

SERIOUS INFECTIOUS EVENTS FOLLOWING CESAREAN SECTION

By

JANET BURTON GLOWICZ

DISSERTATION

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Supervising Committee:

Joy Don Baker, Supervising Professor  
Susan Baxley  
Daisha J. Cipher

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## DEDICATION PAGE

My parents taught me to be a lifelong learner and I am thankful for their love. This milestone represents the end of an educational journey, and the beginning of a journey in which questions indicate opportunities for new learning. The support and encouragement provided by Norman Glowicz has made this journey possible. I delight in sharing this achievement with my sons Stephen, Timothy and Daniel and their wives, Misti, Kelly and Mariah. Thank you for unending support, I can't wait to see where your journey takes you!

For those who work in infection prevention and those who care for patients at the bedside, your desire to prevent adverse outcomes is at the core of this study. I dedicate it to all those who seek to improve healthcare by preventing infectious complications among the most vulnerable hospitalized patients.

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## ABSTRACT

**SERIOUS INFECTIOUS EVENTS FOLLOWING CESAREAN SECTION**

Janet Burton Glowicz, PhD

The University of Texas at Arlington, 2017

Supervising Professors: Joy Don Baker, Susan Baxley, Daisha CIPHER

The purpose of this study was to evaluate trends in the incidence of serious infectious events (SIE), defined as organ space infection, sepsis, and Cesarean Section (CS) wound disruption, during the birth admission or resulting in between January 1, 2009 and December 31, 2014 in the State of Texas. A retrospective analysis of the Public Use Data File, maintained by the Texas Health Care Information Collection was conducted. Records of 627,555 women who had CS and 1,023 women readmitted for CS wound disruption, were included.

During the study period, there was a large decrease in the rate at which SIE occurred ( $R^2=.59$ ). This was potentially influenced by a large decrease in the rate of the diagnosis of endometritis ( $R^2=.41$ ). Decreases in the diagnosis of and readmission for CS wound disruption were not as large ( $R^2=.06$ ;  $R^2=.03$ ). A large increase in the diagnosis of sepsis ( $R^2=.32$ ) among women who gave birth by CS was identified.

Characteristics of women associated with increased odds of developing SIE included being age 19 years and under, Black race. Treatment exposures; internal fetal monitoring, and induction of labor were associated with increased odds of SIE. Comorbid conditions that increased the odds of being diagnosed with SIE included chorioamnionitis, anemia, post term pregnancy, severe pre-eclampsia, obesity, diabetes, early onset of labor, and abnormal fetal heart rate. The odds of being diagnosed with cellulitis and abscess of the trunk were highly increased among women diagnosed with a SIE. Women who gave birth at facilities located in rural

counties had lower odds of being diagnosed with a SIE; women who gave birth by CS at teaching facilities had increased odds of being diagnosed with a SIE. No conclusions about pathogens could be drawn.

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## CHAPTER ONE: INTRODUCTION

This chapter introduces the background and significance of infectious morbidity following Cesarean Section (CS) and provides a framework for the study of serious infectious events (SIE) potentially related to the surgical site. The research purpose is defined and the research questions are stated. Assumptions underlying the research are included.

### **Background and Significance**

Globally, maternal morbidity and mortality are important measures of public health. It is known that Cesarean Section is associated with severe maternal morbidity and mortality, which are regularly measured in the United States (Callaghan, Mackay & Berg, 2008). However, the frequency at which women experience serious infectious events (SIE), defined as septicemia, organ space infection, or wound disruption, following CS is not known. Surgical site infections (SSI) are one of the most common healthcare-associated infections and infection is a leading cause of maternal mortality (Callaghan, 2015, Magill et al., 2014). However, CS SSI are not required to be publicly reported and are not measured in a manner that continuously evaluates their impact on women's health. This study examines the occurrence of SIE following delivery of an infant by CS within the context of maternal morbidity and mortality.

Puerperal fever has a long and significant history in the medical literature and prior to seminal work in hand hygiene, the discovery of germ theory and treatment with antibiotics, it was a common occurrence resulting in extreme suffering and death (Lane, Blum & Fee, 2010; Loudon, 2000). Drastic improvements in the ability of women to survive childbirth were attained in the 20<sup>th</sup> century. The United States attained a rapid decline in maternal mortality, from 607 deaths per 100,000 women who gave birth in 1915 to 9.2 deaths per 100,000 deaths in 1980. This has been hailed as one of the "Ten Great Achievements of Public Health" (Lu,

Highsmith, de la Cruz, & Atrash, 2015; Singh, 2013). On the cusp of the 21<sup>st</sup> century some experts believed that maternal deaths had fallen to an irreducible minimum (Centers for Disease Control and Prevention [CDC], 1999). The CDC rejected this speculation and argued that there was no biologically plausible explanation why further declines in maternal mortality could not occur.

### **Maternal Mortality**

Despite these early advances in maternal mortality, a 2015 report prepared by officials at the U. S. Health and Human Services, Health Resources and Services Administration indicated that the maternal mortality rate has steadily risen each year since 1987. Deaths of women are included in the maternal mortality rate if the death occurred within 42 days of the end of a pregnancy, from any non-accidental cause related to, or aggravated by pregnancy, regardless of the duration of the pregnancy (Callaghan, 2012). In 2011, 17.8 maternal deaths per 100,000 live births occurred (Lu et al., 2015). Infection and sepsis were the third leading cause of maternal death following cardiovascular disease, and non-cardiovascular disease (Lu, et al 2015). Nationally, a large racial disparity among women affected by maternal mortality exists. In 2011, the maternal mortality rate among White women was 11.8 deaths per 100,000 live births; 41.1 among Black women and 15.7 among women of all other races (CDC, 2015).

The rate of maternal mortality is higher and the racial disparity greater within the State of Texas. For example, the maternal mortality rate was 30.74 per 100,000 live births among all women in 2011, but the death rate among Black women was 67.3 maternal deaths per 100,000 live births (Texas Department of State Health Services, 2013; Texas Department of State Health Services, 2014). Epidemiologists speculate that nationally more accurate reporting of deaths associated with childbirth is responsible for at least some of the increase in maternal mortality

(Callaghan, 2015; Lu et al. 2015). Beginning in 2003, 41 states including Texas added checkboxes to death certificates allowing medical providers to indicate maternal death.

(Callaghan, 2015; CDC, 2015).

### **Maternal Morbidity**

Women are affected by severe maternal morbidity approximately 50 times more frequently than maternal mortality (Lu, 2015). Severe maternal morbidity is defined as a life-threatening condition or complication, occurring during a hospital delivery, that if uninterrupted, will result in death (CDC, 2015; Lu, 2015). At the CDC epidemiologists perform retrospective reviews of the medical records of women who have given birth and identify incidences of severe morbidity by using diagnostic codes included in medical records from the National Inpatient Sample (CDC, 2015). Examples of conditions that signify life-threatening conditions are acute myocardial infarction, cardiac arrest, pulmonary edema, sepsis, shock, or hysterectomy. In 2011, the CDC (2015) reported that 163 women were affected by severe maternal morbidity for every 10,000-hospital deliveries, this was a statistically significant increase occurring over the previous two decades (test for trend  $p < 0.014$ ).

Although the research on severe maternal morbidity is limited, two groups of researchers have performed population-based studies to examine associated factors. Callaghan et al., (2008) used the National Hospital Discharge Survey to investigate severe maternal morbidity occurring between 1991 and 2003. They reported that elevated relative risk (RR) for severe maternal morbidity was associated with CS delivery (RR = 6.06; 95% confidence interval [CI] 5.02-7.09), being less than 20 years old (RR=1.40, CI 1.09-1.70) or over 40 years of age (RR=1.95, CI 1.60-2.29), Black race (RR=1.95, CI 1.60-2.29), and residing in the Northeast (RR=1.41, CI 1.10-1.71) or the Southern United States (RR=1.47, CI 1.13-1.81).

Gray, Wallace, Nelson, Reed and Schiff (2012) conducted a population-based, case control study in the State of Washington by linking birth certificate records to hospital discharge data to identify risk factors associated with the development of severe maternal morbidity. They calculated adjusted odds ratios (aOR) and identified several factors that were associated with a two-fold or greater increase in the development of severe maternal morbidity. These included having a prior CS compared to no history of CS (aOR=2.10, 95% CI 1.88-2.23), multiple gestation compared to singletons (aOR=2.54, 95% CI 2.26-2.82), having a preexisting condition compared to not have a preexisting condition (aOR = 2.10, 95% CI 1.88-2.23), Black race compared to White (aOR=1.82, 95% CI 1.64-2.07), and being over the age of 40 (aOR=2.98, 95% CI 2.11-2.81).

A major limitation of all analyses of severe maternal morbidity is the exclusion of complications that occur following discharge from the hospital after delivery. For example, a SIE associated with a surgical site infection following CS and may be a life-threatening complication directly related to childbirth. However, if the woman has been discharged to home prior to the onset of the infection the incident would not be included in calculations of severe maternal morbidity.

### **Serious Infectious Events following Cesarean Section**

The World Health Organization (2016) has reported that, at a national level, CS rates of 10-15% are associated with decreases in maternal, neonatal and infant mortality, but rates above this level are not associated with improved maternal health. International studies have demonstrated a strong association between CS and the development of infection. Researchers in Denmark compared infectious morbidity among 32,468 women and reported that 7.6% of those who gave birth by CS developed an infection, compared to 1.6% of women who gave birth

vaginally (Leth, Moller, Thomsen, Uldberg, & Norgaard, 2009). The odds of a mother developing an infection after CS were nearly five times higher than among women giving birth vaginally (OR 4.17, CI 4.08-5.43).

Rates of CS deliveries have risen every year since 2000, and in 2011, over one and a quarter million births, or 32.8% of all births in the United States, occurred by CS (Osterman & Martin, 2014). Public reporting of CS SSIs is not required, therefore information about how many women are affected annually by SIE following CS or whether the incidence of SIE following CS is increasing, decreasing or stable is limited.

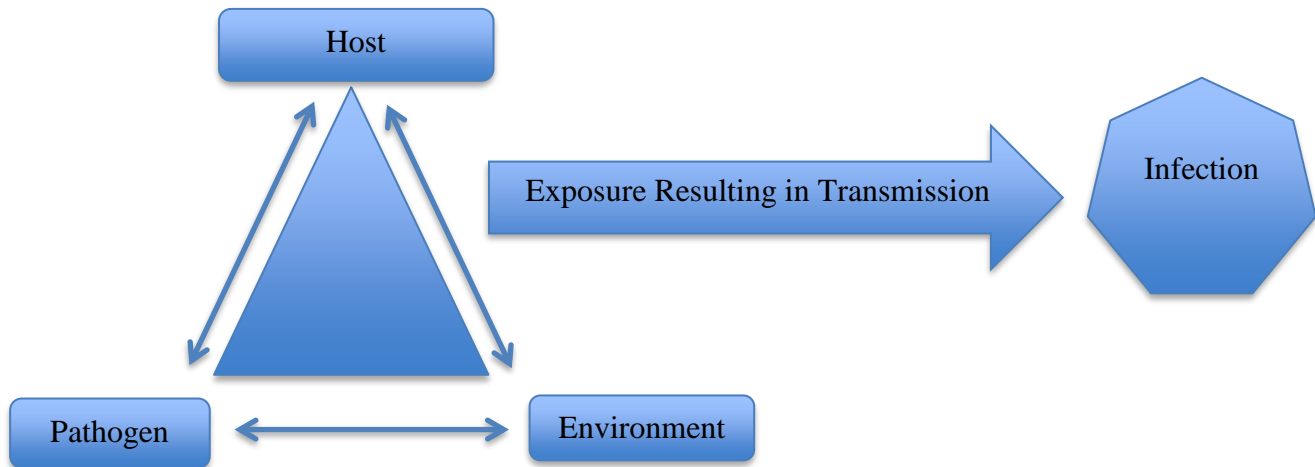
### **Theoretical Framework**

Germ theory was widely accepted following the experiments of Robert Koch, who was able to show that microorganisms cause specific diseases (Tabrah, 2011). Although Koch definitively linked bacterium to causation of infection, he was not able to explain reasons why some people who are exposed to microorganisms become infected and some do not. Nearly 200 years following Koch's discoveries, epidemiologic research continues to attempt to explain why some individuals are more susceptible to infections than others. The epidemiologic triad offers a framework for research exploring the likelihood of developing infections and effectiveness of prevention measures.

### **The Epidemiologic Triad**

The Epidemiologic Triad (Figure 1.1) triad depicts the constant interaction between the host, the pathogen and the environment that influence the development of infection (CDC, 2012). Infection will not occur if any of the elements of the triad are not present and attributes of the host, pathogen or environment may increase or decrease the likelihood of the development of infection. Women undergoing CS are exposed to an opportunity for infection that may be

transmitted via the inoculation of the wound during surgery or by the ascension of resident bacteria from the vagina to the uterus.



**Figure 1.1** The Epidemiologic Triad (CDC, 2012) A depiction of the Epidemiologic Triad with the exposure resulting in infection; adapted from *Principles of Epidemiology in Public Health Practice, Third Edition: An Introduction to Applied Epidemiology and Biostatistics*. Public domain.

**The Host.** This study focuses on CS; therefore, the host is a female of childbearing age. Each individual has characteristics that cause her to be more or less vulnerable to infections. Modifiable host characteristics, or traits that may be changed, include body mass index, nutritional status and knowledge of infectious processes leading to compliance with prevention measures (Anderson, Chaboyer & Gillespie, 2013). As an example, obesity is noted to increase the likelihood of development of infection (Mu, Edwards, Horan, Berrios-Torres, & Fridkin, 2011). Therefore, reducing body mass index prior to surgery might be an effective prevention measure. Host characteristics that cannot be modified include gender, race, age, and the presence of chronic health conditions. When non-modifiable characteristics are associated with the development of infection, prevention measures must be focused on either the pathogen or the



environment. For example, CS SSIs are associated with being over the age of 26 years (Mu et al., 2011). Since age cannot be modified, using effective skin antisepsis to ensure the best possible elimination of resident pathogens with appropriate antibiotic prophylaxis might prevent infection.

**The Pathogen.** Pathogens are microscopic organisms, bacteria, viruses, fungi, parasites or prions that cause disease (CDC, 2016). Reservoirs of pathogenic bacteria exist endogenously on the patient's skin, or within the patient's reproductive tract and exogenously on the skin of healthcare providers, in the surgical environment of care, or on instruments brought to the sterile field (Bratzler et al., 2013; Owens & Stoessel, 2008). Characteristics of pathogens that may be associated with disease transmission include the amount of bacteria, or dose, that is needed to cause infection, and the ability of the pathogen to invade tissues and establish infection.

Increasing antimicrobial resistance has rendered certain bacteria difficult to treat, and certain types of preventive antibiotics ineffective (CDC, 2016a). In fact, the CDC has reported that one in seven surgical site infections occurring in 2014 was caused by resistant bacterium. Aseptic practices, such as hand hygiene, skin cleansing, and donning of surgical attire are interventions aimed at preventing the inoculation of surgical wounds with pathogens (AORN, 2016)

**The Environment.** A clean surgical suite is foundational to aseptic practice and environmental surfaces within the perioperative area that are not adequately cleaned present a high risk of exposure to pathogens (Munoz-Price et al., 2012). The environment of the labor and delivery perioperative area influences the vulnerability of hosts and the survival of pathogens within reservoirs. For example, the temperature of the operating room is required by industry standards and hospital licensing codes to be 68-73° Fahrenheit (Texas Administrative Code, 2009). This cool temperature, in association with the administration of anesthetics may cause the

patient to develop hypothermia, affecting the person's ability to fight infection, thereby increasing the vulnerability of the host to infection (AORN, 2016).

The safety culture and teamwork of members is another aspect of the surgical environment that can protect patients and reduce infectious diseases. The effectiveness of teamwork is illustrated by results from a project undertaken by surgeons and nurses in response to facility-wide policy change requiring the administration of preventive antibiotics before the skin incision instead of during the CS, after the infant was delivered and the cord was clamped (Young, Hacker, Dodge, & Golen, 2011). To institute this change, house staff, obstetricians, anesthesiologists, neonatologists and perioperative nurses worked together to achieve 100% adherence to the policy within five weeks of implementation. A reduction in SSI, although not statistically significant, was attained. Among 525 women included in a pre and post implementation evaluation, the odds of developing a CS SSI were higher among women who got antibiotics after the baby's cord was clamped (Odds Ratio [OR]=2.21 95% Confidence Interval [CI] 0.89-5.54) compared to those who received antibiotics before the skin incision. The researchers attributed the lack of statistical significance to sample size and rapid implementation of the policy resulting in limitations in the ability to collect information about women prior to the policy change. However, an environment in which the perioperative personnel worked as a team to improve care was demonstrated.

### **Study Purpose**

The purpose of this study is to identify trends in the incidence of SIE following CS over a five- year period, from January 1, 2010 through December 31, 2014 in the State of Texas. Demographic characteristics of women affected by CS SIE, such as age, race and place of

residence, are described. The study also explores the frequency at which certain pathogens are associated with SIE.

### **Statement of Study Questions and Hypotheses**

For the purposes of this study, a serious infectious event is defined as the presence of a diagnostic code within the discharge record indicating septicemia, major puerperal infection, endometritis or wound disruption that occurs during the admission for CS delivery or results in readmission to an acute care facility following the CS. The following questions were used to describe the characteristics of incident SIE following CS.

1. In the State of Texas, over a five-year period, has the incidence of serious infectious events following CS increased, decreased or remained the same?
2. What demographic characteristics of women, such as age, race, geographic location of residence, treatment exposures, and co-morbidities are associated with SIE?
3. What characteristics of facilities, such as designation as a teaching or non-teaching facility or location in a rural compared to an urban facility, are associated with SIE?
4. Among women with SIE following CS, what pathogens are most frequently identified in diagnosis codes?

### **Assumptions**

The following assumptions are accepted as true, and influence the methods used to explore the study questions and hypotheses:

1. Demographic characteristics of women who develop SIE following CS can be identified and quantified.
2. All childbearing women who deliver by CS may be affected by an SIE regardless of age, race, or geographic location or residence or facility where care is rendered.

3. SIE may occur during the birth admission or result in readmission.

### **Summary**

Maternal morbidity and mortality have increased every year since 1987 (Callaghan, 2015; Lu, 2015). Nationally, in 2011, the third leading cause of maternal mortality was infection and sepsis (Lu, 2015). Rates of maternal mortality and maternal morbidity have increased in the preceding decades, but it is unknown if serious infectious events following CS are increasing, decreasing or continuing to occur at a stable rate. Racial disparities have been identified among women whose deaths are associated with childbirth and among women who experience severe maternal morbidity, but it is unknown if disparities exist among women affected by serious infectious events following CS.

While we know that CS delivery is the single most important risk factor for the development of maternal infection, we do not know how frequently women are affected by SIE following CS (Leth et al., 2009, Lu, 2015). Neither SIE or CS SSIs are publicly reported; therefore, medical providers are currently limited to information available to them at single institutions. To advance our knowledge in this domain, this study describes the incidence of SIE following CS and characteristics of affected women who gave birth in Texas between the years of 2010-2014. Analysis of trends in SIE following CS will provide important information by identifying characteristics that make women more vulnerable to infection. The development of surveillance methods and the monitoring of trends in SIE may lead to the development of interventions that ultimately help to avert a leading cause of maternal morbidity and mortality.

