Biosafety at the Microbe Level: Needs of the Clinical Laboratory

James W. Snyder, Ph.D.
University of Louisville
What Are the Major Issues Confronting Clinical Laboratories?

OBJECTIVES

• Biosafety
• Biosecurity
• Biosafety Plan
• Risk Assessment
• Mitigation of Risk
• Survey Results
• Summary/Conclusions
Biosafety

Reducing the risk of unintentional exposure to pathogens and toxins or their accidental release
Biosecurity

Protection, control and accountability for biological materials within laboratories in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release.

“More than locking doors”
## Outreach to Clinical Laboratories

12. How many sentinel clinical laboratories do you have within your jurisdiction?

<table>
<thead>
<tr>
<th>Total from all respondents</th>
<th>Total # of laboratories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sentinel clinical laboratories which meet the APHL-CDC-ASM definition</td>
<td>4,192</td>
</tr>
<tr>
<td>Additional clinical laboratories (as described in the ELC Performance Measures Guidance)</td>
<td>1002</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sentinel clinical laboratories which meet the APHL-CDC-ASM definition</th>
<th>Additional clinical laboratories (as described in the ELC Performance Measures Guidance)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Per a jurisdiction (state, local or territorial)</td>
<td>n</td>
</tr>
<tr>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>1-49</td>
<td>27</td>
</tr>
<tr>
<td>50-99</td>
<td>18</td>
</tr>
<tr>
<td>100-199</td>
<td>6</td>
</tr>
<tr>
<td>200+</td>
<td>5</td>
</tr>
</tbody>
</table>

Ref: 2016 APHL Biosafety and Biosecurity Survey
Biosafety Management Plan

Addresses the laboratory practices and procedures designed or intended to reduce risks associated with potential biological safety hazards encountered by the staff, students, and personnel working in laboratories where infectious agents and toxins studies are handled.
A Biosafety Checklist: Developing A Culture of Biosafety

Background

There is an inherent risk in a laboratory handling any infectious agents. Biosafety practices should be adhered to in all laboratories that receive potentially infectious material in order to ensure laboratory personnel, public and environmental safety. Recent incidents involving biosafety lapses highlight the need to enhance the culture of biosafety across the laboratory community in the United States. The Association of Public Health Laboratories (APHL) has developed A Biosafety Checklist: Developing A Culture of Biosafety to serve as a starting point for laboratories to assess the biosafety measures that they have in place.

Intended Use

A Biosafety Checklist: Developing A Culture of Biosafety is intended for any laboratory performing testing on infectious agents or clinical specimens that could contain infectious agents in the United States. It is designed to provide laboratories with the broad recommendations for components that should be considered for inclusion in any laboratory's biosafety policy. The checklist consists of six sections:

1. Risk Assessment
2. Selection of Safety Practices
   - Biosafety Level
   - Engineering Controls
   - Personal Protective Equipment (PPE)
   - Laboratory Practices
3. Biosafety Competencies
4. Safety Orientation and Training
5. Audits, Monitoring and Safety Committee
6. Administrative Controls

This checklist is for your laboratory's internal use only. The questions in this checklist are included to guide biosafety discussion within your laboratory and do not address biosecurity practices. Some questions may not be applicable to every laboratory and some laboratories may want to add additional questions to perform their risk assessments. This tool can be modified to meet your laboratory's needs as necessary and information gained from this tool can be used to help laboratories identify areas for improvement in their biosafety practices.
Risk can be defined as the probability that a health effect will occur after an individual has been exposed to a specified amount of hazard.

Risk assessment is the process of gathering all available information on a hazardous substance and evaluating it to determine the possible risks associated with exposure. This is followed by determining the mitigation strategies necessary to provide protection.
Risk Assessment

• A systematic process of evaluating the potential risks that may be involved in a projected activity or undertaking.”

• “The identification, evaluation, and estimation of the levels of risk involved in a situation, their comparison against benchmarks or standards, and determination of an acceptable level of risk”

• Essential component of maintaining safety in the laboratory

Goal: identify and mitigate risks of working in a laboratory environment
How to Perform a Biosafety Risk Assessment

Purpose:
This procedure describes the steps necessary to perform a risk assessment in either a section as a whole, for a new test, or for a specific infectious agent, using the template developed by members of the LSB Safety Committee.

