# The Importance of Biosafety in the Laboratory Management and the Existed Problem of the Status of the Bio-Biosafety Labs

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# Abstract

Many universities and research institutes have Bio-Safety Labs (BSL). The biosafety laboratory plays an important role in investigating the pathogens and developing the novel drugs. Meanwhile, the management and the construction of the biosafety laboratory is also very important in terms of prevent the infectious microorganisms from transmitting to the external environment. In the past several years, we have made a lot of progress in the biosafety laboratory. However, there are still some problems in the Bio-Safety Labs. In this article, we mainly analyze some of the existed problems and the status. We should take the laboratory biosafety seriously due to its close connection to the public health security.

# Keywords

#### Laboratory Biosafety, Management, Construction, Biosafety Equipment, Protection, Training.

# **1.** Introduction

Infectious disease is a matter that should be concerned by the whole world. It's related to social stability, national security, economic growth and development of human society. Many people have died of the epidemic diseases caused by the pathogens (see <u>table 1</u>). Such as the Spanish flu in 1918, the severe acute respiratory syndrome coronavirus (SARS-CoV) in 2003, the HIN1 flu pandemic in 2009, the Middle East respiratory syndrome (MERS) in 2012, and the latest outbreak of COVID-19[1-4]. Moreover, each outbreak of epidemic disease is likely to result in the global economic crisis. Many families were affected by the epidemics directly or indirectly. So, it's important for every country to pay great attention and provide strong support to ensure the biological safety and the public health security. Biosafety laboratory is the workplace for the researchers and the students to study the known or the potential hazardous pathogens. If the protective measures are not appropriate, there are high risks that the laboratory workers were infected and the infectious microorganisms are spread out to the general public, finally leading to the outbreak of some epidemics. So, the Laboratory biosafety is such an important aspect of the public health security. Although, we have made great efforts to improve the biosecurity measures, there are still some problems we should value.

| Pandemic Disease   | <b>Confirmed Cases</b> | Death Cases          |
|--|------------------------|----------------------|
| 1918 Spanish flu   | 10,000,000,000         | 50,000,000           |
| 2003 SARS-CoV  | 8,000                  | 916                  |
| 2009 HIN1 flu pandemic   | 60,800,000             | 151,700-575400       |
| 2012 MERS  | 2,066                  | 720                  |
| 2019 COVID-19  | 4,534,731 <sup>①</sup> | 307,537 <sup>①</sup> |
| 1) The date was updated to 17 May 2020. The confirmed cases and death cases are still increasing |                        |                      |
| day by day.  |                        |                      |

Table 1 The confirmed cases and death cases of the main pandemic disease[1-4]

The infective microorganisms were classified four risk groups (Risk group 1, 2, 3 and 4) based on the infectivity and the individual and community risk. Laboratory facilities are designated as basic-Biosafety Level 1, basic-Biosafety Level 2, containment-Biosafety Level 3. and maximum containment-Biosafety Level 4. The agent is assigned to which biosafety level should be based on the risk assessment. Only risk group for a particular agent is insufficient for the risk assessment, other factors should also be taken into consideration. Such as pathogenicity of the agent and infectious dose, natural route of infection, stability of the agent in the environment, and so on. Besides, we should also especially pay attention to the following aspects.