## CHAPTER TWO: REVIEW OF THE LITERATURE

The purpose of this chapter is to review the literature related to serious infectious events following cesarean section (CS). Most SIE are caused by surgical site infections (SSI), for the purposes of this study sepsis is also considered an SIE. The significance of SIE following CS are described and demographic characteristics of hosts, pathogens and the environments that may be associated with the development or prevention of infection, using the epidemiologic triad are identified. Research evaluating methods of surveillance used to identify SSI are discussed. Finally, gaps in the literature will demonstrate the need for this study.

### **Cesarean Section Surgical Site Infection Defined**

The clinical manifestations of CS SSI occur across a spectrum of illness ranging from infections of the superficial wound requiring non-invasive treatment with antibiotics to severe infections requiring hysterectomy. Infectious symptomology of CS SSI is attributed to the surgical procedure when the infection is present within 30 days following the CS (CDC, 2016b). The anatomical classifications of SSI are specified by the depth of the infected tissue, and range from superficial to deep and organ/space infections (See Figure 2.1; Mangram et al., 1999).

Defining features of superficial CS SSI are the presence of purulent drainage, disruption of the skin or subcutaneous tissue of the wound, and cultures yielding bacterium, with or without fever (CDC, 2016b). Deep infections may present with purulent drainage from deep within the wound. Additional characteristics associated with deep wound infections include the presence of abscesses not within the organ space, spontaneous dehiscence of the wound (or intentional opening of the surgical wound to treat, debride, or culture the wound), and fever or localized pain and tenderness. Organ space infections involve tissues deeper than the muscle or fascia that were manipulated during the surgery, and are detected by physician diagnosis, imaging studies,

or histopathology. Defining signs of organ space infections following CS include abscesses within the pelvic cavity or reproductive tract, and pain, fever, or purulent drainage from the uterus. Endometritis is an example of a common organ space infection following CS (CDC, 2016b).

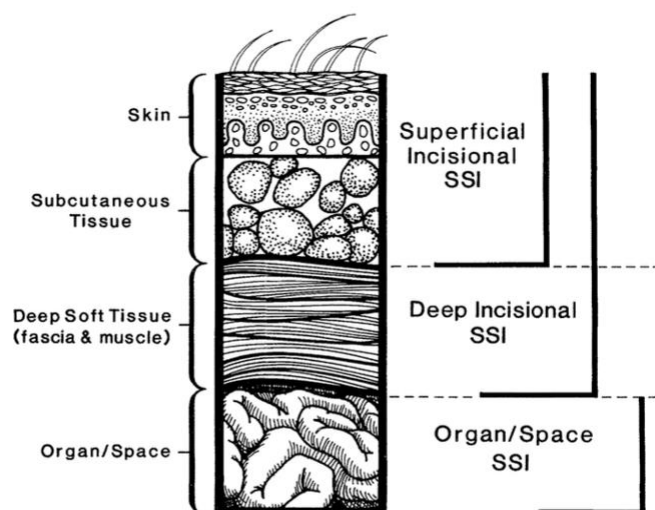


Figure 2.1 Surgical Site Infection Anatomy (Mangram 1999) A cross-section of the abdominal wall depicting levels of surgical site infections. From, “Guideline for the prevention of surgical site infection, 1999.” By A. J. Mangram, T. Horan, M. L. Pearson, L. C. silver, W. R. Jarvis & the Hospital Infection Control Practices Advisory Council. *Infection Control and Hospital Epidemiology* 20, p. 251. Reprinted with permission.

### **Significance of Serious Infectious Events following Cesarean Section**

Rates of CS deliveries have risen dramatically, from 22.9% in 2000 to 32.7% in 2013, with over 1.25 million women giving birth by CS in 2013 (Osterman & Martin, 2014). Public reporting of certain SSI is mandatory, but reporting of CS SSI is not. Studies of CS SSI often report incidence rates at single institutions and estimates of incidence rates vary widely. The most recent national report of CS SSI was provided by the Centers for Disease Control and Prevention in 2009 (Edwards, et al., 2009). At that time the National Healthcare Safety Network

(NHSN) received voluntary reports from 56 hospitals about 570 SSI among 30,994 women who delivered by CS. The rate of infection ranged from 1.46% (303 SSI per 20,743) CS among women at low risk of developing infection CS, to 3.82% (48 SSI per 1256 CS) among women considered to be at high risk of developing infection. CS SSI are not required to be reported to the NHSN therefore, it is not known if this reflects an accurate benchmark for the incidence of CS SSI (Edwards et al., 2009). Olsen, Butler, Willers, Gross, and Fraser (2008), working at an academic teaching facility in the Midwestern United States, reported a 5% incident CS SSI rate among 1,065 women in a two-year study period.

Studies conducted within the United States show that CS SSIs have a significant financial cost. Using administrative data from a single facility, Olsen, Butler, Willers, Gross, and Fraser (2010) compared medical claims costs between women with CS wound infection (n=80), women who developed endometritis (n=121), and women who developed no infection (n=309). The researchers suggested that \$3,400 and \$4,000 could be attributed to the care required for each infection. Using a 5% infection rate among all CSs done in 2010, costs could have exceeded \$229 million dollars in that year alone (Osterman & Martin, 2014). The cost of SSI could exceed these estimates depending on the infectious agent.

Anderson et al. (2009) matched 150 patients with SSI caused by Methicillin Resistant *Staphylococcus aureus* (MRSA), and 128 patients with SSI caused by Methicillin Susceptible *Staphylococcus aureus* (MSSA), to 231 uninfected controls. The researchers suggested that SSI caused by MRSA was associated with five additional days of hospitalization and \$24,000 in additional treatment costs. They concluded that \$60,000 could be saved for each MRSA SSI case that was prevented. These cost estimates did not consider obstetric sepsis, which likely exceeds the cost of SSI.

## **Obstetric Sepsis**

Sepsis is a life-threatening condition resulting in organ dysfunction due to the host response to infection (Rhodes, et al, 2016). Sepsis is associated with high mortality rates, particularly if treatment is delayed (Singer, Deutschman, Seymour, 2016). The sequential organ failure assessment (SOFA), a scoring system for the evaluation of organ failure, has been used to clinically operationalize the definition of sepsis. Scores greater than 2 are associated with in-hospital mortality of greater than 10%. Septic shock, a subset of sepsis that results in hypotension, is associated with mortality rates of greater than 40%.

The Society of Critical Care Medicine promulgated definitions of sepsis for use among non-pregnant adults and there is not yet agreement on how the physiologic changes of pregnancy may affect the early diagnosis of sepsis (Maguire, Power, Downey, O'Higgins, Sheehan, Turner, 2016). A retrospective study of in-hospital births in California between the years of 2005-2007 examined the continuum of illness among women using diagnosis codes for sepsis (Acosta, Knight, Lee, Kurinczuk, Gould, et al., 2013). The outcome variables included (a) uncomplicated sepsis; defined as women with diagnostic codes indicating septicemia, (b) severe sepsis; women with a sepsis code, and transfer to an intensive care unit, or other indicators of severe morbidity, or death, and (c) women with septic shock as indicated by the presence of the diagnostic code for septic shock. The absolute risk of developing sepsis was 10 per 10,000 births with severe sepsis occurring at a rate of 4.9 per 10,000 births. The case fatality rate of women with septic shock was 14.3%. Sepsis is a serious infectious event and studies evaluating the association of sepsis and CS have not been performed.



## The Epidemiologic Triad

The epidemiologic triad, consisting of host, pathogen and, environment is used to describe factors associated with the development or prevention of SSI. Characteristics of women more likely to develop CS SSI, infectious agents associated with CS SSI, and hazards related to the environment of care identified in the literature are reviewed.

### Host (Patient) Demographic Characteristics

All women who deliver infants by CS are at risk of developing an SIE but not all women become infected. Patient characteristics, identified in the review of the literature, that have been explored for a possible association with CS SSI, include age, comorbid conditions, socio-economic status, increased body mass index, endogenous contamination of the wound, laboring prior to CS, and emergent procedures.

**Age.** Age is frequently associated with SSI following any type of surgery, but studies of CS SSI have yielded divergent results. Using a categorical variable to examine the association of CS SSI with age, Mu et al. (2011) identified a 31% increase in odds of developing a CS SSI when comparing women over the age of 26 to women below that age ( $p = 0.0017$ ). Olsen et al. (2008) compared 17 women under the age of 18 with 283 women over that age and, possibly due to the small sample size, did not detect any relationship between age and development of SSI. Similarly, Stamilio and Scifres (2014) found no increase in infection associated with age. After the age of 35, the likelihood of having a CS increases by about 5% per year, but the associated increase in risk of infection remains unknown (Wilson, 2007).

**Comorbid conditions.** Comorbidities are defined as separate disease entities that are present during the course of care (Valderas, Starfield, Sibbald, Salisbury, Roland, 2009).

Diabetes is frequently associated with SSI, and is of concern during cardiac surgeries, however,

it does not appear to increase the likelihood of developing a CS SSI. Olsen et al. (2008) detected no increase in CS SSI among women with gestational or chronic diabetes mellitus compared to those who did not have diabetes. However, only 17% of 391 study patients who had a CS delivery had a perioperative serum glucose level. Availability of these test results might have led to detection of hyperglycemia during the perioperative period, allowing for a thorough analysis of the relationship between hyperglycemia and CS SSI. Stamilio and Scifres (2014) reported that obesity was the primary factor associated with CS SSI, and that the presence of diabetes or other comorbid conditions did not increase the likelihood of SSI development.

**Socio-economic status.** Information about the relationship between socio-economic status (SES) and potential associations with the development of CS SSI is sparse. Olsen et al. (2008) assessed SES by comparing those with private insurance to those who did not have private insurance, and no differences related to the development of CS SSI were noted. They suggested that their findings might have limited external validity as their sample was recruited from an inner city academic teaching facility that serves many women from low socio-economic backgrounds. Mu et al. (2011) did not detect a relationship between CS delivery at academic teaching facilities and development of CS SSI; however, no measures of SES were included in the analysis. Variables relevant to SES such as, maternal educational attainment, maternal occupation and business industry, or access to federal nutritional programs aimed at assisting pregnant women were not included by any researchers exploring risk factors for the development of CS SSI among studies identified in the literature review. As a result, few conclusions may be drawn about the relationship between SES and the development of CS SSI.

**Body mass index (BMI).** Obesity has been associated with emergent CS delivery and operative complications, including higher rates of SSI (American College of Obstetricians and

Gynecologists, 2013; Anderson, Chaboyer, & Gillespie, 2013). Infection rates are estimated to occur in 13%-30% of cases among obese women, with most infections being diagnosed after discharge from the hospital (Alanis, Villers, Law, Steadman, & Robinson, 2010; Amer-Alshiek et al., 2013; Mu et al., 2011; Olsen et al., 2010). Amer-Alshiek et al. (2013) documented a 9.2% increased risk of CS SSI for every one-unit increase in BMI. A number of factors have been hypothesized to explain the increased incidence of SSI among obese women, such as greater subcutaneous adipose tissue, poor perfusion of the adipose tissue, and alterations in the immune response (Nobbs and Crozier, 2011). Obese women are more likely to require readmission and surgical treatment for their wounds (Stamilio & Scifres, 2014). Anderson et al. (2013) conducted an integrative review to assess how obesity effects risk of CS SSI. In this review, the authors suggested that methodological differences, such as variations in timing of data collection and misclassification of BMI, limited comparability of studies.

**Endogenous contamination.** Rupture of the pregnancy membranes creates the opportunity for bacteria resident within the vagina to invade the uterus. Other conditions that increase the likelihood of CS SSI are chorioamnionitis, presence of fetal meconium, or initiation of labor prior to CS, with or without ruptured membranes (Haas et al., 2014; Mu et al., 2011). Interventions that reduce the normal bacterial flora of the vagina reduce the likelihood of developing endometritis. Two randomized control trials (RCTs) comparing 489 women who received a vaginal cleansing with betadine prior to CS to 481 who did not, reported 3-5% reductions in postoperative infection among the women who received vaginal cleansing (Hass et al., 2010; Yildirim et al., 2012). Outcomes measured by Haas et al. (2010) included the development of fever, endometritis, sepsis, readmission, or wound infection. Yildirim et al.

(2012) observed no measurable benefit to vaginal wash if membranes were intact or if labor had not yet begun at the time of the CS.

The skin is the body's primary defense against infection and the surgical skin incision creates a direct portal of entry for bacteria. Prior to surgery, it is important that measures be taken to avoid micro-abrasions to the skin by removing hair at the surgical site with clippers (AORN, 2016). Nurses leading a quality improvement initiative in Canada found that educating women about inappropriate hair removal procedures before surgery elicited a decrease in CS SSI wound infections (Ng, Alexander, Kerr, Ho, Amato, Katz, 2013).

In 1999, the CDC recommended showering or bathing prior to surgery using chlorhexidine gluconate (CHG) as a skin antiseptic because it is known to reduce skin flora for up to 24 hours after bathing (Mangram, et al., 1999). In 2012, Webster and Osborne reviewed seven studies including over 10,000 individuals that reported effects of preoperative bathing with CHG. No relationship between bathing with CHG and the incidence of SSI was detected. Variability in the implementation of CHG bathing, coupled with the possibility that CHG has a varying degree of impact on SSI depending upon the type of surgery, may be masking true relationships.

Skin antisepsis immediately prior to surgery is usually performed with one of two common formulations; chlorhexidine gluconate (CHG) with 70% alcohol, or povidone iodine (PI) with 70% alcohol. Amer-Alshiek et al. (2013) hypothesized that surgical skin preparation with CHG may be superior to PI because it dries quickly after application and continues to reduce skin flora over a prolonged period (Amer-Alshiek et al., 2013). However, studies testing the effectiveness of CHG compared to PI on SSI have major limitations that lead the scientific community to question validity of the results. Hadiati, Hakimi, Nurdiati and Ota (2014)

performed a systematic review of six studies with over 1,500 participants and determined that the quality of evidence did not allow for differences in infection rates to be attributed to skin antiseptics using CHG or PI.

**Laboring prior to a CS and emergent procedures.** Unplanned CS are indicated when a woman's labor fails to progress, when a woman's cervix is fully dilated but she is unable to deliver the baby vaginally or when emergent conditions like hemorrhage or fetal cardiac decelerations develop. According to Yeast, Jones, and Poskin, (1999) primiparous women who have elective induction of labor have a two-fold higher incidence of CS. This is associated with a concomitant, 51% increase in odds of CS SSI associated with initiation of labor before CS, and if an emergent procedure is performed an additional 23% increase in odds of developing a CS SSI (Mu et al., 2011). When comparing women, who developed CS SSI to those who did not, Olsen et al. (2008) found that odds of developing SSI was greater when labor was induced ( $p=.01$ ) or prolonged for more than 12 hours ( $p = 0.07$ ). Emergent conditions may not allow time for standard preparation for surgery, and at least one study excluded women who had emergent CS due to conditions like fetal cardiac decelerations or hemorrhage, from the calculation of incident SSI rates (Olsen et al., 2008).

**Monitoring the fetal heart rate during labor.** During labor, strong uterine contractions can diminish blood flow to the placenta or compress the umbilical cord, resulting on stress to the fetus (Neilson, 2013). Monitoring of the fetal heart rate assists in the detection of patterns indicating fetal distress. This may be done externally, intermittently by auscultation; externally, continuously by ultrasound Doppler; and internally, by placing an electrode on the fetal scalp. Although the use of external fetal monitoring poses no direct risk of infection, Cochrane reviewers have found that it may be associated with either no change in the number of CS births

or an increase in CS births and vaginal deliveries assisted by instruments (Alfrevic, Devane, Gyte, 2013; Neilson, 2013). Internal fetal cardiac monitoring, accomplished by an electrode in the fetal scalp, may be used when maternal abdominal adiposity renders external monitoring ineffective or when fetal stress is suspected (Ayers, Spong, Chandrharan, 2015). Placement of a fetal scalp electrode requires ruptured membranes and should not be used when mothers have a history of genital herpes, or hepatitis B or C. Guidelines for the use of fetal monitoring note that fetal tachycardia (>160 beats per minute) may be associated with intrauterine infection, but make no mention of how frequently infection is associated with internal fetal monitoring. Research performed as early as 1978 has shown an increase in endometritis when internal fetal monitoring is used, particularly when the membranes have been ruptured for more than 12 hours (Perloe and Curet, 1978). However, studies about infections associated with the use of fetal scalp electrodes have been hampered by small sample sizes, retrospective design, and lack of control groups.

**Characteristics of women affected by obstetric sepsis.** In a national study performed in England, comorbid infections of the respiratory and urinary tracts were identified as the most frequent sources of obstetric sepsis (Acosta, Harrison, Rowan, Lucas, Kurinczuk, Knight, 2016). The study included 646 women admitted to critical care for sepsis who were currently pregnant or who had been pregnant in the previous 42 days, regardless of the outcome of the pregnancy. Women who were most likely to develop sepsis included women ages 16-19 years (Relative Risk [RR] 2.5 [Confidence Interval 1.9-3.3]), women over the age of 40 (RR 1.8[CI 1.2-2.6]), women of low SES, with the lowest quintile having the highest risk (RR 6.5 [CI 4.9-8.5]), giving birth by CS (RR 6.2 [CI 4.9-7.8]) and multiple gestation (RR 4.4 [CI 3.1-6.3]).

## Pathogen

To determine the pathogens causing SSI following surgery, Weigelt, et al. (2010) reviewed the records of 8,302 patients with corroborative positive wound cultures occurring between 2003 and 2007. They noted that 2,227 wound infections (26.8%) were caused by Methicillin Susceptible *Staphylococcus aureus* (MSSA), and 1,138 (13.7%) were caused by Methicillin Resistant *Staphylococcus aureus* (MRSA). MRSA was identified as the causative pathogen in 53% of CS SSI (Thurman, Anca, White and Soper, 2010).

*Staphylococcus aureus*. To examine the association between nasal carriage of MSSA and MRSA with the development of CS SSI, Egozi et al. (2015) randomized 658 women into control and intervention groups and screened for nasal carriage of *Staphylococcus aureus* (SA). The control group included 374 women who were screened immediately prior to surgery and received no intervention to eradicate SA from the nares. The intervention group included 284 women who were screened for nasal carriage 1-4 weeks prior to surgery, and if positive, received treatment with Mupirocin nasal ointment. The prevalence rate of nasal carriage of SA ranged from 13.2% (among controls) to 20.1% among women in the intervention group. The SSI rates were similar in the two groups; 11.7% in the control group and 13.1% in the intervention group ( $p= 0.69$ ). Results of this trial suggest no relationship between nasal carriage of SA and CS SSI. Although the results from this study were limited in that, the authors did not differentiate between susceptible and resistant strains of *Staphylococcus aureus*.

Researchers have also examined the prevalence of MSSA and MRSA nasal carriage among pregnant women. In 2007, Beigi and Hanrahan found that 21 of 96 (21.8%) pregnant women receiving care at an inner city public hospital in the Midwestern United States carried SA in the nares; of these two of the 96 (2.1%) women carried with MRSA. Nares and vaginal culture

results were available for 28 of the women and 23 (82.1%) had concordant cultures. Although the sample size was small, the findings from this study were consistent with MRSA carriage rates detected in a larger study conducted by Patel and Kaufman (2011). Specifically, Patel and Kaufman (2011) found that 31 of 1,045 (2.9%) pregnant women screened for nasopharyngeal carriage were positive for the organism. MRSA carriage was not associated with CS SSI or neonatal adverse events among a subset of 31 women colonized with MRSA compared to 46 women with negative cultures.

