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Retrospective Analysis of Obstetric Sepsis Screening

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ABSTRACT

RETROSPECTIVE ANALYSIS OF OBSTETRIC SEPSIS SCREENING

This project was designed to evaluate outcomes following implementation of routine screening for sepsis in the obstetric population. A retrospective analysis of the electronic medical record of 204 women who met sepsis criteria using obstetric-adjusted systemic inflammatory response syndrome (SIRS) criteria and a source of infection was the method used. Outcomes were evaluated for neonates born to the women who developed sepsis during labor. The incidence of sepsis was 0.401 per1,000 and included those with antepartum, intrapartum, or postpartum admissions. The setting was a tertiary center with 5,075 deliveries over the study period. There were 92 (45.2%) who had sepsis, 87 (42.6%) who had severe sepsis, and 25 (12.3%) who met septic shock criteria. There were no deaths and two ICU admissions. Mean lactic acid level for women with sepsis (*N*=203) was 2.4 +- 1.3 mmol/L. Fourteen combinations of positive SIRS criteria were present; no combination was uniquely associated with the severity of sepsis. An Apgar score of ≤ 6 at one- and five-minutes of age was more likely when the mother developed sepsis in labor, odds ratio 12.1 (95% confidence interval, 7.86, 18.61) for the one-minute Apgar, and 3.06 (95% confidence interval 1.40, 6.75) for the five-minute Apgar score. The use of a standardized process for screening for sepsis provided for early identification and timely treatment of obstetric women with sepsis. Neonates born to women who met sepsis criteria in labor were more likely to require resuscitation at the time of birth than those born to women without sepsis.

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We, the undersigned, certify that the project of the following student meets the required standards of scholarship, format, and style of the university and the student's graduate degree program for the awarding of the Doctor of Nursing Practice degree.

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CHAPTER 1: INTRODUCTION

Maternal mortality is increasing in the United States (MacDorman, Declerq, Cabral & Morton, 2014; Moaddab et al., 2016). Sepsis during the perinatal period, though rare, is associated with maternal mortality. The Centers for Disease Control and Prevention list infection as the third most common cause of maternal death in the United States (Centers for Disease Control and Prevention, 2016a). Bauer, Bateman, Bauer, Shanks, and Mhyre (2013) analyzed data from the 1998-2008 Nationwide Inpatient Sample in the United States and concluded that the rate of severe maternal sepsis and sepsis-related deaths in the United States steadily increased during that period.

Historically an emphasis has been placed in the United States on preventing maternal deaths related to hemorrhage, preeclampsia, and hypertensive disorders of pregnancy (MacDorman et al., 2014). Sepsis has not yet received national attention in the form of a standardized screening process in the perinatal population. Given that sepsis is now identified as the third leading cause of death, it is imperative to bring focus to decreasing maternal deaths by concentrating on sepsis identification and management in the obstetric population.

Significance

The Centers for Medicare & Medicaid Services (CMS) announced that in October 2015, it would require reporting of data related to severe sepsis and septic shock as a new core measure (Morath, 2015). Sepsis is sometimes challenging to identify, and its association with mortality was one of the reasons a core measure was developed to address this condition (Drake, 2015). The measure, called SEP-1 is a core measure that applies to all inpatients 18 years and older with a diagnosis of severe sepsis or septic shock (Drake, 2015). The results of this initiative are

subject to reporting and included in a facility's CMS and The Joint Commission certification review. Payment to a hospital is linked to this core measure, beginning in the reimbursement period for the year 2017 (Drake, 2015). The need to meet the standards of this core measure is one of the reasons the Kaiser Permanente, Roseville (KP ROS) perinatal leaders decided to initiate routine sepsis screening in the perinatal population. This program, KP Roseville Obstetric Sepsis Screening (KROSS), uses obstetric-adjusted SIRS criteria to prompt the investigation of sepsis in the obstetric, inpatient population.

Systemic inflammatory response syndrome (SIRS) criteria act as an early indicator to trigger further assessment for sepsis (Klouwenberg, Ong, Bonten, & Cremer, 2012). The challenge with applying SIRS criteria to pregnant women stems from the normal physiologic changes that occur in pregnancy. Heart rate, respiratory rate, and white blood cell count are usually elevated during pregnancy (Albright, Mehta, Rouse, & Hughes, 2016). These values are part of the standard SIRS screening criteria**.**

Studies have identified opportunities to modify the SIRS screening criteria to predict accurate, but not overly sensitive, triggers for further evaluation during pregnancy (Albright, Ali, Lopes, Rouse, & Anderson, 2015; Barton & Sibai, 2012; Bauer et al., 2014; Shields, Wiesner, Klein, Pelletreau, & Hedriana, 2016). Recommended modifications include using an elevated heart rate, respiratory rate, and white blood cell count. To date, there are no standards for obstetric-specific SIRS criteria. The formal evaluation of obstetric-adjusted SIRS criteria provides an opportunity to increase understanding of the factors and complications associated with obstetric sepsis.

Problem

This study is designed to address questions related to screening for sepsis in the obstetric population. This study will evaluate the incidence and severity of sepsis in the KP ROS inpatient obstetric population identified using obstetric-adjusted SIRS criteria. Those who screen positive for sepsis using obstetric-adjusted SIRS criteria will be further evaluated to address the lack of published information about sepsis in this population.

Purpose

In February 2017 routine screening for sepsis was implemented in the obstetric population at the Kaiser Permanente (KP) Roseville Women's and Children's Hospital. This program, entitled KP Roseville Obstetric Sepsis Screening (KROSS), was initiated for two reasons: to meet the Centers for Medicare & Medicaid Services (CMS) sepsis core measure (SEP-1) requirements, and to support early identification and management of obstetric patients with sepsis. The research project is designed to evaluate the success and impact of KROSS on the detection, treatment, and morbidity of obstetric sepsis.

Historically an emphasis has been placed in the United States on preventing maternal deaths related to hemorrhage, preeclampsia, and hypertensive disorders of pregnancy (MacDorman et al., 2014). Sepsis has not yet received national attention in the form of a standardized screening process in the obstetric population. Given that sepsis is now identified as the third leading cause of death, it is imperative to bring focus to decreasing maternal deaths by concentrating on sepsis identification and management.

Given the dearth of literature on obstetric sepsis, this research study represents an opportunity to collect data to allow objective assessment of the modifications and generalizations upon which the KROSS initiative was based, as

described in the background and rationale for this research study. With this retrospective study, we hope to advance the understanding and care of obstetric sepsis. It is the intent of this analysis to meet the call in the literature to provide the information needed to create an evidence-based standard for obstetric sepsis screening (Maguire et al., 2016). By advancing the scientific basis of diagnosis and management of obstetric sepsis, the care of the obstetric population will be improved.

Background

Systemic inflammatory response syndrome (SIRS) criteria act as an early indicator to trigger further assessment for sepsis in men and women. Altered mental status or two or more of other criteria (temperature, heart rate, respiratory rate, white blood cell count) must be present to meet SIRS criteria. The challenge with applying SIRS criteria to pregnant women stems from the normal physiologic changes that occur in pregnancy. Heart rate, respiratory rate, and white blood cell count are usually elevated during pregnancy (Albright, Mehta, Rouse, & Hughes, 2016). These values are part of the standard SIRS screening criteria**.**

This project was designed to evaluate the efficacy of a KP Roseville obstetric-sepsis screening (KROSS) initiative specifically designed for the pregnant or newly delivered woman. Approximately 500 women give birth in the labor and delivery unit at KP Roseville. This hospital has the largest delivery volume among the thirteen KP Northern California maternity centers. The obstetric units care for ante-, intra-, and post-partum women, and receive transfers in from hospitals with lower acuity levels. This facility often pilots new obstetric initiatives, and the interdisciplinary obstetric leadership team decided to implement routine screening for sepsis in the obstetric population.

The KROSS initiative uses pregnancy-adjusted SIRS criteria for sepsis screening. A higher maternal heart rate, respiratory rate, and white blood cell count are used in place of the standard adult sepsis SIRS criteria. Large California healthcare systems, Sutter Health and Dignity Health, use obstetric-adjusted values to screen for sepsis (Olvera & Dutra, 2016; Shields et al., 2016). Fetal heart rate tachycardia is included as a SIRS criterion. Fetal heart rate tachycardia is commonly associated with maternal temperature and infection (Faksh & Martin, 2016) and is known as a symptom of chorioamnionitis (Desale, Thinkhamrop, Lumbiganon, Qazi, & Anderson, 2016). Standard adult SIRS criteria (Bone, Balk, Cerra, Dellinger, & Knaus, 1992) are used for the remaining screening items (see Table 1).

Table 1

Systemic Inflammatory Response Syndrome (SIRS) Values Comparison

Variable	Adult, non-obstetric population[a]	Adjusted for obstetric population
Altered mental status	Present	Same
Temperature		
Low	> 100.4˚F (38˚ C)	Same
High	< 96.8˚F (36˚ C)	Same
Heart rate	> 90 bpm	> 110 bpm
Respiratory rate	> 20 breaths per minute	> 24 breaths per minute
White blood cell count (mL)	< 4,000	Same
Low	> 12,000	> 15,000
High	> 10% bands	Same
Bands		
Fetal heart rate	Not included	> 160 bpm for 10 minutes

Note. bpm = beats per minute; [a]Adult, non-obstetric SIRS from Bone et al., 2012.

Theoretical Framework

Relationships are central to the successful implementation of a perinatal sepsis screening process. The pregnant patient is at the center of the relationship, with clinicians operating individually and as a team to provide safe and effective care to the patient. The members of the clinical team employ evidence-based practices to provide safe and effective care to the patient. Also, the care team members interact with each other, often in a system of checks and balances, making sure to remain informed about the patient's clinical status, and to anticipate next steps should the condition worsen. An example of this occurs when the nurse notices some initial indicators of infection, such as an elevated fetal heart rate or a mother's low-grade temperature. The nurse notifies the provider, often anticipating that an order for antibiotics will be received. During this time, the nurse keeps the patient informed, but tries to mitigate any alarm. The relationship-based care (RBC) model provides a framework to address the multi-faceted dimensions of care between and among the clinical team, the patient, and her family.

Origins of Relationship-Based Care

Relationship-based care is a practice model based on concepts adopted from existing caring theories and nursing models (Koloroutis, 2004). A group of healthcare leaders designed the model with the expressed desire to transform clinical practice (Koloroutis, 2004). The model includes a philosophical model and an operational framework, which center on the "needs and priorities of patients and their families" (Koloroutis, 2004, p. 15). The model contains 12 assumptions and utilizes a change model developed by Feigen called I_2E_2.

Assumptions

The 12 assumptions of the relationship-based care model align with the three types of relationships: relation of the nurse to the patient and family, the relationship of the nurse to the healthcare team members and organization, and relationship to self (Koloroutis, 2004). While the model specifically addresses nurses, it includes others, as the authors state that "each and every member of an organization, in all disciplines and departments, has a valuable contribution to make" (Koloroutis, 2004, p. viii). Included in the three types of relationships are key values. Some of these values reflect the importance of self-care, connectedness to others, and the alignment of the team and individuals to shared values. These values reflect and circle back to the idea of change. That is, the three types of relationships are linked to the assumptions, which in turn set the stage for change, with the goal of assisting the patient in healing. An example of the interconnectedness of the relationships might take place when a new practice is introduced, such as the sepsis screening process. The knowledge that they are "making a positive difference for patients, families, and their colleagues" (Koloroutis, 2004, p. viii) in turn helps the clinicians "own their own practice" (Koloroutis, 2004, p. ix). This knowledge helps individuals deliver high-quality care to the patient and to work as a team. This teamwork often leads to harmony, which in turn allows patients to receive consistent care.

