



# Lessons in Defense Against the Dark Arts

## Updates to Brucella and Review of Rule-Out Testing

Erin Bowles

2023 Regional Meetings





# In the Harry Potter Books, Which of the Following Never Taught the Defense Against the Dark Arts Class?

- A. Professor McGonagall
- B. Severus Snape
- C. Remus Lupin
- D. Gilderoy Lockhart
- E. Mad-Eye Moody



# In the Harry Potter Books, Which of the Following Never Taught the Defense Against the Dark Arts Class?

- A. Professor McGonagall**
- B. Severus Snape
- C. Remus Lupin
- D. Gilderoy Lockhart
- E. Mad-Eye Moody



# Lesson 1

# Reclassification of *Ochrobactrum* species into the *Brucella* genus (12/19/2022)



- All *Ochrobactrum* species were recently reclassified into the *Brucella* genus to align taxonomical nomenclature with phylogenetic analyses. This change in nomenclature has been reflected in many of the rapid microbial identification systems used in clinical laboratories.
- Laboratories should note any bacteria identified as '*Brucella*' on rapid or sequence-based systems and handle all organisms identified as '*Brucella*' species in a class II biosafety cabinet. All bacterial isolates presumptively identified as "*Brucella* species" should be referred to your state public health laboratory for additional testing



# Which *Brucella* species considered to be Classical *Brucella* species cause disease in humans and must be reported as Select Agents?

- A. *Brucella suis*, *Brucella abortis*, *Brucella melitensis*
- B. *Brucella suis*, *Brucella microtti*, *Brucella abortis*
- C. *Brucella abortis*, *Brucella canis*, *Brucella suis*
- D. *Brucella abortis*, *Brucella melitensis*, *Brucella ovis*
- E. *Brucella canis*, *Brucella suis*, *Brucella melitensis*



# Which *Brucella* species considered to be Classical *Brucella* species cause disease in humans and must be reported as Select Agents?

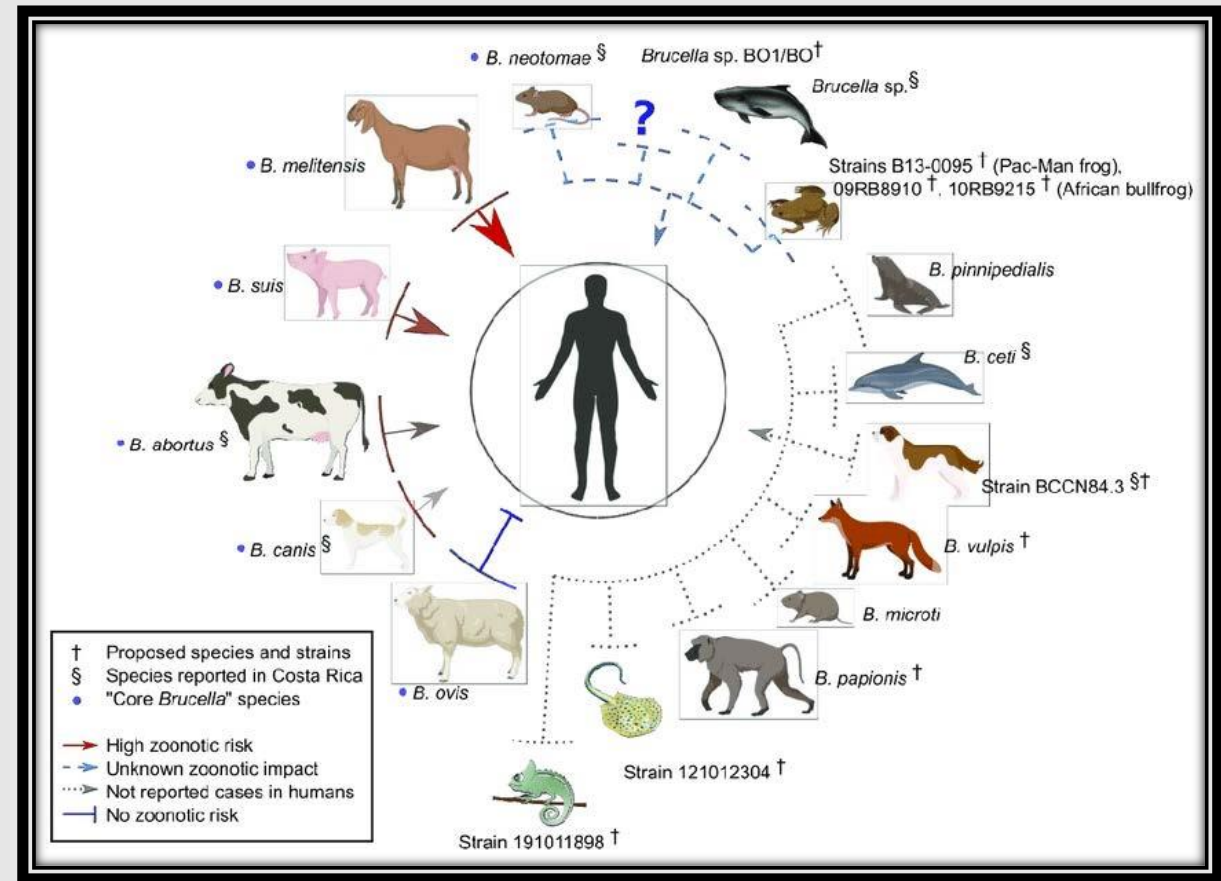
- A. *Brucella suis*, *Brucella abortis*, *Brucella melitensis*
- B. *Brucella suis*, *Brucella microtti*, *Brucella abortis*
- C. *Brucella abortis*, *Brucella canis*, *Brucella suis*
- D. *Brucella abortis*, *Brucella melitensis*, *Brucella ovis*
- E. *Brucella canis*, *Brucella suis*, *Brucella melitensis*

