Increasing Hand Hygiene Performance in Health Care Workers with Electronic Real-Time Prompting

by

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A thesis submitted in conformity with the requirements for the degree of Doctor of Philosophy
Graduate Department of Mechanical and Industrial Engineering
University of Toronto

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2019

Abstract

Poor hand hygiene (HH) by health care professionals is a major cause of healthcare-acquired infections. Improving HH compliance among staff is the most effective way to reduce healthcare acquired infections. This thesis evaluates the ability of an electronic monitoring system with real-time prompting capability, to improve HH behaviours, its ability to capture high resolution audit data, and presents alternate system deployment strategies.

To investigate HH behaviours, 120,441 dispenser activations on a nursing unit were counted before, during, and after installation of the system. The effect of changing the prompt duration on HH performance was determined by a randomized control trial including 90,776 HH opportunities from 185 participants on three nursing units. Sustainability of performance and participation was observed on four nursing units including observations from 419 participants over a year. Results showed that real-time prompts of 20 seconds’ duration nearly doubled HH activity and caused HH to occur sooner after entering a patient room. These improvements were sustainable over a year.
Analysis of HH audit capabilities was conducted on data collected on a musculoskeletal rehabilitation unit over 12 weeks. Results showed that continuous collection of HH data that included temporal, spatial, and personnel details provided information on actual HH practices, whereas direct observation or dispenser activation counts showed only aggregate trends. Aggregate performance at patient and soiled utility rooms were both 67%, although individual compliance varied greatly. The number of HH events that occurred inside patient rooms increased with longer visits, whereas HH performance at patient room exit decreased. Eighty-three percent of missed HH opportunities occurred as part of a series of missed events, not in isolation.

The system was deployed two more times on the unit at six month intervals. There was a significant increase in aggregate dispenser use with every deployment and a decrease over several weeks following each withdrawal. Intermittent deployment of the system counteracted potential declines in participation rates sometimes seen with continuous system use.
Acknowledgments

Thank you to my supervisor and co-author, Geoff Fernie, for the trust and confidence to complete such meaningful work. Who’s vision to include designers and design thinking in the research process brought me to the lab in the first place. To my committee, Tilak Dutta and Bruce Haycock, for the occasional reality-check and continuous support. To Pamela Holliday, my ever-encouraging co-author and voice on the unit who helped make this journey a pleasure. To the staff at Toronto Rehab whose great compassion for patients led them to participate in these studies.

For funding this work, I am grateful for the grants provided by the Ontario Ministry of Health and Long-Term Care (#06036), and the Canadian Institutes of Health Research (MOP-102687). Additional support was provided by the Toronto Rehab Foundation. Equipment and space were funded by grants from the Canada Foundation for Innovation, Ontario Innovation Trust and the Ministry of Research and Innovation.

Finally, to my family Laura, Charlotte, and Kieran, thank you for understanding and supporting this crazy dream of mine. I love you too.
# Table of contents

Acknowledgments ...................................................................................................................... iv  
Table of contents ....................................................................................................................... v  
List of tables ............................................................................................................................ vii  
List of figures ........................................................................................................................... viii  
List of abbreviations ................................................................................................................ ix  

Chapter 1 Introduction .............................................................................................................. 1  
  1.1 Motivation ....................................................................................................................... 1  
  1.2 Objectives & research questions .................................................................................... 2  
  1.3 Overview ....................................................................................................................... 3  
  1.4 Contributions ................................................................................................................ 4  

Chapter 2 Background .............................................................................................................. 6  
  2.1 Healthcare-acquired infections ...................................................................................... 6  
  2.2 Preventing HAIs ............................................................................................................ 24  
  2.3 Hand hygiene ............................................................................................................... 31  

Chapter 3 The hand hygiene prompting system ...................................................................... 70  
  3.1 System overview .......................................................................................................... 70  
  3.2 System logic .................................................................................................................. 73  
  3.3 Components ................................................................................................................ 78  
  3.4 Previous publications .................................................................................................. 87  

Chapter 4 Effect of real-time prompting on hand hygiene ..................................................... 91  
  4.1 Background .................................................................................................................. 92  
  4.2 Methods ....................................................................................................................... 93
List of tables

Table 2-1: Standard precautions for the care of all patients................................. 26
Table 2-2: Moments for hand hygiene.................................................................. 43
Table 2-3: Predictive factors for hand hygiene compliance................................. 46
Table 2-4: Effect of behaviour of other HCPs on HCP hand hygiene compliance... 52
Table 4-1: Summary of study methods. ................................................................. 95
Table 4-2: Effect of electronic monitoring system on dispenser activation count . 100
Table 4-3: Effect of real-time prompt duration on hand hygiene performance...... 102
Table 4-4: Observation results, overall and by unit .............................................. 106
Table 5-1: Soiled utility room HH performance by HCP group. ............................ 120
Table 6-1: Aggregate dispenser activation count results....................................... 135
List of figures

Figure 2-1: Model of actionable feedback .............................................................. 60
Figure 3-1: System components ............................................................................ 71
Figure 3-2: Finite-state-machine diagram of system logic........................................ 75
Figure 3-3: Internal zone controller with non-prompt entry................................. 77
Figure 3-4: Docking station performance feedback display element ..................... 85
Figure 4-1: Likelihood of washing before given time ............................................ 104
Figure 4-2: Weekly mean performance (A) and participation data (B) ................. 105
Figure 5-1: Number of handwash events before and after patient room entry (A)  
and exit (B)........................................................................................................ 115
Figure 5-2: Change in aggregate HH performance at patient room entry and exit  
and the number of times handwashing occurred while inside patient rooms 117
Figure 5-3: Individual, HCP group, and unit level HH performance results. ........ 118
Figure 5-4: Histogram of all consecutive missed opportunity series lengths ........ 119
Figure 6-1: Hand hygiene performance and participation change over time. ....... 134
Figure 6-2: Activation counts of individual dispensers.......................................... 136
Figure 7-1: Change in dispenser activation counts ................................................ 142
Figure 7-2: Hand hygiene performance feedback to staff. ................................... 144
List of abbreviations

ABHR: alcohol-based hand rub
C. diff: Clostridium difficile
CDC: Centers for Disease Control & Prevention
CHG: Chlorhexidine gluconate
CMS: Centers for Medicare & Medical Services
EMS: electronic monitoring system
HAC: hospital-acquired condition
HAI: healthcare-acquired infection
HCP: health care professional
HH: hand hygiene
HICPAC: Healthcare Infection Control Practices Advisory Committee
ICC: Intracluster correlation coefficient
ICU: intensive care unit
ID: identification
IR: infrared
IRED: infrared emitting diode
JCAHO: Joint Commission on Accreditation of Healthcare Organizations
MOHLTC: Ministry of Health & Long-Term Care
MRSA: Methicillin-resistant Staphylococcus aureus
OR: odds ratio
PPE: personal protective equipment
PSI: Patient Safety Indicator
S. aureus: Staphylococcus aureus
SSI: surgical site infection
UTI: urinary tract infection
VRE: Vancomycin-resistant Enterococci
WHO: World Health Organization
Chapter 1 Introduction

1.1 Motivation

When patients in healthcare environments develop an infection that was not present at admission, they are considered to have a healthcare-acquired infection (HAI). These HAIs are among the most common adverse events in healthcare [1] affecting up to 10% of patient populations equaling millions of people in North America every year [2]. HAIs significantly increase morbidity and mortality of patients [3] leading to additional days of treatment and increased risk of death [4, 5]. The financial costs of treating HAIs has been estimated at $4.5 billion per year in the United States alone [2]. The treatment of HAIs often require the use of antibiotics. With exposure to antibiotics, pathogens can develop the ability to resist treatment by existing medications [6] which can lead to further increases in morbidity and mortality of patients and additional costs. It is estimated that elimination of the preventable portion of HAIs will result in financial savings that exceed the cost of implementing the required interventions [7, 8].

The most common mode of transmitting an HAI is through contact, either directly from one person to another, or indirectly through contaminated intermediate objects or people including health care staff [9]. To prevent the spread of HAIs, appropriate hand hygiene (HH) is the single most important procedure [10]. HH significantly reduces the amount of pathogens on hands reducing patient morbidity and mortality from HAIs [11, 12], and is one of the suggested methods to slow the development of antibiotic resistant pathogens [13]. It is estimated that up to 70% of HAIs are preventable [14].
Despite knowing for over 100 years that performing HH can reduce the occurrence of HAIs [15], compliance among health care workers is low. The overall average of health care professional (HCP) compliance with recommended HH procedures is reported to be 40% [16]. Studies investigating ways to increase HH compliance include interventions in the following categories: system change, education, feedback, reminders, safety climate, incentives, goal setting, and accountability [17, 18]. In a systematic review evaluating the efficacy of such interventions, it was shown that while associated with improvements in HH in health care workers, the effect on results vary widely. Mean change in HH compliance with interventions among interrupted time series studies ranged from a decrease of 14.8% to an increase of 83.3% [18].

Type, duration, and frequency of interventions have also been shown to affect the potential sustainability of improvements in HH compliance. In a study with two intervention phases, during the first week of intervention 1 staff were given a series of brief education sessions reviewing the rationale and procedures for HH and information about observed infections. HH performance improved during that first week but returned to baseline by the fourth. During the second intervention phase, staff were provided with daily anonymous feedback on the previous day’s HH errors. By the second week, compliance increased to the highest level so far and remained there for the duration of the study [19]. Nevertheless, the optimal intervention strategy to both increase and sustain HH compliance has not be identified.

1.2 Objectives & research questions

A novel technology has been developed by the research team at Toronto Rehabilitation Institute. This technology, a system to monitor and increase HH compliance among health
care staff, uses real-time prompts to clean when opportunities are missed. The overall objectives of this research are to increase HH performance in health care workers and to investigate the use of high resolution audit data to understand HH behaviours.

This thesis answers the following research questions:

1. How does use of the system change overall HH activity?
2. How does the prompt function of the system affect HH behaviours?
3. How does the passage of time affect HH performance and the sustainability of staff engagement?
4. In addition to compliance with accepted HH guidelines, what measures are available through continuous monitoring of individual staff to assess HH behaviours contributing to the risk of transmitting HAIs?

1.3 Overview

Chapter 2 presents a review and analysis of current literature about the causes, prevalence, and impact of HAIs and their connection to the hands of health care workers. Current and emerging methods for monitoring and improving HH compliance are also discussed.

Chapter 3 describes the design of the electronic monitoring system (EMS) that was developed by our team and used throughout this thesis.

Chapter 4 presents study results from investigations into three aspects of HH behaviour affected by electronic real-time prompting. The system’s impact on overall HH activity was measured with dispenser-activation counts. The primary mechanism of behaviour change,
real-time prompting, was assessed with a controlled trial, and time series analyses were used to determine the sustainability of performance increases and participation levels over a year. These were assessed across multiple hospital units at different sites integrating multiple study design suggestions outlined by previous systematic reviews of HH intervention studies. This multi-part investigation gives a full understanding of the functioning and effect of the system on HH behaviours, an approach that has not been previously reported.

Chapter 5 demonstrates the value of collecting high-resolution, individual participant data for understanding HH behaviors. Examples of three measures of HH performance in addition to those outlined by the World Health Organization (WHO) were developed and applied to clinical data. These measures augment the existing understanding of HH behaviors by extending the boundaries of measurement beyond single moments and places to continuous accounting of time and space by individuals, not only groups.

Chapter 6 investigates the effect of intermittent system deployment as a strategy to counteract potential reductions in health care staff participation levels that may occur with continuous use deployments.

1.4 Contributions

This thesis was constructed, researched and written by me, with guidance from my supervisor and committee. The work presented in Chapter 3 – Chapter 6 was conducted collaboratively with others. In all of these cases I did the majority of the work, but benefitted from the advice and assistance of others. Contributions of the co-authors are described in each section. A summary of my contributions to each work follows:
Chapter 3: The hand hygiene prompting system – I was a primary contributor, along with Geoff Fernie, and Bruce Haycock to the development, testing, production and installation of the version of the HH technology used throughout the thesis.

Chapter 4: Effect of real-time prompting on hand hygiene – I led the design of the studies, co-conducted data collection, performed all data processing, analysis and reporting, with advice from co-authors as appropriate.

Chapter 5: Secondary measures of hand hygiene performance – I led the design of the study, co-conducted data collection, performed all data processing, analysis and reporting, with advice from co-authors as appropriate.

Chapter 6: Effect of intermittent system deployment – I led the design of the study, co-conducted data collection, performed all data processing, analysis and reporting, with advice from co-authors as appropriate.

Other than the collaborations listed above, the work presented in this thesis is my own.
Chapter 2 Background

2.1 Healthcare-acquired infections

Healthcare-acquired infections are a common cause of morbidity and mortality and are among the most common adverse events in healthcare [1]. The Centers for Disease Control and Prevention (CDC) define a HAI as being a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s) [20, 21]. This applies to any setting where health care is delivered including; acute care hospitals, chronic care facilities, ambulatory clinics, and dialysis centers [9].

For an infection to be considered healthcare-acquired, there must be no evidence that the infection was present or incubating at the time of admission to the health care facility [21]. Therefore, if a patient has an infection at the time of admission, it would not be considered healthcare-acquired. Microorganisms that do not produce adverse reactions are not considered infectious [20]. An infection that occurs in the following situations is also considered healthcare-acquired: (1) an infection acquired in a health care environment that becomes evident only after discharge and (2) a newborn acquires an infection resulting from passing through the birth canal [21].

Environments other than acute care hospitals, such as long-term care facilities, may change or use alternate criteria for diagnosing infections for their patients [22]. HAIs can also occur in ambulatory and home environments if they are associated with medical or surgical interventions [9].
The National Healthcare Safety Network categorizes HAIs into 13 major types. They are: urinary tract infection (UTI), surgical site infection (SSI), bloodstream infection, pneumonia, bone and joint infection, central nervous system infection, cardiovascular system infection, eye/ear/nose/throat or mouth infection, gastrointestinal system infection, lower respiratory tract infection, reproductive tract infection, skin and soft tissue infection, and systemic infection [20].

In order for a patient to develop an HAI, Damani describes a “chain of infection” consisting of six links where each link in the chain must be present. The required links are: (1) a causative agent, (2) an infectious reservoir, (3) a portal of exit from the reservoir, (4) a mode of transmission, (5) a portal of entry into the host, and (6) a susceptible host [23]. If any of these links are broken, HAIs can be prevented. The remainder of section 2.1 describes these links. Section 2.2 and 2.3 presents methods for preventing HAIs with a focus on HH as a way to break the mode of transmission link.

This thesis uses the term healthcare-acquired infection (HAI) throughout, to replace the use of hospital-acquired infection and nosocomial infection as recommended by the National Healthcare Safety Network in 2008 [20].

2.1.1 Microbiology of the skin

The skin is a physical barrier protecting people from potentially harmful organisms or causative agents. It is normal for a person’s skin to be colonized with many microorganisms including bacteria, fungi and viruses that can have important effects on health. Different parts of the body have different amounts of bacteria and colony forming units [24].
The microorganisms found on the skin can generally be divided into two types or flora: resident and transient [25]. Resident flora are those bacteria normally found on the host and exist mainly on the surface of the skin and under the superficial cells of the stratum corneum. Resident flora reside permanently on the host and are resistant to removal [26]. The presence of resident flora helps prevent the colonization of the skin by other microorganisms through microbial antagonism and competition for resources which is thought to be a major mechanism of preventing the adherence of pathogens [27, 28]. The most common bacteria, found on the hands of most people is Staphylococcus epidermidis [29, 30]. Transient flora contains the organisms that cause nearly all infectious diseases. The transient flora reside on the superficial layers of the skin and are more easily removed with HH [16]. The likelihood of transmitting transient bacteria from one person to another depends on the species, bacterial load, viability on skin, and the dermal water content [31, 32].

Skin microbiota are dependent on the location on the body and on the physiology of the location. Specific bacteria are more commonly associated with either moist, dry, or sebaceous areas of the body. The most diverse places are the dry areas of the body including the forearm and parts of the hand. These sites consist of greater phylogenetic diversity than the digestive system or oral cavity of the host [24, 33]. Along with having the most diversity of microorganisms, the dry parts of the body have the most variability over time compared to areas that are at least partially enclosed like the inside of the ear or nose [34].

HAIs can be caused by agents found on patients themselves or from an outside source. Endogenous sources are places on the patient’s body, like the skin, nose, mouth, or
gastrointestinal tract where microorganisms are normally present. Exogenous sources are those external to the patient, like health care staff members, visitors, medical devices or the health care environment [20]. Factors like occupation, clothing, and antibiotics use can change microorganism levels on the skin. Cleaning hands is an exogenous process that can also be used to change or remove harmful microorganisms from the host [24].

In a study to characterize the bacterial diversity on hands, the palmar surfaces of 51 young healthy adults were examined. A typical hand supported more than 150 unique species-level bacterial phylotypes. While a core group of bacteria were found on most hands, there was also a great amount of intra and interpersonal variation. The study found that hands from the same individual shared 17% of species-level phylotypes, whereas hands from different individuals shared 13%. The composition of bacteria on the hand was significantly affected by an individual’s sex, with women having significantly more diversity of bacteria than men, handedness, and the amount of time since hands were cleaned [35].

2.1.2 Pathogenic microorganisms

There are five main types of microorganisms: bacteria, fungi, viruses, protozoa, and algae. This section describes the following three types of microorganisms most commonly associated with HAIs: bacteria, fungi, and viruses.

Bacteria

Bacteria are living things that come in a variety of shapes, typically spheres and rods. Some bacteria are capable of movement through tail-like structures called flagella. Unlike viruses, bacteria do not need a host cell to reproduce. Most HAIs are caused by bacteria, transmitted
by contact or airborne routes. Patients with underlying diseases are more susceptible to infection but most HAIs occur in patients who are not immunosuppressed [36]. The bacteria cell wall is a multilayered structure that protects bacteria from their environment. The cell walls of most bacteria fall into one of two groups: Gram-negative and Gram-positive [37]. Gram refers to the clinician Hans Christian Gram, who in 1884, developed a method for differentiating bacteria into two varieties based on their response to staining which is determined by the chemical and structural composition of the bacterial cell wall [38].

**Gram-negative bacteria**

Bacteria that can be decolorized and stain red with carbol fuchsin are Gram-negative [38]. These Gram-negatives have a thin peptidoglycan cell wall plus an overlying lipid-protein bilayer containing lipopolysaccharide known as the outer membrane [37, 38].

Many Gram-negative bacteria thrive in aqueous sources. HAI outbreaks have been traced to contaminated medications, hand lotions, water, disinfectants, infusion fluids [39], blood products, inhalation therapy equipment, and hemodialysis machines. It is unlikely that airborne transmission contributes significantly to spread of Gram-negative bacilli in hospitals [36].

A number of different Gram-negative bacteria cause HAIs. Overall, Gram-negative bacteria are associated with up to 64% of all HAIs [40]. *Escherichia coli* is the most common Gram-negative bacteria, usually associated with causing UTIs, diarrhea, respiratory illness and pneumonia [40, 41].
Many Gram-negative bacteria can survive on the hands for more than an hour. Colonization rates of Gram-negative bacteria on the hands of health care workers have been described as ranging from 21% to 86.1%, with the highest rate found in intensive care units (ICUs) [42]. *Klebsiella spp.* were found on the hands of 17% of ICU staff sampled, with up to 10,000 bacteria per hand [43].

Survival on environmental surfaces can last for many months. Generally, Gram-negative bacteria survive for longer on inanimate surfaces than on human skin [44]. In most cases, this type of bacteria is transmitted by devices such as urinary catheters, ventilation equipment and suction tubes [45-47].

**Gram-positive bacteria**

Bacteria that retain the crystal violet staining are Gram-positive. These bacteria have a thick, relatively impermeable wall that resists decolorization, made up of peptidoglycan and secondary polymers [38]. Gram-positive bacteria do not have the lipopolysaccharide outer membrane like Gram-negative bacteria. Instead, the peptidoglycan layer is many times thicker. Growing through this layer of peptidoglycan are long anionic polymers, called teichoic acids. These differences compensate for the potential loss of structural integrity from not having an outer membrane [37].

Infections from Gram-positive bacteria are usually from human reservoirs, either community-acquired strains or organisms acquired through contact with HCPs who are colonized or carry organisms on their hands from contact with other patients [36].
*Staphylococcus aureus*

*Staphylococcus aureus* (*S. aureus*) is the most common Gram-positive bacterium causing HAIs [48]. *S. aureus* accounts for 11.1% to 17.2% of all HAIs. *S. aureus* can cause a range of illnesses, from minor skin infections to life-threatening diseases such as pneumonia, meningitis, toxic shock syndrome, and sepsis [41, 49, 50]. Hand carriage of *S. aureus* has repeatedly been associated with different types of HAIs [51, 52]. Colonization of the hands of HCPs with *S. aureus* has been reported to range from 10.5% to 78.3% with up to 24,000,000 cells found per hand [53].

In the 1980’s, methicillin-resistant *S. aureus* (MRSA) was uncommon in most hospitals in the United States. By 1997 approximately one third of isolates of *S. aureus* were resistant to methicillin, and the rate was higher among isolates from ICUs than from other areas of the hospital (35% vs 32%, *P* < .01) [54]. In Britain, deaths related to MRSA increased 25-fold between 1993 and 2002 [55]. In German ICUs, 14.3% HAIs due to *S. aureus* were methicillin-resistant. This proportion is highest for UTIs (26.4%), followed by primary septicemia (23.3%), and lower respiratory tract infections (12.9%) [56]. Methicillin resistance in *S. aureus* is increasing worldwide [57-59]. Between 1980 and 2014 there was an increase in mortality for diarrheal diseases in the United States (including MRSA) [60].

To assess the impact of methicillin resistance on the outcomes of patients with *S. aureus* SSIs, Engemann et al. analyzed data for 479 patients comparing patients with sternotomy incisions infected with methicillin-sensitive *S. aureus* with patients with sternotomy incisions that were positive for MRSA. They found that patients infected with MRSA had a significantly greater 90-day mortality rate than patients infected with methicillin-susceptible
*S. aureus* (adjusted odds ratio, 3.4; 95% confidence interval, 1.5–7.2) and stayed in hospital longer (median additional days; 5). Median hospital charges were $29,455 for control subjects, $52,791 for patients with methicillin-susceptible *S. aureus* SSI, and $92,363 for patients with MRSA SSI. Patients with MRSA SSI had a 1.19-fold increase in hospital charges and had mean attributable excess charges of $13,901 per SSI compared with patients who had methicillin-susceptible *S. aureus* SSI. Methicillin resistance is independently associated with increased mortality and hospital charges among patients with *S. aureus* SSI [61].

**Enterococcus**

Enterococci are the fourth leading cause of HAIs in the United States [62]. The most common species are *Enterococcus faecium* and *Enterococcus faecalis*, which frequently cause UTIs [63]. Vancomycin-resistant enterococci (VRE) have become a major HAI pathogen in some hospitals [64]. The emergence of VRE has led to an increased recognition of cross-transmission of VRE, including the role of health care workers’ hands [65, 66]. Noskin et al. showed that artificially inoculated VRE can last for at least 60 minutes on gloved and ungloved fingertips and that handwashing for 30 seconds will eliminate colonization [67].

**Clostridium difficile**

*Clostridium difficile* (*C. diff*) is the primary spore-forming bacteria causing HAIs. Vegetative cells of *C. diff* can survive for at least 24 hours on inanimate surfaces, and spores can survive for up to five months. Patients can be contaminated from the hands of HCPs and
from inanimate surfaces [68]. Transmission of *C. diff* in an endemic setting on a general medical ward has been shown to occur in 21% of patients, with 37% of them suffering from diarrhea [69].

It is estimated that between 15% and 55% of all cases of healthcare-acquired antibiotic-associated diarrhea is caused by *C. diff* [68, 70-72]. Cases of *C. diff* have an overall mortality rate of 15% [73]. Patients with diarrhea caused by *C. diff* stay in hospital, on average, 3.6 additional days. In the United States this adds approximately $3,669 per case or $1.1 billion per year [74].

**Fungi**

Fungi are multi-celled organisms that are similar to plants but have their own kingdom. They include infections such as athlete's foot and *Candida*. Common organisms such as molds and mushrooms are also fungi. Fungi should be treated with anti-fungal drugs since antibiotics generally have no effect. HAIs are less commonly caused by fungi than bacteria but their frequency is increasing [75-77]. Fungi can cause septicemia, UTIs, or SSIs [40, 78]. Rates of HAIs caused by fungi vary by country. In New Zealand, 6% of all HAIs were caused by fungi [79]. In the United States, an increase in isolation of yeasts from 7.6% to 10.6% has been reported over ten years in patients with HAIs [80].

While the most important fungus with respect to HAIs is *Candida albicans*, causing 21% of all UTIs among ICU patients [40], the impact of non-albicans *Candida spp.* is increasing [75]. Device-associated bloodstream infections caused by *Candida spp.* have become more common among critically ill patients [81-83]. On fingertips, only 20% of viable cells of
*Candida albicans* and *Candida parapsilosis* remain detectable after one hour [84, 85], while *Candida* spp. can survive on surfaces for up to 150 days [86, 87].

