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Infection Control and Biosafety: A Compare and Contrast Study

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INFECTION CONTROL AND BIOSAFETY: A COMPARE AND CONTRAST
STUDY

A Master Thesis

Submitted to the Faculty

of

American Public University

by

Cara Lamberson Leitch

In Partial Fulfillment of the

Requirements for the Degree

of

Master of Public Health

August 2015

American Public University

Charles Town, WV

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DEDICATION

I dedicate this thesis to my family. Paul and Carol, thank you for watching the kids whenever I needed time to work. Mom, you always had faith in me since I was a kid even when I did not. Jenny, you set the example on what hard work and dedication looks like. Shayne, you have watched me from the beginning working on this degree and have stood by me and supported me every step of the way. I love you. To my boys, Nathaniel and Jonathan, I love you more than you can imagine, and I am so excited to finally spend more time with you both. Finally, Dad, I hope that I make you proud. You have always been the quiet, calm motivator in my life. I love you and miss you so much.

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ABSTRACT OF THE THESIS

INFECTION CONTROL AND BIOSAFETY: A COMPARE AND CONTRAST
STUDY

by

Cara Lamberson Leitch

American Public University System, July 21, 2015

Charles Town, West Virginia

Professor Carol Hoban, Thesis Professor

The 2014 Ebola outbreaks demonstrated the need for better procedures in controlling the spread of infection among healthcare workers. Not only did other countries experience the inadequacies with infection control procedures, but even in the United States, procedures have been found to be insufficient for safely treating patients with highly infectious agents such as Ebola. As a result, biosafety professionals began reaching out to provide assistance to the healthcare community. The purpose of this

study is to analyze infection control measures and biosafety practices to identify similarities and differences to make recommendations for future improvements for protecting healthcare workers. A grounded theory approach was employed as the research method, and data was collected through a survey from participants who practice infection control and biosafety. Data was analyzed through comparative analysis and inductive reasoning. Participants and relevant literature indicated areas in need of improvement for protecting healthcare workers from exposure and how the biosafety community can assist in mitigating the risks when working with patients who have highly infectious diseases. The study found that use of personal protective equipment and training, engineering improvements, and following protocols were the top three areas in need of improvement.

TABLE OF CONTENTS

CHAPTER	PAGE
I. INTRODUCTION	1
II. LITERATURE REVIEW	5
III. METHODOLOGY	16
Subjects and Setting	16
Data Collection Technique	19
Statistical Analysis	21
Limitations of the Study.....	21
IV. RESULTS.....	23
Job Roles.....	23
Facility Type.....	25
Infectious Waste Handling.....	25
Hand Hygiene	28
Facility and Engineering Design	30

Safety Training	30
Areas in Need of Improvement	33
Improvements Made Since the Ebola Outbreak	34
V. DISCUSSION	35
Infectious Waste Handling.....	36
Hand Hygiene	38
Facility and Engineering Design	40
Safety Training	42
Improvements	45
Summary	47
Recommendations	51
LIST OF REFERENCES	52
APPENDICES	56

LIST OF FIGURES

FIGURES	PAGE
1. Current Job Role.....	24
2. Type of Facility	25
3. Waste Handling	27
4. Safety Training	31
5. Satisfaction with Job Training	33
6. Improvements since Ebola Outbreak.	35

LIST OF TABLES

TABLE	PAGE
1. Hand Sanitizer Locations	29

LIST OF APPENDICES

APPENDIX	PAGE
Appendix A: Institutional Review Board Approval	56
Appendix B: Survey Questions	57

Introduction

Infection Control and Biosafety: A Compare and Contrast Study

During the 2014 Ebola outbreaks in West Africa, many healthcare workers were exposed to this deadly virus. As of May 27, 2015, there were 11,157 deaths from Ebola. There were 15,015 confirmed cases of Ebola and 27,091 cases suspected, probable, or confirmed. Of these cases, 869 infections were healthcare workers resulting in 507 deaths from the three main countries affected: Sierra Leone, Liberia, and Guinea (Centers for Disease Control and Prevention, 2015). There were multiple factors that contributed to healthcare workers becoming infected. The areas impacted the hardest by the outbreak had limited resources available, including having enough or adequate personal protective equipment (PPE) and appropriate training. In many cases, healthcare workers had adequate PPE, yet workers still became infected. The pictures, descriptions, and videos created of how the PPE was worn, removed, or decontaminated displayed inadequacies in the infection control procedures being used, which prompted biosafety professionals to reach out and assist with the training of healthcare workers in implementing procedures; the goal was to reduce the risk of disease transmission to other healthcare workers. Some of the support provided by biosafety professionals included better training and procedures for the use of appropriate PPE, proper wear, doffing without contaminating oneself, decontamination of PPE and tools. In addition waste

management procedures, specimen transport, work flow or facility design, and decontamination practices were established to help combat the spread of the Ebola virus. This translated to precautions that were needed for treating patients with other infectious diseases (OSHA, NIOSH, EPA, 2014).

Prior to the Ebola outbreak, the Healthcare Infection Control Practices Advisory Committee (HICPAC) recognized the need for improving infection control procedures. The charge of HICPAC is to provide suggestions to the Department of Health and Human Services on infection control measures in healthcare settings. Guidance includes preventing and reducing the number of hospital-associated infections (HAIs), increasing surveillance, and addressing concerns with antimicrobial resistant organisms (Centers for Disease Control and Prevention, 2014). The 2007 HICPAC guidelines on infection control now contain an appendix for protections against the spread of Ebola in healthcare settings (Centers for Disease Control & Prevention, 2015). The improvement of infection control procedures can also be applied to help decrease the spread of other diseases in hospitals, not just Ebola.

Infection control is described by the World Health Organization as “the aim to ensure the protection of those who might be vulnerable to acquiring an infection both in the general community and while receiving care due to health problems, in a range of settings. The basic principle of infection prevention and control is hygiene” (World Health Organization, 2015). Biosafety is “the discipline addressing the safe handling and

containment of infectious microorganisms and hazardous biological materials” (BMBL, 2009, p. 1). Biosafety utilizes a combination of risk assessment and containment principles to reduce or prevent exposures to research personnel working with infectious agents (Centers for Disease Control and Prevention and National Institutes of Health, 2009). While the goal of biosafety and infection control is overall containment of the pathogen, the focus of how containment is achieved is different in some respects. Infection control and healthcare personnel such as physicians and nurses are focused on treating patients and reducing the spread of disease, especially to those who are immunocompromised. The treating healthcare professional and surrounding environment are typically not the main priorities; whereas, in biosafety, the focus is on containing the infectious organism during research so the worker or environment does not become infected or contaminated. This paper will assess the similarities and differences between infection control procedures and biosafety principles and practices to determine methods of bridging the gap between the professions to help control the spread of infection in hospitals.

This research is important because healthcare associated infections (HAIs) continue to occur. The threat of emerging and reemerging infectious diseases will only increase. The frequency of global travel contributes to the spread of emerging and reemerging infectious diseases not endemic to the United States. Hospitals and healthcare workers must not only be prepared to treat communicable infectious diseases

while protecting their staff, but also recognize the uniqueness of the biosafety profession. The biosafety profession possesses a skill set focused primarily on containment measures and can assist with ensuring healthcare workers are adequately trained to protect themselves from becoming infected while performing their duties. There are very few hospitals in the United States that have staff with the knowledge, training, expertise, and other resources to effectively treat Ebola patients without spreading the disease to others. In fact, only three of these facilities existed in the U.S. prior to the Ebola outbreak. As other countries suffer from endemic deadly infectious diseases, the United States will continue to be at risk for the spread of diseases through global travel and trade. Recognizing these risks, the government has increased the number of hospitals capable of handling patients infected with highly pathogenic agents such as Ebola, Severe Acute Respiratory Syndrome (SARS), Middle East Respiratory Syndrome (MERS), and potentially in the future, Highly Pathogenic Avian Influenza (H5N1).

After the United States saw its first several Ebola patients, 55 hospitals have since been established as Ebola treatment centers. These centers are provided with guidance for suspected Ebola patients which includes training and demonstrating proficiency in infection control procedures, PPE, waste management procedures, facility design and setup, along with the safe transport of patient specimens. All healthcare facilities outside of the 55 Ebola treatment centers are expected at minimum, to identify, isolate, and inform the infection control program, state, and local public health authorities. They

must also have training on transporting patient samples, managing infectious waste, and be proficient in donning and doffing PPE (Centers for Disease Control and Prevention, 2015). Based on recent events, the current state of general hospital practices and preparedness for handling patients with infectious diseases and current literature on HAIs has demonstrated the need for better infection control procedures. The purpose of this paper is to assess infection control procedures and biosafety principles and practices to determine similarities and differences and discuss recommendations for improvement to decrease the spread of infection. The recent Ebola outbreaks serve as the primary example of the gaps in current infection control procedures and how biosafety concepts and practices can be incorporated into an infection control program. This analysis is also relevant for containment of other infectious diseases faced in the healthcare environment and can assist with examining and improving current hospital preparedness.

