DLS ECHO Biosafety Session: February 28, 2023

Risk Assessment in Clinical Laboratories

Crystal Fortune, MPH, MLS (ASCP)^{CM} RBP (ABSA)

Newborn Screening Short-term Follow-up Coordinator and Biosafety Officer

Montana Laboratory Services Bureau

Agenda

- Didactic and Case Presentation
- Discussion
- Summary of Discussion
- Closing Comments and Reminders

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RISK ASSESSMENT IN CLINICAL LABORATORIES

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Biosafety Officer, Montana Public Health Laboratory, Helena, MT

PURPOSE OF BIOSAFETY

- To reduce the risk of exposing:
  - Laboratory personnel
  - The public
  - The external environment

to infectious agents by establishing effective containment….

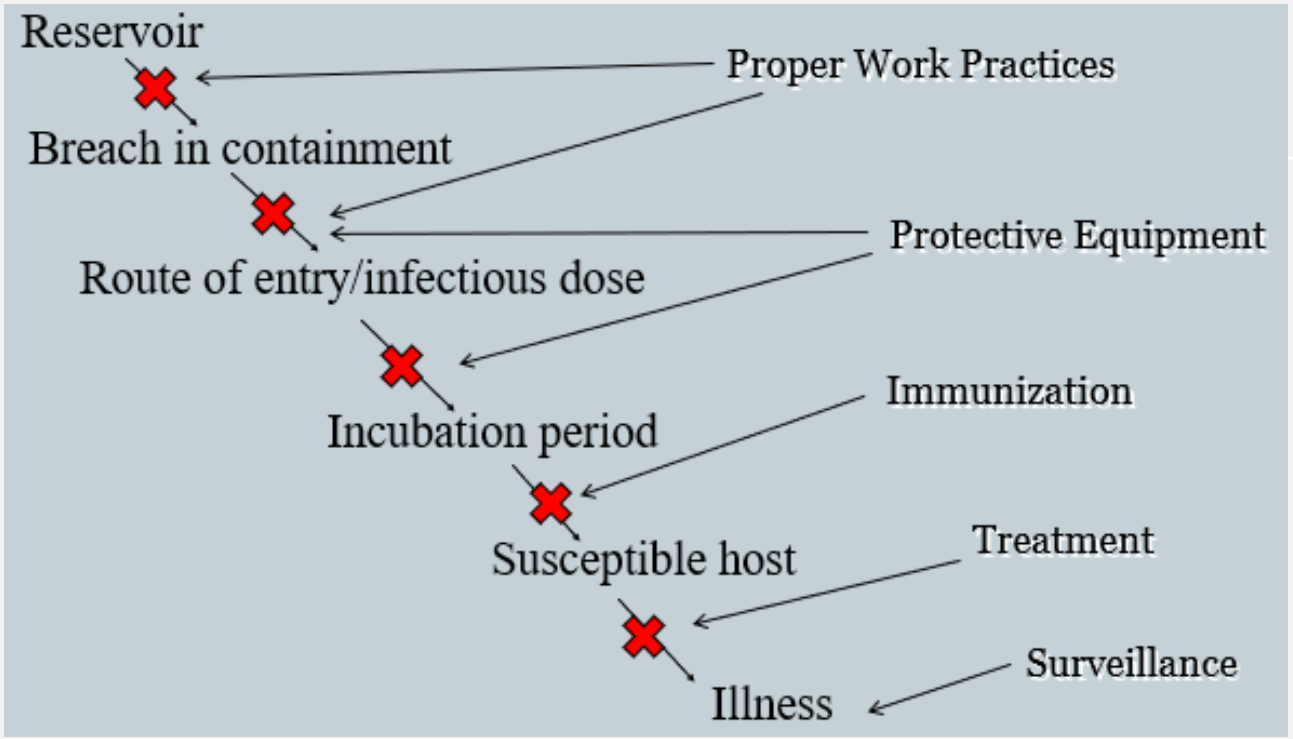
CONTAINMENT

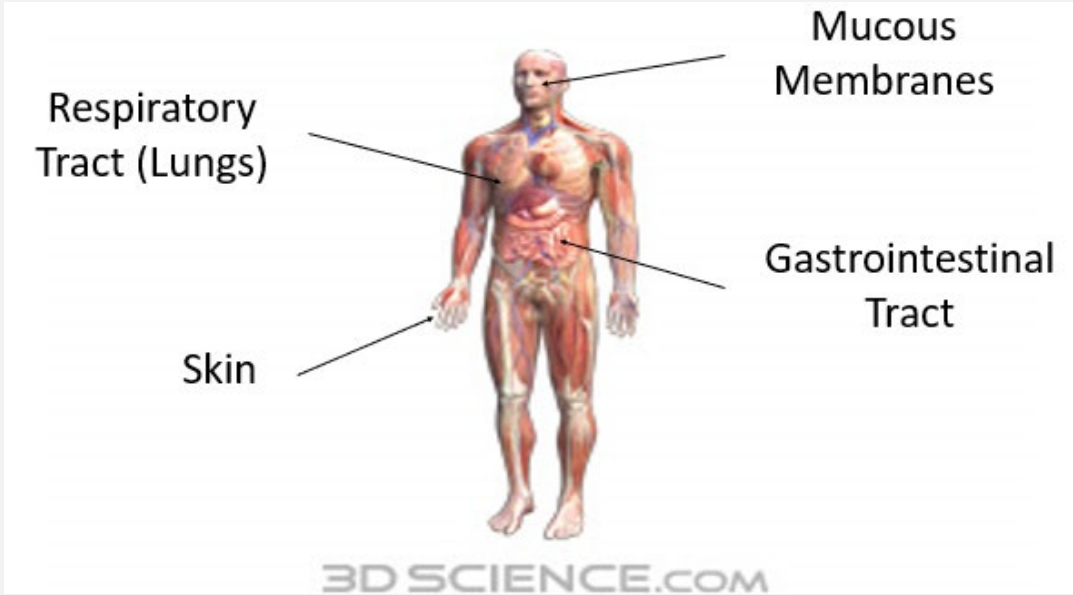
The combination of microbiological practices, safety equipment and facility safeguards to protect laboratory workers, the environment , and the public from exposure to infectious microorganisms that are present in the laboratory.

