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The Effectiveness of an Intervention Designed to Improve Chlorhexidine (CHG) Bathing Technique in Adults Hospitalized in Medical Surgical Units

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The Effectiveness of an Intervention Designed to Improve Chlorhexidine (CHG) Bathing Technique in Adults Hospitalized in Medical Surgical Units

by

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Dedication

This work is dedicated to my husband Sean Denny and my children, Katelynn, Krysten, and Ryan. Their love, support and understanding made this journey possible. I am also grateful to my family (mom and dad), my wonderful friends, professors and co-workers for their support and encouragement throughout the program. A special recognition to my faculty advisor and dissertation chair; Dr. Munro, thank you for always believing in me and inspiring me to reach my goals.

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Abstract

Central line associated bloodstream infections (CLABSIs) are one of the most fatal types of healthcare associated infections (HAIs) and their economic impact is significant. Although some studies have found no signification reduction in CLABSI rates with chlorhexidine gluconate (CHG) bathing; good evidence exists to support the use of CHG bathing as an intervention to reduce CLABSIs (Bleasdale et al., 2007; Climo et al., 2009; Climo et al., 2013; Montecalvo et al., 2012). CHG bathing performance may influence the effectiveness of the CHG bathing protocol.

The purpose of this study was to determine the effect of a targeted educational approach involving simulation on the delivery by nursing assistants of a CHG bathing protocol. The study aims were (1) to compare the effectiveness of removal of simulated skin microbes by nursing assistants who receive training for a CHG bathing protocol with simulation training to simulated skin microbe removal by nursing assistants who receive training for a CHG bathing protocol without simulation training and (2) to examine the influence of a demographic factor, years of practice as a nursing assistant on the percentage of simulated microbes present following performance of bathing.

Thirty nursing assitant volunteered for this study and were randomized to either the intervention group (training for a 2% CHG cloth bathing protocol with simulation training) or the control group (training for a 2% CHG cloth bathing protocol without simulation training). For aim (1) an independent *t*-test (inferential tests of group differences) was used to examine if there was any difference between the intervention group and the control group on the percentage of

microbes remaining on the mannequin post bathing. For aim (2) a Pearson correlation was computed to assess the relationship between years of practice as a nursing assistant and the percentage of microbes remaining post bathing.

Results showed no statistically significant differences between the two groups on demographc factors. For aim (1) the *t*-test revealed a statistically significant ($p < .001$) difference between the intervention group and the control group on the percentage of simulated microbes remaining on the mannequin post bathing. For aim (2) there was no correlation between the years of practice as a nursing assistant and the amount of microbes left on the mannequin post bathing ($p=.709$).

This study provided an innovative method of assessing the percentage of simulation microbes remaining on the mannequin and made it possible to quantitatively measure bathing performance. Monitoring the compliance with CHG bathing is an important component when evaluating the effectiveness of a CHG bathing protocol. The findings of this study suggest that simulation training was an added benefit to the nursing assistants who received it, as they performed better than those who did not receive simulation training.

Chapter I: Introduction

Central line associated blood stream infections (CLABSIs) are one of the most fatal types of healthcare associated infections (HAIs), with a mortality rate of 12%--25% (CDC, 2016). HAIs result from an infectious agent that is acquired during hospitalization, more commonly referred to as nosocomial infections. CLABSIs are classified as nosocomial blood stream infections (BSIs) associated with the use of central venous catheters (Raad, Alakech, Chatzinikolaou, Johnson & Tarrand, 2004), and thus are a subset of HAIs.

The Centers for Disease Control and Prevention (CDC) reported that approximately one out of every twenty hospitalized patients will contract a HAI during the course of their hospitalization (CDC, 2016). The HAI prevalence survey published in 2014, reported an estimated 722,000 HAIs in U.S. acute care hospitals in 2011, of which 75, 000 hospitalized patients died. More than half of those deaths occurred outside of the intensive care unit (ICU) setting (Magill et al., 2014). The direct medical cost of HAIs ($5.7 to 6.8 billion annually) are comparable to the annual costs of stroke ($6.7 billion), diabetes mellitus with complications ($4.5 billion), or chronic obstructive lung disease ($4.2 billion) (CDC, 2009).

The hospital regulatory agency known as The Joint Commission (TJC) has called for implementation of evidenced based measures to prevent HAIs due to multidrug resistant organisms in acute care hospitals (TJC, 2016). The Center for Medicare and Medicaid (CMS) guidelines further stress the importance of HAI prevention through its policy of non-reimbursement for HAIs (CMS, 2016). Patients suffer unnecessarily and hospitals stand to lose financially without a prevention plan in place to eliminate HAIs, including CLABSIs.

CLABSIs are considered present when a recognized pathogen is cultured from one or more blood cultures in a patient with a central line, and the organism cultured from blood is not related to an infection at another site (Guerin, Wagner, Rains, & Bessesen, 2010). The criterion for diagnosis of CLABSIs has been established by the CDC's National Healthcare Safety Network (NHSN); these criteria allow for categories of infections to be identified consistently so that facilities can compare their rates to national benchmarks (CDC, 2016).

Although central venous catheters can predispose a large number of patients to the risk of acquiring a HAI, they are an essential part of care for certain patient populations. Patients requiring intravenous lifesaving medications as well as long term intravenous antibiotics depend on these catheters (Bianco, Coscarelli, Nobile, Pileggi, & Pavia, 2013). There are a number of controllable risk factors associated with CLABSI development. Controllable risk factors include catheter insertion with less than maximal sterile barriers, technique, location of placement, heavy colonization of the insertion site or contamination of a catheter hub, and duration of catheter placement greater seven days (Safdar, Kluger, & Maki, 2002). Many controllable risk factors can be modified to help prevent CLABSIs, including those related to sterile technique during catheter insertion and maintenance of the catheter. Proper site preparation with an effective skin disinfectant such as chlorhexidine can reduce risk (Climo, Sepkowitz, Zuccotti, Fraser, Warren, Perl, Speck, Jernigan, Robles & Wong, 2009).

Researchers working with the CDC believe hygiene regimens that use chlorhexidine gluconate (CHG) serve as a prevention method against HAIs including CLABSIs (Sievert, Armola, & Halm, 2011). CHG bathing in the intensive care unit setting has shown an impact on the reduction of CLABSIs (Bleasdale et al., 2007; Climo et al., 2009; Climo et al., 2013; Montecalvo et al., 2012). CHG has been used for whole-body cleansing in critically ill patients

and this intervention has been associated with reductions of methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant enterococci (VRE) and subsequent development of healthcare associated blood stream infections (Climo et al., 2009). Montecalvo et al. (2012) found that CHG bathing was associated with significant reductions in CLABSIs and these reductions were reportedly sustained post-intervention when CHG bathing was unmonitored. In a study conducted by Soma et al. (2012) pediatric patients with central lines who received greater exposure to CHG baths, had associated lower colony counts of cultivable cutaneous bacteria and fewer different bacterial phenotypes.

Nursing assistants are valuable partners of the acute care healthcare team. They are often asked to undertake a wide range of tasks, including CHG bathing for patients in the acute care hospital setting. Nursing assistant training is frequently completed using a condensed educational approach due to the constraints of a fast-paced clinical environment (Ward, Stewart, Ford, Mullen, & Makic, 2014). The CHG bathing training content may involve a brief educational session and distribution of a bathing points hand out. Due to the minimal training involved in the application of the CHG bathing process, variations may exist in technique from nursing assistant to nursing assistant.

A descriptive study on current patient bathing practices among nursing assistants compared to recommended practice in adults hospitalized in medical surgical units was conducted as a preliminary study prior to this dissertation study. The purpose of the study was to examine the current state of CHG bathing practice in the acute care hospital setting. In the study twenty patients with central lines in place were observed as they received their morning care including their bath from a nursing assistant. The findings of the descriptive study revealed that out of twenty patients observed only nine (45%) were bathed with 2% CHG cloths. Of those

patients bathed with the 2% CHG cloths only two (22%) patients had no areas missed during bathing below the jaw line. This study provided evidence to support the need for further exploration and optimization of the 2% CHG cloths bathing protocol.

Routine decolonization of patients' skin with CHG bathing as standard intervention to prevent CLABSIs needs further exploration. More rigorous research with adult patients outside of the intensive care unit setting is needed to explore the efficacy of CHG bathing in the reduction of CLABSIs, colonization of MRSA or VRE (Sievert et al., 2011). It is important to test the efficacy of a CHG bathing intervention performed by nursing assistants to more accurately determine its impact on CLABSI reduction. CLABSI rates are reportable and transparent to the consumers. Today's hospital consumers can compare their local hospitals side by side on HAIs rates, including CLABSIs via the Medicare Hospital Compare web site. Hospital administrators are investing in evidence-based practices in an effort to attain a zero incidence rate of CLABSIs.

Statement of the Problem and Purpose

The implementation of CHG bathing as a standard intervention to decrease the incidence of CLABSIs needs further investigation outside of the intensive care unit clinical setting. There are various studies in the literature demonstrating the benefits of CHG bathing in the intensive care unit setting (Bleasdale et al., 2007; Climo et al., 2009; Climo et al., 2013; Dixon et al., 2010; Montecalvo et al., 2012). However, studies focused on the use of CHG bathing as a standard intervention to reduce CLABSIs outside of the intensive care unit setting are lacking. When a patient is hospitalized outside of the intensive care unit, the nursing assistant is often tasked with completion of the CHG baths. It is important to optimize the delivery of the CHG bathing intervention with this group of caregivers to ultimately determine its impact on CLABSI

reduction. The purpose of this study is to determine the effect of a targeted educational approach involving simulation on the delivery by nursing assistants of a bathing protocol. Enhancing performance of CHG bathing by nursing assistants is the first step toward a goal of reducing CLABSIs in adults hospitalized in medical surgical units.

