

2020

The Association Between Central Line Insertion Practices and Central Line-Associated Bloodstream Infections

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Walden University

College of Health Sciences

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Mona Ahmed Elgowainy

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Walden University

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Abstract

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Bloodstream Infections

by

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BS, University of North Carolina at Charlotte, 2007

MSPH, University of North Carolina at Charlotte, 2012

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Public Health

Walden University

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Abstract

Healthcare-associated infections, specifically central line-associated bloodstream infections (CLABSI), continue to remain a serious public health concern in the United States. Though CLABSI can often be prevented, healthcare professionals struggle to have a positive impact on CLABSI rates. The primary purpose of this study was to determine whether CLIP Bundle adherence has an impact on CLABSI standardized infection ratio (SIR) rates in various patient care areas in California. The research questions were focused on assessing whether there was an association between patient care areas, CLABSI rates, and CLIP Bundle adherence scores. A quantitative, cross-sectional study design utilizing secondary data was used to assess the association between CLIP Bundle adherence and CLABSI rates. Quantile regression analyses indicated CLIP Bundle adherence was consistent across all patient care areas, but that critical care area was significantly negatively associated with CLABSI SIR rates. In addition, quantile regression analysis indicated there was no statistically significant difference between critical care areas and general care areas as compared with neonatal care area with regard to CLIP Bundle adherence. Results from ANOVA analyses indicated there was a statistically significant association between patient care area and SIR, but not between patient care area and CLIP Bundle adherence. Results indicated that reduced infection rates were associated with an increased CLIP Bundle adherence. The study positively impacts positive social change by encouraging health care providers to implement the CLIP Bundle to improve patient care in their healthcare facilities nationwide to reduce the national incidence of CLABSI rates.

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Dedication

I dedicate this dissertation to Daddy and Mommy, Theodore, all my family members, and my new family- Daniel, Dahlia, Shia, and Marley. Without all of you, I would not be here to complete this final academic milestone. I love you all so much, and thank you for all your love, encouragement, and support.

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Chapter 1: Introduction to the Study

Introduction

Healthcare-acquired infections (HAIs) are types of infections that result from receiving medical care from health care facilities (Office of Disease Prevention and Health Promotion [ODPHP], 2018). HAIs can be acquired from any healthcare facility, such as a hospital, surgery center, or long-term care facilities (ODPHP, 2018). The most common pathogen associated with HAIs are bacteria, though infection can also result from fungi and viruses (ODPHP, 2018). Some of the most common HAIs include central line-associated bloodstream infections (CLABSI), catheter-associated urinary tract infections, surgical site infections, and ventilator-associated pneumonia (Centers for Disease Control and Prevention [CDC], 2014). HAIs are a significant public health concern as they may result in increased morbidity and mortality, prolonged length of hospital stays, and increased medical care costs for patients (Polin, Denson, Brady, & Committee on Fetus and Newborn, & Committee on Infectious Diseases, 2012). Annually, HAIs affect more than two million patients of all ages in the United States. (Polin et al., 2012). In addition, HAIs have an economic burden in the United States and can contribute to over two billion dollars annually in costs to the healthcare system (ODPHP, 2018).

One of the most common HAIs is CLABSI (Sadowska-Krawczenko, Jankowska, & Kurylak, 2012), in which the infection occurs as a result of pathogens entering the bloodstream through a central line catheter (CDC, 2011a). Patients in intensive care units (ICUs) are at a significantly higher risk of acquiring CLABSI and subsequent central line

complications (Hina & McDowell, 2017). The most recent data from CDC (2018c) indicated an 11% decrease in CLABSI between 2015 and 2016 compared to the national baseline. Much of this success is due to infection prevention efforts, such as appropriate hand hygiene practices, adequate central line insertion techniques, and utilization of maximal sterile protection barriers (CDC, 2011b).

Central line insertion practices (CLIP), which refers to proper central line placement and management, was introduced by the CDC (2018a) to prevent or reduce the risk of CLABSI occurrence. In addition, CDC's National Healthcare Safety Network (NHSN) developed the CLIP Bundle, which comprises of eight components that include proper hand hygiene practices, appropriate skin preparation, and use of all five maximal sterile barriers (sterile gloves, sterile gown, cap, mask, and large sterile drape for the patient) when inserting a central line (CDC, 2018a). Though a decrease in infection rates have been achieved, CLABSI continues to remain a public health concern.

The most recent data indicates that there are over 30,000 cases of CLABSI that still occur in ICU units in the United States (CDC, 2018d). Conducting a study to determine the CLIP Bundle adherence scores for California hospitals can help healthcare providers identify quality improvement opportunities to reduce CLABSI risk (CDC, 2018a). Currently, CLIP Bundle adherence is only mandated in two states, including California (Quan et al., 2016). Therefore, the implications of the study can impact positive social change by influencing policymakers and health care providers to implement the CLIP Bundle in their healthcare facilities nationwide to reduce the national incidence of CLABSI.

This chapter provides an overview of the research study. It begins with the background information on the prevalence of CLABSI and a description of a CDC developed protocol to prevent or reduce the occurrence of CLABSI. This chapter then provides a detailed description of the problem statement and the purpose of the study. Further, I note the research questions and hypotheses. Next, I explain the theoretical framework, the nature of the study, the definitions, and the assumptions, scope, delimitations, and limitations of the study. In addition, I provide an overview of how the results of this study could contribute to the field in the significance of the study section. Finally, I include a summary of the chapter to highlight the important areas that are discussed in this chapter.

Background

CLABSI is among the most common types of HAIs in the United States, and it remains highly prevalent in acute care settings (Linder, Gerdy, Abouzelof, & Wilson, 2017; Liu, 2017). Patients with CLABSI often experience longer hospital stays, increased medical costs, and an increased risk of mortality (Lin et al., 2015; Kuo et al., 2018). Though CLABSI can occur within various hospital departments, they are more frequent among patients receiving central lines in ICUs, representing nearly 35% of reported infections (O'Neil et al., 2016).

The neonatal population is very susceptible to HAIs, and CLABSI (Legeay, Bourigault, Lepelletier, & Zahar, 2015). The neonatal population has many risk factors associated with CLABSI, including underdeveloped immune systems, low birth weight, the presence of a central line, and the use of ventilation devices (Legeay et al., 2015).

CLABSI is also highly prevalent among the adult population, especially those with comorbidities (Pepin et al., 2016). However, both the neonatal population and the adult population are highly susceptible to CLABSI due to poor catheter insertion technique, inadequate hand hygiene, and poor skin preparation (World Health Organization [WHO], 2018a). Healthcare professionals receiving education and instruction regarding the proper way to insert a catheter into a patient can reduce the risk of CLABSI (Legeay et al., 2015). In addition to proper catheter insertion, practicing adequate hand hygiene and proper skin preparation prior to inserting a catheter can also reduce the risk of CLABSI (Goudet et al., 2013; Ling et al., 2016).

As improper catheter insertion and inadequate hand hygiene practices are among the biggest risk factors for CLABSI, a comprehensive program was developed by the CDC (2018a) to prevent or reduce the risk of CLABSI occurrence. To address both risk factors, the CLIP Bundle was initiated, which comprises of eight components that include proper hand hygiene practices, appropriate skin preparation, and use of all five maximal sterile barriers (sterile gloves, sterile gown, cap, mask, and large sterile drape for the patient) when inserting a central line (CDC, 2018a). The CLIP Bundle components were revised in 2016, and as such, there is a paucity of literature regarding the implementation and reporting of the CLIP Bundle (CDC, 2018a). In addition, currently, reporting of the CLIP Bundle is only mandated in two states, therefore creating a gap in the literature regarding the impact of CLABSI rates when using the CLIP Bundle (Quan et al., 2016).

Consequently, due to the paucity of research on this subject in the literature, the study was needed to add valuable information to the literature regarding the use of the

CLIP Bundle to provide proper central line placement and management techniques, as well as appropriate hand hygiene techniques, to reduce the risk of CLABSI. In addition, the study was needed to understand the impact of CLABSI rates in various patient care areas not previously studied with the use of the CLIP Bundle.

Problem Statement

CLABSI continues to remain the most common HAI seen in the United States (CDC, 2018c). In many cases, HAIs, and specifically CLABSIs, can be prevented (Christina, Ioanna, George, Konstantinos, & Georgios, 2015). Proper hand hygiene techniques are among the best practice guidelines to prevent the spread of bacteria and reduce infection, yet infection rates continue to be problematic in the healthcare setting (Sadowska-Krawczenko et al., 2012). There are many studies describing the epidemiology of CLABSI (Kato et al., 2018; Venturini et al., 2016), as well as infection prevention strategies such as hand hygiene protocols, CLABSI intervention bundles, and safety programs. Empirical evidence from these studies indicate the positive impact of infection prevention strategies on CLABSI rates, but none, to the best of my knowledge, have investigated the impact of the CLIP Bundle on minimizing CLABSI rates (Woodward & Umberger, 2016).

Furthermore, previous CLABSI studies have focused primarily on the intensive care setting. These studies have not included other patient care areas with different types of patients with different care needs, such as rehabilitation and critical access care. In addition, previous studies did not investigate the impact of a comprehensive program, combining infection prevention strategies, and central line insertion practices and

maintenance, and CLABSI rates. Therefore, the empirical value of the newly released CLIP Bundle data on reducing CLABSI rates in different patient care areas is uncertain. Understanding the impact of the CLIP Bundle can contribute to positive social change by helping health care professionals recognize the necessity of a comprehensive program to reduce CLABSI rates among various patient care areas in the United States.

Purpose of Study

The primary focus of this quantitative study was to determine whether CLIP Bundle adherence has an impact on CLABSI rates in patient care areas in California. I examined the association between CLIP Bundle adherence scores, which is calculated as the total number of adherent insertions divided by the total number of CLIP Bundle observations and standardized infection ratio (SIR), defined as the number of infections reported compared to the number of infections predicted in different patient care areas (CDC, 2018b). Rather than utilizing aggregated infection rates previously provided by NHSN, SIR was utilized, which allowed for comparisons of risk-adjusted rates within different strata. SIR was calculated to control for various factors, such as facility bed size, facility type, the average length of stay, and the use of a ventilator, which may potentially impact the risk of acquiring CLABSI (CDC, 2018b).

Finally, the study was to determine whether there were differences among CLIP Bundle adherence scores between patient care areas, such as critical care areas, neonatal critical care, general care areas, and special care areas. An understanding of the associations mentioned above will fill a gap in the literature regarding the practice of the CLIP Bundle to address hospital CLABSI rates. In addition, this research may raise

awareness of the benefits of monitoring and tracking the CLIP Bundle adherence scores for an effective CLABSI risk-reduction quality improvement initiative.

Research Questions and Hypotheses

RQ1: Is patient care area associated with CLABSI SIR rates, controlling for central line days, region, and bed size?

H_01 : Patient care area is not associated with CLABSI SIR rates, controlling for central line days, region, and bed size.

H_{a1} : Patient care area is associated with CLABSI SIR rates, controlling for central line days, region, and bed size.

RQ2: Is patient care area associated with CLIP Bundle adherence, controlling for central line days, region, and bed size?

H_02 : Patient care area is not associated with CLIP Bundle adherence, controlling for central line days, region, and bed size.

H_{a2} : Patient care area is associated with CLIP Bundle adherence, controlling for central line days, region, and bed size.

RQ3: Is there an association with CLIP Bundle adherence scores and CLABSI SIR rates within different patient care areas?

H_03 : There is no association with CLIP Bundle adherence scores and CLABSI SIR rates within different patient care areas.

H_{a3} : There is an association with CLIP Bundle adherence scores and CLABSI SIR rates within different patient care areas.

Theoretical Framework

The theoretical framework for this study was the chain of infection, an extension of the epidemiologic triad model (CDC, 2012). The epidemiologic triad model is used to show that infectious disease arises from the collaboration of an agent, host, and environment (CDC, 2012). As an extension of this model, the chain of infection is indicative of the fact that transmission of infection occurs when the agent exits the host (or reservoir) through a portal of exit, which begins the mode of transmission, and enters a susceptible host through a portal of entry (CDC, 2012). The chain of infection framework, which is shown in Figure 1, can be applied to this research as it can provide insight into the CLABSI incidence rates among the population (CDC, 2012). By using the CLIP Bundle, the chain of infection should be disrupted and the risk of infection potentially decreased (CDC, 2012). Theoretically, if CLIP Bundle adherence scores are higher, CLABSI SIR rates will be lower (CDC, 2018b).

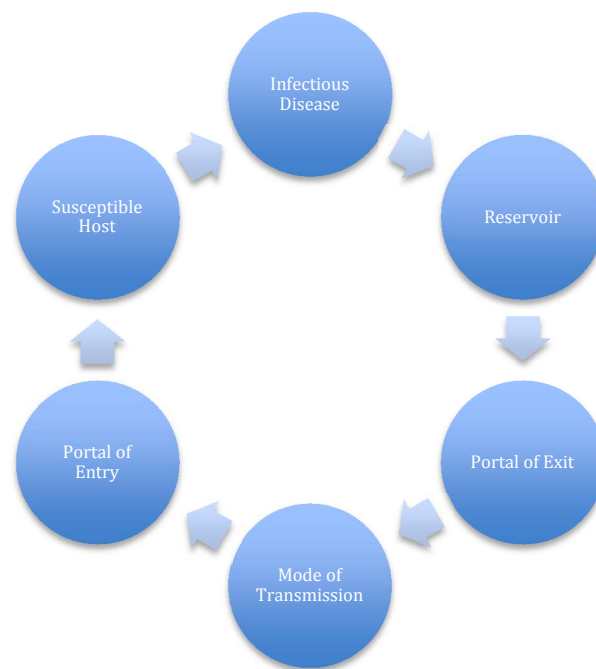


Figure 1. Chain of infection. Source: CDC (2012).

Nature of Study

Due to the CDC collecting and publishing CLABSI data and CLIP Bundle adherence scores amongst California facilities, the nature of this study was quantitative. By utilizing two statewide databases, I analyzed secondary data to identify the incidence of CLABSI among different patient care areas in hospitals in California. Additionally, I utilized these secondary datasets to identify associations between the CLIP Bundle adherence scores and SIR rates and to determine whether there are differences between the CLIP Bundle adherence scores across the different patient care areas.

I collected CLABSI data from various health care facilities in California by the California Department of Public Health (California Health & Human Services Agency [CHHS], 2018). I calculated one of the dependent variables, CLABSI SIR rates, by the numbers of infections reported and a number of infections predicted that have already been collected in the secondary dataset (CHHS, n.d.). I calculated the second dependent variable, CLIP Bundle adherence scores, as the total number of adherent insertions (i.e., adherence to all eight components of the CLIP bundle) divided by the total number of CLIP insertions throughout various hospital locations (CHHS, n.d.). Among the independent variables, patient care areas were categorized to include critical care, neonatal critical care, general care areas, and specialty care areas; all of these are representative of NHSN categorized care areas that are used for risk adjustment (CHHS, n.d.).