Literature Review

Articles by infection control specialists like Aziz, discuss numerous considerations for infection control in hospitals for reducing transmission of illness, specifically for handling an influenza pandemic, which is a respiratory illness transmitted through respiratory droplets from an infected person who is coughing and sneezing or by touching contaminated surfaces then introducing the pathogen by touching the mucous membranes. Aziz identifies the foundation of infection control as meticulous hand hygiene and measures to contain the spread of respiratory droplets from infected persons. Isolating sick patients from others, keeping doors closed, and posting signs indicating respiratory precautions are also key components to reducing the spread of illness. Early identification and segregation of patients exhibiting flu symptoms is necessary since there is a high risk of transmission; however, negative airflow and/or filtration are not considered necessary. For handling the deceased, surgical masks may be considered if there is a risk of splashes to the mucous membranes; however, protective eyewear is not indicated. Aziz states that gloves are only required for procedures that may involve non-intact skin, invasive procedures, or a potential for blood and body fluid exposure, but not when handling patients with pandemic influenza. When gloves are utilized, guidance is given for how to remove them without contaminating oneself. Hand hygiene is emphasized in between patients, and the option of hand washing with soap and water or

applying an alcohol-based hand gel is given. Visitors must be trained on hand hygiene and instructed on wearing PPE before entering a posted area (Aziz, 2008).

Limitations of this study include no indication of additional precautions for handling waste from a patient with pandemic influenza beyond standard infection control principles. There is also the possible risk of influenza surviving on fabrics (clothing) that could allow the spread of the virus and the discussion of not wearing scrubs to and from work and out in public; but there is no further discussion on potential contamination spreading between patients as healthcare providers move from room to room. The article also discusses signage for areas where respiratory precautions must be utilized, but it doesn't address if specific PPE is indicated on the signs.

Morgan, et al. (2015) explains deficiencies in hospital preparation for treating Ebola patients and other emerging and reemerging infectious diseases. The authors conducted a survey of 1,973 international infection prevention specialists, hospital epidemiologists, infectious diseases doctors, and hospital leadership personnel through the Society for Healthcare Epidemiology of America (SHEA). Those coordinating Ebola preparedness measures (62.1%) were epidemiologists and infection control specialists who primarily relied on guidance from the Centers for Disease Control and Prevention (CDC) and information generated in-house. Only 30% of these providers were trained in using appropriate PPE, donning, and doffing procedures. Most participants in the survey still indicated that they felt moderately prepared to handle suspected patients with Ebola.

The most common and biggest challenge cited by 37% of the participants was related to PPE, which included training, acquiring PPE, and changing guidelines. The authors noted a lack of training in wearing and removing PPE. Participants (26%) stated the second largest challenge was the varying and fluctuating recommendations (Morgan, et al., 2015).

The limitations of the study conducted by Morgan, et al. (2015) included a lack of recommendations for how healthcare workers (HCW) can receive better training. While the authors noted the lack of training and PPE, there was no reference for how to overcome these challenges aside from additional government funding. No discussion of how the funds would be appropriated and who would provide appropriate training were made, potentially resulting in a waste of government funds without a plan in place for how to best utilize resources.

Lateef (2009) theorized that hospital design and infrastructure was a critical component for infection control by using the SARS outbreak in a Singapore hospital as a learning experience. Since hospitals are public buildings with multiple public access points for visitors, patient admissions, and even administering courses, these facilities are vulnerable to pathogens and illnesses being brought in from numerous different sources at multiple entrances. Global travel has increased vulnerabilities of countries opening their borders to non-indigenous pathogens, and emerging and reemerging infectious diseases. Closing hospital entrances and strictly limiting the number of people coming

into a hospital is impractical, so other areas within the hospital must be assessed for the ability to isolate, screen people at entrances for fever and who are high risk, control traffic flow, and implement other infection control procedures to reduce the spread of infection. Appropriate collaborations need to be in place to avoid a shortage of supplies and equipment needed to manage patient and healthcare worker health. Having single patient rooms can help with controlling the spread of infection and can be more easily turned into isolation rooms during an outbreak, if needed. Ventilation is also critical for controlling infection with directional or negative airflow in rooms and certain areas of the hospital to help keep other spaces and individuals from contamination or infection from diseases that can be transmitted through droplets or aerosols. Lack of hand hygiene continues to be a major cause of the spread of infection. Providing additional sinks to encourage more hand washing, proper ventilation, and the use of private rooms for isolating patients has shown a decrease in the rate of HAIs (Lateef, 2009).

This study does not mention waste handling procedures as a potential issue especially when a hospital is overwhelmed with the outbreak of an emerging disease. While the study suggests hospital staff needs a behavior change to improve hand hygiene, there is no discussion of how to make the behavioral change. Training is a key component of behavioral change that is not examined.

In an article written by experts from The Society for Healthcare Epidemiology of America (SHEA), a major concern in hospitals is the spread of organisms resulting in

HAI. Recommendations were developed from results of the authors' literature review of infection prevention and visitors, along with a survey sent to SHEA members to share visitor practices employed at their own institutions. Based on the authors' research, much of the literature regarding HAIs demonstrates horizontal transmission of organisms through the hands and possibly clothing of healthcare workers. Standard and isolation precautions should be practiced by healthcare workers to reduce the spread, but it is less clear if visitors of patients play a significant role in the transmission of organisms in the hospital, which questions the need for visitors to adhere to isolation precautions. While it is recommended that the use of contact isolation precautions be specific to the pathogen for visitors, hand hygiene is recommended for all visitors. Visitor compliance with hand hygiene practices were shown to increase when alcohol hand rub dispensers were placed in hospital lobbies and entrances to intensive care units with visual or audio behavioral cues to perform hand hygiene. Along with reminders of hand hygiene, educating visitors on the importance of hand hygiene and proper technique. Both sinks with soap and alcohol based rubs should be easily accessible to increase compliance, however overall visitor and healthcare worker compliance to practice hand hygiene still remains a major challenge (Munoz-Price, et al., 2015).

A limitation of this study is the lack of discussion for proper removal of PPE. Proper removal of PPE is crucial for preventing contamination of oneself or others. The study also does not indicate when hand washing is preferred over using an alcohol based

rub. The study discusses the use of brochures and signs to educate visitors on precautions; however, the study does not indicate if the precautions state to use contact, airborne, or immunocompromised precautions in a vague manner, or if the signs and brochures specifically state what PPE must be worn and how to conduct hand hygiene.

The Association for Professionals in Infection Control and Epidemiology (APIC) utilizes guidance provided by the CDC such as the 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. This document provides a vast amount of information for various pathogens encountered in a hospital, common HAIs, and how to prevent transmission of infectious agents in the healthcare environment. The guideline has since added recommendations for handling Ebola patients (Siegel J.D.; Rhinehart E.; Jackson M.; Chiarello L.; and the Healthcare Infection Control Practices Advisory Committee, 2010).

Several limitations of this guideline include a lack of overall risk assessment. Guidance is given to specific organisms that are normally encountered in hospitals and recommend certain precautions such as standard precautions, contact precautions, etc. However, not every pathogen can be accounted for, which is why healthcare professionals should have a basic understanding of risk assessment for other pathogens. The precautions outlined are also vague and do not explicitly account for donning and doffing PPE which is quite frequently a point of contamination.

According to Pittet et al. (2008), the risk of developing HAIs in developing countries are two to 20 times greater than in industrialized countries due to multiple factors such as economic limitations, the delivery of care, and human behavior; however, most solutions can be easy and inexpensive. Evidence demonstrates that lack of hand hygiene is the biggest contributor to the spread of HAIs. Lack of hand hygiene occurs in both developed and underdeveloped countries, but is more prevalent in underdeveloped countries due to limited resources such as lack of running water, soap, paper towels, and training and not following recommendations from the World Health Organization. The use of an alcohol-based hand rub is recommended in developing countries with constrained resources and infrastructure. Regardless of the method of hand hygiene used, behavioral changes in healthcare workers must occur. They must be trained and understand how to properly wash their hands and/or apply the hand rub. A safety culture must be developed and supported by hospital management to evaluate, implement and re-evaluate hand hygiene measures. Reminders and work flow will also aid in hand hygiene compliance. For developing countries, the task is much greater due to lack of policies, standard practices, and infrastructure (Pittet, et al., 2008).

While proper hand hygiene is one of the key components to reducing the spread of infection, there are other controls not mentioned in this article that can be utilized by countries with limited resources that are not mentioned in this study. Patient and work flow is a pertinent part of keeping the spread of infectious diseases down and can be an

inexpensive step toward achieving lower HAIs. Early identification of where infectious waste will go and how to move it from the source of generation to the storage location can help decrease contamination and accidental releases into the treatment areas.

Kortepeter, Smith, Hewlett, and Cieslak (2015) emphasize the need for prudent practices and additional specialized facilities designed to treat patients with hemorrhagic fever viruses or other deadly diseases with a high mortality rate and no vaccination.

After the outbreak of Ebola in West Africa that resulted in the United States seeing its first Ebola victims, the need for better hospital preparedness became apparent. Staff must be highly skilled and retrained frequently to minimize direct contact with patients, reduce human error, and handle sharps such as needles and syringes without accidental inoculation. Maneuvering patients and work flow must be choreographed and practiced. The most notable risk is the process of removing, or doffing, PPE, so as not to contaminate oneself and must be practiced and observed by colleague along with the flow of patient movement, hospital staff, and materials. For these reasons, it is crucial for every hospital to establish, maintain, and practice preparedness procedures before a major event like an outbreak occurs. The authors suggest building a network of referral centers for patients to be transported to that can provide a higher level of care and are part of a major hospital or medical facility that are tied to high containment laboratories. The centers would still be able to sustain normal, daily operations while providing higher

level care and support to patients and medical facilities in the event of another outbreak (Kortepeter, Smith, Hewlett, & Cieslak, 2015).

