TURNING ON A DIME: CAN YOUR BIOSAFETY PLAN HANDLE AN EMERGING PATHOGEN?

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Objective

- Explain how a strong occupational health program supports a biosafety program.
- Apply the exposure assessment tool to determine if an exposure occurred.
- Use the root cause analysis process to determine how the exposure may have occurred.

What is the GOAL?

- Protecting our most valuable asset:
  - Our lab professionals
- Preventing laboratory associated infections (LAIs)

Public Health Laboratory Superheroes

Laboratory Associated Infections

- Health care workers (HCW) who die of an occupationally associated illness receive little public attention, yet the CDC calculates that Hepatitis B causes 125-190 deaths/yr. among HCW's in the U.S.
  - Compare to very high profile of deaths in policemen (n=157) and firefighters (n=100)
- Data on HCW infections is also in short supply

Slide courtesy of Dr. Michael Pentella, University of Iowa State Hygienic Laboratory

Occupationally acquired infections in healthcare workers: Part I. Annals of Internal Medicine. 10: 826-834

Let Me Tell You a Story….

"We received a phone call …."

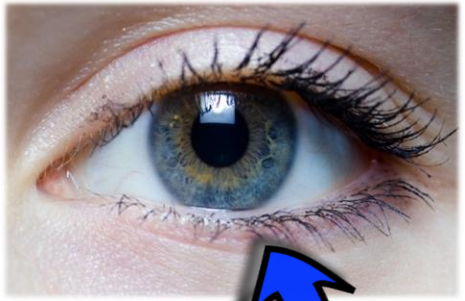
"Then we called the clinical lab…"

Whenever a New Pathogen Emerges, it is Critical to Determine:

- How it is spread
  - Contact
  - Droplets
  - Aerosols
  - Fomites
  - Ingestion
- The location of the body where it will be found
- The types of specimens the lab may receive
- What other testing may be ordered on those specimen types