Primary-you and immediate area

Secondary-area outside of your containment laboratory

PORTALS OF ENTRY OF BIOLOGICAL AGENTS





INFECTIOUS DOSE

Organism	Route	Infectious Dose
E. coli O157:H7	Ingestion	~10
N. meningitidis	Parenteral inoculation, inhalation (primarily), and ingestion	unknown
Salmonella enterica spp.	Ingestion	~1000 for non-typhoid; 10^5 for enteric fever
Shigella spp.	Ingestion	~10-200

The number of microorganisms required to initiate infection can vary greatly with the specific organism and the route of exposure (information above is from the Pathogen Safety Data Sheets published by the Public Health Agency of Canada)

LABORATORIANS' RISK IS GREATER

Organism	Risk/100,000 microbiologists	Risk/100,000 general population
Brucella	641	0.08
E. coli O157:H7	8.3	0.96
N. meningitidis	25.3	0.62

Ellen Jo Baron and J. Michael Miller "Bacterial and fungal infections among diagnostic laboratory workers: evaluating the risks "Diagnostic Microbiology and Infectious Disease March 200860(3):241-6"

STANDARD MICROBIOLOGICAL PRACTICES FOR ALL BIOSAFETY LEVELS

- Limited access when work is in progress
- No eating, drinking, smoking, handling contact lenses or applying cosmetics
- Do not pipette by mouth
- Handle sharps appropriately

STANDARD MICROBIOLOGICAL PRACTICES FOR ALL BIOSAFETY LEVELS

- Limit generation of aerosols
- Decontaminate work services
- Decontaminate all infectious and potentially infectious wastes
- Post biohazard sign whenever infectious agents are present or in use
- Institute a pest control program
- Train staff in procedures and biosafety

BIOSAFETY LEVEL 2-FACILITY DESIGN

Institution level

- Appropriate signs and labels
- Medical surveillance and immunization program
- Site-specific biosafety manual

Safety Equipment (Primary barriers):

- BSCs available, with HEPA filters
- PPE: Lab coat, gloves, face and eye protection as needed
- Safety centrifuge

BIOSAFETY LEVEL 2-FACILITY DESIGN

Facilities (Secondary Barriers):

- Eyewash readily available
- Spill clean-up
- Air flows into lab without re-circulation to non-lab areas
- Restricted access when work is in progress
- Validated method of waste decontamination

Other design/construction issues:

- Separate from public areas

PRIMARY CONTAINMENT/BARRIERS

Safety equipment

- Personal Protective Equipment (PPE)
- Biological Safety Cabinets (BSC)
- Mechanical pipetting devices
- Safety centrifuge cups
- Removable rotors

CLASSES OF BIOLOGICAL SAFETY CABINETS

Class II (A1, A2, B1, B2)

- Protects worker, product, environment
- Use for work with
  - aerosol-transmissible micro-organism
  - tissue culture/virology
  - Large volumes or high concentrations
  - Trigger point indicators

SECONDARY CONTAINMENT/BARRIERS

- Separation of lab from public access
  - Autoclave facilities
  - Hand washing and eyewash facilities
  - Specialized ventilation systems
  - Directional airflow
  - Restricted access zones

RISK ASSESSMENT

- Assessment of risk focuses on agent hazards
  - Organisms and their potential to cause disease (Infectious dose? Vaccinations? Treatment? Severity?)
- Laboratory facility design and safety equipment
- Analytical process (platforms and laboratory hazards)
- Personal Protective Equipment
- Skill level/physical well-being of personnel
- Management/administration involvement

Evaluate and prioritize risks. Remember, risk is never zero!

HIGH RISK ACTIVITIES IDENTIFIED

- Sniffing plates?
- Generating aerosols – anything that imparts energy to a suspension (catalase)
- Subculturing, picking colonies
- Making slides
- Inoculating biochemicals
- Improper use of Biosafety Cabinets

ANY STORIES?

Does anyone have other high-risk activities to discuss?

