Biorisk Management Basic-level Materials

Biorisk Management Principles

- ***Biosafety*** **:** containment principles, technologies and practices that are implemented to **prevent the unintentional exposure** to the biological agents and toxins, or their accidental release

- ***Biosecurity*** : protection, control and accountability for biological agents and toxins within laboratories, in order to **prevent their loss, theft, misuse, diversion of, unauthorized access or intentional unauthorized release** (sometimes stressing protection of assets)

Biorisk: combination of

1) the probability of occurrence of harm

2) the severity of harm where the source of harm is a biological agent or toxin

Biorisk Management Model

3 Key Components

1. Biorisk Assessment
2. Biorisk Mitigation
3. Biorisk Performance

Identifying biorisks

measures to reduce biorisk

refining measures to manage/reduce risk to biosafety and biosecurity

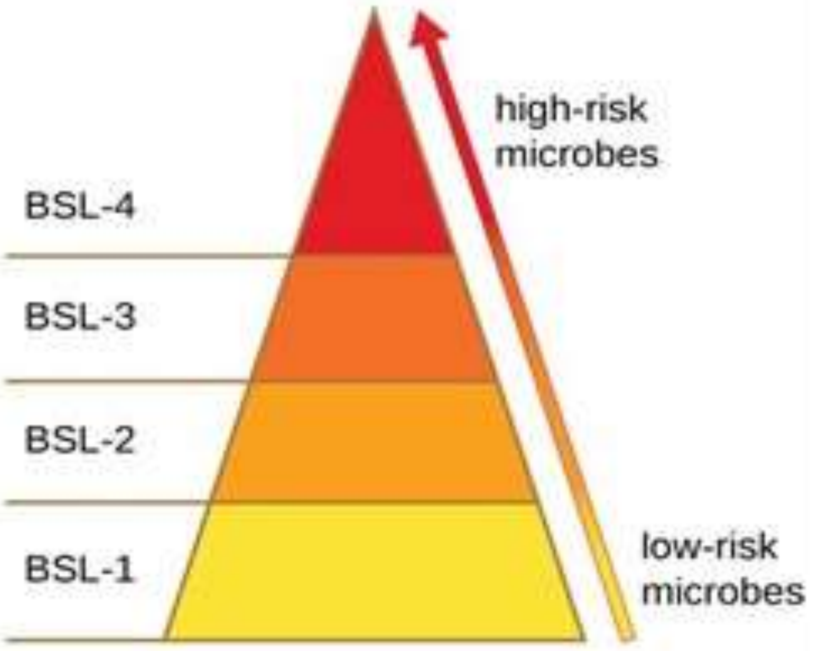
Biosafety

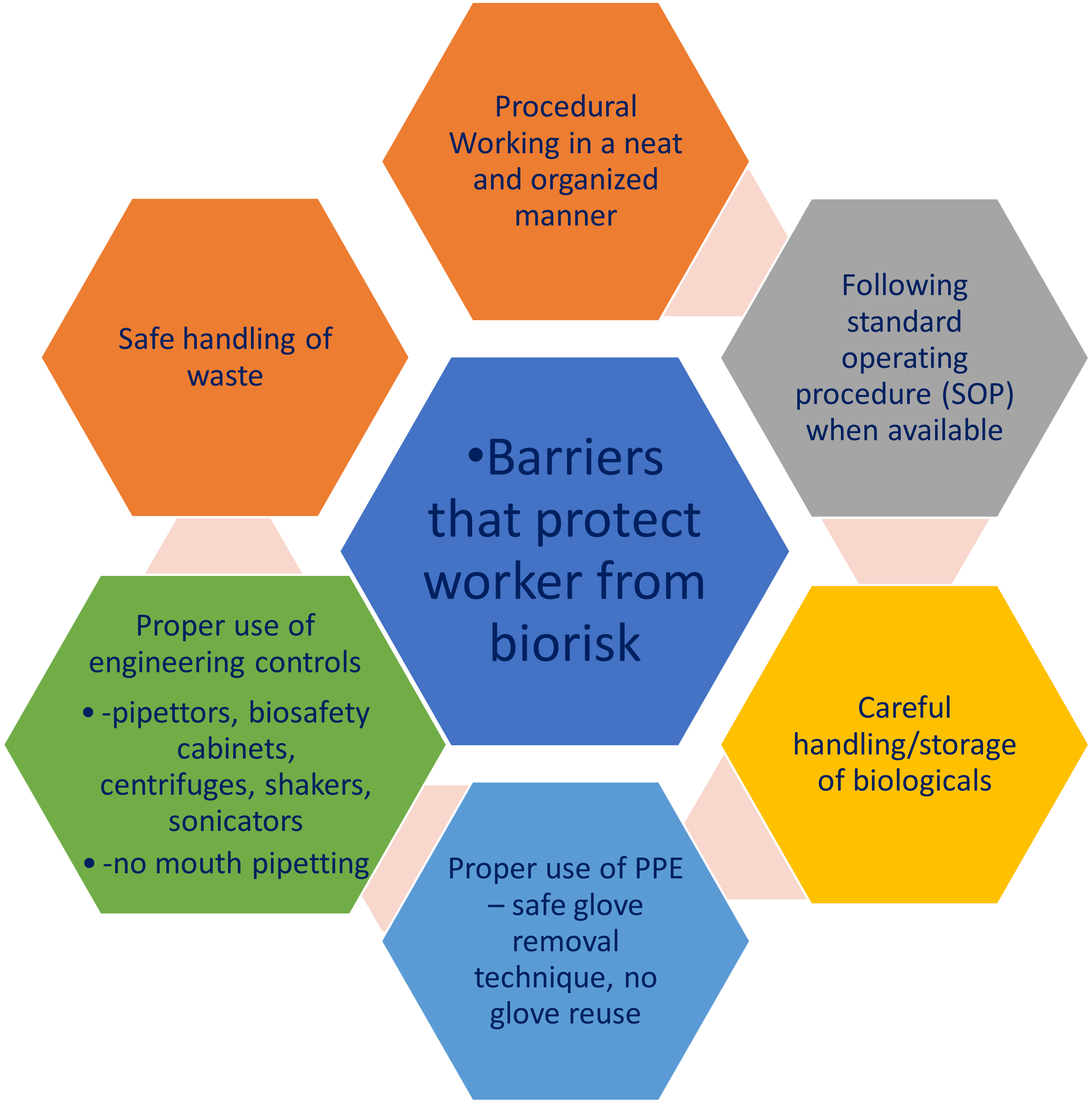
- **Barriers that protect worker from biorisk**
  - ❑ Primary - equipment
  - ❑ Secondary – design of the infrastructure/building
  - ❑ Personnel – qualities of workers (training, vetting)
  - ❑ Procedural – working techniques (general and specific work practices)