Specific Aims

The specific aims of this study are to:

1. Compare the effectiveness of removal of simulated skin microbes by nursing assistants who receive training for a CHG bathing protocol with simulation training to simulated skin microbe removal by nursing assistants who receive training for a CHG bathing protocol without simulation training.
2. Examine the influence of a demographic factor, years of practice as a nursing assistant, on the percentage of simulated microbes present following performance of bathing.

Definitions of Relevant Terms

Hospital Acquired Infections (HAIs). HAIs are the result of the presence of an infectious agent that occurs during hospitalization (CDC, 2016).

Central Line Associated Blood Stream Infections (CLABSIs). CLABSIs are defined as the recovery of a pathogen from a blood culture (a single blood culture for organisms not commonly present on the skin and two or more blood cultures for organisms commonly present on the skin) in a patient who had a central line at the time of infection or within the 48-hour period before development of infection. The infection cannot be related to any other infection the patient might have and must not have been present or incubating when the patient was admitted to the facility (CDC, 2016).

Chlorhexidine Gluconate (CHG). CHG as a topical antiseptic solution has a main action of reducing bacterial colonization on the patients' skin and is commercially available at concentrations ranging from 0.5% to 4% formulations with and without alcohol (Milstone, Passaretti & Perl, 2008).

CHG Bathing. Daily chlorhexidine bathing replaces soap and water bathing. St.Anthony's Hospital uses 2% CHG (alcohol free) impregnated cloths for patient bathing on those patients who have a central line catheter in place. St.Anthony's Hospital also uses CHG bathing for all patients in the ICU setting. The manufacturer of the CHG cloths provides a universal ICU decolonization protocol for CHG bathing technique in the ICU.

Nursing Assistants. A certified nursing assistant, or CNA, helps patients with healthcare needs under the supervision of a Registered Nurse (RN) or a Licensed Practical Nurse (LPN). St. Anthony's Hospital has a one-day class for all CNAs that have been recommended by their manager to become patient care technicians (PCTs); a type of nursing assistant with added skills (Foley catheter insertion and ostomy care). Nursing students employed at St.Anthony's Hospital are hired in as PCTs after completing the semester in nursing school called Nursing Fundamentals.

Significance to Nursing

The CDC guidelines for the prevention of intravascular catheter-related infections, 2011 refers to 2% chlorhexidine wash for daily skin cleansing to reduce catheter-related infections as a category II level of evidence (CDC, 2016). CHG bathing variation between nursing personnel must be avoided to optimize results. This study may shed light on the impact of simulation CHG bathing as an essential training effort towards CLABSI prevention.

Chapter II: Review of Literature

This chapter reviews and synthesizes the current literature on central line associated blood stream infections (CLABSIs). This chapter also expands on the current practice of CHG bathing as an intervention for reduction of skin microbe colonization. A literature search was conducted using the following search terms: central line infection definition and CHG bathing. The search was conducted using PUBMED and CINAHL search engines. All articles that met inclusion criteria (indexed in PUBMED or CINAHL, written in the English language and published in peer reviewed journals) were included. Articles that only provided an abstract and unpublished studies were not included. All peer-reviewed articles were analyzed for scientific rigor and relevance to this study. First, studies on CLABSIs were reviewed including a description of identified risk factors. Then, hygiene regimens to reduce skin microbes were explored. The usage of CHG soap was also reviewed. The conceptual framework for the research study is discussed. A summary is provided, including current knowledge gaps where additional research is warranted.

CLABSIs

Hospital acquired infections (HAIs) are often device-associated as in the occurrence of CLABSIs. The hospital setting provides an ideal environment for antibiotic-resistant pathogens to flourish and migrate to central venous catheter devices (Montecalvo et al., 2012; Ritz, Pashnik, Padula & Simmons, 2012). These catheters are an essential part of care for specific patient populations (Bianco, Coscarelli, Nobile, Pileggi, & Pavia, 2013), but can

potentially serve as a nidus for infections (Armellino et al., 2014; Chopra, O'Horo, Rogers, Maki, & Safdar, 2013). CLABSIs are associated with increased patient morbidity and mortality, and their economic impact is significant with estimated direct costs ranging from $7,288 to $29,156 per episode (Edwards, Purpura, & Kochvar, 2014). There are an estimated 23,000 CLABSI episodes per year; according to data retrieved from 2009 CDC report (CDC, 2009). At that estimated rate the heath care system stands to lose $1.6 to $6.7 billion annually from CLABSI associated costs.

Risk Factors

Risk factors have been identified that are associated with the development of CLABSIs. They include the patient, the environment and the skin's resident bacteria (Safdar et al., 2002; Sanford & Gallo, 2013). Factors such as age, sex, underlying disease, use of medication, lifestyle and hygiene play an important role in the disruption of the skin's resident bacteria, a condition referred to as dysbiosis (Dominguez-Bello et al., 2010; Safdar et al., 2002). Coagulase-negative staphylococci (CoNS) and *Staphylococcus epidermidis* cause the greatest number of infections and are most frequently the causative agents of indwelling medical device infections (Schommer & Gallo, 2013).

Most CLABSIs result from contamination of the catheter by bacteria residing on the patients' skin at the time of catheter insertion (extraluminal) or later from microorganisms migrating from the skin to the catheter tip (intraluminal) (Bleasdale et al., 2007; Safdar & Maki, 2004). Skin colonization with multi-drug resistant bacteria such as MRSA and VRE add an increased risk of infection in hospitalized patients (Ngo & Murphy, 2005). Reduction of

potential pathogens on the skin plays an important part in CLABSI prevention (Armellino, Wotmann, Parmentier, Musa, Eichorn, Silverman, Hirschwerk & Farber, 2014).

Hygiene Regimen

Topical antiseptic solutions are used as a preventative measure to reduce or eliminate skin microbes (Climo et. al, 2009; Rupp et al., 2012). This intervention is primarily used in hospitalized patients who are already in an immune compromised state and may have an indwelling medical device (Viray et al., 2015). Topical antiseptic skin cleansing is also recommended for use prior to surgical procedures (CDC, 2016). The agent most commonly used and recommended is chlorhexidine (CDC, 2016).

Source control is described as an infection control measure to reduce the number of pathogens through decolonization strategies (Montecalvo et al., 2012). CHG bathing is used as an intervention for source control, both for the preoperative patient population and more recently for patients with a central venous catheter (Kassakian, Mermel, Jefferson, Parenteau, & Machan, 2011). Preoperative bathing or showering with an antiseptic skin wash product is a well-accepted procedure for reducing skin bacteria (microflora) (Edmiston et al., 2013).

Some evidence (mainly from quasi-experimental studies) exists on the benefits of using CHG bathing, instead of soap and water bathing, to reduce bacterial skin microflora and prevent CLABSIs (Bleasdale et al., 2007; Climo et al., 2009; Climo et al., 2013; Dixon et al., 2010; Montecalvo et al., 2012). Bleasdale et al. (2007) found that patients in the CHG intervention arm were significantly less likely to acquire a primary blood stream infection. Climo et al. (2009) (2013), found that daily bathing with CHG may reduce the acquisition of MRSA and VRE, subsequently reducing the development of hospital acquired blood stream infections. However,

there have also been studies that found no significant reduction in CLABSI rates with CHG bathing (Bass, et al., 2012; Noto, et al. 2015). Both Bass (2012) and Noto (2015) listed low rates of CLABSIs prior to the study. Noto et al. (2015) reported that lower limits of infection rates may exist beyond which CHG bathing no longer provides detectible benefits.

CHG

Chlorhexidine is a topical antiseptic solution that has been used since the 1950s (Milstone, Passaretti, & Perl, 2008). Chlorhexidine has an excellent record of safety and efficacy for the following indications: hand washing, preoperative skin preparation, vaginal antisepsis, treatment of gingivitis as well as body washes to prevent neonatal sepsis (Milstone et al., 2008). Hand washing with chlorhexidine has been shown to reduce skin flora by 86%-92%; it has a reported residual skin effect that helps to prevent rapid regrowth of skin organisms and enhances the duration of skin antisepsis (Milstone et al., 2008).

CHG is a broad-spectrum antimicrobial agent active against both gram-positive and gram-negative bacteria (Karki & Cheng, 2012). CHG is also active against yeasts and viruses, including enveloped viruses such as HIV, cytomegalovirus, influenza, respiratory syncytial virus, and herpes virus (Stokowski, 2011). CHG is not, however, effective against rotavirus, adenovirus or enterovirus (Stokowski, 2011). CHG exerts its antibacterial effect by binding to the negatively charged bacterial cell wall, altering the bacterial cell osmotic equilibrium (Milstone et al., 2008). CHG is commercially available at concentrations ranging from 0.5% to 4% and formulations with and without alcohol. Each formulation is approved for a specific use; bathing products have concentrations ranging from 2%-4%. Bathing can be performed with 2% CHG impregnated polyester cloths or 4% CHG liquid soap.

Application of CHG on a patient's body without rinsing has been found to have an optimal impact compared to application of CHG that involves a post application rinse (Karki & Cheng, 2012; Supple et al., 2015). The CHG-impregnated wipes may have an advantage over the liquid CHG soap because the CHG in the wipes is not rinsed from the skin and the residual CHG extends the potential for antiseptic activity (Stokowski, 2011). Supple et al. (2015) found that CHG concentrations on patients' skin were higher when using cloths than when the solution was used.

