Workshop on
Biological Risk Management (BRM) in Diagnostic Laboratories. Razi Conference Center, Tehran. Iran, 14-16 PM, 19 April, 2016

Biological Risk Management

GHSC

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Overview

- Introduction
- Definitions
- Risk Groups
- Type of Activity
- Examples
- Case Studies

Risk Management Milestones

- Risk Assessment
- Risk Mitigation
- Risk Performance
- Risk Communication

What is a Hazard?

A hazard is a source that has a potential for causing harm

Hazard does not pose a risk without specific environment or condition

What is Biohazard?

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

Examples:

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

What is a Risk?

- **Risk** is the combination of the probability and consequence that a damage by a hazard occurs as well as the extent of the damage.
- This is a biosafety Risk
- A biological risk is mostly determined by the biological characteristics of the organism and the type of activity.
- A quantitative risk assessment in biosafety is very difficult.
- The personal risk perception and acceptance may differ from the effective risk.
- Biorisk encompasses risks from the biosafety and biosecurity perspective, associated with biological materials

What is a Threat?

- Threat is the probability the a hazard be intentionally used to cause harm to the people, process, product or environment
- This is a Biosecurity Risk

Expanded Definition of Risk

- **Risk** is the **likelihood** of an undesirable event, involving a specific **Hazard**, that has **Consequences**
- **Likelihood** is the probability of occurring an event
- **Consequences** is the severity of an event

Group Work

- List 10 Hazards in your workplce
- List 10 potential Risks in your workplce

- Share your thought within your Group

Risk Assessment

Risk = Hazard x Probability x consequence (Damage)

RECOGNISE
(hazards)

EVALUATE
(assessment)

CONTROL
(safety measures)
(containment)

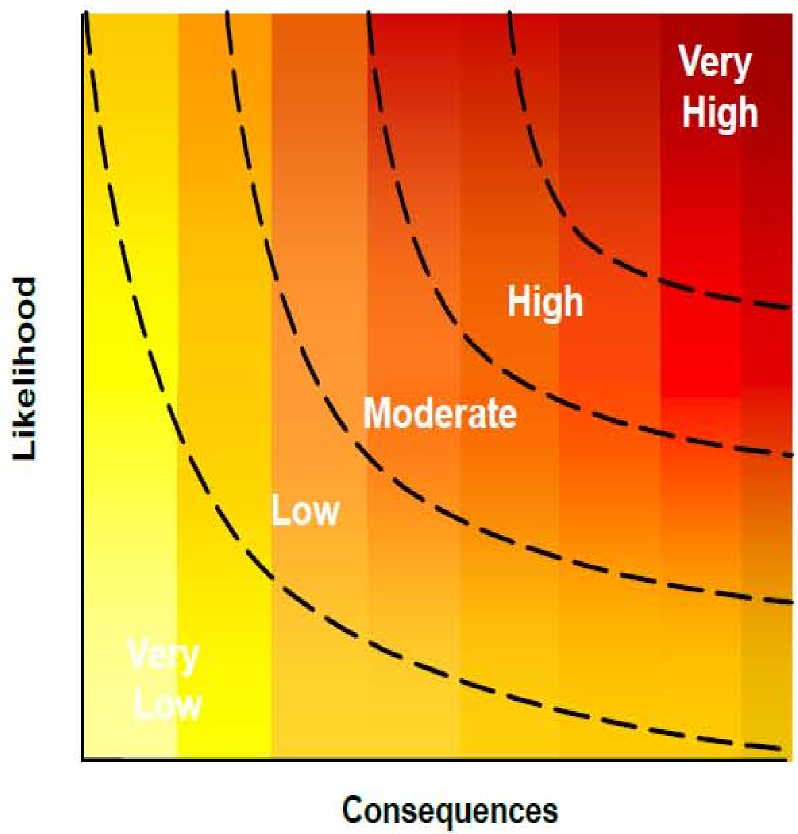
Risk Equation

Risk = Hazard X
Probability X Consequence

Risk X Vulnerability
--= Disaster
Management

100 X 100
-- = 1000
10
100 X 10
-- = 10
100

Risk is a Function of Likelihood and Consequences



BIOSECURITY ENGAGEMENT PROGRAM

International BIOLOGICAL THREAT REDUCTION

Risk Assessment

Biorisk Matrix

Likelihood	*Consequence*				
	1. Insignificant	***2. Minor***	***3. Moderate***	***4. Major***	***5.Catastrophic***
5. Certain	Medium	Medium	High	High	High
4. Common	Low	Medium	Medium	High	High
3. Possible	Low	Low	Medium	Medium	High
2. Unlikely	Low	Low	Low	Medium	Medium
1. Rare	Low	Low	Low	Low	Medium