This article discusses how to prepare for treating patients with filoviruses such as Ebola, but it does not detail the specific hazards encountered that would warrant a large change in clinical settings. For instance, the authors describe what preparations should be made including disposal of waste and donning and doffing PPE; however, the article does not illustrate the type of waste and how much to expect from an Ebola patient. This would give a better indication of the steps needed for proper handling, removal, decontamination, and disposal of waste. The logistics of handling waste would probably involve changing of gloves or other PPE throughout the process so as not to contaminate the outside of waste containers.

One article discusses guidelines for training programs for laboratory workers working with high-risk pathogens in high containment laboratories, specifically BSL-3 research laboratories. This article emphasizes the importance of competency and risk assessment for establishing and maintaining a safe work environment. Some of the key training concepts include biosafety, biocontainment, hazardous characteristics of pathogens, proper care, use, and storage of PPE and safety equipment, local, state, and federal regulations, institutional policies regarding waste disposal, visitor access, review and approval of all protocols prior to working in the laboratory, safe use and disposal of sharps, and emergency response procedures. Training and adherence to SOPs is of

utmost importance. Training includes a supervised hands-on component and mentorship after all other training is completed. Demonstrations by the trainee are performed for assessment before final approval to work unsupervised (Homer, et al., 2013).

One limitation of this paper is the approximate amount of time a training program like this can take one individual to complete. While training programs will vary between one institution and another, having a suggested or approximate time frame up front can help readers gain a better understanding of the magnitude of such a program. It appears that the overall process can potentially take months to complete depending on the individual's progress throughout the training program. A big hurdle that wasn't discussed is gain. While the training is critical, management support is just as crucial in the planning stages of such an aggressive training program.

The *Biosafety in Microbiological and Biomedical Research Laboratories* (BMBL) outlines how a risk assessment should be conducted and what elements to consider for working safely in a laboratory environment. Working safely with pathogens requires a strong knowledge base in good microbiological practices and procedures. Principles of biosafety include containment, strict observance of microbiological practices and procedures through awareness, training, proficiency, primary and secondary barriers, PPE, and biosafety levels. The development of a risk assessment will help guide the level of containment, design of the facility, and work practices appropriate for the type of biological agent and procedures being conducted. "Risk assessment is a process

used to identify the hazardous characteristics of a known infectious or potentially infectious agent or material, the activities that can result in a person's exposure to an agent, the likelihood that such exposure will cause a LAI, and the probable consequences of such an infection" (Centers for Disease Control and Prevention and National Institutes of Health, 2009, p. 9). The BMBL describes facility features, PPE, engineering controls, and microbiological practices commensurate with the risks of handling certain infectious agents with the goal of reducing the likelihood of laboratory acquired infections (LAIs), and harm to the community and environment (Centers for Disease Control and Prevention and National Institutes of Health, 2009). Regardless of the level of risk, the minimum requirements include the use of PPE, hand washing before leaving the laboratory and after removing gloves, and decontamination of work surfaces and waste streams prior to disposal. (Centers for Disease Control and Prevention and National Institutes of Health, 2009).

A limitation of the BMBL is that it does not specifically detail how the safety practices can be applied to clinical laboratories in the healthcare setting, other than to follow the OSHA Bloodborne Pathogen Standard. It mentions that the director of the laboratory is responsible for establishing how clinical workers can protect themselves from exposure to bloodborne pathogens, but does not provide specific resources for the additional hazard of handling patients that may have a communicable disease. This is in part because the BMBL is not meant to be a medical book; however, there are gaps in the

healthcare setting with respect to safety that the BMBL could potentially address upon collaboration.

Methodology

Subjects and Setting

The first part of the research involved collecting both primary and secondary source data through the review of literature. Current literature on infection control and biosafety helped define and describe each method of controlling the spread of infection in hospital and biomedical or microbiological laboratory settings. The literature reviewed included government websites, academic research databases, journals, books, and regulations.

The second part of the research was a non-experimental study employing a cross-sectional survey design. Data was collected through interviews and a questionnaire. The interviews were conducted by the researcher, primarily interviewing those with a background in infection control or who have worked in a hospital setting. Local interviews were conducted in person, and all other interviews were administered over the phone. The identities of the participants were kept confidential as well as the specific facilities they mentioned during the interview. The questionnaire was sent to biosafety professionals through the American Biological Safety Association (ABSA) email list serve utilizing Survey Monkey® as the method of data collection. Informed consent was obtained from the questionnaire through Survey Monkey® by checking the agree box at the beginning of the survey. Informed consent forms with signatures were collected from the interviewed participants.

The questions in the interviews and questionnaire were the same for both biosafety experts and healthcare workers such as physicians, nurses, and infection control specialists. Participants had the option of not responding to questions or skipping questions. The survey consisted of both open and closed questions. Open questions allowed the participants to elaborate on procedures specific to their organization which provided better data for compare and contrast purposes. The survey questions are provided in Appendix B.

Several different types of non-probability sampling were used to obtain the data. A combination of purposive sampling and snowball sampling was employed. The researcher identified a population of biosafety professionals by sending the questionnaire to the ABSA list serve. For the healthcare audience, convenience sampling and snowball sampling techniques were used for interviews and distribution of the questionnaire due to the lack of email list serve available to the general public. During the interview process, participants identified others who would fit into the study based on their expertise. Due to the time-consuming interview process, fewer participants were used for interviews, which may not indicate a representative sample. Advantages of the interviews provided greater flexibility for the researcher and control over the questions and allowed for participants to provide more detailed comments and dialogue.

Although the study presented no more than minimal risk, it involved a questionnaire and survey, which required Institutional Review Board (IRB) review and

approval. The research involved direct interaction with individuals through a web survey, emails, telephone, or in person, where the researcher had access to some identifiers. The risk was minimal because there was a low probability and magnitude of harm or discomfort for the participants. Participants answered questions regarding infection control and biosafety in their work environment. Participants also had the option of elaborating on their responses and further discussing their work environment practices. The discussion of their work environment indicates a low risk study since this is considered to be part of their daily routine. While the researcher had access to the individuals participating, identities were kept confidential and the specific facility or employer names were not requested. In some cases participants chose to share the name of their facility, however, the researcher kept the information confidential and has not disclosed specific names of facilities in the study. The participants were not considered to be vulnerable or at-risk populations such as prisoners and minors. The IRB approval letter can be found in Appendix A.

This is a qualitative study which explores the differences in infection control procedures and biosafety practices. The 2014 Ebola outbreaks and infection among healthcare workers calls for an investigation of what current infection control procedures are being utilized. Biosafety principles and practices were examined also, to determine similarities and differences in how each contributes to protecting healthcare workers.

Data Collection Technique

This study is a non-experimental design since the data was collected from a survey that included questionnaires and interviews. A cross-sectional survey was conducted of biosafety professionals and healthcare workers. The questionnaire was developed and distributed to biosafety professionals who are accessible through the American Biological Safety Association (ABSA) email list serve of 1172 members, roughly 80% of which specialize in biosafety and primarily work in biomedical and microbiological laboratories. The same questionnaire was sent to infection control specialists, physicians, nurses, and other healthcare workers to gather data regarding infection control procedures in the healthcare setting. Data was collected between May 22 and June 26, 2015. The online questionnaire was administered through a web based survey tool developed using Survey Monkey® for electronic distribution. The survey consisted of 32 questions.

The research method employed was a grounded theory approach. The experiences and views of participants in the study were the main source of data collected. Opportunity sampling was used for the interviews in this study. Participants were selected who have either infection control knowledge and/or biosafety knowledge, were from local hospitals or clinics, medical centers, or those referred by other healthcare workers for interviews. The interviews and questionnaire consisted of open and closed questions. Questionnaires and interviews were both employed to improve the reliability

and validity of the study. There were no questions that could influence the participants' responses to eliminate bias. Comparative analysis and inductive reasoning were utilized for analyzing data. Data collected revealed what type of procedures and training hospitals have that utilize regular infection control procedures verses the training received in microbiological and biomedical research laboratories that work with high consequence pathogens. The researcher was the tool by employing the questionnaire and conducting interviews.

Survey responses were submitted by 97 individuals. Nine individuals were interviewed with the same 32 questions, while the other 88 completed the online questionnaire. Questions focused on waste handling procedures, personal protective equipment, training, facility design, and improvements made since the Ebola outbreak.

Statistical Analysis

Statistical analysis was conducted using SPSS for Windows version 23. Due to the large number of biosafety personnel who responded to the survey in comparison to infection control personnel, the Mann-Whitney U test was used to determine statistical significance. There are two main categorical, independent groups, biosafety and infection control. A third group, "other" was added to account for responses from indirectly related professions, but this is not the primary focus group of the study. Among and within each group, all observations are independent.

Limitations of the Study

There were five identified limitations to this study. The first limitation of this study was the short time frame for conducting the research. If time permitted, administering a pilot survey with a local chapter of the American Biological Safety Association would have been more beneficial for refining the survey questions. The second limitation was that the survey questions could have been more specific by not allowing participants to provide more than one response. The third limitation was the possibility of biased responses of interviewees. The presence of the researcher may sway the participant to answer the questions differently than what they normally would. Also one interviewee may have a different perspective than another on the infection control methods being utilized. Fourth, opportunity sampling was used for the interviews, which had some disadvantages such as not being a representative sample of the target population. Participants in both groups were selected either by the researcher or through word of mouth contacts from other participants. The fifth identified limiting factor was a potential conflict of interest since the researcher is a biosafety professional. All possible attempts were made to not show bias throughout the study, while applying experiential knowledge in the discussion section.

