Translating the Evidence of the Use of the Sepsis Screening Tool into Clinical Practice to
Improve Sepsis Identification and Reduce Sepsis Mortality

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Abstract

Background: Sepsis is a life threatening syndrome that occurs rapidly when the body’s response to blood infection injures its own tissues and organs. Sepsis is the most costly disease in the U.S. and the number one killer of patients admitted to acute care hospitals. On October 1, 2015, the CMS will start chart abstraction initiatives for Severe Sepsis and Septic Shock for the FY 2017 Payment Determination. In reviewing 2013 and 2014 data from a hospital system made up of over 150 acute hospitals, the majority of patients diagnosed with sepsis were not screened for sepsis in either the ED or the in-patient units, meaning that the hospital system as a whole has $20,000,000 at stake. The aim of this study is to examine if the use of a sepsis screening tool will improve sepsis identification and decrease mortality in hospitalized patients.

Methods: A retrospective study was performed to evaluate the number of sepsis cases and the risk adjusted mortality index from nineteen facilities that participated in a Quality Improvement Collaborative. Data from January to June 2014 (before a sepsis screening tool was used) was compared with the data from January to June 2015 (after implementation of a sepsis screening tool began). Demographic data was analyzed using descriptive statistics. Results: The result of statistical analysis showed that the number of identified sepsis cases increased significantly after participation in the quality collaborative. The sepsis mortality rate declined, however the length of the study was too brief for the findings to be statistically significant. Significance and Implications: The results demonstrated that each hospital increased sepsis identification by 52 sepsis cases per hospital after joining the quality collaborative. The reduction in mortality suggests that the quality collaborative is heading in the right direction. Keywords: sepsis, sepsis screening tool, and sepsis diagnostic tool.
Problem Identification and Significance

In 2007, the Institute of Medicine set a goal that ninety percent of all healthcare decisions in the United States will be evidence-based by the year 2020 (Olsen, Aisner, McGinnis, & Roundtable on Evidence-Based Medicine, 2007). Patients are at increased risk whenever the care that they receive is not evidence-based (Health Research Institute, PricewaterhouseCoopers, 2007). According to a research study done by Schuster and associates (1998), 30 to 45 percent of patients in the U.S. are not receiving care based on research evidence; and 20 to 25 percent of the care that is administered is not needed.

Applying these findings to the conditions of sepsis is still a challenge and would mean achieving full compliance to the published practice guidelines for treating sepsis (Burney, et al., 2012). Sepsis is a life threatening syndrome that can occur rapidly. Sepsis occurs when the body’s response to blood infection injures its own tissues and organs (Czura, 2011; Dellinger, et al., 2007). The infection could be bacterial, viral, parasitic, or fungal in origin (Dellinger, et al., 2007). The associated signs and symptoms of sepsis are so subtle, that if hospital staffs do not know what to look for, they will miss them (Hall, Williams, DeFrances, & Golosinskiy, 2011). The sepsis mortality rate will increase up to 8% for every hour that the patient does not receive the empiric antibiotics. (Kumar et al, 2006). It is important to be mindful of the fact that by the time the patients arrive for care, they have been ill for hours. Time is of the essence when an abnormal set of vital signs has been identified (Kumar et al, 2006). Many patients who survive sepsis are debilitated for the rest of their lives. Roughly, 40 percent of all ICU patients have sepsis on admission or experience sepsis during their intensive care unit (ICU) stay (Hall, Williams, DeFrances, & Golosinsky, 2011). Sepsis is the most costly disease treated in the U.S.
On October 1, 2015, the Centers for Medicare and Medicaid Services (CMS) will start a chart abstraction initiative for Severe Sepsis and Septic Shock. The Management Bundle (NQF #0500) measures for the FY 2017 Payment Determination and Subsequent Years (CMS, 2014). That means that hospital Medicare payments will be reduced if the measures stated in the guidelines were not met. In addition to this measure, there is a penalty that the hospital receives when its sepsis mortality is higher than the national average. One particular healthcare system, made up of more than 150 acute hospitals, struggles to regularly screen patients for sepsis (unpublished data).

In reviewing 2013 and 2014 data, the majority of patients diagnosed with sepsis were not screened for sepsis in either the ED or the in-patient units (unpublished data). The reasons for not screening patients are multifaceted. Some clinicians do not know what to look for, others are simply too pressed for time, and the majority do not know the benefits of using the sepsis screening tool. The reason why it costs so much to treat and comes with such a high mortality rate is that septic patients are identified in the late stage of the sepsis continuum. Sepsis starts with infection, then progresses to SIRS (Systemic Inflammatory Response Syndrome), and then to severe sepsis, and finally to septic shock within a matter of hours (Bone, Balk, Cerra, Dellinger, & Fein, 1992).

**Purpose and Clinical Question**

The particular hospital system being studied has 20 million dollars at stake (unpublished data) for the CMS Value Based-Purchasing (VBP) payment program. The main goal of this paper
is to attempt to decrease sepsis mortality by increasing the use of the sepsis screening tool for the early identification and treatment of sepsis, in compliance with the published sepsis treatment guidelines. Early identification of sepsis patients with the use of the sepsis screening tool has proven to improve patient outcomes by preventing sepsis deterioration (Bruce, Maiden, Fedullo, & Kim, 2015). This study will examine the evidence to see if the use of a sepsis screening tool will improve sepsis identification and mortality in hospitalized patients. The PICOT format (patient population [P], intervention of interest [I], comparison intervention of interest [C], outcomes of interest [O], (Greenhalgh, 2014; Craig & Smyth, 2012) and time it takes for intervention to achieve outcomes [T]) (Stillwell, Fineout-Overholt, Melnyk, & Williamson, 2010) was used to establish the following clinical question: Is there a difference in the number of identified septic patients (O) and sepsis mortality (O) in hospitalized adults (P) who were screened with the sepsis screening tool (I) during the course of in-patient admission (T), compared to those who were not screened (C) with the sepsis screening tool?

The following databases were accessed in order to attempt to answer the clinical PICOT question: Summons, Google Scholar, Cumulative Index to Nursing and Allied Health Literature (CINAHL), TRIP (Turning Research into Practice), Cochrane Database of Systematic Reviews (CDSR), PubMed, McMaster, and accesss. Pre-appraised sources such the published Sepsis Guidelines (2004, 2008, and 2012) were also accessed. The following keywords were used to search for the evidence literature: sepsis, sepsis screening tool, and sepsis diagnostic tool. The librarian at Drexel University was also consulted to offer strategy suggestions for the literature search. Inclusion criteria consisted of studies published January 1, 2010 to January 1, 2015, in the English language, conducted on patients aged 19 years and older. The search yielded 13 systematic reviews and 55 studies for review and critical appraisal. The search criteria had to be
expanded to include articles written more than five years past, simply because there were only a few articles returned by the original search criteria that include enough of a description of the sepsis screening tool to assess whether or not the same sepsis screening tool was used across all studies. The remaining studies filtered down to 15 studies that appeared to be relevant.

Assessing the Quality and Results of the Evidence

Critical Appraisal of Evidence

The clinical PICOT question guided the method used to evaluate the overall quality of the evidence presented in the research articles. A systematic assessment of the retrieved research articles was conducted to highlight the strengths and weaknesses of each article, as well as their similarities and differences, and evaluate any gaps in evidence. In this manner, all articles providing low scientific evidence for their findings were filtered out (Demaerschalk, 2004; Rychetnik & Wise, 2004). The fitness of the study design was assessed for each of the articles, the articles that answer my clinical PICOT question (Fineout-Overholt, Melnyk, Stillwell, & Williamson, 2010), and support the use of the sepsis screening tool were selected for this paper. Studies selected for this paper were primary studies, because the search results did not yield any systematic reviews, and primary studies provided the highest quality of research evidence available. There were a total of 15 studies retrieved by the search results that appeared to be relevant, five of which were selected for critical appraisal. The remaining studies only mentioned the use of the sepsis screening tool in combination with the intervention of the sepsis treatment bundle, and did not provide any detailed description of the content of the sepsis screening tool or data that could be used to evaluate the effectiveness of the tool itself. These articles often referred back to an earlier study done by Moore and associates (2009) to show that the tool has shown to
be effective in the past, but the studies did not provide data to validate the evidence in their own clinical settings.

The effectiveness of the sepsis screening tool was most frequently evaluated based on its ability to identify sepsis in its early state. Nurses administering the screening would then alert the physicians who would begin timely intervention to stop the progression of sepsis. Out of the five studies chosen for critical appraisal, only one study actually provided the data necessary to measure the sensitivity and specificity of the tool, independent of the results it helped to produce in clinical settings. Even on the sepsis guidelines, the grading of recommendation for using the sepsis screening tool was 1C, meaning that use of the tool is strongly recommended for use, but the quality of evidence supporting the use of the tool was low since it was only supported by “well-done observational studies with controlled RCTs” (Dellinger et al., 2012, p. 586).