The transmissibility of yeasts from hands is high. In an ICU, 46% of the hands of 146 HCPs were colonized with a yeast. The most common species were *Candida* and *Rhodotorula* spp. Respiratory therapists were found to have the highest colonization rate (69%) [88]. In another ICU study of an outbreak of *Candida albicans*, the strain was found on the hands of health care workers immediately after attending infected patients in two of 17 nurses [84]. In a long-term-care facility, 41% of 42 health care workers were found to have *Candida* spp. on their hands [89].

**Viruses**

Viruses are pathogens that infect living cells and tissues and are usually found in the living epidermis [90]. They are the smallest type of microbe, approximately 1/100 the size of a regular bacteria. Viruses are not living things and cannot replicate without infecting a living cell including fungi and bacteria. Viruses can be divided into five main groups by method of transmission: blood-borne viruses (hepatitis B virus, hepatitis C virus, and human immunodeficiency virus), respiratory route viruses (influenza virus, rhinovirus, coronavirus, and adenovirus), fecal-oral route viruses (rotavirus, enteroviruses, and hepatitis A virus), herpes viruses obtained from direct contact with skin, mucous membranes, or wounds (herpes simplex viruses, varicella zoster virus, cytomegalovirus, and Epstein-Barr virus), and exotic viruses such as viral hemorrhagic fever viruses (Ebola virus, Marburg virus, and Lassa fever virus) and rabies virus [91].
Viruses account for approximately 5% of all HAIs. On pediatric wards, the proportion is higher at 23% [92]. Most diseases caused by viruses are systemic, affecting the whole body. Since viruses invade host cells, it is difficult to kill them without harming the host cell itself. Antibiotics have no effect on viruses. The body's immune system can usually defend itself from less serious infections. For serious viral infections, such as human immunodeficiency virus and hepatitis, antiviral drugs that stop the virus from reproducing are used.

Hands play a major role in the transmission of viruses especially in blood-borne, fecal, and respiratory tract viruses. The detection and transmission of some viruses from the hands of health care workers has been described in a number of studies. In a dialysis unit, 23.8% of samples obtained from health care workers’ hands were positive for hepatitis C virus RNA after treating hepatitis C virus-positive patients despite the use of standard precautions. The rate was 8% after treatment of hepatitis C virus-negative patients [93]. Viruses from the respiratory tract are often found on hands. For example, rhinoviruses are found on the hands of up to 65% from people that have a common cold [94]. Rotavirus has been described as persisting on hands for up to 260 min, with 57% recovery after 20 min, 42.6% recovery after 60 min, and 7.1% recovery after 260 min [95]. Adenoviruses and hepatitis A virus have also been described to persist on human skin for many hours [96, 97].

Studies investigating the persistence of viruses on surfaces show that rotavirus and hepatitis A virus can survive for up to 60 days depending on the room temperature, humidity, and type of surface including surfaces with frequent hand contact like patient charts [98, 99]. Influenza A virus may survive on steel surfaces for up to 48 hours and on other materials such as paper for up to 12 hours [100].
2.1.3 Transmission

Patients can become exposed to harmful microorganisms through inhalation, ingestion, inoculation, contact, and transplacental transmission. HAIs are most commonly transmitted to patients via contact and inhalation of contaminated airborne microbial particles [101].

Contact transmission can be divided into direct, indirect, and contact with droplets [23]. Direct contact involves skin (or mucosa) to skin contact and the direct physical transfer of microorganisms from one patient to another or via hands of a HCP during patient care such as bathing or when providing therapy. Approximately half of all HAIs are due to inadequate HH by health care staff [102]. Indirect contact is when a patient touches a contaminated intermediate object, usually inanimate, such as furniture in the patient room or equipment used in providing treatment [23, 103]. Indwelling medical devices such as urinary catheters, vascular access devices, endotracheal tubes, tracheostomies, enteral feeding tubes and wound drains can be associated with development of HAIs [104].

Approximately 1,000,000 squames of skin are shed from normal skin daily [101]. These squames containing viable flora contaminate the immediate patient environment including linens, clothing, furniture and other nearby objects [105]. These contaminated objects can in turn be touched by other patients or HCPs and transferred to other patients, other people, or objects. Objects often contaminated with harmful microorganisms are bed linens, bedside tables and pressure cuffs [106]. Droplet transmission occurs when contaminated respiratory secretions are projected into the air by coughing or sneezing. Those secretions travel through the air potentially contaminating people or surfaces nearby [23].
Airborne transmission describes organisms that have a true airborne phase as part of their pattern of dissemination, such as tuberculosis [103]. Airborne droplet transmission is via particles that are less than 5μm that can remain suspended in the air and travel long distances potentially infecting patients, staff, and surfaces several meters away. Droplets larger than 5μm usually travel only a short distance of less than one meter [107]. Microorganisms within airborne droplets can be acquired by inhalation through the respiratory tract [23].

Some pathogens are able to survive on inanimate surfaces for long periods of time. These surfaces can act as long-term reservoirs during hospital outbreaks. Surfaces in busy, crowded units that have repeated contact with patients or hands of HCPs, including toilets, bedrails and doorknobs, have a greater amount of microorganisms than less frequently touched surfaces such as walls or windows and require more frequent cleaning and disinfection [103].

In their study investigating the role of contaminated environmental surfaces as reservoirs of MRSA in hospitals, Boyce et al. collected environmental cultures from the rooms of 30 patients colonized or infected with MRSA. Twenty-seven percent of the 350 collected samples were contaminated with MRSA. Contamination occurred in 73% of rooms of infected patients and 69% of rooms of colonized patients. The uniforms and gowns of 65% of nurses that had direct contact with patients with MRSA present in a wound or urine, were contaminated. Forty-two percent of staff that contacted contaminated surfaces and not patients contaminated their gloves [106].
HAI pathogens can be transient on the hands of some health care workers while actively multiplying in the hands of others. The hands of health care staff may serve as a passive vehicles of transmitting HAIs, but may also be reservoirs of HAI organisms [42].

In their study of the acquisition and transmission of *C. diff* infections, McFarland et al. collected specimens from 428 patients when admitted to a general medical ward and every three days for eleven months afterwards. Seven percent of patients tested positive at admission, 21% of those with negative results at admission acquired *C. diff* while admitted. Of those with *C. diff*, 37% had diarrhea. Both frequency and amount of time to acquire infection were significantly affected in patients that shared rooms with patients that had positive cultures. Among staff caring for infected patients, 59% had positive cultures of *C. diff* collected from their hands. Tests of the patient environment showed that 49% of rooms with infected patients and 29% of the rooms where patients were not infected were contaminated. At discharge, 82% of those patients infected still tested positive for *C. diff* [69].

### 2.1.4 Prevalence

Prevalence rates of HAIs in the United States reportedly range from 3.5% to 9.9%, affecting millions of patients every year [2, 108]. Factors including unit type, patient populations, and surgical procedures explain this range in infection rate [104, 109]. In a prospective, observational study of all infections occurring on the general and trauma surgery services at a single university hospital during a 3.5-year period, the authors identified 2,457 infections: 608 community-acquired, 1,053 on hospital wards, and 796 in the ICU. Most infections treated by surgeons were hospital-acquired. The most common sites of infection were the
abdomen, lung, and in wounds. The most common isolates were *Staphylococcus epidermidis*, *S. aureus*, and *Candida albicans*. The overall mortality rate was 13%, from 5% after acquiring infections in the community to 25% after acquiring infections in the ICU [78]. Plowman et al. report that 7.8% (95% CI; 7.0, 8.6) of patients in their 1994-95 study of the costs of HAIs in England, presented with one or more HAIs during the in-patient period [110].

In a study investigating the change in HAI rates over 10 years, researchers found steady increases in both HAI and community-acquired infections. Among 484,013 patients there was an increase in HAIs from *Acinetobacter baumannii* (from 1.9% in 1990 to 3.6% in 1999; \(P < .001\)) and *Candida albicans* (from 2.4% to 3.2%; \(P < .001\)), and increases in both HAI and community-acquired infections by MRSA (HAI: from 4.7% to 40.2% \(P < .001\); community-acquired: from 2.7 to 15.6% \(P < .001\)) [111].

2.1.5 Implications

This section describes the impact of HAIs on morbidity and mortality, financial burden on the health care system and their effect on antibiotic resistance.

**Socioeconomic**

HAIs in hospitals are a significant cause of morbidity and mortality in the United States [3], leading to additional days of treatment for patients [112-115], an increased risk of death [4, 5], and further financial burden on health care systems.
Klevens et al. report that in 2002, the estimated number of HAIs in hospitals in the United States was approximately 1.7 million. The estimated deaths associated with HAIs were 98,987: of these 35,967 were for pneumonia, 30,665 for bloodstream infections, 13,088 for UTIs, 8,205 for SSIs, and 11,062 for infections of other sites [3]. Multiple other studies confirm that the most prevalent HAIs are UTI, lower respiratory tract infection, SSI, and bloodstream infection [4, 116, 117]. The duration of additional hospitalization due to HAIs has been estimated to be 1 to 4 days for UTIs, 7 to 8.2 days for SSIs, 7 to 21 days for bloodstream infections, and 6.8 to 30 days for pneumonia [2]. Overall, patients with an HAI remained in hospital 2.5 times longer than uninfected patients [110].

Direct costs of treating an HAI can be measured by an increased length of patient stay, the number of tests required to diagnose, and the cost of drugs used to treat [8, 118]. HAIs account for > 90% of costs in surgical patients from orthopedics, gynecology, urology, and general surgery. Antibiotic therapy is the second largest cost. Patients with multiple HAI infections cost the most to treat while those with only a UTI cost the least [118].

Expenses can be calculated by reviewing patient records and services provided to patients diagnosed with HAIs to determine which were connected to their treatment [119]. Costs can also be calculated by matching similar patients that do and do not have HAI(s) and comparing the costs of treatment [8, 120]. In the United States, the estimated average costs of these infections are $558 to $593 for each UTI, $2,734 for each SSI, $3,061 to $40,000 for each bloodstream infection, and $4,947 for each pneumonia. The overall financial burden created by HAIs has been estimated to be $4.5 billion per year in the United States alone; even minimally effective infection control programs are cost-effective [2].
In the United Kingdom, patients with HAIs incurred hospital costs 2.9 (95% CI; 2.6, 3.0) times higher than uninfected patients. National estimates projected that 320,994 patients contract at least one HAI per year costing the National Health Service an estimated £930.62 million per year [110].

There are also indirect costs, such as the costs of rehabilitation after hospitalization, outpatient medications, and follow-up appointments [103]. Additionally, with longer patient stays, fewer beds are available to treat other patients.

**Antibiotic resistance**

Antibiotics, or antimicrobials, are medications that fight infections caused by bacteria by preventing or slowing their growth. Antibiotic resistance is when bacterial infections that could previously be treated with antibiotics, develop the ability to resist those treatments by existing medications and continue to harm the host. Antibiotics are used widely to treat infectious diseases in humans and animals [6]. Indiscriminate use of antibiotics is a major factor in promoting antimicrobial resistance.

Other factors that contribute to the entry of resistant pathogens into hospitals include: the transfer of patients with resistant pathogens from other health care facilities, patient-to-patient transfer of pathogens from poor HH practices, and transfer of resistant genes among organisms [121]. The most common bacterial pathogens include penicillin resistant Streptococcus pneumoniae, MRSA, VRE, multidrug-resistant Gram-negative bacilli, and *C. diff*[121-123].
The past 30 years have shown an increase in resistance to antimicrobials among microorganisms isolated from infected patients. Almost every major bacterial pathogen has acquired clinically important resistance to antimicrobials during this period [122]. This increase of HAIs parallels the increased use of antibiotics in hospitals [36]. Globally, an increase in the occurrence and spread of antibiotic-resistant bacteria in hospitals has been reported. It is known to be more common in hospitals, primarily in ICUs, although use of antibiotics in the community setting is often the origin of hospital antibiotic resistance [121, 122]. Outbreaks caused by multi-resistant organisms have occurred in critical care units and newborn nurseries, where heavy use of antibiotics was shown to be a major factor in the continuation of infections [36, 124, 125].

The use of antibiotics in the ICU is higher than in non-ICU areas. This higher rate of use parallels the higher rates of resistance observed in ICU areas for third-generation cephalosporins and Enterobacter species, vancomycin and enterococci, and antipseudomonal penicillins. In other cases, rates of use were similar throughout the hospital, but resistance remained high in ICUs. For example, use of the methicillin group of agents was similar in all hospital areas, but rates for MRSA or methicillin-resistant coagulase-negative staphylococci were higher in ICUs. This suggests that other factors such as cross-transmission play a role in developing antibiotic-resistance [54].

Analysis of data reported to CDC’s National Healthcare Safety Network shows that the percentage of enterococci associated with HAIs that are resistant to vancomycin increased 20 times from January 1989 to March 1993. The percentage of healthcare-acquired VRE increased from 0.3% in 1989 to 7.9% in 1993 (P < .0001). Among patients in ICUs with
HAIs, the percentage of VRE increased from 0.4% in 1989 to 13.6% in 1993 ($P < .0001$).

Vancomycin resistance varied by site of infection: gastrointestinal, skin and soft tissue, and bloodstream sites had the highest percentage of resistant enterococci (7.8%, 4.1%, and 3.8%, respectively). Many of these strains are resistant to all available antimicrobial agents including β-lactams and aminoglycosides, making them nearly untreatable [64].

Suggested methods to slow the development of antibiotic resistance include: minimizing the use of antibiotics to limit the selection and emergence of a resistant clone, improving HH, isolation practices to limit transmission of any antibiotic-resistant organisms, and the implementation of systems to quickly identify new patients that may be carrying antibiotic resistant pathogens [13].

Despite the need for new antimicrobial agents to treat HAIs, some pharmaceutical companies are reducing anti-infection research programs. The United States Food & Drug Administration’s approval of new antibacterial agents has decreased by 56% (1998–2002 vs. 1983–1987). Ways to increase development of new antimicrobial agents and new strategies to delay or prevent resistance are needed since the introduction of new antimicrobial drugs has declined [126].

2.2 Preventing HAIs

HAIs are a preventable cause of morbidity and mortality. In an effort to estimate the proportion of potentially preventable HAIs, Harbarth et al. conducted a systematic review of published literature describing multi-modal, and intervention and transmission studies attempting to reduce HAIs [14]. This evaluation of thirty reports suggests that the potential
exists to decrease HAI rates, from a minimum reduction effect of 10% to a maximum effect of 70%. The reduction effect depends on the health care setting, study design, baseline infection rates and type of infection. Based on these estimates, at least 20% of all HAIs are likely preventable [14].

Similarly, in their study evaluating the efficacy of infection surveillance and control programs in preventing HAIs in United States hospitals, Haley et al. estimate that 32% of HAIs can be prevented. To accomplish this reduction, they suggest that hospitals must institute organized surveillance and control activities, have infection control and prevention staff in place, and utilize a system for reporting infection rates to staff [7].

2.2.1 Standard precautions

Standard precautions are a set of infection control practices used to prevent the transmission of diseases that can be acquired by patients while in health care settings. These practices should be followed when providing care to all patients if they appear infectious, symptomatic, or not. Multiple agencies including the CDC and WHO have developed and promote standard precautions that include: performing HH, use of personal protective equipment (PPE), appropriate patient placement, respiratory hygiene, safe injection, and safe handling of potentially contaminated equipment [127, 128].
Table 2-1: Standard precautions for the care of all patients in all health care settings.

<table>
<thead>
<tr>
<th>Component</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hand hygiene</strong></td>
<td>After touching blood, body fluids, secretions, excretions, contaminated items; immediately after removing gloves; between patient contacts.</td>
</tr>
<tr>
<td><strong>Personal protective equipment</strong></td>
<td></td>
</tr>
<tr>
<td>Gloves</td>
<td>For touching blood, body fluids, secretions, excretions, contaminated items; for touching mucous membranes and non-intact skin.</td>
</tr>
<tr>
<td>Gown</td>
<td>During procedures and patient-care activities when contact of clothing/exposed skin with blood/body fluids, secretions, and excretions is anticipated.</td>
</tr>
<tr>
<td>Mask, eye protection, face shield</td>
<td>During procedures and patient-care activities likely to generate splashes or sprays of blood, body fluids, secretions, especially suctioning, endotracheal intubation, during aerosol-generating procedures on patients with suspected or proven infections transmitted by respiratory aerosols wear a fit-tested N95 or higher respirator in addition to gloves, gown and face/eye protection.</td>
</tr>
<tr>
<td><strong>Soiled patient-care equipment</strong></td>
<td>Handle in a manner that prevents transfer of microorganisms to others and the environment; wear gloves if visibly contaminated; perform hand hygiene.</td>
</tr>
<tr>
<td><strong>Environmental control</strong></td>
<td>Develop procedures for routine care, cleaning, and disinfection of environmental surfaces, especially frequently touched surfaces in patient-care areas.</td>
</tr>
<tr>
<td><strong>Textiles and laundry</strong></td>
<td>Handle in a manner that prevents transfer of microorganisms to others and to the environment.</td>
</tr>
<tr>
<td><strong>Needles and other sharps</strong></td>
<td>Do not recap, bend, break, or hand-manipulate used needles; if recapping is required, use a one-handed scoop technique only; use safety features when available; place used sharps in puncture-resistant container.</td>
</tr>
<tr>
<td><strong>Patient resuscitation</strong></td>
<td>Use mouthpiece, resuscitations bag, other ventilation devices to prevent contact with mouth and oral secretions.</td>
</tr>
<tr>
<td><strong>Patient placement</strong></td>
<td>Prioritize for single-patient room if patient is at increased risk of transmission, is likely to contaminate the environment, does not maintain appropriate hygiene, or is at increased risk of acquiring or developing adverse outcome following infection.</td>
</tr>
<tr>
<td><strong>Respiratory hygiene</strong></td>
<td>Instruct symptomatic persons to cover mouth/nose when sneezing/coughing; use tissues and dispose in no-touch receptacle; observe hand hygiene after soiling of hands with respiratory secretions; wear surgical mask if tolerated or maintain spatial separation, &gt;3 feet if possible.</td>
</tr>
</tbody>
</table>

Note. From [9].
Of these precautions, HH is the most effective way to reduce HAIs and the transmission of antimicrobial-resistant pathogens [129]. HH includes both washing of hands with soap and water and the use of alcohol-based hand rub (ABHR). ABHR is the preferred preparation for cleaning when hands are not visibly soiled. HH should be performed before and after contact with the patient or the patient environment, before an aseptic procedure, and after contact with body fluids. Section 2.3 presents HH in greater detail.

PPE includes such items as gloves, gowns, and face shields. Use of PPE depends on the risk of exposure to body fluids and contaminated surfaces, and does not eliminate the need for HH. Respiratory hygiene, also referred to as cough etiquette, prevents the spread of infection through respiratory secretions by requiring people to cover their nose and mouth when coughing or sneezing, followed by HH. Table 2-1 shows recommendations for the application of standard precautions for the care of all patients in all health care settings, developed by the Healthcare Infection Control Practices Advisory Committee (HICPAC) et al. [9].

2.2.2 Transmission-based precautions

Transmission-based or isolation precautions are necessary during the care of patients with highly transmissible or epidemiologically important pathogens. These practices are designed to interrupt contact, droplet, and airborne transmission [107]. For diseases that have multiple transmission routes, multiple transmission-based precautions may be used. These precautions are used in addition to the standard precautions [9]. For all transmission routes, it is advisable to limit transport of patients, use patient-specific equipment, and house
patients in single-bed rooms when possible. If single-bed rooms are not available, it may be possible to cohort patients with the same infection as long as no other infections are present.

Contact precautions are used to prevent transmission of infectious agents spread by direct or indirect contact with the patient or patient environment. Contact Precautions also apply when excessive wound drainage, fecal incontinence, or other discharges from the body are present or expected. Avoid touching potentially contaminated surfaces or equipment. Wear gloves to prevent contact with or transmission of pathogens. Wear a clean, nonsterile gown when entering and remove it before leaving the room [107]. When single-patient rooms are not available, separate beds by more than three feet to reduce contact between patients [9].

Droplet precautions are used for patients infected with pathogens that spread by respiratory droplets larger than 5μm produced when coughing, sneezing, or during procedures such as bronchoscopy. When single-patient rooms are not available, separate beds by more than three feet with curtains drawn between the beds. Everyone entering the patient room should wear a mask, especially when within one meter of the patient [107]. Patients on droplet precautions should also wear a mask when travelling outside their room [9].

Airborne precautions are used for patients infected with pathogens spread by respiratory droplets smaller than 5μm that can be suspended in the air and travel long distances. The patient should be moved to an isolation room that is under negative pressure with twelve changes per hour, discharged to the outdoors, with the door closed. Air filtration is needed if the air is circulated within the facility [107]. When dedicated airborne infection isolation rooms are not available, patients should be moved to single-bed rooms, with the door
closed. All people entering rooms under airborne precautions should wear a mask or respirator, depending on the disease, before entering the room [9].

### 2.2.3 Decontamination

Proper cleaning, disinfection, and sterilization of medical devices, surgical equipment and objects in the patient environment are necessary to reduce the risk of introducing pathogens to the patient that may cause infections. Risk of infection can result from a breach of host barriers, person-to-person, and environment-to-person transmission. Instruments and items for patient care are categorized as being either critical, semi-critical, or noncritical according to the degree of risk for infection associated with their use. Each level requires different levels of decontamination [130].

### Cleaning

Cleaning is the removal of visible soil, including organic and inorganic material, from objects and surfaces. Cleaning is required before high-level disinfection and sterilization because materials that remain on the surfaces reduce the effectiveness of the processes. Cleaning can be done manually or mechanically using water with detergents or enzymatic products [130].

Noncritical items are those that come in contact with intact skin but not mucous membranes. Intact skin is an effective barrier to most microorganisms. Noncritical items can be patient care related such as bedpans, blood pressure cuffs, and stethoscopes. Non-critical surfaces include bed rails, furniture and floors. The risk of acquiring infection from non-critical
items is minimal so low-level disinfection or simple cleaning is adequate. Most reusable noncritical items can be decontaminated where they are [103, 130].

Manual cleaning is used for fragile instruments or when mechanical methods are not available. Friction and fluidics are used with manual cleaning. Friction can be accomplished by rubbing or scrubbing with a brush. Fluids under pressure are used to remove materials from items being cleaned after brushing and when the object does not allow use of a brush. Common types of mechanical cleaners are ultrasonic cleaners, washer-decontaminators, washer-disinfectors, and washer-sterilizers [130].

Sterilization

Critical items are any object that may enter sterile tissue or the vascular system and must be free from all microorganisms. This category includes surgical instruments, catheters, implants, and ultrasound probes used in sterile body cavities. Most of the items in this category are purchased sterile but may be decontaminated after use.

Critical medical devices must be sterilized and kept from being contaminated before use to avoid infections in patients [103]. Sterilization destroys all microorganisms on the surface of an object or in a fluid to prevent disease transmission associated with the use of that item, by physical or chemical methods. When chemicals are used to destroy all forms of microbiologic life, they can be called chemical sterilants. The same chemicals used with shorter exposure periods also can be part of the disinfection process (high-level disinfection) [130].
Most medical and surgical devices used in health care are heat stable and are sterilized using steam. Since 1950 there has been an increased use of plastics and other materials that are not heat stable or that are moisture sensitive, requiring low-temperature sterilization. For devices made of such materials, processes using ethylene oxide gas, hydrogen peroxide gas plasma, peracetic acid, and ozone can be used [130]. Ionizing radiation is another method used primarily for industrial sterilization of single-use items [103].

Disinfection

Semi-critical items contact mucous membranes or non-intact skin. This category includes respiratory therapy and anesthesia equipment. Semi-critical items require high-level disinfection using chemical disinfectants. High-level disinfection is a physical or chemical process performed on inanimate objects and surfaces that destroys most pathogenic organisms, but not bacterial spores. Cleaning, followed by high-level disinfection with liquid chemicals or wet pasteurization should eliminate enough pathogens to prevent transmission of infection. While sterilization is preferable to disinfection, it may not be practical in a busy hospital [130].

2.3 Hand hygiene

For over 150 years the medical community has known that performing HH before contacting patients can reduce the spread of disease. In the mid 1800’s, two physicians working independently, each concluded that the spread of puerperal fever was due to unwashed hands transmitting the disease to patients [131]. In 1846, Ignac Semmelweis, working in the maternity clinic at the General Hospital of Vienna, observed that the
mortality rate of mothers in the First Clinic (10%) were much higher than in the Second Clinic (< 4%). The First Clinic was staffed by physicians and medical students while the Second Clinic was served by midwives. Semmelweis concluded that the doctors and students, who also conducted autopsies, carried “cadaverous particles” from dead bodies to the mothers in the First Clinic. In 1947, after insisting that those conducting autopsies wash their hands in a chloride of lime solution before attending to the maternity clinic, mortality rates fell in the First Clinic to those of the midwives who did not conduct autopsies [131, 132]. When Semmelweis left Vienna, handwashing frequency decreased and mortality rates increased on the First Clinic. Application of contemporary statistical analyses of the effect of Semmelweis implementing handwashing at the hospital, including control groups from other hospitals, supports the hypothesis that the “cadaveric particles” caused the increased mortality rate on First Clinic [133].