Due to the time-consuming interview process, fewer participants could be used when employing interviews, which did not indicate a representative sample (Eysenck, 2004). A larger sample size for this survey study was difficult to obtain. The survey was

distributed to the ABSA email list serve which has 1172 members. Infection control list serves were sought out as well such as APIC and Certification Board of Infection Control and Epidemiology, Inc. (CBIC), only to discover that they do not have a list serve that is readily available for the public to use. Either membership or address labels had to be purchased in order to have access to infection control members. The researcher contacted 29 known colleagues and healthcare personnel who were identified through the 55 Ebola treatment centers online and requested participation in the online questions and assistance with spreading the survey to other individuals in the healthcare industry. Therefore, the exact number of individuals from the healthcare industry who received the survey request is unknown. The total number of participants was 98. The sampling size for the infection control population was much smaller than the biosafety population. Several participants with a background in infection control were also members of the ABSA list serve, while others who responded were either those interviewed by the research, or the survey was shared by word of mouth. The researcher predicted the infection control sample would be significantly smaller than the biosafety sample; therefore, the interviews mainly targeted individuals who actively work with infection control personnel, healthcare providers, or who had previous experience in infection control.

Results

There were 98 total participants who began the survey, but one was omitted since they did not answer any of the questions beyond providing informed consent, so $n = 97$. Of the 97 participants, nine were directly interviewed by the researcher, and 88 responded to the online questionnaire. Participants could choose to not answer any of the questions, so the number of responses varies throughout the survey representing 97 responses or less.

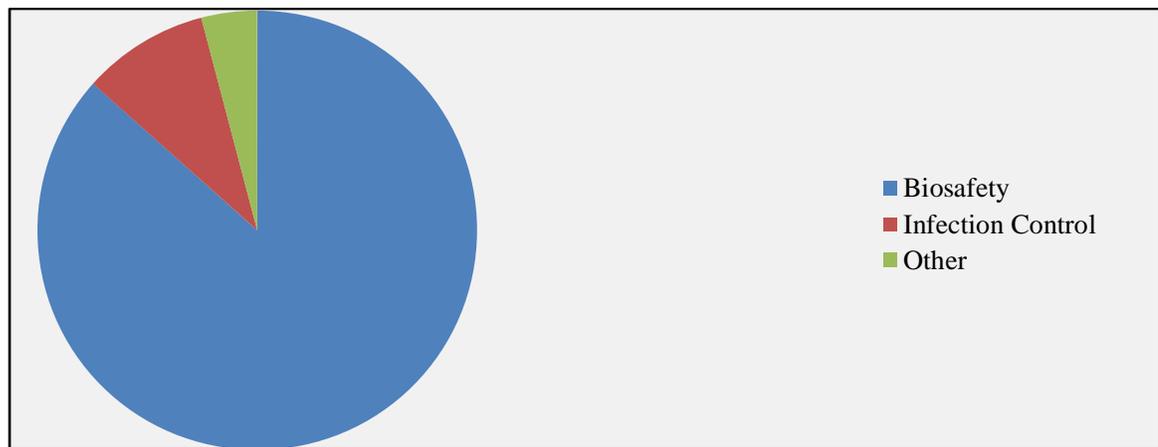
Job Roles

Participants were able to choose multiple categories of job roles since there may be some overlap of responsibilities. Based on the description of primary job roles, participants were placed in one of three main categories, *biosafety*, *infection control*, and *other*. The *biosafety* category includes participants who indicated biosafety or microbiological or biomedical research laboratory as their primary role. *Infection control* includes infection control personnel, physicians, and nurses. The *other* category includes the job types of those who did not indicate a direct function in biosafety or infection control, but have some indirect link to either or both.

Figure 1 shows that the majority of the participants, 86.6% ($n = 84$), indicated they have some level of experience in biosafety and/or microbiological/biomedical laboratories, 9.3% ($n = 9$) have a background in infection control to include nurses and physicians, and 4.1% ($n = 4$) who indicated another job role. Those who selected “other”

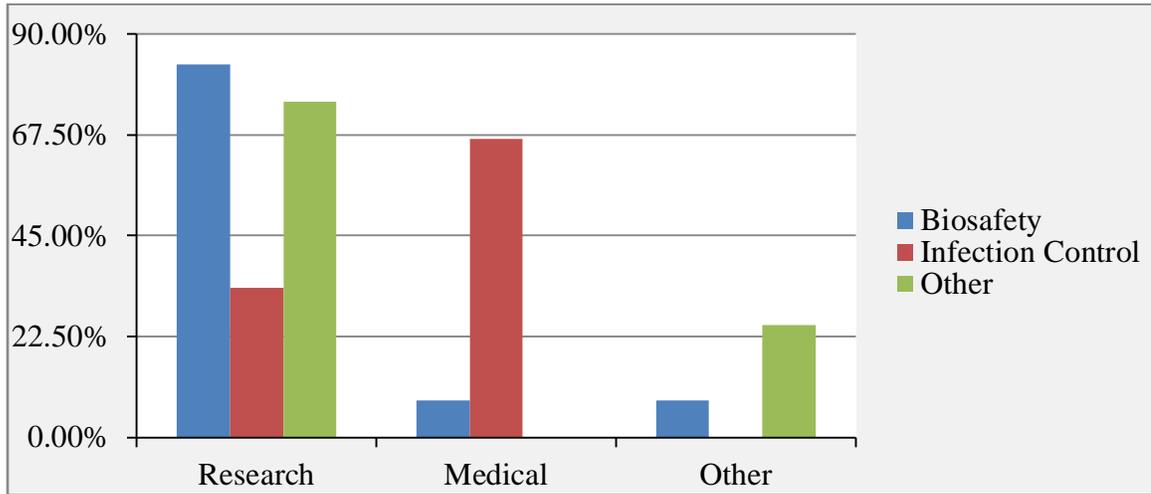
included compliance personnel, environmental and occupational health and safety staff, consultants, a veterinary pathologist, and one from a public health laboratory. For the purposes of this study, the following descriptors are used to describe the three main groups in the study: *biosafety*, *infection control*, and *other*.

Figure 1: Current Job Role



Facility Type

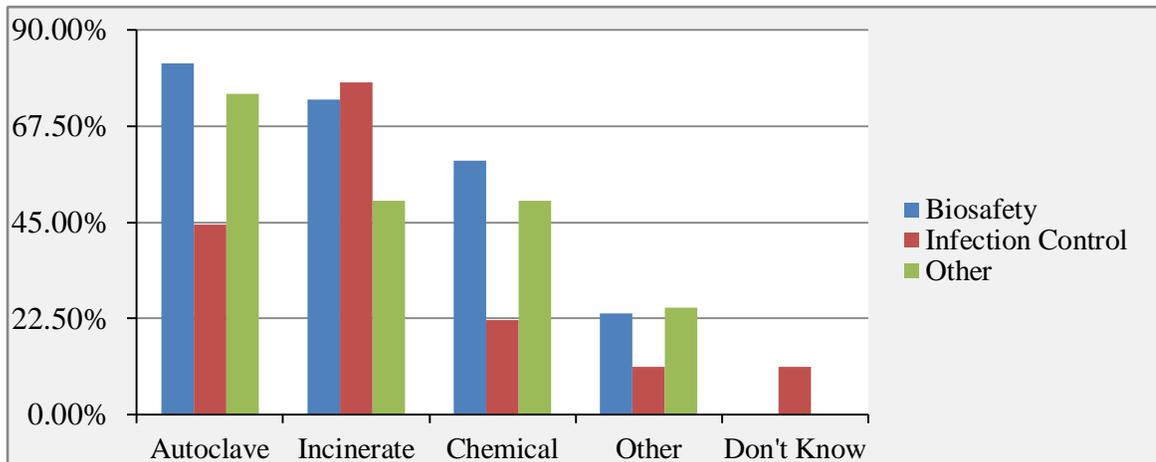
The survey asked participants to select what type of facility they work in ($n = 97$). This question also allowed for more than one answer since some facilities are medical facilities and universities. Responses from biosafety personnel ($n = 84$) indicate that 83.33% work in a research facility and 8.33% in a medical facility. Responses from infection control personnel ($n = 9$) showed that 33.33% work in a research facility, and 66.67% work in a medical facility.

Figure 2: Type of Facility**Infectious Waste Handling**

For infectious waste handling, participants were able to choose from the following options: *autoclaving* (i.e. steam sterilization), *incinerating*, *chemically inactivating*, *don't know*, or *other*. Participants could choose more than one selection based on the different types of waste being treated such as liquid waste or solid waste. All participants answered the question, so $n = 97$. All responses from the healthcare environment (i.e. those who follow infection control practices) regarding handling infectious waste place the waste into red bags. Red bags are then either picked up by a contractor for further processing or by their safety office. On the other hand, responses from microbiological/biomedical laboratory personnel (i.e. those who follow biosafety practices) included treating the infectious waste themselves either through chemical inactivation, autoclaving, or having the waste picked up for incineration by a contractor.

As shown in Figure 3, autoclaving waste was indicated by 82.1% of the biosafety participants, while 44.4% of the infection control participants stated they autoclave their waste. 73.8% of the biosafety group and 77.8% of the infection control group indicated that their waste is incinerated. Other waste treatment methods were indicated by all three groups (22.7%), which included effluent decontamination systems or bio digestion through alkaline hydrolysis. Effluent decontamination systems are built-in systems in a facility where waste streams from the laboratory ultimately go into a “cook tank” to sterilize the waste prior to flushing into the sanitary sewer. Alkaline hydrolysis is the method in which tissue is digested by a chemical. The infection control group contained one individual who does not know how infectious waste is handled.

