; $p= 0.04$)." <u>Limitations:</u>

				Patients with suspected infection that were admitted to the ICU were included thus eliminating evaluation of those admitted to other inpatient settings.
Freund, et al., 2017	n= 879 International study conducted at 30 total centers (27 in France, 1 in Belgium, 1 in Spain). Twenty-four were academic institutions while 6 were not. Patients who visited one of the Emergency Departments with suspicion of infection were enrolled during a 4-week period in May to June 2016.	Non-randomized comparison cohort study	The study evaluated the prognostic validity of qSOFA compared to SOFA, SIRS and severe sepsis definitions.	The primary outcome was in hospital mortality. Secondary endpoints included ICU admission, ICU stay ≥ 72 hours or a composite of death and ICU stay ≥ 72 hours. Patients with a qSOFA score less than 2 had an in-hospital mortality rate of 3% (95% CI, 2%-5%) compared to patients with a qSOFA score greater than 2 who had a mortality rate of 24% (95% CI, 18%-30%) (absolute difference 21%, 15%-26%). qSOFA predicted in-hospital mortality with a sensitivity of 70% (95% CI, 59%-80%) and a specificity of 79% (95% CI, 76%-82%). SOFA predicted in-hospital mortality with a sensitivity of 73% (95% CI, 61-83%) and a specificity of 70% (95% CI, 67-73%). Patients with a SIRS score ≥ 2 experienced mortality at rate of 11% and had a high sensitivity (93%; 95% CI, 85%-98%) with poor specificity (27%; 95% CI, 24%-31%). An AUROC curve was created for the prediction of in hospital death using qSOFA, SOFA, SIRS and severe sepsis. The highest AUROCs was qSOFA (0.80; 95% CI, 0.74-0.85) followed by SOFA (0.77; 95% CI, 0.71-0.82) compared with SIRS and severe sepsis both at (0.65; 95% CI, 0.59-0.70) ($p < .001$). Fifteen percent (131) patients were admitted to the ICU. Of these patients 34% had ≥ 2 qSOFA criteria, 29% had

				≥two SOFA criteria, 18% had ≥ 2 SIRS criteria and 34% had severe sepsis. Limitations: Calculated qSOFA based upon their worst score during their ED stay rather than serial exams.
Henning, et al., 2017	n=7,637 Two of the cohorts are from a 600-bed urban tertiary care center with approximately 50,000 ED visits annually. The third cohort was from an 800-bed urban academic tertiary care hospital with approximately 100,000 patient care visits annually. Enrollment dates as follows: Cohort 1: Dec 2003- Sep 2004 Cohort 2: Sep 2005- Sep 2006 Cohort 3: Jul 2004-June 2005 Subjects were greater than 18 years of age and had a clinically suspected infection.	Non-randomized comparison cohort study. Secondary analysis of 3 prospectively collected observational cohorts.	qSOFA compared to the 1992 Sepsis (SIRS ≥ 2 plus suspected infection) and severe sepsis (sepsis and organ dysfunction) definitions.	The primary outcome was all-cause in hospital mortality. In hospital mortality of patients with a qSOFA ≥ 2 was 14.2% (12.2%- 16.2%) compared to 2.5% (2.1%-2.9%) for patients with a score less than 2. qSOFA scores greater than 2 predicted in-hospital mortality with a sensitivity of 52% (46%-57%) and specificity was 86% (85%-87%). SIRS + suspected infection had an inpatient mortality rate of 6.8% (6.0%-7.7%). The sensitivity of 1992 Sepsis definition (SIRS + suspected infection) was 83% (79%-87%) and a specificity of 50% (49%-51%). For the 1992, severe sepsis definition the mortality rate was 9.7% (8.5%-10.9%) with a sensitivity of 78% (73%-83%) and a specificity of 64% (63%-65%). Overall the area under the curve for qSOFA was 0.77. Limitations: Unable to fully determine the sensitivity and specificity of the Sepsis-3 septic shock definition due to missing variables. Only included patients admitted from the ED to the hospital.

