Biosafety in the Laboratory

With examples on Ebola African strains
<table>
<thead>
<tr>
<th>Laboratory Biosafety</th>
<th>Laboratory Biosecurity</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Containment principles, technologies, and</td>
<td>• Protection, control and accountability for</td>
</tr>
<tr>
<td>practices implemented to prevent unintentional</td>
<td>valuable biological materials within laboratories,</td>
</tr>
<tr>
<td>exposure to pathogens and toxins, or their</td>
<td>in order to prevent their unauthorized access,</td>
</tr>
<tr>
<td>unintentional release</td>
<td>loss, theft, misuse, diversion or intentional</td>
</tr>
<tr>
<td></td>
<td>release</td>
</tr>
</tbody>
</table>
Biorisk Management Process

- Biorisk = biosafety + biosecurity

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Mitigation</th>
<th>Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk identification</td>
<td>Elimination or substitution</td>
<td>Control</td>
</tr>
<tr>
<td>Hazard/threat identification</td>
<td>Engineering controls</td>
<td>Assurance</td>
</tr>
<tr>
<td>Likelihood evaluation</td>
<td>Administrative controls</td>
<td>Improvement</td>
</tr>
<tr>
<td>Consequences evaluation</td>
<td>Practices and procedures</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Personal protective equipment</td>
<td></td>
</tr>
</tbody>
</table>
Don’t Forget Security

- Physical security
- Personnel management
- Material control and accountability
- Transport security
- Information security
What to Look For?

- Hazard = object with the potential to cause harm
- Risk = likelihood + consequences of a harmful event
- Threat = person with the potential/intention to cause harm
Exercise - What to Look For?

Heating a test tube containing Ebola-suspected blood on burner, but not to the point of disinfection

Hot drink in mug
Exercise - What to Look For?

**Some biosafety risks:**
- Infectious material falling onto mug
- Ingestion of infectious material through bare hands
- Ingestion of infectious material through clothing
- Infection through eyes
- Infection through hair

**Other safety risks:**
- Hair getting burned by burner
- Limbs getting burned by burner
- Burns from hot drink spill
- Slippage and blunt force due to drink spill

**Some biosafety hazards:**
- Hair not tied back
- Infectious material in test tube
- Hot drink in mug
- Lack of PPE (gown, gloves, goggles)

**Other safety hazards:**
- Open burner
- Liquid in mug

**Some threats:**
- Person not following protocol
- Supervisor not routinely checking on staff
## Equipment and Procedures

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Homogenizer</td>
<td>Aerosol generation, Tube breakage, Noise pollution</td>
</tr>
<tr>
<td>Water bath</td>
<td>Infection from microbial growth, Slippage, Burns</td>
</tr>
<tr>
<td>Glassware</td>
<td>Cuts</td>
</tr>
<tr>
<td>Computer</td>
<td>Eye strain, Improper posture, Repetitive strain injury</td>
</tr>
</tbody>
</table>
# Equipment, Procedures, and Chemicals

<table>
<thead>
<tr>
<th>Equipment/Chemical</th>
<th>Hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centrifuge (aerosol)</td>
<td></td>
</tr>
<tr>
<td>Glassware</td>
<td></td>
</tr>
<tr>
<td>Ethanol</td>
<td></td>
</tr>
<tr>
<td>Guanidinium chloride</td>
<td></td>
</tr>
</tbody>
</table>
Equipment and Procedures
## Major Concerns

<table>
<thead>
<tr>
<th>Laboratory</th>
<th>Hospital</th>
<th>Field</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Specimen handling</td>
<td>• Specimen handling</td>
<td>• Transport</td>
</tr>
<tr>
<td>• Donning and doffing</td>
<td>• PPE integrity</td>
<td>• PPE integrity</td>
</tr>
<tr>
<td>• Disinfection</td>
<td>• Donning and doffing</td>
<td>• Donning and doffing</td>
</tr>
<tr>
<td></td>
<td>• Disinfection</td>
<td>• Workload</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Communication</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Security</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Supply</td>
</tr>
<tr>
<td>PPE Hazards</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td><img src="image" alt="Eye" /></td>
<td><img src="image" alt="Ear" /></td>
<td><img src="image" alt="Nose" /></td>
</tr>
<tr>
<td><img src="image" alt="Down Arrow" /></td>
<td><img src="image" alt="Down Arrow" /></td>
<td><img src="image" alt="Down Arrow" /></td>
</tr>
</tbody>
</table>
Personnel

• Training and practice
• Workload and fatigue
• Infection control
• Health (incl. mental) and immunity status
• Professional relationships (buddy, biosafety officer)
Exercise - Facility

• Heating, ventilation, and air conditioning (HVAC)
• Filtered air
• Windows
• Access control
• Work surfaces
• Pest control
Point-of-Care and Hospital

- Minimal primary containment
- Premium on PPE and practices
- 40 µL – 15+ mL volume
- Pressurized/ aerosolized/ open fluids
Serology Testing Lab

- Biosafety cabinet
- ≈ 200 µL volumes
- Surge capacity
- Increased safety after inactivation
- Cleanliness affects accuracy
Nucleic Acid Testing Lab

