BIOSAFETY & BIOSECURITY IN LABS

MEHDI EL HARRAK
DVM PhD
Member Of the Biological Standard Commission (OIE)

INTRODUCTION

- New infectious agents and diseases have emerged.
- Work with infectious agents in public and private research, public health, clinical and diagnostic laboratories, and in animal care facilities has expanded.
- Recent world events have demonstrated new threats of bioterrorism.

PRESENTATION OUTLINE

Historic
Definition
Primary barrier
Secondary barrier
Biosafety Classification

HISTORY

1941 - Meyer and Eddie

74 lab associated brucellosis infections in US

1949 - Sulkin and Pike

222 viral infections (21 fatal)

- Only 27% related to known accidents

HISTORY

1951,1965, 1976 - Sulkin and Pike

Surveys for lab-associated infections

- More than 5,000 labs
- Cumulative total of 3,921cases cited
- Most commonly reported:

Hepatitis Brucellosis
Tuberculosis Tularemia
Typhoid Venezuelan Equine Encephalitis

HISTORY

1951, 1965, 1976 - Sulkin and Pike (cont.)

Surveys for lab-associated infections

- **Fewer than 20% associated with known accidents**
- Exposure to infectious aerosols plausible (but unconfirmed) for >80% of reported cases

Most manipulations of liquid suspensions of microorganisms produce aerosols and droplets

Causative incident is unknown. Less obvious exposures such as the inhalation of infectious aerosols or direct contact of the broken skin or mucous membranes with droplets containing an infectious microorganism or surfaces contaminated by droplets may possibly explain the incident.

The accidental release of microbial aerosols is a probable cause of many LAIs, which demonstrates the importance of worker training

BIOSAFETY/BIOSECURITY

- New discipline introduced in 1984

The safe handling and containment of infectious microorganisms and hazardous biological materials

Based on 2 principles:

- **Risk assessment**
- **Containment**

DEFINITIONS

- **BIOSAFETY:** Set of standards and procedures defining all aspects of protection of workers and the environment against **accidental** dissemination of biological agents, including technology to ensure confinement of pathogens (filters, sealed equipment, etc.).

- **BIOSECURITY:** Procedures aimed at avoiding **deliberate** dissemination of pathogens (by theft, diversion or other hostile acts).

WHAT IS BIOSAFETY?

- **Measures employed when handling biohazardous materials to avoid infecting oneself, others or the environment.**
- Achieved through;
  - ✓Administrative Controls
  - ✓Engineering Controls
  - ✓Personal Protective Equipment
  - ✓Practices and Procedures

Laboratory safety is every employee's responsibility!

WHAT IS BIOSECURITY?

- Measures employed to protect biohazardous materials, or critical relevant information, against theft or diversion by those who intend to pursue intentional misuse.
- Achieved through;
  - ✓ Physical barriers
  - ✓ Psychological barriers
  - ✓ Monitoring Activities
  - ✓ Personnel Clearance

WHAT IS A BIOHAZARD?

A potential hazard to humans, animals or the environment caused by a biological organism, or by material produced by such an organism

Mise en présence (volontaire ou non)
d'agents biologiques (identifié ou inconnu)
Avec une ou plusieurs personnes
En un ou plusieurs endroits

Organización Mundial de Sanidad Animal

World Organisation for Animal Health

Organisation Mondiale de la Santé Animale

OIE

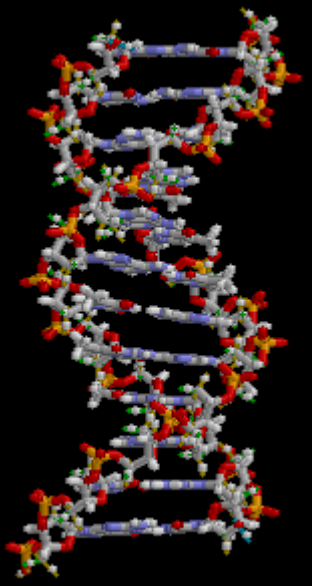
"ANIMAL DISEASES" A HUMAN HEALTH THREAT?