				Does not report the AUC for 1992 Sepsis and Severe Sepsis definitions.
Churpek, et al., 2016	n=30,677 Adult patients admitted to the University of Chicago, a 500-bed urban tertiary care center between November 2008-January 2016. Patients were included if an infection was suspected and they were in the ED or the wards.	Non-randomized comparison cohort study.	qSOFA was compared to SIRS, NEWS and MEWS.	The primary outcome was in hospital mortality. The secondary outcome was a composite of death or ICU stay any time after suspicion of infection. "Using each patient's highest score during their non-ICU stay, algorithm discrimination for in-hospital mortality in all non-ICU patients was highest for NEWS (AUC 0.77, 95% CI, 0.76-0.79), followed by MEWS (AUC, 0.73, 95% CI 0.71-0.74), qSOFA (AUC 0.69, 95% CI, 0.67-0.70) and lastly SIRS (AUC, 0.65, 95% CI, 0.63-0.66) ($p<0.01$ for all pairwise comparisons)." Sensitivities for inpatient mortality were as follows: NEWS ≥ 9, 72%; MEWS ≥ 5, 71%; qSOFA ≥ 2, 69%; and SIRS ≥ 2 was 94%. For the secondary outcome of any ICU stay or mortality SIRS ≥ 2 was 91% sensitive and 13% specific, qSOFA ≥ was 53.6% sensitive, 66.7% specific; MEWS ≥ 5 was 59.1% sensitive, 70% specific; and NEWS ≥ 7 was 76.5% sensitive and 52.7% specific. <u>Limitations:</u> Used the patients highest score during their non-ICU stay.
Wang, et al., 2016	n=477 The study took place at a single center in Beijing, China from July to December 2015. It included adult patients in the	Non-randomized comparison cohort study. Retrospective analysis was	qSOFA, SOFA, APACHE II and MEDS scores were calculated.	The primary outcome was 28-day mortality. The secondary outcome was ICU admission. Twenty-eight-day mortality for the entire cohort was 27.5%.

	Emergency Department with clinically diagnosed infection. Clinically diagnosed infections were specifically defined with certain characteristics/diagnostic criteria and limited to pneumonia, intraabdominal infections, skin/soft tissue infections, cerebral infections and pyelonephritis.	completed on a prospective observational database.		"The average values of APACHE II, MEDS, SOFA and qSOFA were considerable higher in non-survivors and patients admitted to the ICU than survivors and non-ICU admissions. ($p<0.001$). For 28-day mortality, the AUC of the four tools was as follows; qSOFA (0.666, 95% CI, 0.609-0.723), SOFA (0.729, 95% CI, 0.676-0.782), MEDS (0.751, 95% CI, 0.703-0.800) and APACHE II (0.732, 95% CI, 0.682-0.782). The AUC of qSOFA and MEDS had a statistically significant difference ($P<0.05$). The 28-day mortality of patients with a qSOFA ≥ 2 was significantly higher than patients with a qSOFA < 2 (42.2% vs 17.4%, $p < 0.001$). The AUCs in predicting ICU admission were as follows: qSOFA (AUC 0.636, 95% CI, 0.572-0.700), SOFA (AUC =0.682, 95% CI, 0.624-0.741), MEDS (AUC= 0.661, 95% CI 0.602-0.721) and APACHE II (AUC=0.640, 95% CI, 0.579-0.702). No difference was found in AUCs among the score systems. <u>Limitations:</u> Clinically diagnosed infection included specific diagnostic criteria and diagnoses that may have eliminated certain patients from the study. The patients in this study had a higher median age, 73 years (60-79). Eluding to the fact that this cohort had higher severity of illness it was reported that 92% of the entire cohort had a qSOFA ≥ 2.

