Biosafety and Risk Assessment for Clinical Laboratories

Carrie Anglewicz
Michigan Department of Health and Human Services
Bureau of Laboratories

Prevent Disease – Promote Wellness – Improve Quality of Life

Objectives

- Explain the importance of biosafety
- Identify the components of a biosafety risk assessment
- Recognize strategies to mitigate risk when working in the laboratory

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Why is Biosafety Important?

- “New” diseases
- “Old” diseases
- New technology
- Same human behavior

What is Biosafety?

- "The discipline addressing safe handling and containment of infectious microorganisms and hazardous biological materials" –BMBL 5th Edition

- Risk Assessment- the basis of a biosafety program

Laboratory Acquired Infections (LAIs)

TABLE 1.

Comparison of 10 most commonly reported LAIs

1930–1978[a]				1979–2015			
Rank	Agent[b]	No. LAIs	No. deaths	Rank	Agent[b]	No. LAIs	No. deaths
1	*Brucella* spp.	426	5	1	*Brucella* spp.	378	4[c]
2	*Coxiella burnetii*	280	1	2	*Mycobacterium tuberculosis*	255	0
3	Hepatitis B	268	3	3	Arboviruses[d]	222	3
4	*Salmonella enterica* serovar Typhi	258	20	4	*Salmonella* spp.	212	2[e]
5	*Francisella tularensis*	225	2	5	*Coxiella burnetii*	205	3
6	*Mycobacterium tuberculosis*	194	4	6	Hantavirus	189	1
7	*Blastomyces dermatitidis*	162	0	7	Hepatitis B virus	113	1
8	Venezuelan equine encephalitis virus	146	1	8	*Shigella* spp.	88	0
9	*Chlamydia psittaci*	116	9	9	Human immunodeficiency virus	48	Not known
10	*Coccicioides immitis*	93	10	10	*Neisseria meningitidis*	43	13
		2,168	48			1,753	24

[a]Adapted from reference 27.
[b]Not included are 113 cases of hemorrhagic fever contracted from wild rodents in one laboratory in Russia in 1962 (486).
[c]All deaths are aborted fetuses.
[d]Typical arboviruses and orbiviruses, rhabdoviruses, and arenaviruses that are associated with arthropods or have zoonotic cycles (233), with additional arboviral reports added.
[e]One death was a secondary exposure case (47).

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LAIs

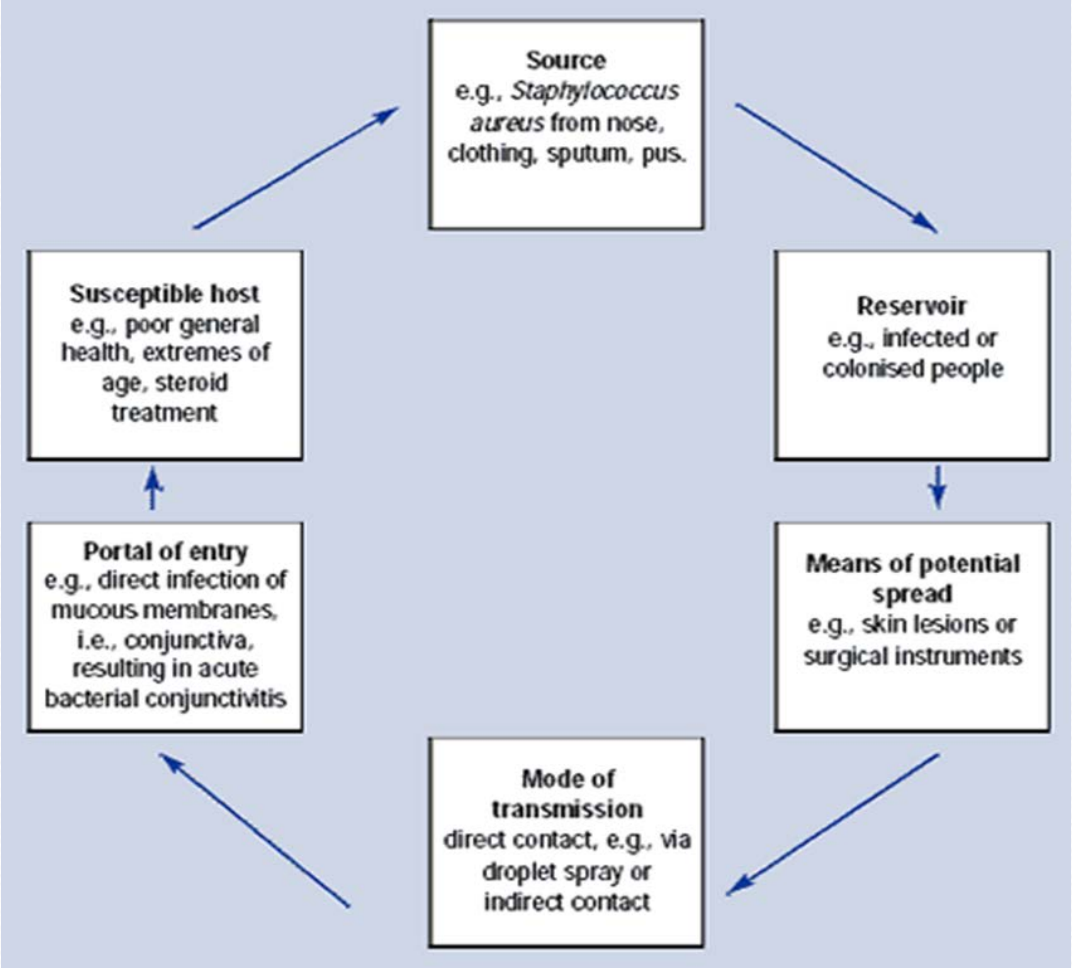
TABLE 3.