- Laboratory biosafety levels (BSL)
  - standards for biosafety stringency
  - Containment Levels 1-4
  - Different containment required for work with pathogens of different risk
  - Provides guidelines on:
    - Facility design
    - Engineering controls
    - PPE
    - General work practices
    - Specific work practices

Biosafety Levels

Biological Safety Levels	Description	Examples	CDC Classification
BSL-4	Microbes are dangerous and exotic, posing a high risk of aerosol-transmitted infections, which are frequently fatal without treatment or vaccines. Few labs are at this level.	Ebola and Marburg viruses	
BSL-3	Microbes are indigenous or exotic and cause serious or potentially lethal diseases through respiratory transmission.	*Mycobacterium tuberculosis*	
BSL-2	Microbes are typically indigenous and are associated with diseases of varying severity. They pose moderate risk to workers and the environment.	*Staphylococcus aureus*	
BSL-1	Microbes are not known to cause disease in healthy hosts and pose minimal risk to workers and the environment.	Nonpathogenic strains of *Escherichia coli*	




Barriers that protect worker from biorisk
Procedural Working in a neat and organized manner
Following standard operating procedure (SOP) when available
Careful handling/storage of biologicals
Proper use of PPE – safe glove removal technique, no glove reuse
Proper use of engineering controls
-pipettors, biosafety cabinets, centrifuges, shakers, sonicators
-no mouth pipetting
Safe handling of waste

DIFFERENCE BETWEEN DISINFECTION AND STERILIZATION

BYJU'S
The Learning App

DISINFECTION

DISINFECTION IS THE PROCESS OF ELIMINATION OF PATHOGENIC MICROORGANISMS. HOWEVER, THE PROCESS IS NOT EFFECTIVE IN CASE OF VEGETATIVE SPORES

STERILIZATION

STERILIZATION REFERS TO ANY PROCESS THAT ELIMINATES, REMOVES, KILLS, OR DEACTIVATES ALL FORMS OF LIFE AND OTHER BIOLOGICAL AGENTS PRESENT IN A SPECIFIED REGION

- Sterilization inactivates all microbes (often done with steam autoclave)

- Disinfection inactivates all or most *harmful* microbes
  - Chemicals are often used on surfaces for disinfection
  - Effectiveness depends on:
    - Chemical (alcohols, chlorine compounds, hydrogen peroxide, others)
    - Concentration of chemical
    - Contact time between chemical and microbe
    - Pasteurization, ultraviolet radiation

Biological Safety Equipment

- Specialized equipment helps reduce risk when working with biomaterials
- Barriers that protect worker from biorisk
    - Primary – equipment
- Personal Protective Equipment (PPE)
    - Gloves
    - Lab coats – washing schedule or disposable
    - Respirators (e.g. N95, not surgical masks) – protect respiratory tract from aerosols
- Liquid pipetting devices
- Instruments
- Sharps containers
- Biosafety cabinets






Biorisk Assessment

- Objective assessment of conditions and the level of risk they present to biosafety and biosecurity
  - Identify hazards and methods to control them
  - Evaluate risks

What steps are performed during biorisk assessment ?????

- Allows risks to be prioritized
- Allows effective plans to mitigate (reduce) and monitor risk
- Allows decision of whether risk is acceptable or not
- What constitutes the hazard severity and its likelihood of occurrence are different for every situation. A matrix of situations should be used when conducting a risk assessment of the lab and to identify methods to reduce risk for both biosafety and biosecurity.

Biorisk Assessment

- Common Risk Matrix

Risk Matrix

		Likelihood of Occurrence			
		Very Unlikely Little or no chance of occurrence	**Unlikely** A rare combination of factors would be required for an incident to result.	**Possible** Not certain to happen but an additional factor may result in an accident	**Probable** More likely to occur than not
Hazard Severity	**Minor** No or minor injury (first aid)	CARE	CARE	CARE	CAUTION
	Moderate Off-site medical treatment or DAFW*	CARE	CARE	CAUTION	ALERT
	Serious More than one DAFW, long-term absence	CARE	CAUTION	ALERT	STOP!
	Major Permanent disability or harm, fatality	CAUTION	ALERT	STOP!	STOP!