In the United States, 1843, Oliver Wendell Holmes investigated the spread of puerperal fever and presented his results to the Boston Society for Medical Improvement and published his findings in the New England Quarterly Journal of Medicine and Surgery [134]. In the hopes of reaching a larger audience he republished the paper as a booklet titled Puerperal Fever as a Private Pestilence in 1855 [135]. The overriding message in these publications was that puerperal fever was transmitted by physicians not washing their hands [136].

Through a series of studies conducted in the 1960s about the acquisition of S. aureus by infants, Mortimer et al. demonstrated that the hands of health care staff members, in this case nurses, were probably the most important source of transmitting HAIs to patients.
While *S. aureus* was sometimes spread by becoming airborne, (6%-10% of the time) the majority of cases were from the hands of caregivers. Fifty-four percent of babies touched by carriers of *S. aureus* that did not wash their hands became colonized by the caregiver’s strain. Non-carrier nurses that contacted a baby that was colonized with *S. aureus* and then touched another baby without washing first, transferred *S. aureus* from the first baby to the second 43% of the time. With the use of antiseptic handwashing, transmission rate dropped to 14% [137, 138].

### 2.3.1 Indications for hand hygiene

The following is a list of indications and recommendations for HH in health care settings developed by the CDC, HICPAC, the Society for Healthcare Epidemiology of America, Association for Professionals in Infection Control and Epidemiology, Inc., and the Infectious Diseases Society of America [103]. Each recommendation was classified into one of the following four categories:

- **IA:** Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.
- **IB:** Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies and a strong theoretical rationale.
- **IC:** Required for implementation, as mandated by federal and/or state regulation or standard.
- **II:** Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale.
Indications for Hand Hygiene Actions

A) Wash hands with a non-antimicrobial/antimicrobial soap and water when hands are visibly soiled or contaminated with proteinaceous material. (IA)

B) If hands are not visibly soiled, use an ABHR for routinely decontaminating hands in all other clinical situations described in items 1 through 8 listed below. (IA)

Decontaminate hands

1) before having direct contact with patients. (IB)

2) before donning sterile gloves when inserting a central intravascular catheter. (IB)

3) before inserting indwelling urinary catheters, peripheral venous catheters, or other invasive devices that do not require a surgical procedure. (IB)

4) after contact with a patient’s intact skin (as in taking a pulse or blood pressure, or lifting a patient). (IB)

5) after contact with body fluids or excretions, mucous membranes, non-intact skin, or wound dressings, as long as hands are not visibly soiled. (IA)

6) if moving from a contaminated-body site to a clean-body site during patient care. (II)

7) after contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient. (II)

8) after removing gloves. (IB)

C) Wash hands with antimicrobial/non-antimicrobial soap and water if exposure to Bacillus anthracis is suspected or proven. The physical action of washing and rinsing hands under such circumstances is recommended because all hand antiseptics have poor activity against spores.
2.3.2 Preparations used for HH

Antiseptics available for safe and prolonged use for decontaminating hands fall into three main categories and opportunities: plain soaps for removing visible dirt and organic matter, antiseptics with antimicrobial ingredients, and ABHRs [139, 140].

Plain soap

Non-medicated or plain soaps are detergent-based products that contain little or no antimicrobial ingredients. Washing of hands with plain soap, also known as social washing, has few indications in health care [141]. Use of plain soap is recommended when hands are visibly soiled with body fluids, before eating, after using the washroom, and when bacterial spore contamination is possible [16].

Much like the cleaning process described in section 2.2.3 on decontamination, washing with non-medicated soap reduces the numbers of microorganisms and viruses on the skin by mechanically removing what could not be removed by other processes [140]. This mechanical process, however, been shown to be incomplete. In a study evaluating the prevalence of Gram-negative bacilli as part of the non-transient flora on the hands of nurses, researchers found that Gram-negative bacilli was still on the hands of ten out of ten HCPs after having washed their hands five times with plain soap and water [142].

Continuous use of soaps and detergents can cause damage to hands by increasing pH level, reducing lipid content, drying out the skin, and can increase microbial shedding of skin squames [103].
Antimicrobial agents

Antimicrobial agents is a general term for the drugs, chemicals, or substances that either kill (cidal) or slow the growth (static) of microbes [143]. These agents include antibacterial drugs, antiviral agents, antifungal agents, and antiparasitic drugs. Historically, two of the most commonly used agents in clinical handwashes have been chlorhexidine and triclosan [140].

Introduced in the 1950’s, chlorhexidine is used as an antiseptic, disinfectant and preservative. Chlorhexidine gluconate (CHG) is commonly used either at 0.5% to 0.75% in aqueous solutions and at 2% to 4% in other detergent preparations [144]. At low concentrations, it is effective against Gram-positive and Gram-negative bacteria primarily through damaging the cell membrane, and also by hindering adenosine triphosphatase activity. At higher concentrations, it prompts precipitation of cytoplasmic protein and nucleic acids. CHG is also capable of damaging the cytoplasmic membrane of yeasts and preventing the outgrowth of bacterial spores [145, 146].

Triclosan, in clinical use since 1965, is a broad-spectrum antibiotic and anti-fungal agent found in many consumer and health care products including handwashes, hand lotions and creams, and surgical scrubs [147]. In antiseptic soaps, it is generally used at 1% concentration [140]. Triclosan prevents lipid synthesis in pathogens by inhibiting the enzyme enoyl-acyl carrier protein reductase [148]. In clinical studies, mutations selected by exposure to triclosan caused cross-resistance with other antimicrobial agents in *Escherichia coli*. The ability of *Escherichia coli* to acquire genetic resistance to triclosan and related compounds suggest that its continued widespread use could select resistance against
multiple drugs [149, 150]. In 2017, Halden et al. published *The Florence Statement on Triclosan and Triclocarban*, describing the hazards of and lack of demonstrated benefit from common uses of triclosan and triclocarban. Their recommendations include that 1) the use of antimicrobial chemicals be avoided except where health benefit and safety can be demonstrated. 2) Where antimicrobials are necessary, use safer alternatives that are not persistent and pose no risk to humans or ecosystems [151].

When comparing the efficacy of 4% CHG and 1% triclosan on the composition of the hand bacterial flora of clinical staff on a surgical unit, it was found that the CHG solution was consistently more effective at reducing total counts than triclosan and was more likely to eliminate Gram-negative bacteria. Whereas, 1% triclosan was able to eliminate MRSA, while 4% CHG could not ($P = .0001$) [152].

**Alcohol-based hand rub**

When hands are not visibly soiled, the use of ABHR is the preferred preparation for decontaminating hands [16]. ABHRs are less technique dependent than use of soap and water [153], act quickly, are effective against a broad antimicrobial spectrum, do not require additional facilities such as sinks, removes risk of contamination from contaminated bars of soap or water, and do not contribute to increased antibiotic resistance [154].

Drawbacks to use of ABHR are a limited duration of antimicrobial activity, dry skin with extended use, little effect on visibly soiled hands, and little or no effect on bacterial spores [103, 155]. In a study comparing the efficacy of an alcohol based solution versus antiseptic soap to reduce hand contamination, both preparations reduced bacterial counts. However,
the median reduction of bacterial contamination using the alcohol-based solution was significantly higher than the reduction by handwashing (83% (interquartile range 78-92%), 58% (58-74%), respectively, $P = .012$) [156].

The primary antimicrobial ingredient in most alcohol-based products is either ethanol, isopropanol, or n-propanol, and may contain other active ingredients such as hexachlorophene, quaternary ammonium compounds, povidone-iodine, or triclosan [157]. Alcohols are able to kill bacteria by denaturing; alcohol molecules bond with the cell membrane making it more soluble in water, causing the membrane to fall apart. Proteins inside the bacteria then bond with alcohol where their amino acids also lose structure, causing the protein and therefore the bacteria to die. Solutions of 60% - 80% alcohol are most effective, providing an optimal balance of active ingredient and the required amount of water to allow the denaturation process to occur [158]. Other factors that can affect efficacy are contact time, volume of alcohol used, and wetness of hands [159].

Recommendations for the use of ABHR have expanded over the past few decades. In 1985 the CDC only recommended the use of ABHR when sinks were not available [16, 160]. In 1995, the Association for Professionals in Infection Control HH guidelines extended use of ABHR in clinical settings [161]. In 1996 HICPAC recommended that a waterless antiseptic agent be used with patients with multidrug-resistant pathogens [162]. In the 2009 the WHO guidelines on HH in health care describe ABHRs as the “gold standard to protect patients from the multitude of harmful resistant and non-resistant organisms” transmitted by HCPs’ hands [17].
Gloves

The use of disposable nonsterile medical gloves is recommended to prevent contamination of the hands of HCPs [9]. Gloves should be worn when contact with blood, body fluids, mucous membranes, and non-intact skin is expected. Gloves are also recommended when working with patients that are under contact precautions and when working with potentially contaminated equipment or surfaces [16, 163, 164]. To prevent contamination of or by the gloves themselves, HCPs should remove their gloves after patient care, not reuse gloves, and change gloves between patients and when moving from a potentially contaminated body site to a clean body site within the same patient [9, 103, 165].

The use of gloves does not replace the need for HH and does not guarantee protection from HAIs [166]. HH should be performed before putting on gloves and after their removal. If the hands of a caregiver are contaminated, the gloves may become contaminated when being put on and contaminants passed onto the patient. If gloves become contaminated while in use, they may contaminate the caregiver’s hands during glove removal. It is also possible that glove integrity can be compromised. Perforations have been found in 17% of gloves [167] and 83% of gloves with perforations are not detected by the wearer [168]. In their study of the effectiveness of gloves to prevent hand carriage of VRE, Tenorio et al. found that, after having contact with a patient colonized or infected with VRE, 17 of 44 HCPs acquired the patient’s VRE strain(s) on their gloves. Five of those HCPs had a patient’s strain on their hands after glove removal. Gloves reduced the risk of HCP hand contamination by 71% [166].
2.3.3 Hand hygiene compliance

Compliance with HH practices among HCPs is known to be low. Compliance rates have been described to vary between 16 and 81% [169], with an overall average of 40% [16]. In their study investigating predictors of HH compliance, Pittet et al. observed 2834 opportunities for HH from multiple HCP groups. The average compliance rate was 48%, varying across hospital unit type and HCP category. This section describes the HH guidelines used by HCPs and the predictors and barriers to compliance with them.

Guidelines and reporting

The promotion of HH requires a clear, robust and simple conceptual framework. The WHO First Global Patient Safety Challenge ‘Clean Care is Safer Care’ consists of educational and promotional tools to increase HH. Among them are the *Your 5 moments for Hand Hygiene*: a set of five moments when HH is required to interrupt microbial transmission during patient care. These moments are applicable to a wide range of patient care activities and health care settings.[170] Direct observation of the WHO’s *Your 5 Moments* guidelines, or adaptations of them, have become the primary measure of HH compliance in health care worldwide [18, 171, 172].

Beginning 2015 in the United States, the Hospital-Acquired Condition (HAC) Reduction Program was launched. This is a Medicare pay-for-performance program that links Medicare payments to health care quality in inpatient hospital settings. Section 1886(p) of the Social Security Act established the HAC Reduction Program to encourage hospitals to reduce HAIs. The HAC Reduction Program requires the Secretary of Health and Human
Services to reduce payments to hospitals that rank in the worst-performing 25% of all hospitals with respect to HAC quality measures. The Centers for Medicare & Medicaid Services (CMS) may reduce these hospitals’ payments by one percent. Hospitals are assigned a HAC score based on data for six quality measures in two domains with Domain 1 representing 15% of the total HAC score, and Domain 2 representing 85%. The measures for the 2019 fiscal year are:

- **Domain 1 – CMS Patient Safety Indicator (PSI) 90 (CMS PSI 90)**
  - PSI 03 — Pressure ulcer rate
  - PSI 06 — Iatrogenic pneumothorax rate
  - PSI 08 — In-hospital fall with hip fracture rate
  - PSI 09 — Perioperative hemorrhage or hematoma rate
  - PSI 10 — Postoperative acute kidney injury requiring dialysis rate
  - PSI 11 — Postoperative respiratory failure rate
  - PSI 12 — Perioperative pulmonary embolism or deep vein thrombosis rate
  - PSI 13 — Postoperative sepsis rate
  - PSI 14 — Postoperative wound dehiscence rate
  - PSI 15 — Unrecognized abdominopelvic accidental puncture/laceration rate

- **Domain 2 – National Healthcare Safety Network HAI measures:**
  - Central line-associated bloodstream infection
  - Catheter-associated urinary tract infection
  - Surgical site infection (colon and hysterectomy)
  - Methicillin-resistant *Staphylococcus aureus* bacteremia
  - *Clostridium difficile* infection
The Patient Protection and Affordable Care Act requires the CMS to publicly report hospitals’ performance information. Following the Scoring Calculations Review and Corrections period, the CMS publicly reports hospitals’ measure scores, domain scores, and HAC Reduction Program data on the Medicare website (www.medicare.gov/hospitalcompare/search.html) [173].

All studies for this thesis took place in Ontario, Canada. In 2008, the province’s Ministry of Health and Long-Term Care (MOHLTC) launched the Just Clean Your Hands program in an effort to improve HH practices to reduce the spread of HAIs among patients and staff. This program presents guidelines and recommendations around how to measure HH compliance and provides tools to track and report results. As part of the Public Hospitals Act; Regulation 965 [174], the MOHLTC also required hospitals to report on a number of patient safety indicators including HH compliance. Inpatient settings at all publically funded hospitals are required to report results of HH compliance monitoring to the MOHLTC. These self-reported results are made publicly available via the Health Quality Ontario website, searchable by institution, region, and indicator [175].

While the MOHLTC HH program is based on work by the WHO, recommendations are not identical. Table 2-2 presents descriptions of when and why HH should take place for each program. Moment 1 for the WHO is HH before patient contact only. The WHO has no distinct indicator for before environment contact. The MOHLTC has expanded the WHO Moment 1 to include HH before both patient and patient environment contact. The WHO provides separate moments for after contacting the patient or patient environment whereas the MOHLTC again collapses both indications into a single moment [176, 177].
Table 2-2: Moments for hand hygiene.

**WHO Your 5 Moments for Hand Hygiene**

<table>
<thead>
<tr>
<th>Moment</th>
<th>When</th>
<th>Why</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Before touching a patient</td>
<td>Clean your hands before touching a patient when approaching him/her.</td>
<td>To protect the patient against harmful germs carried on your hands.</td>
</tr>
<tr>
<td>2 Before clean/aseptic procedures</td>
<td>Clean your hands immediately before performing a clean/aseptic procedure.</td>
<td>To protect the patient against harmful germs, including the patient's own, from entering his/her body.</td>
</tr>
<tr>
<td>3 After body fluid exposure/risk</td>
<td>Clean your hands immediately after an exposure risk to body fluids (and after glove removal).</td>
<td>To protect yourself and the healthcare environment from harmful patient germs.</td>
</tr>
<tr>
<td>4 After touching a patient</td>
<td>Clean your hands after touching a patient and her/his immediate surroundings, when leaving the patient's side.</td>
<td>To protect yourself and the healthcare environment from harmful patient germs.</td>
</tr>
<tr>
<td>5 After touching patient surroundings</td>
<td>Clean your hands after touching any object or furniture in the patient's immediate surroundings, when leaving - even if the patient has not been touched.</td>
<td>To protect yourself and the healthcare environment from harmful patient germs.</td>
</tr>
</tbody>
</table>

**MOHLTC Your 4 Moments for Hand Hygiene**

<table>
<thead>
<tr>
<th>Moment</th>
<th>When</th>
<th>Why</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Before initial patient/patient environment contact.</td>
<td>Clean your hands when entering: before touching patient or before touching any object or furniture in the patient's environment.</td>
<td>To protect the patient/patient environment from harmful germs carried on your hands.</td>
</tr>
<tr>
<td>2 Before aseptic procedure.</td>
<td>Clean your hands immediately before any aseptic procedure.</td>
<td>To protect the patient against harmful germs, including the patient's own germs, entering his or her body.</td>
</tr>
<tr>
<td>3 After body fluid exposure risk.</td>
<td>Clean your hands immediately after an exposure risk to body fluids (and after glove removal).</td>
<td>To protect yourself and the healthcare environment from harmful patient germs.</td>
</tr>
<tr>
<td>4 After patient/patient environment contact.</td>
<td>Clean your hands when leaving: after touching patient or after touching any object or furniture in the patient's environment.</td>
<td>To protect yourself and the healthcare environment from harmful patient germs.</td>
</tr>
</tbody>
</table>

Note. Data adapted from [176, 177].
Among its original set of recommendations, the MOHLTC indicates that direct, manual observation is the recommended method for HH compliance data collection and provides a paper observation tool for recording data. The use of direct manual observation to determine HH compliance presents a number of implementation issues related to cost [178], time, biases, sample size, and standardization across institutions. While direct observation was still the primary method for collecting data in 2008, there have been advances made in the development of EMSs that potentially address a number of these concerns [179].

The MOHLTC patient safety indicator for HH is called *Hand hygiene compliance among health care providers*. This indicator measures HH compliance by health care staff before initial contact with the patient or patient environment and after contact with the patient or patient environment. These measures align with Moments 1 and 4 of the *Your 4 Moments for Hand Hygiene* guidelines seen in Table 2-2 [177]. The MOHLTC requires a minimum number of HH observations to be reported based on the number of beds in the reporting facility. A facility with 100 beds requires a minimum of 200 opportunities to be observed, or two per bed. The minimum number of observed opportunities is 50, even when there are less than 25 beds [180]. These observations are reported as a percentage of compliance by Moment and site, annually. Institutions with multiple sites report each site separately.

The *Just Clean Your Hands* program recommendations for recording and reporting HH compliance are broader than those for the MOHLTC. They include observations for all four Moments, HCPs, and HH technique. Tools to track and generate reports including graphs are provided. Sample size recommendations are the same as those for MOHLTC reporting.
Predictors of compliance

Multiple observational and interventional studies have been conducted to identify the predictive factors for HH compliance. These predictors can be grouped into general categories including HCP group, type of patient care, risk of contracting HAIs, and level of institutional support (Table 2-3) [17].

In their 2008 investigation into the effect of professional education on HH compliance, Duggan et al. covertly observed 2,373 HH opportunities from multiple HCP groups for 22 weeks both before and after a site visit from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), now known as the Joint Commission. They found that while unit location, time of shift, and day of the week were factors associated with adherence to HH guidelines, the strongest predictor was HCP group. Attending physicians and medical trainees were less likely to follow HH guidelines ($P < .001$). The HCP group predictor also extended into the ability of the JCAHO site visit to affect HH compliance. Whereas nurses and therapist/technician groups’ HH compliance improved after the JCAHO visit ($P = .001, P < .001$), the medical trainees’ compliance remained relatively unaffected ($P = .072$) and the attending physician group compliance rate went down ($P = .177$) [181].

In 2001, Lipsett and Swoboda published findings from their study of HH compliance among HCP groups and their risk of acquiring and transmitting infections. HH opportunities were classified as being either high or low-risk. High-risk opportunities included after contact with a patient or body fluid and after patient care. Low-risk opportunities included indirect patient contact or hospital maintenance. Groupings and overall compliance results for this study were physicians; 15%, nurses; 50%, and nursing support personnel; 37%. In high-risk
opportunities, physicians (OR 5.58, 95% CI 2.49–12.54; nursing support personnel, OR 1.73, 95% CI 1.13–2.64; nurses, OR 0.98, 95% CI 0.77–1.23) were significantly less likely to perform HH compared to nurses [182].

**Table 2-3: Predictive factors for hand hygiene compliance**

<table>
<thead>
<tr>
<th>Predictive factors for hand hygiene compliance</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HCP group</strong></td>
<td></td>
</tr>
<tr>
<td>Non-doctor HCP status (with attending doctors as reference group)</td>
<td>Duggan et al., 2008 [181]</td>
</tr>
<tr>
<td>Respiratory therapist (with nurses as reference group)</td>
<td>Harbarth et al., 2001 [183]</td>
</tr>
<tr>
<td></td>
<td>Harbarth et al., 2002 [184]</td>
</tr>
<tr>
<td><strong>Type of patient care</strong></td>
<td></td>
</tr>
<tr>
<td>Under precaution care (perceived as greater risk of transmission to HCPs themselves</td>
<td></td>
</tr>
<tr>
<td>• care of patient under contact precautions</td>
<td>Dedrick et al., 2007 [185]</td>
</tr>
<tr>
<td>• care of patient in isolation room</td>
<td>Swoboda et al., 2007 [186]</td>
</tr>
<tr>
<td>Completing care / between patients</td>
<td>Pessoa-Silva et al., 2007 [187]</td>
</tr>
<tr>
<td><strong>Activities perceived as having a high risk of cross-contamination or cross-infection to HCPs</strong></td>
<td>Lipsett &amp; Swoboda, 2001 [182]</td>
</tr>
<tr>
<td>(e.g. after direct patient contact; before wound care; before/after contact with invasive devices or aseptic techniques; before/after contact with body fluid secretions; contact with nappies/diapers; or assessed by level of dirtiness of tasks)</td>
<td>Harbarth et al., 2001 [183]</td>
</tr>
<tr>
<td></td>
<td>Harbarth et al., 2002 [184]</td>
</tr>
<tr>
<td></td>
<td>Kudzu et al., 2005 [188]</td>
</tr>
<tr>
<td></td>
<td>Jenner et al., 2006 [189]</td>
</tr>
<tr>
<td></td>
<td>Pessoa-Silva et al., 2007 [187]</td>
</tr>
<tr>
<td></td>
<td>Trick et al., 2007 [190]</td>
</tr>
<tr>
<td></td>
<td>Haas &amp; Larson, 2008 [191]</td>
</tr>
<tr>
<td><strong>Type of unit</strong></td>
<td></td>
</tr>
<tr>
<td>• Intensive care unit</td>
<td>Novoa et al., 2007 [192]</td>
</tr>
<tr>
<td>• Neonatal ICU</td>
<td>Harbarth et al., 2001 [183]</td>
</tr>
<tr>
<td>• Acute haemodialysis unit</td>
<td>Arenas et al., 2005 [193]</td>
</tr>
<tr>
<td><strong>During the 3-month period after an announced accreditation visit</strong></td>
<td>Duggan et al., 2008 [181]</td>
</tr>
<tr>
<td><strong>Strong administrative support</strong></td>
<td>Rosenthal et al., 2003 [194]</td>
</tr>
</tbody>
</table>

Note. Adapted from [17].
In addition to predicting HH compliance rates associated with the level of risk of HH opportunities, HCP group assignment has been shown to predict colonization of hands with pathogenic organisms. In a study that included evaluations of colonization rate of HCP hands and the effect of HH frequency, 22 species of Gram-negative bacteria were found on the hands of 103 HCPs resulting in a 21% colonization rate. The frequency of HH was inversely correlated with colonization. Workers who cleaned their hands more than eight times per day were significantly less likely to be colonized than those that cleaned less than eight times per day. HCP group was a significant predictor of colonization. Nurses had the highest frequency of HH: 9%, physicians: 42%, and other hospital personnel: 22% ($P < .001$). Of 541 HAIs found among patients during the study, 119 (22%) were caused by the same species on the hands of HCPs [195].

Similarly, in a study investigating the transient flora found on the hands of HCPs, 1200 specimens were collected from 50 members of different HCP groups over six months. Transient flora was found on 39% of hands. By HCP group, transient flora were found on physicians: 45%, nurse assistants: 25%, nurses: 15%, stretcher-bearers: 10%, and radiology technicians: 5% [196].

**Perceived barriers to compliance**

In addition to the predictors of HH compliance above, HCPs report numerous perceived barriers to compliance. These barriers generally focus on the accessibility of HH supplies, skin irritation from HH preparations, high-workloads, lack of knowledge about HH guidelines, and a lack of institutional support [17, 19, 102, 197-200].
Access to product

Easy access to HH preparations is essential for compliance with HH guidelines. The amount of time required for HCPs to clean their hands can also affect HH compliance. Location of HH equipment and type of HH preparations available can influence the amount of time required to complete HH [165, 201]. In a study investigating the effect of the amount of time spent cleaning hands on HH compliance, researchers found that it took nurses an average of 62 seconds to leave a patient’s bedside, wash their hands with soap and water, and return to the patient [201]. They estimate that 75% less time is required when using bedside ABHR dispensers. Given the study unit’s 40% HH compliance rate, between 2.1 and 6.4 hours per shift are devoted to handwashing, whereas only 1.1 to 1.6 hours would be required if ABHR was used [201].

Providing easy access to HH materials is achievable by most health care facilities [169]. For example, ABHR should be made available at the entrance to every patient room, at the bedside, and in all high-traffic locations [16]. The introduction and promotion of the use of ABHR for regular patient care has been reported to have resulted in an increase in HH compliance from 48% to 66% and a decrease in the rate of HAIs from 16.9% to 9.9% [129].