# 2. Existed Problems and Status of the Bio-Biosafety labs

#### 2.1 Construction - Infrastructure Assurance

Feasible design principle and substantial construction are the prerequisites for basic security requirements. The layout and the construction of the laboratory should be consistent with national and local development planning, requirement of the environment protection, difference of geography and climate, actual demand of teaching and research. For example, the weather in the south of China is more humid than the weather in the north of China, so the difference of the weather should be taken into consideration when designing and setting the parameters. In this article we especially emphasize the importance of the scientific design and construction. Why do we have mentioned the importance of the lab design and construction? Because you will find there so many problems that you can't solve it at all due to the unreasonable and the impracticable construction. Users should pay more attention to two key points that may lead to potential risks. One point is that the strategies were not assessed adequately by the professionals before the construction. The other point is that the acceptance work is just a form of things. For instance, the ultraviolet lamp should be installed on the roof of the room for all-round surface disinfection, it's a basic and simple common sense for everyone, but there is still biosafety laboratory which was not installed ultraviolet lamp when the laboratory was designed. So, we will have to purchase moveable ultraviolet for regular disinfection. The autoclaves should be installed in the Biosafety Level 2 and higher Biosafety Level lab, which play an important role in the field of disinfection and sterilization. However, there were still someone who didn't installed autoclaves for the biosafety lab. The negative pressure inside the lab can prevent any infectious microorganisms from being transmitted to the outside. The wastes, used centrifuge tubes, tips and other consumables should be sterilized immediately inside the biosafety lab when the experiment was done. Sterilization can eliminate the possibility of the infectious agents transmitted to lab workers, the public and the environment. It is equivalent to take the contaminated materials to the outside artificially if the autoclaves were not installed. These unreasonable design and construction should had been avoided if the program was checked strictly. Improper construction not only increases the difficulty of modification later, but also brings a lot of troubles when you manage the lab. Equally, proper facility design, appropriate containment equipment (including liquid effluent treatment equipment for treating biohazardous liquid waste streams in containment laboratories) should be also taken into account. The disposal of liquid wastes and solid wastes should be treated by properly trained personnel equipped with proper Personal Protective Equipments (PPEs) and devices[5].However, some laboratories have no waste disposal devices. Thus, scientific and reasonable lab construction is an important precondition for running a lab safely.

#### 2.2 Biosafety equipment and personnel protection

Biosafety precaution should become a routine part of laboratory work. Principle investigator, administrator, researchers, and the students should have a consciousness of biosafety concept all the time. Firstly, the correct Biological Safety Cabinets (BSCs) should be selected according to the type of protection needed. The BSCs are designed to protect the operator, the laboratory environment and work materials from exposure to infectious aerosols and splashes that may be generated when manipulating materials containing infectious agents, such as primary cultures, stocks and diagnostic specimens. BSCs, when properly used, have shown to be highly effective in reducing laboratory-acquired infections and cross-contaminations of cultures due to aerosol exposures and the

environment[6]. Installing it in the right place, using it properly, annual certifying its operation, regular testing its performance, well-trained and experienced operators are essential elements to play its protective role during the process of the experiment. It's easier to neglect the routine maintenance if the BSCs can work or without failure alarm. For example, high-efficiency particulate air (HEPA) filters should be changed regularly for the sake of effectively trapping all the infectious agents. HEPA filters can trap 99.97% of particles of 0.3 in diameter and 99.99% of particles of greater or smaller size. Thus, most microorganisms can be removed when the air flow through the HEPA filters, similar to sterilization by filtration. They play an important role in providing sterilized room air for the work surface and preventing the contaminated air flow into the atmosphere. But actually, the HEPA filters may not be never changed for several years or until the service life comes. Such a situation will make the BSCs lose the protective ability for the operating materials, the personnel and the environment. Aerosols are important sources of infection. Accordingly, special attention should be paid to reduce the extent of their formation and dispersion. The most common used safety equipment, personal protective equipment and clothing, laboratory coats, gowns, coveralls, goggles, safety spectacles, face shields, respirators, gloves, pipetting aids, etc. should be prepared enough and be used in the right way to eliminate or reduce certain hazards. The use of safety equipment is no assurance of protection unless the operator is well-trained and operates with the right techniques. The equipment should also be tested regularly to ensure its effective safe performance. We should further emphasize the importance of using safety equipment correctly to our students. Meanwhile, the operators should receive formal training provided by qualified professionals. Disinfection and sterilization are very crucial for biosafety in the laboratory. Perfect disinfection and sterilization could protect the material being operated, the personnel, and the environment from being contaminated or infected by the microorganisms. At present, the main gas disinfectants used in laboratory disinfection in the world are formaldehyde, gaseous chlorine dioxide (GCD) and vaporized hydrogen peroxide (VHP). Because of its high toxicity, lack of environmental friendliness and residue, formaldehyde has been gradually replaced with GCD and VHP[7]. However, you will find only a few laboratories in the universities have gas disinfectants. Most of the pharmaceutical production enterprises are also still using formaldehyde. Formaldehyde is a suspected carcinogen. It is a dangerous, irritant gas that has a pungent smell and its fumes can irritate eyes and mucous membranes. We hope that more ecofriendly, more convenient, safer disinfectants can be designed and applied to the biosafety laboratory for enclosed space disinfection and sterilization to keep the cleanliness of the operating environment. Alcohols, sodium hypochlorite, bromogeramine, hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) and peracids are also commonly used disinfectants for disinfecting and sterilizing. The most effective and reliable way of sterilizing laboratory materials is saturated steam under pressure by autoclaves. This sterilization means could kill all the microorganisms and spores. Otherwise, it is necessary to notice that we should be careful to operating the autoclaves due to the high temperature and pressure during the process of sterilizing. Error operation may lead to the tremendous destruction. In China, the personnel who operate the autoclaves must have passed the examination of the operating license of special equipment in case of the incidence of accidents.

