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EXPLORING INAPPROPRIATE GLOVE USE IN LONG TERM CARE

by

Deborah Patterson Burdsall

A thesis submitted in partial fulfillment of the requirements for the Doctor of Philosophy degree in Nursing in the Graduate College of The University of Iowa

August 2016

Thesis Supervisor: Professor Sue E. Gardner

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Graduate College The University of Iowa Iowa City, Iowa

CERTIFICATE OF APPROVAL

PH.D. THESIS

This is to certify that the Ph.D. thesis of

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has been approved by the Examining Committee for the thesis requirement for the Doctor of Philosophy degree in Nursing at the August 2016 graduation.

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To my husband, Richard Ellwood Burdsall Dans les champs de l'observation le hasard ne favorise que les esprits préparés. In the field of observation, chance favours only the prepared mind. — Louis Pasteur René Vallery-Radot, *The Life of Pasteur*, translated by Mrs. R. L. Devonshire (1919)

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iv

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ABSTRACT

Healthcare personnel (HCP) frequently wear gloves when they care for patients in Standard Precautions to prevent contact with potentially infectious blood or body fluids. When HCP use gloves appropriately they reduce the risk of cross-contamination and decrease the risk of healthcare-associated infections (HAI). However, if HCP use gloves inappropriately they may inadvertently spread pathogens to patients and the patients' environment. This study used a descriptive structured observational design to investigate three aspects of HCP glove use in a United States long-term care facility (LTCF). First, the PI examined the degree of inappropriate HCP glove use in a random sample of 76 HCP. Results indicate that the HCP used gloves inappropriately, failing to change gloves 66% of the time when a glove change was indicated. Over 44% of the HCP gloved touch points were defined as contaminated. Second, the PI examined the reliability of a new glove use tool (GUST). Results indicate the GUST is a reliable tool when used by trained observers documenting HCP glove use during toileting and perineal care events in LTCF, with intraclass correlation coefficients (ICC 2,1) over 0.75 for indicators of inappropriate glove use. Third, exploratory analysis indicated significant differences between inappropriate glove use in females and males. Female HCP had significantly more failed glove changes and contaminated touch points than male HCP in this study (p = 0.003). Future research studies should assess US HCP glove use to provide data needed for development of strategies to improve HCP glove use and reduce HAI.

Keywords: Environmental contamination, epidemiology, glove use, healthcare personnel (HCP), infection prevention and control, healthcare-associated infection (HAI), long-term care facility (LTCF), pathogen transmission, patient colonization, personal protective equipment (PPE), Protection Motivation Theory.

vi

PUBLIC ABSTRACT

Healthcare personnel (HCP), including nurses, nurses' aides (CNAs), physicians and therapists, frequently wear gloves when they care for patients to prevent contact with blood or body fluids that may contain disease causing organisms. When healthcare personnel use gloves correctly they reduce the risk of spreading germs and decrease the risk of healthcare-associated infections. However, if healthcare workers use gloves inappropriately they may inadvertently spread disease-causing germs to patients and the patients' environment. This study looked at how 74 CNAs and 2 nurses used gloves when working in a United States long-term care facility. Results indicate that 66% of the time HCP did not change gloves when they should. Over 44% of the HCP gloved touch points were probably contaminated. The study tested a novel tool called the GUST, which allowed trained observers to record specific actions of HCP, including when HCP did not change gloves and then touched patients, objects and surfaces with contaminated gloves. The study indicates that trained observers can use the GUST reliably when they watch HCP use gloves while assisting patients with toileting. The study determined that female and male HCP used gloves differently. Female HCP were significantly more likely than male HCP to not remove gloves when they should have done so and to touch patients or the environment with contaminated gloves in this study (p = 0.003). More research is needed to describe glove use so that researchers can develop strategies to improve glove use and prevent infections.

LIST OF TABLES	xi
LIST OF FIGURES	xii
LIST OF RESEARCH RESOURCES	xiii
CHAPTER ONE: INTRODUCTION	1
Purpose	7
Specific Aims	7
Degree of inappropriate glove use.	7
Failed glove changes	7
Contaminated touch points	
Reliability	
Exploratory Analysis	9
Definition of Terms	10
Inappropriate Glove Use	10
Toileting	11
Perineal Care	11
CHAPTER TWO: REVIEW OF THE LITERATURE	12
The Evolution of Patient Care: From Care with Bare Hands to Care with Gloved Hands	12
Effect of Guidelines and Regulations on Glove Use	
Consequences of Inappropriate Use of Gloves	
The Need for a Glove-Use Surveillance Tool	
Summary	
CHAPTER THREE: METHODS	
Setting and Sample	
Setting.	
Sample	
Recruitment and Enrollment of HCP.	
Study Variables	
Primary study variables	
The five facets of glove use.	
Facet number One: Touch points.	
Facet number Two: Gloved touch points.	
Facet number Four: Actual glove changes	
i deet number i bui. i tetudi giove enanges	

Facet number Five: Glove changes at a glove change point	38
The two indicators of inappropriate glove use	39
Indicator number One: Failed glove changes.	39
Indicator number Two: Contaminated touch points	39
Exploratory study variables	40
HCP Gender.	41
Licensure or certification of HCP.	41
Duration of HCP experience.	41
Shift and day of patient-care event	41
Number of HCP assisting with toileting and perineal care.	42
Number of patients assigned to the HCP	42
Study Procedures	43
Co-observer recruitment and training.	43
Observations of selected HCP	43
Data Analysis	45
Summary statistics	45
Inappropriate glove use	46
Failed glove use.	46
Contaminated touch points.	46
Reliability	47
Exploratory analysis	48
CHAPTER FOUR: RESULTS OF THE DATA ANALYSES	49
Recruitment and Enrollment Results	49
Characteristics of the non-responders	49
Degree of Inappropriate Glove Use	50
Failed glove changes	51
Contaminated touch points.	51
Reliability of the GUST	52
Intraclass correlation coefficients for indicators of inappropriate glove use	53
Occurrence agreement between observers on type of surface touched with contaminated gloves.	53
Exploratory Analyses of Differences in Degree of Inappropriate Glove Use by Select Variables of Interest	54
Gender of HCP.	54
Duration of HCP experience.	55

HCP licensure and certification.	55
Number of HCP assisting with the patient-care event.	55
Shift of patient-care event	55
Weekdays and weekends (day).	56
CHAPTER FIVE: DISCUSSION AND CONCLUSIONS	57
Discussion of Findings	57
Recruitment and Enrollment of HCP.	57
Characteristics of HCP and Patient-Care Event	58
НСР	58
Patient-Care Events	59
Degree of Inappropriate Glove Use.	60
Failed glove changes	60
Contaminated touches	61
Other findings on glove-use behavior	
Reliability of the GUST	
Exploratory Analyses.	
Implications	
Limitations	71
Recommendations for Further Study	
Summary and Conclusion	
REFERENCES	74
APPENDIX A: TABLES	
APPENDIX B. FIGURES	107
APPENDIX C. RESEARCH RESOURCES	114

LIST OF TABLES

Table A.1. Regulations, Guidelines and Recommended Practices that Direct Glove Use
Table A.2. Examples of Situations when Gloves must be used during Patient Care
Table A.3. Description of the 11 Long-Term Care Patient Care Units 96
Table A.4. Characteristics of Co-observers (N=11)
Table A.5. Characteristics of HCP Observed for Inappropriate Glove Use and forExploratory Analysis (N=76)
Table A.6. Characteristics of the Toileting and Perineal Care Events for DescribingInappropriate Glove Use and for Exploratory Analysis (N=76)
Table A.7 Analyses of Distributions of the Number of Failed Glove Changes (N=76)100
Table A.8. Descriptive Statistics of the Two Indicators of Failed Glove use (N=76)101
Table A.9. Characteristics of the Toileting and Perineal Care Events Observed for theReliability of the GUST (N=61)
Table A.10. Intraclass Correlation Coefficients for the Characteristics of Glove Use (N=61)
Table A.11. Occurrence Agreement between PI and Co-Observer for Type of SurfaceTouched by HCP with Contaminated Gloves (N=61)
Table A.12. Failed Glove Changes by HCP and Patient Care Event Factors duringObserved Patient Care Events (N=76)105
Table A.13. Number of Contaminated Touch Points by HCP and Patient Care EventFactors during Observed Patient Care Events (N=76)

LIST OF FIGURES

Figure B 1. Protection Motivation Theory and HCP Glove-Use10	07
Figure B 2. Flow of Healthcare Personnel Selected for Observation	08
Figure B 3. Distribution of Failed Glove Changes10	09
Figure B 4. Distribution of Contaminated Touch Points1	10
Figure B 5. Frequency of Observed Healthcare Personnel Glove Use	11
Figure B 6. Frequency of Surfaces Touched with Contaminated Gloves1	12
Figure B 7. Differences in the two indicators of inappropriate glove use between Females and Males1	13

LIST OF RESEARCH RESOURCES

Research Resource C 1. Glove Use Surveillance Tool (GUST) © 2015	114
Research Resource C 2. Development of Glove Use Surveillance Tool (GUST)	118
Research Resource C 3. University of Iowa Institutional Review Board Approval Letter	123
Research Resource C 4. Resident Patient Informational Letter	124
Research Resource C 5. Healthcare Personnel Informational Letter	125
Research Resource C 6. Healthcare Personnel Meeting Script.	126
Research Resource C 7. Glove Use Debriefing Statement	127

CHAPTER ONE: INTRODUCTION

Physical touch is both an essential part of the human experience and a vital component of patient assessment and care (Bush, 2001; Modrcin-Talbott, Harrison, Groer & Younger, 2003). While healthcare personnel (HCP) touch can be healing and therapeutic, HCP's contaminated hands or gloves can transfer pathogens to multiple body sites on the same patient, to HCP themselves, to other patients, or to objects and surfaces in the healthcare environment (Stiefel et al., 2011; Guerrero et al., 2012; Ellingson et al., 2014; Dubberke et al., 2014). This cross-contamination increases the risk of adverse iatrogenic conditions, including healthcare-associated infections (HAI) (Weber, Rutala, Miller, Huslage & Sickbert-Bennet in Rutala, 2010). An HAI is defined as:

a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s) that 1) occurs in a patient in a health care setting (e.g., a hospital or outpatient clinic), 2) was not found to be present or incubating at the time of admission unless the infection was related to a previous admission to the same setting. (McKibben et al., 2005)

Infections may cause disability and death, and increase healthcare costs. In United States (US) hospitals alone, one out of every 25 patients acquires an HAI, accounting for 1.7 million infections and almost 99,000 deaths annually (Klevins et al., 2007; Magill et al., 2014). Patients and residents who live or stay in long-term care facilities (LTCF) are at significant risk of acquiring HAI. Researchers estimate that between 1.6 million and 3.8 million infections occur in LTCF annually (Smith et al., 2008). LTCF infections are responsible for over 30% of hospital readmissions from LTCF, costing between \$673 million and \$2 billion annually (Strausbaugh & Joseph, 2000; Erikson et al., 2007; Smith et al., 2008; Uchida, Pogorezelska-Mazairz, Smith & Larson, 2013). Infections acquired in LTCF cause approximately 388,000 deaths a year (Strausbaugh & Joseph, 2000).

Properly performed hand hygiene helps prevent infections by controlling the spread of organisms, thereby reducing the risk of HAI (Ellingson et al., 2014). Ignaz Semmelweis studied the effect of hand hygiene on maternal and infant death rates in Vienna in the 1840's. Semmelweis published his findings in 1861, concluding that:

Cadaverous particles adhering to the hands were destroyed by chlorine washings. In this way, the incidence of disease among maternity patients was brought within the limits set in the second clinic. Chlorine washings had the same effect on the incidence of disease among the newborn... [providing] unchallengeable proof for my opinion that childbed fever originates with the spread of animal-organic matter (p. 57).

Subsequently, hand hygiene by HCP has become the keystone of infection prevention and control. HCP can remove pathogens from their hands with soap, water and friction, or they can inactivate pathogens with skin antiseptics such as ethyl or isopropyl alcohol. Studies show that when HCP keep their hands clean, either with soap and clean water, hand sanitizer or alcoholbased disinfecting wipes, fewer pathogenic organisms are transferred to patients and the healthcare environment, and HAI rates decrease (Siegel, Rhinehart, Jackson & Chiarello, 2007; Siegel et al., 2007; Allegranzi & Pittet, 2009; Allegranzi et al., 2010; Ellingson et al., 2014). However, hand hygiene does not prevent contact between the skin of HCP hands and pathogens. In addition, Semmelweis (1861) noted that "Ordinary washing with soap is not sufficient to remove all adhering cadaverous particles. This is proven by the cadaverous smell that the hands retain for a longer or shorter time" (Semmelweis & Carter, 1983, p.52). Pathogens such as vancomycin-resistant Enterococcus, methicillin-resistant Staphylococcus aureus, or spores from *Clostridium difficile* can remain on HCP's hands and increase the risk of cross-contamination (Hayden, Blom, Lyle, Moore & Weinstein, 2008; Stiefel et al., 2011; Guerrero et al., 2013; Ellingson et al., 2014; Landelle et al., 2014). Pathogens may enter HCP's tissues or bloodstream through the skin on their hands, increasing the risk of infections with viruses such as human

immunodeficiency virus, hepatitis B virus, hepatitis C virus, or with bacterial pathogens (Beltrami et al., 2003; Do et al., 2003; Siegel et al., 2007; OSHA, 2012).

The Occupational Safety and Health Administration (OSHA) requires healthcare organizations to develop programs that protect HCP from infections resulting from physical contact or occupational exposure to "blood or other potentially infectious materials that may result from the performance of an employee's duties" (OSHA, 2012). Therefore, infection prevention and control strategies focus on both hand hygiene and hand protection to control HCP's exposure to pathogens. Exposure control plans such as OSHA's Bloodborne Pathogens Standard (2001) mandate that healthcare organizations develop systems to train HCP to perform appropriate hand hygiene and use personal protective equipment (PPE), including gloves, when there is a risk of exposure to blood, secretions, excretions, non-intact skin or other potentially infectious materials.

The CDC Healthcare Infection Control Practices Advisory Committee's (HICPAC) 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings recommends the use of Standard Precautions and Transmission-Based Precautions to protect both HCP and patients from infectious agents. Standard Precautions require that HCP wear PPE, especially gloves, to avoid contact with blood, secretions, excretions, non-intact skin or other potentially infectious materials which may contain pathogens (Siegel et al., 2007; CDC, 2014). HCP must change gloves as a Standard Precaution at the following "glove change points" during patient care: (a) when HCP's gloves have touched blood or body fluids, (b) after HCP completes a patient task, (c) after HCP's gloves touch a potentially contaminated site before moving to a clean site, and (d) between patients (OSHA, 2012; Siegel et al., 2007; WHO, 2009).

A "failed glove change occurs" if HCP do not change their gloves at these glove change points in the sequence of patient care.

Gloves are easy to apply and relatively inexpensive, and are readily available in US healthcare settings. Vinyl or nitrile gloves cost between 1.0 cents and 6.0 cents per glove (Medline, 2015). When HCP wear gloves for self-protection during patient-care events, they may not change gloves at glove change points and they may continue to touch the patient or multiple surfaces in the patient environment for extended periods, leading to numerous "contaminated touch points" (O'Boyle Williams, Campbell, Henry & Collier, 1994; Loveday, Lynam, Singleton & Wilson, 2014). This behavior is especially problematic when the risk of contact with secretions and excretions is high, as with perineal care and toileting assistance. When HCP use gloves as a substitute for hand hygiene, or if they continue to use gloves after they are soiled or contaminated, they may transfer pathogens from the contaminated surfaces of these gloves to themselves, the patients or the environment. This glove-use behavior ultimately increases the chance that HCP or patients will acquire pathogens that can cause HAI. In fact, researchers report an association between contaminated gloves, contaminated patient environments, and the transmission of pathogens to patients and HCP (Weber et al., 2010; CDC, 2014).

Inappropriate glove use appears to have contributed to the transmission of Ebola virus to nurses and other HCP in Africa, Spain, and possibly in Texas (Khan, Tshioko & Heymann, 1999; Minder, 2014; CDC, 2014). Ebola is an extremely severe infection with a short incubation period (2-21 days), making the consequences of inappropriate glove use or breaches in personal protective equipment more readily apparent than when the time from exposure to infection may be prolonged by persistent colonization followed by infection as with MRSA (CDC, 2014; Smith et al., 2008; David & Daum, 2013; Ridgway et al., 2013).

Because transmission of pathogens and HAI related to inappropriate glove use are rarely apparent immediately, healthcare organizations should perform surveillance both for glove use and for hand hygiene during routine patient care. Experts (Girou et al., 2004; Eveillard, 2011; Fuller et al., 2011; Loveday, Lynam, Singleton & Wilson, 2014) have identified the need for improved glove-use surveillance and a glove-use surveillance tool, but only a few tools currently exist that specifically facilitate surveillance for HCP use of gloves during sequences of patient care. Loveday, Wilson and their team at the University of West London (2013) developed a glove-use tool that allows observers to audit the sequence of touches. The investigators used the WHO My Five Moments for Hand Hygiene to categorize the risk of cross-contamination. However, the language of this tool is specific to acute care in the United Kingdom (UK); a tool specific to health care in the US is still lacking.

To address this gap, the PI developed the Glove Use Surveillance Tool (GUST), which allows trained observers to document how HCP use gloves while practicing Standard Precautions (Appendix C 1). The GUST was developed to examine glove use in Standard Precautions because the definitions for appropriate and inappropriate glove use differ for Standard Precautions and for Transmission-Based Precautions. Moreover, Standard Precautions are used more widely than Transmission-Based Precautions. The GUST is a six-category tool that allows trained observers to record the type of surface (i.e., environment, equipment, patient sites and body fluids, HCP's body) and the sequence of the surfaces touched during a patient-care event as well as when gloves are worn or changed. From this information, trained observers can assess the five facets of glove use, including: 1) the number of touch points, 2) the number of gloved touch points, 3) the number of glove change points, 4) the number of actual glove changes, and 5) the number of glove changes at glove change points. From the five facets of glove use, trained

observers can determine the two indicators of inappropriate glove use: 1) the number of failed glove changes, 2) the number of contaminated touch points and surfaces touched with contaminated gloves. The GUST is suitable for both acute care facilities and LTCF.

We field tested and revised the GUST from 2012 to 2014 in a convenience sample from one suburban LTCF. The PI and development team simplified the GUST by consolidating the body sites, surfaces, and equipment frequently touched during patient care. In April 2014, trained observers observed 40 patient-care events. We observed an average of 6.4 "contaminated touch points" per patient-care event. We also observed that HCP were using gloves inappropriately, especially when assisting patients with toileting and perineal care. Only 3 of 40 observed patientcare events had no contaminated touch points. Therefore, cross-contamination between sites on the same patient and their environment may have occurred in 93% of the observed patient-care events.

To date, the characteristics of glove use have not been systematically studied in either acute care hospitals or in LTCF. Glove use in each setting should be evaluated, as the HCP that provide care in each setting may differ significantly. For example, more CNAs work in LTCF than nurses or patient care technicians. Therefore, CNAs are the HCP who perform toileting and perineal care using gloves in LTCF, however nursing HCP of all certifications and licensures use gloves to assist with toileting and perineal care across the healthcare continuum. This study determines facets of glove use and the degree of inappropriate glove use, including identifying surfaces in the patient environment that HCP touch wearing gloves that have touched contaminated body sites in a LTCF. In doing so, this study addresses a significant nursing issue because nursing personnel provide the majority of patient care in LTCFs.

The PI revised the GUST in response to the field studies and expert review by eight leading infection prevention experts (Appendix C 2). The expert review established the content validity of GUST; this study also tests its reliability.

Purpose

The purposes of this study were to use the GUST to: 1) describe the degree of inappropriate glove use by HCP when helping patients with toileting or while doing perineal care in a LTCF; 2) determine the inter-rater reliability of the GUST by comparing the data recorded by the principal investigator (PI) and one other trained co-observer drawn from a pool of trained co-observers; and 3) explore the association between the two indicators of inappropriate glove use and selected HCP and patient-care event characteristics.