Skin irritation

Skin irritation by HH preparations can be a significant barrier to HH compliance [16, 202]. Frequent use of these products, especially soaps and other detergents, can lead to dryness, cracking, eczema, and chronic irritant contact dermatitis. In a study about the prevalence of skin damage on the hands of nurses, 85.6% of 410 nurses that worked more than 30 hours
per week in acute care settings reported having skin damage at one time, while 25.9% had
damage at the time of the study. Predictors of skin damage in this population were the type
of soap used and the number of times gloves were worn \( P = .04 \) [203].

In a review of the literature on the effect of hand care practices on skin integrity, irritant
contact dermatitis is shown to be a highly prevalent occupational risk to HCPs due to
frequent HH, with a prevalence range of ~10% - 45% [139]. The use of ABHR may be a
better option for maintaining skin integrity than using plain soap and water or antiseptic
handwashes, since they are effective at counteracting pathogens and irritate skin less [139,
154, 204, 205].

Several studies have shown that lotions can also be used to protect hands by increasing skin
hydration, replacing skin lipids, and reducing skin irritation associated with hand hygiene
preparations. Regular use of hand cream or lotion can help prevent irritant contact dermatitis
and improve skin condition [139, 206, 207]. Further studies are needed to assess the
possible interaction between protective hand creams and lotions and antiseptic agents [103].

**Workload**

The amount of time available to perform HH can affect HH compliance rates. In their
investigation into the cause and mode of transmission of an outbreak of infections from
*Enterobacter cloacae*, Harbarth et al. observed periods of increased workload caused by
overcrowding and understaffing on the neonatal intensive-care unit. During the outbreak,
the unit meant to accommodate only 15 patients, housed up to 25. Infected patients required
more invasive procedures and devices. Overall HH compliance during the outbreak was
63% with HH not performed regularly between patient contacts. During the same period, 75% of staff did not clean their hands before contact with a patient’s intravenous line. In follow-up studies after the outbreak, with reinforcement of HH procedures, overall HH compliance increased to 75%, with non-compliance before contact with intravenous lines reduced to 30% [208].

Another study identifying the predictors of noncompliance with HH guidelines during routine patient care demonstrates an association between noncompliance and HCP workload. Workload, or activity index, was calculated as the number of HH opportunities per hour. HH compliance was worse when the activity index was high. Compliance decreased on average (±SD) by 5% ±2% for every ten opportunities per hour when the intensity of patient care exceeded ten opportunities per hour (P < .001). The lowest compliance rate was in ICUs (36%), where mean indications for HH were more frequent (43.4 opportunities per hour). The highest compliance rate was on pediatric units (59%), where the mean activity index was lower than elsewhere (24.4 opportunities per hour). These findings suggest that high workloads may decrease the quality of patient care [208].

**Knowledge of guidelines & perception of risk**

Boyce et al. summarize that a lack of knowledge of guidelines for HH, recognition of HH opportunities during patient care, and lack of awareness of the risk of cross-transmission of pathogens are barriers to good HH practices [16]. This lack of knowledge can affect an individual’s ability to correctly perceive susceptibility to a disease, the perceived seriousness of a disease, and evaluation of the barriers and benefits of HH compliance that can influence decisions around HH behaviours [209].
In a study of variables influencing HCP compliance with universal precautions in an emergency department, the authors report that the concept of susceptibility to disease is connected to the HCP’s belief or fear that they are personally vulnerable to it. And that the perceived seriousness of a disease might be determined by the emotional response the idea of the disease produces. HCPs weigh the obstacles to compliance, such as difficulty, pain, or risk, against the possible benefits, like a change in susceptibility to disease. Staff that believe they are at a high-risk for acquiring an infection are more likely to follow guidelines they think are achievable and effective [210].

Role models & institutional support

In their assessment of the influence of role models on HH compliance, Lankford et al. evaluated the effect of medical staff role models on HH compliance and whether HH frequency of HCPs was affected by the related actions of peers or senior care providers [211]. They found that when more than one HCP was in a patient room at a time, and a higher-ranking person in the room did not perform HH, other HCPs were significantly less likely to clean their hands ($P < .001$). In every case, the higher-ranking HCP was either a physician or nurse. This influence on HH behaviour did not work in a positive direction; when the higher-ranking HCP did clean their hands, the other HCPs were no more likely to follow the example than when in the room alone (Table 2-4).
**Table 2-4: Effect of behaviour of other HCPs on HCP hand hygiene compliance.**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Odds ratio (95% confidence interval)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Room entry alone</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>In a room when a peer performs hand hygiene</td>
<td>1.1 (0.6 - 2.3)</td>
<td>0.7</td>
</tr>
<tr>
<td>In a room when a higher-ranking person performs hand hygiene</td>
<td>0.8 (0.4 - 1.3)</td>
<td>0.3</td>
</tr>
<tr>
<td>Highest ranking person in the room</td>
<td>0.6 (0.4 - 1.0)</td>
<td>0.07</td>
</tr>
<tr>
<td>In a room when peer does not perform hand hygiene</td>
<td>0.4 (0.2 - 1.0)</td>
<td>0.05</td>
</tr>
<tr>
<td>In a room when higher ranking person does not perform hand hygiene</td>
<td>0.2 (0.1 - 0.5)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Note. Adapted from [211].

Institutional support of HCPs in achieving improvements in HH compliance can be demonstrated in multiple ways including the development of a safety climate, and by providing appropriate training. Gershon et al. report that several factors of organizational management are correlated with HH compliance. HH compliance rates were higher for HCPs that felt they worked in an environment with a strong safety climate or culture than those who did not (26% vs 9%, \( P < .001 \)). Staff who received annual safety training about blood borne pathogens were more likely to comply with HH guidelines than those that did not receiving training (26% vs 15%, \( P < .001 \)) [212].

Additional ways for institutions to provide support for increased HH compliance include efforts to prevent high-workloads and understaffing, provide access to guidelines, HH preparations, HH facilities and skin care products, and leadership in the form of sanctions, support, and rewards [103, 213].
2.3.4 Improving hand hygiene compliance

Measures

To understand and assess the impact of interventions to increase HH compliance, health care institutions must be able to accurately measure HH activity. Traditionally, there have been three methods to collect this data.

Direct observation

Direct observation, also known as overt human auditing, is the gold standard for auditing HH compliance. The WHO recommends direct observation of their own 5 Moments for HH despite acknowledging multiple potential biases [17, 214]. Potential drawbacks of using direct observation to measure HH compliance include unrepresentatively small sample sizes, human error, and multiple biases [215, 216]. Three biases will influence compliance results: observation bias, or the Hawthorn effect, where the presence of an observer changes the behaviour of the subject. Observer bias, where the observer systematically interprets the methods and rules of compliance differently from others. Selection bias, where the observer systematically choses times of day or week, locations, HCP groups, or other variables leading to unrepresentative samples [17]. These drawbacks result in unreliable HH compliance reporting with a strong positive bias inflating compliance results [215].

To investigate the effect of the Hawthorne effect and observer bias on HH compliance rates, Pan et al. published a study in 2013 where overt and covert observers collected HH data over a year in a 2200-bed teaching hospital providing primary and secondary care. Overt observations were conducted by two groups: intensive care nurses and unit ambassadors.
Covert observations were collected by medical students. The annual HH compliance rates observed by the medical students using covert observation were significantly lower than those of the nurses and unit ambassadors (44.1% versus 74.4% and 94.1%; \( P < .001 \)). The medical students found significantly lower annual compliance rates for 4 of 5 WHO HH indicators compared to the nurses and unit ambassadors (\( P < .05 \)). The medical students reported significantly lower compliance rates than nurses and unit ambassadors for all professional categories (\( P < .001 \)). Both the students and nurses reported lower compliance rates for doctors than nurses; both \( P < .001 \) [217]. While covert observation can reduce the Hawthorne effect, it does not eliminate selection biases around HCP groups, time of day, or increase sample size.

Advantages of direct observation include being the only method to date capable of collecting data for all indications of HH and having the ability to assess HH technique, including the duration of HH events and whether or not rings were worn at the time [218].

**Indirect measures**

To overcome the selection bias potentially associated with direct observation, indirect measures of HH activity can be used. These measures, such as tracking the volume of products consumed during HH, including soap, ABHR, or the number of times dispensers are used, count activity by everyone and may be able to count throughout the day [218]. In addition to removing biases, indirect measures are less expensive to implement, requiring fewer people and time to collect and process data. Unfortunately, since the HH events are not associated with opportunities, these methods do not measure HH compliance but are proxies for compliance, measuring only how often all people, in aggregate, clean their
hands. When individuals cannot be differentiated, it is not possible to separate staff use from that of patients or visitors. Temporal resolution of these measures is dependent on the frequency of data collection.

To study the use of feedback to sustain increased HH compliance, Bittner et al. recorded the daytime consumption of soap and paper towels, nurse staffing levels, and the number of occupied beds to estimate the number of HH events per occupied bed per hour. They also calculated patient to nurse ratios. The changes in these numbers were used to measure the effect of the study’s feedback intervention. The use of these indirect measures was able to confirm previous findings that the number of HH events (estimated) correlates negatively with nursing workload [219].

Self-reporting is the collection of HH compliance data through self-assessment by the participants themselves. This data can be gathered at any time interval by survey or journal style. Information gathered can include compliance by indication, overall, for product, time or location, and may be anonymous or by HCP group or identified individuals. Type of measure include frequency, percent, and categorical (never, sometimes, always). Validation of this measure has usually been done against direct observation and has produced mixed results; some similar to direct observation and previous literature, sometimes overestimating and sometimes inconclusive [220-222].
Interventions to increase HH

Administrative

Kelen et al. conducted two studies to determine the effect of changing the use of barrier precautions from being merely guidelines where staff were able to choose what precautions to follow, to becoming mandatory procedures with prescribed actions [223, 224]. Observations took place in an emergency department during two, one-month phases, 12 months apart. Knowledge of procedures and access to materials were removed as factors of compliance. Before each phase, staff attended training sessions on the use of barrier precautions and all PPE required were made available outside observed rooms. Between phases, the hospital initiated a policy requiring all HCPs to follow barrier precautions during all patient interventions. Overall compliance increased from 44% before the policy implementation to 72.7% after ($P < .01$). By HCP group, compliance significantly increased in phase 2 for physicians, nurses, and technicians ($P < .01$), whereas housekeeping staff and paramedics did not ($P = .10$). During phase 1, guidelines existed but were not regularly monitored or enforced. During phase 2, institutional policy change included the addition of sanctions for observed infractions that include immediate counseling and reporting to supervisor. Repeated infractions could impact performance appraisals.

Sahdev et al. measured the effect of education, availability of HH materials, and the introduction of legislation mandating the use of barrier precautions on HH compliance using direct observation [225]. The study, which took place in a hospital trauma room, consisted of three phases. Phase 1) where use of PPE by the trauma team was recorded having no intervention, phase 2) was preceded with educational seminars and the introduction of a cart
immediately outside the trauma room stocked with necessary PPE, making access easier, and phase 3) was preceded with notification to team members that the use of barrier precautions was mandatory and that non-compliance could be disciplined. The use of mask and eye protection increased from 7% in phase 1 to 31% and 52% in phases 2 and 3. Gown use increased from 24% in phase 1 to 55% and 82% in phases 2 and 3. The improvements observed in the use of masks and eye protection and gowns among all phases were all highly significant whereas use of gloves increased insignificantly, likely because it was already high during baseline. This study demonstrates that by providing knowledge to staff about the risks of HAIs combined with easy access to HH supplies, and the introduction of formal policies and sanctions for noncompliance, the use of barrier precautions can be increased significantly.

Knowledge

In an observational study assessing the use of universal precautions by surgical residents across 81 trauma rooms, overall compliance was 16%. Use of gloves was usually followed, but other PPE such as eyewear and gowns were generally not observed even during invasive procedures. Participants reported that the reasons for non-compliance were lack of knowledge about guidelines, forgetting the guidelines, and not having enough time to implement the guidelines. The authors suggest that passive knowledge transfer is unreliable and that ongoing auditing and in-person training is required to prevent HAIs [226].

A cross-sectional survey using self-administered survey data collected from 330 HCPs (registered nurses, nurse practitioners, licensed practicing nurses, and certified nursing assistants) in nursing homes evaluated their knowledge, beliefs, and practices about HH.
More than 80% of participants believed that HH is useful, 60% reported familiarity with guidelines, but only 40% could identify the correct duration for HH. Knowledge and beliefs were not associated with glove use or HH frequency. Authors identified the need for training to incorporate specific recommendations and ensure that current guidelines are followed [227].

Another survey about knowledge, belief, and practice around HAIs, this time on a neonatal intensive-care unit asked primarily nurses 77 questions in seven topic areas including HH, glove use, and infection control [228]. Seventy-eight percent of those surveyed knew that the length of stay, total parenteral nutrition, catheters, and severity of illness were risk factors for HAIs among their patients. Ninety-three percent reported that HCPs affect the outcomes of patients with HAIs, 99% reported that HH is a useful way to reduce infections, and 81% reported practicing appropriate HH. Ninety-five percent knew that gloves should be changed after touching potential sources of pathogens such as diapers, but only 53% of 147 staff regularly changed gloves after they became soiled or ripped, between procedures, or between patients. While knowledge and belief in the use of infection control practices to prevent HAIs may be high, it is not necessarily reflected in actual practice.

Feedback

Use of HH performance feedback has been shown to increase HH performance and reduce HAI rates. On four occasions over five years, in a study on a medical ICU, HH practices were monitored for all staff that came in contact with patients. HAI rates were tracked over the same time period, calculated as a percentage of the number of infections per 100 patient discharges. Required HH procedures were posted outside every patient room. HH
performance feedback data and deficiencies in practice were presented to all HCP groups after the first and third observation periods during in-service rounds to physicians, nurses, aides and orderlies, respiratory technologists, and laboratory personnel. Before the first feedback session, overall HH compliance before and after patient contact was 14/28%, increasing to 73/81% \((P < .001)\) after feedback. The corresponding rates of HAIs decreased from 33% before feedback to 12% after. Four years later, the collection/intervention process was repeated. Before the second feedback intervention, HH compliance before and after patient contact had fallen to 26/23% and increased again after receiving performance feedback to 38/60% \((P < .01, \text{after patient contact}; P < .001)\). The rate of HAIs had returned to baseline, 33% and fell to 0% after the second round of feedback. Each feedback session significantly increased HH compliance over the short term but was not sustainable over the intervention interval tested [199].

In this study, authors used a higher frequency of feedback with a shorter follow-up period. HH compliance of staff on an ICU was observed on all weekdays. A three-week baseline phase was followed by a three-week intervention where staff received daily feedback memos about the previous day’s HH compliance results. Six months later, a follow-up observation period took place. Average weekly HH compliance increased from 63% during baseline to 92% during the intervention period and fell to 50% during follow-up observations [48]. Daily performance feedback produced a high-level of HH compliance but was not sustainable after discontinuing the intervention.

Variability in the effectiveness of feedback to increase compliance with clinical guidelines can be attributed to the characteristics of when and how feedback is provided. In a
descriptive, qualitative, cross-sectional study of six Veterans Affairs Medical Centers, researchers identified four properties of feedback that contribute to increased compliance; timeliness, individualization, punitiveness, and customizability [229].

Figure 2-1: Model of actionable feedback. Adapted from [229].

The authors created a model of “actionable feedback” in which these properties are arranged in a hierarchal order of impact on behaviour change (Fig 2-1). To be most effective, feedback should be provided frequently enough to allow change before the next evaluation opportunity, be provided at an individual level as opposed to a group, be delivered in a non-punitive way to increase the chance of being accepted, and allow for customizable delivery of feedback to further engage the participant in the process and increase understanding and acceptance of the information. Inclusion of the recipients of feedback in the development of
its content and delivery will increase feedback relevance, importance, credibility, and comprehensibility [230].

Multimodal

Multimodal interventions are often suggested to be the most promising way to increase HH compliance. It is hypothesized that the cumulative effect on HH compliance of multiple simultaneous interventions will be greater than that of any single intervention [17, 194, 231, 232]. One obstacle to using a multimodal approach is that any effect on compliance cannot be attributed proportionately to the component parts of the intervention, making it difficult to further improve the intervention [103].

In a study that provided a program of education, training, and performance feedback to staff working on ICUs at a tertiary care hospital, researchers observed an increase in HH compliance from 23% to 65% \( (P < .0001) \) and a reduction in the number of HAIs from 47.55 per 1000 patient-days to 27.93 per 1000 patient days \( (P < .0001) \) [233]. The multiple interventions were provided throughout the intervention phase and no follow-up observations were conducted. Lam et al. also conducted a multimodal interventional study on a neonatal intensive-care unit where the intervention consisted of HH education, optimization of care procedures, provision of ABHR, improvement in HH facilities, regular compliance auditing, and tracking of infection rates for one year. Overall HH compliance increased from 40% to 53%, and HAI infection rate decreased from 11.3 to 6.2 per 1000 patient-days [234]. In another study investigating multimodal intervention on HH frequency, focus group sessions, improved HH equipment, and feedback to staff about HH frequency were implemented. By the end of the intervention phases, staff on the
experimental unit performed HH significantly more often than staff on the control unit \( (P < .004) \). This study did have a follow-up phase; two months after ending the intervention there were no differences in HH frequency between units \( (P = .68) \) [235].

**Electronic monitoring systems**

Hand hygiene performance calculations are based on individual opportunities. Performance results can range from 0% - 100%. Which opportunities captured during direct observation auditing can influence results greatly. The fewer opportunities captured, the greater the influence on results. It is therefore beneficial to capture as many opportunities as possible to better represent performance. Ideally, all opportunities would be captured which is not possible using direct observation. Continuous electronic monitoring of all health care staff is currently the only way to capture all opportunities.

In 2016, Health Quality Ontario, advisor to the government of Ontario on issues related to the monitoring, reporting, and improvement in the quality of health care in the province, conducted a review of the MOHLTC patient safety indicators. The review was done to evaluate whether the current indicators still met the criteria of public reporting and if there were new indicators that should be added. In addition to the recommendation that HH compliance remain one of the publicly reported patient safety indicators, the report recommends that “hospitals be allowed to use either audit or electronic monitoring to collect data on hand hygiene compliance”. At the same time, however, the report notes that “metrics arising from electronic monitoring will have to be reconciled with those currently reported using audit” [236] which would require electronic methods of data collection to be validated.
Ten systematic reviews of HH studies that include some form of electronic monitoring or electronic performance improving technology were published since 2001 [18, 237-245]. Two of these reviews deal exclusively with electronically assisted systems. In 2014, Ward et al. included 42 articles in their review focusing on system adoption and accuracy [241]. The technologies were divided into four categories: electronically assisted/enhanced direct observation ($N = 5$), video-monitored direct observation systems ($N = 4$), electronic dispenser counters ($N = 15$), and automated HH monitoring networks ($N = 18$). The authors concluded that the evidence provided was not adequate enough to recommend any particular technology stating that “there is very limited data as to if these systems can improve hand hygiene compliance”. A number of recommendations for future studies include focusing on effectiveness and cost analyses. Srigley et al., 2015, focused on system efficacy and reduction of HAIs [242]. Seven studies met inclusion criteria with systems that provide reminders but no feedback ($N = 2$), monitoring systems with aggregate feedback ($N = 3$), and individual feedback with real-time reminders ($N = 2$). All studies had a high or unclear risk of bias. Like Ward, data was found insufficient to make recommendations. The authors suggest, among other things, that future studies would benefit from stronger study design, testing in multiple settings, collecting baseline data and use of system-independent measures. PubMed was searched for systematic reviews about HH studies published between Jan 1, 1990, to June 30, 2017, with the term Hand Hygiene AND Technology OR Performance OR Compliance OR Intervention.
Electronically assisted direct observation

Recording of direct observations can be moved from paper based systems to electronic ones. This change in recording method is reported to reduce processing time, reduce cost of data collection, and remove transcription errors. Electronic applications can be used on dedicated devices or existing smartphones or tablets and can be customized to meet the needs of different institutions. In a study comparing direct observation with electronic collection of observations over six days on an ICU, there was no significant differences detected in the collected data [246]. This likely means that the same inherent biases connected to direct observation still exist in electronic versions.

Electronic dispenser counters

Automated dispenser activation counters allow for more accurate tracking of HH events over other indirect measures such as manually counting paper towel use. By automating the process, data can be collected continuously and assessed at a higher time resolution. To evaluate the utility of an electronic device to record use of wall-mounted soap and ABHR dispensers, a research team installed them in a number of dispensers on 16-bed ICU; at the unit entrance, in one bed area, and in an isolation room [247]. These counters were able to track up to 1450 dispenser activations, approximately ten days’ worth of data. This information needed to be transferred to a separate storage device before it was over written. Activations were recorded into ten minute bins but not time stamped by the system so the date and time of starting each recording session, approximately every six days, was recorded manually. To account for use of dispensers that were not instrumented, activations were estimated by weight. Staff were permitted to continue use of personal dispensers that
were not accounted for in any way. Data was collected for 47 days. By averaging hourly activations for the 24-hour daytime cycle, researchers were able to show an increase in activations in the bed areas between 08:00 and 09:00 that likely corresponded with the start of medical reviews, and a different pattern of use at the unit entrance with increased use during visiting hours. Authors note that extraction and processing of data was time consuming and that their installation was not able to track all dispensers on the unit or to differentiate between individuals or staff and visitor use. They suggest that these counters would excel at assessing the effect of interventions to increase HH frequency, particularly when the use of soap versus ABHR is being investigated.

Marra et al. compared direct observation, product usage, and electronic dispenser counters on a 40-bed ICU over 12 weeks. Direct observation was used whenever HH was required, whereas all dispenser activations were included. During the study period 2,249 opportunities were observed with an overall compliance of 62.3%. The mean number of opportunities per patient-day was 26.8. The mean number of dispenser activations was 53.8. For the highest and lowest mean weekly compliance, dispenser activations, and product consumed did not match. Meaning there was no significant correlation between the observed rate of HH compliance and the ABHR consumed ($r = 0.18$; $P = .59$). Assuming a 62% compliance rate and the amount of product consumed, it is estimated that there were 172,457 opportunities, meaning direct observation captured 1.3% of opportunities. Authors suggest that direct observation should not be the gold standard for measuring HH compliance because it captures only a minority of opportunities and lacks correlation with other measures [248].
Automated monitoring networks

In addition to monitoring when HH is performed, automated monitoring networks also track HH opportunities, generally the entry to and exit from patient environments, and may provide some type of feedback to HCPs. In all cases, highly granular data is recorded and may be used to generate additional feedback to participants [249]. These systems can be categorized based on the resolution of personnel identification; individual, HCP group, or aggregate, and the type and time of feedback provided; real-time or post-opportunity, and indiscriminate, HCP group, or individual feedback.

An example of a simple system providing real-time feedback indiscriminately was demonstrated in a study by Fakhry et al. where motion detectors were installed immediately outside patient room doorways that activated loud speakers whenever anyone passed through. The message played was: “Please clean your hands with hand rub dispensers when entering or exiting any clinical ward”. Once played, the message could not be activated for the following 20 seconds. HCP group and HH compliance were gathered manually. Overall, HH compliance increased from 7.6% to 49.9% ($P < .001$) [250].

Swoboda et al. investigated a much more complex automated monitoring system that monitored entry and exit to individual patient rooms and the use of dispensers, sinks and toilets. The system was able to determine if HH had been performed before crossing the room threshold. The system issued the voice prompt “please wash their hands” if HH hand not occurred beforehand [251]. HH compliance data was divided by room type; isolation rooms and non-isolation rooms. HH compliance increased in non-isolation rooms from 16.9% to 24.0% (OR, 1.41; 95% CI: 0.96-2.08) during the intervention phase. Results from
isolation rooms increased from 23.3% to 33.4% (OR, 1.45; 95% CI: 0.91-2.32). While showing that the HH compliance of HCPs is higher in isolation rooms than non-isolation rooms, it also demonstrates the ability of an electronic system to monitor time and place, and to calculate HH compliance without the use of direct observation [186].

Electronic monitoring of HH compliance of individual HCPs is possible. This is usually accomplished by requiring health care staff to wear electronic badges that attribute data collected by the system to the wearer of the badge. In a 2014/15 study, researchers investigated whether the use of an electronic badge based system increased HH compliance and reduced HAIs. Badges used in the study had an indicator light that initially glowed yellow then turned red until HH was completed and validated by the caregiver. Validation was accomplished by the wearer holding their hand close to the badge after using ABHR. When the sensor detects the presence of ABHR, HH is confirmed. Washing at a sink is determined by proximity to the sink and the amount of time spent there. Once HH is validated, the light turned green. Badges also emitted an audible tone to prompt HH. All caregivers with direct patient contact were required to participate in the study. Patient room entries and exits are recorded. It is not clear if badges produced prompts at every opportunity or if the system allowed for proactive HH. Individualized data was collected automatically for processing. The number of observations recorded increased over 1000 times on both study units from baseline direct observation to intervention with the electronic system. Whereas HH compliance significantly decreased on unit 1 (98.8% to 95.2%; \( P = .03 \)) and unit 2 (99.0% to 96.7%; \( P < .02 \)).
This significant result, despite compliance remaining above 95%, demonstrates a potential difficulty in transitioning to electronic systems and comparing results to those obtained through direct observation. Electronic systems can continuously monitor staff and record many more opportunities than direct observation. Automated recording of observations is not subject to the same biases as those generated by people. This will likely produce HH compliance results that are much lower than those produced by direct observation despite improving actual compliance [252].

