Biological Risk Assessment for Clinical Laboratories
Objectives

• Describe the concepts of risk assessment (Why and What?)
• Describe the basic steps of the risk assessment process (Who, When and How?)
• Perform a basic risk assessment exercise
Why Do Risk Assessments?

Approximately 500,000 US laboratorians work with or handle infectious materials and/or cultures every day.

Because of where you work and what you do…
Why Do Risk Assessments?

• To *reduce* and *minimize* the risk of exposure to workers and the environment
• But remember:

*Risk is never zero!*
Why Do Risk Assessments?

- Prevent laboratory-acquired infections (LAIs) from:
  - Direct contact (spills/splashes) to mucous membranes
  - Inhalation of aerosols
  - Percutaneous inoculation from cuts, sharps, vectors, non-intact skin
  - Ingestion
  - Indirect contact (contamination from fomites*)

*Fomite - an inanimate object (as a computer, doorknob, phone or work surface) that may be contaminated with infectious organisms and serve in their transmission
Definitions

**Hazard** is something that is intrinsically dangerous such as an object, a chemical, an infectious agent or a situation.

**Risk** is:

- the chance of injury or loss when exposed to a hazard.
- based on the probability of exposure and the severity of consequence from that exposure
- A prediction
Definitions

• **Risk Assessment (RA)** is a process that involves hazard identification and hazard control

• Risk assessment requires
  - knowledge of the hazards
  - understanding of the work, the environment, and the staff
  - management involvement and support
Definitions

Risk Assessment (RA) overall process:

1. Identify hazards
   - What may happen?
   - How may it happen?
2. Evaluate risks
   - How likely, how severe?
3. Determine controls to mitigate risk
   - To reduce risk if it is not acceptable
4. Implement controls
5. Review effectiveness of controls and adjust
RA Process

1. Identify hazards
2. Review risk assessment
3. Implement controls
4. Evaluate Risk
5. Mitigate Risk
Who Does Risk Assessments?

• *Ideally, a multidisciplinary team*
  - Laboratory staff
  - Management/supervisors
  - Health and safety specialists (biosafety, occupational health …)
  - Facility staff
  - Scientists with unique expertise & experience
    - Microbiologists, molecular biologists, chemists
    - Veterinarians
    - Others
When?

*Ideally, at regular intervals*

- More frequently in problem areas
- When there is an incident, accident or exposure
- When changes occur
  - Move, renovation or new facility
  - New infectious agent or reagent
  - New piece of equipment, technique or procedure
  - New scientific information available
Risk Assessment Is Not New

- We conduct risk assessments all the time…
Steps of RA

1. Gather information and identify the potential hazard
2. Evaluate and prioritize the risk (likelihood and consequence)
3. Determine what additional safety precautions (controls) are needed to reduce the risk (mitigation)
4. Implement controls
5. Review and evaluate effectiveness, adjust
“Biosafety is an inexact science, and the interacting system of agents and activities and the people performing them are constantly changing.”

Every etiologic agent is different
Every laboratory is different
Every person is different

Risk Assessment: Interaction of Factors

Source: B. Johnson, Anthology of Biosafety, IV, 2001
Risk Assessment Considerations

Biological Agent

Environment

People

Bacteria, fungi, viruses, protozoa, algae, prions, recombinant organisms, cell lines, cell cultures, human/animal specimens, toxins…
Agent Definitions

• Pathogenicity - the ability/capacity of an infectious agent to cause disease

• Virulence - the quantitative ability of an agent to cause disease, the disease-evoking severity of a pathogen (virulent agents cause disease when introduced in small numbers)

• Transmissibility/communicability - contagious, ease of spread between persons or species by contact with the sick or their fluids
Some Agent Factors to Consider

- Toxigenesis
- Stability in the environment
- Infectious dose
- Route of transmission
- Indigenous or rare
- Availability of data
- Availability of vaccine/treatment
- Host range (humans, animals, plants)
- Antibiotic resistance
- Resistance to disinfection
Agent: Route of Transmission

- Inhalation, ingestion, percutaneous, direct contact, indirect contact (fomites)

- Infection/disease can differ based on the route of transmission
  - *B. anthracis*
    - Inhalational anthrax
    - Cutaneous anthrax
    - Gastrointestinal anthrax
**Infectious Dose** - The number of microorganisms required to initiate infection can vary greatly with the specific organism and the route of transmission.