APHL RISK ASSESSMENT BEST PRACTICES

May 6, 2016

- Components of a Risk Assessment
- Risk Mitigation
- Examples of risk assessment templates

RISK ASSESSMENTS

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

Personal Protective Equipment		
Item	**Yes**	**No**
1. Laboratory staff aware of personal protective equipment (PPE) requirements for this laboratory		
2. Do staff receive annual PPE competency assessment?		
3. PPE Care:		
a. Appropriately stored in laboratory?		
b. Inspected prior to use and in good condition?		
c. Not worn in laboratory area?		
4. PPE Selected:		
a. Facial shields/splash guards?		
b. Disposable laboratory coats?		
c. Nitrile gloves?		
d. Respiratory protection?		
i. Users are enrolled in a respiratory protection program?		
e. Cryo or autoclave gloves?		
f. Over sleeves/booties/bonnet		
5. Closed-toe shoes that cover entire foot worn in laboratory?		
Comments:		

PATHOGEN SAFETY DATA SHEETS

Agency of Canada | publique du Canada

Public Health Agency of Canada
www.publichealth.gc.ca

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Home > Laboratory Biosafety and Biosecurity > Biosafety Programs and Resources > Pathogen Safety Data Sheets and Risk Assessment > Neisseria meningitidis

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NEISSERIA MENINGITIDIS

PATHOGEN SAFETY DATA SHEET - INFECTIOUS SUBSTANCES

SECTION I - INFECTIOUS AGENT

NAME: *Neisseria meningitidis*

SYNONYM OR CROSS REFERENCE: Meningococci [1], meningococcemia, meningococcal infection, meningococcal meningitis.

CHARACTERISTICS: *Neisseria meningitidis* belongs to the family Neisseriaceae [2]. It is a Gram-negative, non-spore forming, non-motile, encapsulated, and non acid-fast diplococci, which appears in kidney bean shape under the microscope [1, 3]. It requires an aerobic environment with 5% CO_2 and enriched media containing blood for growth [1]. Medium-sized, smooth, transparent, non-pigmented, non-hemolytic, and convex colonies are produced on blood agar after overnight incubation at 35-37°C [1, 3]. It is oxidase and catalase positive [3]. It has at least 12 serogroups, with serogroups A, B, C, W-135, and Y being the most commonly encountered serogroups from invasive disease cases [2, 4].

SECTION II - HAZARD IDENTIFICATION

PATHOGENICITY/TOXICITY: *N. meningitidis* has a wide range of clinical manifestations, ranging from transient mild sore throat to fatal meningitis or meningococcal septicemia [3]. Meningitis and septicemia are the most common presentations of the disease [3].

Transient meningococcemia: Patients present with mild flu-like symptoms such as fever, joint pain, and occasionally rash. The illness lasts for a few days or weeks [3].

Meningitis [1, 3]: Most patients also present with signs of meningeal irritation, including, neck stiffness, bulging fontanelle (in infants), irritability, lying on one side away from light, and inability to extend the knee when hip is flexed in supine position (positive kernig's sign) [3, 4]. Convulsions, declining level of consciousness, and coma may occur [3]. The petechial rash of meningococcemia may also occur [1].

Meningococcemia: Patients present with rapid onset of fever, vomiting, photophobia, convulsions, skin rash, lethargy, irritability, drowsiness, diarrhea, muscular pain, arthralgia,

http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php

Primary Risk Assessment is based on healthy laboratorians with knowledge of the agents they are working with
Disinfectant: Vesphene

Organism (if many involved chose the most hazardous)	**Task (task frequency**)**	**Route(s) of exposure and associated risk*****	**Specific Safety Practices**	**Biosafety Level Recommended**	**Engineering Controls Required**	**PPE Required**	**Disposal Considerations**	**Associated risk with PPE, Controls, and Safety Practices**
CRE/CRPA **Risk Group: 2*** **Infectious dose: Varies** **Primary route of infection: Percutaneous** **Organisms from Sterile Sources (i.e. *N. meningitidis*)** **Risk Group: 2*** **Infectious dose: unknown**	Specimen accessioning (Daily)	Inhalation-L Ingestion-L Percutaneous-L Mucous membrane-L	SOP review.	BSL-2	Specimens remain in biohazard bags for transport.	Gloves, lab coat	All waste goes into autoclave bag or disinfectant filled bucket and autoclaved.	Inhalation-L Ingestion-L Percutaneous-L Mucous membrane-L
	Specimen processing and media inoculation (Daily)	Inhalation-M Ingestion-M Percutaneous-L Mucous membrane-L	SOP review.	BSL-2	Biosafety Cabinet for isolates from sterile sources Safety shield for isolates from non-sterile sources	Gloves, lab coat, N-95 respirator Gloves, lab coat	Same as above	Inhalation-L Ingestion-L Percutaneous-L Mucous membrane-L
	MCIM/CARBAR	Inhalation-M Ingestion-L Percutaneous-L Mucous membrane-L	SOP review.	BSL-2	Biosafety Cabinet for isolates from sterile sources Safety shield for isolates from non-sterile sources	Gloves, lab coat, goggles	Same as above	Inhalation-L Ingestion-L Percutaneous-L Mucous membrane-L
	Plate reading and sub-culturing, preparing	Inhalation-M Ingestion-L Percutaneous-M Mucous membrane-L	SOP review.	BSL-2	Biosafety Cabinet for isolates from sterile sources	Gloves, lab coat, N-95 respirator	Same as above	Inhalation-L Ingestion-L Percutaneous-L Mucous membrane-L

*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-high**-associated with disease that is serious or lethal, is readily spread from person to person, and intervention not usually available.

