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An Evalution of Sepsis Initiatives to Reduce the Severity of Severe Sepsis in a Two-Hospital System

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Abstract

Sepsis is the most expensive clinical condition to treat, with a very high mortality rate (Torio & Moore, 2016). The goal of sepsis treatment is to intervene as early as possible utilizing established criteria. There are several evidence-based approaches in the literature to address early identification of sepsis, decreasing sepsis severity, and reducing morbidity and mortality. Clinical Decision Support (CDS) are tools within certified electronic health records that provide clinicians with patient-specific knowledge presented at appropriate times that enhance decision-making and improve patient outcomes (Villegas & Moore, 2018). Electronic sepsis alerts are examples of CDS that are developed to monitor changes indicative of sepsis in the patient's condition and alerting providers to expedite early intervention.

Yet, despite all these improvement initiatives, sepsis rates continue to rise. Health care systems have invested millions of dollars in expanding electronic health record tools, including the CDS sepsis alert, in order to increase the early identification of sepsis and implementation of early interventions. Yet the opportunity for improving their use is missed due to the lack of evaluation of its effectiveness.

This project was a program evaluation of one health care system's sepsis CDS and associated improvement initiatives that are focused on the prevention of sepsis among adult medical-surgical patients. The W.K. Kellogg Step by Step Guide to Evaluation (2017) was used to conduct the program evaluation of their sepsis CDS, including electronic sepsis order sets, sepsis education, and an overhead code sepsis process. Despite these initiatives, the organization's Medicare quality sepsis scores demonstrate that a large percentage of their patients are not receiving evidence-based sepsis care, as documented in the electronic health record (EHR). The analysis and recommendations provide needed information to guide future quality improvements in sepsis care to improve sepsis prevention, improve patient outcomes, and reduce health care costs. The use of systematic program evaluation methods can be used as a strategy to determine the improvement gains from a quality improvement project.

Keywords: electronic sepsis alert, sepsis criteria, machine learning, clinical alerts, clinical decision support, vital signs, clinical deterioration.

An Evaluation of Initiatives to Reduce the Severity of Severe Sepsis in a Two-Hospital System

Sepsis is the most expensive clinical condition to treat in the United States (Torio & More, 2016). The highest mortality and cost are associated with patients who develop sepsis while in the hospital (Castellucci, 2020). The goal of sepsis treatment is to intervene as early as possible utilizing established criteria.

In 2014, electronic health records (EHR) were in place nationwide in all acute care hospitals as required by the Health Information for Economic and Clinical Health Act (HITECH) of 2009 (Health Information Technology for Economic and Clinical Health Act, 2009). The goal of the EHR is to improve the quality of care, reduce medical errors, and decrease administrative costs (Health & Human Services, 2004). EHR technology has drastically changed our practice, workflow, and how we coordinate care for our patients. The development of automated clinical decision support systems (CDS) operationalize clinical logic into triggers, warnings, messages, and alarms (McBride & Tietze, 2019). These automated detection systems or electronic alerts (EAs) are tools to accomplish the EHR envisioned goals, especially in preventing medication errors. Recently, other electronic alerts specific to clinical conditions have been designed. Electronic sepsis alerts monitor changes in the patient's condition to expedite early intervention, resulting in a decrease in severity and mortality (Villegas & Moore, 2018). These EAs are very costly. The literature does not reflect that hospitals who have implemented these EAs have completed a formal evaluation of the clinical outcomes and their investment return. A large amount of time, money, and resources have been spent on the EHR. Ongoing dollars will continue to be needed to support these electronic systems. With healthcare costs increasing and more quality outcomes tied to pay-for-performance, it is imperative to determine if these systems have impacted quality, safety, and communication. As organizations, we are still learning how to maximize the benefits of the EHR by knowing how to use the massive data available in in the EHR.

Healthcare Problem

EAs are rule-based detection systems based on international sepsis definitions and criteria. A cloud-based system patrols the EHR, constantly evaluating patient's laboratory values and changes in vital signs (VS), which are the early signs of deterioration in sepsis. If specific changes are detected, the alert fires, notifying the nurse to evaluate the patient further, implement a sepsis bundle, and notify the physician. There are currently three levels of severity for hospital sepsis based on ICD-10 coding: sepsis, severe sepsis, and septic shock (Paoli et al., 2018). The cost and mortality increase with each level of severity.

Another aspect that affects the EA is the completeness and timeliness of VS EHR entries. These entries are necessary for the electronic alert to fire as soon as these changes are detected by the surveillance (Huff et al., 2018; Yeung et al., 2012). In the emergency department (ED) and the intensive care unit (ICU), VS are automatically populated into the EHR from the bedside monitors. This is not true in the medical/surgical (M/S) units of the project organization. Identifying the barriers to timely and complete VS documentation on the M/S units is essential in triggering the EA. The purpose of these EA is to detect and treat early clinical deterioration in potential sepsis patients, resulting in a decrease in sepsis frequency, severity, and mortality.

To further complicate the sepsis picture, there is a current gap between new knowledge and practice which has not yet been resolved. The criteria to diagnose sepsis have evolved over the years. In 1991, the Sepsis-1 definition was developed at a consensus conference in which four systemic inflammatory response syndrome (SIRS) criteria were established (Bone et al.,1991). Sepsis-1 was defined as infection or suspected infection leading to the onset of SIRS. Severe sepsis involves organ dysfunction (Marik & Taeb, 2017). Septic shock occurs when hypotension persists despite adequate fluid resuscitation. In 2001, the International Sepsis Definitions Conference (2003) recognized the limitations of the definition. However, due to a lack of supporting evidence, they only expanded the list of diagnostic criteria resulting in the Sepsis-2 definition (Marik & Taeb, 2017). The definition of sepsis, severe sepsis, and septic shock remained unchanged for two decades. Only the criteria changed (Marik & Taeb, 2017). In 2016 a task force of the Society of Critical Care Medicine and the European Society of Intensive Care Medicine proposed a new sepsis definition, Sepsis-3.

The Sepsis-3 definition is “life-threatening organ dysfunction caused by a dysregulated host response to infection” (Singer et al., 2016, p.2). Organ dysfunction can be assessed by utilizing the Sequential (Sepsis-related) Organ Failure Assessment (SOFA) score of two or more points. This criterion has been predominately used in ICU to predict mortality. A quick (q) SOFA score of two equates to in-hospital mortality greater than 10% (Singer et al., 2016). The qSOFA criteria were developed to be used at the bedside and as a potential screening tool. Septic shock was then defined as a subset of sepsis in which the patient experiences “ profound circulatory, cellular, and metabolic abnormalities … with a greater risk of mortality than with sepsis alone” (Singer et al., 2016, p.2). Septic shock has an associated mortality rate of greater than 40%. The task force eliminated the category of severe sepsis as it appeared to be

redundant. The Sepsis-3 definition does not focus on inflammation as the SIRS criteria seem inadequate from a specificity and sensitivity perspective as supported by the literature (Kim & Park, 2019). SOFA and qSOFA criteria are used in the organ dysfunction assessment process. Table 1 compares the traditional and revised Sepsis-3 definitions of sepsis. Table 2 contrasts the SIRS and qSOFA criteria. It has taken several years for all the necessary medical societies to endorse the new Sepsis-3 definition and SOFA criteria. However, there is still inconsistent research findings on the effectiveness of the Sepsis-3 definition and use of the qSOFA criteria as a screening tool.

The gap involves several factors:

- Current practicing physicians and nurses have been educated on Sepsis-1 and Sepsis-2 definitions and criteria. Newly educated physicians and nurses have been educated on Sepsis-3 definitions and criteria.
- ICD-10 coding has three categories of sepsis: sepsis, severe sepsis, and septic shock. New ICD-11 coding is scheduled for release in 2022.
- Most commercial payors have adopted the Sepsis-3 definition and criteria. Payment is based on the documentation that the patient had organ dysfunction not SIRS.
- Medicare uses Sepsis-2 definition and criteria in their publicly reported sepsis bundle and payment documentation.
- Most major EHR systems have automated detection sepsis systems based on SIRS criteria, not qSOFA criteria.

