

KEMRI Bioethics *REVIEW*

VOL VI ISSUE III, 2016



Biosafety and **Biosecurity**

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From the Chief Editor

Prof Elizabeth Bukusi

Welcome to our third issue of 2016 focusing on **Biosafety and Biosecurity**. Biosafety and Biosecurity are related concepts that are geared towards the management and containment of various biological agents that are hazardous to human life. Despite its significance in wellbeing of the population, the subject of Biosafety in research and healthcare has not received sufficient attention in terms of information, training and administration. Biosecurity on the other hand is a new area that has rapidly gained traction and attention thanks to the global threat of bioterrorism.

In this issue of the KEMRI Bioethics Review, we provide information on the importance of Biosafety and Biosecurity to public health and national security. Inside this issue: Dr. Andrew Githeko & Dr. Diana Karanja highlight the Biosafety concerns of Vector Borne Diseases, Walter Oloo and Evans Apondi shed light on bioterrorism and its implication on national security. Waste management is an integral part of biosafety, Julia Wangui from USAMRD-K writes on the ethical issues in biomedical waste management. Our final article by Michael Opiyo focuses on the importance of biosafety and biosecurity for Public Health and National security.

We hope this issue on biosafety and biosecurity will inform and stimulate further discussions and research on the new challenge of bioterrorism and what institutions must do to ensure biological agents and materials do not fall to the wrong hands where it can be used to cause harm. Enjoy reading and be informed.

The Chief Editor

The **KEMRI Bioethics Newsletter** is published every 3 months and hosted on the KEMRI website. We publish articles by KEMRI affiliated authors and from other contributors from all over Kenya. The scope of articles ranges from ethical issues in biomedical science, healthcare, technology, law, religion and policy.

The chief editor encourages submission of articles as a way of creating awareness and discussions on bioethics

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A word from the Director, KEMRI

Dr Gerald Mkoji

Welcome to this issue on Biosafety and Biosecurity. Biosafety addresses the safe handling and containment of infectious microorganisms and hazardous biological materials including their toxins, in the laboratory through the application of containment principles and the risk assessment to prevent exposure of lab workers to pathogens or the inadvertent escape of pathogens from the laboratory. Biosafety is an integral part of biomedical research, it ensures the adoption, and use of good microbiological work practices, appropriate containment of biological materials, and administrative considerations, to minimize the risk of exposure of workers to infectious agents.

Biosecurity, on the other hand, refers to measures that are taken to stop the spread or introduction of harmful biological organisms to human, animal or plant life. The measures taken include a combination of approaches that have been put in place by biosciences laboratories, customs agents, and agricultural officials, to prevent the use of dangerous pathogens and toxins. Biosecurity aims to protect human health and agricultural produce through the prevention, control and management of biological risk factors. In addition, biosecurity aims to protect against acts of bioterrorism and prevent adverse biosecurity events, and to advise on appropriate interventions. In other words, biosecurity ensures that biological agents are not used to cause harm.

Both biosafety and biosecurity seek to minimize risks posed by harmful biological agents in the environment. However, there is an increasing awareness of the potential harm of dangerous biological agents landing in the wrong hands, and the ever increasing terrorist threats call for extra security measures to protect target or vulnerable populations. Biosafety and biosecurity measures alone, however, may not be sufficient in the wake of the increasing threats of bioterrorism in Kenya. Cognizant of such threats, KEMRI has sought the support of government security agencies through the political leadership, to beef up security in the In-

stitute, as an additional measure, given that KEMRI handles biological materials that can potentially cause harm to humans, if they accidentally escaped or ended up in the wrong hands. KEMRI has, overtime, accumulated a large collection of biological agents acquired, through research activities undertaken in the Institute, and often times, the custodians of such materials are the scientists working in the various laboratories within the Institute. While the custodians of such materials will do their best to ensure that potentially infectious biological materials are securely stored, there is concern that the existing arrangements for storage of such materials may not be adequate, hence, the need to enhance security of the materials.

Bioterrorism is a new and emerging threat within our borders that calls for concerted efforts and collaboration of stakeholders in the health sector and security agencies, in dealing with this challenge. There is also, need for national guidelines and policies to govern acquisition, transportation, handling and storage of biological specimens, pathogens and toxins by research institutions, universities, health facilities, and biological laboratories in Kenya. Besides, researchers and laboratory staff need to appreciate that just as biosafety practices are routine, laboratory biosecurity measures should also, be part of the routine in all biological laboratories. On a long term, KEMRI seeks to put in place measures to ensure that dangerous biological materials are not only securely stored, under strict controls, but are also, only accessible to authorized personnel, and strictly used for research or public health investigations. In the meantime, I urge all staff of KEMRI and collaborative partners in particular, those who regularly handle and have access to potentially dangerous biological materials, to exercise care, professionalism, and ethical practices in handling such materials, in order to prevent accidental escape, and ensure that these do not end up in the hands of people with ill intentions. Enjoy your reading of this issue of KEMRI Bioethics Review.



A word from the Deputy Director, Research and Development

Dr Evans Amukoye

Biosafety and Biosecurity are critical areas in daily research activities. These are the strategies applied to ensure that the dangerous pathogens isolated during or used in research are contained efficiently and do not cause harm inside or outside the laboratories. We live in times when biological agents or by products are a potential weapon that can be used in acts of terrorism; biosecurity is thus a way to ensure that hazardous biological agents are used for the purposes that may be beneficial to humankind and not to inflict harm. There is also the human and environmental threat posed by re-emerging lethal infections - like the Ebola virus. The situation calls for more preparedness for Kenya in terms of our capacity to mitigate risks and to safely handle such outbreaks from without or within our borders.

We live in times when biological agents or by products are a potential weapon that can be used in acts of terrorism.

The proper management of bio-risks in the country starts with the facilities that collect, store, or handle these biological agents, this is why the government has dedicated more resources towards physically securing institutions like KEMRI. This will ensure access control, intrusion detection and quick response in case of any threat. Biosecurity efforts must also focus on hospitals as these are potential areas that can be exploited. KEMRI is ready to offer technical assistance through trans-

fer of biosafety knowledge especially on the risk / threat assessment and this would be of particular benefit to health care workers at the county level. A concerted effort in leveraging the expertise of KEMRI and other well endowed institutions of

KEMRI is ready to offer technical assistance through transfer of biosafety knowledge especially on the risk /threat assessment

higher learning, like the universities with large repositories of biological agents to help in raising awareness and in training would be beneficial to the larger Kenyan community and strengthen civilian response for disaster preparedness, emergency planning and for management in the face of actualized threat.