Most chlorhexidine antiseptic products contain alcohol, which begins to kill bacteria and inactivate viruses immediately (Stokowski, 2011). The products that contain only CHG rely on a cumulative effect for maximum bactericidal activity (Milstone et al., 2008). CHG-impregnated washcloths are single use, disposable and require no rinsing. This method eliminates the need for a reusable water basin. CHG-impregnated wipes have been primarily used in the intensive care unit (ICU) and on patients who need to be bathed in bed. These prepackaged cloths are costlier than other preparations of CHG but have been shown to also reduce bathing time (Eigsti, 2011). The no water/no basin bath is thought to be a better practice for all patients who are immune-compromised, have fresh surgical wounds, or are otherwise at high risk for infection (Stokowski, 2011). Although the CHG-impregnated cloths offer an alternative to the use of the disposable hospital bath basin, a recent study indicates that when CHG liquid soap was added to the bath basin the bacterial growth in the basin was significantly decreased (Powers et al., 2012).

CHG bathing has been associated with reduction in HAIs, (Armellino et al., 2014; Bleasdale et al., 2007; Cassir et al., 2015; Climo et al., 2013; Climo et al., 2009; Dixon et al., 2010; Gralin et al., 2013; Johnson et al, 2010; Kassakian et al., 2011; Matinez-Resendez et al., 2014;

Montecalvo et al., 2012; Petlin et al., 2014; Ritz et al., 2012; Vernan et al., 2006; Viray et al., 2014; Wendt et al., 2007) as it reduces both occupant and transitory skin flora and has a lasting effect for up to twenty-four hours (Agency for Healthcare Research and Quality, 2016). CHG bathing provides a promising intervention towards reduction of bacterial skin colonization, which is a risk factor for developing CLABSIs.

Simulation Training

Simulation training is used in nursing programs to enhance educational outcomes and has been shown to improve practical competence (Roh & Lim, 2014). Liaw et al. (2016) used web-based simulation and enhanced the nurse's role in recognizing and responding to deteriorating patients. The use of simulation has also been used with medical students. Makransky et al. (2016) used a simulation based learning environment with medical students to bridge the gap between theory and practice in medical education, using medical genetics as an example, with promising results. However, simulation is not routinely incorporated into training of nursing assistants. Simulation will be used in this study to enhance the knowledge and performance of the CHG bathing protocol.

Conceptual Framework

The development of CLABSIs involves many risk factors as is evident in the review of the literature. The patient, the environment and the role of bacteria on the patients' skin appear to be the most significant variables in the acquisition and development of CLABSIs. CHG bathing has been shown to decrease the incidence of CLABSIs as evidenced in the review of the literature. This study will focus on optimizing the delivery of a CHG intervention by focusing on the nursing assistants who deliver the intervention in an effort to decrease CLABSI

development. It is important to optimize the delivery of the CHG bathing intervention and reduce variation in technique among the personnel in order to determine the impact of CLABSI reduction. A CONSORT model (CONSORT, 2015) of this study, designed to test the effectiveness of a targeted educational approach involving simulation on the delivery by nursing assistants of a CHG bathing protocol compared to a usual education control group is shown in Figure 1. This model aided in providing a framework for data analysis of the final phase of this study. The completed CONSORT diagram is presented in the Results section (see Figure 6).

Summary

Patients with diagnosed CLABSIs are most likely to have their health adversely affected and have a longer and costlier hospital stay (O'Horo, Silva, Munoz-Price, & Safdar, 2012; Wendt, Schinke, Wurttemberger, Oberdorfer, Bock-Hensley & von Baum, 2007). In order to combat CLABSIs it is important to implement measures that decrease the number of hospital pathogens colonized on the patients skin (Montecalvo et al. 2012).

CHG bathing as an intervention to reduce cutaneous microbial bioburden on the patients' skin has resulted in reduction of VRE, MRSA and CLABSIs ((Dixon & Carver, 2010; Karki & Cheng, 2012) Studies support the use of CHG bathing to reduce CLABSIs, particularly in the intensive care setting (Bleasdale et al., 2007; Climo et al., 2009; Climo et al., 2013; Dixon et al., 2010; Montecalvo et al., 2012; Rupp et al. 2012; Sievert, Armola, & Halm, 2011).

Hospitals are continuing to strive for a zero incidence rate of CLABSIs; in this pursuit it is important to look outside of the ICU at high-risk patient populations in non-ICU settings. It is important to focus attention on the nursing assistants who are primarily responsible for administering the intervention to assure that through practical competence optimal delivery of the intervention is attained. There are currently no studies in the literature that focus on the

delivery of the CHG bathing intervention by nursing assistants and the efficacy of delivery. This study will focus on the delivery of an intervention by the nursing assistants to enhance performance of CHG bathing.

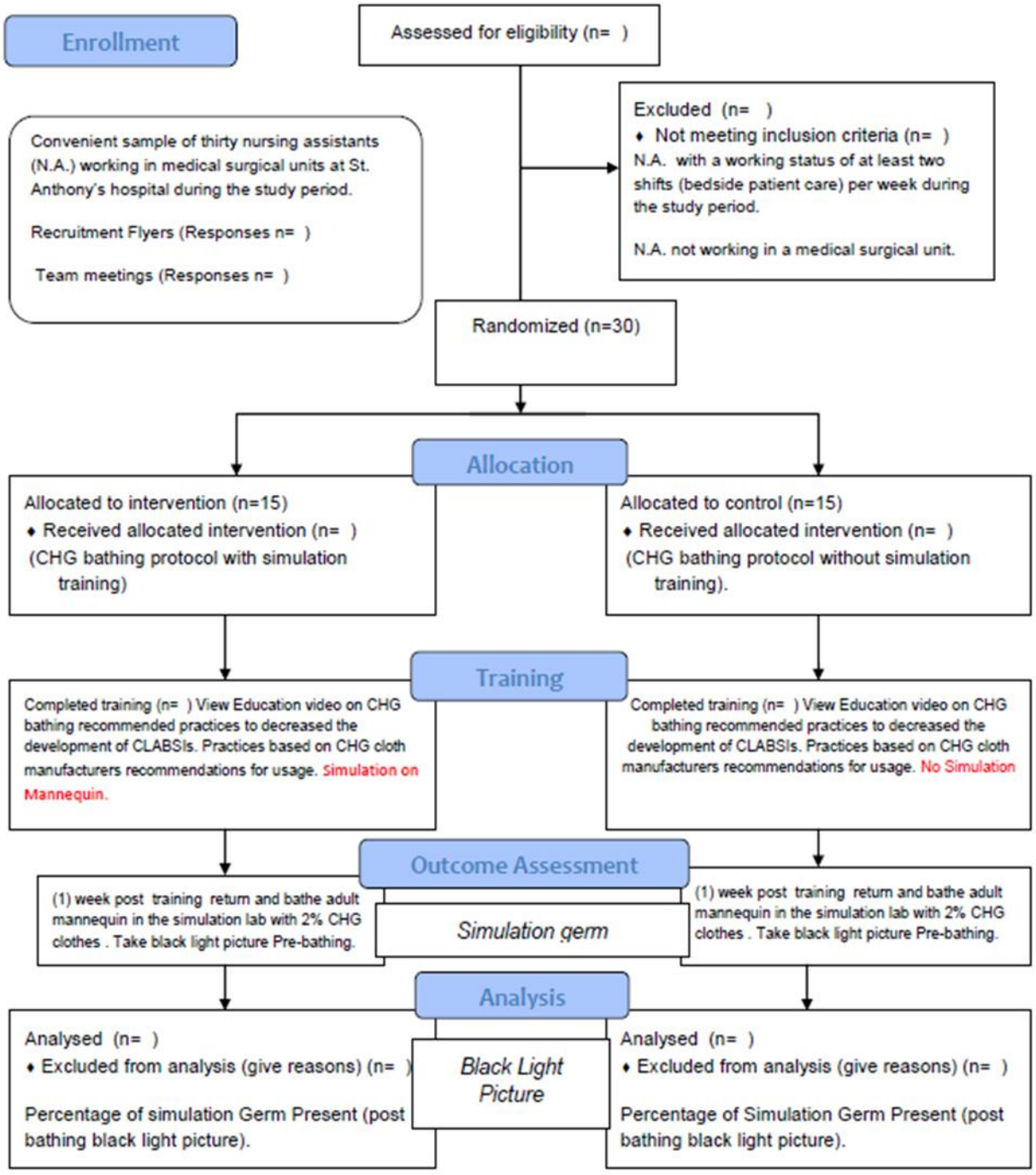

Figure 1 *CONSORT Study Flow Chart* .

Chapter III: Methods

This chapter describes methods for the study. The study design, setting and sample are included in this chapter. Measurements and study procedures are listed. Plans for study data analysis conclude this chapter.

Design

This study used a quasi-experimental, two group prospective design to address two specific aims; (1) compare the effectiveness of removal of simulated skin microbes by nursing assistants who receive training for a CHG bathing protocol with simulation training to simulated skin microbe removal by nursing assistants who receive training for a CHG bathing protocol without simulation training, (2) Examine the influence of a demographic factor, years of practice as a nursing assistant on the percentage of simulated microbe present following performance of bathing. Nursing assistants were randomized to one of two groups. One group of nursing assistants received training for a 2% CHG cloth bathing protocol with simulation training and the other group of nursing assistants received training for a 2% CHG cloth bathing protocol without simulation training. Effectiveness of bathing was measured in both groups by the percentage of simulated skin microbe remaining on the mannequin post bathing. This process was evaluated by preparing the mannequin with simulation germ that was only visible under black light. After the participant completed the bathing process a black light picture was taken of the mannequin and analyzed via a computer based software recognition program. This program calculated the percentage of simulation germ remaining on the mannequin.