In the same way that appropriate hand hygiene decreases cross-contamination and can decrease infection rates, decreasing inappropriate glove use could decrease the risk of HAI. A reliable glove-use observation tool would allow trained observers to record how HCP use gloves during Standard Precautions, to identify inappropriate glove use, and to develop interventions that could ultimately decrease HAI.

Specific Aims

Degree of inappropriate glove use.

Failed glove changes

- Calculate the percentage of total glove change points when HCP failed to change their gloves during toileting or perineal care events.
 [(Total number of failed glove changes ÷ Total number of glove change points) × 100]
- Calculate the median number of failed glove changes per patient-care event.
 - 7

Contaminated touch points

- Compare the percentage of total gloved touch points that were contaminated
 [(Total number of contaminated gloved touch points ÷ Total number of gloved
 touch points) × 100] with the percentage of total bare-handed touch points that
 were contaminated [(Total number of contaminated bare-handed touch points ÷
 Total number of bare-handed touch points) × 100]
- Compare the percentage of patient-care events with one or more contaminated gloved touch points (Total number of patient-care events with one or more contaminated gloved touch points ÷ Total number of patient-care events ×100) to the percentage of patient-care events with one or more contaminated bare-handed touch points (Total number of patient-care events with one or more contaminated bare-handed touch points ÷ Total number of patient-care events ×100).
- Compare the number of contaminated gloved touch points per patient-care event to the number of contaminated bare-handed touch points per patient-care event.
- Identify the surfaces (i.e., environmental surfaces, equipment and supplies, HCP clothing, HCP skin and personal equipment, patient sites without visible blood or body fluids, patient sites with visible blood or body fluids, and surgical sites, tracheostomies, vascular access, or urinary catheters) and surfaces and items in the patient environment that were touched most frequently by the HCP after a failed glove change during perineal care or toileting events and the frequency at which they were touched.

Reliability

• Describe the correlation between the PI and one trained co-observer's

documentation on the GUST while independently observing HCP assist with toileting and perineal care events of (a) the total number of HCP touch points, (b) the total number of HCP gloved touch points, (c) the number of glove change points indicated by regulations and guidelines, (d) the number of actual time the HCP change gloves, and (e) the number of HCP glove changes at a glove change point where glove changes are indicated according to regulations and guidelines, also known as the five facets of glove use, and the two indicators of inappropriate glove use, which include: (a) the number of time HCP fail to change gloves at a glove change point and (b) the number of times HCP touch patients, environmental surfaces and objects with contaminated gloves.

• Describe the occurrence agreement, i.e., the times both the PI and a trained coobserver identify the same surface touched by a contaminated HCP glove when the PI and co-observer watch HCP assist patients with toileting or perineal care.

Exploratory Analysis

• Explore the association between the two indicators of inappropriate glove use, describing the relationship between the number of failed glove changes and the number of contaminated touch points, and selected HCP and patient-care event characteristics: (a) HCP gender, (b) level of HCP licensure or certification, (c) duration of HCP work experience, (d) shift and day of patient-care event, and (e) the number of HCP assisting with the patient-care event.

Definition of Terms

Inappropriate Glove Use

For this study, inappropriate glove use was defined as: (a) failed glove changes, and (b) contaminated touch points.

- Failed glove changes were defined as the point when HCP failed to removed gloves immediately after touching a surface contaminated or potentially contaminated with patient blood, secretions or excretions, or failed to change gloves after caring for one patient and beginning to care for another patient.
- 2. Contaminated touch points were defined for both gloved and bare-handed touches. Contaminated gloved touch points were defined as those touch points that occurred after a failed glove change. Contaminated bare-handed touch points were defined as barehanded touch points on a surface potentially contaminated with patient blood, secretions or excretions. A bare-handed contaminated touch was considered inappropriate glove use because gloves should have been worn in this case.

The two indicators of inappropriate glove use were determined by establishing the sequence of the occurrence of the five facets of glove use, which were defined as follows:

- 1. Touch points were defined as occurring when the HCP's gloved or ungloved hand touched any part of the patient or patient environment.
- 2. Gloved touch points were defined as occurring after the HCP's gloved hand touched any part of the patient or patient environment.
- Glove change points were defined as occurring when the HCP touched a surface contaminated or potentially contaminated with patient blood, secretions or excretions, and between caring for different patients.

- Actual glove changes were defined as occurring when the HCP removed gloves and either replaced them with a clean pair of gloves or continued patient care with bare hands, irrespective of glove change points.
- 5. Glove changes at a glove change point were defined as the point when the HCP removed gloves immediately after touching a surface contaminated or potentially contaminated with patient blood, secretions or excretions, or between caring for different patients.

Toileting

• Toileting was: (a) any use of a toilet, commode, bedpan or urinal by a patient for urination or defecation, (b) care of a urinary catheter, ostomy, suprapubic catheter or ileal conduit, or changing an incontinence product, (c) use of cleansing, hygiene and moisturizing products to clean and moisturize the periurethral, perineal and perianal areas or ostomies after a patient urinated or defecated, (d) ambulation or transfer of a patient to a toilet or a commode.

Perineal Care

 Perineal care, commonly known as peri care, was the use of cleansing, hygiene and moisturizing products to clean and moisturize the periurethral, perineal and perianal areas of the patient. Routine perineal care was also part of bathing and toileting.

CHAPTER TWO: REVIEW OF THE LITERATURE

The second chapter examines the evolving phenomenon of glove use by HCP. The first section describes the evolution of HCP providing routine patient care with their bare hands to providing this care with gloved hands. The second section discusses how different guidelines and regulations describe glove use for direct patient care, and how HCP self-protection became an important consideration. The third section discusses the consequences of inappropriate glove use on transmission of pathogens in healthcare and the limitations of the current evidence. The final section presents a glove-use surveillance tool that researchers and infection preventionists could use to determine how HCP use gloves during patient care.

The Evolution of Patient Care: From Care with Bare Hands to Care with Gloved Hands

Until the 1980's, HCP did not consider it necessary to use gloves for routine patient care. For example, a 1964 nursing textbook showed photographs of a HCP's bare hands touching the skin immediately adjacent to a large sacral pressure area. The communicable disease portion of that textbook directed nurses to wear gowns and masks, but not gloves, when caring for persons isolated for infectious diseases (Brunner, Emerson, Ferguson & Suddarth, 1964). A nursing procedure manual created in 1974 described the process of bare-handed incontinence care and mentioned that HCP should wear gloves only when rinsing fecal material from linens (Lutheran Home, 1974). HCP were instructed to wash their hands to remove contaminates rather than to wear gloves to prevent contamination.

Disease-causing pathogens can contaminate the skin of the hands. When properly performed, hand hygiene removes most hand contamination and prevents infections. However, proper hand washing is time consuming, requires clean running water, soap and clean towels, and can dry and damage skin (Larson, 1995; Larson, 2013; Lynch, Jackson, Cummings &

Stamm, 1987; Sax et al., 2007; Sax, Uckay, Richet, Allegranzi & Pittet, 2007). Hand hygiene using alcohol hand rubs takes less time, and emollients in these products help maintain skin integrity; however, hand hygiene does not prevent contact between the skin and fluids or surfaces. Gloves provide a barrier to protect the skin from contact with chemicals, blood, nonintact skin, mucous membranes, and pathogenic organisms.

In general, regulations, guidelines and infection control literature categorize gloves as personal protective equipment (PPE). When HCP change gloves at glove change points during patient care, they limit both contamination of the environment and spread of organisms between HCP, the patient, and the patient's environment (Boyce & Pittet, 2002; Flores & Pevalin, 2006; Siegel et al., 2007; Trick et al., 2007; Pittet, Allegranzi & Boyce, 2009; OSHA, 2012).

In the 1980's, hepatitis B and the human immunodeficiency virus were found to be transmitted by an infected patient's blood or body fluids. This newly identified threat caused HCP to shift from caring for patients with their bare hands to providing care while wearing gloves and other PPE. The early literature on glove use from the 1980's and 1990's described how HCP were exposed to bloodborne viruses because they did not wear gloves (CDC, 1987; Care, 1993; Richardson, 2000). The literature subsequently documented how HCP began using gloves for any patient-care event that could involve contact with blood, body fluids or mucous membranes (Lynch, Jackson, Cummings & Stamm, 1987; Larson, 1983; Larson & Kretzer, 1995; Larson, 1995; OSHA, 2012). During the 1980's, several researchers also demonstrated that gloves protected HCP hands from contamination with *Clostridium difficile* spores (Fekety et al., 1981; Johnson et al., 1990; McFarland, Mulligan, Kwok & Stamm, 1989). Other investigators described using gloves to control outbreaks or to decrease the incidence of multidrug-resistant organisms (Patterson et al., 1991; Berthelot et al., 2001, Siegel et al., 2007).

Gloves are effective and easy to use and they can help protect HCP and patients against a wide variety of infectious threats, both recognized and unrecognized. Consequently, gloves have become a ubiquitous tool that most HCP use while caring for patients.

Effect of Guidelines and Regulations on Glove Use

Several healthcare regulations and guidelines address glove use. Examples are:

- Occupational Safety and Health Administration (OSHA) (2012): "Bloodborne Pathogen Regulation 29 CFR 1910.1020"
- Centers for Medicare and Medicaid Services (CMS) (2009): "483.65 (F441)
 Infection Control"
- Centers for Disease Control and Prevention (CDC) (2002): "Guideline for Hand Hygiene in Healthcare"
- CDC (2007): "Guideline for Isolation Precautions"
- The World Health Organization (WHO) (2009): "WHO Guidelines on Hand Hygiene in Healthcare"
- Public Health Agency of Canada (2013): "Hand Hygiene Practices in Healthcare Settings"
- Australian Government, Department of Health and Ageing (2010): "Australian Guidelines for the Prevention and Control of Infection in Healthcare"
- National Health Service (England) (2014): "epic3: National Evidence-Based Guidelines for Preventing Healthcare-Associated Infections in NHS Hospitals in England"

In the US, at least five distinct regulations or guidelines currently specify how gloves should be used as a routine patient-care practice (Lynch, Jackson, Cummings & Stamm, 1987). The regulations, guidelines, and studies examining glove use are:

- 1. Universal Precautions (1985-88)
- 2. Body Substance Isolation (1987)
- Standard Precautions (Garner et al., 1996; Siegel, Rhinehart, Jackson & Chiarello, 2007)
- Transmission-Based Precautions (Garner et al., 1996; Siegel, Rhinehart, Jackson & Chiarello, 2007)
- Universal or routine gloving (Bearman et al., 2007; Harris et al., 2013; Trick et al., 2004; Yin, Schweizer, Herwaldt, Pottinger & Perencevich, 2013)

These regulations, guidelines and recommended practices direct HCP to wear gloves when they could have contact with blood, body fluids or contaminated surfaces, but each regulation or guideline has a slightly different focus and goals. Table A 1 describes the similarities and differences among the guidelines and regulations. Universal Precautions (1988) direct HCP to change gloves between patient contacts. The other regulations and guidelines are more specific, and direct HCP to change gloves at four common moments:

- After the gloves have had contact with blood or body fluids.
- After completing a patient-care task.
- Before moving from a contaminated site to a clean site when caring for a patient.
- Between patients.

Table A 2 gives a more detailed description of when gloves and hand hygiene are to be used based upon CDC hand hygiene guidelines and the WHO My Five Moments for Hand Hygiene (2009).

Healthcare policies, procedures, training and in-service education in the US incorporate OSHA regulations, which give specific directions on how gloves are to be used. HCP orientation must include OSHA-mandated content and the information must be reinforced annually to fulfill OSHA requirements (OSHA, 2012). As a result, HCP routinely and consistently receive information that reinforces the use of hand hygiene and gloves or other PPE as a Universal Precaution (OSHA) for self-protection.

Bloodborne pathogen training materials often consist almost exclusively of text copied verbatim directly from the OSHA regulations. This approach to HCP training ensures that the entire regulation is covered as mandated, but does not include a way to demonstrate that the HCP received the intended message. In many healthcare facilities, HCP have few opportunities to ask a trainer or an educator for clarification. Moreover, trainers are required to know the subject matter, but may not know principles of adult education and, thus, may not communicate effectively with HCP.

An OSHA (2007) standards interpretation states:

OSHA requires that disposable gloves be changed as soon as practical when contaminated and as soon as feasible when they are torn or punctured. These requirements protect the employee from exposure to the hazards of bloodborne pathogens. OSHA does not require that gloves be changed between patients if they are not contaminated and their barrier properties have not been compromised.

Moreover, OSHA does not require educational materials to include information about protecting patients. The imbalance between self-protection and patient protection in the OSHA documents and in OSHA-mandated education may inadvertently minimize patient safety and may cause HCP to assume that gloves are primarily for their own protection. OSHA acknowledges that Standard Precautions can be used as a substitute for Universal Precautions – in essence, making Standard Precautions equivalent to Universal Precautions even though the scope of Standard Precautions includes contact with mucous membranes and non-intact skin, and addresses both HCP and patient safety.

According to the results of several studies, HCP's behavior during patient care reflects the self-protection message that HCP receive during OSHA training. Studies in the mid-1990's found that repeated Universal Precaution training increased the likelihood that HCP would use gloves. Furthermore, HCP glove use increased during patient care when HCP perceived a greater threat to themselves, and a greater need for self-protection (Larson & Kretzer, 1995; O'Boyle Williams, Campbell, Henry & Collier, 1994; Diekema, Schuldt, Albanese, & Doebbeling, 1995). O'Boyle Williams and colleagues (1994) noted that glove use increased after an average of 2.7 training experiences.

The most seasoned healthcare professionals – those who influence a healthcare facility's culture and supervise and orient new employees – have been required to attend annual Universal Precautions/Standard Precautions training for as many years as they have worked in healthcare. On the basis of the results from the O'Boyle Williams study, we hypothesize that inappropriate glove use and failed glove changes at glove change points may be a natural consequence of repeated training that emphasizes danger, HCP risk, and self-protection.

Self-protection instincts are a strong behavioral motivator, especially when selfprotection is reinforced with annual training that overemphasizes gloves as self-protective equipment for the HCP. While not tested in this study, the Protection Motivation Theory (Maddux and Rogers, 1983; Rogers, 1975) helps explain why OSHA training may reinforce HCP

natural instincts for self-protection, especially when dealing with patient excretions. This theory posits that four factors affect a person's intention to adopt recommended preventive health behaviors (Maddux & Rogers, 1983):

- The noxiousness or severity of the threatened event (perception of how distasteful or dangerous the event would be).
- The probability that the event could occur (how likely and how often the event might occur).
- The efficacy of a recommended coping response (how well the recommended practices protect people from the threat or prevent the threatened outcome).
- Self-efficacy expectancy (Maddux & Rogers, 1983) (whether people think they can master a behavior, and whether the behavior produces the desired outcome/protection against the threat) (Bandura & Adams, 1977; Bandura, 1982).

Studies that tested the Protection Motivation Theory found that people adopt preventive health behaviors to address highly threatening situations if they think that the preventive behaviors are easy to perform and readily available (Witte & Allen, 2000). HCP are taught that caring for patients without gloves threatens their own health. On the basis of their real life experience, HCP know they are likely to touch blood, urine, feces, drainage and mucous membranes with their bare hands during patient-care events (high noxiousness). Therefore, the threat event is contact with potentially infectious blood or body fluids; and the probability of exposure to the threat event of bloodborne pathogens and multi-drug resistant organisms during patient-care events is high. HCP training provides evidence that gloves protect them from the threat of blood and body fluid exposure (high efficacy of gloves) (Duckro, Blom, Lyle, Weinstein & Hayden, 2005; Siegel et al., 2007). Gloves are easy to apply and wear and are universally available in US healthcare facilities because regulations mandate that gloves are available (reinforce self-efficacy). Therefore, HCP can use gloves without disrupting their workflow.

HCP who focus on self-protection may view removing and changing soiled gloves during patient-care events as a threat to self, and therefore a counter-intuitive action (Aboelela et al., 2006; Borg et al., 2009; Erasmus et al., 2009; Eveillard et al., 2011a). Glove changes also increase the time needed to care for patients, especially when HCP perform hand hygiene between glove changes and let their hands dry before applying clean gloves (Rock, Harris, Reich, Johnson & Thom, 2013). In addition, contaminated gloves and surfaces may appear clean, thereby suggesting that gloves and surfaces are clean. Consequently, HCP may think that they do not need to remove their gloves (Weber, Rutala, Miller, Huslage & Sickbert-Bennett, in Rutala, 2009; Rutala & Weber, 2013). Figure B 1 depicts the proposed relationships among Protection Motivation, glove overuse, cross-contamination with gloves, and HAI.

When they developed Body Substance Isolation, Lynch and colleagues (1990) recognized that HCP might use gloves inappropriately and might not change gloves at glove change points, noting that if the "purpose of wearing gloves is to protect themselves from bloodborne illness [HCP] often wear gloves excessively and fail to put on clean gloves just before contact with mucous membranes and non-intact skin. We believe that excessive glove use may reduce the risk of transmission of bloodborne illness to personnel, but is likely to increase cross transmission of organisms among patients" (Lynch et al., 1990, p. 10).

Several researchers found that HCP do not follow published standards when using gloves in the sequence of patient care. In fact, HCP utilize gloves when gloves are not required and do not change gloves as required during the sequence of patient care (Denman et al., 1992; Eveillard et al., 2011; Fuller et al., 2011; Girou et al., 2004; Kim, Roghman, Perencevich & Harris, 2003;

Loveday, Lynam, Singleton & Wilson, 2014; Morgan et al., 2010; Savage, Fuller, Besser & Stone, 2011; Thompson et al., 1997). These observations confirm that HCP do not consistently use gloves as indicated by policy, guidelines or regulations in the reported studies. Girou and colleagues (2004) hypothesized that HCP in a French hospital did not change or remove contaminated gloves, in part, related to policies established to control multi-drug resistant organisms. After the policies were introduced, these investigators observed that HCP donned gloves routinely before entering patient rooms and they did not change the gloves during the sequence of patient care. Barrett and Randle (2008) found that student nurses perceived that gloves were to be used to not only keep their hands clean, but also as a substitute for hand hygiene. The researchers noted that the student nurses' perceptions were particularly important, as they reflected the held beliefs of the future workforce.

Sacar and colleagues (2006) observed that HCP did not remove gloves 21% of the time between dirty and clean activities. In this study, HCP self-reported that they wore gloves during phlebotomy; however, they reported that they changed gloves between patients only 51.6% of the time. Of the respondents, 97.8% felt they were at risk of acquiring an infection from their patients; however, 41.9% responded that patients were not at risk of acquiring an infection from HCP.

Loveday and colleagues (2014) completed a mixed methods study within six wards of a UK hospital. During the observational portion of the study, the tool developers used the WHO My Five Moments for Hand Hygiene model to identify inappropriate glove use. The team observed 163 glove-use episodes and determined that HCP used gloves inappropriately in 42% of the episodes. Subsequent HCP interviews determined that the decision to use gloves was

based upon emotion and socialization. The identified emotions were disgust and fear; peer pressure and the social norms also influenced HCP decisions regarding glove use.

Inappropriate glove use by HCP is a safety hazard because HCP may view gloves as a substitute for hand hygiene, using gloves rather than cleaning their hands, contaminating the patient and patient's environment when they fail to change their gloves at glove change points, and transmitting microbes (Diaz et al., 2008; Eveillard et al., 2010; Savage, Fuller, Besser & Stone, 2011; Whitby, McLaws & Ross, 2006). The next section describes the evidence that inappropriate glove use plays a role in transmission of pathogenic organisms.

Consequences of Inappropriate Use of Gloves

Guidelines and regulations direct HCP to change gloves at specific glove change points when gloves are contaminated or soiled; or between caring for different patients. However, these documents do not identify or define clearly what constitutes contamination. HCP assume that gloves and environmental surfaces that look clean are not contaminated (Rutala, 2010). Moreover, HCP may be more likely to touch places such as infected wounds or the perineum with gloved hands than to touch them with their bare hands (Hayden et al., 2008). Consequently, HCP may be less likely to recognize glove change points, may fail to change gloves, and may be more likely to transfer pathogens between contaminated areas and clean areas when they wear gloves than when they provide care with bare hands.