Accuracy of available systems requires real-life clinical validation before deployment. In phase 1 of a study to validate the accuracy of an automated system that uses radiofrequency identification technology to monitor individual staff’s HH compliance through individually assigned badges, researchers participated in simulations of care, following planned paths throughout the unit. In phase 2, HCPs wore the badges while providing patient care. In both phases, direct observation was used to record HH activity to compare with data collected by the system. In phase 1, 88.5% of HH events were correctly attributed to the correct badge and 100% of patient room entries and exits were captured. In phase 2, accuracy of the system to attribute HH dropped significantly to 52.4% ($X^2 = 225.38, P < .01$) and only 54.3% of patient room entries and 49.5% of exits were captured ($P < .01$). The study authors attribute much of the drop in accuracy to incorrect wearing of badges and limitations of the radiofrequency identification technology to accommodate differences in the way staff interact with HH dispensers [253].
Development objectives

Based on a review of the literature, the development of interventions to increase HH compliance in health care should reinforce the accepted WHO guidelines for HH and address the known predictors and barriers to following those guidelines. Interventions should be multimodal and include such elements as education about the indications for HH, and provide timely, actionable feedback.

Along with developing new interventions, there is a need for objective measures of HH activity and compliance that are able to record all HH opportunities; at all times and places for every individual HCP. Without comprehensive and reliable data, it is difficult to produce the actionable feedback suggested for improving HH compliance, to validate interventions, or to calculate the effect of HH on HAIs.

Numerous technological systems have been developed to increase HH activity and increase HH compliance in health care over the past decade. Their associated publications have been shown to use generally weak study designs generating potentially biased results. To compare or demonstrate the efficacy of any new intervention, it is recommended that high-quality quasi-experimental studies, randomized trials or decision-analytic modeling studies be conducted and published [254].
Chapter 3 The hand hygiene prompting system

This chapter presents the technology used throughout the thesis that was developed by myself, Geoff Fernie, Bruce Haycock, and the research team at the Toronto Rehabilitation Institute at Toronto, Canada. The overarching goal of the hand hygiene prompting system (HHPS) is to reduce the incidence of HAIs through increased HH performance among health care workers. To achieve this, the HHPS centers around a wearable electronic monitoring device (badge) that prompts the individual wearer to clean their hands whenever a HH opportunity has been missed.

Development of the technology went through numerous iterations with increasing size of testing stages, including multiple clinical deployments. Previous related publications are summarized at the end of this chapter. Based on these earlier deployments and studies, changes were made to the previous version of the system developed by Geoff Fernie, Alexander Levchenko, and the research team including but not limited to: refinement of system logic, creation of additional monitored zone types, development of a docking station to maintain badges and transfer data to the database, expanded capabilities of the database to manage devices and generate reports, and the redesign of components for manufacturability.

3.1 System overview

This novel technology is composed of five main elements: 1) zone controllers that are used to define monitored areas, 2) dispenser controllers that indicate HH activity, 3) personal badges that receive, record, and process information from the controllers to determine entry
and exit from monitored zones, when participants clean their hands, and produce real-time
prompts if HH opportunities are missed, 4) a docking station to transfer recorded data from
the badges to a 5) database for further analysis and reporting. The following text explains
the workings of the system and presents brief descriptions of studies that took place using
development versions of the technology.

Figure 3-1: System components: zone controller (left), dispenser controller (centre), wearable
monitor or badge (right).

To increase and sustain HH compliance behaviours, the HHPS relies on the principles of
operant conditioning, utilizing both positive and negative reinforcement stimuli on a
continuous schedule, delivering reinforcement every time a response occurs [255]. The
HHPS generates these stimuli by providing immediate feedback to the wearer of the badge
in three ways.

First, every time a HH event takes place with the use of any instrumented soap or ABHR
dispenser, two green LEDs on the badge are illuminated: one on the top of the badge and
one on the front. The top LED indicates to the participant that the HH event has been recognized by the badge while the front facing LED lets the people around the participant know that HH has recently occurred. If we assume that high HH compliance is a goal of staff, this declaration of cleanliness should be perceived as positive reinforcement [255].

Second, when a HH opportunity is missed, the badge issues a negative reinforcement via a discrete vibration that only the wearer of the badge can feel. This prompt serves to alert the participant that the system has interpreted their actions as likely not satisfying the system defined HH procedures. The HHPS provides two ways to prevent the negative reinforcement stimulus from occurring. First, staff can actively avoid receiving the stimuli by cleaning their hands before the HH opportunity occurs. Staff may escape or discontinue the prompt by cleaning their hands at any instrumented dispenser. By using a dispenser, the prompt stimulus is immediately removed and the green LEDs are illuminated, providing the positive stimulus once again.

Finally, whenever wearing a badge, the participant knows that their HH behaviours are being monitored. These behaviours are used to calculate compliance measures that can assess changes in performance. By communicating performance results to the participant, they are able to see how use of the HHPS and following prompts can improve performance outcomes. These stimuli are generated in real-time and are different from traditional educational interventions that provide feedback through reports of aggregate HH performance, delivered after the fact.
As with any intervention to change behaviours, this system has limitations that may impact its ability to increase HH performance. These limitations include the culture of the unit where it is installed and the generally acceptability of the staff there to embrace new technologies and monitoring. The financial requirements to install and maintain the system may be prohibitive or difficult to justify. Staff may also develop methods to game the system.

3.2 System logic

The HHPS is designed to increase HH compliance during monitored zone entries and exits (opportunities). Monitored zones are typically the patient environment demarked by the patient room doorway. These entry and exit opportunities correspond with the WHO moments 1 and 4/5, and the MOHLTC moments 1 and 4.

The logic of the system was developed to be easy for the participant to understand utilizing the following set of simple rules. Two programmable time constants are used by the system to allow both proactive and reactive HH at monitored opportunities. The clean timer starts with the use of any instrumented soap or ABHR dispenser. While the clean timer is active, the participant may cross monitored zone boundaries without being prompted. The prompt timer, starts at the crossing of a monitored zone boundary if the clean timer is not active, allowing staff a period to respond to the prompt to clean their hands. The current default timer durations are clean timer: 60 seconds, prompt timer: 20 seconds.

The system calculates overall HH compliance by adding the number of times a participant entered or exited a monitored zone having cleaned their hands within the defined clean and
prompt time constants either before or after entry or exit, divided by the total number of opportunities. Compliance can also be calculated separately by entry or exit opportunities.

3.2.1 Badge logic

To determine HH compliance and for the badge to produce real-time prompts to clean, it is necessary for the system to know both the location of the participant and to monitor all HH activity (dispenser activations). Embedded in every badge is firmware to monitor and record these factors.

Based on the time of HH and location of the participant, the badge applies rules to determine whether the wearer was clean at the time of crossing a monitored boundary and if a prompt to clean should be issued. The logic of these rules and the associated time constants can be understood as a finite-state-machine where the wearer of the badge can exist in only one of six possible states at a time. Figure 3-2 shows the possible states and how they are assigned. Detection of a dispenser activation initiates the clean timer. Detection of a zone controller assigns or confirms location relative to the zone boundary. If the ID of the detected zone controller indicates that movement across a zone boundary has occurred, the prompt timer is initiated if the clean timer is not already active. Expiration of either timer changes system state. Most often the participant will be in S1: outside monitored zones with no timer active, followed by S4: inside the monitored zone with no timer active. While much less time is spent in the states associated with crossing monitored zone boundaries, it is these opportunities where increases in HH performance can have the biggest impact on reducing the spread of HAIs. The badge will issue a prompt to clean every time a missed HH opportunity is detected.
3.2.2 Database logic

Information collected by the badges is uploaded to a database for generating reports and conducting statistical analyses. The database is able to apply more complex rules to
determine HH compliance than the badge. Where the onboard logic of the badge deals only in the present tense, considering just the current location and clean state of the participant when determining when to prompt, the database is able to look backwards in time.

Consider the following example: a participant enters a patient room without performing HH, the badge issues a prompt to clean, in response to the prompt the participant exits the patient room and uses a dispenser in the hallway in under 20 seconds, then re-enters the patient room within 60 seconds. This series of events includes two entries, one exit and one dispenser activation. Using only the logic on the badge to determine compliance, the first entrance and exit would count as missed and only the second entry would have been considered clean resulting in 33% compliance. The database, however, is able to retroactively apply credit to the initial entry and subsequent exit as being compliant since they occurred within the 20 second prompt timer resulting in 100% HH compliance for the series. HH opportunities where HH occurred < 60 seconds beforehand are marked as clean. HH opportunities where HH occurred > 60 seconds beforehand but < 20 seconds after are marked as with prompt. All others are marked as missed.

A further example of how the database is able to apply more complex rules than the badge is how compliance is calculated around situations where staff leave a patient room carrying items to the soiled utility room. Staff were concerned they would be unfairly penalized for not cleaning their hands at patient room exit while carrying dirty linens to the soiled utility room since their hands were full. To accommodate this situation, the database was configured to retroactively credit a missed patient room exit if the next recorded event was
entry to the soiled utility room and exit from the soiled utility room was marked as *clean* or *with prompt* (Fig 3-3).

![Diagram of internal zone controller]

**Figure 3-3:** Internal zone controller with non-prompt entry.

### 3.2.3 System architecture

Our clinical tests demonstrated that to perform efficiently the system must guarantee a reaction time (the time interval between crossing a monitored zone boundary and when the badge issues a prompt) not exceeding one second [257]. The one second reaction time ensures that the wearer receives the prompt to perform HH before contacting the patient or the patient environment and that the prompt is associated with entering/exiting the patient environment and not with any other activity. If prompts are delivered outside the defined...
reaction time it is difficult for the participant to associate the prompt with the missed opportunity [258]. The participant may become confused or lose confidence in the accuracy of the system.

To ensure the desired reaction time, the system uses a distributed embedded architecture. None of the components required to determine the need for or issuing of prompts are connected by any wired or wireless network. The system logic is embedded in every wearable badge.

This type of network has multiple benefits: low cost, all monitoring and real-time data processing occurs within the individual badges. Each badge operates independent from all others and does not rely on a central control and processing unit. If one badge fails, the rest will continue to work. There is no limit to how many badges can be used by the system and increased numbers of badges will not affect or slow the badge’s ability to process data, allowing the badge to generate prompts within the defined reaction time. Performance is not affected by the number of participants or the number of monitored zones or HH dispensers. Monitored zones can be added or taken away at any time without reprogramming of the badges.

3.3 Components

3.3.1 Infrared communication

Modulated infrared (IR) light is used as the method of communication via infrared emitting diodes (IREDs) between the monitored zone controllers, dispenser controllers, and the badges. Use of IR allows definition of monitored areas with high accuracy and is a low-cost
solution compared to alternatives such as radio frequency options that travel through walls and require additional hardware. Radio signals may also interfere with other devices on the hospital unit. There are no health concerns with using IR at the intensities produced by the controllers [259].

The system uses IREDs to transmit controller identification (ID) codes to the badges. The IREDs used in the system emit pulsed signals of less than 17ms to the environment below, shining an invisible light downwards for a maximum duty cycle of 45% every time they are activated. The IREDs used are the LUMEX OED-EL-1L2. They have a wavelength of 940nm, which is in the near infrared region of the spectrum, also referred as IR-A, with a forward current of 100mA. The maximum radiant intensity is 60mW/sr. The half transmission angle is +/- 30deg.

Historically, infrared energy has been treated as a possible threat to people as radiant heating. While heat can affect the skin, it is generally accepted that IREDs do not pose a hazard, due to lack of energy and the natural reflectance of the skin to near infrared light [260, 261]. Instead, injury to the eye is considered the area of concern. Because the energy emitted from IREDs is so small, there is no Canadian safety standard that deals with IREDs. Instead, most manufacturers use the International Lamp Safety Standard (IEC-62471) to assess risk of devices using IREDs for eye safety.

To assess the risk of our system, we have applied the International Lamp Safety Standard. An example calculation is given in Eye Safety of IREDs used in Lamp Applications [262]. Our calculations show that for both eyes and skin, the IREDs in our system are well below
the accepted exposure limits and are deemed to be in the exempt/no-risk group as set out by the Lamp Safety Standard.

A potential drawback of using IR is that line of sight is required for reliable reception of communication and is addressed in section 3.3.3.

3.3.2 Controllers

Controllers or beacons transmit unique modulated ID codes using low intensity IR emitters at 38 KHz that are received by the badge. These codes are used to differentiate both monitored zones and wall-mounted soap and ABHR dispensers. Controllers have the ability to adjust the intensity of the IR signal to accommodate differing lighting conditions and structural elements. Onboard low battery detectors indicate when batteries must be changed. Signal intensity and battery status are displayed when the controller is active with a set of LEDs, three blue for intensity, one red for battery. The blue LEDs are also used to display the unique ID code of the controller. Pairs of IR emitters are positioned and angled within their enclosures to define monitored areas. A custom protocol was developed for the system to ensure reliable detection of signals from the controllers that removes the possibility of false prompts.

Zone controllers

Zone controllers (Fig 3-1) are used to define the monitored zone boundaries. They are mounted on the ceiling in pairs with one controller on the inside of the zone and one outside. To save battery life, zone controllers are usually asleep and are activated by a passive infrared motion sensor when movement in close proximity to the monitored area is
detected. Placement of the zone controller, along with the IR intensity setting defines the boundary.

Zone controllers can be one of four different types. Type 1 indicates an internal zone that has one entrance. Type 2 indicates the outside of any monitored zone, typically the hallway. Type 2 is also referred to as a non-monitored zone. There are multiple controllers in this zone that define a single area meaning that travel from controller to controller within the same non-monitored zone does not register as moving from one zone to another. Type 3 indicates an internal zone with multiple entrances allowing the entrance used be to determined. Type 4 indicates an internal zone where prompting is not required at entry but is required at exit, like at a soiled utility room or washroom.

When activated, a zone controller transmits its unique ID where the first part of the ID indicates the zone type and the remaining code is unique to that individual controller. In the future, zone controllers could be configured to transmit additional information such as infection risk level requiring specified HH procedures or low battery level. Battery life varies based on activity levels in the area which can be affected by the number of patients, staff, and visitors, level of care being delivered, and other factors.

Dispenser controller

Dispenser controllers (Fig 3-1) are used to indicate use of wall-mounted soap and ABHR dispensers. To ensure all dispenser activations are captured, every dispenser on the unit must be instrumented. These controllers are mounted on the wall above dispensers and point downward towards the participant. Inside dispensers, attached to the underside of the
dispenser lever, is a vibration switch. The switch is connected to the dispenser controller. Every time the dispenser lever is pressed the switch is closed completing a circuit which triggers the controller to transmit its ID.

There are currently two types of dispenser controller that reflect what substance is being dispensed. Type 1 indicates ABHR. Type 2 indicates soap. These dispenser types can be expanded to include additional preparations or other information as required. Like the zone controllers, the dispenser controllers transmit their unique IDs when activated where the first part of the ID indicates the zone type and the remaining ID is unique to that controller. Signal intensity and battery status are displayed while the controller is active. Battery life is affected by the number of times the dispenser is used.

Additionally, dispenser controllers can be outfitted with electronic activation counters. The counter is installed in-line with the controller switch. Whenever the dispenser lever is pressed, in addition to initiating the controller to transmit its ID, the activation counter records the location of the dispenser and the time and date of the activation to an on-board micro Secure Digital card.

3.3.3 The badge

Badges (Fig 3-1) are worn by all staff on the participating unit. Every badge has its own unique ID number that is associated with an individual staff participant for reporting purposes. The badge looks for signals from the zone and dispenser controllers to use to determine if and when to issue prompts. The badge only receives signals; it is not a
transmitter. To reliably receive IR signals from the controllers, the badge should be worn at chest level with the IR receiver facing upwards and the green LED facing outwards.

To save power, badges spend most of their time in a sleep mode checking for controller signals periodically. The power saving intervals are configured to ensure that the reaction time to issue prompts is less than one second. When a dispenser activation is detected, the green LEDs are illuminated indicating to wearer that the HH event has been recognized. By default, the duration of the green LEDs is the same duration as the clean-state time constant. This allows the wearer to know when the system considers them to be in or out of the clean-state.

When staff are given their badge at the beginning of their shift, the embedded logic of the badge assumes that they are outside any monitored zone and are in a non-clean state. The badge ID, time constants, and prompt settings are defined by a configuration file before issuing the badge to the participant.

In addition to decoding controller IDs and issuing prompts to clean, the badges record the unique ID and time, to the second, of every dispenser activation. They also record the ID of every zone controller associated with crossing a monitored boundary, and when the boundary crossing occurred. Every HH event (dispenser activation or boundary crossing) is also tagged with the badge’s unique ID number to ensure future data processing can be attributed to the participant wearing the badge.
Badges decode the modulated IDs from zone controllers to determine when the HCP enters or exits monitored zones, and decodes modulated IDs from dispenser controllers to process HH events.

Real-time prompts to perform HH can be issued to the wearer through tactile and/or auditory methods. The tactile prompt is generated by an eccentric rotating mass vibration motor, commonly known as a pager motor (Precision Microdrive: Pico Vibe 7mm vibration motor #307-001). The auditory prompt is generated by an electro-mechanical sound transducer (with electro-magnetic coil), or buzzer. By varying the input signal voltage and or frequency to the buzzer, the sound can be changed (Dig-Key part number 668-1193-1-ND).

Prompt configurations can be set to use either prompt type, both, or neither. A badge will issue a prompt to perform HH every time it determines that a zone change has occurred without detecting a dispenser activation < 60 seconds beforehand.

3.3.4 Docking station

The primary functions of the docking station are to upload recorded data from the badges to the database for further processing, provide power to recharge the badges’ batteries, and to display aggregate performance results of the participating unit.

These functions are handled by two software applications. The Dock application takes care of downloading data from the badge. The data file is named with a combination of the badge ID and the time/date of the first recorded event and placed in a folder for uploading to
the database. After the data is copied to the docking station it is removed from the badge. Then the Dock Display application sends the data to the database for processing. After being sent to the database, the original data file is moved to a folder containing all records for the day as a backup. The Dock Display then requests an update of performance results from the database that is displayed on a monitor attached to the docking station (Fig 3-4).
While in the docking station, the badge is powered by USB allowing previously recorded data to be accessed no matter what the state of the battery. The recharging of the batteries is handled by the badge itself, not the docking station.

With each staff participant having their own badge, there could be upwards of 100 badges per unit. The docking station is configured in boxes that are attached to an upright frame. Each box can accommodate 40 badges; each frame can support three boxes for a total of 120 badges per docking station. Each box has its own ID that is sent along with the badge ID allowing the system to know what docking station was used to upload the data.

3.3.5 Database

The system’s structured query language database is hosted on a secure server within the participating hospital’s network. The database is used to manage information about participants, system hardware, and to produce a series of reports. A database manager application was written to easily access and interact with the database.

The database uses information from the following categories to generate reports and statistics:

- Personnel: ID, HCP, unit assignment
- Spatial: institution, facility, unit, room
- Temporal: time that each zone and dispenser controller was recorded by the system
- Object: every zone and dispenser controller, badge, docking station
When generating reports the database manager is able to select from these factors to focus on relevant information. Potentially useful reports include individual participant HH compliance compared to HCP group, unit, of facility, for relative comparisons. Identification of personnel, times, and locations of high and low compliance or fluctuations. Monitoring of trends such as: declining compliance later in shift. Reports on specific times and situations such as meal times or outbreaks.

The database can also be used to assist in monitoring its own performance by tracking the last time a controller or badge has been used. This is helpful in identifying lost or damaged devices. It can also be useful in determining optimal placement of dispensers based on records of which location and types of dispensers get used most often.

Given that the badges have already provided continuous and immediate feedback to the participant, results of any written reports about individual performance should not differ greatly from existing perceptions of how often they have been issued prompts.

3.4 Previous publications

The performance of the previous generation of the system has been described in multiple studies. The following is a selection of works relevant to the development of the current version used in this thesis.

In 2008 a description of the outcome of focus groups of health care staff at a complex, continuing care facility was published. Participants felt comfortable receiving individual performance feedback and wanted to see anonymous group information for comparison. It
was suggested that a period of anonymous use to familiarize them with the system would be welcome before sharing data with management. They wanted the badge to operate silently so as not to disturb patients at night. We noted that staff in this trial were observed pasting their individual feedback sheets on locker doors and even writing comments on each other’s sheets. This was the first time a description of the IR system was published [263].

A commentary in 2009 describes the potential value of the IR system as a prompting tool and as a more objective measure of performance. It also introduces the idea of using measures of body posture to deduce the current activity of the caregiver and further enhance the potential to recognize opportunities [264].

A paper published in 2010 reports the architecture of the previous version in greater detail. It reports that our trials showed the need for a guaranteed reaction time between entering the patient environment and receiving the prompt not exceeding one second. The paper concludes that the distributed system with all the logic and data storage in the badges provides a guaranteed reaction time and is scalable without affecting performance with a practically unlimited number of wearable badges [257].

Also in 2010 we described the results of our first clinical trial of the previous version on two nursing units with 15 nurse participants. This study was limited because nurses had to consent to participate and they needed reminding to put the badges on. It was noted that many times patient room entry and exit opportunities merged because caregivers moved quickly from patient to patient and performed HH once between patients. Even so, this paper predicted the potential of the system to more than double HH for patient room entries
and exits. It also identified that more than 25% of opportunities after body fluid contact merge with room exits because caregivers leave the room immediately to dispose of waste [265].

A second small trial using the previous version of the system was published in 2011. There were 1438 opportunities recorded over 145 hours of testing. Effect of the system on HH behaviours was measured by change in average HH events per hour per participant. Baseline counts were collected by direct observation. Use of the system increased average hourly HH events by ~53%, from 4.2 events per hour during baseline to 6.42 events per hour during the intervention phase. This change may be underestimated since baseline counts could have been inflated by the Hawthorne effect of direct observation [256].

Technical refinements to the previous generation were described in 2012. The discussion mentions some results from a qualitative study of nurses’ and administrators’ beliefs and intentions related to the perceived impact of the technology. Nurses concentrated on their personal safety and their families’ safety as a source of motivation to perform HH while administrators identified professional commitment, incentives and goal setting. Administrators also highlighted positive aspects for teams whereas nurses were not interested in group conformity or being compared to others [266].

The most thorough of the previous studies utilizing the previous generation of the technology was published in 2013. A total of 93 dispensers were instrumented. The study was done in three phases – first phase badge inactive but recording data, second phase with only status light indicator operating, and third phase with prompt function enabled. The
number of opportunities per hour remained fairly constant over all three phases. HH actions did not change with the second phase but more than doubled when the prompt was turned on. This was the first significant study that showed the success of the system is derived from the real-time prompting which more than doubled HH [267].

Finally, published in 2014, the results of a trial conducted at St Michael’s hospital were reported. Ten nurses on a cardiac unit participated. All alcohol dispensers on the unit were instrumented. The prompt function was not enabled. The project tested the effectiveness of providing individual feedback to the nurses daily on their performance in the form of a printed report. There was no change in performance seen, implying that the real-time prompt function is required to increase HH performance. This study is also valuable because it was done in an acute care environment [268].
Chapter 4 Effect of real-time prompting on hand hygiene

The paper in this chapter was co-authored with Pamela Holliday and Geoff Fernie, who have provided written permission for it to be used in this thesis. GF and I worked together to design the study. I built, installed, and maintained the technology. PH was the main contact with participants. I conducted all of the statistical analysis and wrote the manuscript. PH and GF edited the manuscript.

This paper has been published by the American Journal of Infection Control as:


Effect of electronic real-time prompting on hand hygiene behaviors in health care workers

Abstract

Background: Poor hand hygiene by healthcare workers is a major cause of nosocomial infections. This research evaluated the ability of an electronic monitoring system with real-time prompting capability to change hand hygiene behaviors.

Methods: Handwashing activity was measured by counting dispenser activations on a single nursing unit before, during, and after installation of the system. The effect of changing the
prompt duration on hand hygiene performance was determined by a cluster-randomized trial on 3 nursing units with 1 acting as control. Sustainability of performance and participation was observed on 4 nursing units over a year. All staff were eligible to participate.

Results: Between June 2015 and December 2016, a total of 459,376 hand hygiene opportunities and 330,740 handwashing events from 511 staff were recorded. Dispenser activation counts were significantly influenced by use of the system ($\chi^2[3] = 75.76; P < .0001$). Hand hygiene performance dropped from 62.61% to 24.94% (odds ratio, 0.36; confidence interval, 0.34-0.38) when the prompting feature was removed. Staff participation had a negative trajectory of -0.72% ($P < .001$), whereas change in average performance was -0.18% ($P < .001$) per week for the year.