Definitions

The following section describes terms that were used throughout the study. Many of these terms may have multiple meanings, are often used in the healthcare field, or are referenced in the secondary dataset that was utilized for this study.

Central line-associated bloodstream infection (CLABSI): Type of HAI acquired within 48 hours of central line/central venous catheter placement; considered a primary infection unrelated to any additional secondary infection from another source; commonly occurs with prolonged catheter use and poor hand hygiene techniques (Joint Commission, 2018).

Central line/central venous catheter: Terms used to describe a medical device that is inserted in a large vein of a patient's neck, chest, groin, or arm; this tube is used to administer fluids, blood, or medication and can remain in the patient for weeks or months at a time (CDC, 2011a).

Central line days: Represents the total count of the number of patients with central lines for each day of the month, at the same time each day (CHHS, n.d.).

Central line insertion practices (CLIP): Protocol developed by the CDC's NHSN to ensure proper central line placement and management; the goal of the protocol is to prevent or reduce the risk of CLABSI occurrence (CDC, 2018a).

CLIP adherence scores: Referenced in the secondary dataset that indicates that healthcare professionals answered "yes" to all eight components of the CLIP Bundle for central lines inserted following January 1, 2016 (CDC, 2018a).

CLIP Bundle: Use of NHSN's CLIP protocol following January 1, 2016, that requires performing all of the following components: (a) performing appropriate hand hygiene; (b) utilizing appropriate skin prep (povidone iodine or alcohol for patients less than 60 days old, chlorhexidine gluconate (CHG) for patients greater than 60 days old); (c) allowing skin preparation agent to completely dry before central line insertion; and (d) use of all five maximal sterile barriers (sterile gloves, sterile gown, cap, mask, and large sterile drape that covers the patient's entire body; CDC, 2016a).

Critical care areas: Hospitals with 25 or fewer acute care inpatient beds, with an average length of stay of 4 days or less; these hospitals are typically located more than 35 miles from another acute care hospital; includes major teaching hospitals, medical/surgical care, burn critical care, trauma critical care, long-term acute critical care, and pediatric critical care (CHHS, n.d.).

Extrinsic risk factor: External, modifiable risk factors, such as hospitalization, lack of maximal sterile barriers, and the location of the central line that can contribute to infection (Joint Commission, 2018).

General care areas: Various wards in hospitals, including adult, pediatric, medical/surgical, surgical, long-term acute care, rehabilitation, labor, delivery, recovery, behavioral health/psychiatric, jail (CHHS, n.d.).

HAI (healthcare-associated infection): Infections acquired in healthcare settings after receiving care; infections can occur as a result of poor hand hygiene and/or devices used in medical procedures (CDC, 2014).

Intrinsic risk factor: Internal, nonmodifiable risk factors, such as age, comorbidities, and an individual's bacterial flora, that can contribute to infection (Joint Commission, 2018).

Mixed acuity care areas: Hospital areas for the treatment of patients whose conditions are at varying levels of acuity (critical care, general care, specialty care, etc.) (CHHS, n.d.).

Neonatal critical care: Care areas within hospitals specifically utilized by for neonatal patients; further subdivided by birth weight categories: ≤ 750 grams, 751-1000 grams, 1001-1500 grams, 1501-2500 grams, and $> 2,500$ grams (CHHS, n.d.).

Pathogen: Infectious agent, such as bacteria, viruses, or fungi, that causes a disease to its host (Science Daily, 2018).

Specialty care areas: Specialized care areas in the hospital, such as oncology, hematology, bone marrow transplant, solid tumor ward, and solid organ transplant (CHHS, n.d.).

Standardized infection ratio (SIR): Value used in the secondary dataset that was calculated as the number of infections reported compared to the number of infections predicted in different hospital locations (CDC, 2018b); SIR value > 1.0 indicates more CLABSI episodes were reported than predicted, based on national aggregate data; SIR value < 1.0 indicates fewer CLABSI episodes were reported than predicted, based on national aggregate data (CDC, 2018e).

Assumptions

This study was based upon statewide data submitted by California facilities and published by NHSN to the CDC's website. For the purposes of this study, I assumed that data was reported truthfully and accurately. In addition, I assumed that all California facilities were truthful in reporting CLIP Bundle adherence scores, indicating their complete participation among all eight components of the Bundle, which contributes to the SIR calculation. Finally, I assumed that all cases of CLABSI were accurately reported to represent the truthful incidence of infection in California facilities.

Scope and Delimitations

The scope of the research was to address the impact the CLIP Bundle adherence score had on CLABSI rates among different patient care areas in California facilities. Various patient care areas that reported CLIP Bundle adherence scores were included in this study: critical care, general care, neonatal critical care, specialty care, and mixed acuity care. The scope of the study was limited to the number of CLABSI cases as reported by the hospitals in 2015; similarly, the infections predicted were limited to those determined by the 2015 national baseline data (CHHS, n.d.).

The study included both the neonatal population and the adult population, as CLABSI rates were reported for both population types. The chain of infection was the best framework chosen for this study as it identifies components that could potentially be disrupted, thus reducing the risk of infection (CDC, 2012). Using all the components in the CLIP Bundle introduces a disruption to the chain of infection, thereby reducing the

risk of CLABSI (CDC, 2012). Because the data only includes data from California facilities, it may not be generalizable to other states.

Limitations

Study limitations included the use of a secondary dataset. Because the data was already collected and published by the CDC, there may have been data quality issues, missing data, or incorrect data; as a result, CLABSI rates may be under- or overestimated. In addition, although SIR adjusts for certain factors, such as facility bed size, facility type, the average length of stay, and the use of a ventilator, it does not adjust for individual patient factors that can potentially impact risk of infection (CHHS, n.d.). Additionally, SIR is not able to be compared across different hospitals due to the lack of standardization of methodology in calculating the SIR (CHHS, n.d.).

Another limitation included the reporting of CLIP adherence scores; as the CLIP Bundle includes eight components; healthcare professionals could only answer “yes” if compliant to all eight components, and the data provides no visibility into knowing which components were missing if answered “no” (CHHS, n.d.). Similarly, because reporting the CLIP adherence scores was based on self-reported data, bias could influence the study outcome, as the answers may not be entirely truthful. Finally, because the data is only representative of facilities in one state, the results of the study may not be generalizable to other states. To address limitations, measures were taken in the data analysis section to adjust for these potential biases.

Significance

To address a gap in the research, I explored the impact that CLIP Bundle adherence has on CLABSI rates. This study was innovative as it was focused on a relatively new technique developed by the CDC to improve central line practices and reduce CLABSI occurrence (CDC, 2018a). The results of this study elucidated the statewide incidence of CLABSI among different patient care areas in California hospitals. In addition, the results of this study provided insight into the CLIP Bundle adherence scores and SIR rates among different patient care areas in California facilities. Finally, the results of this study provided insight into understanding the association between the CLIP Bundle adherence scores and SIR rates among different patient care areas among California hospitals. Insights from this study could lead to positive social change by providing valuable information that can serve to aid medical and public health officials to enhance central line clinical and aseptic preventative techniques to reduce CLABSI rates.

Summary

Though many HAIs, specifically CLABSI, can be prevented, they remain a prevalent public health problem in the healthcare setting. The two biggest risk factors of CLABSI include improper central line insertion and management techniques and inadequate hand hygiene techniques; failure to properly adhere to either of these results in an increased risk of developing CLABSI. CLIP was developed by the CDC to help healthcare professionals improve central line insertion practices and management and reduce the CLABSI incidence. Additionally, by introducing the CLIP Bundle, healthcare

professionals could improve their hand hygiene techniques, thereby continuing to reduce the CLABSI incidence.

Due to a paucity of literature regarding the use of the CLIP Bundle, this quantitative study contributes to the current literature and can potentially determine what impact the CLIP Bundle adherence scores among various patient care areas within California facilities have on CLABSI rates. Finally, this research promotes social change by raising awareness of the benefit of monitoring and tracking the CLIP Bundle adherence scores for an effective CLABSI risk-reduction quality improvement initiative. Chapter 2 provides a more in-depth analysis of the current literature associated with CLABSI, including the epidemiology of CLABSI, pathogenesis of CLABSI, risk factors associated with CLABSI, infection prevention strategies, and CLIP Bundle.

Chapter 2: Literature Review

Introduction

HAIs are a significant public health concern as they may result in increased morbidity and mortality, prolonged hospital stays, and increased medical care costs for patients (Polin et al., 2012). Annually, HAIs affect more than two million patients of all ages in the United States (Polin et al., 2012). One of the most common HAIs is CLABSI (Sadowska-Krawczenko et al., 2012) in which the infection occurs because of pathogens entering the bloodstream through a central line catheter (CDC, 2011a). Central line catheters are placed into a patient's chest or neck vein to draw blood and/or to deliver fluids and medications (Johns Hopkins Medicine, n.d.). Central lines can be kept in place for several weeks or months if necessary (Johns Hopkins Medicine, n.d.). As a result of prolonged use, patients in ICUs are at a significantly higher risk of acquiring CLABSI and subsequent central line complications (Hina & McDowell, 2017).

In many cases, HAIs, and specifically CLABSI, can be prevented (Christina et al., 2015). Proper hand hygiene techniques are among the best practice guidelines to prevent the spread of bacteria and reduce infection (Sadowska-Krawczenko et al., 2012). Legeay et al. (2015) attributed the common occurrence of CLABSI to poor hand hygiene and poor central line insertion techniques. CLIP, which refers to proper central line placement and management, was introduced by the CDC (2018a) to prevent or reduce the risk of CLABSI occurrence. In addition, the CDC's National Healthcare Safety Network (NHSN) developed the CLIP Bundle, which comprises eight components: proper hand hygiene practices, appropriate skin preparation, and use of all five maximal sterile barriers (sterile

gloves, sterile gown, cap, mask, and large sterile drape for the patient) when inserting a central line (CDC, 2018a). Monitoring and tracking the CLIP Bundle adherence scores can help healthcare providers identify quality improvement opportunities to reduce CLABSI risk (CDC, 2018a).

Though many studies examine proper hand hygiene techniques and proper central line placement and management (Kato et al., 2018; Venturini et al., 2016), there is a paucity of literature regarding the practice of the CLIP Bundle to address hospital CLABSI rates (Woodward & Umberger, 2016). The literature is even more scarce when it comes to determining how adhering to the CLIP Bundle impacts the rates of CLABSI in different patient care areas and throughout different hospitals in California. Therefore, the purpose of this quantitative research study was to use secondary data to determine if CLIP Bundle adherence has an impact on CLABSI rates in different patient care areas among different hospitals throughout California. Future researchers and healthcare professionals can use this information to develop better preventative techniques to reduce the occurrence of CLABSI in hospitals.

I begin this chapter by describing the literature search strategy used to find relevant articles and explaining the theoretical framework applied to this topic. Following these sections, I discuss the past literature on the public health and epidemiology impact of CLABSI, the pathogenesis of CLABSI, risk factors associated with CLABSI (such as patient populations and hospital locations), and infection prevention strategies. I close this chapter with a detailed summary and conclusion section of the literature discussed.

Literature Search Strategy

To obtain the most recent and relevant literature, I searched the majority of the articles through the Walden Library databases. The health sciences databases were among the most frequently accessed databases. The main Health Sciences databases search included: CINAHL & MEDLINE Combined Text, CINAHL Plus with Full Text, MEDLINE with Full Text, and Science Direct. Due to the clinical nature of the topic, I also searched the nursing databases. The main nursing databases searched included: ProQuest Health & Medical Collection, and ProQuest Nursing & Allied Health Source. The key search terms included *central line-associated bloodstream infections, CLABSI, CLABSI risk factors, CLABSI prevention, central line insertion practices, CLIP, central line placement, central venous catheters, central line management, and infection prevention strategies*. In addition to searching Walden Library databases, I explored relevant information regarding CLABSI and CLIP protocol via the CDC website. In addition, I also searched legitimate medical websites, such as Johns Hopkins and the Joint Commission, for additional CLABSI information.

Utilizing the health sciences databases and nursing databases, the search parameters for the most current and relevant articles were from 2012-2018. The most pertinent articles were reviewed and included in this literature review. Because there was limited published literature regarding CLIP, the majority of the information came directly from the CDC's website. However, because the eight components of the CLIP all encompass infection prevention strategies, I searched the Walden Library databases for articles that examine various infection prevention strategies as they related to CLABSI.

Theoretical Framework

The theoretical framework for this study was the chain of infection, an extension of the epidemiologic triad model (CDC, 2012). The epidemiologic triad model is used to show that infectious disease arises from the collaboration of an agent, host, and environment (CDC, 2012). As an extension of this model, the chain of infection is indicative of the fact that transmission of infection occurs when the agent exits the host (or reservoir) through a portal of exit, which begins the mode of transmission, and enters a susceptible host through a portal of entry (CDC, 2012). The chain of infection framework, which was shown in Figure 1 in Chapter 1, was applied to this research as it could provide insight into the CLABSI incidence rate among the population (CDC, 2012).

The reservoir is the habitat where the microorganisms live and thrive, which can include humans, animals, and the environment (CDC, 2012). In the case of CLABSI, humans are the reservoirs, as microorganisms are spread from person to person (CDC, 2012). The portal of exit is the passageway through which the microorganism leaves the host, which typically corresponds to the location of where the microorganism is contained (CDC, 2012). The mode of transmission refers to the way the microorganism is transmitted from the reservoir to the host directly or indirectly; in the case of CLABSI, the mode of transmission is direct contact through person to person (CDC, 2012). The portal of entry refers to the way in which the microorganism enters the host (CDC, 2012). However, for the microorganism to multiply and spread, the portal of entry must provide access to the tissues of the host (CDC, 2012). The final link in the chain is the susceptible

host that the microorganism infects (CDC, 2012). Humans can be extremely susceptible hosts for microorganisms to enter if they are immune-compromised, are surgical candidates, or if they are kept in the hospital for long periods of time (CDC, 2012). Using the chain of infection, microorganisms can infect susceptible hosts and lead to the development of CLABSI (CDC, 2012).

The chain of infection framework as it relates to infection prevention has been described by Mitchell and Gardner (2014). The chain of infection has been described as a biomedical framework, as it highlights the importance of education, individual responsibility, and treating infected patients in isolation (Mitchell & Gardner, 2014). The chain of infection framework can be applied to the prevention of CLABSI if any link in the chain is broken (Mitchell & Gardner, 2014).

Central Line-Associated Bloodstream Infections

CLABSI is among the leading cause of HAIs affecting patients in the United States (CDC, 2011a). Although this type of HAI is highly preventable, CLABSI remains extremely prevalent in acute care settings in the United States (Liu, 2017; Linder et al., 2017). In addition to the clinical nature of HAIs, CLABSI represents a chief public health concern. Further, patients who are affected by CLABSI often experience longer hospital stays, increased hospital and medical care costs, and an increased risk of mortality (Lin et al., 2015; Kuo et al., 2018).