Concepts of Relationship-Based Care

Two sets of concepts support the assumptions of the model related to change. One is Feigen's model of change called I_2E_2. The formula I_2E_2 stands for inspiration, infrastructure, education, and evidence (Koloroutis, 2004, p. 6). The model of change is depicted as a spiral headed upward. Inspiration is viewed as

the first step to uniting individuals with “vision and purposefulness” (Koloroutis, 2004, p. 7). Infrastructure refers to the processes and structures that support the vision. Education relates to both training and individual competence. This step encompasses the opportunities for “personal growth and professional development” (Koloroutis, 2004, p. 9). Evidence is linked to measurable outcomes. It also “links directly back to inspiration” (Koloroutis, 2004, p. 9), and thereby supports the ascension of the spiral upward. Using the example of the sepsis screening process, the inspiration would be to prevent septic shock by employing a standardized screening process, which will be presented to the staff through training. The final step will be to disseminate the findings to the clinicians. The success of this type of initiative lends itself to future improvements in care in an upward spiral of quality.

These I_2E_2 are linked to the “5 Cs”. The 5 Cs include clarity, competency, confidence, collaboration, and commitment (Koloroutis, 2004, p. 9). The 5 Cs represent the conditions necessary for an individual to change (Koloroutis, 2004, p. 9). That is, individuals need to understand their role and the meaning of the change (clarity), have the skill to perform their role in the change (competency), have confidence that they have the skills and knowledge to contribute (confidence), can work together (collaboration), and share a commitment to the goal (commitment) (Koloroutis, 2004).

Concept Relationships

The model used to describe relationship-based care resembles a flower or a pinwheel. At the center of the flower are the patient and family. The “petals”, or dimensions of care, are leadership, teamwork, professional practice, care delivery, resources, and outcomes. The “flower” is surrounded by a shaded area called the

"caring and healing environment" (Koloroutis, 2004). Each of these dimensions is "essential to the implementation of relationship-based care" (Koloroutis, 2004, p. 14). A way of thinking about this model would be to examine each of the dimensions separately as single entities, and then in relation to the patient and family, and next in concert with one or more of the other dimensions. For example, leadership is required to institute standards of professional practice, provide for resources, and establish outcomes as a measurement of care. For the perinatal sepsis screening project, the perinatal leadership team will validate that the project meets established practice guidelines, ensure that the clinicians receive the training needed, and will monitor the results following implementation. Each of these steps contributes to the care of patients hospitalized in the perinatal units.

A central tenet of the RBC model is that relationships contribute to the shaping of the practice culture. An assumption is "substantive change comes from within each individual", and as the individuals change, the community and culture changes (Koloroutis, 2014, p. 250). These changes occur because of work completed within each dimension. Professional nursing practice encompasses the roles of nursing as "sentry, healer, guide, teacher, collaborator and leaders" (Koloroutis, 2004, p.129), and includes competency in caring and the three dimensions of skills: critical thinking, technical skill, and interpersonal skill. Nurses who embrace the role of nursing and have the skills appropriate for their level of expertise, are then appropriately able to express skilled, caring behaviors. A nurse who recognizes that a patient's condition is deteriorating, and advocates for a physician to immediately evaluate the patient, while providing reassurance to the family, demonstrates competence, and caring in the role. Having every nurse act in such a manner contributes to a culture of excellence and caring.

Research Findings

Relationship-based care, as a practice model, has not been tested as a theory. It references other theorist's work, such as Watson, Leininger, Benner, and leadership authors Kouzes and Pozner (Koloroutis, 2004). The RBC model has been evaluated in a variety of settings as it relates to a change in institutional culture or process improvement. Hedges, Nichols, and Filoteo (2012) reported on the use of RBC in conjunction with teamwork training to improve communication among nurses and other clinicians. While small improvements were noted in patient satisfaction overall, significant improvement among Spanish-speaking patients was noted in response to four patient care questions. This improvement was attributed to an adaptation of the RBC model where the nurses were asked to have "focus time" with their patients. In this study, the focus time included the use of Spanish interpreters to engage patients in discussion with the nurses about the patient's concerns (Hedges et al., 2012).

Mellot, Richards, Tonry, Bularzik, and Palmer (2012) reported an increase in teamwork and collegiality, from 58% to 90%, among nurses and ancillary staff following implementation of the RBC model. The authors describe the many benefits noted by individual clinicians and positive impacts on patients because of the focus on RBC. Woolley et al. (2012) reported the positive impact on two clinical quality indicators following training related to RBC. The indicators, which were falls and hospital-acquired pressure ulcers, showed significant downtrends in frequency following RBC training, implementation of hourly rounding, and use of communication boards in patient rooms. Of note, the authors discussed one of the dimensions of RBC, which is resource-driven practice, as key to success in the culture change. They cite the change in nurse's mindset from "I need more time to

meet all of my patients' needs" to "I will identify what needs are essential to be met today" (Woolley et al., 2012, p. 182).

Relationship-Based Care and Sepsis Screening

Relevance to Project

The perinatal sepsis screening project will take place in a suburban hospital where approximately 500 women give birth to infants every month. Obstetricians, residents, and certified nurse midwives (CNM) provide obstetrical services on the inpatient units. Obstetrical and anesthesia providers work 12-hour shifts. These long shifts can potentially lead to lapses in communication as no single provider has responsibility for an individual patient's care throughout her labor. RBC contains several assumptions that make it relevant to this population and setting. One assumption, "healthy relationships among members of the healthcare team lead to the delivery of quality care" (Koloroutis, 2004, p. viii) is particularly applicable to this workplace setting.

A prevalent nursing culture in this unit's past was to defer to the physicians regarding the assessment of high-risk maternal conditions. In the past five years, this culture has evolved to one where the nurses now feel empowered to follow through on certain conditions, such as severe range hypertension. Part of this change occurred because of collaborative teamwork simulation training. Nurses are instructed during simulation training to "prompt" the physician, resident or CNM to provide protocol-based care for the patients. The nurses are now accustomed to notifying the obstetrical providers when certain patient conditions are met and making sure the protocol is followed. The sepsis screening project uses a visual job aid and protocol that is used to guide the clinical team. Training l included case studies and opportunities to reinforce the nurses' role as sentry,

healer, and teacher, which are roles identified in RBC. The purposeful linking of roles, relationships, quality, and teamwork make RBC particularly apt for this project.

Model Selection

Implementation of a new process in the clinical setting is frequently complex. There are practical issues to be solved related to providing training, and measuring process, outcome, and balance indicators. Additional challenges include planning for the change, anticipating barriers and facilitators of the process, and sending a clear message out to hundreds of busy clinicians about their updated roles and responsibilities. The perinatal sepsis screening project represents a process improvement measure, an implementation of an evidence-based practice model, and an educational endeavor. Theories that address systems, quality improvement, or learning could be used as models for sepsis screening implementation. However, RBC pulls together the many concepts of project implementation, including caring, into one model. This gathering of concepts has as its core the patient and family yet remains focused on the clinicians who provide that care. It uniquely looks at the importance of the relationship among team members, and the relationship of an individual to self. The core outcome of the perinatal sepsis screening project is to prevent maternal morbidity and mortality related to sepsis. This goal can provide the shared vision that may facilitate culture change, teamwork, and personal growth among the perinatal team members, key aspects of RBC (Koloroutis, 2004).

RBC and Sepsis

Discussions in the sepsis literature focus on the importance of screening. Inherent in many articles related to early recognition is an unwritten presumption

that nurses will be accountable for the routine screening. Crista Schorr, nurse scientist, spoke recently as part of an online seminar concerning early sepsis recognition and highlighted the critical role that nurses play in sepsis screening (Centers for Disease Control and Prevention, 2016b). Schorr emphasized the unique contribution that nurses bring to this initiative, and that through nurse engagement, early treatment occurs (Centers for Disease Control and Prevention, 2016b).

A recommended strategy to engage nurses in sepsis screening is to emphasize that it is more than a routine duty (Centers for Disease Control and Prevention, 2016b). Nurse engagement aligns with RBC. One important assumption is related to a nurse's willingness to change, which is linked to inspiration and a common vision (Koloroutis, 2004, p. ix). This is relevant to perinatal sepsis screening. The goal is to support a culture where nurses own the practice of early identification. Valuing nurses is also seen as key to the culture of patient improvement (Koloroutis, 2004, p. viii). Unit leadership will be engaged to recognize the efforts of individual nurses "owning" the screening.

Per RBC assumptions, individuals are satisfied when roles and practices are aligned, and that patient experiences "improve measurably when staff members 'own' their own practice and are valued for their contributions". Change takes place "when an infrastructure is implemented to support new ways of working" (Koloroutis, 2004, p. ix). Routine sepsis screening will represent a sizeable change in practice. This change resides in interactions between the patient and the clinician. Per the RBC model, "transformational change happens one relationship at a time" (Koloroutis, 2004, p. ix). Ideally, these transformations will reduce maternal deaths from sepsis.

Research Questions

Primary research question:

What is the incidence and severity of sepsis in the KP Roseville inpatient obstetric population identified using obstetric-adjusted SIRS criteria?

Secondary research questions:

Which maternal morbidities are associated with sepsis in the KP Roseville inpatient obstetric population?

What are the demographic characteristics of women who screen positive for sepsis in the KP Roseville inpatient obstetric population?

What is the severity of sepsis associated with the sources of infection identified by the presence of obstetric-adjusted SIRS criteria in the KP Roseville inpatient obstetric population?

What is the relationship between cervical dilation and length of rupture of membranes, and lactic acid levels in the KP Roseville inpatient obstetric population?

Which obstetric SIRS criteria are associated with end-organ dysfunction, morbidity, and mortality in an obstetric population?

In which phase of labor, ante-, intra-, or post-partum, were those who screened positive using obstetric-adjusted SIRS criteria?

Which neonatal morbidities are associated with maternal sepsis in the KP Roseville inpatient population?

CHAPTER 2: LITERATURE REVIEW

Sepsis in the adult, non-pregnant population has been widely researched. Less research is available related to sepsis in the perinatal population. A review of the literature identified several articles related to the incidence and contributing factors for sepsis in this population. Two articles address the concept of routine sepsis screening by nurses and the lived experience of those surviving sepsis. The following articles provide background information to support the implementation of routine sepsis screening in the perinatal population.

Sepsis in the Perinatal Population

Bauer, Lorenz, Bauer, Rao, and Anderson (2015) used a retrospective chart review to investigate the cases of women who died of sepsis in Michigan between 1999-2006. The women were either pregnant or had given birth within the past 42 days. A total of 22 deaths were related to sepsis, of those, 15 either came to the hospital with sepsis or developed sepsis during a hospitalization. The researchers established standardized procedures to ensure that sepsis was the cause of death. Descriptive statistics were used to evaluate the data. Noted trends were delays in recognition and treatment of sepsis and inappropriate antibiotic administration. Fever was absent in most cases.

A strength of this study is the detailed analysis of the vital signs presentation in each of these cases. The commentary compellingly summarizes recommendations to prevent maternal mortality related to sepsis. A limitation of this study is that some information was not available due to the retrospective nature of the study and that information was particularly limited in the cases where the women died at home (Bauer et al., 2015).

Abir, Akdagli, Butwick, and Caravalho (2016) used a descriptive retrospective study to evaluate the clinical and laboratory characteristics of pregnant or recently delivered women with sepsis, severe sepsis, and septic shock during 2007-2013, in a tertiary level center in California. The researchers evaluated the records women of 35 women, of whom 18 met diagnostic criteria.

Descriptive statistics were used to evaluate demographic data, the data related to sepsis, and neonatal outcomes. The most common co-morbidities were obesity and diabetes, and the genital tract was the most common site of infection in the sepsis and severe sepsis groups. The respiratory tract was the most common source in the septic shock group. Most women were diagnosed during the postpartum period. Only 50% of the blood cultures grew an organism, with E. Coli the most frequently identified. A strength of this study was the use of expert clinical evaluation to in accurately determining the presence of and severity of sepsis. There were identified limitations associated with the use of ICD9 coding for case identification (Abir et al., 2016).