** Daily = 4 or more days per week, Periodically = 1-3 days per week, Sporadically = < 4 days per month.

***Inhalation, Ingestion, Percutaneous, Mucous membrane **Low**-organism is unlikely to infect by this route, **Mod**-organism may infect by this route, **High**-organism is likely to infect by this route.

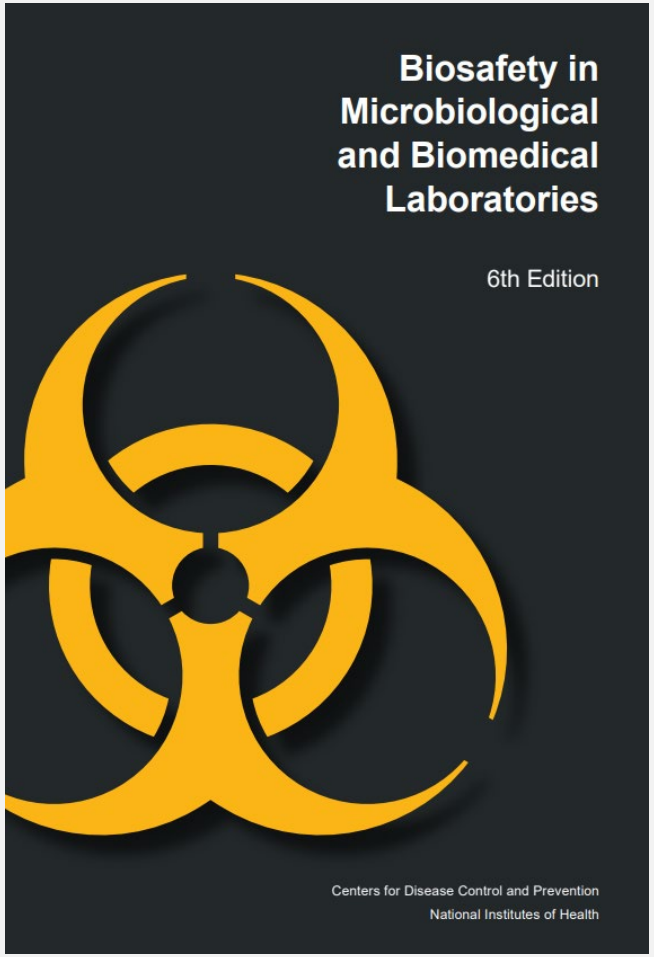
CONSIDERATIONS FOR CLINICAL LABORATORIES

What challenges do you anticipate in clinical laboratories in your jurisdiction?

CONSIDERATIONS FOR CLINICAL LABORATORIES

- Establish relationships with local public health
  - Active surveillance
- Establish policy that physicians contact the laboratory when they suspect infectious diseases
- Know your staff!
- Ensure staff are aware of trigger points
- Consider fomites!

CONSIDERATIONS FOR CLINICAL LABORATORIES



Appendix N—Clinical Laboratories

Clinical Laboratory Biosafety

Most contemporary medical decision-making utilizes the result(s) of at least one diagnostic test conducted in a clinical laboratory as a part of evidence-based care.[1,2] Clinical laboratories are one of the first lines of public health defense because they detect and report epidemiologically important organisms and identify emerging patterns of antimicrobial resistance. The safe, effective operation of clinical laboratories is critical for both the care of individual patients and the health of laboratory professionals, the community, and the environment.

In 2016, following the U.S. Ebola crisis, the U.S. Clinical Laboratory Improvement Advisory Committee (CLIAC) recognized "the matter of biosafety in clinical laboratories as an urgent unmet national need." In particular, CLIAC indicated the need for concise, understandable guidance to help enable clinical laboratories to assess and mitigate risks when the identity of the infectious agent is unknown or unconfirmed.[3] This appendix focuses on biorisk management (BRM) in a clinical laboratory environment and includes considerations to effectively assess and mitigate risks and evaluate the performance of the implemented controls in reducing risks associated with the handling, storage, and disposal of hazardous biological materials.[4]

Conducting Risk Assessments in a Clinical Laboratory Environment

Risk assessment is the process of evaluating the risk(s) that arise from agent and laboratory hazards, taking into account the adequacy of existing controls, prioritizing those risks, and deciding if the risks are acceptable.[5] The risk assessment generates information that guides the selection of appropriate microbiological practices, safety equipment, and facility safeguards that can reduce Laboratory-associated infections (LAIs). In addition, the integration of the risk assessment process into daily laboratory operations results in the ongoing identification and prioritization of risks and the establishment of risk mitigation protocols tailored to specific situations; this promotes a positive culture of safety.[6] Please refer to Section II for additional information.

Risk assessment is the foundation of every comprehensive BRM system. The BRM approach is similar to the Quality Management System (QMS) or Individualized Quality Control Plan (IQCP) that clinical laboratories commonly use to establish quality standards for laboratory testing. QMS and IQCP include processes for risk assessment, quality control planning, and quality assessment.[7] BRM includes processes for risk assessment, risk mitigation and performance evaluation of implemented controls to reduce risks; this has become known as the Assessment Mitigation Performance (AMP) model.[4] Ideally, BRM and QMS should be integrated and mutually supportive systems in a clinical laboratory.