Another general concern about the studies retrieved by the search criteria is that the studies were conducted in large academic medical settings with sample sizes ranging from 400 to 17,000 patients. The large sample sizes help to validate the quality of studies, but raise the question of whether or not the evidence can be translated into smaller, acute hospital settings. Use of the sepsis screening tool does not require the availability of abundant resources, which only larger hospitals could provide. Therefore, the sample size of studies providing the evidence is only a minor concern, since the methods used to produce the evidence can easily be scaled down during the process of implementation.

The Critical Appraisal Skills Program (CASP) diagnostic checklist was chosen for the evaluation of the research articles. Corresponding data from each of the five articles was extracted and plugged into the “12 questions to help you make sense of a diagnostic test study” CASP framework (Critical Appraisal Skills Programme, 2013), thereby allowing side by side
evaluation of the articles based on the quantitative evidence. The CASP framework was chosen because it contains the necessary questions to validate the performance of the sepsis-screening tool and it makes it easier to see which studies will be useful to reference during the process of implementation, and which studies best answer the clinical PICOT question (Critical Appraisal Skills Programme, 2013).

Comparing and Contrasting of Evidence

The first study by Lopez-Bushnell and associates (2014) was conducted in the General Medical-Surgical Unit, in which all patients were screened for sepsis each shift (see Appendix A). Two hundred twenty five patients screened positive for sepsis between March 2008 and April 2009. In addition to this initial period of testing, the investigators reported that early detection and early intervention reduced sepsis mortality by 30% through the fourth quarter of 2012. This data is in comparison with sepsis outcomes before the implementation of the program. The total number of patients was not mentioned in the study, making it difficult to validate its calculations. The table graphs included in the study depict a decreasing trend in sepsis mortality rates from the third quarter of 2007 to the third quarter of 2010. The sepsis screening tool was described well, and a sample tool was included in the study. No data was provided regarding the efficacy of the sepsis screening tool.

The second study, Kent and Fields (2012) reports that the utilization of the sepsis screening tool increased identification of patients at risk for sepsis (see Appendix B). Data were collected on patients before the implementation (n = 200) and after the implementation (n = 206). However, due to the limited number of patients who were screened during the study, it was premature to report a reduction in sepsis mortality. The study limited the days and times of data collection, making the data open to bias, and therefore limited in terms of the validity of the
findings. The study was done in the emergency department. Sample data were collected before and after the intervention on Mondays, Wednesdays, and Fridays, between 7 AM and 3 PM on all adult patients who were screened for sepsis. The sepsis screening tool was described well, and a sample tool was included in the study. No information was provided regarding the efficacy of the sepsis screening tool. There was also not enough data provided to test the performance of the sepsis screening tool.

Semler and associates (2015) screened intensive care unit admitted patients (N = 1,843) to identify those who were septic (n = 407) (see Appendix C). The septic group had a mortality rate of 15%. Both the paper version and the electronic version of the sepsis screening tool were well described in the study. The paper sepsis screening tool was compared with the electronic clinical decision support system (CDSS) sepsis screening tool. The findings suggest that there is no significant difference between the utilization of the paper screening tool as opposed to the CDSS. The study noted, however, that there was a bias towards using the paper screening tool, because the physicians did not like the CDSS guiding them with suggestions of what to do next, and they did not appreciate the fact that their performance would be measured based on how many times they ignored the electronic prompts. No information was provided regarding the efficacy of the sepsis screening tool. There was also not enough data provided to calculate the sensitivity and specificity of the tool.

Gigliotti and associates (2014) included a total patient population of 17,061 in their study (see Appendix D). Of these patients, the nurse practitioner (NP) screened 3,268 for sepsis using the sepsis screening tool, leaving 13,793 patients who were not screened for sepsis. The findings reveal a risk estimate at a 95% confidence level, and show that the patient who was not screened for sepsis by the sepsis team of NPs was 2.59 times more likely to die during hospitalization with
risk estimate ranges of 2.154 – 3.115. The study provided a full description of the sepsis screening tool and mentioned that it had a sensitivity of 77%. However, no data was provided regarding the specificity of the tool. A likelihood ratio of 137.065 was provided, but there’s not enough data to measure the performance of the sepsis screening tool.

Moore and associates (2009) reported the results of their study, in which 927 patients were screened for sepsis (see Appendix E). Of these 927 patients, 109 were true positive, 4 were false negative, 27 were false positive, and 787 were true negative. The test was performed in the surgical intensive care unit (SICU), and all adult patients were screened for sepsis. The sepsis screening tool was described well in the study and a sample tool was included. A two-by-two table was provided for the calculation of the sensitivity and specificity of the sepsis screening tool. Outcomes included an increase in sepsis identification and a reduction in sepsis mortality with a decline of 35.1% to 23.3% over five months of the study.

Five studies used the exact same sepsis screening tool, and they all compared data before and after the implementation of the screening tool. All of the studies were performed in large academic settings, and all of the studies found improvements in sepsis identification and reductions in sepsis mortality. That being said, the differences between the studies are worth noting. The five studies were conducted in a variety of settings, from the intensive care unit (ICU), to the medical-surgical unit, to the emergency department (ED). Two of the five studies used an electronic screening tool, while the others used paper. The five studies also varied greatly in how well they tested the effectiveness of the tool independently of the outcomes. The Moore and associates (2009) study was the only study out of the five that provided enough data to show just how effective the screening tool was. All five of the studies did suggest, however, that the sepsis-screening tool worked.
The sepsis screening tool consist of three sections: assessment of systemic inflammatory response syndrome (SIRS; defined by low and high temperature (≤ 96 degrees Fahrenheit or ≥ 100.9 degrees Fahrenheit), heart rate greater than 90 beats per minute, respiratory rate of greater than 20 breaths per minute, white blood count < 4,000 billion cells per liter or > 12,000 billion cells per liter, altered mental status, and hyperglycemia (plasma glucose > 140 mg/dl) in the absence of diabetes), clinical suspicion of infection, and assessment of acute organ dysfunction (Systolic Blood Pressure less than 90 mm Hg or MAP less than 65 mm Hg, SBP decrease greater than 40 mm Hg from baseline, Creatinine greater than 2 mg/dL (176.8 mmol/L) or Urine Output less than 0.5 mL/kg/hour for 2 hours, Bilirubin greater than 2 mg/dL (34.2 mmol/L), Platelet count less than 100,000 billion cells per liter, Lactate greater than 2 mmol/L (18 mg/dL), Coagulopathy (INR greater than 1.5 or aPTT greater than 60 seconds) (Lopez-Bushnell, Demaray, & Jaco, 2014; Kent & Fields, 2012; Semler, et al., 2015; Gigliotti, Steele, Cassidy, & Bell-Gordon, 2014; Moore, et al., 2009). If the patient meets at least two of the SIRS criteria (first section) and there is either a clinical suspicion of, or a confirmed infection (second section), the patient meets the sepsis definition (Dellinger, et al., 2007; Dellinger, et al., 2012). The bedside nurse then notifies the physician to confirm the infection and diagnose the patient for sepsis. The third section is the continuation of the screening process where nurses assess for any end organ dysfunction. If the patient meets one of the end organ dysfunction criteria, in addition to the two positive SIRS criteria and has a suspected or confirmed infection, then the patient meets the definition of severe sepsis (Dellinger, et al., 2007; Dellinger, et al., 2012). The nurse will then notifies the physician and request an order to initiate the time sensitive sepsis treatment guidelines (Dellinger, et al., 2007; Dellinger, et al., 2012). The sepsis screening tool serves as an organized set-up for presenting the clinical case to the physician. See Figure 1.
Interpretation of Evidence

Despite the varying evidence presented in the five studies examined, there was one shared factor between studies. All studies suggested that using the sepsis screening tool in combination with carefully-followed guidelines increased the rate of sepsis identification within the patient population and decreased sepsis mortality overall. All studies measured sepsis mortality rates before and after the use of the sepsis screening tool, and each study noted an overall reduction in sepsis mortality.

The one thing that was greatly lacking in almost every study (with the exception of Moore et al. 2009) was an independent evaluation of the performance of the sepsis screening tool apart from the outcomes that it helped to produce. The effectiveness of the sepsis screening tool was almost always measured in combination with the procedure of carefully following the guidelines and carrying out the treatment bundle. In addition to not measuring the specificity and sensitivity of the tool, the studies did not provide data to measure how carefully the guidelines were followed and how thoroughly the treatment bundle was implemented. Because the tool was almost always tested in combination with the treatment bundle, it is difficult to say that implementing the use of the screening tool will likely reduce a hospital’s sepsis mortality rate by a certain amount. The rate of success with which a hospital reduces sepsis mortality among their patient populations is equally dependent upon both the effectiveness of the tool and the ability of the staff to carefully follow the treatment guidelines. The ideal study would measure both of these factors independently, measuring the sensitivity, specificity and likelihood ratios of the tool itself, and then measuring how quickly and how thoroughly the treatment bundle was implemented.
Implementing the use of a sepsis screening tool will have very little impact on outcomes if providers delay diagnosis and treatment once sepsis has been identified. It is for this reason that the effectiveness of the tool and the effectiveness of the hospital staff need to be measured independently of each other. If there was a study that could show that the treatment bundle was carried out exactly, each and every time that sepsis was diagnosed, and that the diagnosis and treatment always came within an hour of identification, then it might be more scientifically appropriate to say exactly how effective the sepsis screening tool is at reducing overall sepsis mortality.

