THE RELEVANCE OF BIORISK MANAGEMENT IN THE LABORATORY

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Abstract

Biorisk management involves a variety of policies and processes to maintain the biosecurity, biosafety, and biocontainment of those infectious agents and toxins. It is the effective management of risks caused by working with infectious agents and toxins in laboratories. In order to safeguard laboratory personnel, the general public, and the environment from the infectious agents and toxins utilized in the lab, a variety of methods, procedures, and equipment are combined to form biosafety. The precautions taken to prevent the loss, theft, or abuse of toxic substances and infectious agents are referred to as biosecurity. As the anthrax attacks of 2001 shown, infectious diseases and toxic substances can be employed maliciously to harm people or groups. Designing laboratories and safety equipment to successfully contain infectious agents and toxic substances and avoid an unintentional discharge is known as biocontainment. It is a challenging field of study, yet laboratory design is a key component of biosafety. In order to ensure proper containment of all biological materials at all biosafety levels, Biosafety in Microbiological and Biomedical Laboratories outlines highly strict architectural standards for biological laboratories.

INTRODUCTION

In countries with little resources, like Nigeria, biosafety and biosecurity measures have proven challenging due to administrative, cultural, and financial barriers. Diagnostic and research laboratories have made significant advancements in biosafety and biosecurity over the past ten years as a result of increased awareness of biorisk management. Thus, it is more important than ever to find and fix biorisk management gaps. The clinical diagnostic laboratory’s goal is to consistently offer top-notch diagnostic services. Their goals are quality management, constant technical improvement, assurance of workplace safety, and biosecurity. Handling clinical samples that are rated at the highest risk category because of their unknowable nature results in biorisks.

It is logical to think about how to incorporate the biorisk management system given that laboratories are already implementing the Quality Management System from the International Standard Organization and beginning to report its favorable influence on everyday activities. A biorisk management system will enable a laboratory to continue operating at a high quality by proactively decreasing near misses and incidents and increasing the efficiency of the diagnostic process through risk-based biosafety and biosecurity (Shigematsu, 2016).

Public health concerns are raised by emerging and re-emerging pathogens, particularly those that fall within Risk Groups (RG) 3 and 4 and have the potential to result in public health emergencies, such as Bacillus anthracis, Yersinia pestis, filoviruses, or arenaviruses. Depending on the route of infection, these agents can cause severe to fatal disease in humans and animals, posing a high risk to
both individuals and society. To reduce any potential harm to the public’s health, the handling of such substances is often limited to high containment facilities. In Biosafety Level (BSL) 3 and BSL4 laboratories, respectively, RG3 and RG4 agents are handled (WHO, 2004).

SYSTEM FOR BIORISK MANAGEMENT

A method or procedure known as "biorisk management" is used to manage and reduce safety and security risks related to the handling, storing, and disposal of biological agents and poisons in laboratories (WHO, 2006). Lab biosafety and biosecurity procedures are integrated when a biorisk management system is put into place. Maintaining a proper balance between protecting biological materials and sustaining a setting that fosters basic research is crucial (Gaudioso et al., 2006). Also, the company must concentrate on the reasons for nonconformities and look for strategies to continuously enhance biorisk performance inside the organization if it is to guarantee effective and efficient laboratory performance. 7 In this respect, a biosecurity risk assessment could help in methodically identifying and assessing biosecurity threats particular to facilities and could help in defining the necessary level of security (CEN, 2018). So, the results of an assessment help in choosing and prioritizing mitigating actions to lower the risks to a manageable and acceptable level. These solutions could subsequently be included in a biorisk management program.

The European Council for Standardization, which produced the international Laboratory Biorisk Management Standard, defines biorisk as the sum of the likelihood that harm will occur and the seriousness of that harm when the source of that harm is a biological agent or toxin (European Committee for Standardization, 2008). The cause of harm could be theft, misuse, diversion, illegal access, unintended unlawful release, accidental release or loss, or unintentional exposure.

By giving instruction on the appropriate handling and management of pathogens that pose serious health hazards, biorisk reduction entails developing expertise in managing high-consequence diseases (WHO, 2007).