Number of LAIs associated with indicated primary work purpose

	Clinical		Research		Production		Teaching		Site not listed		Field	Total		
	1930–1975[a]	1979–2015	1930–1975	1979–2015	1930–1975	1979–2015	1930–1975	1979–2015	1930–1975	1979–2015	1979–2015	1930–1975	1979–2015	1930–2015
Bacteria	396	783	914	122	40	81	69	181	378	45–59	1	1,797	1,212–1,226	3,009–3,023
Rickettsiae	27	1	455	204	18	0	0	0	73	0		573	205	778
Viruses	173	215	706	497	73	9	15	13	82	9–10	16	1,049	760–761	1,809–1,810
Parasites	18	5	70	77	0	0	4	81	23	6	1	115	170	285
Fungi	43	4	155	16	2	0	18	1	135	4–5	0	353	25–26	378–379
Unspecified	20	—	7	0	1	0		0	6			34	—	34
Total	677	1,008	2,307	916	134	90	106	276	697	58–74	18	3,921	2,372–2,388	6,293–6,309

[a]Adapted from reference 28.

Chain of Infection



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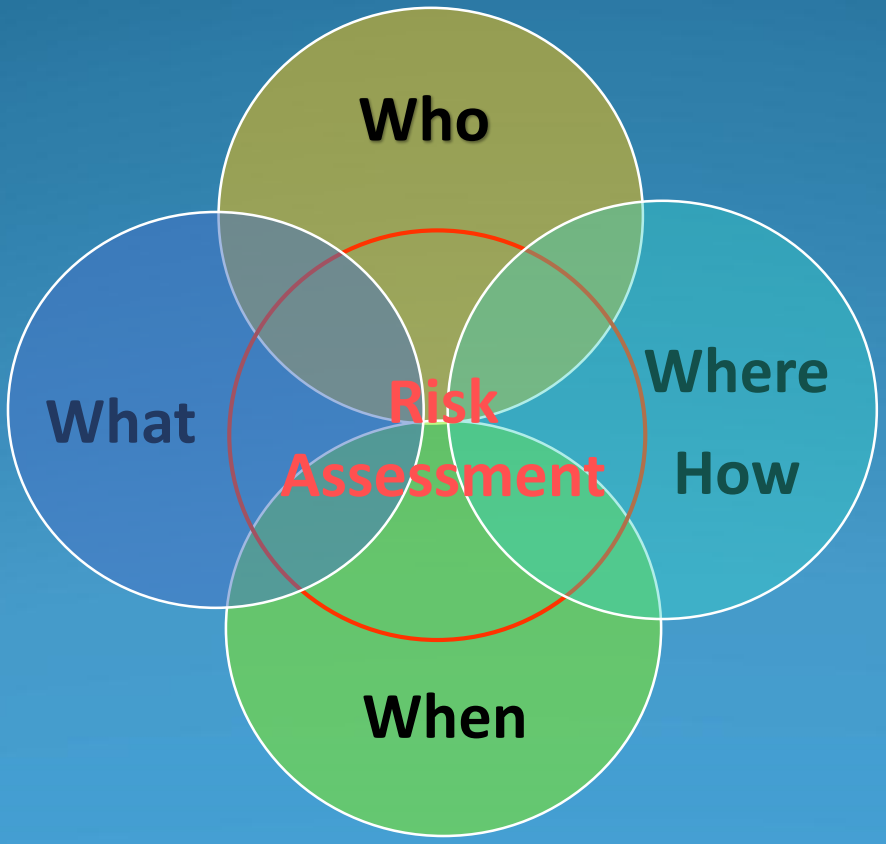
Biosafety Risk Assessment



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Biosafety Risk Assessment

- Examines *likelihood* and *consequence* of exposure
- Specimen collection to disposition
- Mitigate risks
  - Risk is never zero

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Biosafety Risk Assessment

It's not the same as IQCP

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Helpful Guidelines and Resources

- OSHA / MIOSHA
- CDC resources
  - Website
  - Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories
    (MMWR 2011; 60(Supp/ Vol. 61)
  - Biosafety in Microbiological and Biomedical Laboratories (BMBL)
- WHO Biosafety Manual
- Public Health Agency of Canada: Pathogen Safety Data Sheet

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Steps to Perform Biosafety RA

1. Identify the hazards
2. Prioritize the Risk
3. Evaluate the proficiency of staff
4. Identify biosafety gaps and mitigate
5. Review the risk assessment

1. Identify the Hazards

- **Hazard**: determined by ability to infect and cause disease or injury
  - Virulence, route of transmission, infective dose, stability in environment, host range, availability of preventive measures

Centers for Disease Control and Prevention. Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories. MMWR 2011; 60 (Supplement/ Vol. 61)