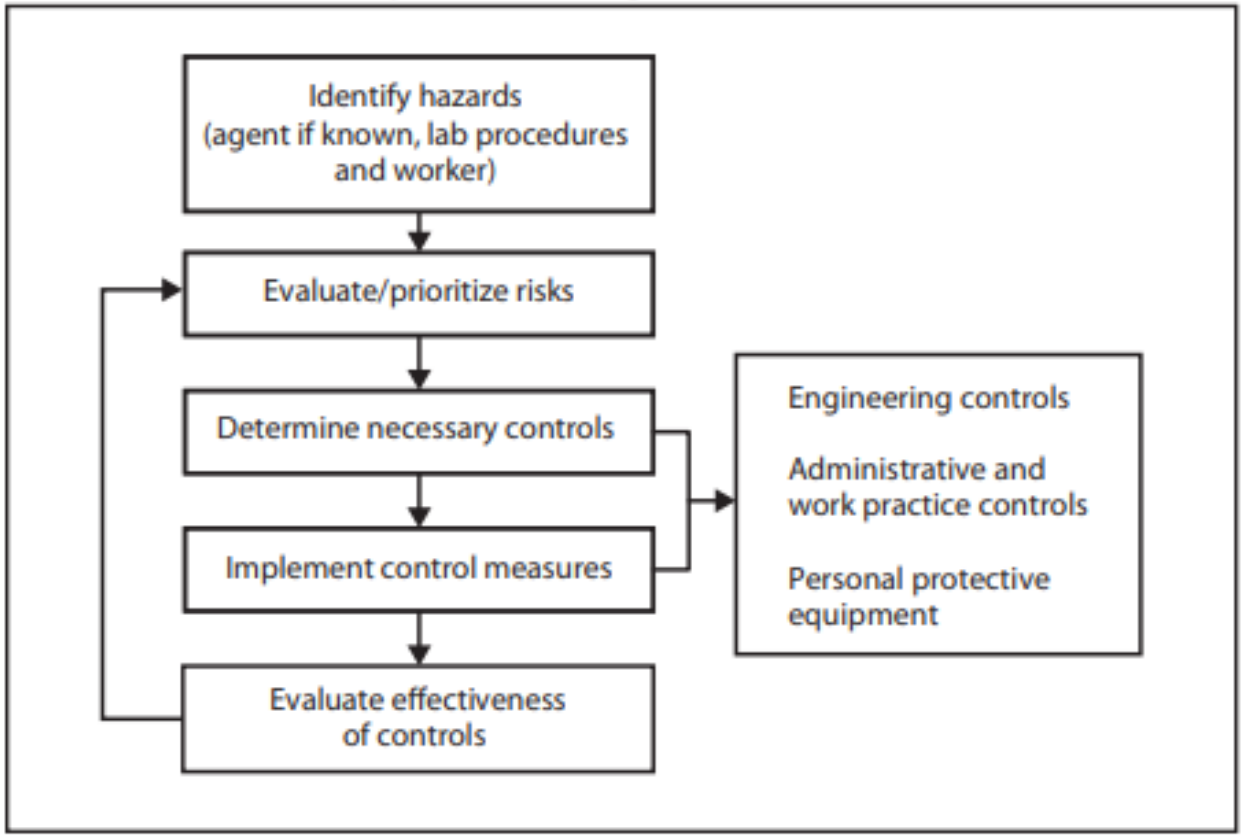
BLUE RIBBON PANEL, 2012

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Supplement / Vol. 61
January 6, 2012

Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories

Recommendations of a CDC-convened, Biosafety Blue Ribbon Panel

FIGURE 1. Risk assessment process for biologic hazards



BLUE RIBBON PANEL, CONT.

TABLE 1. Laboratory activities associated with exposure to infectious agents

Routes of exposure/transmission	Activities/practices
Ingestion/oral	• Pipetting by mouth • Splashing infectious material • Placing contaminated material or fingers in mouth • Eating, drinking, using lipstick or lip balm
Percutaneous inoculation/nonintact skin	• Manipulating needles and syringes • Handling broken glass and other sharp objects • Using scalpels to cut tissue for specimen processing • Waste disposal (containers with improperly disposed sharps)
Direct contact with mucous membranes	• Splashing or spilling infectious material into eye, mouth, nose • Splashing or spilling infectious material onto intact and nonintact skin • Working on contaminated surfaces • Handling contaminated equipment (i.e., instrument maintenance) • Inappropriate use of loops, inoculating needles, or swabs containing specimens or culture material • Bites and scratches from animals and insects • Waste disposal • Manipulation of contact lenses
Inhalation of aerosols	• Manipulating needles, syringes, and sharps • Manipulating inoculation needles, loops, and pipettes • Manipulating specimens and cultures • Spill cleanup

Source: Sewell DL. Laboratory-associated infections and biosafety. Clin Micobiol Rev 1995;8:389–405 (*18*).

BLUE RIBBON PANEL, CONT.