Multiple research teams have studied how the presence of organisms on the patient and in the patient environment increases the HCP's risk of contaminating their hands, gloves, gowns and clothing during the sequence of patient care. Gloves worn by HCP for prolonged periods have touched items within the healthcare environment multiple times, which may lead to crosscontamination between patients and the environment (Diaz et al., 2008; Eveillard et al., 2009;

Eveillard et al., 2010; Eveillard et al., 2011a; Eveillard et al., 2011b; Eveillard, 2011c; Girou et al., 2004; Thompson et al., 1997).

Hayden and colleagues (2008) completed a structured observational trial in which they looked at hand or glove contamination acquired when HCP cared for patients colonized or infected with vancomycin-resistant Enterococcus (VRE). The researchers cultured the intact skin of these 22 patients, selected environmental surfaces, and the surfaces of HCP hands and gloves before and after the sequence of patient care. The researchers used a standardized form (not included in the study report) to record each time the HCP touched the patient or the environment. HCP who wore gloves during the sequence of patient care were significantly less likely to contaminate their hands than HCP who did not wear gloves, but they also touched more surfaces during the sequence of patient care than did HCP with bare hands (7.9 touches with gloves vs. 3.4 touches with bare hands [p < 0.001]). The risk of contaminating gloves and bare hands was significantly associated with the number of touches (odds ratio [OR], 1.1 [95% CI, 1.01-1.19]; p = 0.02). HCP contaminated their gloves 57% of the time when touching a patient, and 69% of the time when touching both a patient and the environment.

Snyder and colleagues (2008) cultured gowns and gloves worn by HCP during patient care in a 29-bed medical intensive care unit. They detected no VRE or methicillin-resistant *S. aureus* (MRSA) on unused gloves or glove boxes in the patient rooms. However, the researchers detected MRSA on 14 of 79 (17.7%) and VRE on 7 of 91 (7.7%) gloves sampled after use. The researchers found a higher risk of glove and/or gown contamination if the HCP touched the patient's head, neck or endotracheal tube or tracheostomy site (p < 0.05), and found an association between glove and/or gown contamination and the presence of a percutaneous endoscopic gastrostomy and/or jeujenostomy tube (p < 0.05). They also observed that 13% of

HCP who acquired either MRSA or VRE on their gloves also acquired it on their hands, supporting the recommendations for hand hygiene after glove use.

Morgan and colleagues (2012) assessed how caring for patients on Contact Precautions with positive MDRO cultures detecting Acinetobacter baumanii, Pseudomonas aeruginosa, MRSA or VRE was associated with HCP gown and glove contamination after patient care. HCP did not change their gowns or gloves during patient-care events in this study. The investigators cultured HCP gloves after 167 episodes of care for patients with A. baumanii, 86 episodes of care for patients with P. aeruginosa, 152 episodes of care for patients with MRSA, and after 180 episodes of care for patients with VRE. Of the gloves cultured, 49 of 167 (29.3%) grew A. baumanii, 15 of 86 (17.4%) of the gloves cultured grew P. aeruginosa, 17 of 152 (11.2%) of the gloves cultured grew MRSA, and 18 of 180 (10.0%) of the gloves cultured grew VRE. Ninetyone percent of the isolates from the gloves cultured had the same pulse field gel electrophoresis (PFGE) pattern as the isolates from the patient rooms. In the multivariable analysis, gown and glove contamination was significantly associated with positive cultures obtained from items in the patient's environment (OR, 4.2; 95% CI 2.7-6.5), greater than 5 minutes spent by HCP in the patient's room (OR 2.0; 95% CI 1.2-3.4), contact with a ventilator (OR 1.8; 95% CI 1.1-2.8), and performance of physical examinations (OR 1.7; 95% CI 1.1-2.8). PPE was less effective at preventing hand contamination after glove removal when patients were colonized or infected with A. baumanii (4.2%) or P. aeruginosa (3.5%) than when patients were colonized or infected with MRSA (3.3%) or VRE (1.7%).

Girou and colleagues (2004) found that 100% of 22 gloves sampled yielded positive cultures after an average of eight contacts between the gloves and the patient or the patient's environment. These researchers recovered pathogenic bacteria from 19 glove samples (86%), and

found that 59% of the glove samples grew $> 3 \times 10^4$ colony forming units (CFU). In 13 of 19 instances (68%), the pathogen contaminating the glove was the same strain as that infecting or colonizing the patient (Girou et al., 2004).

Weber and colleagues (2010) demonstrated that high touch environmental surfaces within the patient-care area such as bedrails, over bed tables and bedside lockers become recontaminated within a single eight-hour shift after they were disinfected. More recently, Loftus and colleagues (2012) studied contamination of 3-way stopcocks. They previously demonstrated that interoperative stopcock contamination was associated with increased patient mortality (Brindeiro et al., 2011). Loftus and colleagues hypothesized that the stopcocks were contaminated by frequent contact with anesthesia providers' hands. They cultured both the stopcocks and the hands of the anesthesia providers, but they did not culture gloves used by the anesthesia providers. The researchers found that of 128 contaminated stopcocks, only 12 (9.4%) had isolates that were related to the isolates on the anesthesia provider's hands. In a related editorial (2012), Zingg and Pittet hypothesized that stopcocks may have become contaminated because anesthesia providers handled the stopcocks without changing their gloves or performing hand hygiene. Thus, gloves may be a vehicle for cross-contamination when HCP do not remove gloves between touching patients and touching environmental surfaces.

Results of studies that assessed the role of gloves in the pathogenesis of HAI vary substantially. Johnson and colleagues (1989) demonstrated that glove use could decrease transmission of *C. difficile*. Berthelot and colleagues (2001) noted that an outbreak of *Klebsiella oxytoca* colonization was terminated after they instructed HCP to use gloves in a manner consistent with Body Substance Isolation when inserting nasogastric tubes and administering enteral feedings (Berthelot et al., 2001). Recently, Yin and colleagues (2013) noted that over a

nine-year period, rates of bacteremia, central line-associated bloodstream infections and hospitalacquired pneumonia were significantly lower during RSV season, when HCP practiced universal gloving, than during the rest of the year when HCP did not wear gloves for all patient contact (Yin et al., 2013).

Trick and colleagues (2004) compared universal gloving with Contact Precautions and did not detect a significant difference in the rate at which residents were colonized with four multi-drug resistant organisms (MDRO) (1.5 infections/colonizations with MDRO per 1000 resident days with universal gloving vs. 1.6 infections/colonizations with MDRO per 1000 resident days with Contact Precautions) (Trick et al., 2004). Bearman and colleagues (2007) compared their usual practice of using Contact Precautions for patients infected or colonized with MDRO (Phase 1) with universal gloving (Phase 2) in an intensive care setting. The researchers found that while glove use increased during Phase 2, hand hygiene rates decreased 7.3% (p < 0.001) before patient contact and decreased 5% after patient contact (p = 0.011) when compared with glove use and hand hygiene rates during Phase 1. Acquisition of MDRO did not change significantly in Phase 2 when universal gloving was used, but rates of ventilatorassociated pneumonia, catheter-associated bloodstream infections and catheter-associated urinary tract infections increased significantly. The authors attributed the increased rates of HAI to either a chance finding, a decrease in hand hygiene, or a change in the configuration of the study unit which may have confounded infection prevention and control practices. The authors also surveyed HCP and found that HCP believed glove use was associated with a decreased risk of cross-transmission, and they felt that they provided better care during the universal gloving portion of the trial.

Harris and colleagues (2013) recently conducted a multi-site cluster randomized trial in 20 medical and surgical ICUs to assess whether rates of VRE and MRSA acquisition were different in ICUs practicing universal gowning and gloving for all patient contact compared with units using CDC's Transmission-Based Precautions and Standard Precautions. These precautions direct a HCP to: (a) use Contact Precautions and consistently wear gowns and gloves when caring for patients known to be infected or colonized with VRE, MRSA or other MDRO; and (b) use Standard Precautions when caring for all other patients, which includes using gowns and gloves when there is potential for HCP contact with patient blood, body fluids or mucous membranes or non-intact skin. In the intervention group, HCP complied with universal glove use 86.16% of the time, and with universal gown use 85.14% of the time. However, the researchers did not assess whether HCP used gloves and other PPE in a manner consistent with Standard Precautions. The researchers found no difference in acquisition of VRE between the two study groups. In contrast they found a 40.2% relative reduction in MRSA acquisition in the intervention ICUs compared with a 15.0% reduction in the control ICUs. Harris and colleagues found that HCP hand hygiene rates on room exit were significantly higher in the intervention arm of the study than in the control arm of the study. As hand hygiene alone has been shown to prevent transmission of pathogens, the difference in MRSA acquisition between the two arms of the study may have been associated, at least in part, with the significantly higher rates of hand hygiene when HCP in the intervention arm exited patient rooms.

Chai et al. (2005) and Yap et al. (2004) observed significant increases in rates of MRSA infections, including ventilator-associated pneumonia and bacteremia, during the SARS outbreak in 2003. These researchers hypothesized that HCP changed their gloves infrequently, resulting in increased transmission of multi-drug resistant pathogens. Chai and Yap discussed alternative

explanations of their findings, including a shift in resources from general infection prevention and control surveillance to SARS-related surveillance, or a change in the transmission patterns mimicking the "cloud phenomenon" of airborne transmission which Bassetti, Bischoff and Sherertz (2005) previously described.

One reason that the results of studies assessing the effect of glove use on HAI varied may be the fact that investigators did not examine how gloves were used. In addition, published studies have not used robust methods to assess the relationship between glove use and HAI, in part because researchers have not developed a tool to monitor glove use by HCP. Another potential difference is the number of patients for whom each HCP cared. Theoretically, if a HCP is assigned one or two patients as is common in critical care areas, the chances that HCP wear the same gloves when caring for more than one patient are less than for HCP assigned between six and 20 patients, as is common in long-term care settings, because there are more opportunities to move between patients while wearing the same pair of gloves.

If overuse and misuse of gloves by HCP affect hand hygiene and lead to transmission of microorganisms on the surfaces of contaminated gloves, then information on glove use should help infection prevention staff and all HCP improve glove use and hand hygiene rates. For example, we need to know whether hand hygiene rates are different when HCP use gloves in conjunction with gowns and other PPE for Contact Precautions than when they use gloves as part of Standard Precautions or universal gloving. We also need to determine if there is a relationship between the time of day or the day of the week when HCP perform patient-care events and inappropriate HCP glove use. Most prior papers describing hand hygiene and glove use do not specify when the researchers observed HCPs, or if the observations were performed only during the day on weekdays, or if they included HCP assisting patients on night shifts and weekends.

The Need for a Glove-Use Surveillance Tool

Fuller and colleagues (2011) attempted to monitor both hand hygiene and glove use with a validated hand hygiene observation tool (HHOT). They describe the difficulties they encountered documenting glove use and hand hygiene simultaneously with a tool made specifically for hand hygiene surveillance. Fuller and colleagues (2011) observed that "there is no comprehensive, validated reliable measure of glove use reported in the literature" (p. 1197). Girou and colleagues and Eveillard state that glove use by HCP during patient care should be studied further (Eveillard, 2009; Girou et al., 2004). Eveillard states that glove changes within the sequence of patient care (intra-series events) and glove changes between patients (extraseries events) should be studied separately (Eveillard, 2011).

To date, only Loveday, Wilson and colleagues from the University of West London have published studies describing a surveillance tool specifically designed to assess glove use as part of Standard Precautions or in the context of universal gloving. The researchers focused on developing a training tool to improve HCP glove use, rather than a descriptive tool to collect data about glove use (Loveday, Wilson, from conversation, 2014). The Loveday/Wilson tool is based upon the WHO My Five Moments for Hand Hygiene, thus the tool is not specific to a healthcare facility that utilizes a two moment model. The language of the tool is specific to healthcare in the UK, utilizing terms that are not used in US healthcare such as *sister*, *porter*, *junior doctor*, *senior doctor*, and *sluice*. The tool requires observers to assess the type of touches (contaminated vs. uncontaminated), and record the likelihood of contact with blood and body fluids while observing practice rather than immediately afterward while analyzing the data. Researchers have also developed tools to assess glove use within the context of Transmission-Based Precautions (Ross et al., 2011; CDC, 2012). However, these tools were developed to assess compliance with all components of Transmission-Based Precautions, which include not only gloves but also gowns, masks and eye protection.

The GUST frames glove use within the context of how HCP use gloves during Standard Precautions. It provides a tool for trained observers to record the frequency and sequence in which specific surfaces are touched by HCP wearing gloves during patient care. Observers can determine the number of contaminated touch points that occur after a failed glove change. This information may help infection preventionists and researchers determine the extent that contaminated touch points contribute to cross-contamination between patients and environmental surfaces during patient-care events.

Summary

HCP glove use during the sequence of patient care has evolved over the last 50 years from an occasional occurrence to an almost universal phenomenon across the entire healthcare continuum. When used appropriately, gloves protect the skin of HCP hands from pathogens and contaminants and prevent the transfer of disease-causing organisms from HCP hands to patients and the environment. HCP are trained to use gloves to protect themselves, and this training reinforces natural self-protection instincts. Current research indicates that HCP use gloves inappropriately during the sequence of patient care. HCP may fail to change gloves at glove change points and contaminate the patient and the patient's environment with contaminated gloves because their training reinforces the natural human instinct of self-protection. In addition, HCP may wear a single pair of gloves rather than change gloves during patient-care events because they fear contact with patient blood, body secretions and excretions. Regardless of why HCP misuse gloves, inappropriate glove use and failure to change gloves at glove change points can lead to cross-transmission among patients and the environment, increasing the patients' risk

of colonization and infection. Thus, we need a reliable glove-use surveillance tool to identify and measure how HCP use gloves within the sequence of patient care. For this study, the principal investigator and other trained observers observed HCP assisting patients with perineal care and toileting, as both are high frequency glove-use events that occur in LTCF and in most inpatient healthcare organizations, and both patient-care events are associated with a high probability that gloves will become contaminated.

CHAPTER THREE: METHODS

This study used a descriptive structured observational design to: 1) examine the degree of inappropriate glove use by HCP during toileting and perineal care, 2) examine the reliability of the GUST, and 3) explore associations between the two indicators of inappropriate glove use and select characteristics of the HCP and the patient-care events. The PI used the GUST to record HCP glove-use behavior when they assisted patients with toileting and perineal care. The characteristics of HCP glove use were divided into the five facets of glove use and the two indicators of inappropriate glove use. The GUST data also included the type of surfaces touched after a failed glove change. The reliability of the GUST was examined by comparing the PI's observations of HCP using gloves during patient toileting and perineal care and with those of trained co-observers. Other study variables were collected for exploratory analyses to identify HCP or patient-care event characteristics that may be associated with the degree of inappropriate glove use. These exploratory analyses generated hypotheses for future studies.

Setting and Sample

Setting.

The study setting was 11 licensed units of a 296 bed suburban LTCF, the average unit size was 28.7 beds (range 10 to 42 beds). The PI and the other trained observers had 24-hour access to the 11 units, providing an opportunity to observe patient-care events on all days and shifts. The patient care provided on the 11 units was representative of care in US LTCF (see Table A 3).

All rooms were licensed by the Illinois Department of Public Health. Two units were licensed as sheltered care, two units were licensed as combined intermediate and skilled care, and seven units were licensed as skilled care, and certified by CMS for Medicare A patients. All rooms had private toilets. Some rooms had private showers, and each unit also had a shared shower room with a toilet.

Gloves were readily available on all units in both public areas, shower rooms, and in each patient room and bathroom to enhance availability and workflow. The facility required HCP to attend orientation and annual retraining on infection prevention and bloodborne pathogens, which included training materials based upon current glove use standards. The LTCF's policies and procedures for toileting or perineal care followed CMS and the CDC/WHO guidance for hand hygiene and glove use during Standard Precautions. Per the facility policies and procedures, the HCP were to:

- 1. perform hand hygiene before patient care,
- assemble supplies that included cleansing wipes or washcloths, soap, towels, and barrier creams or other treatments,
- put on a clean pair of gloves to remove soiled incontinence pads or briefs and any soiled or wet clothing,
- 4. place soiled pads or clothing in appropriate trash and linen hampers,
- 5. remove the soiled gloves and performed hand hygiene,
- 6. put on clean gloves to provide perineal care, apply barrier creams or other treatments,
- 7. remove gloves and perform hand hygiene,
- 8. adjust clothing, clean incontinence products or clean bedding,
- 9. assist the patient with hand hygiene,
- 10. clean and disinfect lifts between patients, and
- 11. perform hand hygiene.

Sample.

The target sample included 105 randomly selected HCP performing toileting and perineal care including: 1) Registered Nurses (RN) licensed by the state, 2) Licensed Practical Nurses (LPN) licensed by the state and 3) Certified Nursing Assistants (CNA) certified by the state who provided direct patient care.

The LTCF patients were not the subjects of the study, therefore, no identifying patient characteristics were collected. For simplicity's sake, both short stay patients and long term residents were categorized as patients in this study. In general, short stay patients were younger and lived in the community or were temporarily in a short stay post-acute bed. Long-term patients were older and resided in the LTCF. The patients or the patient's power of attorney for healthcare were given a letter explaining the study including instructions on how to ask questions and how to refuse any observations while HCP were assisting with their care.

Other types of patient-care events were excluded to keep the sample focused, and to avoid low frequency patient-care events with few touch points. Although gloves were frequently used during other patient-care activities such as dressing, bathing, grooming and medication administration, the goal of this study was to describe the interaction between the patient, the HCP and the environment during toileting and perineal care.

The University of Iowa IRB approved the study protocols (Appendix C 3). Because the purpose of this study was to examine "processes" of glove use during patient-care events in an institution, written consent from the HCP was not required. The administration of the facility granted written permission to observe HCP glove use during patient-care events. Residents, patients, and families received a letter prior to the observations (Appendix C 4).

Recruitment and Enrollment of HCP.

Recruitment and enrollment of HCP for the study occurred in three steps. For the first step, the PI held meetings to educate and elicit cooperation with the study procedures. HCP received a letter during group meetings describing the purpose of the study and the HCPs' right to refuse to be observed during the study. The PI also met with HCP privately after the meetings if they had questions (Appendix C 5; Appendix C 6). For the second step, the PI randomly selected RNs, LPNs and CNAs for the study sample from those HCP who agreed to participate in step one. Third, the PI approached the randomly selected HCP and asked to observe them assist a patient with toileting or perineal care.

HCP were given the opportunity to opt out of the study, or to decline to be observed during a patient-care event, at three different points: 1) at the informational meetings before the randomization, 2) at the beginning of the observation session, and 3) after the observation session when the PI read a debriefing statement to the HCP (Appendix C 7). If the HCP declined to participate immediately before the patient-care event, or after the debriefing statement, an alternative HCP was selected. The PI kept information on the HCP who refused to participate in order to evaluate sampling bias.

The PI used a random number generator to select a sample of 105 RNs, LPNs and CNAs from a population of RNs, LPNs and CNAs who were regularly assigned to care for patients on the 11 study units. The randomly selected HCP were stratified by HCP category, shift and patient care unit to ensure observations were representative of the distribution of toileting assistance and perineal care events on the study units.

Study Variables

Primary study variables.

The PI used the sequence of HCP actions and touch points relating to glove use during the patient-care events to provide structure to the study observations. The primary study variables evolved from these observations.

The primary study variable was inappropriate glove use, which was defined as the number of failed glove changes and the number of contaminated touch points during a toileting or perineal care event. The number of failed glove changes, the number of contaminated touch points, the type of surface touched, and the sequence of surfaces touched during the event were recorded during structured observations of the patient-care events on the GUST (see Appendix C 1). Additionally, the times in the sequence when gloves were donned, changed or removed were recorded. These observations were operationalized as the five facets of glove use, and the two indicators of inappropriate glove use.

The five facets of glove use.

Facet number One: Touch points.