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Hazard

- **Agent**: Pathogens, chemicals, toxins
- **Procedure**: new methodology, instrumentation, equipment, reagents, aerosol generation
- **Staff**: new staff, complacency, fear,
  lack of training/knowledge/proficiency
- **Environment**: unfamiliar to staff, disrepair, safety issues

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High Risk Activities: Trigger Points

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High Risk Activities

- Test Results: GNDC, GN coccobaccili, Reading plates
- Sniffing plates
- Source of specimen: Respiratory, Blood Culture, CSF
- Working with sharps
- Doffing PPE
- Generating aerosols
  - Using a vortex
  - Centrifuging
  - Using automated analyzers
  - Making slides

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Other Considerations: Working with…

- Chemicals
- Environmental Hazards- Worksite
- Unknowns

2. Prioritize the Risk: What is acceptable risk?

- Perception and tolerance of risk is different in every institution and "culture"
- Judgement call and ever changing
- Deciding on the probability of exposure is most objective way to measure risk

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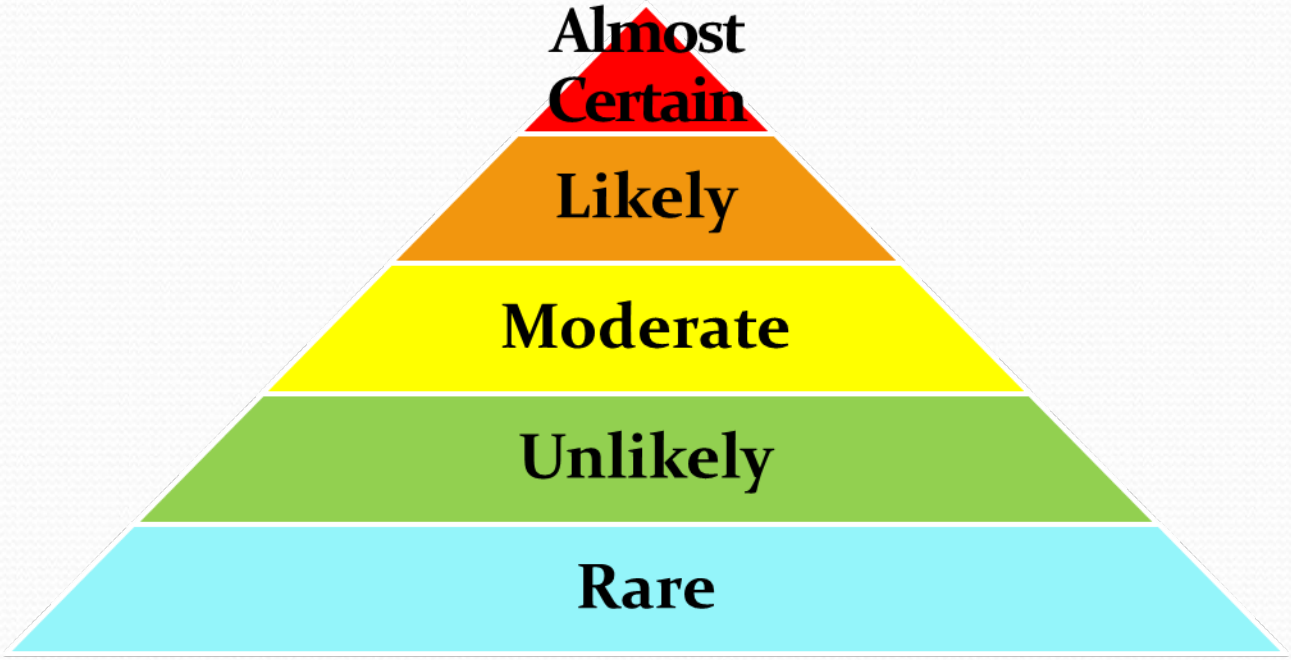
2. Prioritize the Risk

- What is the **likelihood** (**probability**) of exposure?



2. Prioritize the Risk

- What are the **consequences** (severity)?
  - Depends on several factors: available vaccines, host immunity, treatment options
  - **Catastrophic: Death**
  - **Critical/Major: Disease and squealae**
  - **Moderate: medical treatment, asymptomatic infection**
  - **Minor: colonization leading to carrier state**

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2. Prioritize the Risk: Matrix

			Potential Consequences				
			L6	L5	L4	L3	L2
			Minor injuries or discomfort. No medical treatment or measureable physical effects.	Injuries or illness requiring medical treatment. Temporary impairment.	Injuries or illness requiring hospital admission.	Injury or illness resulting in permanent impairment.	Fatality
			Not Significant	**Minor**	**Moderate**	**Major**	**Severe**
Likelihood	Expected to occur regularly under normal circumstances	**Almost Certain**	**Medium**	**High**	**Very High**	**Very High**	**Very High**
	Expected to occur at some time	**Likely**	**Medium**	**High**	**High**	**Very High**	**Very High**
	May occur at some time	**Possible**	**Low**	**Medium**	**High**	**High**	**Very High**
	Not likely to occur in normal circumstances	**Unlikely**	**Low**	**Low**	**Medium**	**Medium**	**High**
	Could happen, but probably never will	**Rare**	**Low**	**Low**	**Low**	**Low**	**Medium**