**Antimicrobial prophylaxis.** Researchers have explored the issue of whether or not all women undergoing CS should receive antimicrobial prophylaxis, at what point in time administration of prophylaxis should occur, and what dosing regimens should be used. In a meta-analysis, Smaill and Grivell (2014) identified 95 randomized and quasi-randomized control studies with over 15,000 participants examining the impact of preoperative antibiotics on adverse outcomes, including SSI, among women delivering by CS. Large reductions in CS SSI were observed when women having urgent or emergent CS received preoperative antibiotics; specifically, superficial and deep wound infections were reduced by 60% and endometritis was reduced by 62% compared to women having emergent or urgent CS who did not receive antibiotics. Among women given prophylaxis before elective CS surgery, 40% reductions in incident wound infection and 60% reductions in endometritis were identified compared to women who received no prophylaxis (Smaill and Grivell, 2014).

The timing of antimicrobial prophylaxis prior to CS is important because the antibiotic must reach tissue levels to effectively kill bacteria, but early administration before clamping the umbilical cord could result in neonatal complications. Serious antibiotic-related complications that could affect neonates include candidial infections such as thrush, masking of neonatal sepsis,



false negative microbiological specimens if infection is suspected, and later development of antibiotic resistant infections (Murtha, 2014). Several researchers have reported that the administration of prophylactic antibiotics before skin incision has reduced maternal wound and uterine infection rates by as much as 50% and prevented 5.4 infections for every 100 CS procedures (Kittur, McMullen, Russon, Kay, & Warren, 2012; Mackeen, Berghella, & Baxter, 2014; Owens, Brozandki, Meyn, & Wisenenfeld, 2009) compared to administration post-cord clamping. No differences in the incidence of neonatal sepsis or other neonatal infectious complications were observed when antibiotic prophylaxis given before skin incision was compared to administration after cord clamping (Brown et al., 2013; Owens et al., 2009).

Considering the existing research, the Infectious Disease Society of America (IDSA) recommends that a single dose of a first-generation cephalosporin be administered as a prophylactic antibiotic before CS because the antibiotic effectively kills pathogens that commonly reside among the normal flora of the vagina and skin (Bratzler et al., 2013). *Cefazolin*, when given intravenously, quickly reaches serum and tissue levels that are optimally effective to kill infective organisms. When women are allergic to cephalosporins, the IDSA recommends the use of *Clindamycin*, which is effective against similar organisms and has a similar half-life.

During pregnancy, women have higher than average fluid volumes and glomerular filtration rates that could potentially require higher doses of antibiotics (Murtha, 2014). Two studies' authors investigated the pharmacokinetics of *Cefazolin* specifically among samples of obese women undergoing CS to determine whether antibiotics reach adequate tissue levels to sufficiently kill bacteria. Pevzner et al. (2011) measured the tissue penetration of prophylactic cephalosporin given within 60 minutes of CS skin incision and found that obese and extremely

obese women did not attain antimicrobial penetration of abdominal adipose tissue at levels that would inhibit growth of gram-negative bacteria. Stitley et al. (2013) compared 2-gram and 4-gram doses among obese women, and reported that plasma and tissue concentrations of the antibiotic at the time the incision was closed, were statistically significantly higher in all tissue samples when 4-gram doses were given. Notably, no study participants developed infection. These two studies highlight the epidemiologic triad; the constant interplay between patient or host characteristics (in this case, obesity), infectious agents, and the surgical environment that converge to result in disease.

### **Surgical Environment**

A CS procedure involves creating a skin incision, opening the peritoneum, incising the uterus, delivering the baby and placenta, and then closing the uterus, fascia, and skin (Pandit & Kahn, 2013). The surgical incision creates a portal of entry for bacteria and is the exposure of interest for the current study. The opportunity for uterine infection begins when the pregnancy membranes rupture, and the opportunity for wound infection is initiated when the skin is incised. Wound healing represents the end of the opportunity for infection to occur.

**Perioperative care area.** The environment of care within the perioperative care area is one of the most challenging areas of the hospital to manage, and is highly regulated by multiple federal and state agencies (AORN, 2016). Standards pertaining to ventilation, traffic patterns, clothing, and general hygiene have been promulgated in efforts to reduce patient exposure to pathogens during this critical time. The operating room in which CSs are done poses additional challenges because it is often located within the labor and delivery unit, remote from a facilities main surgical area. This results in the opportunity for variations in practices and processes that protect patients. Increased personnel, such as a team devoted to the delivery of the baby and

family members attending the patient are two of the most visible differences in the CS surgical room compared to a facilities main operating room. Allowing nonmedical personnel into the surgical room requires operating room staff to pay attention to visitor hygiene, donning of appropriate surgical garb, and use of personnel protective equipment (AORN, 2016). No literature exploring potential differences between a hospital's general surgical area and the labor and delivery surgical area was identified in the literature review.

**Surgical instrument reprocessing.** In addition to differences in practices within the operating room, variation in the reprocessing of surgical instruments may occur as the instruments may require transport to a reprocessing area that is geographically remote from the main reprocessing area. Due to the lower volume of surgical procedures, institutions may rely on surgical technicians to reprocess instruments in the labor and delivery operating room, while the main operating room may have staff dedicated to this responsibility. Despite having responsibility for highly technical equipment that is directly related to patient safety, only the states of New York, New Jersey, and Connecticut require certification of personnel who reprocess surgical instruments (IAHCSMM, 2015). Potential variations in practice related to the transport and cleaning of surgical instruments create challenges to the maintenance of a safe environment of care, and could pose direct threats to patient safety. Studies in which researchers examined the existence and impact of potential variations in practice related to the reprocessing of surgical instruments in the labor and delivery perioperative area were not identified.

**Surgical procedure and duration.** The surgical procedure is considered an exposure that places women at risk of SSI. As with the elements of the epidemiologic triad, avoidance of CS eliminates a woman's risk of SSI. Characteristics of the surgical procedure that may influence the development of infection include, the duration of surgery, the receipt of general

anesthesia, the type of skin incision, development of fluid collections and methods of wound closure. The length of time from skin incision to closure is positively associated with SSI development. Mu et al., (2011) reported a 14% increase in odds of developing an infection for every 10-minute increase in duration of surgery. Therefore, SSI prevention efforts have sought to minimize surgery duration. Wound healing begins immediately through hemostasis, a process by which the body responds to injury by recruiting platelets to the surgical site. Substances released during platelet aggregation form a clot that acts as a protective barrier against bacteria (Nobbs & Crozier, 2011). Use of cautery to control bleeding during surgery may improve the speed by which tissue is exposed, but may result in seromas, fluid collections that lead to abscesses. Studies of hemostasis without use of cautery are limited in number and no differences in infection rates have been identified (Moreira & Amaral, 2014).

**General anesthesia.** General anesthesia is delivered via endotracheal intubation and requires short term mechanical ventilation. A review of more than 300,000 Taiwanese women who delivered by CS found that the development of SSI following receipt of general anesthesia was as much as than three times higher among women who received neuraxial (spinal or epidural) anesthesia (Tsai, Hsu, Fan and Huang, 2011). Limitations of this study included the use of data from insurance claims, which provided an incomplete picture of patient characteristics. However, speculation about the biological mechanism responsible for the association of SSI with the receipt of general anesthesia center on decreased perfusion of tissue (Freise, et al., 2008). Neuraxial anesthesia provides a sympathetic block resulting in vasodilation and increased blood flow to tissue. Tsai et al., (2011) found that 14.3% of 12,531 women receiving general anesthesia also had antepartal hemorrhage, but only 5.8% of 291,303 who received neuraxial anesthesia experienced hemorrhage. Therefore, it is possible that general anesthesia use could be

confounding the relationship between SSI and emergent conditions, as general anesthesia has been associated with emergent procedures.

**Skin incision.** Cesarean section incisions may be transverse, curvilinear on the lower abdomen (pfannenstiel), vertical, or paramedian (a form of a vertical incision made on the side of the abdomen) (Pandit & Kahn, 2013). Obese pregnant women often have a skin fold (pannus) that lies over the area in which a transverse skin incision is made, creating an environment thought to be conducive to bacterial growth. Vertical and paramedian skin incisions avoid placement beneath the pannus (Pandit & Kahn, 2013). However, researchers have consistently reported lower rates of infection and wound disruption when transverse skin incisions are used and even when placed beneath the pannus of obese women (Alanis et al., 2010; Marrs, Moussa, Bahea and Blackwell, 2014, Stamilio and Scifres, 2014; Thornburg et al, 2012). One study examining the relationship between placement of the surgical incision with CS SSI reported inconclusive findings and attributed the difference to selection bias. The authors recommended random control trials to evaluate the influence of the placement of the skin incision in the development of infection (Marrs et al., 2014).

**Prevention of fluid collections.** Clotting factors released by the body when bleeding occurs contain histamine and activation results in vasodilatation and increased permeability of the blood vessels. This process allows white blood cells, antibodies, and plasma proteins to enter the wound bed (Nobbs & Crozier, 2011). Thus, fluids may collect in the subcutaneous tissue of obese women, whose circulation may be hampered by lack of vascularity and adipose tissue weight. Olsen, et al., (2008) reported that 20% (16/81) women with CS SSI also had a subcutaneous hematoma compared to 2% (6/308) women who did not develop an infection; increasing the odds of CS SSI by 12 times (95% CI 4.7-33.1). Alanis et al. (2010) reported that

drains used to prevent fluid collection also increased the odds of infection development (OR 2.3,  $p = 0.009$ ) and speculated that the drain acted as a reservoir for bacteria (Alanis et al., 2010).

Negative pressure wound dressings may be an alternative to drains to assist in preventing fluid collections. In response to anecdotal reports of increasing use of prophylactic negative pressure wound dressings, Echebiri et al., (2015) examined the cost effectiveness of negative pressure wound dressings. Given the expense associated with negative wound pressure dressings and no substantiated risk reduction associated with the method, their evidence suggests that these measures should be used only when the negative pressure dressings cost less than \$200 and the infection rate is greater than 13%.

**Wound closure and dressings.** Closure of the surgical wound may also effect the likelihood of infection development. The uterus, fascia and skin are routinely closed with sutures (or staples for the skin), while the subcutaneous tissue may not be sutured and heals by granulation (Pandit & Kahn, 2013). Suturing the subcutaneous tissue could increase the odds of infection because it is time consuming and may result in a longer duration of the surgery. In a randomized controlled trial with 361 participants, Esmer et al. (2013) found no differences in rates of wound separation or infection when subcutaneous tissues were sutured versus non-sutured.

The method used to close the surgical wound influences the amount of pain women feel after surgery and the appearance of the scar when healing is complete. Ibrahim, Moustafa, Al-Hamid and Hussein (2014) conducted a clinical trial to assess the effect of subcuticular sutures compared to interrupted skin suturing on superficial wound infections. No differences between the treatment and control groups emerged. Nuthalapaty, Lee, Lee, Kuper and Higdon (2013) attempted to show that early removal of staples was as effective as delayed removal. The study

was terminated early due to difficulty enrolling subjects. Thus, the study was underpowered to detect differences of interest. However, the authors noted that instances of wound disruption did occur and that early staple removal could result in clinical harm.

Several randomized control trials have compared the effectiveness of dressing materials and SSI to enhance our knowledge about how SSI rates might be reduced through use of particular materials. Infection rates associated with three specific methods of dressing surgical wounds have been evaluated. First, the jubilee dressing consists of a hydrofiber, wicking, inner layer combined with a hydrocolloid outer layer (Burke et al., 2012). The dressing controls leakage from the wound while protecting surrounding skin from maceration. Gregson (2011) reported lower infection rates after implementation of the jubilee dressing compared to infection rates prior to the dressings use, but disruption in supplies and variation in preoperative hair removal may have influenced results. Second, Dryden, Goddard, Madadi, and Saeed (2014) used a pre-test post-test design to evaluate the effect of wound dressings using antimicrobial surghoney on infection rates (Dryden, Goddard, Madadi, & Saeed, 2014). They observed a 60% reduction in incident cases of CS SSI when they compared 186 women who received the dressing to 590 women who did not. Four (2.15%) CS SSI occurred in the intervention group and 32 (5.42%) in the control group. However, their study results could have been confounded by other protocol changes at the facility, such as changes in the timing of antimicrobial prophylaxis. Finally, silver impregnated dressings that release antibacterial ions into the surgical wound have also been tested for their effectiveness in reducing incident infections (Connery, Downes, & Young, 2012); however, results from one retrospective review comparing 36 women who received a silver impregnated dressing to 36 women who received a gauze dressing without silver were inconclusive.

## Surveillance for CS SSI

Measurement of incident CS SSI is foundational to efforts to reduce infections, as the effectiveness of prevention measures cannot be determined without consistent surveillance. The CDC (2016b) recommends active engagement in case identification through ongoing, systematic collection of data about all persons who have a targeted surgical procedure before and after the surgery is done. Information about these persons should be collected for the duration of time during which an infection is likely to develop, usually 30 days after the surgery. This is done to identify and record signs and symptoms of incident infections (Anderson et al., 2014). In practice, direct observation of patients is difficult, as hospital stays are short. SSIs are most commonly identified through patient chart reviews after the patient has been discharged from the facility. Insufficient time following the surgery, and failure to identify patients that have been readmitted is a limitation of several studies of incident CS SSI (Anderson et al., 2013; Marrs, et al., 2014).

Post-discharge surveillance using indirect methods has been the topic of several studies. One of those studies by Wilson et al. (2013) followed 4,107 women who delivered by CS and evaluated them for presence of infection at three time periods: (a) prior to discharge, (b) during a post-partum home health visit by a nurse midwife, and (c) via self-report by the patient using a survey. Just over 400 infections were noted, 66% of the infections were identified during an inpatient episode of care or by midwives conducting home visits (Wilson et al., 2013).

Halwani, Turnball, Harris, Witter and Perl (2015) conducted a prospective cohort study to investigate the use of telephone interviews to ask patients about symptoms of SSI at seven, 14 and 30 days' post-discharge. The authors called 193 patients who delivered by CS between April and August of 2010. Among 19 infections that were identified, 14 (73.7%) were found during



routine surveillance and five SSI were identified by telephone interview. Interviews of patients by telephone to assess for SSI have also been attempted in Brazil, but extant studies have limited external validity given high attrition rates (175 of 528 [33%] participants were lost to follow up). Assessment of the reliability or validity of tools used to conduct telephone interviews has not been established.

Researchers acknowledge that deep and organ space SSI frequently result in readmission (Anderson et al., 2014; Halwani et al., 2015; Ming, Chen, Miller, Sexton and Anderson, 2012). Ming et al. (2012) reviewed SSI surveillance that included 177,706 procedures targeted for the Surgical Care Improvement Project (Coronary Artery Bypass Grafting, colon surgeries, Total Hip Arthroplasty, Total Knee Arthroplasty, Abdominal Hysterectomy, Vaginal Hysterectomy and vascular procedures) performed between 2007 and 2008 at 37-networked hospitals. They identified 1,919 (1.07%) SSI. The majority of SSIs (1,223/64%) were considered complex (deep or organ space infections) and 87% of them were diagnosed during an inpatient stay. Ming et al. (2012) noted that superficial SSIs were frequently diagnosed without a wound culture and that MRSA and SA were the most common pathogens causing deep and organ space infections. They argued that efforts targeting SSI diagnosed during inpatient episodes of care would be an efficient means for the identification of severe infections, including complex superficial and deep infections requiring invasive treatment (debridement of the wound or drainage of abscesses), and organ space infections.

Administrative coded data was used effectively by epidemiologists at the State of New York Department of Health to validate study the accuracy of SSIs reported by facilities to the National Healthcare Safety Network (Haley et al., 2012). By utilizing ICD 9 diagnosis codes, epidemiologists identified errors in SSI surveillance of infections occurring after coronary artery

bypass grafting, colon and hip arthroplasty surgeries. Errors in reporting of infections occurred most frequently among patients who had undergone colon surgery and 195 additional incident infections diagnosed in 2009 were identified. While administrative coded data does not fully align with CDC definitions of SSI it is useful in establishing rates of readmission, and frequency of invasive treatment, thereby providing a measure of the severity of infections.

### **Summary**

While prevention measures have been tested to prevent CS SSI, and knowledge about their effectiveness is growing, there continues to be limited information about the incidence rate for CS SSI or sepsis associated with CS. Previous studies of SSI using administrative coded data have shown that SSI may be underreported by as much as 7.5% (Haley et al., 2012).

Additionally, rates of infection likely vary by patient age, race, ethnicity, and geographic area of residence. The last report from the National Healthcare Safety Network, which established the risk model for development of CS SSI, did not include variables related to socio-economic status.

It is not known how often women are readmitted for treatment of CS SSI and the severity of infections is unreported. Surveillance using inpatient administrative codes generated by the delivery admission or upon readmission to a hospital may be an effective method of screening large numbers of records for the incidence of serious infections following CS (Goldfield, et al. 2008). Utilization of administrative coded data to identify readmissions that occur within the 30 days following surgery was viewed by the State of New York as an efficient method of finding incident SSI among patients who had undergone cardiac bypass surgeries, colon surgeries and hip procedures, but this has not been attempted as a means of identifying CS SSI. Studies that have used administrative coded data to evaluate sepsis have demonstrated the ability of coded

data to differentiate between uncomplicated and severe sepsis. The incidence of obstetric sepsis in the State of Texas has not been evaluated. There is a literature gap describing SIE following CS and explorations of associations between demographic characteristics of the patient as host, the pathogen(s), and the environment of care could assist in the development of targeted prevention measures that reduce maternal morbidity caused by SIE associated with CS.

## CHAPTER THREE: STUDY METHODS

The purpose of this chapter is to describe methods used for the study of serious infectious events (SIE) following Cesarean Section (CS). In this chapter, the data source, methods of data collection, and ethical considerations are detailed; sample inclusion and exclusion criteria are discussed, and data management and analytic procedures are described.

### **Methods**

This study used secondary data collected by the Texas Department of State Health Services, Center for Health Statistics (2016) that were aggregated in the Texas Health Care Information Collection (THCIC) Public Use Data File (PUDF). The THCIC was created in 1995 and has been maintained by the Texas Bureau of Health Statistics since 2004. The PUDF contains patient-level information reported by facilities following inpatient hospital stays to obtain payment for care that has been provided (Texas Department of State Health Services, 2016). The Texas Health and Safety Code, Chapter 108 (2015) specifies the requirements for quarterly data submission. Prior to 2015, hospitals located in rural counties were exempt from submission if the county in which the facility was located had a population of fewer than 35,000 residents. Hospitals were also exempt from reporting if Medicaid or Medicare payments were not accepted, or if there were fewer than 100 hospital beds within the county. Most Texas counties are rural (178/254, 70%), this study included data submitted from 50 hospitals located in rural counties.

### **Administrative Coding**

Between 2010 and 2014, the Centers for Medicaid and Medicare Services (CMS) required that diagnosis and procedure codes be assigned using the International Classification of Diseases, Ninth Edition (ICD-9) codes. The National Center for Health Statistics and CMS

published guidelines for the use of ICD-9 codes on the CDC website (CDC, 2015a). Codes pertaining to obstetrics included 5 digits and fell between the numbers 630-679; the 4<sup>th</sup> and 5<sup>th</sup> digits indicated whether a diagnosis occurred during the birth admission or during a readmission. Codes ending with “00” were unspecified as to the admission, “02” indicate during the birth admission, and “04” indicate a readmission. The ICD-9 coding manual defines the postpartum period as the first six weeks following delivery and the peripartum period as the first five months following delivery (CDC, 2015a).