The five selected studies showed a reduction in overall sepsis mortality after the sepsis screening tool was implemented. These results are enough to answer the clinical PICOT question in the affirmative: the sepsis screening tool helps to increase the identification of sepsis and to reduce sepsis mortality. This suggests that it is safe to recommend implementing the tool in any clinical setting. The tool has proven itself to be useful in a variety of hospital settings, but that doesn’t mean that the tool is perfect. Moore and associates (2009) suggested that if a patient screened positive for sepsis, there was an 80.3% chance that the patient did, indeed, have sepsis. Further research needs to be conducted to see if there are ways to raise the predictive value of the tool, thereby making it even more useful. The protocols described in the studies for implementing the sepsis treatment bundle may also need to be adjusted for smaller, non-academic hospital settings. For example, if the only attending physician is on-call, asleep in his/her bed and the patient screens positive for sepsis at 2 A.M., the bedside nurse would have to know that the screening tool is accurate enough and the results of the test urgent enough for him/her to immediately call the physician.

The effect measure of using the sepsis-screening tool is as follows:
**Results:** The sepsis screening tool had a sensitivity of 96.5%, which means that the sepsis screening tool is very good at detecting patients who are at risk of sepsis. It also showed a specificity of 96.7%, which means that the sepsis screening tool is very good at ruling out patients who do not have sepsis. In addition, the performance of the sepsis screening tool resulted in a 12.2% prevalence of sepsis in the tested population. The positive likelihood ratio is 29, which means that if the patient screens positive with the sepsis screening tool, the doctor can be 29 times more certain that the patient actually has sepsis. The negative likelihood ratio is 0.036. This means that the likelihood of a patient actually having sepsis when the results of the screening were negative is about 0.036 times out of a hundred. In other words, individuals without the disease are about thirty times more likely to have a negative test result when screened for sepsis than individuals with the disease. The pre-test odds are 0.138. The post-test odds are 4.06. The post-test probability is 80.3%. Thus, after testing positive with the sepsis screening tool, the patient’s chance of having sepsis is 80.3%.

The implementation of the sepsis screening tool and sepsis treatment protocol reduced sepsis mortality rates from 35.1% to 24.2%. There was no decrease in sepsis mortality in other ICUs that did not use the sepsis screening tool.

Out of all the studies, the Moore and associates (2009) study demonstrated most clearly that the sepsis screening tool is both accurate and effective. If each of the studies provided enough data to validate the performance of the tool apart from outcomes, it would be much easier to see whether or not the screening tool truly is as accurate as it can be. Since only one of the studies provided data about the efficacy and sensitivity of the tool, it is only fitting to say that the tool should be used, but independently validated in each new hospital setting. By doing so,
different hospitals may discover ways of adjusting the tool to make it more effective in their particular settings and patient population.

**Strategies for Moving the Evidence-Based Recommendations into Practice**

The need to improve sepsis outcomes and decrease health care cost is the driving force behind implementing (Cannon & Boswell, 2014) the use of the evidence-based sepsis screening tool. The way to detect sepsis before a patient starts presenting symptoms of septic shock is to screen the patient when no outward symptoms are noticeable. The primary evidence-based practice being implemented is the early identification of every sepsis patient by the bedside nurse who would screen every patient for sepsis using the sepsis screening tool. Screening patients for sepsis is part of bundled treatment recommendations to improve sepsis mortality (Dellinger et al., 2012).

Sepsis screening involves escalating levels of expertise. The initial assessment involves the triage/bedside nurse assessing the patient for systemic inflammatory response syndrome (SIRS) criteria (temperature, heart rate, respiratory rate, and white blood count). If the results are positive, then the nurse must make further assessments to find out if there is any suspicion, possibility of, or probable cause of infection. If the result is positive, the nurse notifies the physician to evaluate and confirm the findings and initiate evidence-based treatment guidelines (sepsis bundle). The treatment intervention is full compliance with the 2012 Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock (Dellinger, et al., 2012). The primary outcomes being measured are the number of patients identified with sepsis and the overall reduction in sepsis of mortality. Making the use of the sepsis-screening tool as part of the everyday provision of nursing care, continuing the existing
In January 2015, the healthcare system being studied took measures to improve sepsis outcomes by selecting 19 hospitals with high sepsis mortality rates to participate in a quality improvement collaborative. The collaborative exists to strengthen the identification and treatment of sepsis to reduce sepsis mortality by educating and mentoring its constituents about the evidence-based sepsis screening tool and sepsis treatment guidelines, facilitating collaboration between the participating hospitals, facilitating the implementation of standardized sepsis screening tools, treatment protocols, and order sets, increasing engagement and commitment by all stakeholders, collecting and analyzing their data every month, sharing lessons learned and best practices, and celebrating improved outcomes.

**Theoretical Framework**

Moving evidence into clinical practice is an arduous task (Grady, 2010). There’s no one-size-fits-all approach. The process is not linear, but rather dynamic (Grady, 2010). It’s not one-dimensional, but rather multidimensional (Nutley, Walter, & Davies, 2003). In this paper, different frameworks and models will be utilized to attempt to successfully move the evidence-based practice of the use of the sepsis screening tool into clinical practice. One strategy is to adopt an evidence-based practice model (or EBP model) to avert costly mistakes, wasted time, and wasted resources (Schaffer, Sandau, & Diedrick, 2012). An EBP model provides guidance and simplifies the intricate challenge of translating research into practice (Schaffer, Sandau, & Diedrick, 2012). The chosen EBP model to move evidence-based recommendation into practice is the Promoting Action on Research Implementation in Health Services (PARiHS) framework.
The PARiHS framework is a multi-dimensional framework which considers the relation between the three important elements of implementation. The three important elements are the evidence (the evidence of sepsis screening tool), the context (learning the organizational culture and acquiring full leadership engagement), and the facilitation (creating a detailed plan for implementing the desired interventions) (Ullrich, Sahay, & Stetler, 2014; Stetler, Schaffer, Sandau, & Diedrick, 2012; Damschroder, Helfrich, & Hagedorn, 2011). The framework recommends starting on a small-scale to test, learn, and fine-tune all planned strategies in order to enable easier large-scale implementation later.

The first element of the PARiHS framework is the quality of evidence (Ullrich, Sahay, & Stetler, 2014; Stetler, Schaffer, Sandau, & Diedrick, 2012; Damschroder, Helfrich, & Hagedorn, 2011). The specified published research source of evidence for this intervention is the study done by Moore and associates (2009), which validates the effectiveness of the sepsis screening tool for the early identification of sepsis. There is also much evidence supporting the effectiveness of early aggressive treatment of sepsis in compliance with the sepsis treatment bundle guidelines (Turi & Von Ah, 2013). The evidence that is needed for a successful implementation is the evidence from the current outcomes data of each hospital, which will prove why the implementation (Bradley, et al., 2004) of the sepsis screening tool is necessary. This data includes the number of patients identified with sepsis and sepsis mortality. The comparison of this data before and after implementation will be measured to ascertain the effectiveness of the strategies and overall success (Bradley, et al., 2004; Nutley, Walter, & Davies, 2003) of the utilization of sepsis screening tool. These outcomes data will be fed back to the clinical practitioners and hospital leaders regularly to inform them as to whether or not their new practice is making a difference. This data will also help to sustain their engagement (Bradley, et al., 2004;
Nutley, Walter, & Davies, 2003). Other important elements of evidence for this project are the clinicians’ clinical experience and overall level of understanding. A research study suggests that the more educational preparation a nurse has, the more the nurse will utilize the evidence in everyday provision of nursing care (Cannon & Boswell, 2014). The evidence-based sepsis-screening tool must be perceived as practical and beneficial to clinical practice, especially by novice nurses (Bradley, et al., 2004).

The next element within the PARiHS framework is the receptive context. The context consists of the quality of the physical, social, cultural, structural, system, and professional environment (Ullrich, Sahay, & Stetler, 2014; Stetler, Schaffer, Sandau, & Diedrick, 2012; Damschroder, Helfrich, & Hagedorn, 2011). This includes multiple influences that will mediate a clinician’s practice such as, government regulations (i.e. CMS’ VBP Sepsis core measures, accountability, and cultures) (DesForges, 2001). These influences will have disparate power, but will form part of the preclusion or enticement to implement the sepsis-screening tool (Nutley, Walter, & Davies, 2003).

Assessing the current state of organizational context is very important before proceeding (Craig & Smyth, 2012) to implement the sepsis-screening tool. Creating a designated quality improvement team to manage the task of implementing the sepsis-screening tool to improve sepsis outcomes could provide a solid foundation (Craig & Smyth, 2012). The quality improvement team will oversee the process to guide the implementation and management of the program, and will also be the driving force in sustaining the program. According to King’s Fund report on getting better with evidence, there are four key factors to putting evidence to practice: having sufficient resources, having enough of the right people on board early enough, and
perceiving that the proposed change is beneficial to the frontline staff, and that the approach is practical and interactive with the current clinical practice (Wye & McClenahan, 2000, p. 15).