Sample and Setting. The study included a convenience sample of thirty nursing assistants working in medical surgical units at St. Anthony's hospital, a not-for-profit 395-bed acute care hospital in St. Petersburg, Florida. St. Anthony's Hospital has approximately 250 nursing assistants assigned to the inpatient hospital units. The setting for this study took place in the simulation laboratory at St. Anthony's Hospital. St. Anthony's is part of the BayCare Health Care system, which includes fourteen hospitals (magnet and non-magnet). This study included the same setting for both the intervention group (CHG bathing protocol with simulation) and the control group (CHG bathing protocol without simulation).

Inclusion and Exclusion Criteria. Inclusion criteria consisted of nursing assistants with a working status of at least two shifts (bedside patient care) per week during the study period in adult medical surgical units. Nursing assistants working in the intensive care or other non-medical surgical units were excluded. This study provided data to support the determination of the appropriate sample size needed to produce an effect in future studies.

Measures

Demographic Data Form. The investigator used an investigator developed demographic data form (Figure 2). This instrument included participant initials, gender, home unit, years of experiences in the acute care hospital setting and whether or not they are a nursing student and if so, nursing program and year in program. These demographic data were used to assess equivalence in nursing assistants groups and explore the influence of years of experience as a nursing assistant on bathing performance. The nursing assistants were randomized to two groups: the intervention group (CHG bathing protocol with simulation training) and the control group (CHG bathing protocol without simulation training). Descriptive statistics were included in the two group demographic samples.

Appendix A

Demographic Survey

Study ID#

Please provide the following information for descriptive purposes.

First three letters of your First Name:_____

Last three letters of your Last Name :_____

Gender: *(please circle one)* Male Fermale

Plese list your Home Unit:_____

Shift: *(please circle one)* 7A-7P 7P-7A

Nurber of Hours worked per Week? _____

Years of practices as a Nursing Assistant: _____

Are you a nursing student? *(please circle one)* YES NO

If YES, what program? *(please circle one)* Associates Degree Bachelors Degree

Or Other: _____

Please list current year of the nursing program? _____

Thank you for Participating!

Figure 2 *Demographic Survey*

Instruments. The efficacy of simulation training in the intervention group and the control group was determined by comparing simulation microbes still present on the mannequin post bathing as assessed by software methodology. A computer based software recognition program was used to measure the percentage of microbes present on the mannequin after bathing (using microbes present on the mannequin prior to bathing as the baseline). Supine pictures were taken of an adult mannequin under blacklight pre- and post- bathing for each nursing assistant in both the treatment group and the control group. The simulation microbe glows *(Figure 3)* under the blacklight, and ultraviolet fluorescence microbes detected by black light were quantified from photographs by the computer based software program to determine the percentage of simulation microbes still present on the mannequin post CHG bathing. When applying the simulation microbes on the mannequin a stencil was used to assure the application was the same for all participants.

Before and after pictures were taken in the following sequence; right humerus *(Figure 4)* and forearm, chest and abdomen, left humerus and forearm, bilateral thighs and bilateral lower legs. The back of the mannequin was not used for this study, to avoid having one nursing assistant attempt to move the heavy mannequin on their own and also the potential of having the simulation microbes rub off the back once the mannequin's back touched the sheets.

In order to more accurately calculate the percentage of simulation microbe remaining on the body post CHG bathing the following technique was used; each body part was assigned a weight based on the simulation microbe shown on the before picture as detected by the pixels on the computer recognition software program. The final weights were calculated as such; chest 0.335, abdomen 0.185, right humerus 0.063, left humerus 0.063, right forearm 0.045, left forearm 0.045, right thigh 0.08, left thigh 0.08, left lower leg 0.052 and right lower leg 0.52. These provided a proportional representation of the mannequin's body parts on the photos. Once the percentage of pixels (microbes remaining on the mannequin post bathing) were captured by the software program a percentage was calculated. The principle investigator compared each post bathing digital picture and the corresponding post bathing percentage to assess for accuracy.

Figure 3 *Black light Picture with Simulation Germ*

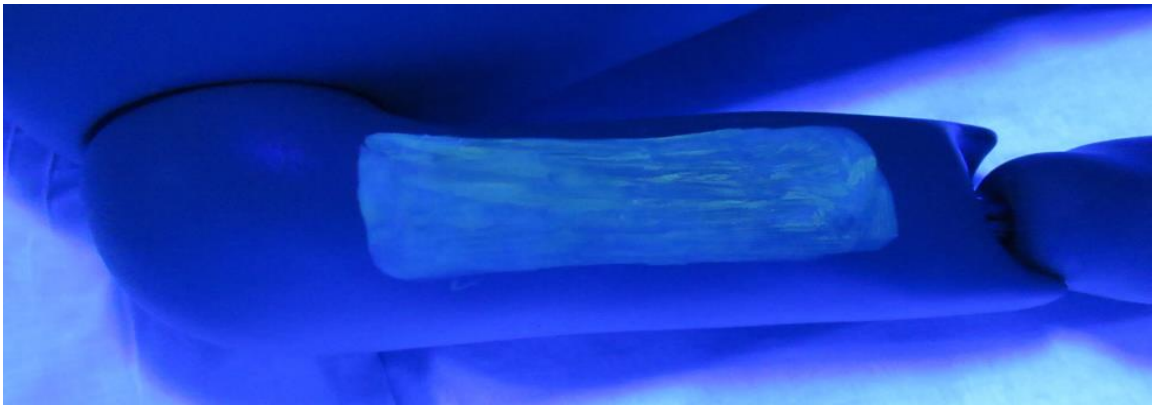

Figure 4 *Before Black Light Picture of the Right Humerus.*

Procedures

***IRB Approvals*.** Approval for involvement of human subjects was obtained from St. Anthony's Hospital (BayCare IRB) and the University of South Florida (USF) IRB prior to initiation of the study. Once the written IRB approval was obtained, a list of nursing assistants working in medical surgical units was requested through the hospitals' team resources (human resources) department. A flyer was emailed to the nursing assistants' hospital email with study information including dates and times for voluntary participation. This flyer was also posted on the medical surgical nursing units. The principal investigator explained the study at unit meetings and unit huddles. Informed consent was explained (allowing time for questions and answers) and obtained prior to participation in the study; the voluntary nature of participation was stressed. A master list of participants was created that includes the nursing assistants' initials, study identification number and the units where they work. All data was kept confidential in a password-protected spreadsheet. Eligibility was determined using the inclusion and exclusion criteria of the sample. A master list of participants was created that includes the nursing assistants' initials, study identification number and the units where they work. All data was kept

confidential in a password-protected spreadsheet. Eligibility was determined using the inclusion and exclusion criteria of the sample.

Bathing protocol. The nursing assistants were randomized to two groups of fifteen participants each. Research randomizer (a computer algorithm) was used to randomize the nursing assistants to one of two groups. The nursing assistants were assigned a code based on group membership. Both groups of nursing assistants received a pre-recorded standard classroom education session on CHG bathing recommended practices to decrease the development of CLABSIs, and a printed handout provided by the CHG cloth manufacturer (*Figure 5*). These practices are based on the CHG cloth manufacturers' recommendation.

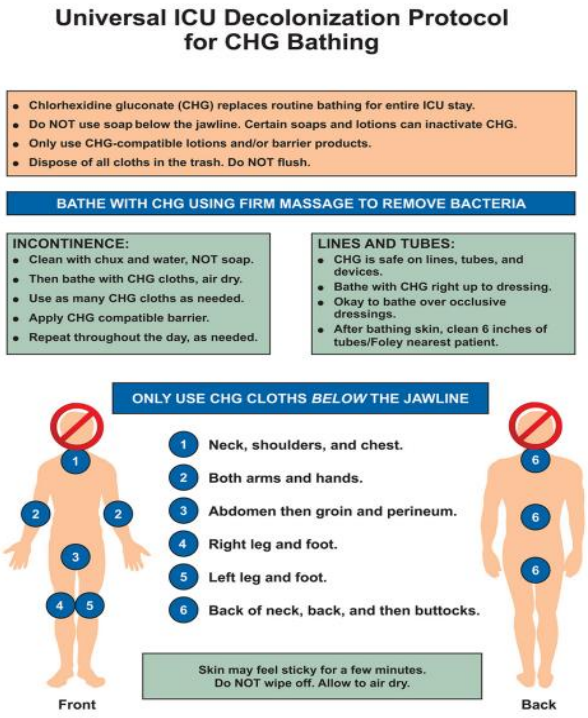

Figure 5 *Universal ICU Decolonization Protocol for CHG Bathing*

Nursing assistants in the control group received a pre-recorded classroom training session and printed material, without any simulation training. Nursing assistants in the intervention group received the same pre-recorded and printed material in a classroom training session, followed by simulation training. Simulation training included bathing an adult mannequin with disposable cloths that simulate the impregnated 2% CHG (alcohol free) cloths as instructed in the classroom, with guidance and feedback from the principle investigator. A standard script was used was used with the intervention group during the simulation training (*Appendix A*). The script was used to control for any variability between the two simulation sessions provided for the intervention group. One week after initial training, the intervention group and the control group returned to the skills lab and complete a post-test, demonstrating the CHG bathing technique on the adult mannequin. During the post-test session supplies such as gloves and simulation 2% CHG cloths were readily available for the nursing assistant to use. Ten packages containing two simulation 2% CHG cloths each (total of 22 cloths) were available for use as needed.