Routes of Laboratory Infection

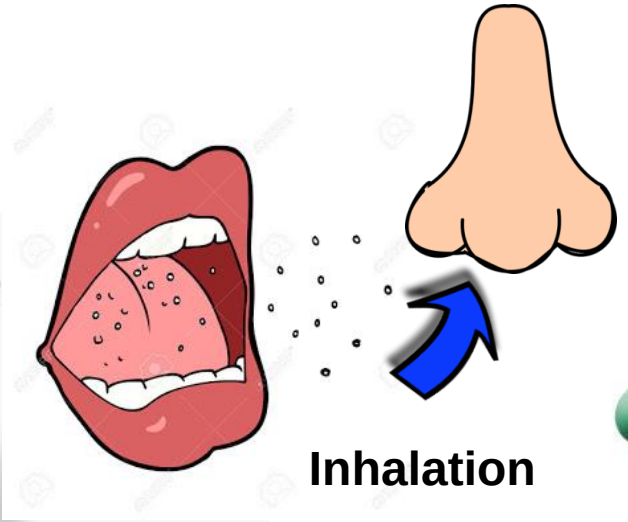
Mucosal membrane splash



Ingestion

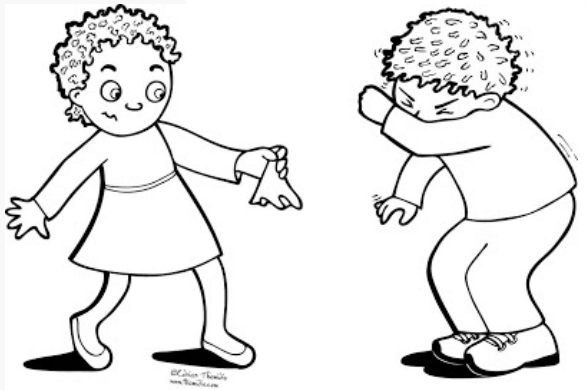
Needlestick

Lab Animal/Vector Exposure



Inhalation

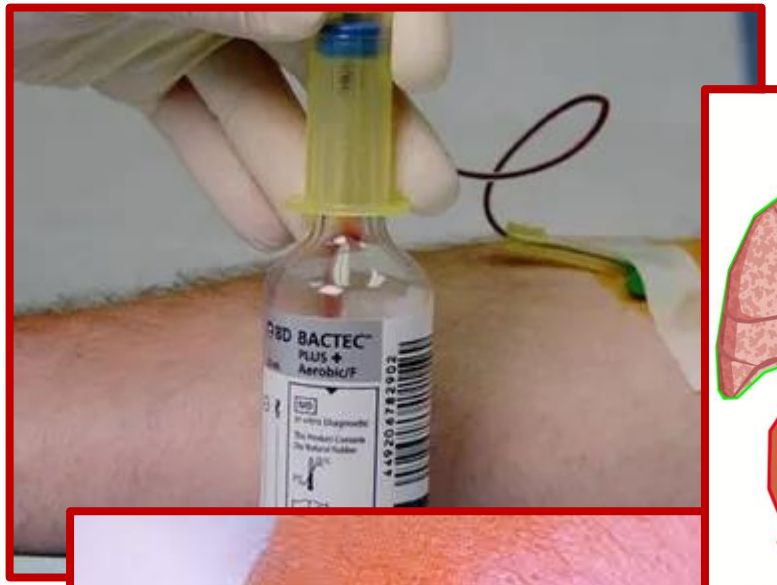
Unknown

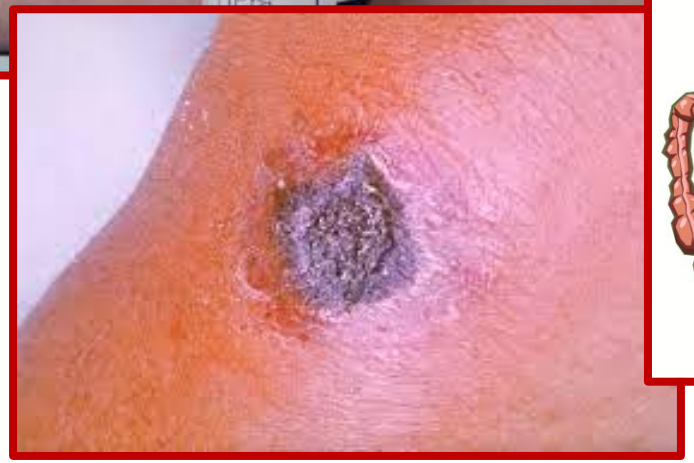


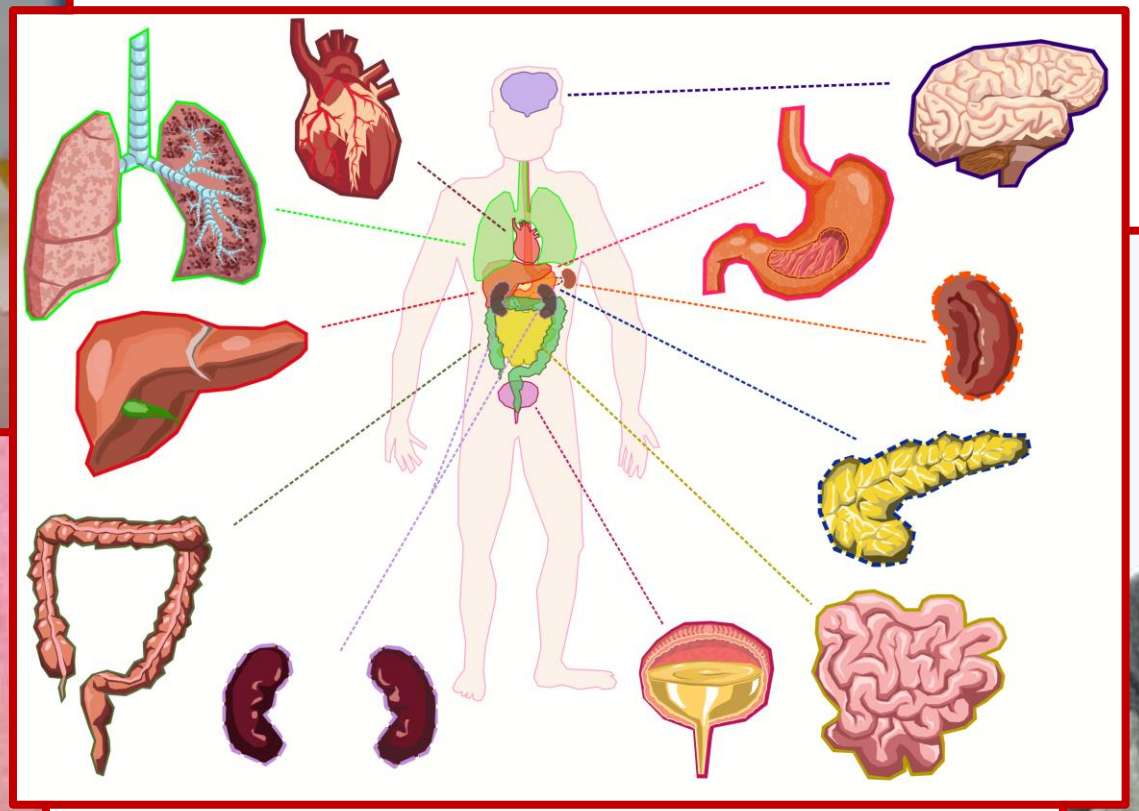
Sick Co-Worker

D. L. Sewell. 1995. Clinical Microbiology Reviews. 8: 389-405.

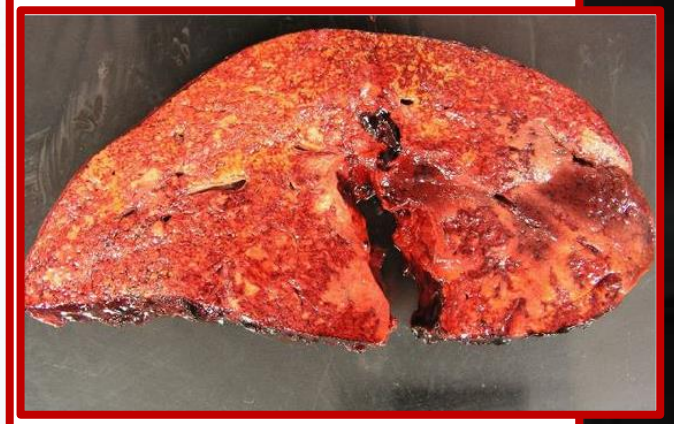
What is the Body Site Where the Emerging Pathogen is Typically Found?







What is the Specimen Type the Laboratory Will Receive?



What Other Testing May Be Ordered On the Specimen?

CSF Specimen:

- Microbiology
  - Micro Culture
  - Syndromic multiplex panel
- Hematology
  - Cell count
  - Cell differential
- Chemistry
  - Glucose
  - Protein

How Do You Determine If You've Had Lab Exposures?

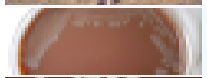
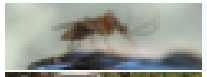
It Takes a Team of Partners

Conference Call(s) with Partners

- Look at the big picture
- Ask questions
- Provide guidance
- Determine action plan for follow-up treatment or prophylaxis
- Discuss disposal of any remaining organism
- Determine who is responsible for what actions
- Evaluate and determine what changes need to be made to prevent further occurrences

Exposure Monitoring Guide (See Handout)