Until these factors are resolved, clinicians live in both worlds trying to make sense of how to detect sepsis early in their patients. While the EA assists in early sepsis detection, nurses must continue to use their critical-thinking and assessment skills. Whether one is using the Sepsis-2 or Sepsis-3 definition, documenting organ dysfunction is key in satisfying payment requirements.

Literature Review

Synthesis of Literature

The John Hopkins Nursing Evidence-Based Practice (JHNEBP) model was chosen as the framework to approach the literature review for this DNP project. This model provides an approach to clinical decision problem-solving within a health care organization, by providing several practical tools for developing the practice question and evaluating the evidence-based research related to the problem. If the data supports that a change is needed, then the translation of evidence can be implemented. This framework has a very detailed guide for the entire process from practice question to translation. It also considers the external and internal factors that can affect a clinical problem and the ability to assess the best evidence in the practice, education, and research domains of nursing and other supporting professions (White et al., 2016). This DNP project focusing on EAs is influenced heavily by internal and external factors, lending itself to the JHNEBP model.

Table 1

Comparison Traditional and Revised (Sepsis-3) Definitions

Category	Traditional Definition	Sepsis-3 Definition
Sepsis	Suspicious or known infection + $\geq$ 2 SIRS	Suspicious or known infection + increase of $\geq$ 2 SOFA
Severe sepsis	Sepsis + organ dysfunction	Not a category
Septic shock	Sepsis + refractory hypotension after adequate fluid or need of vasopressors	Sepsis + vasopressors and lactate > 2 mmol/L

Note. Adapted from "Sepsis: Early Recognition and Optimized Treatment," by H. Kim, & S. Park, 2019, *Tuberculosis and Respiratory Diseases*, 82, p. 7 (https://doi.org/104046/trd.2018.0041). Copyright 2019 by the Korean Academy of Tuberculosis and Respiratory Diseases.

Table 2

SIRS versus qSOFA Criteria

SIRS ($\geq$ 2 criteria)	qSOFA ($\geq$ 2 criteria)
Temperature (>38*C or <36*C)	Systolic blood pressure ($\leq$ 100 mm Hg)
Heart rate (> 90 beats/minute)	Respiratory rate ($\geq$ 22 breaths/ minute)
White Blood Cell (< 4000 or > 12000 or bands >10%)	Altered mental status (Glascow Coma Scale <15)
Respiratory rate ($\geq$ 20 breaths/minute, PaCO2 <32 mm Hg)	

Note. Adapted from "Sepsis: Early Recognition and Optimized Treatment," by H. Kim, & S. Park, 2019, *Tuberculosis and Respiratory Diseases*, 82, p. 7 (https://doi.org/104046/trd.2018.0041). Copyright 2019 by the Korean Academy of Tuberculosis and Respiratory Diseases.

The literature search regarding sepsis EAs has been somewhat challenging as there are many terms for the same topic. The terms are still evolving. Many studies have suggested in their discussion that standardization of terms is crucial moving forward. The databases used to conduct the literature search were PubMed, CINAHL, Agency for Healthcare Research and Quality (AHRQ), Center for Medicare and Medicaid Services (CMS), Google Scholar, and Google. The initial search terms used were:

- Electronic Alerts (EAs) generating 929 articles
- EAs and medical-surgical patients generating three articles
- EAs and clinical deterioration generating 13 articles
- EA s and sepsis generating 40 articles
- EAs and vital signs generating 32 articles

Most of the EA articles discussed medication alerts. Very few discussed disease-specific bedside alerts. Reference lists helped locate additional information with different labels, such as clinical decision support systems and automated detection systems. The inclusion criteria included: studies published from 2015 forward, EA, adult medical-surgical inpatients, clinical deterioration, clinical diagnosis, clinical criteria, and measured outcomes. Three themes emerged reviewing the research: design of the EA, content of the EA, and outcome measures evaluating the EAs' effectiveness. Later search terms included sepsis definitions and criteria. In a more recent search, deep learning, machine learning algorithm, and artificial intelligence refer to a new method for updating sepsis criteria. A total of 18 studies were selected based on quality and relatability to the project aims. The appraisal and the literature's level and quality were evaluated using the criteria outlined in John Hopkins Nursing Evidence-Based Practice: Models and Guidelines (Dang & Dearholt, 2018). A summary of the synthesis and appraisal of the literature is located in Appendix A.

Before delving into the synthesis of literature regarding sepsis EAs, the non-research evidence appraisal of Lavin et al. (2015) presented several recommendations regarding health information technology that has a bearing on this DNP project and supports the Sittig-Singh model. These three nursing authors have published many articles and presented on nursing informatics and patient safety. The experimental-reflective reasoning model was used to categorize nurses' experiences regarding the EHR, reflect on the themes and draw conclusions and recommendations. Nurses conduct few research studies on the EHR, much less on sepsis alerts. Nursing standards and nursing process need to be embedded in the EHR. This would require some needed standardization of language. Utilizing voice-activated technology would also speed up documentation and make it less of a burden. Technology improvements such as speed of the screens, higher reliability of computers on wheels to include battery life and wireless connection, and design of devices for ease of use in patient rooms impact nurses' ability to interact with the EHR effectively and efficiently. The authors highly encouraged all nurses and nursing leadership to be at the table and actively provide meaningful feedback using a common language with the health information technologists.

As mentioned above, the electronic (e) bedside alert research can be grouped into four themes: *design* of the e-alert, which is the structure and how it looks; *content* of the alert, which is the criteria that makes the alert fire; *measured outcome*s for the alert, which are the outcomes that informs one that the alert accomplished what it was supposed to do, and new approaches to sepsis criteria such as machine learning. There is some overlap of themes depending on the study.

Design of the EA studies

In the Holmes et al. (2015) study, the purpose was to determine if an electronic health record alert occurring in emergency department triage would increase the usage of triage protocols. This study was included because it was one of the very few randomized control studies on clinical EA. Nurses were randomized to receive either a passive e-alert or no alert at all. A passive e-alert does not require an action to proceed. The computer screen is asking the nurse to consider an action. The e-alert notified the triage nurse that the patient was eligible for a specific protocol. Although there was an overall increase in protocol usage by both groups, pre and post-intervention rates were very low. Random effect was considered. A passive EA showed little benefit in increasing triage protocol utilization. The authors suggested further research on active alerts, as possible contamination may have occurred between randomized groups.

The goal of the Powers et al. (2018) study was to answer three questions:

- Are hard-stop e-alerts effective in improving patient health and healthcare delivery outcomes?
- Are there adverse effects or unintended consequences of hard-stop e-alerts?
- How do hard-stop e-alerts compare to soft-stop e-alerts?

This study develops definitions of hard-stop, soft-stop, and passive e-alerts that hopefully can be used in future studies, providing standardization of terms. A hard-stop EA prevents one from moving forward until the action is completed, or only allowed to proceed with an override by a third party. A soft-stop EA allows one to proceed with or without documentation of the reason for the override. This study involved physicians primarily. A systematic review of 32 studies evaluating electronic stops was presented. The studies did not report on patient health, process, and healthcare delivery outcomes. User experience and adverse events were also not reported. The authors support further research, including all the above outcomes. They further support the inclusion of screenshots of the alerts. The majority of studies showed improvement in process outcomes such as documentation compliance and order rates. The results were mixed for patient health and healthcare delivery outcomes. Unintended consequences were alert fatigue and delay in treatment. Hard-stops were preferred to soft-stop alerts in achieving outcomes. The authors supported carefully implemented hard-stop alerts with assessment for harm and third-party override ability. With nurses as the most significant healthcare professionals in the acute care setting, more design studies should involve nurses. This was the only study found in the literature search regarding electronic stops.

The Long et al. (2019) study was the first to focus on visual, verbiage, and structural elements of an EA. Nurses were the participants. The study's purpose was to determine the best way to present an e-sepsis alert to improve decision-making by evaluating three user interfaces, elements of sepsis alerts, and visual preferences of alerts. Nurses preferred pop-up alerts. They also preferred a recommendation with the alert, not just an assessment. How the information is displayed and how it is highlighted is very important to acceptance by the nurses. Nurses rated temperature, heart rate, blood pressure, and white blood cell count as the most valuable sepsis alert elements. Respiratory rate (RR) was ranked very low. This was interesting as RR is often the first sign to change in deterioration. The word critical was chosen as the perceived highest severity word. The authors suggest that a single alert design is not appropriate. Different healthcare groups require different pieces of information; therefore, their alerts should be different. The information included in this study is key to the acceptance of an alert and requires additional research.

