The use of a sporicidal disinfectant on environmental surfaces to reduce healthcare onset Clostridium difficile in two high risk units

Thesis

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Abstract

Background

Clostridium difficile infections (CDI) lead to significant morbidity, mortality, and associated healthcare costs continue to grow. The purpose of the study was to reduce the risk of potential cross transmission of healthcare onset CDI (HO-CDI) via implementation of a new sporicidal disinfectant, Virasept™, as a sole cleaning agent for 2 inpatient care units with high CDI rates.

Methods

This study conducted an environmental cleaning intervention on 2 units, a Bone Marrow Transplant Unit (BMTU) and an Acute Leukemia/ Lymphoma Unit (LL). These unit’s rooms were daily and terminally cleaned with a phenolic 3M disinfectant for 11 months in P1; and a sporicidal, Virasept™, for 3 months in P2. Cleaning audits were performed by Environmental Services (ES) and investigators, and ES implemented a fluorescent marking gel (Dazo™) application to high touch surfaces (HTS) to assess cleaning compliance. Areas were inspected with a black light to assess for residual fluorescence; if present, the area was not adequately cleaned. In addition, hand hygiene compliance was observed and patient satisfactions of the disinfectants scent were collected. Risk ratios (RR) and 95% confidence intervals (95% CI) were calculated to assess potential efficacy of Virasept™ in reducing CDI incidence. CDI rates were considered healthcare onset (HO-CDI) if PCR was positive on or after hospital day 4. Stool samples were sent at the discretion of treating clinicians. Rates were calculated as number of CDI cases per 10,000 patient days.
Results

<table>
<thead>
<tr>
<th>BMTU/LL</th>
<th>Cancer Hospital (without BMTU/LL)</th>
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<tbody>
<tr>
<td>HO-CDI #</td>
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<tr>
<td>P1</td>
<td>Phenolic* 2-12/2011</td>
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<tr>
<td>P2</td>
<td>Virasept™ 1-3/2012</td>
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*Reference Group (2/11-12/11)

The patients in the James BMTU and James LL units were at an 18% increased risk of contracting HO-CDI during P2 vs. P1; however, this increased risk was not statistically significant.

Conclusions

Environmental Services initiatives represent one component of a multi-pronged approach to CDI reduction. CDI rates were not impacted by meticulous daily/terminal cleaning with the sporicidal disinfection and improved hand hygiene. CDIs occurred within the high risk patient populations, not in the hospital environment. This likely reflects the baseline level of immune-suppression of the high risk patient population of the Bone Marrow Transplant Unit and the Acute Leukemia and Lymphoma Units. Therefore the patients’ internal environment is altered because of antibiotic usage and immune-compromised state. As a result, in this extremely high risk population, CDIs were less likely due to cross transmission and require aggressive focus on antibiotic stewardship.
Dedication

To my parents, Roger and Kay Snider for all their love and encouragement throughout my life, especially during my studies at The Ohio State University. Without them I would not be as driven and successful.

A special thanks to my sister, Kasey Snider and my boyfriend Ryan Bleakney for their love and support.
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In addition, I would like to express my gratitude to my advisor Dr. Jill Clutter, board member Dr. Sarah Varekojis, and my Microbiology Laboratory Manager Jane Poulson for their support during my graduate studies including the writing and collection of data.

Finally, I would like to give a notice of permission to use previously copyrighted materials that appear extensively in the text.
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Field of Study

Major Field: Allied Medical Professions
Area of Emphasis: Allied Health Management
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Chapter 1: Introduction

Background of the Problem

_Clostridium difficile_ is the most common enteric infection encountered in hospitals with significant medical and economic consequences.\(^1\) _Clostridium difficile_ infections (CDIs) occur frequently in hospitalized patients who have been taking antibiotics. Besides antibiotic exposure, patients with an increased risk of CDIs are patients undergoing gastrointestinal surgery, a serious underlying illness, immune-compromising conditions, advanced age, and longer length of hospital stay.\(^2\) This creates major health problems because hospitals house numerous ailing people in close proximity to one another, and whose conditions leave them susceptible to infections such as _C. difficile_.\(^3\) The problem is intensified by the fact that _C. difficile_ is potentially fatal and can cause other severe conditions such as pseudomembranous colitis, toxic megacolon, colon perforation, and sepsis.\(^4,5\)

CDIs result in an increase of 2.6 to 4.5 days in length of hospital stay, increased morbidity and mortality, and higher costs. Additional healthcare costs are due to extended hospitalization, re-hospitalization, laboratory tests, and medications.\(^6\) CDI costs range from $2,500 to $3,500 per episode.\(^7\) According to Ghantoji et al, in United States based studies, recurrent _C. difficile_ cost increases from $13,655 to $18,067 per case\(^6;\) and recurrent CDIs occur in 20% of the cases.\(^8\) Patients who develop CDIs have 50% higher healthcare costs compared to patients free of _C. difficile_.\(^9\) According to the Center of Disease Control, CDI causes 14,000 deaths yearly.\(^10\) Also, it is currently estimated that 500,000 healthcare onset CDI cases occur annually.\(^11\) This leads to an excess cost of 1.3 billion dollars a year in the United States.\(^12\) In conclusion, CDIs lead to additional healthcare resources and morbidity or death and high healthcare cost for the patients. _C. difficile_ is a healthcare-wide patient safety problem.\(^9\)
Significance of the Problem

The human intestinal tract consists of normal flora that is employed as a defense mechanism against the production of enteric pathogens.\textsuperscript{1} \textit{C. difficile} is a harmless organism that is a part of the normal intestinal flora.\textsuperscript{1,13} Thus, \textit{C. difficile} lives in the intestines with a large amount of other bacteria. These bacteria maintain control of \textit{C. difficile}.\textsuperscript{3} Three to 5\% of the adult population live relatively healthy with \textit{C. difficile}.\textsuperscript{1,3,13}

A CDI occurs when there is an alteration in the patient's normal intestinal flora followed by \textit{C. difficile} colonization either by exposure to the organism or its spores. Also, disturbances in the intestinal tract by human intervention such as antibiotics, can lead to the establishment of pathogenic \textit{C. difficile}.\textsuperscript{1} For that reason, the balance of normal intestinal flora is shifted when a \textit{C. difficile} carrier takes a course of antibiotics. While the antibiotics affect the other normal intestinal flora, antibiotics have no effect on \textit{C. difficile}.\textsuperscript{3} The fact that \textit{C. difficile} is resistant to a wide range of antibiotics enables the bacterium to colonize and infect even in the presence of antibiotics.\textsuperscript{11} Without normal intestinal flora present, \textit{C. difficile} develops toxins that cause diarrhea, fever, and, in the extreme case, death. Additionally, the toxins produced by \textit{C. difficile} make the infection contagious, thus making \textit{C. difficile} a problem in hospitals.\textsuperscript{3} About 20\% to 7\% of hospitalized adults are colonized with \textit{C. difficile} due to frequent use of antibiotics and exposure to \textit{C. difficile} in the hospital environment.\textsuperscript{4,13}

\textit{C. difficile} spores can be found in a hospital environment and are generally found on high touch surfaces (HTS) such as bed linens, bed rails, bathroom fixtures, toilets, and medical equipment.\textsuperscript{4,5} One of the main ways to deal with the \textit{C. difficile} problem is hygiene.\textsuperscript{3} \textit{C. difficile} spores are able to survive on environmental surfaces up to 5 months even after exposure to a variety of environmental disinfectants.\textsuperscript{13} Surfaces may look clean, but if they have not been disinfected using an Environmental Protection Agency (EPA) approved \textit{C. difficile} disinfectant or bleach, the surface may still be contaminated.\textsuperscript{4}

Prevention of CDIs plays a vital role in infection control programs in healthcare organizations. Examples of routine infection prevention are facility
wide surveillance, contact precautions, adherence to hand hygiene protocols, and environmental controls. Another important role in healthcare is awareness of patient satisfaction, since patients are randomly selected to evaluate their respective stays. Excellent service to current patients is critical to attracting new patients. Patient satisfaction is critical to a healthcare organization pursuing high performance. Having infection prevention and high patient satisfaction will enable a healthcare organization to thrive.

Objectives

The purpose of this study was to determine if routine use of Virasept™, a new EPA approved disinfectant, could reduce the incidence of healthcare onset CDIs on the Arthur G. James Cancer Hospital Bone Marrow Transport Unit (BMTU) and James acute Leukemia and Lymphoma unit (LL) at The Ohio State University Wexner Medical Center (OSUWMC). The study focused on these two units because they had the highest rates of healthcare onset C. difficile in 2010. The study used Virasept™ disinfectant, with a claim to kill and/or inactivate C. difficile spores on hard non-porous surfaces. The study also compared this to a phenolic 3M disinfectant, a multi-purpose germicidal detergent used on hard, non-porous surfaces. The phenolic and Virasept™ disinfectants are effective against bacteria, fungus, mycobacterium and viruses. In addition the Virasept™ disinfectant can kill and/or inactivate C. difficile spores.

All HTS for both daily and terminal cleaning of all patient care rooms in the James BMTU and James LL were cleaned with the standard phenolic disinfectant or Virasept™ disinfectant for a total of fourteen months. For eleven months from February–December, 2011 (Period 1) the patient care rooms were cleaned with the phenolic. In the following three months of January-March, 2012 (Period 2) rooms were cleaned with the Virasept™ disinfectant. The numbers of healthcare onset CDI cases were compiled from February 1, 2011 through March 31, 2012.