Mohamed-Ahmed, Nair, Acosta, Kurinczuk, and Knight (2015) used a population-based control analysis to evaluate the United Kingdom (UK) Obstetric Surveillance System and the UK Confidential Enquiry into Maternal Death data related to severe sepsis and death in pregnant and recently delivered women. They identified 43 deaths out of 358 women who met the criteria for severe sepsis in an inpatient setting, excepting those who had influenza. Those who died were compared to those who survived. Demographic data and clinical data included the primary source of infection, time of diagnosis and antibiotic administration, highest lactate levels, medical morbidities, delivery information, the onset of sepsis, and which systemic inflammatory response syndrome (SIRS) criteria were present.

Continuous variables were summarized as means or medians. Categorical variables were summarized as frequencies. Chi-square tests were used for differences in proportions between groups using $p < 0.05$. Tests for collinearity and multivariable logistic regressions were performed to estimate the adjusted odds ratio with 95% confidence interval (Mohamed-Ahmed et al., 2015).

Findings included that women who died were more likely to have never received antibiotics, have medical co-morbidities, and be multiparous. The two most important co-factors associated with progression to death were immunosuppression and anemia. Strengths of this study include the evaluation of severe sepsis and the comparison of those with severe sepsis to those who died. This study was limited in that the researchers were unable to view the medical records of those who survived sepsis due to privacy protections, and therefore only the date, and not the time of antibiotic administration, was available (Mohamed-Ahmed et al., 2015).

Acosta et al. (2016) performed a retrospective evaluation of 646 pregnant or newly delivered women in the United Kingdom who developed severe sepsis and had a critical care admission during 2008-2010. The researchers evaluated the patient clinical information to ensure the diagnosis met protein C worldwide evaluation in severe sepsis (PROWESS) study criteria and systemic inflammatory response criteria (SIRS). The severity of sepsis was determined by the acute physiology and chronic health evaluation (APACHE) II score, and patient demographics were evaluated using the index of multiple deprivation scores to determine the presence of deprivation.

Descriptive statistics and logistic regression were used to evaluate the data. One in three pregnant or newly delivered women admitted to the critical care units had a diagnosis of sepsis. Rates were highest for those 16-19 years of age.

Pneumonia was the most common cause of infection followed by genital tract infections. Lower socioeconomic status and Cesarean delivery were associated with a higher risk of severe sepsis. A strength of this study was the large sample size and the use of obstetric specific SIRS criteria. Limitations included lack of data related to contributing organisms related to sepsis (Acosta et al., 2016).

Acosta et al. (2013) evaluated the state of California vital statistics and hospital records of 1598 recently delivered women who had a diagnosis of sepsis, severe sepsis, or septic shock between 2005-2007. The researchers evaluated demographic delivery type and outcome, complications, and comorbidities. Descriptive statistics, chi-square, Fischer's exact, Mann-Whitney U, and linear regression were the statistical tests used to evaluate the data. Findings were compared to those who delivered in California at the same time without a diagnosis of sepsis.

Data analysis revealed an incidence of severe sepsis twice as high as the estimated national rate. Socioeconomic disparities existed among those who developed sepsis and those who did not. Risk factors, such as Cesarean delivery, multiple gestation, and comorbidities of diabetes or preeclampsia were identified. Those with an increasing number of risk factors were associated with a higher likelihood of developing sepsis (Acosta et al., 2013).

The strengths of this study include the large sample size and the large number of variables evaluated. This was the first population-based cohort study to compare the severity of sepsis in the United States. One limitation of this study is that the researchers relied on ICD9 coding for the severity of sepsis. The records were not reviewed for accuracy of coding for the sepsis diagnosis and severity of sepsis. The study evaluated inpatient live births and did not evaluate sepsis in

those who developed sepsis after discharge from the delivery admission, nor those who had experienced a fetal death (Acosta et al., 2013).

Routine Sepsis Screening

Jones et al. (2015) performed an observational study of a routine sepsis screening as a quality improvement project. They used pre- and post-implementation data for the years 2006-2008 and 2009-2011, respectively. They evaluated the cases of those identified with sepsis with ICD9 coding and used a hospital claims database to evaluate financial data and length of stay. The project initially started on two units and grew to include several more. They used a sample test of proportions and reevaluated the findings with a Lowess plot with a bandwidth of 0.1 and plotted averages of death rate, followed by a binomial distribution and exact method. A final evaluation used cumulative sums of deviations and bootstrap analysis to determine confidence intervals.

Findings included an increase in screenings over the 3-year period from 10% to 33%, with inpatient death rates decreasing from 29.7% pre-implementation to 27.1% post-implementation (2009-2014). Hospital costs decreased without a compensatory increase in discharges to post-acute care. Significant cost decreases were noted in the Medicare “outlier” status, with savings estimated to be $2.4 million compared to the baseline period. Positive screens averaged 11-12% over the three-year period (Jones et al., 2015).

Strengths of the study include the description of routine sepsis screening by nurses in an inpatient setting and the description of the calculation of cost savings. Limitations of this study are that the findings do not identify which inpatient units used the screening, nor is there a listing of the number of patients screened. Also,

the implementation period is stated as 2006-2011, yet there is data included from 2014 (Jones et al., 2015).

Experience of Sepsis

Gallop et al. (2015) used a triangulated design to study the experiences of patients who had an intensive care unit (ICU) admission due to severe sepsis. The study included an evaluation of the experiences of the patient's caregivers. These patients were evenly divided between a hospital in the United States and one in Great Britain. The researchers performed semi-structured interviews with 22 patients and 17 caregivers. Both patients and caregivers completed the EQ-5D and Hospital Anxiety and Depression score tools. The EQ-5D measures functional ability.

Saturation was achieved after 22 patient interviews were completed. The authors found five themes: awareness and knowledge of severe sepsis, the experience of hospitalization, the ongoing impact of severe sepsis, impact on caregivers, and support after severe sepsis (Gallop et al., 2015). The strengths of the study included the use of the two validated questionnaires in conjunction with the interviews and the comparison of results in the United States and the United Kingdom. A limitation of this study was the mix of patients who had varying degrees of health before the ICU admission. It is unknown if a significant difference existed in the themes between those with pre-existing illness and those with greater independence before the ICU admission (Gallop et al., 2015).

Application to a Routine Perinatal Sepsis Screening Project

Sepsis is a known cause of death in the perinatal population. Population-based studies identified characteristics associated with severe sepsis and death

from sepsis (Abir et al. 2016; Acosta et al., 2013; Acosta et al., 2016; Bauer et al., 2015; Mohamed-Ahmed et al., 2015). While many studies benefitted from working with large populations such as that of the United Kingdom or the state of California, they were also limited in the availability of some clinical data or by being linked solely to inpatient delivery data. The studies revealed a variation in the vital signs and SIRS criteria used to identify sepsis in this population.

Although there is a lack of consistent findings related to those who developed severe sepsis or died from sepsis in this population, several authors identified trends related to delay in recognition of sepsis and appropriate treatment. Bauer et al. (2015) and Acosta et al. (2016) recommend early identification of sepsis through routine assessment of vital sign criteria and antibiotic administration one hour after sepsis is identified. Jones et al. (2015) described the implementation of routine sepsis screening in some inpatient hospital units and found marked financial benefits from the implementation without an associated increase in admissions to post-acute care settings. The study highlighted the critical role nurses play in the identification of sepsis when a routine screening process is used.

Currently, there is no national standard for routine screening of sepsis in perinatal units. A review of the literature identified the need for early identification and treatment of sepsis in the perinatal population to prevent severe illness and mortality. There is a gap in the literature related to a routine process to evaluate and treat sepsis in this vulnerable population (Maguire et al., 2016). Evaluation of a systematic method for screening, using pregnancy-adjusted SIRS criteria to trigger evaluation and treatment of sepsis, will assist in filling the gap in the literature.

CHAPTER 3: METHODS

This project represents a retrospective analysis of selected demographic and outcome variables related to the implementation of routine maternal sepsis screening at KP ROS using obstetric-adjusted SIRS criteria. Variables of interest related to the pregnant women in an antepartum, intrapartum, or postpartum phase of pregnancy were identified. Additional variables were identified for those newborns delivered of women who developed sepsis during labor. Sepsis was defined as the presence of infection accompanied by either maternal altered mental status, or two or more obstetric-adjusted SIRS criteria.

Setting

The data was collected at the KP Roseville, a tertiary level maternity hospital. Data were collected from pregnant or recently delivered women who were admitted as inpatients to the obstetric units or intensive care unit (ICU). Newborns were admitted either to the postpartum (Mother/baby) unit or the neonatal intensive care unit (NICU).

Sample

Population

Participants were those who came to the KP Roseville hospital for ante-, intra-, or post-partum inpatient care. Most participants were members of KP, an integrated health system, and most received prenatal care. Some women presented after they were discharged home from their postpartum stay and then readmitted with a diagnosis of infection. The newborns were born to women who delivered at KP ROS. No women or infants who transferred to KP ROS for care were included in the sample. All women who met inclusion criteria had data abstracted from the

electronic medical record related to the variables of interest by the principal investigator.

Recruitment

No recruitment took place.

Investigative Techniques

Research Design

The medical records of all inpatient women who are pregnant or newly delivered had a data analysis report run through the KP electronic medical record (EMR). The report identified those who had a lactic acid level drawn. A separate report listed those who had a diagnosis of infection or sepsis during the study period. Some women were identified during the time of the study by the nurses who cared for them. A patient label, containing the patient's name and medical record number, was placed in a binder for the principal investigator to later retrieve for review.

The women in this population had data abstracted from the EMR related to the variables of interest by the principal investigator. The presence of obstetric-adjusted SIRS criteria and a source of infection were identified through review of the EMR. Newborns were born to women who were diagnosed with sepsis during labor were identified during the EMR review. The EMR of each newborn was then reviewed and data abstracted for the newborn variables of interest.

Comparison data, when available, were collected from two sources. An electronic report supplied information related to the one- and five-minute Apgar scores for all newborns delivered of women at KP ROS during the study period. KP ROS electronically transmits post-discharge maternal delivery data to the

California Maternal Data Center. Information related to maternal age, race, number of deliveries, the rate of hypertension, preeclampsia, diabetes, and obstetrical hemorrhage of women who were discharged from KP ROS during the study period were collected from the CMDC site for comparison to the ROS inpatient obstetric sepsis group.

Length and Duration of the Study

Data collection began upon approval of the Northern California Kaiser Permanente and California State University, Fresno Institutional Review Boards (IRB). Data were collected from the records of those who met the inclusion criteria during the study period of March 1 through December 31, 2017.

Data

Data Collection

Manual chart review was required to determine diagnosis, maternal clinical findings, and neonatal outcomes. Altered mental status, maternal temperature, white blood cell count, including bands, respiratory rate, heart rate, and fetal heart rate were evaluated for the presence of SIRS criteria. Those who met the SIRS inclusion criteria had their records evaluated for a documented presence of infection. Once the individual met the diagnosis of sepsis, data were collected and recorded for that individual. Seventy variables were abstracted from the maternal chart, and seven from that of a newborn's chart. Information was listed in an excel spreadsheet. When available, the value of selected continuous variables (e.g., temperature) was recorded.

Data collection for those who meet the inclusion criteria included maternal patient demographic information: age, race, and ethnicity. Other maternal clinical

data were collected: patient's body mass index, number of pregnancies and number of deliveries, history of prior Cesarean delivery, results of group B strep culture collection, if antibiotics were administered prior to the diagnosis of sepsis, and fetal gestational age at the time of diagnosis and delivery, if applicable. The presence of the co-morbidities of diabetes, hypertension, anemia, and asthma was collected.