ANALYSIS OF BIORISK

In the diagnostic medical laboratories, there are hazards involved with every procedure. Workers in laboratories that handle clinical samples containing highly contagious organisms run a significant risk of developing infections acquired in the lab. Those who work in microbiological laboratories are at a higher risk than others (Aksoy et al., 2008). Laboratory-acquired infections could be spread via injuries caused by infected needles and sharp cutting tools used in diagnostic procedures. These infections could have a negative impact on laboratory workers’ performance and, in severe situations, result in their death (Weinstein & Singh, 2009). Contagious diseases that are acquired in laboratories have also shown the ability to move outside of the lab and into the general public (Gaudioso & Zemlo, 2007).

According to studies, most hospitals in developing nations, particularly those in Africa, have rudimentary and severely compromised infection control programs because there is a lack of awareness of the issue, a lack of staff trained in infection control procedures, an outdated infrastructure, an inconsistent supply of gloves, masks, and disinfectants, and inadequate laboratory backup (Samuel et al., 2010). It seems unlikely that the situation in the commercial and public clinical diagnostic laboratories, which are a crucial component of the majority of hospitals in Nigeria, will differ.

The containment principles, methods, and procedures used in laboratories to minimize unintentional exposure to infections and poisons or their unintentional discharge have been referred to as laboratory biosafety (WHO, 2006). In different parts of the world, a number of diseases linked to laboratories have emerged, involving both known and previously unidentified substances (Gaudioso & Zemlo, 2007). The safety of the lab staff may not always be guaranteed by the use of protective gear and safety devices alone. The danger of laboratory-associated infections should always be mitigated by a mix of rules and measures for the protection of laboratory personnel. The improper containment and improper disposal of biomedical wastes provide a risk of infection to patients, healthcare professionals, and the general public (Hegde et al., 2007). Moreover, studies have linked proper room ventilation to a lower risk of contracting an airborne virus in healthcare facilities (Knibbs et al., 2011).

In Nigeria, hospitals and diagnostic centers are at the forefront of disease identification. They must be able to handle and recognize biological agents, whether they are well-known or novel. Despite the fact that diagnostic labs are crucial to the battle against infectious illnesses, lab personnel typically encounter numerous occupational risks that could be harmful to their health (Zaveri & Karia, 2012).

It is possible to establish strong biosafety and biosecurity capabilities using a variety of biorisk assessment tools or guidelines, such as the Biorisk Assessment Model (BIORAM) developed by Sandia National Laboratories, the Danish book An Efficient and Practical Approach to Biosecurity, the Food and Agriculture Organization’s (FAO) Safety Laboratory Mapping Tool, and the Biosecurity Self-Scan Toolkit and the Biosecurity Vulnerability Scan, both developed by the N (Sijsnael et al., 2014). There isn’t currently a publicly accessible biosecurity checklist for laboratory inspections, despite the fact that several instruments are
available to evaluate biosafety and biosecurity programs within institutions or to identify biosecurity/biosecurity shortcomings at the national level. Recently, Malaysia recognized the necessity for such a biosecurity checklist to increase its laboratory safety and security capabilities by concentrating on improving biosecurity performances within laboratories to detect and prevent the purposeful release of biological events. Malaysia has requested assistance from the Biological Weapons Conference to create such a checklist (Sijneseael et al., 2014).

In order to forbid the creation, manufacture, stockpiling, and use of biological weapons in conflict, the multilateral Biological Weapons Convention (BWC) was founded in 1972. (Biological Weapons Convention, 2018). Presently, 182 BWC signature nations have committed to putting policies into place that will enhance international collaboration in the area of peaceful biological activity. According to the BWC's sixth review conference, each state party must create a legal framework to safeguard and account for biological materials that represent a threat to proliferation (Biological Weapons Convention, 2018). As part of the European Union Council Resolution 2016/51 supporting the BWC, an Extended Support Program was launched within the framework of the BWC (European Union Council, 2016). This Extended Support Programme discusses the significance of encouraging BWC adherence and strengthening national capacities for carrying out BWC commitments. The Science and Technology Research Institute for Defence (STRIDE), the Ministry of Defence's lead technical organization in Malaysia for the BWC, has indicated the need to address laboratory safety and security as well as establish more reliable systems to prevent the deliberate release of biological agents. Malaysia was one of the signatory parties to be chosen. By creating a thorough biosecurity checklist for laboratory assessments and monitoring, this capacity-building initiative's main goal is to increase Malaysia's capabilities in the field of biosecurity. A customized biorisk management checklist might provide an organized way for enterprises to assess and keep track of their biorisk management strategy, particularly in the context of biosecurity. In this essay, we discuss how Malaysian and Dutch scientists created a biosecurity checklist for laboratory evaluation. The checklist that was presented was the model for the particular Malaysia checklist, but it may also be used as a model for other nations.