A national bio-surveillance would be an important mitigation for managing threat going forward, and I encourage KEMRI scientists to take the lead in designing bio surveillance programs and systems that will help gathering, integrating, interpreting, and communicating essential information that might relate to disease activity and threats to human, and both animal, or plant health as they do ultimately impact human health. The success of the national biosecurity and biosafety efforts will depend on how effective various institutions of health perform their core functions individually and collectively as a team working together.

Dr Evans Amukoye

Ag DDRD

BIOSAFETY AND VECTOR BORNE DISEASES: ARE THERE CONCERNS?



DR. Andrew Karanja Githeko-KEMRI CGHR
DR. Diana Karanja-KEMRI CGHR

Relevance – medical research

Medical research and practice involves the handling of infectious agents and its vectors. Researchers and medical practitioners may be at an exceptionally high risk due to their frequent encounter with these organisms. These agents may be contracted through handling of infected tissues such as blood. For example, non arboviral diseases such as hepatitis B and HIV can be contracted through handling of blood. Diseases such as anthrax, T.B., Legionnaires disease are air borne diseases and they are particularly contagious through direct contact. While vector borne diseases have a low risk of infections in laboratory conditions, this may not be the case in field research conditions where safety conditions are poor or do not exist. Moreover, some of the personnel involved in field research may not

be aware of the level of risk they are exposed to. In some cases the level of risk can be eliminated by vaccination, for example, yellow fever, or by chemoprophylaxis such as malaria. However, such interventions are not available for dengue, chikungunya, and zika virus infections. In the case of plague; a vector borne bacterial disease, the infections can be controlled with antibiotics.

Vector borne diseases

Malaria stands out as the most important vector borne disease in Kenya attracting considerable research. The main areas of research include drug resistance, immunology, and transmission and vector behavior studies. Technical staff in malaria research settings handle blood through venipuncture use of needles which puts them at risk of need stick injuries. Although the risk of contracting malaria is minimal, through such injuries, there is a low possibility of contracting hepatitis B, and HIV. Equally, immunological studies require drawing

venous blood, and accidental injuries to technical staff could also occur. It is therefore important to practice biosafety measures that mitigate against these risks. Moreover, individuals exposed to these risks must be careful and inculcate a culture



Mosquito control by spraying- google image

of high biosafety standards in their workstations. Such efforts and actions require support through regular training and monitoring of safety practices.

Understanding the intensity of malaria transmission is particularly important while monitoring baseline transmission and the effects of interventions. Assessment of the levels of malaria transmission requires collection of mosquitoes that are seeking human host for a blood meal or those that have already fed on a human host. Those mosquitoes that are seeking a blood meal were traditionally collected using the human landing or the human bait collection technique. This includes the direct exposure of humans to intense biting by malaria vectors, and other mosquito species that are vectors of arboviruses. This activity exposes field researchers to a higher risk of malaria infection and in some cases arboviral infection. Other potential areas of risk include handling live and infected mosquitoes in the laboratory. This can arise from mosquitoes fed through membrane feeding. Accidental bites from such mosquitoes can infect laboratory staff.

There are three active arboviruses in Kenya, and these include dengue, chikungunya and rift valley fever. Although there are no recent records of urban and peri-urban yellow fever transmission, little is known about sylvatic transmission where the cycle may be sustained between monkeys and forest species of *Aedes* mosquitoes. The zika virus transmission is rapidly spreading and there are possibilities that it will become established in Kenya. Arbovirus transmission occurs in certain foci that can be regarded as transmission hot spots. *Aedes aegypti*, which frequently bites at dawn and dusk, is the most common vector of arboviruses in Kenya. Due to its biting behavior, the vector presents a major risk to affected human populations and health investigators because impregnated bed nets do not offer complete protection against bites from this mosquito. Investigators entering a transmission zone may be at risk of contracting the circulating arbovirus. While in the case of yellow fever, vaccination gives effective protection, this is not the case with arboviral infection. Handling of live and infected vectors in the laboratory and insectaries could lead to accidental infections to investigators. In the case of dengue there are published reports on accidental infections arising from hypodermic accidents in the laboratory.

3. Emerging risk due to climate change and epidemics

Climate change is associated with vector borne disease outbreaks and epidemics. It is also associated with geographic range expansion of vector borne disease transmission. These events will require field and laboratory investigations by researchers, and this increases the risk of exposure to personnel. In a recent chikungunya outbreak in Northern Kenya, health workers were among the affected from direct bites by the vector and

this impacted negatively on the health delivery services in the area. In this regard, there is need to document incidents of health workers and researchers infected during research activities dealing with disease outbreaks, as this remains largely undocumented. Data on such incidents is required in order to formulate appropriate policies and interventions for infection control. Additionally, there exists known but undocumented cases of researchers acquiring dengue virus during field activities.



Sleeping under treated bed nets reduces malaria incidences- google image

4. Bioengineering and Bioterrorism

Developments in biotechnology have led to the possibility of gene editing and gene transfer between organisms which include pathogens. It is technically feasible to modify an arbovirus to enhance its potency or its mode of transmission. Such transgenic materials can be used for military purposes or for bioterrorism. It is therefore essential to maintain high security on cryopreserved viral material to prevent it from falling into the wrong hands. A system of documenting such materials must be strongly reinforced and sustained.

5. Bioethics and regulatory mechanism

From the foregoing, there is need for concern about the biosafety in handling arboviruses in the

field and in the laboratory. It is not clear if there exists coherent guidelines to mitigate against these risks. Taking into consideration the expected increase of exposure to this risk due to climate change, steps should be taken by ethics committees to put in place procedures for protecting investigators against disease outbreaks. Of major concern are investigators of pathology whose etiology is unknown. This may include a new viral infection or a new strain with altered pathogenesis. The Hantavirus pulmonary syndrome, an aerosol borne infection in North and South America presents a useful reference to biosafety issues regarding viral infection risk management.

6. Reducing risks and exposures

In conclusion, there are grounds for concerns regarding risks from arboviral transmission and climate change. Breeding of *Aedes aegypti* close to human habitats is likely to increase during droughts when people store water in open containers outdoors and indoors. This vector bites at pre-dusk period and at dawn, and therefore bed nets may not prevent the risk of being infected by the arbovirus. As noted, the range of transmission by this vector may be increasing. This has been observed in the case of rift valley fever, dengue and chikungunya. The zika virus may follow the same pattern. With regard to biosafety issues, KEMRI will need to develop strategic guidelines to reduce the risk of researchers being exposed to arboviral transmission, particularly during epidemic investigation.

BIOTERRORISM AND ITS IMPLICATION ON NATIONAL SECURITY.