An additional objective of the study was to determine Environmental Service (ES) compliance with the disinfection processes of HTS in the patient
care rooms in James BMTU and James LL. The standardized observational compliance forms were collated during both P1 and P2 with the phenolic and the Virasept™ disinfectants, respectively. The compliance forms determined percent compliance of HTS disinfection. These compliance forms have been used successfully for the last four years at the OSUWMC for the Departments of Environmental Services and Clinical Epidemiology.

Along with environmental compliance, another objective was the use of Dazo, a fluorescent marking gel. Dazo was applied to HTS in each room. Following ES cleaning, areas were analyzed with a black light to evaluate for residual fluorescence to detect surface disinfection. Dazo was performed during both the usage of the phenolic and Virasept™ disinfectants, in order to check HTS compliance. The use of Dazo provided the percentage of HTS cleaned, to ensure that ES compliance was controlled for during the usage of both phenolic and Virasept™ disinfectants.19

Another objective of the study was to determine if hand hygiene compliance during the usage of both the phenolic and Virasept™ disinfectants. Maintaining hand hygiene compliance is important in healthcare facilities, in order to prevent transmission of C. difficile. Hand hygiene compliance was compiled from February-December, 2011 for the phenolic disinfectant and from January-March, 2012 for the Virasept™ disinfectant.

A final objective of the study was to determine patient satisfaction regarding the phenolic disinfectant versus the Virasept™ disinfectant. The patient satisfaction forms included scent acceptability of the disinfectant used during hospital admission. The patient satisfaction forms were collected on December 2011 for the phenolic disinfectant and January 2012 for the Virasept™ disinfectant.
Research Hypothesis

Can healthcare onset CDIs in the James BMTU and James LL be reduced by using Virasept™, a sporicidal disinfectant to clean environmental surfaces? Is ES compliant with the disinfection processes of HTS in patient care rooms in the James BMTU and James LL? Do healthcare workers maintain hand hygiene compliance? Are patients admitted to the James BMTU and James LL accepting of the scent of Virasept™?

Research Approach

This study compared two different disinfectants to determine if the healthcare onset C. difficile rates varied between the two disinfectants. Comparing a phenolic, to Virasept™, a sporicidal disinfectant, determined if the sporicidal lowered healthcare onset C. difficile rates, which could result in less potential cross-transmission of C. difficile among patients. Therefore the two different disinfectants were the independent variables and the observed C. difficile rate was the dependent variable.

Additionally, the study assessed ES compliance with the disinfection processes of HTS in the James BMTU and James LL patient care rooms. ES compliance included Dazo application, which was essential for either the phenolic or Virasept™ to compare the efficacy of each disinfectant to the HTS against the healthcare onset C. difficile rates.

Finally the study assessed healthcare workers hand hygiene compliance and patient satisfaction regarding the phenolic and Virasept™. Maintaining hand hygiene compliance is necessary to prevent transmission of C. difficile throughout the healthcare facility. Patient satisfaction forms included acceptability of the scent and any potential physical reaction to the disinfectant. Patient satisfaction was important as these patients were immunocompromised and have less tolerance for environmental irritation. High patient satisfaction is critical to a healthcare organization pursuing high performance.15
Definition of Terms

Anaerobic

An anaerobic organism is an organism that does not require oxygen for growth. The organism could possibly react negatively and may even die if oxygen is present.

Antibiotic-Associated Diarrhea

Antibiotic-associated diarrhea results from an imbalance in the normal intestinal flora caused by antibiotic treatment.

Antibiotics

An antibiotic is a compound or substance that kills or slows down the growth of bacteria.

Bacteria

Bacteria are single-celled micro-organisms. Bacteria have a wide range of shapes from spheres to rods. Bacteria are often grouped into colonies that typically live in soil, water, organic matter, or the bodies of plants and animals. Some bacteria are pathogenic and cause infectious diseases. Antibiotics are used to treat these bacterial infections.

Bacterial Spore

A spore is a thick-walled resting cell produced by the organism to protect itself from unfavorable environmental conditions. Spores of C. difficile can survive up to 5 months in the environment.

Clostridium difficile

C. difficile is an anaerobic, gram positive, spore-forming, and toxin producing bacillus.
**CDI Case**

When a diarrhea stool sample yields a positive result in the lab for *C. difficile* toxin B gene from the Gene Xpert, the patient is considered to have a CDI. Therefore, this patient is a CDI case.

**Disinfectant**

Disinfectants are substances that are applied to environmental objects to destroy micro-organisms that are living on those objects.

**Enteric Bacteria**

Enteric bacteria are bacteria of the intestines.

**Environmental Protection Agency**

The U.S. EPA is an agency of the federal government of the United States in charge of protecting human health and the environment, by writing and enforcing regulations based on laws passed by Congress.

**Fastidious Organism**

Organisms, termed fastidious organisms, require specialized environments due to complex nutritional requirements.

**Gene Xpert Assay**

The Gene Xpert *C. difficile* Assay is performed on the Cepheid Gene Xpert System for rapid detection of the *C. difficile* toxin B gene sequence from diarrheal stool samples. The test utilizes automated real-time polymerase chain reaction (PCR) to detect toxin gene sequences associated with toxin producing *C. difficile*.21

**Gram Positive Bacillus**

For the majority of the time, bacteria can either be gram positive or gram negative depending on how it stains with a gram stain. When viewing the
bacteria microscopically, gram positive bacteria stain purple whereas gram negative bacteria stain pink. Gram positive bacteria are able to retain the crystal violet stain because of the high amount of peptidoglycan in the cell wall. Similarly, there are two basic shapes bacteria can possess. Bacilli are elongated rods while cocci appear round or spherical. Gram positive bacillus appears as elongated rods and purple under the microscope.

**Healthcare Onset**

A patient with a *C. difficile* toxin testing that is positive on or after hospital day four is considered Healthcare Onset.22

**Healthcare Onset Infection**

A hospital acquired infection is an infection whose development is facilitated by the hospital environment, such as one acquired by a patient during a hospital admission or due to a device placed during an admission.

**Polymerase Chain Reaction (PCR)**

PCR is a technique in molecular microbiology that amplifies a single piece of DNA into thousands or millions of copies of that particular DNA sequence. A Polymerase Chain Reaction is an in vitro technique to rapidly generate large quantities of a given DNA segment. It involves separating the DNA into its two complementary strands, binding a primer to each strand where synthesis will start, and using DNA polymerase to synthesize a complementary strand, resulting in a two-stranded DNA from each single strand. The process is then repeated in cycles to generate multiple copies of that DNA sequence.20

**Toxin Producing**

The toxins produced by *C. difficile* kill human intestinal cells by causing them to burst open, allowing the bacteria to use them as fuel. This results in severe diarrhea and, in rare cases death.23
**Vegetative cell**

The vegetative state of a cell is the active growth phase of the organism. If *C. difficile* is in the vegetative state is challenged, but not killed, the bacterium forms a spore. *C. difficile* vegetative cells can survive up to 6 hours.\(^{13}\)

**Limitations**

The study compared two different disinfectants in the James BMTU and James LL, which was a limitation of the experiment, only used the patients admitted from February 1, 2011 to March 31, 2012. Therefore, the study only included the patients admitted to the James two units for the healthcare onset *C. difficile* rate comparison. Since, the patients were not randomly assigned to the James BMTU and James LL units, selection bias could have occurred during the study. In addition, the length of each time period in the study was a limitation. Eleven months of CDI rates and environmental compliance for the phenolic disinfectant was not equivalent to the three month with the Virasept\(^{\text{TM}}\) disinfectant.

A human factor limitation would have been proper cleaning compliance from ES. ES were to follow the patient room cleaning policy in order to properly disinfectant the HTS in the patient rooms and bathrooms. The ES department required education on how to clean and disinfect each patient’s room according to a protocol including a check list of each environmental surface in the room. Therefore, each environmental surface in the patient room was cleaned and disinfected in the exact same manner. Along with cleaning compliance, ES were to use the proper disinfectant for each period of experiment.

Another human factor limitation was access, education, and usage of alcohol based hand rubs for the healthcare staff and visitors. The education and compliance with hand washing from the healthcare staff was a limitation. Based on previous data, when a supervisor or manager monitored hand hygiene compliance of their own staff, the reports indicated extremely high compliance. When a healthcare staff member monitored hand hygiene compliance from a different unit, hand hygiene compliance was low. As a result, for this study hand
hygiene observations were performed by anonymous observers from the Ohio Hospital Association.

A final limitation was the physicians’ usage of broad spectrum antibiotics. The OSUWMC did not have restrictions on antibiotic usage. The two James locations consist of patients with long term antibiotic use. Therefore they were at an extremely high risk of acquiring *C. difficile*. As a result, these locations were an excellent test to determine the healthcare onset *C. difficile* rates of the two different disinfectants.
Chapter 2: Review of Literature

*C. difficile* is the most common enteric infection encountered in hospitals with significant medical and economic consequences. The infection spreads quickly because it is difficult to eradicate the *C. difficile* spores from high-risk environments as spores are resistant to heat and standard disinfectants. Hospitalized patients with diarrhea can circulate the infection and health care workers become vehicles for the spread of *C. difficile*. Hospitalized patients receiving antibiotics are at a greater risk of acquiring *C. difficile*. For some patients, the administration of antibiotics to treat infections due to other pathogens may have allowed for the development of *C. difficile*. As *C. difficile* spores are difficult to eradicate from the environment along with the difficulty of the human intestinal tract to re-establish normal flora, *C. difficile* can relapse.

