Review Article
Advancements in Life Sciences – International Quarterly Journal of Biological Sciences

ARTICLE INFO

Date Received: 27/02/2022;
Date Revised: 14/06/2022;
Date Published Online: 31/07/2022;

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How to Cite:
Huda NU, Munir N, Shahid F, Iftikhar I, Rehman MH et al., (2022). Biosecurity and Biosafety concerns of Research and diagnostic Laboratory under International Guidelines. Adv. Life Sci. 9(2): 151-156.

Keywords:
Biosecurity; Biosafety; Research/Clinical Laboratory; Bio risk; Biosafety Levels; Bio risk; DURC (dual-use research of concern)

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Biosecurity and Biosafety concerns of Research and diagnostic Laboratory under International Guidelines

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Abstract

Currently, academic research labs and diagnostic laboratories are facing a serious issue of biosecurity and biosafety globally. The high rate of mutations and continuous new emerging infectious diseases with the risk of bioterrorism demands that each lab personnel share equal responsibility for biosecurity & biosafety at their work. The primary job of government authorities is to implement a well-organized detection system and limit the spread of hazardous biological agents by providing a biologically safe setting for lab scientists and for the common man in communities and institutes. The safety of lab personnel, lab environment, and pathogens depends on effective and safe laboratory working and pathogen handling which determines the reliable and accurate results of laboratory experiments. The aim of this article is to address the basic components of laboratory biosafety, laboratory biosecurity, and laboratory management. Further DURC (dual-use research of concern) deals with the commencement of lawful reasons to generate information, knowledge, technology, and products that are used for either harmful or beneficial purposes. The precautions are taken to ensure laboratory biosecurity and biosafety should be a part of the laboratory safety policy manual for guidance and implementation for a safe laboratory environment.

Introduction

Biosecurity and biosafety guiding principles are a set of standards, regulations as well as SOPs that are required for the laboratory workers who work with infectious microorganisms. These guiding principles are intended to ensure the proper implementation of biosecurity and biosafety policies and standard operating procedures (SOPs) at each level of the laboratory management system. Historically, at the beginning of the 20th century laboratory-acquired infections (LAIs) were very common and about4,000LAIs were reported globally from 1930 to 1978 [1]. World widely many challenges are encountered regarding laboratory biosafety and biosecurity that must be addressed and need appropriate guidelines to guidelines to control the bio risk for laboratory personnel. The World Health Organization (WHO)has categorized the lab bio risk age into 4 groups based on the mode of transmission, inherent factors, and specific characteristics of the organism [2]. According to WHO, biosafety is the application of confinement techniques, technology, and procedures to reduce the spread of the unwanted pathogen, their toxin exposure, or unintentional release. Biosafety involves administrative controls SOPs, personal protective equipment (PPE), and engineering control. Biosecurity, as per WHO is the personal and the institutional security checks implemented to avoid the failure, misuse, loss, or intentional and accidental discharge of any virus or its toxicity. The main pillars of biosecurity control include information, material, personal and information, material, personal and physical [3].

The purpose of research in life sciences is to benefit mankind instead of its misapplication which can cause harm. So, biosecurity and biosafety are now indispensable elements for all laboratories.

Methods

Literature search and selection criteria

For this review paper, Google web, google scholar, WHO website, CDC and NCBI database were used to get all information. All information from all tools was used to understand the biosafety and biosecurity in laboratory along with the PPEs much better. More than 20 articles were thoroughly studied which were published previously.

Discussion

Laboratory Biosafety/ Biosecurity Management

The lab personnel must follow the training and guidelines in order to identify and control the hazardous condition so the risk of infectious pathogens to laboratory staff could be eliminated or reduced to its minimum level.

Specimen Receiving

Essential safety is required in every department of hospital and laboratories for the minimum risk of infections that is easily affect humans by inhaling the dangerous aerosols, by spillage the dangerous acid and sample that contain virus like COVID 19 [4-5].Blood, body fluids, tissues and microbial cultures are extremely infectious specimen that carries certain infections. In various medical care facilities these are all gathered from fields and areas of sample collection. The following are some general sample collection guidelines: These are some guidelines consist for sample receiving include:

1. Check (ID/name of the patient, date of collection, biohazard label) is proper labeled or not.
2. Personal protective equipment (PPEs) follows while receiving the sample.
3. The condition of sample checks like: (Volume/amount, biohazard tag and temperature).
4. Check the sample container, if any leakage or contamination occurs it will be rejected immediately [2, 6].

