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Preparedness and Vulnerability of Hospital and Healthcare Systems in Biological and Pandemic Incidents

Krista M. Sobecki

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PREPAREDNESS AND VULNERABILITY OF HOSPITAL AND HEALTHCARE SYSTEMS IN BIOLOGICAL WEAPON AND PANDEMIC INCIDENTS

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PREPAREDNESS AND VULNERABILITY OF HOSPITAL AND HEALTHCARE SYSTEMS
IN BIOLOGICAL WEAPON AND PANDEMIC INCIDENTS

A Master's Thesis

Submitted to the Faculty

of

American Military University

by

Krista Sobecki

In Partial Fulfillment of the

Requirements for the Degree

of

Master of Arts

July 2015

American Military University

Charles Town, WV

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DEDICATION

I dedicate this thesis to my friends and family, and specifically my parents. My parents taught me the importance of education and instilled in me the value of hard work. If it were not for their love and support, this would not have been possible.

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The coursework for the Emergency and Disaster Management Master Degree was challenging but gratifying. The lessons I have learned throughout my pursuit of this degree will follow me and impact my work throughout my career in the field.

ABSTRACT OF THE THESIS

PREPAREDNESS AND VULNERABILITY OF HOSPITAL AND HEALTHCARE SYSTEMS
IN BIOLOGICAL WEAPON INCIDENTS

by

Krista Sobecki

American Military University, April 26, 2015

Charles Town, West Virginia

Dr. Randall Cuthbert, Thesis Professor

Throughout history, biological and pandemic outbreaks have plagued the global population. In recent history, the fear of a bioterrorism event has become even more prevalent. Because of events such as the anthrax attacks following September 11th, and even more recently with the Ebola outbreak, preparedness and vulnerability of the population to these biological agents has become an even bigger priority. On the front lines of the fight to combat these biological agents are the hospital and healthcare systems of the United States. The ability of hospitals and healthcare systems to prepare for and respond to a biological weapons or a pandemic incident may be the difference between life and death for a large number of the population. This paper will examine the current state of preparedness and vulnerability of

hospital and healthcare systems in the in the Western Pennsylvania region. Research consisted of qualitative analysis of past and current regulations regarding preparedness for biological events, case studies of past events, and review of academic journals, media reports, and government resources. Research shows that the threat of bioterrorism and pandemic events remains a serious threat. While the probability of bioterrorism and mass pandemic outbreaks may be low, the risk and potential consequences should it occur is far too high to not be prepared for the incident. However, results show that there will be many obstacles and challenges to overcome in order to ensure that hospital and healthcare systems are fully prepared to respond to the threat of bioterrorism and pandemic events. These challenges must be met and overcome in order to guarantee that safety of patients and victims.

Table of Contents

CHAPTER	PAGE
INTRODUCTION	8
LITERATURE REVIEW	11
Definitions	11
The Existing Threat	11
Policies, Procedures, and Regulations	22
The Anti-Vaccine Movement	30
THEORETICAL FRAMEWORK	33
METHODOLOGY	36
FINDINGS	40
Results	40
The State of Preparedness in Western Pennsylvania	45
CONCLUSIONS	51
Recommendations	52
REFERENCES	59

Introduction

Shortly after the devastating attacks of September 11, 2001, letters laced with anthrax began surfacing. These letters were sent through the United States mail service, resulting in the death of five American citizens and infecting 17 more (FBI, 2015). The anthrax attacks, later deemed “Amerithrax” by the Federal Bureau of Investigation, became one of the worst biological weapons incidents in United States history (FBI, 2015). Since those events more than a decade ago, this country has regularly faced threats by biological agents, both intentional and naturally occurring. More recently, the Ebola outbreaks in West Africa have only further ignited the fear of biological outbreaks, as well as led citizens to question the ability of the United States to respond to biological weapons incidents. While the Ebola threat has faded from the media, citizens are now facing new biological threats, including Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and Avian Influenza, also known as Bird Flu. These incidents show that the United States needs to continue to treat biological outbreak response as a top priority. This fact may also mean that terrorists may view vulnerability as a prime opportunity to attack the United States.

While chemical, biological, radiological, and nuclear weapons (CBRN) are a high priority of homeland security, biological weapons present unique and difficult challenges to preparedness and response efforts. Hospital and healthcare systems will be on the front lines of responding to a biological weapon incident. While current regulations and policies are in place that hospitals are required to follow, as well as regulating bodies that oversee if these regulations are being adhered to, the question must be asked if these are enough to ensure that hospitals and healthcare systems will be ready and able to respond to an intentional or natural biological outbreak. Our nation’s citizens take for granted that when they seek treatment in a hospital, the hospital has

control of the situation and will correctly treat whatever ailment they are afflicted with. Citizens rely on the faith they have in this country's healthcare systems, and a break of that faith could have long-term repercussions. In the unfortunate event that a biological weapons incident or pandemic occurs within the United States, lack of preparedness on the part of the country's healthcare systems could result in dire consequences for its citizens. These preparedness efforts must allow for the treatment of all its citizens, and must also keep the hospital workers safe so that staff members are available to continue treating victims.

The purpose of this paper will be to address if hospitals and healthcare systems possess the capability to effectively prepare for, and respond to a bioterrorism incident or pandemic event. Specifically, this paper will look at the preparedness procedures that are in place for hospital and healthcare systems within the Western Pennsylvania area that are part of the Region 13 Task Force. The Western Pennsylvania region holds particular interest to the researcher. The researcher currently lives and works in the region's healthcare field. The Western Pennsylvanian region is also quite unique. While severe weather is a high risk, the threat of natural disaster is quite low. This creates a unique environment that has allowed the area, and specifically the metropolitan area of Pittsburgh to flourish. Part of this flourishing area includes world-class healthcare systems and medical research facilities that are known worldwide. The natural topography has allowed for a robust infrastructure system, that could greatly impact not only regional response to a bioterrorism or pandemic event, but may also be critical to national response to these events.

Discussion on this topic will start with understanding the threat faced by understanding the biological agents that pose the most danger, as well as the case studies where these agents infected people. This paper will discuss and clarify what regulations and policies are currently in

place that hospitals are required to follow in regards to preparedness for biological incidents. It will also examine what deficiencies or vulnerabilities may currently exist in this preparedness that could put citizens at risk should an outbreak occur. These findings will be further explored along with recommendations for addressing the issues discovered.

Literature Review

Definitions

It is important to define common terms that will be used throughout this discussion. Bioterrorism is defined in the Weapons of Mass Destruction (WMD) statute, Title 18 U.S.C. Section 2332a, as “the threat (or conspiracy) to use a weapon of mass destruction, including any biological agent, toxin, or vector as defined in Title 18 U.S.C Section 178 against a national of the United States or within the United States” (FBI, 2011, p. 10). A biological weapon of mass destruction is “any weapon involving a disease organism...capable of causing biological malfunction, disease, or death in a living organism” (FBI, 2011, p. 10). A biological pandemic is defined as “an infectious disease in human populations that has spread worldwide and affected many people in almost all countries” no matter how rapidly or slowly the disease spreads (Steen, 2015, p. 1). An outbreak, on the other hand, is defined as “the occurrence of cases in excess of what would normally be expected in a defined community, geographical area or season” or “a single case of a communicable disease long absent from population, or caused by an agent not previously recognized in that community or area” (WHO, 2015).

The Existing Threat

In understanding where the vulnerabilities of hospital preparedness lie, it must first be understood the threat faced by biological weapons and pandemics. The Center for Disease Control and Prevention (CDC) has categorized biological agents into three categories. An agent is categorized by how easily it can be transmitted or spread, the amount of human deaths occur because of the agent, the impact to public health and social disruption, and if the release of the agent requires public health reaction (CDC, 2007). Category A agents are the highest priority

agents, which include organisms and toxins (CDC, 2007). These agents pose the greatest risk to national security and public health. Agents are deemed Category A because, 1) the agent is easily spread or transmitted from person to person, 2) the agent causes high death rates and could cause a major impact to public health, 3) the agent has the ability to cause public panic and great social disorder, and 4) it will require special actions for public health preparedness (CDC, 2007). The following agents discussed are Category A agents in which experts have deemed a high threat to national security and public health.

Anthrax is caused by *Bacillus anthracis* (CDP, 2014). Anthrax has the ability to form spores, which makes it easily transmitted and more resilient, living in the environment for decades. Dormant anthrax cells can become active within the body, which begins the rapid infection (CDP, 2014). A person is infected with anthrax either by inhalation and infection through the respiratory tract, ingestion and absorption through the digestive tract, or through cuts or abrasions in the skin (CDP, 2014). Anthrax infection begins with flu-like symptoms, including chills, fever, nausea, and swelling of the lymph nodes (CDP, 2014). If the infection occurred through inhalation, the victim may also feel malaise, fatigue, and develop a nonproductive cough and chest discomfort (CDP, 2014). Two to four days after the initial symptoms present, the victim may experience a brief period of improvement (CDP, 2014). Once the infection becomes acute, the patient will experience a quick onset of severe respiratory distress with dyspnea, stridor, diaphoresis, and cyanosis (CDP, 2014). Final stages of the infection include respiratory failure and hemodynamic collapse (CDP, 2014).