By Walter Oloo and Evans Apondi of Kemri CGHR Kisumu safety office

Introduction

As we go to our houses to rest in the evenings we do a lot of planning for the next day with sureties that we will get there. You wake up in the morning, drop your kids to school kissing them goodbye and as you drive away, see someone drop a glass vial or a well-sealed envelope and walk away. You think nothing of it, but then moments later you become a statistic of bioterrorism. Throughout time immemorial, the quest to dominate another is limited to the imagination of one man passed against another. From smeared arrows to poisonous snakes, from infected blankets to super bugs created in a laboratory etc., we fight bioterrorism. Sometimes common flu and symptoms such as headaches, dizziness, nausea, vomiting, coughs and shortness of breath are the first signs of a bioterrorism attack. Through history, warring groups have used a wide range

of tactics and technologies to defeat their enemies. These weapons have evolved from throwing sticks at one another to unthinkable weapons of mass destruction called bioterrorism meant to cause terror and never choosing the innocent from the guilty. What is bioterrorism? Until the first envelope containing anthrax was opened, many analysts still doubted the seriousness of the possibility of a bioterrorist attack. Biological warfare was long considered too technically difficult to pose a significant threat to the population of the United States and the world at large.

Definition;

Bioterrorism is a criminal act against unsuspecting civilians using pathogenic biological agents, such as biological warfare agents. It is the intentional or threatened use of bacteria, fungi or toxins from living organisms to produce mass disturbance and involves intimidation of nations or people to accomplish mostly political or social ends. Biological warfare has been used for

decades, from the cadavers poisoning to the modern technology allowing ammunitions and massive deployment of biological weapons. Bioterrorism is an attractive weapon because most biological agents are relatively easy and inexpensive to obtain, can be easily disseminated, and can cause widespread fear and panic beyond the actual physical damage they can cause. Bioterror and Biological Warfare agents are most often colorless, by-and-large odorless microorganisms (bacteria, viruses, and fungi) or toxins (usually protein toxins) derived from microorganisms that can be spread in air as aerosols or in food or drink to infect as many people as possible. These agents are typically found in nature, but it is possible that they could be mutated or altered to increase their ability to cause disease, make them resistant to current medicines, or to increase their ability to be spread into the environment. They are easily concealed, and thus difficult to detect before an attack. A biological weapon is useful to terrorists mainly as a method of creating mass panic and disruption to a state or a country. They are also difficult to detect when released, so a bio warfare or bioterror attack would be difficult to ascertain, especially due to the usually nondescript initial signs and symptoms expected in casualties from

such an attack.

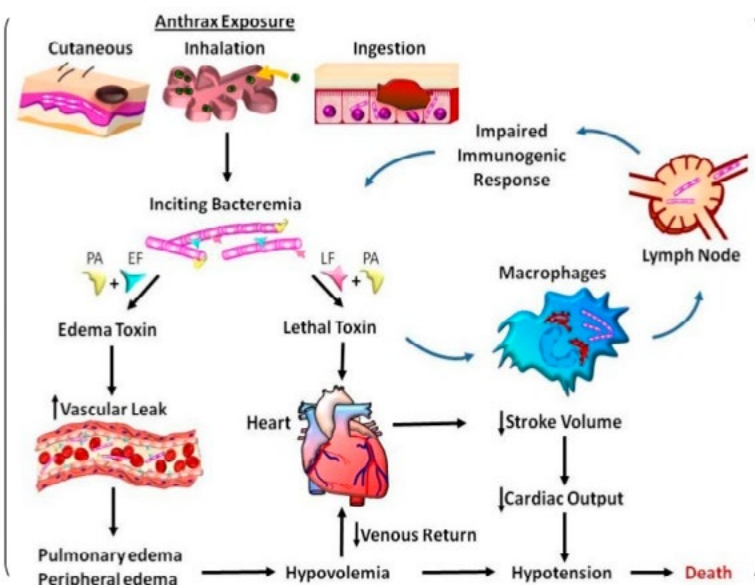
The most likely target for bioterrorism attack is a major city or other densely crowded areas, such as transportation hubs, major sports events or public rallies and especially government buildings. Once an attack has occurred, most biological agents would need an incubation period of several hours or days in order to cause sickness. The main functions of bioterrorism are to cause panic, disruption and chaos, so biological agents don't have to cause a fatal disease to be effective. In fact, many biological warfare agents are categorized as 'incapacitating agents' that are not intended to produce a fatal disease. They are more effective if they incapacitate and produce strain on a health care system by having many thousands of sick patients overwhelm treatment facilities that contain only limited quantities of drugs and only a few isolation beds. Also, it is much easier to spread an incapacitating agent from person to person, because it would not cause enough alarm to require quarantining of exposed persons, which could limit additional exposure.

Biological Agents in Bioterrorism

There are several types of biological agents that could be useful for bioterrorism.

First classification;

These are lethal agents, such as the Ebola, Lassa and other viruses that cause viral hemorrhagic fever, anthrax caused by *Bacillus anthracis* spores, smallpox virus, pneumonic plague caused by *Yersinia pestis* or purified protein toxins, such as the *Ricinus communis* toxin ricin or *Clostridium botulinum* toxin. In addition, there are incapacitating agents that cause brucellosis, mediated by *Brucella* species, Q fever caused by *Coxiella burnetii*, tularemia caused by *Francisella tularensis*, mycoplasmal infections caused by *Mycoplasma fermentans* and mold toxins, such



as the T2 mycotoxin.

Second classification;

Category A- These can easily be disseminated, have high mortality, and requires special action for public health preparedness. Includes; Tularemia, Anthrax, Small pox, Botulinum toxin, Bubonic plague and Viral hemorrhagic fever.

Category B- These are moderately easy to disseminate, moderate morbidity and mortality, and requires specific enhancement of diagnostic ability by the public health system. Includes;

- Food safety threats (for example,, Salmonella species, E coli O157:H7, Shigella, Staphylococcus aureus)
- Glanders (Burkholderia mallei)
- Melioidosis (Burkholderia pseudomallei)

encephalitis, western equine encephalitis)

- Water supply threats (for example,, Vibrio cholerae, Cryptosporidium parvum)

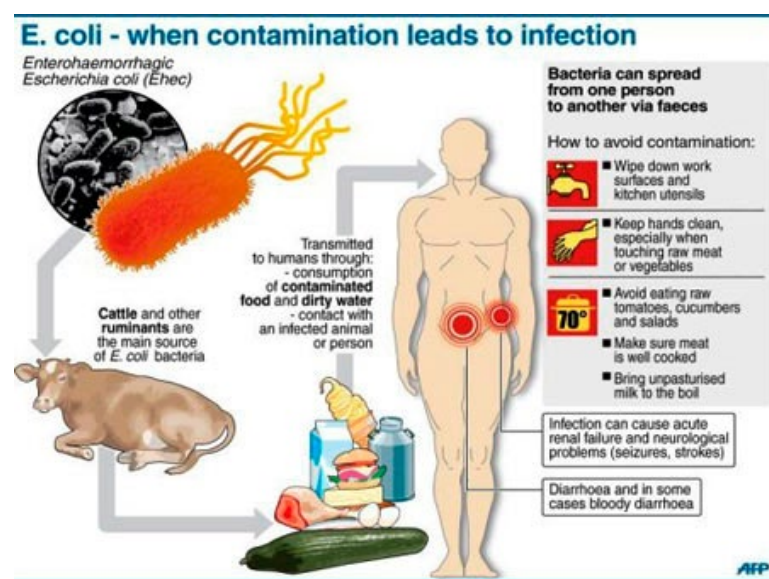
Category C

Category C agents are emerging pathogens that might be engineered for mass dissemination because of their availability, ease of production and dissemination, high mortality rate, or ability to cause a major health impact. Includes;