*DAFW – Day Away From Work

CARE	Minor harm possible, serious harm very unlikely to occur; implement controls and ensure care is taken when performing activity.
CAUTION	Minor harm probable, major harm unlikely to occur; follow all control measures, increased level of competence required and ongoing self-assessment of risks identified.
ALERT	Moderate degree of harm probable but major harm unlikely; critically assess the risks and appropriate controls. Specific competence required and ongoing assessment of risks by individual and/or supervisor.
STOP!	Serious or major harm will probably occur; stop the activity and critically assess the risks, review safety aspects of activity and implement further, appropriate controls. Consider referencing HSE or other Best Practice, consider involving HSS.

https://www.dur.ac.uk/computer.science/current/healthandsafety/riskassess/raform/genriskassess/

Risk Matrix

https://www.youtube.com/watch?v=-E-jfcoR2W0

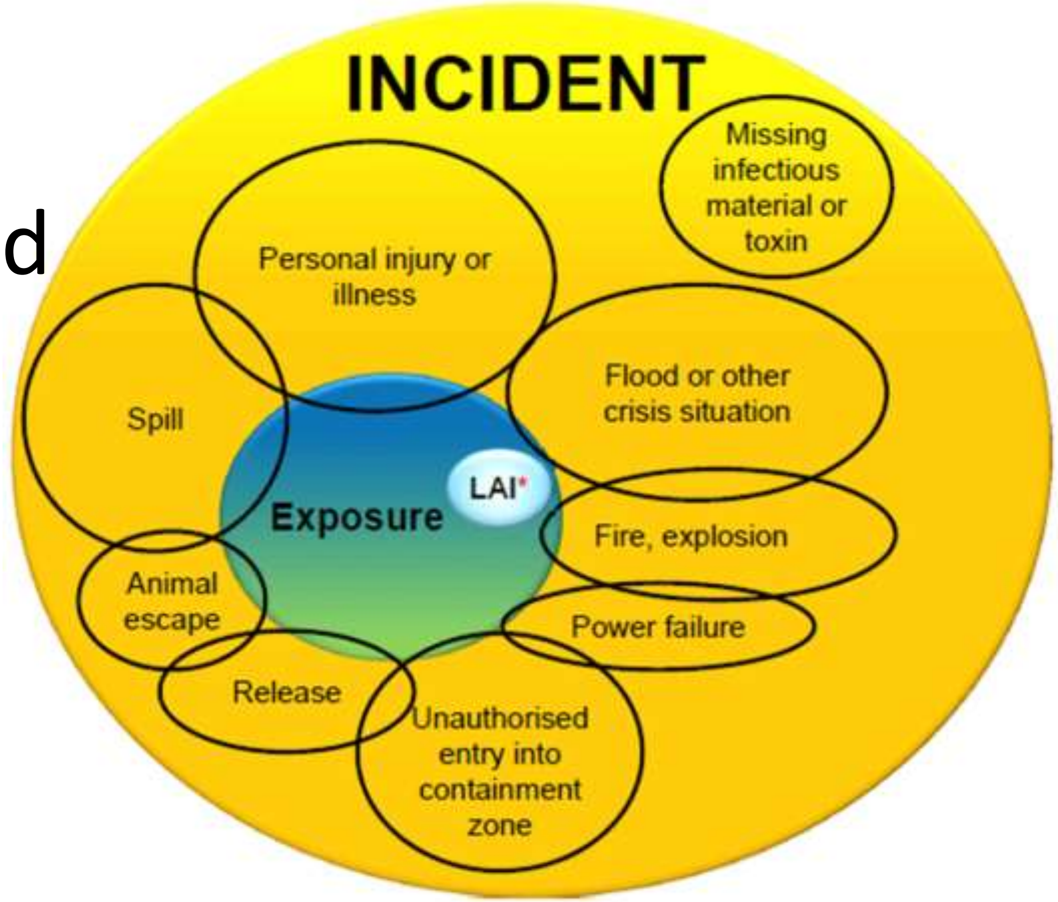
Risk Assessment for Containment Laboratories

- Assessment for containment laboratories
- Barriers that protect worker from biorisk
  - Secondary – design of the infrastructure/building
- Risk assessment - consideration of factors important for containment
  - Locking doors, security
  - Laboratory layout and workflow
  - Air handling and filtration
    - High Efficiency Particular Air (HEPA) filters
  - Handwashing access
  - Biosafety cabinet accessibility and maintenance
  - Sterilization (e.g. autoclave) access
  - Proper signage – post biosafety/biosecurity warnings
  - Containment suits

Risk Assessment for Lab Animal Facilities

- Assessment for lab animal facilities
- Animal biosafety levels mirror concepts for standard biosafety levels
  - ABLS1-4
- Small animal housing can represent containment for infected rodents
  - Disposable cages
  - HEPA filtered racks
- Large animals requires:
  - special facilities, equipment
  - knowledge of their behavior

- Graphic of risks and perceived probability
- Biorisk is dynamic
- Assessment is continuous



Biorisk Administration and Management Best Practices

- Biorisk management requires ethics, diligence, transparency
  - Establish and implement management policies
  - Monitoring and reporting (compliance)
  - Oversee training schedule
  - Record-keeping
  - Biological Agent Use Registration – keep track of biological agents
  - Biomedical waste management

Biorisk management systems, should be able to:

1. establish the *principles* that enable the management and staff of laboratories to achieve their biosafety and biosecurity objectives
2. define the essential *components* that integrate biosafety and biosecurity processes into the laboratory's overall governance, strategy and planning, management, quality management system, reporting processes, policies, values, and culture;
3. describe a comprehensive biorisk management *process* that identifies biorisks (both biosafety and biosecurity risks) and reduces and/or maintains them at acceptable levels.

Biorisk Mitigation

Mitigation = reduction/alleviation

- Biorisk mitigation - practices and equipment that will help reduce the biological risk (e.g. risk of infection)
  - Include all measures to increase biosafety and biosecurity
  - Work practices, PPE, equipment, infrastructure, etc.