It has been estimated that nearly 250,000 CLABSI infections occur annually in the United States, resulting in nearly 60,000 deaths (Drews, Bakdash, & Gleed, 2017; Haddadin & Regunath, 2017). Of the 250,000 CLABSI infections, nearly 80,000 occur in

ICUs (O'Neil et al., 2016). Central lines are often provided for critically ill patients in ICUs and those undergoing surgical procedures to aid in fluid and medication delivery (Liu 2017; Reyes, Bloomer, & Morphet., 2017). Patients already diagnosed with CLABSI may require the removal of their initial central line to replace it with a second central line, which increases the risk of developing CLABSI for the second time (Isguder et al., 2017). Prolonged hospital stays as a result of CLABSI can range from 5-20 days and can be associated with a mortality rate ranging from 4%-20% (Drews et al., 2017; Zavotsky, Malast, Festus, & Riskie, 2015). CLABSI also contributes to a significant financial burden on patients. Zavotsky et al. (2015) determined that a single episode of CLABSI can range from \$30,000-\$56,000, which includes the cost of central line changes, prescribed medications, microbiological and laboratory tests, and additional days in the hospital.

CLABSI can be caused by a wide variety of pathogens including bacteria and fungi (CDC, 2017a). In January of 2017, the NHSN from the CDC developed a list of over 500 organisms responsible for causing various laboratory-confirmed bloodstream infections (LCBI; CDC, 2017a). Gram-positive organisms were among the most prevalent microorganisms responsible for causing CLABSI in humans (Haddadin & Regunath, 2017). Specifically, the most common isolated Gram-positive microorganisms include coagulase-negative *Staphylococci*, *Enterococci*, and *Staphylococcus aureus* (Haddadin & Regunath, 2017). Gram-negative organisms were the next most common causative microorganisms including *Klebsiella*, *Enterobacter*, *Pseudomonas*, *E. coli*, and *Acinetobacter* (Haddadin & Regunath, 2017). Finally, fungi such as *Candida* species are

also common causative CLABSI agents (Haddadin & Regunath, 2017). Gram-negative and Gram-positive bacteria are the most common microorganisms that contaminate central lines (Lin et al., 2015).

Lin et al. (2015) conducted a prospective surveillance study among 156 critically ill patients that aimed to identify the incidence and microbial characteristics of CLABSI in a large medical center. The incidence of CLABSI was determined to be 3.93 per 1,000 central line days (Lin et al., 2015). The authors concluded that Gram-negative bacteria caused 39.2% of CLABSI episodes and that Gram-positive bacteria caused 33.2% of the CLABSI episodes (Lin et al., 2015). Further, a retrospective study conducted by Kuo et al. (2018) indicated the CLABSI incidence among adult ICUs was 3.47 per 1,000 central line days. Gram-negative bacteria were also the leading pathogen causing CLABSI episodes (59.3%), which is similar to Lin et al. (2015) findings. Kuo et al. (2018) also determined that Gram-positive bacteria (24.8%) was second with fungi (23.4%) being the third leading cause of CLABSI, which also corresponds to Lin et al. (2015) findings.

The most common causative pathogens isolated included *Staphylococcus aureus*, *Enterococcus*, *Enterobacter* spp., *Klebsiella* spp., and *Acinetobacter* spp. (Kuo et al., 2018). It is also important to note that the authors identified that 9% of the pathogens were multidrug resistant organisms (Kuo et al., 2018). Similar results were also obtained from a prospective cohort study conducted by Venturini et al. (2016) that indicated the incidence of CLABSI was 3.73 per 1,000 central line days among children admitted to a single hospital. Venturini et al. (2016) identified nine CLABSI episodes, among which five were caused by *Enterobacter* spp., which was one of the most common causative

pathogens in Kuo et al.'s (2018) research as well. To ensure healthcare professionals are treating CLABSI effectively, it is important for healthcare professionals to be aware of the most common causative agents associated with CLABSI.

Pathogenesis of Central Line-Associated Blood Stream Infections

CLABSI is one of the most common HAIs affecting patients in acute care settings in the United States (CDC, 2011a). Due to the delicate location of the central line in a major vein close to the heart, healthcare providers must follow strict protocols to ensure the central line is placed properly to minimize the risk of infection (CDC, 2011a). However, because the central line can remain in the patient for long periods of time, the risk of infection can increase even if proper protocols are used (CDC, 2011a). This is due to pathogens entering the bloodstream via the central line and subsequently causing an infection in the patient (CDC, 2011a).

It is important to note that both intrinsic and extrinsic risk factors can be responsible for causing an infection (CDC, 2011a). Examples of intrinsic risk factors, which are nonmodifiable patient characteristics, can be the patient's age, comorbidities, and the specific bacterial flora of the patient (Joint Commission, 2018). According to the Joint Commission (2018), there are numerous extrinsic factors, which are external factors that can be modified, that can contribute to an infection. These extrinsic factors can include hospitalization prior to central line insertions, use of multiple central lines, the location of the central line, microbial colonization at the insertion site, and the lack of maximal sterile barriers during the central line insertion (Joint Commission, 2018).

It is also important to note that there are various routes of transmission for which microorganisms can contaminate the central line. Such routes include microorganisms on both the patient and the healthcare professional inserting the central line and the microorganisms on the various sections of the catheter of the central line, such as the catheter hub and lumen (Joint Commission, 2018). In addition, the central line can be contaminated with microorganisms by extraluminal contamination or intraluminal contamination (Joint Commission, 2018). Extraluminal contamination occurs as a result of the patient's own skin flora contaminating the central line during improper insertion and/or inadequate skin preparation, prior to central line insertion (Joint Commission, 2018). Intraluminal contamination occurs after the central line has been inserted and has been further manipulated by healthcare professionals and/or the patient (Joint Commission, 2018). In addition, intraluminal contamination can be the result of contaminated fluid and medications given through the central line (Joint Commission, 2018).

Risk Factors Associated with Central Line-Associated Blood Stream Infections

Population

HAIs can affect all populations, but the literature starkly creates a division between the neonatal population and the adult population (Legeay et al., 2015; Hina & McDowell, 2017; Hooven & Polin, 2014;). The neonatal population, defined as infants under one year of age, are very susceptible to HAIs due to their underdeveloped immune system (Legeay et al., 2015). In addition, low birth weight neonates have a higher risk of developing HAIs while in the neonatal intensive care unit (Legeay et al., 2015).

Bloodstream infections are among the most prevalent HAIs acquired by neonates (Legeay et al., 2015). Neonates' underdeveloped immune system, coupled with extrinsic factors, such as the presence of a central venous catheter, use of ventilation devices, and poor catheter insertion techniques, result in a higher risk of developing an infection (Legeay et al., 2015). In addition, the risk of CLABSI increases when healthcare professionals manipulate the catheter, as well as the increased duration of the central line remaining in the patient (Legeay et al., 2015).

The neonatal population often requires a prolonged hospital stay and frequent invasive and/or surgical procedures (Hooven & Polin, 2014). In addition, neonates typically have underlying illnesses that cause their prolonged stay in the NICU, which is an inherent risk factor for acquiring infections (Hooven & Polin, 2014). Due to these underlying illnesses, neonates will often require central venous catheters (CVC) and ventilation devices while in the NICU (Hooven & Polin, 2014). Additionally, to ensure proper nutrition in the NICU, neonates require parenteral nutrition, which refers to intravenous feeding (Mayo Clinic, 2018). Parenteral nutrition can be delivered via a tunneled catheter, with a portion of the catheter tunneled underneath the skin before it enters the vein, or an implanted catheter, which is inserted entirely underneath the skin, requiring a needle to infuse the nutrition (Mayo Clinic, 2018). Due to the thinner and more permeable skin of neonates, microorganisms can easily contaminate the skin and catheter, leading to an infection (Hooven & Polin, 2014). Romanelli et al. (2014) conducted a case-control study which included newborns who underwent surgical procedures and were diagnosed with a bloodstream infection; the controls were newborns

who underwent surgical procedures and did not have the presentation of a bloodstream infection. The authors determined the most prevalent risk factors for developing a bloodstream infection were parenteral nutrition and the use of invasive ventilation devices (Romanelli et al., 2014).

Although bloodstream infections and CLABSI are common in the neonatal population, they are also prevalent in the adult population. As indicated by many studies, an adult patient is defined as 18 years or older (Hina & McDowell, 2017; Pepin et al., 2016). According to the CDC (2018b), the latest data indicates there has been roughly a 51% reduction in CLABSI among the adult population. Though this marked reduction has shown progress in CLABSI prevention, there is still room for improvement. For the adult population, the majority of the current literature focuses primarily on CLABSI episodes in ICUs.

Hina and McDowell (2017) conducted a structured literature review to summarize the efforts used to minimize CLABSI among adults in ICUs. The authors included 10 articles in the review that demonstrated effective interventions to minimize CLABSI in adult ICU patients (Hina & McDowell, 2017). The authors concluded the use of broad antimicrobial agents to disinfect the patient's skin, and insertion of the catheter in the subclavian vein was among the most effective interventions implemented to reduce the risk of CLABSI (Hina & McDowell, 2017). To conclude, the catheter insertion site and improper skin preparation are determined to be risk factors for CLABSI among adults in ICUs (Hina & McDowell, 2017).

According to Pepin et al. (2016), adults with comorbidities are at higher risk of developing CLABSI than those without comorbidities. However, although comorbidities are a higher risk factor for other types of HAIs, such as surgical site infections, Pepin et al. (2016) determined that patients who had renal disease, liver disease, and cerebrovascular disease were at higher risk of developing CLABSI. Finally, advanced age has also been shown to be a risk factor for developing CLABSI (Kaye et al., 2014). A matched retrospective cohort study conducted among a multi-center hospital system resulted in 81% CLABSI episodes among patients with a mean age of 74.4 years (Kaye et al., 2014). In addition, the mortality rate was 2.1 times higher (OR = 2.1, $p < 0.001$) among cases compared to controls (Kaye et al., 2014). Further, the length of stay in the hospital was 45% higher among the cases compared to controls (29.2 days compared to 20.2 days, respectively) (Kaye et al., 2014).

Catheter Type and Insertion Site

There are various types CVCs that can be used in a central line (Joint Commission, 2013). The catheter can be inserted through a peripheral vein or proximal central vein (Smith & Nolan, 2013). The main functions of these types of catheters are to deliver medication, fluids, and hemodynamic monitoring (Smith & Nolan, 2013). There are four main types of CVCs used for central lines that include non-tunneled, tunneled, implantable ports, and a peripherally inserted central catheter (PICC) (Joint Commission, 2013). Non-tunneled CVCs are inserted through the skin and threaded into central veins, such as the internal jugular, subclavian, or femoral vein (Joint Commission, 2013). Though these types of catheters are more commonly used because of their short-term

duration of use, non-tunneled CVCs contribute to the majority of CLABSI episodes (Joint Commission, 2013).

On the other hand, tunneled CVCs are implanted directly in the internal jugular, subclavian, or femoral vein (Joint Commission, 2013). These types of catheters are more long-term and invasive, as they require general anesthesia and a surgical procedure; however, there is a lower risk of infection compared to non-tunneled CVCs (Joint Commission, 2013). Implantable ports represent a cross between non-tunneled CVCs and tunneled CVCs, as they are tunneled beneath the skin and inserted in the subclavian, or internal jugular vein (Joint Commission, 2013). Similar to tunneled CVCs, implantable ports require general anesthesia and surgical procedure for insertion and removal but has a higher level of patient comfort (Joint Commission, 2013). Finally, PICCs are less frequently used for central lines because they are inserted through the skin into basilic, brachial, or cephalic veins (Joint Commission, 2013). However, PICCs are easier to insert and do not require an invasive surgical procedure (Joint Commission, 2013).

Healthcare professionals must be cognizant of the type of catheter used, as well as the insertion site, as these can inherently be risk factors for CLABSI (Smith & Nolan, 2013). Non-tunneled CVCs and PICCs are among the two CVC types with the lowest risk of CLABSI, as they are used in the short-term, typically less than three weeks (Joint Commission, 2013). Conversely, tunneled CVCs and implantable ports are the two types of CVCs with the highest risk of CLABSI due to the range of utilization being weeks to months (Joint Commission, 2013). Smith and Nolan (2013) indicated that among patients with long-term catheters inserted in the internal jugular and subclavian sites, there was a

higher risk of infection and catheter related complications. However, among patients with short-term catheters, the risk of infection and catheter related complications was higher among CVCs inserted through the femoral vein, compared to the subclavian vein (Smith & Nolan, 2013).

Hospital Location and Patient Care Area

The location within a hospital is widely addressed in the current literature with the most common location where CLABSI is prevalent being the adult ICUs (Curlej & Katrancha, 2016; Hina & McDowell, 2017; Hong et al., 2013; Liu et al., 2017; Spelman et al., 2017) and neonatal intensive care units (NICUs; Ceballos et al., 2013; Goudie, Dynan, Brady, & Rettiganti, 2014; Hooven & Polin, 2014; Worth et al., 2018). The CDC (2018c) indicates there has been a marked reduction in CLABSI episodes in ICUs (46% decrease), yet the ICU remains the most prevalent hospital location for infection. Patients required to be in the ICU include those who have undergone surgical procedures, critically-ill patients, and patients with comorbidities that need additional monitoring (CDC, 2018d). As a result of the critical nature of patients' health in ICUs, the risk of complications and infection increases, which contributes to the ever-remaining presence of CLABSI (CDC, 2018d).

NICUs contain critically-ill neonates, who also require constant monitoring and utilization of assistive devices (Worth et al., 2018). Worth et al. (2018) conducted a prospective cohort study to determine the burden of CLABSI events among neonatal and pediatric ICUs, which indicated 82 cases of pediatric CLABSI episodes, representing 2.21 cases per 1,000 central line days, and 95 neonatal CLABSI episodes, representing

0.67 cases per 1,000 peripheral line days. Consistent with other literature, CLABSI episodes were higher among low birth weight neonates (Worth et al., 2018). As previously indicated, the neonatal population is highly susceptible to acquiring CLABSI due to their underdeveloped immune system, thinner and more penetrable skin, frequent surgical procedures, and need for long-term monitoring in NICUs (Hooven & Polin, 2014). Though these risk factors cannot be controlled, proper hand hygiene protocol is essential to the reduction of CLABSI in this population (Ceballos et al., 2013).

Inadequate Hand Hygiene & Skin Preparation

As indicated above, there are many nonmodifiable factors that can contribute to the development of CLABSI. However, inadequate hand hygiene and skin preparation are the most common risk factors for CLABSI (CDC, 2011a). The WHO (2018a) indicated that healthcare professionals are involved in the spread of infections to patients in acute care settings. In addition to patients' colonization of microorganisms, healthcare professionals can spread infection when going from patient to patient, which emphasizes the need for adequate hand hygiene (WHO, 2018a). Simple tasks such as taking blood pressure, pulse, or temperature may result in spreading of microbes and transferring them to patients (WHO, 2018a).