Biosecurity

The successful mitigation of the risks that the biological sciences will be intentionally or unintentionally misused in a way that harms people, animals, plants, or the environment includes raising awareness of the dangers and developing an understanding of them. 2016 Novossiolova

In a 2010 information note, the World Health Organization (WHO) defined biosecurity as a comprehensive and integrated approach to analyzing and managing pertinent threats to human, animal, and plant life and health, as well as risks to the environment that are related to those risks. According to another document, the primary objective of biosecurity is "to prevent, control and/or manage risks to life and health as appropriate to the particular biosecurity sector," with the secondary objective being "to enhance the ability to protect human health, agricultural production systems, and the people and industries that depend on them" (INFOSAN, 2010).

Precautions are put in place to reduce the chance of invasive pests or illnesses arriving at a specific region that could harm crops and livestock as well as the larger environment, and these measures often involve mandatory terms of quarantine (Fitt, 2013).

The phrase is now generally understood to refer to controlling biological risks to individuals, industries, or the environment. They could come from exotic or local organisms, but they could also include pandemic diseases and the possibility of bioterrorism, all of which pose risks to the general public's health (Fitt, 2013).

The phrase "laboratory biosecurity" was first used by the WHO in the late 1990s to refer to the prevention of the theft of biological materials from research facilities in response to the threat of biological terrorism (Koblentz, 2010). While laboratory biosecurity is typically understood to mean "a set of systems and practices employed in legitimate bioscience facilities to reduce the risk that dangerous biological agents will be stolen and used maliciously," laboratory biosafety refers to the actions taken "to reduce the risk of accidental release of or exposure to infectious disease agents" (Salerno et al., 2007). Joseph (2017)’s source addendum: "By the unintentional release of a pathogen from containment, whether by direct discharge into the environment or via a laboratory-acquired infection, biosafety focuses on protecting the researcher, their contacts, and the environment. Contrarily, biosecurity focuses on restricting access to pathogens of importance and on the credibility of the scientists who are given this access (thus lowering the risk of an intentional release of a pathogen) and/or access to sensitive data relating to a pathogen's virulence, host-range, transmissibility, resistance to medical countermeasures, and environmental stability, among other things" (Kanabrocki, 2017; NASEM, 2017).

LABORATORY BIOSECURITY PROGRAM ELEMENTS INCLUDE: (Salerno et al., 2007)

Transportation security, information security, program management, material control and accountability, physical
Biosecurity protocols are used to prevent harmful biological materials from falling into the hands of malicious parties because many countries have developed biological weapons for military use and many civilian medical research projects have the potential to be used in military applications (dual-use research) (Koblentz, 2010).

Collaboration between scientists, technicians, policymakers, security engineers, and law enforcement personnel is necessary for biosecurity (Saleno et al., 2007).

Small-scale hazards can escalate quickly due to the emergent nature of newer biosecurity threats, which makes the establishment of effective policy difficult due to the lack of time and resources for analyzing threats and determining the likelihood of their occurrence (Del et al., 2013; Jaspersen & Montibeller, 2015). With time, it’s conceivable that more synergies with various fields, like virology or the detection of chemical pollutants, will emerge (INFOSAN, 2010).

Future policy implementation for biosecurity still has several unknowns. Policymakers must be able to estimate the probability and evaluate the hazards in order to properly plan out preventive policies, however due to the biosecurity issue’s ambiguous nature, it is difficult to anticipate and also entails a complex process because it calls for a multidisciplinary approach. They may face an unanticipated trade-off as a result of the policy decisions they make to handle a current threat (Koblentz, 2010).

Toby Ord, a philosopher, questions whether the current international conventions governing biotechnology research and development regulation, as well as self-regulation by biotechnology companies and the scientific community, are sufficient in his 2020 book The Precipice: Existential Risk and the Future of Humanity (Ord, 2020; Ord, 2021).