60% Of the >1,700 known pathogens affecting humans are of animal origin.

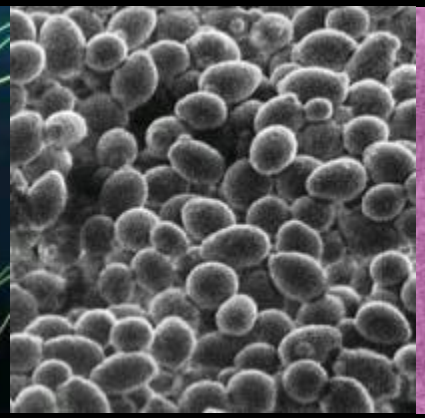
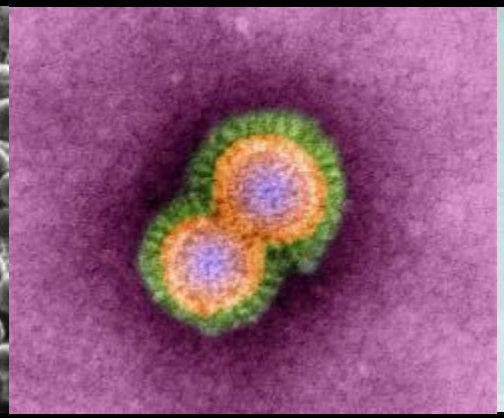
75% Of the 156 pathogens associated with emerging animal diseases can be transmitted to humans.

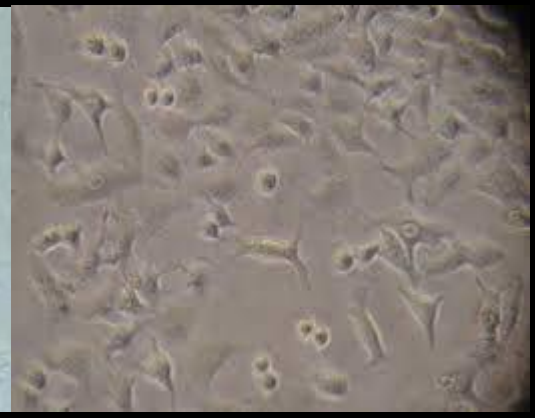
80% agents that can be used for bioterrorism are pathogens of animal origin

BIOLOGICAL ORGANISMS



- Viruses, bacteria, fungi, and parasites and their product.
- Blood and body fluids, as well as tissues from humans and animals.
- Transformed cell lines and certain types of nucleic acids .

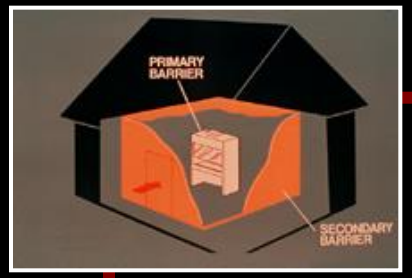


PRIMARY CONTAINMENT

- First line of defence.
- Ensures protection of personnel and immediate environment from exposure to the infectious agent.
- 'Protective envelope' that encapsulates the infectious agent or animal.
  - ✓ Petrie dish, vial, stoppered bottle….
  - ✓ Biological safety cabinets, glove boxes and animal caging equipment, etc.

Effectiveness of control is based on the integrity of the containment.