<table>
<thead>
<tr>
<th>Organism</th>
<th>Route</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>E. coli</em></td>
<td>ingestion</td>
<td>( \sim 10^8 )</td>
</tr>
<tr>
<td><em>E. coli</em> O157:H7</td>
<td>ingestion</td>
<td>( \sim 10 )</td>
</tr>
<tr>
<td><em>N. meningitidis</em></td>
<td>inhalation, direct contact</td>
<td>unknown</td>
</tr>
<tr>
<td><em>Salmonella</em> spp.</td>
<td>ingestion</td>
<td>( \sim 100)-1000</td>
</tr>
<tr>
<td><em>Shigella</em> spp.</td>
<td>ingestion</td>
<td>( \sim 10)-180</td>
</tr>
<tr>
<td><em>Brucella</em> spp.</td>
<td>inhalation, direct contact, ingestion</td>
<td>10-100*</td>
</tr>
</tbody>
</table>

*By aerosol and subcutaneous routes in laboratory animals*
Risk Assessment Considerations

- Biological Agent
- Environment
- People
Host factors: Immune Status

- Age or life-stage
- Pre-existing conditions/medical status (stress, autoimmune disease, chemotherapy, non-intact skin, allergies, other infections/disease, medications, antibiotics)
- Pregnancy (Cytomegalovirus, HIV, Herpes simplex virus)
- Nutrition, diet
- Immunizations (HBV, Meningococcus, Pneumococcus)
Host: Behavioral Factors

• Stress, fatigue, mental status
• Cultural differences, age, habits
  **Perception** of risk
• **Attitude** toward safety
  o Follow procedures?
  o Use equipment/PPE as designed?
  o Take shortcuts?
• **Competency**
  o Education and experience
  o Trained?
  o Students, language barriers
• Dexterity or reaction time affected by medications or PPE?
Risk Assessment Considerations

- Biological Agent
- Environment
- People
Environmental Factors

Place (facility)
- research, clinical, industrial, public health, BSL-2/3
- workflow-is the lab crowded/cluttered?
- lab equipment (biosafety cabinet [BSC], animal cages, sharps, centrifuges, vortex, autoclaves …)
  - is it available?
  - does it protect or is it a hazard by itself?

PPE (hazard or protection?)
- appropriate PPE available?
- is it used?
- are people trained?
Environmental Factors (Procedures)

- hand washing-cracked skin?
- large volume, high agent concentration
- centrifuging, autoclaving
- sharps
- generating aerosols-anything that imparts energy to a suspension
- waste management
- inoculating biochemicals
- doffing procedures
- not using or improper use of BSC
**Steps of RA**

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Risk Assessment

Very seldom is risk assessment a black and white issue

• Involves personal and social value judgments

• Everyone has different perceptions of risk and what is "acceptable"
Evaluate and Prioritize Risk-Example

Likelihood (probability) of occurrence

• Rare: could happen, but probably never will
• Unlikely: could happen but rare
• Possible: could happen but not likely
• Likely: could happen sometime
• Almost certain: expected to occur
Evaluate and Prioritize Risk-Example

Consequence (severity) of exposure

- Minor: Colonization, asymptomatic
- Moderate: Medical treatment or first aid
- Major: Infection and recovery
- Critical: Disease and sequelae
- Catastrophic: Death
Evaluate and Prioritize Risk-Example

- Performing Gram stain:
  - Potential Hazard: Aerosols from flaming slides — mucous membrane exposure
  - Likelihood: Possible
  - Consequence: Colonization; medical treatment
  - Risk: Moderate

- AFB culture work-up
  - Potential Hazard: Aerosols — inhalation
  - Likelihood: Likely
  - Consequence: Infection; medical treatment; disease
  - Risk: High
**Risk Matrix - Example**

- **Likelihood**
  - 1- Rare
  - 2- Unlikely
  - 3- Possible
  - 4- Likely
  - 5- Almost certain

- **Consequence**
  - 1- Minor
  - 2- Moderate
  - 3- Major
  - 4- Critical
  - 5- Catastrophic

**Legend:**
- **Red** = HIGH RISK
- **Yellow** = Moderate Risk
- **Green** = low risk
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Hierarch of Controls

Elimination
- Physically remove the hazard

Substitution
- Replace the hazard

Engineering Controls
- Isolate people from the hazard

Administrative Controls
- Change the way people work

PPE
- Protect the worker with Personal Protective Equipment
Some Engineering Controls