- Nipah virus
- Hantavirus
- SARS
- H1N1 a strain of influenza (flu)
- HIV/AIDS

Many of the most lethal biological agents, such as the hemorrhagic fever viruses, are quite unstable in the environment due to their susceptibility to sunlight and extreme temperatures and would not be effective if deployed in an aerosol at long range, for example, by aircraft sprayers thus these would be disseminated by infecting individuals who will then pass on the infection to others, such as by getting to crowded places such as a bus terminus or infect others in a hospital setup those with weak immune systems who easily catch the infection before the first case can be isolated. Most viruses that would be useful as bioterror agents quickly cause unique signs and symptoms that would allow isolation of the victims and thus prevent further spread of the disease. Many of the bacterial or viral incapacitating agents, however, slowly produce illnesses that would not be noticeable until sometime later, and during this period they could be slowly and unknowingly spread to others. Official denial if detected helps this process and allows further penetration into the population. Thus if an attack is obvious and results in immediate fatalities, we should expect an all out response. A commonly used agent is;

- Psittacosis (Chlamydia psittaci)
- Brucellosis (Brucella species)
- Epsilon toxin of Clostridium perfringens
- Q fever (Coxiella burnetii), Ricin toxin from Ricinus communis (castor beans)
- Abrin toxin from Abrus precatorius (Rosary peas)
- Staphylococcal enterotoxin B
- Typhus (Rickettsia prowazekii)
- Viral encephalitis (alphaviruses, for example,; Venezuelan equine encephalitis, eastern equine



Anthrax; It is one of the most preferred biological warfare agent for many reasons;

1. It is extremely lethal; a can contains up to 100 million lethal doses in just one gram of spore.
2. Inhalation is always fatal if symptoms are allowed to progress without any treatment.
3. It is a silent and invisible killer, easy to produce in large quantities and is extremely inexpensive.
4. It is easy to weaponize because it is extremely stable as a dry powder in the form of spores, thus it can live for many years and still be lethal to the human body.

Anthrax spores are put in aerosol form then disseminated in a spray can, it can also be freeze dried into a bomb. It is the most used because there is no accurate detection capability in place i.e. they are odorless, colorless and tasteless spores. In case of inhalation anthrax, there will be death of the first infected since no one will suspect the flu like symptoms as the anthrax spores germinate in the lungs. A single release can travel miles as it takes only a single gram of the spores to kill 10 million people and this could create a high fatality rate. This was used by the Germans, the US, Aum shinrkyo sect during World War II.

The Signs and Symptoms of Some Biological Agents

Most bioterror agents do not cause unique clinical signs and symptoms that are immediately recognizable in exposed individuals. Thus this gives the agent sufficient incubation time and enables the agent to spread before it is suspected, hence giving the terrorist time to invade other cities so that there is a massive outbreak.

Anthrax.

This is the most dangerous biological agent and occurs as the spore form of *Bacillus anthracis*. Although the inhalation of anthrax spores is uni-



Mail laced with deadly anthrax-google image

formly and rapidly fatal, anthrax infection can be successfully treated in its early stages with antibiotics like doxycycline or ciprofloxacin. Victims of an inhalation anthrax attack will present initially with a flu-like illness with malaise, dry cough and mild fever. This phase of the disease usually takes a few days, followed by severe respiratory distress. Anthrax can be treated, but only before it enters the severe respiratory distress phase. Most patients in the severe systemic phase will die with or without antibiotic treatments and usually before a laboratory diagnosis can confirm the presence of the bacterium in blood and tissues. If anthrax spores enter the skin, cutaneous anthrax infection can occur, resulting in a black scab over the contaminated area. At this point the infection remains treatable with antibiotics, but if left untreated approximately 20% of cases result in death. Persons with cutaneous anthrax can also have headaches, muscle aches, fever, nausea and vomiting, indicating a systemic form of the infection. Ingestion of contaminated meat can also result in infection (gastrointestinal anthrax). If left untreated, this form can result in 25-60% fatalities. Gastrointestinal anthrax can produce intestinal bleeding and similar signs and symptoms to systemic forms of the disease. Person-to-person transmission of *Bacillus anthracis* is poor, and this

type of infection is not considered contagious. Thus terrorist mostly use this by producing spores which are then spread not infect people by either of the means.

Hemorrhagic fever viruses.

Viral hemorrhagic fevers caused by Ebola, Marburg, Lassa or Bolivian Hemorrhagic Virus are rapidly progressing diseases that show extremely high mortality rates. Many of these infections are caused naturally by contact with contaminated food, but they can also occur by contact with urine, feces or saliva. The viruses are fairly fragile, and dispersing them as an aerosol would not be expected to maintain their viability for long periods of time. Patients usually present with high fever, muscle aches and pain, hypotension and prostration. In severe cases, patients have signs of disseminated vascular coagulation with signs of mucous membrane hemorrhage and shock. At this stage the disease is almost always fatal. For some hemorrhagic fever viruses the antiviral ribavirin offers some benefit. Patients require immediate fluid, plasma or blood support. Although these viruses are airborne, person-to-person transmission can be for the most part prevented by wearing gowns, gloves and masks. Fortunately, these viruses do not persist in the environment for long periods, and most outbreaks in Africa have been limited by immediately isolating patients.

Plague.