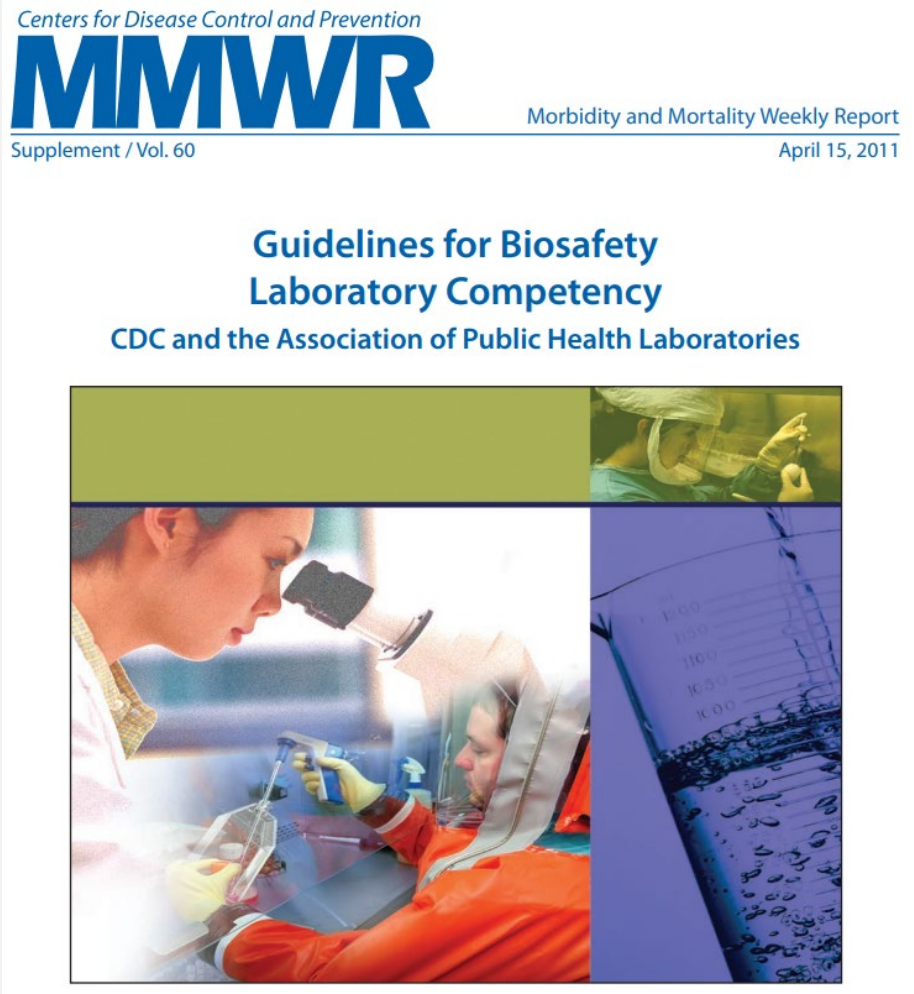
TABLE 2. Risk prioritization of selected routine laboratory tasks

	Exposure risk			
Task or activity	**Potential hazard**	**Likelihood**	**Consequence**	**Risk rating**
Subculturing blood culture bottle	Needle stick — percutaneous inoculation	Likely	Infection; medical treatment	High
	Aerosols — inhalation	Moderate	Infection; medical treatment	Medium
	Splash — direct contact with mucous membranes	Moderate	Infection; medical treatment	High
Centrifugation	Aerosols — inhalation	Likely	Infection; medical treatment	High
Performing Gram stain	Aerosols from flaming slides	Moderate	Colonization; infection	Moderate
Preparing AFB smear only	Aerosols from sputum or slide preparation	Likely	Illness; medical treatment; disease	High
Performing catalase testing	Aerosols — mucous membrane exposure	Unlikely	Colonization; infection	Low
AFB culture work-up	Aerosols — inhalation	Likely	Illness; medical treatment; disease	High

Abbreviation: AFB = acid-fast bacillus.

CONSIDERATIONS FOR CLINICAL LABORATORIES

- Use risk assessment to determine which precautions should apply to which tasks
- Consider all phases of testing
- Use biosafety competencies for guidance to ensure individuals at all levels know their responsibilities
- Use checklists to guide in factors to consider



BIOSAFETY CHECKLISTS

BIOSAFETY CHECKLIST **APRIL 2015**

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.