Plague is a disease caused by bacterium *Yersinia pestis* (CDP, 2014). Plague is responsible for killing a third of population in the Middle Ages during the Black Death. Today, antibiotics are effective in treating the plague; however it still exists in rural areas throughout the nation,

infecting about ten to twenty people each year (CDP, 2014). The last plague epidemic occurred in Los Angeles from 1924 to 1925 (CDP, 2014). Plague is usually transmitted from rats to humans through fleabites, also known as bubonic plague (CDP, 2014). The plague can also be aerosolized and transmitted through the air, infecting the victim through inhalation in the respiratory tract, also known as pneumonic plague (CDP, 2014). Symptoms of the plague include high fever, chills, headache, and weakness (CDP, 2014). Those infected with bubonic plague will experience swollen and tender lymph nodes. Those infected with pneumonic plague will experience spitting up blood and shortness of breath, which if left untreated, can lead to respiratory failure (CDP, 2014).

Tularemia is caused by bacterium *Francisella tularensis* which is found in animals, specifically rodents and rabbits (CDP, 2014). A person can become infected with tularemia if the skin is broken or the bacterium gets into the mucous membranes when handling an infected animal (CDP, 2014). The disease may also be transmitted through the bite of infected deerflies, ticks, or mosquitos, through inhalation of dust, or through ingestion of contaminated food (CDP, 2014). The incubation period of tularemia is between three to 14 days, with symptoms usually appearing in three to five days (CDC, 2003). Symptoms of this disease are sudden fever, chills, headaches, diarrhea, muscle aches, joint pain, dry cough, and progressive weakness (CDP, 2014). Some infected with tularemia may include ulcers on the skin or in the mouth and swollen and painful lymph nodes (CDC, 2003). Progression of the disease can lead to respiratory issues such as pneumonia, chest pain, spitting up blood, and respiratory failure (CDP, 2014).

Smallpox is caused the virus *Variola major* (CDP, 2014). This disease was declared eradicated by the World Health Organization in 1980 after a worldwide vaccination program (CDP, 2014). The vaccinations were stopped after the disease was deemed eradicated due to the

belief that prevention for the disease was no longer necessary (CDC, 2007). Smallpox can infect a person through inhalation, and spread from person to person as an aerosol (CDP, 2014). It can also be spread through direct contact with bodily fluid or contaminated clothing, bedding, or other contaminated articles (CDC, 2007). The incubation period of smallpox is between seven and seventeen days, during which time the infected individual is not contagious (CDC, 2007). Initial symptoms include malaise, a high fever between 101 to 104 degree Fahrenheit, rigors, vomiting, headache, and backache (CDP, 2014; CDC, 2007). About two to 4 days after the fever begins, a rash on the face, tongue and mouth, hands, and forearms will appear, and spread to the trunk and lower extremities (CDP, 2014). The development of the rash is slow and the pox will appear at the same stage (CDP, 2014). This early rash stage is when the infected person is most contagious, and continues to be contagious until the pox scab over and have fallen off (CDP, 2014; CDC, 2007). The mortality rate of smallpox for those who have been vaccinated is three percent, and is 30% in those who are unvaccinated (CDP, 2014).

Viral hemorrhagic fever (VHF) is caused by viral agents such as Filoviruses (Ebola and Marburg), Arenaviruses, and Flaviruses (Dengue) (CDP, 2014). These viruses are zoonotic and dependent on an animal or insect to survive. Humans are not natural carriers of these viruses, and are only infected once contact is made with an infected animal or insect (CDP, 2014). Once humans are infected, however, the viruses can be transmitted from person to person, usually through contact with the person, or through contact with the infected body fluids (CDP, 2014). Initial symptoms of infection include nausea, vomiting, abdominal pain, diarrhea, chest pain, cough, and pharyngitis (CDP, 2014). As the disease progresses, victims will experience bleeding under the skin, in internal organs, or bleeding from the mouth, ears, and eyes (CDP, 2014). If the disease continues to progress, victims will experience shock, nervous system malfunctions,

coma, delirium, and seizures (CDP, 2014).

Botulinum toxin is produced by the bacteria *Clostridium botulinum*, and is one of the most lethal substances known to man (CDP, 2014). A person can become infected with botulinum toxin through ingestion, inhalation, and injection. One of the most common ways to be infected is through foodborne botulism (CDP, 2014). Foodborne botulism can create a public health emergency due to the fact that many people can become infected by eating contaminated food, either through improper food safety procedures or intentional contamination (CDC, 2014). The clinical symptoms of botulism include drooping eyelids, double vision, weakened jaw clench, difficulty speaking and swallowing, and respiratory muscle paralysis (CDP, 2014). In foodborne botulism, these symptoms usually appear eighteen to 36 hours after ingestion of contaminated food however it may take up to 10 days for symptoms appear (CDC, 2014). If left untreated, the disease could progress to cause descending paralysis of the arms, legs, and trunk (CDC, 2014; CDP, 2014).

These Category A agents are of great concern to national security and public health officials because these are the agents that could be used in a bioterrorism attack. Prior to the events of 9/11 and the Amerithrax attacks, experts were arguing that national preparedness must focus on the use of biological agents (Khan & Sage, 2000). Much of the planning and preparedness for terrorist attacks have been readying the country for an overt attack, such as a bombing (Khan & Sage, 2000). However, a biological attack will be covert. This will present very different challenges than will be seen or experienced with any other terrorist attack.

Steven Block, a professor of biological sciences at Stanford University, discusses the unique challenges faced in a bioterrorism attack. Block (2014) states that there are several reasons why the likelihood of a terrorist group using a biological weapon is greater than an

unfriendly nation. First, the ability to acquire materials to create the biological agent needed for an attack is easily obtained (Block, 2014). Additionally, creating and using these biological agents does not require a high degree of scientific knowledge or ability (Block, 2014). With the decades long threat posed by Al Qaeda, as well as the newer threats the United States faces by group such as ISIS and Boko Haram, any of these groups have the ability to obtain and release and agents causing a large scale disease outbreak or pandemic (Marohn, 2015, p. 1). Some evidence has shown that Al Qaeda training manuals have called for the use of biological weapons, and that Al Qaeda “has made unexpected efforts in developing bio-weapon capability among other weapons of mass ‘disruption/destructions’ in the past and possibly, are doing so even now” (Roul, 2009, p. 1).

Second, Block discusses the fact that biological agents are easily concealed (2014). A small amount of biological agent in the correct strain has the potential to infect hundreds or thousands of people and create an outbreak, a pandemic, or even an epidemic (Block, 2014). The obstacle to this would be that the individual or terrorist group would need to have the correct dispersal device to ensure that agent infects a large number of people. However, as Block (2014) explains, mass casualties from dispersal may not be absolutely necessary to gain the intended results the terrorist group may be aiming for (p. 7). A small number of infected individuals from an intentional release of a biological agent have the potential to create mass panic and cause social disruption.

This truth can be seen with the Amerithrax attacks. While it is considered the worst biological attack in U.S. history, there were a limited number of illnesses and deaths (Powers & Ban, 2002, p. 1). Five Americans were killed and 17 were sickened by the military grade anthrax that was sent through the mail by Dr. Bruce Ivins (FBI, 2015). Because of the fairly

unsophisticated way in which Irvins, who committed suicide before charges were brought against him, sent the anthrax, the incident did not cause mass casualties. However, “the incident aroused significant fear and disruptions” because this attack demonstrated “terrorists’ ability to acquire high-quality anthrax” (Powers & Ban, 2002, p. 1).

Another example that proves this theory correct is the recent Ebola outbreak in West Africa. Very few cases appeared in the United States, none of which originated here. Four people were diagnosed with Ebola in the United States, two of which died (Kellogg, 2015, p. 2). Yet, the United States was on the verge of mass panic. Hospitals were receiving instructions daily as to what to do should there be a potential case of Ebola infection appear at an emergency room. Every patient that came to an emergency room was asked specific questions to determine if there was any risk of Ebola infection. The topic dominated news reports throughout the country for months. It’s clear that the end, that is mass panic and social disruption, is the same regardless of means it took to get there. Even more so, this event placed public doubt in the government’s ability to respond to a biological event. “What Ebola taught everyone about the U.S. public health system was that there is no rhyme or reason to how the federal government, states, and local government would react and interact during an infectious disease crisis” (Kellogg, 2015, p. 3).

Finally, Block discusses that because the release of the agent would be a covert attack, the release of an agent will not be as obvious as an explosion or as quickly realized as a chemical attack (Block, 2014, p. 9). Many of these Category A agents have incubation periods that requires days or weeks before symptoms begin to appear. This means that those responsible for dispersal potentially have days or weeks to make a clean getaway without detection that anything has happened. Because many of the initial symptoms of these agents are similar to that of

common illnesses, it may be weeks more before any hospitals realize that they are dealing with something much more serious than a normal illness. The time it takes for doctors and hospitals to realize the victims are infected with a biological agent, the sick are spreading the illness farther and farther. If those infected travel during their initial symptoms, there is a potential that a small, localized outbreak could be spread nationally or even internationally. “Last year, one out of every seven people in the world crossed a border” (Marohn, 2015, p. 1).

Because of this, Block calls for the improvement of the United States capabilities to combat the threat of bioterrorism. He argues that this improvement must include the development of surveillance and detection equipment to allow for the earliest possible realization that symptoms are caused by a biological agents rather than a common illness (Block, 2014, p. 9). Block (2014) argues, “We should not have to wait for the biological equivalent of Hiroshima to rally our defenses” (p.9).