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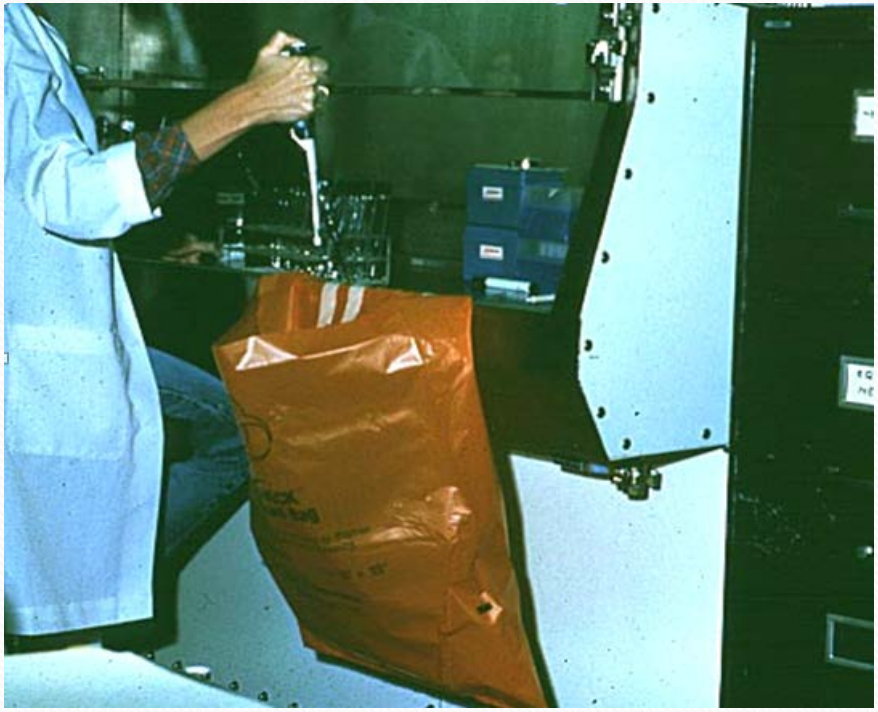
3. Staff: Biosafety Competencies

- **Skills, Training**: Proper technique, use of engineering controls, proper use of PPE, drills, exercises
  - How often do you train on BSC use and PPE?



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3. Staff: Biosafety Competencies

- **Abilities**: Judgement; ability to discern hazards and understand risk when "unknown" situations arise, know when to involve management, accident reporting

- **Knowledge**: Testing principles, symptoms of disease, hazards and risks

3. Staff: Health Status

- **Pathogen Targets**: *Listeria* sp., *Toxoplasma* sp., rubella virus, Zika virus: advisable for pregnant laboratorian?
- **Immunocompetency**: underlying immunodeficiency or suppressive therapies cause increase vulnerabilities
- Availability of vaccinations
- Encourage use of medical leave when ill: skills, judgement and reaction time may be impaired

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Risk Assessment Templates

Documenting that you've evaluated hazards and risks

Cell phones should not be used while working in the lab

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How: Risk Assessment Templates

- There is no 'one' right way to perform a risk assessment

- Format depends on facility: a couple of examples
  - Risk Matrix
  - Procedural template provided by Bureau of Laboratories
    - http://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_5103-378020--,00.html

Editable Procedural Template

Clinical Laboratory Biosafety Risk Assessment

Procedure	Potential Hazard(s)	Control/Protection	Additional Information
Specimen Handling	Centrifugation	• Ensure integrity of specimen container and sealed cap • Use r…ifuges inside B…aking sure not t…the cabinet • Employ safety cups / sealed rotors. • If using counter top or full size centrifuge, load and unload sealed centrifuge rotors in BSC	• If a specimen breaks inside centrifuge, wait 60 minutes for aerosols to settle before opening lid and assessing the spill. • Follow manufacturer's maintenance schedule

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Template for Analyzers

LABORATORY ANALYZERS AND GENERAL EQUIPMENT

The *Biosafety in Microbiological and Biological Laboratories* (BMBL) 5th Edition provides guidance on facilities, work practices, PPE, and medical surveillance

Laboratory / Room:
Assessor:
Laboratory Equipment/Analyzer:
Specimen Type (ex: serum, stool, whole blood):
Biosafety Level: 1 2 3 4

Is the instrument an open system? (caps are removed to test sample) YES NO

Is there splash potential? YES NO

Does the procedure generate aerosols? (vortex, centrifuge, sonicate) YES NO

** *If YES to any of above questions, list mitigation steps at end of assessment*

Decontamination procedure is verified and performed regularly? YES NO

Waste disposal follows OSHA Bloodborne Pathogen Standard and local health codes YES NO