The Despins (2017) study aimed to conduct a systematic review of automated sepsis detection using EHR data. Thirteen studies met the inclusion criteria of: (a) automated detection approach with the potential to detect sepsis or sepsis-related deterioration in real or near real-time; (b) in the ED, neonatal, pediatric or adult inpatients; and (c) performance results on the impact of the detection. The samples were extensive in each study. Automated sepsis detection has great potential, but alerts did not necessarily lead to earlier interventions. The results were inconsistent among the thirteen studies and findings did not support improved patient outcomes. The author supported the need for more research in this area. Just because an alert is generated does not mean healthcare professionals will intervene with appropriate orders.

Content of the EA Studies

The study conducted by Kollef et al. (2014) was a randomized trial to determine if real-time EAs sent to a rapid response team (RRT) improved patient care. These real-time EAs did not decrease intensive care unit transfers, hospital mortality, or the need for subsequent long-term care. There was a one to two-day decrease in length of stay. Any decrease in length of stay is of benefit to the patient and has a favorable financial implication. The authors discussed that perhaps 30-day mortality might be a better outcome measure than hospital mortality. This study is an example of one that has content and outcome elements.

The purpose of Finkelsztein et al. (2017) was to compare qSOFA and SIRS for predicting adverse outcomes for patients with suspected sepsis outside the ICU. This was a retrospective study in which qSOFA and SIRS scores were calculated before admission to an ICU. The results demonstrated that qSOFA scores were better at predicting mortality, ICU-free days, and organ dysfunction-free days. The authors hoped that these findings might help determine the usefulness of qSOFA. This study is another example of how EHR data can be helpful retrospectively to gain new insight.

The Churpeck et al. (2017) study compared qSOFA with other commonly used early warning scores, namely, SIRS, modified early warning score (MEWS), and national early warning score (NEWS). The patients in the study were outside of the ICU. The study found that the standard early warning scores were more accurate than the qSOFA score for predicting in-hospital mortality and ICU transfer. NEWS was the most accurate score in this study. The usefulness of qSOFA outside the ICU needs further testing.

Despins (2018) conducted a systematic review of non-experimental research: (a) to identify the EHR data used in automated ICU patient detection approaches; (b) describe types of deterioration detected; and (c) to present predictive values and sensitivity and specificity results of these approaches. There was much variation in the ability to focus on specific clinical events. Variability in the detection approaches and accuracy of the measures limits the usefulness of the study. Further research is needed to determine the right combination of variables that optimizes the identification of early deterioration while minimizing alert fatigue. The author noted that high-speed data processing is essential for timely alerts. Clinical bedside EAs are still in their infancy and will continue to improve based on the research.

However, in the meantime, clinicians need to continue to use their critical thinking skills to detect early deterioration of their patient's status to prevent failure to rescue.

The study by Huff et al. (2018) was a quality improvement project to: (a) improve the frequency and documentation of VS; (b) develop an electronic vital sign alert system (VSA) that incorporated a sepsis screen; (c) improve clinical outcomes by an increase in rapid response teams (RRT), a decrease in the number of code blues, unplanned ICU transfers, and decreased length of stay and mortality; and (d) improvement in the sepsis bundle compliance. Finally, the authors wanted to evaluate nurse satisfaction with the VSA. The full complement of VS documentation increased to 89%. RRT activation decreased, and code blues remained the same. Unplanned ICU transfers in the first 24 hours increased by 31%. Although not statistically significant, the LOS for this patient group only decreased from 5.53 days to 4.29 days. However, it is significant from a patient and financial perspective. Mortality also decreased for this patient group. There was a 21% increase in sepsis recognition. The authors concluded that the VSA was effective in their hospital. There is very little research on the impact of complete VS electronic documentation. VS are crucial to the early detection of clinical deterioration. In sepsis, respiratory rate is the first VS element to change and is often left undocumented. A RRT was an intervention for early deterioration. It was interesting that RRT activation decreased instead of increasing.

Stevenson et al. (2018) used a qualitative approach to investigate factors for VS inadequate documentation in the EHR. They also noted that this topic has limited attention in the research literature. VS monitoring is a critical way in which clinical staff recognizes patient deterioration. They identified several barriers to inadequate VS documentation in the EHR: (a) lack of policy or procedure, (b) use of paper recording tools instead of the EHR or using both, (c) lack of space in the EHR for additional readings, and (d) lack of ability to trend VS easily in the EHR. The authors noted that because of these design barriers, clinical staff need to be involved in EHR documentation design.

The Villegas & Moore (2018) study was a systematic review and analysis of six research studies on existing sepsis screening tools. An increasing body of evidence supports that earlier recognition can be achieved with earlier evidence-based treatment when an effective sepsis screening tool is used. The majority of published work focuses on surgical patients limiting the applicability to other patient types. There are very few randomized trials related to sepsis screening. More research is needed to identify the optimal screening tool. There are many definitions of sepsis in the literature. Not all of the associated criteria are meant to be used as screening tools. Some are used to predict the mortality of ICU patients.

The Li et al. (2019) study used retrospective data to evaluate seven revised versions of the current electronic Cerner Modified St. John Rule in their ability to detect early sepsis and deterioration. The specifics of each version were illustrated. Each version was rated on sensitivity, specificity, PPV, NPV, and AUROC. Option six was ultimately chosen by an expert panel to be implemented. Sensitivity over specificity was chosen because there were fewer false negatives and fewer sepsis cases were missed. Retrospective data can be used to test clinical alerts before implementation. EHR data is a rich database of information that can be used to improve clinical outcomes and save lives in the case of sepsis. Hopefully, the authors will publish a follow-up implementation study.

Measured Outcomes of the EA studies

Fletcher et al. (2018) evaluated the impact of a real-time EHR-based alert dashboard on outcomes of an RRT activation and secondarily unexpected ICU transfer, cardiac arrests, and death compared with no dashboard usage. There was a statistically significant increase of the first RRT activation but no significant difference in overall RRT, ICU transfers, cardiac arrest, or mortality. This was a unique study. All patients were continuously displayed in a single view screen ranked by an early warning severity score. All healthcare professionals could see this view in the EHR, and any one of them could activate the RRT. Although the authors did not speak to this, the fact that so many people could look at the dashboard may have increased the initial RRT activation. With no dashboard, only the bedside nurse could activate the RRT. Perhaps central monitoring of this dashboard, like telemetry, might yield other outcomes more favorable to cardiac arrest and death outcomes.

Seetharaman (2019) conducted a retrospective observational cohort study to assess whether early antibiotic administration in patients with SIRS and organ dysfunction decreases patient mortality. He used a best practice e-alert that included vital signs and specific lab work in determining if this EA would result in earlier administration of antibiotics and a decrease in mortality. Time to antibiotic administration in the study patients did not affect 30-day mortality rates. There was an increase in antibiotic use with the alert and an increase in C-difficile infections. Mortality was affected by patient severity of illness, gender, and institution. Sepsis is a highly complex condition as evidenced by the constantly changing criteria based on research. Research on potential sepsis criteria is needed to develop more sensitive and specific criteria.

The Rhee et al. (2019) study developed an abbreviated electronic version (e-SOFA) of the Sequential Organ Failure Assessment (SOFA) criteria and compared the two for prevalence overlap and mortality outcome. The SOFA score utilizes the Sepsis-3 definition, and e-SOFA utilizes the CDC adult sepsis event definition. There was good overlap, and mortality was higher for the e-SOFA because it identified a smaller, more severe sepsis cohort. The e-SOFA would be easier to use because the data is readily available in the EHR and could lend itself to automated sepsis surveillance with variable EHR systems. This study is an excellent example of taking an accepted sepsis definition and applying criteria available in the EHR for an EA.