CLINICAL LABORATORY BIOLOGICAL EXPOSURE MONITORING GUIDE

	Disease (Organism/Agent)	Notes	Exposure Risks and Routes of Transmission in the Laboratory Setting*	Incubation Period	Symptoms (Will depend on route of transmission)
	Anthrax, Woolsorter's disease (Bacillus anthracis)	1, 5**, 8, 14	Direct and indirect contact of broken skin with cultures and contaminated laboratory surfaces, accidental parenteral inoculation, exposure to infectious aerosols. LD50 is 2,500-55,000 for spores and will depend on the route of exposure. < 10 spores necessary for cutaneous anthrax infection.	Typically 1–6 days, with a range up to 60 days.	Cutaneous: painless sore with black eschar. Inhalational: Fever and chills, chest discomfort, body aches. Gastrointestinal: Fever, chills, swelling of neck and neck glands, sore throat, painful swallowing, stomach pain, fainting, abdominal swelling. Injection anthrax: Fever, chills, blisters or bumps that may itch, painless skin sore with black eschar, swelling around sore.
	Blastomycosis (Blastomyces dermatitidis)	8, 14	Accidental parenteral inoculation with infected tissues or cultures of yeast form. Pulmonary infections from inhalation of conidia from mold-form cultures.	3 weeks – 3 months	Flu like symptoms, fever, cough, night sweats, myalgia (muscle pain) and arthralgia (joint pain), weight loss and anorexia, chest pain, fatigue.
	Brucellosis, Undulant fever, Malta fever, Mediterranean fever (Brucella abortus, B. suis, B. melitensis)	1, 5, 14	*Brucella* spp. have a very low infectious dose and are easily aerosolized. Ingestion, inhalation, accidental parenteral inoculation or contact with broken skin or mucosa. Direct exposure to samples or cultures (outside containment). ID is 10-100 organisms by aerosol or subcutaneous exposure.	5 days – 5 months	Initial symptoms: fever, sweats, malaise, anorexia, headache, pain in muscles, joints, and/or back, fatigue. Chronic symptoms: recurrent fevers, arthritis, swelling of the testicle and scrotum area, swelling of the heart (endocarditis), neurologic symptoms (in up to 5% of all cases), chronic fatigue, depression, swelling of the liver and/or spleen.
	Glanders (Burkholderia mallei)	1, 5**, 14	Ingestion, inhalation, accidental parenteral inoculation, and contact with broken skin or mucosa with cultures and infected tissues, purulent drainage, blood and sputum. There is increased risk for individuals with diabetes.	1–14 days	Fever with chills and sweating, muscle aches, chest pain, muscle tightness, headache, nasal discharge, light sensitivity (sometimes with excessive tearing of the eyes), ulceration at the site of localized infection, lymphadenopathy, abscess formation.
	Melioidosis, Whitmore's disease (Burkholderia pseudomallei)	1, 5**, 14	Ingestion, inhalation, inoculation, and direct contact via skin abrasions and mucous membranes.	1 day – years	Localized: Localized pain or swelling, fever, ulceration, abscess. Pulmonary: Cough, chest pain, high fever, headache, anorexia. Bloodstream: Fever, headache, respiratory distress, abdominal discomfort, joint pain, disorientation. Disseminated: Fever, weight loss, stomach or chest pain, muscle or joint pain, headache, seizures.
	Psittacosis (Chlamydia psittaci)	1, 14	Infectious aerosols in the handling, care, or necropsy of naturally or experimentally infected birds, mice and eggs.	5–14 days	Abrupt onset of fever and chills, headache, muscle aches, nonproductive cough, splenomegaly, rash.
	Botulism (Clostridium botulinum toxin)	1, 5**, 13	Exposure to toxin, and especially associated with activities that have high potential for aerosol or droplet formation. 0.70-1.0 µg of inhaled aerosolized toxin is likely enough to kill a 70 kg / 150 lb person.	6 hours – 10 days	Double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, difficulty breathing, thick-feeling tongue, dry mouth, muscle weakness.
	C. diff (Clostridioides difficile)	1, 14	Infectious aerosols are the most likely route of laboratory-associated infections (LAI) and could serve as a reservoir for vegetative cells and spores.	2–3 days	Severe diarrhea, fever, stomach tenderness or pain, loss of appetite, nausea.
	Coccidioidomycosis, Valley Fever (Coccidioides immitis, C. posadasii)	8, 14	Inhalation of spores. Rarely, contact with broken skin can cause cutaneous infection.	1–3 weeks	Fatigue, cough, fever, shortness of breath, headache, night sweats, muscle aches or pains, rash on upper body or legs.
	Q fever (Coxiella burnetii)	3, 5, 8, 14	Inhalation of infectious aerosols. Accidental parenteral inoculation. Exposure to experimentally or naturally infected animals, their tissues, or body fluids. ID by inhalation is ~10 organisms.	9–39 days	Acute: Fever, chills, myalgia, arthralgia, headache, pneumonia, hepatitis.
	Dermatophytosis, Ringworm (Microsporum, Epidermophyton and Trichophyton)	8, 14	Contact with skin, nail lesions, contact with contaminated surfaces.	4–14 days after skin comes in contact with fungus	Ringworm can affect skin on almost any part of the body as well as fingernails and toenails. The symptoms of ringworm often depend on which part of the body is infected, but they generally include itchy skin, ringshaped rash, red, scaly, cracked skin and hair loss.
	Encephalitis, EEE (Eastern Equine Encephalitis virus)	3, 5, 8, 12	Inhalation of infectious aerosols, accidental parenteral inoculation. Exposure to infected animals and mosquitoes in the lab.	1–10 days	Sudden onset of headache, high fever, chills, and vomiting severe cases may progress to disorientation, seizures, or coma.
	Ebola virus disease, EVD (Ebola virus)	3, 5**, 13	Direct contact of infectious material with mucous membranes, accidental parenteral inoculation.	2–21 days	Fever, severe headache, muscle pain, weakness, fatigue, diarrhea, vomiting, abdominal pain, unexplained hemorrhage.