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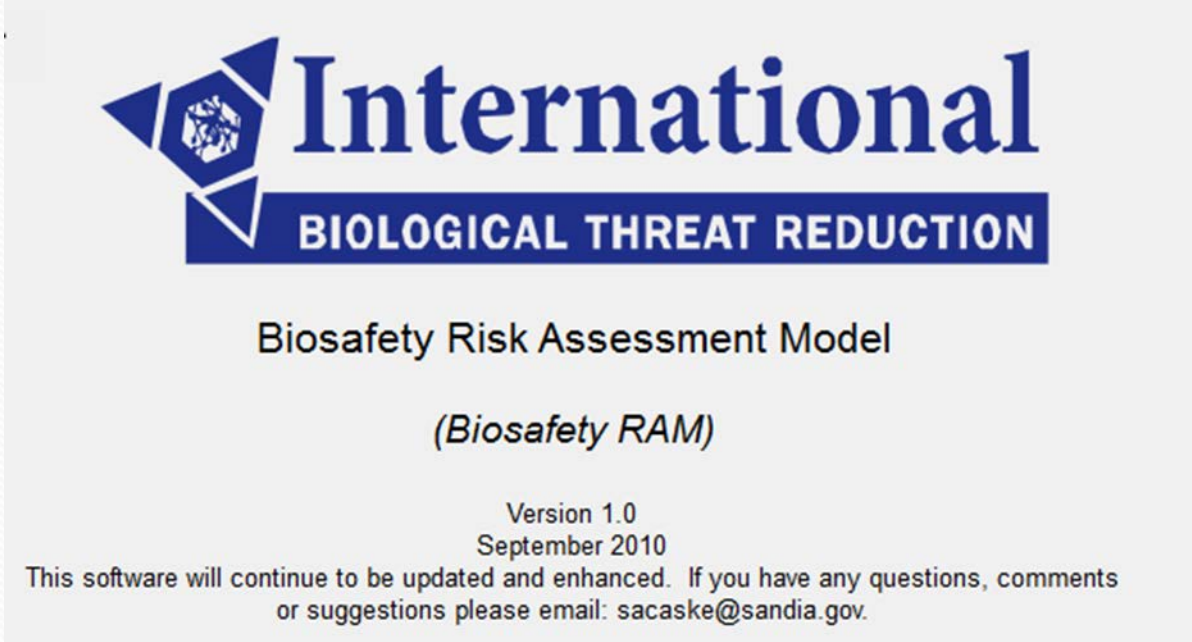
Risk Matrix



Example only: Not an endorsement!!

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BioRAM Risk Matrix

Likelihood of Exposure

Potential Exposure From Laboratory Processes

Type of Material

What type of material will be used in this procedure? (If the procedure will have both purified material and diagnostic samples

4 = Purified biological materials
2 = Diagnostic samples (e.g. blood, urine, tissue, saliva, etc)
1 = Environmental samples (e.g. soil, water, etc)

What is the greatest volume of material

4 = Over 10 liters
2 = Up to 10 liters
1 = Milliliter volume

Inhalation Exposure

What is the potential for aerosols to be

4 = A notable potential for the gene
1 = A limited quantity of aerosols m
0 = No procedures in use which ma

Are aerosolization experiments being c

4 = Large scale aerosolization exp
3 = Small scale aerosolization exp
0 = No aerosol experiments are be

Percutaneous Exposure

What is the amount of sharps used in th

4 = A large volume of sharps in use
3 = A small volume of sharps in use
0 = There are no sharps in use

Inhalation

Is this agent known to cause infection via inhalation in humans (to cause infection via droplets or droplet nuclei that have entered the upper or lower respiratory tract) in a laboratory setting?