- Safety Equipment (BSC, sharps containers, centrifuge safety cups, eyewash, sealed rotors)

- Facility Design (directional airflow, lockable doors, hands-free faucets)
Some Administrative Controls and Work Practices

- Training
- Signage
- SOP’s and site-specific safety manuals
- Medical surveillance program (including a process to address unusual absences, sickness, and injury)
- Frequent hand washing
- Appropriate use of PPE
- No mouth pipetting
- Limiting use of needles and sharps
- Minimizing aerosols
PPE

• PPE is your *last resort*, after all other mitigation steps have been taken
• Proper technique for donning and doffing PPE is as important as having the correct PPE-staff must be trained!
• *More PPE is not always better* (decreased dexterity and sensitivity, uncomfortable, hot)
• PPE can vary on what you are doing and where you are doing it-depends on risk assessment!
• Institutions must establish policies for adherence
<table>
<thead>
<tr>
<th>Routes of Transmission</th>
<th>Mitigation Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>inhalation</td>
<td>BSC, respiratory protection, centrifuge safety cups</td>
</tr>
<tr>
<td>ingestion</td>
<td>No mouth pipetting, gloves, hand washing</td>
</tr>
<tr>
<td>percutaneous</td>
<td>Safer sharps, sharps containers, cover compromised skin</td>
</tr>
<tr>
<td>direct contact with mucous membranes</td>
<td>Gloves, hand washing, face protection</td>
</tr>
<tr>
<td>indirect (fomites)</td>
<td>Disinfecting surfaces, spill procedures, designated clean and dirty areas</td>
</tr>
</tbody>
</table>
Steps of RA

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Review and Evaluate Effectiveness

- Review incidents, accidents, illnesses
  - Encourage and support non-punitive reporting

- Identify causes/problems, make changes, follow-up training
  - Document and maintain records

- Conduct routine lab inspections

- Repeat RA when incidents or changes occur
Perform a Risk Assessment

• In order to simplify the entire process and make it more practical for laboratorians, a **Job Hazard Analysis** framework can be used to break down a complex process into individual steps.

• Each step is then evaluated separately, and mitigation controls can be determined and implemented at each step of the process.
OSHA Job Hazard Analysis

• “A technique that focuses on job tasks as a way to identify hazards before they occur.

• Ideally, after you identify uncontrolled hazards, you will take steps to eliminate or reduce them to an acceptable risk level.”

• https://www.osha.gov/Publications/osha3071.html
Job Hazard Analysis Steps

- Break procedure down into individual components
- Determine hazard(s) associated with individual component* (hazard ID)
- Identify way to deal with each hazard (hazard control)

*5 P’s: pathogen, people, place, PPE, procedures
## Job Hazard Analysis - Example

<table>
<thead>
<tr>
<th>Procedure or Process</th>
<th>Principal Steps (Procedure)</th>
<th>Health Hazards (Pathogen)</th>
<th>Safety Equipment/ Engineering controls (Place)</th>
<th>Administrative Controls and Work Practices (Personnel)</th>
<th>Recommended PPE</th>
</tr>
</thead>
</table>
| **Slide Catalase Test** | 1. Touch colony of organism with stick or plastic loop  
2. Put on slide  
3. Add Hydrogen Peroxide  
4. Observe for bubbles | Pathogen (?)  
Aerosol generation  
Chemicals Sharps | Perform this test in a tube, BSC, or use other engineering controls.  
Sharps containers | Proper BSC usage; safe sharps handling; aerosol containment; SOPs and demonstrated competency | Gloves  
Lab coat  
Face shield (optional if using a bench shield or BSC) |
| **Hematology differential** | 1. Label slide  
2. Open tube  
3. Place drop of blood on slide  
4. Swipe to make diff  
5. Air dry  
6. Stain | Sharps  
Aerosol generation  
Auto-inoculation  
Spill Chemicals | Use automated system, splash shields, absorbent pads, tube holders  
Sharps containers | SOPs and demonstrated competency; Safe sharps handling; Aerosol containment  
Splash shield | Gloves  
Lab coat  
Face shield (optional if using a bench shield or automated system) |
Don’t Forget:

- There is some risk in everything we do—we can reduce it, but not eliminate it
- To ask questions
- Your staff, their training and competency
- To evaluate, review and adjust