Observers recorded the touch points during the patient-care events on the GUST. They occurred when the HCP gloved or bare hand touched any part of the patient or patient environment. The touch points were numbered and recorded in the order in which they occurred (#1, #2, #3, etc.), and observers wrote the surface touched next to the numbers for the touch point. Numbers for bare-handed touch points were circled and gloved touch points were indicated by the number only. If the HCP touched multiple areas of the same surface or object without moving to a different item or surface (i.e., from a patient body site, to clothing, equipment or environmental surfaces), all the touches on that surface counted as one touch. Correct documentation required: (a) an unobstructed view, (b) attention to the HCP actions, (c)

discrimination between a bare-handed touch point and a gloved touch point, and (d) an accurate assessment of whether the HCP touched a clean or contaminated surface. The number of touch points was obtained by adding all touch points recorded on the front of the GUST forms during the GUST analysis either the observer or other personnel trained to analyze the GUST data. The person analyzing the GUST documentation counted the number of touch point occurrences, and recorded them on the back of the GUST form or entered them directly into a spreadsheet.

Facet number Two: Gloved touch points.

The gloved touch points were numbered and recorded in the order in which they occurred (#1, #2, #3, etc.), and observers wrote the surface touched by HCP with a gloved hand next to the numbers for the touch point. Numbers for bare-handed touch points were circled and gloved touch points were indicated by the number only. If the HCP touched multiple areas of the same surface or object with a gloved hand without moving to a different item or surface (i.e., from a patient body site, to clothing, equipment or environmental surfaces), all the gloved touches on that surface counted as one touch. Correct documentation required: (a) an unobstructed view, (b) attention to the HCP actions, (c) discrimination between a bare-handed touch point and a gloved touch point, and (d) an accurate assessment of whether the HCP touched a clean or contaminated surface. The number of gloved touch points was obtained by adding all gloved touch points recorded on the front of the GUST forms during the GUST analysis either the observer or other personnel trained to analyze the GUST data. The person analyzing the GUST documentation counted the number of gloved touch point occurrences, and recorded them on the back of the GUST form or entered them directly into a spreadsheet.

Facet number three: Glove change points.

Glove change points were determined by observers on the GUST as occurring after the HCP touched a surface that was contaminated or potentially contaminated with patient blood,

secretions or excretions, and between caring for different patients. The glove change point was defined as the next action after a contaminated touch point or between different patients. Correct documentation required: (a) an unobstructed view, (b) attention to the HCP actions, (c) discrimination between a bare-handed touch point and a gloved touch point, and (d) an accurate assessment of whether the HCP touched a clean or contaminated surface. Glove change points were indicated on the GUST with the documentation of a touch in the Contaminated Patient Sites/Soiled Equipment, Environment and Supplies Category, which included touching the perineal area, mucous membranes, soiled dressings, diapers, linen, equipment, or environment, or between different patients. Observers needed to use a higher level of critical thinking to identify glove change points than other facets of glove use behavior. The number of glove change points was obtained from the front of the GUST forms during the GUST analysis. The person analyzing the GUST documentation counted the number of gloved change point occurrences, and used information written by the observer on the GUST to determine if the HCP touched a contaminated surface or touched different patients. The person analyzing the documentation then records the number of glove change points on the back of the GUST form or entered them directly into a spreadsheet.

Facet number Four: Actual glove changes.

Observers recorded actual glove changes on the GUST during the patient-care events. Actual glove changes were defined as occurring when HCP removed gloves and either replaced them with a clean pair of gloves or continued patient care with bare hands, irrespective of glove change points. Glove removal was recorded by observers after the last touch point observed during the sequence of care (e.g., gloves removed after touch point #___). Observers documented when HCP put on clean gloves before the next touch point occurring in the care sequence (e.g., before touch point #___). Correct documentation required: (a) an unobstructed

view, (b) attention to the HCP's actions, and (c) an accurate assessment of the point in the sequence of HCP's actions when the HCP changed his or her gloves. If the HCP had double-gloved, removing the top glove was recorded as an actual glove change. The person analyzing the GUST documentation counted the number of actual glove change occurrences documented on the front of the GUST form and recorded them on the back of the GUST form or entered them directly into a spreadsheet.

Facet number Five: Glove changes at a glove change point.

Glove changes at a glove change point were recorded by observers on the GUST during the patient-care events. Glove changes at a glove change point were defined as the point when HCP removed gloves immediately after touching a surface contaminated or potentially contaminated with patient blood, secretions or excretions, or between caring for different patients. Correct documentation required: (a) an unobstructed view, (b) attention to the HCP actions, and (c) an accurate assessment of the point in the sequence of care when the HCP changed gloves.

The number of glove changes at a glove change point was obtained from the front of the GUST forms during the GUST analysis. The persons performing the GUST analysis needed to make additional higher-level decisions to identify glove changes at glove change points than they did to identify other facets of glove use behavior. For example, they had to determine exactly where a contaminated touch point occurred and whether the observer recorded the HCP glove change immediately after the contaminated touch. The person analyzing the GUST documentation counted the number of glove changes at a glove change point and recorded them on the back of the GUST form or entered them directly into a spreadsheet.

The two indicators of inappropriate glove use.

Indicator number One: Failed glove changes.

Failed glove changes were defined as the point when HCP failed to remove gloves immediately after touching a surface contaminated or potentially contaminated with patient blood, secretions or excretions, or failed to change gloves between caring for different patients. Correct documentation required (a) an unobstructed view, (b) attention to the HCP actions, and (c) an accurate assessment of the point at which the HCP should have changed his or her gloves in the sequence of care.

The number of failed glove changes was obtained from the front of the GUST forms during the GUST analysis. The person analyzing the GUST information had to identify when the HCP touched a contaminated area, or when the HCP touched a different patient and did not change gloves. The person performing the GUST analysis had to make additional decisions, such as determining exactly when in the sequence of patient care a contaminated touch occurred, and then if the observer recorded the HCP glove change immediately after the contaminated touch.

Indicator number Two: Contaminated touch points.

Contaminated touch points could be either gloved or bare-handed. Both are equally important and relevant to the study. Contaminated gloved touch points suggest the role that contaminated gloves may play in cross-contamination and HAI. Bare-handed touch points suggest the level risk of HCP occupational exposure to pathogens as well as a lack of HCP knowledge, understanding, or focus on risk of exposure to patient's blood, body fluid or potentially infectious materials. Both are aspects of inappropriate glove use and comparison of the two will provide insights into the relative role of each in HAI. Contaminated gloved touch points were defined as the point when HCP failed to remove gloves immediately after touching a surface contaminated or potentially contaminated with patient blood, secretions or excretions, or failed to change gloves between caring for different patients, and continued to touch surfaces with the same pair of gloves. Correct documentation required: (a) an unobstructed view, (b) attention to the HCP actions, and (c) accurate identification of the contaminated touch points and their place in the sequence of HCP actions. Contaminated bare-handed touch points were defined as points when a HCP's bare hand touched a surface contaminated or potentially contaminated with patient blood, secretions or excretions, or other potentially infectious materials.

The number of contaminated gloved and bare-handed touch points were obtained from the front of the GUST forms during the GUST analysis. The person analyzing the GUST information identified a touch in a contaminated category, or when the HCP ended the patientcare event and failed to change gloves. The person performing the GUST analysis had to make additional decisions, such as determining if the touch was a bare-handed or gloved touch, exactly when in the sequence of care the touch occurred and what was touched to determine if a contaminated touch point occurred, and if the observer recorded the HCP glove change immediately after the contaminated touch.

The person doing the GUST analysis used the guidance on the back of the GUST to calculate overall HCP glove use, including the frequency of the five facets of glove use, the two indicators of inappropriate glove use, the percentage of inappropriate glove use and the specific surfaces touched with contaminated gloves, along with comments specific to the patient-care event if applicable.

Exploratory study variables.

The observers recorded demographic study variables on the GUST to describe the HCP sample and to provide information for exploratory analyses. HCP and/or patient-care event

characteristics were also measured to describe the following characteristics of the HCP and patient-care events and for exploratory analysis.

HCP Gender.

Gender was examined because some evidence suggests that gender may impact hand hygiene behavior (Pittet, 2000). Gender was collected via HCP self-report. For this study, gender was indicated as female or male.

Licensure or certification of HCP.

The PI hypothesized that participants with more education and training would be more likely than others to use gloves appropriately. Therefore, we collected data on licensure or certification. The HCP's category was known when participants were randomly selected and defined either by the HCP's job description or licensure status. The job categories were also identified from information on the HCP's nametag and the color of his or her uniform.

Duration of HCP experience.

Duration of the HCP's clinical experience was examined because the longer the HCP has been working, the more their glove-use behavior may be influenced by training and experience. The duration of HCP experience was defined as the number of months HCP had worked in any healthcare settings. Number of years and months worked was collected via HCP self-report, converted into months worked and divided into two categories, less than 4 years (48 months and under), and 4 years and greater (49 months and over). HCP with at least four years of experience would have extensive experience with frequently performed patient-care events such as toileting patients and peri care and they should be proficient in these tasks (Benner, 2001).

Shift and day of patient-care event.

The shift and day of the patient-care events were examined because levels of staff and supervision fluctuate, and changes in staffing may affect HCP glove use. The time and date of

the patient-care event were defined as the time of day expressed on a 24-hour clock. The date was expressed as month, day and year and the day of the week was categorized as weekday or weekend. The time of the patient-care event were categorized as 04:30-07:30, 11:00-14:00, and 19:00-24:00 to be congruent with both a two shift patient care model and with a three shift patient care model.

Number of HCP assisting with toileting and perineal care.

The number of HCP assisting with toileting and perineal care was recorded because it could affect glove use. For example, one HCP could do the dirty tasks and one HCP could do the clean tasks. The person doing the clean tasks would not need to wear gloves. The number of HCP assisting was defined as the number of HCP participating and providing care in an observed patient-care event. If more than one HCP provided care, the randomly selected HCP was the one observed. The number of HCP assisting was recorded as one HCP assisting, or two or more HCP assisting with the patient-care event.

Number of patients assigned to the HCP.

The number of patients assigned to the HCP was examined because HCP caring for multiple patients have less time for each patient and may take less time to think critically about gloves while caring for patients. The number of patients assigned to the HCP was defined as the number of patients for which the HCP had primary responsibility during their assigned shift. At times, HCP may have been assigned to help with patient care on a particular unit. In this case the HCP would not have primary responsibility for any patients; thus, the observer would record "zero patients" for this variable. This variable was collected for descriptive purposes only and not for the exploratory analysis.

Study Procedures

The study results may have been affected by: (a) characteristics and training of the coobservers, (b) HCP changing their usual glove use behavior because they were being observed, (c) how the observers documented HCP glove use behavior, and (d) how the person doing the GUST analysis interpreted the observer's documentation. For this study the major considerations were: (a) recruiting and training appropriate co-observers, (b) observing HCP performing the appropriate number and type of patient-care events, and (c) accurately entering and analyzing the GUST data.

Co-observer recruitment and training.

Co-observers were recruited from a convenience sample of nurses or pre-professional healthcare students who either worked or volunteered at the LTCF and who expressed interest in the study. Ten nurses and one medical school student volunteer were selected. Co-observers were trained on the use of the GUST using: (a) classroom lecture, (b) one video of simulated patientcare events developed for GUST training, and (c) two or more sessions observing actual toileting or perineal care events with the PI providing guidance and feedback.

Observations of selected HCP.

HCP on the 11 study units were observed. The 76 HCP had consistent assignments, and the LTCF utilized a two shift model of 07:00 to 19:00 (days) and 19:00 to 07:00 (nights). Observation sessions of HCP performing patient care were scheduled based on the HCP work schedules. The PI obtained toileting schedules for specific patient in advance in order to identify the optimal observation times. Data collection times and days were chosen such that HCP were observed on a variety of shifts and days. The PI sought to have at least 30% of all observations

on the night shift, and 20% on a Saturday or Sunday, rather than limit observations to weekday daytime hours.

In order to obtain paired observations for reliability analysis, co-observers were randomly selected for observation sessions from the convenience sample of available co-observers. The PI and co-observer introduced themselves to the randomly selected HCP and asked to observe toileting or perineal care to "watch for barriers to HCP hand hygiene". The PI felt that HCP might alter their glove use behavior if they knew the actual study goal, thus this minor deception was an employed to minimize the Hawthorne Effect. Chen and colleagues (2015) noted that studies on the Hawthorne Effect indicate the effect was most apparent within the first 10 to 15 minutes of direct observation. Therefore, the deception was important for this study, as a majority of observations lasted 15 minutes or less. Data collection for the patient-care event started when the selected HCP entered the patient room or the unit's shower room to provide toileting or perineal care. The PI and the co-observers watched the same toileting or perineal care event at the same time and recorded their observations on separate GUST forms. Observers included a toileting or perineal care event observation in the sample only if the HCP physically touched the patient's body, clothing, supplies, and the environmental surfaces during the patientcare event. The toileting or perineal care events concluded when the HCP exited the patient room or shower room after completing the patient-care event. Touches by the HCP that occurred when the HCP temporarily left the patient environment before the toileting or perineal care was completed were recorded as a part of the patient-care event. When two or more HCP participated in the patient-care event, the PI and the co-observer observed the randomly selected HCP.

The PI and co-observers watched HCP use gloves during patient care events and used the GUST to record HCP and patient care event characteristics as well as the type and sequence of

HCP glove use during the toileting or perineal care. The observers recorded the length of the patient-care event by indicating the start time and the stop time. Each GUST also included the respective co-observer's initials. The PI read a short debriefing statement at the conclusion of the observed patient-care events. The PI again reassured the HCP that no identifiable characteristics were collected, and asked the HCP for permission to include the information from the observed patient-care event in the study sample (Appendix C 7).

The PI then excluded any patient-care event shorter than 90 seconds from further analysis because the pilot data indicated that toileting and perineal care events lasting more than 90 seconds provided the most useful data. The PI then independently completed and double-checked the documentation on the GUST. After the PI completed the six-category grid, the PI finished the decision rule determinations. The PI assigned a code to the HCP observations. In order to identify the set as a "pair" of observations, the PI stapled the GUST forms together. The original paper copies were kept in a locked private office in a binder in chronological order.

Data Analysis

The PI double-entered data from each completed GUST form into Excel. First, the PI entered the data from the GUST forms into an Excel spreadsheet. One week later the PI reentered the data into a separate Excel spread sheet. The PI then compared the two datasets and any discrepancies were resolved by comparing the original GUST forms. The PI then entered the data in the reconciled Excel spreadsheet into SPSS and R for analysis.

Summary statistics.

Categorical level characteristics of the HCP and the patient-care events were described with frequencies and percents. Continuous level characteristics were described with means and standard deviations.

Inappropriate glove use.

Inappropriate glove use was described by computing the two indicators of inappropriate glove use, (a) number of failed glove changes and (b) number of contaminated touch points.

Failed glove use.

The PI summed failed glove changes and total number of glove change points across all observations and computed the percentage of total failed glove changes as [(total number of failed glove changes at a glove change point ÷ total number of glove change points) × 100]. The PI also calculated the mean number of failed glove changes per patient-care event and assessed for normality using graphs, skewness, kurtosis and Shapiro-Wilk Test. A 95% confidence interval was constructed.

Contaminated touch points.

The PI first summed total touch points to calculate contaminated touch points. Then, the PI summed the contaminated gloved touch points and the total number of gloved touch points across all observations. The percentage of total contaminated gloved touch points was computed as [(number of contaminated gloved touch points \div total number of gloved touch points) × 100]. The percentage of patient-care events with one or more contaminated gloved touch points was also computed [(number of patient-care events with contaminated touch points \div total patient-care events) × 100]. The mean number of contaminated touch points for each patient-care event were also calculated and assessed for normality using graphs, skewness, kurtosis and Shapiro-Wilk Test. A ninety-five percent confidence interval was constructed.

Next, the PI summed the contaminated bare-handed touch points and the total number of bare-handed touch points. The percentage of total bare-handed contaminated touch points was computed as [(number of contaminated bare-handed touch points \div total number of bare-handed touch points) \times 100]. The percentage of patient-care events with one or more contaminated bare-

handed touch points was also computed [(number of patient-care events with contaminated barehanded touch points \div total patient-care events) × 100]. The mean number of contaminated barehanded touch points for each patient-care event were also calculated and assessed for normality using graphs, skewness, kurtosis and Shapiro-Wilk Test. A ninety-five percent confidence interval was constructed. The total number of contaminated touch points was calculated as the sum of contaminated gloved touch points and contaminated bare-handed touch points.

The percentage of contaminated gloved touch points was visually compared to the percentage of contaminated bare-handed touch points as these are these are summary values. Likewise, the percentage of patient-care events with one or more contaminated gloved touch points was visually compared to the percentage of patient-care events with one or more contaminated bare-handed touch points as these are also summary values. The number of gloved contaminated touch points per patient-care event was compared to bare-handed contaminated touch points per patient-care event was compared to bare-handed contaminated touch points per patient-care event sumples t-test and a related samples Wilcoxon Signed Rank test. Significance was set at 0.05.

The frequency with which surfaces were touched with contaminated gloves by the HCP after a failed glove change during the toileting and perineal care were calculated. The frequencies were then visually compared.

Reliability.

Inter-rater reliability of the GUST was examined by computing intraclass correlation coefficients (ICC) for the five facets of glove use and the two indicators of inappropriate glove use. The PI used ICC (2, 1) instead of other types of ICC because the combinations of both the paired observers and the HCP were selected randomly, the measures were one-time measures, and the observations were not averaged (Shrout and Fleiss, 1979). ICC were computed for the five facets of glove use in addition to the two indicators of inappropriate glove use because the

frequency of the five facets of glove use are essential to compute the frequency of the two indicators. Therefore, the ICC of each facet was calculated in order to evaluate the overall reliability of the GUST.

Occurrence agreement for identifying contaminated surfaces was examined by computing the percent of occurrence agreement between the two raters on categories of surfaces touched [(Number of matched surfaces \div Total number of unique surfaces identified by the PI or coobserver) \times 100]. The PI used occurrence agreement, rather than total or nonoccurrence agreement, because it was more meaningful to identify the items touched versus those that are not touched with contaminated gloves. HCP touch only some of the multiple surfaces that they could touch while helping with toileting and perineal care. The surfaces that HCP do not touch will not become cross-contaminated. Moreover, total agreement includes both occurrence and nonoccurrence agreement and thus it inflates estimates of agreement and is not relevant to the goals of cross-contamination with gloves (Hartman, 1977).

Exploratory analysis.

The PI analyzed whether select HCP characteristics (i.e., gender, licensure or certification,), and patient-care event characteristics (i.e., time and day of patient care event, duration of HCP experience, number of HCP assisting with the patient-care event, and number of patients assigned to HCP) affected the number of failed glove changes per patient-care event, and the number of contaminated touch points per patient-care event. Differences in number of failed glove changes and number of contaminated touch points among the groups were examined with independent samples t-tests and Mann-Whitney U Tests to generate hypotheses regarding characteristics of the HCP and/or the patient-care event that may affect the two indicators of inappropriate glove use. The level of significance for the tests was set at $\alpha = 0.10$ because these analyses were exploratory.

CHAPTER FOUR: RESULTS OF THE DATA ANALYSES

The following four sections present the results of the data analysis. The first section describes the recruitment and enrollment results including the characteristics of the HCP and the patient-care events. The second section describes the degree of inappropriate glove use. The third section addresses the reliability of the GUST. Finally, the fourth section presents exploratory analyses of the relationship between degree of inappropriate HCP glove use and selected HCP and patient-care event characteristics.

Recruitment and Enrollment Results

Recruitment and enrollment of HCP for the study occurred in three steps (Figure B 2). First, the PI held meetings to educate HCP and elicit their cooperation with the study procedures. None of the HCP declined participation at this step. Second, the PI randomly selected RNs, LPNs and CNAs for a total of 105 HCP. Third, the PI approached the 105 randomly selected HCP while they were on duty, and asked to observe them assist a patient with toileting or perineal care between July 14, 2015 and September 26, 2015.

Characteristics of the non-responders.