Plague is caused by the bacterium *Yersinia pestis*, which is usually spread from rodents to man through the bites of infected fleas or other insects. In humans, the disease usually occurs in the form of bubonic plague. In rare cases, the infection spreads to the lungs via the bloodstream and causes secondary pneumonic plague. Person-to-person transmission has been described for pneumonic plague but is rare in primary bu-

bonic plague. In a bioterror attack the bacterium could be spread by inhalation of droplets containing *Y. pestis* or terrorists could simply disseminate infected fleas or other biting insects. If left untreated, inhalation of *Y. pestis* is nearly always fatal within 2-3 days. Patients usually suffer severe pneumonia with malaise, high fever, cough, spitting up blood and labored breathing. Eventually patients go into septic shock and die because of respiratory failure and circulatory collapse. Respi-



Vector control to control arboviruses-Google Image

ratory plague is very contagious, and strict isolation is necessary. Early treatment with antibiotics, such as doxycycline, ciprofloxacin or other antibiotics, at the first appearance of signs and symptoms is crucial for survival. The epidemiology of plague in bioterrorism would differ substantially from that in naturally occurring infections. The organism would most likely be released as an aerosol. An outbreak of pneumonic plague would follow, and patients would present with symptoms initially resembling those of other severe respiratory infections. The size of the outbreak would depend on the quantity of biological agent used for the attack, the characteristics of the strain, and the environmental conditions at the time of the release of the organism. Symptoms would most likely occur within 1 to 6 days following exposure, and most people would die quickly after onset of symptoms thus making it suitable for attacks,

such as the Black Death. The occurrence of cases in areas not known to have enzootic infections together with no known risk factors for infection and an absence of great numbers of dead rodents all indicate the deliberate dissemination of plague.

Botulism.

Botulism is caused by toxins released from the bacillus bacterium *Clostridium botulinum*. This can occur naturally by ingestion of infected foods, but a terrorist attack may utilize an aerosol of the bacterium or the purified toxins. The botulism toxins are neurotoxins and cause characteristic neurological signs and symptoms within 1-5 days, such as dry mouth, double vision, excessive pupil dilatation, local paralysis, and difficulty in swallowing. The neurotoxins usually do not cause a fever, and patients are alert and oriented. Most patients die of respiratory failure, so respiratory support is essential and may have to be continued for several weeks to months. The toxin can be removed from skin by washing with soap and water. Clothes must be placed in a sealed plastic bag for biohazard disposal. If the toxin is used, there is no danger of transmission from infected patients. Although an antitoxin is available, it is only effective in preventing further progression; it cannot reverse neurological damage that has occurred and is mostly used in an attack targeting soldiers in a war situation.

Smallpox.

Smallpox is caused by the naturally occurring Variola Virus. After exposure, the incubation period for smallpox is approximately 7-17 days, average 12 days, during which nonspecific signs and symptoms, such as fever, malaise and aches occur within a few days. Characteristic rashes develop, starting as papules that progress to vesicles and then pustules that can form scabs in 1-2 weeks. At

this stage the disease can be mistaken for chicken pox, and it can be spread to others, so quarantine is important for anyone who has direct contact with a patient. Death from smallpox is usually the result of severe toxemia, septic shock or disseminated intravascular coagulation. The first public health measure following the diagnosis of a smallpox case will most likely involve vaccination of several thousand individuals deemed at risk and quarantine of the infected. The vaccine is believed to be effective in preventing smallpox in people who have been exposed to the virus, if administered within 72 hours of exposure. Yet, even assuming adequate vaccine coverage of populations, the potential for mass mortality stemming from only one case of smallpox is vast. At present, the capacity of the public health system to effectively diagnose, quarantine, and identify smallpox infection is limited, due in large part to an underestimation of the actual threat of bioterrorism.

Brucellosis.

Brucellosis is caused by bacteria of the genus *Brucella*. Historically brucellosis was caused by contact with infected livestock or after ingestion of infected milk. Aerosols of *Brucella* are considered very effective at infection and are the form used by terrorists. Brucellosis is considered one of the agents less likely to be utilized in a bioterrorism attack, in part because it results in a high morbidity, but low mortality. However, it remains a threat because the disease process is long and incapacitating. The disease develops slowly over several months as a flu-like infection with nonspecific signs and symptoms, including intermittent fever, chills, night sweats, malaise, muscle pain and soreness, cough and eventually joint pain and soreness, gastrointestinal complaints, nausea, vomiting, diarrhea and constipation. It might be diagnosed as Chronic Fatigue Syndrome or

Fibromyalgia Syndrome, but it is rarely fatal. The chronic form of the disease can mimic miliary tuberculosis with suppurative lesions in the liver, spleen and bone, as such with clearly no direct diagnosis in place it might take so long before an action is taken and as such many people will be infected

Mycoplasmas.

Pathogenic mycoplasmal infections are caused by several species of mycoplasmas, including *M. fermentans*, among others. These airborne and insect-borne bacterial infections are rarely fatal, but they can cause severe chronic infections that may result in patients being diagnosed with Chronic Fatigue Syndrome, Fibromyalgia Syndrome or Rheumatoid Arthritis.

As with brucellosis, the chronic signs and symptoms are many and varied from patient to patient,

Q fever.

Q fever is caused by the bacterium *Coxiella burnetii*. This can occur naturally from contact with goats, cheep and cattle. The most common method used by bioterrorists is aerosolization whereby the lethal dose is 1-10 organisms for effectiveness, however it has low mortality and person to person spread is very rare. The disease develops slowly over a month or more, with fevers, malaise, headache, muscle pain and soreness and other signs and symptoms. About one-half of patients will have pneumonia with cough and chest pain. In some patients the disease can progress to hepatitis. Treatment includes antibiotics and immune support

Tularemia.

Tularemia or rabbit fever is usually caused by contact with infected animals that carry the bacteria *Francisella tularensis*. It can also be caused by ingestion of contaminated food or water and is the route mostly used by terrorists' e.g. by in-

fecting a central water tank or a commoner's hotel infecting a lot of water and food. When aerosols are used as the infective route, the disease that evolves has slightly different signs and symptoms. After an incubation period of 2-10 days, patients present with fever, chills, headache, nausea, vomiting, diarrhea and muscle aches and pains. Many patients will have a pneumonia with coughing.

Airborne (person-to-person) transmission can occur but is considered rare. The treatment is a 2-3 week course of antibiotics plus immune support

Diagnosis and Treatment of Biologic Agents

When detected early, most of the biological agents, even some of the most lethal agents, can be effectively treated with antibiotics or antivirals. However, an attack may go unnoticed for some time, and it might take some fatalities before public health officials notice that an attack may have occurred.

Many agents useful for a bioterror attack, even the lethal agents, produce nonspecific clinical signs and symptoms, so it is important to be aware of these if many casualties occur within a short period of time in one location. Public health officials are being trained to spot these 'clusters' of illness and take appropriate action such as having on hand modest amounts of certain antibiotics that can be taken as soon as certain signs and symptoms occur could save lives. If a terrorist group has the latest information and advanced expertise to produce resistant variants of biological agents, they could produce bacteria and viruses that can withstand the standard antibiotics and antivirals used for treatment. Although this scenario is considered unlikely, it could pose some potential problems for treatment of attack victims. For most agents there are alternative drugs that can be used. Although some of these are not as

effective as the first line treatments, they should be adequate for most patients.