New Approaches to Early Sepsis Detection

The sepsis screening tools such as NEWS, MEWS, SIRS, SOFA, and qSOFA are rules-based alerts The EA is based on these screening tools and is therefore also rules-based. After reviewing the literature, none of the existing screening tools have been specific and sensitive enough to detect early sepsis deterioration. The EHR has ushered in big analytics in healthcare. New approaches such as machine learning are yielding promising results. Machine learning is an application of artificial intelligence (AI) that provides systems the ability to automatically learn from their own experience without being explicitly programmed (McBride & Tietze, 2019). Machine learning algorithms (MLA) can process tasks and large amounts of data (Burdick et al., 2020). This appears to be a possible solution to learning from the massive amounts of EHR data to test algorithms for new sepsis screening tools.

Zhang et al. (2018) used clinical knowledge and machine learning to develop and maintain best-practice order sets. This was the first study that attempted to use machine learning in the clinical setting. They simulated six revisions of a morning lab order set using retrospective EHR data. Results suggest that this approach improved usability while updating the best practice clinical content.

Lauritsen et al. (2020) developed a machine learning model to assess early sepsis detection timeliness. Retrospective EHR data of seven years from multiple hospitals were used from all 18 years and older patients outside of the ICU. Their deep learning system learned characteristics of critical factors and interactions from the event sequence data. The mathematical platform is very complex and will not be discussed in detail here. This approach may be very useful in further defining early deterioration criteria based on retrospective EHR sepsis data. The authors concluded that their sequential deep learning model could detect sepsis at a very early stage. They suggest a prospective confirmatory study to determine the model's usefulness in real-time.

The purpose of the Burdick et al. (2020) study was to develop and validate an MLA that would predict severe sepsis up to 48 hours before onset. This retrospective analysis of EMR data included 510,497 inpatient and ED encounters over six years. The MLA performance was compared to commonly used sepsis scoring systems and evaluated at 0, 4, 6, 12, 24, and 48 hours before severe sepsis onset. The MLA outperformed the rules-based screening tools MEWS, SOFA, and SIRS. Sepsis can be influenced by patient age, race, and comorbidities. The MLA demonstrated that it could be tailored to these specific factors. The MLA had a high specificity, which could decrease alarm fatigue.

Models

The socio-technical model of Sittig and Singh (S&S) for studying health information technology in a complex adaptive healthcare system aligns perfectly with the DNP project.

The S&S model was developed specifically to be used in studying health information technology (HIT) from design, development, implementation, use, and evaluation by considering eight dimensions: (a) hardware and software; (b) clinical content; (c) human-computer interface; (d) people; (e) workflow and communication; (f) organizational policies and procedures; (g) external rules, regulations and pressures; and (h) system measurement and monitoring (Sittig & Singh, 2010). These human and technical components cannot be studied in isolation but must be studied together as a complete functioning system (Sittig & Singh, 2017). Their conceptual model has been successfully used to validate its usefulness in understanding these dimensions' dynamic behaviors as a single, complex adaptive system (Sittig & Singh, 2017). Since this project involves the EHR, the S&S model will be a very comprehensive approach to identify barriers and issues that adversely impact the early recognition of sepsis patients in this organization. This model allows the electronic sepsis alert processes to be evaluated within the EHR system. The impact of this model on evaluating the improvement initiatives will be discussed later in the paper.

S&S emphasize that their model is NOT a set of independent parts studied in isolation, analyzed in isolation, and then integrated back to understand the complex system. One must study how the eight dimensions interact simultaneously to understand the system (Sittig & Singh, 2010). One of the dimensions is workflow and communication. This occurs as a two-way street between human and non-human factors, each interacting and influencing the other. An example of this is a triggered sepsis alert (non-human), and the nurse (human) is notified to take action. The trigger may not be designed well enough to make the nurse react. As a result, no additional data is generated. If the nurse reacts, then the data (non-human) is captured in the EHR for others to be aware of the patient's condition. However, all the other seven dimensions interact simultaneously with workflow and communication and must be considered influences. The S&S model provided a valuable framework to identify potential barriers by dimension. This framework was relevant to this DNP project.

The Institute for Healthcare Improvement (IHI) model provides a variety of methods to conduct process analysis. Workflow analysis of the VS process on the medical/surgical units will be conducted utilizing the IHI flowchart method (Orginc et al., 2018). This will provide a visual depiction of the existing VS process for completeness and timeliness on the M/S units.

Fuller et al. (2018) noted that many barriers can affect the documentation of VS. A thorough flowchart analysis will uncover the barriers in the project organization.

Approach

Program evaluation has been used by institutions of higher education, school districts, government agencies, public health, and private organizations. Program evaluation is a systematic approach to determine the quality and value of a program, initiative, or strategy (Adams & Neville, 2020). The goal of program evaluation is to make an impact on stakeholders, such as clients, providers, administrators, and policymakers regarding the effectiveness and efficiency of programs (Royse et al., 2016). There are many frameworks to use such as the Centers for Disease Control and Prevention (CDC, 1999) and easy evaluation (Adams & Neville, 2020) to name a few. However, the W.K. Kellogg Foundation model was chosen for this DNP project. Within the Kellogg framework, there are multiple evaluation types, methodologies, and approaches. This flexibility is the rationale for utilizing this framework. Details of the model will be discussed in the methodology section.

Project Description

Project Purpose

The purpose of this DNP project is to evaluate sepsis improvement initiatives for adult medical-surgical patients, including automated detection systems, to reduce the frequency, severity, and mortality of sepsis in a two-hospital system located in Florida. The project organization recently implemented a vendor SIRS EA, the vendor sepsis EA, electronic sepsis order sets, and an overhead code S process. An overhead page, code S, is activated by the charge nurse when a sepsis alert is triggered. Despite these initiatives, the organization's Medicare quality sepsis scores demonstrate that a large percentage of their patients are not receiving best practice sepsis care, as evidenced by EHR documentation. The vendor projected specific performance outcomes as a result of implementing the sepsis Alert. These are reflected in the objectives.

Project AIMS and Objectives

1. Utilize the Sittig-Singh socio-technical theory to evaluate the interoperability and quality of human and non-human actors in the network of an electronic sepsis alert.
    a. Apply the eight dimensions of the Sittig-Singh model during the project.
    b. Determine the impact of these dimensions on the initiatives.
    c. Create a timeline grid of implemented initiatives to correlate with data.
2. Evaluate electronic sepsis alert performance measures as presented by the vendor in 2018.
    a. Reduction in sepsis mortality by 17%
    b. Reduction in length of stay (LOS) by 17.5%.
    c. Reduction in severe sepsis and septic shock to a single-digit percentage.
3. Evaluate nursing staff workflow and performance involving sepsis alerts

a. Determine sepsis order set usage.

b. Determine the overall completeness of VS documentation in severe sepsis review.

c. Determine the timeliness of VS entry into the EHR.

d. Develop the workflow diagram of the VS documentation process on the medical-surgical units.

4. Summarize the impact of sepsis reduction initiatives and areas for improvement.

a. Present summary findings and goal achievement

b. Present recommendations to nursing for improved process performance for vital sign documentation and sepsis alert team.

c. Identify future process evaluations and recommendations

Methodology

The W.K. Kellogg Foundation (2017) step-by-step guide was used as the DNP program evaluation framework. This framework was chosen because of the detailed process that is clearly articulated. This framework has seven major areas to consider in the process (Kellogg, 2017):

a. Prepare for conducting an evaluation – this includes determining who benefits from the evaluation, what are the potential risks, what else is happening concurrently that may affect the evaluation, what type of evaluation, and which evaluation approach.
b. Determine who the stakeholders are and how and when to engage them – create a plan to involve them, identify the areas for their input, and have the stakeholders participate regularly.
c. Identify underlying assumptions for why the initiative or program will result in the predicted outcome – developing a theory of change or logic model helps guide the evaluation process.
d. Develop the evaluation plan – evaluation questions need to be determined, and a measurement framework to identify the data sources, frequency of data collection, and the quantitative/qualitative measure of change. Other areas to address in the plan are data collection methods, analysis strategies, reporting findings, and recommendations.
e. Collect and analyze the data – collect data from multiple sources and analyze the data utilizing quantitative and qualitative methods.
f. Communicate and interpret the results – stakeholders may have insights into the findings utilizing reflective thinking.
g. Make informed decisions – interpretation of the findings will lead to recommendations for future improvements.