# Classical *Brucella* Species



Agents that can cause brucellosis:

- ***Brucella abortus***
- *Brucella canis*
- *Brucella ceti*
- *Brucella inopinata*
- ***Brucella melitensis***
- *Brucella microti*
- *Brucella neotomae*
- *Brucella pinnipedialis*
- *Brucella ovis*
- *Brucella papionis*
- ***Brucella suis***
- *Brucella vulpis*



CDC LOCs presentation 1/23/23

Note: There are several novel *Brucella* strains that have been described from frogs, bats, Australian rodents and a sting ray that haven't been designated as species.

**Bold red print designates *Brucella* species that are considered select agents that cause brucellosis in humans**



# Which Organisms Are Impacted?



## **Ochrobactrum** species

- *Ochrobactrum anthropi*
- *Ochrobactrum cicero*
- *Ochrobactrum cytisi*
- *Ochrobactrum daejeonense*
- *Ochrobactrum endophyticum*
- *Ochrobactrum gallinifaecis*
- *Ochrobactrum grignonense*
- *Ochrobactrum haemotophilum*
- ***Ochrobactrum intermedium***
- *Ochrobactrum lupini*
- *Ochrobactrum oryzae*
- *Ochrobactrum pectoris*
- *Ochrobactrum pituitosum*
- *Ochrobactrum pseudointermedium*
- *Ochrobactrum pseudogrignonense*
- *Ochrobactrum rhizosphaerae*
- *Ochrobactrum thiophenivorans*
- *Ochrobactrum tritici*

## Reclassification (New *Brucella* species)

- *Brucella anthropi*
- *Brucella ciceri*
- *Brucella cytisi*
- *Brucella daejeonensis*
- *Brucella endophytica*
- *Brucella gallinifaecis*
- *Brucella grignonensis*
- *Brucella haematophila*
- ***Brucella intermedia***
- *Brucella lupine*
- *Brucella oryzae*
- *Brucella pectoris*
- *Brucella pituitosa*
- *Brucella pseudointermedia*
- *Brucella pseudogrignonensis*
- *Brucella rhizosphaerae*
- *Brucella thiophenivorans*
- *Brucella tritici*



**New *Brucella* (*Ochrobactrum*) species are considered non-classical *Brucella***

**Bold print designates most commonly isolated from human specimens**

# Implications of Adopting the *Brucella* Name Change



## Is it Brucellosis or an opportunistic *Ochrobactrum* infection?

- If name change is adopted without including additional report comments or education about the name change, clinicians who are unaware may inappropriately treat patients for brucellosis.
- Possible administration of post-exposure prophylaxis (if specimen collection created high risk of aerosolization) and other infection prevention and control concerns
- Laboratories must be aware which species are considered select agents as they must be packaged and shipped as category A infectious substances.
- Laboratories must be aware of which *Brucella* species cause brucellosis and require reporting to the Federal Select Agent Program
- Nationally must clarify CSTE case definition