Twenty of the RNs and all six LPNs declined; stating they were too busy with their primary patient care duties to participate. This LTCF realigned nursing job responsibilities immediately prior to the data collection. The staff nurses had less administrative support, therefore they had more direct responsibilities for clerical nursing jobs, care planning, and patient and family communication. Because of these additional primary responsibilities, they had less time to assist the CNAs with toileting and perineal care. One female CNA was unavailable because of family and medical leave. One female CNA and one male CNA declined to be observed when approached by the PI on the patient units, stating they felt uncomfortable being watched performing patient care. Although the patients were not the subjects of the study, they

were given the opportunity to refuse to have their care observed. Three patients and one patient healthcare power of attorney refused to have patient care observed, however, since no patient data was collected, no characteristics of the patients refusing observations were collected. The PI and co-observer waited while the selected HCP completed care for the patient that refused observations, and then the PI and co-observer watched the HCP provide care to the next patient who agreed to have their care observed.

Therefore, we observed two RNs and 74 CNAs for a total of 76 HCP from the original randomly selected sample of 105 for a 72% participation rate. The participation rate for RNs, LPNs, and CNAs was 9%, 0%, and 96% respectively. None of the participants refused to have their observations included after the "true" purpose of the study (observing glove use rather than barriers to hand hygiene) was disclosed to them when the observation was completed.

Degree of Inappropriate Glove Use

The PI documented HCP glove use on the GUST to assess the degree of inappropriate glove use while observing the 76 different HCP perform toileting and perineal care. Table A 4 summarizes the characteristics of the HCP observed. Table A 5 summarizes the characteristics of the toileting and perineal care events used to describe inappropriate glove use and for the exploratory analysis.

In order to determine the degree of inappropriate glove use, the five facets of glove use were recorded. All touch points, including both bare-handed and gloved touch points, were collected to compare different types of touch points and to describe the scope of gloved touch points to bare-handed touch points. Table A 6 provides the means (\pm SD), medians (ranges), and 95% CI for the five facets of glove use. A total of 2271 touch points occurred during the 76 patient-care events. HCP wore gloves for 1810 (80%) of these touches and changed their

gloves166 times. While HCP changed their gloves a median of twice for each patient-care event, only a median of one glove change came at a glove change point (range 0-6).

The distribution of each of the two indicators of inappropriate glove use was examined to determine the appropriate measure of central tendency and variability. In addition to graphing each indicator for visual inspection (Figure B2 and B3), each indicator was examined using estimates of skewness and kurtosis, and Shapiro-Wilk analyses for normality (see Table A 7) (Bannon, 2013). All tests showed that the indicators of inappropriate glove were not distributed normally (Field, 2009; Bannon, 2013). To facilitate comparison, the means, medians, standard deviations, ranges and 95% CI are reported for each indicator in Table A 6.

Failed glove changes.

The PI observed a total of 351 glove change points across the 76 toileting or perineal care events. HCP failed to change their gloves at 230 (66%) of the 351 glove change points. The median number of failed glove changes was 2.0 per patient-care event (see Table A 6). Figure B 5 illustrates the number of failed glove changes as they relate to glove change points, glove changes at a glove change point, and contaminated touch points.

Contaminated touch points.

The HCP touched surfaces with contaminated gloves 802 times of 1810 (44%) glove touch points across the 76 toileting or perineal care events. In comparison, the PI did not observe any bare-handed contaminated touch points (0%) during which the HCP touched blood, body fluids, or other potentially infectious materials with bare hands. Therefore, the total percentage of contaminated touch points was 44% as only glove contaminated touch points contributed to the sum. Sixty-three (83%) of the 76 patient-care events had one or more contaminated gloved touch points compared with none (0%) with one or more contaminated bare-hand touch points.

A median of eight contaminated gloved touch points occurred per patient-care event (see Table A 6). In comparison, a median number of zero contaminated bare-handed touch points occurred per patient care event (related samples Wilcoxon Signed Rank; p value = 0.000) (see Table A 6). A related samples Wilcoxon Signed Rank Test was used because contaminated gloved touch points were not distributed normally and the sample was dependent.

Figure B 6 displays the frequency of the top 15 objects or surfaces touched with contaminated gloves that were considered clean, were used in a public area, or were used between different patients. Wipes, wipe packages, patient skin, clothing, and patient equipment such as wheelchairs, walkers and patient care lifts were touched most frequently with contaminated gloves.

Reliability of the GUST

To test the reliability of the GUST, the PI and trained co-observers independently recorded the glove use of 44 different HCP, during the paired observations of 61 toileting and perineal care events. On the basis of sample size calculations (Zou, 2012), assuming that there are two observations per patient-care event (k), assuming an alpha of 0.05 and assuming an 80% assurance, we needed a sample size of 60 events ensure that the lower limit of the 95% one-sided confidence limit for the ICC was no less than 0.65.

Table A 8 provides a description of the 11 trained co-observers. The paired observations of individual toileting and perineal events were the unit of analysis for examining the inter-rater reliability, therefore the fact that a HCP was observed performing different patient events did not violate assumptions of statistical tests. Table A 9 summarizes the characteristics of the 61 toileting and perineal care events observed for the reliability analysis.

Intraclass correlation coefficients for indicators of inappropriate glove use.

The PI used a two-way random effects, single measure, absolute agreement ICC (2, 1) for the inter-rater reliability analysis for the GUST. ICC (2, 1) were calculated for the two indicators of inappropriate glove use, 1) failed glove changes, and 2) contaminated touch points and the five facets of glove use: 1) total touch points, 2) gloved touch points, 3) glove change points, 4) actual glove changes, and 5) glove changes at glove change point (see Table A 10).

An ICC of 1.0 indicates perfect agreement, and zero indicates no agreement. ICC results of 0.80 or 0.90 are desirable if important decisions such as performance evaluation or grading are being determined from the data. However, in general, ICC results that exceed 0.70 are considered an acceptable level of reliability for the measurement of study variables (Hays & Reviki, 2005; Van Ness, Towle & Juthani-Mehta, 2008; Graham, Milanowski & Miller, 2012). Our sample of 61 patient-care events provides enough power to detect an ICC of 0.80; therefore, our sample was more than adequate to detect an ICC of 0.70 and 0.75. Four of the five facets of glove use had ICC greater than 0.75 and both indicators of inappropriate glove use had ICC exceeding 0.70. Glove changes at a glove change point, which requires a higher level of decision making, did not reach the 0.70 threshold.

Occurrence agreement between observers on type of surface touched with contaminated gloves.

The PI used occurrence agreement to assess the inter-rater reliability for surfaces touched by the HCP with contaminated gloves, defined as touches after a failed glove change. The PI used a set of decision rules to compute occurrence agreement for types of surface touched. First, the PI examined the documentation of each patient-care event for contaminated touch points, noting that some sequences included more than one contaminated touch. Second, the PI

compared the paired observations and counted documentation of HCP contaminated touch points (a) recorded by both the PI and the co-observer on the separate GUST forms (b) within two to three touch points (c) on the same surface, as documentation of the same HCP contaminated touch point. A mean occurrence agreement was calculated. The occurrence agreement for 15 commonly touched surfaces is presented in Table A 11. The highest percent agreement occurred with the following surface categories: 1) patient lift and lift sling, 2) clean wipes and wipe packages, 3) cream or ointment tubes, 4) clean briefs, and 5) toilet or commode. Low agreement categories were: 1) HCP clothing, skin or hair and 2) sink/faucet.

Exploratory Analyses of Differences in Degree of Inappropriate Glove Use by Select Variables of Interest.

Exploratory analyses were conducted to identify differences in degree of inappropriate glove use by gender of HCP, duration of HCP work experience (less than 4 years vs. 4 years and greater), HCP licensure and certification, number of HCP assisting with the patient-care event, by shift of patient-care event (days vs. nights), and by day of patient-care event (weekday vs. weekend). For these exploratory analyses, the PI used data from the observations of 76 different HCP assisting with individual toileting and perineal care events (see Table A 4 and Table A 5). Analyses for differences by HCP licensure or certification (RN vs. LPN vs. CNA), and the number of HCP involved in the patient-care event were not performed because the variability was extremely low (see Tables A 4 and A 5).

Gender of HCP.

The PI observed 52 female HCP (69%) and 24 male HCP (31%) (see Table A 4). The results of the Mann-Whitney U Test for the difference between males and females rejected the null hypothesis for both indicators of inappropriate glove use, indicating that there was a

significant difference between females and males in the number of failed glove changes (p = 0.004) (Table A 12), and in the number of contaminated touch points (p = 0.003) (Table A 13) (Figure B 7). A Mann-Whitney U Test was used because the two indicators of inappropriate glove use were not distributed normally but the samples were independent.

Duration of HCP experience.

Forty-eight (63%) of the 76 observed HCP had worked in healthcare for 4 years or longer (see Table A 4). The results of the Mann-Whitney U Tests failed to reject the null hypothesis, indicating that the duration of HCP experience was not associated with frequency of either the failed glove changes (Table A 12) or contaminated touch points (Table A 13).

HCP licensure and certification.

Seventy-four CNAs and two RNs were observed during patient-care events. Due to the extremely low variability in licensure and certification in the observed sample of HCP, differences in inappropriate glove use by HCP of different licensure and certification were assessed using descriptive statistics only, e.g. medians, (see Table A 12 and Table A 13).

Number of HCP assisting with the patient-care event.

Of the 76 HCP observed, 66 (87%) HCP worked by themselves, and nine HCP had either or one or two other HCP assisting with patient care. Because so few care events involved more than one HCP, differences in inappropriate glove use by the number of HCP assisting with the patient-care events were done using descriptive statistics only, e.g. medians (see Table A 12 and Table A 13).

Shift of patient-care event.

Forty-eight HCP (63%) were observed on the day shift (07:00-19:00), and 28 HCP (37%) were observed on the night shift (19:00- 07:00) (see Table A 5). The results of the Mann-Whitney

U Tests failed to reject the null hypothesis, indicating that the work shift of the patient-care event was not associated with either failed glove changes (Table A 12) or contaminated touch points (Table A 13).

Weekdays and weekends (day).

Fifty-six HCP (74%) were observed on weekdays, and 20 HCP (26%) were observed on weekends (see Table 6). The results of the Mann-Whitney U Tests failed to reject the null hypothesis indicating that the frequency of failed glove changes (Table A 12) or of contaminated touch points (Table A 13) was not associated with the day the patient-care event occurred (i.e., weekday vs. weekend day).

CHAPTER FIVE: DISCUSSION AND CONCLUSIONS

This chapter first presents the discussion of findings, followed by implications of the findings for practice. The chapter also discusses the strengths and limitations of the study and recommendations for further research.

Discussion of Findings

The discussion of study findings is presented in five sections. The first section discusses recruitment and enrollment. The second section discusses the characteristics of the HCP and sample of patient-care events. The third section discusses the degree of inappropriate glove use. The fourth section discusses the reliability of the GUST. Finally, the fifth section discusses the findings of the exploratory analyses of the relationship between the degree of inappropriate HCP glove use and selected HCP and patient-care event characteristics.

Recruitment and Enrollment of HCP.

Three steps of HCP recruitment and enrollment were successfully completed, resulting in an adequate sample size for reliability testing. The PI completed the first two steps, education of the HCP, and random selection of HCP, as planned. A staffing change at the LTCF impacted the third step, affecting the participation of HCP with different licensures and certifications. The facility reduced the number of administrative and support nurses in July 2015, immediately before the study observations began. The LTCF charged the staff nurses with increased supervision, clerical work, nursing management, treatments, family communication and care planning responsibilities. As a result, when the PI approached the 23 RNs and six LPNs that were selected randomly, all but two RNs declined to participate, stating they were "too busy" and could not leave their primary assignments to assist the CNAs with toileting or perineal care. The staffing change did not affect CNA participation, as the CNA-patient ratio remained stable. Therefore, CNAs represent a majority of the HCP observed in this study. Because the sample of

HCP in this study is greatly biased toward CNAs and the findings may represent only CNA glove-use behavior rather than all HCP in LTCF.

Only two CNAs, one male and one female, declined to be observed because they felt "uncomfortable being watched." One additional CNA was not available for observation. This represents a high rate (96%) of participation by CNAs. Moreover, none of the HCP refused to have observations of their care included in the study even after the "true" reason for the observation was disclosed.

The study designs of previous observational studies of HCP glove use were consistent with healthcare infection prevention and control surveillance that relies on direct observation. As a result, none of the other studies consented HCP prior to observations (Denman, 1993; Eveillard et al, 2009, 2011; FitzGerald et al., 2013; Flores & Pevalin, 2006; Girou et al., 2004; Kim et al., 2003; Loveday et al., 2013). Therefore, the published literature does not provide data on the rate of HCP participation in prior studies of glove use.

Characteristics of HCP and Patient-Care Event.

HCP.

The CNAs observed in the study had more experience than the general population of CNAs who work in US LTCF. The study CNAs averaged 8.5 years of experience with a median of 6 years of experience and service in long-term care. The average length of service for nursing assistants in US LTCF is an average of 5 years (median of 2.5 years) (CDC, 2004). The two RNs also had more experience (average of 13.5 years) than RNs in a national study of United States LTCF. In that study, only 18% of the RNs had over 10 years of experience (Grant et al., 2007). According to the Protection Motivation Theory (Maddox and Rogers, 1983), HCPs with more experience may be more motivated to use gloves for patient care because they have attended

more training on their use and have more experience handling potentially infectious blood or body fluids. The PI investigated this relationship in the exploratory analyses discussed below.

Male CNAs accounted for 32% of the observed CNAs, which is higher than the national average of 22% (Bureau of Labor Statistics, 2015). Nonetheless, most of the CNAs were female, which is consistent with gender distribution in the health care professions.

Each HCP was observed once to examine both the degree of inappropriate glove use and to gather data for the exploratory analyses, which is a major strength of this study. Thus, the study provides a more accurate estimation of HCP glove use. If the study included HCP with particularly good or particularly poor glove-use behavior more than once, it could overly influence the results. For example, Denman et al. (1993) indicated that dependence may have influenced their results because they observed individual HCP during multiple patient-care events. In contrast, Trick and colleagues (2007) observed each HCP only one time. However, other investigators have not discussed whether dependency could be an issue in their studies of hand hygiene and glove use. In other words, they did not state whether individual HCP were observed more than once (Eveillard et al., 2009; Eveillard et al., 2011a; Eveillard et al., 2011b; Eveillard et al., 2012; FitzGerald et al, 2012; Fuller et al., 2011; Girou et al., 2004; Kim et al., 2003; Pittet, Thompson et al., 1997).

Patient-Care Events.

Over 35% of the patient-care events observed in this study occurred during the night shift and 25% occurred during the weekends. Other investigators specified when they observed HCP and some noted that they observed practice at times other than the day shift. Eveillard et al. (2010) observed gloving and hand hygiene practices during evening hours (18:00-22:00); and Kim and colleagues (2003) included "day and night" observations. Girou and colleagues (2004) specified that observations occurred during morning or afternoon shifts; and Flores and Pevalin

(2006) specified that observations were completed in daytime hours. However, the current study contrasts sharply with these other publications in that the investigators did not indicate how many observations occurred at different times during the day (Denman, 1993; Eveillard et al, 2009, 2011; FitzGerald et al., 2013; Loveday et al., 2013). Thus, another significant strength of the current study was the intentional inclusion of care given during nights and weekends, as there are different staffing levels, different job responsibilities, and different levels of supervision on night shifts and weekends.

Degree of Inappropriate Glove Use.

Degree of inappropriate glove use was assessed in terms of failed glove changes and contaminated touches. The discussion of contaminated touches included a discussion on the types of surfaces contaminated by the contaminated touches.

Failed glove changes.

Failed glove changes occurred 66% of the time at a glove change point, which is higher than found by other glove-use studies that assessed whether HCP removed or changed gloves between dirty and clean activities. In those studies, HCP used gloves inappropriately 16% to 42% of the time (Sacar et al., 2006; Thompson et al., 1997; Girou et al., 2004; Eveillard et al., 2011a; Loveday et al., 2013; Loveday et al., 2014; Wilson et al., 2014). The higher rate of inappropriate glove use found in this study may, in part, result from the more specific definition of a failed glove change used in this study. Moreover, the GUST facilitated a higher level of surveillance intensity and more structured observations, allowing for more thorough analyses when identifying failed glove changes than did the tools and methods used for other studies. Finally, because HCP were consented for this study, the observers were able to observe all aspects of the patient-care event rather than extrapolate HCP glove use behavior from responses to a questionnaire, or from observations made from behind a door or curtain, as done in other

studies (Sacar et al., 2006; 2011a; Loveday et al., 2013; Loveday et al., 2014; Wilson et al., 2014). Therefore, the findings of this study are likely to provide a more accurate description of glove-use behavior than that provided by other studies, and suggest that inappropriate glove-use behavior may be substantially higher than previous studies suggest.

Contaminated touches.

All of the contaminated touches observed for this study occurred with gloved hands; no HCP were observed performing bare-handed contaminated touches. The consistent use of gloves may be a result of training combined with a change in behavior predicted by the Protection Motivation Theory (Maddox and Rogers, 1983). HCP were reminded of the severity of the threat from exposure to bloodborne pathogens and MDRO at each infection prevention training. Training included content that emphasized pervasive MDRO colonization in LTCF patients. Gloves were readily available, and were easy to use. Therefore, the LTCF glove-use training supported all components of the Protection Motivation Theory.

Of the observed patient-care events, 83% included one or more contaminated touch point. This finding is consistent with the observations of Thompson et al. (1997), who found that gloves could have been responsible for potential microbial transfer in 82% of observed interactions.

Moreover, a high proportion (over 44%) of the HCP gloved touches in the current study were contaminated touches after failed glove changes. The frequency of contaminated gloved touches illustrates the significant potential for cross-contamination between patients and the healthcare environment from inappropriate glove use during toileting and perineal care and supports the findings of earlier studies (Girou et al., 2004; Whitby et al., 2006; Diaz et al., 2008; Hayden et al., 2008; Eveillard et al., 2010; Morgan et al., 2010; Weber et al., 2010; Savage et al., 2011; Rutala, 2010).

The surfaces HCP frequently touched have epidemiological significance because the items or body sites can be reservoirs for transmission of virulent organisms in the social environment of a LTCF. The surfaces of equipment and supplies that are used by multiple patients, and surfaces touched by patients, HCP, volunteers and visitors are especially problematic. In the study LTCF, wipes were used as a substitute for washcloths, soap and water, especially during toileting and perineal care. HCP frequently touched cleansing wipes and the wipe packages with contaminated gloves both when providing care, when organizing the room after patient care, and when they replaced the wipe packages in the cabinets. HCP were also observed using wipes from the same packages for patient hand hygiene instead of soap and water, or as a substitute for the alcohol-based hand wipes for hand hygiene. Moreover, common wipe packets were used between patients during toileting events in shower rooms. In three patient-care events, HCP retrieved opened wipe packages from other patients' rooms to use when providing care for different patients, potentially spreading pathogens on the wipe packages from one patient to another.

HCP often touched the patients' skin. The HCP frequently touched patients' hands, arms, backs, buttocks, necks and faces with contaminated gloves. Since patients in this LTCF were scheduled for showers or bathing once weekly, the HCP actions maybe one mechanism for the development of a "fecal patina" on the patients' skin (Weinstein, 2012).

HCP often touched patients' clothing with contaminated gloves. Laundry is done weekly in this LTCF, and it is not uncommon for patients to wear clothing multiple days if it is not visibly soiled. Multiple toileting and perineal care events have the potential to contaminate clothing repeatedly. Both of these findings are important, as most patients in LTCF spend their days outside their rooms in public areas. Thus, their skin and clothing could be a source of

virulent organisms for other patients.

In this study, HCP touched the perineal area 80 times with gloves that had touched other surfaces, providing a potential vector from environmental surfaces to a patient's perineal area. In addition, HCP touched both the inside and the outside of absorbent clean pads and briefs after failed glove changes, potentially contaminating the products before they were used. Thus, gloves could directly or indirectly contaminate the perineum, which could become a source for infections, particularly urinary tract infections (UTIs)

The HCP frequently touched the hand grips of both wheelchairs and walkers, as well as the wheelchair pedals, with contaminated gloves. Multiple people often touched wheelchair handles with bare hands, including volunteers and therapy personnel as they transported patients through public areas in the LTCF. Similarly, HCP frequently touched lifts and lift slings while wearing contaminated gloves. Multiple HCP used these lifts repeatedly on a daily basis to move multiple patients. The facility's policies and procedures required HCP to clean and disinfect this equipment between patients, and HCP receive reminders and perform return demonstrations during orientation and quarterly lift-use training. Even though cleaning and disinfecting wipes are readily available hanging on the lifts, none of the HCP used the wipes on any equipment or surfaces while the PI was observing their practice. Moreover, HCP touched numerous other objects or surfaces - gait belts, staff phones, beds, bed linens, towels, ointment containers, call lights, alarms, cabinets, doors, sinks and counters HCP skin, and HCP uniforms - with contaminated gloves. Thus, wheelchairs, walkers, lifts and other objects could become contaminated by direct contact with patients or by contact with HCP contaminated gloves and could become a source of virulent organisms for subsequent patients.