April, et al., 2016	n= 214 The population of this study was patients > 17 years old admitted to any ICU from the Emergency Department with suspected infection between August 2012 and February 28th 2015. The study evaluated patients at San Antonio Military Medical Center, an urban tertiary care center with an approximate ED census of 90,000 patients annually.	Non-randomized comparison cohort study (retrospective analysis)	qSOFA and SIRS SOFA and LODS	The primary outcome evaluated the prognostic accuracy of SIRS vs. qSOFA for predicting in hospital mortality. In-hospital mortality was predicted similarly between SIRS and qSOFA with the AUROC values of 0.65 (95% CI, 0.56-0.74) and 0.66 (95% CI 0.57- 0.76) respectively. "Two or more SIRS criteria predicted in-hospital mortality with 97.4% sensitivity, 2.3% specificity, 1.0 positive likelihood ratio and 1.1 negative likelihood ratio." "Two or more qSOFA criteria predicted in-hospital mortality with 89.7% sensitivity, 27.4% specificity, 1.2 positive likelihood ratio and 0.4 negative likelihood ratio." <u>Limitations:</u> Only includes patients admitted from the ED to the ICU and does not include patients with suspected infection admitted to other locations within the hospital. Excluded 61 patients with advanced directives and this is unclear if they were DNR/DNI or intervention based advanced directives.

Raith, et al., 2017	n= 184, 875 Patients greater than 17 years old that were admitted with suspected infection in the Australian and New Zealand Intensive Care Society Adult Patient Database between 2000 and 2015 were screened for inclusion. This included data from 182 ICUs.	Non-randomized comparison cohort study. Retrospectively completed.	SOFA, qSOFA and SIRs.	The primary outcome was in-hospital mortality. The secondary outcome was composite in-hospital mortality and ICU stay of 3+ days. In total 32,634 (18.7%) of patients died in the hospital. In total 102,976 (55.7%) of patients experienced the secondary outcome. In-hospital mortality was discriminated as follows; SOFA (AUROC, 0.753, [99% CI, 0.750-0.757]), SIRS (AUROC, 0.589 [99% CI, 0.585- 0.593]) and qSOFA (AUROC, 0.607, 99% CI [0.603-0.611]). The differences between the groups was statistically significant (p<.001) and as follows: SOFA vs. qSOFA 0.146 [99% CI, 0.142-0.151] SOFA vs SIRS 0.164 [99% CI, 0.159-0.169] qSOFA vs SIRS 0.018 [99% CI, 0.013-0.123]. An increase in a SOFA score of 2+ has better prognostic accuracy for the prediction of in-hospital mortality than SIRS or qSOFA. There were statistically significant findings between the groups when evaluating the secondary outcome. Reported as differences all with p<.001. SIRs vs qSOFA; AUROC difference -0.003; 99% CI (-0.007 to 0) qSOFA vs. SOFA; AUROC difference 0.131; 99% CI (0.127-0.134) SIRS vs. SOFA; AUROC difference 0.127; 99% CI (0.123-0.131)

				Limitations: Patients were already admitted to the ICU and it does not account for the scores of those admitted elsewhere in the hospital. Ultimately it cannot relate the applicability of qSOFA outside the ICU setting.
Williams, et al., 2016	n=8,871 The study took place at a university affiliated Australian hospital's Emergency Department between October 2007 to December 2008 and then again between June 2009 to May 2011. Patients were included if they were over 17 years old and admitted with suspected infection as determined by the ED and Medical Staff.	Non-randomized cohort study.	Sepsis-2 and Sepsis-3 clinical criteria	The primary outcome was 30-day mortality. The secondary outcome was one year mortality. Mortality at 30 days associated with organ dysfunction was similar between Sepsis-2 and Sepsis-3 definitions (Sepsis-2: 12.5%; 95% CI, 10.8%-14.2%; Sepsis-3: 11.4%; 95% CI, 10.1%-12.8%; difference 1.0%, 95% CI -1.1% to 32.%). One year mortality (Sepsis-2: 25.5%; 95% CI, 23.3% to 27.7%; Sepsis-3: 26.3%; 95% CI, 24.4%-28.2%; difference; 0.8%; 95% CI -2.1 to -3.6%). SIRS and qSOFA showed similar discrimination for Sepsis-3 organ dysfunction (AUROC, 0.72-0.73; difference; 0.01; 95% CI 0.0-0.03). A qSOFA ≥ 2 had high specificity but poor sensitivity (96.1%; 95% CI, 95.7%-96.6% and 29.9%; 95% CI, 27.9% -31.8%). SIRS had specificity of 61.1% (95% CI, 60.0%-62.3%) and sensitivity of 72.3% (95% CI, 70.3%-74.1%). Limitations: Single center

