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Review Article

Biosafety and Biosecurity Measures in Clinical/Research Laboratory: Assistance with International Guidelines

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Abstract: Nowadays, laboratory biosafety and biosecurity are serious global issues in clinical laboratories and academic research labs. With the high rate of biological harm caused by evolving infectious diseases and bioterrorism, we all are equally responsible for biosafety and biosecurity at the workplace, but it is the main responsibility of governments from all over the world that must raise their awareness and preparedness for detecting and containing hazardous biological agents, this responsibility includes not only providing a biological safe environment for laboratory workers and also biosafety of others in the institution and community. Safe and effective laboratory operations and pathogen handling determine the safety of the laboratory workers, pathogens, and the laboratory environment, these all are the important variables in the successful performance of laboratory assays. The basic concepts of laboratory management, laboratory biosafety, and laboratory biosecurity are addressed in this article. In addition, DURC (dual-use research of concern) is the research that is commenced for lawful reasons that produce knowledge, information, technology, and/or products that can be used for both good and bad aspects. Biosafety and biosecurity measures should be included in the laboratory policy manuals for the guidance of laboratory personnel.

Keywords: Biosafety, Biosecurity, Research/Clinical Laboratory, Biorisk, Biosafety Levels, DURC

1. INTRODUCTION

Biosafety and biosecurity guidelines are the set of policies, standards, and procedures, these are essential for lab personnel who deal with bacteria, viruses, parasites, and fungi. These guidelines are intended to ensure that biosafety and biosecurity policies and procedures are properly managed and regulated at all levels of lab management [1]. Laboratory-acquired infection (LAI) is very common in the world, as underlying reports of LAI showed at the beginning of the 20th century, almost 4,000 LAIs occurred in the year from 1930 to 1978 globally [2]. Many biosafety and biosecurity challenges are encountered in laboratories around the world, and that need to be addressed the proper guidelines of biorisk management for lab workers. The World Health Organization (WHO) has proposed an agent categorization for laboratory use that divides the into four risk groups based on these characteristics, inherent factors, and the mode of transmission. The four groups cover the hazards to both the laboratory staff and the community [3]. In addition, Biosecurity is defined by the World Health Organization as the containment, principles, technology, and practices used to prevent the deliberate abuse or release of microorganisms. It is based on four primary controls are physical, personal, material and information [4]. Life sciences research is meant to be beneficial but could easily be misapplied to cause harm. Biosafety and biosecurity have become now essential elements for laboratories.

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2. LABORATORY BIOSAFETY/ BIOSECURITY MANAGEMENT

It is important to follow the training and guidelines for Identification and controlling the hazardous condition in the lab, and eliminating or reducing the risks of infectious agents for the protection of the lab staff from bio-hazardous material.

2.1 Sample Receiving

Extremely infectious biological specimen such as blood, tissues, body fluids and microbiological culture carries certain infections. These are collected from fields, collection points, and sample collection areas in different healthcare facilities. General guidelines for sample receiving include the following: (1) Check proper labeling (patient's ID/name, date of collection, biohazard label). (2) Receiving Samples with proper personal protective equipment (PPEs). (3) Check Sample condition (Temperature, Volume/amount, biohazard tag). (4) Check sample container or device. The sample will be rejected if; there is any leakage occurred in the sample container [3, 5]

2.2 Sample Processing

Facilities of the clinical & research laboratories are defined as basic-biosafety levels (BSL) 1 to 4. The infectious material is characterized in Risk of four Groups (RGs) based on relevant risk to laboratory workers and the community Table 1 lists the descriptions of the WHO and NIH risk group classifications. This allows all lab personnel to deal with all samples and pathogens responsibly and harmlessly. Samples processing should be performed according to their risk factor of BSL level [5].