Group Exercise 1

- **Step 1:** Let's discuss this **scenario**. A young child is left alone in a kitchen while there is pot of water heating on the stove

- What could go wrong?
- What is the single most important

risk for this scenario?

- What is the hazard associated with that risk?
- Define the Likelihood and Consequence
- **Take 15 Minutes and write your answers on the board**

Step 2, several possibilities

- The pot is full of boiling water, the child is alone not in strapped chair, a stool is nearby
- The pot is full of boiling water, the child is with her mother in a strapped chair
- The pot is with cold water, the stove is off, the child is not strapped.
- The pot is with cold water, the child is with her mother and strapped on the chair
- Assess the Risks in each case based on

probability and consequence

Factors in Risk Assessment

- **Characteristics of microorganisms** (animal, plant or human pathogen, zoonoses)
- **Use of animals or plants**
- **Type of activity** (research, diagnostics, large or small scale)
- **Methods, techniques, procedures**
- **Working environment (Biosafety level)**

Characteristics of Organisms 1

- **Virulence / attenuation:** Extent of the capability of the pathogenic organism to damage the host organism (eg. live attenuated vaccines vs. wild type strains)
- **Pathogenicity:** Ability of an organism to cause disease
- **Infectious dose**
- **Transmission route**
- **Environmental stability**
- **Communicability**
- **Prevention or treatment**
- **Resistance pattern** (to disinfectants, antibiotics etc.)
- **Reproduction and growth**
- **Endemic / exotic**

Characteristics of Organisms 2

- Host range
- Degree of natural or acquired immunity of the host
- Production of non-cellular entities such as toxins and allergens
- Presence of oncogenic nucleic acid sequences

$\Rightarrow$ animal pathogens
$\Rightarrow$ human pathogens
$\Rightarrow$ plant pathogens

Risk Group 1 - 4

Example: Pathogenicity

Laboratory strains which have lost their pathogenicity (*Escherichia coli* K12, *E. coli* B etc.) **Group 1**

- *Escherichia coli* wild type **Group 2**

- Entero-hemorrhagic strains (*Escherichia coli* 0157:H7, O103:H2) **Group 3**

-

Classification of Risk Groups

Group 1	Microorganisms unlikely to cause disease or harm in humans and animals (BMBL) No or low individual and community risk (WHO) **Example**: *Lactobacillus bulgaricus* (yoghurt bacteria) Yeast *E.coli* K12