Exposure Assessment Form (See Handout)

Clinical Laboratory Biological Exposure Evaluation Tool- Electronic Version

CLINICAL LABORATORY BIOLOGICAL EXPOSURE EVALUATION TOOL														
Complete this form for each person who may have been potentially exposed to determine exposure risk, and indicate if more than one person may have been involved.										*Multiple exposures?*		Yes:	No:	
Patient Name(s) or Identifier(s):														
Multiple exposure locations?		Yes:	No:	If yes, list locations:										
Date of Occurrence	Worked With Organism (Y/N):		Did Not Work With Organism, But Was... (Y/N)			Personal Protective Equipment (PPE worn vs. not worn) (Y/N)						Predisposition (Y/N)		
	Within BSC	Outside BSC	Less than 5 feet away	More than 5 feet away	Unsure	Gloves	Labcoat or Gown	Safety glasses	Face Shield	Respirator (N95, PAPR, etc.)		Pregnant	Immuno-compromised	Other

Were any of the following activities or types of manipulation performed?											
Item	Yes	No	Item	Yes	No	Item	Yes	No	Item	Yes	No
Removed caps or swabs from culture containers, opened lyophilized cultures, opened cryotubes			Cleaned up spill			Gram stain			Splashed media with culture*		
Manipulated needles, syringes or sharps (scratch, puncture, cuts)			Flaming a loop			Opened a culture plate** (even without manipulating culture)			Filtered specimens under vacuum		
Aspirated and transferred body fluids			Wet preps			Examined growth on media			Used automated system		
Vortexing*			Rapid antigen testing			Sniffed plate			Prepared isolate(s) for automated identification or susceptibility testing		
Centrifuge setup or run*			Blood culture bottle subculture			Catalase test*			Spotted for MALDI-TOF		
Sonication*			Withdrew needles from stopper			Oxidase test			Applied matrix for MALDI-TOF		
Harvested tissue			Expelled air from tube or bottles			Slide agglutination			Loaded plate in MALDI-TOF		
Handled broken or leaky specimen or container			Expelled last drop from a pipette			Urease test			Antibiotic resistance testing		
Blood culture bottle inoculation			Separated needles from syringes			Subculture isolate			Threw contaminated items into biohazardous waste		
Inoculation of media			Prepared smears			Cooled loop in culture media			Serology testing		
Mixed, blended, grinded, or shaking			Heat fixation			Liquid suspension preparation (e.g., pouring, splitting or decanting)			Improper PPE doffing		
Spilled infectious material			Stained slides			Spilled media with culture*			Other:		
Describe any other activity(ies) that may have led to an exposure or any additional precautions or engineering equipment used (e.g., splash guard):											

Complete Exposure Assessment Form

- General questions:
  - When did this occur?
  - Where was the organism worked with?
  - Who else was within 5 feet?
  - What PPE was worn?
  - What is the immune status of the individual working with the specimen and others who were within 5 feet?
- Specific Activities and Manipulations:
  - Answer yes or no to a list of common laboratory activities that are performed on specimens
- Based on answers determine whether there was an exposure and what it the level of risk.
- Determine what post-exposure follow up steps will be taken

Monkeypox Exposure Assessment

- General questions:
  - When did this occur? 7/11/22 1st shift
  - Where was the organism worked with? In the main laboratory outside a BSC
  - Who else was within 5 feet? 2 other individuals
  - What PPE was worn? Standard precautions (gloves and lab coat)
  - What is the immune status of the individual working with the specimen and others who were within 5 feet? Immune competent
- Specific Activities and Manipulations:
  - Answer yes or no to a list of common laboratory activities that are performed on specimens Lab answered yes they had vortexed a capped tube, opened the tube on an open bench and placed the tube on the analyzer

NOTE: Always ask if other specimen types were received and what other testing was performed on the patient

- Lab only received the swabs for HSV and VZV testing.