There are various microbes that can be spread via the hands, which can include *Staphylococcus aureus*, *Klebsiella*, *Enterobacter*, *Pseudomonas*, and *Candida*, all of which can contribute to the development of CLABSI (WHO, 2018a). Though the CDC (2016a) and WHO (2018b) have developed hand hygiene protocols for healthcare professionals, hand hygiene compliance remains low in healthcare settings. Alsubaie et

al. (2013) conducted an observational study to estimate hand hygiene compliance among healthcare professionals and concluded that the noncompliance rate was 58% and the main factors associated with noncompliance was the demanding and hectic nature of the ICU setting.

In addition to proper hand hygiene protocols, healthcare professionals must also properly prepare patients' skin before insertion of the catheter (CDC, 2017b). According to the CDC (2017b), if the skin is not properly disinfected, the risk of infection increases. As a result of microorganisms colonizing the skin, if healthcare professionals fail to properly prepare the skin prior to catheter insertion, microorganisms can easily enter the bloodstream (CDC, 2017b). Additionally, if the catheter is not sterile, there is a potential to introduce bacteria, which may enter the bloodstream and lead to the development of CLABSI (Haddadin & Regunath, 2017). Current literature indicates conflicting evidence regarding the most effective skin preparation agent, but a consensus has been established that scrubbing the skin with a detergent before the antiseptic is applied has been deemed ineffective (Camacho-Ortiz & Roman-Machna, 2016). The following section will discuss effective infection prevention strategies that have been shown to reduce CLABSI.

Infection Prevention Strategies

The WHO (2018b) and the CDC (2016b) describe the importance of hand hygiene and aseptic technique as effective intervention efforts to reduce the spread of infection. As evidenced above, there are many nonmodifiable risk factors that contribute to the development of CLABSI. However, proper hand hygiene and aseptic techniques are modifiable behaviors healthcare professionals can improve upon to reduce the spread of

infection (WHO 2018b; CDC, 2016b). In addition to receiving training for catheter insertion and maintenance, healthcare professionals need the appropriate education and training to ensure proper hand hygiene protocols (CDC, 2016b). Storr and Kilpatrick (2012) discuss a multimodal strategy for hand hygiene, which consists of multiple implemented components to reduce the spread of infection. This strategy comprises the basic infrastructure to allow for the practice of hand hygiene (i.e., continuous and safe water supply and access to alcohol-based hand sanitizer), consistent training and education for healthcare professionals, evaluation and feedback to improve hand hygiene practices, and reminders about the importance of hand hygiene in the workplace (Storr & Kilpatrick, 2012).

Mitchell and Gardner (2014) also argue for a multi-faceted approach to infection prevention. The authors reference the chain of infection framework and the importance of many infection prevention strategies to break the chain, such as the use of maximal sterile barriers, the use of proper hand hygiene techniques, and the use of an alcohol-based sanitizer (Mitchell & Gardner, 2014). Additionally, they note the lack of infection prevention surveillance in many infection prevention protocols and propose the utilization of such surveillance tools (Mitchell & Gardner, 2014). Further, healthcare professionals should ensure patients' skin is properly prepped before catheter insertion (Goudet et al., 2013; Ling et al., 2016). Ling et al. (2016) described the importance of using alcohol-based chlorhexidine to disinfect components of the catheter and for prepping patients' skin, prior to catheter insertion, and during dressing changes. Goudet et al. (2013) discussed the use of povidone iodine as a common antiseptic agent to

prepare the skin but indicates published research recommends the use of alcohol-based chlorhexidine as the current superior antiseptic agent. Finally, Russell et al. (2019) discussed the importance of a multidisciplinary approach to minimize CLABSI events, which included infection prevention, care standardization, and team-based monitoring. By incorporating a multi-disciplinary approach, healthcare professionals contributed to a reduction in CLABSI events (Russell et al., 2019).

Though proper hand hygiene and aseptic techniques are vital to infection prevention, healthcare professionals are recognizing the importance infection prevention bundles, which incorporate various infection prevention strategies (Drews et al., 2017; Lee et al., 2018; Legeay et al., 2015; Richter & McAlearney, 2018; Scott, Gohil, Quan, & Huang, 2016). Legeay et al. (2015) described the four strategies to reduce the spread of infection which include use of maximal sterile barriers prior to catheter insertion, use of chlorhexidine skin preparation agents, selecting the ideal insertion site, and proper inspection and maintenance of the catheter. Compliance of infection prevention bundles have been shown to reduce CLABSI episodes (Lee et al., 2018). Lee et al. (2018) conducted a prospective cohort study in which compliance of a central line bundle were assessed. The central line bundle, which is comprised of the four components listed above, were only completed among 53.7% of the population, with compliance only 28.5% in ICUs, resulting in the highest incidence of CLABSI episodes (Lee et al., 2018). The low rate was explained by failure to complete all four components (Lee et al., 2018). The highest compliance rate and lowest CLABSI rate was seen among the general wards, for which all four components of the central line bundle was observed (Lee et al., 2018).

Further, Hakko et al. (2015) performed an observational cohort study in which a central line bundle intervention was implemented, which included components such as removal of all the previous central lines placed within the last 24 hours, the use of aseptic techniques, hand hygiene protocols and maximum barrier precautions (sterile gown, gloves, caps, masks, surgical scrub), the use of dedicated lumen for parenteral nutrition, and changing infusion sets for parenteral nutrition in 24 hours. Compliance of the intervention was tracked, and among 2,196 ICU patients (732 central lines placed for 4,366 central line-days), the infection rates remained zero for 38 months following the implementation (Hakko et al., 2015). Similarly, Drews et al. (2017) conducted a prospective observational study that sought to increase adherence to a central line maintenance kit in an effort to reduce CLABSI incidence in ICUs and general wards. The kit contained human factors engineering (HFE) principles, which nurses practice in clinical care, to improve adherence. In implementing the use of the central line maintenance kit intervention, compliance was increased and CLABSI rates decreased (Drews et al., 2017). Finally, Styslinger et al. (2019) discussed the importance of a central line insertion checklist, in an effort to provide standardized, aseptic insertion of central lines. The researchers indicated that catheter maintenance was a significant issue that occurred post-insertion, and indicated further research is needed to define and implement central line maintenance best protocols (Styslinger et al., 2019).

In addition to infection control programs, healthcare professionals can improve the safety culture by improving communication and teamwork to reduce the spread of infection. The Comprehensive Unit-Based Safety Program (CUSP) has been proven to be

an effective intervention to reduce CLABSI (Richter & McAlearney, 2018). CUSP was developed to improve teamwork and safety culture among healthcare professionals, and implementation can range from the unit level to the hospital system level (Richter & McAlearney, 2018). Richter and McAlearney (2018) indicated that CUSP has been successful when implemented in hospital units, but has not been implemented nationwide. The authors conducted a prospective cohort study that indicated when CUSP was implemented, CLABSI rates decreased from 1.95 to 1.04 episodes, per 1,000 central line days (Richter & McAlearney, 2018). Additionally, the results indicated adequate staffing, healthcare professionals' communication, learning, and teamwork were all significantly associated with zero or reduced CLABSI rates (Richter & McAlearney, 2018).

Central Line Insertion Practices Bundle

CLIP, initially developed by the CDC in 2014, and later revised in 2016 (2018a), is a protocol to ensure proper central line placement and management, which can subsequently prevent or reduce the risk of CLABSI occurrence. The CLIP Bundle has 8 components within it, which include proper hand hygiene practices, appropriate skin preparation, and use of all five maximal sterile barriers (sterile gloves, sterile gown, cap, mask, and large sterile drape for the patient) when inserting a central line (CDC, 2018a). Proper hand hygiene practices include thoroughly washing hands with antibacterial soap and water and use of alcohol-based sanitizer (CDC, 2018a). Appropriate skin preparation includes use of chlorhexidine gluconate for patients ≥ 60 days, and povidone iodine, alcohol, or chlorhexidine gluconate for patients < 60 days old (CDC, 2018a). In addition,

the skin preparation agent must be completely dry before insertion of the central line (CDC, 2018a). The CLIP Bundle was modified in 2016 to ensure all precautions were considered in order to reduce the rates of CLABSI (CDC, 2018a). For central line insertions following 2016, the CLIP Bundle adherence score requires a “Yes” to all 8 components (CDC, 2018a). In addition to following the CLIP Bundle protocol, CLIP forms have been developed to track documentation (Quan et al., 2016). Quan et al. (2016) developed an electronic health record program to track the CLIP elements and increase documentation compliance. The results indicated the electronic health record program increased CLIP compliance and resulted in decreased CLABSI rates (Quan et al., 2016). Scott et al. (2016) indicated that although monitoring CLIP has been effective at reducing CLABSI rates, improvements can be made to the current national standards for CLIP compliance. In a study conducted by Scott et al. (2016) using a convenience sample of 100 ICU patients and 100 non-ICU patients to determine CLIP compliance, it was found that among all the CVCs inserted, 69% had CLIP forms submitted. However, this calculation did not consider any missing CLIP components, resulting in a 31% reduction in CLIP compliance (Scott et al., 2016). As a result of how recent the CLIP Bundle protocol is, there is a paucity of literature assessing the impact of CLIP Bundle adherence on CLABSI rates. In addition, there is a paucity of literature regarding the implementation of the CLIP Bundle, as reporting is currently only mandated in California and New Hampshire (Quan et al., 2016). Therefore, the study will fill this gap in the literature by assessing the CLIP Bundle adherence score among different patient care areas within various California facilities.

Summary and Conclusions

HAIs remain a prevalent public health problem in the United States, as a result of increased morbidity and mortality, prolonged hospital stays, and increased medical care costs (Polin et al., 2012). Although largely preventable, CLABSI is among the leading cause of HAIs affecting patients in the United States (CDC, 2011a). The CLABSI incidence rate remains a concern within different hospital locations, specifically the ICU (Christina et al., 2015). In addition to both extrinsic and intrinsic factors associated with increased risk of infection, microorganisms can assume various routes of transmission to contaminate the central line (Joint Commission, 2018).

The literature indicates a stark division between the neonatal population and adult population as a risk factor for CLABSI (Legeay et al., 2015; Hooven & Polin, 2014; Hina & McDowell, 2017). The neonatal population have a greater risk of developing CLABSI in the NICU, due to their underdeveloped immune system, low birth weight, use of assistive devices, and poor catheter insertion techniques (Legeay et al., 2015). On the other hand, adults have an increased risk of developing CLABSI when in ICUs, due to comorbidities, and improper catheter insertion site, and inadequate skin preparation (Hina & McDowell, 2017). Because the many causative agents of CLABSI are fungi, proper hand hygiene and aseptic technique are described as effective interventions to reduce the spread of infection (CDC, 2016b; WHO, 2018b). Developed by the CDC (2018a), the CLIP Bundle is a protocol that combines proper central line placement and management, along with proper hand hygiene practices. As CLIP Bundle adherence is currently only mandated in two states, there is a paucity of literature to indicate the effectiveness of the

application of the CLIP Bundle on CLABSI rates. Thus, the research I conducted will fill a gap in the literature to determine if the CLIP Bundle adherence has an impact on CLABSI rates within different patient care areas in California. Additionally, this research may raise awareness to the benefit of monitoring and tracking the CLIP Bundle adherence for an effective CLABSI risk-reduction quality improvement initiative across the United States.

In Chapter 3 I focus on the research design and rationale, the methodology (including population, sampling procedures, and operationalization of constructs), and threats to validity.

Chapter 3: Research Methods

Introduction

The focus of this quantitative study was to determine whether CLIP Bundle adherence has an impact on CLABSI rates in different patient care areas among California facilities. The overall purpose was to examine the association between CLIP Bundle adherence scores and SIR among different patient care areas in California (CDC, 2018b). CLIP Bundle adherence scores are calculated as the total number of adherent insertions divided by the total number of CLIP Bundle observations. SIR is defined as the number of infections reported compared to the number of infections predicted. Additionally, the study was conducted to determine whether there are differences among CLIP Bundle adherence scores between patient care areas. By examining these associations, the study allowed for further understanding and awareness regarding monitoring and tracking the CLIP Bundle adherence scores for an effective CLABSI risk-reduction quality improvement initiative.

Chapter 3 begins with the selected the research design as it related to the research questions and the rationalization for choosing the research design. In addition, I identify and describe the population and sampling procedures, which includes a power analysis to determine the sample size. I also describe the procedures and data collection as they relate to the database that I used in the study. I also identify and explain an in-depth data analysis plan in this section, detailing potential statistical tests that I used and how the results were interpreted. I discuss threats to internal and external validity and potential

efforts to minimize validity. Finally, I discuss ethical procedures as they related to the confidentiality of participants' data in the database.

Research Design and Rationale

This study addressed whether CLIP Bundle adherence has an impact on CLABSI rates among different patient care areas in California healthcare facilities. I employed a quantitative, cross-sectional, retrospective study design to investigate the association between both CLABSI SIR rates and CLIP Bundle adherence scores across different patient care areas in the healthcare facilities. The main dependent variables that I used in this study were CLABSI SIR rates and CLIP Bundle adherence scores. The main independent variable used in the study was patient care area, namely, critical care areas, neonatal critical care, general care areas, special care areas, and mixed acuity care areas. The calculation of the SIR that appears in the dataset already incorporated adjustment for covariates, which include facility bed size, facility type, average length of stay, and use of a ventilator (CHHS, n.d.). One confounding factor that may have needed to be adjusted for is region. As all the data is coming from California facilities, region could be a potential confounding factor that may have influenced the results. Additionally, a potential confounding factor to adjust for was central line days. Central line days are calculated by summing the daily count of number of patients with central lines for each day of the month, at the same time each day (CHHS, n.d.). Finally, bed size could have been a potential confounding factor, which could be indicative of the hospital size. The potential confounding factors of region, central line days, and bed size were controlled for in the analyses.

As noted, I used a quantitative, cross-sectional, retrospective research design in this study, as it was an appropriate design choice to address the research questions in the study regarding CLABSI. This research employed the use of a nonexperimental design, as no randomization occurred. A nonexperimental design was appropriate for the study as it allows for the description of a relationship between two or more variables without the obligation of implying causation and without any manipulation of variables from the researcher (Statistics Solutions, 2019). By accessing two archived databases, this retrospective and nonexperimental research design allowed for assessment of the potential association between CLIP adherence scores and CLABSI SIR rates among different patient care areas, which was needed to address the research questions in the study.

Methodology

Population

The target population that was selected for this study was California hospitals that reported data on CLABSI to CDC's NHSN. The two databases that were used contain data for the calendar year 2015 and represented hospitals among California counties identified by the Electronic Licensing Management System (CHHS, n.d.). The data that were used were aggregated at the hospital-level, and therefore did not contain any patient-level identifying information. In order to answer the research questions, the variables that were analyzed in this study included patient care areas, CLIP Bundle adherence scores, and SIR rates.