SECONDARY CONTAINMENT



- Protects the environment external to the laboratory from exposure
- Includes facility design and operational practices

BIOLOGICAL RISK ASSESSMENT

- **Process used to identify the hazardous characteristics of a known infectious or potentially infectious agent or material, the activities that can result in a person's exposure to an agent, the likelihood that such exposure will cause a LAI, and the probable consequences of such an infection.**

- **The information identified by risk assessment will provide a guide for the selection of appropriate biosafety levels and microbiological practices, safety equipment, and facility safeguards that can prevent LAIs.**

BIOLOGIC AGENTS CLASSIFICATION

Classification based on 5 criteria:

1. infectivity
2. severity of disease
3. transmissibility
4. origin of the agent, whether indigenous or exotic
5. nature of the work being conducted

BIOLOGIC AGENTS CLASSIFICATION

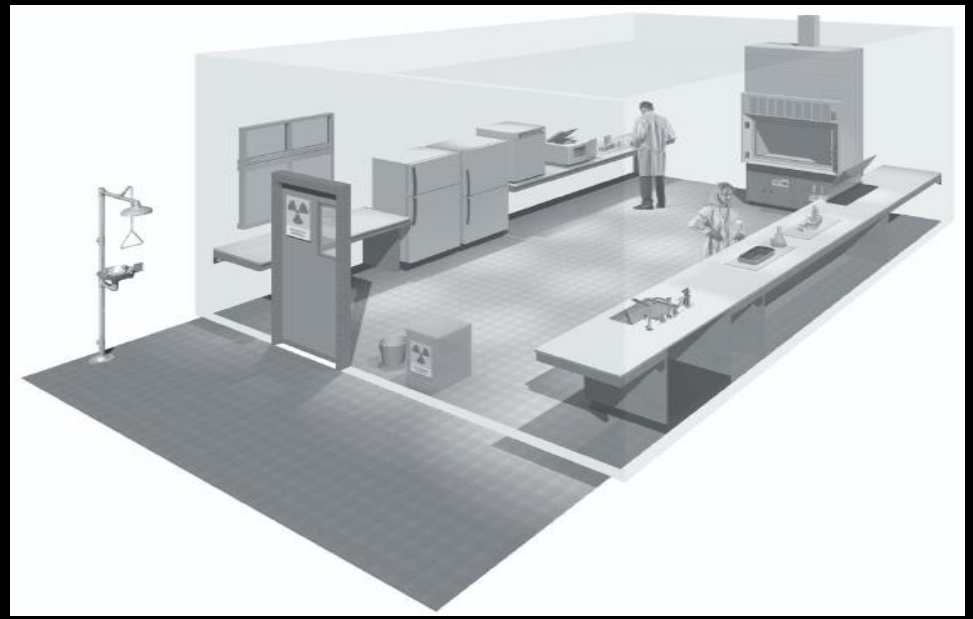
Classification based on six criteria:

1. **Geographical Importance**
2. **interspecies transmissibility**
3. **Existence and Nature of vectors or carriers**
4. **Economic and / or medical impact**
5. **Specific measure (s) (s) of containment .**
6. **Existence of prophylaxis and / or effective treatment**

BIOSAFETY AND BIOSECURITY CLASSIFICATION

CONTAINMENT LEVEL 1

- Basic laboratory
- Requires no special design features
- Biosafety cabinets are not required and work may be performed on the open bench.



BIOSAFETY LEVEL 1

Suitable for work involving well-characterized agents not known to cause disease in healthy adult humans and of minimal potential hazard to laboratory personnel and the environment.

Sink for hand washing
Work surfaces easily cleaned
Bench tops
Sturdy furniture
Windows fitted with fly screens

Examples:
Bacillus subtilis
Naegleria gruberi
Infectious canine hepatitis virus
E. coli