Figure 3: Waste Handling



The Mann-Whitney U test demonstrates that there is a significant difference between the biosafety group (82.1%) and infection control group (44.4%) for autoclaving waste, where $p = .027$. Autoclaving infectious waste is performed by almost twice as many biosafety personnel than infection control personnel. There was no significant difference between the two groups for treating waste via incineration ($p = .680$), chemical inactivation ($p = .062$), or other waste treatment option ($p = .526$). The significance level for each test was .05.

In the infection control group, all waste that is red bagged is picked up by a contractor for inactivation and final disposal. There is no additional handling of the waste by healthcare personnel in house such as autoclaving with the exception of one case where highly infectious waste such as Ebola waste is autoclaved onsite, and Ebola infected liquid waste is treated in the toilet with chlorine for 30 minutes prior to flushing. For research personnel, most of the waste that is autoclaved is treated onsite. After which the waste is then sent offsite by a commercial vendor for final disposal primarily through incineration. Results indicate that in general research laboratory personnel handle infectious beyond red bagging, which includes additional treatment measures.

Question 14 in the survey asked how infectious waste is removed from the point of origin to the treatment site. Eighty-eight participants responded to the question, but 13 of the responses were not detailed enough to determine whether waste is autoclaved on site or sent offsite with a commercial vendor, so $n = 75$. Two of these were from the

infection control group and one was from the biosafety group. Overall, the biosafety group accounted for 57 of the responses, 39 of which indicated autoclaving at least some of their infectious waste, while 18 indicated they only send the waste offsite with a commercial vendor for further processing. Only one participant from the infection control group indicated autoclaving waste on site, five indicated the waste is removed by a commercial vendor, and four “other” participants indicated autoclaving infectious waste, while eight indicated infectious waste is sent offsite only.

Hand Hygiene

Review of the literature revealed that hand hygiene appears to be the primary concern in hospitals. Hand washing protocols are not rigorously followed, and in many cases, the use of hand sanitizers has been employed for greater compliance in hand hygiene due to the convenience, expediency, and location of sanitation stations as opposed to sinks. The survey conducted asked how hands are cleaned between each patient. This question was not applicable for biosafety personnel, so only infection control personnel responded. Approximately one third of the group stated they wash their hands between seeing patients, one third said they use hand sanitizer, and the other third indicated the use of both hand washing and hand sanitizer.

Tables 1-4 below display the frequency of hand sanitizer use in a variety of locations, such as *inside patient rooms*, *outside patient rooms*, *inside laboratories*, and *other* locations. Other locations included corridors, outside of cafeterias, lobbies, and

outside of bathrooms. Only 28.9% and 23.7% of the facilities reveal hand sanitizers located inside and outside of patient rooms, respectively. Laboratories indicate that 35.1% have hand sanitizers, while 43.3% denote other locations of hand sanitizers.

Table 1: Hand Sanitizer Location

	Frequency	Percent
Inside Patient Rooms	28	28.9
Outside Patient Rooms	23	23.7
Inside Laboratories	34	35.1
Other Locations	42	43.3

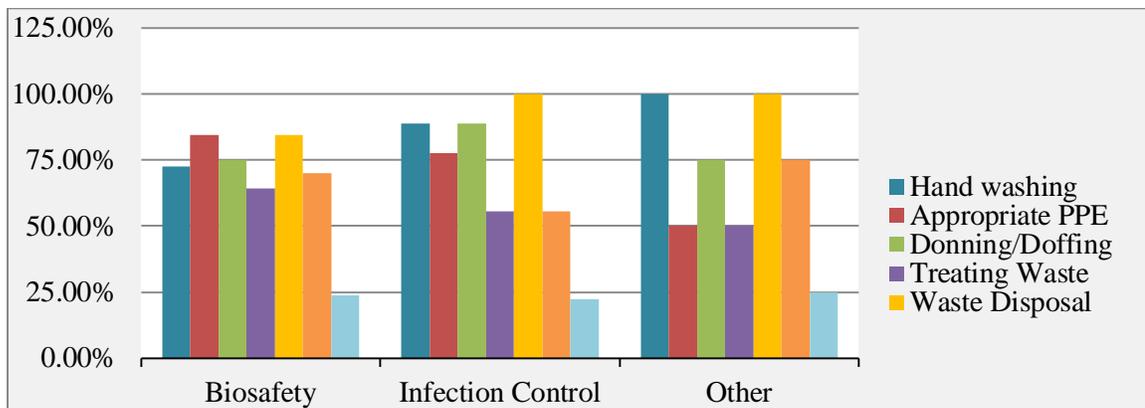
Facility and Engineering Design

Participants were asked about specific facility and engineering design features of their work environment that helps contain pathogens (n = 97). Forty-nine percent indicated they have designated isolation or quarantine areas, and 4.1% stated they did not know if their facility had these areas. Of the participants that work in facilities with isolation or quarantine areas, 72.9% indicated these areas have negative airflow. Fifty-eight percent identified HEPA filtration as an engineering feature, and 60.4% have an anteroom or staging area before entering the isolation or quarantine areas.

Safety Training

Participants were asked to indicate what type of safety training they receive at their workplace. They could select from a list of training or identify other trainings not accounted for. The list includes training in *hand washing, appropriate PPE, donning and doffing PPE, treating infectious waste, transporting infectious waste, disposing infectious waste, none, or other*. Figure 4 displays the participants responses for each type of training (n = 95). The figure shows that 88.9% of the infection control group indicated training in hand washing and donning and doffing PPE, and 100% stated they received training in infectious waste disposal. In these three categories of training there are higher percentages of infection control participants than indicated by biosafety participants. A higher rate of the biosafety group stated they had training in appropriate PPE, treating infectious waste, and transporting waste.

Figure 4: Safety Training



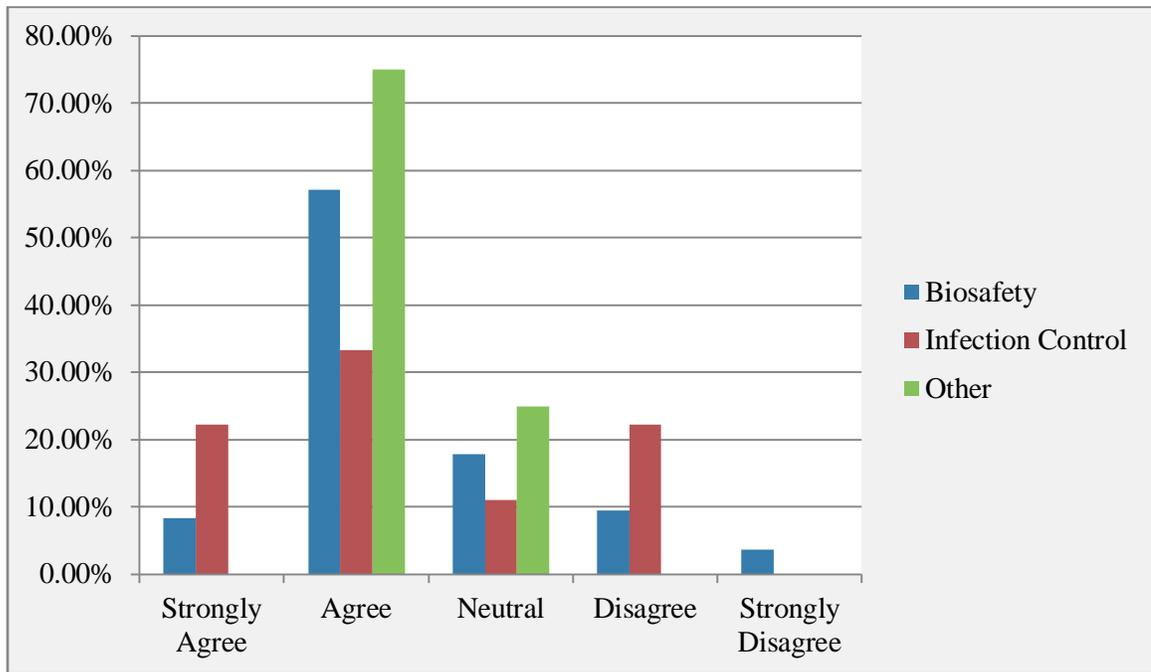
Participants were asked how training is conducted and how frequently they receive training at their worksite. The options to choose from for how training is conducted (n = 96) were *classroom*, *demonstration*, *hands on*, and *other*. They could select multiple responses. For frequency of training participants (n = 96) could choose multiple options such as *upon hire*, *annually*, *after an incident occurs*, *never*, *don't know*, and *periodically*. Approximately 77% of the biosafety group indicated that classroom training is conducted. Fifty percent also specified training involved demonstrations, 46.4% have had hands on training, while 48.8 % indicated other. Other training was described as mostly web-based training in addition to classroom training. Several high containment laboratories described their training was far more interactive with their audience through classroom, demonstration, and hands-on training. Classroom training was indicated by 66.7% of the infection control group, while 33.3% described that training included demonstrations, 55.6% stated they received hands on training, and 44.4% indicated other training. Other training described primarily included web-based training or hands on training for hand washing.

Training received upon hire was indicated by 72.6% and 66.7% of biosafety and infection control groups, respectively. Annual training was received by 77.4% of biosafety personnel and 77.8% of infection control personnel. Biosafety (38.1%) and infection control (11.1%) groups stated they received training after an accident occurred

and 32.1% of biosafety and 44.4% of infection control pointed out that periodic training was received.