Clinical indicators were the severity of sepsis, the source of the infection, lactate level at the time of diagnosis, cervical dilation at time of sepsis diagnosis, and types of treatment received. Measurements were gathered about the presence or absence of end-organ dysfunction, including creatinine and bilirubin level, platelet count, blood pressure, urine output, oxygen saturation, and which SIRS criteria were present at the time of the diagnosis of sepsis. The timing of administration of antibiotics before the diagnosis of sepsis, or severe sepsis/septic shock, respectively. The mode of delivery, whether vaginal, Cesarean, or vacuum or forceps delivery, were collected.

Maternal outcomes were evaluated: intensive care unit admission, the occurrence of obstetric hemorrhage, pulmonary edema, or death. The results of maternal blood cultures, urine culture, or placental pathology were collected. Women with placenta results showing chorioamnionitis, funisitis, or fetal surface vasculitis were identified as being positive for the presence of chorioamnionitis, in accordance with the Committee on Obstetric Practice (2017). The length of time from rupture of membranes to the diagnosis or sepsis was collected for those women in labor at the time of the diagnosis of sepsis. The neonatal outcomes, where applicable, obtained included gestational age at the time of delivery, one- and five-minute of age Apgar scores, neonatal intensive care unit (NICU) admission, if body cooling was initiated, and NICU length of stay.

Vital signs values were those that were recorded within 30 minutes of each other at the time when two or more SIRS values were present. The white blood cell count value used in for sepsis screening was collected prior to being used as a SIRS criterion. The lab values for end-organ dysfunction were those recorded at the time of SIRS criteria being met, or within one-hour prior that time.

Not all measures of end-organ dysfunction were measured or documented in the medical record. The MAP was documented in 28 (13.7%) of the cases, and urine output was adequately documented in 74/181 (40.9%) of cases. Not all of the labs listed on the maternal sepsis screening pathway were ordered. In particular, APTT was ordered in 56 (27.4%) of cases and bilirubin in 93 (45.6%) of cases.

Data Analysis Plan

Some data was collated into categories. These included ranges for age and BMI, the severity of sepsis, and groupings of SIRS criteria. Descriptive statistics were used for demographic and clinical characteristics data. Bivariate analysis, Pearson's r, was used for correlation among selected continuous variables. Chi-square testing was used between and among categorical variables. An odds ratio was calculated for one- and five-minute Apgar values when compared to the values of all newborns who were delivered at KP ROS during the study period. Statistical analysis, with the exception of the odds ratio, was calculated using SPSS version 23. The odds ratio was calculated using MedCalc software (https://www.medcalc.org/calc/odds_ratio.php).

Benefits, Risks, and Ethical Considerations

Benefits

Currently, there is limited information about sepsis in the obstetric population. A few studies evaluated the use of standardized early warning or predictive systems for sepsis in the obstetric population, with mixed results (Albright et al., 2014; Lappen, Keene, Lore, Grobman, & Gossett, 2010). With this study, we hoped to advance the understanding and care of obstetric patients with sepsis. Ideally, this study will further knowledge related to the characteristics and outcomes of women who develop sepsis during pregnancy. This information may be used to establish guidelines for sepsis screening in this population.

Risks

With chart review, there runs a risk of disclosure of protected health information (PHI). All PHI, including patient names, medical record numbers (MRN), and date of admission were kept strictly confidential. Each subject was assigned a unique, de-identified study number, which was linked to the identifying information in a separate linking file. The linking file was kept in a private drive on a facility approved and password protected servers accessible only to the study investigators. The de-identified dataset was used for analysis. Only summarized and de-identified data was shared outside the study team. All data files containing PHI will be kept for the length of time specified by the CSU Fresno IRB and then electronically deleted.

Ethical Considerations

Patient care was provided to the study members per usual healthcare standards. Study participants did not need to provide consent as the data were

analyzed retrospectively following the patients' discharge from the hospital. No significant risks to the subjects were anticipated as it was a retrospective study.

Bias

There is limited information related to sepsis and lactate levels in pregnancy. Lactate levels are used in the adult, non-pregnant patient with sepsis to stratify the severity of sepsis and to direct clinical management. Albright et al. (2015) used a retrospective analysis to evaluate the severity of sepsis in pregnant patients and reported on a variety of clinical indicators and mean lactic acid concentrations. Abir et al. (2016) and Albright et al. (2015) report only limited numbers of the patients in their studies had serum lactates listed. In this study, serum lactate levels and other markers of end-organ dysfunction were used to determine the severity of sepsis. Lack of published data related to lactate levels in pregnancy, labor, and postpartum may limit the validity of the findings in this study.

Potential threats to the trustworthiness of the data include beginning the study period before routine screening was well established, where there may have been an uneven use of the screen or inexact use of the management guidelines. This resulted in lack of some laboratory data. Several variables were not uniformly collected, and the number of those with data in the sample is reflected in the analysis and listings in the accompanying tables.

This study is limited to subjects from one facility in a large suburban area. Most subjects were members of an integrated health system and received adequate prenatal care. These factors may limit generalizability to other settings and populations.

Summary

The SEP-1 core measure requires actions to be performed in specified time frames in those patients meeting sepsis criteria (Drake, 2015). This measure does not distinguish between the obstetric and the non-pregnant adult population. Given the dearth of literature on obstetric sepsis, this study represents an opportunity to collect data to allow objective assessment of the modifications and generalizations upon which the SEP-1 initiative was based.

CHAPTER 4: RESULTS

Incidence and Severity

From March 1 through December 31, 2017, a total of 5,075 women gave birth at KP Roseville. During that time 204 pregnant, post-partum, or recently delivered women developed sepsis, as defined by meeting two or more obstetric-adjusted SIRS criteria and having a source of infection. The number of those meeting sepsis criteria include 13 women who were diagnosed, treated and sent home as part of the antepartum phase of pregnancy. Ten women returned to the hospital for postpartum readmission after they were discharged from the hospital following delivery. Two women developed sepsis during more than one hospitalization. Both had intrapartum and postpartum readmissions, and one had an antepartum readmission. For these two women, each hospitalization during which she developed sepsis was counted as a distinct episode of sepsis for data abstraction purposes.

Antepartum and postpartum readmission patients were combined with the intrapartum and postpartum patients when calculating the incidence of sepsis during the 10-month study period. An incidence rate of inpatient, obstetric sepsis of 0.401 per 1,000 births was calculated for KP ROS during the study period.

The severity of sepsis was categorized per the level of end-organ dysfunction as sepsis, severe sepsis, and septic shock (see Table 2). Out of the 204 cases of sepsis, 92 women (45.1%) met sepsis criteria, 87 (42.6%) met severe sepsis criteria, and 25 (12.3%) met septic shock criteria. Most women had severity defined by the lactic acid levels. Those meeting severe sepsis for a reason other than a lactic acid level of 2.0-3.9 mmol/L include six who had urine output (UO) less than 30 mL per hour, four with a creatinine level of 1.5 mg/dL or greater, one

Table 2

Severity of Sepsis Criteria per End-Organ Dysfunction Categories Used in the Maternal Sepsis Screening Pathway

End Organ Dysfunction	Sepsis	Severe Sepsis	Septic Shock
Lactic acid (mmol/L)	< 2.0	2.0 – 3.9	> 3.9
Systolic Blood Pressure (mm Hg)		< 90[a]	< 90[b]
Mean Arterial Pressure		< 65	< 65 [b]
Urine output		≤ 30 mL/hour for 2 hours	
Creatinine		≥ 1.5 mg/dL	
Platelet count		< 100,000	
Bilirubin		> 2 mg/dL	
APTT		> 60 seconds	

Note. APTT = Activated partial thromboplastin time; [a] Must be at least 5 mm Hg lower than patient's baseline rate; [b] Following fluid resuscitation.

with a systolic blood pressure of 90 mm Hg or less, and one who had a mean arterial pressure (MAP) of less than 65. No woman met septic shock criteria by having persistent hypotension following fluid resuscitation. No women had an elevated bilirubin level, platelet count less than 100, 000, elevated partial thromboplastin time, nor systolic blood pressure decrease of less than 40 mm Hg from her baseline blood pressure.

Maternal Demographic Data

Information related to age and race was collected on those women who were pregnant or recently delivered and screened positive for sepsis during an inpatient stay at KP ROS. That information was compared to all women who delivered during the study period at KP ROS (see Table 3). There was no

statistical difference noted in the race of the women who developed sepsis when compared to those who delivered during the study period. A statistical difference for age, χ^2 (df=3) = 8.42, $p < 0.05$, for those who were the ages 20-30 was noted when compared to those who were the ages of 30-40.

Table 3

Comparison of Age and Race in Women with Sepsis Diagnosis to All Women Who Delivered

Risk Factor	Women with Sepsis (%) *N*=204	All Women (%) *N*=5075	df	χ^2	*p*
Age (years)			3	8.42	.04
< 20	4	2			
20-30	52	40			
30-40	42	55			
> 40	3	4			
Race			4	8.18	.09
Asian/Pacific Islander	22	14			
Black	9	7			
Hispanic	21	20			
White	46	58			
Other	3	2			

Note. χ^2 value for cells with values > 5

Demographic and obstetrical history variables were evaluated as a percent of the total number of women with sepsis who met the criteria. The number of those in each category were then sorted by those who met sepsis criteria and those who met severe sepsis or septic shock criteria, and using chi-square analysis, evaluated for statistically significant differences (see Table 4).

Table 4

Frequency of Demographic and Obstetric Factors in Women with Sepsis Diagnosis and Comparison of Those Who Met Severe Sepsis or Septic Shock Criteria N=204

Demographic and Delivery Factors	Sepsis *N* (%)	Severe Sepsis or Septic Shock *N* (%)	df	χ^2	*p*
Age (years)			3	6.78	.08
< 20	7 (3.4)	1 (0.5)			
20-30	48 (23.5)	57 (27.9)			
30-39	34 (16.7)	51 (25.0)			
≥ 40	3 (1.5)	3 (1.5)			
Race			4	5.78	.22
Asian/Pacific Islander	16 (7.8)	33 (16.2)			
Black/African American	10 (4.9)	8 (3.9)			
Hispanic	16 (7.8)	23 (11.3)			
White	48 (23.5)	45 (22.1)			
Other/Decline to State	2 (1.0)	3 (1.5)			
Parity			1	6.81	.01
0	56 (27.5)	87 (42.6)			
≥ 1	36 (17.6)	25 (12.3)			
Cesarean delivery history					
Yes	12 (5.9)	4 (2.0)	1	6.27	.01
No	80 (39.2)	108 (52.9)			
Fetal death			1	.57	.45
Yes	2 (1.0)	1 (0.5)			
No	90 (44.1)	111 (54.4)			
Gestational Age (181) [a]			1	1.77	.18
< 37 weeks	12 (6.6)	10 (5.5)			
≥ 37 weeks	63 (34.8)	96 (53.0)			
Twin gestation			1	.04	.84
Yes	2 (1.0)	2 (1.0)			
No	90 (44.1)	110 (53.9)			
Delivery Type (190) [a]			3	4.23	.24
Vaginal	50 (26.3)	58 (30.5)			
C-section	31 (16.3)	37 (9.5)			
VAVD	3 (1.6)	7 (3.7)			
Forceps	0 (0)	4 (2.1)			

Note. χ^2 value for cells with values > 5; [a] *N* noted in parentheses for missing data

Risk Factors Present

Maternal Conditions

Selected risk factors for sepsis were abstracted from the medical record and were compared between women with sepsis and those who met criteria for severe sepsis or septic shock using chi-square analysis (see Table 5).