- Mitigation of a specific risk - based on the pathogen and the experiments that will be conducted
  - risk assessment helps direct a specific mitigation
  - mitigation can change with scenario

Workplace Immunization

- Immunization to mitigate biorisk
- Risks associated with receiving vaccine must be clearly told to employee
- Storage and testing of pre-immune serum (was the person previously exposed to the agent?, have they been exposed since starting work on or near the agent?)
- Work in certain labs may mandate vaccination against the pathogen (employee has right not to work in the lab)
- Serum antibody titers to be retested at relevant intervals
- If required, must meet vaccination schedule (booster shots)
- Should use federally approved, safety and efficacy tested vaccines, administered by health professional

Transport of Biological Materials

- Biological material must be transported in a safe way to reduce biorisk
- Containment, marking, and transparency is key
- Mailing or shipping of hazardous materials (‘dangerous goods”) is Regulated, and subject to local and international rules and standards
  - Only trained and certified individuals can ship hazards
  - Permits/Licenses required – Agriculture, Health, Trade
- Biological hazards = a hazardous material (i.e. a biorisk)
- Different biological hazards = different shipping requirements
  - Toxins, Infectious, Medical, Genetically modified – different hazard classes
  - Different permits/approvals
  - Different packaging – ensure containment of biologic material
  - Different shipping requirements (routes, transport, contacts, tracking)
- **Rules ensure safety** of the public, environment, agriculture
- Improper shipping of hazards is a Crime (fines, prison)

Laboratory Biosecurity Principles

- Must protect, control and be accountable for biological agents and toxins within laboratories, in order to prevent their loss, theft, misuse
- versus “biosecurity” as referring to protection of assets, e.g. national assets
- Important concepts:
  - Access control – keep out unauthorized individuals
  - Inventory – keep track of biomaterials
- Implementation
  - Door locks
  - Freezer locks
  - Freezer inventories – formal, detailed, current
  - Proper signage

Dual Use Research of Concern (**DURC**)

- DURC recognizes that some materials used in research can also be used for additional (i.e. dual) purposes that are of concern, and ideally avoided

- **Dual Use Research <u>of Concern</u> (DURC): <u>Subset</u> of research that has the <u>greatest potential</u> to generate knowledge, information, or products that could be <u>readily misused</u> to pose <u>significant threat</u> to public health and national security.**

Microbial examples: increasing pathogenicity or transmission, altering host range, reducing host resistance or immunity, reviving extinct microbes

Should facilitate beneficial biological research while mitigating the risks of misuse

Recombinant or Synthetic Nucleic Acid Molecules

- Mankind has increasing ability to modify genetic material of organisms, including combining material from different sources (i.e. recombining) and creating material in (synthetically)

molecules that are constructed by joining nucleic acid molecules and can replicate in a living cell (i.e.recombinant nucleic acids);

nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair
with naturally occurring nucleic acid molecules (i.e. synthetic nucleic acids)

- Novel genetic material which can change biological properties of organisms is generally considered a biorisk, especially when the biological properties are unknown or different in ability to cause disease

- **Recombinant/synthetic molecules are given special consideration in order to manage their biorisk**
  - **Approvals**
  - **Handling/storage/tracking**

Institutional Biosafety Committees (IBCs)

What is an Institutional Biosafety Committee IBC?
Institutional Biosafety Committees (IBCs) were established under the NIH Guidelines to provide local review and oversight of nearly all forms of research utilizing recombinant or synthetic nucleic acid molecules. Infectious agents and toxins , Stem cells and Bio-technologies that could pose a threat,

