Introduction To Biosecurity

Practical Medical Biology

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Objectives

- Describe the concept of and need for a laboratory biosecurity programme
- Be able to list components of a biosecurity programme

Introduction :Definitions and concepts

- **Risk**:- A combination of the probability of occurrence of harm (injury, illness, . . death, damage etc) and the severity of that harm.

risk = probability × disutility

- **Biorisk**:- the risk associated with biological materials in the laboratory has a safety and a security component.
- Biorisk encompasses risks from the biosafety and laboratory biosecurity perspective , associated with biological materials.

Key components of bio risk management

- 1. Biorisk Assessment: Process of identifying the hazards and evaluating the risks associated with biological agents and toxins, taking into account the adequacy of any existing controls, and deciding whether or not the risks are acceptable.
- 2. Biorisk Mitigation: Actions and control measures that are put into place to reduce or eliminate the risks associated with biological agents and toxins.
- 3. Performance: The implementation of the entire biorisk management system, including evaluating and ensuring that the system is working the way it was designed. Another aspect of performance is the process of continually improving the system.

Laboratory Biosecurity is Biorisk Management

- Biosecurity measures to protect the release of high consequence microbial agents, biological pathogens, toxins, critical information, pests or diseases as a result of theft or misuse.
- **Laboratory biosecurity** refers to institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins.
- **Biosecurity** deals with the prevention of misuse through loss, theft, diversion or intentional release of pathogens, toxins and any other biological materials.

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Biosafety and Biosecurity

- **Laboratory biosafety** - containment principles, technologies and practices to prevent unintentional exposure to pathogens and toxins, or their accidental release
- **Laboratory biosecurity** - institutional and personal security measures designed to prevent loss, theft, misuse, diversion or intentional release of pathogens and toxins.
- Biosafety refers to the development and implementation of administrative work practices, facility design and safety equipment to prevent the transmission of biologic agents to workers, other persons or the environment

Biosafety and biosecurity

- **Biosafety + Biosecurity = Biorisk management**
- Whereas **biosafety** aims at protecting public health and environment from accidental exposure to biological agents, **biosecurity** deals with the prevention of misuse through loss, theft, diversion or intentional release of pathogens, toxins and any other biological materials.
- The prevention goals of biosecurity are defined independently of the origin of the biological material. It is considered that biosafety and biosecurity are complementary to address biorisk issues. With time biosecurity has become associated with biosafety to form the contemporary approach of “biorisk management”.
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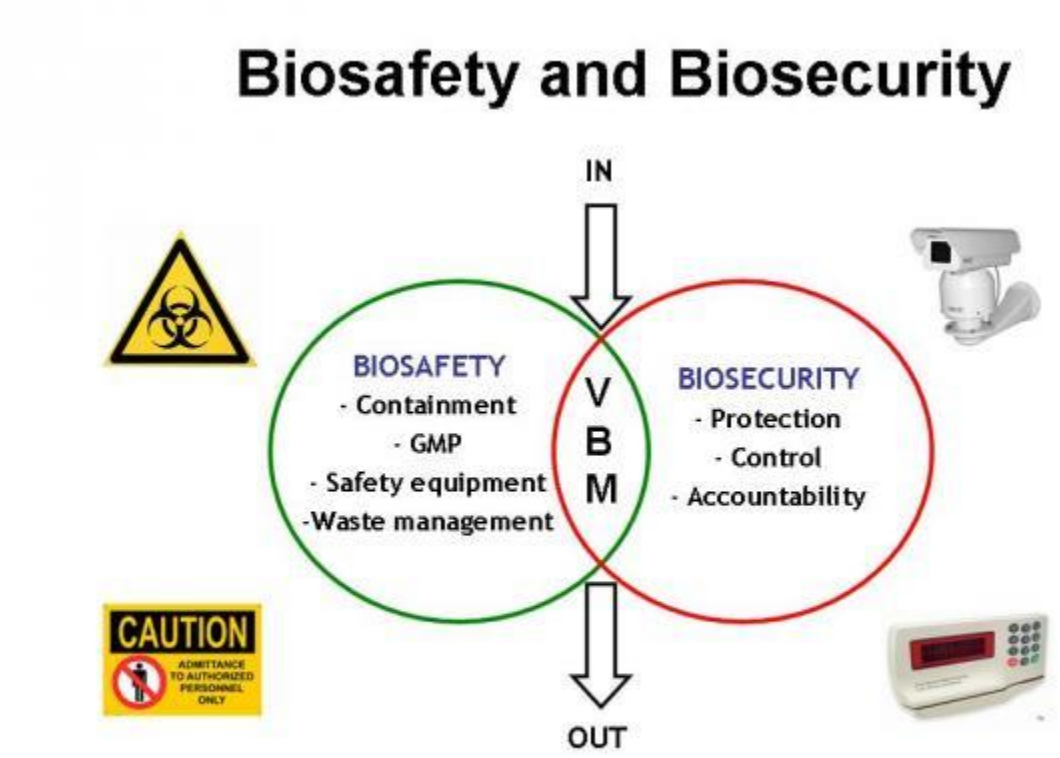
Biosafety and biosecurity

- The main elements of **laboratory biorisk management** system are the following:

1. Risk Assessment,
2. Facility physical requirements,
3. Equipment and maintenance,
4. Occupational Health and medical programmes,
5. Good Microbiological Practices,
6. Emergency response and contingency planning,
7. Personnel and competency,
8. Biological agents and toxins inventory and information,
9. General safety,
10. Clothing and personal protective equipment,
11. Human factors,
12. Accident/Incident investigation,
13. Decontamination, disinfection and sterilization,
14. Transport procedures,
15. Security.