Procedure:
Perform the procedure according to the steps in the following table.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Decide if the biosafety risk assessment will be for a section as a whole, for new testing being brought on board, or for a specific infectious agent (e.g. Ebola virus).</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Gather input from laboratory scientists working in the area and appropriate laboratory management. This information will be used to populate the standard biosafety risk assessment template. See Appendix A for an example of a completed template, formatted for iPassport.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Identify the most infectious organism(s) encountered in the section or the test. Annotate the infectious dose (if not known, write &quot;unknown&quot;) and route of infection*.</td>
<td></td>
</tr>
</tbody>
</table>
| 4    | Determine to which WHO Risk Group Classification the infectious organism belongs*:  

  1 = Low: Not associated with disease  
  2 = Moderate: Associated with disease that is rarely serious  
  3 = High: Associated with disease that is serious or lethal  
  4 = High: Associated with disease that is serious or lethal, is readily spread from person to person, and intervention is not usually available. |                           |
| 5    | List the tasks that are performed in the section or test and the frequency of the performance of each task. Tasks are grouped together based on exposure level.  

  Daily: 4 or more days per week  
  Periodically: 1 – 3 days per week  
  Sporadically: Less than 4 days per month |                           |
| 6    | Evaluate the level of risk associated with each route of exposure:  

  *Inhalation*: (Low, Moderate or High)  
  *Ingestion*: (Low, Moderate or High)  
  *Percutaneous*: (Low, Moderate or High)  
  *Mucous Membrane*: (Low, Moderate or High)  

  Low: Organism is unlikely to infect by this route  
  Moderate: Organism may infect by this route  
  High: Organism is likely to infect by this route |                           |
| 7    | Determine if there are any specific safety practices that need to be used for each task. SOP review was included for every task.                                                                                   |                           |
| 8    | Determine recommended biosafety level, appropriate for the risk.                                                                                                                                           |                           |
## Department Risk Assessment Form

**Risk assessment performed by:** __________________________  **Reviewed by:** __________________________  **Date:** ____________

Risk Assessment is based on healthy laboratorians with knowledge of the agents they are working with.

### Primary Disinfectant:

<table>
<thead>
<tr>
<th>Organism (if multiple choose most hazardous)</th>
<th>Task (task frequency**)</th>
<th>Route(s) of exposure and associated risk***</th>
<th>Specific Safety Practices</th>
<th>Biosafety Level Recommended</th>
<th>Engineering Controls Required</th>
<th>PPE Recommended</th>
<th>Disposal Considerations</th>
<th>Associated risk with PPE, Controls, and Safety Practices</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Inhalation-Ingestion-Percutaneous-Mucous membrane</td>
<td>SOP review.</td>
<td></td>
<td>Gloves, lab coat</td>
<td></td>
<td>Inhalation-L Ingestion-L Percutaneous-L Mucous membrane-L</td>
<td></td>
</tr>
<tr>
<td>Risk Group*</td>
<td></td>
<td>Inhalation-Ingestion-Percutaneous-Mucous membrane</td>
<td>SOP review.</td>
<td></td>
<td>Gloves, lab coat</td>
<td></td>
<td>Inhalation-L Ingestion-L Percutaneous-L Mucous membrane-L</td>
<td></td>
</tr>
<tr>
<td>Infectious dose (if known)</td>
<td></td>
<td>Inhalation-Ingestion-Percutaneous-Mucous membrane</td>
<td>SOP review.</td>
<td></td>
<td>Gloves, lab coat</td>
<td></td>
<td>Inhalation-L Ingestion-L Percutaneous-L Mucous membrane-L</td>
<td></td>
</tr>
<tr>
<td>Primary route of infection:</td>
<td></td>
<td>Inhalation-Ingestion-Percutaneous-Mucous membrane</td>
<td>SOP review.</td>
<td></td>
<td>Gloves, lab coat</td>
<td></td>
<td>Inhalation-L Ingestion-L Percutaneous-L Mucous membrane-L</td>
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</table>

**WHO classifications:**
1. **Low** - not associated with disease
2. **Moderate** - associated with disease that is rarely serious
3. **High** - associated with disease that is serious or lethal
4. **Very high** - associated with disease that is serious or lethal, is readily spread from person to person, and intervention not usually available.