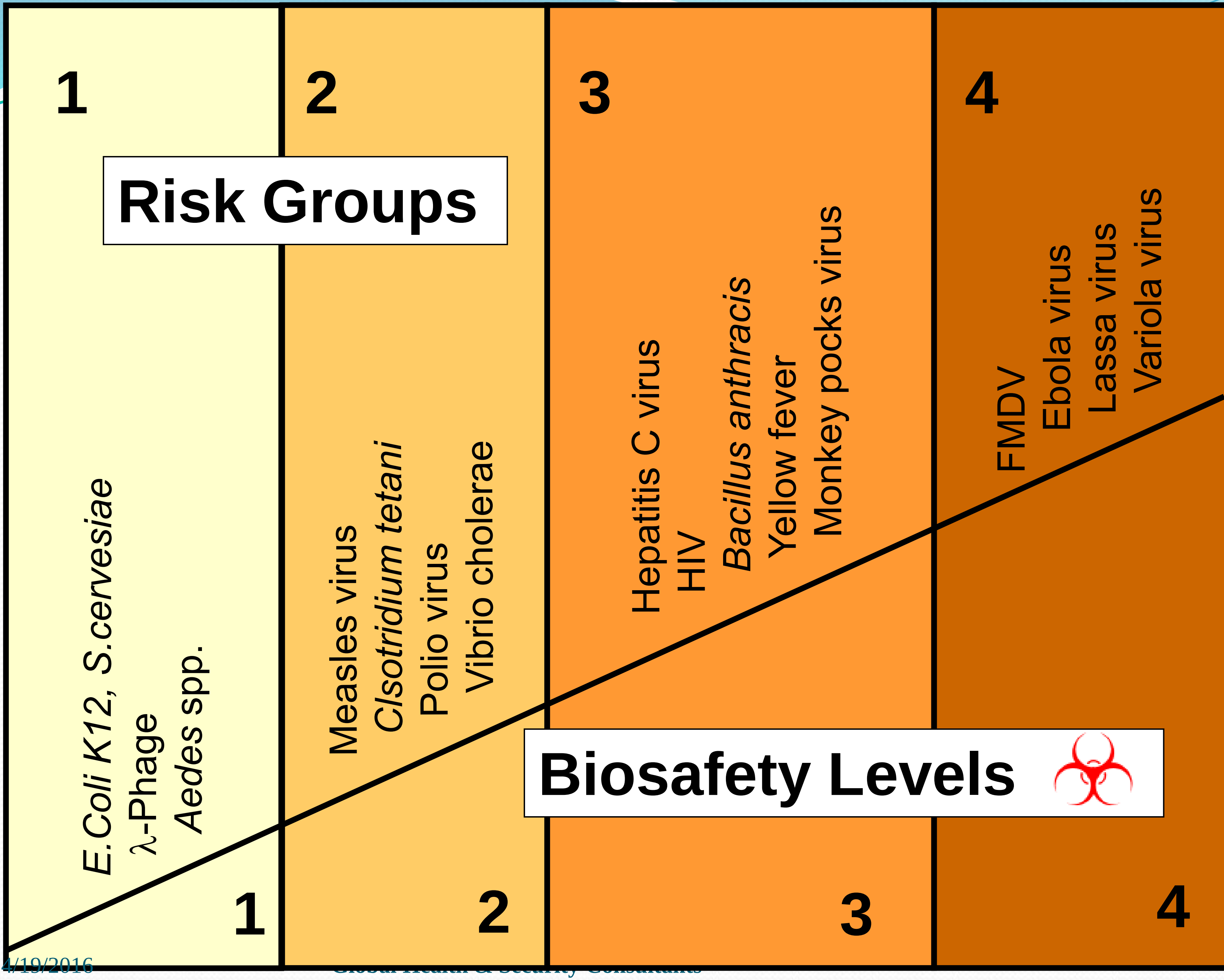
Classification of Risk Groups

Group 2	• Can cause human and animal (plant) disease and might be a hazard to workers • Unlikely to spread to the community • There is usually effective prophylaxis or treatment available Moderate individual risk, low community risk (WHO) **Example**: Polio, Vaccinia, *Toxoplasma gondii*

Classification of Risk Groups

Group 3	• Can cause severe human disease and present a serious hazard to workers • May present a risk of spreading to the community, in some cases airborne • For some agents: prophylaxis or treatment available High individual risk, low community risk (WHO) **Example**: TB, HCV, HIV

Group 4	• Cause severe human or animal (plant) disease and are a serious hazard to workers • May present a high risk of spreading to the community / environment • There is usually no effective prophylaxis or treatment available • Big economic loss for animal pathogens High individual and community risk (WHO) **Examples (only viruses):** Ebola, Lassa, Variola, FMD


Risk Groups
1
2
3
4
E.Coli K12, S.cervesiae
λ-Phage
Aedes spp.
Measles virus
Clsotridium tetani
Polio virus
Vibrio cholerae
Hepatitis C virus
HIV
Bacillus anthracis
Yellow fever
Monkey pocks virus
FMDV
Ebola virus
Lassa virus
Variola virus
Biosafety Levels
1
2
3
4

Type of Activity

- **Research**
- **Diagnostic** (medical microbiology, veterinary, soil, food, quality control etc.)
- **Activities involving animals** (small, large, insects, fish etc.)
- **Activities involving plants** (seeds, no seeds, exotic etc.)
- **Production:** small scale / large scale
- **Transport,** Type of package, quantity, shipment cargo
- **Culture collection / Storage**

Type of Activity: Critical Questions

- Which are the critical steps in an activity? (e.g. centrifugation, homogenisation, etc.)
- Where could an exposure happen?
- What type of exposure?
- Level of exposure?
- Probability of exposure?
- ……..