Definitions

- When not specified, the definition are taken from the WHO guidance (WHO/CDS/EPR/2006.6)
- **Accountability:** Accountability ensures that Valuable Biological Materials (VBM, see definition below) are controlled and traced as intended, by formally associating the specified materials with the individuals who provide oversight and are held responsible for them.
- **Biological laboratory:** A facility within which microorganisms, their components or their derivatives are collected handled and/or stored. Biological laboratories include clinical laboratories, diagnostic facilities, regional and/national reference centres, public health laboratories, research centres (academic, pharmaceutical, environmental, etc.) and production facilities (manufacturers of vaccines, pharmaceuticals, large scale GMOs, etc.) for human, veterinary and agricultural purposes.
- **Biorisk:** The probability or chance that a particular adverse event (in the context of this document: accidental infection or unauthorized access, loss, theft, misuse, diversion or intentional release), possibly leading to harm, will occur.
- **Biorisk assessment:** The process to identify acceptable and unacceptable risks (embracing biosafety risks (risks of accidental infection) and laboratory biosecurity risks (risks of unauthorized access, loss, theft, misuse, diversion or intentional release)) and their potential consequences.
- **Biorisk management:** The analysis of ways and development of strategies to minimize the likelihood of the occurrence of biorisks. The management of biorisk places responsibility on the facility and its manager (director). The manager should be able to demonstrate that appropriate and valid biorisk reduction (minimization) procedures have been established and are implemented. A biorisk management committee should be established to assist the facility director in identifying, developing and reaching biorisk management goals.

Definitions

- **Biosecurity**: the protection, control and accountability for Valuable Biological Materials agents and toxins within laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorized access or intentional unauthorized release.
- **Biosafety** (*BE legal definition*): Safety for human health and the environment, including the protection of biodiversity, during the use of genetically modified organisms (or micro-organisms), and during the contained use of pathogenic organisms for humans. A combination of procedures, containment measures and construction technologies with the purpose of minimizing the risk of contaminating laboratories and prevent escape of GMO and/or pathogens into the surrounding environment.
- **Code of conduct, code of ethics, code of practice:** Non-legislated guidelines which one or more organizations and individuals voluntarily agree to abide by, that set out the standard of conduct or behaviour with respect to a particular activity.
- **Contained Use:** any operation in which micro-organisms are genetically modified or in which genetically modified and/or pathogenic micro-organisms are cultured, stored, used, transported, destroyed or disposed of and for which physical barriers, or a combination of physical barriers together with chemical and/or biological barriers, are used to limit their contact with the general population and the environment (definition from the Belgian legal framework).
- **Dual Use**: Dual-use items are goods, software and technology normally used for civilian purposes but which may have military applications, or may contribute to the proliferation of Weapons of Mass Destruction (WMD). Regulation (EU) No 388/2012 of the European Parliament and of The Council of 19 April 2012 amending Council Regulation (EC) No 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.

Definitions

- **Laboratory biosecurity:** Laboratory biosecurity describes the protection, control and accountability for Valuable Biological Materials (VBM, see definition below) within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release.
- **Misuse:** The misuse of Valuable Biological Materials (VBM, see definition below) describes their inappropriate or illegitimate use, despite existing and subscribed agreements, treaties and conventions.
- **Synthetic Biology:** the definition by the SynBio community is "the design and construction of new biological parts, devices and systems and the re-design of existing, natural biological systems for useful purposes" (Schmidt and Pei, 2011).
- **Threat:** The likelihood for an adverse event to occur, as an expression of intention to inflict evil, injury, disruption or damage.
- **Transfer of VBM:** Legal and/or administrative policies and procedures relating to the oversight and approval process for the transfer of custody and/or ownership of Valuable Biological Materials (VBM, see definition below) between countries, entities (organizations, institutions, facilities, etc.) or individuals.
- **Transport of VBM:** Procedures and practices to correctly categorize, package, document and safely and securely transport VBM (see definition below) from one place to another, following applicable national and/or international regulations.
- **Valuable Biological Materials**: Biological materials that require protection, control and accountability (economic, archival, historical, reference). May include: pathogens and toxins, non-pathogenic organisms, vaccine strains, foods, genetically modified organisms, cell components, genetic elements and extra-terrestrial samples.