Appendix C

Study	Subjects and Setting	Design	Intervention and Comparison Intervention	Outcomes
MacRedmond, et al., 2010	n=37 Vancouver, Canada. St Paul's Hospital, tertiary care center with 500 beds. ED serves greater than 60,000 patients per year.	Before/After	Intervention: Multidisciplinary team that consisted of physicians and nurse educators from the ED and ICU, members of the quality and utilization management team. Met bimonthly over an 8-month period to address sepsis care. PDSA and Lean thinking was used. Interventions: Staff Education, sepsis algorithm and an order set and invasive hemodynamic monitoring. Compared to historical control group of 98 patients admitted from the ED to the ICU between Jun 2003-July2004. Charts were audited again at 10 months.	Data was collected over six months. Included patients were those that were admitted via the ED and had a diagnosis of severe sepsis based on suspected of proven infection with hypotension or lactate > 4. After education, every nurse improved their identification of septic patients (sign test, Z=-3.1, p=0.002) Sensitivity improved from 75% to 92.3%. (x^2 (1df)=22.4; p<0.001). Specificity of the assessment was not different, 91.1% before and 90.1% after (x^2 (1df)=0.43; p=0.84). Post protocol mortality was significantly lower, ARR 24%, 95% CI 3%-47%. Time to antibiotics improved, EGDT was faster, resus goals were met quicker. 62.2% of patients had resus goals met in 6 hours in the post protocol group compared with 13.5% in the pre-protocol group (p<0.0001). Standard deviation also decreased in the post protocol group indicating less variance in adherence to protocol. 100% of patients had lactate measurements completed. <u>Limitations:</u> Old Definitions Before/After design-Hawthorne effect

				Based on early goal directed therapy (no longer necessary)
Nguyen, et al., 2010	n=330 Two-year study started in October 2003 Three month quartiles, Three initial phases, baseline, education, operational, followed by five QI phases.	Before/After	Implementation of an QI bundle in Septic Emergency Department patients. 1. Establish physician champion. 2. Bundle creation 3. Survey staff 4. Bundle implementation 5. QI phases.	Bundle compliance improved from zero at baseline to 51.2% during the last quartile. Over the two-year period mortality decreased 19% (20.8% vs. 39.5%) when comparing those who had the bundle and those who did not. <u>Limitations:</u> Focus on EGDT- guidelines have changed How was initial bundle compliance zero?
Kent, et al., 2012	N=406 536 Bed hospital, community hospital. 60 bed Emergency Department, with approx. 80,000 patients per year, 225/day.	Before/After	Implementation of a nursing-based screening measure for the early recognition of sepsis, with the utilization of SBAR to evaluate the identification of sever sepsis.	Before: 200 patients before, 28% met SIRS criteria, 21% met infection criteria, 1% met organ dysfunction criteria and would have progressed to SBAR commo. After: 15% met SIRS criteria, 7% with infection and 2% with organ dysfunction. <u>Limitations:</u> Sample size led to inconclusive results but imply future opportunities to increase communication amongst staff and expedite care for septic patients. Prior to new definitions
Gatewood, et al., 2015	n= 1,032 presented to ED with sepsis POA but…. N=624 were in final based on exclusion critieria. University of Washington Medical Center Emergency	Before/After	Implementation of QI project that involved: 1. Nurse screening at triage (SIRS + suspected infection) and management protocol	Before: Under-resuscitation with IV fluids in 54% of cases Delays in antibiotics in 54% of cases No Lactates in 27% of cases After:

	Department, May 2011-October 2012, 450 bed hospital.		2. Computer assisted screening algorithm and Sepsis alert 3. MD and Nurse specific order sets	Bundle compliance improved from 28% to 71% after. (Nurse screening and order set improved compliance to 50%, followed by EMR alerts to 70% compliance) Blood culture collection before was 90% and never went below 96% after. Antibiotic delivery within 3 hours improved from 46% to 81%. Initial lactate measurement improved from 63% to peak at 97%. Bundle, antibiotic, intravenous fluid compliance after go live compared to baseline (74%, 30%, 54%, $p<0.001$, $p=0.008$, $p< 0.001$) After suggested order sets ($p<0.001$, $p<0.001$, $p<0.001$) Bundle and antibiotics increased after suggested order sets when compared with Go-Live (31%, 25%, $p<0.001$, $p<0.001$) while IV fluid compliance did not change significantly 8%; $p=0.163$.
McColl, et al., 2017	n=332 (167 pre, 185 post) Two large Canadian tertiary care EDs and included adult patients with suspected severe infection that met two SIRS criteria.	Before/After	Intervention: Implementation of sepsis bundling with triage flagging, RN Medical directive, education campaign, and a modified sepsis protocol.	Primary outcome was 30-day all-cause mortality and sepsis protocol use. The unadjusted all-cause mortality was significantly lower in the post intervention group (30.7% vs. 17.3%; abs difference 13.4%; 95% CI 9.8-17; $p=0.0006$). Higher rate of sepsis protocol use in the post-intervention group (20.3 vs. 80.5%, abs difference 60.2%, 95% CI 55.1-65.3; $p<0.001$). Improvements in time intervals from: triage to MD assessment, first fluid bolus, antibiotic administration.

				Lower rate of vasopressor requirement and ICU admission post intervention. Higher rate of lactate clearance in the post-intervention group when the protocol was used (23.3% vs 29.3%, p=0.05). <u>Limitations:</u> Paper charting Single site Hawthorne effect?
Miller, et al., 2013	n= 4,329 Patients greater than 18 years old with severe sepsis or septic shock admitted to one of 18 ICUs among 11 hospitals	Before/After	Implement a septic shock bundle Evaluate resulting changes in mortality Determine the significance of individual bundle elements in predicting mortality	Primary outcome: Bundle compliance; mortality Relative mortality declined 59% from 21.2% at baseline to 8.7% for 2010 ($p<0.0001$). An absolute increase in all or non-bundle compliance, from 4.9% at baseline to 73.4% in 2010. Percentage of patients ineligible for later bundle elements increased over time ($p<0.01$). Compliance with lactate measurement ($p<0.001$), obtaining blood cultures ($p<0.0001$) and compliance with antibiotic administration before blood cultures ($p<0.01$) predicted ineligibility for the later bundle elements. <u>Limitations:</u> Hawthorne effect? Selection bias? New large hospital opened in 2007

Seoane, et al., 2013	N=1,105 Large academic tertiary referral center between July 2008 to January 2012. Patients with severe sepsis and septic shock.	Before/after	Formation of an interdisciplinary sepsis steering committee that utilized rapid cycle changes to implement change and implementation of management protocols. Case review was utilized to obtain data.	Significant decrease in antibiotic administration, medians reported: Before: 2008- 140 (1-820) to After: 2011 72 (1-1020) p<0.001 Decrease in median length of stay: Before:2008- 8 days (1-54) After: 2011- 7 days (1-33)p=0.036 <u>Limitations:</u> Old definitions Treatment time zero is when patients were identified as having severe sepsis or septic shock, not when they entered the ED. Single site and site specific
Grek, et al., 2016	n= Single site at 304 bed tertiary academic center. Patients were identified in the ED and followed through disposition.	Before/After	Multidisciplinary approach with multiple interventions to improve sepsis care through increase compliance with bundles. Utilized DMAIC and PDSA and FMEA to complete QI work.	<u>Adherence to Surviving Sepsis Guidelines:</u> Pre implementation: all or non-bundle compliance= zero - Lactate 40% - Blood cultures before antbx 76% - Antbx within 3 hours 60% - Fluid bolus of 30ml//kg 33% Post implementation: 51% - Lactate 100% - 50% improvement antbx within 3 hours, blood culture collection, fluid bolus <u>Mortality:</u> Overall improved mortality pre/post SSRT Severe sepsis patients admitted from the ED O/E 0.884 to 0.662 p=0.49 <u>Limitations:</u> Old Definitions however they do redefine bundle with the publication of the ProCESS trial.