Bioterror Attack Preventive and Treatment Procedures

If no cure is in place, then the area shall be destroyed by any means necessary to eliminate the agent and maintain safety. If an outbreak did indeed occur, then whatever it takes to minimize harm to human life without loss of many should be done such as masks, isolations and quarantine.

Antibiotics;

Are effective only if there was actual exposure, and the biological agent was bacterial and susceptible to the antibiotic chosen for chemo prophylactic use.

Antivirals.

Use of antivirals against viral agents should only be done under the direct care of a physician, and their use is only recommended after a confirmed infection. They are not recommended for chemo prophylactic use due to a relatively high rate of com-

plications and adverse reactions compared to the commonly used antibiotics. Some antivirals have to be given intravenously, and this can only occur in a supervised clinical setting. Cost and availability are factors that severely limit their use, and almost all cannot be used in pregnant women and some cannot be used for children because they

mostly show adverse reactions.

Vaccines.

Nationwide vaccinations against all agents that could be used for a bioterror attack preparation should be used. Specific vaccines can potentially protect against bacterial and viral bioterror agents. Most of these vaccines would have to be administered over a relatively long time period to be effective. For example, the current anthrax vaccine must be administered in multiple doses over an 18-month period to be effective, and it is not even known conclusively that the vaccine is effective against inhalation anthrax. This vaccine is not recommended for civilian use due to the relatively high rate of adverse reactions, including fatalities and autoimmune diseases that have re-



Ebola quarantine - Google Image

sulted from its use.

Passive Immunization.

Passive immunization by administration of immune sera containing antibodies against specific bioterror agents is a costly alternative that can only be used after a confirmed exposure. Newer developments include passive immune sera or

pure antibodies that can target toxin molecules themselves instead of the microorganisms. For example, antibodies against the anthrax lethal and bloat factors (the lethal toxins) or their protective factor (a transport factor needed to transport the lethal toxins into cells) can potentially stop a fatal form of systemic anthrax.

Mass education

Mass education, of the public on some of these agents such that they can easily recognize the possible symptoms that look out of place. They should also be more effective in spotting signs or protect themselves e.g. use of masks and isolating an infected.

Biosurveillance

Indicators should also be put in place to help prevent spread in case of a bioterror attack e.g. if detected as soon as it occurs such as chemical indicators and fibre optics against known agents.

What should be done in case of a bioterrorism attack.

One needs to quickly remove their clothing and wash off their skin. Most biological agents cannot penetrate intact skin. Showering with soap and water will remove most agents from the skin. If one has already inhaled or ingested an agent, decontamination using soap and water may not be helpful. However, exposure to other family members might be prevented by means such as isolation, wearing of safety gear such as masks, and seeking of medical help from health experts.

The two most important tools used by public health officials are isolation and quarantine. Isolation is keeping people known to be ill away from other people. Quarantine is keeping people who may have been exposed away from other people. The problem is that many times we may not know who has been exposed. In such cases, the public health officials will likely recommend that

everyone stay in their homes and avoid all public gatherings also paralyzing all forms of traffic. By doing this, they isolate the sick and quarantine those infected but who do not yet have symptoms. There may be the possibility of transmission of disease from one human to another (for example, measles, influenza, avian flu, smallpox, plague, and viral hemorrhagic fevers). In the case of either a bioterrorism attack or just a natural outbreak, it may be necessary to avoid contact with infected people or just remain inside for a period of time until the infected people are no longer contagious.

Conclusion

Bioterrorism has existed for countless of years and there is no doubt that it will be used in the future. The only thing we have to worry about now is how it will be put to use next. Despite going through the trouble of setting up pacts to prevent the use of biological weapons, its presence continues to cause problems on a world wide scale.

It is often said that what we fear the most is in fact fear itself. Happiness cannot negate it but simply aids in distracting the mind from fear. Ignorance on the other hand harbors fear and provides it a space to grow enveloping the mind. This feeling of terror and insecurity arises from any situation that is presented to us in which we have no control over and is not within the boundaries of our own comfort and in the present times we are too busy looking for bombs and guns and not any powdery substance that can easily cause death as such and quicker and consider bioterrorism as a real threat and instead of spending millions going to war we should save the millions in preparing vaccines and equipping ourselves for an attack, thus as the scouts we once were we should stick to our motto, **"BE PREPARED!"**.

IMPORTANCE OF BIOSAFETY AND BIOSECURITY TO PUBLIC HEALTH AND NATIONAL SECURITY



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The responsibility of health and research institutions in protecting staff from biohazard material.

Health facilities and research institutions use several hazardous materials, particularly for diagnostic purposes and medical research; these need to be carefully used. It is mandatory that each institution complies with the requirements of Occupational Safety and Health Act of Kenya in protecting their employees from harm due to the various hazards. This can be accomplished by creating awareness of the nature of all hazards in a workplace and carrying out the necessary risk assessments to spell ways of mitigating any of those risks.

Institutions can achieve this by training their staff on occupational hazards, disseminating to all staff all the necessary laws and regulations concerning the hazards, controlling what they can handle, minimizing or reducing the likelihood of exposures to hazards and continuing with con-

stant monitoring of risks and exposures to them. Each institution need to have dedicated staff whose duty is to deal with occupational hazards and guiding fellow staff on how to protect themselves and work safely. Measures have to be put in place to offer the most appropriate methods of disposal of waste as another means of controlling the hazards.

The new challenge of bioterrorism.

With the increasing knowledge on materials and organisms, especially those that are used in research, bioterrorism has become a major threat to national and international security. Samples that are collected for normal research purposes could harbor very dangerous organisms, and if these fall into wrong hands, many people could be harmed.

It has also become increasingly difficult to know in good time when people have changed into or have been influenced into terrorist activities. It is, therefore, very important that employers re-examine their staff time after time to monitor their

What institutions **MUST** do to ensure biological agents and materials do not fall to wrong hands.

The following are some of the things institutions **MUST** do to ensure wrong hands do not have access to dangerous substances:

- (i) Document and record all biological agents in their custody.
- (ii) Filter all agents that come into their facilities.
- (iii) Restrict access to all identified dangerous substances without any complacencies or exemptions.
- (iv) Have particular person(s) who must always bear the full responsibility of the dangerous substances. This person(s) should be constantly monitored, if possible, to ensure safety.
- (v) Develop robust security measures to control entry into and exit from their facilities.
- (vi) Develop an accountability system for each employee or staff.
- (vii) Restrict visitors' access to the premises and when allowed entry, each visitor must be continuously monitored until they leave the premises.
- (viii) Inspect every luggage or package carried by any person (whether employee or visitor).
- (ix) Have only known and approved procedures performed in their premises.
- (x) Transport of dangerous biological substances and their reception should only be done by well-trained personnel specifically assigned that duty. There **MUST** not be any mysterious destinations of any hazardous materials.
- (xi) Only minimal amounts of dangerous biological material should be stored in an institution to meet its requirements; excess of the threshold must be destroyed in a documented manner.

nature. This is quite a difficult task for any institution because no one is exempt from changing into a bad character besides the fact that the usual normal activities and procedures such as disciplinary actions could instantly inspire a negative change in an employee.