While these Category A agents are certainly an area of great concern, there are other agents that are of just as much, if not more concern. Public health officials are more concerned about airborne illnesses, such as Severe Acute Respiratory Syndrome (SARS), Middle East Respiratory Syndrome (MERS), Avian Influenza, and even influenza (Kellogg, 2015, p. 8-9). Melissa Markey, a public health official who specializes in public health law states, “I’m far more worried about things like SARS and MERS or the flu because they are airborne. If they ever really get traction, we could see a highly transmissible disease with many fatalities” (Kellogg, 2015, p. 8).

According to the World Health Organization (WHO), Severe Acute Respiratory Syndrome, or SARS, the first epidemic of the 21st century (2013). Symptoms of SARS begin with a high fever greater than 100 degree Fahrenheit, headache, a feeling of discomfort, and body aches

(WHO, 2013). Some may experience mild respiratory symptoms that develop into a dry cough after two to seven days (WHO, 2013). Most patients eventually develop pneumonia (WHO, 2013). SARS is transmitted by close person-to-person contact through respiratory droplets when an infected person coughs or sneezes (WHO, 2013). During the outbreak of 2003, more than 8,000 people worldwide became ill, with 774 deaths (WHO, 2013).

Middle East Respiratory Syndrome Coronavirus (MERS-CoV) is a viral respiratory disease that was first found in 2012 in Saudi Arabia (WHO, 2015). The disease has now been reported in 26 countries including the United States (WHO, 2015). The common symptoms of MERS infection include a fever, cough, and shortness of breath that progresses into pneumonia (WHO, 2015). If the disease progresses further, it can cause respiratory failure and organ failure specifically of the kidneys, as well as septic shock (WHO, 2015). Perhaps the most concerning fact is that it is not yet understood how MERS is transmitted. MERS is a zoonotic disease transferred to humans through either direct or indirect contact with possibly camels, however it is not yet known exactly what kind of contact transmits the disease and what is the source of MERS (WHO, 2015). Transmission from human to human occurs only when there is close contact with an infected person (WHO, 2015). No vaccine or specific treatment other than supportive care currently exists to combat the spread of MERS (WHO, 2015).

Avian Influenza is another disease that is currently in an outbreak stage. The outbreak, also called bird flu, is currently spreading across the Midwest of the United States (Reuters, 2015). This outbreak is causing egg shortages across the United States has rejected 40 million birds confirmed to have avian influenza in 16 states (Reuters, 2015). Because of the shortage, egg prices have soared in the United States and Canada. It is also causing the United States to begin to look abroad to have eggs brought into the country, a move that has never been done in

the United States (Reuters, 2015). This outbreak is causing a large disruption in the United States' economy and commerce. This current strain of Avian Influenza has yet to transmit to humans as it did in the 2003 outbreak that occurred in Asia (CDC, 2015). The symptoms of Avian Influenza are wide in range from conjunctivitis to flu-like symptoms including fever, cough, sore throat, and achiness (CDC, 2015). Severe viral infections cause pneumonia, acute respiratory distress, respiratory failure, and multi-organ disease sometimes with neurological disruptions such as altered mental states and seizures (CDC, 2015). The outbreak of Avian Influenza H5N1 has been responsible for the most human illnesses and deaths to date (CDC, 2015).

While many of the agents and diseases discussed above may seem to be foreign to the United States with little chance of reaching the country and causing a pandemic event, one disease that many experts discuss as one of the greatest biological threats is dealt with on a yearly basis. Influenza (flu) is “the most obvious – and the most frequently ignored – infectious disease today is influenza” (Kellogg, 2015, p. 2). The flu is a respiratory illness that is caused by a virus with symptoms ranging from mild to severe, potentially resulting in death (CDC, 2015). These symptoms include fever and chills, cough, sore throat, runny or stuffy nose, body aches, headaches, fatigue, vomiting, and diarrhea (CDC, 2015). However, complications from the flu can arise, causing pneumonia, bronchitis, sinus and ear infections, and even congestive heart failure for those who are already afflicted with the condition (CDC, 2015).

Influenza is a highly transmissible virus, which mutates quickly and often (Kellogg, 2015, p. 9). The transmission of the flu can be spread from person to person up to six feet away (CDC, 2014). An infected person is contagious beginning one day before symptoms develop, and up to seven days after becoming sick (CDC, 2014). This past flu season, which occurs from

October to May, was rated as “moderately severe overall” (CDC, 2015). One of the biggest obstacles to this past flu season was that the flu vaccine that was administered did not contain the correct strains that were seen during the flu season. Every year, the flu vaccine is created with the strains that research believes to be the most likely to present during the season. However, a strain emerged this past flu season that had not been believed to emerge. For many, this rendered the vaccine ineffective. Not only does this create an argument for those who do not believe vaccines are effective, it also creates public doubt in the ability of the public health sector to respond to pandemic incidents. The WHO committee that was convened to review the response to the 2009 H1N1 pandemic found that the pandemic was poorly handled by the organization. The committee concluded that, “the world is ill-prepared to respond to a severe influenza pandemic or to any similarly global, sustained and threatening public-health emergency” (Kellogg, 2015, p. 5).

Another area of concern is the effect that climate change may have on the spread of biological agents. As discussed above, many of these agents are currently foreign to the United States and do not naturally appear in this country. However, it is possible that if climate change begins to effect the natural environment of the United States, perhaps causing the climate to become more adequate for many of these agents to thrive, the country could experience natural outbreaks of these diseases. Agents, such as Ebola, thrive in arid environments, which is why it is a serious problem in areas of Africa. If the climate of the United States become more arid, it may be more likely to see natural occurrences of Ebola in the country. Additionally, if it becomes common knowledge that the environment of the country has shifted to support new diseases and allow for greater transmission of them, this may cause the nation’s enemies to exploit this change. The use of biological agents may become more desirable to groups such as

al Qaeda and ISIS, especially if the climate change allows for a great number of causalities or allows the disease to prosper. Time will tell if climate change is a severe problem that will have to be addressed as it is currently believed, or if current patterns are just part of natural weather fluctuations. Either way, it is critical that the United States continues to prepare for biological terrorism and pandemic events.

With the sheer number of biological agents that can strike the population either through intentional release or natural occurrence, there is absolutely an existing threat. Unless actions are taken to stop the spread of a biological agent, every outbreak has the potential to reach pandemic levels. Because of this, preparedness efforts must clearly be a priority for hospital and healthcare systems in order to ensure that outbreaks are recognized quickly and treated to contain the transmission to healthy individuals. The best way that this goal can successfully be achieved is through policies, procedures, and best practices that keep both the patient and the hospital staff safe from the continued spread of the disease.

Policies, Procedures, and Regulations

It can be seen that there are more than a few current and potential biological events that should be of concern to the nation's public health systems, especially at the hospital level. These current outbreaks continue to have the potential to infect more citizens within the United States. At any time, a patient infected with one of the diseases discussed above could walk into an emergency room anywhere in the country. Because of this, it is crucial that hospital and healthcare systems know and follow the policies, procedures, and regulations that are set forth by regulating bodies that oversee preparedness for biological terrorism and pandemics.

One of the ways to ensure that the best practices are in place is to look at how policies and

procedures have changed, evolved, and matured over time. However, past policies and regulations are increasingly hard to find. Discussions with those who rely on these policies believe this is due to the fact that agencies do not want confusion as to what the current procedures are, or risk having staff members using an outdated procedure (W. Smith, personal communication, June 3, 2015). It is agreed on that bioterrorism and pandemic preparedness have taken a higher priority in national security and hospital emergency preparedness post 9/11. However, it is also agreed that while the policies are much better than they were, there is still much room for improvement. “A well-established preparedness program is a prerequisite for an effective response of health and medical systems, including hospitals, to disasters” (Djalali, et al., 2014, p. 1). The policies and procedures that have come out by regulating bodies have increasingly focused on emergency preparedness with an all-hazards approach encompassing bioterrorism and pandemic preparedness. This section will discuss those procedures put forth by the larger regulating agencies for hospital and healthcare systems in Western Pennsylvania.

In Western PA hospitals, several agencies hold top priority in ensuring the regulations, policies, and procedures are being followed and strictly adhered to. These agencies include the Occupational Safety and Health Administration (OSHA), the Pennsylvania Department of Health (DOH), the Joint Commission on Accreditation of Health Care Organizations (JCAHO), and the Centers for Medicaid and Medicare Services (CMS). These agencies have regulatory as well as punitive powers over hospitals in the Western Pennsylvania region. If the regulations set forth by these agencies are not followed, there is the potential that the hospital and healthcare systems could lose vital accreditation and monetary reimbursement that allow the hospital to continue to operate. Unfortunately, participation with these agencies is voluntary, for the most part. Hospital and healthcare systems only have to follow these regulations if they choose to get or

keep accreditation, ranking, or whatever it may be the agency awards to participating hospitals. Discussion of these agencies and their standards are not listed in any particular order.

The first agency discussed is the Occupational Safety and Health Administration (OSHA) that is housed under the U.S. Department of Labor. OSHA's mission is to "assure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education, and assistance" including "protecting health care workers" that may respond to emergencies that involve biological agents (OSHA, 1997, p. 1). While OSHA does not have a standard that specifically addressed biological terrorism and pandemic preparedness, it does have numerous standards that require preparedness for emergency response that are applicable to this specific topic.