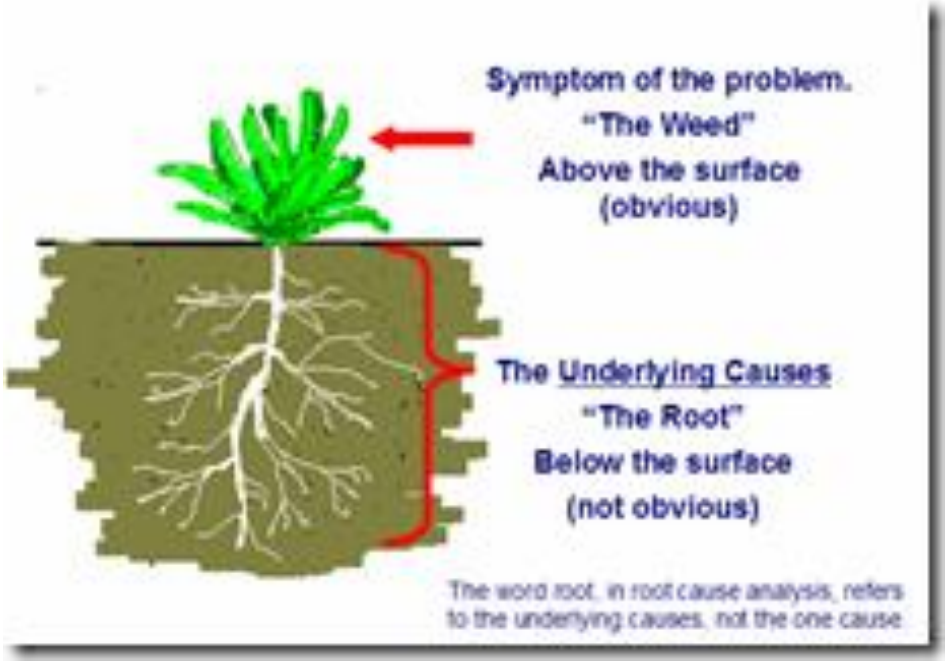
Monkeypox Exposure Assessment (cont.)

- Based on answers determine whether there was an exposure and what it the level of risk. (https://www.cdc.gov/poxvirus/monkeypox/lab-personnel/lab-procedures.html)
  - Monkeypox primary routes of exposure:
    - Prolonged personal (often skin to skin) contact
    - Contact with fomites
    - Direct spread to fetus through the placenta
    - Contact with Monkeypox infected animals
      - Scratches or bites
      - Preparing and eating infect meat
  - It is not known how easily Monkeypox is acquired through inhalation of lab generated aerosols, but it is thought to take extended exposure time to aerosols and to be a low risk for someone with a healthy immune system.
  - The concentration of Monkeypox in blood specimens received for other testing is low
- Determine what post-exposure Prophylaxis will be taken
  - Fever watch