Conclusions: Use of electronic monitoring with real-time prompts of 20 seconds’ duration nearly doubles handwashing activity and causes handwashing to occur sooner after entering a patient room. These improvements are sustainable over a year.

Manuscript

4.1 Background

Improving the hand hygiene (HH) performance of health care workers will significantly reduce the chance of their patients contracting nosocomial infections [16, 270, 271]. Numerous electronic monitoring systems (EMSs) have been developed to improve HH performance but rigorous validation of these systems is lacking [18, 237-245].
A novel EMS developed at Toronto Rehabilitation Institute uses electronic badges worn by health care workers to increase HH performance by providing real-time prompting in the form of a discrete vibration when HH is required upon entering and exiting a patient area.

While earlier studies conducted using this system indicated doubling of HH activity [267, 272], further investigations to more fully understand its effect on HH behaviours were undertaken. The aims of this work were to determine whether the EMS changes health care worker HH behaviours when measured independent of any assumptions made by the EMS, the contribution of the prompting signal and the optimal duration of that signal to changing behavior, and whether long-term use of the EMS can be sustained in terms of both health care worker participation and HH performance improvements.

4.2 Methods

4.2.1 Study design and participants

Three studies are presented. A quasi-experimental trial with a reversal phase was conducted to evaluate the effect of the EMS on HH activity. Dispenser activation counts were monitored on a single nursing unit before the EMS was installed, during use of the EMS, and after the system was removed. The influence of real-time prompting on HH behavior was evaluated with a cluster-randomized trial with a reversal phase on 3-participating nursing units. These 3 units that provide care to similar patients at the same hospital site were randomly selected as either the control group, or to receive 1 of 2 interventions that reduced the prompt duration. To measure changes in HH performance and staff
participation over time, 4 nursing units using the EMS were observed continuously for 1 year.

The research was completed at Toronto Rehabilitation Institute (Toronto, Canada). The 5 nursing units were from 2 different hospital sites with a musculoskeletal and a geriatric unit at 1 site, and 3 brain and spinal cord rehabilitation units at a second site. Every staff, student, and volunteer assigned to the participating units was eligible to participate, including nurses, physicians, allied health practitioners, administration members, and facilities employees.

All installations were conducted as part of a quality improvement initiative. The University Health Network Ethics Board waived the requirement for consent based on the quality improvement focus of the projects [Appendix A].

4.2.2 Procedures

The EMS utilizes electronic badges worn by health care staff members that communicate with sensors installed at monitored zone entrances and in all wall-mounted handwash dispensers. The badges apply rules to the information gathered from these sensors about when staff should wash based on the wearer’s location, HH activity, and time constants. When appropriate, the badge prompts wearers to wash by vibrating if they have missed an opportunity. After washing at an instrumented dispenser, lights on the badge glow green, indicating the action has been recognized. All information collected by the badge is uploaded to a database by a docking station for report generation. HH performance is calculated by dividing the number of times handwashing occurred within 1 minute before,
or 20 seconds after entering or exiting a monitored zone, by the total number of zone entries and exits (opportunities). The operation of this system has been previously reported [257, 264, 265].

This system was installed on all 5 study units. Electronic badges were assigned to every member of staff and labeled with the name of the user. Several additional badges were given professional category names for use by occasional visiting staff.

In addition to prompts and LED indicators on the badges, performance feedback was provided by displaying graphs of aggregate nursing unit performance on a screen attached to the docking station. The system-defined compliance of the unit for the previous week was shown as a prominent circle graph. A secondary bar graph of the proceeding 8 weeks was also presented to indicate performance trends. In addition to the performance within the nursing unit where the dock was installed, performance graphs of other units were displayed.

Table 4-1: Summary of study methods.

<table>
<thead>
<tr>
<th>Study</th>
<th>Objective</th>
<th>Study design</th>
<th>Nursing unit(s)</th>
<th>Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dispenser activation</td>
<td>Effect of electronic monitoring system on HH activity</td>
<td>Quasi-experimental</td>
<td>MR</td>
<td>August 2016 - December 2016</td>
</tr>
<tr>
<td>Prompt duration</td>
<td>Effect of prompt duration on HH performance</td>
<td>Cluster-randomized</td>
<td>BSC1, BSC2, BSC3</td>
<td>April 2016 - August 2016*</td>
</tr>
<tr>
<td>Sustainability</td>
<td>Change in HH performance and staff engagement over time</td>
<td>Observational</td>
<td>BSC1, BSC2, BSC3, GR</td>
<td>June 2015 - November 2016</td>
</tr>
</tbody>
</table>

BSC, brain and spinal cord rehab; GR, geriatric rehab; MR, musculoskeletal rehab. *Prompt duration study is nested in the sustainability study.
Staff were given multiple demonstrations and training sessions. It was explained that information about their handwashing activities and movement on the units was being continuously recorded by the electronic badges. Information and instructions were also posted beside the docking stations along with researcher contact information. After the project launch, training was provided on an ad hoc basis when new staff arrived.

The effect on dispenser activation counts was measured in all 47 soap and 64 alcohol-based hand rub (ABHR) wall-mounted dispensers on the participating musculoskeletal nursing unit (10 single patient rooms and 10 double rooms). The dispensers were instrumented with both the standard EMS dispenser electronics and a secondary electronic time-stamped event recording device. These event recorders provided an independent, objective measure of change in HH behavior by documenting every time handwash dispensers were used whether a badge was worn or not. Data collection consisted of 3 phases: count-baseline, count-intervention, and count-return. The number of times dispensers were used during count-baseline phase was collected for 4 consecutive weeks from August 22 to September 18, 2016. Data collection was then suspended for 2 weeks while staff members were trained in the use of the EMS and the remaining system components, including the docking station, were installed. On the first day of the count-intervention phase, staff were issued individual electronic badges and dispenser use data collection resumed for 4 weeks. At the end of the count-intervention phase, the badges and docking station were removed from the unit. An immediate increase in activity was expected to occur with the introduction of the EMS and a slower decrease in activity when the system was removed. To capture the anticipated slower decrease, the count-return phase lasted twice as long as each of the previous phases. The
count-return phase ran for 8 consecutive weeks ending December 25, 2016. The automated collection of all dispenser activations was not revealed to staff members.

The prompt duration investigation consisted of 3 back-to-back, 6-week phases: prompt-baseline, prompt-intervention, and prompt-return. Data were collected during the 18 weeks between April 11 and August 14, 2016. The EMS was already in use by the 3 participating brain & spinal cord rehabilitation nursing units (8 single patient rooms and 17 quad rooms) before prompt-baseline data collection to allow staff to become familiar with the devices and for HH performance levels to stabilize. Prompt duration was set at the default 20 seconds for all participants during prompt-baseline. Each of the 3 participating units formed a cluster and was randomly assigned 1 of 3 different prompt duration settings: default 20 seconds (control), half duration 10 seconds, or no prompt 0 seconds. Prompt changes could not be concealed because of the nature of the intervention. After collecting 6 weeks of prompt-baseline data, all badges were set to the assigned prompt durations. Prompt-intervention began at week 31 of the 52-week EMS installation. Although prompt duration on badges was changed, HH performance calculations remained based on users having 20 seconds to wash after room entry if required. Upon completion of the 6-week prompt-intervention phase, all badges were reset to the default prompt duration. Data collection continued in the prompt-return phase for 6 more weeks.

The exploration of performance and participation sustainability required continuous collection of data for 1 full year on 4 nursing units at 2 sites: 1 geriatric rehabilitation nursing unit (10 single patient rooms and 9 double rooms) and the 3 nursing units that were
also involved in the prompt duration study. The data were collected between June 15, 2015 and November 13, 2016 (Table 4-1).

### 4.2.3 Outcomes

The primary outcome of the dispenser activation study was the amount of HH activity, as measured by the number of times wall-mounted handwash dispensers were used.

The primary outcome of the prompt duration study was overall HH performance as measured by the EMS. The secondary outcome was time to wash after room entry when handwashing had not occurred within 1 minute before entering the patient room. This measure was used to determine whether the prompt duration, in addition to changing if staff washed, also influenced when they washed.

The primary outcomes of the sustainability exploration were change in overall average HH performance as measured by the system and the change in the number of participants as measured by the difference in numbers of unique badges used.

### 4.2.4 Statistical analysis

We divided the time-stamped dispenser activation count data from each individual dispenser into the 3 phases: count-baseline (4 weeks), count-intervention (4 weeks), and count-return (8 weeks). To better assess rate of change in HH activity after system removal, the count-return phase data were subdivided into 2 4-week phases: count-return1, and count-return2. To determine whether there was any change in HH activity, data from the 4 resulting 4-week phases were examined with a 1-way, repeated measures analysis of variance by ranks
(Friedman test). This was followed by multiple comparisons between phases with Bonferroni corrections applied to identify differences.

The effect of prompt duration was calculated at the opportunity level using logistic regression with a logit link function. The comparison of prompt duration interventions compared with control on HH performance employed a generalized linear mixed-effect model with nursing unit as a random effect to account for clustering of the interventions. Generalized linear models with logistic regression were also used to assess performance change within groups. Pearson’s χ² tests were run to see whether there was a relationship between prompt duration and the likelihood of washing within a given time after entering a monitored patient room when the user still required washing.

To determine the yearlong trajectory outcomes of overall performance and participation levels, we built an unconditional multilevel growth model with nursing units as subjects. Measurements were taken at weekly intervals for 52 weeks on all 4 nursing units. The first week was used for training staff and was not included in performance calculations but was used to establish the baseline for maximum participation because the highest number of unique users on participating units happened in the first week in every case.

Statistical analyses for all studies were completed using R version 3.3.2 (R Foundation for Statistical Analysis, Vienna, Austria).
Table 4-2: Effect of electronic monitoring system on dispenser activation count, dispenser group by phase.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Dispenser activation count, n (%)</th>
<th>Absolute count change*, n</th>
<th>Relative count change*, %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n = 120,441)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dispenser group</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>21,262 (18)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Intervention</td>
<td>41,383 (34)</td>
<td>20,121</td>
<td>94.63</td>
</tr>
<tr>
<td>Return 1</td>
<td>32,360 (27)</td>
<td>11,098</td>
<td>52.20</td>
</tr>
<tr>
<td>Return 2</td>
<td>25,436 (21)</td>
<td>4174</td>
<td>19.63</td>
</tr>
<tr>
<td><strong>Dispenser type</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol-based hand rub</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>14,807 (12)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Intervention</td>
<td>31,032 (26)</td>
<td>16,225</td>
<td>109.63</td>
</tr>
<tr>
<td>Return 1</td>
<td>21,506 (18)</td>
<td>6699</td>
<td>45.24</td>
</tr>
<tr>
<td>Return 2</td>
<td>15,900 (13)</td>
<td>1093</td>
<td>7.38</td>
</tr>
<tr>
<td>Soap</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>6455 (5)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Intervention</td>
<td>10,351 (9)</td>
<td>3896</td>
<td>60.36</td>
</tr>
<tr>
<td>Return 1</td>
<td>10,854 (9)</td>
<td>4399</td>
<td>68.15</td>
</tr>
<tr>
<td>Return 2</td>
<td>9536 (8)</td>
<td>3081</td>
<td>47.73</td>
</tr>
<tr>
<td><strong>Dispenser location</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outside patient room</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>15,271 (13)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Intervention</td>
<td>30,538 (25)</td>
<td>15,267</td>
<td>99.97</td>
</tr>
<tr>
<td>Return 1</td>
<td>20,232 (17)</td>
<td>4961</td>
<td>32.49</td>
</tr>
<tr>
<td>Return 2</td>
<td>15,006 (12)</td>
<td>-265</td>
<td>-1.74</td>
</tr>
<tr>
<td>Inside patient room</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>5991 (5)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Intervention</td>
<td>10,845 (9)</td>
<td>4854</td>
<td>81.02</td>
</tr>
<tr>
<td>Return 1</td>
<td>12,128 (10)</td>
<td>6137</td>
<td>102.44</td>
</tr>
<tr>
<td>Return 2</td>
<td>10,430 (9)</td>
<td>4439</td>
<td>74.09</td>
</tr>
</tbody>
</table>

*From baseline phase.

4.3 Results

In total, 120,441 handwash dispenser activations were recorded and analyzed for the effect on dispenser activations. Three of the original 111 counter/dispensers became damaged and were removed from analysis. Overall dispenser activation counts were significantly
influenced by the use of the EMS ($\chi^2[3] = 75.76; P < .0001$). Median activation counts significantly increased from 113 in the count-baseline phase to 186.5 with the introduction of the electronic badges during count-intervention phase (difference, 142.5; $r = -0.48$). When the badges were taken away, median activation counts dropped to 180.5 but did not reach baseline levels until the fourth phase (median, 166.5 and difference = 49.5; $r = -0.21$). In all cases the critical difference ($\alpha = 0.05$ corrected for the number of tests) was 50.06.

Dispenser activation counts increased by almost double with the introduction of the electronic badges with a relative count change of 94.63%. All groups of dispensers showed increased use during the count-intervention phase (Table 4-2). The largest group count change was in ABHR dispensers just outside patient room entrances with a 120.69% relative increase. The smallest change was in soap dispensers outside patient rooms at 21.71%. Count-return1 showed reduction in some but not all categories when badges were removed. In count-return2, 8 weeks after badge removal, in-room counts were still high but ABHR dispensers in the hallways were back to count-baseline. Results are provided in Table 4-2 along with absolute and relative count changes from the count-baseline phase.

Data evaluating the effect of prompt duration consisted of 90,776 HH opportunities, and 57,371 wash events recorded from 185 active participants. Intracluster correlation coefficient (ICC) for overall HH performance during prompt-baseline phase was very low at 0.001, indicating no difference between units.

Both reductions to the prompt duration in the prompt-intervention phase decreased HH performance ($P < .0001$) whereas the control group that retained the default prompt duration
of 20 seconds increased performance level ($P = .038$). The absolute percentage point
difference in performance between the control unit and the unit with prompts reduced to 10
seconds was -15.60% ($P < .0001$). Performance on the unit with the prompt completely
removed dropped by -26.37% ($P < .0001$). During the 6-week prompt-return phase, HH
performance on both intervention units improved but performance on all units was below
prompt-baseline levels (Table 4-3).

**Table 4-3: Effect of real-time prompt duration on hand hygiene performance, by intervention and
phase.**

<table>
<thead>
<tr>
<th>Prompt duration setting</th>
<th>Clean opportunities, n</th>
<th>Total opportunities, n</th>
<th>Overall performance, %</th>
<th>Absolute change*, %</th>
<th>Odds ratio* (95% confidence interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control prompt, 20 s</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>6604</td>
<td>8927</td>
<td>73.98</td>
<td>—</td>
<td>1</td>
</tr>
<tr>
<td>Intervention</td>
<td>5439</td>
<td>7213</td>
<td>75.41</td>
<td>1.43</td>
<td>1.08 (1.00–1.16)</td>
</tr>
<tr>
<td>Return</td>
<td>4586</td>
<td>6532</td>
<td>70.21</td>
<td>-3.77</td>
<td>0.83 (0.77–0.89)</td>
</tr>
<tr>
<td>Reduced prompt, 10 s</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>11,612</td>
<td>16,223</td>
<td>71.58</td>
<td>—</td>
<td>1</td>
</tr>
<tr>
<td>Intervention</td>
<td>7955</td>
<td>13,858</td>
<td>57.40</td>
<td>-14.17</td>
<td>0.54 (0.51–0.56)</td>
</tr>
<tr>
<td>Return</td>
<td>7844</td>
<td>12,568</td>
<td>62.41</td>
<td>-9.16</td>
<td>0.66 (0.63–0.69)</td>
</tr>
<tr>
<td>Removed prompt, 0 s</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>6109</td>
<td>9758</td>
<td>62.61</td>
<td>—</td>
<td>1</td>
</tr>
<tr>
<td>Intervention</td>
<td>3315</td>
<td>8801</td>
<td>37.67</td>
<td>-24.94</td>
<td>0.36 (0.34–0.38)</td>
</tr>
<tr>
<td>Return</td>
<td>3907</td>
<td>6896</td>
<td>56.66</td>
<td>-5.95</td>
<td>0.78 (0.73–0.83)</td>
</tr>
</tbody>
</table>

*From baseline phase.

There was a significant association between the use of the default 20-second prompt and the
likelihood of washing within 20 seconds after entering a patient room if washing had not
been done beforehand. When compared with staff using the shorter 10-second prompt, those
using the default 20 seconds were more than 2 times more likely to wash ($\chi^2[1] = 155.50$;
more likely to wash than those staff members who were given no prompting at all ($\chi^2[1] = 670.14; P < .0001$ and odds ratio, 8.47; 95% confidence interval, 7.06 - 10.19) (Fig 4-1A).

After the 30-second mark, the increased likelihood of washing by those with the longest prompt duration plateaus compared to those with the 10-second prompt, and decreases compared to those staff members with no prompt (Fig 4-1A).

Performance and participation data were collected from 4 nursing units for 52 weeks each. In total, 402,849 opportunities, and 291,700 wash events were recorded from 419 healthcare staff members for an overall performance score of 64.05% for the study period. The growth model shows that time had a significant effect on average HH performance (Fig 4-2A) with a negative trajectory of -0.18% per week ($P < .001$). There was a large ICC of 0.46 between units, indicating that the trajectory of performance scores differed between units.

As shown in Table 4-4, HH performance on 2 units remained constant, whereas performance dropped on the remaining 2 units. Participation change over time was more dramatic (Fig 4-2B) with a -0.72 ($P < .001$) reduction in percentage of users per week. ICC for participation was much lower at 0.19 indicating similar declines in participation across units.
Figure 4-1: Likelihood of washing before given time between prompt duration settings (A). I and II indicate the end of 10-second and 20-second vibration prompts. After 30-seconds (III) the increased likelihood of washing due to receiving the default 20-second prompt begins to decrease. Cumulative percentage of handwashing events after entering patient room when washing was required (B).
Figure 4-2: Weekly mean performance (A) and participation data (B) with trajectory confidence interval (CI). Best fit regression line is shown for the entire year, but there is evidence of stabilization at week 21 for performance and week 30 for participation.
Table 4-4: Observation results, overall and by unit (performance interclass correlation, 0.46 and participation interclass correlation, 0.19)

<table>
<thead>
<tr>
<th>Unit</th>
<th>Opportunities, n</th>
<th>Wash events, n</th>
<th>Performance (95% confidence interval), %</th>
<th>Performance trajectory* (P value)</th>
<th>Participants, n</th>
<th>Participation trajectory* (P value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time series</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>402,849</td>
<td>291,700</td>
<td>64.05 (57.66–77.49)</td>
<td>-0.18 (&lt; .001)</td>
<td>419</td>
<td>-0.72 (&lt; .001)</td>
</tr>
<tr>
<td>Individual unit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>104,803</td>
<td>46,055</td>
<td>53.58 (50.07–57.09)</td>
<td>0.02 (.864)</td>
<td>152</td>
<td>-1.97 (&lt; .001)</td>
</tr>
<tr>
<td>2</td>
<td>75,971</td>
<td>59,987</td>
<td>60.52 (57.60–63.44)</td>
<td>-0.09 (.366)</td>
<td>80</td>
<td>-0.38 (&lt; .001)</td>
</tr>
<tr>
<td>3</td>
<td>68,408</td>
<td>62,910</td>
<td>74.96 (73.00–76.91)</td>
<td>-0.34 (&lt; .001)</td>
<td>86</td>
<td>-0.22 (.035)</td>
</tr>
<tr>
<td>4</td>
<td>153,667</td>
<td>122,748</td>
<td>67.13 (64.68–69.58)</td>
<td>0.32 (&lt; .001)</td>
<td>101</td>
<td>-0.33 (.005)</td>
</tr>
</tbody>
</table>

*From multilevel growth model, % per week.

4.4 Discussion

Dispenser activation counters were used as a system-independent evaluation of the EMS. The use of both real-time prompting and dispenser activation counters allows for tracking the effect of individuals using badges and on those who do not wear them [273]. Because handwashing events from every person on the unit, including staff, patients, and visitors were counted with no exclusions, we expect that the increase in dispenser usage during the count-intervention phase was probably even greater than double for those who wore badges. The soap dispenser in the unit’s staff-only washroom was an outlier, with consistently many
more activations than any other dispenser. This shows the EMS will have little effect on situations where staff already meet best practice guidelines and does not blindly increase HH activity in all situations. The largest change in activation counts during the count-intervention phase was seen in the ABHR dispensers located outside the patient rooms (Table 4-2). This reinforces the results from the prompt duration study where real-time prompting was shown to increase handwashing activity near patient room entrances.

The results of testing the effect of changing prompt duration also revealed that the rate of cumulative in-room handwashing stabilizes approximately 10 seconds after prompting ends or 10 seconds after room entry with prompting removed. This delay reflects intent to wash, or the time it takes to get to a dispenser once staff have decided to wash. There was a similar number of handwashes by staff members at all prompt duration settings up to the 5-second mark (Fig 4-1B). This initial number of washes across prompt duration settings indicates an existing tendency to wash upon patient room entry. Prompting staff to clean reinforces this trend. What is not clear is why there is such a large difference in the likelihood to wash at the 10-second mark between staff receiving 10-second and 20-second prompts. Presumably with the same prompt up to 10 seconds, the likelihood should be the same. Perhaps this reflects a threshold of tolerance of the vibration prompt; that is, it is easier to not notice or to ignore a vibration prompt of 10 seconds but 20 seconds is not so easily missed.

The 6-week intervention phase of the prompt duration study was nested within the sustainability exploration starting at week 31. Despite reduced performance when the prompt was shortened or removed, the additional attention to staff might have had a small positive effect on overall performance and staff engagement for the remainder of the year.
When evaluated week to week, the initial downward trend in performance turns positive at week 21, and at week 30 for change in participation. Other studies have reported a high variability in the results produced by EMS in different institutions [274]. We have also seen nursing units within our single institution exhibit differing levels of enthusiasm to participate, unique cultures and leadership styles. The overall small decline in performance contrasts with an increasing trend reported recently [275]. One difference may be that use of the system was encouraged but was not a requirement of employment. There were no sanctions applied for failure to participate or rewards given to those who did.

We plan to investigate alternative methods of increasing both performance and participation levels. One such method might see badges issued to staff on a 1 month on, 2 months off strategy similar to that reported by Kerbaj et al. [276], as opposed to 12 consecutive months in an effort to address potential issues of use-fatigue, desensitization to the prompt, and loss of novelty.

The EMS is not yet commercially available. It is easy to install because all of the components are battery-powered and no hard-wiring is needed. The system uses no radio or wireless networks. All signals from zone and dispenser controllers use low-powered, near-visible light to communicate with the badges, with no potential for adverse effects on the health of users or the operation of other electronic equipment. The system is expandable to any number of users and locations and is expected to be cost-effective when it comes to market.
4.5 Conclusions

Use of the EMS on an in-patient rehabilitation unit results in an immediate, almost doubling in the number of handwashing events. This increase is maintained for about 8 weeks after system removal, implying there is a learned behavior effect present.

Real-time prompting when opportunities are missed increases overall HH performance. These prompts also shift the time of handwashing closer to the time of patient room entry. This change in when handwashing occurs reduces the likelihood of health care workers contacting the patient or patient environment without first washing their hands, therefore reducing the risk of transmitting infection [170, 277].

Staff participation levels using the EMS are difficult to maintain within the context of a quality improvement initiative. Increased HH performance is largely sustainable over the course of a year in the staff members who continued to participate.

This study adds to the evidence that use of an EMS increases HH performance and that such systems should be considered in our toolkit to positively promote HH. Future work will focus on implementation strategies that are cost-effective for large-scale deployment and to improve participant engagement. This study was conducted in a rehabilitation environment. Future studies should explore the system’s effectiveness in other health care environments.
Chapter 5 Secondary measures of hand hygiene performance

The paper in this chapter was co-authored with Pamela Holliday and Geoff Fernie, who have provided written permission for it to be used in this thesis. GF and I worked together to design the study. I built, installed, and maintained the technology. PH was the main contact with participants. I conducted all of the statistical analysis and wrote the manuscript. PH and GF edited the manuscript.

This paper has been accepted for publication by the American Journal of Infection Control and is available as an in-press, corrected proof as:


Secondary measures of hand hygiene performance in health care available with continuous monitoring of individuals

Abstract

Background: Hand hygiene (HH) compliance in health care is usually measured against versions of the World Health Organization’s *Your 5 Moments* guidelines using direct observation. Such techniques result in small samples that are influenced by the presence of an observer. This study demonstrates that continuous electronic monitoring of individuals can overcome these limitations.
Methods: An electronic real-time prompting system collected HH data on a musculoskeletal rehabilitation unit for 12 weeks between October 2016 and October 2017. Aggregate and professional group scores and the distributions of individuals’ performance within groups were analyzed. Soiled utility room exits were monitored and compared with performance at patient rooms. Duration of patient room visits and the number of consecutive missed opportunities were calculated.