Sampling and Sampling Procedures

This study was a secondary analysis of archived data from calendar year 2015, accessed from CDC's NHSN, a healthcare-associated infection tracking system. Because the data were publicly available, I used a nonprobability purposive sampling technique for this study (Laerd Dissertation, 2012). Purposive sampling is used when focusing on characteristics of the population of interest, to answer research questions. (Laerd Dissertation, 2012). Specifically, some characteristics of the population of interest included: CLABSI SIR rates, CLIP bundle adherence scores, central line days, region, and bed size. In order to report infection surveillance data, NHSN requires that facilities follow a mapping procedure as a decision-making tool to identify the appropriate CDC location (CDC, 2019a). The first step requires determining the acuity level of the facility (i.e., critical care units, neonatal critical care units, long-term acute care, etc.); if the facility is composed of at least 80% of patients that are of the same acuity level, locations are created in NHSN (CDC, 2019a). If the facility can be split in to two or more locations for surveillance, it will be deemed a mixed acuity location (CDC, 2019a). Step two requires defining the type of service for the location; this requires determining if the patient care area is a general medical, surgical, or medical/surgical unit, or if the general care area comprises patients from a specific service type (such as cardiac, burn unit, etc.; CDC, 2019a). The data that I used in the study, which were aggregated at the hospital level, consisted of facilities that report CLABSI data to NHSN. Therefore, there was a mix of acute and nonacute hospitals included in this study. To consolidate further, the patient locations that were included in the study were: critical care areas, neonatal critical

care, general care areas, and specialty care areas. These specific patient care areas that were utilized in this study were chosen because they have similar types of care, and according to previously published data, have equivalent risks of CLABSI (CDC, 2019a).

To obtain data on relevant study variables, I access data from two separate CDC databases. One dataset that was used in this study was archived data from 2015 that contained CLABSI SIR calculations among facilities in California. The second dataset that was used in this study was archived data from 2015 that contained CLIP Bundle adherence scores and patient care areas among facilities in California. By merging the two archived datasets, I was able to perform secondary data analysis to examine the association CLIP Bundle adherence scores have on SIR rates in different patient care areas in California facilities. Inclusion criteria included California hospitals reporting CLABSI data to CDC's NHSN in 2015, reported CLABSI cases, predicted CLABSI cases based on national baseline data from 2006-2008, and central line days (CHHS, n.d.). There was a total of 366 different facilities available in the merged datasets. No facilities were excluded from this study.

I performed a power analysis using G*Power software to estimate the sample size that was required for the study. To avoid the probability of Type 1 error, or the rejection of a true null hypothesis (false positive), the alpha level was set to 0.05 with a power of 0.80, with an effect size of 0.25 and four groups (Hunt, 2015). To answer RQ1 and RQ2, I completed an *a priori* power analysis to determine the minimum number of facilities required was 180 facilities (Heinrich-Heine-Universität Düsseldorf, 2019). I then performed a linear regression to answer RQ1 and RQ2. To answer RQ3, I completed *a*

priori power analysis to determine the minimum number of facilities required was 68 facilities (Heinrich-Heine-Universität Düsseldorf, 2019). Analysis of variance (ANOVA) was then performed to answer RQ3.

Data Collection of Archival Data

In order to track HAIs, NHSN serves over 25,000 medical facilities in the United States (CDC, 2019b). NHSN comprises various types of facilities including but not limited to acute care hospitals, long-term acute care hospitals, rehabilitation hospitals, ambulatory surgery centers, and facilities with dialysis centers (CDC, 2019b). Data are publicly available and allow for facilities to measure HAIs, identify problems, and areas for improvement and intervention (CDC, 2019b). Though the data are collected by CDC's NHSN, the data are stored on CHHS webpage. Data was publicly available and free of charge to access. However, to ensure I was able to use the data for educational purposes, I also requested permission to access the data from the site administrator listed on the CHHS webpage.

I obtained approval from the Walden University Institutional Review Board (IRB; approval number 06-27-19-0548881); I began data collection and analysis by obtaining the archived data from the CDC's NHSN database, which is publicly available and housed on the CHHS website. As mentioned above, I accessed two separate datasets to obtain data on SIR rates and CLIP Bundle adherence. No patient demographic data or identifiable information was collected on patients or appeared in the database. The data was collected and utilized for incidence of CLABSI cases and CLIP Bundle adherence scores.

Operationalization of Variables

The two dependent variables that I used in this study were CLABSI SIR rates and CLIP Bundle adherence score. Both dependent variables were continuous variables. The main independent variable that I used in this study was patient care areas. The independent variable was recoded as a categorical variable. Central line days was a potential confounding variable that could possibly affect the analysis and was statistically controlled for in the analyses. In addition, region could be considered a potential confounding factor and could have possibly affected the analysis; as all the data was coming from California facilities, region could be a potential confounding factor that may influence the result and was statistically controlled for in the analyses. Finally, bed size was identified as a potential confounding factor that could possibly affect the results, and it was statistically controlled for in the analyses. Definitions for the variables to be considered in the analysis are provided here:

Central line days: Represents the total count of the number of patients with central lines for each day of the month, at the same time each day (CHHS, n.d.).

CLIP adherence scores: Referenced in the secondary dataset that indicates that healthcare professionals answered “yes” to all eight components of the CLIP Bundle (for central lines inserted following January 1, 2016); the adherence score is calculated by taking the total number of adherent central line insertions divided by the total number of CLIP observations (CDC, 2018a).

Critical care areas: Hospitals with 25 or fewer acute care inpatient beds, with an average length of stay of four days or less; these hospitals are typically located more than

35 miles from another acute care hospital; includes major teaching hospitals, medical/surgical care, burn critical care, trauma critical care, long-term acute critical care, and pediatric critical care (CHHS, n.d.).

General care areas: Various wards in hospitals, including adult, pediatric, medical/surgical, surgical, long-term acute care, rehabilitation, labor, delivery, recovery, behavioral health/psychiatric, jail (CHHS, n.d.).

Mixed acuity care areas: Hospital areas for the treatment of patients whose conditions are at varying levels of acuity (critical care, general care, specialty care, etc.) (CHHS, n.d.).

Neonatal critical care: Care areas within hospitals, specifically utilized by for neonatal patients; further subdivided by birth weight categories: ≤ 750 grams, 751-1000 grams, 1001-1500 grams, 1501-2500 grams, and $> 2,500$ grams (CHHS, n.d.).

Specialty care areas: Specialized care areas in the hospital, such as oncology, hematology, bone marrow transplant, solid tumor ward, and solid organ transplant (CHHS, n.d.).

Standardized infection ratio (SIR): Value used in the secondary dataset, which is calculated as the number of infections reported compared to the number of infections predicted, in different hospital locations; SIR value > 1.0 indicates more CLABSI episodes were reported than predicted, based on national aggregate data; SIR value < 1.0 indicates fewer CLABSI episodes were reported than predicted, based on national aggregate data (CHHS, n.d.).

Data Analysis Plan

The data was imported from an Excel file into Stata for data analysis. Because I used secondary data, there was a potential for missing data. In order to ensure clean data was used for the analysis, I performed descriptive statistics, such as frequencies, on the variables to determine the occurrence of missing data. Once missing data was identified, I then cleansed the data to avoid using missing data in the analysis. In addition, I deleted data where zero cases of CLABSI cases were reported in the datasets. Finally, I performed descriptive statistics for all variables to determine any outliers in the data. Outliers were determined by assessing the studentized residuals, as well as assessing multicollinearity (Pennsylvania State University, 2018). If outliers were present, these values were presented as such, so as not to skew data results.

The research questions and hypotheses are restated below:

RQ1: Is patient care area associated with CLABSI SIR rates, controlling for central line days, region, and bed size?

H_01 : Patient care area is not associated with CLABSI SIR rates, controlling for central line days, region, and bed size.

H_{a1} : Patient care area is associated with CLABSI SIR rates, controlling for central line days, region, bed size.

RQ2: Is patient care area associated with CLIP Bundle adherence, controlling for central line days, region, and bed size?

H_02 : Patient care area is not associated with CLIP Bundle adherence, controlling for central line days, region, and bed size.

H_{a2} : Patient care area is associated with CLIP Bundle adherence, controlling for central line days, region, and bed size.

RQ3: Is there an association with CLIP Bundle adherence scores and CLABSI SIR rates within different patient care areas?

H_{03} : There is no association with CLIP Bundle adherence scores and CLABSI SIR rates within different patient care areas.

H_{a3} : There is an association with CLIP Bundle adherence scores and CLABSI SIR rates within different patient care areas.

In order to determine the correct statistical test to perform, certain assumptions of the statistical tests should be met. One potential statistical test to perform with the data was linear regression. The assumptions of linear regression include: linear relationship between the independent (categorical or continuous) and a dependent variable (continuous), multivariate normality, little or no multicollinearity, no autocorrelation, and homoscedasticity (Statistics Solutions, 2019). I used Stata to determine if the assumptions hold true. To test for linearity, I used scatter plots and histograms (Statistics Solutions, 2019). Histograms were created to assess skewness and outliers, and scatterplots were created to assess strength of any linear association in continuous data (Statistics Solutions, 2019). To test for multivariate normality, I performed a goodness-of-fit test, such as the Kolmogorov-Smirnov test (Statistics Solutions, 2019). Multicollinearity was assessed by variance inflation factor analysis (Statistics Solutions, 2019). To test for homoscedasticity, I used a scatter plot to determine if the residuals are equal across the regression line (Statistics Solutions, 2019).

To test the hypotheses for RQ1, linear regression was performed using CLABSI SIR rates as the dependent variable and patient care areas as the independent variable. To test the hypotheses for RQ2, linear regression was performed, using CLIP Bundle adherence scores as the dependent variable and patient care areas as the independent variable. For RQ1, CLABSI SIR rate (dependent variable) was a continuous variable, and patient care areas (independent variable) which became a categorical variable, was coded as different categories to represent each patient care area. For RQ2, CLIP Bundle adherence score (dependent variable) was a continuous variable, and patient care areas (independent variable) which became a categorical variable, was coded as different categories to represent each patient care area. Probability values (p-values) were assessed to determine statistical significance; statistical significance was set to 0.05. Therefore, a p-value less than the significance level of 0.05 indicated statistical significance and rejection of the null hypothesis. A p-value greater than the significance level of 0.05 indicated no statistical significance, and indicated a failure to reject the null hypothesis.

A second potential statistical test to perform with the data was one-way analysis of variance (ANOVA). The six assumptions of a one-way ANOVA include: continuous dependent variable, two or more categorical, independent variables, independence of observations, no significant outliers, normal distribution of dependent variable, and homogeneity of variances (Laerd Statistics, 2018a). To test the hypotheses for RQ3, I performed an ANOVA, using CLIP Bundle adherence scores (continuous, ratio variable) and CLABSI SIR rates (continuous, ratio variable) as the dependent variables (respectively) and patient care areas (categorical variable) as the independent variable.

Patient care areas were recoded as a categorical variable, to assess the CLABSI SIR rate and CLIP Bundle adherence score among each patient care area. In order to account for confounding variables, I performed tests of multicollinearity, as well as inclusion of variables such as central line days, region, and bed size in the regression models. To interpret the results, statistical significance was set to 0.05. Therefore, a p-value less than the significance level of 0.05 indicated statistical significance and rejection of the null hypothesis. A p-value greater than the significance level of 0.05 indicated no statistical significance, and indicated a failure to reject the null hypothesis.

Threats to Validity

Threats to External Validity

Because the data were collected from hospitals located in one state (California), there was a potential threat to the external validity, as the results may not be generalizable to other populations in the United States. In addition, because CLIP adherence reporting is currently only mandated in two states (including California), the results of this study may not be generalizable to other patient care areas in the United States. Finally, because the dataset only included data on CLABSI rates, the results of the study may not be generalizable to other HAI cases in the United States.

Threats to Internal Validity

As I assessed secondary data, there may be threats to internal validity. History, which indicates events that may occur during the study period that could potentially impact the outcome was a threat to internal validity (Creswell, 2014). For example, a hospital may have implemented a new hand hygiene protocol throughout the entire

facility, which may impact CLABSI rates, as the data would have been collected and analyzed after the new implementation. Secondly, as CLIP Bundle adherence scores were collected based on self-reported responses regarding compliance with eight quality indicators, the study faced a threat to internal validity. As various healthcare facilities across California were assessed, there could be a potential differential in collection methods among each of the quality indicators, resulting in a threat to internal validity. In addition, there could be bias associated with data that is put into the electronic medical record, as well as what is abstracted out of the electronic medical record. Finally, because the CLIP Bundle adherence score was an aggregated score of all eight quality indicators, there was no differentiation to determine which quality indicator was or was not performed by healthcare professionals; this may not allow for a deeper analysis of which component was not systematically adhered to, which could result in a potential threat to internal validity.

Ethical Procedures

This study was a quantitative secondary data analysis of archival data from CDC's NHSN database. I accessed data that were aggregated by hospital-level and contained no patient demographic information. All data were anonymous and not associated with individuals' private information. Data from NHSN is publicly available and I accessed it with the intention of keeping aggregation intact. In addition, I completed an application to Walden University's IRB to ensure proper protections and ethical standards were met. Data were stored on a password-protected computer, only maintained in my possession. No one else had access to the data in the Excel file or SPSS

file. Data were also stored on a password-protected USB as a backup. Data will be stored for a minimum of five years and then will be destroyed.

Summary

The purpose of this quantitative cross-sectional research study was to determine the impact CLIP Bundle adherence scores have on CLABSI SIR rates in different patient care areas in California facilities. In Chapter 3, I describe the methodology required to conduct the study of archived data. The study used one main independent variable of patient care area in California and two dependent variables, which were CLIP Bundle adherence score and CLABSI SIR rates. This chapter also detailed the population and sampling methodology that was employed. The research questions and hypotheses and the data analysis plan were also outlined. One-way ANOVA and linear regression were conducted to determine the differences and associations between CLIP Bundle adherence scores and CLABSI SIR rates in different patient care areas, respectively. Threats to external and internal validity were outlined in this chapter. Finally, ethical procedures were explained to ensure privacy and protection of data. Analyses were only conducted once I obtained approval from Walden's IRB (06-27-19-0548881).

In Chapter 4, I discuss the process of data collection, including the time frame for data collection. Baseline descriptive statistics of the sample will be provided, as well as explaining how representative the sample is of the population of interest. Statistical findings, organized by research questions and hypotheses will be reported in the next chapter. Finally, tables and figures will be produced to illustrate the results of the study.

Chapter 4: Results

Introduction

The focus of this quantitative study was to determine whether CLIP Bundle adherence had an impact on CLABSI rates in different patient care areas in health care facilities in California. Patient care areas that were evaluated in this study were neonatal care area, critical care area, and special care area. Patient care areas that contained no CLIP Bundle adherence values were general care areas and mixed acuity care areas. As a result, those two patient care areas were dropped from the analysis, leaving neonatal care area, critical care area, and special care area to be considered for data analysis.