Table 5

Frequency of Risk Factors in Women with Sepsis Diagnosis and Comparison to Those Who Met Severe Sepsis or Septic Shock Criteria N=204

Risk Factors	Sepsis *N* (%)	Severe Sepsis or Septic Shock *N* (%)	df	χ^2	*p*
Anemia[a]			1	6.03	.01
Yes	26 (12.7)	16 (7.8)			
No	66 (32.4)	96 (47.1)			
Asthma			1	.41	.53
Yes	6 (2.9)	10 (4.9)			
No	86 (42.2)	102 (50.0)			
Body Mass Index (*N*=203)[b]			4	1.78	.78
Normal (18.5-24.9)	8 (3.9)	6 (3.0)			
Overweight (25.0-29.9)	29 (14.3)	33 (16.3)			
Class 1 (30.0-34.9)	29 (14.3)	44 (21.7)			
Class 2 (35.0-39.9)	16 (7.9)	19 (9.4)			
Class 3 (≥ 40.0)	9 (4.4)	10 (4.9)			
Diabetes			1	.58	.45
Yes	7 (3.4)	12 (5.9)			
No	85 (41.7)	100 (49.0)			
Hypertension			1	1.31	.25
Yes	27 (13.2)	25 (12.3)			
No	65 (31.9)	87 (42.6)			
Preeclampsia			1	.08	.78
Yes	8 (3.9)	11 (5.4)			
No	84 (41.2)	101 (49.5)			
Group B Strep Culture (*N*=184)[b]			1	.28	.28
Positive	14 (7.6)	13 (7.1)			
Negative	64 (34.8)	93 (50.5)			

Note. χ^2 value for cells with values > 5; [a]Hemoglobin <11 g/dL or less at time of admission; [b] N noted in parentheses

For the women in labor, 58 (28.4%), developed positive SIRS criteria when the cervix was dilated between 6-10 cm, followed by those dilated at 10 cm, 52 (25.5%), and those with less than 6 cm of dilation, 36 (17.6%). There were widely varying lengths of time that women had ruptured amniotic membranes before they developed sepsis. The length of time the membranes were ruptured before the women developed sepsis ranged from those with intact membranes to two who had membranes ruptured for 204 and 237 hours. Those two values were outliers, as the rest of the length of time for the rest of the 192 women varied from 0-79 hours, with a mean of 11.6 hours and a median of 9.95 hours.

Phase of Pregnancy

Most of the 204 women, 146 (71.6%), developed sepsis during the intrapartum phase of pregnancy, followed in frequency by these phases: postpartum 35 (10.2%), antepartum 13 (6.4%), and as part of a post-partum readmission 10 (4.9%). Some of the women presented with positive SIRS criteria upon admission, 23 (11.3%), but most developed SIRS-positive criteria during the inpatient stay, 181 (88.7%). Those who developed sepsis during the varying phases of pregnancy were compared to those who developed severe sepsis or septic shock in the same phase, using chi-square analysis (see Table 6). A statistically significant difference was seen among all phases of pregnancy, $\chi^2(df=3) = \chi^2\, 9.82, p < .05$, for those who developed severe sepsis or septic shock.

Table 6

Frequency of Phase of Pregnancy in Women with Sepsis Diagnosis and Comparison of Those Who Met Severe Sepsis or Septic Shock Criteria at Time of Sepsis Diagnosis N=204

Phase	Sepsis *N* (%)	Severe Sepsis or Septic Shock *N* (%)	df	χ^2	*p*
			3	9.82	.02
Antepartum	6 (2.9)	7 (3.4)			
Intrapartum	65 (31.9)	81 (39.7)			
Postpartum	12 (5.9)	23 (11.3)			
Postpartum Readmit	9 (4.4)	1 (0.5)			

Note. χ^2 value for cells with values > 5

Outcomes

Source of Infection

The obstetric provider notes provided information related to the documented source of infection (see Table 7). In three cases there was no identified source of infection. In 26 cases there were diagnoses of chorioamnionitis, and in which the placenta was evaluated by a pathologist, and the pathology reports were negative for a diagnosis of chorioamnionitis.

Systemic Inflammatory Response Syndrome (SIRS) Criteria

There were 14 combinations of SIRS criteria associated with the women with the diagnosis of sepsis. None had altered mental status as the sole SIRS criteria. No women had a temperature less than 36° Centigrade, or a white blood cell (WBC) count of less than 4,000 x 10^9 /L, or greater than 10% bands present

Table 7

Frequency of Source of Infection in Women Diagnosed with Sepsis, Per Medical Record Documentation N= 204

Source	N	%
Chorio	126	61.8
Chorio diagnosis, placenta negative	26	12.7
Endo	21	10.3
UTI/Pyelo	14	6.9
Two diagnoses	5	2.5
Pyelo and pneumonia (2)		
Chorio and UTI (2)		
Endo/pelvic abscess (1)		
URI	2	1.0
No diagnosis documented	3	1.5
Other diagnoses with one occurrence[a]	7	3.4

Note. Chorio= chorioamnionitis; Endo= endometritis; UTI= urinary tract infection; Pyelo = pyelonephritis; URI = upper respiratory tract infection; [a] Abdomen, fever of unknown origin, influenza, mastitis, pneumonia, viral gastrointestinal, vulvar cellulitis

concurrently with another SIRS criterion. Of the 14 SIRS combinations, there were 147 occurrences of two SIRS, 48 of three SIRS combinations, and nine combinations of four SIRS values present at the time of the sepsis diagnosis. The most frequent combinations of SIRS criteria were associated with an elevated maternal temperature and either elevated maternal heart rate (124), fetal heart rate tachycardia (74), or elevated maternal WBC count (45). There was no statistical difference noted among the 14 SIRS combinations and the severity of sepsis, nor whether there were two, three, or four SIRS combinations present.

Fetal heart rate tachycardia (FHRT), in association with one other SIRS criterion, was evaluated for its usefulness in determining the severity of sepsis. A

table listing the number of women who met sepsis criteria by having FHRT as one of two SIRS criteria displays the number and percent of women who were identified because FHRT was used as a SIRS criterion to screen for sepsis (see Table 8).

Table 8

Frequency of Lactic Acid Values and Severity of Sepsis of Pregnant Women Who Had Fetal Heart Rate Tachycardia (FHRT) with One SIRS Criteria Compared to Those Who Had No FHRT, or FHRT and Two Other SIRS Criteria N= 158

Lactic Acid (mmol/L)	FHRT and 1 SIRS		FHRT and 2 SIRS or No FHRT	
	N	%	N	%
< 2.0 (Sepsis)	27	17.1	43	27.2
2.0 - 3.9 (Severe)	19	12.0	49	31.0
> 3.9 (Septic Shock)	5	3.2	15	9.5

Note. FHRT= Fetal heart rate tachycardia, 160 beats per minute for > 10 minutes; SIRS = Systemic inflammatory response syndrome criteria

Fifty-one women who were pregnant were identified with sepsis as a result of including FHRT as a SIRS criterion, and of those, 24 (15.2%) had lactic acid levels ≥ 2 mmol/L. Those meeting severe sepsis or septic shock criteria required additional treatment beyond antibiotics due to the severity of sepsis present.

Maternal Treatment Factors and Outcomes

No women in this sample died. Several variables were evaluated for their relationship to the timing of the diagnosis of sepsis or their association with sepsis. Eighteen women received antibiotics for group B streptococcus prophylaxis before receiving the diagnosis of sepsis. Others received antibiotics for a diagnosed infection before having two or more SIRS criteria present. In these cases, there was documentation indicating that chorioamnionitis was diagnosed due to the presence an elevated maternal temperature. Those women later developed two or more SIRS criteria and ultimately met the criteria for sepsis.

Of the women in labor, 91% had an epidural in place before meeting SIRS criteria. Complications of interest were admission to the intensive care unit (ICU) or the development of pulmonary edema (see Table 9).

Antibiotics were administered, when indicated (*N*=202), to 145 women (71.8%) within one hour of a sepsis diagnosis and to 186 (92.1%) within three hours. Fluid resuscitation, either 2 L or 30 mL/kg of normal saline) was provided to 68.6% of the women with severe sepsis or septic shock. An additional12 women (5.9%) received an initial one-liter bolus.

Table 9

Frequency of Treatment or Complication Variables in Women with Sepsis Diagnosis and Comparison to Those Who Met Severe Sepsis or Septic Shock Criteria

Treatment or Complication *N*	Sepsis *N* (%)	Severe Sepsis or Septic Shock *N* (%)	df	χ^2	p
Antibiotics prior to sepsis diagnosis (204)			1	.75	.39
Yes	28 (13.7)	28 (13.7)			
No	64 (31.4)	84 (41.2)			
ICU admission after sepsis diagnosis (204)			1	.02	.89
Yes	1 (0.5)	1 (0.5)			
No	91 (44.6)	111 (54.4)			
Epidural in Place at Time of Sepsis Diagnosis (145)			1	5.95	.02
Yes	55 (37.9)	77 (53.1)			
No	10 (6.9)	3 (2.1)			
Pulmonary edema (204)			1	3.70	.05
Yes	3 (1.5)	0 (0)			
No	89 (43.6)	112 (54.9)			

Note. χ^2 value for cells with values > 5; ICU= Intensive care unit.

The percentage of women with sepsis who had diabetes, hypertension or preeclampsia, or experienced an obstetrical hemorrhage following delivery were compared to the population of all women who delivered during the study period (see Table 10).

Table 10

Descriptive Comparison of Morbidities of Those with Inpatient Obstetric Sepsis to All Women Who Delivered During Study Period Per Discharge Diagnosis N=204

Condition	With Sepsis Diagnosis (%) *N*=204	Who Delivered (%) *N*=5075
Diabetes	9.3	17.3
Hypertension & Preeclampsia	34.8	21.5
Hemorrhage after delivery	9.6	9.7

Maternal length of stay following either the diagnosis of sepsis, or delivery, ranged from one to fifteen days. Most, 176 (86.2%), remained in the hospital three days or less. One stayed in the hospital for 15 days as a result of an abscess while the rest of the women stayed eight days or less.

Lab and Pathology Results

Blood cultures were collected on 153 (75%) of the women identified with sepsis. Five of the blood cultures collected had positive results. There were 69 urine samples sent for culture. Of those 69, 21(30.4%), were positive. Placentas were sent to a pathologist for examination in 145 cases. The placentas were considered to be positive for chorioamnionitis if the presence of funisitis, fetal surface vasculitis, or chorioamnionitis was present. Of the 145 placentas sent for examination, 109 were positive for chorioamnionitis, and two were positive for bacterial growth. Positive placental findings were associated with a diagnosis of chorioamnionitis, endometritis, pyelonephritis, and urinary tract infection.

A creatinine level greater than or equal to 0.8 mg/dL is elevated in pregnancy. In the women with sepsis 161 women had creatinine values recorded at the time of the diagnosis of sepsis. Of these 52 (25.5%) had a creatinine ≥ 0.8

mg/dL. There was a significant statistical difference in the women with elevated creatinine who developed severe sepsis or septic shock when compared to those without elevated creatinine levels, χ^2 (1, N=161) = 0.12, $p < .05$.

Lactic Acid Levels

Lactic acid levels were the indicators of end-organ dysfunction most often used to determine the severity of sepsis. The mean lactic acid level for all women was 2.4 with a standard deviation of 1.3. Bivariate correlations were performed between lactic acid level and cervical dilation and creatinine levels to determine the level of association present (See Figures 1 and 2).