The control group completed the bathing procedure before the intervention group did; the same evaluation procedure was used for both control and intervention groups. The mannequin was prepared with simulation microbes that glow under black light from the chest down, to simulate pathogens colonized on the skin. The mannequin was prepared by applying the simulation microbes to both humerus, forearms, thighs, lower legs and the chest and abdomen areas. The back of the mannequin was not used in this study. A digital picture was taken under black light of the prepared mannequin with the simulation microbes prior to the bathing intervention. This was done pre-bathing for each nursing assistant. This pre-bathing picture of the mannequin was coded with the nursing assistants' study identification number.

The mannequin had a central line in place, and the nursing assistants were asked to bathe the mannequin with the simulation disposable cloths that simulate the impregnated 2% CHG (alcohol free) cloths. The primary investigator and research assistant waited outside the simulation lab door and asked to be notified when bathing was completed. A blacklight picture of the mannequin was taken by the primary investigator after the CHG bathing protocol was administered by the individual nursing assistant. The digital pictures were coded with the nursing assistants' study identification number. Both the pre-bathing and post-bathing digital pictures were scanned to the computer software program and the software program analyzed the amount of simulation microbes post-bathing in a percent format where each of the UV fluorescent supine areas on the mannequin pre-bathing totaled 100%. The nursing assistants did not see the results after bathing the mannequin to maintain confidentiality of the data. The control group began the study on March 8th 2016 and ended March 19th 2016. The intervention group began the study on April 12th 2016 and ended on April 23rd 2016. The data collection period was completed within two months when all thirty nursing assistants completed the CHG bathing protocol on the mannequin.

Data Management

The Statistical Package for Social Sciences (SPSS) version 22.0 was utilized for the data analysis in this study. To maintain subject confidentiality, all data was kept confidential in a password-protected spreadsheet. Results were reported using only de-identified data and without subject identifiers.

Data Analysis

Descriptive statistics were used to analyze demographic data; they include mean, standard deviations and percentages.

To meet the specific aims, the following analyses were conducted:

1. To examine the optimization of the delivery of an intervention designed to reduce CLABSI in adults hospitalized in medical surgical units: an independent t-test (inferential tests of group differences) was used to compare the intervention group (CHG bathing protocol with simulation training) and the control group (CHG bathing protocol with no simulation training) on the percentage of simulation microbes remaining on the mannequin post bathing.

2. To examine the influence of a demographic factor, years of practice as a nursing assistant on the percentage of microbes present, correlation was used.

Chapter IV: Findings

The findings for this study will begin with a description of the sample and the 2 groups (intervention group, CHG bathing protocol with simulation training; and control group, CHG bathing protocol with no simulation training). This is followed by findings according to each of the study aims: (1) compare the effectiveness of removal of simulated skin microbes by nursing assistants who receive training for a CHG bathing protocol with simulation training to simulated skin microbe removal by nursing assistants who receive training for a CHG bathing protocol without simulation training and (2) to examine the influence of a demographic factor, years of practice as a nursing assistant on the percentage of simulated microbes present following performance of bathing. The completed CONSORT model (CONSORT, 2015) of this study, is shown in Figure 6.

Participant Characteristics

The samples consisted of thirty nursing assistants who volunteered to participate in this study and were randomized to one of two groups of fifteen participants using research randomizer. The first group (group one) of fifteen participants was the intervention group and the second group (group two) of fifteen participants was the control group. The sample characteristics collected were as follows: gender, home unit, shift, number of hours worked per week, years of practice as a nursing assistant, whether they were in nursing school and if so what program and year. There were no demographic differences between the two groups.

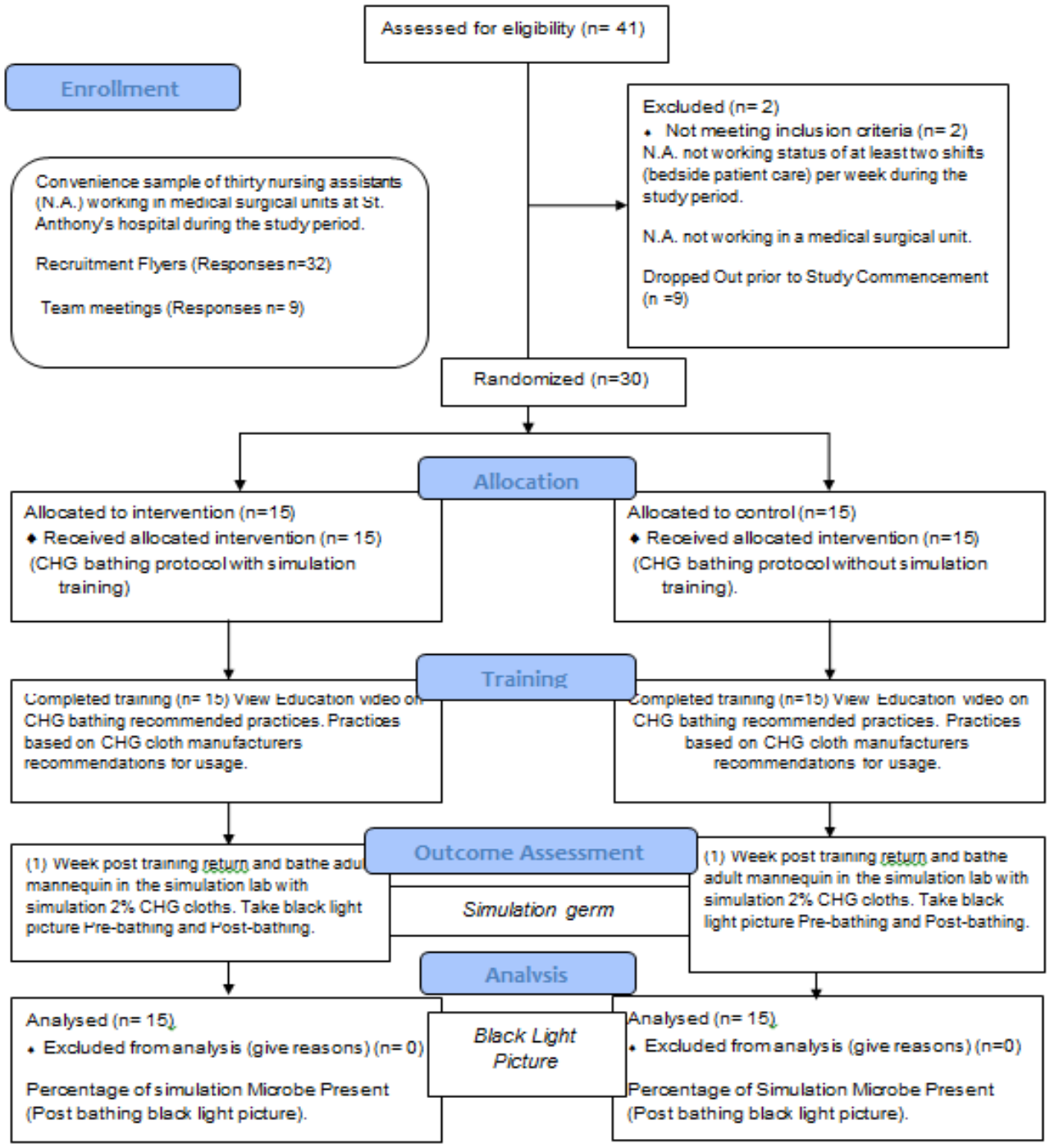

Figure 6 *Completed CONSORT Study Flow Chart*

Intervention Group. Descriptive analyses were used to describe the intervention group sample. This group received a targeted educational approach involving simulation with the bathing protocol. The intervention group consisted of twelve females (80%) and three males

(20%). Most nursing assistants in this group worked day shift (86.7%) and (13.3%) worked nights. Fourteen nursing assistants in this group worked thirty-six hours a week (93.3%) and only one worked twenty-four hours per week (6.7%). There were three nursing students in this group (20%) and the other twelve (80%) participants were nursing assistants by trade (see Table 1 and Table 2).

Control Group. Descriptive analyses were also used to describe the control group sample. This group received no simulation training. The control group consisted of twelve females (80%) and three males 20%. Most nursing assistants in this group worked during the day shift (80%) and (20%) worked nights. Twelve nursing assistants in this group worked thirty-six hours a week (80%) and three worked twenty-four hours per week (20%). There were six nursing students in this group (40%) and the other nine (60%) participants were nursing assistants by trade (see Table 1 and Table 2).

Total Group. Table 1 illustrates the results related to overall and group comparisons of the demographic characteristics for gender, shift, hours worked and student status using the Chi-Square tests to identify any potential differences between groups, not controlled for by randomization. Table 2 also demonstrates the results related to years of experience and group comparisons using an independent t-test (inferential tests of group differences) to again identify any potential differences between groups.