The overall purpose was to examine the association between CLIP Bundle adherence scores and SIR between different patient care areas in hospitals located across California. CLIP Bundle adherence scores are calculated as the total number of adherent insertions divided by the total number of CLIP Bundle observations. SIR is defined as the number of infections reported compared to the number of infections predicted.

The objective of this study was to examine the following research questions:

RQ1: Is patient care area associated with CLABSI SIR rates, controlling for central line days, county, and bed size?

H_0 1: Patient care area is not associated with CLABSI SIR rates, controlling for central line days, county, and bed size.

H_a 1: Patient care area is associated with CLABSI SIR rates, controlling for central line days, county, and bed size.

RQ2: Is patient care area associated with CLIP Bundle adherence, controlling for central line days, county, and bed size?

H_02 : Patient care area is not associated with CLIP Bundle adherence, controlling for central line days, county, and bed size.

H_{a2} : Patient care is associated with CLIP Bundle adherence, controlling for central line days, county, and bed size.

RQ3: Is there an association with CLIP Bundle adherence scores and CLABSI SIR rates between different patient care areas?

H_03 : There is no association with CLIP Bundle adherence scores and CLABSI SIR rates within different patient care areas.

H_{a3} : There is an association with CLIP Bundle adherence scores and CLABSI SIR rates within different patient care areas.

This chapter begins with a discussion about the data collection and preparation process followed by the descriptive statistics for the variables of interest. Next, I present the results in detail, with an evaluation of statistical assumptions and statistical analyses, organized by the study research questions and hypotheses. Finally, in the last section of this chapter, I summarize the study findings for the individual research questions and provide transitional material from the research findings to introduce the discussion in Chapter 5.

Data Collection and Preparation

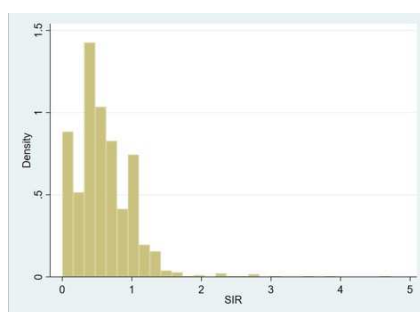
I obtained two secondary datasets from the California Department of Public Health for calendar year 2015 (CHHS, n.d.). The CLABSI in Hospitals dataset contained

CLABSI SIR values from hospitals in California and the CLABSI in Patient Care Areas dataset contained CLIP Bundle adherence scores and patient care areas from the same hospitals in California. Merging the two archived datasets allowed these variables to be examined together in the same analyses. The variables that I used from the merged dataset included SIR, CLIP Bundle adherence scores, patient care areas, central line days, county, and bed capacity. A total of 366 unique facilities were included in the analysis. It is important to note that not all facilities had the same patient care areas; however, patient care areas that included both SIR and CLIP bundle adherence rate were included in the analysis. Central line days, county, and bed capacity were all variables that were controlled for in the statistical analyses. Central line days and county were already included in the merged dataset; however, in order to obtain data on bed capacity, I also utilized a third database from CHHS (CHHS, 2020). By using facility ID as the key identifier, I was able to bring the variable bed capacity to utilize in the merged datasets. Including these variables in the analysis may obscure the true impact of the association, so it is important to control for these variables. I performed all statistical analyses using Stata, version 15 (StataCorp, 2017). Statistical significance was determined at $p < 0.05$ level.

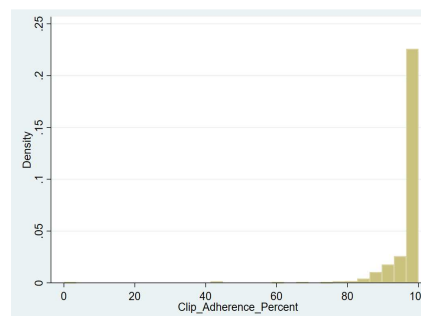
Descriptive Statistics

I assessed the dependent variables SIR and CLIP Bundle adherence scores for normality using histogram frequency plots, which helped to visualize the distribution of values. It is important to test for normality to determine if the data is normally distributed (Laerd Statistics, 2018b). If the data are skewed, extreme tails will influence the

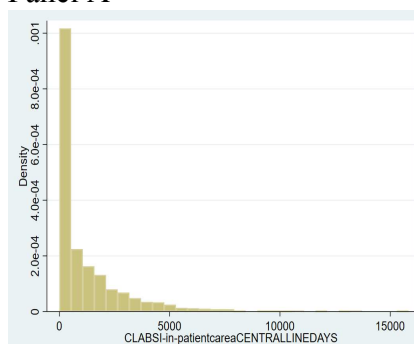
statistical tests, as outliers could adversely affect the results and result in an over- or underestimation of the true association. Examining normality allows for determination of the appropriate statistical test to be performed if assumptions of normality are met (Laerd Statistics, 2018b). As seen in Figure 2, Panels A and B, respectively, both the SIR and CLIP Bundle adherence scores were not normally distributed. In addition to assessing the dependent variables for normality, I also assessed central line days and bed capacity for normality. As seen in Figure 2, Panels C and D, respectively, central line days and bed capacity were not normally distributed.



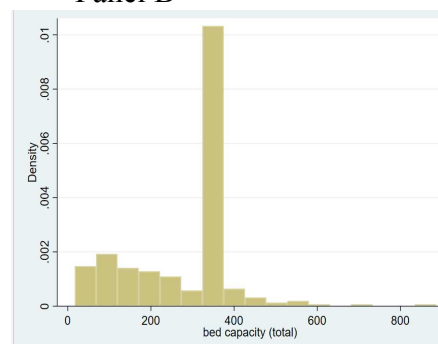
Panel A



Panel B



Panel C



Panel D

Panel A: SIR frequency distribution test for normality

Panel B: CLIP Bundle adherence frequency test for normality

Panel C: Central line day frequency test for normality

Panel D: Bed capacity frequency test for normality

Figure 2: Study variables tests for normality.

Given that the dependent variables of SIR and CLIP Bundle adherence were right and left-skewed, respectively, nonparametric versions of the statistical tests were utilized, as the data violated assumptions of the parametric statistical tests. Before any multivariate analysis can be performed, the variables must be assessed for normality (Laerd Statistics, 2018b). Upon discovering the dependent variables were skewed, I determined that the assumptions of linear regression were violated (Laerd Statistics, 2018b). Therefore, quantile regression was the statistical technique chosen, as it does not require the data to meet the assumptions of a normalized distribution (Woolridge, 2010).

Descriptive statistics were used to analyze SIR, central line days, CLIP Bundle adherence, and bed capacity. The results are shown below in Table 1.

Table 1.

Central Line Days, Central Line Insertion Practices Bundle Adherence, Bed Capacity Descriptive Statistics

	N	Mean (SD)	P25	Median	P75	Range
SIR	1136	0.60 (0.439)	0.37	0.52	0.80	0 - 4.72
CLIP adherence percent	980	97.1 (6.54)	96.8	99.2	100	0-100
Central line days	1140	1200.7 (1812.05)	88	411	1624	1- 15384
Bed capacity	305	289.1 (133.59)	173	369	359	17- 866

Note. P25 indicates quartile where 25% of the data fall below this point
 Median indicates quartile where 50% of the data fall above and below this point
 P75 indicates quartile where 75% of the data fall above this point

As seen in Table 1, the median SIR was 0.52 infections (interquartile range [IQR]: 0.37-0.80). The median central line days was 411 days (IQR: 88 -1,624 days). The

median CLIP Bundle adherence rate was 99.2% (IQR: 96.8- 100%). Bed capacity values were calculated based on unduplicated facility ID numbers. The median bed capacity was 369 beds (IQR: 173- 369 beds).

Descriptive statistics of patient care areas are displayed in Table 2.

Table 2.

Central Line Insertion Practices Bundle Adherence Patient Care Area Descriptive Statistics

	Count	Percent
Neonatal care area	594	52.1
Critical care area	422	37.0
Special care area	124	10.9
Total	1140	100.0

As seen in Table 2, the largest percentage of patient care areas included in the analysis were neonatal care areas, which represented slightly over half ($n = 594$; 52.1%). Critical care areas included in the analysis represented just over one-third ($n = 422$; 37.0%). Finally, the smallest percentage of patient care areas included in the analysis were special care areas, which represented just over one-tenth ($n = 124$, 10.9).

CLIP Bundle adherence and SIR were stratified by patient care areas and can be seen in Table 3 and Table 4, respectively.

Table 3.

Central Line Insertion Practices Bundle Adherence by Patient Care Area

	Median	Mean (SD)	Count
Neonatal care area	99.4	96.9 (6.61)	566
Critical care area	99.0	97.3 (6.52)	410
Special care area	98.3	98.3 (0.29)	4

Table 4.

Standardized Infection Ratio by Patient Care Area Descriptive Statistics

	Median	Mean (SD)	Count
Neonatal care area	0.5	0.6 (0.03)	594
Critical care area	0.5	0.6 (0.56)	418
Special care area	0.6	0.7 (0.40)	124

As seen in Table 3, when CLIP Bundle adherence was stratified by patient care area, the median values were similar, ranging from 98.3% to 99.4%; specifically, special care area was 98.3%, critical care area was 99.0%, and neonatal care area was 99.4%. As seen in Table 4, when SIR was stratified by patient care area, the median SIR ranged from 0.5 to 0.6; specifically, neonatal care area and critical care area were both 0.5 and special care area was 0.6.

The variable county was reported as a categorical class variable and was grouped into 58 counties from 10 large geographic regions (California Census, 2019). The California Census provides regional groupings of counties based on hard-to-count populations, like-mindedness of counties, and the make-up of community-based organizations (California Census, 2019). In addition, Table 5 also provides an aggregated summary of the California counties that were used in the data analysis. As seen below, the largest regions were Los Angeles County ($n = 343$, 30.1%), and San Francisco Bay Area ($n = 191$, 16.8%). The smallest regions were North Coast ($n = 27$, 2.4%) and Northern San Joaquin Valley ($n = 53$, 4.6%).

Table 5.

California Region Groupings from California Census

Region	Region Description	Counties	Count (%)
1	Superior California	Butte, Colusa, El Dorado, Glenn, Lassen, Modoc, Nevada, Placer, Plumas, Sacramento, Shasta, Sierra, Siskiyou, Sutter, Tehama, Yolo, Yuba	85 (7.5)
2	North Coast	Del Norte, Humboldt, Lake, Mendocino, Napa, Sonoma, Trinity	27 (2.4)
3	San Francisco Bay Area	Alameda, Contra Costa, Marin, San Francisco, San Mateo, Santa Clara, Solano	191 (16.8)
4	Northern San Joaquin Valley	Alpine, Amador, Calaveras, Madera, Mariposa, Merced, Mono, San Joaquin, Stanislaus, Tuolumne	53 (4.6)
5	Central Coast	Monterey, San Benito, San Luis Obispo, Santa Barbara, Santa Cruz, Ventura	77 (6.7)
6	Southern San Joaquin Valley	Fresno, Inyo, Kern, Kings, Tulare	60 (5.3)
7	Inland Empire	Riverside, San Bernardino	124 (10.9)
8	Los Angeles County	Los Angeles	343 (30.1)
9	Orange County	Orange	99 (8.7)
10	San Diego- Imperial	Imperial	80 (7.0)

Note. From California Census, 2019.

Statistical Results

To test the assumptions to determine which model should be used for determining if patient care areas are associated with CLABSI SIR rates, controlling for central line days, region, and bed capacity, I used a multivariable linear regression. I performed statistical tests on the model to assess residual normality, skewness, and heteroscedasticity. By testing these assumptions and understanding the results, it then determines which type of statistical analysis can be run. In this case, because the assumptions of linear regression were not met, a nonparametric version of linear regression was used- quantile regression. Table 6 presented below reflect the results of the statistical tests. In addition, Figure 3 represents the scatterplot of residuals of SIR to patient care areas and central line days and region.

Table 6.

Tests for Heteroscedasticity, Skewness, and Kurtosis of Residual for SIR Multilinear Regression Model

Source	χ^2	df	p
Heteroscedasticity	126.68	42	0.0000
Skewness	33.27	12	0.0009
Kurtosis	3.49	1	0.0619

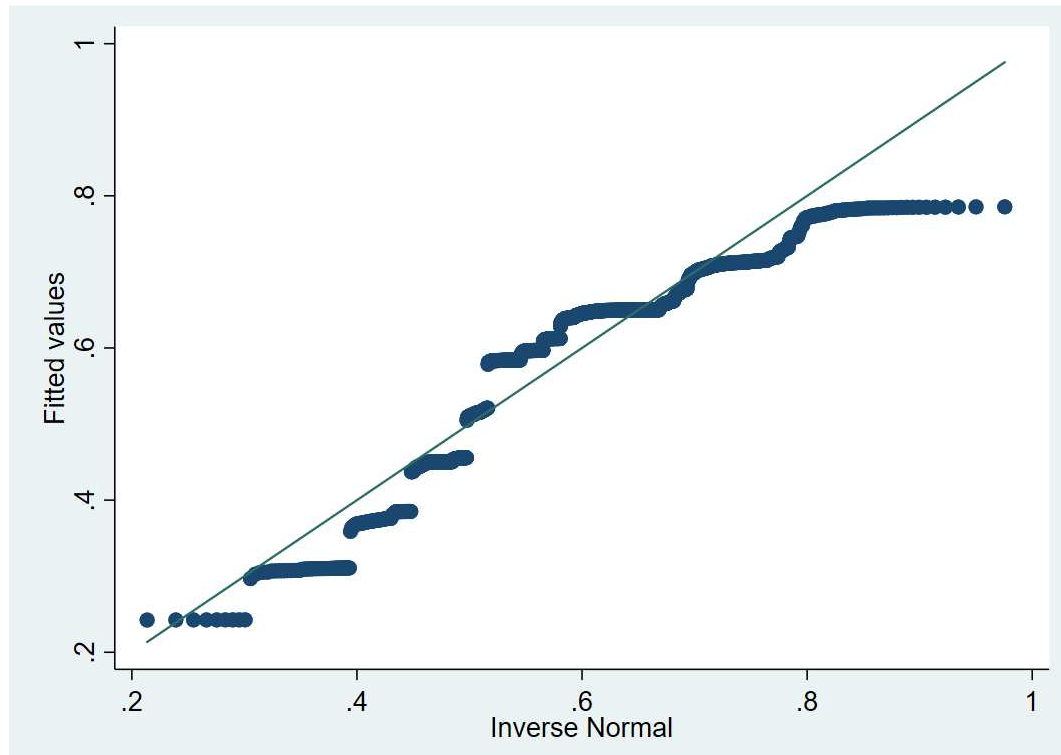


Figure 3. Scatterplot of qnorm of residuals SIR to patient care area and central line days and region.