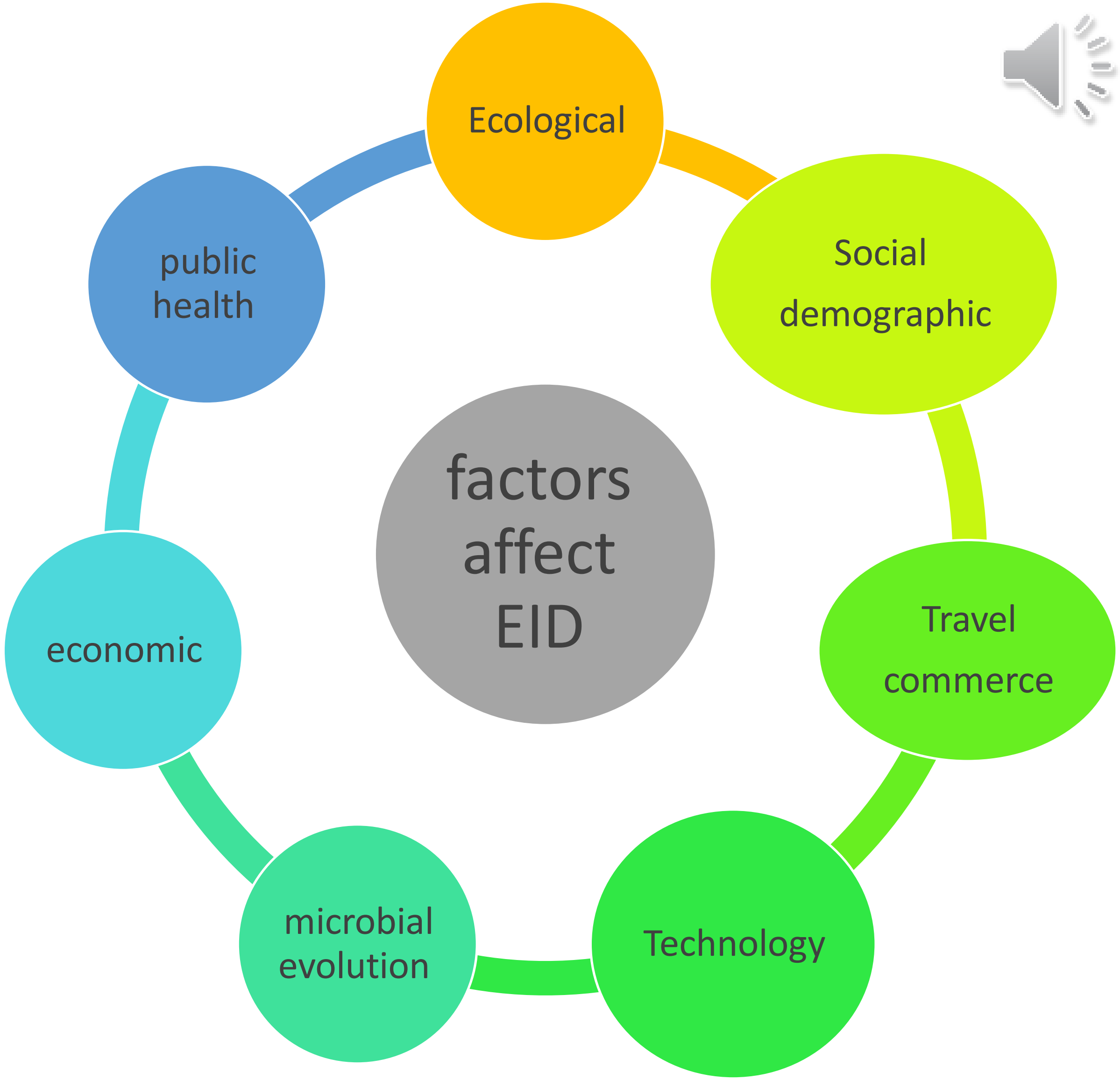
What is the role of the Biosafety Committee?
The **Biosafety Committee** is a standing **committee** established by the Provost to: Ensure that all activities involving biohazardous materials are conducted in compliance with federal, state and local regulations and applicable University policies.

What is IBC protocol?
IBC protocols are intended to ensure compliance with Federal Regulations outlined in the NIH Guidelines for Recombinant DNA, which ensure that novel, dangerous organisms are not created by genetic engineering.

Emerging Infectious Disease (EID)

The World Health Organization (WHO) defines an **emerging infectious disease** (**EID**) as "one that has appeared in a population for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range"

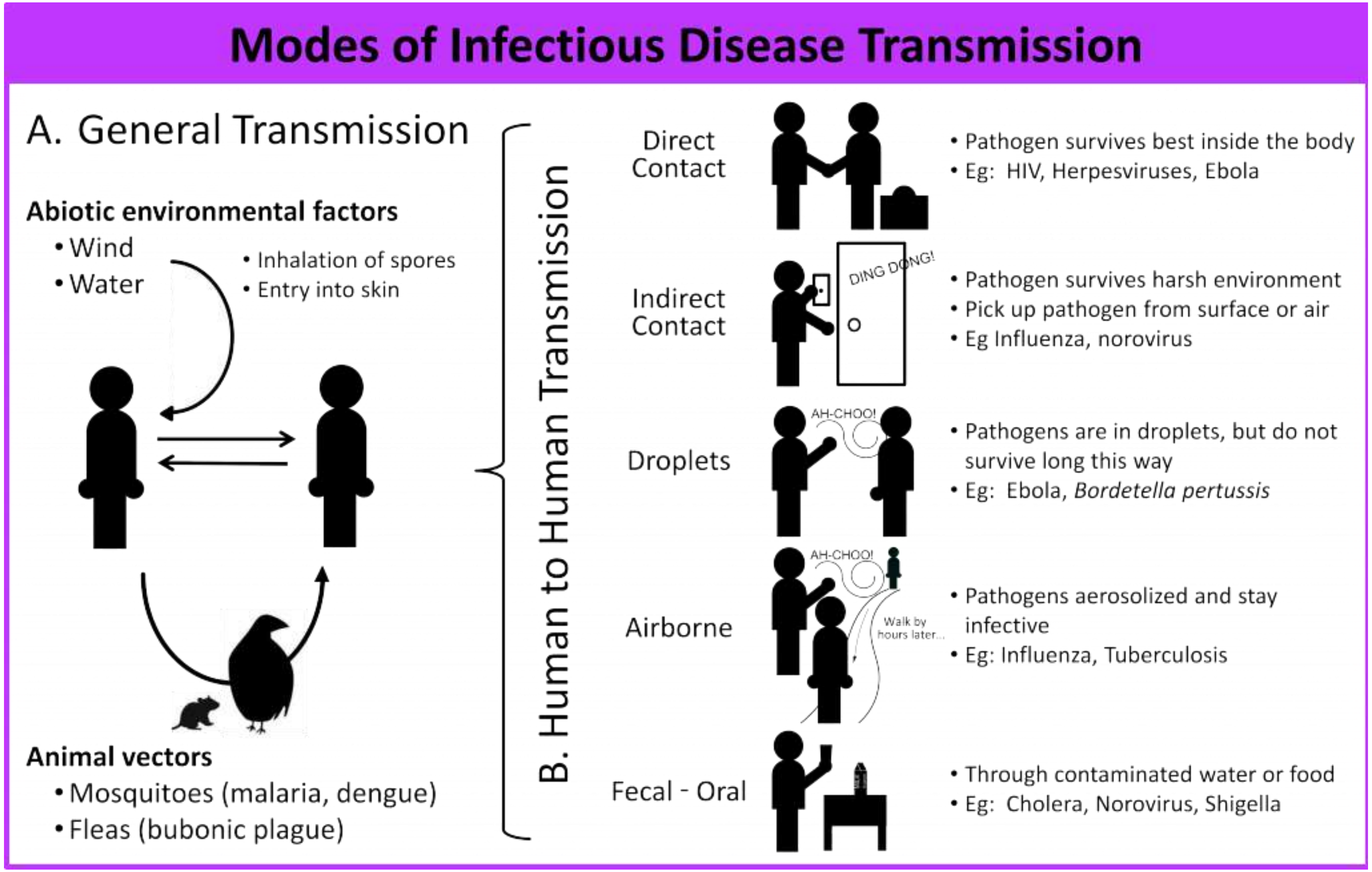
- Global mobility (travel/trade) can accelerate EID spread
- Zoonosis (diseases affecting both animals and people) important in EID
- Example : Covid -19