EDUCATION’S IMPORTANCE

By addressing societal difficulties, the development of the biological sciences and biotechnology has the potential to help humanity greatly. Yet, it is also plausible that such advancements may be used against one’s own people, as demonstrated by a limited number of bioterrorism occurrences and, in particular, by the several large-scale offensive biological warfare programs run by powerful nations in the 20th century. This problem, known as the "dual-use dilemma," needs to be addressed by a variety of various actions. However, a process of engagement between scientists and the security community, as well as the development of strong ethical and normative frameworks to support legal and regulatory measures that are developed by states, is one way to guarantee that the life sciences continue to generate significant benefits and do not become susceptible to misuse for hostile purposes (Novossiolova, 2016; Whitby et al., 2015).

BIOSAFETY

Because significant outbreaks are caused by widespread infections, biosafety and biosecurity are now essential elements of robust national laboratory systems. The Global Health Security Agenda highlights biosafety as one of the criteria to effectively address infectious disease threats in response to international health security demands. Yet, because of disjointed implementation techniques, biosafety management systems (BMS) in low- and middle-income countries (LMIC) continue to be inadequate. Other reasons for implementation inefficiencies include a lack of resources, a lack of technical experience, excessive equipment expenses, and a lack of political will (Orelle et al., 2021).

Biosafety has gotten more attention in global health capacity development programs since the World Health Organization’s 58th World Health Assembly in 2005 recognized the significance of biosafety. The Global Health Security Agenda (GHSA), an international partnership of nearly 70 countries and significant international organizations (such as WHO, OIE, and FAO) involved in the fight against infectious diseases, is one example of the significant international efforts that have been made to advance a world free from infectious disease threats (Mouille et al., 2018). This GHSA urges nations to transform global health security and make new, specific commitments in support of the International Health Regulations (IHR) (Susanti et al., 2018). The goal of the Global Health Security Act (GHSA), which consists of 11 "action packages," is to lessen the potential for hazardous infections to spread quickly both within and across borders (Bakanidze et al., 2010).

The overarching objectives of the GHSA’s biosafety-biosecurity action package are to: "Implement a comprehensive, sustainable, and legally embedded national oversight program for biosafety and biosecurity, including the safe and secure use, storage, disposal, and containment of pathogens found in laboratories and a small number of holdings across the country, including research, diagnostic, and biotechnology facilities. A cadre of specialists in biological risk management has the expertise to train others in their own institutions. Best practices for strengthened, long-term biological risk management are implemented using widely used instructional resources. The promotion of quick, culture-free diagnostics is a feature of biological risk management. Also, the transfer of infectious materials will be considered (Khan et al., 2016).

The biosafety-biosecurity action plan makes no mention
of particular steps despite these specific goals. Globally, and particularly in low- and middle-income countries (LMIC), there are significant gaps in the design and implementation of the necessary laboratory biosafety and biosecurity programs. These gaps are caused by a number of factors, including variations in national and local infrastructures, funding and priority availability, regulatory frameworks, and accessibility to knowledge, training, and equipment resources (Mouille et al., 2018).

The creation of biosafety management systems has involved numerous institutions, groups, and nations (BMS). An organization can successfully detect, assess, regulate, and evaluate the biosafety and biosecurity risks inherent in its operation by using BMS, which is based on a management system approach (Albertkova et al., 2019). However, they typically have concentrated just on a few essential components of a national BMS due to a variety of limitations, such as time limits, money restrictions, or simply a limited grasp of what a BMS is (Naroeni et al., 2016). Lessons learned from our extensive work in Burkina Faso (creation of a national biosafety guideline, creation of a tool for assessing biosafety and biosecurity, conducting biosafety and biosecurity assessments, creation of national biosafety regulations, and training of national assessors); other collaborations in Armenia, Burundi, Cameroon, Guinea, Ghana, Georgia, Laos, Mauritania (organization of biosafety support, trainings, and/or We offer a conceptual framework defining important stages to meet the biosafety requirements set forth by the GHSA, drawing on our broad global experience. We offer information on how to establish a sustainable biosafety management system (BMS) at the national level in order to successfully increase biosafety and biosecurity capabilities.