After a patient is discharged, to obtain payment for the hospital stay, inpatient records were reviewed by personnel at the facility. These hospital personnel assigned administrative codes indicating the diagnoses and procedures corresponding to the patient care provided. These records were then submitted on a quarterly basis to the Texas Department of State Health Services (Texas DSHS, 2016). Upon receipt, Texas DSHS removed patient identifiers from the records and unique identifiers were assigned. THCIC collected information about 25 diagnosis codes, 25 procedure codes and 10 emergency codes for each admission. Dates of service and other indirect identifiers were removed from the PUDF to avoid identification of the patient via deductive disclosure. For example, patient age was categorized so that date of birth could not be used indirectly to identify patients. Zip code and county of residence were retained in the records.

### **Ethical Considerations**

The United States Health and Human Services Office of Human Research Protection (2016) publishes the Combined Federal Regulations 46.116 (d), which states that de-identified, publicly available data does not require institutional review. Regulatory Services at the University of Texas at Arlington (UTA) reviewed the proposed study and determined the data

were de-identified and intended for public use. Therefore, the study was exempt from institutional review. This research was conducted via data use agreement between UTA and THCIC (Appendix A), which approved the use of the data for this study via a data sharing agreement with the researcher (Appendix B). Under this agreement, data users must agree before analyzing data that no attempts to link the PUDF with any other publicly available records (e.g., vital statistics) will be made. The Texas Health and Safety Code (2015) specifically prohibits any attempt by data users to identify treating physicians or patients whose records are included in the THCIC PUDF data.

### **Sample Inclusion and Exclusion Criteria**

County of residence, gender, age, procedural codes, diagnostic codes and discharge status were used to identify eligible patients. Procedural and diagnostic codes used for inclusion criteria are listed in Table 3.1. All female residents of Texas who gave birth by CS at a facility that submitted data to THCIC during the five-year period between January 1, 2010 and December 31, 2014 were eligible for inclusion in the study sample. All records that indicated residence outside of the State of Texas were excluded from the study sample. Residents of Texas who gave birth at facilities outside of the State of Texas were not eligible for inclusion. All records of males, or records with missing or invalid gender data, were excluded from the study sample. Patients were excluded if the participant's age was under the age 10 years or over the age of 60 years.

Records with no procedural code for CS were excluded unless a diagnostic code indicating disruption of the cesarean section wound was present. When the diagnostic code for disruption of the CS wound occurred in the absence of the procedural code for CS, the patient was classified as having a readmission for wound disruption.

Table 3.1 Codes Indicating Cesarean Section or Serious Infectious Event

<b>Procedural Codes</b>	
<b>Name of Code</b>	<b>Numeric Indicator</b>
Cesarean Section	74.0, 74.1, 74.2, 74.4, 74.91, 74.99
<b>Diagnostic Codes</b>	
Disruption of CS Wound	67410, 67412, 67414
Major Puerperal Infection	67000, 67002, 67004
Puerperal Endometritis	67010, 67012, 67014
Puerperal Sepsis	67020, 67022, 67024
Sepsis, Severe Sepsis	99591, 99592

*Note:* Diagnosis Codes were taken from Centers for Medicaid Services, 2014.

Exclusion criteria related to the discharge disposition are relevant because they may be affected by maternal mortality or influence readmission. All records indicating that the patient left “against medical advice” or with missing discharge information were excluded. If the discharge disposition indicated “expired, the diagnosis codes were inspected for potential serious infectious events (SIE). If no applicable code indicating a potential infectious event was identified, the patient who expired was excluded. For example, if a record indicated that a patient expired and the diagnosis code indicated an amniotic embolism (i.e., not an infectious event), the record was excluded because there was no opportunity for infection to develop. If the discharge code indicated “sepsis” or “endometritis,” the patient record was included.

### **Data Management**

Data fields obtained from THCIC were selected to assist in the description of the characteristics of the environment, the host, and the pathogens associated with SIE. Only the selected data fields were retained for analysis and used to apply inclusion and exclusion criteria, and to generate variables for descriptive analysis. The THCIC data fields used in this study are listed in Appendix C.

## Generation of Variables

Patient demographic information, provider information, 28 diagnosis codes and 25 procedural codes were recoded prior to analysis. The generation of variables for analysis was performed as follows:

1. Rural Facility: THCIC ID with Provider City and Zip were used to determine if the facility was in a county classified as a rural county by the Texas Department of State Health Services (2015). This was coded as, “yes” when the facility was in a rural county.
2. Teaching Facility: This variable was coded as “yes” when the facility indicated that it was a member of the Council of Teaching Hospitals.
3. Critical Care: This variable was coded as “yes” when any one of the Specialty Unit Fields 1-5 indicated admission to an intensive or coronary care unit.
4. Patient Age: When records indicated that a patient’s age was not within childbearing years (00- 90 days of age, <10 years, or over 60 years) the records were excluded. Categories were then combined to attain age categories that included women by decade of age. Age categories were recoded as: 1) 19 years and younger, 2) 20-29 years, 3) 30-39 years, and 4) 40 years and above.
5. Patient race included in the PUDF was assigned to one of the 5 following categories: 1) American Indians, Aleut and Eskimo, 2) Asian, 3) Black, 4) White, and 5) Other. Race was recoded to so that American Indians and Asians were included in the, “Other” category. Three race categories, “White,” “Black,” and “Other”, remained. Race was missing in 499 (0.08%) of records. Records with missing data were excluded listwise from statistical models.



6. Patient Ethnicity was coded as 1) Hispanic origin, 2) Non-Hispanic origin, or 3) Unknown. Ethnicity information was missing in 4,257 (0.68%) records. These records were excluded listwise from analysis of association between ethnicity and SIE.
7. Rural Residence was coded as “yes” when the county of residence included in the THCIC was identified as a rural county by the Texas Department of State Health Services (2015).
8. Emergency Admission was coded as “yes” when the THCIC field “Type of Admission” indicated an emergency admission.
9. Length of stay was operationalized as the number of days’ women were hospitalized, as identified by THCIC.
10. Discharge status was coded as “yes” when the patient was discharged. Patients were classified as “expired” when records indicated that the patient was deceased and a diagnostic code indicating an SIE was present in the record.
11. Serious infectious event was coded as “yes” when any of the diagnostic codes listed in Table 3.1 were present in any of the diagnostic code fields.
12. Wound disruption was coded as “yes” when diagnostic codes 67410, 67412, or 67414 were present in any of the diagnostic code fields.
13. Major puerperal infection was coded as “yes” when the diagnostic codes 67000, 67002 or 67004 were present in any of the diagnostic fields.
14. Endometritis was coded as “yes” when diagnostic codes 67010, 67012, or 67014 were present in any of the diagnostic code fields.
15. Puerperal sepsis was coded as “yes” when diagnostic codes 67020, 67022, or 67024 were present in any of the diagnostic code fields.

16. Sepsis was coded as “yes” when diagnostic codes 99591 or 99592 were present in any of the diagnostic code fields.
17. A dichotomous variable representing all patients with sepsis was created. This variable was necessary to ensure that records including codes duplicate codes for sepsis and puerperal sepsis were only counted once. This variable was coded as “yes” when either puerperal sepsis or sepsis was present in the record.
18. Pathogen was coded as “yes” when diagnostic codes indicated a pathogen.
19. Pathogen code retained the code used to identify the specific pathogen.
20. Principal diagnosis was retained as provided by THCIC.
21. Other diagnoses 1-5 were retained as provided by THCIC.
22. Cesarean section delivery status was coded as “yes” when any of the procedural codes indicated that a CS was performed.
23. Internal fetal monitoring was coded as “yes” when the procedural code 7532, “Fetal EKG Scalp,” was present.
24. Surgical induction of labor was coded as “yes” when any of the following procedural codes were present: 7301, “Artificial Rupture of Membranes;” 7309, “Other Artificial Rupture of Membranes;” or 731, “Other Surgical Induction of Labor”.
25. Medical induction of labor was coded as “yes” when the procedural code 734, “Medical Induction of Labor,” was present.
26. Repair of the abdominal wall was coded as “yes” when the procedural code 5472, “Repair of the Abdominal Wall,” was present.
27. Percutaneous drainage of abscess was coded as “yes” when the procedural code 5491 was present.

28. Excisional debridement was coded as “yes” when the procedural code 8622 was present.

29. Non-excisional debridement was coded as “yes” when the procedural code 8628 was present.

### **Data Analysis**

Analysis was conducted using the Statistical Package for the Social Scientist (SPSS) version 23 (IBM, 2013), Open Epi (Dean, Sullivan & Soe, 2013), and Microsoft Excel respectively. Dichotomous and categorical variables were examined using frequencies and percentages. Continuous variables were examined using means, medians, standard deviations and ranges. Descriptive analyses were conducted for each year (2010-2014) independently and aggregately for all five years. Analysis of the SIE incidence rate, characteristics of women, facilities and pathogens was performed in accordance with the research questions as presented in Chapter One. Odds ratios (OR) and 95% confidence intervals (CI) to indicate statistical significance were computed. These odds ratios represent the likelihood of being diagnosed with SIE for each independent variable.

### **Trends in the Diagnosis of Serious Infectious Events**

Diagnostic codes indicating a SIE during the birth admission (Table 3.1) or upon readmission for CS wound disruption were used to calculate SIE the incidence rate ( $SIE/CS*1,000$ ) for each quarter of each year in the study period, and as an aggregate rate for the five-year period. This analysis provided 20 sequential, repeated incidence rates that were used to identify trends in SIE incidence over the five-year study period. Descriptive statistics examined on the incidence rate variable included the median incidence rates per quarter, standard deviation, and range of SIE rates for each type of SIE (major puerperal infection, endometritis,

sepsis, CS wound disruption and readmission). To ensure that incidence rates were normally distributed, a Kolmogorov-Smirnov test of normality was computed.

To examine changes in incidence rates over time, linear regression modeling using quarterly time intervals as the independent variable and SIE incidence rates as the dependent variable was fit for aggregated SIE and stratified by discrete (endometritis, wound disruption, readmission for wound disruption, and sepsis) SIE. This method was chosen because a linear relationship between time and SIE rate was assumed, there was no evidence of seasonality in the occurrence of SIE following CS, and observations were independent (Daniel, 1999). Linear regression was performed only after normality was verified by the Kolmogorov-Smirnov test. The incidence rate was plotted by discharge quarter and Microsoft Excel was used to plot a trend line. The  $R^2$  statistic was calculated to identify the amount of change in SIE incidence rates explained by time. To evaluate the direction and significance of changes in SIE rates over time, the beta ( $\beta$ ) coefficient and  $F$  statistic were computed.

Post-hoc analyses were conducted to describe the severity of infections. Specifically, the frequency and proportion of women with an SIE who required repair of the abdominal wall, percutaneous drainage of abscesses, excisional or non-excisional debridement were tabulated. A  $t$  test was computed to compare the mean length of stay among women with SIE was compared to those without SIE.

### **Characteristics of Women Diagnosed with Serious Infectious Events**

The frequency and proportion of SIE following CS occurring in each age, race, and ethnic category were calculated for the composite SIE and for discrete SIE identified by diagnostic code (endometritis, sepsis, wound disruption and readmission with the diagnosis of wound disruption). To determine if age or race were associated with the likelihood of developing

SIE following CS, an odds ratio was calculated. Odds ratios were also calculated for independent variables, including ethnicity, rural residence and treatment exposures (internal fetal monitoring, surgical induction of labor, medical induction of labor and emergent admission).

“Principal Diagnosis Code” and the first 5 of the 28 “Other Diagnosis” codes were aggregated to represent the 10 most frequent comorbid conditions diagnosed among women with SIE. Appendix D provides a list of diagnosis codes identified in the records. To determine if the most frequent diagnostic codes were associated with increased likelihood of being diagnosed with an SIE, the diagnosis codes were recoded to dichotomous variables and odds ratios were calculated.

### **Serious Infectious Events at Rural and Teaching Facilities**

The frequency and proportion of women who develop SIE following CS in rural or teaching facilities were calculated. Odds ratios were computed to describe the association between SIE development following CS, when care was provided at rural versus urban facilities, and teaching facilities compared to non-teaching facilities. Women admitted to facilities located in rural counties were compared to women admitted to urban facilities. Women admitted to facilities that designated membership in the Council of Teaching Hospitals were compared to women admitted to non-teaching facilities. Odds ratios were also computed to examine the association between SIE and rural facilities, teaching facilities, and exposure to various treatment modalities (e.g. internal fetal monitoring, medical induction of labor, and surgical induction of labor) that may make women more vulnerable to infection.

### **Diagnostic Codes Indicating Pathogens**

Diagnostic codes were searched for the presence of codes indicating a pathogen. The frequency of SIE that included specific diagnostic codes indicating a pathogen were tabulated.

## Summary

The Texas Center for Health Statistics (2016) reported that over 650,000 women gave birth by CS between 2010 and 2014. The incidence of SIE and characteristics of women, the environment and pathogens causing infections were evaluated using administrative data collected by the THCIC and available for public use. Data sources similar to the PUDF have been used successfully in studies of both SSI and sepsis. This study utilized administrative coded data to , to identify and evaluate trends in the incidence of SIE at facilities reporting data to THCIC. SIE were evaluated in the aggregate and according to discrete events (endometritis, sepsis, or CS wound disruption).

## CHAPTER FOUR: RESULTS

The purpose of this chapter is to present the results of data analysis performed for the study of serious infectious events (SIE) following Cesarean Section (CS). Descriptive statistics about participants, trends in the incident diagnosis of SIE, characteristics of women that increase or decrease the likelihood of the development of each type of SIE (endometritis, sepsis, and CS wound disruption), characteristics of facilities, and the frequency of pathogens listed in diagnosis codes are presented. Secondary findings about the severity of SIE are included.

### **Study Participants**

Records of 627,555 females that had CS procedures and 1,023 women that were readmitted with a diagnostic code indicating CS wound disruption between January 1, 2010 and December 31, 2014 were eligible for inclusion in this study (see Table 4.1). The number of CS procedures identified quarterly ranged from 13,397 to 35,142, with a median of 31,659 CS procedures performed each quarter. The minimum number of procedures occurred during the 4<sup>th</sup> quarter of 2010 and was 21,750 CS lower than the maximum number of procedures. To determine if this was an error, the raw data was re-examined and this number was confirmed. There were no comments made by facilities to THCIC to explain this low number of CS and no patterns of seasonality were observed.

Patient demographic characteristics and treatment exposures identified in the records are presented as frequencies and percentages in Table 4.2. The age category with the largest proportion of patients was ages 20-29 years (49.66%), followed by 30-39 years (39.24%), 19 years and younger (7.48%), and 40 years and older (3.62%). Records of 331,935 (52.87%) White females, 77,035 (12.26%) Black females and 191,472 (30.50%) females of other races were included. Patients residing in rural counties accounted for 56,040 (8.9%) of the sample.

Table 4.1 Records Included by Discharge Quarter

<b>Discharge Quarter</b>	<b>Cesarean Section</b>	<b>Readmission</b>	<b>Total</b>
1 Q 2010	30795	23	30818
2 Q 2010	30816	64	30880
3 Q 2010	34197	64	34261
4 Q 2010	13397	23	13420
1 Q 2011	30207	57	30264
2 Q 2011	30268	58	30326
3 Q 2011	34112	98	34210
4 Q 2011	33118	45	33163
1 Q 2012	30407	34	30441
2 Q 2012	30490	57	30547
3 Q 2012	34924	46	34970
4 Q 2012	33018	51	33069
1 Q 2013	30387	48	30435
2 Q 2013	30748	50	30798
3 Q 2013	34342	57	34399
4 Q 2013	33398	56	33454
1 Q 2014	31607	36	31643
2 Q 2014	31712	45	31757
3 Q 2014	35142	49	35191
4 Q 2014	34470	62	34532
<b>Total</b>	<b>627555</b>	<b>1023</b>	<b>628578</b>

Characteristics of study participants including the frequency and proportion of women who received treatment exposures, and who had comorbid conditions are provided in Table 4.2. Medical induction of labor (e.g., cervical ripening) was identified in 64,048 (10.2%) of records. Surgical induction of labor (e.g., artificial rupture of membranes) was identified in 51,836 (8.2%) of records. The procedural code for internal fetal cardiac monitoring was present in 6,173 (1.0%) of records. The number of patients admitted emergently was 108,831 (17.3%) and 23,281 (3.7%) received critical care at some time during the admission.



Table 4.2 Study Participants

<b>Age</b>	<b>Number (%)</b>
19 years and younger	47,008 (7.48)
20-29 years	312,156 (49.66)
30-39 years	246,648 (39.24)
40 years and above	22,766 (3.62)
<b>Race</b>	
Black	77,035 (12.26)
White	331,935 (52.81)
Other	191,742 (30.50)
<b>Ethnicity</b>	
Hispanic	259,835 (41.34)
<b>Geographic Location of Residence</b>	
Rural Residence	56,040 (8.9)
<b>Treatment Exposures</b>	
Medical Induction of Labor	64,048 (10.2)
Surgical Induction of Labor	51,836 (8.2)
Internal Fetal Monitoring	6,173 (1.0)
Emergency Admission	108,831 (17.3)
Critical Care	23,381 (3.7)
<b>Comorbidities</b>	
Abnormal Fetal Heart Rate	97,037 (15.4)
Anemia	83,486 (13.3)
Previous Cesarean Section	65,549 (10.4)
Early Onset of Labor	50,628 (8.1)
Post Term Pregnancy	34,313 (5.5)
Chorioamnionitis	16,026 (2.50)
Obesity	14,094 (2.2)
Diabetes	12,630 (2.00)
Cellulitis of Trunk	1231 (.2)

### **Trends in the Diagnosis of Serious Infectious Events**

A total of 5,954 SIEs were identified among 5,802 records of 627,555 (0.92%) females who had Cesarean Section surgeries. Table 4.3 presents the composite SIE and discrete events by discharge quarter. There were 1,023 (17%) records that included a diagnosis code for CS wound disruption without an associated CS, and these were considered readmissions. All other SIE were detected during the birth admission.