Appendix B is a visual depiction of the Kellogg model. This framework defines evaluation as a process of “collecting and summarizing evidence that leads to conclusions about the value, merit, significance, or quality of an effort" (Kellogg, 2017, p.14). Evaluative thinking is the focus of the process, which involves "dialogue, reflection, learning, and improving" (Kellogg, 2017, p.14). One of the Kellogg evaluation guiding principles is that evaluation planning should begin when new strategies, initiatives, and programs are conceptualized (Kellogg, 2017). It has been the authors experience, that this principle is often not followed in the healthcare setting. Often the focus is the implementation, and the evaluation outcomes are often lost in the process. If one plans how to evaluate the program or initiative from the very beginning, there is increased likelihood that it will occur.

This DNP project utilizes the following types of evaluation:

- Performance monitoring focuses on using electronic order sets, electronic alerts, and sepsis team activation when the alert is triggered.
- Process evaluation answers the question of why vital signs are not complete and entered in a timely fashion.
- Outcome evaluation determines if there has been a reduction in frequency, severity, LOS, and sepsis patients' mortality.

An evaluation approach defines the way one goes about designing, implementing, and using the evaluation (Kellogg, 2017). The approach chosen for this evaluation is the empowerment evaluation. This approach provides the organization with the tools and knowledge that will assist them in improving their initiatives. Hopefully, this approach will help the organization learn new strategies for analyzing their sepsis data, participate in the interpretation of the findings, and have future improvements to implement because of this project. The evaluation methodology used will be outcome mapping, reflecting on how these initiatives are impacting the outcomes of sepsis patients. A mixed method quantitative and qualitative data approach will be employed, resulting in a more robust and complete evaluation (Kellogg, 2017).

A logic model was developed to illustrate the connections among resources, activities, outputs, and outcomes. Table 3 reflects the sepsis initiatives Logic Model. The questions to be answered in this program evaluation are:

- Did the organization's initiatives reduce the frequency, severity, and mortality of sepsis cases?
- What are the perceived organizational barriers to sepsis improvement?
- What improvements can be made to the VS workflow process on the medical/surgical units to improve completeness and timeliness of electronic entry?

These evaluation questions were based on the type of evaluation, the approach of the evaluation, and the outputs of the logic model. The framework of the Kellogg model truly supports the process of determining the evaluation questions to be answered.

Implementation of Evaluation

This evaluation occurred during the Covid-19 pandemic limiting the availability of staff and face-to-face conversations. These hospitals were extremely busy caring for Covid-19 patients. It was necessary to pull clinical support staff in quality and IT into staffing. Initially, a literature search was conducted on electronic alerts. An initial email was sent to the preceptor explaining potential options for the project. The initial discussion in October of 2019 with the organizational preceptor helped narrow this DNP topic from electronic clinical bedside alerts to an evaluation of sepsis initiatives, including the recently implemented SIRS and severe sepsis electronic alerts in their EHR system. Despite several new sepsis initiatives, the organization's Medicare quality sepsis scores demonstrate that a large percentage of their patients are not receiving timely sepsis care as defined by Medicare's sepsis bundle. This is significant since this two-hospital system ranks number three nationally for the highest number of Medicare admissions in the United States. Table 4 displays the Medicare hospital compare data for these organizations. Status quo is not an option for this system. Sepsis care improvement is a top priority for them.

Table 3

Sepsis Initiatives Logic Model

Program Implementation			Intended Outcomes		
Inputs	Components/Activities	Outputs	Initial	Intermediate	Long-term
EMR Mentor time Preceptor time Staff time- decision support, quality, IT staff, sepsis committee members DNP student time	***Data*** - Obtain data from pre & post initiatives: Overall sepsis LOS 2018-2020, LOS & mortality by ICD-10 sepsis code, Covid-19 patients coded with sepsis, sepsis order set usage, sepsis alert usage -Obtain latest hospital compare data for pre/post -Obtain data on VS completeness & timeliness of entry ***Surveys*** - Develop sepsis committee survey to determine success & barriers in sepsis initiatives ***Workflow -VS*** - Develop a process for onsite observations -Develop workflow diagrams. ***Code Sepsis*** -Obtain data on usage ***Alert Action*** -Develop a process for reviewing alert action documentation	Data obtained Sepsis committee surveys completed & data compiled VS audit completed Workflow diagram completed Alert action documentation categorized.	Increase in order set usage Increase response to e-sepsis alert Increase staff awareness around early recognition of sepsis patients Ongoing improvement in VS compliance	Staff suggestions to improve the VS process	Hospital compare data improved Cost savings for overall sepsis care Decrease in mortality of sepsis patients Decrease in frequency & severity of sepsis

Environmental context: Organization utilizes six sigma, IHI quality improvement methods, committed to quality improvement, team environment.

Note: Adapted from "Understanding and Applying Program Logic Models," by J. McDavid, I. Huse and L. Hawthorn, 2019. *Program Evaluation and Performance Measurement: An Introduction to Practice*, p. 55, copyright 2019 by SAGE Publications, Inc.

Table 4

Medicare Hospital Compare Compliance with Sepsis Bundles

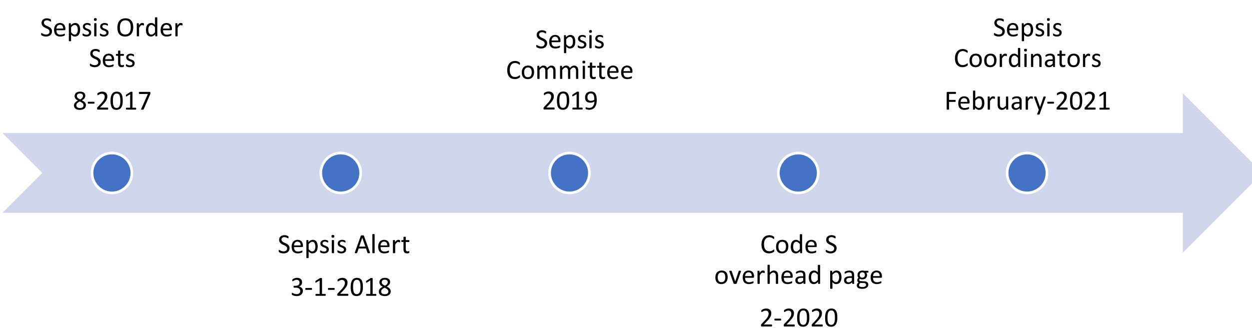
% Compliant	Hospital #1	Hospital #2	Closest Competitor	Fl Average	US Average
% compliant 4-1-18 to 3-31-19	40%	41%	67%	67%	58%
% compliant 1-1-19 to 12-31-19	52%	51%	71%	68%	60%

Note: Data obtained from Center for Medicare & Medicaid Services (2020, June 22).

A gap analysis was performed on electronic sepsis alerts supported by the literature to current sepsis practices at the project organization. An additional literature search, including the term sepsis, was conducted following the preceptor's initial meeting to include the project's additional focus. A chronological timeline was developed for the implemented initiatives to determine timeframes for data abstraction. Table 5 displays this timeline. Electronic order sets were available for use in August of 2017. The SIRS and Sepsis alerts were implemented in March of 2018. The physicians and staff were educated on functionality of these EAs.

Table 5

Timeline of Implemented Sepsis Initiatives



Stakeholders were identified for the project, and an initial stakeholder meeting was scheduled for

October 2020. At this virtual meeting, a PowerPoint presentation was used to convey the project's nature, including potential enterprise data that would be needed. A consensus was obtained for moving forward with the project. Attendees included the Chief Information Officer, who serves as the preceptor for this project, Clinical Informatics Director, Corporate Manager of Quality, and Decision Support Manager. All enterprise data was requested at this initial meeting. The request included:

- length of stay for sepsis by ICD-10 code for 2018 thru February 2021
- sepsis mortality by ICD-10 code for 2018 thru February 2021
- sepsis order set usage for inpatient-only (not ED) for 2018 thru February 2021
- sepsis alert usage for 2018 thru February 2021
- sepsis bundle data from Medicare
- completeness of VS in EHR
- timeliness of VS entry in EHR
- # of times sepsis team activated from 2020 thru February 2021
- number of Covid-19 cases with sepsis from 2020 thru February 2021

Any issues abstracting this data would be discussed at future meetings. Initially, the collection of Medicare sepsis bundle data by the quality staff was discussed. In this system, each hospital has approximately 80 to 100 sepsis cases monthly. A contracted vendor selects a sample of 20 from the total number of sepsis cases, the minimum number required by Medicare. Clinical quality abstractors review the cases utilizing a manual grid of the Medicare sepsis bundle seven elements that must be met on each patient to be compliant. This data is then entered into the Medicare data reporting website. Physician fallouts are discussed with the attending physicians by the physician educator. Nursing fallouts are sent to the director to be discussed with the nurse. While this organization submits only 40 abstracted sepsis cases monthly to Medicare, its competitor submits data on 100% of their sepsis cases. There is a monthly system Sepsis Committee meeting where this data is discussed, and recommendations made. The DNP student attended these virtual meetings for eight months. During the initial meeting, the quality manager commented that during the Covid-pandemic, their mortality scores have increased because many of these patients developed sepsis as a Covid complication. It was determined that the number of Covid-19 patients who also had a sepsis diagnosis would not be abstracted. The Decision Support Manager will abstract length of stay data for sepsis, severe sepsis, and septic shock. Finally, completeness and timeliness of vital sign data were addressed.