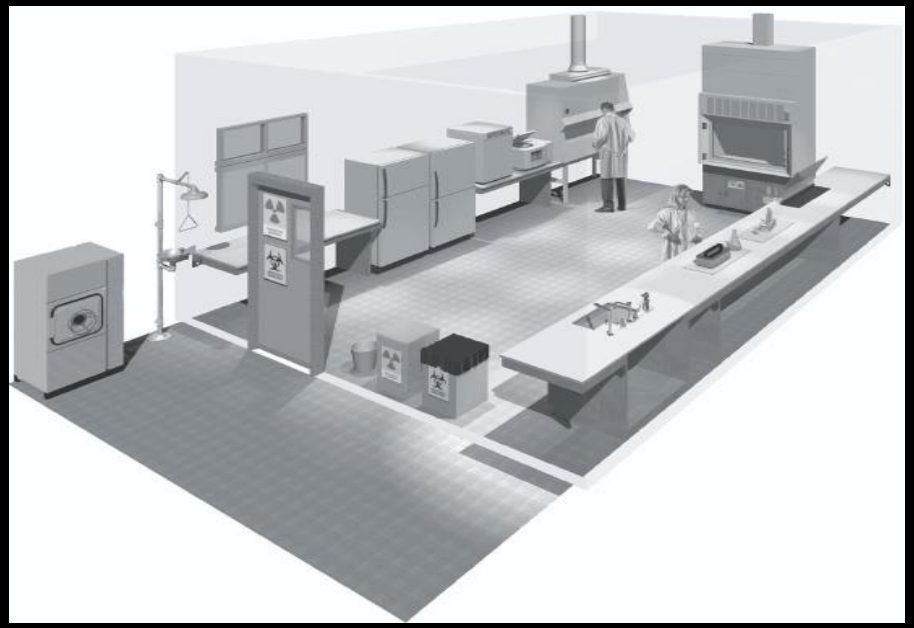
BIOSAFETY LEVEL 1

BSL	Agents	Practices	Safety Equipment	Laboratory Facilities
1	**Not known to consistently cause disease in healthy adults.** Examples: Bacillus Subtilis, Naegleria gruberi, Canine hepatitis.	Standard Microbiological Practices	None Required	Open bench top. Sink Required

CONTAINMENT LEVEL 2

Clinical, diagnostic, research and teaching facilities with level 2 agents.

- Requires a class I or class II biological safety cabinet if any potential for aerosol or splash exists.
- An emergency plan for handling spills must be developed.
- Access should be controlled.



Biosafety Level 2

BSL	Agents	Practices	Safety Equipment	Laboratory Facilities
2	**<u>Associated with human disease.</u>** Hazard of mucous membrane exposure (Liquid borne) Examples: E.coli hepatitis B, salmonellae,	BSL-1 practice *plus:* •Restricted Access •Biohazard warning signs •“Sharps” precautions. •Biosafety Manual for Decontamination	Primary barriers: **Class I or Class II** Biosafety Cabinets or other containment devices used for manipulations of agents that cause splashes/aerosols of infectious materials. Personel Protection required	BSL-1 *plus:* Autoclave must be available