**Task frequency:**
- **Daily** = 4 or more days per week
- **Periodically** = 1-3 days per week
- **Sporadically** = < 4 days per month

**Route(s) of exposure and associated risk:**
- **Inhalation**
- **Ingestion**
- **Percutaneous**
- **Mucous membrane**

**PPE:**
- Gloves, lab coat

**Disposal Considerations:**
- Inhalation-L
- Ingestion-L
- Percutaneous-L
- Mucous membrane-L

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*H:\LSB\Safety\Safety Committee\Risk Assessment*
Current Status of Non-public Health Clinical Laboratories
Biosafety Survey
Survey: Clinmicronet, Local Microbiology Club
11 questions related to biosafety, biosecurity, risk assessment, utilization of LRN Sentinel Level Protocols
Total Responses: 16
• 3 PHLs (1 international laboratory)
• 1 Veterans Administration Hospital
• 12 Private or Academic Medical Centers
Survey Results

Questions

1. Does your laboratory or institution have a biosafety officer (BSO) and if so, are they certified?
   
   Response: Yes (2)    No (14)

2. If no BSO, who serves as the Safety Officer?
   
   - IBO in one academic medical center
   - Master Technologist in Virology
   - Chief Technologist
   - Additional duty of Laboratory Manager
   - Microbiology is responsible for Biosafety
   - “I don’t know”
Survey Results

Questions

3. Does your laboratory have a Biosafety Plan? (YES): 9 (NO): 6

4. Do you have a Risk Assessment Plan? 9 (YES); 5 (NO); 2 didn’t know
   - “home grown but looking for a better checklist”

5. How frequent is your Risk Assessment Plan reviewed and updated: Annually/or as needed (12); Never (1); Don’t know (3)

6. How recent was your risk assessment conducted?
   - “just before CAP inspection”
   - “Not sure”
   - “Never”
   - “Within the Year (majority)
Survey Results

Questions

7. Do your personnel know the difference between biosafety and biosecurity?

Yes: (1)
- “Not entirely”
- “Haven’t asked, but probably not”
- “They understand biosafety, but not biosecurity since we do not have any BT agents”
- “I think so”
- “Most do, I think”
- “I sure hope so”
- “Some do, some don’t”
- “I do, doubt if the others do”

No (4)
Survey Results

Questions

8. Does your laboratory utilize the ASM Sentinel Level Protocols for Rule Out and Refer? 100%

9. Does your laboratory use commercial identification systems (conventional, automation, MALDI) to identify suspected biothreat agents?
   Yes (2)  No (9)  No Response (7)

10. How many personnel are certified for packaging and shipping?
   YES (16): range of personnel certified 1- all personnel certified
Survey Results

Questions

11. Does your laboratory frequently interact with your State Health Laboratory for Training?

   YES (11)    NO (3)*    No Response (2)
Resources for Training and BSO Certification

American Biological Safety Association (ABSA)

Behavioral-Based Improvement Solutions
Creating a Culture of Safety

Routine Training
Routine review of SOPs
Routine review of signage
Reward notable safety performance
Continual communication
Summary and Conclusions
Summary and Conclusions

• Education and Training of Clinical Laboratories in Biosafety, Biosecurity, Risk Assessment and Mitigation

• Administrators, VP Operations, Managers and CLIA License Holder need to promote and influence the importance and practice of safety including risk assessment

• Strengthen partnership between public health and clinical laboratories

• Develop a culture of safety in clinical laboratories

• Safety as part of the laboratory’s QA program

• Reach out to state health laboratory BSO: Excellent resource for training and evaluating the laboratory
Resources

American Association of Public Health Laboratories (APHL)
www.aphl.org

American Biological Safety Association (ABSA)
www.absa.org

Behavioral-Based Improvement Solutions
sean@seancaufman.com
THANK YOU!!!!!! QUESTIONS?