- Biosafety cabinet
- $\approx 200 \, \mu L$ volumes
- Surge capacity
- Increased safety after inactivation
- Cleanliness greatly affects accuracy
Exercise - Environment

- Agent’s presence outside the lab
- Community health status
- Nearby population density
- Presence of hosts or vectors
- Local militant/terrorist activity
Expert Guidance and Regulations

Department of Health
Research Institute for Tropical Medicine
National Reference Laboratories for Emerging Infectious Diseases
Filinvest Corporate City, Alabang, Muntinlupa City 1781

INTERIM GUIDELINES FOR SPECIMEN COLLECTION, PACKAGING AND TRANSPORT
FOR CONFIRMATORY TESTING OF EBOLA VIRUS DISEASE (EVD)
Version 2 | 29 September 2014

BACKGROUND

Ebola virus disease (EVD) is a viral hemorrhagic fever and one of the most virulent viral diseases known to humankind. The current EVD outbreaks in affected countries in West Africa have a case fatality rate of 50%-60%. The virus is transmitted to people from wild animals and spreads in the human population through person-to-person transmission. Person-to-person transmission by means of direct contact with infected persons or their body fluids/secrections is considered the principal mode of transmission. The patient becomes contagious once they begin to show symptoms. The incubation period ranges from 2 days-21 days.

Laboratory confirmation is needed to classify a patient as a confirmed case of Ebola Virus Disease (EVD) to initiate appropriate clinical management and epidemiological investigations. The Research Institute for Tropical Medicine (RITM), the National Reference Laboratory for Emerging and Re-emerging Infections, performs WHO-recommended methods of molecular detection by polymerase chain reaction (PCR) and Enzyme-linked
How Do We Prove All This?
How Do We Prove All This?
Assessment Tools

- Policy and procedural documents
- Inventories
- Staff training certificates
- Facility/equipment maintenance records
- Communications
- Medical records

- Photos/videos
- Regulatory compliance certificates
- Audit records
- Floor layout and plans
Exercise - Assessment Tools

**Consequence**
- Needlestick injury
- Blood splash on BSC
- Used blood collection vial on receiving area

**Likelihood**
- Improbable
- Remote
- Occasional
- Probable
- Frequent

The graph uses a color-coded risk matrix to represent the likelihood and consequence of each event:
- **Tricolor** indicates negligible risk (1)
- **Yellow** indicates low risk (2)
- **Light Green** indicates moderate risk (3)
- **Green** indicates significant risk (4)
- **Dark Blue** indicates catastrophic risk (5)

Each event is assessed based on the likelihood and consequence, which helps in identifying the risk levels for proper management and mitigation strategies.
## Exercise - Assessment Tools

### Emergency Preparedness

<table>
<thead>
<tr>
<th>Item</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Emergency contact information posted?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. First aid kit maintained?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Biological spill kit maintained?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Staff aware of occupational injury procedures?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments:

### Documentation And Training

<table>
<thead>
<tr>
<th>Item</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Employee(s) completed right-to-know training?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Employee(s) completed unit-specific training?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Employee(s) read and understand safety and health plans?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Door sign up-to-date and posted?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Laboratory microwaves and refrigerators labeled with “Not for Food or Drink – Biohazard”?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments:
Pathogen Safety Data Sheet

- Name and physical characteristics
- Pathogenicity, epidemiology, and host range
- Stability and viability
- First aid and medical
- Exposure protection
- History of military/terrorist use
- Weaponizable forms
- Storage, handling, and transport
- Regulatory and other information
Exercise - Mitigation Measures

Elimination or substitution

Engineering controls

Administrative controls

Practices and procedures

Personal protective equipment
## Mitigation Measures

<table>
<thead>
<tr>
<th></th>
<th>Engineering</th>
<th>Administrative</th>
<th>Practices and Procedures</th>
<th>PPE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Advantages</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Efficient</td>
<td></td>
<td>Authority</td>
<td>SOP-based</td>
<td>Cheap</td>
</tr>
<tr>
<td>Can eliminate hazard</td>
<td></td>
<td>approach</td>
<td>Cheap</td>
<td>Easy to use</td>
</tr>
<tr>
<td><strong>Disadvantages</strong></td>
<td></td>
<td>Indirect</td>
<td>Needs training</td>
<td>Must not fail</td>
</tr>
<tr>
<td>Expensive</td>
<td></td>
<td>approach</td>
<td>Needs supervision</td>
<td>Uncomfortable</td>
</tr>
<tr>
<td>Complex</td>
<td></td>
<td>May be</td>
<td></td>
<td>Some additional hazards</td>
</tr>
<tr>
<td>Some additional hazards</td>
<td></td>
<td>expensive</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Mitigation Measures

Relative Impact on Safety

- Laboratory
- Hospital
- Field

- Engineering
- Administrative
- Practices and Procedures
- PPE
Biosafety Cabinet Use
Constant Cleaning
Emergency Response
Performance - Audit

LEVEL 4
Regulators

LEVEL 3
3rd party auditor

LEVEL 2
Institutional audit team

LEVEL 1
Laboratory staff