The p -value for Heteroscedasticity ($p = 0.000$) seen in Table 6 is significant, indicating there is heteroscedasticity and thus the variance is not constant. Regarding skewness, the p -value is significant ($p = 0.0001$), indicating there is skewness of the data in the model, implying a lack of symmetry of the data distribution. In addition, the χ^2 value is significantly greater than 1 ($\chi^2 = 33.27$), indicating skewed data. Finally, with a kurtosis value greater than 3, this indicates extreme values at the tail end(s) of the distribution (which is also confirmed with the graphical display). The results of the statistical tests provide evidence that linear regression models were not robust, thus the need to perform a quantile regression. As seen from the scatter plot in Figure 4, the results of the residual analysis revealed heterogeneity of the residuals for the SIR model.

To test the assumptions to determine which model should be used for determining if patient care areas are associated with CLIP Bundle adherence, controlling for central line days, region, and bed capacity, a multivariable linear regression was performed that included patient care areas, central line days, region, and bed capacity. Statistical tests were performed on the model to assess residual normality, skewness, and heteroscedasticity. Table 7 reflects the results of the statistical tests. In addition, Figure 4 displays a plot of the residuals to patient care area and central line days and region.

Table 7.

Tests for Heteroscedasticity, Skewness, and Kurtosis of Residual for Central Line Insertion Practices Bundle Adherence Multilinear Regression Model

Source	χ^2	df	p
Heteroscedasticity	37.19	33	0.2821
Skewness	10.22	12	0.5968
Kurtosis	2.00	1	0.1578

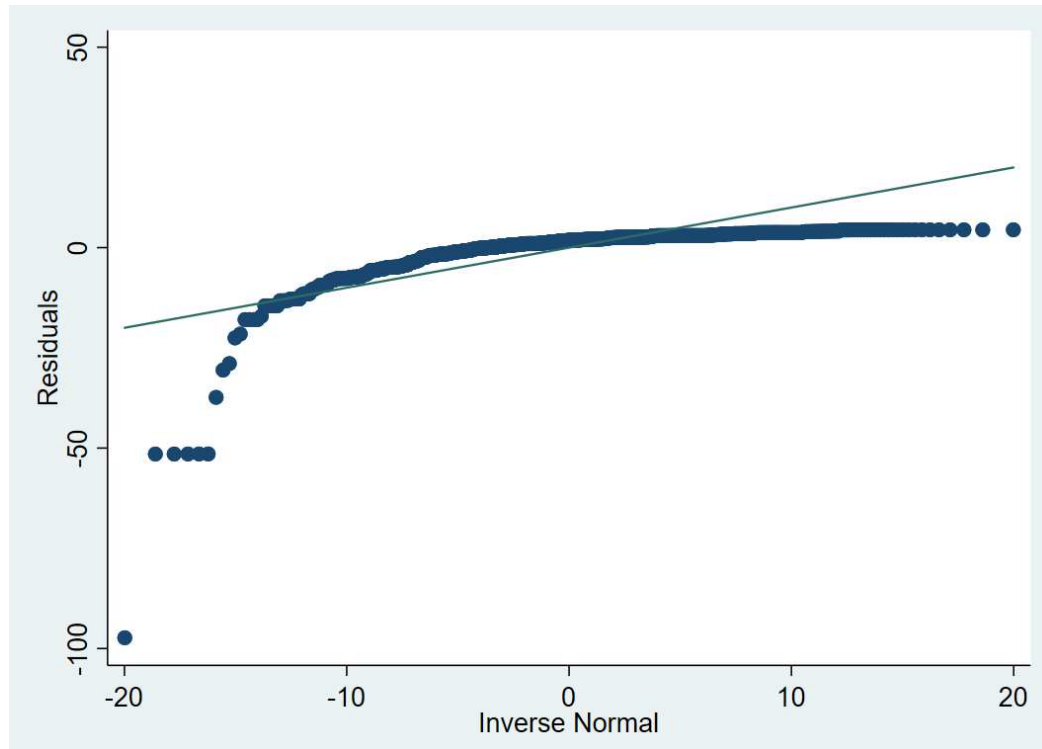


Figure 4. Scatterplot of qnorm of residuals CLIP Bundle adherence to patient care area and central line days and region.

The p -value for Heteroscedasticity ($p = 0.282$) seen in Table 7 is not significant, indicating a lack of heteroscedasticity and suggesting the variance is constant. Regarding skewness, the p -value is not significant ($p = 0.60$). In addition, the χ^2 value is greater than 1 ($\chi^2 = 10.22$), indicating highly skewed data or a lack of symmetry of the data distribution. Finally, with a kurtosis value greater than 1, this indicates extreme values at the tails of the distribution. The results of the statistical tests provide evidence that linear regression models were not robust, thus the need to perform a quantile regression. As seen from the scatter plot in Figure 4, the results of the residual analysis revealed heterogeneity of the residuals for the SIR model.

Quantile Regression Results

The dependent variables of SIR and CLIP Bundle adherence rates, continuous independent variables, and initial linear regression models all displayed skewness, and residual analysis of the initial multivariable linear regression models violated the assumptions of normality. Therefore, a median (or quantile) regression was performed, rather than log-transforming the dataset. Quantile regression predicts the median, rather than the mean, as in a normalized linear regression (Woolridge, 2010). Therefore, I used quantile regression in the analysis of Research Questions 1 and 2, which provided the ability to interpret the results, while also providing robust analysis of structurally skewed variables (Woolridge, 2010).

Quantile Regression: Patient Care Area Association with Standardized Infection Ratio

Research Question #1: Is patient care area associated with CLABSI SIR rates, controlling for central line days, region, and bed capacity? The results of the SIR quantile regression can be found in Table 8. The neonatal critical care area was set as the reference value for patient care area and Superior California (Region 1) was set as the reference value for region. Reference values are needed in a regression model when nominal data with no hierarchy or order is used. Reference values are used to compare the other levels of the same variable in the model.

Table 8.

Quantile Regression: Patient Care Area Association with Standardized Infection Ratio Rates

Source	Coefficient	SE	t	$P > t $ (95% CI)
Constant	0.49	0.66	7.36	0.00 (0.36-0.62)
<u>Patient care area</u>				
Neonatal critical care area	ref	ref	ref	ref
Critical care area	-0.07	0.03	-1.98	0.05 (-0.14 0.00)
Special care area	0.01	0.05	0.31	0.76 (-0.08-0.11)
<u>Central line days</u>				
Central Line Day	0.0003	9.20e ⁻⁶	2.43	0.02 (4.23e ⁻⁶ – 0.00)
<u>Region</u>				
Superior California	ref	ref	ref	ref
North Coast	-0.24	0.10	-2.43	0.02 (-0.44- -0.47)
San Francisco Bay Area	0.19	0.06	3.22	0.001 (0.07-0.31)
Northern San Joaquin Valley	-0.48	0.08	-0.60	0.55 (-0.20-0.11)
Central Coast	0.03	0.07	0.43	0.67 (-0.11- 0.17)
Southern San Joaquin Valley	-0.01	0.08	-0.12	0.90 (-0.16-0.14)
Inland Empire	0.09	0.06	1.37	0.17 (-0.04- 0.21)
Los Angeles County	0.18	0.06	3.32	0.001 (0.08- 0.21)
Orange County	0.17	0.07	2.52	0.01(0.04-0.30)
San Diego – Imperial	0.24	0.07	3.34	0.001 (0.01-0.37)
<u>Bed capacity</u>				
Bed capacity	-0.003	0.00	-2.31	0.02 (-0.001 - 0.000)

Critical care area is significantly associated with SIR, when controlling for central line days, region, and bed capacity ($p=0.05$). In addition, central line days is significantly associated with SIR ($p=0.02$), where for every single day increase in central line days, SIR increased at a rate of 0.0003. As a result, the more days on a central line, the higher the chance of getting an infection. The North Coast had a decreased SIR ($p=0.02$) with a 0.24 rate reduction in SIR. In addition, San Francisco Bay Area, Los Angeles County, Orange County, and San Diego-Imperial had higher SIR rates as compared to the referent group (Superior California, Region 1). San Francisco Bay Area ($p=0.001$) increased SIR rates by 0.19; Los Angeles County ($p=0.001$) increased SIR rates by 0.18; Orange County ($p=0.01$) increased SIR rates by 0.17; and San Diego – Imperial ($p=0.001$) increased SIR rates by 0.24. Finally, bed capacity was associated with a decrease SIR rate by 0.0003 ($p=0.02$). Therefore, this inverse relationship indicates the higher the bed capacity, the lower the SIR rate.

Quantile Regression: Patient Care Area Association with Central Line Insertion Practices Bundle Adherence

Research Question #2: Is patient care area associated with CLIP Bundle adherence, controlling for central line days, region, and bed capacity? The results of the CLIP Bundle adherence quantile regression can be found in Table 9. Neonatal critical care area was set as the referent value for patient care area; Superior California (Region 1) was set as the referent value for region.

Table 9.

Quantile Regression: Patient Care Area Association with Central Line Insertion Practices Bundle Adherence

Source	Coefficient	SE	t	P > t (95% CI)
Constant	99.42	0.41	242.55	0.00 (98.61-100.22)
<u>Patient care areas</u>				
Neonatal critical care area	ref	ref	ref	ref
Critical care area	0.03	0.21	0.15	0.88 (-0.38 – 0.44)
Special care area	-1.13	1.27	-0.89	0.37 (-3.62- 1.35)
<u>Central line days</u>				
Central line day	-0.0002	0.00	-3.27	0.001 (-0.0003 - -0.00008)
<u>Region</u>				
Superior California	ref	ref	ref	ref
North Coast	0.66	0.60	1.10	0.27 (-0.51- 1.83)
San Francisco Bay Area	-0.22	0.37	-0.06	0.95 (-0.74 – 0.70)
Northern San Joaquin Valley	0.57	0.47	1.22	0.22 (-0.35 – 1.49)
Central Coast	1.16	0.44	2.63	0.009 (0.30 – 2.03)
Southern San Joaquin Valley	0.36	0.45	0.80	0.43 (-0.53 – 1.25)
Inland Empire	1.16	0.39	2.97	0.003 (0.40 – 1.93)
Los Angeles County	0.89	0.35	2.58	0.01 (0.21 – 1.57)
Orange County	0.68	0.41	1.66	0.10 (-0.13 – 1.50)
San Diego - Imperial	0.54	0.43	1.25	0.21 (-0.31 – 1.39)
<u>Bed capacity</u>				
Bed capacity	-0.002	0.0007	-2.18	0.03 (-0.003- -0.0002)

Patient care area is not significantly associated with CLIP Bundle adherence, when controlling for central line days, region, and bed capacity. However, when controlling for patient care area, region, and bed capacity, central line days was significantly associated with CLIP Bundle adherence ($p=0.001$), where for every single day increase in central line days, CLIP Bundle adherence decreased by 0.0002%. As a result, the more days on a central line, the lower the CLIP Bundle adherence. Central Coast, Inland Empire, and Los Angeles County increased CLIP Bundle adherence, when controlling for patient care area, central line days, and bed capacity. Central Coast increased CLIP Bundle adherence by 1.2% ($p=0.009$); Inland Empire increased CLIP Bundle adherence by 1.2% ($p=0.003$); and Los Angeles County Region 8 increased CLIP Bundle adherence by 0.89% ($p=0.01$). Finally, higher bed capacity significantly decreases CLIP Bundle adherence ($p=0.03$). Bed capacity decreased CLIP Bundle adherence by 0.002%; therefore, this inverse relationship indicates the higher the bed capacity, the lower the CLIP Bundle adherence percentages.

Association Between Central Line Insertion Practices Bundle Adherence and Central Line-Associated Blood Stream Infection Standardized Infection Ratio

Research Question #3: Is there an association with CLIP Bundle adherence scores and CLABSI SIR rates within different patient care areas? To answer research question 3 regarding if there is an association with CLIP Bundle adherence scores and CLABSI SIR rates within patient care areas, I performed a Kruskal- Wallis test. Because both CLIP Bundle adherence scores and CLABSI SIR rates were both skewed, they violated the assumptions of ANOVA, therefore, a nonparametric version of

ANOVA was used. Two analyses were performed – one to assess the effect of patient care area on SIR and the other to assess the effect of patient care area on CLIP Bundle adherence. As seen in Table 10, there was a significant effect of patient care area on SIR (df: 2, 15.7, p=0.000) for the three patient care areas of neonatal care area, critical care area, and special care area. However, as seen in Table 11, there was not a significant effect of patient care area and CLIP Bundle adherence (df: 2, 4.3, p=0.115) for the three patient care areas of neonatal care area, critical care area, and special care area.

Table 10.

Kruskal-Wallis: Standardized Infection Ratio Rates on Patient Care Area

Source	χ^2	df	p-value
Neonatal care area n = 594 Critical care area n = 418 Special care area n = 124	15.721	2	0.0004

Table 11.

Kruskal-Wallis: Central Line Insertion Practices Bundle Adherence on Patient Care Area

Source	χ^2	df	p-value
Neonatal care area n = 566 Critical care area n=410 Special care area n=4	4.325	2	0.115

Conclusion

As discussed in Chapter 4, quantile regression analysis indicated that critical care area was significantly associated with SIR, when controlling for central line days, region, and bed capacity ($p=0.05$). A negative relationship existed with critical care area and CLABSI SIR rates, which indicated that there was a reduced infection rate, compared to all other patient care areas. In addition, quantile regression analysis indicated there was no statistically significant difference between critical care areas and general care areas as compared with neonatal care area, with regard to CLIP Bundle adherence. This result indicated that CLIP Bundle adherence was consistent across all patient care areas, with critical care showing significant reduction in infection rates, which suggests room for improvement in other patient care areas. As a result, reduced infection rates were associated with an increased CLIP Bundle adherence. Finally, results from ANOVA analyses indicated there was a statistically significant association between patient care area and SIR; however, there was not a statistically significant association between patient care area and CLIP Bundle adherence. Chapter 5 will include discussion of results, conclusions, and recommendations.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

The primary purpose of this study was to determine whether CLIP Bundle adherence has an impact on rates of CLABSI among various patient care areas in California. Patient care areas are different areas in hospitals in which patients receive treatment. In this study, the patient care areas examined were critical, neonatal, and special care areas. The study was quantitative in nature. Analysis of secondary data from two statewide databases was a means to identify the incidence of CLABSI among various patient care areas within hospitals in California and to examine whether there exists an association between the CLIP Bundle adherence scores and patient care areas. I performed an assessment of these associations to address a gap in the literature regarding the practice of the CLIP Bundle use in hospitals regarding CLABSI rates. The findings may raise awareness of the benefits of monitoring and tracking CLIP Bundle adherence scores for an effective CLABSI risk-reduction quality improvement initiative.