Specimen Processing

The Basic-biosafety levels (BSL) 1- 4 explained, facilities of clinical and research laboratories. Risk of four Groups (RGs) is based on the characterization of contagious substance that are relevant to the community and the workers of laboratory, risk group classifications of WHO and NIH are described in the lists of Table 1. This permit all the laboratory personals, deals with pathogens and specimen are not harmful or effective. According to their risk factor of BSL levels samples processing should be performed [6].

Lab-Biosafety

A biosafety policy is a collection of precautionary measures aimed at lowering the risk of laboratory mishaps and bio-hazard exposures. In a biosafety program, the primary or secondary barrier is a set of connected components. Mechanical micropipette tools, biosafety cabinets, and personal protective equipment (PPE) are examples of primary barriers. The secondary barrier includes facility design, facility design features, hand washing stations, lab separation from easy accessibility, and standard operating procedures (SOPs). Biosafety strategies should be implemented in terms of protecting laboratory personnel, their families, the atmosphere from biohazards, and other contaminations related to the laboratory. The productive biosafety system exists on the course of action of the biosafety advisory group. The job of the biosafety advisory group

is the execution of the danger evaluations, requirements, ensuring and establishing levels of biosafety. Furthermore, a board organizes hazards evaluation, risk relief, and threat assessment. Laboratory supervisors, technologists, administrators, and supporting staff are all responsible for biosafety. Biosafety strategy or program should be developed by the upper administration, wellbeing facilitators, security officers and researchers, etc. [2, 4, 7-10].

Risk Assessment

Biosafety levels are classified on the basis of their risk that caused by the pathogens. Two categories of risk assessment are laboratories hazard caused by personnel and pathogen or agent hazards. In laboratory hazards most of the error occur following;

- Method of handling the sample
- Airborne transmission
- Horizontal transmission

In most of the agent hazardous cases, they required the information belongs to their properties and characteristics:

- Source of the infection and spread diseases by their ability
- Which part of agents that leads to pathogenesis(virulence)
- Its origin, life cycle, route of transferring the disease and their treatment procedures [6].

Biosafety Level (BSL)

Biosafety levels are the major source of preventing infectious reactions by different ways. Biosafety levels (BSL) are being used in laboratories to evaluate which precautions are needed to protect people, surroundings, and the general population. Biosafety levels are classified on the basis of their risk levels, contaminants, and their working procedure [6].

Biosafety Level-1 (BSL-1)

BSL-1 elaborates that pathogens that have the unknown etiology and does not harm the individuals severely. The experiment or tests performed in BSL-1 on open benches, no special requirements are needed for such pathogens. The example of pathogens that are to be treated on open benches: *S. cerevisiae*, *E. coli*, *Naegleria gruberi*, and *Bacillus subtilis* [11].

SOPs and PPEs required in BSL-1:

1. Must clean your hands before and after the procedures performed in the laboratory.
2. Instead of using manual pipetting, use the graduated pipettes.
3. Smoking, drinking and eating are not allowed in standardized laboratory. Put on cosmetics, contact lenses are also prohibited.
4. Beware of doing spillage in the laboratory. If this happens follow the SOPs.
5. There is no need to wear gloves in BSL-1 if proper hygiene and handling of specimen is done.

There is no need of the special equipment like biosafety cabinet in the BSL-1 but some of the general equipment in BSL-1 are:

1. Laboratory overalls must be wearing.
2. When there is spillage that effect eyes. To prevent this procedure there must be the eyewash station to remove the hazardous materials from eyes.
3. For cleaning the hands, sink is available.
4. Doors of laboratory must be locked, and the laboratory area detached from other areas.
5. The bench or shelf must be water resistant or water repellent.