- Different EIDs can have different impacts: health (mortality), economic, social
- EID risk can be real, but can also be • sensationalized by media
- Nature and severity of the EID, impacts severity • of control measures
- Efficiency of EID Transmission between people: • impacts disease spread and control
- Example: Covid-19 •

Emerging Infectious Disease (EID)

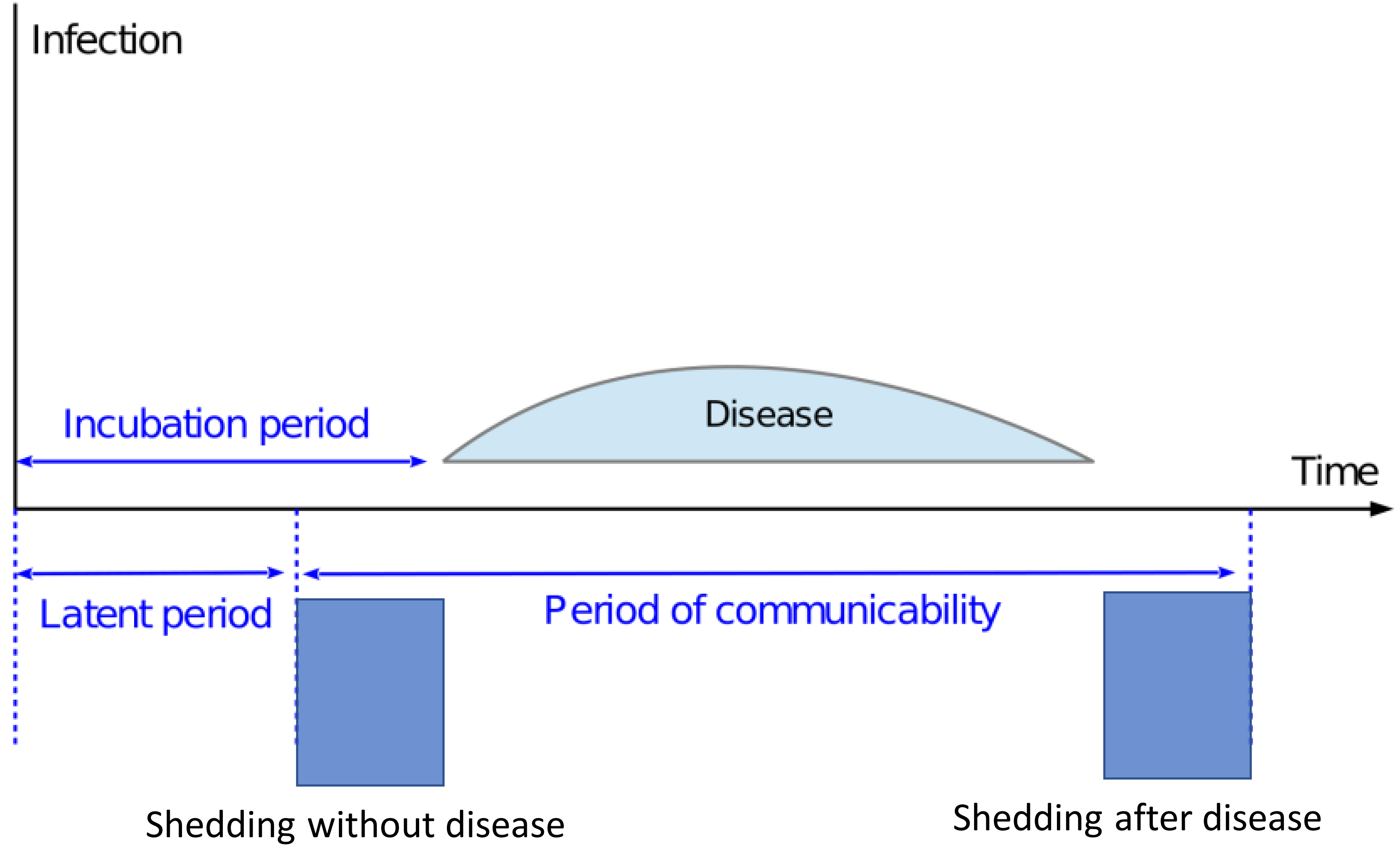
- Disease transmission affects EID impacts