OSHA document 3152 provides an overall look at what is required for hospitals to be prepared to respond to emergency situations. This document also outlines the current requirements that hospital must adhere to and have in place. These requirements include a hospital emergency response plan that should address drills, the used of the Hospital Incident Command System, communication, decontamination plans for patients, staff, and the facility, the ability to identify hazardous agents, alternative care sites, the use of personal protective equipment (PPE), air monitoring and prevention of cross-contamination, and recovery from the event (OSHA, 1997, p. 3). This document also discussed the requirements for training staff to respond to emergency situations that are defined as the greatest threats to that hospital, which could include biological events. These requirements include training of employees, including physical response, performing emergency drills, training in correctly completing correct documentation, and understanding individual roles during the response (OSHA, 1997, p. 4-5). Should these procedures not be in place, healthcare workers could file OSHA violations against

their employer. This discussion will briefly touch on the standards that are identified within this document that most impact hospital preparedness for biological events, as an in-depth discussion of every OSHA standard would be excessive.

The first standard that will be discussed is OSHA 29 CFR 1910.134 Respiratory Protection Standard. This standard sets the goal to protect healthcare workers from inhalation of harmful airborne agents, including pathogenic agents that can cause human disease (OSHA, 2009, p. 50). This standard requires that respirators be used “when engineering controls have been shown to be technologically or economically infeasible or while they are being instituted for the control of the hazard” (OSHA, 2009, p. 50). That means that every hospital that may require the use of respirators must have a comprehensive plan in place, including an administrator that oversees this program to ensure proper respirator selection, training, certification, fit testing, maintenance, and cleaning of the equipment (OSHA, 2009, p. 50).

OSHA 29 CFR 1910.132 Personal Protective Equipment Standard states that healthcare employers must provide PPE and ensure that workers are able to use it properly (OSHA, 2009, p. 50). This PPE can include protection for eyes, face, head, as well as gowns, gloves, boot, respirators, and full PPE suites (OSHA, 2009, p. 50). The PPE standard requires that hospitals assess what hazardous materials workers may come into contact with, and ensure that the facility houses the correct level of PPE for those identified hazards with proof through a written certification (OSHA, 2009, p. 50). Workers must also receive training properly don and doff the PPE, as well as how to maintain, clean, and dispose of the equipment (OSHA, 2009, p. 50).

The final standard that has the greatest impact on hospital response to biological events is OSHA 29 CFR 1910.1030 Bloodborne Pathogens Standard. This regulation is intended to protect workers from exposure to bloodborne pathogens through occupational contact with

bodily fluids contaminated with blood, human tissue or organ, or items visibly contaminated with blood (OSHA, 2009, p. 50). The standard requires that facilities have a control plan in place, work practice controls, PPE, vaccination, exposure communication plans, and documentation plans in place within the organization (OSHA, 2009, p. 50).

Housed under the Pennsylvania Department of Health (DOH), the Bureau of Public Health Preparedness “leads the commonwealth in preventing, responding to and reducing the public health and medical consequences of emergencies and disasters” (DOH, 1998, p. 151-2). DOH conducts an annual survey of hospitals to ensure compliance with regulations and standards set forth by the department, which include emergency preparedness standards. Deficiencies found during these surveys require immediate corrective action and response within a specific timeframe. Follow up surveys and audits can be conducted when deficiencies are found. In addition, complaints can be made to DOH that could result in a site visit. At this time, DOH surveyors can ask to review anything they wish, whether it directly involves the subject of the complaint or not.

Similar to OSHA, DOH does not have a regulation or standard that specifically addressed biological events. However, Chapter 151 addressed Fire, Safety, and Disaster Services, and can be applied to biological event preparedness. Similar to many regulatory standards, Chapter 151 requires that hospitals have an internal and external disaster plan that must be made available to all personnel and easily accessible throughout the hospital (DOH, 1998, p. 151-2). Education and training on the disaster plans must also be made available along with rehearsed disaster drills (DOH, 1998, 151-3,4). Unfortunately, specific specifications regarding what these drills must include are vague. Therefore, it is not required that full-scale drills be performed, leaving out the valuable opportunity for staff to physically practice response to disasters, specifically biological

incident response. Finally, this plan also calls for a communication plan to be in place that allows for the reporting of emergencies. This plan must also contain provisions for how to communicate an emergency when the disaster “significantly interrupts or alters hospital services and threatens the health and safety of patients” (DOH, 1998, p. 151-6). This regulation would specifically apply to a hospital during a biological event in the situation that the facility itself becomes contaminated and patients not infected with the biological agent must be diverted to other hospitals.

The next agency discussed is the Joint Commission on Accreditation of Health Care Organizations (JCAHO). JCAHO’s mission is “to continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality of life” (JCAHO, 2015, p. 1). Similar to DOH, JCAHO conducts hospital surveys looking for compliance with standards and regulations set forth by the agency. Deficiencies found must be immediately addressed within a specified timeframe. For less serious issues found, a written report of how and when the deficiency was addressed will be submitted to JCAHO. Serious issues found during a survey will result in a revisit by JCAHO surveyors to determine the issue has been resolved. Failure to comply with standards or correct deficiencies could result in loss of accreditation. It is important to understand that hospital accreditation is not required through JCAHO. Adhering to its regulations is voluntary and only needed if a hospital is looking to become accredited or keep its accreditation.

Two JCAHO standards specifically apply to biological terrorism and pandemic preparedness. Emergency Management Chapter standards require hospitals and healthcare systems to house an all-hazard Emergency Operations Plan (EOP) that allows the hospital to

respond to many different types of events that can occur (JCAHO, 2015, p. 1-2). The EOP must include plans to respond and recovery from all disasters identified in a Hazard Vulnerability Analysis (HVA) that must be kept as part of the EOP (JCAHO, 2015, p. 3-4). The HVA ranks identified disasters that the hospital could face from the least likely to the most likely, the demand the disaster could put on the hospital resources, and the consequences that the hospital could face if the disaster occurred. JCAHO expects that each hospital conduct their own assessments and determine how each disaster identified will impact their organization (W. Smith, personal communication, June 3, 2015). The Emergency Management Chapter also requires plans for communication, dispersion of resources and assets, security and safety, utilities and facilities, and patient care during disaster response and recovery (JCAHO, 2015, p. 2-27).

Finally, as part of this chapter, hospitals must conduct and document two activations of the EOP each year, potentially through conducting drills, one of which must include a mass influx of patients greater than the hospital normally treats (JCAHO, 2015, p. 24). One of the drills must also be part of a community-wide exercise (JCAHO, 2015, p. 25). A drawback of this provision is that the standards for these drills are vague. There is no specification about what scenario must be drilled, as well as no specification on the scale of the exercise. Therefore, rather than conducting full-scale exercises, hospitals can meet the regulation requirement by only conducting tabletop exercises. This provision also does not require that hospitals practice their highest-ranking threats. Therefore, a hospital could conduct the same drill scenario several times and still meet the requirement, never actually practicing response to the incidents that are most likely to happen, and which will greatly affect the hospital.

JCAHO also houses a chapter on Infection Prevention and Control (W. Smith, personal communication, June 3, 2015). This regulation, IC.01.06.01, prepares hospitals to respond to a

surge of patients infected with a biological agent (W. Smith, personal communication, June 3, 2015). This regulation requires that hospitals have a plan in place for response to a biological event, how the plan will be activated, as well as to identify resources that can be utilized to determine the cause of infections during a patient surge (W. Smith, personal communication, June 3, 2015). IC.01.06.01 requires that each hospital have a communication plan in place to let hospital staff know about any diseases that could cause an influx of infected patients (W. Smith, personal communication, June 3, 2015). Finally, this regulation requires a written plan of how the hospital will sustain patient care that may require long-term care (W. Smith, personal communication, June 3, 2015).

A drawback to this plan is that the requirement only exists at the hospital level. While each hospital will be able to communicate within its walls, and may potentially be able to communicate with hospitals within the immediate area, there is no provision to be able to communicate with hospitals nation wide. This presents the issue that, should there be an outbreak or a biological attack, it will be critical that all hospitals are aware of situation and know what symptoms to be on the lookout for. During this event, until information is gathered and more is learned about the biological release, it may be unknown how far spread an outbreak or a biological agent has been released. When this happens, communication will be the best ally for early detection and gathering critical information about the incident.

The final agency to be discussed, and one that just recently stepped into emergency management regulations is the Center for Medicare and Medicaid Services (CMS). Until recently, CMS had no conditions of participation for emergency management in order to receive Medicare and Medicaid reimbursement (F. Peterson, personal communication, May 28, 2015). However, CMS has just released proposed standards for emergency management. CMS

conducted research on current preparedness standards and found that what is in place is not comprehensive enough, with guidelines falling short of what is needed to ensure hospital and healthcare systems are at the proper level of preparedness (F. Peterson, personal communication, May 28, 2015). CMS found several areas that were lacking, and put forth their own condition of participation to address the gaps found. These standards are currently out for comment and review by the hospital emergency management community (F. Peterson, personal communication, May 28, 2015). Should these standards pass, this would create an entirely new culture of emergency management within the hospital setting. Instead of voluntary compliance with agencies like JCAHO, CMS standards would require involuntary compliance in order for a hospital to receive reimbursement through Medicare and Medicaid. In other words, every provider that receives Medicare and Medicaid dollars will have to comply with these emergency management standards (F. Peterson, personal communication, May 28, 2015).