				Single Site
Tromp, et al., 2010	n=825 Single site at a 953 bed university hospital in the Netherlands Completed over three study periods. Period 1: Before new bundle Period 2: After sepsis protocol was used and before training and performance feedback Period 3: After training and performance feedback	Before/After	Two consecutive interventions: 1. Nurse driven care bundle training about sepsis that included performance feedback	Measure — Period 1 — Period 2 — Period 3 Lactate w/in 6hr — 22.6% — 73.5% — 80.3% Blood Cx — 83.1% — 78.6% — 86.3% Chest Xray — 67.3% — 88.1% — 82.7% Urine — 49% — 54.6% — 66.7% Antbx w/in 3 hr — 37.7% — 49.6% — 55.9%
Powell, et al., 2014	N= Baylor Health Care System	Before/after	Implementation of a systems approach to reduce sepsis mortality using a multidisciplinary approach and PI tactics (STEEEP Academy, PDSA)	ED to ICU time improved for patients with severe sepsis: June 2011: 507 minutes to June 2012: 281 minutes Median time from ED arrival to antibiotic administration: 122 minutes to 74 minutes. Median time from ED arrival to completion of IV fluid bolus: 119 minutes to 88 minutes. Compliance time for time of ED arrival to antibiotic administration within 180 minutes improved from 70% to 90%. Compliance for time of ED arrival to completion of IV fluid bolus within 180 minutes improved from 56% to 83%. Mortality: 555 lives saved Hospital Standard Mortality Ratio: 120.5 to 75.4 <u>Limitation: System specific culture</u>

Wang, et al., 2013	n= 195 Patients with severe sepsis and septic shock Between June 2008 and December 2009	prospective Before/after	Implementation of SSC bundles	With statistical significance all sepsis resus measures and management bundle measures improved $p<0.05$. Limitations: Chinese Hospital System Single site study

Appendix D

Emergency Department Procedure XXXX

A. Subject: Sepsis Alert Procedure

B. Effective Date: January 10, 2013

C. Purpose:
To reduce mortality from sepsis through early identification, early and appropriate interventions, early hemodynamic monitoring, and prevention of progression and complications. Goals of care include: antimicrobial therapy, source control, and early goal-directed therapy to treat shock and provide oxygen delivery (EGDT).

D. Procedure:

Identification of potential patients

a) The RN or MD assesses patients for SIRS criteria
   (1) Respiratory rate > 20
   (2) Heart rate > 90
   (3) WBC > 12,000 or < 4,000 or > 10% bands
   (4) Temperature >38.3 or < 36.0
b) If the patient meets three or more SIRS criteria and there is a clinical suspicion of an infection:
   (1) Medical communications is called (xxxxx) to initiate a "Sepsis Alert"
c) Medical communications will activate the "Sepsis Alert" by:
   (1) Call Attending 1 (xxxxxx) or Attending 2 (xxxxxxx)
   (2) Announce "Sepsis Alert in room_____" on ED Board
   (3) Text Page "Sepsis Alert in room_____" to paging group:
      (a) ED pharmacist on call
      (b) ED 2nd or 3rd year Resident
      (c) Charge RN
      (d) MET RN
      (e) RN Supervisor
      (f) Bed Center
      (g) ED Medical Director on call
      (h) ED Quality Coordinator

Initiate Continuous Bedside Care Model

d) The patient should be moved to an adequately-sized room with appropriate monitors and equipment
e) RN will staff the patient 1:1 with the assistance of an assigned tech

f) The resident physician will remain at the patient's bedside until the treatment goals are met. (See ED Clinical Protocol)

Immediate Plan

g) Start two IVs (18g or larger) and provide fluid bolus as indicated
h) Draw and send CBC, CMP, Lactic acid, two sets of blood cultures
i) Administer antibiotics within one hour of arrival
j) Take vital signs Q15 minutes for minimally two hours.

Determination of Disposition

k) Disposition will be determined with consultation with the intensivist. ICU admission is recommended for septic patients who meet any of the following criteria;
   a) Need for mechanical ventilation
   b) Need for pressors
   c) Systolic B/P measurement of <90 at any point in the ED visit
   d) Lactate measurement of > 4.0