4 = Preferred Route
2 = A possible route
1 = Unknown
0 = Not a route

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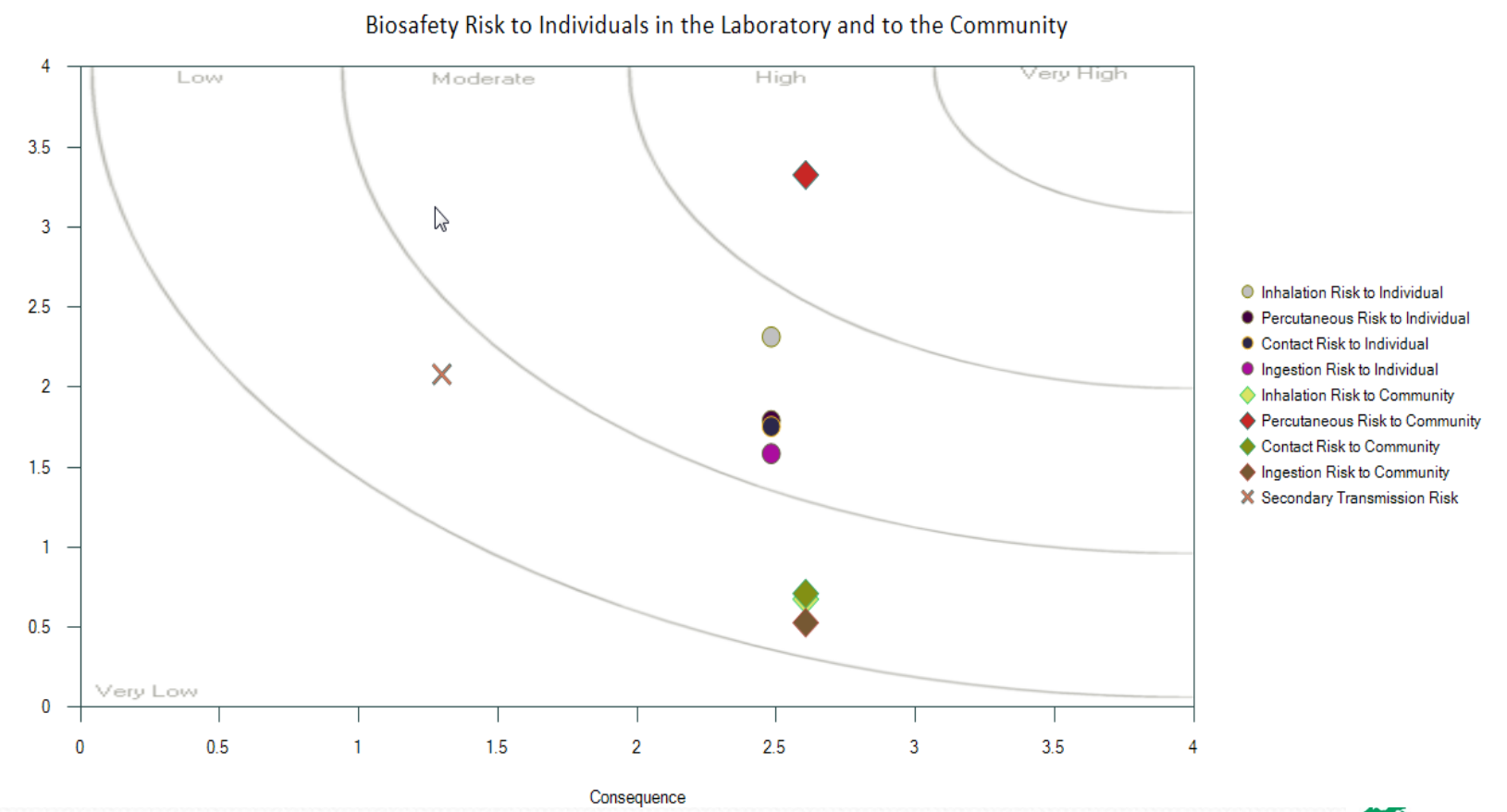
BioRAM Risk Matrix



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Using a Matrix

- At what value do you determine mitigation and what mitigation?
- Where do you document?

Who Does the Assessment?

- Up to facility
  - Someone knowledgeable about the test, environment, hazards and risks
- Biosafety Officer
- Bench staff
- Ideally a team effort with contributions from management, bench staff, safety

How to find Biosafety Gaps

- **Gap Analysis**: Have someone from a different department observe the procedure and fill out a RA
  - Fresh Eyes!

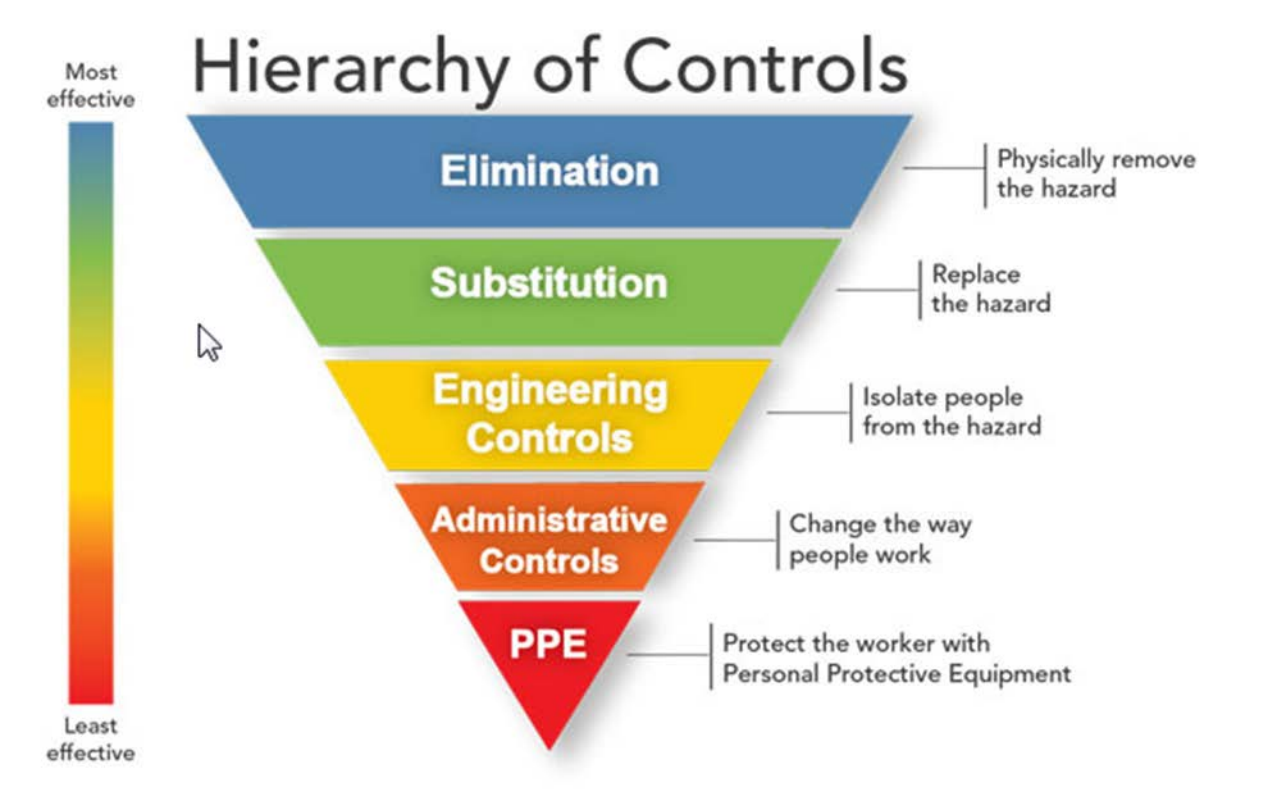
- Review BMBL, OSHA, CDC, etc.