Using a 5-point scale (1= *strongly disagree*, 5= *strongly agree*), participants indicated their level of satisfaction with the training they receive on the job, n = 93. As shown in Figure 5, over half of the biosafety group (57.1%) indicated they strongly agree, while 33.3% of the infection control group indicated they strongly agree. Those who responded neutral were 17.9% of the biosafety group and 11.1% of the infection control group. A larger percentage of the infection control group (22.2%) responded that they disagree in being satisfied with the safety training received at their workplace, compared to cumulative disagree and strongly disagree responses from the biosafety group (13.1%).

Figure 5: Satisfaction with Job Training



Areas in Need of Improvement

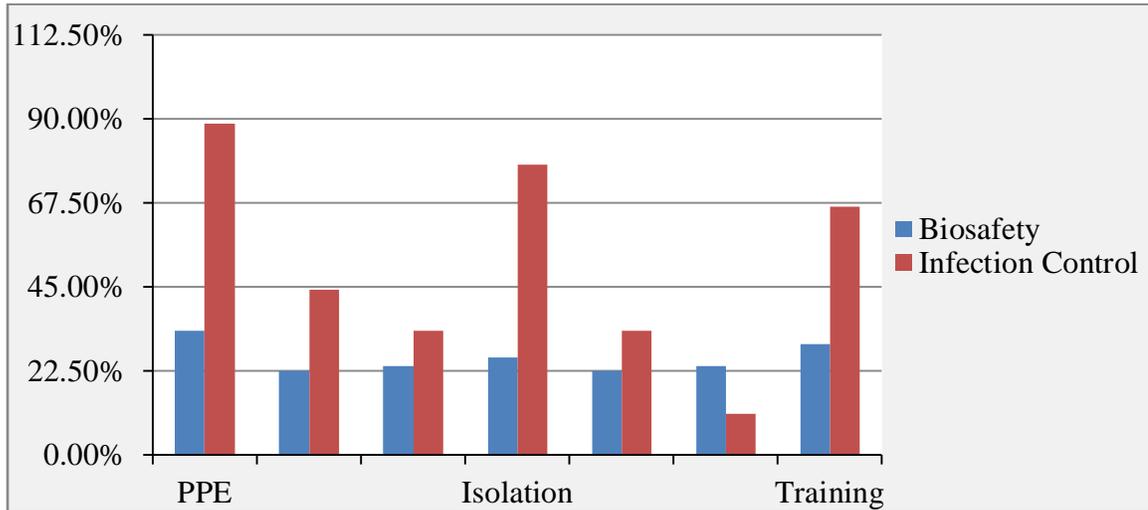
The survey asked participants to identify areas in need of improvement in their facility and describe other areas of concern. Results of the survey indicate that PPE use and training, facilities and engineering improvements, and following SOPs and protocols are the three biggest areas in need of improvement identified by both biosafety and infection control (n = 94). For the biosafety group, 51.9% indicated that wearing appropriate PPE was the main area in need of improvement in their work environment. Following SOPs and creating protocol-specific procedures were also identified by 45.7% and 39.5% of the biosafety group, respectively. The area of concern indicated most frequently from the infection control group was the availability of engineering controls (66.7%). Engineering controls would include biosafety cabinets, sharps containers, anything that puts a protective barrier between the worker and the hazard. Training on donning and doffing PPE was next at 55.6%. Other areas identified as needing improvement included having appropriate PPE available, having enough PPE, hand washing, waste handling and training on waste handling, decontamination and training on decontamination, facility design such as flow of work and patients, airflow, air filtration, and isolation, training on engineering controls, and training on protocols and SOPs.

The majority of both the biosafety group (74.1%) and infection control group (77.8%) indicated other concerns they have with their work environment. The most commonly described other area of concern by the biosafety group (38.5%) was lack of a

good occupational health program which includes pre-employment physicals, health screenings, vaccinations, lack of policies, and lack of support from upper management. Infection control personnel indicated the lack of formal training on a regular basis and lack of on-site program to evaluate.

Improvements Made Since the Ebola Outbreak

Many of these areas of concern did see improvement since the Ebola outbreaks. Figure 6 shows the improvements in various practices by biosafety personnel and infection control personnel. The greatest improvement made by both the biosafety and infection control groups was in PPE, 33.3% and 88.9%, respectively. PPE, isolation, and training were the top three areas of improvement since the Ebola outbreaks identified by both groups. Participants could elaborate further on the specific areas of improvement. Several participants from the infection control group indicated that the overall general awareness regarding infectious diseases has improved in hospitals. Additional training has been implemented in hand washing, appropriate PPE, and removal of PPE. Improvements have also been made in establishing, revising, and following protocols, as well as increased communication between emergency departments and other hospital staff.

Figure 6: Improvements since Ebola Outbreak

Discussion

In one interview with an infectious disease doctor who provides occupational health medical services for biomedical and microbiological laboratories, he described the overall goal of infection control to be similar to biosafety: to achieve containment. After the numerous healthcare workers in West Africa and two nurses at a Texas hospital were infected while treating Ebola patients, the medical community realized they were not ready to handle highly infectious diseases with a high mortality rate, so they have since increased and improved their training. Some medical facilities reached out to biosafety professionals who work in high containment laboratories for assistance.

Biosafety professionals and researchers, especially those who work in high containment laboratories, handle infectious agents that can cause serious or lethal disease on a daily basis unlike hospital staff. Donning and doffing procedures are practiced extensively in these environments, and proof of proficiency must be documented in accordance with the Select Agent Regulations. High containment laboratories have the most dangerous pathogens and stringent requirements than any other laboratory working with infectious material; therefore, a comprehensive training plan, incident response plan, and security plan are typically written by biosafety professionals and reviewed extensively by the Select Agent Program inspectors from the CDC and/or USDA.

Infectious Waste Handling

All groups identified in the survey collect infectious waste in red bags and sharps containers. The majority of the infection control group indicated their waste is removed via contractor for further processing and disposal. Similarly, much of the biosafety group sends infectious waste offsite by a contractor; however, most process the waste further by autoclaving or chemically inactivating the waste prior to packaging the material for contractor pickup. Data suggests that the biosafety group handles waste more extensively by autoclaving and packaging up the material to be sent offsite for further processing or final disposition than the healthcare community. It is therefore likely that due to the additional handling and processing of infectious waste by the biosafety group that they have more experience in safely handling waste without contaminating the surrounding

areas or themselves. It is also likely that laboratory environments already have protocols established to safely handle and decontaminate waste prior to sending offsite for final disposition. Additional safety controls described by the biosafety group include training and establishing procedures for the flow of waste from the point of generation to the site of inactivation to the contractor for removal. Typically in high containment research laboratories, red bags are either sprayed or wiped down with disinfectant prior to removing from a biosafety cabinet and/or laboratory space. In these laboratories all waste must be decontaminated prior to leaving the work space (Centers for Disease Control and Prevention and National Institutes of Health, 2009). It is this researcher's opinion that because of this primary difference in waste handling, that biosafety and research personnel can assist healthcare providers with their waste handling techniques and work flow for processing waste, especially in situations of infectious disease outbreaks or increased amounts of waste are generated.

Hand Hygiene

The most common theme and major challenge found in the literature review of healthcare settings is the continuous lack of hand hygiene. Studies have consistently shown that hand hygiene is the most important factor in infection control, yet the compliance rate is below 50%. Of all protective measures employed for infection control, hand hygiene is the least expensive, easiest, and most effective mechanism to reduce the rate of HAIs (Doan, Kong, Kirkpatrick, & McBryde, 2014). Surprisingly,

however, hand hygiene was not indicated as one of the top three concerns by any of the study groups. One explanation could be that participants may be answering questions based on what their practices and actions are, but not necessarily the overall practices of those in their work environment. Another possibility is that participants may view their hand hygiene procedures as adequate, while those observing and conducting studies witness variations and deficiencies in healthcare practice.

For research laboratories, and primarily high containment laboratories, researchers do not rely on alcohol-based sanitizers as a means to clean or decontaminate their hands. Hand washing for at least 20 seconds after removing gloves is the industry standard for laboratory workers, but there is still a variation of how well hands are washed in practice. Several factors must be considered in order to properly conduct hand hygiene. Washing hands is the physical act of removing microorganisms from the skin. The focus is not to kill the infectious agent, but to remove it from the skin. Using alcohol-based hand sanitizers are effective at killing some pathogens, but certainly not everything. Methicillin Resistant Staphylococcus Aureus (MRSA) for instance is not susceptible to alcohol. It is likely that one of the reasons that MRSA is a commonly spread HAI is because hospital staff are washing their hands less and are relying more on alcohol-based hand sanitizers. Hand washing would allow them to actually remove the contamination from their hands as opposed to just rubbing it around with hand sanitizer.

Hands should also be washed after removing gloves each time. If gloves become contaminated they should be removed immediately and properly without contaminating oneself. Contaminated items should never be handled more than necessary and should just be removed rather than trying to decontaminate the gloves by rubbing alcohol on them as shown in some videos. Removing gloves in a safe manner takes practice, and there should be no need to decontaminate the gloves first.

If healthcare providers decide to use alcohol-based sanitizers on their hands or gloves, they need to be aware of contact time and concentration of the product which are important factors to consider during the process of decontamination. All disinfectants have a certain contact time to be effective at inactivating certain pathogens to render an object safe to handle. Alcohol evaporates very quickly and needs a longer contact time than many other disinfectants.