*C. difficile* is an anaerobic, gram positive, spore forming, and toxin producing bacillus. The bacterium *C. difficile* is a common cause of antibiotic-associated diarrhea. *C. difficile* is recognized to cause 15% to 25% of all episodes of antibiotic-associated diarrhea. Besides antibiotic-associated diarrhea, CDIs can cause pseudomembranous colitis, toxic megacolon, perforations of the colon, sepsis, and occasionally death. CDIs may resolve in about 20% of patients within 2-3 days after discontinuation of the antibiotic to which the patient was previously exposed. Recommendations for CDI treatment is withdrawal of the implicated antibiotic and avoiding of unnecessary antibiotics. When continued antibiotic treatment is necessary, it is best to use antibiotics with a low probability of causing *C. difficile*.

Patients with an increased risk of CDIs are those with antibiotic exposure, gastrointestinal surgery, serious underlying illness, immune-compromising conditions, advanced age, and long lengths of hospital stay. Most *C. difficile* cases develop due to prolonged use of antibiotics during healthcare treatment.
Of the CDIs acquired in the healthcare setting as many as 90% of cases may be associated with antibiotic usage. As a result, *C. difficile* has emerged as the most common cause of hospital acquired diarrhea with broad spectrum antibiotic use.

The rates of CDIs tripled in the United States from the years 2000 to 2005. Also, the number of hospital discharge diagnosis of CDIs doubled between 2001 and 2005. In 2006, the CDI discharge diagnosis rates in United States hospitals exceeded 70,000 cases per year. This is an increase from less than 150,000 cases in 2000. It is currently estimated that there are approximately 500,000 cases of CDI per year in United States hospitals and long term care facilities. A 2006 study estimated a total of 12,600 initial *C. difficile* cases and 5,600 recurrent *C. difficile* cases just in the state of Ohio, according to different more current definitions of initial and recurrent cases. In May 2008, Jarvis et al used 648 acute care facility survey respondents to find an overall prevalence rate. Survey results reveal 1,443 *C. difficile* positive patients out of 110,550 inpatients. Therefore the overall *C. difficile* prevalence rate is 13.1 per 1,000 inpatients. Of the 13.1 inpatients per 1,000, 73% of the patients are healthcare associated CDIs.

CDIs result in an increase of 2.6 to 4.5 days in length of hospital stay, increased morbidity and mortality, and higher costs of health care. CDI cost ranges from $2,500 to $3,500 per episode. After the first occurrence, the risk of another CDI increases up to 60%. Additional healthcare costs are due to extended hospitalization, re-hospitalization, laboratory tests, and medications. According to Ghantoji et al, in United States based studies, for recurrent CDIs the cost increases from $13,655 to $18,067 per case. The cost difference is almost entirely due to an increased length of stay. Patients who develop CDIs have 50% higher healthcare costs compared to patients free of *C. difficile*. *C. difficile* is a considerable public health hazard in the United States resulting in more deaths than all other intestinal infections combined. According to the Center of Disease Control (CDC), CDIs cause 14,000 American deaths yearly. The associated mortality rates of CDIs range from 6.9% to 16.7%. In Ohio,
during 2009 there were 1,221 CDI related deaths, with 469 listed as the primary underlying cause of death and 752 as any reported cause of death.\textsuperscript{29}

This leads to an excess cost of 1.3 billion dollars a year in the United States, which is an added financial burden on healthcare institutions.\textsuperscript{12} Other studies have estimated an annual CDI cost for the United States between $750 million and $3.2 billion.\textsuperscript{4,6,9} The state of Ohio had an excess healthcare cost for initial hospital onset cases of CDIs between $21 and $41 million in 2006.\textsuperscript{26} But most studies have under estimated the cost because they did not include outpatient costs. With high cost associated with CDIs, the use of additional resources for prevention and control is necessary.\textsuperscript{6}

The human intestinal tract consists of normal flora employed as a defense mechanism against the production of enteric pathogens.\textsuperscript{1} C. difficile is a harmless organism that is represents a small part of normal human intestinal flora; it is carried by 3\% to 5\% of healthy adults in their lower gastrointestinal tract.\textsuperscript{1,13} A CDI occurs when there is an alteration in the patient's normal flora followed by C. difficile colonization either by exposure to the organism or its spores. Disturbances in the intestinal tract by interventions such as antibiotics, leads to the establishment of pathogenic C. difficile.\textsuperscript{1} About 20\% to 7\% of hospitalized adults are colonized with C. difficile due to the frequent use of antibiotics and exposure to C. difficile within the hospital environment.\textsuperscript{4,13} C. difficile is resistant to a wide range of antibiotics which enables it to colonize and infect in the presence of antibiotics.\textsuperscript{11} Extended antibiotic use or use of multiple antibiotics increase the risk of CDI.\textsuperscript{7} Restoration to normal flora is key to prevent CDIs in patients.\textsuperscript{11} Colonization by C. difficile will stop when more normal intestinal bacteria are restored.\textsuperscript{8}

C. difficile can be present as a vegetative cell in the colon and for a short time outside the colon, or as a spore outside the colon.\textsuperscript{13} C. difficile spores resist stomach acidity and germinate in the small intestine, which produce vegetative bacteria that release two toxins.\textsuperscript{7} Outside the stomach the vegetative form is sensitive to oxygen and can be readily killed by brief oxygen exposure. As a result, the vegetative form of C. difficile survives for 15 minutes on dry surfaces,
but can remain viable on moist surfaces for up to 6 hours.\textsuperscript{13} \textit{C. difficile} is normally fastidious in its vegetative state but is capable of forming spores when environmental conditions no longer support its growth.\textsuperscript{13} When exposed to air or any environment not suitable for growth, \textit{C. difficile} becomes dormant and forms a bacterial spore.\textsuperscript{4,13} The \textit{C. difficile} spore form is heat stable and able to survive a variety of harsh conditions, i.e. the acidic environment of the stomach and environmental surfaces even after exposure to disinfectants.\textsuperscript{13} In spore form, \textit{C. difficile} can survive on environmental surfaces for five months which makes it difficult to eradicate.\textsuperscript{4,13} As \textit{C. difficile} spores live outside the human body for such a long time, \textit{C. difficile} spores can be present in the hospital environment.\textsuperscript{5}

\textit{C. difficile} is shed in feces. Spores are deposited on surfaces through contamination by an infected person’s hands, or by objects or clothing exposed to fecal matter.\textsuperscript{4} A surface that becomes contaminated with feces may serve as a reservoir for spores.\textsuperscript{4,30} Direct exposure to contaminated patient care items and HTS in the patient’s room have been implicated as sources of infection.\textsuperscript{13} \textit{C. difficile} spores are generally found on HTS such as bed linens, bed rails, bathroom fixtures, toilets, and medical equipment in the rooms of patients with \textit{C. difficile}.\textsuperscript{4,5} \textit{C. difficile} spores are transferred to patients mainly through the hands of healthcare personnel who have touched a contaminated surface.\textsuperscript{4,30} Surfaces may look clean, but if they have not been disinfected using bleach or an EPA approved \textit{C. difficile} disinfectant, the surface may still be contaminated.\textsuperscript{4} If environmental surfaces are still contaminated with \textit{C. difficile}, spores can be spread from person to person through surface contamination.\textsuperscript{5} Spores from the environment can be re-activated when they are ingested and move into the intestinal tract. In the intestinal tract they germinate and begin to grow and reproduce.\textsuperscript{4} This adds to the difficulty of eradication of \textit{C. difficile} in this cycle.

With \textit{C. difficile} being acquired by fecal-oral transmission, there are three types of \textit{C. difficile} transmissions in the healthcare setting. The first type of transmission is through direct transfer of \textit{C. difficile} from a patient to the environment. The second type is through direct transfer of \textit{C. difficile} from a person’s hands to a patient. The final type of transmission is an indirect transfer
from a health care worker who was in contact with the contaminated environment and transferred *C. difficile* to a patient. Environmental contamination plays an important role in the transmission of *C. difficile* in the healthcare setting.

The frequency of acquiring *C. difficile* has been linked to the level of environmental contamination. The environment around patients are more contaminated than the environment around *C. difficile* carriers. Many studies have demonstrated widespread environmental contamination with *C. difficile* in the rooms of patients with CDIs ranging from 2.9% to 75%. For example, patients admitted to a room previously occupied by a patient with *C. difficile* have a higher risk of obtaining *C. difficile*. According to Carling et al, an admitted patient has a 73% increased risk of acquiring the same pathogen of a previous patient compared to another admitted patient not occupying that room. In an environmental study by Verity et al, 660 environmental swabs were collected from isolation patient rooms with 23% positive for *C. difficile*, for a total of 152 swabs. This study also noted that one-quarter of all environmental sites in the patient rooms were contaminated with *C. difficile* despite routine cleaning.