Mitigation

Reminder:

- Risk is never zero, so we are reducing risk, rarely completely eliminating it!

Biosafety Risk Mitigation



NIOSH http://www.cdc.gov/niosh/topics/hierarchy/default.html

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Mitigation

- **Elimination / Substitution of hazard**:
  - Is this procedure necessary?
  - Use less hazardous surrogates, attenuated strains

Mitigation

- **Engineering Controls**: to isolate/contain hazard
  - Primary containment: Biosafety cabinets, sharps containers, centrifuge safety cups
  - Secondary containment: building features like directional airflow, handwashing sinks, self-closing doors

Mitigation

- Space considerations: overloading biosafety cabinets, spill and trip hazards
- Instrumentation:
  - Use closed systems when possible
  - Ensure decontamination, check manufacturer service agreements
  - Beware of automated Identification systems
    - Don't use them for slow growing GNR, box-car shaped GPR,
    - MALDI-ToF: use 0.2µ filter

Mitigating High Risk Activities

- Sharps- one handed methods and new devices, plastic blood culture bottles and tubes
- Doffing: Removing gloves- "beaking method", use glow-germ to show technique
- Sniffing plates- Change policies
- Generating aerosols
  - Using a vortex- use inside biosafety cabinet
  - Centrifuging-use inside biosafety cabinet, invest in sealed bucket / rotor
  - Using automated analyzers*- vigilance on when and how to use
  - Making slides- inside biosafety cabinet, fixation

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Mitigation

- **Administrative Controls**: Change the way people work
- SOPs
- Work practices: catalase in a tube (in a BSC)
- Provide training, exercises and drills (Hands-On)

  PPE, Spill clean-up, Use of BSC
- Medical surveillance: includes reporting of accidents
- Lead staff in creating/maintaining safer workplace

Mitigation

- **Administrative Controls**
  - What's your policy on cell phones in the lab?
    - Cleanliness, distractions, carrier of organisms outside of lab

Cell phones should not be used while working in the lab

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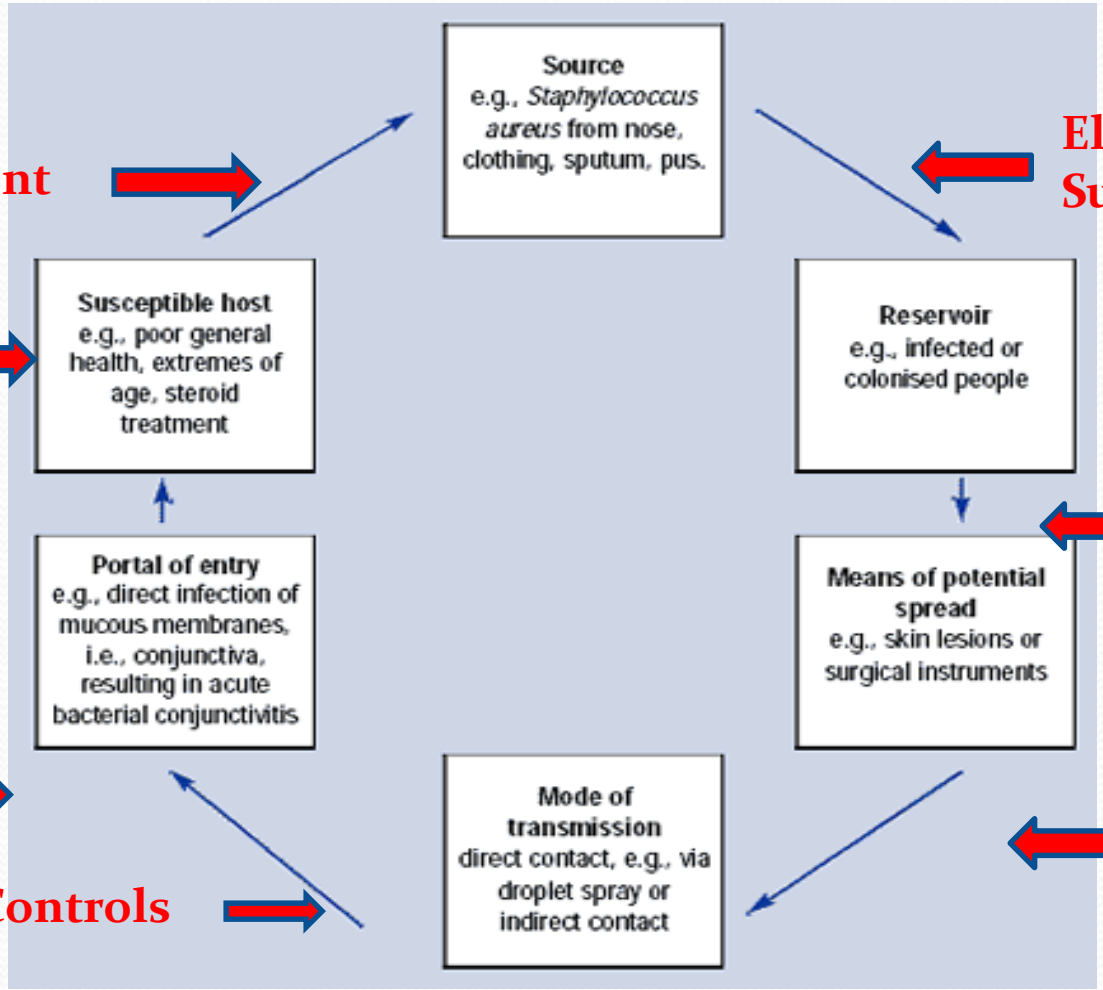
Mitigation: PPE