These challenges can, however, be overcome when institutions put stringent working measures that prevent easy or common access to any possible bioterrorism agent or material at workplace. These materials and organism ought to be fully documented and inventoried such that their movements, increase or reductions can be promptly detected and dealt with.

Automatic monitoring systems such as CCTV

should be installed at all places where these materials and organisms may be stored or accessed.

Institutions need to be abreast with current knowledge on methods and substances that can be used for bioterrorism and the list need to be constantly reviewed by expert personnel.

Biosafety in Medical Research

Medical research involves the participation of humans, animals or their products, in order to find solutions to the various medical problems and challenges. This requires that any procedures and interventions be carried out in as safe manner as possible using the most appropriate ethical means.

To ensure safety, all forms of medical research



Laboratory biosafety measures-Google Image

have to obtain in-depth understanding of all the materials used in research: their properties and effects when in contact with human or animal tissues.

Biosafety is about safely handling living organisms or their products such as naked DNA that can often be dangerous; this leads to minimizing their risks to human health. Biosafety refers to the containment principles, techniques or technologies and practices that should be used to help prevent the unintentional exposure to pathogens and toxins, or their accidental release. All biological materials must be considered dangerous unless proven safe. This is because no such materials can be deemed safe or dangerous just by looking or holding.

There are several aspects that biosafety in medical research can be considered, including ensuring the toxicity of an agent, environmental effects of biological materials after use, pathogenicity of each organism in case of contact or entry into the body and possibility of allergenicity of each material.

Every medical research personnel should have

adequate understanding of biosafety, including receiving training on all aspects of biosafety before starting their work. During their day-to-day activities, they should practice safe procedures to ensure biosafety. Other unknown effects could also arise and it is important to continue receiving new information about every material used in medical research.

Laboratory Biosecurity

In the laboratory, it is paramount to ensure there is protection, accountability and control of all biological materials so that no unauthorized access, misuse, theft, loss, diversion or intentional release occurs. Laboratory biosecurity aims to prevent both the likelihood of the occurrence of an adverse event involving exposure to biological agents and toxins and the consequence of such exposures.

It is important for the laboratory to consider the possibility that exposures to dangerous biological materials (pathogenic agents and toxins) result from both accidental and deliberate release; both must be prevented.

Role of KEMRI in Occupational Health and

Safety

The Kenya Medical Research Institute plays a very important role in Occupational Health and Safety in various aspects. It has established a strong department set aside for matters dealing with health and safety for the institute as well for its employees. The department has dedicated staff employed solely to deal with health and safety issues, and as a result, the institute proves its big role in embracing health and safety. Many activities targeting the welfare of staff are regularly organized to review occurrences, assessments and associated policies to ensure nothing goes wrong with employees' occupational health and safety.

KEMRI sets the pace and standard for almost all organizations in Kenya by leading in its practices on health and safety, using state of the art equipment for best research, hazard control, disposal, monitoring and control of its materials with which it performs research.

Legally, KEMRI has complied with all statutory requirements on health and safety, including medical cover for its employees, annual medical examination, medical surveillance for employees who may be exposed to hazardous material due to their occupational roles and the general control of all its hazardous materials for research, qualification of practice licenses for its plants such incinerators, generators and productions.

Therefore, many other institutions often visit the various KEMRI centers to learn how they manage, comply and sustain their operations with respect to the staff safety and health.

Bio-risk Management

This would involve a combination of related procedures that include having a database of what bio-risks exist in an institution, employing the right staff who can safely handle the hazards,

continuous research and updating of any new information associated with the biological materials, documenting the storage of any biological materials, restricting access to dangerous biological materials, screening staff into and out of the institutions to ensure safety and developing a very strict security system that should always be reviewed to avoid any mishaps, among many other things we can do to better manage bio-risk.

Ethical issues in Biomedical waste management

Medical research aims to perform technical and complicated procedures to find solutions to many health issues. In the process, there is the usage of dangerous substances that adversely affect human health. Since there are limited alternatives for these procedures, the best available means must be used to prevent harming life and at the same time taking great care on how the byproducts of research will be handled.

Surrounded by the public, research as well as health institutions should develop and use an effective plan to manage their waste. The implementation of such plans must consider the proximities with the people around, avoiding depletion of their environment and prohibiting neglect of caution when disposing any of the byproducts or waste in general.

The benefit of any intervention programs should carefully consider the ethical perception when carrying out disposals. It should be remembered that the way waste is packaged, transported, treated, labeled or destroyed can have an important effect on the overall outcome of any interventions.

Bioterrorism and its implication on national security

As largely mentioned elsewhere, bioterrorism has a major impact on any security arrangements

and organizations. Only people with adequate knowledge about dangerous biological substances have the capability to acquire and use them effectively in a negative way to harm the public. With that in mind, it will be very important to ensure all staff working with biological materials are constantly assessed and certified safe from time to time. Factors that may lead to abrupt or programmed changes in normal humans such as radicalization, should be identified and prevented as much as possible.

Every institution that handles, harbors or transports dangerous biological materials must develop and use strict security measures to prevent any unintended use of its products. They, therefore, need the support and training in conjunction with the national security organs on the best ways to prevent such negative effects of research and healthcare. During budgeting for all research and healthcare operations, the national and the county governments must ensure adequate funding is availed to implement any needed security measures since a single lapse will affect the whole nation or large region. In other words, there is need for security personnel to work hand in hand with anyone handling dangerous biological materials for research or during healthcare to ensure safety.

Biosecurity and Biosafety

7a) Training

This area is often neglected by institutions as they only aim to concentrate on their core businesses. It is true that many health and safety personnel are still ill-equipped with adequate and specific knowledge on most dangerous substances. This is because many have not received the required training for such substances or they have not had enough opportunities to interact and gain experiences working with those substances.

Overcoming this challenge towards the success of biosecurity and biosafety will result into a bigger achievement and prevention of negative effects will be a reality. Every institution has specific challenges depending on what they handle; it is important that their health and safety staff receive specific training on the aspects related to their materials as much as possible to ensure adequate preparedness is achieved for the benefit of the whole organization.

Exchange expertise programs should be encouraged knowing that most formulations of dangerous substances are done away from our local facilities or the information on their uses are crafted in developed countries. Our governments need to support individuals and institutions to train them on all possible aspects of health, safety and biosecurity.