The Biosecurity Programme

- Should be adapted to needs of the institution
- Should include input from scientific personnel and laboratory management, biosafety officers, maintenance, IT, administrators, and law enforcement

The Biosecurity Programme

- Should be based on a accountability for pathogens
- Storage location
- Identification of personnel with access
- Description of use
- Documentation of transfers
- Inactivation or disposal of materials

Laboratory Biosecurity Programs

- Are intended to protect pathogens, toxins and security-related information from theft.
- Achieved by instituting a culture of responsibility, graded security measures
- restricts access to to dangerous pathogens and toxins to authorized persons and
- establishes accountability over these materials based on assessment of security risks

Institutional Laboratory Biosecurity Protocols

- Should Include how to Handle Breaches or near-breaches in laboratory biosecurity including
- incident notification
- reporting protocols
- investigation reports
- recommendations and remedies
- oversight and guidance through the Biosafety Committee

Biosecurity Protocols

- Should establish means to identify, report, investigate, and remediate breaches in biosecurity.
- Should describe specific training for personnel
- Should become part of routine laboratory work

Biosecurity Challenges

- Ensuring efficient sharing of research and reference materials, specimens and information
- Preventing undue interference with day to day lab activities
- Providing legitimate access to important materials and research
- Assuring compliance with national and institutional standards

Conclusion Laboratory

- biosecurity refers to institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins
- The WHO has published guidance on Laboratory Biosecurity
- Each institution will have a unique biosecurity programme based on identified vulnerabilities

Laboratory Safety and Biosafety

- Risk assessment is an important responsibility shared between laboratory safety personnel, directors, principal investigators, institutional biosafety committees, animal care and use committees, biosafety professionals, etc.
- **Risk assessment is used to**:
- – Identify the hazards associated with a known hazardous or potentially hazardous agent or material
- – Activities that can result in an exposure
- – Likelihood that such an exposure will cause an injury or Laboratory Associated Infection (LAI)
- – Consequences of such an exposure/infection Risk Assessment

Laboratory Safety and Biosafety

- **Risk Assessment**

Primary factors in the risk assessment process:

– Agent/material hazards
– Laboratory procedure hazards
– Capability of lab personnel to control hazards
– Training
– Technical proficiency
– Good habits
– Operational integrity of containment and facility safeguards

Risk Assessment

Chemical Hazards

— Identity of the chemical

– Quantity that is hazardous

– Usual route of exposure

– Type of **hazard(s)**

- Corrosive
- Explosive
- Flammable
- Reactive
- Toxic

✓ How does the chemical act on the body?

✓ Symptoms of over exposure

✓ Physical properties

✓ Chemical compatibility

- **Biological Hazards**
- – Capability to infect and cause disease in a susceptible host
- – Virulence as measured by the severity of disease
- – Availability of preventive measures and effective treatments for the disease
- **Four biosafety levels :**
- – Risk group associated with the agent
- – Laboratory practices and techniques
- – Safety equipment
- – Laboratory facilities/containment
- BSL1 BSL2 BSL3 BSL4

Laboratory Safety and Biosafety

Risk Assessment

- Identify laboratory procedure hazards
- Agent/chemical concentration
- Equipment and procedures that generate small particulates and aerosols
- Sharps
- Procedures involving animals
- Bites, scratches, zoonotic diseases
- Complexity of a laboratory procedure
- Changes in procedures
- New techniques and/or equipment

Risk Assessment

- Select precautions indicated by the risk assessment
- lab practices, safety equipment, and facility safe guards
- Additional safe guards may be warranted
- Laboratory personnel will differ in their susceptibility or sensitivity
- Pre-existing conditions, medications, compromised immunity, pregnancy, breast- feeding, etc.
- Medical Surveillance

Risk Assessment

- Evaluate proficiencies of staff
- Ensure that personnel have technical proficiency – Scientific procedures – Emergency procedures
- Ensure that the necessary safety equipment is available and operating properly
- A non-certified biosafety cabinet represent a potentially serious safety hazard
- A chemical fume that is overloaded presents a serious safety hazard

Risk Assessment

- Laboratory personnel should demonstrate that they know how to handle the agents/materials and the equipment **safely**

Risk Assessment

- Review the risk assessment:
  - Safety/biosafety professional
  - Subject matter expert
  - Institutional biosafety committee
- Review of the risk assessment and the selected safeguards by knowledgeable individuals is always beneficial and often required by regulatory or funding agencies
- Review of high risk protocols should be standard practice
- This step will promote the use of safe work practices in the laboratory

Risk Assessment

- There is no one specific way to conduct a risk assessment, in fact the process can be fairly subjective.
- **The BMBL suggests a five step approach**

– Hazardous Characteristics of Biological Agents
– Identify laboratory procedure hazards
– Determination of the appropriate biosafety level and select additional precautions
– Evaluate proficiencies of staff regarding safe practices and the integrity of safety equipment
– Review the risk assessment

- **Job Hazard Analysis**

– A systematic process for identifying hazards
– Way to prevent workplace injuries
– Establish and document safe job procedures
– Training tool