Results: Overall, 76,130 patient room and 1,448 soiled utility room HH opportunities were recorded from 98 health care professionals. Aggregate unit performance for patient and soiled utility rooms were both 67%, although individual compliance varied greatly. The number of handwash events that occurred while inside patient rooms increased with longer visits, whereas HH performance at patient room exit decreased. Eighty-three percent of missed HH opportunities occurred as part of a series of missed events, not in isolation.

Conclusions: Continuous collection of HH data that includes temporal, spatial, and personnel details provides information on actual HH practices, whereas direct observation or dispenser counts show only aggregate trends.

**Manuscript**

5.1 Background

Direct observation of the World Health Organization’s (WHO) “Your 5 Moments” guidelines is the primary measure of hand hygiene (HH) compliance in healthcare [18, 171, 172]. This aggregate measure, with a focus on direct patient interactions, provides only a partial understanding of the HH behaviors that contribute to the potential spread of health
care-acquired infections [16, 271]. Because of small sample sizes and inherent biases, manual audits contribute little to our knowledge of actual HH practices [279-281]. With the advent of electronic monitoring systems (EMSs), and the ability to collect information continuously about individual participants’ activity comes substantially more information [241-244]. Although many EMSs focus on developing different methods of collecting and reporting compliance against the existing primary measure, we suggest that this additional data can be used to more fully understand health care professional (HCP) HH activity by developing additional or secondary measures of HH performance.

The aims of this study are to demonstrate the value of high-resolution, individual participant data for understanding HH behaviors by reporting and comparing the performance of individual participants, HCP groups, and unit level aggregate results. We also investigate 3 measures of HH performance in addition to those outlined by the WHO: (1) time as it relates to calculating HH compliance and the amount of time spent in patient rooms, (2) the number of consecutive missed HH opportunities by individuals, and (3) HH performance in additional monitored areas. These secondary measures augment existing understanding of HH behaviors by extending the boundaries of measurement beyond single moments and places to continuous accounting of time and space by individuals, not only groups.

5.2 Methods

Data collection for this cross-sectional study was completed using an EMS developed by the research team at Toronto Rehabilitation Institute, Canada. Electronic badges worn by staff collect information about handwashing activity from electronic controllers installed in all soap and alcohol-based hand rub (ABHR) dispensers and on the ceiling, inside and outside
all monitored zones including all patient rooms [267, 272]. The dispenser controllers transmit unique identification codes to badges indicating a handwash event has occurred. Zone controllers on the ceiling are used to monitor staff movement into and out of monitored zones. These zones operate at the room level, with transitions occurring at the doorway or threshold of the monitored room. This recorded information is used by the badges to produce real-time prompts to wash within a second of crossing the threshold if staff have not washed their hands within the defined time constant of 60 seconds before crossing [257]. Badges prompt the wearer to wash by producing a discrete vibration detectable only by the wearer. This vibration lasts for 20 seconds or until an instrumented soap or ABHR dispenser is used, whichever comes first. The badges collect a rich audit record of temporal and spatial information for each participant including time and location of handwashing, dispenser type, zone changes, and HCP group allocation [269].

The EMS was installed on a musculoskeletal rehabilitation, nursing unit. Monitored zones included all patient rooms: 10 single-bed, and 10 double-bed. In consultation with unit managers and infection prevention and control practitioners, the soiled utility room was identified as a concern because of the concentration of contaminated materials and was also instrumented as a monitored zone [282]. All wall-mounted dispensers were instrumented: 47 soap, and 64 ABHR. There is an ABHR dispenser immediately outside every patient room. Inside, there is an ABHR dispenser beside every bed. All patient rooms have a centrally located sink with a soap dispenser. Every patient room has a single bathroom with a soap dispenser located inside. Therefore, single-patient rooms have 1 ABHR and 2 soap dispensers inside, and 1 ABHR dispenser immediately outside the room beside the doorway.
Multibed patient rooms have 1 additional ABHR dispenser per additional bed located on the wall beside the patient’s bed.

Data were collected during three 4-week sessions between October 03, 2016 and October 29, 2017 as part of a quality improvement initiative. The University Health Network Ethics Board waived the requirement for consent based on the quality improvement focus of the project. Generally, staff participation in such projects is required within the institution. For this study, however, there were no repercussions for nonparticipation. All staff members working on the unit were asked to participate for the entire study, issued their own electronic badges, and assigned to 1 of 5 HCP groups: administration, allied health, doctor, housekeeping, or nurse.

5.2.1 Statistical analysis

HH performance for patient rooms was calculated by dividing the number of times handwashing occurred within 1 minute before, or 20 seconds after entering or exiting a patient room divided by the total number of patient room entries and exits (opportunities) [265]. Soiled utility room performance was calculated for exit opportunities only. It was determined that because staff often carry contaminated objects into the soiled utility room and there are no patients in that area, it would not reduce the risk of hand or patient cross-contamination to require washing at entry [265]. For all measures, the binomial dependent variable of HH performance, missed or clean, was analyzed with logistic regression.
Figure 5-1: Number of handwash events before and after patient room entry (A) and exit (B). Colour bars below histograms show time constants used to determine performance: handwashes occurring within 60s before (Clean) and up to 20s after (With prompt) patient room entry or exit count as compliant opportunities. Ignored Prompt indicates number of times staff were prompted to wash but did not comply within 20s. Dashed vertical lines at 0s indicate when prompt to wash was initiated.
The series length of missed HH opportunities was determined by counting the number of consecutive patient room HH opportunity misses by an individual. For the sake of comparison, single missed opportunities are reported as series of length 1. Use of any handwash dispenser (ABHR or soap) at any time or the end of a participant’s shift terminated the series.

Analyses of patient room visit duration and series length frequency of missed HH opportunities were calculated by HCP group with Kruskal-Wallis tests. Statistical analyses were completed using R version 3.3.2 (R Foundation for Statistical Analysis, Vienna, Austria).

5.3 Results

Patient rooms were visited 38,065 times (76,130 entry and exit opportunities) by 98 unique participants (housekeeping \( N = 6 \), administration \( N = 7 \), doctor \( N = 8 \), allied health \( N = 18 \), nurse \( N = 59 \)). Aggregate HH performance for the entire study was 67%. Figure 5-1 indicates when handwashing events occurred relative to the time of patient room entry and exit (0 seconds), along with the percent of opportunities when handwashing occurred before entry/exit, after being prompted, or not at all.

The amount of time spent in patient rooms significantly predicted HH performance at both patient room entry, \( P < .0001 \), \( (B[SE] = -.0001 \ [< .0001]) \), and patient room exit, \( P < .0001 \), \( (B[SE] = -.0002 \ [< .0001]) \) (Fig 5-2). HCP group assignment was a significant predictor of how long staff stayed inside patient rooms per visit: \( H (527.19) = 4 \), \( P < .0001 \). The majority of all patient room visits were less than 1 minute in duration. The median duration of patient
room visits by HCP was 27 seconds for housekeeping, 41 seconds for administration, 51 seconds for allied health, 51 seconds for nurses, and 104 seconds for doctors.

**Figure 5-2:** Change in aggregate HH performance at patient room entry and exit and the number of times handwashing occurred while inside patient rooms over time up to 60 minutes. HH Performance scale is left y-axis. The number of dispenser activations that occurred while inside patient rooms is right y-axis.

HCP group was a significant predictor of HH performance when visiting patient rooms, \( \chi^2 (4) = 2750.72, P < .0001 \). The aggregate HCP group performance of doctors, allied health professionals, and administrators was the same at 87%. Nursing and housekeeping group performance was 67% and 57%. The distribution shapes of HH performance by individuals, within HCP groups, were all negatively skewed: there were more high performers than low in every group. The distribution for those in the nursing group was the widest, with the lowest individual user performance score of 10%. The distributions within the other HCP
groups were bimodal, showing higher scores for the majority and lower performance scores for a smaller number of individuals in each group (Fig 5-3).

The frequency of consecutive missed opportunity series lengths is shown in Figure 5-4. The majority of missed HH opportunities (83%) was part of a series of missed opportunities, whereas only 17% occurred as single isolated events. HCP group was a significant predictor of the series length of missed HH opportunities: \( H(170.57) = 4, P = .0001 \). The median length of all missed series was 4. By HCP group, administration had the shortest median
missed series at 1, whereas housekeeping had the longest at 11. The longest single series of missed opportunities was 146 by housekeeping staff.

![Histogram of consecutive missed opportunity series lengths for all users. Median and interquartile range of missed series lengths are presented by HCP group.](image)

**Figure 5-4:** Histogram of all consecutive missed opportunity series lengths for all users. Median and interquartile range of missed series lengths are presented by HCP group.

The soiled utility room was visited 1448 times by staff from only three of the five HCP groups for an aggregate HH performance compliance of 67%. For the given dataset, HCP group was a strong predictor of HH performance when exiting the soiled utility room: $\chi^2 (2) = 35.70$, $P < .0001$. HCP group results for HH performance at the soiled utility room are presented in Table 5-1.
Table 5-1: Soiled utility room HH performance by HCP group.

<table>
<thead>
<tr>
<th>HCP group</th>
<th>Performance, %</th>
<th>Opportunities, n</th>
<th>B (SE)</th>
<th>Odds ratio (95% confidence interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allied Health</td>
<td>91.14</td>
<td>79</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Facilities</td>
<td>59.57</td>
<td>371</td>
<td>-1.94* (0.41)</td>
<td>0.14 (0.06 - 0.30)</td>
</tr>
<tr>
<td>Nurses</td>
<td>68.44</td>
<td>998</td>
<td>-1.56* (0.40)</td>
<td>0.21 (0.09 - 0.43)</td>
</tr>
</tbody>
</table>

Note: Hand hygiene performance based on exit only. R2 = .02 (Hosmer-Lemeshow), .024 (Cox-Snell), .034 (Nagelkerke). * P < .001.

5.4 Discussion

Electronic HH monitoring systems capable of tracking individual HCP HH actions have benefits over traditional observational HH audits or electronic systems that only report aggregate performance. Specifically, we suggest that aggregate-based audits do not report the length of time spent in patient rooms, track consecutive missed HH opportunities, combine potentially important information such as length of time spent in patient rooms with HH performance or, focus on potentially hazardous areas outside of the patient environment such as the soiled utility room.

5.4.1 Personnel reporting resolution

Tracking and reporting aggregate unit level hand hygiene performance among health care staff may show overall trends but does not identify staff activities that might put patients at greater risk of infection. To more effectively achieve the goal of reducing cross-contamination of patients, one needs to know how individuals are performing. Although HCP group is a predictor of performance, the distribution of performance by individuals
differed within HCP groups. Figure 5-3 presents unit level aggregate, HCP group level aggregate, and individual performance by HCP group demonstrating how aggregate reporting can mask individual staff performance. The nursing group had a long distribution tail in contrast to the other groups, which had larger concentrations of high-performing individuals and smaller concentrations of lower performers.

Analyses of the distributions allow us to compare between and within groups. We are able to identify poor and excellent performers in each discipline. Ultimately, infections are spread by individuals, not groups of people. Such information can be used to understand the actual levels of compliance, versus small unrepresentative samples obtained via other methods such as self-reporting or direct observation [218].

5.4.2 Time constants for calculating compliance

All sophisticated methods of calculating HH performance other than monitoring product use or handwash counts rely on time-based evaluations to calculate compliance. Even auditors involved in direct observation, although not explicitly defined beyond the terms "before" and "after", subjectively use time to determine compliance. It is therefore important to understand what time constants are being used, how they were chosen, and how they impact performance results. By tracking when and where handwashing occurs, the system used in this study is able to monitor and credit both proactive washing that takes place before an opportunity and reactive washing that takes place immediately after a missed opportunity while being prompted.
Our system allows users to wash up to one minute prior to entry and exit and up to 20s following entry and exit. Figure 5-1 demonstrates that changes to the system’s time constants would impact performance results and that comparisons to other systems using differing constants would be difficult. When selecting the amount of time allowed for compliant washing, it would be easy to argue that shorter is better: providing less time for potential hand recontamination results in less chance of spreading infection. This decision, however, needs to be balanced with practical application and acceptance of the system as a whole by participating staff [283]. A time constant before room entry should allow completion of the handwash activity including application of ABHR to the skin and an amount of time where the ABHR is still effective before the opportunity. The amount of time permitted after room entry, in this case, allows staff time to respond to prompts to wash: locating and moving to a dispenser and time to use it. Electronic application of time constants result in objective and consistent application of rules.

5.4.3 Time spent in patient rooms

Beyond using time to calculate performance, it can also be used to understand HH behaviours through expanded reporting and analysis. In general, as the amount of time spent in a room increases, so does the likelihood of contacting a patient or the environment. Length and type of patient care affect ungloved HCP hands with a linear increase of bacterial contamination over time [284]. Figure 5-2 shows that aggregate HH performance at patient room exit varies over time more than that at room entry. At shorter room visits, the exit performance is relatively high, but at around the 8-minute mark it crosses and stays below entry performance. Shortly after the 22-minute mark, changes in HH performance for
patient room entry and exit are parallel with each other. Correspondingly, the number of handwashes that occur during patient room visits increases over time. The effect of length of stay in patient room on HH performance is dominated in this analysis by the much larger sample of nurses. Future work will evaluate the effect of length of stay of different HCP groups.

One possible explanation for the decrease in patient room exit performance is that washes that happened more than 1 minute before exit are sometimes interpreted by staff as satisfying the environment exit wash requirement. Figure 5-1 further supports this, showing that the 46.5% of the time staff washed before entering the patient room, but only 36.12% of the time before exiting. Systems that rely on only time constants to determine HH compliance presume that handwash events that occur outside those time constants do not satisfy entry and exit opportunities when they might. A handwash event that occurs more than 60 seconds before patient room exit does satisfy exit performance rules as long as nothing in the patient environment is touched before leaving.

5.4.4 Consecutive missed HH opportunities

Our results suggest that it would be valuable to monitor consecutive events, or chains of activities, by an individual HCP rather than observing HH in single events such as entering or leaving 1 room.

Manual auditing methods usually involve the auditor standing close to a patient room so that HCPs can be seen entering and leaving the room and their HH actions can be recorded. If HH is missed upon room exit, then the HCP is typically not followed beyond line of sight to
see what HH actions follow, thus ignoring consecutive missed opportunities by a single HCP [285]. We may be missing potentially important information using the traditional approach or any other method that does not collect individual participant data. Our results show that chains of missed opportunities are not infrequent; 83% of missed HH opportunities occur as part of a series of events, not in isolation (Fig 5-4).

Some of these chains of missed opportunities may be explained by accepted practice and are not considered by auditors to be missed HH opportunities. In our institution, the housekeeping staff wash, glove, and then perform some tasks moving room-to-room without removing gloves and washing. They empty waste baskets twice during the day shift and sweep daily. If there is a need to touch the patient environment in addition to the waste basket, then the staff are required to perform appropriate HH. Another case of accepted practice for a chain of missed HH occurs by unit aides who deliver and pick up meal trays to each patient room without washing and removing gloves between patient rooms. The premise is that the unit aide only touches the tray and nothing else in the patient environment. This is the same case for delivering water each day. Nursing staff on the night shift make room-to-room hourly rounds to check patients and may not need to touch the patient or patient environment.

The EMS used in this study was configured to reflect the institution’s best practice guidelines, which direct all staff to clean their hands every time they enter or exit the patient room, regardless of whether they contact the patient or the patient environment. Therefore, the EMS does not currently differentiate tasks exempt from HH procedures from those that
are not, and results include such room-to-room task sequences by housekeeping and nursing staff.

To allow the EMS to identify series of patient room visits that are exempt from HH procedures and to ensure that every patient room visit within the series is exempt, a measure based on known patterns of activities could be developed. Room visit duration can be used to help differentiate 1 type of task from another. Westbrook et al. [286]. show that for nurses, the mean task duration of direct patient care is 31% longer than for indirect patient care. By combining patient room visit duration with HCP group allocation, time of day, and the number of consecutive missed opportunities, it might be possible to classify patient room visits as requiring or not requiring HH.

5.4.5 Additional monitored areas

The EMS can be used to identify HH performance in specific locations or monitored zones other than the patient rooms. Activities performed in the soiled utility room may be as important as other areas owing to the potential for spread of infection because items that have been in contact with the patient or patient’s environment are collected there. The soiled utility room on the nursing unit in this study housed a rolling rack on which plastic bags of dirty laundry are kept for pickup. Articles for high-level disinfection, a macerator, and sharps and biowaste containers are also located in the soiled utility room. Recognition by the facility of this area being at high risk of hand contamination is demonstrated by having a hands-free automatic entrance, 2 sinks in the room with soap dispensers at each, and an ABHR dispenser immediately outside the room.
Our results identified the same aggregate HH performance on exit from the soiled utility room as that with overall patient room performance (67%), yet a soiled utility room might be expected to be a more hazardous environment. The soiled utility room should be included in audits and given the same importance as the patient environment. The ability of the EMS to record the location of HH in non-patient areas may help focus training and education programs to prevent the spread of infections.

We intend to extend analysis of these secondary measures to include further temporal and spatial factors such as additional monitored areas including clean utility and medicine rooms, time between patient room visits, the order of visits, and patterns of dispenser use.

5.5 Conclusions

The monitoring of time and place is central to calculating HH performance and can be used to extend our understanding of HH behaviors. The amount of time allowed by systems for staff to wash before and after entering and exiting the patient zone affects estimates of compliance. The definitions and impact of these time constants should be transparent to evaluators of technologies and staff participants. It is likely that extra washes performed inside the room before exit are sometimes perceived by staff as satisfying the exit washing requirement. This could be a result of unclear understanding of the time constants or a potential weakness of the EMS to identify handwashing events associated with patient room exit.

The high resolution of HH performance data collected by continuous monitoring of individuals shows that aggregate scores do not accurately reflect the HH practice of HCP
groups and that the distributions of individual scores within HCP groups can vary greatly. Continuous individual monitoring also reveals the actual chain of risk of spreading infection via consecutive missed opportunities versus reporting of specific moments in isolation from others. Although some of these missed opportunities can be explained by institutionally accepted exemptions from standard HH practice, it is unlikely that decisions made about these exemptions were informed by high-resolution data that reveal the potential impact of those decisions.

Analysis of HH performance shows that different HCP groups on the same unit perform different tasks, spend different amounts of time in patient areas, and in some cases, follow differing HH procedures. In addition to the patient environment, monitoring of HH compliance should include other locations such as the soiled utility room. Use of these measures should be considered when attempting to identify high risk locations and activities, for developing targeted training and interventions and may lead to the establishment of HCP group-specific HH protocols.
Chapter 6 Effect of intermittent system deployment

The paper in this chapter was co-authored with Pamela Holliday and Geoff Fernie, who have provided written permission for it to be used in this thesis. GF and I worked together to design the study. I built, installed, and maintained the technology. PH was the main contact with participants. I conducted all of the statistical analysis and wrote the manuscript. PH and GF edited the manuscript.

This paper has been accepted for publication by the American Journal of Infection Control and is available as an in-press, corrected proof as:


Effect of intermittent deployment of an electronic monitoring system on hand hygiene behaviors in health care workers

Abstract

Background: Improving hand hygiene compliance among health care professionals is the most effective way to reduce health care-acquired infections. Electronic systems developed to increase hand hygiene performance show promise but might not maintain staff participation over time. In this study, we investigated an intermittent deployment strategy to overcome potentially declining participation levels.
Methods: An electronic monitoring system was deployed 3 times at 6-month intervals on a musculoskeletal rehabilitation nursing unit in Toronto. Each deployment lasted 4 consecutive weeks. Each wall-mounted soap and hand rub dispenser was outfitted with an activation counter to assess the impact of system deployments on overall handwashing activity.

Results: System deployments took place in October 2016, April 2017, and October 2017. A total of 76,130 opportunities were recorded, with an aggregate hand hygiene performance of 67.43%. A total of 515,156 dispenser activations were recorded. There was a significant increase in aggregate dispenser use with every deployment and a decrease over several weeks following each withdrawal. Participation was high at the beginning of each deployment and declined during each deployment but was restored to a high level with the start of the next deployment.

Conclusions: Intermittent deployment of an electronic monitoring intervention counteracts potential declines in participation rates sometimes seen with continuous system use. However, adoption of this strategy requires the acceptance of lower periods of performance between each deployment.

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6.1 Background

Improving hand hygiene (HH) compliance among health care professionals is considered the most effective way to reduce the occurrence of health care acquired-infections (HAIs) [16, 271]. Two major challenges of any intervention aimed at improving HH performance
are the sustainability of increases it produces in the performance of staff and the sustainability of participation by the staff over the long term [244]. Methods of improving performance, such as poster campaigns, training sessions, and user feedback based on product use, have mixed results [237, 288, 289].

The development of electronic monitoring systems (EMSs) to audit and increase HH performance shows promise but might not be sustainable in terms of staff participation over time. In previous work, we showed that with continuous deployment of an EMS over the course of a year in a quality improvement context, HH performance among participating staff is largely sustainable, but participation levels may decline [269]. These reductions in participation over time may be due to several factors, including use-fatigue, desensitization to the prompt, and the opinion that system rules do not apply to different professional roles [290, 291]. In this study, we investigated the effect of intermittent deployment of an EMS on HH performance and staff participation over a 56-week period as a way to overcome declining participation levels.

6.2 Methods

The EMS used in this study was developed by the research team at Toronto Rehabilitation Institute. The system uses smart badges worn by staff to collect information about handwashing activity from electronic controllers installed in all soap and alcohol-based hand rub (ABHR) dispensers and on the ceiling, inside, and outside of all monitored zones including all patient rooms [267, 272]. The controllers transmit unique identification codes to the badges via low-powered infrared light, with no potential adverse effects on the health of users or the operation of other electronic equipment. This information is used by the
badges to produce real-time prompts to wash only when opportunities have been missed. A missed opportunity is defined as a patient room entry or exit without handwashing occurring within 60 seconds beforehand. The prompts are vibrations felt only by the badge wearer and not audible to others, lasting 20 seconds. Green light-emitting diodes on the badge light up after washing at instrumented dispensers, remaining on while the wearer is considered to be clean (set at 1 minute for this study).

Every staff member working on the study unit was issued an electronic badge. Staff retrieve the badge from the docking station at the beginning of each shift and return it at the end of the shift. The dock provides automated badge recharging and transfer of collected data to a server. Daily aggregate HH performance results for the previous 7 days are displayed on a monitor attached to the system’s docking station during system deployments. No results are provided between deployments. Before the initial deployment, staff were given live demonstrations and training sessions on the EMS. Written instructions were also posted beside the docking station along with researcher contact information. After the project launch, training was provided on an ad hoc basis in response to staff enquiries and when new staff arrived.

The EMS was installed on a musculoskeletal rehabilitation nursing unit at a teaching hospital in Toronto. A total of 111 wall-mounted soap and ABHR dispensers and 20 patient rooms were instrumented. The system was deployed 3 times at 6-month intervals. The first and third deployments occurred in the same month in consecutive years. Each deployment lasted 4 consecutive weeks. Each wall-mounted dispenser was also outfitted with an activation counter to assess the impact of EMS deployments on overall handwashing
activity. Dispenser activation counters were installed before the first deployment and continued to collect data throughout the study. Staff were not aware of dispenser activation data collection.

Data collection was conducted as part of a quality improvement initiative. The University Health Network ethics board waived the requirement for consent based on the quality improvement focus of the project. The EMS is not yet commercially available; it is expected to be cost effective when it comes to market.

6.2.1 Statistical analysis

The EMS calculates HH performance by dividing the number of times handwashing occurs within 1 minute before or 20 seconds after entering or exiting a monitored zone divided by the total number of zone entries and exits (opportunities) [265]. Simple linear regression was used to evaluate the effect of time, measured weekly for 56 weeks, on HH performance and staff participation. HH performance was calculated at the aggregate unit level. Staff participation was calculated as the percentage of unique badges used compared with the number used in the first week of the initial deployment. The first week of the first deployment was used for training staff and was not included in HH trajectory analyses, but it was used as baseline for staff participation [269].

Analysis of variance was used to detect group differences during the 3 deployments on HH performance and participation. Multiple comparisons of the 1-way analyses, with Bonferroni corrections applied, were conducted to identify which deployments differed.
Activation counts from each dispenser were recorded continuously for 6 weeks before, 4 weeks during, and 16 weeks after each system deployment intervention. Data from the 2 weeks immediately preceding each deployment were not included in analyses, because the researchers’ presence on the unit for system installation and maintenance may have influenced counts. The remaining data were divided into 4-week phases. The phase preceding each deployment was designated baseline, and the phase immediately following each deployment was designated return. Change in dispenser activation counts between baseline, intervention, and return phases for each deployment were examined with a 1-way repeated-measures analysis of variance by ranks (Friedman test). These were followed by multiple comparisons between phases with Bonferroni correction applied to identify activation count differences before, during, and after each system deployment.