A sample of VS data will be extracted from the day shift and night shift. This data is needed for the calculation of completeness and timeliness of entry into the EHR. This is an area of concern identified by all the stakeholders. This data is not currently being tracked. Vital sign data will be supported by workflow analysis on the M/S units to identify barriers to the VS process.

Multiple meetings were held with the individual stakeholders further to refine data requests and other courses of action when data was not available. Refinements included developing a survey for sepsis committee members to provide input on successes and barriers of sepsis initiatives. A qualitative five question survey was distributed to all the 23 sepsis committee members. Appendix C contains the actual survey. Since nursing documentation of response to sepsis alert was not a required field, IT could not pull this data.

Another aspect of this project is reviewing and analyzing the CMS management bundle for severe sepsis and septic shock. This is the composite measure publicly reported and what prompted this organization to focus on sepsis as a top-quality priority.

Data Management Plan

Several data sets will be collected and analyzed to determine if the improvement initiatives reduced the frequency, severity, and mortality of sepsis patients. Data analysis aspects are displayed in Table 6. The frequency and severity of sepsis by ICD-10 coding will be compared with the sepsis initiatives timeline to determine if improvement has occurred. Covid-19 sepsis cases have been identified and were eliminated from the overall data results. The stakeholders have validated data to ensure accuracy, validity, and reliability. The program evaluation was conducted from January 2021 through July 2021. The expertise of the decision support staff and the information technology staff were

Table 6

Data Management Plan

Data	Data Management & Display	Data Analysis	Strengths	Weaknesses	Timeline
LOS for sepsis by ICD-10 code for 2018-2021	Excel spreadsheet, bar graph, table	Descriptive - quantitative frequency	Needed to determine outcomes	Potential coding error	12-1-20
Sepsis mortality by ICD-10 code for 2018-2021	Excel spreadsheet, bar graph, table	Descriptive- quantitative frequency	Needed to determine outcomes	Potential calculation error	12-1-20
Sepsis order set usage for inpatient only (not ED)	Excel spreadsheet graph, timeline table	Descriptive- quantitative frequency	Needed to determine outcomes	Abstraction error	1-1-21
Covid sepsis cases 2020-2021	Excel spreadsheet graph	Descriptive- quantitative	Needed to compare	Potential coding error	3-31-21
Medicare bundle sepsis data	Excel spreadsheet, graph, table, scoreboard grid	Descriptive - quantitative frequency	Needed to determine outcomes	40 cases monthly	1-1-21
VS completeness in EHR	Excel spreadsheet, scatter plot, graph	Descriptive - quantitative frequency, central tendency	Needed to determine scope of problem	Sample only	1-1-21
Timeliness of VS entry	Excel spreadsheet, scatter plot, graph	Descriptive - quantitative frequency , central tendency	Needed to determine scope of problem	Sample only	1-1-21
Sepsis alert usage	Excel spreadsheet, grid	Descriptive - Frequency	Needed to determine scope of problem	Abstraction error	1-1-21
# of times sepsis team activated 2020 - 2021	Excel spreadsheet, bar graph, table	Descriptive – quantitative frequency	Needed to determine outcomes	Manual-accuracy	3-1-21
Structured survey	Microsoft word, graph	Descriptive - qualitative themes	Identify additional barriers	Bias	3-31-21

instrumental in creating programs to abstract the data. Several times during the project, adjustments were made when the data was not available. Interprofessional collaboration was key to the success of this project. These professionals brought valuable insight into the data portion of the project.

Findings

Aim 1

This aim was to utilize the Sittig-Singh socio-technical theory to evaluate the interoperability and quality of human and non-human actors in an electronic network. These human and non-human factors need to be studied as a single, complex adaptive system. Without this framework, important aspects of the project would never have been uncovered. A grid is provided in Table 7 which shows the electronic sepsis alert impacted by the eight dimensions. All the objectives for aim one were accomplished: the S&S framework was used; impact of the dimensions on the project were determined; and the initiative timeline grid was created for the project.

Table 7

Impact of Dimensions on Project

Dimension	Project Impact	Dimension	Project Impact
Hardware & software	Is there a delay in receiving timely alert	*Workflow & communication*	Does staff understand workflow of process
Clinical content	Vital signs not entered timely or complete	*Internal policy, procedure, culture*	Review existing vital sign policy & procedure
Human/computer interface	Lack of understanding between VS & alert	*External rules, regulations, pressures*	Publicly reported quality scores
People	Staff finds design of alert not effective, alert fatigue	*System measurement & monitoring*	Has this alert process ever been monitored

Aim 2

This aim was to evaluate electronic sepsis alert performance measures as presented by the vendor in 2018. The vendor presented a detailed workplan for the implementation of the e-sepsis alert. The project timeline was six months. All data presented is sepsis cases only. The first measure was sepsis mortality decrease by 17%. Table 8 shows the sepsis mortality rates for both hospitals for Fiscal Year (FY) 2018 through February of FY 2021 without Covid. Their fiscal years run July through June. The author felt it was important to present frequency, severity, cost, and mortality-data without Covid to not skew the data.

Table 8

Comparison of Sepsis Mortality FY 18 thru February FY 21 without Covid cases

Overall sepsis mortality mean	FY 18	FY 19	FY 20	FY 21
Hospital 1	14.1%	14.70%	16%	20.3%
Hospital 2	13.3%	11.75%	13.45%	18.8%

There was a slight decrease in sepsis mortality in FY 2019, but over time each hospital's sepsis mortality has increased. The vendor projection was not met.

In October of 2019, the hospitals began to track hospital-acquired sepsis mortality. Hospital-acquired sepsis carries the highest mortality and cost (Castellucci, 2019). Table 8 displays the hospital-acquired mortality rate for each hospital FY20, which was for nine months, and for FY21, which was for eight months. As was stated earlier, hospital-acquired sepsis carries a 40% higher mortality rate.

The second vendor measure was a reduction in length of stay (LOS) by 17.5%. Table 10 shows the LOS for each hospital for FY18 through February FY21. This data includes with Covid (C) and without Covid (NC). LOS change was calculated without Covid patients. LOS is an important measure. Patients are happier if their hospital stay is shorter. From a hospital finance perspective, for every *overall 0.1%*

decrease in LOS, there will be a net positive impact on the bottom line of approximately $300,000 to $400,000 (HCPro, 2004). The LOS decreased at each hospital. Hospital one decreased by 3.9% and hospital two decreased by 13.1%. The vendor projection of a 17% reduction in LOS was not met.

Table 9

Comparison of Hospital-acquired Sepsis Mortality FY 20 and FY 21

Hospital-acquired sepsis mortality mean	FY20	FY21
Hospital 1	19%	26.6%
Hospital 2	23%	25%

Table 10

Comparison of Sepsis LOS FY 18 thru February FY 21

Overall LOS	FY 18	FY 19	FY 20-C	FY 20-NC	FY 21-C	FY 21-NC
Hospital 1	9.26	8.97	8.2	8.23	9.89	8.9
Hospital 2	7.6	7.27	7.03	6.97	7.16	6.56

The third vendor measure was a reduction in severe sepsis and septic shock to a single-digit percentage. Table 11 shows the percentage of severe sepsis and septic shock for each hospital for FY 18 through February FY 21 with and without Covid. There was a steady increase in the percentage of severe sepsis and septic shock cases at both hospitals, regardless of the impact of Covid. The overall vendor projection of a reduction of severe sepsis and septic shock to a single-digit percentage was not achieved.