Implementing the sepsis screening requires minimal investment in terms of funds. The sepsis screening tool could be integrated into the current nursing assessment tool in the electronic health record (E.H.R.) or as a paper checklist. Creating a dedicated form for the sepsis-screening tool is also an option. In terms of a front line nurse’s time, it will take an additional three minutes in their nursing assessment time to complete the sepsis-screening tool. Training time for nurses could range from one to four hours, depending on their level of knowledge, skills, experience, and engagement (Benner, 1982). Resources must also be allocated in collecting, creating, and reporting data (Bradley, et al., 2004). Data gathered will be used for providing feedback and evaluation of the newly implemented process to the individual and the team; and then correlated with the hospital system’s performance and outcomes (Bradley, et al., 2004).

The second factor is having enough of the right people on board early enough (Bradley, et al., 2004; Wye & McClenahan, 2000). It is very important to identify and recruit all potential multidisciplinary stakeholders with different levels of experience or training at the beginning of the project (Bradley, et al., 2004; Wye & McClenahan, 2000). They will be the supporters, levers, and influencers to help guide the project towards successful implementation (Bradley, et al., 2004; Wye & McClenahan, 2000) of the sepsis-screening tool and to help foster change. One best practice to consider implementing is to have each member of the charter team sign a commitment to improving sepsis outcomes (Pronovost, Berenholtz, & Needham, 2008).
The following stakeholders were required to be members in the STOP Severe Sepsis Collaborative:

An Executive Sponsor, (the sponsor is the executive leader and ensures that the project remains an organizational priority).

A designated Sepsis Coordinator/Team Champion (typically a nurse in ICU or ED), who organizes the team, articulates clear goals, makes decisions through the collective input of members, and actively promotes and facilitates good teamwork.

A Physician Champion, (a unit medical director or a physician who provides care in the ICU or in ED) who advocates and supports the implementation of the initiative.

An ED Nursing Director, an ICU Nursing Director, and a Medical-Surgical Floor Nursing Director - These nurse leaders educate and communicate the initiative to their unit staff. They assist with resource allocation, ensuring team members can participate in collaborative activities. They also assist with communication and implementation of new processes.)

A Lab Director, (This person educates and communicates the initiative to the laboratory staff).

A Pharmacy Director, (The Pharmacy Director is a required member of the Sepsis Team) this person educates and communicates the initiative to the pharmacy staff).

A Quality/Data Collector, (This person collects monthly data and ensures that the data is submitted in a timely manner). The Data Collector also maintains communication with the charter’s leadership team and conveys relevant information to the project improvement team.)

An Infection Preventionist/Epidemiologist, (this person is an infection prevention resource to the charter team and provides the infection rate data).
A Case Manager, (this person is the Case Management resource to the charter team and provides the admission, discharge status, and transfer status of all sepsis patients), and the An HIM Manager/Director/Champion or CDI, (This person educates and communicates the initiative to the CDI/HIM/Coder staff).

The third factor is that the proposed change is perceived to be beneficial to the frontline staff. Sharing stories about patients whose lives were affected by sepsis due to delayed identification could boost engagement in the implementation. It could also be beneficial to present clinicians with data regarding their current clinical practice in sepsis screening, such as their unit’s monthly code blue, yearly and current year to date total number of sepsis patients identified, and sepsis mortality. Providing staff with feedback about their current clinical practice in a non-threatening manner, such as using a face-to-face approach and or small group meetings, may increase their engagement (Bradley, et al., 2004; Wye & McClenahan, 2000) in implementing the sepsis-screening tool.

The fourth factor is that the approach needs to be practical and interactive with current clinical practice. The three minutes of a clinician’s time that it takes to complete the sepsis-screening tool must be equated to saving a patient’s life. If the nursing staff does not perceive it as such, they will have to call a code-blue (a resuscitation process where a team of clinicians made up of at least five people who show up to take-over the care of a highly critical near-death patient) for a patient who presents the obvious signs of septic shock such as low blood pressure, shallow or no breathing, faint or no pulse, low level of consciousness to no response. Every code blue can end up utilizing exhaustive resources and take at least four hours of clinical time. In addition, the more the nurses utilize the sepsis-screening tool, the more the nurses become
familiar with the sepsis disease continuum, thus enhancing the nurses’ skill development in identifying sepsis patients.

The third element within the PARiHS framework is facilitation. Facilitation, according to the PARiHS framework, not only includes how to approach the organization with the desired intervention, but also how to brace people for change, and how to maintain the ongoing development of an effective implementation strategy (Schaffer, Sandau, & Diedrick, 2012; Ullrich, Sahay, & Stetler, 2014; Stetler, Damschroder, Helfrich, & Hagedorn, 2011). One strategy to utilize in order to speed up the implementation of the sepsis screening tool is adopting the 6 E’s of implementation strategy (Pronovost, Berenholtz, & Needham, 2008). The six E’s are Engage, Educate, Execute, Evaluate, Endure, and Expand. One strategy was introduced on a monthly basis to give each hospital time to apply into their own context.

The first strategy is to Engage all of the relevant stakeholders by showing them their current number of identified sepsis cases and sepsis mortality rates and then make the numbers real by telling stories of the sepsis patients who went undetected until it was too late (Powell & Fowler, 2014).

The next strategy is to Educate all of the stakeholders. This involves providing the scientific research evidence supporting the proposed implementation of the sepsis-screening tool to all levels of staff (Powell & Fowler, 2014; Dodge, 2010). Included with this evidence was a brief summary of the hospital’s current sepsis data and lists of other evidence to consider. Also, during this stage standardized training for the nurses on how to use the sepsis screening tool was provided by adopting the strategy of the three developmental stages in skill acquisition (Green & Seifert, 2005).
The third strategy is to Execute. To effectively implement the use of the sepsis screening tool, we created an implementation toolkit based on identified barriers to implementation (Pronovost, Berenholtz, & Needham, 2008, p. 964). This toolkit provided a framework for redesigning processes and includes three principles: standardize care processes, create independent checks, i.e. checklists, and learn from mistakes. The checklists standardize knowledge and understanding among clinicians and patients about best practices. The quality team will evaluate any sepsis death to determine whether it was preventable (Powell & Fowler, 2014).

The fourth strategy is to Evaluate. This is the stage where feedback is obtained (Pronovost, Berenholtz, & Needham, 2008) as to whether or not the implementation of the sepsis screening tool was successful. The Quality Team compares their baseline data versus their performance measures collected before and after the implementation. Every month after the implementation, the Quality Team will post a report on the monthly rate of completion of the sepsis screening tool, the monthly number of sepsis patients identified, and the monthly sepsis mortality on each unit’s communication board. This report will then be compared with similar data from before the implementation using simple graphs. The Quality team will also regularly evaluate for any unintended consequences (or threats) of using the sepsis screening tool that may arise.

The fifth strategy is to Endure (Pronovost, Berenholtz, & Needham, 2008). To sustain the implementation of the sepsis screening tool, the quality team initiative must continue its existence and continue to measure and provide feedback on clinician performance and overall
hospital sepsis outcomes. The sepsis screening tool must be integrated into the provision of daily nursing care. Sepsis education and training must also be incorporated into new staff orientation.

The sixth strategy is Expand (Pronovost, Berenholtz, & Needham, 2008). This stage is where the sepsis screening tool is being introduced and applied to other nursing units.

Methods

A retrospective study was performed. Data on the number of sepsis cases and the risk adjusted mortality index from January 2014 to June 2015 were extracted from 19 facilities who participated in the quality collaborative. Data from January to June 2014 (before a sepsis screening tool was used) was compared with the data from January to June 2015 (after the implementation of using the sepsis screening tool began).

Patients diagnosed with sepsis (870, 871, or 872) must have a suspicion of or a confirmed infection in addition to meeting at least two systemic inflammatory response syndrome criteria (Levy, et al., 2003). Severe sepsis means sepsis plus evidence of an end-organ dysfunction (Mikkelsen, et al., 2009). Septic shock means severe sepsis combined with either hypotension despite adequate fluid resuscitation or serum lactate greater than or equal to 2 mmol/L (Mikkelsen et al., 2009).

Sepsis cases are measured by the number of cases identified by the DRG (Diagnosis Related Group) code 870 (septicemia or severe sepsis with mechanical ventilation of 96 plus hours), 871 (septicemia for severe sepsis without mechanical ventilation or with mechanical ventilation for less than 96 hours), and 872 (septicemia or severe sepsis without mechanical ventilation and without major complication or comorbidity) (CMS, 2014).
Sepsis mortality is defined as subjects who died and were coded with sepsis DRG 870, 871, and or 872 and measured by sepsis inpatient risk-adjusted mortality index.