http://sitn.hms.harvard.edu/wp-content/uploads/2014/12/Figure3-1024x651.png

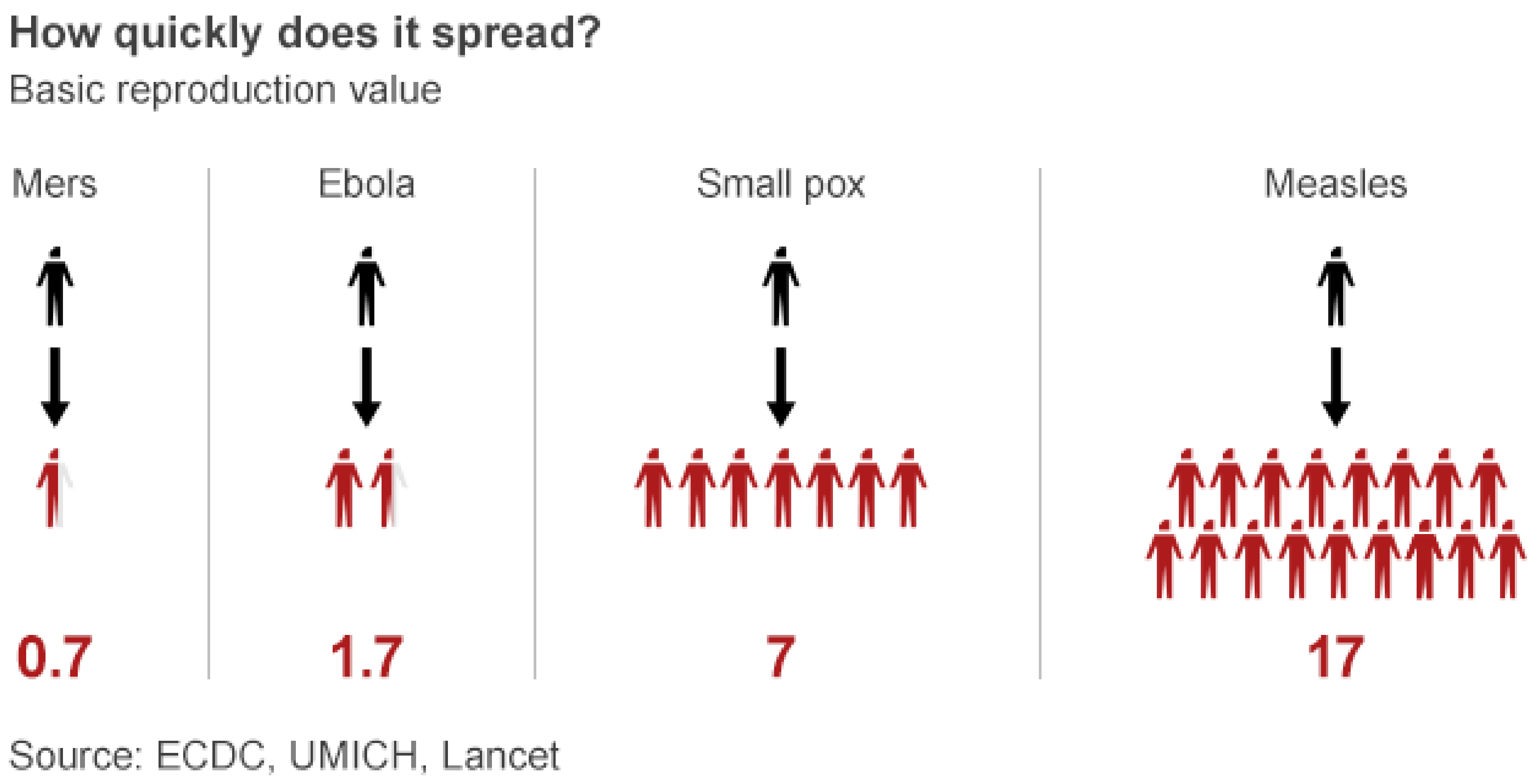
Emerging Infectious Disease (EID)

- Disease transmission affects EID impacts
- Latent Period vs. Pathogen Shed



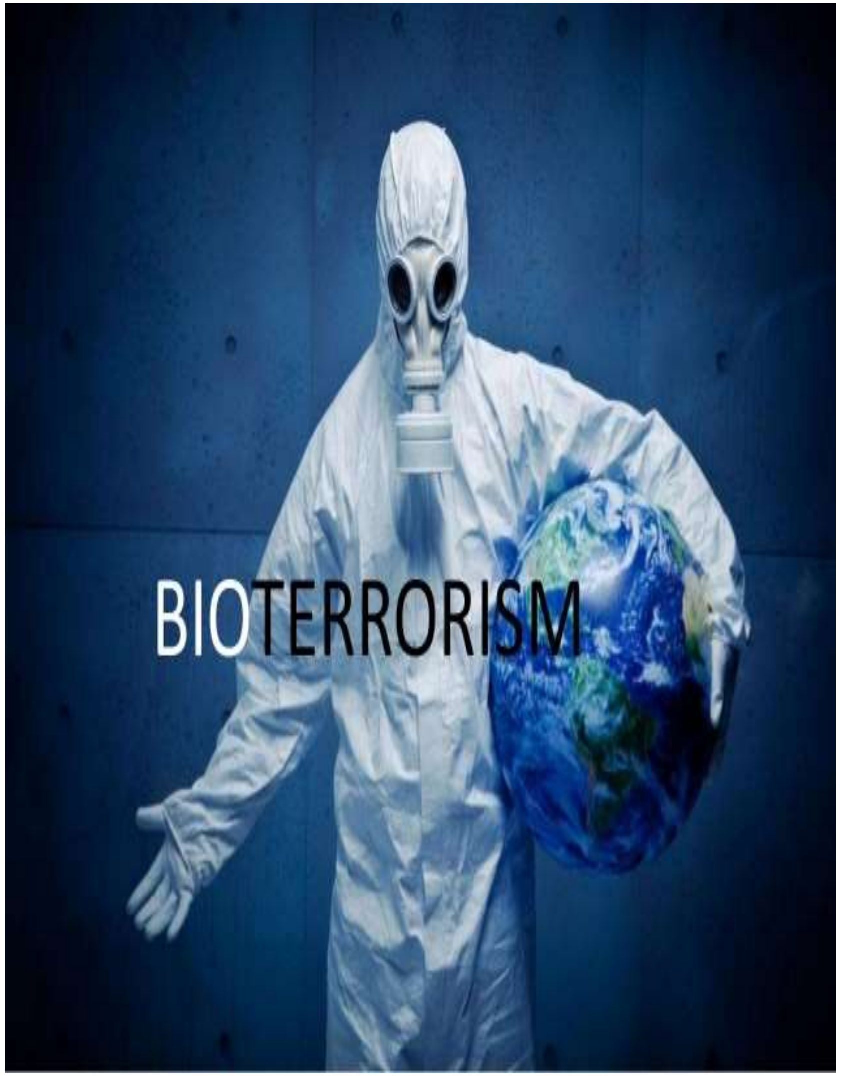
Emerging Infectious Disease (EID)