There were no significant differences between the intervention group and the control group on any of the demographic variables seen on Tables 1 and 2 above. The intervention group and the sample group had the same number of males and females, randomly assigned to each group. There were more day shift participants than night shift participants in both the

Table 1 *Characteristics of Sample (Gender, Shift, Hours Worked per Week and School Status) by random assignment by frequency and percent. The Chi-Square tests were used to identify any potential differences between groups, not controlled for by randomization.*

Variable	Intervention (SIM) N=15	Control (No SIM) N=15	Total Sample N=30	*p* value
Gender, n (%)				1.000
Female	12 (80)	12 (80)	24 (80)	
Male	3 (20)	3 (20)	6 (20)	
Shift, n (%)				.624
Day Shift (7A to 7P)	13 (86.7)	12 (80)	25 (83.3)	
Night Shift (7P to 7A)	2 (13.3)	3 (20)	5 (16.7)	
Hours Worked per Week, n (%)				.283
36 Hours / Week	14 (93.3)	12 (80)	26 (86.7)	
24 Hours / Week	1 (6.7)	3 (20)	4 (13.3)	
School Status, n (%)				.232
Nursing Student	3 (20)	6 (40)	9 (30)	
Not Nursing Student	12 (80)	9 (60)	21 (70)	

Table 2 *Characteristics of Sample (Years of practice as a Nursing Assistant) by random assignment by mean and Standard Deviation. An independent t-test (inferential tests of group differences) was used to identify any potential differences between groups.*

Variable	Control (No SIM) N=15	Intervention (SIM) N=15	Total Sample N=30	*p* value
Years of Practice				.516
Mean	5.4887	6.7273	6.108	
Standard Deviation	4.19802	5.9605	5.10449	

intervention and control groups. Both groups had more participants who worked thirty-six hours a week than who worked twenty-four hours a week. The control group had six students (60%) while the intervention group that had three students (20%) but this difference was not statistically significant (p = .232). In summary, random assignment successfully controlled for any potential differences between the two groups in reported demographic characteristics.

Analysis for the Specific Study Aims

Research Aim 1. The primary aim of this study was to examine the optimization of the delivery of an intervention designed to reduce CLABSI in adults hospitalized in medical surgical units; by comparing the intervention group (CHG bathing protocol with simulation training) and the usual care treatment group (CHG bathing protocol with no simulation training) on the percentage of simulation microbes on the mannequin post bathing. To examine if there was any difference between the intervention group (Independent Variable) and the control group (Independent Variable) on the percentage of microbes (Dependent Variable) remaining on the mannequin post bathing an independent t-test (inferential tests of group differences) was used. See Table 3 for results.

Table 3 *Results of t-test and Descriptive Statistics for Microbes left on the body after bathing.*

	Condition						95% CI for Mean Difference		
	Treatment Group (Simulation)			Control Group (No Simulation)					
	M	SD	n	M	SD	n		t	*df*
Microbe	.3867	.11	15	.7080	.09	15	-.24382, -.39892	-8.489*	28

*$p < .001$

The group statistics resulted in a difference of -.32 between both group means (mean difference -.32). The Levene's test revealed a value greater than .05 (.274) therefore equal variances were assumed. The *t* test revealed a statistically significant ($p < .001$) difference between the intervention group and the control group on the percentage of simulated microbes remaining on the mannequin post bathing. Those nursing assistants who received simulation training (Intervention Group) removed more of the simulated microbes from the mannequin than nursing assistants who did not receive simulation training. These results suggest that simulation training made a difference on the overall performance (removal of simulated microbes post bathing) of the nursing assistants as evidenced by the simulated microbes remaining on the mannequin post bath. Sample digital pictures of the mannequin under black light from both the control and intervention group post bathing are shown in Figure 7 and Figure 8.

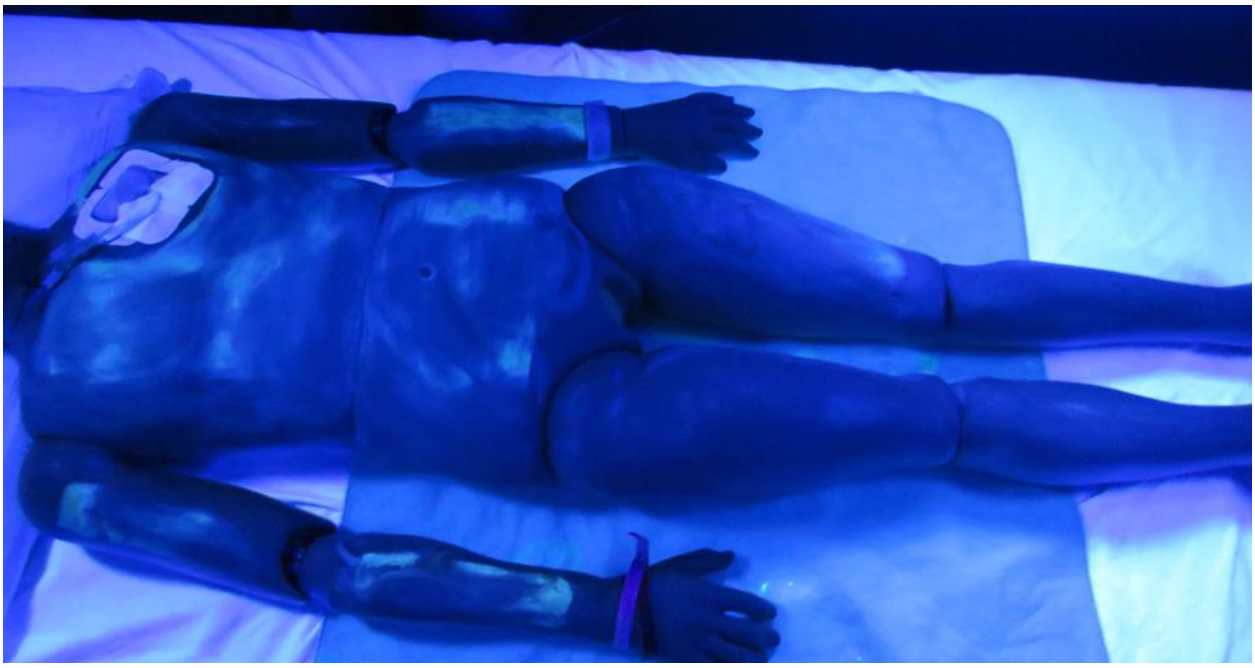

Figure 7 *Black light picture with simulation microbe post bathing, control group participant.*

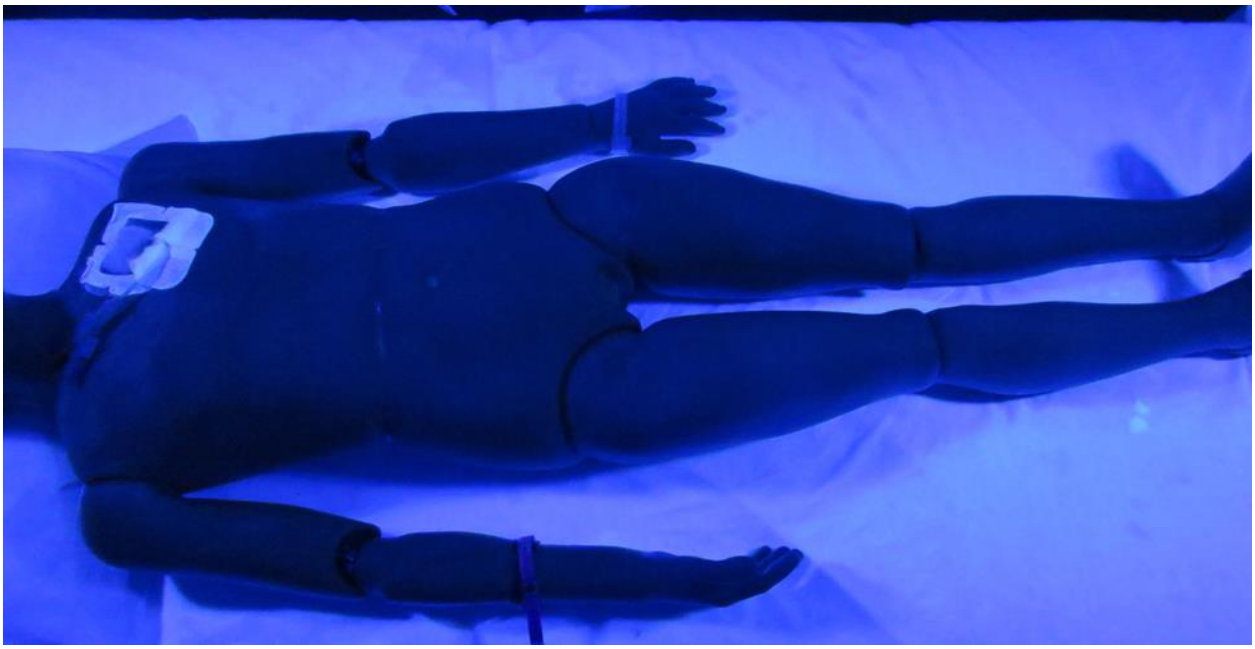

Figure 8 *Black light picture with simulation microbe post bathing, intervention group participant.*

Research Aim 2. The second aim of this study was to examine the influence of a demographic factor, years of practice as a nursing assistant on the percentage of microbes present. A Pearson correlation was computed to assess the relationship between years of practice as a nursing assistant and the percentage of microbes remaining post bathing. All thirty nursing assistants and the corresponding years of experience were analyzed. There was no correlation between the years of practice as a nursing assistant and the amount of microbes left on the mannequin post bathing [r (28) = -.071, p=.709]. A scatter plot summarizes the results in Figure 9.

In summary, this analysis suggests that how many years of practice the nursing assistant had did not affect on the amount of simulated microbes removed from the mannequin. A nursing assistant with many years of experience and one with few years of experience could both perform similarly with no correlation trend noted.