The null hypothesis is that pre and post participation means of outcome measures (the number of sepsis cases and the risk-adjusted mortality index) are equal. The alternate hypothesis is that the pre and post participation means of the outcome measures (the number of sepsis cases and risk adjusted mortality index) are not equal.

**Human Subjects Protection**

The hospital system being studied does not currently have an Institutional Review Board. A request to obtain de-identified data to run a secondary analysis was submitted. On August 31, 2015, the hospital system’s executives and legal counsel approved the request. See Appendix F.

Application for exempt status was submitted to Drexel University Institutional Review Board. On September 10, 2015, Drexel University Institutional Review Board determined that the project is not research involving human subjects as defined by DHHS and FDA regulations. See Appendix G.

Demographic data was analyzed using descriptive statistics. See Figure 2.

**Strengths and Limitations**

The main goal of the study was to increase sepsis identification and improve sepsis mortality through an increased use of the sepsis-screening tool. Infrequently, the sepsis-screening tool may not have been utilized consistently due to sudden nurse turnovers and hospital leadership changes.

Hospitals participate regularly on the monthly educational webinar where tools and best practices were introduced. There is no current process to validate their clinical practice at the bedside apart from trusting the hospital’s report that they are using the sepsis-screening tool.
Results

IBM SPSS 22 was used to perform t-test analysis. A two-tailed paired t-test was performed comparing the number of identified sepsis cases before joining the quality collaborative (January to June 2014) and after participation in the quality collaborative (January to June 2015). The outcome shows that the number of identified sepsis cases has increased significantly after participation in the quality collaborative.

A two-tailed paired t-test was performed comparing the number of sepsis mortality rate (RAMI: risk adjusted mortality index) before joining the quality collaborative (January to June 2014) and after participation in the quality collaborative (January to June 2015). The outcome shows that the sepsis mortality rate has declined after joining the quality collaborative; however this study was not carried out long enough for the findings to be statistically significant. See Figure 3.

Significance and Implications

The results show that each hospital had significantly increased sepsis identification by 52 sepsis cases per hospital after joining the quality collaborative. The results suggested that participation in the quality collaborative aided the use of the sepsis screening tool, thus closing the gap between research evidence and clinical practice.

The reduction in mortality suggests that the quality collaborative is heading in the right direction. The results also suggest that the quality collaborative must continue to improve, and sustain the reduction in sepsis mortality.

Due to the rapid progression of the sepsis disease, from a simple infection to septic shock, transferring patients from acute hospitals to larger medical centers is not an option. The results
suggest an opportunity for growth, i.e. training our smaller acute hospitals to recognize and treat sepsis.

This DNP project demonstrated better understanding of how to increase sepsis identification and to lower sepsis mortality for all the community hospitals nationwide.
References


http://www.casp-uk.net/


## Appendix A


<table>
<thead>
<tr>
<th>The type of question</th>
<th>Assessment criteria</th>
<th>Response (YES/CAN’T TELL/ NO)</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Screening questions</strong></td>
<td>1. Was there a clear question for the study to address?</td>
<td>Yes</td>
<td>The main objective of the article was to reduce sepsis mortality in general units by following the 2008 Surviving Sepsis Campaign Treatment Guidelines for Severe Sepsis and Septic Shock. The guidelines were designed for adult patients, age 18 and above. The guidelines recommend the use of sepsis screening tool in an acute hospital setting to improve sepsis mortality (Dellinger, et al., 2007).</td>
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<td><em>A question should include information about:</em></td>
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<td>– setting</td>
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<td>– and outcomes</td>
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<td></td>
<td>2. Was there a comparison with an appropriate reference standard?</td>
<td>Yes</td>
<td>The screening tool utilization was compared before and after implementation. The article also suggested that they have used the discharged diagnosis of sepsis and were comparing the outcomes before and after implementation.</td>
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<td></td>
<td>*HINT: Is this reference test the best available indicator in the circumstances?</td>
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<tr>
<td><strong>Detailed questions</strong></td>
<td>3. Did all patients get the diagnostic test and the reference standard?</td>
<td>Yes</td>
<td>It was stated in the study page 11, &quot;All patients on medical-surgical units now screened each shift&quot; but no data was provided.</td>
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<td><em>Consider:</em></td>
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<td>– Were both received regardless of the results of the test of interest?</td>
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<td>– Is there any bias? (review the 2 x 2 table for verification)</td>
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<td>4. Could the results of the test of interest be influenced by the results of the reference standard?</td>
<td>No</td>
<td>The test was compared before and after the implementation of the sepsis screening tool. Though, there was no blinding done. The data collection was abstracted and reviewed by the members of the SMIT (Sepsis Mortality Improvement Team).</td>
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<td><em>Consider:</em></td>
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<td>– Was there blinding?</td>
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<td>– Were tests performed independently?</td>
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<td>5. Is the disease status of the tested population clearly described?</td>
<td>Yes</td>
<td>Based on the sepsis screening tool, the patient who is suspected of having an infection will be screened for the presence of SIRS (Systemic Inflammatory Response Syndrome): Temp &gt; or equal to 38 or &lt; or equal to 36 centigrade, Heart Rate &gt; or equal to 90, Respiratory Rate &gt; or equal to 20 or PaCO2 of less than or equal to 32, WBC &gt; or equal to 12,000, or &lt; or equal to 4,000 or bands &gt; or equal to 10%. If SIRS criteria were met, the patient was referred to MD for further assessment and possible treatment. If SIRS criteria were not met, the patient was excluded.</td>
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<td><em>Consider:</em></td>
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<td>– presenting symptoms</td>
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<td>– disease stage or severity</td>
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<td>– co-morbidity</td>
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<td>– differential diagnoses (spectrum bias)</td>
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<td>Question</td>
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<td>6. Were the methods for performing the test described in sufficient detail?</td>
<td>Yes.</td>
<td>The protocol was explained well and a copy of the tool was included in the study. The protocol was designed for nurses to follow the sequence on how to screen the patient for sepsis.</td>
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<tr>
<td>HINT: Was a protocol followed?</td>
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<tr>
<td>7. What are the results?</td>
<td></td>
<td>The article stated on 13, &quot;Through the use of the protocol, and tools...... nurses are able to recognize patients with sepsis. This process led to early identification of patient deterioration and prompt management using appropriate skills.&quot; There was no data provided such as sensitivity, specificity, or likelihood ratios to support the statement. However, the author provided graphical data of their observed mortality and sepsis mortality, which shows a downward trend on both graphs.</td>
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<td>Consider:</td>
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<tr>
<td>- Are sensitivity and specificity and/or likelihood ratios presented?</td>
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<tr>
<td>- Are results presented in such a way that we can work them out?</td>
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<tr>
<td>8. How sure are we about these results?</td>
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<td>The author stated on page 13 of the article &quot;Between March 2008 and April 2009, 225 patients screened positive for sepsis….This early intervention reduced the mortality of patients with sepsis by 30%.&quot; The article did not provide information about how they have validated their results. Not enough data was provided to validate results. The article provided data on how many patients screened positive for the disease, i.e. 225. The article did not state how many patients there were who screened negative that did have sepsis. Nor did it specify how many screened positive that did not have sepsis, or how many screened negative that did not have sepsis.</td>
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<td>Consider:</td>
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<td>- Could they have occurred by chance?</td>
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<td>- Are there confidence limits?</td>
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<tr>
<td>- What are they?</td>
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<tr>
<td>9. Can the results be applied to your patients/the population of interest?</td>
<td>Yes.</td>
<td>The characteristics of the patients described in the study are not different from our patient population.</td>
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<td>Hint: Do you think your patients/population are so different from those in the study that the results cannot be applied (Such as age, sex, ethnicity and spectrum bias)?</td>
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<tr>
<td>10. Can the test be applied to your patient or population of interest?</td>
<td>Yes.</td>
<td>The test could be applied to our patient population because the screening tool was designed using a sequence that is easy to follow by any bedside clinical nurse that has received training on how to use it.</td>
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<td>Consider:</td>
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<tr>
<td>- resources and opportunity costs</td>
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<tr>
<td>- level and availability of expertise required to interpret the test’s current practice and availability of services</td>
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<tr>
<td>11. Were all outcomes important to the individual or population considered?</td>
<td>Yes.</td>
<td>The sepsis screening tool will improve identification of sepsis disease. With early identification and a timely response by the provider, treatment intervention can be initiated. Thus, sepsis mortality will improve.</td>
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<td>Consider:</td>
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<tr>
<td>- Will the knowledge of the test result improve a patient’s well-being?</td>
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<tr>
<td>- Will the knowledge of the test result lead to a change in patient management?</td>
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<tr>
<td>12. What would be the impact of using this test on your patients/population?</td>
<td>Using the sepsis screening tool could identify patients at risk of sepsis in the early phase of the sepsis continuum. With the early identification of sepsis, treatment protocol could be initiated to stop the progression of the sepsis disease. However, not enough data was provided to validate the results of the study.</td>
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</table>
Appendix B