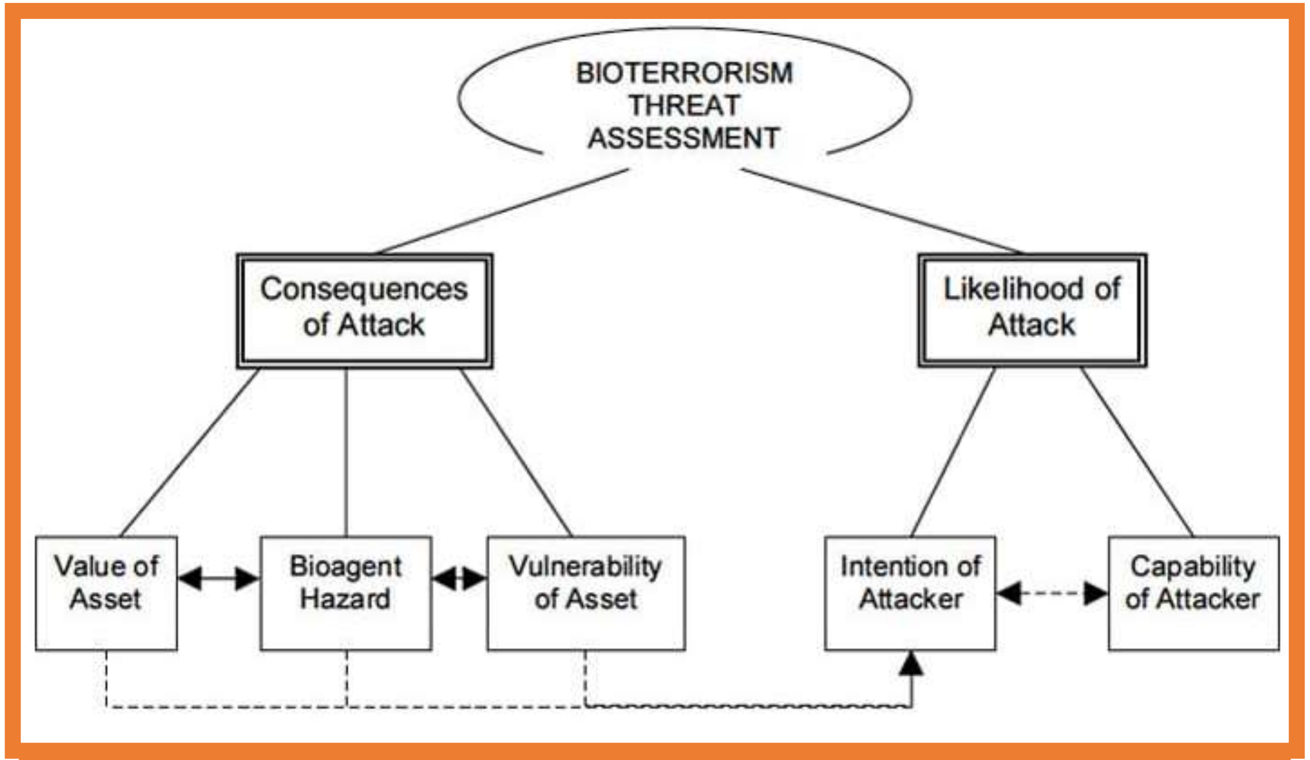
- Disease transmission affects EID impacts



What is bioterrorism?

Bioterrorism is the intentional release or threat of release of biologic agents (i.e. viruses, bacteria, fungi or their toxins) in order to cause disease or death among human population or food crops and livestock to terrorize a civilian population or manipulate the government





BIOTERRORISM THREAT=
VULNERABILITY x INTENT x CAPABILITY

This figure will focus on the capabilities and motivations of potential bioterrorists and assess their impact on actual usage of bioweapons., indicating the relationship between the intention and capability of an attacker , This equation points to the role of intent, vulnerability, and capabilities in regards to the threat of an attack

Understanding of emerging infectious disease helps individuals understand the nature of the threat and realities of the risk .

Understanding of biorisk management helps mitigate effects of bioterrorism

Ethical responsibility for labs should be in mind to manage bio risk

Although many sources of guidance for managing bio risk, there is currently no universally-applied set of standards

International Standards

Always manage biorisk in individual labs through risk assessment and then custom application of general standards

Significant Standards:

- World Health Organization (WHO) – human disease response, lab biosafety
- United Nations Food and Agriculture Organization (FAO)
- Office International des Epizooties (OIE) – animal health
- International Standardization Organization (ISO)
- National Institutes of Health (NIH)
- US Occupational Safety and Health Administration (OSHA) - labor


THANK YOU