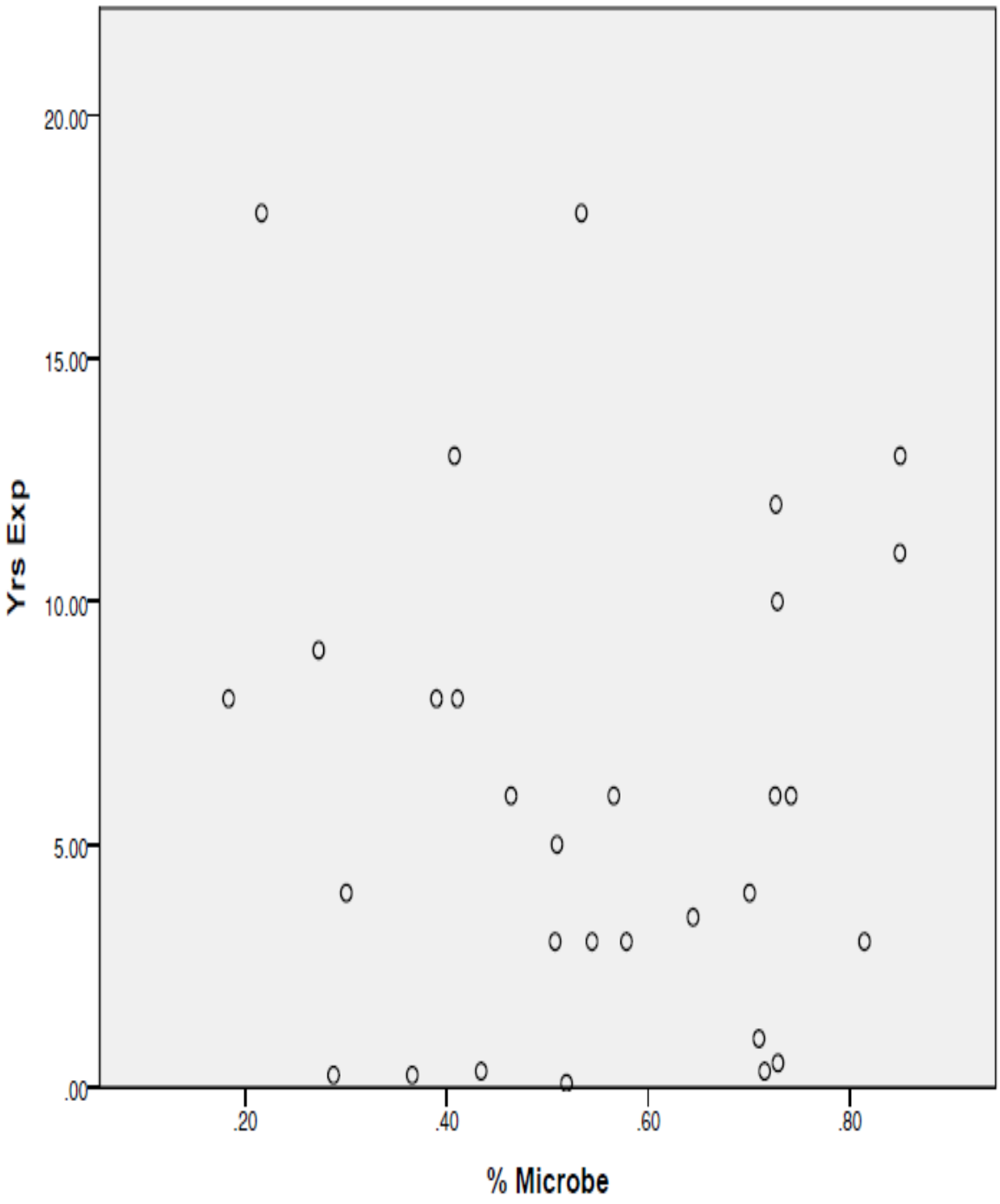

Figure 9 *Scatter Plot Years of Experience as a Nursing Assistant and Percentage of Microbe on Mannequin Post Bath.*

Chapter V: Discussion and Conclusion

This chapter includes a synthesis of the study results. This is followed by a discussion on the study limitations and nursing implications. Future research recommendations conclude this chapter.

Summary of the Study

The purpose of this study was to examine the optimization of the delivery of an intervention designed to reduce CLABSI in adults hospitalized in medical surgical units. The intervention was optimized by including simulation training to assist in enhancing the nursing assistants' performance when bathing a patient (simulated by a mannequin) with 2% CHG cloths. The nursing assistants' performance was measured by the amount of simulation microbes remaining on the body of the mannequin post bathing. This innovative method of assessing the percentage of simulation microbes remaining on the mannequin made it possible to quantitatively measure bathing performance.

CLABSIs result in thousands of deaths each year and produce billions of dollars in added costs to the U.S. healthcare system (CDC, 2016). Monitoring the compliance with CHG bathing is an important component when evaluating the effectiveness of a CHG bathing protocol. The preliminary descriptive study on current patient bathing practices among nursing assistants compared to recommended practice in adults hospitalized in medical surgical units conducted prior to this study showed evidence to support the need for further exploration and optimization of the 2% CHG cloths bathing protocol.

Hospital organizations could benefit from adding this CHG bathing simulation protocol when training hospital staff to perfume this task. As stated in the review of the literature CLABSIs have an estimated direct cost ranging from $7, 288 to $29,156 per episode. A hospital with five CLABSIs in a year could save anywhere from $36,400 to $145,780 by implementing an intervention that can assist in bring the CLABSI rate down to zero. The additional cost associated with the training would be minimal compared to the cost of a CLABSI incident.

This dissertation study yielded two main findings. Analysis of the first aim results revealed that there was a statically significant (p <.001) difference between those in the intervention group (simulation) and the control group (no simulation) on the percentage of simulated microbes remaining on the mannequin post bathing. Those nursing assistants who received simulation training (Intervention Group) removed more of the microbes from the mannequin than nursing assistants who did not receive simulation training. The results suggest that simulation training was an added benefit to the nursing assistants who received it, as they performed better than those who did not receive simulation training. At the time of simulation training many of the participants in this group made comments regarding the training they had received prior to the simulation session. The comments included statements as such; "I was really never taught how to bathe the patient with these cloths, I figured it was a simple task so I did not ask for directions." Many other comments surrounding the application and rationale for the 2% CHG cloths were expressed during the simulation session. It was evident that there was a need for further training and education.

Analysis of the second aim revealed that years of experience did not correlate with microbe removal. It did not matter how many years of experience the nursing assistant had related to the amount of microbes removed from the mannequin. This study suggests that no

matter what previous training was received, or how long the nursing assistant had practiced, there was still a need for additional training to improve CHG bathing performance.

Study Limitations

There are several limitations that should be considered when interpreting the results of this study. This study included a convenience sample of thirty nursing assistants working in medical surgical units at St. Anthony's hospital during the study period. This was one setting in one geographic location possibly limiting the generalizabity of the sample to the larger population of nursing assistants in other acute care hospital settings. Another limitation is the simulation environment of the study. In real life conditions, the performance of the nursing assistant may vary and may not reflect the performance (good or bad) shown under simulation. A mannequin was used and this limited the application of the bathing protocol to the anterior supine areas only. The sample size for this study was small and there is the possibility of an underestimation or overestimation of the extent of relationships identified. Although the results revealed a statistically significant finding in the group means, it is important to expand the study to include a larger sample across different hospitals to support generalizability of these findings.

Implications for Nursing and Implications for Further Research

It is important to monitor compliance and training effectiveness when it comes to CHG patient bathing in an effort to control CLABSI. The descriptive study conducted as a preliminary to this dissertation research revealed a need for further training on the 2% CHG bathing protocol. Many studies in the literature share the limitation of monitoring and evaluation of CHG bathing compliance. A recent quality improvement project, conducted in a 621-bed academic medical center revealed that CHG bathing compliance rates may be affected by multiple factors, including the beliefs and attitudes of the nursing staff, as well as perceived or true barriers (Hines

et al., 2015). This is an area of research that needs further exploration. It is also important to also look at other areas in nursing that solely rely on classroom instruction and handouts as this maybe inadequate and nurses may benefit from a simulation environment or direct observation in their trainings.

This dissertation study could serve as the pilot for a larger study across the acute care settings to determine generalizabity of the findings. Once the CHG bathing intervention is appropriately delivered, further research on the effectiveness of a daily bathing protocol with 2% CHG cloth for reducing CLABSIs in adults hospitalized in medical surgical units could be conducted. This longitudinal study would help to determine the impact of this optimized intervention on reducing CLABSIs in adults hospitalized in medical surgical units.

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Appendices

Appendix A: Script for Simulation Session

CHG Bathing Cloths

- Six-cloth bundle (three packets).
- Use all six cloths.
- Do not use above jawline.
- Disposable.

CHG Bathing Process

- If using a warm CHG cloth, check the temperature of the CHG cloth prior to use. Gloves diminish sense of heat.
- Cloths may be used without being warmed.
- Open bundle by using notch on back of package.
- Bathe with CHG once daily for entire hospital stay (patient with Central Lines).
- Use a clean CHG cloth for each area of the body to reduce the chance of spreading germs from one area to another.
- Do not use above jawline.
- Do not rinse off.

Use Prior Routine for Face, Scalp, and Hair

- Wash face and head first before starting with CHG.
- Use shampoo cap or directly use shampoo sparingly, avoid contact with rest of the body, as it may deactivate CHG.
- Cleanse face with regular washcloth.
- Do NOT use 2% CHG cloths near eyes or ears.