Examples: Cultivation (eggs vs. cells); pipetting; use of centrifuges; vortex; microscopy; packaging; transport; waste disposal; cell sorters;

Aerosol Generation

, Forming of aerosols by vortex mixer

- Sonicating, blending, mixing, vortexing
- Centrifuging
- Pouring, pipetting
- Opening containers at non-ambient pressures, fermenters, freezer vials
- Loading syringes and injecting
- Intranasal inoculation of animals
- Changing bedding of shedding, infected animals
- Harvesting tissue, eggs
- Tissue grinders / homogenizers
- Lasers
- Cell sorters (FACS)
- Dried / lyophilised cultures

Forming of aerosols by injection needle

Risk Assessment - Summary

- **Recognition:** organisms, type of activity
- **Evaluation:**
  - probability to harm human health in case of exposure
  - Probability to harm the environment (human, animal, plant) in case of accidental release
- **Control:** safety measures (primary and secondary containment)

Risk Mitigation

Substitution (replace hazardous material)

Technical safety measures (engineering controls)

- ✓ Facility design
- ✓ Directional airflow, ventilation
- ✓ Isolators for animals
- ✓ ......

Organisational measures

- ✓ SOP
- ✓ Guidelines and
- ✓ Practices, procedures
- ✓ Training
- ✓ Access control
- ✓ .....

Personal Protective Equipment

- ✓ Does not eliminate the hazard!!

Mitigation Control Measures

Five categories of mitigation control measures:

- Elimination or Substitution
- Engineering Controls
- Administrative Measures
- Practices and Procedures
- Personal Protective Equipment

Elimination or substitution

- Replacement of biological agents
- Elimination or replacement of hazardous material
- Replacement of equipment
- Reduction of replacement of staff
- ...

Engineering Controls

- Physical changes to work stations, spaces, connections, renovation, clean rooms
- Ventilation, negative or positive, filtration
- biosafety level, depending on the agents of disease
- equipment, control, calibration and validation
- materials, pathogens and toxins
- production facilities, vaccines, biopharnaceutical
- or any other relevant aspect of the work environment that reduce or prevent exposure to hazards

Administrative Controls

- Policies and planning
- Standards and guidelines
- SOPs
- Procedures and practices
- validation
- Training

Personal Protective Equipment (PPE)

- As a primary barrier
- Not a final solution, always in combination with other measures
- Varies depend on the type of activity,
- Based on Biosafety Level,
- Type of Biological Agent or Toxin

Mitigation in Work Practices I

Controlling Exposure

- Replace biological agent
- Reduce the number of employees at risk of exposure: restricted access, etc.
- Reduce exposure by direct and indirect contact: hand washing, decontamination, PPE, isolators, etc.
- Reduce percutaneous exposure: eliminate use of sharps, use container to appropriate collect sharps, prevent scratches and bites, etc.
- Reduce exposure by ingestion: automated pipetting, no smoking, drinking, eating, keep hands away from mouth and eyes, etc.
- Reduce exposure by inhalation: BSC, careful handling of fluids, use of filters, etc.

Work Practices II

- Handling and transport of animals: prevent transmission of zoonotic agents and exposure, use appropriate caging (filters), etc.
- Personal hygiene: hand washing, showering, PPE, GMT
- Housekeeping: clean areas, disinfection of surfaces and floors, dust suppression, wet mopping and use of HEPA-filtered vacuum cleaner, etc.
- Waste disposal: sufficient space for storage
- Cleaning cages: avoid escape of animal during and after cleaning, PPE, etc.
- Correct internal and external transport
- Dialogue between biosafety and scientists

Risk Assessment - Summary

- Risk assessment system needs to be established, implemented and maintained

- Risk assessment needs to be reviewed on a regular basis (new organisms, new methods, new equipment, construction, etc.)

- Risk assessment needs to be done in a group!