These standards are very similar to the standards put forth from other agencies. The proposed standards will have five core requirements including an established and written all – hazards emergency preparedness program and plan that is based on a risk assessment, preparedness policies and procedures, a written communication plan, at least annual training and testing of the emergency preparedness program and plan, and establishment of emergency power systems (CMS, 2014, p. 79085-79094). These requirements would be maintained by the hospital, with annual review and update (CMS, 2014, p. 79085).

Should these conditions of participation be passed, it could have an immensely positive impact on hospital preparedness. One hope by those currently in the hospital emergency management field is that emergency management and preparedness would take a priority in the functioning of a hospital. Right now, at least within the Western Pennsylvania area, emergency

management tends to be an additional responsibility taken on by an administrator that is already tasked with another position. It tends to be someone that works in emergency medicine, environmental health and safety, or security. While this may be cost-efficient, it certainly does not allow emergency management to get the full focus required to properly prepare a hospital for disaster and emergency incidents. In fact, conducting emergency management operations in this manner tend to force emergency management to take a backseat to more pressing matters. Therefore, it does not take precedent as it should until an emergency happens, or until it is time for various agencies to conduct their annual inspections.

The Anti-Vaccine Movement

Another threat that will continue to have a great impact on this country's vulnerability to biological agents, and one that must be mentioned in this discussion, is the current anti-vaccine movement that is sweeping through the United States. For decades, there has been a belief that vaccines, specifically the measles vaccine, have a causal link to the development of autism in children who receive the vaccine (Troy, 2010). However, studies continue to prove that there is no evidence that there is any link between vaccinations and the development of autism (Troy, 2010). Science has proven and continues to support the fact that, while there are side effects to any vaccine, the complications that may occur are rare and that the effects of vaccines far outweigh the risk of the complications. Unfortunately, this no longer seems to be the accepted belief for an increasingly growing number of Americans.

The issue has now become that Hollywood celebrities have become increasingly outspoken about alleged harm of vaccinations, backing the anti-vaccine movement. These celebrities have turned on the Center for Disease Control's education campaign for childhood vaccinations. The

general public listens to celebrities who claim their own children have developed autism after receiving vaccinations, and take their claims as truth. These celebrities refute scientific evidence in favor of pushing the anti-vaccination agenda. Some celebrities have even gone so far as to claim that vaccinations were the government's attempts at "population control" to kill citizens and make it seem as if the death was caused by a disease (Troy, 2010).

It can be seen the anti-vaccination movement is taking hold in the general public by looking at the current outbreaks that have taken place in recent years. Diseases that had been deemed eradicated by the CDC have now resurfaced. One such outbreak was the January 2015 measles outbreak that took place in Disneyland and Disney California (Doheny, 2015). In 2000, the CDC declared that measles had been eliminated in the United States. According to the California Department of Public Health, by the end of January, at least ninety-five people had been diagnosed with the measles, almost the same number of people diagnosed for all of 2014 (Doheny, 2015). Of the 34 patients diagnosed from California, 28 were not vaccinated for measles (Doheny, 2015).

Experts agree that this anti-vaccination movement could potentially have a devastating impact on our national security. "Our number one defense against many biological threats, including pandemic influenza, smallpox, and anthrax is vaccinations" (Troy, 2010). If this nation's enemies, such as ISIS and Al-Qaeda, begin to understand that the population is becoming increasingly vulnerable to diseases that vaccinations had once eradicated, biological terrorism may become a more appealing option for a future attack. This movement can also lead to even more naturally occurring diseases to take hold within the population and begin to spread. This has already been seen with the measles outbreak. It may only be a matter of time before SARS, MERS, and influenza become deadly outbreaks, or even pandemics.

Theoretical Framework

As can be seen from the contents of past studies and research, there is a great deal of questions left to be answered regarding the current state of preparedness and vulnerability in hospitals in regards to biological weapons and pandemic incidents. It is all too clear that there is disagreement among experts as to the level of threat that bioterrorism and pandemic incidents pose. However, the consensus is that regardless of the probability of an outbreak occurring, either intentionally or naturally, the potential casualties, loss of life, and disruption to the normal way is far too high to fail to prepare for this type of incident.

While there is an overwhelming amount of available research on the subject of bioterrorism and pandemics, there is very little available research specifically addressing the state of hospital preparedness for these types of events. This is quite concerning considering that, unlike a bombing or mass shooting in which first responders will be the first to encounter victims, in the case of bioterrorism or naturally occurring pandemics, the hospitals will be the first to encounter victims. Even more so, the hospitals will act as “first receivers” possibly not even aware that they are treating victims infected with a biological agent or toxin (CDP, 2014). Because of this, it could be assumed that understanding the level of hospital preparedness and response to handle biological agents would be a high priority. While there seems to be an endless amount of policy and procedures created by agencies and departments responsible for oversight of hospital emergency preparedness, there is very little available research that shows if these policies and procedures have had any effect on raising the level of preparedness and decreasing the vulnerabilities of hospitals and healthcare systems. As this topic continues to evolve, and more evidence and data is gathered as to the probability of the next bioterrorism or

pandemic event, these policies and procedures are only going to multiply and become more complex. However, without solid evidence that these policies and procedures are having any impact on the preparedness levels, best practices cannot be created from them. If best practices have come from these policies, there is no guarantee that those practices are, in fact, useful.

In addition, with ever advancing and ever evolving technological and microbiological advancements, it is not unreasonable to think that a biological agent that may, at one time, been confined to only a small region of the globe be created to have the ability to survive, thrive, and spread worldwide. In the hands of a terrorist organization, this could have catastrophic consequences. As more and more is learned about these biological agents, including scientific advances in creating biological weapons, it will become even more crucial to prepare hospital and healthcare systems to respond to pandemics that may reach global proportions. Research on this topic will continue to be crucial in understanding if hospital and healthcare systems are truly ready to confront a worldwide pandemic head on. The only way this will be learned is through research and studies that take an objective look at our current state of preparedness and vulnerabilities to determine where the strengths and weaknesses lie. Even more importantly, this research must provide recommendations for addressing those weaknesses.

A review of prior literature and research on this topic will not only provide the foundation for, but also serve as a backdrop with which to compare and contrast new research findings. The threat of biological terrorism and pandemic outbreak is not about to go away any time soon. It has been a threat to humanity for centuries, and will continue to be. The time to understand the level of preparedness and the current vulnerabilities that exist will not be in the midst of a biological agent pandemic. This issue must be addressed now. This thesis will review

the issues faced by hospitals, come to a conclusion about the state of preparedness, address any vulnerabilities that are found, as well as discuss recommendations to fix any of the vulnerabilities that may be found.

Methodology

In his definitive work, *Research Design: Qualitative, Quantitative, and Mixed Method Approaches*, John Creswell (2009) discusses all methods to be used when approaching a research topic. This work was used in discovering the methodology that will be used throughout this thesis. Of the three research methodologies discussed by Creswell (2009) it was decided that this topic would best be explored utilizing a qualitative research approach (p. 4). Qualitative research is “an approach for exploring and understanding the meaning individuals or groups ascribe to a social or human problem” (Creswell, 2009, p. 4). This approach to research involves exploring emerging questions that uses data inductively; that is, building the analysis of the topic from particular data to general idea, and interpreting the meaning of those results (Creswell, 2009, p. 4). This approach allows for a flexible structure that focuses on individual meaning of the topic to fully understand the full intricacy of the topic (Creswell, 2009, p. 4). Exploration of this topic will use primarily literature from past research as well as case studies in order to collect data and reach conclusions about the topic, falling in line with the qualitative approach.

This thesis falls into the pragmatic worldview (Creswell, 2009, p. 10). While this worldview lends itself best to a mixed method approach, because it is flexible, it also works well under a qualitative approach. This worldview “arises out of actions, situations, and consequences” with “a concern [for] applications – what works – and solutions to problems” (Creswell, 2009, p. 10). There is a focus on the research question identified, and the truth used to discover the answer to this questions if what works at the time (Creswell, 2009, p. 10). The research is based on consequences, which “always occurs in social, historical, political, and other contexts” (Creswell, 2009, p. 10). The pragmatic worldview is concerned with finding solutions to the research question, which with this research topic, is exactly what the intended outcome of

the thesis. It is the goal of this paper to discover what the truth of the current situation is at this time, what if any obstacles and challenges currently exist, and discover a solution to overcome those obstacles and challenges if there are any found.

The qualitative approach will test the validity of the following hypothesis:

H1: current preparedness efforts and regulations in place for hospitals and healthcare systems are sufficient to prepare for a biological outbreak or intentional biological weapons incident.

The following research questions will be answered:

1. What past preparedness policies and procedures were in place for hospital and healthcare systems?
2. What can be learned from past case studies involving hospital response to biological weapons and pandemic incidents?
3. What are the current preparedness policies and procedures in place for hospital and healthcare systems?
4. Are the current preparedness policies and procedures believed to be adequate to respond to biological weapon and pandemic incidents?

The independent variable in this study will be the policies and regulations that are in place that hospitals follow to prepare for biological incidents, as well as the biological weapons that exist that may be used in a biological weapons incident. The dependent variable will be the

level of preparedness and vulnerability that exists in the United States' hospital and healthcare systems to defend against and respond to a biological outbreak.