**Table 4.3 Serious Infectious Events by Discharge Quarter**

Discharge Quarter	Cesarean Sections	Serious Infectious Events	Major Puerperal Infection	Endometritis	Sepsis	Cesarean Section Wound Disruption	Readmission
Q1 2010	30795	328 (10.65)	52 (1.69)	206 (6.69)	18 (0.58)	56 (1.82)	23 (.75)
Q2 2010	30816	362 (11.75)	46 (1.49)	203 (6.59)	20 (.65)	103 (3.34)	64 (2.08)
Q3 2010	34197	361 (10.56)	11 (.32)	240 (7.02)	27 (.79)	98 (2.87)	64 (1.87)
Q4 2010	13397	109 (8.14)	1 (.07)	61 (4.55)	7 (.52)	41 (3.06)	23 (1.72)
Q1 2011	30207	310 (10.26)	3 (.10)	204 (6.75)	23 (.76)	90 (2.98)	57 (1.89)
Q2 2011	30268	287 (9.48)	8 (0.26)	161 (5.32)	21 (.69)	101 (3.34)	58 (1.92)
Q3 2011	34112	350 (10.26)	9 (0.26)	235 (6.89)	13 (.38)	99 (2.90)	98 (2.87)
Q4 2011	33118	304 (9.18)	2 (.06)	222 (6.70)	17 (.51)	72 (2.17)	45 (1.36)
Q1 2012	30407	275 (9.04)	4 (.13)	192 (6.31)	16 (.53)	70 (2.30)	34 (1.12)
Q2 2012	30490	289 (9.48)	4 (.13)	172 (5.64)	23 (.75)	96 (3.15)	57 (1.87)
Q3 2012	34924	318 (9.11)	2 (.06)	209 (5.98)	29 (.83)	94 (2.69)	46 (1.32)
Q4 2012	33018	346 (10.48)	1 (.03)	232 (7.03)	25 (.76)	92 (2.79)	51 (1.54)
Q1 2013	30387	271 (8.92)	2 (.07)	169 (5.56)	18 (.59)	87 (2.86)	48 (1.58)
Q2 2013	30748	274 (8.91)	3 (.10)	179 (5.82)	23 (.75)	83 (2.70)	50 (1.63)
Q3 2013	34342	279 (8.12)	3 (.09)	165 (4.80)	22 (.64)	95 (2.77)	57 (1.66)
Q4 2013	33398	275 (8.23)	2 (.06)	168 (5.03)	29 (.87)	82 (2.46)	56 (1.68)
Q1 2014	31607	260 (8.23)	3 (.09)	162 (5.13)	28 (.89)	74 (2.34)	36 (1.14)
Q2 2014	31712	238 (7.51)	0	134 (4.23)	25 (.79)	84 (2.65)	45 (1.42)
Q3 2014	35142	279 (7.94)	2 (.06)	183 (5.21)	30 (.85)	77 (2.19)	49 (1.39)
Q4 2014	34470	286 (8.30)	3 (.09)	163 (4.73)	31 (.90)	95 (2.76)	62 (1.80)
<b>Total</b>	<b>627555</b>	<b>5801</b> <b>(9.24)</b>	<b>161</b> <b>(.26)</b>	<b>3660</b> <b>(5.83)</b>	<b>444</b> <b>(.71)</b>	<b>1689</b> <b>(2.69)</b>	<b>1023</b> <b>(1.63)</b>

The distribution of SIE rates across quarters were assessed for skewness, range, and normality of distribution. These results are included in Table 4.4. The diagnostic code for major puerperal infection was used infrequently after 2010. In 2011, the CMS instructed coders to stop using the code for major puerperal infection and to use the more specific diagnostic codes for puerperal endometritis and puerperal sepsis instead. When tested for normality, the variable major puerperal infection was found to have non-normal distribution as determined by a statistically significant Kolmogorov-Smirnov test for normality. Therefore, linear regression analysis was not performed for this variable. Further analysis to identify characteristics of

women associated with the diagnosis code for major puerperal infection was not conducted because this code was rarely used.

Table 4.4 Dispersion of SIE across Discharge Quarters

Type of Event	SIE	Major Puerperal Infection	Endometritis	Sepsis	CS Wound Disruption	Readmission
Median Quarterly Rate per 1,000 CS	9.07	.09	5.73	.75	2.76	1.64
Standard Deviation	.11	.05	.09	.01	.04	.03
Kolmogorov-Smirnov (significance)	.15 (.20)	.36 (.00)	.16 (.20)	.17 (.11)	.14 (.20)	.16 (.20)

Linear regression analysis of SIE rates was conducted for the composite SIE (an aggregate of all SIE) and each discrete SIE (i.e. endometritis, sepsis, CS wound disruption and readmission for CS wound disruption). The  $R^2$ ,  $\beta$ , and  $F$  statistic for the incidence rate of the composite and discrete SIE are presented in Table 4.5.

Table 4.5 Linear Regression Statistics for Serious Infectious Events

Type of SIE	R Squared	Standardized Beta	F (Sig)
SIE Rate	.60	-.77	26.53 (<.001)
Endometritis Rate	.41	-.64	12.33 (.002)
Sepsis Rate	.32	.57	8.65 (.009)
CS Wound Disruption Rate	.06	-.25	1.19 (.28)
Readmission Rate	.02	-.13	.315 (.581)

A total of 5,801 records with a diagnosis code for SIE were identified. Figure 4.1 displays the results of linear regression of SIE rates across 20 quarters. The aggregate incidence rate was 9.24 SIEs per 1,000 CS procedures. A large decrease ( $R^2 = .60$ ) in SIE occurred during the study

period. SIE could be expected to decrease at a rate of .77% each quarter.

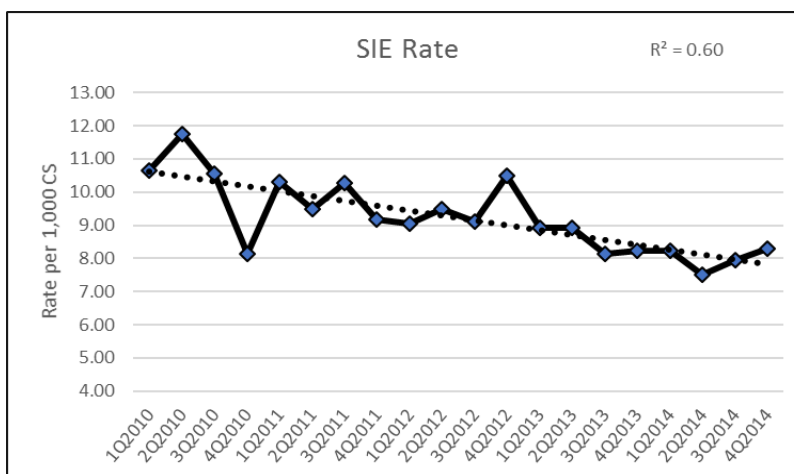


Figure 4.1 Incidence of serious infectious events by discharge quarter.

Three thousand six hundred sixty records (61% of SIE) with a diagnostic code for endometritis were identified with an incidence rate of 5.83 infections per 1,000 CS. Linear regression analysis of endometritis rates was conducted, results are displayed in Figure 4.2. Over the 20 quarter years in the study, a large decrease ( $R^2 = .41$ ) in the incident diagnosis of endometritis occurred.

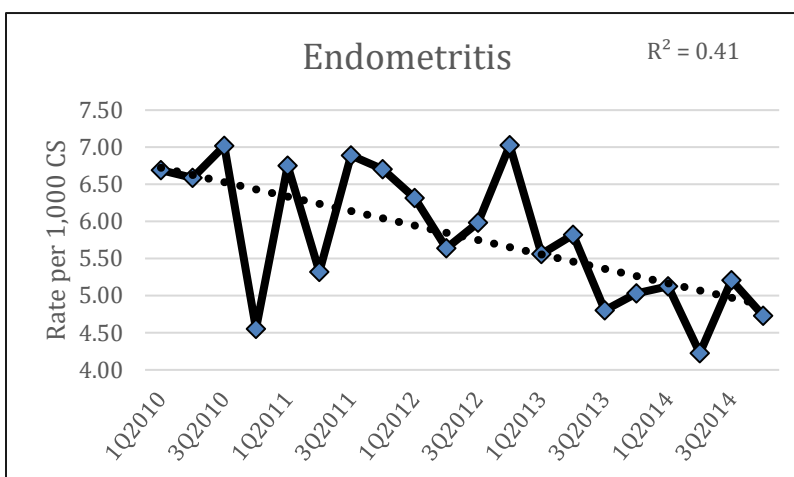


Figure 4.2 Incidence of endometritis by discharge quarter.

Four hundred forty-four (8% of SIE) women were diagnosed with either puerperal sepsis or severe sepsis during the study period, yielding an incidence rate of .71 case of sepsis for every 1,000 CS. Linear regression analysis of sepsis rates are displayed in Figure 4.3. A large increase

( $R^2 = .32$ ) in the use of the diagnostic code for sepsis occurred during the study period. The incidence of sepsis could be expected to increase at a rate of .57% each quarter.

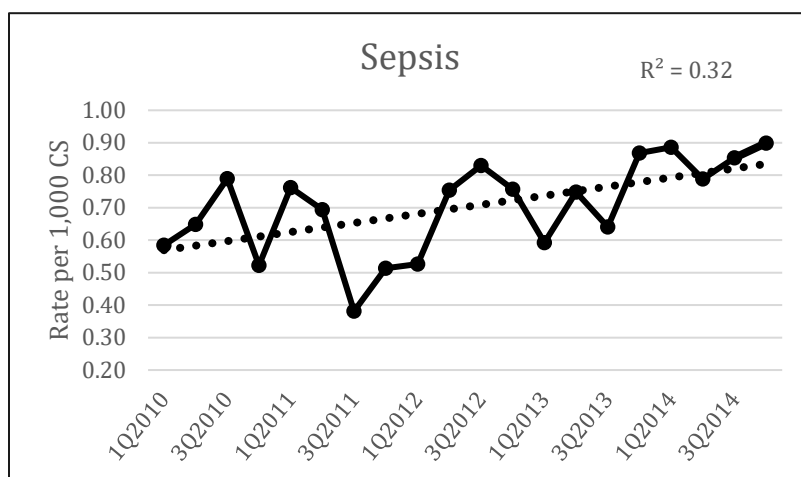


Figure 4.3 Incidence of sepsis by discharge quarter.

One thousand six hundred eighty-nine women (29% of SIE) were diagnosed with CS wound disruption during the study period for an incidence rate of 2.69 for every 1,000 CS procedures. Linear regression analysis of CS wound disruption rates is displayed in Figure 4.4. Among women diagnosed with CS wound disruption, 646(38%) were diagnosed during the birth admission. The diagnosis of CS wound disruption decreased, but the change over the 20 quarter years' time was not as large as the decreases in SIE and endometritis ( $R^2=.06$ ). The rate of CS wound disruption could be expected to decrease .25% each quarter.

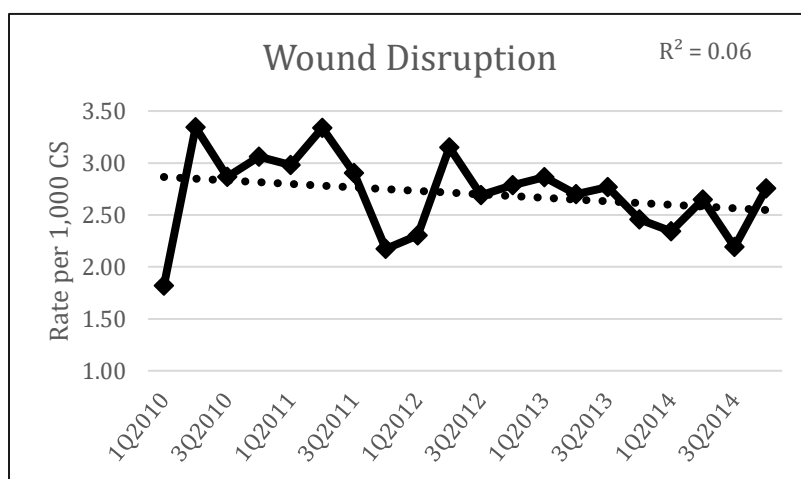


Figure 4.4 Incidence of CS wound disruption by discharge quarter

One thousand twenty-three of the women with wound disruption (61% of women with wound disruption) were readmitted, the readmission rate was 1.63 per 1,000 CS. The results of linear regression analysis of the rate of readmission for CS wound disruption is presented in Figure 4.5. The rate of readmission for CS wound disruption decreased ( $R^2=.03$ ), but the decrease was not as large as the decrease in endometritis. The rate of readmission could be expected to decrease by .13% each quarter.

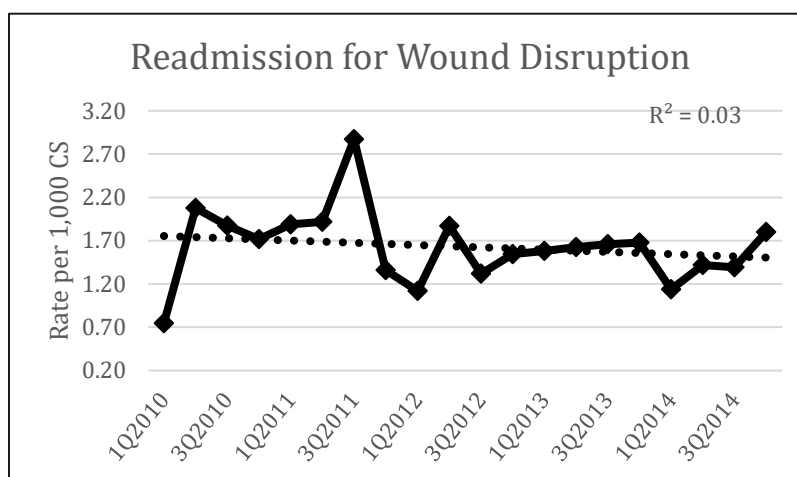


Figure 4.5 Incidence of readmission for CS wound disruption.

### Severity of Infectious Events

The severity of SIEs are presented as secondary findings. The mean length of stay among women diagnosed with a SIE was statistically significantly longer than women not diagnosed with a SIE. Specifically, mean length of stay was 6.26 days ( $p < .001$ ) for women with a SIE diagnosis compared to 3.30 days among women who were not diagnosed with a SIE. Women with sepsis had a mean length of stay of 14 days; women with endometritis stayed 5.97 days, and women with wound disruption stayed 5.35 days. Among women readmitted with wound disruption, the mean length of stay was 5.42 days.

The frequency of procedural codes to treat SIE indicated the severity of illness when wound disruption was diagnosed. Additional procedures were required by 469 (27.77%) of

women with wound disruption. Procedures to treat wound disruption included 10 records with the procedural code for repair of the abdominal wall, 87 records with the procedural code that indicated percutaneous drainage of abscesses, 162 records with the procedural code for excisional debridement of wounds and 210 records with the procedural code for non-excisional wound debridement.

### **Characteristics of Women Diagnosed with Serious Infectious Events**

Characteristics of women diagnosed with a SIE are presented by age, race, county of residence, comorbid conditions and treatment exposures, with associated odds ratios (OR) and 95% confidence intervals (CI) in Table 4.6. Women age 19 years and under had statistically significantly increased odds of being diagnosed with any SIE (OR 2.32, 2.16-2.50) when compared with women in other age groups. Black women had increased odds of being diagnosed with an SIE when compared to White women or women of other races (OR 1.79, CI 1.68-1.91). Women who were residents of rural counties were 32% less likely to be diagnosed with an SIE. The odds of SIE diagnosis were statistically significantly elevated among women who had internal fetal cardiac monitoring (OR 6.81, CI 6.15-7.55) compared to those who did not. When compared to women who did not have labor induced the odds of SIE were elevated for both medical (OR 1.98, CI 1.86-2.12) and surgical inductions (OR 1.53, CI 1.42-1.66). labor. Elevated odds of SIE diagnoses were identified among women admitted emergently (OR 2.10, CI 2.04-2.28) compared to non-emergent admission.

Each of the comorbidities identified as the ten most frequently occurring diagnosis codes among women with SIE were associated with statistically significantly elevated odds of SIE, except for history of a previous CS. Women with SIE had significantly elevated odds of also being diagnosed with cellulitis (OR 30.64, CI 27.83-33.73).

Table 4.6 Women Diagnosed with a Serious Infectious Event

<b>Serious Infectious Events = 5801</b>		
<b>Age</b>	<b>Number (%)</b>	<b>Odds Ratio (CI)</b>
19 years and younger	908 (15.65)	2.32 (2.16-2.50)
20-29	2951 (50.88)	1.05 (.99-1.11)
30-39 years	1771 (30.52)	.67 (.64-.71)
40 years and over	170 (2.93)	.80 (.68-.93)
<b>Race</b>		
White	2770 (47.7)	.81 (.77-.86)
Black	1156 (19.93)	1.79 (1.68-1.91)
Other	1874 (32.30)	0.89 (.84-.94)
<b>Ethnicity</b>		
Hispanic	2538 (43.75)	1.1 (1.04-1.16)
<b>Geographic Location of Residence</b>		
Rural Residence	363 (6.25)	.68 (.61-.76)
<b>Comorbidities</b>		
1. Cellulitis of the Trunk	329 (5.67)	30.64 (27.83-33.73)
2. Chorioamnionitis	773 (13.33)	5.87 (5.46-6.33)
3. Anemia	1478 (25.48)	2.23 (2.11-2.36)
4. Post Term Pregnancy	588 (10.14)	1.95 (1.79-2.13)
5. Severe Pre-Eclampsia	363 (6.26)	1.94 (1.75-2.16)
6. Obesity	198 (3.41)	1.54 (1.33-1.77)
7. Diabetes mellitus	176 (3.03)	1.52 (1.32-1.77)
8. Early Onset of Labor	630 (10.86)	1.39 (1.28-1.51)
9. Abnormal Fetal Heart Rate	1150 (19.82)	1.35 (1.27-1.44)
10. Previous Cesarean Section	374 (6.45)	.59 (.53-.66)
<b>Treatment Exposures</b>		
Internal Fetal Monitoring	367 (6.32)	6.81 (6.15-7.55)
Medical Induction of Labor	1065 (18.36)	1.98 (1.86-2.12)
Surgical Induction of Labor	703 (12.11)	1.53 (1.42-1.66)
Emergency Admission	1793 (30.90)	2.10 (2.04-2.28)
Receipt of Critical Care	646 (11.1)	3.05 (2.83-3.29)

### Women Diagnosed with Endometritis

Characteristics of women diagnosed with endometritis are presented in Table 4.7.

Women ages 19 and younger were significantly more likely to be diagnosed with endometritis (OR 3.06, CI 2.82-3.32) when compared to women of other age groups. Older mothers had reduced odds of being diagnosed with endometritis. Black women had significantly greater odds of being diagnosed with endometritis (OR, 1.85, CI 1.71-2.01) than women who were not Black.



Hispanic women were 15% more likely to be diagnosed with endometritis than non-Hispanic women. Residents of rural counties were significantly less likely to be diagnosed with endometritis (OR .55, CI .48-.64) when compared to residents of urban counties.

Table 4.7 Women Diagnosed with Endometritis

<b>Endometritis = 3660</b>		
<b>Age</b>	<b>Number (%)</b>	<b>Odds Ratio (Confidence Interval)</b>
19 years and younger	720 (19.67)	3.06 (2.82-3.32)
20-29	1939 (53.00)	1.07 (1.01-1.13)
30-39 years	919 (25.10)	.52 (.48-.56)
40 years and over	81 (2.21)	.60 (.48-.74)
<b>Race</b>		
White	1669 (45.60)	.75 (.70-.80)
Black	750 (20.49)	1.85 (1.71-2.01)
Other	1240 (33.88)	.95 (.89-1.03)
<b>Ethnicity</b>		
Hispanic	1641 (44.83)	1.15 (1.08-1.23)
<b>Geographic Location of Residence</b>		
Rural Residence	188 (51.36)	.55 (.48-.64)
<b>Comorbidities</b>		
1. Cellulitis of the Trunk	64 (1.74)	9.07 (7.13 – 11.54)
2. Chorioamnionitis	617 (18.36)	7.75 (7.12 – 8.44)
3. Anemia	1117 (30.51)	2.86 (2.64 - 3.08)
4. Severe Pre-eclampsia	284 (7.76)	2.45 (2.17 – 2.16)
5. Early Onset of Labor	430 (11.74)	1.52 (1.38 – 1.68)
6. Abnormal Fetal Heart Rate	69 (1.89)	1.20 (.93 – 1.55)
7. Diabetes mellitus	69 (1.89)	.94 (.74 – 1.19)
8. Previous Cesarean Section	216 (5.90)	.83 (.70 - .98)
9. Obesity	34 (.01)	.41 (.29 - .57)
10. Post Term Pregnancy	528 (14.42)	.40 (.15 – 1.06)
<b>Treatment Exposures</b>		
Internal Fetal Monitoring	303 (8.28)	9.1 (8.11-10.20)
Surgical Induction of Labor	618 (16.88)	2.26 (2.07-2.46)
Medical Induction of Labor	93 (2.54)	3.01 (2.80-3.24)
Emergency Admission	988 (26.99)	1.77 (1.64-1.89)
Receipt of Critical Care	273 (7.46)	2.1 (1.80 – 2.26)

Women diagnosed with cellulitis of the trunk (OR 9.07, CI 7.13 – 11.54) and chorioamnionitis (OR 7.75, CI 7.12 – 8.44) were significantly more likely to be diagnosed with endometriosis. Women with anemia were also nearly three times as likely to be diagnosed with

endometritis (OR 2.86, CI 2.64 - 3.08) when compared to those who did not have anemia.