I used descriptive statistics to characterize CLABSI cases and CLIP Bundle adherence rate. The median SIR, which is a calculation that identifies the number of CLABSI cases by comparing the number of actual reported CLABSI cases to the United States baseline reported CLABSI cases, was 0.52 infections in the patient care areas, ranging from a rate of 0 to a rate of 4.72. According to the CHHS (n.d.), an SIR value greater than 1.0 indicates that more infections were observed than predicted; conversely, an SIR less than 1.0 indicates that fewer infections were observed than predicted. The broad range of SIR (0 to 4.72) presented some outliers, but with a median value of 0.52,

it can be concluded that the number of infections observed was fewer than the number of infections predicted, and therefore, the SIR rate among the patient care areas in the study was low. CLIP Bundle adherence rate ranged from 96.8%-100%, with the median CLIP Bundle adherence rate of 99.2%. This result demonstrated the high adherence to the CLIP Bundle with very low variability across all patient care areas utilized in the study. The neonatal care area had the highest CLIP Bundle adherence rates at 99.4%, followed closely by special care areas at 98.3%, which represented the lowest CLIP Bundle adherence rates. Among the patient care areas, neonatal care areas had the lowest SIR, with a median value of 0.50 (range 0.00-1.50), whereas special care areas had the highest infection rates, with a median value of 0.62 (range 0.05-2.30). As a result, the median CLABSI SIR rate for all patient care areas was under 1.0, which indicates that the observed rates of infections were lower than the predicted rates of infections in all patient care areas examined in this study. Finally, with respect to region, there were few statistically significant differences compared to the reference group of Superior California, which suggests the CLABSI SIR rate and CLIP Bundle adherence were comparable across geographic regions.

In the remainder of this chapter, I elaborate on the interpretations of the study findings, limitations of the study, recommendations for further research, and positive social change implications. I conclude the chapter with a summary of the study and the implications of this research.

Interpretations of Findings

Research Question 1

To address RQ1, I examined whether patient care areas were associated with CLABSI SIR rates. Results from the quantile regression analysis indicated that critical care area was significantly associated with CLABSI SIR, compared to the referent category of neonatal care area, when adjusting for central line days, region, and bed capacity. As described earlier, the term *critical care area* incorporates medical, surgical, burn, trauma, long-term acute, and pediatric critical care, all serving as ICUs (CHHS, n.d.).

This finding is not surprising as patients who receive treatment in the ICU include those who have undergone major surgical procedures, are critically ill, or have comorbidities that require additional monitoring (CDC, 2018d). These patients often require the insertion of central lines to aid in fluid and medication delivery. Because of prolonged hospital stays or prolonged catheter use, patients in ICUs are at a significantly higher risk of acquiring CLABSI and subsequent central line complications (Hina & McDowell, 2017; Liu 2017; Reyes et al., 2017). In addition, the critical nature of patients' health in ICUs increases the risk of complications and infection, which contributes to acquiring a central line infection (CDC, 2018d). Though the CDC indicated a marked reduction in CLABSI episodes in recent years, the ICU continues to remain the most prevalent hospital location for infections (CDC, 2018d).

The finding of higher SIR rates in critical care settings versus non-ICU settings is consistent with the literature. This is in spite of the fact that there are notable differences

between the present study and previous research. For instance, many existing studies were prospective to assess the incidence of CLABSI in ICUs. In contrast, the current study was retrospective, which allowed for assessment of CLABSI rates in various hospital patient care areas. Prior CLABSI researchers often focused on population types, such as neonatal or adult, whereas I focused on three patient care areas in California facilities to assess an aggregate relationship between patient care areas and CLABSI rates. Finally, many current studies address the catheter type and insertion site as risk factors for acquiring CLABSI (Smith & Nolan, 2013); however, I did not have data on either of these risk factors and was unable to determine if there was an association between said risk factors and CLABSI SIR rates in ICUs.

Research Question 2

The second research question was to determine whether patient care area was associated with CLIP Bundle adherence. I found that CLIP Bundle adherence was not statistically different between critical care areas and general care areas compared with the referent category of neonatal care area after adjusting for central line days, region, and bed capacity. The CLIP Bundle underwent modification in 2016 to incorporate all eight components to reduce the rates of CLABSI (CDC, 2018a). As the development and implementation of the CLIP Bundle are relatively new with only two states mandating reporting, there is a paucity of literature assessing the impact of CLIP Bundle adherence on CLABSI rates (Quan et al., 2016). As a result, I am unable to provide comparisons to existing literature. However, researchers to date have supported the concept of using central line practice bundle components (e.g., hand hygiene and aseptic technique

practices, education, surveillance, and quality improvement initiatives) as a comprehensive effort to reduce CLABSI incidence (Reyes et al., 2017; Roberts, 2015; Russell et al., 2019).

Despite a paucity of literature regarding the impact of CLIP Bundle adherence on CLABSI rates, infection prevention strategies addressed in prior research are consistent with the results of this study. Legeay et al. (2015) described four strategies to reduce the spread of infection, which included the use of maximal sterile barriers prior to catheter insertion. A major component of the CLIP Bundle is to utilize maximal sterile barriers prior to catheter insertion, to avoid spreading bacteria. In addition, Mitchell and Gardener (2014) discussed the importance of a multifaceted approach to infection prevention to help to break the chain of infection. Infection prevention strategies such as CLIP Bundle adherence directly align with the theoretical framework chosen for this study, the chain of infection, an extension of the epidemiologic triad model (CDC, 2012). According to the chain of infection framework, infection transmission occurs when the agent leaves the host (or reservoir) through a portal of exit, which begins the mode of transmission, and enters a susceptible host through a portal of entry (CDC, 2012). In this study, the chain of infection framework applied because the use of a comprehensive infection prevention strategy like the CLIP Bundle showed how a broken link can disrupt the infection process. By implementing the eight components of the CLIP Bundle—which include proper hand hygiene practices, appropriate skin preparation, and use of all five maximal sterile barriers (sterile gloves, sterile gown, cap, mask, and large sterile drape for the patient—when inserting a central line, health care professionals can break the chain and

disrupt infection (CDC, 2018d). Finally, Lee et al. (2018) indicated that compliance of infection prevention bundles has been shown to reduce CLABSI episodes. The findings of this study were consistent with this, as the higher the CLIP Bundle adherence, the lower the infection rate.

Research Question 3

Two ANOVA analyses were performed, one to assess whether there was an association between SIR rates and patient care area, and another to assess whether there was an association between CLIP Bundle adherence and patient care areas.

SIR rates and patient care area. There was a statistically significant association between patient care area and SIR based upon the results from the first ANOVA. Patients who are critically ill, have undergone major surgical procedures, or have comorbidities are likely to suffer from health care-acquired infections such as CLABSI. As shown in published research in acute critical care areas of the hospital to include ICUs, CLABSI is highly prevalent (Curlej & Katrancha, 2016; Hina & McDowell, 2017; Hong et al., 2013; Liu et al., 2017; Spelman et al., 2017). Findings from the current study were consistent with the literature, showing CLABSI prevalence among the neonatal population due to underdeveloped immune systems, underlying illnesses, and surgical procedures. Hooven & Polin (2014) indicated that neonates typically require central venous catheters and have prolonged stays in the NICU, which is an inherent risk factor for acquiring CLABSI. The findings from the current study are consistent with the literature indicating CLABSI is prevalent among patients with comorbidities and advancing age. Pepin et al. (2016) discussed patients with comorbidities, such as renal disease, liver disease, and

cerebrovascular disease were at higher risk of developing CLABSI. In addition, subsequent CLABSI incidence can occur when patients receive treatment for comorbidities, such as hemodialysis (Conwell et al., 2019). Finally, Kaye et al. (2014) discussed that advanced age has been shown to be a risk factor for developing CLABSI.

CLIP Bundle adherence and patient care area. Results from the second ANOVA, which assessed CLIP Bundle adherence by patient care area, indicated there was no association between CLIP Bundle adherence and the neonatal, critical, and special care areas. As previously described for RQ2, there is a paucity of current literature regarding the impact of CLIP Bundle adherence on patient care areas. Accordingly, the findings from this study extend knowledge in the discipline.

Limitations of the Study

As this study was retrospective, a chief limitation was the use of secondary data sets. Previously collected and published by the CDC, the data sets may have had quality issues, such as missing or incorrect data, resulting in under- or overestimated CLABSI rates. Another limitation related to the reporting of CLIP Bundle adherence scores. Health care professionals could only answer *yes* if they complied with all eight components of the CLIP Bundle (CHHS, n.d.). Because there was no identification of noncompliant components in the data set, I was limited in examining the individual components. In addition, because reporting of CLIP Bundle adherence was based on reports by health care professionals and thus subject to interpretation (e.g., in an attempt to cast their facilities in a more favorable light), bias could have affected the study outcomes, as participant responses may not have been entirely truthful.

Another potential limitation was that the data were from facilities in one state, which may limit the application of findings to other hospitals in other states. Also, the data were aggregated at the hospital level and contained no patient-level information; as a result, I had no demographic data to analyze. Finally, the study design was cross-sectional; the data sets contained information from 2015 only. Because of timing of the introduction and implementation of the CLIP Bundle, it is uncertain whether the results would apply in more recent years, due to lack of current data being available at the time of these analyses.

Recommendations

Because there is a paucity of current literature regarding the implementation of CLIP Bundle adherence, future researchers should examine the impact of adherence on CLABSI rates. As I focused only on health care facilities in one state, further scholars should include different states. However, because CLIP Bundle reporting is only mandated in two states, these efforts may depend on the enactment of policies requiring the reporting of CLIP Bundle. Future researchers could also incorporate visibility into comparing adherence and nonadherence to specific components of the CLIP Bundle which could help health care professionals keep better track of their practices in CLABSI reduction quality initiatives.

This study used secondary data only, therefore future scholars should conduct primary data collection to add to the current literature. Primary data collection could allow for researchers to obtain more data, which could provide more insight into utilization of CLIP Bundle adherence. Because data in this study did not indicate which

components of the CLIP Bundle adherence were utilized, primary data collection of these individual components could positively contribute to the current literature and assist healthcare providers in improving care to patients. It would also be beneficial to conduct a mixed-methods study incorporating primary qualitative data from health care professionals to obtain better insight into CLIP Bundle practices, along with health care practitioner's attitudes toward these practices (e.g., barriers to their adoption). In addition, researchers should incorporate sociodemographic characteristics when examining the impact of CLIP Bundle on CLABSI rates which may provide more insight that could elucidate more information regarding risk factors that contribute to acquiring infection. For example, Kaye et al. (2014) indicated advanced age is a risk factor for acquiring infections; therefore, if future researchers collected data points on age and other sociodemographic factors, future research could assess the relationship these factors have on CLIP Bundle adherence. Future research should also incorporate data on clinical information, such as comorbidities, central line placement/location, and pathogenesis, which have all been previously studied as risk factors for CLABSI (Smith & Nolan, 2013; Pepin et al., 2016; Haddadin & Regunath, 2017).

Finally, scholars may wish to incorporate different hospital patient care areas, as I used only neonatal, critical, and special care areas. Though the dataset used in this study had CLABSI SIR data for general care areas and mixed acuity areas, CLIP Bundle adherence data were not available, and therefore, these patient care areas were not a part of the analysis. Because general care areas and mixed acuity areas comprise various levels of acuity and are not classified as a specific ICU location type, there could

presumably be lower risk of infection and consequently, lower CLIP Bundle adherence (CDC, 2019a). Therefore, a final recommendation is for future researchers to collect CLIP Bundle adherence rates for general care, mixed acuity, and other patient care areas that were not part of this study to assess the relationship on CLABSI SIR rates.

Implications

Although many risk factors are associated with CLABSI, in many cases, infection is preventable when health care professionals receive education and instruction regarding the proper way to insert a catheter (Legeay et al., 2015). In addition to correct catheter insertion, practicing adequate hand hygiene and proper skin preparation before insertion can also reduce or prevent the risk of CLABSI (Goudet et al., 2013; Ling et al., 2016). Current literature indicates the importance of bundle interventions, which combine both education and instruction regarding the correct way to insert a catheter, in conjunction with proper practice of hand hygiene and skin preparation. The CLIP Bundle described in this study is an effective risk-reduction infection prevention strategy (Quan et al., 2016; Scott et al., 2016).

The CLIP Bundle comprises eight components that include proper hand hygiene practices, appropriate skin preparation prior to catheter insertion, and use of all five maximal sterile barriers (sterile gloves, sterile gown, cap, mask, and large sterile drape for the patient) when inserting a central line (CDC, 2018d). By educating health care professionals on the CLIP Bundle and implementing this infection prevention strategy in the facilities, health care professionals can prevent or reduce the incidence of CLABSI (CDC, 2018d). Because CLIP Bundle adherence was consistent across all patient care

areas in the study, but did, however, indicate that critical care had a significant reduction in infection rate, this may suggest more compliant CLIP Bundle steps. As a result, there could be opportunities for healthcare professionals to improve care across other patient care areas, in an effort to reduce infection rates. Because CLIP Bundle reporting is currently mandated in only two states, the findings of this study can inspire positive social change by requiring policymakers and health care professionals to implement the CLIP Bundle nationwide, thus significantly reducing the national incidence of CLABSI. Implementation would require collaborative partnerships between health care professionals and policymakers to ensure mandatory reporting and effective practice in a national effort to reduce the incidence of CLABSI. In addition to the potential for affecting practice in health care facilities, the results of this study further positive social change by encouraging the ongoing study of the impact of the CLIP Bundle on CLABSI rates. The results of this study indicated no statistically significant association between patient care areas and CLIP Bundle adherence but these findings could encourage future research among different hospital patient care areas to assess the impact on CLIP Bundle adherence.

Conclusion

CLABSI remains a serious public health problem in the United States. Although CLABSI may be preventable, health care professionals struggle to reduce infection incidence. The purpose of this study was to determine if CLIP Bundle adherence had an impact on CLABSI rates among patient care areas in California hospitals. The study was a means to determine whether there were differences among CLIP Bundle adherence

scores among these patient care areas. This quantitative study entailed the analysis of secondary data from the California Department of Public Health documenting SIR and CLIP Bundle adherence scores for 2015. Findings indicated that critical care areas were significantly associated with CLABSI SIR when controlling for central line days, region, and bed capacity. In comparison, there was no significant association between patient care area and CLIP Bundle adherence when controlling for central line days, region, and bed capacity.

I found a significant association between patient care area and CLABSI SIR; however, there was no significant association between patient care area and CLIP Bundle adherence. If health care professionals are to remain diligent in practicing CLIP Bundle adherence in an effort to reduce CLABSI rates, future research is warranted. Findings from this innovative study fill a gap in the current literature regarding the practice of the CLIP Bundle to address hospital CLABSI rates. In addition, findings raise awareness of the benefits of monitoring and tracking CLIP Bundle adherence scores as an effective CLABSI risk-reduction quality improvement initiative. Finally, this study may contribute to positive social change by providing valuable information to aid medical and public health officials in enhancing central line clinical and aseptic preventative techniques to reduce CLABSI rates.

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