7b) Certification and Accreditation

The way different organizations carry out their day-to-day activities may be similar or different, and unless the national government sets and instills a given minimum standard of operation and then follow up with accreditation inspections, the differences will lead to a disjointed management of biosafety and biosecurity. Most institutions receive accreditation and certifications for other standards but in health and safety, standards are yet to be used in the same measure as the popularly implemented ones. I would recommend, since biosecurity and biosafety are unique entities, institutions are assessed and accredited on the management of biosecurity and biosafety.



ETHICAL ISSUES IN BIOMEDICAL WASTE MANAGEMENT

By Julia Wangui
USAMRD-K

Biomedical waste is a byproduct of biological and medical activities in medical research and healthcare facilities. It is potentially infectious and hazardous in solid or liquid form. Although it can be argued that research data and laboratory results are the most important outputs in biomedical research, biomedical waste is equally important due to the impact of its infectious / hazardous state if not well managed. In 1988, the Environmental Protection Agency (EPA) reported that approximately 3.2 million tons of medical waste was generated every year in hospitals in the United States (1). Biomedical research facilities, clinics and other health facilities equally generate large amounts of waste annually. If not properly managed, the biomedical waste can result in negative health impact to the personnel working in these facilities, visitors and its environs. It can therefore be argued that ethics in waste management is

as fundamental as ethical values in biomedical research and more so proper management can never be overemphasized.

Bio-medical waste is categorized into essentially eight groups; general, infectious / potentially infectious, chemical, sharps, pathological, radioactive, pharmaceuticals and pressurized containers (2-3). Throughout the years, several reported incidents have resulted in immense efforts to ensure that information and processes for the proper management of biomedical waste is both available and pursued. Waste management starts from the point of generation, collection, segregation, treatment, storage, transportation and final disposal. Considering the impact of improperly handled biomedical waste, it is imperative that the personnel at all levels of biomedical waste generation be knowledgeable of the materials and chemicals they are handling, the type

of waste generated, methods of segregation and the suitable neutralizing methods prior to removal from the plethora of primary and secondary sources.

The knowledge of proper waste management though, does not guarantee proper practice of biomedical waste management. A high level of personal and professional integrity, discipline and ethical considerations is imperative to guarantee its proper management. Adherence to standard operating procedures, the organization's code of ethics and the host country's guidance is an important aspect in the diverse disciplines in health and research and therefore waste management. Expounding upon the ethical considerations, there are four ethical codes in relation to biomedical waste that deserve enhanced deliberation. These are: health and safety, green engineering, honesty and service to humanity.

Health and safety:

The first code of ethics described in the National Society of Professional Engineers is "safety, health and welfare of the public" and should be the main priority for all engineers. Since this code is well applicable in biomedical research and toward effective implementation utilizing competency assessment and training, staff are required to have vast knowledge of the materials they are using in their research activities, to understand the hazards and risks these materials pose, understand the type of waste being generated, and finally, the proper management of the waste generated. The use of universal signage language can never be over emphasized in biomedical waste management. Examples of this language include:

It is crucial for staff to ensure that the biomedical waste is managed not only in accordance with



This is a bin used at the point of generation of the potentially infectious and infectious waste (Regulated); the biohazard label and the red bag



The regulated waste on a dolly ready for transportation from the source or secondary storage (5)

the institutional and country's guidelines but also other applicable guidelines. An incident was reported in 1988 of twelve children who were playing with vials of blood found in a trash bin outside the HMO medical office in Indiana. During the time, there was no guideline against disposal of medical waste generated from health clinics in an open dumpster (1). The staff's responsibility extends further than adherence to the stipulated guidelines but also toward ensuring the safety and health of those who may come into contact with the waste generated in our facility. In the instances where there are no guidelines, ethics on safety and health should be the guide in biomedical waste management.

Honesty:

This is critical in biomedical research. It starts with the basic knowledge of proper biomedical waste management, the cons and pros of each method of biomedical waste disposal.

One scenario I found intriguing during my research was an assignment submitted by Mr. Lia Winter. He had been working in Dr. Smith's laboratory and was in charge of waste management. He kept track of the amount of waste generated in the laboratory. During one occasion, he discovered that the waste syringes exceeded the maximum volume his institution allowed for incineration. The syringes contained polyvinyl chloride

(PVC) and there was a regulation on the maximum volume of waste containing PVC material that can be generated in a laboratory. Dr. Smith asked Mr Winter to 'fudge the figures so that the volume could be slightly less than the maximum volume of PVC containing materials. He was faced with an ethical dilemma on what to do. He weighed the four codes of ethics and the implication of wrongly disposed PVC syringes (4).

Lia Winter, did not only consider distortion of the figures immoral, but also considered how incineration of the large volumes of PVC materials would impact on the health and welfare of the citizens. It is our responsibility to be honest, truthful and do the right thing while managing the biomedical waste even when faced with a dilemma between doing the right or the wrong thing.

Service to humanity:

The biomedical waste is an output in the endeavor to serve humanity. How then can this noble endeavor become a curse to those it is meant to serve? Two of the twelve blood vials which the children in Indiana played with were tested and found to be infected with the HIV virus. It is our responsibility to think of the repercussions and benefits of how we manage our biomedical waste.

Dr. Smith requested Mr. Winter to 'decrease the figures' in order to evade paying the fine for exceeding the maximum volume of PVC containing materials allowable. He did not consider the long term cost of this action; the effects of the carcinogenic properties of fumes generated from burning materials containing PVC. Mr. Winter, on the other hand took into consideration the impact of his actions and not wanting to jeopardize his job, his future career and the health of the citizens residing in the area, he came up with a plan.

Green Engineering:

Green Engineering is based on application of

"environmentally conscious attitudes, values and principles combined with science, technology and engineering practice" in order to ensure improved environmental quality. (4) It is therefore important to think of how our methods of medical waste disposal will affect the environment (may pollute the air, contaminate the soil and water). There is a definite need for more methods of reducing the biomedical waste generated in our facility. This is a dilemma that faces many in the endeavor to ensure the safety of personnel, environs and manage waste properly.

In conclusion, while 'safety is every body's business' I would like to reemphasize that 'it starts with me'. It is therefore my responsibility to be informed on the effects of the biomedical waste I generate in the laboratory. Furthermore it is my duty to protect the health of those around me and the environs. My challenge to you, the reader, is what you would do when faced with an ethical dilemma as Mr. Winter's. It is my opinion that since I cannot change what I do not acknowledge, the level of integrity, responsibility is as critical as the level of training and information amongst the staff. Finally, ethical values of an individual will go a long way in making our environment a safer place by ensuring that the biomedical waste is well managed.

Disclaimer: The views expressed in this article are those of the author and do not represent those of the US Army Medical Research Directorate-Kenya, Walter Reed Army Institute of Research or US Department of Defense.

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