Women with severe pre-eclampsia had significantly elevated odds of endometritis (OR 2.45, CI 2.17 – 2.16) when compared to women who were not diagnosed with severe pre-eclampsia. The diagnosis of early onset of labor also associated with significantly increased odds of being diagnosed with endometritis (OR 1.52, CI 1.38 – 1.68) when compared to those who did not have early onset of labor. Women who were diagnosed with obesity, post-term pregnancy, and women who had a previous CS had lower odds of being diagnosed with endometritis when compared to those who did not.

Treatment exposures resulted in elevated odds of endometritis diagnosis. Specifically, internal fetal monitoring increased the odds of being diagnosed with endometritis by 9 times (OR 9.1, CI 8.11-10.20) when compared to women who were not exposed to internal fetal monitoring. Women who experienced medical induction of labor (OR 3.01, CI 2.80-3.24) had elevated odds of endometriosis when compared to women who did not have medical induction of labor. Similarly, women who had surgical induction of labor (OR 2.26, CI 2.07-2.46) had elevated odds of endometriosis when compared to those who did not have surgical induction of labor. Women who were admitted emergently (OR 1.77, CI 1.64-1.89) and those who received critical care (OR 2.1, CI 1.80 – 2.26) had elevated odds of endometriosis.

### **Women Diagnosed with Sepsis**

Characteristics of women diagnosed with sepsis are presented in Table 4.8. Women ages 19 and younger had significantly elevated odds of being diagnosed with sepsis (OR 1.64, CI 1.21-2.17) when compared to women of other age groups. When Black women were compared to White women and women of other races, elevated odds of being diagnosed with sepsis were evident

(OR 1.64, CI 1.29-2.08). Women residing in rural counties were approximately 50% less likely to be diagnosed with sepsis (OR .51, CI .33-.79) than urban residents.

Table 4.8 Women Diagnosed with Sepsis

<b>Sepsis = 444</b>		
<b>Age</b>	<b>Number (%)</b>	<b>Odds Ratio (Confidence Interval)</b>
19 years and younger	52 (11.71)	1.64 (1.21-2.17)
20-29 years	216 (48.64)	.96 (.79-1.15)
30-39 years	160 (36.04)	.87 (.71-1.05)
40 years and over	16 (3.60)	.99 (.60-1.64)
<b>Race</b>		
White	206 (46.40)	.77 (.64-.93)
Black	83 (18.69)	1.64 (1.29-2.08)
Other	155 (34.90)	1.00 (.82-1.22)
<b>Ethnicity</b>		
Hispanic	169 (38.06)	.87 (.71-1.04)
<b>Geographic Location of Residence</b>		
Rural Residence	21 (4.72)	.51 (.33-.79)
<b>Comorbidities</b>		
1. Cellulitis of the Trunk	10 (2.25)	11.74 (6.29 – 21.93)
2. Chorioamnionitis	104 (23.42)	11.69 (9.39 – 14.56)
3. Early Onset of Labor	94 (21.17)	3.07 (2.44 – 3.86)
4. Severe Pre-eclampsia	28 (6.30)	1.96 (1.33 – 2.87)
5. Diabetes mellitus	16 (3.60)	1.82 (1.10 – 3.01)
6. Anemia	69 (15.54)	1.20 (.93 – 1.55)
7. Abnormal Fetal Heart Rate	60 (13.51)	.85 (.65 – 1.12)
8. Post Term Pregnancy	12 (2.70)	.48 (.27 - .85)
9. Obesity	4 (.01)	.40 (.15 – 1.06)
10. Previous Cesarean Section	7 (1.58)	.14 (.07 - .29)
<b>Treatment Exposures</b>		
Medical Induction of Labor	46 (10.36)	1.02 (.75-1.5)
Surgical Induction of Labor	26 (5.86)	.69 (.47-1.0)
Internal Fetal Monitoring	8 (1.80)	Number too few to calculate
Emergency Admission	72 (16.20)	3.02 (2.49-3.65)
Receipt of Critical Care	257 (57.8)	35.58 (29.48-42.94)

The odds of being diagnosed with sepsis were 11 times higher among women who were also diagnosed with chorioamnionitis (OR 11.69, CI 9.39 – 14.56) when compared to those who were not. The diagnosis cellulitis of the trunk occurred 11 times more frequently among women diagnosed with sepsis compared to those who were not, although this diagnosis occurred in only

10 of 444 records of women with diagnosis codes indicating sepsis. Women with early onset labor (OR 3.07, CI 2.44-3.86), those with severe pre-eclampsia (OR 1.96, CI 1.33-2.87), and women diagnosed with diabetes (OR 1.82, CI 1.10-3.01) also had significantly elevated odds of being diagnosed with sepsis.

Women admitted emergently were three times (OR 3.02, CI 2.49-3.65) more likely to be diagnosed with sepsis when compared to women who were not admitted emergently. Nearly 60% of women with a diagnosis code of sepsis also received critical care. The records of all 15 participants with the discharge status “expired” had a diagnosis code for sepsis.

### **Women Diagnosed with Cesarean Section Wound Disruption**

Characteristics of women diagnosed with CS wound disruption are presented in Table 4.9. Women ages 30-39 years had increased odds of being diagnosed with CS wound disruption when compared to women in other age groups. Black women had increased odds of being diagnosed with CS wound disruption (OR 1.75, CI 1.55-1.97) when compared to other White women or women of other races. Women of other races were 27% less likely to be diagnosed with wound disruption than Black women or White women. The odds CS wound disruption diagnoses were not different among rural residents (OR 1.03, CI .88-1.22) compared to urban residents.

Women admitted emergently had increased odds of being diagnosed with CS wound disruption when compared to those not admitted emergently (OR 3.16, CI 2.87-3.48) and were more than twice as likely to receive critical care (OR 2.64, CI 2.24 -3.11). Exposures occurring during care; internal fetal monitoring, and surgical and medical induction of labor were associated with lower odds of being diagnosed with CS wound disruption.

Table 4.9 Women Diagnosed with Cesarean Section Wound Disruption

<b>CS Wound Disruption = 1688</b>		
<b>Age</b>	<b>Number (%)</b>	<b>Odds Ratio (Confidence Interval)</b>
19 years and younger	136 (8.05)	1.08 (.91-1.29)
20-29 years	772 (45.73)	.85 (.77-.94)
30-39 years	708 (41.94)	1.12 (1.02-1.23)
40 years and over	72 (4.27)	1.19 (.93-1.49)
<b>Race</b>		
White	853 (50.53)	1.00 (.89-1.14)
Black	331 (19.60)	1.64 (1.40-1.92)
Other	504 (29.86)	.73 (.64-.84)
<b>Ethnicity</b>		
Hispanic	679 (40.22)	.95 (.86-1.05)
<b>Geographic Location of Residence</b>		
Rural Residence	155 (9.18)	1.03 (.88-1.22)
<b>Comorbidities</b>		
1. Cellulitis of the Trunk	329 (1.95)	30.64 (27.83 – 33.73)
2. Obesity	162 (9.60)	4.67 (3.97 – 5.50)
3. Diabetes mellitus	86 (5.09)	2.62 (2.11 – 3.25)
4. Anemia	270 (16.00)	1.24 (1.09 – 1.42)
5. Previous Cesarean Section	148 (8.76)	.82 (.70 - .98)
6. Chorioamnionitis	31 (1.83)	.72 (.50 – 1.02)
7. Early Onset of Labor	95 (5.62)	.68 (.55 - .83)
8. Abnormal Fetal Heart Rate	75 (4.44)	.26 (.20 - .32)
9. Post Term Pregnancy	24 (1.42)	.25 (.17 - .37)
10. Severe Pre-eclampsia	36 (2.13)	.20 (.10 - .42)
<b>Treatment Exposures</b>		
Internal Fetal Monitoring	15 (.01)	.90 (.54 – 1.5)
Medical Induction of Labor	43 (2.50)	.23 (.17-.31)
Surgical Induction of Labor	60 (3.50)	.40 (.32 - .53)
Emergency Admission	672 (39.81)	3.16 (2.87-3.48)
Critical Care	156 (9.24)	2.49 (2.15 – 2.90)

Women diagnosed with CS wound disruption were significantly more likely to be diagnosed with cellulitis of the trunk when compared to women not diagnosed with CS wound disruption (OR 30.64, CI 27.83 – 33.73). The diagnosis codes for obesity (OR 4.67, CI 3.97 – 5.50) and diabetes (OR 2.62, CI 2.11 – 3.25) were also associated with increased odds of being diagnosed with wound disruption, when compared with women not diagnosed with obesity or

diabetes. Women with anemia were 24% more likely to be diagnosed with CS wound disruption than those who were not diagnosed with anemia (OR 1.24, CI. 1.09 – 1.42).

### Women Readmitted with Cesarean Section Wound Disruption

Characteristics of women readmitted with the diagnostic code indicating CS wound disruption are presented in Table 4.10. Younger women had increased odds of being readmitted (OR 1.37, CI 1.11-1.68) when compared to women of other age groups. Black women were 64% more likely to be readmitted than women who were not black (OR 1.64, CI 1.40-1.92). Women of other races were 25% less likely to be readmitted with CS wound disruption than women of other races.

Table 4.10 Women Readmitted with CS Wound Disruption

<b>Women Readmitted with CS Wound Disruption = 1023</b>		
<b>Age</b>	Number (%)	Odds Ratio (Confidence Interval)
19 years and younger	102 (9.97)	1.37 (1.11-1.68)
20-29	490 (47.89)	.93 (.82-1.05)
30-39 years	389 (38.02)	.95 (.84-1.08)
40 years and over	42 (4.10)	1.14 (.84-1.55)
<b>Race</b>		
White	543 (53.08)	1.01 (.89-1.14)
Black	191 (18.67)	1.64 (1.40-1.92)
Other	289 (28.25)	.73 (.64-.84)
<b>Ethnicity</b>		
Hispanic	426 (41.64)	1.00 (.89-1.14)
<b>Geographic Location of Residence</b>		
Rural Residence	96 (9.38)	1.06 (.86-1.31)
<b>Comorbidities</b>		
Cellulitis of the Trunk	257 (25.12)	170.98 (150-194.67)
Obesity	135 (13.20)	6.63 (5.54-7.94)
Diabetes mellitus	64 (6.20)	3.26 (2.53-4.19)
Anemia	179 (17.50)	1.36 (1.18-1.63)
<b>Treatment Exposures</b>		
Emergency Admission	547 (53.47)	5.51 (4.87-6.23)
Receipt of Critical Care	96 (9.30)	2.53 (2.09-3.06)

There was no difference in the odds of readmission when comparing women who were rural residents (OR 1.06, CI .86-1.31) with urban residents. Treatment exposures that may have increased the odds of wound disruption occurred during the birth admission and could not be

evaluated. Women readmitted with CS wound disruption had significantly elevated odds of being readmitted emergently (OR 5.51, CI 4.87-6.23) and were more than twice as likely to receive critical care (OR 2.35, CI 2.09-3.06) than women who were not readmitted.

The diagnosis cellulitis of the trunk was frequently present, occurring in just over 25% of women upon readmission for wound disruption. The comorbid conditions of obesity, diabetes and anemia were associated with highly elevated odds of being readmitted with CS wound disruption.

### **Diagnosis of Serious Infectious Events at Rural and Teaching Facilities**

Fifty rural facilities (including records of 33,334 participants) and 13 teaching facilities (with records of 62,832 participants) were included in the sample. The frequency and odds of being diagnosed with SIE at facilities located in rural counties or teaching facilities are presented in Table 4.11. Women who gave birth in rural facilities were statistically significantly less likely to be diagnosed with any SIE when compared to women who gave birth in urban facilities. The odds of being diagnosed with a SIE were elevated 2 to nearly 5 times when participants that received care at teaching hospitals were compared to those who did not.

Women who received care at rural facilities were significantly less likely than women who received care at urban facilities to have labor induced medically. There was no difference in the use of internal fetal monitoring or surgical induction of labor at rural facilities compared to urban facilities. Women who received care at teaching facilities had highly elevated odds of having exposure to internal fetal monitoring and medical induction of labor. There was no difference in the use of surgical induction of labor when comparing treatment of women at teaching hospitals to non-teaching hospitals.

Table 4.11 Diagnosis of Serious Infectious Event by Type of Facility

<b>Rural Facility</b>	<b>Number (%)</b>	<b>Odds Ratio (Confidence Interval)</b>
Serious Infectious Event	226 (3.80)	.72 (.63-.82)
Endometritis	131 (3.57)	.67 (.57-.80)
Sepsis	15 (3.38)	.62 (.37-1.0)
Wound Disruption	83 (4.91)	.92 (.74-1.2)
Readmission with Wound Disruption	49 (4.78)	.90 (.67-1.20)
<b>Treatment Exposures at Rural Facilities</b>		
Internal Fetal Monitoring	341 (1.02)	1.04 (.94 – 1.16)
Medical Induction of Labor	2577 (7.73)	.75 (.72 - .78)
Surgical Induction of Labor	2661 (7.98)	.97 (.93 – 1.00)
<b>Teaching Facility</b>		
Serious Infectious Event	1850 (31.89)	4.31 (4.08-4.56)
Endometritis	1273 (34.78)	4.88 (4.56-5.29)
Sepsis	81 (18.24)	2.01 (1.58-2.56)
Wound Disruption	425 (25.18)	3.04 (2.73-3.38)
Readmission with Wound Disruption	319 (31.12)	4.09 (3.58-4.68)
<b>Treatment Exposures at Teaching Facilities</b>		
Internal Fetal Monitoring	2628 (4.18)	6.68 (6.35 – 7.02)
Medical Induction of Labor	8046 (12.81)	1.29 (1.26 - 1.32)
Surgical Induction of Labor	5227 (8.32)	1.01 (.98 – 1.04)

### **Pathogens Listed in Diagnostic Codes of Women with Serious Infectious Events**

Diagnostic codes indicating pathogens were present in only 93 records of women with SIE. Pathogens were listed among women who were affected by sepsis. The records of 32 women included diagnostic codes for *Staphylococcus* species (including eight instances of Methicillin Susceptible Staph aureus [MSSA] and eight instances of Methicillin Resistant *Staphylococcus aureus* [MRSA]). *Streptococcus* species was indicated in 21 records, with six additional records specifying *Streptococcus pneumonia* as a causative pathogen. *E. coli* was specified in twelve records, *Klebsiella pneumonia* in five, *Pseudomonas* species in one and *Haemophilus influenzae* in one record. Diagnostic codes indicating unspecified gram-negative organisms were listed in eight records and unspecified septicemia was listed in seven records.



### Summary

A large decrease in SIE ( $R^2 = .59$ ) occurred in Texas during the study period. This was potentially influenced by a large decrease in the incidence rate of the diagnosis of endometritis ( $R^2 = .41$ ). Cesarean section wound disruptions ( $R^2 = .06$ ) and readmission for CS wound disruption ( $R^2 = .03$ ) also decreased but these changes were not as large as the decrease in endometritis. There was a large increase in the odds of women being diagnosed with sepsis ( $R^2 = .32$ ). Fifteen deaths associated with SIE occurred during the study period and all had the diagnostic code for sepsis present in the records.

The characteristics of women that resulted in increased odds of developing SIE varied depending on the discrete event. Women who gave birth in rural facilities had significantly lower odds of SIE diagnosis than those who gave birth in urban facilities. Women who gave birth in teaching facilities had elevated odds of being diagnosed with a SIE and elevated odds of treatment exposures that may increase the likelihood of SIE development. The findings revealed important differences among women, including treatment exposures and comorbidities that are likely related to the pathogenesis SIE and vary by the type of event.

## CHAPTER FIVE:DISCUSSION

The purpose of this chapter is to discuss the study findings in the context of previous research. Differences between the composite and discrete SIE rates, and differences in the characteristics of women, facilities, and pathogens, will be reviewed. Study limitations and implications for policy, practice, and research are discussed.

### **Discussion**

In this study, serious infectious events (SIE) were defined as the presence of a diagnostic code for major puerperal infection, endometritis, sepsis, or wound disruption in the record of administrative data for female Texas residents. Data were reported by hospitals for women who gave birth by CS in a facility that was required to report data to the Texas Healthcare Information Collection between January 1, 2010 and December 31, 2014. Trends in readmissions for wound disruption were also assessed. There was a large decrease in the incidence rate of composite SIEs ( $R^2=.59$ ) during the five-year study period. This trend was potentially influenced by a large decrease in the rate at which endometritis was diagnosed ( $R^2=.41$ ). There was also a decrease in the rate at which diagnostic codes for wound disruption ( $R^2=.06$ ) were recorded and a decrease in the rate of readmissions for wound disruption ( $R^2=.03$ ), but these declines smaller than decreases associated with other SIE. There was a large increase in the use of diagnostic codes indicating sepsis ( $R^2=.32$ ) during the study period.

### **Importance of Serious Infectious Events**

Among women whose records were included in this study, serious infectious events affected 9.24 women for every 1,000 CS. The effect of these events can be measured through increased healthcare costs, utilization of critical care, and fatality rates associated with sepsis. Olsen and colleagues (2010) reported that room and board were the largest drivers of excess cost

related to CS SSI. They estimated the average cost of SSI following CS at \$3,529 – 3,956 per woman. Olsen and colleagues (2010) did not report the number of women who required critical care, or those that required returns to the operative suite or procedural areas for treatment in cost estimates. Although cost was not directly assessed in this study, results supported Olsen's (2010) findings that the mean length of stay among women with SIE (6.26 days) was twice as long as those without SIE (3.30 days,  $p < .001$ ).

The effect of SIE can also be assessed through utilization of critical care. The odds of receiving critical care were significantly elevated among women with SIE when compared to those without SIE, regardless of the discrete event. Women with endometritis were twice as likely to receive critical care as women without endometritis. Women with wound disruption (including those readmitted) were 2.5 times as likely to receive critical care as women who did not have wound disruption. Sepsis is an emergent condition; therefore, it was not surprising that the odds of critical care utilization was highest among women with sepsis (35.58, 29.48-42.94). More than half (257/444, 57%) of women with sepsis received critical care. The mean length of stay among women with sepsis (14 days) was more than three times as long when compared to women without SIE (3.30 days,  $p < .001$ ).