<table>
<thead>
<tr>
<th>The type of question</th>
<th>Assessment criteria</th>
<th>Response (YES/CAN’T TELL/ NO)</th>
<th>Comment</th>
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</thead>
<tbody>
<tr>
<td>Screening questions</td>
<td>1. Was there a clear question for the study to address?</td>
<td>Yes.</td>
<td>The main purpose of the study was to implement a sepsis screening measure for improving the identification, communication, and treatment of patients with sepsis. The clinical question in the study was “In the ED, what effect will the implementation of a nursing-based screening measure (Intervention one) for the early recognition of sepsis, with the utilization of Situation, Background Assessment, and Recommendation (SBAR) (Intervention two), have on the identification of patients with severe sepsis?” In page 142 of the article, the targeted population was all adult patients presented in ED regardless of presentation or chief complaint. The assumption for the study was that “a more diligent screening process for severe sepsis would result in an early diagnosis and a more prompt and aggressive treatment for severe sepsis” (Kent &amp; Fields, 2012, p. 142).</td>
</tr>
<tr>
<td></td>
<td>2. Was there a comparison with an appropriate reference standard?</td>
<td>Yes.</td>
<td>In page 142 of the study it was stated that patients with discharge diagnoses and presence or absence of criteria on the first 3 sepsis screening measures (SIRS, infection, and organ dysfunction) were the reference group.</td>
</tr>
<tr>
<td>Detailed questions</td>
<td>3. Did all patients get the diagnostic test and the reference standard?</td>
<td>No.</td>
<td>There is a possibility of bias because no data was provided regarding how many patients screened negative that had sepsis and how many patients screened negative, yet had no sepsis. Only those adult patients who were seen during M, W, F, between 7AM and 3 PM who presented to the ED were screened. What happened on other days and other shifts?</td>
</tr>
<tr>
<td></td>
<td>4. Could the results of the test of interest be influenced by the results of the reference standard?</td>
<td>Can’t tell.</td>
<td>Nothing was mentioned about blinding in the study.</td>
</tr>
</tbody>
</table>
5. Is the disease status of the tested population clearly described?

   Consider:
   - presenting symptoms
   - disease stage or severity
   - co-morbidity
   - differential diagnoses (spectrum bias)

   Yes. Based on the sepsis screening tool, Step I, the patient who had a possible infection was screened for the presence of SIRS (Systemic Inflammatory Response Syndrome): Temp ≥ or equal to 100.4 F or < or equal to 96.8 F, Heart Rate > or equal to 91, Respiratory Rate > or equal to 20, WBC > or equal to 12,000, or < or equal to 4,000 or 0.5 K/ul bands. If SIRS criteria were met, the patient screened to step II, assessing if there is a confirmed or even a suspicion of infection. If the patient met Steps I and II, the patient was referred to MD for further assessment and possible treatment using the SBAR communication tool. If SIRS criteria were not met, all screening stops.

---

6. Were the methods for performing the test described in sufficient detail?

   HINT: Was a protocol followed?

   Yes. Protocol was used and the sepsis screening tool was illustrated in the study.

---

7. What are the results?

   Consider:
   - Are the sensitivity and specificity and/or likelihood ratios presented?
   - Are the results presented in such a way that we can work them out?

   The data showed that before implementation, there were total of 45 patients who screened positive for sepsis: 42 with SIRS + Infection; and 3 with Severe Sepsis: SIRS + Infection + organ dysfunction, out of 200 patients.

   After implementation there were total of 15 patients who screened positive for sepsis (13 with SIRS + Infection) and 5 with Severe Sepsis: SIRS + Infection + organ dysfunction out of 206 patients.

   The data presented was not enough to calculate for likelihood ratios and specificity.

---

8. How sure are we about these results?

   Consider:
   - Could they have occurred by chance?
   - Are there confidence limits?
   - What are they?

   Not sure, as there was not enough information provided in the study.

---

9. Can the results be applied to your patients/the population of interest?

   Hint: Do you think your patients/population are so different from those in the study that the results cannot be applied (such as age, sex, ethnicity and spectrum bias)?

   No. The lack of data means that there is not enough evidence to support the results. Therefore, the results cannot be applied to the population of interest.

---

10. Can the test be applied to your patient or population of interest?

   Consider:
   - resources and opportunity costs
   - level and availability of expertise needed to interpret the test’s current practice and availability of services

   Yes. The patient population stated in the study is similar across the country; therefore the test could be applied to the population of interest.
11. Were all outcomes important to the individual or population considered?  

   **Consider:**  
   - Will the knowledge of the test result improve a patient’s well-being?  
   - Will the knowledge of the test result lead to a change in patient management?  

   | Yes. | The sepsis screening tool will improve the early identification of sepsis patients. With early identification and a timely response from the provider, treatment intervention can be initiated. Thus, sepsis mortality will improve. |

12. What would be the impact of using this test on your patients/population?  

   | Using the sepsis screening tool could identify patients at risk for sepsis in the early phase of the sepsis continuum. With the early identification of sepsis, treatment protocol could be initiated to stop the progression of the sepsis disease. However, not enough data was provided to validate the results described in the study. |
Appendix C


<table>
<thead>
<tr>
<th>The type of question</th>
<th>Assessment criteria</th>
<th>Response (YES/CAN’T TELL/ NO)</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening questions</td>
<td>1. Was there a clear question for the study to address?</td>
<td>Yes</td>
<td>On page 2, the authors hypothesized that the implementation of an electronic sepsis evaluation and management tool in the ICU for adult patients with sepsis would improve compliance with the sepsis treatment guidelines and improve clinical outcomes.</td>
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<td>A question should include information about:</td>
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<td>– the population</td>
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<td>– and outcomes</td>
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<td></td>
<td>2. Was there a comparison with an appropriate reference standard?</td>
<td>Yes</td>
<td>In page 3 of the study, it was illustrated. All ICU admissions (1,843) assessed by the provider at admission. The patients who were diagnosed septic were being compared with patients who were not diagnosed septic during admission.</td>
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<tr>
<td></td>
<td>HINT: Is this reference test the best available indicator in the circumstance?</td>
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<tr>
<td>Detailed questions</td>
<td>3. Did all patients get the diagnostic test and the reference standard?</td>
<td>Yes</td>
<td>The provider screened all patients admitted to the ICU. However, reassessment of sepsis using the electronic tool had some challenges. The electronic sepsis tool opened automatically at enrollment, but once the computer closed, electronic sepsis screening relied on providers to reassess rather than prompting with changes in the patient’s status. This could be interpreted as evidence of bias.</td>
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<td>Consider:</td>
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<td>– Were both received regardless of the results of the test of interest?</td>
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<td>– Is there any bias? ( review the 2 x 2 table for verification)</td>
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<td></td>
<td>4. Could the results of the test of interest be influenced by the results of the reference standard?</td>
<td>Yes</td>
<td>Page 2 of the study shows that the researchers used a computer algorithm to randomize ICU patients. However, clinical providers were aware of group assignments. Separate study personnel were blinded until the completion of data collection.</td>
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<td>Consider:</td>
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<td>– Was there blinding?</td>
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<td>– Were the tests performed independently?</td>
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<td>5. Is the disease status of the tested population clearly described?</td>
<td>Yes</td>
<td>In page 4 of the study, demographics and clinical characteristics of the control and intervention group were illustrated (Semler, et al., 2015).</td>
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<td>Consider:</td>
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<td>– presenting symptoms</td>
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<td>– disease stage or severity</td>
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<td>– co-morbidity</td>
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<td>– differential diagnoses (spectrum bias)</td>
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<td>6. Were the methods for performing the test described in sufficient detail?</td>
<td>Yes</td>
<td>The protocol was followed and illustrated on page 3 of the article (Semler, et al., 2015).</td>
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<td></td>
<td>HINT: Was a protocol followed?</td>
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</table>
### 7. What are the results? Consider:
- Are sensitivity and specificity and/or likelihood ratios presented?
- Are the results presented in such a way that we can work them out?

Page 4 of the study shows that there were 1,843 total ICU admissions during the study period. 407 septic patients were identified. Providers identified 189 of these patients and the electronic screening tool identified 218. There was about a 22% incidence of sepsis.

### 8. How sure are we about these results? Consider:
- Could they have occurred by chance?
- Are there confidence limits?
- What are they?

The study results stated on page four of the article, that there was no significant difference between the sepsis assessment and management tool and the control with regard to the primary outcome of time to completion of the indicated resuscitation bundle and time to completion of each individual element of the bundle.

Sensitivity analysis:
Control (hazard ratio, 1.60; 95% CI, 0.45-5.67; p = 0.462)
E tool (hazard ratio, 2.53; 95% CI, 0.52-12.16; p = 0.231)

No difference in ICU mortality:
14.3% vs 14.9%; p = 0.905
No difference in ICU-free days:
17.9 ± 1.4 vs 19.0 ± 0.5; p = 0.473

### 9. Can the results be applied to your patients/the population of interest? Hint: Do you think your patients/population are so different from those in the study that the results cannot be applied (such as age, sex, ethnicity and spectrum bias)?

No.

The results are misleading.

However, we could apply the electronic tool and screening process in our patient population. The population described in the study is similar to the population of the country.