Appendix E

- Age
- Sex
- Emergency Severity Index
- Time of arrival
- Time to exam room
- Time of examination by an LIP
- Time of disposition
- Admission status
- Admission location
- Admission team
- Time of IV access
- Time of lactate results
- If a repeat lactate was drawn
- Time of blood culture #1 collection
- Time of blood culture #2 collection
- Antibiotic #1 name
- Antibiotic #1 start time
- Antibiotic # 2 name
- Antibiotic #2 start time
- Weight in kg
- Hypotension (SBP < 90mmhg or MAP < 65mmhg)
- Milliliters of crystalloid fluid ordered during ED stay
- If vital signs were documented every 15 minutes from the time of the alert
- If the sepsis order set was used to order clinical interventions
- If a patient was screened for sepsis (starting in December)
- The answers to the sepsis screening questions
- The time the sepsis screening was completed
- Mortality status
- RN
- Resident
- Attending Physician

Appendix F

Definition of terms:

Bundle: "A bundle is a structured way of improving the processes of care and patient outcomes: a small, straightforward set of evidence-based practices — generally three to five — that, when performed collectively and reliably, have been proven to improve patient outcomes" (Resnar et al., 2005).

Sepsis alert: Both a label and process, this term provided by a nurse or a physician that indicates an ED patient may be septic. Sepsis alerting a patient results in the provision of resources for the patient's clinical management.

Sepsis Coalition: An interprofessional team with the following members: ED Attending Physician, ED Resident Physician, ED Quality Improvement Coordinator, ED Pharmacist, Quality Improvement Systems Administrator and Analyst, a performance improvement coach, a medical informaticist, 2 nursing informaticist, an RN, and a Doctor of Nursing Practice Student (DNP).

Appendix G

Emergency Department Procedure No. XXXX

A. Subject: Sepsis Alert Procedure

B. Effective Date: January 10, 2013

C. Purpose: To reduce morbidity and mortality from sepsis and septic shock through the application of evidence-based guidelines. Goals of care include: screening, hemodynamic monitoring, fluid resuscitation, source control, lactate measurement, obtaining cultures and antimicrobial therapy.

D. Procedure:

1) Identification of potential patients
    a) The RN or MD assesses patients for:
        (1) A history suggestive of a new infection.
        (2) SIRS criteria:
            (a) Respiratory rate > 20
            (b) Heart rate > 90
            (c) WBC > 12,000 or < 4,000 or > 10% bands
            (d) Temperature >38 or < 36.0
            (e) Consider hypotension
        (3) Signs of organ dysfunction.
    b) If there is a clinical suspicion of an infection and the patient meets 2+ SIRS criteria and/or signs of organ dysfunction:
        (1) Medical Communication center is called to initiate a "Sepsis Alert"
    c) The medical communications center will activate the "Sepsis Alert" by:
        (1) Place sepsis alert and room number on the status board in the ED
        (2) Text Page "Sepsis Alert in room ____" to paging group:
            (a) ED RNs
            (b) ED PCTs
            (c) ED pharmacist
            (d) ED 2nd and 3rd year Resident
            (e) Charge RN
            (f) RN Supervisor
            (g) ED Quality Coordinator
            (h) ED pager 1600

2) Initiate Continuous Bedside Care Model
    a) The patient should be moved to an adequately-sized room with appropriate hemodynamic monitors and equipment.
    b) RN will staff the patient 1:1 with the assistance of an assigned tech.
    c) The resident physician will remain at the patient's bedside until IV access is obtained and antibiotics are initiated (See ED Clinical Protocol).

3) Immediate Plan
    a) Start 2 large bore IVs (18 gauge or larger).
    b) Draw and send CBC, CMP, lactate and 2 sets of blood cultures.

c) Administer fluids as ordered within one hour of arrival.
d) Administer antibiotics as ordered within one hour of arrival.
e) Obtain urine for Dip and culture as soon as possible
f) If respiratory symptoms or pneumonia suspected, obtain Pneumonia alert chest x-ray. If patient is unstable, order this as portable and do not delay IV start or fluids.
g) Take vital signs Q15 minutes for minimally one hour from the time of alert.

4) Determination of Disposition
a) Disposition will be determined with consultation with the intensivist. ICU admission is recommended for septic patients who meet any of the following criteria;
a) Need for mechanical ventilation
b) Need for vasopressors to maintain a MAP > 65mmhg.
c) Lactate measurement of > 4.0 or if lactate does not clear after fluid administration.

Approved: January 2013
Revised: 12/17