Figure 1. Correlation of Lactic Acid to Cervical Dilation of Intrapartum Women at Time of Sepsis Diagnosis, *N*=152

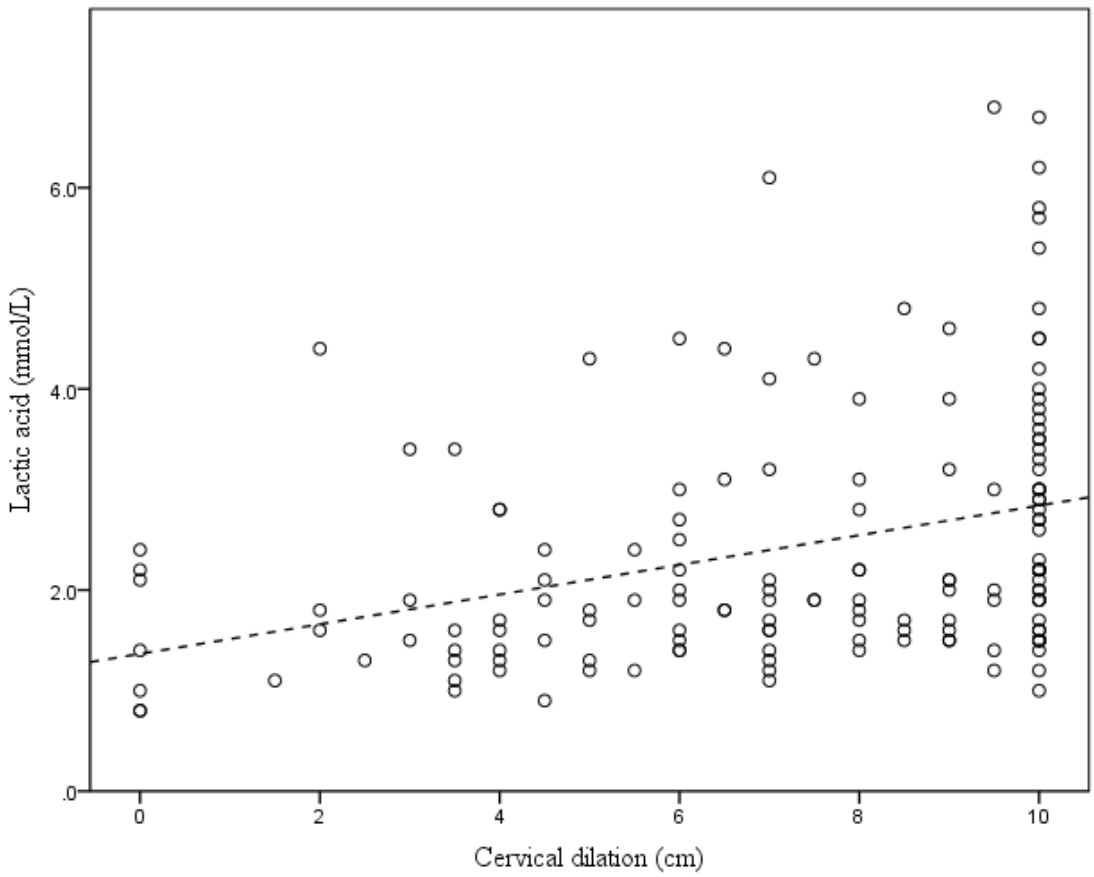

Figure 1. Relationship between lactic acid and cervical dilation of intrapartum women. Pearson's r = .34., $p < .01$.

Figure 2. Correlation of Lactic Acid to Creatinine Level of Intrapartum Women Following Sepsis Diagnosis, *N* =161

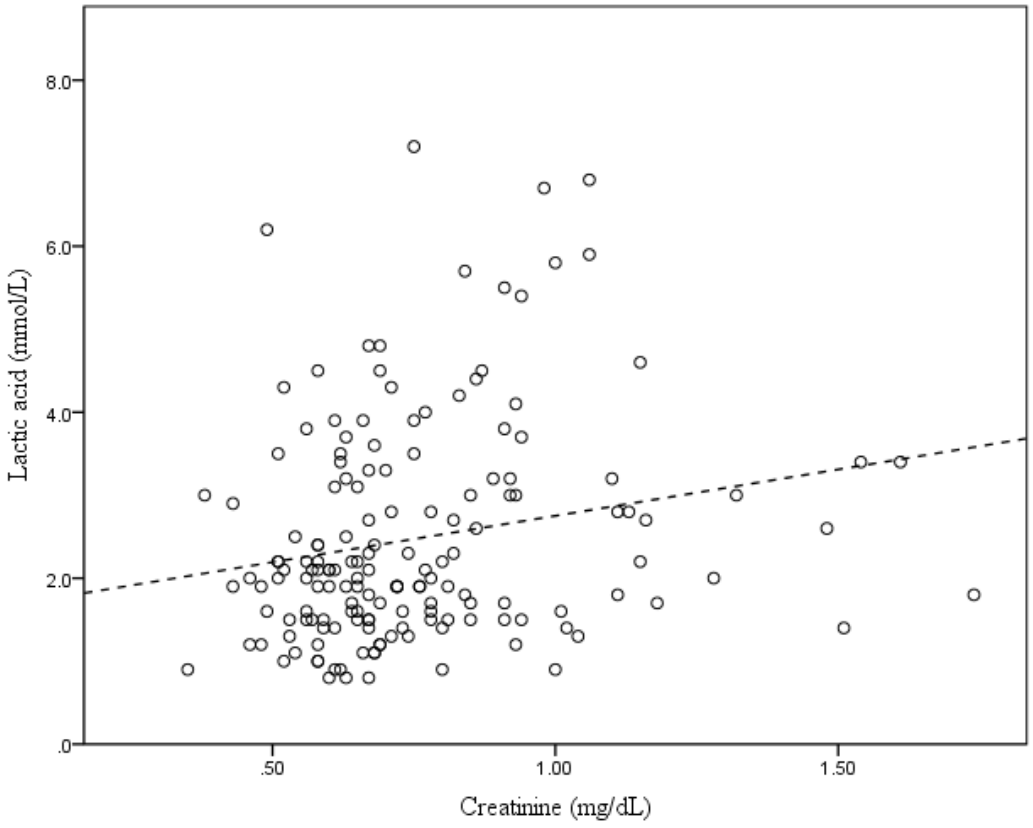

Figure 2. Relationship between lactic acid and creatinine level of obstetric women at the time of sepsis diagnosis. Pearson's r = .20., $p < .05$.

Neonatal Findings

There were 145 infants born to women who developed sepsis during labor. Most, 140 (96.6%), achieved a gestational age of ≥ 37 weeks, which is considered "term." Neonatal intensive care unit (NICU) admissions were identified, when possible, for the infants delivered to mothers with sepsis, although some data were missing. Of the 141 infants with known information related to NICU stay, 27 (19.1%), required a NICU admission. This percentage is higher than that of infants

delivered to all women (with and without sepsis) during the study period (13.7%). The neonatal length of stay (LOS) generally mirrored the four days or less maternal length of stay, with the neonatal LOS of 91.7% compared to that of the mothers with sepsis LOS of 98.0%. One infant required whole body cooling and whose mother was diagnosed with septic shock.

Neonatal Apgar scores at one- and five- minutes of age were collected. The number and percent of the infants with Apgar scores of 7 or more, or 6 or less, were calculated as a cohort study. The odds ratio of Apgar scores at one and five minutes of age for those infants born to mothers with sepsis, when compared to those of all mothers delivering during the study period, are 12.10 and 3.06, respectively (see Table 11).

Table 11

Apgar Scores of Infants Born to Women with Sepsis (Observed) to Those Delivered to All Women During Study Period N = 145

Population	Apgar at 1 Minute of Age				Apgar at 5 Minutes of Age			
	6 or less	%	7 or more	%	6 or less	%	7 or more	%
Intrapartum Sepsis *N*= 145	33	22.8	112	77.2	7	4.8	138	95.2
All Women *N*= 5179	468	9.0	4711	91.0	89	1.7	5090	98.3

Note. One-minute Apgar: Odds ratio 12.10, 95% CI [7.86, 18.61]. Five-minute Apgar: Odds ratio 3.06, 95% CI [1.40, 6.75]

Infant Apgar scores of ≤ 6 at one-minute were associated with the presence of funisitis or vasculitis when compared to chorioamnionitis solely being present on histologic exam of the placenta, χ^2 (1, N=96) =4.68, $p < .05$. No statistical significance was noted between SIRS combinations and the presence of vasculitis or funisitis in the placenta.

CHAPTER 5: DISCUSSION

Common Concerns

Concerns Expressed

There were some common concerns expressed by obstetric clinicians at the study site related to the initiation of routine sepsis screening. These included concerns that providing the volume of fluid resuscitation indicated for those with diagnoses of severe sepsis or septic shock would increase the incidence of pulmonary edema in this population, that lactic acid was not a valid clinical indicator of the severity sepsis, and that many women would be identified as "septic" who would otherwise be identified as having chorioamnionitis. Results from this study provide information which addresses aspects of these concerns.

Pulmonary Edema.

Intravenous fluid resuscitation, per the maternal sepsis screening pathway, was indicated for those who met severe sepsis or septic shock criteria. Normal saline fluid resuscitation was defined as providing either 2 liters or 30 mL/kg of body weight of fluid over 30-60 minutes following diagnosis. In this study, the three cases of pulmonary edema were present in women who did not receive fluid resuscitation. No one who received fluid resuscitation developed pulmonary edema. No one with pulmonary edema required ventilatory support.

Lactic Acid Levels

Elevated lactic acid values are associated with severe sepsis and septic shock and are thought to be related to factors including hypoperfusion (Albright et al., 2015; Surviving Sepsis Campaign, n.d.). The mean lactic acid values in this retrospective analysis study were 2.4 (standard deviation [SD] 1.3). This mean

value is similar to those reported by Albright et al. (2015) in pregnant or recently delivered women identified the emergency department as having sepsis. The mean lactic acid levels for women admitted to the telemetry or ICU units ranged from 2.0- 2.6 mmol/L (SD 1.0-1.6) (Albright et al., 2015). In the Albright et al. (2015) study, lactic acid values were usually drawn on patients who were admitted to the ICU or telemetry units, and therefore those lactic acid values were seen to be associated with women who required a more intensive level of care.

Obstetric clinicians often cite concerns related to the use of lactic acid as an indicator of sepsis due to the amount of energy women expend during labor and pushing. It is thought that lactic acid levels may be naturally higher as labor progresses due to anaerobic metabolism. Nordström. Achanna, Naka, and Arulkumaran (2001) performed an analysis of fetal lactate levels during the second stage of labor and obtained maternal lactate levels while the mother was pushing. The mean maternal lactate levels were noted to rise as the length of pushing progressed, although not in a direct linear fashion, from 2.6 at the time of complete cervical dilation to a range of 4-5 mmol/L, while women in the study pushed up to 75 minutes (Nordström et al., 2001). No discussion of maternal sepsis was noted in this article, and of note, the women were placed in a dorsal position (while pushing) without a uterine tilt (Nordström et al., 2001). No other research has formally evaluated the association of maternal lactate levels for those in labor with or without a diagnosis of sepsis. The correlation in the KP ROS retrospective analysis found a mild to moderate correlation between cervical dilation and lactic acid levels for those women diagnosed with sepsis. There was no correlation noted for lactic acid levels and the length of time of ruptured membranes.

Chorioamnionitis.

Chorioamnionitis, also known as intrapartum intraamniotic infection (III) may be diagnosed with a maternal temperature ≥ 39.0° C, or with an additional risk factor if the maternal temperature falls between 38.0-38.9° C (Committee on Obstetric Practice, 2017). In this study III was the most common source of infection in this study and the documented maternal temperatures ranged from 36.8 to 39.6 ° C. There was no correlation noted between maternal temperature and lactic acid value, nor an association between maternal temperature or the diagnosis of chorioamnionitis and the severity of sepsis. In the maternal sepsis screening pathway, a maternal temperature needed to be associated with one additional clinical value in order for the nurse to notify an obstetric provider to assess the patient for a source of infection.

In the data review for this study, several women at KP ROS were diagnosed with chorioamnionitis as the result of an isolated maternal fever, which aligns with the guidance provided in the Committee on Obstetric Practice bulletin on III (2017). These women were not diagnosed with sepsis, although they received antibiotics for the infection. Some later met SIRS criteria and subsequently received additional evaluation and treatment based on the diagnosis of sepsis.

The results of this study indicate that many women developed sepsis and had chorioamnionitis identified as the source of infection. However, not all women with the diagnosis of chorioamnionitis had sepsis. Also, 26 (17%) of the 152 women with sepsis, with a diagnosis of chorioamnionitis, did not have confirmation of that diagnosis per the placental pathology reports. Therefore, while III may be common, it is not possible to predict the severity of sepsis based on maternal temperature or a diagnosis of III.