The current study is the first to specifically record the sequence of surfaces touched with contaminated gloves. Consequently, comparison data are not available in the literature. The findings of this study indicate that a wide variety of surfaces and shared equipment may be contaminated with potential pathogens and could contribute to cross-contamination in LTCF.

Other findings on glove-use behavior

The study yielded some additional interesting findings. First, the range of touch points during observed toileting and perineal care events was very wide with touch points ranging from 4-65 per patient-care event, and gloved touch points ranging from 0-57 per patient-care event. These results demonstrate the variability of HCP practice and glove-use behavior when caring for patients in this LTCF. When HCP provide appropriate toileting and perineal care assistance and support, they allow patients to do as much as they can for themselves, maintaining the highest practicable level of patient function (CMS, 2015a, F309). Therefore, even with the same patient, the number of total touches and gloved touches for each patient-care event may differ substantially depending on the patient's needs during any particular patient-care event.

Second, HCP used gloves were used in a manner consistent with OSHA bloodborne pathogen regulations, which require HCP to wear gloves if there is the potential for exposure to blood or other potentially infectious materials (OSHA, 2012). However, while toileting and perineal care require gloves in a majority of situations, the HCP put gloves on before the gloves were required. In fact, over 80% of all touches in the patient environment were with gloves even when gloves were not required. This finding highlights the paradigm shift from bare-handed patient care, which used to be the norm, to gloved patient care, and is especially worrisome considering how often HCP touched the environment with contaminated gloves in this sample. This finding is also consistent with the observations of Denman and colleagues (1993) and Wilson and colleagues (2014), who observed that HCP often put on medical gloves outside the

patient zone before a patient-care event. These observations demonstrate that HCP overuse rather than underuse of gloves, and that HCP may transmit potential pathogens by persistent use of contaminated gloves. When HCP overuse gloves, they add unnecessary costs for supplies and they may inadvertently increase costs due to HAI because they transmitted organisms on their contaminated gloves to susceptible patients, while not decreasing the costs of HAI because the HCP did not remove the gloves after they touched contaminated surfaces in 63 out of 76 patientcare events (83%).

Third, the PI observed 10 CNAs double-gloving and removing their top gloves at a glove change point. The CNAs who used the double-glove technique told the PI during their post observation interview that they were thinking about their glove use. The PI did not consider this technique when she designed the study. Given that it effectively simulated glove removal without hand hygiene, and since the PI considered hand hygiene separately in this study, she included removal of the top glove as an actual glove change when she analyzed the data. Double-gloving requires further study, especially given the recent CDC recommendations for Ebola PPE, which include not only double-gloving, but also sanitizing the outer surface of the inner glove with an alcohol-based hand sanitizer after removing the top glove is removed (CDC, 2015).

Finally, most gloves that had touched a contaminated surface did not appear soiled or contaminated. Therefore, HCP often did not have visual cues indicating that they needed to change gloves, which may in part, explain why HCP do not change gloves when indicated. Other researchers have made similar observations (Weber et al., 2009; Rutala & Weber, 2013).

Reliability of the GUST.

The study findings indicate that the GUST has adequate inter-rater reliability, thus the GUST can be used within health care settings to more widely understand glove-use behavior and its impact on HAI rate.

However, observers needed to understand both the GUST and how HCP use gloves during toileting and perineal care to use the tool accurately. Other studies have confirmed that the person who does the observations and the type of pre-observation training can affect results substantially (Braun et al., 2009; Haas & Larson 2007). The PI provided systematic GUST training for all observers, which was a strength of this study.

Nine of the 11 co-observers completed the GUST observations during their work shifts. Thus they may have been interrupted or distracted while observing, while completing the GUST and while analyzing the data after their observation period. Therefore, the level of reliability found in this study may be lower than it would have been if the co-observers had "dedicated" time observe and practice recording their findings.

The facets of glove use that are the easiest to observe and score – touch points, gloved touch points, glove change points, and actual glove changes – had the highest levels of correlation. The ICC (2,1) results were more than adequate for the indicators of inappropriate glove use that required observers to both accurately observe and record HCP practice, and to determine the point at which the contaminated touch point occurred – failed glove changes and contaminated touches – indicating good reliability for these important parameters. In contrast, glove changes at a glove change point had the lowest ICC (2,1). The decision rules for this facet of glove use were complex and required the observer to determine not only that the HCP had changed gloves but that the HCP changed gloves at the appropriate point in the sequence of

patient care.

The study findings indicate the GUST has a moderate level of overall occurrence agreement, but has good occurrence agreement when observers identified contaminated touches on supplies and equipment frequently used between patients. The PI and the co-observers had a higher occurrence agreement on surfaces, objects and body sites that had epidemiological importance. For example, the highest occurrence agreements were contaminated touches on patient lifts and lift sling (79%), and wipes and wipe packages (63%). Three factors may explain the less than perfect occurrence agreement in this study.

First, the co-observers may have been confused about how to indicate what items HCP touched. As an example, there was low agreement (34% - 40%) for touches on patient skin, clothes and hair. In this case, some observers may have documented "skin", while others may have specified the location such as "buttock," "arm," "leg," or "hand," making it difficult to determine the specific category the touch point belonged during the GUST analysis. Second, occurrence agreement was highly influenced by some of the less frequently touched surfaces. For example, the PI documented 16 contaminated touches on HCP gait belts and phones, whereas the co-observers documented eight contaminated touches, leading to low occurrence agreement. The PI documented five contaminated touches on HCP skin, hair or glasses, but the co-observers documented only one contaminated touch point. These low frequency events affected the overall occurrence agreement. The PI looked specifically for these touch points, and thus may have been more attuned to their occurrences. Third, observations may have been affected by which hand touch the observers watched. Hand hygiene generally requires both hands, whereas gloved touches can be done one handed. If observers focused on different hands, their observations may have differed. Finally, because the observers were also LTCF employees, and they may have

introduced observational bias unintentionally.

The GUST is a paper tool and has the same major limitations that affect other paper observational tools, including observers missing HCP actions when recording their observations on the tool and introducing bias and errors when they score HCP behavior and analyze the data (Hlady, Severson, Segre & Polgreen, 2010; Larson, 2013). Although the tool has limitations, the study findings support its use as a reliable glove-use surveillance tool, particularly when used by trained observers who have health care experience and who have protected time to observe HCP practices.

Exploratory Analyses.

This study compared the two indicators of inappropriate glove use, failed glove changes, and contaminated touches by HCP gender, duration of HCP experience, the shift, and the day on which the patient care occurred. Other glove-use studies have not explored these characteristics and their relationship to inappropriate glove use.

In this study, gender was the only characteristic that was associated with the degree of inappropriate use. Female HCP had significantly more failed glove changes and contaminated touches than male HCP. This was an unexpected result. Recent studies have not found a relationship between gender and hand hygiene behavior (Allegranzi et al., 2013; Erasmus et al, 2010). Therefore, the influence of gender on glove-use behavior needs further study. The difference in the observed behavior between females and males may involve social constructs or behavioral expectations that influence HCP behavior when they touch patients during toileting and perineal care. In addition, unmeasured confounding variables could account for this finding.

Inappropriate glove use was not related to the duration of HCP experience. The PI had hypothesized that increased exposure to basic HCP education, bloodborne pathogen training and

infection prevention and control training associated with increased years of healthcare experience would increase HCP glove use which would be consistent with the Protection Motivation Theory. In fact, O'Boyle and colleagues previously noted that glove use increased after multiple exposures to training. However, the study was completed in 1990, only 5 years after the initial OSHA bloodborne pathogen regulation was released. Therefore, few HCP in their study would have been trained to use gloves for occupational exposures. Every HCP in this current study used gloves for each toileting or patient-care event, often over-using gloves. The Protection Motivation Theory is congruent with what was observed in this study. Toileting and perineal care virtually guarantee that the HCP will likely come in contact with body fluids and other potentially infectious materials. The HCP have almost universal access to gloves, and gloves are easy to put on and take off. A combination of Protection Motivation Theory and training seems to have changed the culture and glove use is now universal.

Only two RNs participated in the study and their glove use was similar to that of the CNAs (Table A 12 and Table A 13). Consequently, the study could not assess whether licensure or the number of HCP involved influence glove-use behavior. Similarly, few patient-care events involved more than one HCP. Finally, the shift and day of the week of the patient-care event were not associated with inappropriate glove use. Nonetheless, the median number of contaminated touches per patient-care event on weekdays was almost double those on weekends, which is opposite of what was expected. More study is needed, however, it may be that the number of activities and appointments on weekdays put more time pressure on the HCP, distracting and rushing them during toileting and perineal care so the patients could get to appointments on time.

In summary, gender was the only exploratory characteristic that was significantly

associated with inappropriate glove use. However, given this study was not powered to examine differences in inappropriate glove use by these variables, they should be included in future studies.

Implications

The findings of this study add to the body of literature indicating that gloves may contribute as much or more to colonization and HAI in LTCF than does poor hand hygiene. Although this study did not examine the direct association between inappropriate glove use and HAI, the findings of this study have implications for our current system of infection prevention surveillance and control and for how HCP are trained to use gloves.

To date, the focus of infection prevention process surveillance has focused on hand hygiene. The findings of this study indicate that glove-use behavior should also be monitored. The GUST provides a reliable and systematic measure of glove-use behavior that is applicable across a wide variety of settings in which HCP use Standard Precautions, the most common type of isolation precaution. Infection preventionists need data on glove-use behavior so that they can design training for HCP on glove use for patient care and can monitor improvements in glove use associated with training.

Training on the use of gloves and other PPE is required in health science education programs, including schools of nursing. However, while these programs often emphasize HCP protection and sterile technique, they often do not emphasize clean technique, including the use of clean gloves when appropriate. For example, the PI and the co-observers determined that the contaminated touches could have been reduced during toileting and perineal care if HCP had created a procedure field and removed a sufficient quantity of wipes from the wipe packages before the patient-care event. HCP could place a clean hand towel or washcloth near the patient

and place wipes on this clean surface before the start of cleansing the perineum. HCP who did not prepare a clean field had to re-enter the wipe packs multiple times with contaminated gloves to obtain additional wipes. However, inservice training and HCP orientation often do not discuss preparing a "clean" field before patient-care events.

To date, the content of glove-use training for HCP has been driven by regulations and guidelines that emphasize hand hygiene and self-protection. The findings of the current study indicate that such training may have led to overuse of gloves by HCP. A majority of the HCP glove-use behavior observed in the current study appeared to be practiced and automatic. Therefore, educators in colleges, universities, nurse aide training programs and other HCP training throughout the healthcare system, including inservice training programs in LTCF, must develop curricula that train HCP to use gloves appropriately.

Limitations

This study had a few limitations. The study was performed at a single LTCF, with consistent staff and consistently high levels of staffing compared to other LTCF (CMS, 2015b). Although no data was collected on HCP ethnicity, the LTCF's HCP were primarily from countries other than the US. The HCP educational backgrounds and experiences contributed to the uniqueness of the workforce in the study LTCF. Therefore, the findings of this study may not reflect glove-use behavior in other LTCF or other sectors of the health-care continuum. The majority of HCP in this sample were CNAs. Therefore, the findings of this study may not reflect glove-use behavior of other HCPs. Some healthcare settings, in fact, employ few CNAs. Finally, the observed HCP knew the PI and all but one of the co-observers, which may have introduced bias or had unmeasured effects on the data collection.

Recommendations for Further Study

This study represents the first attempt to use a structured systematic tool and approach to describe HCP glove use during Standard Precautions. Development of an automated, electronic GUST is an important next step to improve usability of the tool. Clearly, this study should be replicated in other healthcare settings and geographical locations with larger, more representative samples of HCP to obtain more stable estimates of glove-use behavior across the healthcare continuum. Larger samples would also allow investigators to test hypotheses about institutional factors, HCP characteristics or patient event characteristics that may affect glove-use behavior.

In addition, future studies should examine not only how HCP use gloves, but also whether HCP view gloves primarily as self-protection or also as tools to improve infection prevention and control. Mixed methods, ethnographic and other qualitative research would be useful to determine why HCP overuse gloves. Research on human factors engineering and HCP work flow would assist in overcoming barriers to appropriate HCP glove use. On the basis of information from these types of studies, training programs must be developed by and for infection prevention staff and educators utilizing adult learning principles and evidence-based instructional methods that will impact how HCP use gloves in practice.

The surprising finding that male HCP had significantly fewer contaminated touches, fewer failed glove changes, and fewer total touch points during toileting and perineal care events than female HCP also deserves further study. For example, a study could test the hypothesis that cultural differences between the way males and females are raised and concern over allegations of sexual misconduct may affect how male HCP deliver personal care to female patients. Finally, studies that examine glove use in relation to cross-contamination and HAI are needed. These

studies would provide further evidence that inappropriate glove use does or does not increase cross-contamination and the risk of HAI.

Summary and Conclusion

Gloves can be used to protect HCP and patients. However, our study documented that glove use is consistent with the Protection Motivation Theory of HCP self-protection, increasing the probability that HCP will overuse gloves. Infection prevention and control programs emphasize hand hygiene, but rarely address glove use, which may contribute to environmental contamination, and cross-transmission and may also increase the risk of HAI. Thus, we urgently need additional studies and more sophisticated tools to address this critical gap. Future studies should assess both how and why HCP use gloves, focus on how glove use relates to human factors and workflow within the healthcare environment in order to identify barriers to appropriate glove use. Such studies will provide information that infection prevention staff and educators can use to design and implement needed training programs and monitoring systems so that they can achieve their goal to prevent HAI and improve patient and HCP safety.

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APPENDIX A: TABLES

Table A 1. Regulations, Guidelines and Recommended Practices that Direct Glove Use

Name of Regulation or Guideline	Regulation, Guideline or Recommended Practice	Date Developed: Agency or Developers	How the Regulation or Guideline Defines Glove Use	Comments	Patient or HCP Protection
Universal Precautions	Regulation	1985 OSHA	Defines glove use in terms of protecting HCP from exposure to bloodborne pathogens such as human immunodeficiency virus and hepatitis B Encourages HCP self-protection	The earliest regulation mandating the use of gloves for general patient-care with strong focus on body fluids that contained visible blood and ignored other body fluids (e.g., urine, saliva, feces, unless visible blood was present)	НСР
Body Substance Isolation (BSI)	Recommended Practice	1987 Lynch, Jackson, Cummings & Stamm	Defines glove use in terms of protecting both HCP and patients Emphasizes the use of barrier precautions, especially gloves, "when contact with potentially infectious body secretions is anticipated" (Lynch, Jackson, Cummings & Stamm, p.243, 1987)	A more comprehensive system than Universal Precautions BSI was incorporated into Standard Precautions	Patients and HCP
Standard Precautions	Guideline	1996, 2007, 2009 CDC (Gardner, HICPAC/ CDC, 1996; HICPAC/ CDC, 2007) (WHO, 2009)	Defines glove use in terms of protecting both HCP and patients from exposures to all bloodborne pathogens and other epidemiologically important pathogens, including multi-drug resistant organisms, from both known and unknown sources (Gardner et al., 1996)	Combines Universal Precautions and BSI	Patients and HCP

Transmission -Based Precautions	Guideline	1996, 2007, 2009 CDC (Gardner, HICPAC/ CDC, 1996; HICPAC/ CDC, 2007) (WHO, 2009)	Defines glove use in terms of protecting both HCP and patients Used for patients who are known or suspected to be infected or colonized with epidemiologically important pathogens that require additional control measures to prevent transmission (HICPAC/CDC, 2007)	Glove use is a mandatory component	Patients and HCP
Universal Gloving (Routine Gloving)	Studies	2004-2013 Bearman et al., 2007; Harris et al., 2013; Trick et al., 2004; Yin et al., 2013	Defines glove use in terms of protecting both HCP and patients Gloves are required for all patient contact within the patient environment	Universal gloving was developed as a less restrictive approach than Contact Precautions for managing patients with known or suspected colonization	Patients and HCP
WHO Guidelines on Hand Hygiene in Health Care	Guideline	2009	Defines five points during patient- care events as five moments for hand hygiene	Defines specific tasks and times when gloves are required (Table A 2)	Patients and HCP
CMS F-441 Infection Control	Regulation	2009	Defines glove use in the same manner as Standard Precautions	Defines inappropriate glove use as "utilizing a single pair of gloves for multiple tasks or multiple residents" (CMS, 2009)	Patients and HCP

Note. CDC = Centers for Disease Control and Prevention; CMS = Centers for Medicare and Medicaid Services: HCP = Healthcare personnel; HICPAC = Healthcare Infection Control Practices Advisory Committee; WHO = World Health Organization.

Examples of patient-care moments and situations that require glove use according to guidelines and regulations that direct how HCP should use gloves	Examples of patient care that do not require glove use according to guidelines and regulations that direct how HCP should use gloves
Changing dressings	Dressing the patient in clothing / gowns
Contacting blood or body fluids, mucous membranes or non-intact skin	Distributing or collecting meal trays
Emertaine commendee, emercia having or closning	Giving oral medication
Emptying commodes, emesis basins or cleaning blood or body fluid spills	Placing non-invasive ventilation equipment and oxygen cannulas
Handling or cleaning instruments	
Inserting and removing intravenous catheters	Moving patient furniture
Providing oral care	Performing subcutaneous and intramuscular injections
Providing wound care	Providing physical or occupational therapy (excluding wound care)
Doing pelvic and vaginal examinations	anorapy (energaning in cane care)
	Removing and replacing bed linen
Assisting patients with toileting activities, including perineal care	Checking vital signs
Suctioning airways	Transporting patients
Caring for patients with highly infectious or multi-drug resistant organisms	Manipulating vascular lines, in the absence of blood leakage
During epidemic or emergency situations	Using the telephone
	Using a computer keyboard
	Writing in a patient chart

Table A 2. Examples of Situations when Gloves must be used during Patient Care

Writing in a patient chart *Note.* Source: WHO InfoSheet6, CDC / HICPAC; CDC = Centers for Disease Control and Prevention; HCP = Healthcare personnel; WHO = World Health Organization.

Level of Care	Number of Units	Number of beds	Duration of Care	Patient Characteristics	CNA/Patient Ratio	Nurse/Patient Ratio
Sheltered	1	10	Long-Term	Cues and reminders to minimal assist from HCP	1:5 to 1:10	1:46
Intermediate	2	36	Long-Term	Dementia patients with moderate assist from HCP	1:6 to 1:18	1:36
Skilled	5	24-34	Long-Term	Extensive assistance to total care from HCP	1:6 to 1:13	1:26
Post-Acute	3	26	Post-Acute	Post-operative supervision to total care from HCP	1:5 to 1:9	1:9 to 1:13

Table A 3. Description of the 11 Long-Term Care Patient Care Units

Note. All patient care units were in one Midwestern United States long-term care facility. Sheltered care patients require medication management and administration, cues, reminders, and supervision with occasional physical assistance from HCP. Intermediate care patients require consistent physical assistance with some activities of daily living, and medication administration but do not require skilled services. Skilled care patients require skilled services such as monitoring of acute change of a chronic illness, complex medication management, intravenous fluids, parenteral nutrition, and skilled therapy services. Post-acute patients are short-term patients who are recovering from surgery, receiving treatments for acute infections, wound care, or receiving extensive physical, occupational, speech, or respiratory therapy.