*C. difficile* can be spread by direct or indirect contact with an infected individual or with a contaminated environment. The level of environmental contamination is related to the severity of the patient’s disease. The more contaminated the environment, the more likely that a healthcare workers’ hands will be contaminated with *C. difficile* spores, which can contribute to the healthcare onset spread of CDIs. Although disinfectant wipes play a role in decreasing the number of pathogenic bacteria from contaminated surfaces, wipes can potentially transfer bacteria to other surfaces if used on more than one surface. As a result, the cleaning processes can potentially redistribute the microorganisms throughout the patient’s room. Therefore, proper environmental decontamination and monitoring of the process is essential for *C. difficile* prevention. This includes use of disinfectants to minimize the spread of pathogens and to prevent transmission to high risk patients. Along with environmental decontamination protocols, it is important to improve the
disinfection, to improve training of environmental service workers by using checklists.¹³

Hospitals must choose an appropriate disinfectant that is effective against *C. difficile* spores. Phenolics and quaternary ammoniums are common disinfectants used in healthcare facilities, but are not effective sporicidals.⁴ Many EPA registered germicides kill the vegetative *C. difficile*, but only hypochlorite solutions also known as bleach, can kill *C. difficile* spores. But the usage of bleach causes problems; including corrosion, pitting, or discoloration of surfaces over time and employee-related respiratory concerns. As a result, the CDC recommends the use of bleach during outbreak situations. The physical motion of cleaning with a routine germicide removes and dilutes spore concentrations and is acceptable in the absence of an outbreak.³⁴ Yet, in a study by Mayfield et al, switching from a quaternary ammonium to bleach in a bone marrow transplant unit reduced the incidence rate of *C. difficile* associated diarrhea from 8.6 to 3.3 cases per 1000 patient days.³⁵ Thus, bleach can be successful in environmental surface disinfection in patient care areas with ongoing transmission of *C. difficile.*³⁴ Notably, the Mayfield et al study did not reduce the patients risk of acquiring CDIs in other hospital units when implementing bleach.³⁵

Recently, the EPA approved a product for use in healthcare settings with a label claim of killing and/or inactivating *C. difficile* spores on hard, non-porous surfaces. In June 2010, Ecolab released Virasept™, the company’s first EPA approved, ready-to-use hard surface disinfectant with an EPA label claim against *C. difficile.*¹⁶,¹⁷ Improved room disinfection, such as using an EPA disinfectant, should potentially lead to a decreased rate of hospital acquired CDIs.¹³

In addition to an EPA approved disinfectant, the speed of diagnosis of *C. difficile* is very useful for immediate isolation and treatment and to control the environmental spread of infection to other patients.¹ Rapid identification of *C. difficile* with implementation of contact precautions is vital, especially to mitigate environmental transmission of *C. difficile.*⁷ Whenever possible, *C. difficile* infected patients should be isolated in a single patient room. Current CDC
recommendation is to continue isolation for the duration of diarrhea, although patients with CDIs continue to shed organisms for up to seven days. Many hospitals continue isolation two to three days after the resolution of diarrhea. In a study performed by Sethi et al, skin contamination of patients with CDIs persisted on the skin after resolution of diarrhea. Continued shedding of *C. difficile* after resolution of diarrhea could possibly contribute to ongoing transmission of *C. difficile*. This study noted that shedding is common for one to four weeks after treatment. According to infectious surveillance programs, 94% of CDIs occurred in patients who received healthcare in an inpatient or outpatient setting. These results provide support to recommend contact precautions could continue until hospital discharge, when *C. difficile* rates remain high despite standard infection control protocols.

Another concept in preventing *C. difficile* transmission is adherence to hand hygiene by staff, patients, and visitors. Compliance with hand hygiene protocols and use of gloves as a barrier to hand contamination should be stressed for staff education. Despite universal knowledge of hand washing as a cornerstone for prevention of healthcare associated infections (HAIs), compliance rates over 50% are difficult to achieve. Hand washing rates range from 9% to 50% in studies of healthcare workers. Guidelines released by the CDC in 2002, recommend alcohol based hand rubs to be used before and after patient care. The vigorous rubbing with sufficient volume of alcohol based hand rubs has been shown to be effective in reducing the density of skin flora. Since alcohol based hand rubs increase hand hygiene compliance, their use is encouraged in health care facilities. Alcohol hand rubs, however, have a limited effectiveness against visibly soiled hands and spore forming organisms such as *C. difficile*. Conventional hand washing with soap and water or an antiseptic soap is preferred over alcohol based hand rubs because of the absence of sporicidal activity of alcohol after caring for a patient with *C. difficile*. A recent study demonstrated that *C. difficile* spores are the most difficult to remove from hands when comparing adherence of spores of different bacterial species. Hand washing remains the most effective means of reducing hand contamination.
According to a recent study by Knight et al, comparing incidence rates of *C. difficile* before and after implementing an alcohol based hand rub policy, a significant decrease in rates of *C. difficile* occurred. After implementing the alcohol hand rub policy, the rate decreased from 4.96 per 10,000 patient days to 3.98 per 10,000 patient days. Compliance of both alcohol hand rub and hand washing increased dramatically. The decreased rate of *C. difficile* is due to improved compliance with preventive strategies, increased awareness of hand hygiene, and effect of hand rubbing in reducing bacteria on hands.\(^9\)

Proper environmental disinfection and hand hygiene in the hospital is linked with another important factor, patient satisfaction. Having a successful patient satisfaction program can be key in developing a patient focused hospital culture, necessary to survive in the growing demand for customer loyalty.\(^{39}\) The management of patient satisfaction has become a critical element in the day to day operations of healthcare organizations pursuing high performance. While retention of patients for future business purposes is important, attraction of new customers for outpatient services translates into increased volume.\(^{15}\) The ultimate goal is that every employee, from the front line workers to the CEO, practices the same behaviors with regard to providing excellent service.\(^{39}\) Excellent service to existing patients and to the network of referring physicians yields patient and referral satisfaction critical to attracting new patients.\(^{14}\)

As a result, CDI prevention is a vital component of infection prevention programs in healthcare facilities. *C. difficile* prevention programs consist of routine infection prevention strategies in addition to heightened activities during outbreaks and when healthcare onset transmission is suspected.\(^7\) The CDC outlined six strategies to eradicate *C. difficile* from a healthcare setting. The strategies involve prescribing / using antibiotics carefully, test for *C. difficile* when patients have diarrhea, isolate patients immediately, wear gloves and gown when treating the patients, wash hands with soap and water, clean the patient room with an EPA approved spore killing disinfectant, and when a patient is transferred to another facility, notify the new facility that the patient has *C. difficile*. Notifying
other facilities about *C. difficile* will help decrease the risk of *C. difficile* transmission.\(^8\)

In addition to these six strategies, public reporting is an important concept. Ohio initiated public reporting for all initial and recurrent cases of healthcare onset CDI that occurred in hospital and nursing home patients. The purpose of the public reporting system was to better determine the burden of CDI among Ohio residents and to establish facility level baseline CDI rates to assist in identifying abnormal disease activity. One goal of public reporting is to motivate healthcare facilities to improve infection control including implementing CDI prevention measures.\(^26\)

Another important concept is facility wide surveillance. Surveillance for CDIs involves collection and interpretation of clinical and laboratory data intended to reduce the morbidity and mortality associated with *C. difficile*. Interventions for preventing CDIs should be incorporated into health care facilities’ infection prevention protocols. Staff should be monitored for compliance along with surveillance being conducted to measure CDI rates.\(^7\)

In conclusion, routine CDI prevention includes environmental disinfection, quickest diagnosis, contact precautions, adherence to hand hygiene protocols, public reporting, and facility wide surveillance. These infection prevention steps are required to facilitate lower *C. difficile* transmission rates in a healthcare setting. Patient satisfaction is important in implementing a new disinfection product, so existing and new patients can share any issues related to their satisfaction with the healthcare facility.
Chapter 3: Methodology

Introductory Paragraph

This study determined if the new EPA registered Virasept™, a sporicidal disinfectant, reduced healthcare onset *C. difficile* rates in specific patient care units. The standard phenolic, non-sporicidal disinfectant was compared to the Virasept™ disinfectant, determined if the sporicidal lowered healthcare onset *C. difficile* rates, which could result in less potential cross-transmission of *C. difficile* among patients. The study also assessed the ES disinfection compliance of cleaning of the HTS in the patient care rooms and bathrooms through the use of a fluorescent marker, Dazo™. Hand hygiene compliance was quantified during both periods. Finally, the study assessed patient satisfaction of the disinfectants used during their hospital stay.

Research Design

The study took place in the James BMTU and James LL at the OSUWMC. The study was approved by the Cancer Institutional Review Board with a protocol number of 2011C0125, in December 2011 (See Appendix A). The numbers of healthcare onset CDI cases were calculated from February 1, 2011 through March 31, 2012. The stools of the patients submitted for *C. difficile* PCR testing were at the discretion of the treating physician. For Gene Xpert *C. difficile* PCR testing, hospital policy stated that stool must be diarrheal or conform to the shape of the container and must be frequent, i.e. at least three times in a 24 hour period. All HTS for both daily and terminal cleaning of all patient care rooms in the James BMTU and James LL were cleaned by ES with the standard phenolic 3M disinfectant or Virasept™ disinfectant for fourteen months. For eleven months of February-December, 2011 (Period 1) patient care rooms were cleaned with the phenolic disinfectant. The next three months of January–March, 2012 (Period
2) rooms were cleaned with Virasept™. The numbers of healthcare onset CDI cases were calculated during these periods using the database from Clinical Epidemiology.