Table 11

Comparison of Percentage of Severe Sepsis & Septic Shock Cases FY 18 thru February FY 21

Cases	FY 18	FY 19	FY 20-C	FY 20-NC	FY 21-C	FY 21-NC
Hospital 1	22.5 %	29.6 %	32%	32%	57.7%	67.5%
Hospital 2	26.8 %	30.6 %	37%	36.8%	40.3%	46%

Aim 3

This aim is to evaluate the nursing staff workflow and performance involving sepsis alerts. Before reviewing data of this aim, Table 12 reflects the annual number of sepsis cases.

Table 12

Total annual admitted sepsis cases – without Covid

Sepsis cases	FY 18	FY 19	FY 20	FY 21 Annualized
Hospital 1	803	901	1138	1110
Hospital 2	1108	1234	1430	1325

The frequency of sepsis cases continues to rise, with a leveling off in FY 2021. There is continued growth in the population, especially seniors. Every year more senior facilities are built, such as memory care, assisted living, independent living, and long-term care. Elderly patients are at higher risk for sepsis.

Sepsis order set usage was determined. The assumption would be that over a period, sepsis order set usage would increase as all the players were educated on the purpose and process. There was an annual increase in order set usage as anticipated. Table 13 reflects the sepsis order set usage. Although the focus of this study is admitted M/S patients, ED sepsis order set usage was also included. Most of the sepsis patients are admitted through the ED, often with a urinary tract infection.

Table 13

Sepsis Order Set Usage for Both Hospitals

Order set	FY 18	FY 19	FY 20
ED Sepsis	4047	5907	6692 *includes Covid
Hospital sepsis admit	485	505	891 *includes Covid
Hospital-acquired sepsis	N/A	31	120 *includes Covid

EAs are also triggered in the ED. The ED physicians order the sepsis order set for only the ED. If the patient is admitted, the orders not completed will occur on the unit. The ED is doing a good job of ordering the sepsis order set. But once the patient is admitted, the hospitalist or attending physician orders an admission order set. In sharp contrast to the ED, the attending physician is NOT ordering the sepsis hospital admission order set for most of sepsis-admitted patients. A review of 80 Medicare abstracted admitted sepsis patient charts revealed that the sepsis order set was only ordered once. This review supports the above admit data.

The overall timeliness of VS entry into the EHR on the M/S units was abstracted for two days at both hospitals. The range for entry into the EHR after the VSs were completed was 27 to 73 minutes, with a mean average of 52 minutes. Overall completeness of the VS documentation revealed that only 30% of the time was a complete set of VSs recorded with the respiratory rate being the most excluded element of the VS. There is no policy or procedure around the VS process. The certified nursing assistants (CNAs) are responsible on the M/S units to obtain the routine VS. A shadow experience was completed to observe the VS process. A detailed cause and effect diagram is contained in Appendix D, which lists the reasons why the VSs are incomplete and not entered in a timely fashion.

The new CNAs are oriented on the process by another CNA. There is a no consistency in the process. Since there is no organizational policy or procedure on VSs, everyone develops their own workflow. The VS caddy is used to record the temperature, blood pressure, pulse, and pulse oximetry of each patient in the order in which the VSs were taken. That data is automatically populated on the digital display. There is no way to digitally record the respiratory rate. No corresponding paper system is used. The staff state they just remember the respiratory rate for 12 patients. No identifying marker is available to inform the CNA which patient's VS is which. The caddy visual display just lists the VS by row in the order in which they were taken. If a patient is off the unit, the CNA must remember this. The CNA stated that you just remember the order in which you take the VS.

Generally, the data is not entered into the EHR which is available in the patient's room. The rooms are small, and the pulldown computer is at the head of the bed, usually with a bedside stand and IV pole on wheels in front of it. The equipment needs to be moved first to be able to access the computer. The CNA then needs to log in, and the list of the assigned patients appears on the screen. The CNAs feel there is lack of privacy, as the patient in the room is often sitting on the edge of the bed and can see the screen. Most CNAs wait until the they have completed the 12 assigned patients VS and enter this data into a hallway computer station. This process usually takes a minimum of an hour to complete depending on the number of interruptions the CNA has during the process. Isolation rooms are done last because of the extended time it takes to gown-up before entering the room. The equipment also needs to be cleaned in between each patient except in the isolation rooms, where a VS caddie is located.

Aim 4

This aim is to summarize the impact of the sepsis reduction initiatives and areas for improvement. The summary and recommendations will be discussed in a later section.

Before Covid, a structured in-person interview with the stakeholders and the sepsis committee questions can be found in Appendix C. Sixteen members responded for a 70% return rate. The following perceived strengths were identified:

- implementation of the sepsis alert
- utilization of the CMS best practice guidelines
- order set usage in the ED
- sepsis bundle checklist in the ED
- clinical education especially sepsis awareness week
- code sepsis overhead page
- hiring of sepsis coordinators
- educational sepsis handouts for the community

The following perceived barriers were identified:

- lack of physician clinical competence and compliance with the sepsis bundle
- physician use of favorites list for order sets contributing to less sepsis order set usage
- manpower shortages
- nurse hesitancy to use the overhead Code S. Physicians not ordering sepsis order set when contacted
- time constraints on nursing to respond and complete all documentation
- poor communication between nurses and providers
- covid pandemic burnout
- physician's perception that sepsis bundle is too prescriptive
- lack of timely follow-up on fallouts
- aging of the senior population
- continued growth in the population
- difference in education focus for physicians and nurses

The sepsis committee members are very committed to sepsis improvement. Some members have voiced that more discussions should occur during the meeting about barriers and possible solutions.

The overhead code sepsis was initiated in February 2020. The goal of the program was to have additional resources to assess the patient when the sepsis alert fires. The patient's nurse is to notify the charge nurse to review the patient. The switchboard operator is notified to call an overhead code S. The nursing supervisor and the laboratory will also respond. To date, this initiative has not been successful. Hospital one activated the code S six times and hospital two never activated it. The nurses are hesitant to activate it because there are so many false sepsis alerts and the physicians have been less than supportive of the follow-up phone calls from the nurse. Several studies validate that a response team had little impact on the sepsis outcomes of the patient (Fletcher et al., 2018; Huff et al., 2018; Kollef et al., 2014).

The sepsis coordinators were hired in February 2021. They are members of the sepsis committee. Their role is to round on the units and assist with daily education of the nursing staff. The impact of their role has not been determined yet because of their short tenure.

In quality improvement, education of staff is often the primary intervention. This is a major strategy of these organizations. Review of educational materials makes evident that the physician advisor approach is very different from the nurse educator's approach. The education of the nurses is geared towards the sepsis-2 definition and systemic inflammatory response criteria. The education of the physicians supports the sepsis-3 definition and organ dysfunction. This gap may be contributing to a disconnect in communication between the nurse and physicians when an alarm is activated. Their perspectives and verbiage used would be very different.

Summary

Both hospitals have seen an increase in sepsis cases. This may be attributed to the overall increase in population, especially of seniors. More senior facilities, such as assisted living and long-term care, are built each year. Compliance to the Medicare sepsis bundle has improved but is significantly lower than the closest competitor hospital, Florida, and US averages. The bundle abstracted data submitted to Medicare is 20 cases a month from each hospital. Their competitor abstracts and submits 100% of their sepsis cases. There was a decrease in the LOS which is significant for the patient and a net positive financial impact. Mortality increased in patients admitted with sepsis and in patients who acquired sepsis after admission. A concerning piece of data is that the percentage of severe sepsis and septic shock are increasing instead of decreasing. A large percentage of the patients moved from the sepsis category to severe sepsis and septic shock. None of the vendor projected performance measures were met after implementing the SA.

Order set usage did increase annually. The emergency department physicians are consistent in ordering the ED sepsis order set when the alert is triggered. The attending physicians are not ordering the sepsis hospital admission order set for most of sepsis-admitted patients. Physicians can create a favorites list of order sets. The organization is currently discussing how to change this process to make sure that the sepsis admission order set is used more appropriately instead of the generic hospital admission order set.