Job Category	Total
Licensure or certification	
No. of RN (%)	2 (3%)
No. of LPN (%)	0 (0%)
No. of CNA (%)	74 (97%)
Gender	
No. of female (%)	52 (69%)
No. of male (%)	24 (31%)
Duration of HCP experience	
No. with less than 4 years (%)	28 (37%)
No. with 4 years or more (%)	48 (63%)
Median No. of patients assigned to HCP [Range]	7.5 [0-2]
Median no. of patients assigned on days (07:00- 19:00) [Range]	6.0 [0-26]
Median no. of patients assigned on nights (19:00-07:00) [Range]	13.0 [7-26]

Table A 4. Characteristics of HCP whose use of Gloves was Observed for the Primary and for Exploratory Analyses (N=76)

Note. HCP = Healthcare Personnel; CNA = Certified Nursing Assistant; RN = Registered Nurse. During some observations, the HCP was assigned to a patient care unit to assist the other HCP, and did not have primary responsibility for a group of patients; therefore, they were assigned 0 patients.

		Frequency of Failed	Frequency of Contaminated
Factor	Frequency (%)	Glove Changes (%)	Touch Points (%)
Type of Event			
Toileting events	54 (71%)	128 (56%)	500 (62%)
Perineal care only events	22 (29%)	102 (44%)	302 (38%)
Shift			
Day shift	48 (63%)	129 (56%)	444 (55%)
Night shift	28 (37%)	101 (44%)	358 (45%)
Day			
Weekday	56 (74%)	168 (73%)	636 (79%)
Weekend	20 (26%)	62 (27%)	166 (21%)
Times of Observations			
Between 04:30-07:00	14 (18%)	54 (23%)	188 (23%)
Between 11:00-14:00	27 (36%)	101 (44%)	350 (44%)
Between 19:00-24:00	14 (18%)	60 (26%)	192 (24%)
At other times	21 (28%)	15 (7%)	72 (9%)
Number of HCP Assisting			
Events with one HCP	66 (87%)	204 (89%)	720 (90%)
Events with two or more HCP	10 (13%)	26 (11%)	82 (10%)

Table A 5. Characteristics of the Toileting and Perineal Care Events Observed for the Primary and Exploratory Analyses (N=76)

Note. Perineal care, includes perianal and periurethral and/or perivaginal cleansing with optional application of ointment or cream; Day = 07:00 to 19:00; Night = 19:00 to 07:00; Weekday = Monday through Friday; Weekend = Saturday and Sunday.

Table A 6. Descriptive Statistics for the PI's Observations of the Five Facets and The Two Indicators of Inappropriate Glove use per Patient-Care Event (N=76)

	Mean	Median	
	\pm SD	[Range]	<i>P</i> value
Number of touch points	29.9 ± 14.2	28.0 [4-65]	
Number of gloved touch points	23.8 ± 13.6	22.0 [0-57]	
Number of bare-handed touch points	$6.0\pm~5.5$	4.0 [0-21]	
Number of glove change points	4.6 ± 2.3	4.0 [0-13]	
Number of actual glove changes	2.2 ± 1.5	2.0 [0-9]	
Number of glove changes at a glove change point	1.6 ± 0.97	1.0 [0,6]	
Number of failed glove changes	$2.9\pm~2.7$	2.0 [0-11]	
Number of contaminated touch points	10.6 ± 10.4	8.0 [0-50]	
Number of contaminated gloved touch	10.6 ± 10.4	8.0 [0-50]	
points			0.0003
Number of contaminated bare-handed	0	0	0.000^{a}
touch points			

Note. SD = standard deviation, CI = confidence interval; PI = Principal Investigator; ^a Related samples Wilcoxon Signed Rank test. Significance was set at 0.05.

Table A 7. Distribution of the PI's Observations of the Indicators of Inappropriate Glove Use (N=76)

The two indicators of inappropriate glove use	Skewness (SE=,276)	Skewness Ratio ^b (Skewness÷ SE)	Kurtosis (SE=.545)	Kurtosis Ratio ^b (Kurtosis ÷SE)	Shapiro-Wilk (df= 76) Statistic	n ^a
No. of failed glove changes	1.07	3.6	0.54	1.0	0.88	<u> </u>
No. of contaminated touch points	1.47	5.3	2.67	4.7	0.87	0.00

Note. SE = standard error of skew or kurtosis; PI = Principal Investigator

^a For the Shapiro-Wilk test, a *p*-value < 0.05 indicates a distribution of scores that is non-normally distributed. ^b For Skewness and Kurtosis ratios, values >2 indicate a non-normal distribution (Bannon, 2013).

Characteristic	Frequency (%)
Gender	
Females	9 (82%)
Males	2 (18%)
Experience as HCP	
Less than 4 years	2 (18%)
4 years or more	9 (82%)
Licensure	
Registered Nurses	10 (91%)
Medical student	1 (9%)
Co-observations completed	61 (100%)

Table A 8. Characteristics of Co-Observers (N=11)

Note. RN = Registered Nurse. The observers underwent 1-3 hours of training, including one to one training sessions with the PI explaining the GUST categories, return demonstration completing the GUST while watching both videos of toileting events and observations of HCP performing toileting and perineal care.

Table A 9. Characteristics of the Toileting and Perineal Care Events Observed by PI and Co-Observers for the GUST Reliability Testing (N=61)

Factor	Frequency (%)	
Toileting events	38 (62%)	
Perineal care only events	23 (38%)	
Shift that the event was observed		
Day shift	33 (54%)	
Night shift	28 (46%)	
Day of the Week Event Observed		
Weekday	45 (74%)	
Weekend	16 (26%)	

Note. Day = 07:00 to 19:00; Night = 19:00 to 07:00; Weekday = Monday through Friday; Weekend = Saturday and Sunday. Perineal care includes perianal and periverbial and perivaginal cleansing with optional application of ointment or cream.

	^a ICC (2, 1)	95% CI	
		Lower Bound	Upper Bound
The 5 Facets of Glove Use			
Touch Points	0.87	0.79	0.93
Gloved Touch Points	0.90	0.84	0.94
Glove Change Points	0.81	0.66	0.90
Actual Glove Changes	0.92	0.88	0.95
Glove Changes at a Glove Change Point	0.57	0.37	0.72
The 2 Indicators of Inappropriate Glove Use			
Failed Glove Change	0.79	0.67	0.87
Contaminated Touch Points	0.78	0.64	0.87

Table A 10. Intraclass Correlation Coefficients Between of the PI's and Co-Observers' Observations for the Characteristics of Glove Use (*N=61*)

Note. CI = Confidence Interval. ICC = Intraclass Correlation.

^a ICC results that exceeded 0.70 were considered an acceptable level of reliability for this study. (Van Ness, Towle & Juthani-Mehta, 2008).

Table A 11. Occurrence Agreement between PI's and Co-Observers' Observations Regarding the Type of Surface HCP Touched with Contaminated Gloves (N=61)

Type of Surface (In Descending Order)	Occurrence Agreement (%)	
Lift and sling	79%	
Wipes / wipe packages / toilet paper	63%	
Cream / ointment tube	63%	
Brief: clean	61%	
Toilet / commode	56%	
Bed linens / towels	54%	
Doors	50%	
Bed and bed controls / call lights	49%	
Cabinets / dresser / table / closet	48%	
HCP's gait belt, phone	46%	
Patient clothes, shoes, hair, glasses	40%	
Wheelchair / walker/ shower chair	40%	
Sink / faucets	40%	
Patient skin	34%	
HCP skin, hair, clothes, glasses	27%	
Overall Occurrence Agreement	49.6%	

Note: PI = Principal Investigator; HCP = Healthcare Personnel. Occurrence agreement is more important than either non-occurrence or total agreement because cross-contamination occurs when items are touched with contaminated gloves.

Table A 12. Median Number of HCP Failed Glove Changes Observed by the PI by HCP and Care Event Factors	
(N=76)	

Factor	Median [Range]	p ^a	
Gender			
Female (n=52)	3.0 [0-11]	*0.004	
Males (n=24)	1.0 [0-7]		
Duration of HCP Experience			
Less than 4 years $(n=28)$	3.0 [0-11]	0.193	
4 years or greater $(n=48)$	2.0 [0-9]		
Licensure and Certification			
CNA	2.0 [0-11]	b	
RN	2.5 [2-3]	b	
Number of HCP assisting			
One HCP	2.0 [0-11]	b	
Two or more HCP	3.0 [0-6]	b	
Shift			
Days: 07:00-19:00 (n=48)	2.0 [0-10]	0.961	
Nights: 19:00-07:00 (n=28)	2.5 [0-11]		
Weekday/Weekend			
Weekdays: Monday-Friday (n=56)	1.0 [0-9]	0.724	
Weekends: Saturday-Sunday (n=20)	2.0 [0-11]		

Note. PI = Principal Investigator; HCP = Healthcare Personnel; ^a Independent Samples Mann-Whitney U Tests. Level of Significance *p < 0.10. Null hypothesis is the distribution of the glove use is the same across the HCP and patient-care event categories of interest. ^b Inferential statistics were not performed due to low variability.

Characteristics	Median [Range]	p ^a
Gender		
Female (n=52)	10.5 [0-50]	*0.003
Males (n=24)	3.5 [0-18]	
Duration of HCP experience		
Less than 4 years (n=28)	8.5 [0-50]	0.278
4 years or greater (n=48)	7.5 [0-44]	
Licensure and Certification		
CNA	8.0 [0-50]	b
RN	10.0 [6-14]	b
Number of HCP assisting		
One HCP	8.0 [0-50]	b
Two or more HCP	9.0 [0-17]	b
Shift		
Days: 07:00-19:00 (n=46)	8.5 [0-28]	0.902
Nights: 19:00-07:00 (n=30)	8.0 [0-50]	
Weekday/Weekend		
Weekdays: Monday-Friday (n=55)	9.0 [0-50]	0.251
Weekends: Saturday-Sunday (n=21)	5.0 [0-28]	

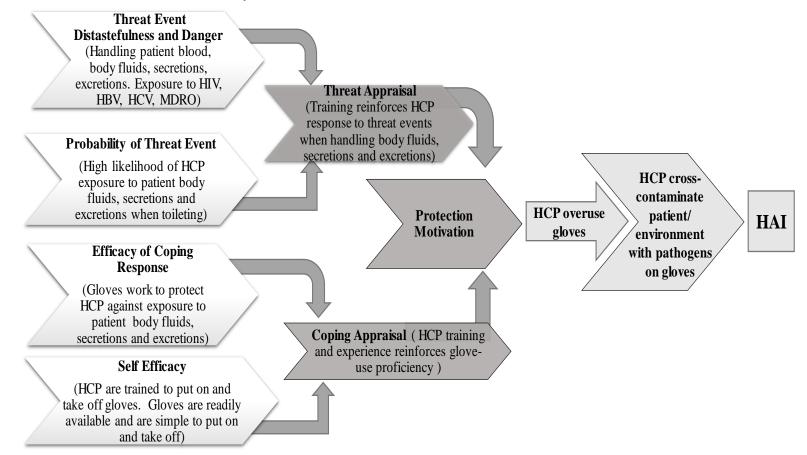
Table A 13. Median Number of HCP Contaminated Touch Points Observed by the PI by HCP and Care Event Factors (N=76)

Note. PI = Principal Investigator; HCP = Healthcare Personnel ^a Independent Samples Mann-Whitney U Tests (Level of Significance *p < 0.10).^b Significance testing was not performed due to low variability.

Null hypothesis is the distribution of the glove use is the same across the HCP and patient-care event categories of interest.

APPENDIX B. FIGURES

Figure B 1. Protection Motivation Theory and HCP Glove-Use



Note. HAI = Healthcare Associated Infection. HBV = Hepatitis B virus. HCV = Hepatitis C virus. HCP = Healthcare personnel. HIV = Human immunodeficiency virus. MDRO = Multi-drug resistant organisms. Adopted from Munro, Lewin, Swart & Volmink (2007). Protection Motivation Theory was used by the PI as an explanatory framework, but was not tested by the current study. It is a behavioral theory proposed by Rogers, 1975; Bandura & Adams, 1977; Bandura, 1982; Maddux & Rogers, 1983, proposing that people adopt behaviors depending on (a) how people perceive the distastefulness or danger of an event, (b) how likely and how often people feel the event is to occur, (c) how well people perceive that the recommended practices protect them from the threat or prevent the threatened outcome, and (d) whether people think they can master a behavior, and whether the behavior produces the desired outcome/protection against the threat.

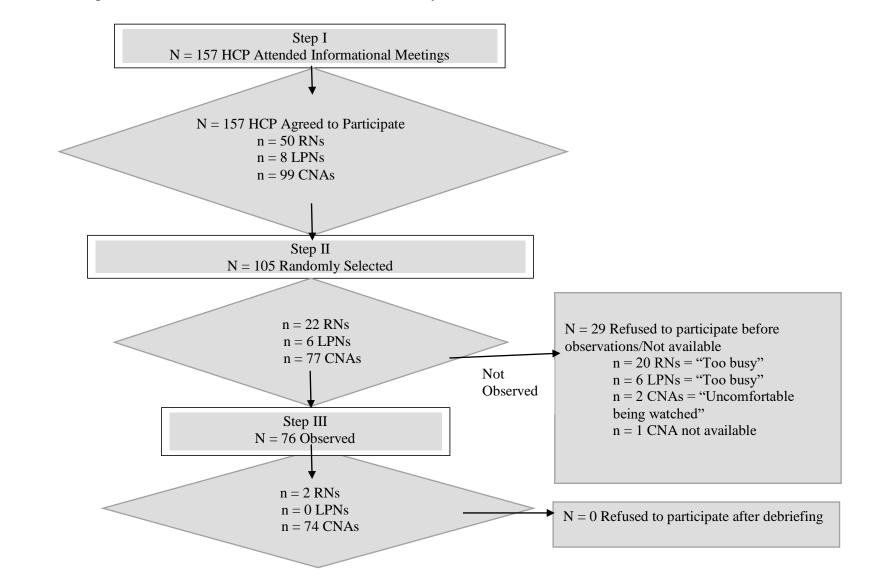


Figure B 2. HCP Participants Selected for Observation in the GUST Study

Note. PI = Principal Investigator; HCP = Healthcare Personnel; RN = Registered Nurse; LPN = Licensed Practical Nurse; CNA = Certified Nursing Assistant.

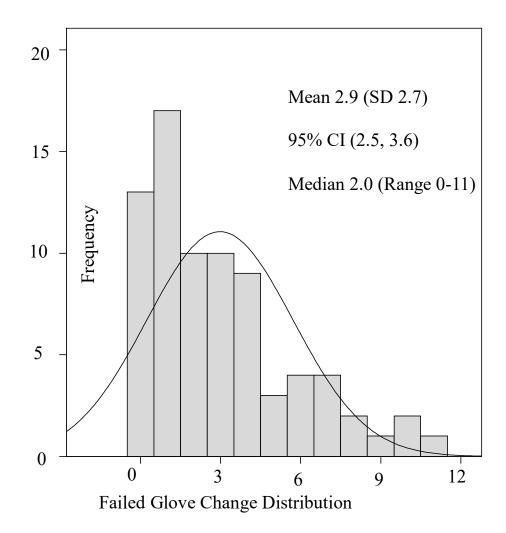
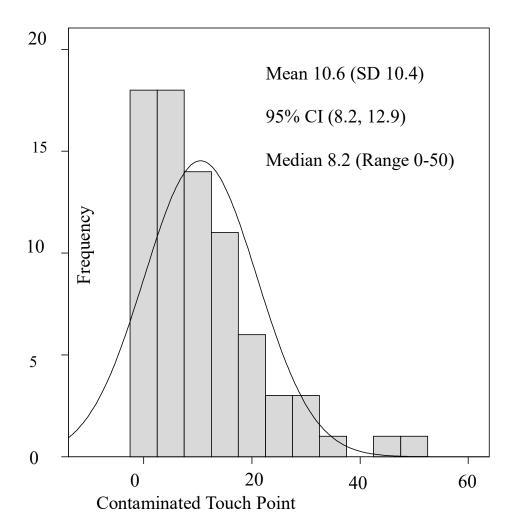


Figure B 3. Distribution of Failed Glove Changes (N=76)

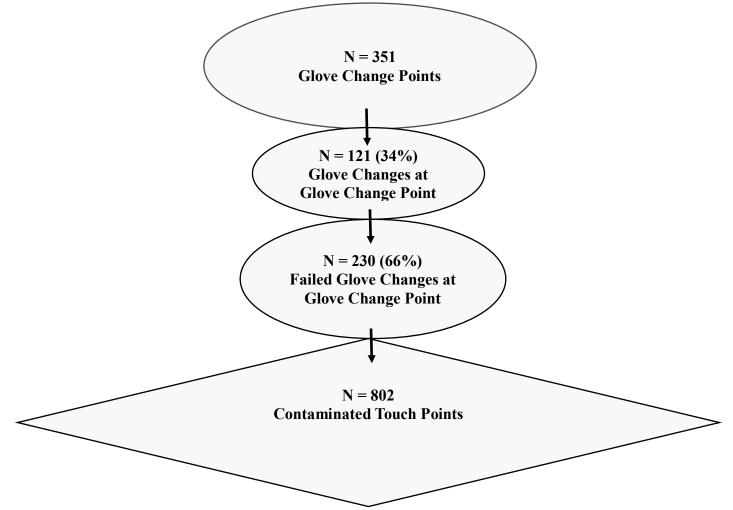
Note. SD = Standard Deviation, CI = Confidence Interval





Note. SD = Standard Deviation, CI = Confidence Interval.

Figure B 5. Frequency at which the PI Observed HCP Facets of Glove Use and Indicators of Inappropriate Glove Use (N=76)



Note. PI = Principal Investigator; HCP = Healthcare Personnel: Glove change points occur after a contaminated touch point or between patients. Glove changes at a glove change point were points where the observed healthcare personnel changed gloves at the appropriate point in patient care. Failed glove changes occurred when healthcare personnel did not change gloves when indicated, resulting in the contaminated touch points.

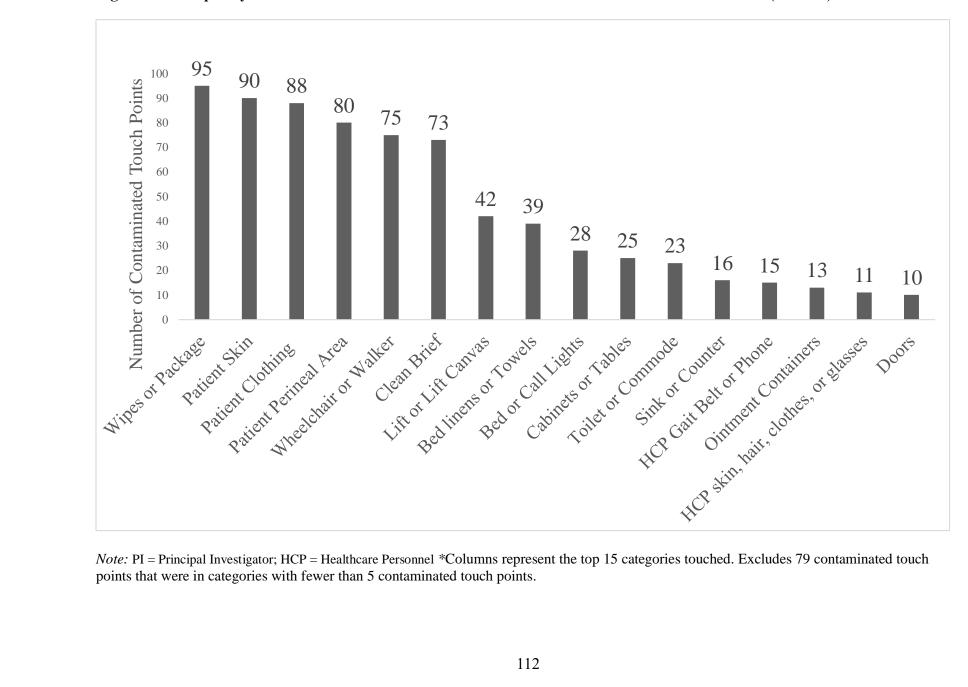


Figure B 6. Frequency at which PI Observed the HCP Touch Surfaces with Contaminated Gloves *(N = 723)

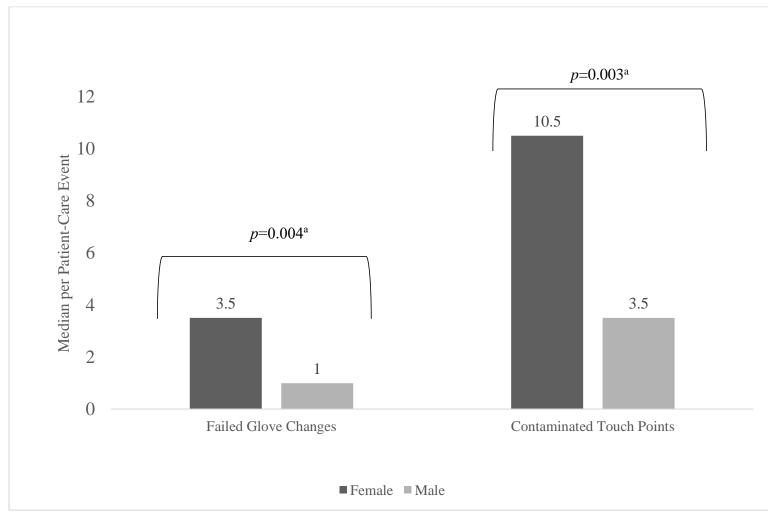


Figure B 7. Differences in the two Indicators of Inappropriate Glove Use for Males and Females (N = 76)

Note. ^a Independent Samples Mann-Whitney U Tests (Level of Significance p < .10). Mann-Whitney U Test indicated rejecting the null hypothesis for the difference between female and male glove use in this sample.