Performance

- Performance is the way in which the risk mitigation measure will be best implementation
- Performance is the result of all the efforts of a company or organization to implement mitigation measure
- Performance will also improves facility BRM: you know that your system works and is sustainable, and that the risk is acceptable

Performance is based on:

- **Control:** Processes, procedures, structures, and responsibilities to manage biorisk
- **Assurance:** Systematic process of checking the system
- through audits and inspections
- **Improvement:** Setting and achieving biorisk management goals based on internal and external feedback

Risk Communication

- Interactive exchange of relevant information
- Risk perception, risk assessment, risk-related factors, risk handling
- Within the facility or with adequate second party
- Create a safety climate and a no-blame-culture
- Reporting system (culture) of non-compliance

Risk Management - Summary

- Risk Management system needs to be established, implemented and maintained

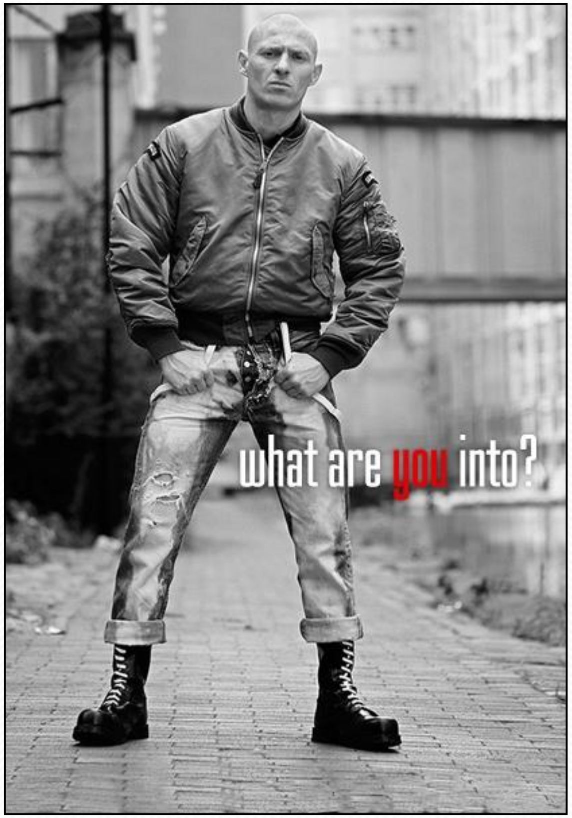
- Risk Management should be both Efficient and Effective

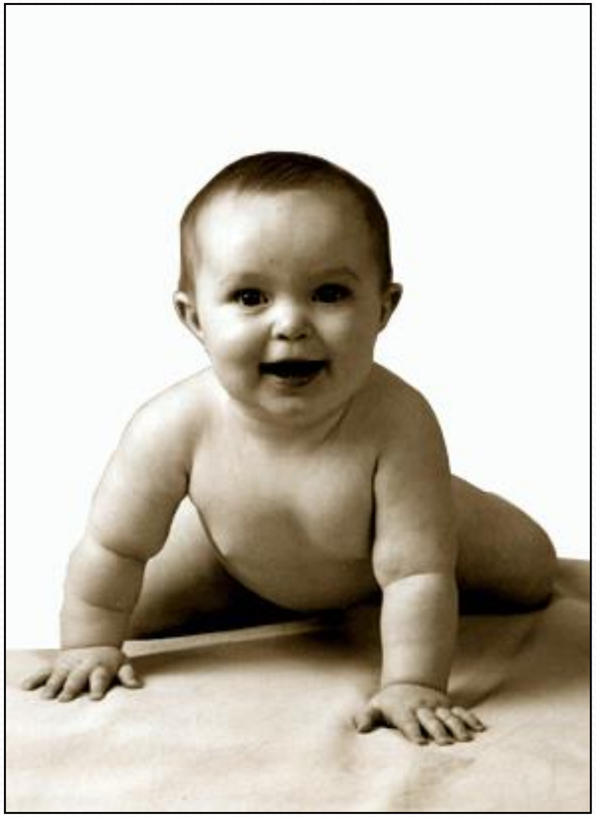
- Risk Management needs to be reviewed on a regular basis (new organisms, new methods, new equipment, construction, etc.)

- Risk Managemme in a group not individuals!

Examples

You are asked to handle blood taken from all three of these donors. Which one you can consider to be safer?






AUTOCLAVE


Shivram

Examples

Examples

Case Studies

Now it's your turn!!!

Wishing You All a Healthy, Safe and Secure World

Thank you

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