### 10. Can the test be applied to your patient or population of interest? Consider:
- Resources and opportunity costs
- Level and availability of expertise required interpreting the test current practice and availability of

Yes.

However, only for our hospitals that has implemented the use of electronic health records and has purchased CDSS software designed with a sepsis algorithm.

### 11. Were all outcomes important to the individual or population considered? Consider:
- Will the knowledge of the test result improve a patient’s well-being?
- Will the knowledge of the test result lead to a change in patient management?

Yes. Using the test will lead to the more early identification of septic patients, and early initiation of treatment. Thus, compliance with treatment guidelines will increase, thereby improving sepsis mortality.
| 12. What would be the impact of using this test on your patients/population? | It will require much engagement from all stakeholders to implement this test. The tool is only useful if the clinicians use it as it was designed. The tool will prompt the clinicians about patients at risk for sepsis but success depends on how the clinicians behave responding to the prompt (whether they act on it or ignore it). |
Appendix D


<table>
<thead>
<tr>
<th>The type of question</th>
<th>Assessment criteria</th>
<th>Response (YES/CAN’T TELL/ NO)</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening questions</td>
<td>1. Was there a clear question for the study to address? A question should include information about: - the population - test - setting - and outcomes</td>
<td>Yes.</td>
<td>The clinical question for the study was: will there be an improvement in the early diagnosis and treatment of sepsis with the implementation of a multi-pronged interdisciplinary intervention including the development of a nurse practitioner sepsis screening team.</td>
</tr>
<tr>
<td></td>
<td>2. Was there a comparison with an appropriate reference standard? HINT: Is this reference test the best available indicator in the circumstance?</td>
<td>Yes.</td>
<td>The reference standard is not screening patients for sepsis.</td>
</tr>
<tr>
<td>Detailed questions</td>
<td>3. Did all patients get the diagnostic test and the reference standard? Consider: - were both received regardless of the results of the test of interest? - Is there any bias? ( review the 2 x 2 table )</td>
<td>Yes.</td>
<td>Yes. The ACNP (Acute Nurse Practitioners) screened all patients admitted to all specialties.</td>
</tr>
<tr>
<td></td>
<td>4. Could the results of the test of interest be influenced by the results of the reference standard? Consider: - Was there blinding? - Were the tests performed independently?</td>
<td>Yes.</td>
<td>Some physicians expressed concerns about the role of the ACNP screening their patients. The new process requires cooperation from Medical staff to foster collaboration. Support from hospital leadership, nursing, and medical staff is necessary to avoid conflict. The assessment team process was tested before and after implementation.</td>
</tr>
<tr>
<td></td>
<td>5. Is the disease status of the tested population clearly described? Consider: - presenting symptoms - disease stage or severity - co-morbidity - differential diagnoses (spectrum bias)</td>
<td>Yes.</td>
<td>The study stated that they have adopted the 2008 Surviving Sepsis Campaign Guidelines (Dellinger, et al., 2007). It has implied that the population is adult patients in an acute care hospital setting.</td>
</tr>
<tr>
<td></td>
<td>6. Were the methods for performing the test described in sufficient detail? HINT: Was a protocol followed?</td>
<td>Yes.</td>
<td>There was a protocol created and followed. Page 78-79 of the study included a description of how the sepsis screening tool was utilized.</td>
</tr>
<tr>
<td>Question</td>
<td>Response</td>
<td></td>
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<tr>
<td>-------------------------------------------------------------------------</td>
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</tbody>
</table>
| 7. What are the results?                                                | **Page 79 of the study stated that internal quality analysis was performed by a group of physicians who attested that the sepsis-screening tool was 77% sensitive for acute care patients and had a positive retrospective screen of 25 hours for SICU patients before sepsis was diagnosed.**  
There was a significant association between whether or not a transfer patient was screened upon arrival by the Sepsis Screening Team (SST) and mortality in the population, \( x^2 (1) = 115.04, p < 0.001 \).  
A transfer patient that was not screened by the team was 2.59 times more likely to die during the hospitalization than a transfer patient that was screened (95% CI: 2.154 – 3.115). |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 8. How sure are we about these results?                                | **A risk estimate graph was presented on page 81 of the study. The Odds R = 2.754 (95% CI: 2.272 – 3.339)**  
Screened by NP (No/Yes)  
Dead = OR: 2.590 (95% CI, 2.154 – 3.115)  
Alive = OR: 0.940 (95% CI, 0.932 – 0.948)  
N of Valid Cases = 17061 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 9. Can the results be applied to your patients/the population of interest? | Yes. **The characteristics of the patients described in the study are not different from our patient population.** |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 10. Can the test be applied to your patient or population of interest?  | Yes. **The test could be applied to our patient population because the screening tool was designed using a sequence that is easy to follow by any bedside clinical nurse that has received the training on how to use it. An Advanced Practice Nurse is not required for the sepsis screening tool to be used effectively.** |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 11. Were all outcomes important to the individual or population considered? | The sepsis screening tool will improve the early identification of sepsis patients. With early identification and timely response from the provider, treatment intervention can be initiated. Thus, sepsis mortality will improve. |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 12. What would be the impact of using this test on your patients/population? | Using the sepsis screening tool could identify patients at risk of sepsis in the early phase of the sepsis continuum. With the early identification of sepsis, the treatment protocol could be initiated to stop the progression of the sepsis disease. |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

<table>
<thead>
<tr>
<th>Type of question</th>
<th>Assessment criteria</th>
<th>Response</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening questions</td>
<td>1. Was there a clear question for the study to address?</td>
<td>Yes.</td>
<td>The study hypothesized that aggressive screening for sepsis would improve early recognition of sepsis and decrease sepsis-related mortality by ensuring the use of appropriate early interventions. The setting was in a Surgical ICU. The population admitted to this unit was all adults.</td>
</tr>
<tr>
<td></td>
<td>A question should include information about:</td>
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<tr>
<td></td>
<td>- the population</td>
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<tr>
<td></td>
<td>- test</td>
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<tr>
<td></td>
<td>- setting</td>
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<tr>
<td></td>
<td>- and outcomes</td>
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<td></td>
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<tr>
<td></td>
<td>2. Was there a comparison with an appropriate reference standard?</td>
<td>Yes.</td>
<td>Yes. The test was done in the SICU and all patients were screened using the sepsis screening tool. The reference standard was patients who were not screened for sepsis.</td>
</tr>
<tr>
<td></td>
<td>HINT: Is this reference test(s) the best available indicator of the disease?</td>
<td></td>
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<tr>
<td>Detailed questions</td>
<td>3. Did all patients get the diagnostic test and the reference standard?</td>
<td>Yes.</td>
<td>The 2 x 2 was on page 1544 of the study, and the calculation of sensitivity and specificity was illustrated. The total number of patients was 927. 109 of these patients screened positive for a diagnosis of sepsis, 27 screened positive and had no diagnosis of sepsis, 4 screened negative and were diagnosed with sepsis, and 787 screened negative and had no diagnosis of sepsis.</td>
</tr>
<tr>
<td></td>
<td>Consider:</td>
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<tr>
<td></td>
<td>- were both received regardless of the results of the test of interest?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- the 2 x 2 table (verification bias)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Could the results of the test of interest be influenced by the results of the reference standard?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consider:</td>
<td>No.</td>
<td>Data was collected and compared before and after the implementation of the sepsis-screening tool.</td>
</tr>
<tr>
<td></td>
<td>- Was there blinding?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Were tests performed independently?</td>
<td></td>
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<tr>
<td></td>
<td>5. Is the disease status of the tested population clearly described?</td>
<td>Yes.</td>
<td>Yes. Page 1543 of the study lists the ICD9 codes (disease classification) that were used to identify patients with sepsis.</td>
</tr>
<tr>
<td></td>
<td>Consider:</td>
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<tr>
<td></td>
<td>- presenting symptoms</td>
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<td></td>
<td>- disease stage or severity</td>
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<tr>
<td></td>
<td>- co-morbidity</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- differential diagnoses (spectrum bias)</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>6. Were the methods for performing the test described in sufficient detail?</td>
<td>Yes.</td>
<td>The protocol was used in the SICU and all patients were screened twice per shift for sepsis.</td>
</tr>
<tr>
<td></td>
<td>HINT: Was a protocol followed?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
7. What are the results?
Consider:
– are the sensitivity and specificity and/or likelihood ratios presented?
– are the results presented in such a way that we can work them out?
Over 5 months, 4,991 screens were completed on 920 patients. The prevalence of sepsis was 12.2%. The screening tool yielded a sensitivity of 96.5%, a specificity of 96.7%, a positive predictive value of 80.2% and a negative predictive value of 99.5%. In addition, sepsis-related mortality decreased from 35.1% to 23.3%.

8. How sure are we about these results?
Consider:
– Could they have occurred by chance?
– Are there confidence limits?
– What are they?
The study provided data to validate its results. Also, two screening tools were used to validate whether or not patients met sepsis criteria. The first tool was a SIRS screening tool utilized by the bedside nurses. When the result was positive, the patients were referred to mid-level providers to assess for infection. Mid-level providers utilized the second sepsis tool, which is infection screening, in order to confirm whether or not the patient has an infection. If the presence of an infection was confirmed, the patient was referred to SICU Intensivists.