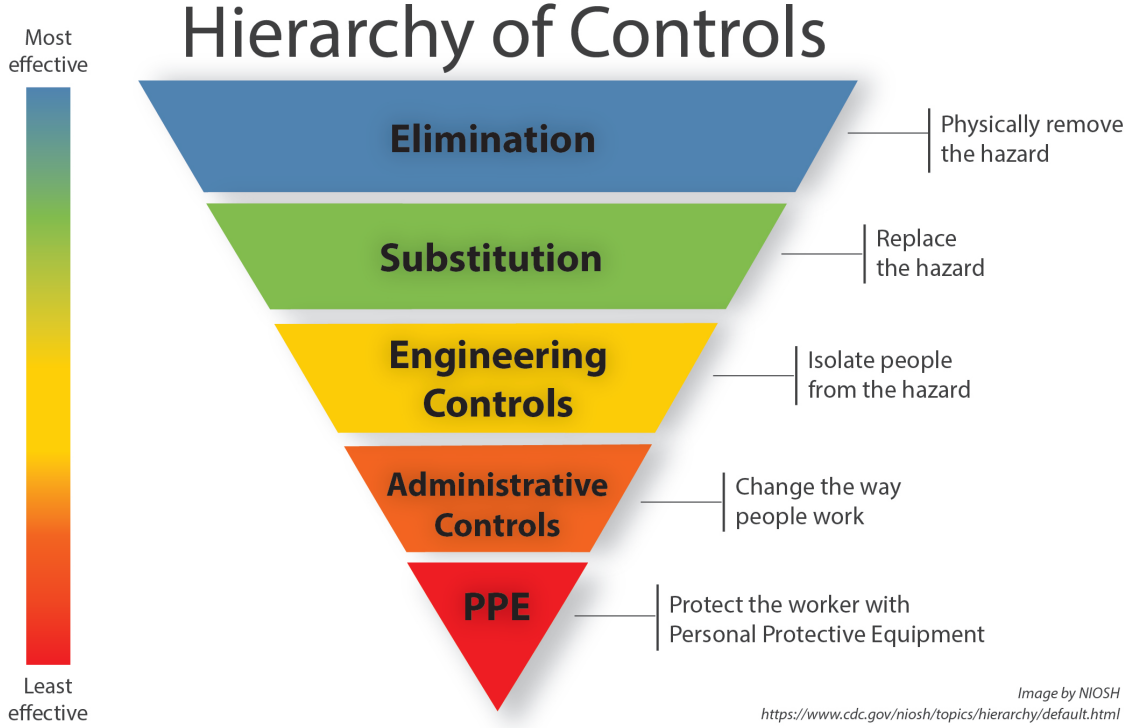
APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

Clinical Laboratory Biosafety Risk Management Program Assessment Checklist

LAB ID and LABORATORY NAME:	
ASSESSOR NAME:	DATE:

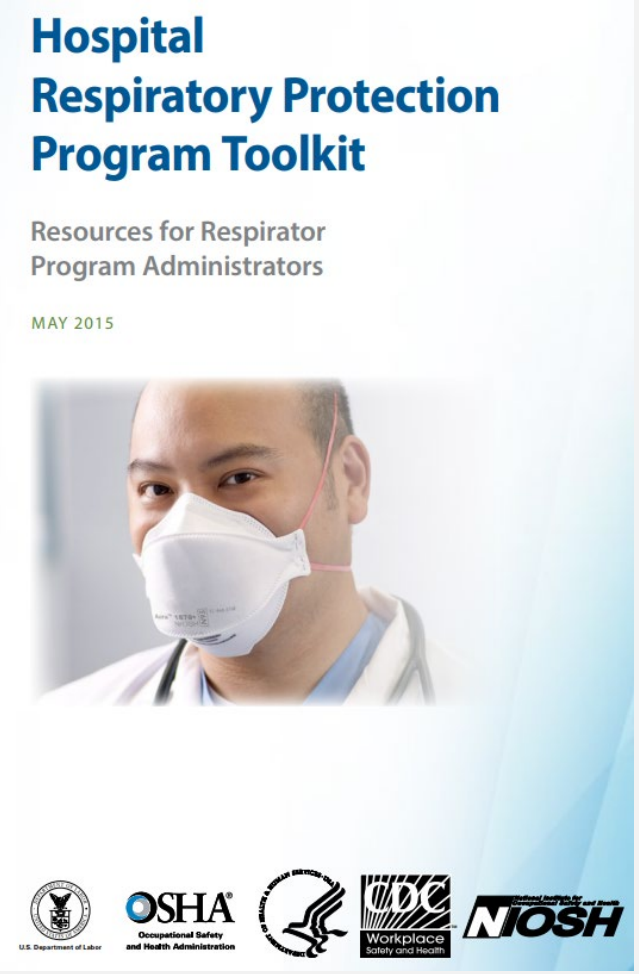
Question	Y	N	NA	Comments
1. ESSENTIAL ELEMENTS FOR MANAGING AN EFFECTIVE BIOSAFETY PROGRAM				
1.1 Responsibility for Managing Biosafety				
Is the laboratory director responsible for ensuring that systems are in place and documented for identifying potential hazards, assessing risks associated with those hazards, and establishing precautions and standard procedures to minimize employee exposure to those risks? Is there a standard operating procedure (SOP) in place to document these?				
Is the laboratory director responsible for providing facilities commensurate with each laboratory's function and the recommended containment level for the agents or materials being handled? Is this written in an SOP?				
Are supervisory staff responsible for the following and are these responsibilities documented? • Conducting, reviewing, and approving risk assessment results. • Developing lab-specific safety plans; • Ensuring completion of initial and refresher training of laboratory workers, and for ongoing monitoring and correction of unsafe practices and conditions within the lab.				
Are employees encouraged to report accidents or incidents and are these reports promoted as nonpunitive and as opportunities for improvement?				
Is compliance with safety policies and completion of safety-related training considered in staff performance evaluations?				