To evaluate the severity of illness among women who gave birth by CS and had the diagnostic code for sepsis included in their records, I utilized criteria like those used by Acosta and colleagues (2013). They defined the presence of the diagnostic code for sepsis as uncomplicated sepsis; if the patient received critical care this was defined as severe sepsis. These findings revealed that 187 (42.1%) women diagnosed with sepsis had uncomplicated sepsis. More than half of women ( $n=257$ ; 57.8%) had severe sepsis, indicated by utilization of critical care. My study also evaluated readmission with sepsis, when it was accompanied by the

diagnostic code for wound disruption. Twenty-seven women were readmitted with sepsis in addition to wound disruption, representing 2.6% of readmissions. Fifteen women diagnosed with sepsis expired during the birth admission. The case fatality rate among women who gave birth by CS and were diagnosed with sepsis was 33.7 per 1,000. In summary, findings from this study suggest that the diagnosis of sepsis has increased and affected women have life threatening infections.

### **Characteristics of Women Affected by Serious Infectious Events**

This study examined characteristics of women affected by CS SIE including age, race, ethnicity and geographic location of residence. Comorbid conditions, and treatment exposures associated with each type of SIE were also examined. The study revealed important differences in characteristics of women according to the type of SIE by which the women were affected.

**Age.** Previous research evaluating the influence of age on the likelihood of developing CS SSI has yielded mixed results (Mu et al., 2011; Olsen et al., 2008; Stamilio & Scifres, 2014). Findings from this study suggest that age affects infection differently depending on the discrete event. For instance, women aged 19 and under had increased odds of developing the composite SIE when compared to women of other age groups. However, their odds of developing wound disruption were not significantly different than women in other age groups.

Women ages 20-29 years had higher odds of being diagnosed with the composite SIE and endometritis, but lower odds of developing wound disruption. Women ages 30-39 had increased odds of developing wound disruption (OR 1.12, CI 1.02-1.23) and women ages 40 and older were found to have lower odds of being diagnosed with the composite SIE and endometritis. Women aged 40 and older were not more likely to be diagnosed with sepsis or wound disruption, or be readmitted, than younger women.

**Race and ethnicity.** This study aligns with studies of maternal mortality and severe maternal morbidity (Callaghan et al., 2008; Gray et al., 2014; Olsen et al., 2008, Texas Department of State Health Services, 2014). Specifically, results suggest increased odds of SIE diagnosis (1.79, CI 1.68-1.91), endometritis (OR 1.85, CI 1.71-2.01), sepsis (1.64, CI 1.29-2.08), and wound disruption (OR 1.74, CI 1.55-1.97) among Black women compared to women who are not Black. Women of other races were 12% more likely to be diagnosed with wound disruption, but no more likely than other women to be readmitted with wound disruption.

Hispanic women had increased odds of SIE diagnosis when compared to non-Hispanic women. Hispanic ethnicity was also associated with increased odds of endometritis diagnosis (OR 1.15, CI 1.08-1.23). There was not a statistically significant difference in the odds of being diagnosed with sepsis or wound disruption among Hispanic women, and Hispanic women were no more or less likely to be readmitted than non-Hispanic women. These findings are interesting considering recent research related to the Human Microbiome Project (Hyman, Fukushima, Jiang, Fung, Rand, Johnson, Vo et al., 2014). Although sample sizes were small, researchers identified associations between vaginal microbiome characteristics and race/ethnicity. The composition of the vaginal microbiome and its relationship to race, ethnicity, and adverse events at the time of birth is a new frontier in research related to infection prevention.

**Rural residence.** Women residing in rural areas may have less access to prenatal care, placing rural residents at higher risk of SIE. Findings from this study did not support this claim. Specifically, results suggest that women who lived in rural areas were 32% less likely to be diagnosed with composite SIE than urban women. The odds of endometritis diagnosis were 45% lower among rural women than urban women. However, the odds of being diagnosed or

readmitted due to CS wound disruption were no different among women residing in rural counties when compared to residents of urban counties.

**Comorbidities.** Comorbid conditions that increased the likelihood of composite SIE diagnosis varied in the amount of influence they exerted on discrete SIE. Comorbid conditions have been defined as separate disease entities that occur during the same admission (Valderas et al., 2009). The ten most frequent comorbidities, identified using the principal and first five diagnosis codes, included the cellulitis and abscess of the trunk, chorioamnionitis, anemia, post-term pregnancy, severe pre-eclampsia, obesity, diabetes, early onset of labor, abnormal fetal heart rate, and previous CS. Results for each condition are described in detail below.

**Cellulitis.** The diagnostic code with the highest odds of being included in a record with a SIE diagnosis was cellulitis and abscess of the trunk. This diagnostic code indicates cellulitis or abscess of the abdomen or abdominal wall. This may not be considered a true comorbidity because cellulitis can be thought of as an entity that commonly presents with infection. This diagnostic code was chosen for inclusion as a comorbidity because it frequently appears in the records of women diagnosed with SIE. Per the National Healthcare Safety Network (NHSN), cellulitis is considered a localized condition that does not meet the criteria for a SSI (CDC, 2016b). However, in addition to cellulitis of the trunk, this diagnosis code is synonymous with abdominal abscesses (CMS, 2011). Women with SIE were 30 times more likely to have this diagnosis code in their records than women without an SIE. These elevated odds were also present among women with CS wound disruption and those readmitted with CS wound disruption, indicating that cellulitis and abscess of the trunk is an important diagnosis in the detection of SIE following CS.

**Chorioamnionitis.** Chorioamnionitis poses a nearly 6-fold increase in the odds being diagnosed with a SIE (OR 5.87, CI 5.46-6.33). The odds of endometritis diagnosis were elevated 7.75 times (CI 7.12-8.44) when women with chorioamnionitis were compared to women who were not diagnosed with chorioamnionitis. When chorioamnionitis was diagnosed, the odds of being diagnosed with sepsis were even higher; women with chorioamnionitis were eleven times more likely to be diagnosed with sepsis when compared to those who were not diagnosed with chorioamnionitis (OR 11.69, CI 9.39-14.56). Previous studies suggest that chorioamnionitis increases the likelihood of developing SSI and the pathogenesis of endometritis and sepsis related to contamination from infected pregnancy membranes is clear (Olsen et al., 2008). However, women who were diagnosed with chorioamnionitis were significantly less likely to be diagnosed with, or readmitted for, CS wound disruption. This may be because chorioamnionitis is diagnosed at the time of birth and wound disruption has a longer incubation period. Antimicrobial treatment for chorioamnionitis may result in reduced odds of wound disruption.

**Anemia.** When women diagnosed with anemia were compared to those who were not, a two-fold increase in composite SIE diagnosis (OR 2.23, CI 2.11-2.36) was detected. Anemia was associated with significantly elevated odds of being diagnosed with endometritis or wound disruption, and readmission for wound disruption. Diagnostic codes describing anemia associated with CS may have indicated that anemia was diagnosed as a condition of the pregnancy, or related to hemorrhage occurring immediately before or during the procedure.

Anemia may be present at the onset of labor, but may also result from hemorrhage and blood loss during labor, including the CS procedure. The American College of Obstetricians and Gynecologists (2015) defines post-partum hemorrhage following CS as blood loss of 1000 milliliters. The Maternal Safety Bundle of Obstetric Hemorrhage focuses, appropriately, on

controlling bleeding and replacing fluids. However, the Society for Hospital Epidemiology of America, *Strategies for the Prevention of Surgical Site Infections in Acute Care Hospitals* (2014) recommend re-dosing prophylactic antibiotics when there is excessive blood loss (Anderson, Podgorny, Berrios-Torres, Bratzler, Dellinger, Greene, et al., 2014). This is considered a routine practice to prevent SSI with the highest level of evidence (Category I) used by the Society.

**Post term pregnancy.** The odds of SIE diagnosis were nearly doubled when women whose pregnancy was post-term were compared to those who were not post-term. The odds of developing discrete SIE varied by condition. Post-term pregnancy increased the odds of being diagnosed with endometritis three-fold (OR 2.92, CI 2.66-3.20); however, the odds of developing sepsis (OR .48, CI .27-.85) or wound disruption (OR .25, CI .17-.37) were significantly decreased when pregnancies were post-term. When pregnancy is post-term, women may be more likely to receive surgical or medical induction of labor, which require rupture of membranes or introduction of medication to the cervix. These interventions may increase the odds of endometritis; however, it is unclear why women with post-term pregnancy would have decreased odds of developing wound disruption.

**Severe pre-eclampsia.** Severe pre-eclampsia was associated with a nearly two-fold increase in the odds of being diagnosed with a SIE. Specifically, women with pre-eclampsia were 2.45 times more likely to develop endometritis and 96% more likely to develop sepsis. The odds of wound disruption (OR .20, CI .10-.42) were 80% lower among women with severe pre-eclampsia. Eclampsia is related to deficient placental implantation and reduced perfusion of the placenta (Endler, 2016). This results in oxidative stress within the placenta, which may increase opportunity for bacteria to evade maternal defenses and infect the uterus. Eclampsia and transient hypertension have not previously been associated with CS SSI (Olsen et al., 2008; Pallasmaa,



Ekblad, Gissler, Alanen, 2015). Researchers performing a secondary review of birth registry data found that severe pre-eclampsia was associated with increased risk of hemorrhage, which may also represent the mechanism by which eclampsia and pre-eclampsia influence the odds of infection following CS.

**Obesity.** Women diagnosed with obesity were compared to women who were not diagnosed with obesity. Obesity was associated with a 52% increase in the odds of being diagnosed with a SIE (OR 1.52, CI 1.33-1.77). Interestingly, obesity was associated with significantly decreased odds of being diagnosed with endometritis (OR .41, CI .29-.57). Women diagnosed with obesity were slightly less likely to be diagnosed with sepsis (OR .40, CI .15-1.06); however, this effect was not statistically significant. The odds of re-admission were increased 4.63 times for obese women compared to non-obese women, and the odds of CS readmission with wound disruption were increased more than six times (OR 6.63, CI 5.54-7.94) among obese women when compared to non-obese women. Nearly 15% of women readmitted for CS wound disruption were also diagnosed with obesity. There is a large body of research related to obesity as a risk factor for the development of CS SSI, and it is known that obese women are more likely than women of normal weight to be readmitted following CS (Anderson et al. 2013).

**Diabetes.** Diagnostic codes were used in this study to identify cases of diabetes that complicated the care of the mother. The odds of being diagnosed with the composite SIE, sepsis, and wound disruption were elevated among women with diabetes when compared to those who do not have diabetes. Women with diabetes were not more likely to be diagnosed with endometritis compared to women without diabetes.

Researchers have drawn various conclusions when evaluating the association between diabetes and CS SSI. Neither Mu and colleagues (2011) nor Olsen (2008) identified a relationship between diabetes and infection following CS. Stamilio and Scifres (2014) concluded that obesity exerted greater influence on the development of CS SSI than diabetes. The present study suggests that the odds of wound disruption were increased 2.62 times among women with diabetes compared to non-diabetic women, and the odds of wound disruption were 4.63 times higher among women diagnosed with obesity. Although obesity may exert greater influence on wound disruption than diabetes; however, the odds of developing wound disruption when diabetes was diagnosed were also significantly elevated. Finally, diabetes increased the odds of developing sepsis by 82%.

**Early onset of labor.** Women with early onset of labor were compared to those who did not have pre-term labor. The odds of being diagnosed with an SIE were increased by 39% among women with early onset of labor compared to non-pre-term women. Pre-term women had a three-fold increase in the odds of sepsis diagnosis (OR 3.07, CI 2.44-3.85) and a 52% increase in the odds of being diagnosed with endometritis (OR 1.52, CI 1.32-1.77) compared to women who were not pre-term. Pre-term premature rupture of the membranes has been associated with pathologic inflammation and infection of the amnion and certain pathogenic bacteria that are resident in the vagina (Cox, et al., 2016). In a Cochrane review, investigators evaluated 22 trials involving 6,872 women and found that antimicrobial treatment following pre-term premature rupture of the membranes may help delay birth and reduce infection (Kenyon, Boulvain, and Neilson, 2013). Antimicrobial treatment of pre-term premature rupture of the membranes and chorioamnionitis may be protective against CS wound infections. As with chorioamnionitis, women with early labor had decreased odds of developing wound infection.

**Previous CS.** The diagnostic code indicating previous CS was present in 374 (6.5%) of women who developed SIE. However, history of CS was not associated with composite or discrete SIE diagnoses. The odds of SIE among women with a previous CS (OR .59, CI .53-.66) were approximately 40% lower than women without history of CS. This may be due to the elective nature of repeat CS.

### **Treatment Exposures**

Each of the three treatment exposures evaluated in this study, including internal fetal monitoring, medical induction of labor, and surgical induction of labor, were associated with significantly increased odds of being diagnosed with the composite SIE. Treatment exposures indicated that an attempt to deliver the infant vaginally was made. Therefore, it is likely that these treatment exposures indicated urgent or emergent unplanned CS. The likelihood of developing SSI following unplanned procedures has been documented in previous studies (Mu et al. 2011; Olsen et al. 2008). Results from the current study indicate that at least a portion of the risk of infection associated with unplanned CS could be attributed to treatment exposures during labor.

When women who were treated with internal fetal monitoring were compared to those who did not, the odds of being diagnosed with endometritis were increased nine times. This is consistent with the pathogenesis of endometritis, as internal fetal monitoring requires ruptured membranes and introduces a direct route of infection from the lower reproductive tract to the uterus. Studies evaluating the risk of infection have shown no increase when internal fetal monitors were used, but these studies were performed before the use of pre-surgical prophylactic antibiotics (Harper, Shanks, Tuuli, Roehl, & Cahill, 2013).

Medical or surgical induction of labor also increased the odds of endometritis diagnosis. This finding is consistent with the pathogenesis of endometritis, as both treatments involve manipulation of the cervix. Medical induction of labor was associated with a three-fold increase in the odds of an endometritis diagnosis, and patients who experienced surgical induction of labor were twice as likely as those who did not have medical or surgical induction of labor to be diagnosed with endometritis. Previous studies have also found that women who experienced labor induction had an elevated risk of CS and greater odds of SIE (Olsen et al., 2008).

### **Facility Characteristics**

The THCIC PUDF allowed for comparison of facilities located in rural counties to facilities located in urban counties, and facilities that reported membership in the Council of Teaching Hospitals were compared to facilities that were not teaching facilities. The odds of being diagnosed with endometritis or sepsis were lower among women who gave birth at rural facilities than women who gave birth at urban facilities. This may be due to lower rates of medical or surgical induction of labor. However, women treated at rural facilities were just as likely as women receiving treatment at urban facilities to have internal fetal monitoring, which significantly increased the likelihood of endometritis diagnosis. While women who gave birth at rural facilities were less likely to be diagnosed with endometritis or sepsis than women who gave birth at urban facilities, giving birth at a rural facility was not associated with lower odds of being diagnosed or readmitted with wound disruption.

Women who gave birth at teaching facilities had significantly greater odds of being diagnosed with composite SIE and each discrete SIEs when compared to women who gave birth at non-teaching facilities. The elevated odds associated with teaching hospitals was potentially influenced by increased odds of being diagnosed with one of the discrete SIE. Women who

received care at teaching facilities had nearly five times the odds of being diagnosed with endometritis, three times the odds of CS wound disruption, four times the odds of being readmitted and two times the odds of being diagnosed with sepsis.

Women who gave birth at teaching facilities had nearly a 7-fold increase (OR 6.68) in odds of receiving internal fetal monitoring than women at non-teaching facilities; this treatment was associated with a nine-fold increase in the diagnosis of endometritis. There may be several reasons for these findings; for instance, teaching facilities may receive patients that require a higher level of care, and rural facilities may transport ill patients to teaching facilities. Providers at teaching facilities might also have greater awareness of CS-related infectious complications, and as a result, providers at teaching hospitals may diagnose and treat symptoms of these infections sooner than providers at non-teaching hospitals.

### **Pathogens**

The ICD-9 coding guidelines specify that puerperal sepsis should be coded using the numbers 041 in order to designate a pathogen (CDC, 2015a). The guidelines also state that puerperal sepsis should be the primary code and other codes for sepsis should only be applied if severe sepsis is being identified. However, the codes for sepsis were used interchangeably among women diagnosed with sepsis; approximately half of the cases included the code for puerperal sepsis and half included the code for severe sepsis without the puerperal sepsis code. Codes identifying pathogens were found to begin with the numbers 038 as well as 041.

The diagnostic codes for *Staphylococcus* species varied substantially as well. For instance, codes for the *Staphylococcus* species appeared in 32 records, sixteen records were unspecified, eight records were coded as methicillin susceptible *Staphylococcus aureus*, and eight additional records were coded as methicillin resistant *Staphylococcus aureus*. Several

diagnostic codes were used to specify *Streptococcus species*, which appeared in 21 records. Groups B and D were used most frequently; each group was identified five times. Diagnostic codes indicating *Escherichia coli* occurred in twelve records. It is likely that *Staphylococci*, *Streptococci*, *E. coli* are important pathogens related to SIE following CS; however, the lack of diagnostic codes indicating pathogens limits the ability to draw conclusions about characteristics of pathogens related to SIE following CS.

### **Limitations**

This study is limited by conditions that affect the collection of data. Although the application of diagnostic and procedural codes is a standardized procedure performed by trained individuals, there is an element of subjectivity and potential for misapplication of coded data. Personnel who assign diagnostic codes utilize only the medical provider documentation of care. Variation in application of codes may occur due to subjectivity in choosing codes as well as variation among medical providers related to the criteria used to diagnose disease. A physician may diagnose CS wound disruption when the wound has failed to heal due to poor granulation, or due to skin or soft tissue infection. There are no ICD-9 codes specific to skin and soft tissue infection following surgery.

Administrative codes used in this study were generated by hospitals for billing purposes and not for clinical decision-making. Facilities may be penalized for the incidence of surgical site infections; thus, codes indicating CS SSI may be under-utilized. When conducting surveillance for SSI, an infection preventionist reviews each chart for signs and symptoms of infection included in medical provider documentation, laboratory results, and treatment records. For this reason, SIE identified in this study do not align fully with SSI as defined by the National Healthcare Safety Network (CDC, 2016b).

The PUDF does not provide dates of service; therefore, only readmissions for CS wound disruption could be detected. Readmissions for CS wound disruption are a discrete event, but detection could have been hampered if variation in coding methods influenced selection of the specific codes used in this study. The directionality of sepsis could not reliably be determined, as women may have been admitted with sepsis and then required CS. As a result of this methodological limitation, rates of SIE following CS identified in this study are likely an underestimation of the true incidence.

The use of administrative coded data also limited the ability to measure some confounding variables associated with increased odds of infection. For example, results from this study identified increased odds of endometritis when internal fetal cardiac monitoring, medical, or surgical induction of labor was performed. Previous studies have shown that the likelihood of infection increases as the amount of time a woman is in labor increases (Olsen et al., 2008). The data used in this study did not include length of time between onset of labor, initiation of the treatment exposure, and the CS, thus no conclusions about this relationship may be drawn.

The increase in the diagnosis of sepsis, and the severity of outcomes associated with sepsis diagnosis is concerning. Because data were pre-existing and de-identified, it was not possible to examine the validity of these diagnoses without reviewing the clinical records. It is not known how physiologic changes during pregnancy effect the diagnosis of sepsis, but the utilization of critical care and the fatalities associated with sepsis indicate that the diagnosis of sepsis has improved. Enhanced detection rates pose an opportunity to further refine identification of events and develop specific prevention measures for SIE (Maguire et al., 2016; Jafarzder, Thomas, Marschall, Fraser, & Gill, 2016).