There are limitations and bias to this study. The study will rely on regulations, policies, and documentation that are available to the public and those in the field of emergency management and hospital preparedness. However, there could be documents that are privileged information and may be unobtainable. It is also possible that documentation is not available to the general public, and therefore, unknown to exist unless the researcher already has knowledge of the existence of the document. In order to correct this potential limitation, the research has reached out to several members of the hospital emergency preparedness community within the Western Pennsylvania region, with varying degrees of involvement with hospital preparedness, from the hospital level, the health system level, and the regional level. With this, it is believed that limitations in the researcher's knowledge of existing documents will be overcome.

Bias is also possible in this study as well, considering this researcher's current position and years working in a healthcare and hospital preparedness setting. The researcher is part of the hospital police and security services field, with increasing involvement in hospital preparedness and emergency management. The researcher holds several certifications from the Federal Emergency Management Agency (FEMA), as well as completed courses through FEMA's Center for Domestic Preparedness which focused completely or in part on decontamination and hospital leadership response during a pandemic incident. The researcher has involvement with pandemic preparedness for the hospital in a limited capacity, as well. Because of the past involvement with the topic of bioterrorism and pandemic events, the researcher's continued interest in the subject matter leads to the topic being identified as the focus of this thesis.

In an attempt to combat any bias, research from many different perspectives and mediums will be used to attempt to gain differing views on the subject. This study will rely on review of scholarly, peer-reviewed articles and academic journals, case studies of past incidents of bioterrorism attacks and pandemic outbreaks, and government resources that have become available for public use. This paper will also review current policies and regulations put forth by various regulatory agencies that oversee hospital and healthcare preparedness for pandemic and biological weapons outbreaks in the Western Pennsylvania region. Finally, this study will also utilize documentation deemed critical to the study of this topic by members of the hospital emergency preparedness community at varying levels in the field.

Findings

It is clear that biological agents, whether released through intentional or natural means, continue to be a threat to this nation, its citizens, and the hospital and healthcare systems that exist to treat victims of these agents. Through the research conducted it is also clear that the hypothesis set forth stating that current policies, procedures, and regulations that are in place to prepare hospital and healthcare systems are not sufficient. There remain large gaps in the preparedness plans that make hospitals extremely vulnerable during a biological event.

“Significant advances have been made in preparing for public health emergencies since the September 11, 2001, and the anthrax attacks, but gaps remain and have been exacerbated as resources have been cut over time” (Kellogg, 2015, p. 5).

While experts continue to stress the importance of biological preparedness within hospital and healthcare systems, and discuss recommendations for how to bridge the gaps in preparedness, little to nothing is being done to ensure these recommendations are being put in place. Current regulations and procedures previously discussed that are followed by many of the hospital and healthcare systems in Western Pennsylvania are redundant and vague, giving little guidance to how to actually complete the conditions set forth by specific agency. Additionally, many of these regulations are voluntary and not required to be met unless there is participation in that agency’s program. In addition to this problem, there are other specific issues found within the research that disprove the hypothesis set forth.

Results

Several glaring issues have been discovered through the research conducted. These issues that were discovered create large gaps in preparedness measures, as well as inhibit the healthcare

workers' ability to best respond to biological events. The disconcerting fact is that prior to 9/11, there was a large push for bioterrorism preparedness. That was more than a decade ago. It can be seen with induction of the CMS conditions for participation, biological preparedness measures are still in their infancy. This is due to several factors.

The first factor that is causing issues in creating proper biological preparedness procedures is the lack of agreement among experts as to level of threat biological terrorism pose to this nation's safety. Many experts that have a large role in creating these preparedness plans see that past bioterrorism events have led to rather small casualty numbers. They, therefore, view these attempts as fairly unsuccessful, and that the current fears of more bioterrorism events are overblown. However, what has not been taken into account is the mass panic and social disruption that these events can cause. As discussed earlier, it may not take mass casualties to have the intended results that a terrorist group or enemy of that state may be aiming for. Complete social and economic disruption could occur if citizens fear stepping outside their front doors and contracting a disease.

Many experts agree, however, that there is not enough being done to prepare for biological events, especially in regards to pandemic preparedness (Kellogg, 2015; Power & Ban, 2002; Marohn, 2015). In fact, the actual lack of these events is precisely what causes it to be such a threat. It is important to understand while the threat of a bioterrorism attack may be low, "there is still ample cause for concern" as "we do not know how 'massive' an attack would have to be to overwhelm the response system, instill fear and panic, and cause serious political or economic fallout" (Powers & Ban, 2002, p. 3). The response to Ebola proved this fact; that is, the United States is woefully unprepared for a pandemic or bioterrorism response. While it was fortunate that there was not a mass outbreak of Ebola within the United States, there was also no ability to

determine if the hospitals would have been able to successfully respond to an outbreak. Although, it is believed that hospitals and healthcare systems would not have been at all successful in this response (Kellogg, 2015; Marohn, 2015). Much of the response to Ebola was just-in-time-training. Agencies such as DOH and the CDC were putting out response measures and procedures, only to change them hours or days later. There was a clear lack of defined procedures or consensus on how to respond. This tends to be a trend in national preparedness. “A lack of clearly defined, long-term national consensus on what a prepared America is...cripples the nation’s biological...preparedness efforts” (Opsahl, 2007, p. 22).

Even more concerning is that very little has been done since the Ebola outbreak, even though there is much to be learned from this response. The Ebola outbreak created an enormous opportunity to learn from an event that hospital across the national prepared for, but did not adversely affect the public’s health. It is a hope by many in the Western Pennsylvania hospital preparedness field that documentation will come out with results, findings, and revised practices for biological response stemming from the Ebola precaution response. However, many are not optimistic and would not be surprised if this documentation is never created (F. Peterson, personal communication, May 28, 2015). This alone shows that all the cases of bioterrorism, outbreaks, and pandemics have taught those responsible for the public’s health very little about the critical state of preparedness in this country.

Another issue found is that the documents that do exist and discuss preparedness procedures and best practices are difficult to find. Many of these documents are only available to find if you know where to look and what to look for. More specifically, almost none of the regulations and procedures that are used for preparedness in Western Pennsylvania hospitals specifically address biological preparedness procedures regardless of the fact that many experts

believe this topic should be a top priority. Additionally, none of the documents tell the reader “how” to prepare and respond, only what is expected to be in place. It is up to the individual hospital or healthcare system to determine what the standard is for the individual facility, potentially creating confusion and incorrectly implemented procedures.

However, there may be reasons why these regulations are intentionally vague. These procedures are in place to cover a large number of hospital and healthcare systems that may have extremely different populations served. Western Pennsylvania Region 13 hospitals serve diverse populations of people. Hospital based in Pittsburgh serve an urban population; where as hospitals in outlying areas serve extremely rural communities. The physical location and the population served could create very different medical issues being treated and far different emergency management conditions. Therefore, these regulations have to be intentionally vague in order to be flexible, adaptable, and applicable to many different scenarios and situations. These documents may also not be explaining a step-by-step procedure in order to ensure that those who may use these regulations as a means to attack a hospital or area. By spelling out in exact detail what is expected of a hospital in response to a biological event, that would basically give terrorists and those who wish to do the United States harm an instruction manual to learn what to expect and how to defeat the obstacles and preparedness measures put in place. In order to allow for those measures to remain obstacles to terrorist groups, as well as make it more difficult for those groups to obtain a successful outcome, vagueness is needed in that documentation.

Another of the obstacles that were found in the research that result in creating an insufficient preparedness environment is a lack of funding for preparedness efforts. Regardless of the urge by experts to ensure that biological event planning takes a priority in preparedness

measurements, there continues to be less and less funding put forth every year (Opsahl, 2007, p. 20). Some public health official states the main reason for this lack of funding is that what is allowed by Congress shifts with “whatever preparedness priorities are politically chic at the time” (Opsahl, 2007, p. 22). This lack of funding at the national level greatly impacts the ability of the United States to have a long-term preparedness plan. The U.S. Department of Health and Human Services (HHS) oversees much of the preparedness planning for biological events (Opsahl, 2007, p. 22). However, decisions to fund the current bio-defense programs are made on a year-to-year basis. Because of that, HHS cannot make a long-term plan. “There is not even a five year plan” (Opsahl, 2007, p. 23). The lack of a common goal allows terrorist groups or enemies of this country a large vulnerability to exploit, with the end result being a catastrophic biological disaster.

At the state and hospital level, resources, including monetary resources, are continually shrinking year by year. Every year, hospitals are being asked to do more with less – less money, less staffing, and less resources. Because of this, hospitals and healthcare systems must allocate money to critical services. It is becoming increasingly difficult to allocate money towards emergency management when there are critical functions in the hospital that are already underfunded. Asking hospital administrator to for money, time, and staff to be put toward training, drills, and preparedness for events that may never happen is becoming harder and harder. A bright spot in this, as discussed above is that regulating agencies, like CMS, are taking notice of the criticality of preparedness efforts. In understanding the importance agencies like CMS play in hospital functioning, namely in receiving monetary reimbursement for services, it has the unique position of putting forth preparedness regulations that must be complied with. Time will tell if these regulations will pass and be put into regular practice.

Many of the recommendations that are found within the research are repeatedly the same measures being discussed and that are deemed critical to proper preparedness. Interestingly enough, this research documentation, which spanned nearly two decades, continually discussed the same needs. It can only be concluded that while the same recommendations are constantly being discussed, these measures still have not been put into place. These recommendations include a need for early detection of biological outbreaks, a system of surveillance for symptoms, a communication plan that allows for hospitals to discuss the symptoms they are seeing, as well as have access to resources who may recognize symptoms as those of a biological agent rather than a common illness. It is also urged that healthcare workers need increased training in public health preparedness in order to recognize when symptoms may point to a potential outbreak, as well as how best to respond to the outbreak. However, none of this will happen if the right environment is not created to allow these practices to take hold.