#### 2.3 Training

Human error, irregular operation, poor experimental habits and misuse of equipment are another kind of reasons causing the majority of the laboratory injuries and work-related infections. A formal, continuous, on-the-job safety training programme is essential to maintain security awareness among the researchers, the administrator, the students. For example, the standard usage of pipettes and pipetting aids, the use and limitations of BSCs, the precautions of avoiding ingestion of infectious materials and contacting with eyes and skin, the use of the centrifuges, homogenizers, shakers, vortex mixers, blenders and sonicators, the disposal treatment of glass, sharps, wastes, etc. The operators should receive and grasp all of these technical methods before they carry out their experiments. Laboratory supervisors, with the assistance of the biosafety officer and other resource person, play the key role in staff training. A formal, professional, effective training should take account of the following elements: needs elements, establishing training objectives, specifying training content and media, accounting for individual learning differences, specifying learning conditions, training evaluation and training revision[6]. Actually, most of the laboratories lack of formal and adequate training. Currently, the common way to study the experimental techniques for the new students is learning from the previous students. There is a possibility that the techniques taught by the previous students are wrong and non-standard. This learning approach should be forbidden because of the informal and false training may lead to the occurrence of the security of incidence. A systematical and effective training depends on management commitment, motivational factors, adequate initial job training, good communications, and ultimately the organization's goals and objectives. Training should not be a one-time event. It should be offered regularly and taken recurrently. It should represent an opportunity for employees to refresh their memories and to learn about new developments and advances in different areas[8]. Of course, all of the measures are supported by budget guarantee

# **3.** Conclusion

We have made great progress in improving the situation of the laboratory biosafety in the past several years. The relevant laws, regulations, rules and laboratory biosafety guide have been made to supervise and constrain the biosafety action. President Xi said the biosafety will be integrated into the national security system. The outbreak of COVID-19 will accelerate the speed of the introduction of 《Biosecurity Law》. The draft of 《Biosecurity Law》 made a provision about the management of the laboratory safety. This suggests that we should further strengthen the supervision of the laboratory. However, there are still some difficulties need to be overcame. The dedicated fund for the laboratory biosafety should be established. The special fund can be used for maintaining the laboratory equipment or training the staff and the students. For example, the maintenance of negative pressure of the biosafety laboratory depends on the ventilation system. The air supply and exhaust air filter should be replaced regularly to guarantee the sterilized air and to prevent the biological aerosols discharged from the laboratory from entering the external environment. The purchase, installation and the labor will be a lot of cost. However, we often found there was no money for replace the supplies. Therefore, we should have some special funds to overcome the difficulties of replacing the supplies used for maintaining the working of the equipment. Moreover, we should develop some reward and punishment measures to urge the students to obey the rules. The fact of the matter is the students frequently ignore the rules because of there is no punishment even if they made mistakes in the laboratory. They didn't pay attention to the precaution of the biosafety. As a result, we won't achieve the ideal goal of the training. All in all, we should overcome the obstacles as soon as possible and develop some measures to ensure the laboratory biosafety effectively.

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