

Feeling ill

The Covid-19 pandemic has shaken the world. Millions have perished and many more have suffered its effects. Global economies have faced huge setbacks and many businesses have collapsed. The pandemic has also raised the bogey of bioterrorism. Can such a pathogen be used for terror? Are we protecting our bio research facilities and pathology labs adequately?



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Above: Researchers work with deadly pathogens inside a BSL4 Lab.

Left: Aerosol control platform inside a Class III Biosafety Cabinet at Biosafety Level 4 (BSL-4) laboratory of the NIAID Integrated Research Facility in Frederick, Maryland.

Right: In a Biosafety Level II laboratory setting, a medical scientist is working on the RT-PCR method for the testing of the novel coronavirus at the Department of Medical Sciences.

Col Ram Athavale assesses biorisk management, biosafety and biosecurity in laboratories



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Therefore, the prime question is: are these labs really following protocols for safety and security? And how safe are we from bioterror?

Worldwide, bio research labs handle deadly pathogens, some with the potential to cause a pandemic. Sometimes researchers make pathogens even deadlier in the course of their research.

Many accidents have occurred at such labs. It is essential to understand biosafety and biosecurity and work towards a global harmonised biorisk management for labs.

Biosafety

Biosafety defines the containment conditions under which infectious agents can be safely manipulated. It is the

application of knowledge, techniques and equipment to prevent personal, laboratory and environmental exposure to potentially infectious agents or biohazards.

Global standards for Occupational Health and Safety (OH&S) are laid down for workplace safety (including labs and research establishments) vide ISO 45001:2018.

Labs that deal with pathogens are graded for safety levels. A biosafety laboratory (BSL) encompasses a set of precautions required for manipulating dangerous biological agents in a safe, secure, and enclosed containment setting.

Based on a composite of the design features, construction, containment facilities, equipment, standard practices, and operational procedures required for

working with agents of different risk groups, four biosafety laboratory protection levels are designated (BSL-1, BSL-2, BSL-3, and BSL-4).

Biosecurity

Biosecurity is a strategic and integrated approach to analysing and managing relevant risks to human, animal and plant life and health and associated risks for the environment. Essentially it deals with regulatory and physical security matters.

Ultimately the aim is to enhance national ability to protect human and animal health, agricultural production systems, and the people and industries that depend on them.

The Global standard for Biosecurity is ISO 350001:2019. It defines a process

to identify, assess, control, and monitor the risks associated with hazardous biological materials. This document is applicable to any laboratory or other organisation that works with, stores, transports, or disposes of hazardous biological materials.

Current shortcomings

The health sector is a booming business and received a huge fillip from the Covid-19 pandemic. Pathology labs and testing centres have sprung up practically overnight. Many of these in the unregulated sector offer services at discounted prices.

Technically, Covid-19 sample analysis falls under BSL 3. Lack of proper resources and trained manpower has led to cutting corners in expertise, safety and

security, thereby increasing risks. Even fly-by-night PPE and mask makers offered products to unassuming clients in dire need of safety measures.

There have even been instances where used (contaminated and discarded) masks and PPE were being recycled and sold to earn a fast buck.

In recent years genetic engineering and biotechnology research institutions have sprung up everywhere. Many universities conduct courses on these subjects. Such labs handle many kinds of bio agents and need to be included in the Biorisk Management paradigm.

Given such dire conditions, pilferage and sabotage chances grow exponentially. Terror groups and ill-intentioned individuals have been on the look-out for such opportunities.

Oversight and monitoring

There is an emergent need for all countries to implement a strict and effective oversight mechanism. Regular monitoring of all labs, employed expertise and the type of work they do is essential to prevent any misadventure with lethal pathogens.

Recent years have also seen a growing incidence of accidents and security breaches at well-guarded and well managed bio-containment facilities in the USA (anthrax, West Nile virus, and tuberculosis), the UK (foot and mouth disease (FMD), the USSR (anthrax), Singapore (SARS) and China (SARS and Covid-19).

In 2016, Kenyan authorities foiled a biological terror plot by militants linked to ISIS. The medical interns were using

BIOSECURITY

County labs to separate anthrax for use against Kenyans and EU countries. Alert authorities and Interpol apprehended the group working in Kenya, Uganda and Ethiopia.