Statistical analyses for this study were conducted using R version 3.3.2 (R Foundation for Statistical Analysis, Vienna, Austria).

6.3 Results

The 3 EMS deployments took place October 3-30, 2016, April 3-30, 2017, and October 2-29, 2017. A total of 76,130 HH opportunities were recorded by 98 unique participants (housekeeping, n = 6; administration, n = 7; doctors, n = 8; allied health, n = 18; nurses, n = 59), with an aggregate HH performance of 67.43%.

Linear regression analyses show that HH performance had a trajectory of -0.08% per week over 55 weeks ($P = .56; R^2 = 0.04$). Similarly, participation levels had a trajectory of -0.10% per week over 55 weeks ($P = .58; R^2 = 0.03$). Figure 6-1 presents HH performance and
participation results weekly by deployment. Participation rates were highest during the first week of each deployment and generally declined over the length of the deployment.

Separate univariate analyses of variance on the outcome variables revealed a significant group effect of deployment on HH performance ($F (2, 9) = 8.89; P < .01$), but not on participation ($F (2, 9) = 1.88; P = .20$). Multiple comparisons of HH performance results between deployment groups show that the first and second deployments differed significantly ($P < .01; d = 4.3$), whereas deployments 1 and 3 ($P = .66; d = 0.87$) and deployments 2 and 3 ($P = .06; d = -1.68$) did not.

*Figure 6-1: Hand hygiene performance and participation change over time. Weeks between deployments have been removed.*
Table 6-1: Aggregate dispenser activation count results.

<table>
<thead>
<tr>
<th>Deployment</th>
<th>Phase (4 weeks each)</th>
<th>Total dispenser activations, n</th>
<th>Relative change, %*</th>
<th>Observed difference (P value, r) * †</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Baseline</td>
<td>19932</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Intervention</td>
<td>39347</td>
<td>97.41</td>
<td>106.50 (&lt;.001, -0.478)</td>
</tr>
<tr>
<td></td>
<td>Return</td>
<td>30493</td>
<td>52.99</td>
<td>94.50 (&lt;.001, -0.456)</td>
</tr>
<tr>
<td>2</td>
<td>Baseline</td>
<td>26457</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Intervention</td>
<td>35080</td>
<td>32.59</td>
<td>40.00 (&lt;.001, -0.233)</td>
</tr>
<tr>
<td></td>
<td>Return</td>
<td>34735</td>
<td>31.29</td>
<td>7.00 (.677, -0.028)</td>
</tr>
<tr>
<td>3</td>
<td>Baseline</td>
<td>24598</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>Intervention</td>
<td>36171</td>
<td>47.05</td>
<td>92.50 (&lt;.001, -0.348)</td>
</tr>
<tr>
<td></td>
<td>Return</td>
<td>31215</td>
<td>26.90</td>
<td>62.00 (&lt;.001, -0.292)</td>
</tr>
</tbody>
</table>

Note: * From baseline phase. † Critical difference = 35.02.

Dispenser activation data were collected from August 22, 2016, and February 18, 2018. Six dispensers were damaged and unable to collect data continuously throughout the 78-week period. One dispenser was removed by the facility for renovations. There were a total of 515,156 dispenser activations from 104 soap and ABHR dispensers. There was a significant increase in aggregate dispenser activation counts with every deployment. Aggregate counts in return phases of deployments 1 and 3 remained significantly higher than their baseline counts, whereas the return phase count of deployment 2 reverted to its baseline level (Table 6-1). Figure 6-2 shows that change in activation counts of individual dispensers were concentrated in the ABHR dispensers located in hallways at patient room entrances.
Figure 6-2: Activation counts of individual dispensers by location by 4-week phases. Most count changes occurred immediately outside patient rooms in alcohol-based hand rub dispensers.

6.4 Discussion

The goal of this study was to determine whether intermittent deployment of an EMS in a quality improvement context would be able to maintain HH performance and staff participation levels over time. In our earlier study evaluating these trajectories for 4 different nursing units that used the EMS continuously for 1 year, showed 1 of the 4 units showed a significant negative trajectory of HH performance, and all 4 units had significant (albeit widely varying) negative trajectories in staff participation [269]. The results of this study show that a possible strategy to counter these negative trajectories might be to alternate periods when staff use and do not use the system (Fig 6-1). These phases of nonuse act to reduce the effects of use-fatigue and desensitization of staff to the real-time prompt feature of the system.
Despite the ability of the system to generate detailed reports of individual performance, this study used only the real-time prompts generated by the badge to provide feedback to the wearer to change behavior. No reports of performance were shared with staff, with the exception of a simple daily aggregate score that was automatically displayed on the docking station. Results of this and previous work examining the effect of prompts to wash and the impact of presenting staff with statistics lead us to conclude that it is the immediate intelligent prompt, not historical reports of performance, that changed staff behavior. This is an important observation, because this approach places no burden on management to circulate and discuss reports, although the opportunity is present if desired.

It has been reported that the additional burden of badge-based systems could lead to resistance to using such systems [18]. For this system, the only additional daily actions required by frontline staff are retrieving and returning their badges to the docking station. The electronic controllers that communicate with the badges are battery powered. The batteries are simple to change and only require annual replacement. Beyond these modest actions, no extra work was required of any hospital staff to keep the system functioning. In fact, such a system could be used to replace regular manual observations with more reliable electronically collected data and save labour [236, 292].

Non-badge-based monitoring systems, such as ones that track product use, require great amounts of effort to be effective. Dispenser count-based systems that rely on dynamic information, like patient and staffing levels, require input from staff to ensure that variables predicting counts are as accurate as possible [293]. Such systems may be useful for examining the effects of interventions but do little on their own to change HH behavior.
Improvements may be realized but at great cost to staff in time and effort by taking the generated reports and turning them into actionable targets and training initiatives that must be delivered repeatedly to be effective [294]. Because non-badge-based systems cannot track individuals’ activity, goal setting and education can be presented only to a general audience [295].

In addition to maintaining HH performance and participation levels, intermittent deployment of an EMS would reduce costs of implementation and allow more staff to participate. A multiunit facility would instrument the entire building with dispenser and patient room zone controllers, but the number of docking stations and badges would depend on the desired deployment length and frequency. For example, if a facility has 6 units and chooses to implement a 1-month deployment every 3 months, then each unit would use the system 4 times a year, and the facility would require only 2 docking stations and 2 sets of badges that would be rotated among the units.

Every time the EMS was removed from the study unit, dispenser activation counts dropped. We can see that the EMS affects HH behaviors and can reasonably conclude that the system-defined compliance rate also decreased when the system was removed. Can we in good conscience consider an implementation strategy that knowingly removes the tool that is helping staff perform better? However, participation rates with continuous deployment in a quality improvement context decline over time. Eventually, there may not be enough staff using the system to justify the cost of installation and maintenance. The intermittent-use strategy will help retain staff participants over time, leading to long-term HH practice improvements. A move from continuous to intermittent use shifts the purpose of the system
away from augmenting practice to teaching. Perhaps the optimal strategy is to have
“respite” periods when the system is removed, with reintroduction when dispenser use drops
below a preset level. This strategy might be supplemented by management encouraging and
rewarding staff to help maintain participation rates during each deployment.

An alternate strategy to maintain HH performance and participation rates is to retain the
continuous-use model but make badge wearing mandatory for staff. To date, studies using
the real-time prompting, badge-based system have largely been conducted in either a
voluntary or quality improvement context. Future studies should investigate the impact of
mandatory participation on HH performance and participation rates. Health care institutions
interested in maintaining the highest possible HH compliance rates may be more interested
in continuous deployment strategies.

Ultimately, activation counts after all interventions decline, but the rate of decline varies.
Future studies will also investigate how different deployment and interval durations and
management strategies affect HH behaviors, to determine the optimal balance between
performance and participation trajectories during deployments and higher handwashing
counts between deployments. The effectiveness of intermittent system deployment in
different hospital environments will also be investigated.

6.5 Conclusions

Intermittent deployment of an EMS is a viable method of counteracting potential declines in
HH performance and participation rates seen with continuous use in a quality improvement
project context in which wearing of badges is voluntary. HH activity significantly increases
with every EMS deployment and declines following removal. The ideal start dates and
length of each deployment and the amount of time between them have yet to be determined
and may be influenced by seasonal variables, such as staffing levels. We conclude that
institutions might choose to deploy docking stations and badges on a rotating basis if they
are willing to accept some performance declines between deployments or might choose to
adopt management strategies that encourage and reward continuous uninterrupted
participation.
Chapter 7 General discussion

7.1 Conclusions

Institutions and researchers continue to be optimistic about the ability of technology to offer solutions to poor HH compliance despite generally poor validation. As methods and technologies to increase HH performance in health care settings mature, so will the sophistication of the studies about them. This section presents responses to the research questions posed in section 1.2.

7.1.1 Objective measure

Chapters 4 and 6 describe the effect of using the system on HH activity by counting the number of dispenser activations before, during, and after three separate deployments of the system on a single nursing unit. There was a significant increase in aggregate dispenser use with every deployment of the system and a gradual decrease in dispenser use over several weeks following each withdrawal. This thesis demonstrates the value of using a continuous, objective measure of change in HH activity to assess the impact of interventions to increase HH performance. By integrating dispenser activation counters, the badge based system is able to evaluate its own impact on HH. Even when the badge portion of the system was disabled in Chapter 6, dispenser counts were available to determine the decline in HH activity. Information from activation counters can also be used to evaluate any other intervention that might be considered.
The collected data can be used to produce feedback and reports that the main system cannot. Figure 7-1 presents baseline and intervention phase dispenser activation counts collected in Chapter 4. By superimposing the collected data onto a map, a compelling and easy to understand feedback tool is created. It is expected that institutions that install an EMS will see declines in their reported HH compliance rates compared to those generated by direct observation. Without an alternate method of assessing change in performance, systems able
to continuously collect large amounts of opportunities may appear to reduce compliance when in fact rates are increasing [252].

7.1.2 Effect of real-time prompting

Results of the prompt duration study in Chapter 4 show that the use of real-time prompts to clean every time HH opportunities are missed increases overall HH performance. Prompting to clean also shifts the time of HH closer to the time of patient room entry reducing the likelihood of staff contacting the patient or patient environment without cleaning their hands first.

Reductions to the prompt duration decreased HH performance ($P < .0001$). The absolute percentage point difference in performance between the control unit receiving 20 second prompts and the unit with prompts reduced to 10 seconds was -15.60% ($P < .0001$). Performance on the unit with the prompt completely removed dropped by -26.37% ($P < .0001$). During the six-week prompt-return phase, HH performance on both intervention units improved (Table 4-3).

There was a significant association between the use of the 20-second prompt and the likelihood of performing HH within 20 seconds after entering a patient room if HH had not been done beforehand. When compared with staff using the shorter 10-second prompt, those using the default 20 seconds were more than two times more likely to clean ($P < .0001$) and more than eight times more likely to clean than those staff members who received no prompting ($P < .0001$) (Fig 4-1A).
The level of feedback described in published interventions cannot be assumed to be the same feedback that reaches frontline staff in real-life. At the facilities studied for this thesis, the only HH compliance feedback many staff actually receive is provided quarterly, on an aggregate level, via a poster (Figure 7-2). This low resolution of feedback on the levels of both temporal and user, makes the information not actionable. Since the performance data for this poster was gathered through direct observation, it likely overestimates HH compliance and may in fact reduce the incentive to improve. One of the goals of developing the system tested was to provide immediate performance feedback to every staff member at the time of the opportunity. Not only does this provide the highest amount of feedback possible, the information is actionable. It is not too late to use the feedback to reduce the risk of transmitting HAIs.
7.1.3 Sustainability of performance and staff engagement

Investigations into the sustainability of HH performance and staff engagement took place in two studies. The first study, described in Chapter 4, examined data collected on four different nursing units over a year where badges were used continuously throughout. HH performance (Fig 4-2A) had a negative trajectory of -0.18% ($P < .0001$) per week with a large ICC of 0.46 between units, indicating that performance trajectories differed between units. The change in participation rate over time was more dramatic (Fig 4-2B) with a -0.72 ($P < .0001$) reduction in percentage of users per week and a ICC of 0.19 indicating similar declines across all units. It was hypothesized that these declines may have been due to issues of use-fatigue, desensitization to the prompt, and loss of novelty.

To investigate this theory, a second study described in Chapter 6, was conducted using an intermittent deployment strategy where badges were issued to staff on a one month on, five month off schedule as opposed to 12 consecutive months. This change in deployment schedule reduced the negative trajectories of both HH performance, -0.08% ($P = .56$) and participation, -0.10% ($P = .58$). Within each deployment, HH performance remained flat. Staff participation rates were highest during the first week of each deployment and generally declined over the duration of the deployment.

Participant acceptance of any system as beneficial and accurate are of vital importance. If staff do not agree to wear a badge, the system cannot provide the prompts necessary to increase HH performance. Full transparency about the purpose of the technology, how it works, and how data will be used, should be employed to avoid suspicion and rumor. In 2008 the research team conducted a study evaluating the acceptability of a badge-based
EMS that utilized real-time prompting to increase HH performance. After trying the system, HCPs completed a survey and attended focus groups to collect their impressions, experiences, and interpretations. Staff were not anxious about being monitored and felt that the system would increase HH compliance. Concerns were raised about the accuracy, availability and confidentiality of the results. It was suggested that clear and concise policies and procedures needed to be in place and presented before deployment [263].

Boyce et al. report that in a before-after quasi-experimental study evaluating the effect of an electronic system on HH compliance, inaccuracy of the tested system negatively impacted results. Average accuracy of the system was assessed at 60%. From baseline to intervention phase, compliance at patient room entry went down 36% ($P = .191$) and by 32% at exit ($P < .001$). Authors report that staff were frustrated with the inaccuracy of the system which contributed to the decline in performance [296].

7.1.4 Additional measures

To demonstrate the value of high-resolution, individual participant data for understanding HH behaviors, Chapter 5 reports three measures of HH performance in addition to compliance with accepted HH guidelines; the amount of time spent in patient rooms, the number of consecutive missed HH opportunities by individuals, and HH performance exiting the soiled utility room.

As the amount of time spent in a patient room increases, so does the likelihood of contacting a patient or the environment. The amount of time spent in patient rooms significantly predicted HH performance at both patient room entry and exit ($P < .0001$). HCP group
assignment was a significant predictor of how long staff stayed inside patient rooms per visit ($P < .0001$). The majority of all patient room visits were less than one minute in duration. Continuous individual monitoring reveals the actual chain of risk of spreading infection via consecutive missed opportunities. This thesis demonstrates that 83% of missed HH opportunities occur as part of a series of misses and not in isolation (Fig 5-4). Activities performed in the soiled utility room may be as important as other areas because items that have been in contact with the patient or patient’s environment are collected there. Despite this, results show the same aggregate HH performance on exit from the soiled utility room as with overall patient room performance (67%).

These secondary measures augment existing understanding of HH behaviors by extending the boundaries of measurement beyond single moments and places to continuous accounting of time and space. To my knowledge, these measures have not been previously reported.

7.2 Limitations

The use of EMSs offer a number of advantages over traditional monitoring and HH improvement interventions such as continuous, objective data collection and automated reporting and feedback. Nevertheless, EMSs are not without potential limitations including system accuracy, effectiveness at improving HH compliance, and costs of implementation versus reductions in HAIs [241]. Additionally, limitations of study designs and the technology used throughout this thesis are described in this section.

All studies in this thesis were conducted in a quality improvement context. This meant that while staff were required to participate by the institution, there were no rewards provided to
participate and no sanctions applied for non-participation. Not all staff choose to wear a badge at all times. Therefore, data collected by the EMS, while extensive, was not exhaustive. The number of HH opportunities collected by the EMS are likely more representative of activity on the units compared to the implied counts based on other collection methods.

During data collection, the participating institution was not regularly collecting HH compliance data through direct observation and were not able to provide such data for evaluation.

The EMS uses IR communication between zone and dispenser controllers and the wearable monitor to determine HH performance and produce reminder prompts. IR requires ‘line of sight’ to send and receive information. A limitation of the EMS is that if this ‘line of sight’ is not maintained, by ensuring that the badge is able to ‘see’ the controllers, the system and participant may become confused about where the participant is and whether or not they have performed HH. Circumstances where ‘line of sight’ can be interrupted include incorrect attachment of the badge to the participant and obstruction of the badge by carrying of linens.

The EMS uses patient room entries and exits as proxies for moments 1 and 4. These events are not strictly always opportunities as defined by the WHO or MOHLTC since there may be times when HCPs do not come in contact with patients or the patient environment during room visits, or the room may be vacant. In a study comparing the compliance rate of health care staff using the WHO My 5 Moments for HH method versus the wash in-wash out
method found that HH compliance was comparable (72% vs 70% respectively). Study authors suggest that if institutions elect to utilize the wash in-wash out method, similar to that of the EMS, they should also provide ongoing education and intermittent assessment of HH before aseptic procedures and after body fluid contact [297]. In a previous study of the EMS it was demonstrated that 85% of all HH opportunities defined by the *Just Clean Your Hands Your 4 Moments for HH* (M1, 2, 3, 4) in a complex continuing care facility are entries and exits (M1, 4) [265].

7.3 Future work

7.3.1 Additional monitored zones

As discussed in Chapter 5, HH compliance in areas outside of the immediate patient environment can affect the level of risk of transmitting HAIs. Cleaning of hands while working in and around the soiled utility room is an obvious area of concern, where the likelihood of contacting contaminated objects is high and has been highlighted by unit managers and ICPs familiar with the studies. Similar locations outside the patient room should be expanded to include washrooms outside the patient environment and central bathing facilities.

Equally important to known areas of high pathogen content, are those where objects within need to be kept clean such as clean utility rooms where fresh linens and medical supplies like catheters are housed, medication rooms where prescriptions are stored and dispensed, and storage areas for health care devices such as blood pressure monitors, portable lifts, and commodes.
The patient room is typically considered to be the patient environment but if the patient environment is considered to be anything that the patient can touch, ambulatory patients or patients being transported, have mobile environments. Work needs to be done to investigate the possibility of expanding the monitored patient environment to include the space around the patient wherever they might be as opposed to the room where their bed is located.

7.3.2 Institutional level monitoring

In its current configuration, the EMS explicitly monitors staff movements between patient rooms and the area outside the patient rooms, where the area outside the patient room is treated as a single monitored zone. This outside-patient-room zone has no defined boundary except for the instrumented patient rooms. HCPs could move from the hallway on one unit to the hallway on another unit on a different floor without leaving that zone. Future work should investigate expanding the ability of the EMS to monitor inter-unit travel (between units) as well as intra-unit (within units). This information would extend our understanding of how HAIs travel throughout a facility on the hands of HCPs, particularly for staff that regularly travel between units.

HCP groups may differ in the scope of travel within a facility. Some staff are assigned to a single care unit in a single facility. These staff will generally arrive at work and go directly to their unit and only provide care in that area. There are, however, a number of groups that regularly travel between units providing care or contacting objects in the environment on multiple units throughout the day. For example, staff delivering food at mealtimes could visit every unit in a facility, multiple time each day. Physicians may visit patients on multiple floors. In both cases, there is the potential to come into contact with people and
objects in numerous localities in a short amount of time, providing the opportunity for microorganisms to be transmitted throughout a facility.

To monitor inter-unit travel, the EMS could be configured to treat each entire unit as a monitored zone, just like each patient room is a monitored zone. By instrumenting all possible routes to travel between units such as stairways and elevators, the system would also be able to determine the path of travel.

7.3.3 HCP specific rules

Results of the studies for this thesis and feedback from participants during data collection have highlighted differences in the HH activities in different HCP groups including a number of tasks that have been exempted from the standard institutional HH requirements. To permit direct comparisons of HH performance between groups during data collection, the system logic was kept the same for all participants. Future work should include development of HCP group specific rules that can accommodate the differing HH requirements of each and may include creation of an opt-out option allowing for a period of time when prompting would not occur: when entering the room of sleeping or cognitively impaired patients, during known repeated in/out sequences such as disinfecting a room after patient discharge, or when entering a patient room under precautions where PPE like gowns may interfere with the EMS’ s ability to produce accurate results. While all HH opportunities and HH events would still be recorded, the prompt function and performance calculations could be altered to better reflect accepted practice. Investigations into how these changes affect HH performance and participation rates would be conducted.
7.3.4 Achievable benchmarks of care

Based on direct observation, HCPs are often led to believe that unit level HH rates are near perfect, providing little incentive to actively attempt to increase performance. By providing a more realistic assessment of actual HH performance, HCPs will see that there is an opportunity to better serve their patients. It is unlikely that achieving 100% HH performance is achievable. By providing realistic targets that are achievable by staff, the use of achievable benchmarks may increase HH compliance [298-300].

7.3.5 Alternate reinforcement and deployment schedules

Changes to prompt duration described in Chapter 4 affected HH compliance. Other changes to the prompt should be investigated to determine if compliance can be improved further such as altering the operant conditioning reinforcement schedules to optimize learning trends, and response and extinction rates. Possible schedules include: continuous, fixed-ratio, fixed-interval, variable-ratio, and variable-interval [255].

One alternate version of varying prompts would be to dynamically adjust reminders based on previous performance. When HH performance by an individual exceeds a determined threshold for a minimum duration, the prompt could be disabled until a return threshold is crossed, reinstating the prompt function. For example: if the HH performance of a nurse remains above 80% for the latest 100 opportunities, the badge could stop issuing prompts to clean, while still recording all HH activity. If the nurse’s HH performance was to fall below 70% in the previous 10 opportunities, the prompt would be reinstated. By allowing this respite from prompts at every missed opportunity by acknowledging generally high HH
performance, the EMS can reduce the potential of de-sensitivity to the prompt without completely removing the prompt.

As demonstrated in Chapter 6, by deploying the system in a non-continuous way, staff participation levels remained high but dispenser activation counts fell significantly between deployments. Similar to alternate reinforcement schedules, alternate deployment schedules could maintain staff participation and performance levels. Future work will investigate how different deployment and interval durations affect HH behaviors.

7.3.6 Identification of moments 2 and 3.

Currently, the EMS is not able to identify moments 2 and 3. While literature indicates that higher HH performance at moments 1 and 4 is generally reflected in higher performance at other moments, this cannot be taken for granted. It would be advantageous to develop a method to monitor all HH moments and provide prompts to perform HH in all circumstances required by the accepted measures of the institution. As a first step in this process, we will be conducting a time-work study with newly developed versions of the EMS badges that contain additional sensors including accelerometers. This additional sensor data, combined with existing factors including time in room, HCP group, time of day, and data about patient condition will be used to develop an artificial intelligence algorithm to identify all moments of HH. Additionally, these data will allow calibration of the background dispenser activation counts to allow that information to more accurately represent HH activity.
7.4 Impact on HAIs

The main objective of this thesis is to increase HH performance in health care workers in order to reduce the prevalence of HAIs. The studies conducted in chapters 3-6 focus on changing HH behaviours but do not measure their impact on infection rates. Future work will include assessing the effect of changes to HH performance on HAI rates which will establish targets for acceptable levels of compliance.

7.5 Conflicts of interest

The HH technology studied throughout this thesis was developed by myself, Geoff Fernie, Bruce Haycock, and the research team at the Toronto Rehabilitation Institute at Toronto, Canada. The inventors of the technology along with the authors of the studies presented in chapters 3-6 may gain financially when the system becomes commercially available. GF is named on patents issued: CA2682361, EP20080733638, US12/078186, US12/569770, GB1107048.9, GB1217739.0. GF and SP are named on patents pending: CA2920688, EP20140835925, US14/911067.
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November 12, 2013

Dr. Geoff Fernie
Toronto Rehabilitation Institute – UHN
University Centre
550 University Avenue
Toronto, Ontario, M5G 2A2

Dear Dr. Fernie:

RE: TRI REB #: 13-004
Automated Hand Hygiene Monitoring System to Improve Hand Hygiene.

Thank you for consulting with the UHN Rehabilitation Medicine and Science Research Ethics Board regarding the development of this project.

Please retain this letter as a formal waiver of the requirement for REB approval of this activity. Given that no specific research protocol is involved, it does not fall under the purview of the UHN Rehabilitation Medicine and Science REB.

The UHN Rehabilitation Medicine and Science REB has deemed your project to be considered as a quality assurance/quality improvement or program evaluation study as defined in Article 2.5 of the TCPS2, and therefore not subject to Research Ethics Board review. Though the project can begin at any time, as Research Ethics Board approval is not required, it may be in the team’s best interest to first have the details of this project reviewed by an ethicist or other appropriate institutional representatives, before commencement of this project.

The UHN Rehabilitation Medicine and Science REB would recommend that you manage risk by the use of disclosure, release, and/or consent forms. If, during the course of this study, there are any changes to the project or any new information that would affect the determination stipulated above, these should be brought to the immediate attention of the Board for re-assessment.

Thank you for your ongoing dedication to responsible conduct of research and best wishes for the successful completion of your project.

Yours sincerely,

[ ] Paul Oh MD, MSc, FRCPC, FACP
Chair, Research Ethics Board
University Health Network
Toronto Rehabilitation Institute