Determine Root Cause

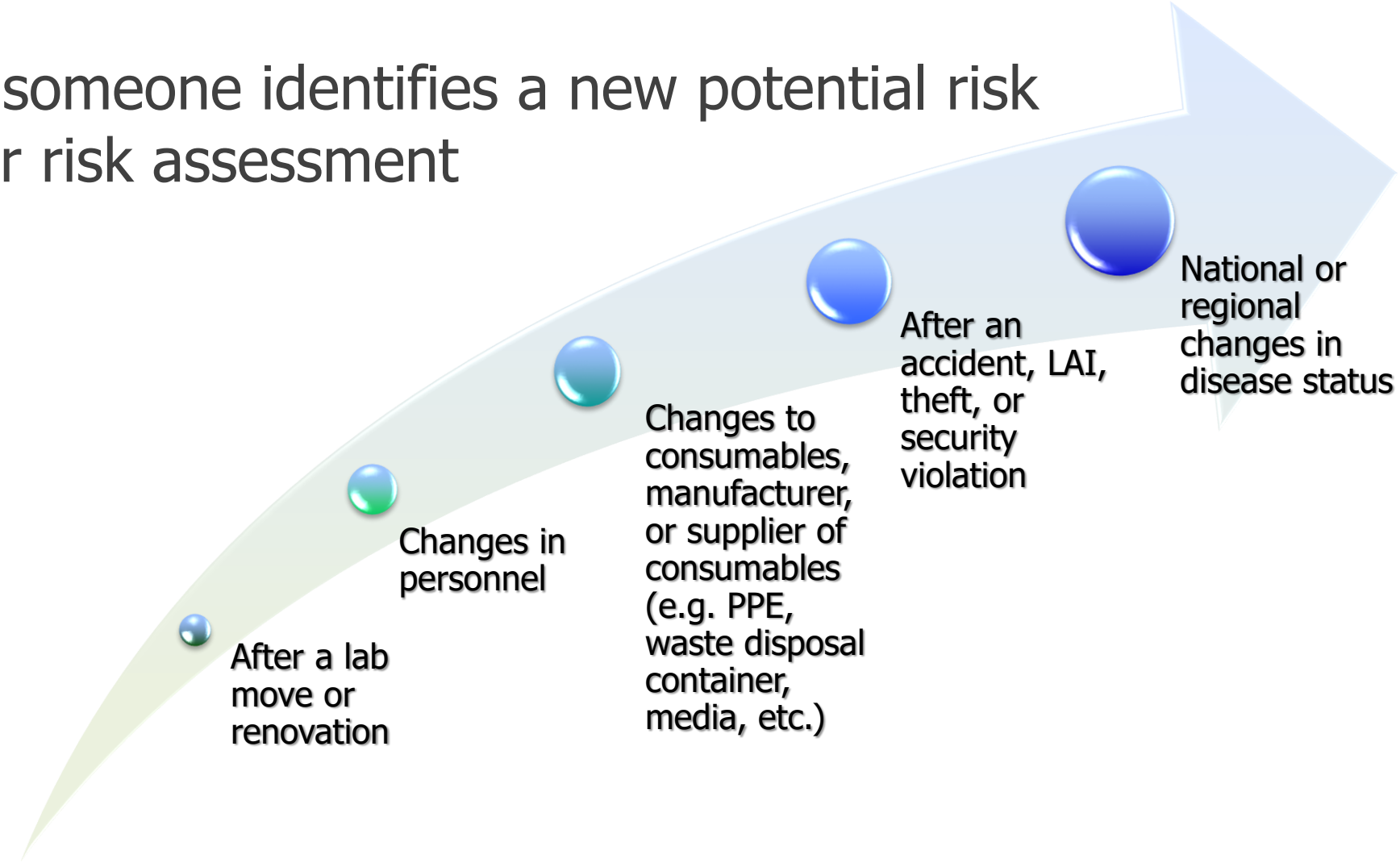
Ask what is the underlying cause?

- Why was there an exposure?
- Lab didn't use any special Monkeypox protocols when working with the specimen
- Clinician didn't order Monkeypox testing and didn't consider it in the patient differential
- Monkeypox new emerging pathogen and clinician was unaware of symptom presentation



When Do You Repeat a Risk Assessment?

- Whenever someone identifies a new potential risk repeat your risk assessment



Repeat Risk Assessment

- What new hazards were identified in the root cause analysis?
  - Clinician may not recognize Monkeypox and may order HSV, VZV, Syphilis or other testing on patients who have Monkeypox.
- Evaluate the risk
  - Moderate risk
- What else can be done to mitigate the risk?
  - Implement enhanced precautions routinely – add eye protection and masks.
  - Offer staff vaccinia vaccine when available.
- Implement controls
- Review effectiveness and continue to adjust as needed

Questions?

Thank you to Erin Bowles for the use of her presentation.

Exercise

- Break up into groups again
- Each group will continue to work on the exercise scenario they've been working on previously.
- Complete the exposure assessment draft tool that you've been given in your handouts as best you can using the information that you've been provided in the scenario.
- Determine whether an exposure occurred and the level of risk associated with the exposure.
- What if any post-exposure prophylaxis do you recommend?
- Who would be consulted or involved in making these decisions?
- What if any changes will you make based on your repeat risk assessment?