- Last line of defense
- Everyone is responsible!
- Administration: provide hands-on training and exercises in donning/doffing (glove removal)
  - Stay current with new methods and PPE
  - OSHA standards
- Staff: should know what PPE they use and why they use it and how to use it
  - More is not always better
- Review regularly

Even Princess Diana wore PPE!

Chain of Infection



Treatment

Vaccines

Elimination / Substitution

PPE

Work Practices

PPE

Engineering Controls

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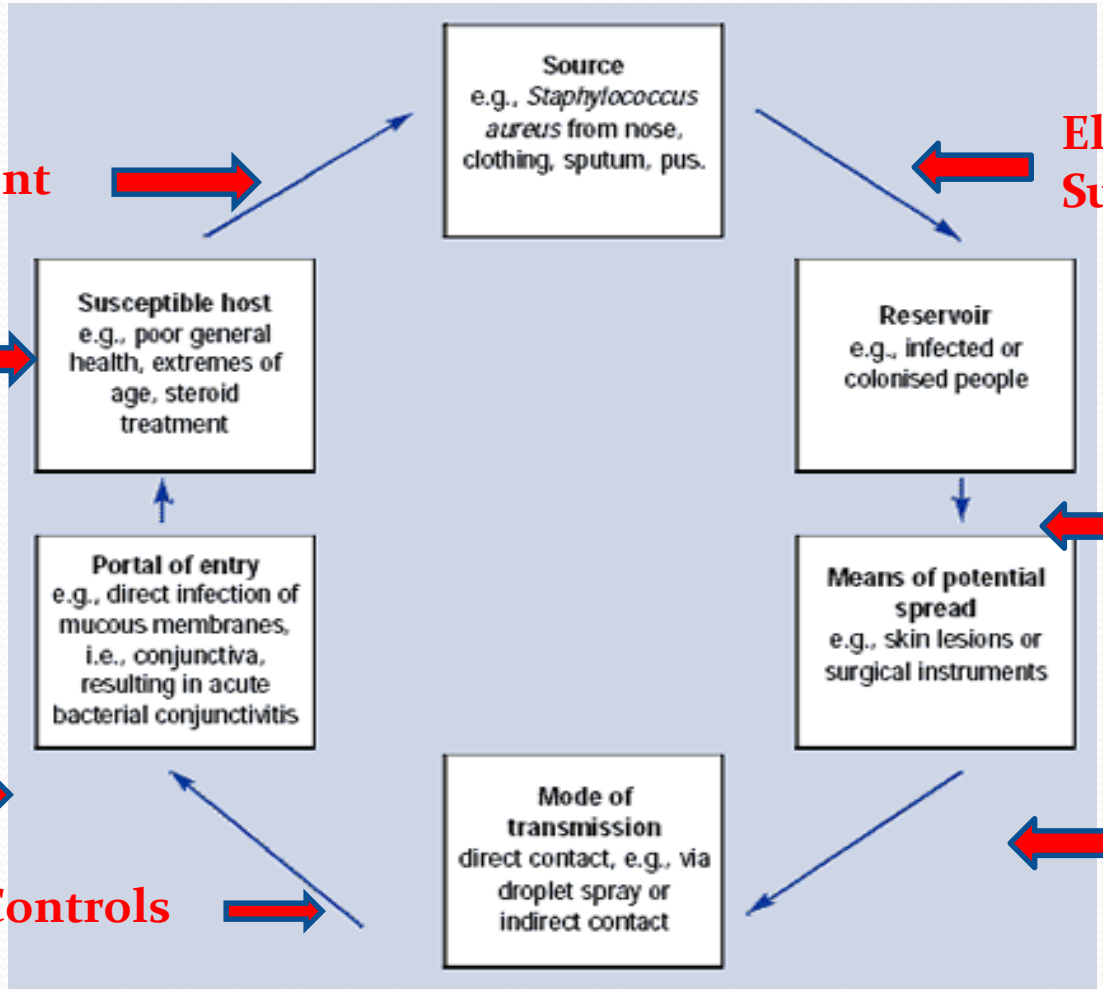
Don’t forget!

- Specimen collection
- Transportation to lab
- Waste handling
- Packaging and shipping

Review and Repeat



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Questions?

Thank You!

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