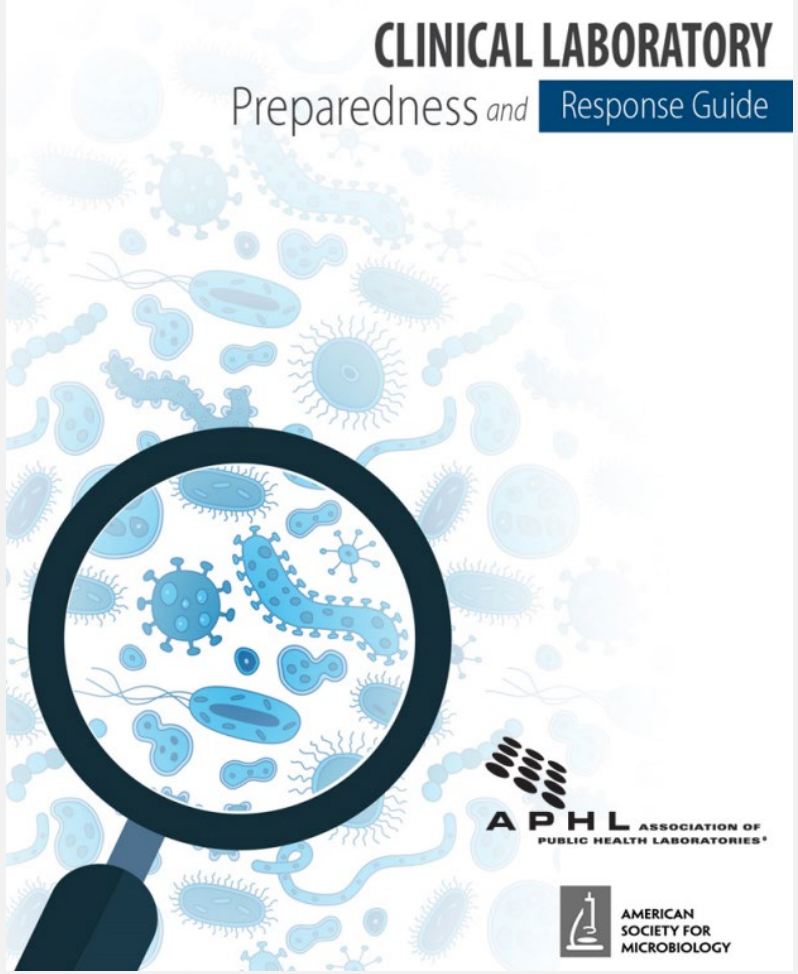
CONSIDERATIONS FOR CLINICAL LABORATORIES



- Prioritize Risk
  - If some controls are lacking, increase combinations of others
  - Establish protocols to limit exposed staff, contamination of instruments
  - If the risk is too high, consider referring samples out

OTHER AVAILABLE RESOURCES





OPEN CHAT

What other resources do you provide clinical laboratories in your jurisdiction?

CASE STUDY INTRODUCTION

A microbiologist is working a rotation in a laboratory that performs regulatory meat testing. Job duties include making bacterial DNA plugs from enteric isolates received for DNA fingerprinting.

What risks may be inherent in this type of work?

(i.e. Tasks? Routes of exposure?)

CASE STUDY-SCENARIO

Two days later, the microbiologist develops fever and diarrhea and is hospitalized overnight.

What might the doctor treating the microbiologist need to know?

CASE STUDY-INVESTIGATION

The doctor orders a stool culture, which reveals a co-infection with Salmonella and *Campylobacter jejuni*. Working in the food laboratory can result in exposure to either of these pathogens.

When the microbiologist returns to work, the laboratory safety officer conducts an investigation to determine if this was a laboratory-associated infection. As a biosafety officer, what would you want to know?

CASE STUDY-EXPOSURE

The microbiologist, two days before becoming ill, had been preparing a patient isolate of *Campylobacter jejuni* for DNA testing.

What is the route of infection for this organism, and what control measures might you recommend?

CASE STUDY-RESULTS

The results of the investigation were as follows:

The incubation time was appropriate for infection with *Campylobacter jejuni*.

The DNA patterns of the microbiologist's isolate and the patient's isolate were a match.

The DNA pattern of the Salmonella did not match any recent isolates.

CASE STUDY CONCLUSION

The waste container where gloves and other supplies were discarded was getting full.

The microbiologist may not have followed good hand-washing technique after disposal of gloves.

What are your recommendations to prevent this from happening again?

ANY FURTHER DISCUSSION OR COMMENTS?

THANK YOU FOR SHARING WITH ME YOUR STORIES, EXPERTISE, AND YOUR TIME!

REFERENCES

- Template for Public Health Laboratory Risk Assessment for Ebola Virus Disease (EVD) Testing, APHL (no date)
- Pathogen Safety Data Sheets, Public Health Agency of Canada
- Biosafety in Microbiological and Biomedical Laboratories, 6th Edition
- Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories, MMWR, January 6, 2012
- Competency Guidelines for Public Health Laboratory Professionals, MMWR, May 2015
- Guidelines for Biosafety Laboratory Competency, MMWR, April 15, 2011
- A Biosafety Checklist: Developing a Culture of Biosafety, APHL, April 2015
- Clinical Laboratory Biosafety Risk Management Program Assessment Checklist, APHL (no date)
- Respiratory Protection Program Toolkit, OSHA, April 2022
- Clinical Laboratory Preparedness and Response Guide, APHL, November 2016

DLS ECHO Biosafety Session: March 22, 2023

Safely Implementing New Diagnostics Platforms Commonly Used in Clinical Laboratories

Christina Egan, PhD
Deputy Director, Division of Infectious Diseases
Wadsworth Center, New York State Department of Health
Albany, NY

Michael J. Perry, MS, MS Ed.
Associate Director, Biodefense Laboratory
Wadsworth Center, New York State Department of Health
Albany, NY