Biosafety Level-2 (BSL-2)

BSL-1 is advanced by adding some safety equipment to form BSL-2 that contains the agents that cause the moderate effect on humans and environment. The main cause of infection in BSL-2 is due to direct transmission and the droplets that we inhale. The agents involved in the BSLL-2 are Salmonella, human cell lines, Staphylococcus aureus and *E. coli*. To prevent from infection, we use the biological safety cabinets in BSL-2. SOPs and PPEs in BSL-2

1. Only laboratory staff is permitted to enter in the lab. Hazardous signs are properly labeled according to their nature as chemicals, toxic materials, and sharp containers.
2. Lab staff is trained properly and vaccinated against the agents that are to be treated in the BSL-2.
3. Put on the goggles, mask to prevent from spillage. All procedures are manually written in the lab that are easily be accessed.
4. All experiments are performed in the biological safety cabinets to prevent from infection.
5. Before and after the experiment, all equipment should be decontaminated.
6. The biosafety cabinets of class 2 with HEPA filters are used in BSL-2 [6].

Biosafety Level-3 (BSL-3)

BSL-3 is the advanced form of BSL-1 and BSL-2 with the addition of negative pressure. The agents that are to be treated under BSL-3 are exotic, and causing severe diseases. The pathogens under BSL-3 are, SARS coronavirus, *Chlamydia psittaci* and *Mycobacterium tuberculosis* [11, 12].

SOPs and PPEs used in BSL-3

1. Only trained staff is permitted to enter in laboratory.
2. Performing any procedures that involve handling and manipulating such agents requires the use of a BSC or other physical containment device.
3. The biosafety cabinets used in BSL-3 are of class 2 or class 3 with negative air flow. BSL-3 contains an anteroom for clean storage of supplies, equipment, dress-in, shower-out capabilities; final HEPA filtration of laboratory exhaust air In addition to the HEPA filters already mounted on confinement devices; gas tight filters for laboratory isolation; laboratory waste decontamination; and advanced access control devices (i.e., biometrics) [12-13].

Biosafety Level-4 (BSL-4)

BSL-4 is the most advanced form of other BSL levels. BSL-4 having the pathogens that caused severe infections leads to death with unknown treatment. The pathogens in the BSL-4 are Marburg, Ebola, Lassa Viruses and CCHF (Crimean-Congo hemorrhagic fever) [11-12].

Personal Protective Equipment (PPE)

1. In research or clinical laboratories personal protective equipment (PPE) is used, it includes surgical masks, respirator N95 mask, goggles, gowns, gloves and face shield [14].
2. Biosafety cabinet 3 are used in BSL-4 that contains the fumigation chamber, dunk tank, or equivalent decontamination methods used for those which are not disinfect in autoclave so that it is safely removed from BSCs [14].

Personal Protective Equipment (PPE)

In research or clinical laboratories personal protective equipment (PPE) is used, it includes surgical masks, respirator N95 mask, goggles, gowns, gloves and face shield [15].

Biological Safety Cabinet (BSC)

The biosafety cabinet has HEPA (high-efficiency particulate air) filters and laminar airflow. During work, aerosols are produced in the Biosafety cabinet that contains infectious materials.

Guidelines for Working in BSC

- Ideal performance and continue honestly.
- Before starting the workers must check the certification, other parameters, and expiry date.
- Protective airflow pattern of biosafety cabinet is not blocked.
- While working in the biosafety cabinet check that the laboratory door must be locked or closed.
- Starting the work in the biosafety cabinet it should be on for at least three minutes before.
- Store the material in a biosafety cabinet and slightly place it around it.
- Don't rush in the room when the biosafety cabinet is in working.
- According to SOPs 70% alcohol or a part of other chemicals are used to clean the surfaces of work.
- Before placing it in the cabinet, every item you used during the procedure should be clean with alcohol [8, 15].

Laboratory Waste Management

The association should guarantee that an arrangement is set up to diminish how much clinical waste produced same as administration system for the regular or natural environment and toxins. The technique of research center waste is isolated nearby light for treatment and removal. Fluid waste is sanitized in balance tanks and kills tanks while Sharp waste and Irresistible solid is discarded by burning. Red bag contain infectious material beside sharps it will be discarded in sharp container or bin, while Green bag contains Noninfectious disposal [8,10,11,12].