Another limitation of this study is the lack of representation from sparsely populated counties in Texas. If a county had fewer than 100 hospital beds, facilities within the county were not required to report data to THCIC; therefore, critical access hospitals may not be represented. The finding lower rates of infection among women who received treatment at facilities located in rural counties is corroborated by lower rates of treatment exposures when care was received at facilities located in rural counties. However, the increased odds of SIE development and treatment exposures at teaching facilities (compared to non-teaching facilities) should not be interpreted as related to quality of care. It is possible that rural hospitals transport severely ill women, including those requiring CS, to urban and/or teaching hospitals. Inter-facility transfers could not be assessed in this study.

Hospitals are required to submit data to THCIC no later than 60 days following the close of a calendar quarter. Hospital billing cycles may not allow all discharges to have been billed or reported. This issue primarily affected the source of payment data, and did not likely effect the results from this study. Considering this time limit, hospitals may have submitted inaccurate or incomplete data. The Texas Department of State Health Services (2016) provides hospitals an opportunity to comment on data to explain incompleteness. The inability of hospitals to communicate complete data due to form constraints or clerical errors could affect conclusions drawn from the data. Given these limitations associated with use of billing records, SIE included in this sample are likely to be underreported.

### **Implications for Policy, Practice and Research**

Sepsis is a life-threatening event, and implications for policy, practice, and research, may have lifesaving implications. Twenty-seven (2%) of women readmitted with CS wound disruption were diagnosed with sepsis. As a matter of policy healthcare organizations should



consider readmission following CS with sepsis a sentinel event and review internal processes to determine if any failures in infection prevention need to be remediated. In practice clinicians need diagnostic criteria that assists them in early diagnosis and rapid treatment of sepsis. Research describing sepsis and its association with early onset of labor, chorioamnionitis, diabetes, and treatment exposures should be performed. Such research could lead to the development of interventions that reduce the incidence of sepsis following CS.

Endometritis was the most frequently diagnosed SIE in this study. Research is needed to develop effective prevention measures to reduce the opportunity for infection to develop when internal fetal monitoring is used. Results from a Cochrane review identified reductions in endometritis incidence when a vaginal wash was performed prior to unplanned CS (Haas et al., 2014). As a matter of practice, nurses may consider the implementation of fetal monitoring as a sign that an urgent/emergent CS may be impending. A vaginal wash could be implemented earlier in the course of care (e.g., prior to internal fetal monitoring).

Research about the vaginal microbiome and its association with pre-term labor and chorioamnionitis, should be investigated in the context of characteristics of women who become infected, as well as women who do not become infected. The identification of pathogenic and protective bacteria within the microbiome could provide important information that could help predict preterm labor and infectious outcomes. Knowledge about the microbiome of the normal pregnant woman and pathogenic changes could assist in predicting outcomes and guiding treatment.

The relationship between eclampsia or pre-eclampsia, bleeding, and infection has not been thoroughly described. Future research should seek to provide insight into the role of pre-eclampsia on infection development. It is not currently known if pre-eclampsia influences the

development of SIE directly or indirectly (through increased risk of bleeding). The association between pre-eclampsia, increased blood loss, and incident infection has not yet been explored.

Anemia was associated with elevated odds of developing endometritis and wound disruption. SIE might be reduced through addition of re-dosing prophylactic antibiotics to protocols for post-hemorrhage management when women have had excessive blood loss associated with CS. Healthcare organizations implementing protocols to address excessive blood loss prior to or during CS should consider adding redosing of antibiotics to those protocols.

Women who were obese or diabetic had highly elevated odds of wound disruption and readmission. Effective prevention measures to prevent wound disruption among obese women are needed. It is not known if weight based dosing of prophylactic antibiotics or chlorhexidine bathing prior to CS would assist in preventing wound disruption among obese women.

Chlorhexidine bathing regimens prior to CS have not been tested, but because the surgical wound may be located beneath skin folds of obese women, this intervention may have benefit for them. Future studies could evaluate methods of bathing and timing of bathing, so that these measures could be implemented in a timely manner.

Future research using administrative data to study SSI or SIE following CS, should include the diagnostic code for cellulitis of the trunk because it is likely to a predictor of the sensitivity of diagnosis codes indicating infection. After October 1, 2015, CMS required the use of ICD-10 codes, and new codes that specify infection of the CS wound are available (CMS, 2016). Cellulitis and abscess require separate codes, and the presence of cellulitis or abscess codes with CS wound infection codes may assist in the identification of CS SSI using administrative data.

Future studies could replicate this work in other states, and the review of clinical records could be performed to test the validity of the administrative coded data. The methods used to detect SIE in this study could be developed and used for ongoing monitoring of CS SIE. Results from this study might also be used by healthcare organizations and providers to develop and evaluate interventions designed to prevent SIE, a leading cause of maternal morbidity and mortality.

### **Summary**

This study highlighted the constant interaction of the host, pathogen and environment in producing infection. A large decrease in SIE occurred during the study period, and this decrease was potentially influenced by a large decrease in endometritis. Decreases in wound disruption and readmission occurred during the study period but were not as large. There was a large increase in the diagnosis of CS-related sepsis over time.

Previous research has identified risk factors for the development of CS SSI (Mu, 2011; Olsen, 2008; Stamilio & Scifres, 2014). This study was able to detect differences in the characteristics of women who developed endometritis, sepsis or CS wound disruption. Differences in the affected women, indicated that it was unlikely that a single intervention will eliminate SIE following CS. Knowledge about the conditions that increase the likelihood of discrete SIE occurrence could assist in guiding the development of specific prevention measures and accurately measuring their effectiveness.

There are no previous studies examining the association of CS with sepsis as a discrete event. Currently public health monitoring of maternal mortality by the State of Texas and the Centers for Disease Control includes only those cases resulting in death; and examination of severe maternal morbidity includes only those cases that occurred during the birth admission.

Serious infectious events included in this study, especially those resulting in readmission would not be detected by public health activities intended to monitor maternal health. This study demonstrated that readmission with sepsis following CS occurs rarely; however, when sepsis readmission does occur, it is life threatening. The occurrence of sepsis associated with CS should be considered a sentinel event, regardless of whether sepsis occurs during the birth admission or upon readmission. This study examined the effect of CS SIE using length of stay and utilization of critical care as indicators of the seriousness of SIE. These measures do not reflect the disruption of maternal/infant bonding, or the stress placed on families by SIE. Ongoing monitoring of SIE rates and the development of specific prevention measures to reduce maternal morbidity and mortality associated with CS are needed.

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## Appendix A

### Data Use Agreement



**TEXAS**  
**Department of State Health Services**

Phone: 512-776-7261 | E-mail: [thcichelp@dshs.state.tx.us](mailto:thcichelp@dshs.state.tx.us)

**Texas Health Care Information Collection  
 Center for Health Statistics**

### Data Use Agreement

#### Hospital Inpatient Discharge Public Use Data File

Sections 108.013(c)(1) and (2) and 108.013 (g) of the Texas Health and Safety Code (THSC) prohibit the Texas Department of State Health Services (DSHS) from releasing, and a person or entity from gaining access to, any data that could reveal the identity of a patient or the identity of a physician unless specially authorized under Chapter 108 of THSC.

Any effort to determine the identity of any person or to use the information for any purpose other than for analysis and aggregate statistical reporting violates the THSC and this data use agreement. By virtue of this agreement, the undersigned agrees that the data will not be used to identify an individual patient or physician.

Any questions about the data must be referred to the DSHS manager in charge of implementing Chapter 108 of THSC. Product support is not provided by DSHS.

The data are protected by United States copyright laws and international treaty provisions.

In this data use agreement, the requestor of the data is referred to as the "licensee," and can be any organization, employee of an organization, consumer or data purchaser that is responsible for complying with the following requirements:

<b>By initialing each item, the licensee gives the following assurances with respect to the use of Texas Inpatient Discharge Data sets:</b>	
DD	The licensee acknowledges the data is limited to the organization's physical location (specified below) unless purchasing a multiple organizational license;
DD	The licensee will not release nor permit others to release the individual patient records or any part of them to any person who is not a staff member of the organization (specified below), except with the written approval of DSHS;
DD	The licensee will not attempt to link nor permit others to attempt to link the outpatient records of patients in this data set with personally identifiable records from any other source;
DD	The licensee will not release nor permit others to release any information that identifies persons, directly or indirectly;
DD	The licensee will not attempt to use nor permit others to use the data to learn the identity of any physician;
DD	The licensee will not nor permit others to copy, sell, rent, license, lease, loan, or otherwise grant access to the data covered by this Agreement to any other person or entity, unless approved in writing by DSHS;
DD	The licensee acknowledges that when releasing or disclosing the data set or any part to others in their organization they will retain full responsibility for the privacy and security of the data and will prohibit others from further release or disclosure of the data;
DD	The licensee agrees to read the User Manual and understand the limitations of the data (User Manual located at: <a href="http://www.dshs.state.tx.us/thcic">www.dshs.state.tx.us/thcic</a> );
DD	The licensee will periodically check the DSHS/CHS/THCIC website for any technical updates to the data ( <a href="http://www.dshs.state.tx.us/thcic">www.dshs.state.tx.us/thcic</a> );
DD	The licensee will use the following citation in any publication of information from this file as: Texas Hospital Inpatient Discharge Public Use Data File, [quarter and year of data]. Texas Department of State Health Services, Austin, Texas. [date of publication];
DD	<u>Subject to applicable law</u> , the licensee will indemnify, defend and hold the DSHS, its members, employees, and its contract vendors harmless from any and all claims and losses accruing to any person as a result of violation of this agreement; and
DD	The licensee will make no statement nor permit others to make statements indicating or suggesting that interpretations drawn from these data are those of DSHS.

## Appendix B

## State University Sharing Data Use Agreement



Phone: 512-776-7261 | E-mail: [thcichelp@dshs.state.tx.us](mailto:thcichelp@dshs.state.tx.us)

For the purposes of this data use agreement an "Organization" is defined by its physical location (street address). Organizations that have multiple physical locations shall restrict access of the requested files listed on this document to the location listed on the document, unless purchasing a multiple organization license. (See page 4)

Note: Organization staff at the location listed on this document or contracted business associates to the licensee listed that do not regularly work at the physical location listed on this document are required to obtain their own data through DSHS, except with the written approval of DSHS.

Sharing of the data between two organizations, regardless of affiliation, is only allowed with the written approval of DSHS.

The licensee is required to comply with all federal and state confidentiality laws. The licensee agrees to the foregoing restrictions and acknowledges that the knowing or negligent release of data in violation of Chapter 108, Health and Safety Code, is punishable by a civil penalty of up to \$10,000 under section 108.014 and is a state jail felony under section 108.0141 and any other remedies available under the law to DSHS.

Please indicate the organization business type; mark only one type:			
X	Business Type	X	Business Type
X	Texas State Agencies and State Universities		Out of State Media
	Texas City/County/Local Government Health Departments		Out of State Agencies
	Texas Reporting Hospitals(provide THCIC ID below)		Out of State Universities
	Texas In-State Media		Out of State Hospitals
	Out of State Health Departments		All other businesses or consumers, including hospital or ASC affiliates, organizations, institutions, corporate offices
	Texas Private universities/colleges		

Signature of Licensee:  Date: 10/28/2016

Print or Type Name of Licensee: The University of Texas at Arlington, a State Institution of Higher Education established under the laws of the State of Texas as an institution of The University of Texas System

Title (if part of an Organization): Dr. Duane Dimos, Vice President for Research

Organization: The University Of Texas at Arlington  
College of Nursing and Health Innovation \*THCIC ID (for reporting hospitals only)

Organization Physical Address: 411 S. Nedderman Drive, Arlington, TX 76010

Mailing Address (if different than above): Box 19407

City: Arlington State: TX ZIP: 76019-0407

Phone Number: 817-272-2776

Fax Number: 817-272-5006

E-mail: jdbaker@uta.edu copy: ogcs@uta.edu

**Note to Licensee: Data product will be shipped to the mailing address provided above.**





Phone: 512-776-7261 | E-mail: [thcchelp@dshs.state.tx.us](mailto:thcchelp@dshs.state.tx.us)

**Public Use Data File**  
**THCIC PUDF State University Sharing Data Use Agreement Form**  
**(SUS-DUA)**

Sections 108.013(c)(1) and (2) and 108.013 (g) of the Texas Health and Safety Code (THSC) prohibit the Texas Department of State Health Services (DSHS) from releasing, and a person or entity from gaining access to, any data that could reveal the identity of a patient or the identity of a physician unless specially authorized under Chapter 108 of THSC.

Any effort to determine the identity of any person or to use the information for any purpose other than for analysis and aggregate statistical reporting violates the THSC and this data use agreement. By virtue of this agreement, the undersigned agrees that the data will not be used to identify an individual patient or physician.

Any questions about the data must be referred to the DSHS manager in charge of implementing Chapter 108 of THSC. Product support is not provided by DSHS.

The data are protected by United States copyright laws and international treaty provisions.

In this data use agreement, the requestor (state university researcher that signed for the data on the "Public Use Data File Hospital Inpatient Discharge Data Form") of the data is referred to as the "licensee", is responsible for complying data use agreement within that form.

The "Licensee's Collaborator" or Licensee's "Research Associate" is a person who has an academically related relationship with the Licensee at the same university. For example, the Licensee is the academic advisor to a student, or the Licensee is academic associate with another employee of the same university.

**Violations of data use agreement may carry civil or criminal penalties as authorized under THSC, Sections 108.014 and 108.0141.**

Signature of Licensee's Research Associate: Janet Glowicz Date: 12/16/2016

Print or Type Name of Research Associate : Janet Glowicz

Academic relationship (within the same University) for sharing the data released to the Licensee: Choose an Item.  
Doctoral Student

Which THCIC Public Use Data Files will the Research Associate be accessing (check all that apply):

Inpatient     Outpatient    Which Calendar (Years or Quarters) \_\_\_\_\_

Print or Type Name of Licensee (State Employee): Dr. Duane Dimos

Title (if part of an Organization): Vice President Research

Organization: University of Texas at Arlington

Organization Physical Address: 411 S. Nedderman Dr.

Mailing Address (if different than above): \_\_\_\_\_

City: Arlington    State: TX    ZIP: 76019-0407

Phone Number: 817-272-2776

E-mail: jbaker@uta.edu    copy: ogcs@uta.edu

December 16, 2016  
Hospital Inpatient Discharge Data





TEXAS  
Department of State Health Services

Texas Health Care Information Collection  
Center for Health Statistics

Phone: 512-776-7261 | E-mail: [thcichelp@dshs.state.tx.us](mailto:thcichelp@dshs.state.tx.us)

The "Research Associate" initial and agree with the following requirements:

By initialing each item, the licensee gives the following assurances with respect to the use of Texas Inpatient Discharge Data sets:	
	The licensee acknowledges the data is limited to the organization's physical location (specified below) unless purchasing a multiple organizational license;
	The licensee will not release nor permit others to release the individual patient records or any part of them to any person who is not a staff member of the organization (specified below), except with the written approval of DSHS;
	The licensee will not attempt to link nor permit others to attempt to link the inpatient records of patients in this data set with personally identifiable records from any other source;
	The licensee will not release nor permit others to release any information that identifies persons, directly or indirectly;
	The licensee will not attempt to use nor permit others to use the data to learn the identity of any physician;
	The licensee will not nor permit others to copy, sell, rent, license, lease, loan, or otherwise grant access to the data covered by this Agreement to any other person or entity, unless approved in writing by DSHS;
	The licensee acknowledges that when releasing or disclosing the data set or any part to others in their organization they will retain full responsibility for the privacy and security of the data and will prohibit others from further release or disclosure of the data;
	The licensee agrees to read the User Manual and understand the limitations of the data (User Manual located at: <a href="http://www.dshs.state.tx.us/thcic">www.dshs.state.tx.us/thcic</a> );
	The licensee will periodically check the DSHS/CHS/THCIC website for any technical updates to the data ( <a href="http://www.dshs.state.tx.us/thcic">www.dshs.state.tx.us/thcic</a> );
	The licensee will use the following citation in any publication of information from this file as: Texas Hospital Inpatient Discharge Public Use Data File, [quarter and year of data]. Texas Department of State Health Services, Austin, Texas. [date of publication];
	The licensee will indemnify, defend and hold the DSHS, its members, employees, and its contract vendors harmless from any and all claims and losses accruing to any person as a result of violation of this agreement; and
	The licensee will make no statement nor permit others to make statements indicating or suggesting that interpretations drawn from these data are those of DSHS.

Copy, Scan and Send of this Document

Licensee and Research Associated should retain a copy of this document and provide a copy of this agreement to [THCICHelp@dshs.state.tx.us](mailto:THCICHelp@dshs.state.tx.us).

## Appendix C

**THCIC Data Fields Used in Analysis**

<b>Data Field</b>	<b>Definition</b>	<b>Purpose of Variable</b>
THCIC ID	Unique ID given to facilities by THCIC	This ID was used to verify the location of hospitals and to generate the variable, “Rural Facility”
Provider City	City in which facility is located, provided by facility	Determine rural or urban location of facility
Provider Zip	Zip code in which facility is located, provided by facility	Determine rural or urban location of facility
Facility Teaching Indicator	Teaching facilities indicate membership in Council of Teaching Facilities	Determine designation as a teaching facility
Specialty Unit 1-5	Specifies units within the hospital that provide specialized care	Determine the receipt of critical care
Sex	Gender as recorded on date of start of care	Females were included. Males, or unknown were excluded
Patient Age Category	Age of patient in years on date of discharge from birth admission, category	Describe the influence of age on development of SIE. Age less than 10 years or over 60 years excluded
Patient State	Patient address, state as provided by patients	Inclusion/Exclusion criteria. Residence outside of Texas is excluded
Race	PUDF code indicating patient race	Describe influence of race on development of SIE
Ethnicity	Code indicating patient Hispanic or Non-Hispanic Origin	Describe influence of Hispanic ethnicity on development of SIE
Patient County	FIPS code of patient’s county	Generate variable “Rural Residence” to explore influence of residence on development of SIE
Type of Admission	Code indicating type of admission	Generate variable, “Emergent Admit”
Length of Stay	Number of days the participant was hospitalized	Compare the length of stay among participants with SIE to those without
Patient Status	Code indicating patient status (i.e. discharge status) at ending episode of care	Inclusion/Exclusion criteria. Used to determine discharge status
Principal Diagnosis	ICD 9 diagnosis	Describe primary diagnosis. Patients with diagnostic code for Cesarean Section Wound Disruption were included
Other Diagnosis Codes 1-28	ICD 9 diagnosis	All available diagnostic codes were surveyed for the presence of a code indicating SIE or a pathogen code. Other diagnosis code fields 1-5 were used to identify and describe co-morbidities.
Surgical Procedure Code; Principal and 1-10	Code for the principal surgical or obstetrical procedure performed during the period covered by the bill	Inclusion criteria. Patients with ICD 9 indicating CS were included

## Appendix D.

**Diagnostic Codes Indicating Comorbidities**

<b>Diagnosis</b>	<b>Code</b>
Abnormality of Fetal Heart Rate	65971
Anemia	64821, 64822, 64824, 2851, 2859
Cellulitis of Trunk	6822
Chorioamnionitis	65841
Diabetes mellitus of mother	64800, 64801, 64802, 64803, 64804
Early Onset of Labor	64421
Obesity, Morbid Obesity	27801, 64914
Post Term Pregnancy	64511
Previous Cesarean Section	65421
Septic Shock	78552
Severe Pre-eclampsia	64251