SIRS Criteria

No specific combinations of SIRS criteria were associated with the severity of sepsis. The addition of fetal heart rate tachycardia (FHRT) as a single SIRS criterion allowed for the identification of 50 cases of sepsis (24.5%) in this population, and 13% of all cases of severe sepsis or septic shock. The country of Ireland developed a Sepsis Predisposition & Recognition Maternity Patients screening tool which includes FHRT of > 160 beats per minute (bpm) as one of 2 SIRS criteria to prompt escalation for medical review (National Sepsis Programme, 2017). Shields et al. (2016) describe a maternal early warning trigger tool used by the Dignity Health system which includes FHRT > 160 bpm as one of two "triggers" that would indicate the need to notify a physician and begin treatment for sepsis. The use of FHRT as part of this KP ROS maternal sepsis screening tool allowed for the early identification of patients who would otherwise not have received a formal evaluation for end-organ dysfunction. Given that information, and that other health systems use FHRT as a trigger or SIRS criterion, it is recommended that FHRT remain one of the SIRS screening criteria.

Assessment of Source of Infection and End-Organ Dysfunction

In this study, no woman had a bilirubin, APTT, or platelet count which met the level of end-organ dysfunction. It is recommended to eliminate the routine screening for elevated bilirubin and APTT values in obstetric sepsis. Platelet count is included as part of a complete blood count (CBC) and can provide information related to coagulopathy, and so will remain a recommended part of the routine screening process to assess for end-organ dysfunction. Urine cultures were sent in 69 cases, and of those, 30 % were positive. The result of positive urine cultures was higher than anticipated, and there may have been additional cases where the

source of infection was related to the urinary tract. It is recommended that urine cultures be routinely obtained for analysis unless there is another confirmed source of infection.

The elevated creatinine levels found in this population were unexpected as the values were not associated with either hypertension or preeclampsia being present as co-morbidities, or pyelonephritis as a source of infection. There was a small, but statistically significant relationship between serum creatinine and lactic acid levels in the women with sepsis in this study. Suh et al. (2013) report that acute kidney injury, including elevated creatinine levels, is common in patients who develop severe sepsis and septic shock.

Additional Considerations

Antibiotics had been administered within the previous 24 hours to 27% of the women who subsequently met two or more SIRS criteria. This finding is surprising as presumably, the antibiotics would have begun to treat the source of infection. Many of the women received several antibiotics as a result of being treated for Group B Strep prophylaxis, sepsis, and for Cesarean delivery surgical site prophylaxis.

There were few commonalities noted in the two women who were admitted to the ICU. The source of infection was either the uterus/placenta or the urinary tract. Each had an elevated maternal temperature and maternal heart rate as two of the three SIRS criteria present. None had positive blood cultures. Lactic acid values ranged from 1.4 to 7.2 mmol/L. The entire maternal length of stay for these women following the sepsis diagnosis or delivery ranged from 3 to 7 days.

The incidence of sepsis in this study approximates a reported incidence of chorioamnionitis of between 3-5 % (Kim et al., 2015). Chorioamnionitis was the

most common source of infection in the study population. The presence of an elevated maternal temperature and fetal heart rate tachycardia ordinarily trigger the bedside nurse to notify the OB provider of the abnormal findings. The incidence rate of sepsis in this study suggests that the routine screening for sepsis using obstetric-adjusted SIRS criteria would not require, in aggregate, an undue burden to the obstetric provider to assess the patient for sepsis.

Documentation of Urine Output and MAP

Decreased urine output and a MAP of less than 65 are markers of end-organ dysfunction in a patient with sepsis as they are surrogates for renal involvement or hypoperfusion. In this study urine output and MAP were documented in 40.7% or 13.7%, respectively, of the medical records of the women who met sepsis criteria. This lack of documentation raises concerns as the need to document on these values was emphasized in the nursing education provided before the implementation of the routine screening program. Nursing education related to the importance of these two values with regard to sepsis, and the need for consistent assessment and documentation of this information, should be crafted to reinforce this aspect of the maternal sepsis screening pathway.

Neonatal Considerations

Perhaps the most significant finding regarding neonatal outcomes was that of the increased risk for low Apgar scores for neonates born to women diagnosed with sepsis during labor. The low Apgar scores were associated with a diagnosis of chorioamnionitis, whether confirmed by placental pathologist review, or not, or from a urinary source. There was no significant statistical association between the presence of FHRT as one of the SIRS criteria and low Apgar scores. The Neonatal

Resuscitation Program (NRP) textbook (Wiener, Zaichkin, & Kattwinkel, 2016) recommends that there be two individuals trained in NRP for the care of the neonate when the mother has been diagnosed with chorioamnionitis. Based on the findings of this study, the recommendation to have two providers assigned solely for the care of the newborn at delivery should be extended to infants born to any women who develop sepsis during labor.

Routine Screening and Use of a Sepsis Pathway

There is limited information to provide a comparison between the number of women identified with sepsis as a result of the implementation of a routine sepsis screening program using obstetric-adjusted SIRS criteria, and the number who would have been identified without this process being in place. Before the implementation of this process, most pregnant or newly delivered women at KP ROS who were acutely ill with infection did not have sepsis added to their discharge diagnoses. Very few women are admitted from the obstetric service to the ICU.

At the study site, most obstetric patients with lactic acid values > 3.9 are managed in labor and delivery and not transferred to the ICU. Sometimes obstetric patients admitted to the ICU were received as transfers from other facilities due to KP ROS being a facility with a level III NICU. Therefore, looking at historical discharge diagnoses or ICU admissions would be of limited value for a pre- and post-implementation comparison.

The Sepsis in Obstetrics Score (SOS) reliably demonstrated a scoring system that identified women at high risk for ICU admission (Albright et al., 2015). The SOS included temperature, systolic blood pressure, heart rate, respiratory rate, blood oxygen saturation, WBC, immature neutrophils, and lactic

acid (Albright et al., 2015). In another study, a reduced number of ICU admissions resulted from the routine use of maternal early warning triggers (MEWTs) (Hedriana, Wiesner, Downs, Pelletreau, & Shields, 2016). Sepsis MEWTs included temperature plus another MEWT (respiratory rate, maternal heart rate, or respiratory rate), to initiate escalation for further assessment for sepsis (Hedriana et al., 2016). The lack of women admitted to the ICU for sepsis at KP ROS limits the ability to compare ICU admissions as a marker of severity of illness.

Compliance with the required assessment elements, such as obtaining blood cultures, serum lactate levels, and other lab values, varied among obstetric providers. However, only one woman did not have a serum lactate drawn. While data is lacking for comparison, before the implementation of routine screening it was unusual for a woman diagnosed with infection to have either a blood culture or serum lactate ordered. Of the 204 women, 186 (96.6 %), received antibiotics, and when indicated, adequate fluid resuscitation, within 3 hours of the diagnosis of sepsis. The implementation of the routine sepsis screening pathway has provided a standard process for early identification, assessment, and treatment of women at risk for sepsis.

Limitations

There are several potential limitations to the generalizability of this study. Most of the women in the study are members of an integrated health-system who have received routine prenatal care. The setting was limited to one facility in a suburb of a major metropolitan area. The subjects were identified through reports from the electronic medical record system or by nurses working on the units. It is possible that not all subjects who met sepsis criteria were identified through these methods. Some laboratory values, such as blood and urine cultures, creatinine, and

APTT were not collected on all women. Not all neonatal variables, such as length of stay and NICU admission, were available for collection.

Additional potential limitations to this study include the determination of the cut-off values for the SIRS criteria and the inclusion of fetal heart rate tachycardia as one SIRS criterion. The use of lactic acid levels as a marker of severity of sepsis in the obstetric population remains under discussion. The end-organ dysfunction values and associated levels of severity of sepsis, while an agreed upon standard in the study setting, still lack consensus in the obstetric literature. The small number of women admitted to the ICU with a diagnosis of sepsis limits the ability to compare the use of the KP ROS SIRS values to other published studies using similar obstetric-adjusted SIRS criteria.

Implications for Clinical Practice

The results of the analysis provide some guidance for clinical practice related to women who develop altered vital signs and lab values in the setting of a source of infection. The presence of specific SIRS criteria combinations is not predictive of the severity of sepsis. Women may frequently experience an elevated temperature or maternal heart rate in the setting of chorioamnionitis. While these women may frequently recover with the provision of antibiotics, it is only by determining the severity of sepsis that those caring for her will know if she requires close observation and fluid resuscitation.

Positive urine cultures were present at a much higher rate than blood cultures. Sending a urine culture for analysis may provide important information about the source of infection. Given that most of the women developed sepsis in labor, and with an epidural present, it may be presumed that many will have an indwelling urinary catheter in place. This would facilitate the collection of a clean

urine sample to send for culture. This is especially pertinent as 12.7% of the women in this study had a diagnosis of chorioamnionitis with a placental pathology report indicating the absence of chorioamnionitis, and no other source of infection identified. Possibly the urinary tract was a source of infection in some of those cases.

An Apgar score of 6 or less indicates that the newborn will require resuscitation at that time. It will be important to stress to those caring for the women who develop sepsis during labor to communicate to those responsible for the newborn at the time of delivery that the mother had sepsis. A minimum of two individuals whose sole responsibility is care for the newborn should be present at the time of delivery for infants born to women who have sepsis.

Education related to routine sepsis screening must emphasize the importance of routinely obtaining, and then recording, intake and output and the mean arterial pressure as a way to assess for the presence or absence of end-organ dysfunction. It is also important to emphasize to clinicians the need for a thorough clinical assessment when a pregnant or newly delivered woman has a creatinine level of 0.8 mg/dL or greater. The elevated creatinine may be associated with preeclampsia, kidney injury, or sepsis, each of which may require additional assessments for physical symptoms or laboratory studies.

Conclusion

This study furthers knowledge related to the variables and outcomes associated with sepsis in the obstetric population. While the results were unable to prove an association between specific SIRS criteria and the severity of sepsis, the analysis provides information about specific variables collected when routine sepsis screening was provided by inpatient obstetric nurses. The use of a

standardized screening pathway for the assessment for sepsis in the obstetric population allowed for early treatment of women with sepsis. There is a need for further research related to sepsis in pregnant and newly delivered women and the associated risks for their neonates. In particular, there is a need to study lactic acid levels in women in labor. It is imperative that obstetric clinicians continue to identify methods to assist in early identification of sepsis to prevent maternal mortality.

REFERENCES

REFERENCES

Abir, G., Akdagli, S., Butwick, A., & Carvalho, B. (2016). Clinical and microbiological features of maternal sepsis: A retrospective study. *International Journal of Obstetric Anesthesia*, *29*, 26-33. doi:10.1016/j.ijoa.2016.09.003

Acosta, C., Harrison, D. A., Rowan, K., Lucas, D. N., Kurinczuk, J. J., & Knight, M. (2016). Maternal morbidity and mortality from severe sepsis: A national cohort study. *BMJ Open*, *6*, e012323. doi:10.1136/bmjopen-2016-012323

Acosta, C. D., Knight, M., Lee, H. C., Kurinczuk, J. J., Gould, J. B., & Lyndon, A. (2013). The continuum of maternal sepsis severity: Incidence and risk factors in a population-based cohort study. *PLOS ONE*, *8*, e67175. doi:10.1371/journal.pone.0067175

Albright, C. M., Ali, T. N., Lopes, V., Rouse, D. J., & Anderson, B. L. (2014). The sepsis in obstetrics score: A model to identify risk of morbidity from sepsis in pregnancy. *American Journal of Obstetrics and Gynecology*, *211*, e1-8.

Albright, C. M., Ali, T. N., Lopes, V., Rouse, D. J., & Anderson, B. L. (2015). Lactic acid measurement to identify risk of morbidity from sepsis in pregnancy. *American Journal of Perinatology, 32,* 481-486. doi:10.1055/s-0034-1395477

Albright, C. M., Mehta, N. D., Rouse, D. J., & Hughes, B. L. (2016). Sepsis in pregnancy. *Journal of Perinatal and Neonatal Nursing*, *30*, 95-105.