3. LAB-BIOSAFETY

A Biosafety plan is a bunch of preventive measures intended to decrease the danger of bio-hazard exposures and reduce the risk of laboratory accidents. A biosafety plan including the group of related components covers lab exercise, primary barrier (personal protective equipment (PPE), biosafety cabinets, and Mechanical Pipetting Devices), and the secondary barrier, such as facility design features, engineering control, facility design, separation of the lab from public access, hand washing stations and standard operating procedures (SOPs). Implemented biosafety programs in the lab should be protecting the lab workers and their families from laboratory-acquired infections, save the environment from contaiminants and maintain the quality of natural environment.

The fruitful biosafety strategy exists on the arrangement of the biosafety committee. The Biosafety committee's role is the execution of the risk assessments, guaranteeing, execution, requirement, and setting up the biosafety levels. Additionally, the committee makes the policy of risk assessment, risk characterization, risk evaluation,

Table 1. Description of the World Health Organization (WHO) and US National Institutes of Health (NIH) risk groups [3, 5].

Risk Groups (RG)	Individual Risk	Community Risk	Descriptions
1st Risk Group (RG1)	Low	Low	Agents that have not been linked to disease in healthy people or animals.
2nd Risk Group (RG2)	Moderate	Low	Agents are linked to comparatively rare diseases, but preventive or treatments are frequently available.
3rd Risk Group (RG3)	High	Low/Moderate	Agents linked to severe human diseases for which there could be treatment and prevention measures (high individual risk but low community risk)
4th Risk Group (RG4)	High	High	Agents that are likely to cause significant or severe human disease for which there are no easily available preventative or therapeutic measures (high individual risk and high community risk)

and risk mitigation.

Biosafety is everybody's duty—the institutional supervisors, the biosafety official(s), the lab administrators, lab technologists/researchers, and other lab supporting staff (housekeeping).

Biosafety policy/program should be made by the upper management, scientists, safety coordinators, security officers, etc [3 , 5 , 7-10].

3.1 Biosafety Level (BSL)

Biosafety levels (BSL) are used to determine which protections are required in a laboratory setting to protect personnel, the environment, and the general public.

3.1.1 Biosafety Level-1 (BSL-1)

BSL-1 involves infectious material or poisons unknown cause infection in a healthy person.

3.1.2 Biosafety Level-2 (BSL-2)

BSL-2 builds on BSL-1, which involves agents causing a moderate risk to personnel, the community, and the environment. For processes with high aerosol potential, work is performed in the Biological Safety Cabinet.

3.1.3 Biosafety Level-3 (BSL-3)

BSL-3 laboratory has special engineering and design features under negative pressure with directional airflow and differential pressure. Only authorized personnel have access to the facility. It involves dealing with biological agents that have the potential to cause serious or deadly diseases by inhalation or other routes. Everything must be handled in a Class II Biological Safety Cabinet.

3.1.4 Biosafety Level-4 (BSL-4)

BSL-4 deals with extremely dangerous and contagious pathogens. Infection from those pathogens is untreatable [4].

4. PERSONAL PROTECTIVE EQUIPMENT (PPE)

Personal protective equipment (PPE) is used in clinical/research laboratories; in this context, PPE includes gloves, surgical masks, gowns, goggles, or a face shield, as well as for special procedures, respirators (N95) [6].

5. BIOLOGICAL SAFETY CABINET (BSC)

BSC has laminar airflow and HEPA (high-efficiency particulate air) filtration. It has designed to contain aerosols produced during work with infectious materials.

5.1 Basic Guidelines for Working in BSC

- Plan work and proceed conscientiously.
- Users must check the certification, expiry date, and other parameters before starting work.
- Do not obstruct the BSC's defensive airflow pattern.
- Until beginning work in the BSC, double-check that the lab doors are locked.
- Make sure the BSC has been running for at least three minutes before beginning work.
- Keep material storage in and around the BSC to a minimum.
- When the cabinet is in operation, restrict traffic in the room.
- Wipe work surfaces with 70% alcohol or any other chemical as per sectional SOPs.
- Wipe each item you need for your procedures with disinfectant before placing it in the cabinet [7].