Spill Management

If the spillage of chemical and biological specimen in laboratory before cleans the spillage everybody associated with the cleanup should evaluate the degree of spill and appropriate protocol must be follow while dealing with spillage. (1) Caution others, take a deep breath, room must be left and stop entry of others. (2) Sign must be placed so that everybody might be able to see (cleaning in process). (3) After 30 minutes reach that area and see the vapor sprayers have settled then start cleaning. (4) Lab must be having a spill-control cushion (Spill Kit). (5) All the PPE (safety goggles, footwear, gloves and gowns) should be followed. (6) Use forceps or heavy gloves in case of glass broken and discard it in sharp bags. (7) To cover the spill used disposable absorbent material. (8) The oil-contaminated infectious material should be disposed of into a red autoclave bag, and the area should be cleaned (9) as if a spill had occurred. (10) Inform the assistants/supervisors. (11) Document the spill on the Incident Reporting Form along with the monthly Safety Indicators [10, 16].

Laboratory-Biosecurity

Biosecurity in the laboratory is referred to as an assortment of defensive measures pointed toward decreasing the chance of determining expulsion (burglary) of biological material. For ensuring public

health security and safety, the world faces new difficulties in the term of likely home and distant fight including the utilization of harmful biological agents or poisons. Whether it is due to contagiousness or the etiology of a potential pandemic, contaminations have posed biosecurity and biosafety challenges, including potential double-use risks in connection with the misuse of such exploration data. The application of biosecurity techniques presents the threat of intentional abuse or the impression of specialized attitudes toward human and animal health, the environment, and the economy. Such an arrangement incorporates the union of interconnected components [17,18].

Actual/Physical Security

The office's actual insurance incorporates access control, an interruption cautioning system, and a surveillance camera system. Without approval, unauthorized people are not allowed to get to the lab.

Personnel Security

Security interviews and security staff integrate outstanding status (personality confirmation, monetary checks educational/capable certification affirmation, military assistance confirmation and public criminal checks).

Monitoring of Materials

Accountability and material control are focused on internal risk and refer directly to employees handling infectious pathogens and poisons that can induce bioterrorism. Responsibilities include maintaining records of inventory, equipment, pathogen inventory and data records (hard copy/electronic copy), as well as material, coordination and person-to-person communications.

Transportation-Protection

Transport assurance refers to the issue of moving infectious or biological material out of an enclosed region, for example, as part of a research, indicative testing community or general security focus or as part of an immunization advance venture. Vehicles may cross borders within a district or comparison office. Requirements for biological material (1) Ensure that the requirements are met. For transportation (approved recipients, rules, material trade courses of action); (2) setting up the circulation (packaging, stepping, checking, gathering, archives, and bundle conveyance to courier); (3) dispatching the board (approved recipients, trade plans of material, supported receipt affirmation, rules, access controls, and the records).

Digital Information Security

Information Security suggests issuing passwords for personal/service PCs and workstations.

CCTV supervision

A 24/7 camera checking office ought to be accessible for the surveillance of criminal operations [9, 19-22].

Conclusion & Recommendations

In order to improve knowledge of Biosafety level 1-4, research/clinical lab administration, biosecurity, and biosafety in laboratories, it is necessary to conduct lectures on the DURC principles throughout the workplace. Clinical and research labs rely on laboratory biosafety and biosecurity for all of their work, and they should consider their risks carefully. To ensure laboratories are safe and secure, management measures, laboratory biosafety measures, and biosecurity guidelines are used. To preserve the benefits of life sciences research while limiting the risk of misuse of knowledge, information, goods, and technologies developed in such research is the mission of DURC. The scientific community, international organizations, and countries need to collaborate and exchange ideas to support the development of a suitable governance mechanism, due to the fact that biosafety and biosecurity do not have national borders. Keeping biodiversity intact and focusing on both ecological and human health is paramount for the international community, as well as working to prevent the exploitation and abuse of research/pathogens.

Competing Interests

The author declares that there is no conflict of interest regarding the publication of this paper.

Author Contributions

Conceived and designed the experiments: SJ, HMR and SJ, HMR analyzed the data: MF, IR and MB contributed materials/ analysis tools: NH, NM, FS and II wrote the paper.

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