ES had a room cleaning policy; it stated that cleaning should always progress from least soiled to most soiled areas. A new clean dry cloth moistened with disinfectant for cleaning HTS is to be used in each patient room. The ES patient room cleaning policy provides detailed cleaning/disinfecting instructions.40

ES cleaned and disinfected all patient care rooms according to a check list of all HTS in the room. The HTS that were disinfected by ES include: bed rails, call button, television remote, phone, bedside table, over bed table, patient chair, other furniture, countertops, door knobs, door surfaces, and light switches. In addition, HTS in the patient bathroom that were disinfected include: sink, faucets, soap dispenser, towel dispenser, handrails, tub or shower, door knobs, light switch, toilet including the flush lever, toilet seat, and toilet bowl. These HTS were disinfected daily and at patient discharge. For this study, the ES workers and nurses in the James BMTU and James LL were informed of the disinfectant product change. ES followed the same cleaning and disinfecting protocol for each study period, with one exception. For Virasept™ disinfection in P2, the Virasept™ was not sprayed in the bathrooms due to concerns of aerosolization, but was cleaned as the rest of the room, with cloths moistened with Virasept™ disinfectant.

ES on the James BMTU and James LL were observed to ensure disinfection compliance. The standardized observational compliance forms were collected during P1 and P2 on all HTS in all patient rooms and bathrooms. The compliance forms provided the unit location, whether it was a daily or discharge/terminal clean, and a list of HTS that were disinfected. Compliance forms assessed the percent compliance of HTS disinfection.

Aligned with ES compliance was the use of Dazo™, a fluorescent marking gel. Dazo™ was applied to HTS in each room prior to the ES cleaning. Following ES cleaning, HTS areas were analyzed with a black light to evaluate for any residual fluorescence to assess surface disinfection. If the marking was visible...
with the black light; the surface was not adequately cleaned. The percentage of HTS cleaned were reported.19

Hand hygiene compliance was collected during both periods from February-December, 2011 for the phenolic disinfectant and from January-March, 2012 for the ViraseptTM disinfectant. Maintaining hand hygiene compliance is another potential risk factor for cross transmission of *C. difficile*.

Patient satisfaction surveys were collected in December 2011 for the phenolic disinfectant and in January 2012 for the ViraseptTM disinfectant. Any patient admitted to the James BMTU or James LL during P1 and /or P2 were included; repeat patients were most likely to identify any potential differences. Patient satisfaction forms included the acceptability of the scent and any potential physical reaction to the disinfectant. Obtaining patient satisfaction was critical because the patients were immune-compromised and may have less tolerance for environmental irritation. It is also important to keep patient satisfaction high, so patients have excellent experiences which will lead people to return and recommend friends and family to come to this organization for their healthcare needs. Excellent service to existing patients is critical to attracting new patients.14

This study assessed healthcare onset *C. difficile* rates for the phenolic versus ViraseptTM to determine any potential effects to reduce *C. difficile*. It is recognized, however, that prevention of cross transmission via meticulous cleaning and hand hygiene represents a small part in healthcare onset case rates. Antibiotic exposure, PPIs and chemotherapy can also affect the healthcare onset rates.

*Research Hypothesis*

Can healthcare onset CDIs in the James BMTU and James LL be reduced by using ViraseptTM, a sporicidal disinfectant to clean environmental surfaces? Is ES compliant with the disinfection processes of HTS in patient care rooms in the James BMTU and James LL? Do healthcare workers maintain hand hygiene compliance? Are patients admitted to the James BMTU and James LL accepting of ViraseptTM?
Subject Selection

The study population included all admitted patients within the James BMTU and James LL at the OSUWMC from February 1, 2011 through March 31, 2012. The BMTU consists of a South and an East pod with a total of twenty-four beds; James LL has seventeen beds, thus an evaluation of forty-one beds, within thirty-nine rooms. These two units had the highest rates of C. difficile recorded in 2010; the overall James Cancer hospital had 5.5 cases/10,000 patient days. However, the rates were 13 per 7,873 patient days, or 16.5 cases/10,000 BMTU patient days and 7 cases 2,579 patient days, or 27.1 cases/ 10,000 James LL patient days. Note, the James LL data was from July-December 2010 only, due to relocation of the leukemia and lymphoma patients as part of a renovation. See 2010 Healthcare Onset Clostridium difficile Infection Rates graph below.

Graph 3.1: 2010 Healthcare Onset Clostridium difficile Infection Rates

Note: James LL data is only from 7/10-12/10.
These case rates were prior to the implementation of the Gene Xpert PCR testing for *C. difficile* which began January 2011. However, CDI case rates for both P1 and P2 within this study were performed with the Gene Xpert PCR testing, so results were comparable. These locations had immune-compromised patients; and represented an excellent place to make an intervention to potentially positively affect a patient’s outcome.

**Instrumentation**

CDI data was collected by Clinical Epidemiology as a part of standard surveillance. Surveillance is a standard way of classifying infections over time; not based on clinical symptoms, solely positive diarrheal stool for *C. difficile* i.e. as a laboratory identified event. The *C. difficile* database included patient information, date positive, date of previous positive, days from previous positive to current positive, admission date, unit, most recent discharge date, days from last discharge to current admission, etc. This database allowed Clinical Epidemiology to classify all *C. difficile* positive testing and focus on healthcare onset *C. difficile* cases which are a positive stool toxin on or after hospital day 4, which is the only category that is publicly reportable.

The Gene Xpert *C. difficile* assay was performed on the Cepheid Gene Xpert System for rapid detection of the *C. difficile* from diarrheal stool samples.\(^{21}\) Implementation of the Gene Xpert PCR testing for *C. difficile* began on January 18, 2011 at OSUWMC. Gene Xpert PCR testing identified the gene for toxin B of *C. difficile* and has a much higher sensitivity than the prior cytotoxin assay test. The higher sensitivity of the Gene Xpert PCR has resulted in more positive test results for *C. difficile*. Consequently, during fiscal year (FY) 2010 there were 162 healthcare onset CDIs compared to FY 2011 with 180 healthcare onset CDIs.\(^{42}\) All patients’ stools suspected of CDI were performed by the Gene Xpert PCR machine for *C. difficile*. All non-diarrheal stools were rejected from OSUWMC Clinical Microbiology Laboratory, unless the patient had ileus and the treating physician called the Laboratory prior to submitting the stool for *C. difficile* PCR testing.
The ES compliance tool was used during both periods on all HTS in all patient rooms / bathrooms in the James BMTU and James LL. The real time observational ES compliance forms were used as a standardized tool for this study (See Appendix B). The form provided the unit location, whether it was a daily or terminal clean, and a list of HTS to be disinfected in the patient room / bathroom. ES compliance forms assessed percent compliance of HTS disinfection.

The hand hygiene observations (See Appendix C) by anonymous observers from the Ohio Hospital Association were collated during use of the phenolic and Virasept™ disinfectants. Existing data of hand hygiene compliance was shared for this study.

Lastly, a patient satisfaction questionnaire (See Appendix D) was used as a standardized tool. The questionnaire provided patients’ acceptability of the scent and the patients’ potential physical reaction to the disinfectant used during their stay at the hospital in these two units. This quantified patient feedback on the disinfectants used during their admission to the hospital.

The *C. difficile* database from Clinical Epidemiology was used to assess case rates which focused on healthcare onset; *C. difficile* toxin testing that is positive on or after hospital day four. These data were compiled monthly.

**Statistical Procedure**

Currently Clinical Epidemiology calculates CDI rates as a part of their standard surveillance per 10,000 patient days. For this study healthcare onset CDI rates were calculated for the James BMTU and James LL as well as the overall James Cancer hospital rate. The *C. difficile* rates were calculated as the number of *C. difficile* cases divided by the total number of patient days per unit per month multiplied by 10,000. The patient days were collected from a finance report and sent to Clinical Epidemiology. For this study, healthcare onset *C. difficile* rates for each unit were calculated per month for each disinfectant.

To assess the efficacy of the Virasept™ disinfectant in reducing the potential CDI incidence, a Risk Ratio (RR) compared P2 using Virasept™ to P1
using the phenolic. The *C. difficile* rates from the James BMTU and James LL during use of the phenolic disinfectant were compared to the *C. difficile* rates from the James BMTU and James LL during use of the Virasept™ disinfectant. This comparison determined if this disinfectant had any impact on *C. difficile* case rates in the James BMTU and James LL.

The environmental disinfection compliance form provided the percent of compliant ES staff during the fourteen months of the study. In addition to ES compliance, the use of Dazo™ provided the percent of HTS cleaned. Hand hygiene data was represented in a percentage of compliance for the James BMTU and the James LL units.

The patient satisfaction questionnaire provided the acceptability of the scent and potential physical reaction to the disinfectant used during hospital admission, on the Likert Scale. The scale assessed percentages of agreement or disagreement regarding the disinfectant used during the patients’ admission.