The lack of VS completeness and timeliness can delay the triggering of the EA. Respiratory rate is the first VS to change in early deterioration of a patient. The respiratory rate was recorded only 30% of the time. The mean average delay from VS taken to entry into the EHR was 52 minutes. The data obtained from shadowing the CNA demonstrated many flaws in the process, along with safety concerns. Overall, the various implemented initiatives have not significantly improved the sepsis outcomes for patients.

Interpretation

The use of a more systematic approach using frameworks and models, such as the Kellogg program evaluation and Sittig & Singh models, will uncover more underlying issues to the clinical problem. From this author's experience, program evaluation is not a framework that is routinely used in hospitals to evaluate quality improvement initiatives. But it is a useful tool to determine the effectiveness of the improvements. Leadership should consider involving the bedside staff in discussing the clinical problem and identifying barriers and solutions to those barriers. Management-driven improvement initiatives are one-sided. Staff provides excellent perspective to the clinical problem.

Our health care worlds are now meshed with the electronic technical world. The Sittig & Singh socio-technical model should be used when examining health information technology. The model considers all the human and non-human factors that could impact the clinical decision support system. If this model had not been used for this project, some barriers would never have been identified for resolution.

When pursuing clinical decision support products, organizations should be skeptical of the vendor’s projected outcomes. As evidenced by this project, these outcomes did not materialize. This does not mean the product will not be useful, but careful examination of the benefits should be evaluated before making the investment. Examining the evidence-based research on the clinical problem will assist in highlighting those benefits. The extensive research on sepsis alerts demonstrated why these alerts can lead to alert fatigue. Currently, the sepsis criteria used from the literature in the sepsis electronic alerts are not sensitive or specific enough to correctly identify early sepsis deterioration. More research utilizing the machine-learning approach is needed to develop more accurate alert criteria.

Clinical decision support systems generate big data. This data on actual sepsis patients can provide valuable information when testing new sepsis criteria. EHR vendors provide healthcare analytics which can also assist in making data-driven decisions. This organization is part of a larger system affiliated with a university. Exploring the system resources potential to use machine-learning algorithms could be a breakthrough.

Medicare will accept a sample of sepsis abstracted cases to measure the timeliness and effectiveness of sepsis care for seniors. These organizations submit 20 cases monthly from each hospital for a total of 480 cases, when the total annual sepsis cases for 2020 were 2,568. Their closest competitor hospital submits 100% of their sepsis cases. To be compliant with the bundle, all seven measures must be met on each patient, as documented in the record. A larger sample may yield better results.

Once barriers to the process are identified, specific outcomes for each aspect should be developed. Overall measures such as mortality are important in sepsis. However, measuring each improvement provides a more complete picture of the effectiveness of the intervention.

The VS process on the M/S units was very enlightening. The lack of VS completeness and timeliness in the EHR is supported by existing research. The act of shadowing staff can yield valuable information that impacts the clinical problem. The following recommendations to improve the VS process are:

- address the safety issue around lack of ability to document respiratory rate at the time of the VS
- address the safety issue around inability to enter patient name or room number on the VS caddy digital display
- develop an organizational policy and procedure for VS to address EHR entry timeliness and completeness
- review placement of in-room computer for easier access for staff
- evaluate length of sign-on time
- address privacy issues around documenting in the room in-front of patient
- cm onsider purchasing software for automatic VS entry from caddy to EHR

Community impact of the clinical problem and involvement in the solutions is another important lesson from this project. The number of senior living facilities located in these counties is potentially impacting the frequency of sepsis cases. Working with the leadership of these facilities could decrease the number of sepsis cases. Community education of the seniors on the signs and symptoms of sepsis, may assist them in seeking treatment earlier.

Limitations

These results and recommendations from this DNP project are specific to this organization and cannot be generalized to other systems. That being said, the frameworks and models used in this project could be helpful for organizations to consider before launching a quality improvement initiative. A well-planned process yields better results.

Conclusions

Program evaluation is a framework that can be useful in determining the effectiveness of quality improvement initiatives. Evaluation of the effectiveness of clinical decision support systems is still in its infancy. None of the current sepsis criteria are sensitive enough or specific enough to really differentiate early sepsis deterioration. As a result, staff experiences alert fatigue and cases are missed. EHR have generated big data on patients who have had the disease or problem. As a profession, development of interprofessional relationships with our colleagues in the information technology and mathematics field is imperative to be able to utilize this big data effectively and purposefully to improve bedside clinical care with electronic alerts.

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Appendix A

Key Literature Appraisal

Author	Title	Appraisal
Burdick et al. (2020)	Validation of a machine learning algorithm for early severe sepsis prediction: A retrospective study predicting severe sepsis up to 48h in advance using a diverse dataset from 461 US hospitals	Level III- High Quality Quantitative retrospective study
Churpek et al. (2016)	Quick sepsis-related organ failure assessment, systemic inflammatory response syndrome, and early warning scores for detecting clinical deterioration in infected patients outside the intensive care unit	Level III – High Quality Quantitative comparative study
Despins (2018)	Automated deterioration detection using electronic medical record data in intensive care unit patients: A systematic review	Level III – High Quality Systematic review
Despins (2017)	Automated detection of sepsis using electronic medical record data: A systematic review	Level III – High Quality Systematic review
Finkelsztein et al. (2017)	Comparison of qSOFA and SIRS for predicting adverse outcomes of patients with suspicion of sepsis outside the intensive care unit	Level III – High Quality Quantitative comparative study
Fletcher et al. (2018)	Effect of a real-time electronic dashboard on a rapid response system	Level II – High Quality Quasi-experimental study
Holmes et al. (2015)	Electronic alerts for triage protocol compliance among emergency triage nurses: A randomized control trial	Level I – High Quality Randomized control trial
Huff et al. (2018)	Implementation of a vital sign alert system to improve outcomes	Level V – Good Quality Non-research
Kollef et al. (2014)	A randomized trial of real-time automated clinical deterioration alerts sent to a rapid response team	Level I – High Quality Randomized control trial
Lauritsen et al. (2020)	Early detection of sepsis utilizing deep learning on electronic health record event sequences	Level III – High Quality Retrospective observational study

Appendix A

Key Literature Appraisal

Author	Title	Appraisal
Li et al. (2019)	Improving the performance of clinical decision support for early detection of sepsis: A retrospective observational cohort study	Level III – High Quality Retrospective observational study
Long et al. (2018)	Evaluation of user-interface alert displays for clinical decision support systems for sepsis	Level III – High Quality Nonexperimental
Powers et al. (2018)	Efficacy and unintended consequences of hard-stop Alerts in electronic health record systems: A systematic review	Level III – High Quality Systematic review
Rhee et al. (2019)	Sepsis surveillance using adult sepsis events simplified eSOFA criteria versus sepsis-3 sequential organ failure assessment criteria	Level III - High Quality Retrospective cohort study
Seetharaman et al. (2019)	Does use of electronic alerts for systemic inflammatory response syndrome (SIRS) to identify patients with sepsis improve mortality?	Level III – High Quality Retrospective Observational study
Stevenson et al. (2017)	Factors influencing the quality of vital sign data in electronic health records: A qualitative study	Level III – Good Quality Qualitative study
Villegas & Moore (2018)	Sepsis screening: Current evidence and available tools	Level III – High Quality Systematic review
Zhang et al. (2018)	Developing and maintaining clinical decision support using clinical knowledge and machine learning: The case of order sets	Level III Quantitative correlational study

Appendix B

The Kellogg Evaluation Process

Note: Visual depiction from W.K. Kellogg Foundation, 2017. *The Step-by-Step Guide to Evaluation: How to Become Savvy Evaluation Consumers.* https://www.wkkf.org/resosurce-directory#10=10&p=19

Appendix C

Survey Questions

1. What is your general understanding of the organizations sepsis initiatives?

2. How in your role do you interact or impact the sepsis initiatives?

3. What do you think are the most successful sepsis initiatives so far?
   Why?

4. What barriers do you think exist that are preventing sepsis improvement?

5. What improvements do you think have helped to eliminate these barriers?

Appendix D

Cause and Effect Diagram