Biorisk management

Laboratory biorisk management is defined by the European Committee for Standardisation under CWA 15793:2011. It includes the task analysis, development of strategies and their implementation to minimise the occurrence of biorisks.

It also establishes policies and practices for risk management in the lab (day to day as well as emergencies). An effective lab management system approach should be built on the concept of continual improvement through a cycle of planning, implementing, reviewing and improving the processes and actions that a lab or institution undertakes.

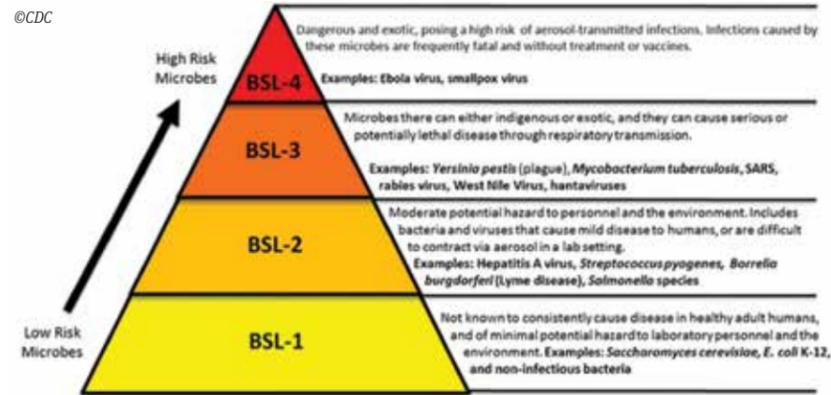
PDCA (Plan-Do-Check-Act)

- **Plan.** Planning, risk and hazard identification and establishing goals
- **Do.** Implementing, infrastructure, training and operational issues
- **Check.** Checking, monitoring, oversight, enforcement and corrective action
- **Act.** Reviewing, including process innovation and acting to make needed changes to the management system.

International outreach

International bodies like WHO, FAO (Food and Agriculture Organisation) and other biosafety agencies are associated with the safe use of biological agents and toxins and highlight the biological challenges and improved awareness.

National initiatives based on obligations of States under the Biological and Toxins Weapons Convention (BWC) and UN Security Council Resolution 1540-2004 pursue common objectives of non-proliferation and prohibition to prevent use of biosciences for bioterrorism or biowarfare. Many countries and regional groups have enacted bilateral agreements to enhance biosecurity and biosafety.



REGULATORY REQUIREMENTS

- Procedures in universities and scientific institutions to monitor research activities to prevent dissemination of information usable for bioterrorism. This should include cyber security
- A policy of outreach to industry to involve it in the process of evolution of biosafety and biosecurity policies, especially in R&D
- A bio intelligence network to identify possible illegal conduct and oversight of life sciences research that can threaten public health or national security
- Legal and institutional procedures and mechanisms for monitoring and regulation.

Preventive measures

Scientists involved in biomedical sciences shoulder larger responsibilities and need to abide by a voluntary code of conduct of research based on the recognised ethical principles and values – and to comply with the requirements of international conventions and treaties relevant to their research work.

Apart from laboratory infrastructure, biosafety measures based on global best practices and preventive measures against accidents, malfunctions and pilferage must all be instituted. Biosecurity is a national security requirement.

Appropriate laws and regulations backed by efficient oversight and enforcement must ensure that advances in life sciences are only used to protect life and not to destroy it.

Education and awareness

Awareness to all those involved in R&D of procedures for laboratory biosafety, biosecurity and biological waste management requires a holistic approach that could include:

- Improved understanding and management of the risks associated with accidental and deliberate misuse of biological agents, including requirements of relevant international conventions and treaties

- Upgrading educational programmes in biology, medicine, microbiology and biotechnology incorporating biosafety, biosecurity and bioethics aspects in accordance with modern international recommendations
- Training in biosecurity, with mock exercises, of trainers, scientists, doctors, pathologists, lab assistants, technicians, laboratory managers, security professionals, bench scientists and all life science students
- Dedicated Biorisk Management training protocol run by a central recognised institution.

Covid-19 has shaken the world out of its slumber in terms of biorisk management. A concerted and coordinated global effort is needed to adequately secure labs and research establishments to prevent accidents and bioterrorism. ■■

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