**ESSENTIAL FACTORS FOR CREATING A BIOSAFETY MANAGEMENT SYSTEM**

1. Establishing a National Biosafety Committee and selecting a National Biosafety Focal Person and a deputy NBFP
2. Creation of national biosafety and biosecurity policies
3. Monitoring and assessing the framework for biosafety management’s implementation
4. Holding a trainers' biosafety and biosecurity training (for the core team of implementers)
5. Modification and creation of the biosafety training curriculum (for central and decentralized levels)
6. Finding, modifying, or creating a biosafety and safety laboratory assessment tool (BSS-LAT)
7. Use the created BSS-LAT to carry out a nationwide biosafety assessment.
8. Instruction for national BSS officers on BSS-LAT assessment procedures
9. Creation of a national standard for biosafety and biosecurity
10. Implementing cascade biosafety and biosecurity trainings at the subnational level
11. Modification and creation of thorough national biosafety and biosecurity regulations
12. National Standard Operating Procedures (SOPs) for Biosafety and Biosecurity should be modified, developed, and standardized.
13. Examining and ensuring that IATA training and certification are acceptable at the country level.
14. Improving or expanding biomedical engineers' ability to maintain biosafety equipment on a nationwide level
15. Creating and implementing biosafety training programs for initial and ongoing instruction.

**THE CREATION OF TRAINING**

The lack of local knowledge and expertise represents a significant barrier to developing and implementing a national BMS. By educating regional authorities who will represent and lead the BMS, this gap can be closed. There are numerous training programs available that can be given through different methods, including in-person training, online training, and paid training (CDC,2019). Also, a lot of respectable organizations offer biosafety training. We advise nations to make sure training is conducted in accordance with local needs and requirements, that it contains specified themes of interest, and that it is given in accordance with the modalities established by national rules and customs based on our experience. At the very least, these should include chances for assisted discussion and information exchange, simulated exercises that investigate theoretical and practical elements, and training materials in a format that allows updating and customization (such Microsoft Office, Google Docs). Support from outside parties can be advantageous for the initiatives indicated here as well, so long as national leadership and ownership are upheld.

In recent years, a rising variety of remote or virtual training options have become accessible and can even serve as the foundation for curricula (Ndolo et al., 2018). Nonetheless, these instruments should be carefully examined, and preference should be given to high-quality materials that can be customized for the local environment. Public channels like YouTube have also developed into a huge source of training materials, offering a wide range of quality yet being adaptable to inclusion in training courses.

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Laboratory biosafety is described as "the containment principles, technologies, and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release" in the World Health Organization publication Biorisk management: Laboratory Biosecurity Guidance from 2006. It states that "the examination of methods and creation of strategies to limit the likelihood of the occurrence of biorisks" constitutes biorisk management (WHO, 2006).

Laboratory biosafety is associated with the word "biocontainment." The phrase was first used in 1966, according to Merriam-online Webster's dictionary, and was described as "the containment of extremely harmful organisms (such as viruses) usually by isolation in secure facilities to prevent their accidental release, especially during research."

While laboratory biosecurity is typically understood to mean "a set of systems and practices employed in legitimate bioscience facilities to reduce the risk that dangerous biological agents will be stolen and used maliciously," laboratory biosafety refers to the actions taken "to reduce the risk of accidental release of or exposure to infectious disease agents" (Salerno et al., 2007).

TYPES OF CONTAMINATION

The term "PRIMARY CONTAINMENT" refers to the initial container that comes into contact with biohazardous material and serves to protect both the immediate lab environment and the personnel from exposure to infectious agents. Primary containment necessitates the use of adequate safety equipment, such as biological safety cabinets, competent microbiological technique, and appropriate storage containers.

Secondary containment, which is provided by a combination of facility design and operational procedures, is the safeguarding of the environment outside the laboratory against exposure to infectious materials.

First made commercially available in 1950 (Wedum, 1969), biological safety cabinets (BSC) are a common technology used in laboratories working with highly pathogenic agents to enable efficient primary biocontainment. There are three basic levels and types (Class I, Class II, and Class III).

Positive pressure personnel suits (also known as "space suits") serve as the "outside" environment for workers in biosafety suites, which are a collection of laboratory rooms that are roughly similar to big Class III cabinets. A couple of examples are the biosafety rooms at USAMRIID in Fort Detrick, Maryland, and the CDC's Maximum Containment Facility (MCF) in Atlanta, Georgia, both in the United States.

Conclusion

Lab biosafety and biosecurity procedures are integrated when a biorisk management system is put into place. So, the results of an assessment help in choosing and prioritizing mitigating actions to lower the risks to a manageable and acceptable level. Public health concerns are raised by emerging and re-emerging pathogens, particularly those that fall within Risk Groups (RG) 3 and 4 and have the potential to result in public health emergencies, such as Bacillus anthracis, Yersinia pestis, filoviruses, or arenaviruses.

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