The State of Preparedness in Western Pennsylvania

Western Pennsylvania was chosen as the specific focus of this paper for several reasons. The first is that the researcher currently lives and works in the region, specifically in the healthcare field in Pittsburgh, and is involved in the preparedness efforts of the healthcare system. Additionally, the Region 13 Counter-Terrorism Task Force is highly involved with the healthcare systems in the Western Pennsylvania region. It is believed that this involvement allows for a greater level of preparedness within the region that transfers to the hospitals and healthcare systems. Finally, the Western Pennsylvania region is well known for the available healthcare and medical research that is used by not only the entire state of Pennsylvania but also the states surrounding it, specifically the University of Pittsburgh Medical Center (UPMC) and

the Allegheny Health System (AHS). Because of this world-class healthcare that is available in the region potentially means that these healthcare systems will take in the victims of an outbreak, even if the outbreak did not occur in the area, or even in the state.

Western Pennsylvania is in a unique state according to hospital preparedness officials. Because the geographical area does not see the amount of natural disasters that, many consider the region to be a low risk area based off of insurance industry threat data (F. Peterson, personal communication, May 28, 2015). That, ironically, puts the region at a high risk for biological events (F. Peterson, personal communication, May 28, 2015). This is not because Western Pennsylvania is a more valuable target for terrorist groups to release a biological agent than any other area with a large metropolitan area, but because Western Pennsylvania is the area that many affected cities may send overflow or evacuate its infected patients to in the event of a biological incident. Western Pennsylvania holds a high level of world class medical resources, including the major healthcare systems with a large bed and surge capacity, large medical research facilities, and high end transportation infrastructure that has a low risk of being impact by natural disasters (F. Peterson, personal communication, May 28, 2015).

It is also important to mention that due to federal regulations such as the Emergency Medical Treatment and Active Labor Act (EMTALA), if an infected patient presented at a Western Pennsylvania hospital, the patient must be given an examination or stabilized, and cannot be turned away until those standards are met. This means that if a hospital were to turn away an infected patient, the hospital could be fined, the physician could be fined, the hospital could be sued, and/or the hospital or physician could lose their Medicare reimbursement status. Because of this law, whether an emergency room within a hospital is trauma rated or deemed able to treat a victim of a biological event, every hospital within Western Pennsylvania must be

ready and able to treat infected patients. That will only be successful if all hospitals have proper biological preparedness plans.

While the region has world-class health systems and a high level of medical resources on hand, Western Pennsylvania hospitals are victim to the same preparedness issues discussed above that all hospitals are facing. Being at risk is the normalcy for hospital emergency management (F. Peterson, personal communication, May 28, 2015). Hospital emergency management in Western Pennsylvania, just as it is across the nation, is very reactive rather than proactive. Overcoming that reactive mindset may be even more difficult in Western Pennsylvania, as well as other regions that are deemed low risk areas. Because the hospital and healthcare systems do not feel that they are at risk, they tend not to do anything more than what is required of them (W. Smith, personal communication, June 3, 2015).

Data shows that these beliefs by those that work in the field are correct. A 2012 survey by the Trust for America's Health organization measured state preparedness levels. The states were measured based on ten indicators to determine preparedness levels with zero being the lowest possible score, and 10 being the highest (Robert Wood Johnson Foundation, 2012, p. 9). Pennsylvania scored 5 out of 10 (Robert Wood Foundation, 2012, p. 9). Twenty-one states score 5 or below (Robert Wood Foundation, 2012, p. 9). Of the key factors that indicated a level of preparedness for the state, Pennsylvania failed to do half of those. One of these indicators was maintaining or increasing the level of funding for public health services (Robert Wood Foundation, 2012, p. 10). Pennsylvania's funding for public health services dropped 6.7% during the 2011-2012 fiscal year.

While this is concerning, the same survey was taken again in 2014 for the 2013-2014 fiscal year. Pennsylvania rose to seven out 10 (Robert Wood Johnson Foundation, 2014, p. 11-12).

Funding for public health services increased by .7%, as well as increasing the flu vaccination rates (Robert Wood Johnson Foundation, 2014, p. 11-12). Pennsylvania vaccinated 46.3% of the state population from the flu during the 2013-2014 fiscal year. This shows that slowly but surely, preparedness efforts are taking hold, and the criticality of the biological incident threat is being taken seriously.

With this information, it can be seen that the hypothesis that was originally presented was disproven. The current preparedness efforts and regulations that are in place for hospitals and healthcare systems are not sufficient to prepare for a biological outbreak or intentional biological weapons incident. At this time, there are still many obstacles and challenges that have not been addressed within these regulations that will fully prepare hospitals and healthcare systems to be prepared to respond to this incident. While there has been a considerably noticeable increase in the regulations and procedures that are now or soon to be in place, showing a clear indication that the threat of biological agents is being taken seriously, the Western Pennsylvania region, as well as the nation, is not nearly prepared enough to respond to this threat.

While many of the research questions were answered, unfortunately being able to find the past procedures and policies for bioterrorism and pandemic events in hospital and healthcare systems could not be completed. The desire was to be able to compare the past procedures with the current procedures in order to ascertain how these procedures have matured and advance pre-9/11 and post-9/11. Unfortunately, in attempting to find these procedures with the help of preparedness officials in the Western Pennsylvania region, it was discussed that agencies tend not to make old and outdated policies available. It is believed that this is so there is no risk of hospital staff using outdated policies to prepare for or respond to a biological agent event.

In looking at the past case studies of hospital response to biological events, it can be seen

that healthcare systems at a whole were greatly unprepared to respond to the events discussed. Much of the response happened with the help of just-in-time training. Luckily enough, these events did not culminate in mass casualties or widespread pandemic. However, because of this there is no way to know if the current training or response would have been adequate. Many experts would agree that had these past events, such as the Ebola outbreak or the Amerithrax attack, created mass casualties, the nation would have been woefully unprepared to handle the surge in victims, as well as the worried well. The just-in-time-training would have been greatly inadequate to properly respond to the initial event, as well as continue to sustain the long-term patient care that would have been needed.

It can be seen that there are numerous policies and procedures in existence for hospital emergency preparedness. Many experts and those who work in the field of hospital preparedness in the Western Pennsylvanian region agree that while the current policies and procedures that are in place are far more advanced than those of the past, there is still much room for improvement. Currently, many of the policies and procedures that are put forth by regulating agencies are voluntary, and required only if the hospital is looking to gain or sustain accreditation from that particular agency. Those current policies that are required to be followed by the hospital, such as those set forth by the Department of Health, are vague. The regulations are not specific to biological preparedness, but are housed under an all-hazards approach. While this is a good start to preparedness, biological terrorism and pandemic events are a unique incident and a serious threat. It requires specific and separate plans that singularly address biological incidents.

It is also a positive sign that agencies, such as CMS, that have a unique role in the functioning of hospitals are becoming increasingly more concerned about emergency management. It is agencies like CMS that can change the perspective of emergency

management and preparedness in the hospital setting. If a hospital wants to continue to be reimbursed for services provided through Medicaid and Medicare, those hospitals will have to adhere to these guidelines, rather than choosing to voluntarily comply. Agencies like CMS has the opportunity to bring about adequate biological preparedness policies and procedures that all hospitals have to follow to continue to function.

However, in order to create these policies and procedures, funding will have to be put toward biological preparedness actions and preparations. In the current state of the economy, it will be difficult convincing administrators who are already operating under tight budgets to disperse funds towards preparing for an event that may never happen, and actually, as many experts agree, has a low probability of happening. Therefore, it may take much convincing to have these funds put forth. However, with fact and research to back these requests, as well as with a clear action plan as to what needs to be done to ensure that the hospital and healthcare systems are adequately prepared, it should make this task easier.

Conclusions

Biological terrorism and pandemic events have been a threat worldwide for centuries. Over and over again, historical accounts of civilization discuss outbreaks of known and unknown diseases that devastate the population. These events will continue to occur without humans having much control over them. However, what public health officials do have control over is how these events are handled. It is clear that at this current time, the threat of these events is quite high, and the measures to combat and respond to them are not sufficient.

Public health and hospital preparedness officials are at a turning point in the battle against biological agents. Improvements in biological preparedness efforts are being made, however slowly. There seems to be a shift in the current consciousness surrounding biological preparedness, coming on the heels of the recent Ebola outbreak, the current avian influenza outbreak, and the recent severe flu season that just ended. Eyes are on biological preparedness, and with the current momentum, hospital preparedness leaders have the ability to seize the opportunity to close the gaps and reduce the vulnerabilities that currently exist in biological preparedness regulations, policies, and procedures. With the help of oversight agencies like CMS that have recognized the importance of emergency management and preparedness efforts, there is a unique opportunity to put biological incident readiness at the forefront of hospital preparedness.