CHG Bathing Process—Using All Cloths

- Use all six cloths in the following order:
    1. Cloth 1: Neck, shoulders, and chest.

2. Cloth 2: Both arms, both hands, web spaces, and axilla.
3. Cloth 3: Abdomen and then groin/perineum.
4. Cloth 4: Right leg, right foot, and web spaces.
5. Cloth 5: Left leg, left foot, and web spaces.
6. Cloth 6: Back of neck, back, and then buttocks.

Please note back of mannequin will not used in this study.

- After application to each body site, be sure to clean tubing from Foleys, drains, G-tube/J-tubes, rectal tubes, chest tubes within 6 inches of the patient.
- *Use additional cloths if needed for incontinence or for obese patients.*

CHG Bathing Process—Key Points

- ***Firmly*** massage skin with CHG cloth.
    - Patient education: *Skin may feel sticky for a few minutes.*
- Clean neck well even if it is not visibly soiled.
- The neck:
    - Commonly accumulates debris and moisture.
    - Is a high-risk area for contaminating lines.
- CHG replaces routine bathing:
    - Do NOT bathe with soap and water while using CHG.
    - Exception: hair and face washed per previous routine.
    - Avoid contact of shampoo and facial soap with body.
    - Shampoo and much soap will inactivate CHG.
- Use CHG cloths after incontinence clean up.
- Do NOT rinse, wipe off, or dry with another cloth. Let air dry.
- Certain lotions will inactivate CHG, ensure to check with manufacturer for compatibility.
- Dispose of leftover cloths.
- Do NOT save, reheat, or reuse.

•Cleansing of Perineum/Vagina: ◦Critical area for cleaning.

◦CHG is safe to use on the perineum and external mucosa.

◦Use CHG cloths to remove bacteria and clean area.

CHG Bathing Process—Cleaning Up

- Do NOT flush washcloths in the toilet.

Central Line Care

- Bathe with CHG liberally around and over dressing.
    - Use CHG cloth on semipermeable dressing only.
    - Do NOT use CHG over gauze.
- Clean skin folds well (neck, groin).
- Clean tube (up to 6 inches) last and discard cloth.
- This applies to all line locations.

Incontinence

- Remove urine/stool with usual chux/cloths and water.
- Do NOT use soap.
- Cleanse with CHG and allow to air dry (about a minute).
- Use as many CHG cloths as necessary.
- Apply CHG-compatible barrier product over affected area, as needed.

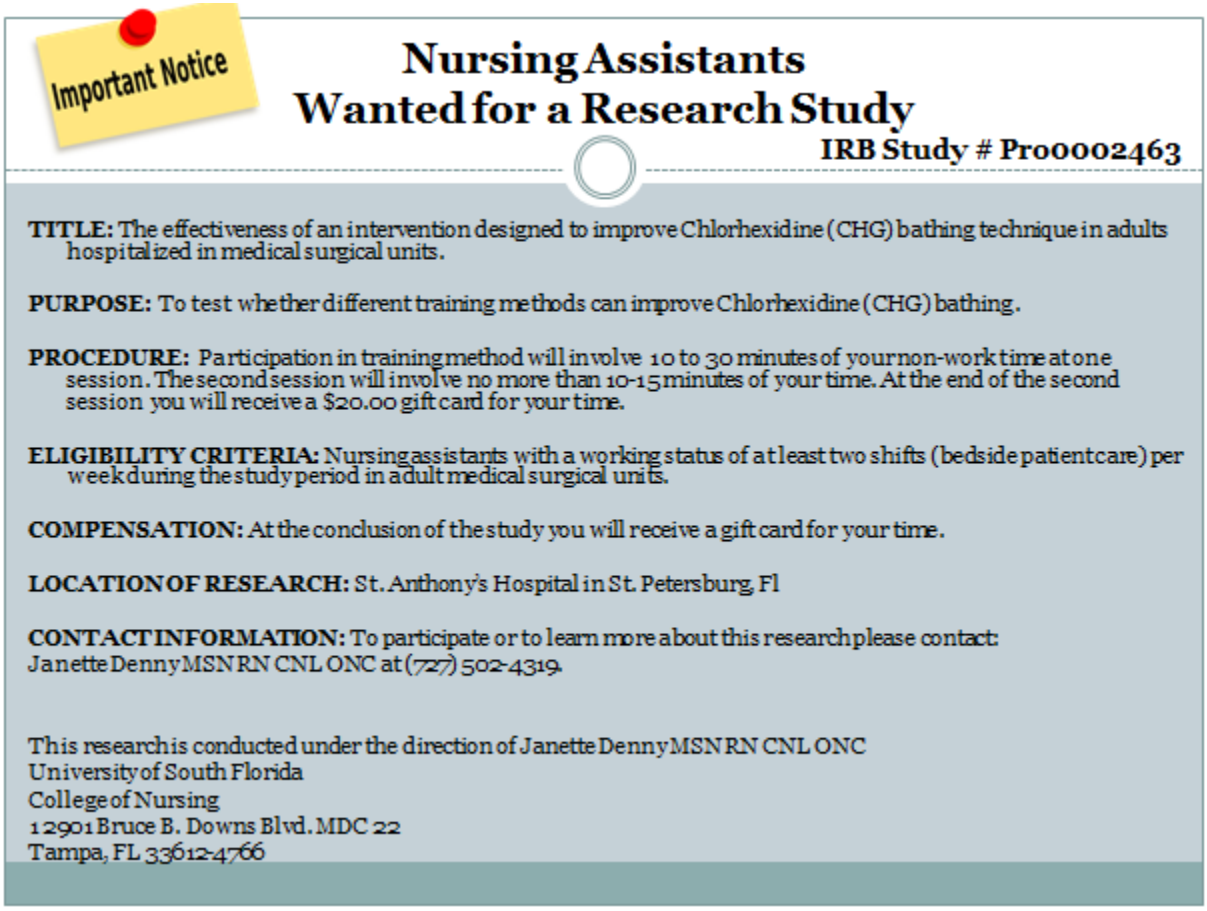
◦If additional bathing is required throughout the day, clean with CHG cloths, then reapply CHG-compatible barrier product, as needed.

Obese Patients

- If one set of six cloths is not sufficient, use more.
- Make sure to clean between all skin folds.
- Discard any unused cloths.

Universal ICU Decolonization: An Enhanced Protocol. September 2013. Agency for Healthcare and Quality, Rockville, MD. http://www.ahrq.gov/professionals/systems/hospital/universal icu decolonization/index.html

Appendix B: Flyer for Study



Appendix C: BayCare Institutional Review Board Approval

3001 W. Dr. Martin Luther King Jr. Blvd.
Tampa, FL 33607

BayCare Health System Institutional Review Board
Ian Matheson, MD., Co-Chairperson
Glenn Stambo, MD., Co-Chairperson

MEMORANDUM: EXPEDITED

TO: **Janette Denny, RN.**

FROM: **Kerri Albert, IRB Specialist**

SUBJECT: **IRB File #2015.095-BSA**

PROTOCOL: ***"The Effectiveness of an Intervention Designed to Improve Chlorhexidine (CHG) Bathing Technique in Adults Hospitalized in Medical Surgical Units." Expedited Category 6 & 7***

The Co-Chairperson of Institutional Review Board (IRB) has reviewed and approved the above protocol under Expedited Review for this submission. Dr. Ian Matheson/Dr. Glenn Stambo has determined that this project is exempt from Continuing IRB review (45 C.F.R 46.110 and 21 CAR 56.110.)

Your project should not be resubmitted for a yearly continuing review to the IRB. *A Final Report [IRB Progress Report] and or Journal article(s) should be submitted at the completion of the project.* This information will be maintained in the study folder.

This action will be reported at the **November 17, 2015** IRB Meeting.

Ian Matheson, MD.
Glenn Stambo, MD.
Co-Chairperson

Appendix D: USF Institutional Review Board Approval

USF
UNIVERSITY OF SOUTH FLORIDA

RESEARCH INTEGRITY AND COMPLIANCE
Institutional Review Boards, FWA No. 00001669
12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612-4799
(813) 974-5638 • FAX (813) 974-7091

December 23, 2015

Janette Denny
College of Nursing
Tampa, FL 33647

RE: **Expedited Approval for Initial Review**
IRB#: Pro00024263
Title: The effectiveness of an intervention designed to improve Chlorhexidine (CHG) bathing technique in adults hospitalized in medical surgical units.

Study Approval Period: 12/23/2015 to 12/23/2016

Dear Ms. Denny:

On 12/23/2015, the Institutional Review Board (IRB) reviewed and **APPROVED** the above application and all documents contained within, including those outlined below.

Approved Item(s):
Protocol Document(s):
Protocol Dissertation Study

Consent/Assent Document(s)*:
Consent .pdf

*Please use only the official IRB stamped informed consent/assent document(s) found under the "Attachments" tab. Please note, these consent/assent document(s) are only valid during the approval period indicated at the top of the form(s).

It was the determination of the IRB that your study qualified for expedited review which includes activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories outlined below. The IRB may review

research through the expedited review procedure authorized by 45CFR46.110 and 21 CFR 56.110. The research proposed in this study is categorized under the following expedited review category:

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB. Any changes to the approved research must be submitted to the IRB for review and approval via an amendment. Additionally, all unanticipated problems must be reported to the USF IRB within five (5) calendar days.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,

John A Schinka, Ph.D.

John Schinka, Ph.D., Chairperson
USF Institutional Review Board