APPENDIX C. RESEARCH RESOURCES

Appendix Resource C 1. Glove Use Surveillance Tool (GUST)

	Clean Environment and Councilian	Liestheeve Drevider	Clean Datient Cites	Contonnin ato d Dations	Constant/Demonton
invironment and Furnishings	Clean Equipment and Supplies	Healthcare Provider (HCP) Clothing, Skin,	Clean Patient Sites, Clothes, Intact Skin	Contaminated Patient Sites/Soiled Equipment,	Surgical/Percutaneou Sites
		Equipment		Environment, and Supplies	
Circle Bare Hand	Circle Bare Hand touches	Circle Bare Hand	Circle Bare Hand touches	Circle Bare Hand touches	Circle Bare Hand
ouches	(W/C, walkers, BP cuffs,	touches	(Intact skin, hair, clean	perineal areas, mucous	touches
examples: doors,	glucometers, monitors, IV pumps,	(clothing, pens,	clothes, including shoes,	membranes, soiled	Surgical sites, open
ables, beds, bedrails,	wipes, dressings, briefs, diapers,	stethoscopes, charts,	adaptive	dressings, diapers, linen,	areas on skin, wounds
abinets, sinks)	linen)	notes, phones)		equipment, environment	vascular, enteral acces
				GUST ©2015 D Pat	terson Burdsall

Same pair of gloves used from touch point # _____ to touch point # _____ Same pair of gloves used from touch point # _____ to touch point # _____

Glove Change Points when HCPs need to change gloves in a patient-care event in Standard Precautions = Glove Change Point	# of
1. After the HCP gloves have touched blood, body fluids, mucous membranes, open wounds	Touches
2. After HCP complete a patient task (example, removing a soiled dressing or brief)	
3. After HCP gloves touch a potentially contaminated site before moving to a clean site	
4. Between different patients	
Total # of Touch Points	
Total # of gloved Touch Points in the patient-care event	
Total # of <i>Glove Change Points</i> in the patient-care event	
Total # of actual glove changes by HCP	
Total # of actual glove changes by HCP that occurred at a Glove Change Point during the patient-care event	
Total # of Failed Glove Changes	
Total # of Contaminated Touch Points after a Failed Glove Change at a Glove Change Point	
Percentage of Failed Glove Changes at a Glove Change Point during patient-care event (# of failed glove changes at a glove change	%
point ÷ total # of glove change points × 100)	
Percentage of Contaminated Touch Points after a Failed Glove Change (# of Contaminated Touch Points ÷ Total Touch Points × 100)	
LIST Surfaces touched after Failed Glove Change	
a	
b	
c d.	
e.	
f.	
g	
h	
i	
j	
k	

Comments: Conclusion and analysis:

GUST ©2015 D Patterson Burdsall

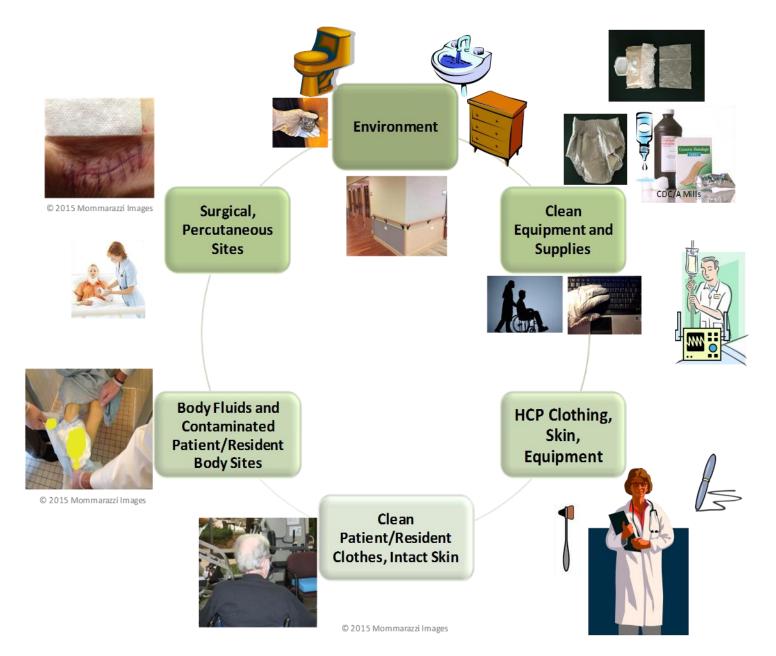
Goals of GUST:

- 1. To record the sequence of touch points when Healthcare Personnel (HCP) touch people, environmental surfaces and equipment with gloves and bare hands during a patient-care event
- 2. To record when HCP put on gloves, removes their gloves, and/or clean their hands during the patient-care event
- 3. To record the number of opportunities for appropriate gloving and glove removal during the patient-care event using the 4 touch points for glove change
- 4. To record the number of times gloves needed to be changed during the patient-care event using the 4 touch points for glove change
- 5. To use the information captured on the GUST to calculate the percentage of appropriate touch points in the patient-care event

Instructions: Please complete in pencil.

- 1. Practice using the form during at least 2 patient-care events in order to get familiar with using it.
- 2. Introduce yourself to the patient/resident/family and the HCP and ask permission to observe their care. If 2 or more HCPs are providing care, record only one HCP behavior.
- 3. Record the date, time started
- 4. Record the job category (Nurse, Nurse's aide, phlebotomist)
- 5. Record the patient-care event that is being observed
- 6. Note and record when fresh, clean gloves are put on by HCP (before touch point #)
- 7. Place a #1 next to the first thing that is touched in the first column (touch point #1)
- 8. Place a #2 next to the second thing that is touched (touch point #2)
- 9. If the HCP touches multiple areas of the same Patient Site, Environmental area, piece of Equipment or Supplies or HCP site in sequence without moving to another category, it counts as 1 touch
- 10. Continue recording the sequence in which people, environmental surfaces are equipment are touched
- 11. Note and record when hand hygiene is performed (after the touch point #____)
- 12. Note and record when gloves are removed (after touch point #____)
- 13. Note and record when new clean gloves are put on by HCP (before touch point #____)
- 14. Record the time the patient/resident care event stopped
- 15. Use the grid to calculate overall HCP glove use
- 16. List the surfaces that were contaminated by the HCP after a failed glove change
- 17. In the *Comments* section, please note any information that may clarify the observations

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Appendix Resource C 2. Development of Glove Use Surveillance Tool (GUST)

Initial Development.

The initial GUST was created as a pragmatic tool to meet the need for a written record of glove use during clinical hand hygiene observation sessions in both acute and long-term care. GUST 1.0 was simply a list of patient body sites and every common surface noted within the patient environment. Modifications occurred over a two-year period when the GUST was used for both glove-use and hand hygiene surveillance. Changes included:

Alphabetizing the surfaces and body sites,

Categorizing the surfaces and body sites into clean or contaminated,

Adding space to record glove changes and hand hygiene,

Indicating bare-handed touches by circling the touch,

Adding time, location, patient-care event and HCP demographics such as job description, and gender,

Adding spaces to record contaminated touch points,

Adding instructions for tool completion,

Adding space for the percentage of contaminated touch points.

Expert Validity Process.

Eight hand hygiene experts were contacted to establish expert validity of the GUST 3.8.

Of the eight experts contacted, seven completed the analysis and gave feedback on the GUST

3.8, either through Survey Monkey, via email, or a combination of both Survey Monkey and

email.

Kathy Aureden MS MT(ASCP) SI CIC Advocate Sherman Hospital Epidemiology and Infection Prevention

Ruth Carrico PhD RN FSHEA CIC Associate Professor Division of Infectious Diseases Clinical Director, Vaccine and International Health & Travel Clinics Associate Founding Director, Global Health Program School of Medicine University of Louisville

Marguerite Jackson PhD RN FAAN Jackson Consulting

Elaine Larson RN PhD FAAN CIC Anna C. Maxwell Professor of Nursing Research Associate Dean for Nursing Research School of Nursing Professor of Epidemiology, Mailman School of Public Health Editor, American Journal of Infection Control Columbia University

James Marx PhD RN CIC Broad Street Solutions San Diego, CA

Steven J. Schweon RN MPH MSN CIC HEM FSHEA Infection Preventionist

Philip W. Smith MD Professor, Division of Infectious Diseases Nebraska Medical Center University of Nebraska, Omaha

Questions for experts with responses and selected comments.

1. Name

2. Do the GUST 3.8 categories appear to represent a realistic and inclusive list of patient body sites, objects, and environmental surfaces that are commonly present in the patient zone? (6/6 replied *yes*) "Incredibly comprehensive." (Carrico) "What about hard surfaces *not* shared between patients, such as the floor, or a doorknob?" (Smith)

3. Are the instructions inclusive and clear? (3/6 replied *yes*, 3/6 replied *no*) "The instructions are inclusive, but the nature of the process is very complicated and is difficult to follow at first (and second) glance. I was finally able to make sense of the process after trying to actually use the tool myself. It took me several tries to follow the path." (Carrico). "Tool is way too complicated, not enough room to complete responses" (Larson). "Use pictures to create a standard way to evaluate a Touch Point. Perhaps separate the observation and the evaluation. It may be difficult for the observer to do both." (Marx). "This is very detailed data collection and will take time to learn how to consistently apply the categories to the observations. I believe the plan for training adequately addresses these issues" (Jackson).

4. Do you think that a trained observer could use the GUST 3.8 to record the sequence of HCW touches (touch points) as HCW progress through a patient-care event? (6/6 replied yes) "If describing the touch point in words is optional, the tool will work well. If a word description is required, a quick sequence of touches may be hard to track and write down at the same time. As long as the observer is very familiar with the tool, writing numbers only would not be a problem even when multiple surfaces are touched in a short timeframe" (Aureden).

5. Do you think a trained observer could use the GUST 3.8 to record when HCW puts on and takes off gloves and when the HCW performs hand hygiene (before and after which touch point)? (6/6 replied yes) "Since donning and taking off gloves does take some time, it should be

120

no problem to record these observations throughout the patient-care event. Again, this would take a good degree of familiarity with the tool per appropriate training period, the duration of which may be observer dependent. Interrater reliability validation must be thorough." (Aureden)

6. Do you think the information collected on the GUST 3.8 can be analyzed in a meaningful way? That is, does the completed GUST clearly indicate to you when the HCW used gloves, changed their gloves and cleaned their hands? (5/6 replied yes, 1/6 replied no). "Plans for data analysis seem complete and appropriate" (Jackson). "I'm unclear how you would adjust for the Hawthorne effect though. "This is a very interesting survey; so much goes on behind closed doors that we just don't know enough about!" (Schweon).

Summary of Responses.

Themes

- Address Complexity
- Address Hawthorne Effect
- Address Training

Modifications to GUST 3.8 completed to address expert review for development of GUST 4.0

- Simplified the form
- Reduced from 14 categories to six categories and combined surfaces to address intuitive categories
- Increased the size of the spaces to allow for more writing
- Moved the analysis portion to the back of the tool
- Simplified the directions
- Developed a training program that incorporates videos of toileting and perineal care events with experienced nursing assistants using mannequins as the patients.
- Created a pictograph to provide a standard way to evaluate touch points

Field Testing

On the basis of the field testing, the PI modified the GUST 4.0 to create the final GUST. The PI:

- Reduced the number and complexity of the GUST from 8 categories to 6 categories,
- Re-designed the table such that the categories are on the X axis and the frequency and identification of surfaces touched in a specific category is on the Y axis,
- Clarified the instructions,
- Changed the analysis section to enable observers to analyze their observations immediately after the patient-care event,
- Included a list of the body sites, surfaces, and objects touched during the patient-care event to facilitate the analysis,
- Re-designed the pictograph to match the categories on the GUST, and to avoid copyright violations for the images

Appendix C 3. IRB Approval

, Un	The viversity of lowa				Human Subjects Office/ Institutional Review Board (IRB) 105 Hardin Library for the Health Sciences 600 Newton Road Iowa City, Iowa 52242-1098 319-335-6564 Fax 319-335-7310 irb@uiowa.edu http://research.uiowa.edu/hso
	IRB ID #:	20150471	7		
	To: Deborah Burdsall				
	From:	IRB-02 Univ of low	DHHS Registration # IRB00000100, a, DHHS Federalwide Assurance # FWA00003007		
	Re:		ale: How Healthcare Personnel Use Glo f a Glove Use Surveillance Tool	oves du	ring Patient-care:Testing the
	Approval Date:		06/03/15		
	Next IRB Approval Due Before: Type of Application: New Project Continuing Review Modification		06/02/16		
			Type of Application Review:	Appro	oved for Populations:
			☐ Full Board: Meeting Date: ⊠ Expedited	🗌 Pri	ildren soners egnant Women, Fetuses, Neonates
			Exempt		
	Source of Supp	port:			

This approval has been electronically signed by IRB Chair: Janet Karen Williams, PHD 06/03/15 0711

Appendix C 4. Resident Patient Informational Letter.

Dear [LTCF]* Patients, Residents and Family Members,

[LTCF] are dedicated to providing you with the highest quality of healthcare. We are participating in a research study with The University of Iowa College of Nursing in order to look at ways to improve safety and reduce the risk of infections.

The purpose of this observational study is to describe barriers to hand hygiene during patient care in long-term care and post-acute rehabilitation, including how healthcare personnel use gloves. Proper hand hygiene is an effective way to help prevent healthcare-associated infections and improve patient safety.

The study involves having two researchers watch your caregivers when they care for you. I am also the principal investigator. I will always be one of the observers. The other observer will be a [LTCF] staff member or healthcare intern. The observers will watch your caregivers, and will not specifically be watching you. This study is done anonymously.

No personal patient information will be collected. All information will be handled confidentially, and will not include your name, room number, diagnoses, age or gender.

The observers will ask for your permission to observe before the patient care begins. You have the right to refuse at any time. By allowing us to observe patient care, you are agreeing to participate in this program, and can help us describe barriers to hand hygiene, which may help us develop strategies to improve hand hygiene and decrease the risk of infection.

If you are the healthcare power of attorney, and do not wish your family member to participate, please notify Deb Burdsall at [email], or by phone at [phone#]

If you have any questions, please do not hesitate to contact Deb Burdsall at [email] or by phone at [phone #]

Sincerely, Deb Burdsall MSN, RN-BC, CIC

*Note. Identification of the LTCF, phone numbers and email addresses removed for publication.

Appendix C 5. Healthcare Personnel Informational Letter

We invite you to participate in a research study. The purpose of this study is to describe barriers to hand hygiene during patient-care in long-term care and post-acute rehabilitation, including how healthcare personnel use gloves when assisting patients and residents. Proper hand hygiene is an effective way to help prevent healthcare-associated infections and improve patient safety.

We are inviting you to be in this study because you are a nurse or a nursing assistant at the [LTCF]. We obtained your name from the staff rosters of the [LTCF]. Approximately 100 people will take part in this study at the University of Iowa. We will choose nurses and nursing assistants at random from the staff rosters.

If you agree to participate, we would like you to allow the PI and one trained observer watch you assist patients and residents with perineal care and toileting. We were looking for barriers to hand hygiene. I am the principal investigator, and will always be one of the observers. The other observer were a [LTCF] staff member or healthcare intern.

We will keep the information you provide confidential, however federal regulatory agencies and the University of Iowa Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. We will not record your name or any other personal information. There will be no way to identify you from the data we collect. If we write a report about this study we will do so in such a way that you cannot be identified.

There are no known risks from being in this study, and you will not benefit personally. However we hope that others may benefit in the future from what we learn as a result of this study.

You will not have any costs for being in this research study. You will not be paid for being in this research study. Taking part in this research study is completely voluntary. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

If you have any questions about the research study itself, please contact Deb Burdsall, [phone#] or Dr. Sue Gardner at [email] or [phone#]. If you experience a research-related injury, please contact: Deb Burdsall, [phone#]. If you have questions about the rights of research subjects, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd., The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

Thank you very much for your consideration. Sincerely, Deb Burdsall Name of PI or Research Team Member: Deb Burdsall Title: Doctoral Candidate, The University of Iowa College of Nursing

Appendix C 6. Healthcare Personnel Meeting Script

- We invite you to participate in a research study.
- The purpose of this study is to describe barriers to hand hygiene during patient care in long-term care and post-acute rehabilitation
- We would like to learn more about how you clean your hands and use gloves when assisting patients and residents.
- Proper hand hygiene is an effective way to help prevent healthcare-associated infections and improve patient safety.
- We are inviting you to be in this study because you are a nurse or a nursing assistant at the [LTCF]. We obtained your name from the staff rosters of the [LTCF]. Approximately 100 people will take part in this study at The University of Iowa.
- We will choose nurses and nursing assistants at random from the staff rosters.
- If you agree to participate, we would like you to allow the PI and one trained observer watch you assist patients and residents with perineal care and toileting.
- We were looking for barriers to hand hygiene.
- I am the principal investigator, and will always be one of the observers. The other observer will be a [LTCF] staff member or healthcare intern.
- We will keep the information you provide confidential, however federal regulatory agencies and The University of Iowa Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research.
- Please don't discuss your observation experience until after we watch all nurses or CFPs (Certified Family Partners/nursing assistants). We will let you know about the results after we collect all the data.
- We will not record your name or any other personal information. There will be no way to identify you from the data we collect.
- If we write a report about this study, we will do so in such a way that you cannot be identified.
- There are no known risks from being in this study, and you will not benefit personally. However, we hope that others may benefit in the future from what we learn as a result of this study.
- You will not have any costs for being in this research study.
- You will not be paid for being in this research study.
- Taking part in this research study is completely voluntary. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.
- If you have any questions about the research study itself, please contact Deb Burdsall, (phone#
- We do not expect any injury related to the research, because we are just watching you at your regular job.
- If you have questions about the rights of research subjects, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City IA 52242-1098, (319) 335-6564, or e-mail <u>irb@uiowa.edu</u>.
- To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.
- Thank you so much for coming today!

Appendix C 7. Glove Use Debriefing Statement

We are collecting information about how healthcare personnel not only clean and wash their hands, but we are also looking at how you used gloves when you cared for the patient.

We are not recording your name or any other information that will allow us to identify you. We are not judging how you personally used gloves or how you cleaned or washed your hands. We are looking for patterns across all the healthcare personnel we observe for this study.

We watched how you took care of this patient to try to get a better idea of how healthcare personnel use gloves when they care for patients, and if there are any patterns that we can identify to help us develop ways to use gloves that may be easier and may help prevent the spread of germs.

If you do not wish to have this observation included in our study, please tell us now, so we can destroy our observations. If you have any other questions, please feel free to ask us now, or you can contact Deb Burdsall at [email], or at [phone#].

Thank you very much for your time and attention.