While the probability of biological terrorism and mass pandemic outbreaks may be low, the risk and consequences of not preparing for the next pandemic or bioterrorism event could cause catastrophic results. While hospitals and healthcare systems may never be able to put procedures in place that prevent any biological event from ever occurring, it can lessen the effects of the event and save as many lives as possible. This problem is not beyond fixing, and

many experts have discussed very specific steps that can be taken to reduce the risk. The public health infrastructure that currently exists at the local, state, and federal levels can be used to create a solid biological preparedness program. However, the current research alone, offers a limited view of the problem as well as limited solutions to combat the issue. Research must continue to be conducted to fully understand the depth of the problem and learn what measures must be taken to diminish the impact of the next biological terrorist or pandemic incident.

This will be especially important in Western Pennsylvania and other regions the have similarities to the region. As discussed previously, Western Pennsylvania has the chance of being uniquely effected by a biological terrorism event or pandemic incident. This could be true regardless of if the next biological event occurs within the state, or across the country. Because of this, the recommendations that have come about because of the research conducted will be even more critical to implement in hospitals within the Western Pennsylvania region.

Recommendations

One of the first recommendation that must be adhered to is that there United States intelligence community must continue to monitor threats to the nation by terrorist groups and enemies of the country. Intelligence and national security resources must be continually focused towards detection and prevention of bioterrorism threats. There is much evidence to suggest that terrorist organizations like al Qaeda, ISIS, and other groups have the scientific knowledge and ability to carry out bioterrorism attacks. Even more so, evidence has shown that these groups have explored the use of biological agents and made preparations to be able to carry out such an attack.

Because of this evidence, the United States intelligence community must continue to not only monitor these threats, but also take them seriously. It is not enough to simply be aware of the threats, but actions must be taken to ensure that these groups do not have the capabilities to carry out the threats. This means that access to biological material and the means to create a biological weapon must be under tight security. There can be no lapse in security, such as the event that just recently occurred in which live anthrax was mistakenly shipped to nine states and two foreign countries. Agencies must immediately report any security breaches that may have allowed agents to leave facilities. Any of these threats that are discovered must be immediately communicated so that hospitals and healthcare systems can be on alert and ready to spot symptoms of the suspected biological agent. In addition, regulating agencies like CMS, JCAHO, and DOH must continue to put forth regulations that ready hospitals to respond to such attacks or threats that are discovered that have the ability to cause an outbreak or release of a biological agent.

The threat of bioterrorism incidents are even more probable due to the ever evolving and advancing technological and microbiological abilities. It is not unreasonable that a biological agent could potentially be created that no longer requires a specific climate to flourish, but can instead survive in any environment or under any conditions, even living outside of the body for long periods of time. These strains could also be created that are resistant to current vaccines and treatments, allowing a greater number of deaths or longer incubation and transmission times. With advances in science and technology, a biological agent that may be seen in the future are endless and potential is terrifying. Because of this, scientific research on pandemics, emerging agents, and the medicine to treat agents that are deemed to have the greatest threat of outbreak

must continue, an even increase. This research must also become profitable to make it desirable to continue and even to increase the amount of research conducted.

Due to lack of support, pharmaceutical companies are not creating vaccines and medicines that could aid in combating biological outbreaks, but are instead focusing on the drugs and medicines that are far more profitable, such as Viagra. Pharmaceutical companies must again be made to realize that profits of creating vaccines and medications that will save the population during a biological event. Again, this may be difficult, as it will take convincing pharmaceutical companies to put forth money and time to create medications that will sit until there is a need for them - a need that may never actually occur. This is why it is a necessity that the creation of vaccination and treatments must be made profitable. It will be absolutely unacceptable to have an outbreak or biological attack occur with an agent that has a known antidote, vaccination, or medication that can combat the attack, but not have enough of the treatment to save lives. The consequences of an event like that occurring would reach far beyond the lives that would be lost.

Additionally, funding must be increased to allow for the development of long-term, strategic planning not only for national biological preparedness, but also reaching down to the local and hospital levels to ensure that regulations are being met and the proper attention is being paid to hospital biological preparedness. The federal government must create achievable standards that make every state accountable for protecting the public against biological events, with the funding used to ensure that resources are available for every state to achieve these goals. Many suggest that these actions should fall under the direction of the Department of Homeland Security, with the need for the agency to shift its focus to disaster preparedness and planning. This work should be completed in conjunction with HHS to oversee the creation of these federal

standards for hospital and healthcare systems. However, it is suggested that one senior official within one of the departments should be designated the lead this and to ensure that these standards are completed and that the agencies are held accountable for these standards.

These standards need to follow the five conceptual categories of emergency preparedness that are currently in place (prevention, mitigation, preparedness, response, and recover), with explicitly clear actions to take, clear lines of communication, and established protocols that state and local governments can adopt to fit their current needs. These standards must be adaptable, flexible, and scalable to meet the needs of every hospital and healthcare system, regardless of its size, the population it serves, or other factors that would come into play.

Part of these standards must also include specific and robust directions as to training and drilling hospital staff for response to a biological event, whether it is a natural occurrence or an intentional release. Right now, regulations for conducting exercises and drills are vague. There is no provision that the greatest threat to the hospital must be addressed, or what kind of drill must be conducted. Therefore, hospital and healthcare systems are losing a valuable opportunity to practice the physical response for the highest threats the hospital faces. Regulations and standards must specifically state that the highest threats as determined by a hospital's HVA must be drilled on a regular basis. These regulations must also specify that at least one drill a year must be a full-scale drill in which a physical response will be practiced. While discussing the response for an incident may be valuable, there is no comparison to physically practicing the response procedures for an incident. The physical response, the actual stress that accompanies going through the motions of response, cannot be replicated in any other way than conducting a full-scale drill. It cannot be stressed enough the value practicing the procedures and response to a disaster incident.

In addition to funding being used to create a long-term, national strategic plan, funding also must be used for public health education, specifically used to combat the anti-vaccine movement. Much of the foundational information the anti-vaccination proponents used to prove the harm of vaccination is junk science. Funding must be put towards conducting definitive research that disputes these studies, as well as educating the public as to why these studies are definitely incorrect, once and for all. Public health officials are fighting an uphill battle going against the word of Hollywood celebrities. Because of this, the public must be educated on the importance of vaccinations and what the consequences could be of not vaccinating children. It is only through a stronger and louder voice that public will learn the truth about the critical importance of ensuring that the public receives the life-saving vaccinations that are available.

The key to response to biological events is early detection. This can only be successful if hospital and healthcare workers are able to identify an outbreak in its early stages and recognize the specific symptoms belonging to biological agents. This can only occur through proper training of hospital staff. Hospital staff will have to be able to recognize that the symptoms they are seeing are not normal for a normal flu or other illness that is usually seen. However, in order to ensure that the correct diagnosis is given, it may take a physician trained in emerging or contagious diseases to confirm a diagnosis. If this is not part of normal medical training, it may need to become part of the training that all new doctors undergo. This would be a huge undertaking or require a complete overhaul of the current medical training curriculum. Unfortunately, the devastation that could occur due to the release of a biological agent that takes weeks before the symptoms to show could lead to a pandemic incident that could claim the lives of a large number of the population. Without trained medical professionals that have the ability to diagnose these outbreaks, this is an all too real possibility.

Early detection will also require clear lines of communication that allow the front-line healthcare workers to contact public health officials, as well as other hospitals and healthcare systems and report what is being seen. Increased surveillance of the diseases is also critical for early detection of a disease reaching the United States from abroad. The faster these incidents are detected, the faster life-saving treatments can be given to those infected, and vaccines or antidotes can be given to those before they fall ill, potentially stopping the further spread of the disease. In addition, the decrease in time it takes for a biological event to be detected could also allow for faster apprehension of an individual or terrorist group who intentionally dispersed a biological agent as part of a biological terrorist attack.

All of these changes will have a huge impact in the current environment of emergency management in the hospital setting. As discussed earlier, as of now in the Western Pennsylvania regions, the tasks of the emergency manager tend to be placed on an administrator who already has other requirements from the current position he or she holds. If these recommendations are put into place, the responsibilities of a hospital emergency manager will be too great to be given to an administrator who already holds another position. This will force emergency management to take the priority and focus in the hospital and healthcare field. These regulations and recommendations will not be able to be met at the last minute when an inspection or survey is imminent. These recommendations will require attention throughout the entire year with a singular person, or perhaps even a team needed to ensure that all are complied with. This will have to become just as high of a priority to meet specifications set forth by these agencies as patient care regulations or any other policy that is already in place.

Regardless of how or why a bioterrorism attack or pandemic event occurs, the fact of the matter is that hospitals and healthcare systems will be on the front lines to combat and control

further spread of the agent, as well as treat its victims. Without the proper measures in place, any response to the biological event, whether occurring naturally or intentionally, will surely be a failure resulting in a potentially catastrophic loss of life. With much research already available to show that public health officials and hospital preparedness leadership are well aware of the vulnerabilities and gaps that exist in the current preparedness procedures, the public will point an accusatory finger at those officials who were supposed to protect the public and have its interest at heart. There will be no one to blame but those who had the opportunity to make corrections to the current regulations and standards, and close the gaps experts are well aware of, but instead chose to do nothing, or simply ignore the problem. While the problem is large, and it will take a large shift in the current public health and hospital preparedness structure, it is a small price to pay for the lives that will be saved when these vulnerabilities are decreased. Biological threats will always be a part of human existence. These threats will more than likely never go away. However, the opportunity exists at this moment to drastically reduce that threat and change the face of biological preparedness. It is time to step up and put these changes into place so that one day the citizens of the United States may never have to be concerned about bioterrorism or a pandemic event.

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