9. Can the results be applied to your patients/the population of interest?
Hint: Do you think your patients/population are so different from those in the study that the results cannot be applied (such as age, sex, ethnicity and spectrum bias)?
Yes. Yes. The population described in the study is similar across the country.

10. Can the test be applied to your patient or population of interest?
Consider:
– resources and opportunity costs
– level and availability of expertise required interpreting the test current practice and availability of services
Yes.
The test was utilized by the clinical bedside nurses. The nurses just need education and training on how to use the sepsis screening tool. As stated in the study, it took 2-3 minutes for the bedside nurses to complete the screening.

11. Were all outcomes important to the individual or population considered?
Consider:
– Will the knowledge of the test result improve a patient’s well-being?
– Will the knowledge of the test result lead to a change in patient management?
The sepsis screening tool will improve the early identification of sepsis patients. With an early identification and timely response from the provider, treatment intervention can be initiated. Thus, sepsis mortality will improve.

12. What would be the impact of using this test on your patients/population?
Using the sepsis screening tool could identify patients at risk for sepsis in the early phase of the sepsis continuum. With the early identification of sepsis, a treatment protocol can be initiated to stop the progression of the sepsis disease. However, not enough data was provided to validate the results described in the study.
Appendix F.

Approval request for de-identified data to do secondary analysis.

Nicolas Abella
Director, Critical Care Medical-Surgical Services
Community Health Systems
4000 Meridian Blvd
Franklin, TN 37067

Dear Nicolas,

Patricia Dougall, VP & Associate General Counsel for Clinical Operations has received all necessary approvals for your request for approval to do a secondary analysis of existing de-identified data from Premier to meet the DNP program requirement. Per the email from Patricia dated August 28, 2015 at 12:44pm, all data will be de-identified, neither CHS nor any hospital name, geographic location will be used. Your paper will not be published and will only be given to your two professors.

Best of luck as you complete requirements for your DNP! Let me know if I can assist you in any other matter.

Sincerely,

[Signature]

Pam Rudig
Senior Vice President and Chief Nursing Officer

CC: Patricia Dougall, Vice President & Associate General Counsel for Clinical Operations

*“Community Health Systems” is a registered trade name of CHSHC, LLC.*
Appendix G.

Drexel Institutional Review Board Approval.

APPROVAL OF PROTOCOL

September 10, 2015

Albert Rundio
Drexel University
CNHP
1505 Race Street
Philadelphia, Pa 19102

Dear Dr. Rundio,

On September 10, 2015 the IRB reviewed the following protocol:

<table>
<thead>
<tr>
<th>Type of Review:</th>
<th>Initial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title:</td>
<td>Translating Evidence of the Use of the Sepsis Screening Tool into Clinical Practice</td>
</tr>
<tr>
<td>Investigator:</td>
<td>Albert Rundio</td>
</tr>
<tr>
<td>IRB ID:</td>
<td>1509003890</td>
</tr>
<tr>
<td>Funding:</td>
<td>Internal</td>
</tr>
<tr>
<td>Grant Title:</td>
<td>None</td>
</tr>
<tr>
<td>Grant ID:</td>
<td>None</td>
</tr>
<tr>
<td>IND, IDE or HDE:</td>
<td>None</td>
</tr>
<tr>
<td>Documents Reviewed:</td>
<td>Request for Letter of Determination of Non-Human Subject Research</td>
</tr>
</tbody>
</table>

The IRB determined that the proposed activity is not research involving human subjects as defined by DHHS and FDA regulations.

IRB review and approval by this organization is not required. This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are made and there are questions about whether these activities are research involving humans in which the organization is engaged, please submit a new request to the IRB for a determination.

Sincerely,

[Signature]

John C. Medendorp
Executive Director
Human Research Protection
**EVIDENCE OF SEPSIS SCREENING TOOL**

**Figure 1.**

**Sepsis Screening Tool**

**Instructions:** Use this tool to screen patients for sepsis.

1. **Are any two of following signs & symptoms of infection both present and new to the patient?**

   **Note:** Laboratory values may have been obtained for inpatients but may not be available for outpatients.

   - Hyperthermia > 38.3 degrees C (100.9 degrees F)
   - Tachypnea > 20 bpm
   - Leukopenia (WBC count < 4000 microL-1)
   - Hypothermia < 36 degrees C (96.8 degrees F)
   - Acute altered mental status
   - Leukocytosis (WBC count >12,000 microL-1)
   - Tachycardia > 90 bpm
   - Hyperglycemia (plasma glucose >140 md/dl in the absence diabetes)

   **Yes**  **No**

   Date: ___/___/___ (mm/dd/yy)  Time: ___:___ (24 hr. clock)  Time: ___:___ (24 hr. clock)

2. **Is the patient’s history suggestive of a new infection?**

   - Pneumonia, empyema
   - Bone/joint infection
   - Implantable device infection
   - Urinary tract infection
   - Wound infection
   - Skin/soft tissue infection
   - Acute abdominal infection
   - Bloodstream infection
   - Other___________________________
   - Meningitis
   - Endocarditis

   **Yes**  **No**

   Date: ___/___/___ (mm/dd/yy)  Time: ___:___ (24 hr. clock)  Time: ___:___ (24 hr. clock)

   **If the answer is yes to both question 1 and 2:**

   - ✓ Activate Rapid Response Team and Notify the Physician.
   - ✓ Get an order to obtain: lactic acid, blood cultures, CBC with differential, basic chemistry labs, bilirubin.
   - ✓ At the physician’s discretion obtain: UA, chest x-ray, amylase, lipase, ABG, CRP, and CT scan.

3. **Are any of the following organ dysfunction criteria present at a site remote from the site of the infection that are not considered to be chronic conditions?**

   **Note:** the remote site stipulation is waived in the case of bilateral pulmonary infiltrates.

   - SBP < 90 mmHg or MAP < 65 mmHg
   - SBP decrease > 40 mm Hg from baseline
   - Bilateral pulmonary infiltrates with a new (or increased) oxygen requirement to maintain SpO2 > 90%
   - Bilateral pulmonary infiltrates with PaO2/FIO2 ratio < 300
   - Creatinine > 2.0 mg/dl (176.8 mmol/L) or Urine Output < 0.5 ml/kg/hour for > 2 hours
   - Bilirubin > 2 mg/dl (34.2 mmol/L)
   - Platelet count < 100,000
   - Coagulopathy (INR >1.5 or aPTT >60 secs)
   - Lactate > 2 mmol/L (18.0 mg/dl)

   **Yes**  **No**

   Date: ___/___/___ (mm/dd/yy)  Time: ___:___ (24 hr. clock)  Time: ___:___ (24 hr. clock)

   Nurse Signature: _______________  Date and Time: ____________________

Nurse Signature: _______________  Date and Time: ____________________
Figure 2.

Descriptive Statistics

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Sepsis Cases</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>19</td>
<td>15.0</td>
<td>188.0</td>
<td>111.263</td>
<td>52.0191</td>
</tr>
<tr>
<td>2015</td>
<td>19</td>
<td>25.00</td>
<td>275.00</td>
<td>163.737</td>
<td>73.94510</td>
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<tr>
<td>RAMI 2014</td>
<td>19</td>
<td>.2</td>
<td>4.0</td>
<td>1.155</td>
<td>0.7762</td>
</tr>
<tr>
<td>RAMI 2015</td>
<td>19</td>
<td>.41</td>
<td>1.64</td>
<td>1.0974</td>
<td>.34946</td>
</tr>
</tbody>
</table>
Figure 3.

Statistical Analysis

<table>
<thead>
<tr>
<th>Paired Differences</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
<th>t</th>
<th>df</th>
<th>Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Sepsis Cases 2015 - Total Sepsis Cases 2014</td>
<td>52.4737</td>
<td>47.6193</td>
<td>10.9246</td>
<td>29.5219</td>
<td>75.4254</td>
<td>4.803</td>
</tr>
<tr>
<td>O/E Ratio 2015 - O/E Ratio 2014</td>
<td>-.05737</td>
<td>.78522</td>
<td>.18014</td>
<td>-.43583</td>
<td>.32109</td>
<td>-.316</td>
</tr>
</tbody>
</table>
Intellectual Honesty Certification

I certify that this assignment is presented as entirely my own intellectual work. Any words and/or ideas from other sources (e.g. printed publications, Internet sites, electronic media, other individuals, groups, or organizations) have been properly indicated using the appropriate scholarly citation style required by the department or College.

I have not submitted this assignment in its entirety to satisfy the requirements of any other course. Any parts of this assignment from other courses have been discussed thoroughly with the faculty member before this submission so that there is an understanding that I have used some of this work in a prior assignment.

Student’s Signature:  Nicolas Abella

Course Submitted:  DNP Project

Term:  Fall 2015

Date:  September 15, 2015