For this study, the main statistical procedure was calculation of the healthcare onset *C. difficile* rates for the James BMTU and James LL. Other statistical procedures in the study were the percentage of disinfection compliance, percentage of HTS cleaned, percentage of hand hygiene compliance, percentages of agreement or disagreement regarding the disinfectant used during the patients’ admission to the James BMTU and James LL at the OSUWMC.
Chapter 4: Results of Data Analysis

The purpose of this study was to determine if routine use of a sporicidal disinfectant, Virasept™ could reduce the incidence of healthcare onset CDIs on the James BMTU and James LL at the OSUWMC. Virasept™ is a recently approved EPA approved product for use in the healthcare setting which claims to kill and/or inactivate C. difficile spores on hard non-porous surfaces.16,17 Also, the study used a phenolic 3M disinfectant, a multi-purpose, non sporicidal, germicidal detergent for use on hard, non-porous surfaces.18

The five study objectives were to determine the number of healthcare onset CDIs during the use of phenolic and Virasept™ disinfectants, routine 1:1 ES observations of room cleaning, percent compliance of HTS cleaning in patient care rooms in the James BMTU and James LL via the, use of Dazo™, hand hygiene compliance, and patient satisfaction regarding the disinfectants.

The first study objective was to determine the number of healthcare onset CDIs during the usage of the phenolic disinfectant and Virasept™ disinfectant, for fourteen months. For the eleven months from February-December, 2011 (Period 1) the patient care rooms were cleaned with the phenolic disinfectant. The following three months of January-March, 2012 (Period 2) rooms were cleaned with the Virasept™ disinfectant.

During the usage of the phenolic disinfectant in P1, healthcare onset CDIs ranged from 14.43 to 87.08/10,000 patient days on the James BMTU and from zero to 70.42/10,000 patient days on James LL. See Healthcare Onset Clostridium difficile Infections Rates for February-December 2011 chart below.
The average healthcare onset CDI rate were 42.03/10,000 patient days for the James BMTU and 26.73/10,000 patient days for the James LL during the usage of the phenolic disinfectant in P1. Furthermore, the overall James Cancer hospital healthcare onset CDI rate without the James BMTU and James LL, in P1 were 7.16/10,000 patient days. See the Phenolic Disinfectant Healthcare Onset *Clostridium difficile* Infection Rate Averages chart below.
During the usage of the Virasept™ disinfectant in P2, healthcare onset CDIs ranged from 46.30 to 71.43/10,000 patient days on the James BMTU and from zero to 47.73/10,000 patient days on the James LL. See Healthcare Onset *Clostridium difficile* Infection Rates for January-March 2012 chart below.
The healthcare onset CDI rate average was 56.04/10,000 patient days for the James BMTU and 22.68/10,000 patient days for James LL during the usage of Virasept™ disinfectant in P2. Furthermore, the overall James Cancer hospital healthcare onset CDI rate without the James BMTU and James LL, in P2 was 9.86/10,000 patient days. See the Virasept™ Disinfectant Healthcare Onset Clostridium difficile Infection Rate Averages chart below.
As a result, the average healthcare onset CDI rates increased from 35.95/10,000 patient days in P1 with the phenolic disinfectant to 42.60/10,000 patient days in P2 with the Virasept™ disinfectant. For a total number of 44 CDIs with 12,238 patient days in the James BMTU and James LL during P1 compared to a total number of 14 CDIs with 3,286 patient days in the James BMTU and James LL during P2. In comparison, the overall James Cancer Hospital healthcare onset CDI rate without the James BMTU and James 10 East, increased from 7.16/10,000 patient days in P1 to 9.86/10,000 patient days in P2. See the Healthcare Onset *Clostridium difficile* Infection Rate Averages chart below.
Risk ratios (RR) and 95% confidence intervals (95%CI) were calculated to access potential efficacy of Virasept™ in reducing CDI incidence, by comparing P2 to P1. P2 had a CDI rate of 42.60/10,000 patient days compared to P1 having a CDI rate of 35.95/10,000 patient days. The CDI RR (95%CI) from the James BMTU and James LL was 1.18 (0.65, 2.16). Therefore, the high risk patients in the James BMTU and James LL were at an 18% increased risk of contracting healthcare onset CDI during P2 compared to P1; however this increase was not statistically significant. In comparison, the RR (95%CI) for the overall James Cancer Hospital without the James BMTU and James LL was 1.38 (0.71, 2.68). The patients admitted to the James Cancer Hospital were at a 38% increased risk of contracting healthcare onset CDI during P2 compared to P1. As a result,
the CDI RR of the James BMTU and James LL is less than the overall James Cancer Hospital CDI RR.

The second objective of the study was to determine if ES were compliant with the disinfection processes of the HTS in the patient care rooms in the James BMTU and James LL. The standardized ES observational cleaning compliance forms were collated during both periods of cleaning with the phenolic and Virasept™ disinfectants. The ES compliance forms determined the percentage of compliance during HTS disinfection. During the phenolic disinfection in P1, ES maintained 99.0% compliance, in similarity in P2 with the use of Virasept™, ES maintained 99.6% compliance when disinfecting each of the HTS. As a result, ES maintained high disinfection compliance using the phenolic and Virasept™ disinfectants on the HTS in the patient care rooms and bathrooms. See the Environmental Service HTS Cleaning Compliance chart below.

Graph 4.6: Environmental Service HTS Cleaning Compliance
The third objective was to determine the percentage of HTS cleaning compliance determined by Dazo™, a fluorescent marking gel with application to HTS. Areas were inspected with a black light to access for residual fluorescence; if present the HTS area was not adequately cleaned. The percentage of HTS cleaning with the phenolic disinfectant from November-December, 2011 at baseline was 58%, on 499 HTS. In contrast, the percentage of HTS cleaning with the Virasept™ disinfectant from January-March, 2012 for Quarter 1 was 96%, on 685 HTS. As a result, the HTS cleaning compliance determined by Dazo™ increased from 58% at baseline to 96% compliance in Quarter 1. See Percentage of HTS Cleaned Determined by Dazo™ chart below.

![Percentage of HTS Cleaned Determined by Dazo™](chart)

Graph 4.7: Percentage of HTS Cleaned Determined by Dazo™

The fourth objective of the study was to determine hand hygiene compliance for the entire study period. Hand hygiene compliance ranged from 24% to 94% for the James BMTU and from 6% to 77% for James LL. Therefore,
the average hand hygiene compliance for the James BMTU and James LL from February-December 2011 while using the phenolic disinfectant was 37%. Yet, the average hand hygiene compliance for the James BMTU and James LL increased for January-March 2012 while using the Virasept™ disinfectant to 76%. Therefore, hand hygiene compliance increased over the study period, to a high 76% compliance. See Hand Hygiene Compliance for the James BMTU and James LL chart below.

The final objective of the study was to determine patient satisfaction regarding the phenolic and Virasept™ disinfectants. The patient satisfaction forms include the opinion on the scent of the disinfectant on the Likert scale and potential physical reaction to the disinfectant, collected on December 2011 for the phenolic disinfectant and January 2012 for the Virasept™ disinfectant.
On the two units, during P1 in December 2011, 74.29% agreed and 25.71% strongly agreed that the scent of the disinfectant used during their hospital stay was acceptable. As a result, an average of 100% of the patients agreed that the scent of the disinfectant used during their hospital stay was acceptable. Furthermore, for the phenolic disinfectant, no patient reported a physical reaction to the disinfectant during their hospital stay. See the December 2011 Phenolic Disinfectant Patient Satisfaction chart below.

In comparison, during P2 in January 2012, 40.63% of the patients in the James BMTU and James LL agreed that the scent of the disinfectant used during their hospital stay was acceptable. In addition, 43.75% of the patients strongly agreed that the scent of the disinfectant used during their hospital stay was acceptable. Importantly, 9.38% neither agreed nor disagreed that the scent of the disinfectant used during their hospital stay was acceptable. But, during P2,
6.25% disagreed that the scent of the disinfectant used during their hospital stay was acceptable. As a result, an average of 84.38% of the patients agreed that the scent of the disinfectant used during their hospital stay was acceptable. Additionally, during P2, no one reported a physical reaction to the disinfectant during their hospital stay. See the January 2012 Virasept™ Disinfectant Patient Satisfaction chart below.

Graph 4.10: January 2012 Virasept™ Disinfectant Patient Satisfaction

In conclusion, 100% of the patients agreed that the scent of the phenolic disinfectant used during their hospital stay was acceptable. In comparison, 84.38% of the patients agreed that the scent of the Virasept™ disinfectant used during their hospital stay was acceptable. Even though Virasept™ had lower scent acceptability, the main patient comment was of the strong vinegar smell. Some patients said Virasept™ strong vinegar smell only lasted for about 10 seconds.
Four patients participated in the questionnaire in both December 2011 and January 2012. Some, who had experienced both disinfectants, thought the strong smell must mean the disinfectant is more powerful and cleans more effectively. Another patient, who had experienced both disinfectants, said Virasept™ is better than the old disinfectant. Yet, two patients had to leave their patient rooms because of the strong smell, with one patient becoming nauseous. Patient satisfaction with the two disinfectants depends on the specific patient and possibly the medical treatment they are receiving or if they have an altered sense of smell.