BIOSAFETY LEVEL 2 EXAMPLES

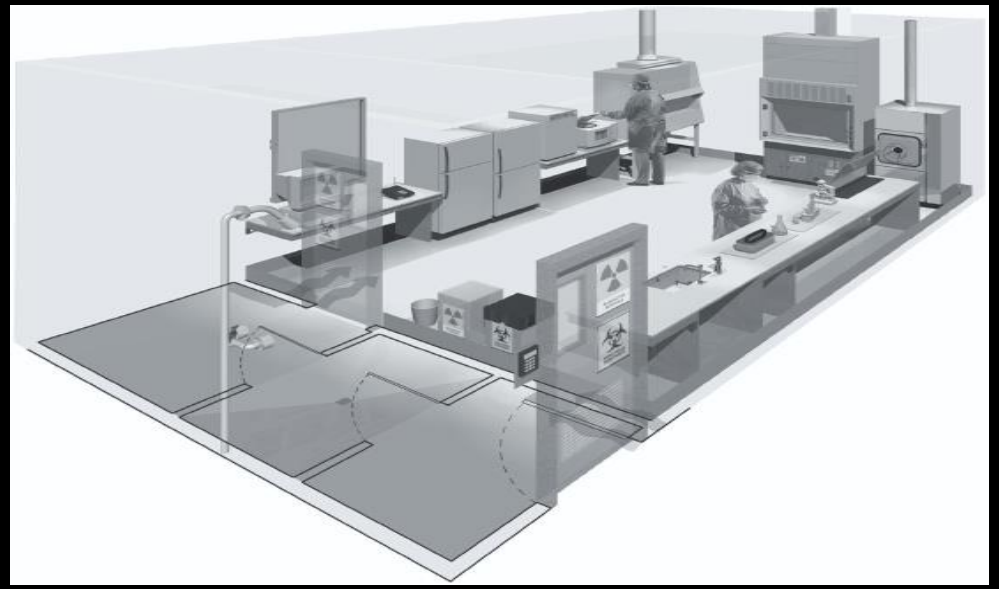
Clostridium botulinum, Cl. chauvoei, Cl. difficile, Cl. haemolyticum, Cl. histolyticum, Cl. novyi, Cl. perfringens, Cl. septicum, Cl. sordellii, Cl. tetani
Corynebacterium diphtheriae, C. haemolyticum, C. pseudotuberculosis, C. pyogenes
Escherichia coli - souches entérotoxinogènes, entéroinvasives et hémorragiques
Mycoplasma pneumoniae, M. hominis
Pasteurella toutes les espèces (à l'exception de P. multocida, type B qui est classée dans le groupe de risque 3)
Salmonella enterica, (S. gallinarum-pullorum)
Staphylococcus aureus

Adénovirus, tous les sérotypes
Coronavirus humains bovin aviaire,
Paramyxoviridae: NCD
Morbillivirus : PPR

CONTAINMENT LEVEL 3

- Specialized design and construction
  - ✓ primary barriers to protect the individual
  - ✓ secondary barriers to protect the environment

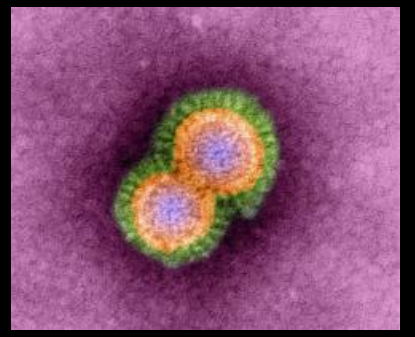
- All staff must undergo special training on the agents being used, PPE, equipment, waste management as well as practices and procedures above and beyond the scope.



BIOSAFETY LEVEL 3 EXAMPLES

Bacillus anthracis
Brucella - toutes les espèces
Coxiella burnetii
Francisella tularensis, type A
Mycobacterium tuberculosis
Pasteurella multocida, type B

Virus de la fièvre de la vallée de Rift
*Flaviviridae**
Herpesviridae
Virus de l'immunodéficience humaine (HIV)
Genre Vesiculovirus
Genre Lyssavirus
Virus rabique des rues
Virus de l'encéphalite équine



BIOSAFETY LEVEL 3

BSL	Agents	Practices	Safety Equipment	Laboratory Facilities
3	**<u>Indigenous or exotic agents. Potential aerosol transmission (air-borne).</u>** Hazards include serious to lethal injuries Examples: anthrax, SARS, Mycobacterium tuberculosis, Q Fever, hanta viruses	BSL-2 practice *plus:* •Decontamination of all waste •Decontamination of lab clothing after usage	Primary barriers: **Class I or Class II Biosafety Cabinets** or other containment devices used for all open manipulations of agents Personnel Protection required: Barrier Protection and respiratory protection	BSL-2 *plus:* Exhaust Air Negative pressure lab space Double-door access Physical separation from access corridors