6. LABORATORY WASTE MANAGEMENT

The organization must ensure that a policy is in place to reduce the amount of clinical waste generated, as well as a good waste management strategy for the natural environment and toxins. Laboratory waste is segregated on-site based on the method for treatment and disposal. Infectious solid and sharp waste is disposed of by incineration while liquid waste is disinfected in kill tanks & neutralization tanks. Non-infectious waste should be in a green bag. Contaminated/ potentially infectious materials except sharps should be in a red bag. Sharps will be disposed of in a sharps container or a danger bin [7-10].

7. SPILL MANAGEMENT

In case of a biological and chemical spill in the lab, before starting to clean up a spill, everyone involved

in the cleanup must assess the extent of the spill and follow the proper cleanup protocol. (1) Take a deep breath, warn others, exit the room, and shut the door. (2) Show the sign for everyone to see (Spill clean-up in progress). (3) Reach the area to begin cleanup after 30 minutes, when the aerosols have settled. (4) Get a spill-control pad (Spill Kit). (5) Put on the proper protective equipment (gloves, gowns, safety goggles, footwear). (6) Pick up any broken glass with forceps or heavy gloves and place it in a sharps bag. (7) Use a disposable absorbent material to cover the spill. (8)Discard infected material into a red autoclave bag after it has absorbed the oil. (9) Clean the area as if it were a small spill. (10) Inform the supervisors/assistants (11) Record the spill on the Incident Reporting Form as well as the monthly Safety Indicators [10-11].

8. LAB-BIOSECURITY

Biosecurity in the lab refers to a collection of protective measures aimed at reducing the possibility of purposeful removal (robbery) of biological material. Nowadays, the world faces new challenges in ensuring public health safety and security in the term of possible domestic and foreign terrorism including the use of harmful biological agents or toxins. The pathogenicity or transmissibility of potential pandemic infections has generated biosafety and biosecurity issues, including potential dual-use risk linked with the exploitation of such research's information or results. [7,12]. A biosecurity strategy addresses the threat that intentional exploitation or the arrival of a natural specialism poses to human and animal health, the environment, and the economy. Such an arrangement incorporates an organization of interrelated components.

8.1 Actual/Physical Security

The facility's physical protection includes access control, a security camera system, and an intrusion warning system. Unauthorized individuals are not permitted to access the lab without prior authorization.

8.2 Personnel Security

Staff security incorporates exceptional status (screening, personality confirmation, instructive/ proficient accreditation confirmation, military assistance confirmation, public criminal checks, and monetary checks) and security interviews.

8.3 Checking/Controlling/Accountability of Materials

Material control and accountability tend to the insider danger and directly implies the staff that works with infectious pathogens and poisons that could be appealing to bioterrorism. Accountability expects coordination, correspondence among materials and persons along with maintaining the records of inventory, pathogens List, equipment, and data record (hard/soft copy).

8.4 Transportation-Protection

The transportation of biological/infectious material outside of an enclosed area, such as an inspection, general safety or symptomatic testing center, or a vaccination development center is referred to as transport protection. The vehicle may be traveling across international borders, within a region, or a similar office. Moving biological material requires (1) ensuring that the prerequisites are met. For transportation (material exchange arrangements, approved beneficiaries, guidelines); (2) preparing the distribution (grouping, bundling, stamping, marking, documents and parcel delivery to the courier) (3) dispatching the board (material exchange arrangements, authorized beneficiaries, guidelines, approved receipt confirmation, the records, and access controls).

8.5 Digital Information Security

Data security suggests to issues the passwords for personal/official computers and laptops.

8.6 Camera Monitoring

A 24 hours camera monitoring facility should be available for the surveillance of illegal activities [12-16].