During the study period from February 2011-March 2012, ES maintained a high 99% disinfection compliance with the 3M phenolic and Virasept™ disinfectants on the HTS in patient care rooms and bathrooms. Even though Dazo™ determined a low ES HTS compliance of 58% at baseline from November-December 2011, ES HTS compliance increased dramatically to 96% in Quarter 1, from January-March 2012. During the study, ES disinfection compliance and hand hygiene compliance increased. Hand hygiene compliance increased significantly from 37% from February-December 2011 to 76% compliance in January-March 2012.

Even with the increase of compliance with ES disinfection and hand hygiene, the total healthcare onset CDI rates in the James BMTU and James LL increased from 35.95/10,000 patient days with the phenolic disinfectant in P1 to 42.60/10,000 patient days with the Virasept™ disinfectant during P2. Yet, with a CDI RR comparison, the high risk patients in the James BMTU and James LL were at an 18% increased risk of contracting healthcare onset CDI during P2 compared to P1. Yet, the CDI RR for the overall James Cancer Hospital without the James BMTU and James LL was 1.38. Therefore, patients in the James Cancer Hospital were at a 38% increased risk of contracting healthcare onset CDI during P2 compared to P1. As a result, the CDI RR of the James BMTU and James LL is less than the overall James Cancer Hospital CDI RR.
Chapter 5: Discussion and Conclusion

With the implementation of a sporicidal disinfectant, the expected results were a decrease in healthcare onset CDIs. Yet, our results actually revealed an increase in healthcare onset CDI rates, even as ES compliance with the sporicidal disinfectant and hand hygiene compliance increased. This study effectively minimized to rule out any potential source of cross transmission of \textit{C. difficile} from any HTS in the patient care environment as the reason for the increase in CDI cases as both hand hygiene and ES compliance with HTS were optimized. For these reasons, the rate of \textit{C. difficile} disease in these patients must be related to patient specific conditions or therapies such as their conditioning regimens, myeloablative chemotherapy, antibiotic prophylaxis and/or PPI use, all of which disturb the GI mucosa and is believed to be potential endogenous sources for CDI development. CDIs are more likely developing within the high risk patient population themselves and less likely to be acquired from the hospital environment. This may be explained by the level of immune-suppression of these high risk patient populations of the Bone Marrow Transplant Unit and the Acute Leukemia and Lymphoma Units. The patients’ internal environment is altered because of their immune-compromised state and therapy.

The rate of CDIs increased in the James BMTU and James LL, as well as in the James Cancer Hospital. In contrast Mayfield et al, switched from a quaternary ammonium to bleach, also effective against CDI, in a BMTU, and saw a reduction in the CDI rates. But, in her study, the bleach did not reduce the CDI rates in the other non BMT units when bleach was implemented.\textsuperscript{35} In our study, it appears that the patients’ risk of CDI must be more dependent on type of treatment, antibiotics, and immune-suppression; and is not related to the environment. Although an antimicrobial stewardship program was not part of this
study, it should be a part of clinical daily focus, to facilitate and mitigate CDIs in high risk patients.

In this study, we did not assess the patients conditioning regimen, antibiotics used, severity of illness, length of stay in either period, and primary diagnoses of these patients, which also may have contributed to the CDI incidence. The rates of *C. difficile* are multi-factorial; however, we have minimized the potential for cross transmission and inadvertent acquisition from the hospital environment based on the rigorously, improved ES cleaning and health care worker hand hygiene. Notably, in a recently published article by Walker et al, using sequence typing, no more than 25% of CDI cases could be linked to a potential ward-based inpatient sources. Even with well-implemented infection control measures, up to three-quarters of new CDIs are not simply explained by conventional transmission. As a result, a better understanding of transmission and additional types of infection control interventions are required to reduce the spread of *C. difficile*.43

Other than antibiotics, the individual patients’ immune-suppression and therapies for their cancer, a potential reason for increased CDI rates could be associated with non-unit hospital employees entering the patient rooms or having contact with the patients. These hospital employees could be from respiratory therapy, x-ray, special lab draws, nutritional services, etc. Observations of hand hygiene and ES disinfection from locations other than the James BMTU and James LL were not included in the study. A possible limitation of the study, the proximity of the patients with CDIs to each other was not measured. Finally, data was not collected on sequential patients in rooms of prior *C. difficile* infected patients.

A recommendation to continue the study for another nine months would be best to additionally compare CDI rates over time. With continuation of the study, an equal number of months of data for the phenolic and Virasept™ disinfectants could be obtained, as the phenolic study period was eleven months and Virasept™ was only three months, which is also a limitation of the study. Another study alternative would be to implement Virasept™ in all patient isolation
rooms to reduce all possible spores from the environment or to implement it on a lower risk unit to assess its impact in an immune competent population. Additional study could also include an assessment of the antibiotics, underlying neoplastic process, days of immune suppression, length of stay and chemotherapy administered, as this too could influence the risk of developing a CDI.

As stated per Hsu et al, despite universal knowledge of hand washing as a cornerstone for prevention of healthcare associated infections, compliance rates over 50% are difficult to achieve. However, according to Knight et al, after implementing an alcohol based hand rub policy, the CDI rate decreased. An overall increase in hand hygiene and ES compliance in the James Cancer Hospital reflects positive aspects of this study, which may have additionally prevented other diseases or infections that are commonly acquired from the hospital environment.

The study concludes with three main points. Antibiotic stewardship in addition to Virasept™ may help reduce the endogenous CDI rates in the immune-compromised patients. Secondly, a longer time frame is desired to study Virasept™, to determine if the CDI rates will change over time. Finally, hand hygiene compliance and ES compliance is very important to maintain, to reduce the risk of cross-transmission. If ES is not cleaning appropriately, then it does not matter which therapies the physician prescribes to the high risk patients, as patients could ultimately acquire C. difficile from the environment or from a healthcare workers' hands.
References


3. The Clostridium difficile Problem. 2/25/12; Available from: http://www.cdiff-compensation.co.uk/Clostridium-Difficile.html.


18. 3M. Phenolic Disinfectant Cleaner Product No. 18 Technical Data. Available from: http://multimedia.3m.com/mws/mediawebserver?mwsId=66666UuZjcFSLXTtnXT6Oxs6EVuQEcuzgVs6EVs6E666666--

19. Lehr C., Snider K., Mangino J. Multi-pronged interventions to reduce Clostridium difficile Infections. 2012, The Ohio State University Wexner Medical Center.


40. The Ohio State University Medical Center: Environmental Service Policy.

41. The Ohio State University Medical Center: Department of Epidemiology Database.

42. Mangino J., Clostridium difficile Infection Update, September 2011. The Ohio State University Medical Center, 2011.

Appendix A: Cancer Institutional Review Board Approval Letter
Dear Dr. Mangino,

The Cancer IRB APPROVED BY EXPEDITED REVIEW the above referenced research. The Board was able to provide expedited approval under 45 CFR 46.110(b)(1) because the research meets the applicability criteria and one or more categories of research eligible for expedited review, as indicated below.

- **Date of IRB Approval:** December 21, 2011
- **Date of IRB Approval Expiration:** December 13, 2012
- **Expedited Review Category:** 5, 7

In addition, the research has been approved for a waiver of documentation of the consent process and an alteration of HIPAA Research Authorization.

If applicable, informed consent (and HIPAA research authorization) must be obtained from subjects or their legally authorized representatives and documented prior to research involvement. The IRB-approved consent form and process must be used. Changes in the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before they are implemented (except where necessary to eliminate apparent immediate hazards to subjects).

This approval is valid for one year from the date of IRB review when approval is granted or modifications are required. The approval will no longer be in effect on the date listed above as the IRB expiration date. A Continuing Review application must be approved within this interval to avoid expiration of IRB approval and cessation of all research activities. A final report must be provided to the IRB and all records relating to the research (including signed consent forms) must be retained and available for audit for at least 3 years after the research has ended.

It is the responsibility of all investigators and research staff to promptly report to the IRB any serious, unexpected and related adverse events and potential unanticipated problems involving risks to subjects or others.

This approval is issued under The Ohio State University's OHRP Federalwide Assurance #0006378.

All forms and procedures can be found on the ORRP website – www.orrp.osu.edu. Please feel free to contact the IRB staff contact listed above with any questions or concerns.

Thomas W. Raasch, OD, PhD, Vice-Chair
Cancer Institutional Review Board
Appendix B: Observational Environmental Service Compliance Form
## CDI Collaborative Environmental Cleaning Audit Tool

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<thead>
<tr>
<th>Date</th>
<th>#</th>
<th>Unit</th>
<th>Daily Clean</th>
<th>Bed Rails</th>
<th>Call button</th>
<th>TV remote</th>
<th>Phone</th>
<th>Bedside tabletop</th>
<th>Overbed table</th>
<th>Patient chair</th>
<th>Other furniture</th>
<th>Countertop/horiz surfaces</th>
<th>Door knobs</th>
<th>Door surface</th>
<th>Light switches</th>
<th>Sink</th>
<th>Faucets</th>
<th>Soap Dispenser</th>
<th>Towel dispenser</th>
<th>Handrails</th>
<th>Tub/shower</th>
<th>Door knob/lever/flush</th>
<th>Toilet seat/back</th>
<th>Toilet bowl</th>
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</tbody>
</table>

**Totals:**

Percent Compliance
Environmental Cleaning Observation Instructions:

<table>
<thead>
<tr>
<th>Date</th>
<th>Enter the date of the observation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit</td>
<td>Select the correct PIP unit from the list (PIP Unit 1 ICU, PIP Unit 2 ICU, PIP Unit 1 Non-ICU, PIP Unit 2 Non-ICU, PIP Whole House).</td>
</tr>
<tr>
<td>Room #</td>
<td>Enter the room number of the room observed (NOTE: mark “I” after room number if this is an isolation room)</td>
</tr>
<tr>
<td>Type</td>
<td>Enter a “1” in the Daily column if observing a daily cleaning or enter a “1” in the Terminal column if observing a terminal (discharge) cleaning. <strong>DO NOT ENTER A “1” IN BOTH COLUMNS FOR THE SAME OBSERVATION</strong></td>
</tr>
</tbody>
</table>

(For the remainder of the form)

Cleaning should always progress from least-soiled areas to most soiled and from high surfaces to low surfaces. Cleaning activities should minimize turbulence to prevent the dispersion of dust.