Do healthcare workers know if alcohol kills Ebola, and if it does, do they know what the contact time must be in order to render it inactivated? Ebola is a very messy disease causing a lot hemorrhaging and diarrhea. As indicated by a study participant, one Ebola patient generated 14 liters of stool with a massive viral load. Healthcare workers treating these patients will be handling large amounts of feces and blood with a significant splash and splatter hazard making contamination of the gloves inevitable. Organic load impacts the effectiveness of decontamination, which means a longer contact time or higher concentration would be required of a disinfectant. An alcohol-based

sanitizer would not be effective. This is why removal of the gloves as opposed to rubbing them with alcohol first should be emphasized.

Hand hygiene and especially the effectiveness of disinfectants are two items that high containment workers train on. Decontamination is of utmost importance and the principles and practices surrounding effective decontamination methods are researched extensively and strictly adhered to in these environments. Alcohol-based hand sanitizers are not used in lieu of hand washing in these laboratories. This is an area of expertise that high containment laboratory research and biosafety professional can offer to healthcare workers.

Facility and Engineering Design

Only about half of the participant indicated they have a designated isolation or quarantine area. Not all of these areas are equipped with negative airflow, HEPA filtration, or a staging area. Isolation areas that have these design features are able to contain highly infectious agents and especially those that are spread through respiratory droplets such as Tuberculosis. While Ebola is not considered to be a respiratory illness, it causes hemorrhaging and diarrhea in such large amounts that splash, splatter, and aerosols of bodily fluids are inevitable. Air exhausting from the room that is HEPA filtered can block these contaminated aerosols from getting into the ductwork, which is especially important if the air is recirculated throughout the building. Negative airflow helps keep contamination in the room since air is going inward and not out into common

areas. A staging area or anteroom gives healthcare workers a space to prepare to enter, but more importantly serves as a transition from a contaminated space to a clean space where PPE may be removed, hands are washed, waste is staged, etc. before entering common areas.

Having the ability to isolate patients with highly communicable diseases is pertinent for any hospital, even if it is just a temporary arrangement until the patient can be transported to a better equipped facility. One participant who was interviewed described that the hospital facility design where the isolation rooms were did not provide a work flow conducive to handling patients with diseases like Ebola. They did not have the right equipment for an isolation room and they were too small for all the items needed to care for a patient, particularly with Ebola. Ultimately, another floor was converted to become the isolation area because the rooms were larger and the work flow was better, including the path of travel and keeping track of moving bodies.

Safety Training

Since the Ebola outbreaks, one of the most identified sources of spreading the disease was inadequate PPE and improper use and removal. As indicated by Morgan, et al. (2015), the lack of training in wearing and removing PPE is alarming and telling of hospital preparedness for handling patients in the future with emerging and reemerging

infectious diseases. Only 30% of these HCWs were trained on appropriate use of PPE, donning, and doffing procedures. The CDC in collaboration with APIC and SHEA put out guidance and training videos on how to properly remove PPE. They consulted with infectious disease doctors, infection control specialists, and epidemiologists to develop the videos; however, there was no indication that biosafety professionals or high containment laboratory workers were ever consulted. From a biosafety professional standpoint the videos lacked a basic risk assessment and awareness of the spread of infectious diseases, appropriate removal of PPE, and decontamination. At the end of one 20-minute video, the last step was to decontaminate hands by using the hand sanitizer. At no point in time was any instruction given to wash hands.

The videos also did not discuss the need to change gloves frequently when handling Ebola patients. If gloves are severely contaminated, they should be removed and replaced with a fresh pair of gloves. Gloves can become easily compromised, and if the HCW continues to wear the same pair of gloves that have been contaminated, the risk of contaminating the inner gloves increases. Therefore, the PPE training videos should include removal of gloves in these situations and indicate the frequency of glove removal during patient care.

As indicated by six specific comments made by the three groups, the use of PPE, how to wear it appropriately, and remove it safely are concerns specifically in the hospital setting. In several interviews, participants discussed the same PPE being worn in

different areas of the hospital. For instance, physicians and nurses leaving a surgery suite or operating room were seen wearing the same booties, hair covers, and lab coats while going to other areas or rooms in the hospital without changing. Then, wearing the same PPE, they would enter back into the surgery area without changing. One participant had a concern with not buttoning up lab coats in a laboratory setting. Another participant expressed concerns with the lack of hazard communication on the posted signage. She described the signs being generic stating “enteric precautions”, with no explanation included on what PPE must be worn and what the actual risk is. The results of the survey support the articles discussed in the literature review by Kortepeter, Smith, Hewlett, & Cieslak (2015) and Morgan, et al., (2015) regarding PPE.

In the Texas hospital where two nurses became sick with Ebola, one of the issues according to an interviewed participant was that there was no observation of the PPE donning and doffing process, which contributed to the two nurses becoming infected. One interview participant who consulted with and provided biosafety training to hospital staff described her initial assessment of a hospital environment. She witnessed many inconsistencies with glove removal including with nurses and physicians. Scrubs and lab coats worn during patient care were then worn in hallways and the cafeteria. Surgical scrubs, booties, and hair covers were worn outside of the surgery suite. When she began training the staff, initially the healthcare workers were not used to doing things in a certain way (i.e., donning and doffing PPE in a particular order). They did not have an

overall understanding of risk assessment or take seriously the need for structured steps of performing tasks involving their safety.

The same interview participant was consulted and provided training to all the healthcare workers that would be part of the Ebola treatment teams. Trainings were run from 5 am - 11 pm for doctors and nurses on different shifts to attend sessions when they were available. All sessions were mandatory and hands-on. The participant indicated that for the most part infection control staff were grateful for the training; whereas some physicians were reluctant and did not like being told they had to attend the training. But during and by the end of the training, everyone was on board. Staff from the emergency department, emergency preparedness, neonatal unit, infectious disease, clinical laboratories, and ICU, along with cleaning and supply managers also trained since they could provide services to an Ebola patient. After the initial 2-week training, training is now conducted on a weekly basis. The healthcare staff now has a better awareness of infectious disease in general, transmission routes, how PPE works, and donning and doffing PPE properly. Since the training was hands-on and everyone was required to practice each component at least three times, their confidence improved greatly. The training and hospital staff walked through the SOPs to make sure everyone knew step-by-step what to do. Initially many of the nurses were scared, but now they serve as trained observers. Infection prevention and emergency department personnel were trained to

provide the training to their peers after the initial two weeks, so the training is now conducted in house.

According to one participant, hospitals are typically set up like trauma centers in general. In her opinion, the awareness and mentality for handling infectious diseases is lacking. Multiple participants pointed out that there was a lot of information put out by the government that was inconsistent and confusing. The CDC and NYU created videos for donning and doffing PPE, which were inconsistent or kept changing, and much of the information was not appropriate. It was clear that the appropriate professionals were not engaged in the discussion before these videos were released. The information and videos created a lot of anxiety for healthcare workers in particular.

Improvements

According to the study data almost every aspect discussed in this paper was improved upon in the hospital work environment since the Ebola outbreak. Vast improvements were made particularly in PPE, isolation, and training. For instance, many hospitals have powered air purifying respirators (PAPR) but they never get used to them since they don't typically need them, so personnel are not familiar with the equipment. It became evident that PPE donning and doffing training was needed not just for gloves, but also for other PPE including the PAPR. One participant noted that almost every university hospital/medical center sought help from biosafety professionals especially from BSL-3 laboratories on help with PAPR use, donning, and doffing.

The United States has excellent public health infrastructure and tracking where patients are and who they came into contact with. An infectious disease consultant who participated in the study described the improvements made since the Ebola outbreaks. Hospitals in the United States have taken their safety controls to another level for potentially airborne diseases and droplet transmission. Every hospital now is expected to be capable of housing suspect Ebola patients for 72-96 hours until the test results are revealed. Any patient positive for Ebola will be transported to one of the 55 hospitals in the U.S. that are designated Ebola treatment centers for further treatment. Special response teams have been established to respond to healthcare emergencies such as a patient who may have been exposed to Ebola. The team has much more intensive training than other healthcare workers. They train with PAPRs, donning and doffing their PPE without contaminating themselves, waste handling procedures, decontamination practices, and more. The special response teams in hospitals are in the ER, ICU, each shift (2 people on at a time per location), so there are at least 24 members of a team in a hospital. In one case, 60 HCWs were needed to treat one Ebola patient. HCWs will drop what they are doing and immediately begin treating suspected Ebola patients. Just to run these 55 Ebola treatment centers and maintain the intensity of training and preparedness is a huge expense; so it is not feasible to have every hospital trained and capable of handling pathogens such as Ebola.

Summary

Hospitals face additional challenges in containment that biomedical laboratories do not. There are more variables in the hospital setting that cannot be controlled such as patient behavior, visitors, and unknown illnesses. For Ebola in particular large volumes of bodily excretions, primarily diarrhea, present an enormous splash hazard and additional precautions must be taken including additional PPE. As described by one participant, for one Ebola patient, 14 liters of stool was generated with a massive viral load, much higher than what is typically found in HIV patients. Also, in the hospital setting, healthcare workers do not always know what to expect; whereas, in a biomedical or microbiological environment, labs can engineer out many of the variables. Biomedical research laboratories are considered to be lighter duty jobs than in a hospital. In research laboratories much of the work is contained within a biosafety cabinet, which is a type of engineering control designed to protect the worker from infectious particulates that may result from the procedures being performed. A hospital setting has many moving parts including patient movement and behavior, transporting and treating patients, which is considered a moderate duty job. Naturally, this leads to more difficulty with wearing PPE such as PAPRs for long periods of time. Healthcare workers can become dehydrated and fatigued much quicker than someone working in a research laboratory wearing the same type of PPE. Overall, more variables exist in the healthcare environment when handling patients and visitors than in a microbiological or biomedical research laboratory where the risks are known.