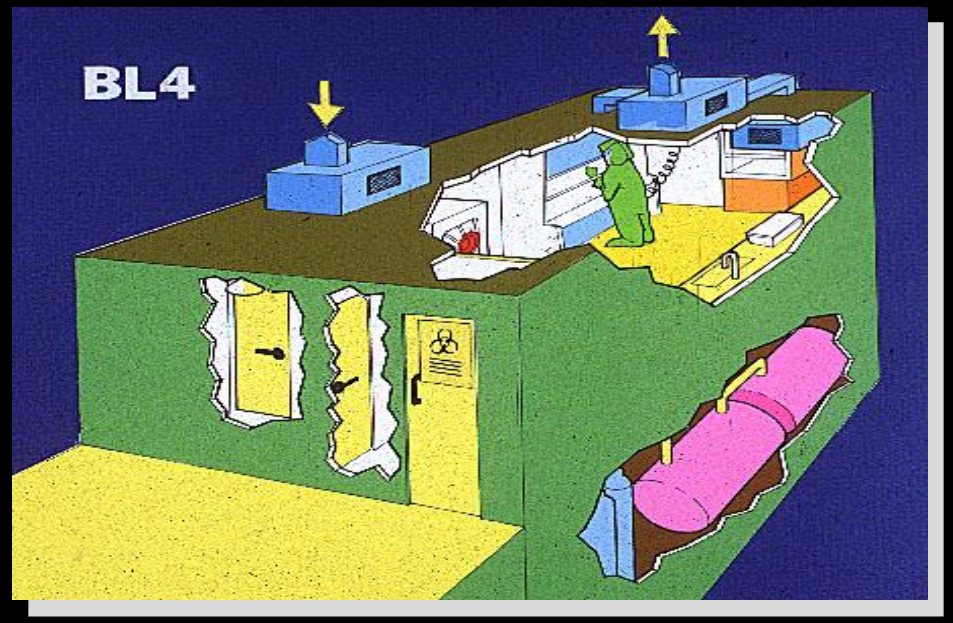
CONTAINMENT LEVEL 4

Design specifications are extremely stringent, worker is completely isolated from infectious material.

GROUPE DE RISQUE 4

Bactéries: Aucun

Virus: Fièvre hémorragique de Crimée-Congo
Virus Ebola
virus de l'herpès B
Poxviridae: Variole



BIOSAFETY LEVEL 4

BSL	Agents	Practices	Safety Equipment	Laboratory Facilities
4	**Dangerous exotic agents. High-risk of life-threatening disease. Aerosol-transmitted and/or unknown modes of transmission** No available vaccine or therapy. Examples: Ebola virus, Foot and mouth disease	BSL-3 practice *plus:* •Clothing change before entering lab. •Shower on exit •Decontamination of all materials on exit from lab	Primary barriers: All Procedures to be conducted in Class III cabinets OR Full-body, air-supplied, positive-pressure personnel suit in combination with Class I or Class II BSC's	BSL-3 *plus:* Separate /Isolated Zone Dedicated supply /exhaust, vacuum and decontaminati system

ANIMAL FACILITIES

- Four standard biosafety levels are also described for activities involving infectious disease work with commonly used experimental animals.
- These four combinations of practices, safety equipment, and facilities are designated Animal Biosafety Levels 1, 2, 3, and 4, and provide increasing levels of protection to personnel and the environment.
- The animal room can present unique problems. In the animal room, the activities of the animals themselves can present unique hazards not found in standard microbiological laboratories. Animals may generate aerosols, they may bite and scratch, and they may be infected with a zoonotic agent.
- The co-application of Biosafety Levels and the Animal Biosafety Levels are determined by a protocol-driven risk assessment

CONCLUSIONS

- **Biohazards** - microorganisms, blood and body fluids, tissues and tissue culture
- **Biosafety** - ensuring that individuals and the environment are not infected
- **Biosecurity** - used in the context of protecting dangerous pathogens and toxins against intentional removal
- Everyone within the community is responsible
- With proper knowledge, planning and care, a biological exposure is avoidable.

The World Organisation for Animal Health

Chapter 1.1.3. **Biosafety and biosecurity: standard for managing biological risk in the veterinary diagnostic laboratory and animal facilities**

Chapter 1.1.4. **Quality management in veterinary testing laboratories**