### Patient Room High Touch Surfaces:

<table>
<thead>
<tr>
<th>Item/Area</th>
<th>Make sure to include:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bedralls</td>
<td>ALL four surfaces of each bedrail</td>
</tr>
<tr>
<td>Call button</td>
<td>cord if applicable; AND Cancel button</td>
</tr>
<tr>
<td>TV remote</td>
<td>control panel if applicable</td>
</tr>
<tr>
<td>Phone</td>
<td>cord if applicable</td>
</tr>
<tr>
<td>Bedside tabletop</td>
<td></td>
</tr>
<tr>
<td>Overbed table</td>
<td>drawer if applicable, may need to open table to clean</td>
</tr>
<tr>
<td>Entire patient chair</td>
<td>both arms AND seat</td>
</tr>
<tr>
<td>Other furniture</td>
<td>any other furniture in room</td>
</tr>
<tr>
<td>Countertops/horiz surfaces</td>
<td>all other horizontal surfaces in room</td>
</tr>
<tr>
<td>Door knobs</td>
<td>all knobs in patient room</td>
</tr>
<tr>
<td>Door surface</td>
<td>areas directly surrounding the door knob on both sides of door</td>
</tr>
<tr>
<td>Light switches</td>
<td>all light switches in room</td>
</tr>
</tbody>
</table>

### Patient’s Bathroom High Touch Surfaces:

<table>
<thead>
<tr>
<th>Item/Area</th>
<th>Make sure to include:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sink</td>
<td>entire basin</td>
</tr>
<tr>
<td>Faucets</td>
<td>and knobs if present</td>
</tr>
<tr>
<td>Soap dispenser</td>
<td></td>
</tr>
<tr>
<td>Towel dispenser</td>
<td></td>
</tr>
<tr>
<td>Handrails</td>
<td>all safety rails</td>
</tr>
<tr>
<td>Tub/shower</td>
<td>shower head, knobs/handles, safety rails, pull cord</td>
</tr>
<tr>
<td>Door knob/Light switch</td>
<td>knob and area around knob on both sides door</td>
</tr>
<tr>
<td>Toilet/lever/flush</td>
<td></td>
</tr>
<tr>
<td>Toilet seat/back</td>
<td>all horizontal surfaces of toilet</td>
</tr>
<tr>
<td>Toilet bowl</td>
<td>inside and outside</td>
</tr>
</tbody>
</table>

### Other:

<table>
<thead>
<tr>
<th>Item/Area</th>
<th>Make sure to include:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Damp dust</td>
<td>wall vents, ceiling, window blinds/shades, top door and window frames, overhead light (if bed empty), TV (including stand/arm), window sills (avoid allowing dust to fall on patient)</td>
</tr>
<tr>
<td>Check curtains and walls</td>
<td>privacy curtain and window curtains (clean or replace per policy) also spot clean walls if soiled</td>
</tr>
<tr>
<td>Dust or Mop Floor</td>
<td>dust mop daily and spot cleaning with wet mop as needed</td>
</tr>
<tr>
<td>Remove trash</td>
<td></td>
</tr>
<tr>
<td>Refill supplies</td>
<td>soap, alcohol gel, paper towels as needed</td>
</tr>
</tbody>
</table>

### Terminal Clean Only:

<table>
<thead>
<tr>
<th>Item/Area</th>
<th>Make sure to include:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remove linens/supplies</td>
<td>all linens and medical equipment per policy, dispose of all disposable items</td>
</tr>
<tr>
<td>Bed frame and mattress</td>
<td>entire bed frame and entire mattress</td>
</tr>
<tr>
<td>Apply clean linens</td>
<td></td>
</tr>
<tr>
<td>Mop Floor</td>
<td>wet mop entire floor last</td>
</tr>
<tr>
<td>Change Privacy Curtain</td>
<td><em>for Isolation rooms only</em> (mark “1” if changed, “0” if not changed and “n/a” if no privacy curtain)</td>
</tr>
</tbody>
</table>
Appendix C: Hand Hygiene Observation Form
<table>
<thead>
<tr>
<th>Date</th>
<th>Obs#</th>
<th>Unit</th>
<th>Job Title</th>
<th>Entering room</th>
<th>Exiting room</th>
<th>Alcohol Hand Sanitizer</th>
<th>Soap &amp; Water</th>
<th>Completed properly</th>
<th>Was not applicable</th>
<th>Enter Name of healthcare worker who was NON-Compliant</th>
<th>Coaching provided?</th>
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### OSUMC Hand Hygiene Observation Instructions

*Please enter each observation on a separate line. If you observe both entering and exiting room please enter as two separate observations.*

<table>
<thead>
<tr>
<th>Date:</th>
<th>Enter the date the observation was completed. (ex: 12/01/2010)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit:</td>
<td>Select the correct unit from the drop down list. (ex: MICU)</td>
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<tr>
<td>Job Title:</td>
<td>Select the job title of the person you observed entering the patient’s room from the drop down list. (ex: MD, RN, OT/PT)</td>
</tr>
<tr>
<td>Timing:</td>
<td>Indicate whether the observation occurred before or after contact with either the patient or their environment by placing a “1” in either the <em>entering room</em> OR <em>exiting room</em> column (DO NOT ENTER IN BOTH PLACES - if you observe an employee entering and exiting a room, please enter as two separate observations.)</td>
</tr>
<tr>
<td>Method:</td>
<td>Indicate what method of hand hygiene the person being observed used by placing a “1” in either the <em>hand sanitizer</em> OR <em>soap &amp; water</em> column.</td>
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<tr>
<td>Performance:</td>
<td>Enter a “1” or “0” in either the “Completed properly” or “Was not applicable” as indicated below:</td>
</tr>
<tr>
<td>Completed properly:</td>
<td>Enter a “1” if Yes, the HCW cleaned their hands with either alcohol gel OR with soap and water for at least 15 seconds. Enter a “0” if No, the HCW did NOT perform hand hygiene upon entering or exiting room OR if HCW used soap and water for less than 15 seconds.</td>
</tr>
<tr>
<td>Was not Applicable:</td>
<td>Enter a “1” in this column if HCW stood at the door of the patient’s room and did not enter the room. (i.e. answering or asking the patient a question). NOTE: Leave this column blank if you entered either a “1” or “0” in the “Completed properly” column.</td>
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<td>Corrective Action:</td>
<td>As an auditor, if you observe someone not performing hand hygiene, stop and coach them on the importance of hand hygiene. Please contact Infection Control/Epidemiology if you need assistance or guidance or further resources on hand hygiene education.</td>
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<td>If a HCW does not complete hand hygiene upon entering and exiting the patient's room and hand hygiene was indicated, please enter the name of the HCW and the their unit (enter the floor name if a HCW works on that unit, enter the department if HCW is from ancillary department, etc.)</td>
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<td>Enter a “1” if you provided coaching during the observation. Enter &quot;0&quot; if you did not provide coaching during the observation.</td>
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</table>
Appendix D: Patient Satisfaction Questionnaire
Patient Satisfaction Regarding Disinfection

The Department of Epidemiology and Facilities are assessing cleaning products at the OSUMC. Please answer the following questions.

1) Please answer the statement: “The scent/fragrance of the disinfectant used during your hospital stay is acceptable.”

☐ Strongly Agree
☐ Agree
☐ Neither Agree or Disagree
☐ Disagree
☐ Strongly Disagree

2) Have you had any ‘Physical Reaction’ to the disinfectant during your current admission?

____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________

3) Were you previously admitted to the James/OSUMC? Yes / No

4) If you were previously admitted, please provide the month, year, and the location.
   Month: Jan / Feb / March / April / May / June / July / Aug / Sept / Oct / Nov / Dec
   Year: 2010 / 2011 / 2012
   Location: Circle one: OSUMC / James

5) Have you had any ‘Physical Reaction’ to the disinfectant during your previous admission?

____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________

6) Any additional comments:____________________________________________________
   _____________________________________________________________
   _____________________________________________________________
   _____________________________________________________________

7) Additional Information:

Unit Location:
   BMTU South Room:________________
   BMTU East Room:_______________
   James 10 East Room:____________

Date:
   Month: Jan / Feb / March / April / May / June / July / Aug / Sept / Oct / Nov / Dec
   Year: 2011 / 2012

Evaluator Initials:________________________

Thank you for your input regarding disinfection at the OSUWMC.