9. CONCLUSION & RECOMMENDATIONS

It is necessary to increase the knowledge with the requirement of BSL-1 to BSL-4, research/ clinical lab administration, lab biosafety, and lab

biosecurity measures. An approach to deliver biosafety, biosecurity, and the DURC concepts in the laboratory through conduct the lectures series in institutes for life sciences faculties/students/ researchers.

Laboratory biosafety and biosecurity measures are the essential elements of clinical and research laboratories, and their risks should all be considered carefully. Laboratory management, laboratory biosafety measures, and laboratory biosecurity guidelines are all used to protect laboratory personnel, the environment, the product, and the community. The importance of laboratory biosafety and laboratory biosecurity policies must be emphasized. One method to deal with this is to introduce the concept through education, in both life sciences and engineering departments.

DURC's mission is to preserve the benefits of life sciences research while reducing the risk of misusing the knowledge, information, goods, or technologies developed because of such research. Finally, since biosafety and biosecurity are not constrained by national borders, significant debate, and exchange of ideas at the levels of the scientific community, international organizations, and countries should be required to develop a suitable governance mechanism at the international level to prevent the exploitation and abuse of research/ pathogens, as well as to mitigate large-scale biological integrity loss, with a focus on both ecological and human health.

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11. CONFLICT OF INTEREST

The authors declare no conflict of interest.

12. REFERENCES

1. L.M. Bayot, and F.Limaiem. *Biosafely guidelines* 1-3(2019).
2. S. Muneer, H.A. Kayani, K. Ali, E. Asif, R.R. Zohra, and F. Kabir. Laboratory biosafety and biosecurity related education in Pakistan: Engaging students through the Socratic method of learning. *Journal of Biosafety and Biosecurity:* 22-70 (2021).
3. A. N. Zaki. Biosafety and biosecurity level 3 facilites *International Jounal of antimicrobialogests* 70-74 (2010)
4. World Health Organization. Biorisk management: laboratory biosecurity guidance. *Biorisk management: laboratory biosecurity guidance*: 7-15 (2006).
5. WHO. *Laboratory biosafety manual. 3rd ed. Geneva:* World Health Organization (2004). http://www.who.int/csr/resources/ publications/biosafety/ WHO CDS CSR LYO 2004 11/en/index.html. (accessed 25 April 2021)
6. World Health Organization. Rational use of personal protective equipment (PPE) for coronavirus disease (COVID-19): *interim guidance*: 1-4 (2020)
7. World Health Organization. *Risk assessment. 4th ed.* (2020).
8. Public Health Agency of Canada. *Laboratory biosafety guidelines. 3rd ed*. Ottawa:4-10 (2004). http://www.phac-aspc.gc.ca/ols-bsl/lbg-ldmbl/ index.html (accessed 25 April 2021)
9. American Biological Safety Association. http:// www.absa.org/ (2021). (accessed 20 May 2021)
10. Centers for Disease Control and Prevention and National Institutes of Health. *Biosafety in microbiological and biomedical laboratories. 4th ed.* Washington: US Government Printing Office (1999). http://www.cdc.gov/od/ohs/biosfty/bmbl4/ bmbl4toc.htm (accessed 20.May.2021)
11. Center for Infectious Disease and Research Policy: *Review panel finds CDC weak on lab safety* (2015).
12. National Science Advisory Board for Biosecurity (NSABB). *Report Recommendations for the Evaluation and Oversight of Proposed Gain-of-Function Research*:4-57 (2016).
13. WHO. Biorisk management: *laboratory biorisk guidance Geneva:*10-15 (2006). http://www.who.int/csr/ (accessed 25 May 2021)
14. R.M. Salerno, J. Gaudioso, *Laboratory biosecurity handbook 1st ed*. 4-30 (2007).
15. Sandia National Laboratories: *Controlling biorisk manual:*16-40 (2012).
16. T. V. Inglesby, and D. A. Henderson. Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science. A decade in biosecurity. Introduction. *Biosecurity and bioterrorism: biodefense strategy, practice, and science* 10 (1): 5-15 (2012).