Barton, J. R., & Sibai, B. M. (2012). Ask the experts: Severe sepsis and septic shock in pregnancy. Retrieved from http://journals.lww.com/greenjournal/Documents/Sep2012_AtE_Barton.pdf

Bauer, M. E., Bateman, B. T., Bauer, S. T., Shanks, A. M., & Mhyre, J. M. (2013). Maternal sepsis mortality and morbidity during hospitalization for delivery: Temporal trends and independent associations for severe sepsis. *Anesthesia & Analgesia, 117*, 944-950.

Bauer, M. E., Bauer, S. T., Rajala, B., MacEachern, M. P., Polley, L. S., Childers, D., & Aronoff, D. M. (2014). Maternal physiologic parameters in relationship to systemic inflammatory response syndrome criteria: A systemic review and meta-analysis. *Obstetrics & Gynecology*, *124*, 535-541.

Bauer, M. E., Lorenz, R. P., Bauer, S. T., Rao, K., & Anderson, F. W. J. (2015). Maternal deaths due to sepsis in the state of Michigan, 1999-2006. Obstetrics & Gynecology, 126, 747-725. doi:10.1097/AOG.0000000000001028

Bone, R. C., Balk, R. A., Cerra, R. P., Dellinger, A. M., Knaus, W.A. (1992) Definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis. Chest, 101, 1644-55.

Centers for Disease Control and Prevention. (2016a, January 21). *Pregnancy Mortality Surveillance System.* Retrieved from http://www.cdc.gov/reproductivehealth /MaternalInfantHealth/PMSS.html

Centers for Disease Control and Prevention. (2016b, September 22). Empowering nurses for early sepsis recognition [Webinar]. *In Tune in to Safe Healthcare*. Retrieved from https://cc.readytalk.com/registration/# /?meeting=5v2cmv5nrclq&campaign=jgtxnnpp9bw2

Committee on Obstetric Practice. (2017). Committee opinion no. 712: Intrapartum management of intraamniotic infection. *Obstetrics & Gynecology*, *130*, e95-e101. doi:10.1097/AOG.0000000000002236.

Desale, M, Thinkhamrop, J., Lumbiganon, P., Qazi, S., & Anderson, J. (2016). Ending preventable maternal and newborn deaths due to infection. *Best Practice & Research Clinical Obstetrics and Gynaecology*, *36*, 116-160. doi:10.1016/j.bpogyn.2016.05.008

Drake, K. (2015). The sepsis core measures initiative. *Nursing Management*, *46*, 33 – 36. doi:10.1097/01.NUMA.0000473506.31055.b6

Faksh, A. & Martin, S. (2016). Maternal sepsis: Current approaches to recognition and clinical management. *Current Women's Health Reviews, 12*, 20-38. doi:10.2174/1573404812666160727121235

Gallop, K. H., Kerr, C. E. P, Nixon, A., Verdian, L, Barney, J. B., & Beale, R. J. (2015). A qualitative investigation of patient's and caregivers' experiences of severe sepsis. *Critical Care Medicine*, *43*, 296-307. doi:10.1097/CCM.0000000000006137250(15)41063-3

Hedges, C. C., Nichols, A., & Filoteo, L. (2012). Relationship-based nursing practice: Transitioning to a new care delivery model in maternity units. *Journal of Perinatal and Neonatal Nursing, 26*(1), 27-36. doi:10.1097/JPN.0b013e3183f0284

Hedriana, H. L., Wiesner, S., Downs, B. G., Pelletreau, B., & Shields, L. E. (2016). Baseline assessment of a hospital-specific early warning trigger system for reducing maternal morbidity. *International Journal of Gynecology and Obstetrics, 132,* 337-341. doi:10.1016/j.ijgo.2015.07.036

Jones, S. L., Ashton, C. M., Kiehne, L., Gigliotti, E., Bell-Gordon, C., Disbot, M., Masud, F., …Wray, N. P. (2015). Reductions in sepsis mortality and costs after design and implementation of a nurse-based early recognition and response program. *Joint Commission Journal on Quality and Patient Safety, 41,* 483-491. doi:10.1016/S1553-

Kim, C. J., Romero, R., Chaemsaithong, P., Chaiyasit, N., Yoon, B. H., & Kim, Y. M. (2015). Acute chorioamnionitis and funisitis: Definition, pathologic features, and clinical significance. *American Journal of Obstetrics and Gynecology, 213,* S29-S52. doi:10.1016/j.ajog.2015.08.040.

Klouwenberg, P. M. C. K., Ong, D. S. Y., Bonten, M. J. M., & Cremer, O. L. (2012). Classification of sepsis, severe sepsis, and septic shock: The impact of minor variations in data capture and definition or SIRS criteria. *Intensive Care Medicine, 38,* 811-819.doi:10.1007/s00134-012-2549-5

Koloroutis, M. (Ed.). (2004). *Relationship-based care: A model for transforming practice.* Minneapolis, MN: Creative Healthcare Management.

Lappen, J. R., Keene, M., Lore, M., Grobman, W. A., &Gossett, D. R. (2010). Existing models fail to predict sepsis in an obstetric population with intrauterine infection. *American Journal of Obstetrics & Gynecology, 203*, e1-5. doi:10.1015/j.ajog.2010.07.040

MacDorman, M. F., Declerq, E., Cabral, H. & Morton, C. (2016). Recent increases in the U. S. maternal mortality rate: Disentangling trends from measurement issues. *Obstetrics & Gynecology, 128*, 447-455. doi:10.1097/AOG.0000000000001556

Maguire, P. J., Power, K. A., Downey, A. F., O'Higgins, A. C., Sheehan, S. R., Turner, M. J. (2016). Evaluation of the systemic inflammatory response criteria for the diagnosis of severe sepsis due to maternal bacteremia. *International Journal of Gynecology and Obstetrics, 133*, 116-119. doi:10.1016/j.ijgo.2015.09.017

Mellott, J., Richards, K., Tonry, L., Bularzik, A M. H., & Palmer, M. (2012). Translating caring theory into practice: A relationship-based care model. *Nurse Leader, 10* (5), 44-49. doi:10.1016/j.mnl.2012.02.006

Moaddab, A., Dildy, G. A., Brown, H. L., Bateni, Z. H., Belfort, M. A., Sangi-Haghpeykar, H., & Clark, S. L. (2016). Health care disparity and state-specific pregnancy-related mortality in the United States, 2005-2014. *Obstetrics & Gynecology, 128*, 869-875. doi:10.1097/AOG.0000000000001628

Mohamed-Ahmed, O., Nair, M., Acosta, C., Kurinczuk, J. J., & Knight, M. (2015). Progression from severe sepsis in pregnancy to death: A UK population-based case-control analysis. *BJOG: An International Journal of Obstetrics & Gynaecology, 122,* 1506-1515.doi:10.1111/1471-0528.13551

Morath, J. (2015, March 27). CMS announces data collection for sepsis bundle measure. [Web log post]. Retrieved from http://www.calhospital.org/cha-news-article/cms-announces-data-collection-sepsis-bundle-measure

National Sepsis Programme. (2017, September 5). National sepsis outcome report. Retrieved from https://www.hse.ie/eng/services/publications/clinical-strategy-and-programmes/national-sepsis-report-2016.pdf

Nordström, L., Achanna, S., Naka, K., & Arulkumaran, S. (2001). Fetal and maternal lactate increase during active second stage of labour. *British Journal of Obstetrics and Gynaecology, 108*, 263-268.

Olvera, L., & Dutra, L. (2016). Early recognition and management of maternal sepsis. *Nursing for Women's Health, 20,* 184-196. doi:10.1016/j.nwh.2016.02.003

Shields, L. E., Wiesner, S., Klein, C., Pelletreau, B., & Hedriana, H. L. (2016). Use of maternal early warning trigger tool reduces maternal morbidity. *American Journal of Obstetrics & Gynecology*, *214*, e1-6. doi:10.1016/j.ajog.2016.01.154

Snyder, C. C., Barton, J. R., Habli, M., & Sibai, B. M. (2013). Severe sepsis and septic shock in pregnancy: Indications for delivery and maternal and perinatal outcomes. *The Journal of Maternal-Fetal and Neonatal Medicine, 26,* 503 – 506. doi:10.3109/14767058.2012.739221

Suh, H. S., Kin, C. S., Choi, J. S., Bae, E. H., Ma, S. K., & Kim, S. W. (2013). Acute kidney injury in patients with sepsis and septic shock: Risk factors and clinical outcomes. *Yonsei Medical Journal, 54*, 965-972. doi:10.3349/ymj.2013.54.4.965

Surviving Sepsis Campaign. (n.d.) 3-hour bundle. Retrieved from http://www.survivingsepsis.org/SiteCollectionDocuments/Bundle-3-Hour-Step1-Measure-Lactate.pdf

Weiner, G. M., Zaichkin, J., & Kattwindel, J. (Eds). (2016). *Textbook of neonatal resuscitation, 7th ed*. Elk Grove Village, IL: American Academy of Pediatrics and American Heart Association

Woolley, J., Perkins, R., Laird, P., Palmer, J., Schitter, M. B., Tarter, K., …Woolsey, M. (2012). Relationship-based care: Implementing a caring, healing environment. *MEDSURG Nursing, 21,* 179-184.pdf

APPENDICES

APPENDIX A: APPROVAL KAISER PERMANENTE IRB

KAISER PERMANENTE

NORTHERN CALIFORNIA INSTITUTIONAL REVIEW BOARD

OFFICIAL COMMUNICATION FROM THE KPNC IRB

October 19, 2017

Holly Champagne,
MSN Principal
Investigator Roseville

Re: Analysis of Findings Following Routine Obstetric Sepsis Screening

Expiration date: 10/16/2018

Thank you for your submission to the Kaiser Permanente Northern California (KPNC) Institutional Review Board (IRB).

On 10/17/2017, a designated member of the KPNC IRB conducted an expedited review and **approved** your new study for one year.

In addition, the following determinations were made:

- The requirement that informed consent be obtained from study participants was waived.
- The requirement that Privacy Rule authorization be obtained from study participants was waived.

Please review the following documents entitled *Important Information about Your IRB Approval*
and *HIPAA Privacy Rule Instructions*. Sincerely,
Kaiser Permanente Northern California Institutional Review Board

CN-17-3001 Expedited Initial Review 1

APPENDIX B: APPROVAL CALIFORNIA STATE UNIVERSITY IRB

FRESNO STATE
College of Health and Human Services

California State University,
Fresno School of Nursing
IRB Approval

November 8, 2017

RE: DNP1718 Analysis of Findings Following Routine Obstetric Sepsis Screening

Dear Holly Champagne,

As the Chair of the Department of Nursing Research Committee, serving as the Institutional Review Board for the Department of Nursing, I have reviewed and approved your review request for the above-referenced project for a period of 12 months. I have determined your study to meet the criteria for Minimal Risk IRB review.

Under the Policy and Procedures for Research with Human Subjects at California State University, Fresno, your proposal meets minimal risk criteria according to section 3.3.7: Research in which the risks of harm anticipated are not greater, probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

The Research Committee may periodically wish to assess the adequacy of research process.
If, in the course of the study, you consider making any changes in the protocol or consent form, you must forward this information to the Research Committee prior to implementation unless the change is necessary to eliminate an apparent immediate hazard to the research participant(s).

This study expires: November 8, 2018

The Research Committee is authorized to periodically assess the adequacy of the consent and research process. All problems having to do with subject safety must be reported to the Research Committee. Please maintain proper data control and confidentiality.

If you have any questions, please contact me through the CSU, Fresno School of Nursing Research Committee at symiller@csufresno.edu.

Sincerely,

Sylvia Miller

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