Understanding the importance of donning and doffing PPE is critical for controlling the spread of infection in hospitals, not just from Ebola, but from common HAIs caused by MRSA, influenza, and higher risk emerging and reemerging diseases such as SARS, MERS, and highly pathogenic avian influenza such as H5N1. In microbiological and biomedical research laboratories, especially those handling high risk pathogens, it is commonplace to train on donning and doffing PPE, hand hygiene, strict adherence to decontamination procedures, handling and sterilizing waste, and other procedures. These types of laboratories work with multiple different pathogens and utilize biosafety practices and procedures that can accommodate and protect workers from a variety of pathogens. Biosafety personnel are responsible for conducting risk assessments to identify the most appropriate controls to put into place. These controls include a combination of engineering controls, administrative controls, standard operating procedures, and PPE. Unlike the rate of HAIs, there is a substantially lower rate of LAIs due to the implementation of the controls and training programs in place for high containment laboratories. Consulting with biosafety professionals from high containment laboratories to employ similar training and require demonstration of proficiency of these skills from healthcare workers hospitals will likely see a decrease in the amount of HAIs and increase their ability to combat a variety of infectious diseases. This will advance our abilities to handle infectious diseases and potential pandemics such as H5N1 immediately.

Many biosafety professionals belong to an organization call the American Biological Safety Association (ABSA). Members of ABSA have the knowledge base and expertise in biosafety that directly support how to contain the spread of infectious diseases such as Ebola Virus Disease. Biosafety professionals can evaluate the design of facilities to determine the setup of rooms for triage, isolation, and treatment of infected patients. Biosafety professionals are highly skilled in conducting comprehensive risk assessments for assessing where the risks are in order to determine controls such as selecting appropriate PPE and training healthcare providers on how to appropriately don and doff PPE without spreading contamination. Developing standard operating procedures that can be effectively utilized by healthcare workers is another task the biosafety profession is proficient in, as well as decontamination practices and preventing the spread of contamination (American Biological Safety Association, 2014). Biosafety professionals implement the hierarchy of controls where PPE is always the last line of defense and is associated with human behavior where errors are more likely to occur than with other controls. Hospitals should also be aware of the hierarchy and factor in facility design and other engineering controls to help contain pathogens rather than rely on PPE as the main barrier of protection.

Hospitals should already be prepared for any potential infectious disease. While the spread of SARS in 2003-2004 was confined primarily to Asia and Canada, the infection could easily have been spread to the United States. The origin of pathogens,

especially non-indigenous pathogens, is a concern due to the vast amount of global travel and potential risks of pathogens not known in the United States (Centers for Disease Control and Prevention and National Institutes of Health, 2009, p. 12). Being prepared for these events in advance is critical to protecting U.S. citizens from the spread of deadly diseases. As seen with the first case of an Ebola-infected individual enter the U.S. through normal travel means (i.e., not by a carefully planned flight with personnel equipped to handle infectious diseases), two healthcare workers and the potential exposure of many more demonstrated the need for better training and understanding the spread of infectious disease in a hospital setting. An advantage that most microbiological and biomedical research laboratories have is the knowledge of what pathogen(s) they are working with in their environment. Biosafety levels are established in advance of working with infectious agents so the agent is handling under the appropriate containment conditions and practices. Unfortunately for hospitals, they never know what they are going to encounter on a daily basis, so they must be prepared to handle potentially deadly, communicable pathogens should they present themselves.

Recommendations

This research may contribute to hospitals incorporating principles and practices in biosafety into their infection control procedures. Healthcare workers can benefit from utilizing practices with a biosafety focus to help prevent the spread of infection while

treating patients with infectious diseases. Current infection control measures are either insufficient or are not being rigorously followed as seen in the number of HAIs. The increase of global travel has and will continue to contribute to the spread of infectious diseases not endemic to the United States. Healthcare workers must be prepared to handle patients with a variety of infectious diseases with potentially severe consequences. Healthcare organizations have a responsibility to protect their workers, and utilizing biosafety professionals and resources can help decrease the risk to healthcare workers.

Utilizing a combination of infection control procedures and biosafety principles and practices can help decrease the spread of infection and number of HAIs. Involving biosafety professionals in the assessment and design phase of a hospital will serve to strengthen the knowledge and confidence of those caring for patients with infectious diseases, especially for emerging and reemerging pathogens. Future studies recommended would be to compare and contrast the number of HAIs in a hospital prior to and after implementing biosafety practices and procedures.

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Appendix A: Institutional Review Board Approval



American Public University System
American Military University
American Public University



Institutional Review Board (IRB)

May 11, 2015

Dear Cara Leitch,

The APUS IRB has reviewed and approved your revised application # 4-2015-42 (submitted May 9, 2015). The approval covers one calendar year. Should you need an extension beyond the one year timeframe, an extension request will have to be submitted. However, this does not mean your research must be complete within the one year time frame. Should your research using human subjects extend beyond the time covered by this approval, you will need to submit an extension request to the IRB.

Sincerely,

Patricia J. Campbell
Chair, IRB

Appendix B: Survey Questions

(Administered through Survey Monkey®)

Infection Control and Biosafety: A Compare and Contrast Study

1. What is your current occupation? Check all that apply.

- Biosafety
- Infection Control
- Microbiological or biomedical research
- Nursing
- Physician
- Other. Specify

2. Do you have previous experience in any of the following? Check all that apply.

- Biosafety
- Infection Control
- Microbiological or biomedical research
- Nursing
- Physician
- Other. Specify

3. What type of facility do you work in? Check all that apply.

- University
- Hospital
- Doctor's office
- Microbiological or biomedical laboratory
- Government facility/laboratory
- Field hospital
- Other. Specify

4. Do you currently work or consult with biosafety professionals?

- Yes
- No

5. Do you work in a BSL-3 or BSL-4 laboratory?

- Yes
- No

6. Are patients with highly communicable diseases treated at your facility or are they sent to another facility?

- Always treated onsite
- Sometimes treated onsite depending on the infectious disease or circumstances
- Always sent to another facility
- Not applicable

7. Does your facility have a protocol for quarantining or isolating patients?

- Yes
- No
- Not applicable

8. Does your facility have a quarantine area or isolation room(s)?

- Yes
- No
- Not applicable

9. Do the quarantine or isolation areas have negative airflow?

- Yes
- No
- Not applicable

10. Is the exhaust air from the quarantine or isolation area HEPA filtered?

- Yes
- No
- Not applicable

11. Is there a staging area or anteroom upon leaving the quarantine or isolation area?

12. Please elaborate on other features in the quarantine or isolation area.

13. How is infectious waste or potentially infectious waste handled at your facility?

Check all that apply.

- Autoclaved
- Incinerated
- Chemically inactivated
- Other

14. Briefly describe how infectious waste is removed from the point of origin and transported to the treatment site (i.e. waste is double bagged, bags are sprayed with disinfectant prior to leaving the place of origin, etc.)

15. Is there a validation process to ensure infectious waste has been rendered noninfectious?

- Yes
- No
- Not applicable

16. Does your facility provide hand sanitizers?

- Yes
- No

17. If your facility provides hand sanitizers, where are they located?

- Inside or just outside of patient rooms
- Inside or just outside of laboratories
- In a field hospital
- Other. Please specify

18. If you work with patients, do you wash your hands between patients or do you use hand sanitizer?

- Wash hands
- Use hand sanitizer
- Both
- Neither
- Not applicable

19. Are patients with communicable diseases allowed to have visitors?

- Yes
- No
- Not applicable

20. Are visitors visiting patients with communicable diseases told of potential risks of exposure?

- Yes
- No
- Not applicable

21. Are visitors instructed to wear personal protective equipment?

- Yes
- No
- Not applicable

22. Are visitors instructed how to don and doff personal protective equipment?

- Yes
- No
- Not applicable

23. What training in occupational health and safety do employees receive? Check all that apply.

- Hand washing
- What types of PPE appropriate for the work environment
- Donning and doffing PPE
- Disposing of infectious waste
- Treating infectious waste
- Transporting infectious waste
- Other. Specify

24. How is the training conducted? Check all that apply.

- Classroom
- Demonstration
- Hands-on
- Other. Specify
- Not applicable

25. How frequently are employees trained?

- Upon hire only
- Annually
- Periodically. Please specify frequency
- Only when an incident occurs
- Never

26. Do you have any concerns about the practices in your facility regarding safety?

- Yes
- No

27. If you answered yes to number 26, please explain your concerns:

28. What areas could be improved upon in your specific work environment that relates to safety? Check all that apply.

- Wearing appropriate PPE
- Having appropriate PPE available
- Having enough PPE
- Receiving adequate training for use of PPE (donning, doffing, etc.)
- Hand washing
- Waste handling
- Training on waste handling
- Decontamination
- Training on decontamination
- Facility Design (i.e., airflow, flow of workspace/traffic, air filtration)
- Available engineering controls
- Training on engineering controls
- Protocol-specific procedures
- Following standard operating procedures (SOPs)
- Training on protocols and SOPs

29. For any items checked above, please provide a brief description of areas in need of improvement.

30. Are there other areas of concern for occupational health and safety in your work environment not mentioned in this survey that you would like to share?