# *Ochrobactrum vs Brucella species*

	<i>Brucella Ochrobactrum species</i>	<i>Classical Brucella (B. melitenis, B. suis, B. abortus, B. canis)</i>
Natural Habitat	Soil and water or in hospital environment	Animal reservoirs, zoonotic
Clinical significance	Rare, infections typically occur through use of contaminated equipment, or in hospital wounds from catheters, opportunistic	Insidious, invasion of multiple tissue types, development of chronic syndrome and focal complications
Reportable Disease	No	Brucellosis
Antimicrobial treatment	imipenem, the newer fluoroquinolones and the aminoglycosides (amikacin or gentamicin)	doxycycline and rifampin (6 weeks)
Antimicrobial Resistance	Yes	Rare

# Problems With Automated Identification Systems



- Automated systems can misidentify *Brucella* (*Ochrobactrum*) species as select agent *Brucella* species and conversely misidentify select agent *Brucella* species as *Brucella* (*Ochrobactrum*) species
- Additionally automated systems may be unable to identify select agent *Brucella* species as well as *Brucella* (*Ochrobactrum*) species, especially if not using a specialized database that includes the select agents classical *Brucella* species

**No identification,  
or misidentification!**



# Quick Sorting of Classical Brucella From Brucella(Ochrobactrum)species



(Select Agent)  
Classical  
Brucella

or

Brucella  
(Ochrobactrum)  
species

- Brucella LRN algorithm is designed to differentiate classical bio-threat *Brucella* species (*B. suis*, *B. abortus*, *B. melitensis*, and *B. canis*)
- **Common characteristics of *Brucella* (*Ochrobactrum*) species that can be used to rule-out** from select agent *Brucella* species (See handout)
  - **Gram stain:** Gram negative rods with parallel sides (1.0-1.5X2.0 $\mu$ m, approximately the length of *Escherichia coli*)
  - **Rapid colony growth on MacConkey agar** (>0.5 mm after 24 h)
  - **Mucoid colony morphology**
  - **Positive motility** (tube-based method recommended for safe handling)
  - **Negative urease**

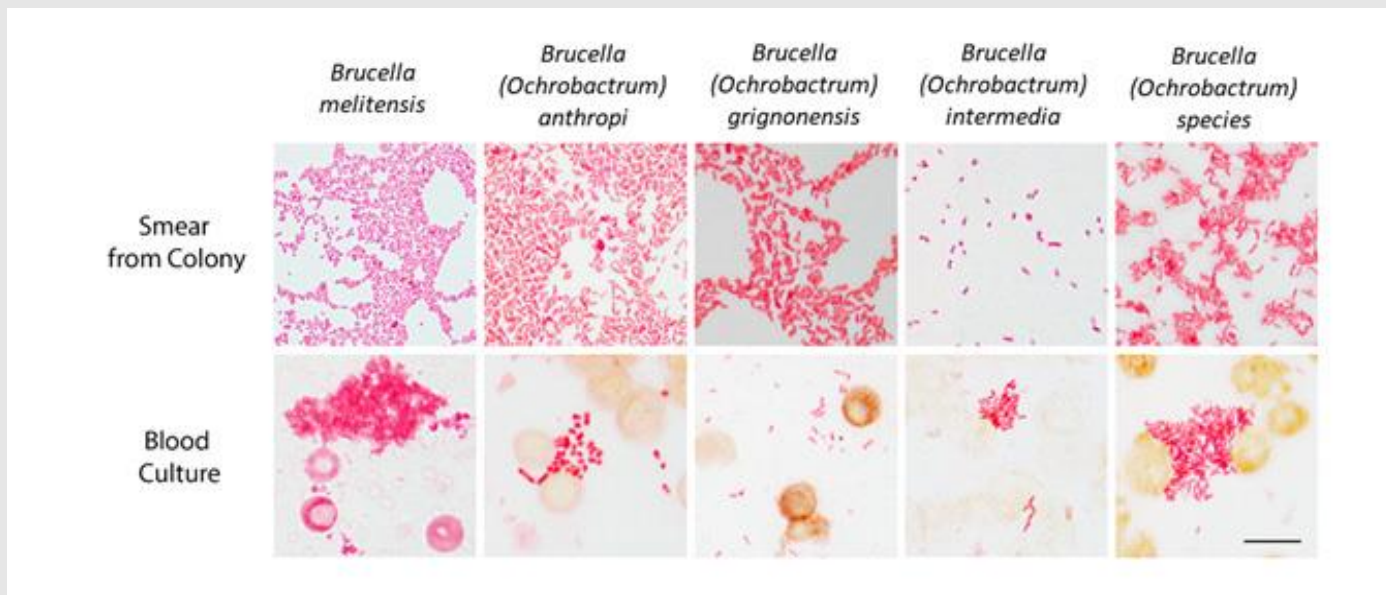
# ***Brucella (Ochrobactrum) species vs Classical Brucella species***



	<b>Brucella (Ochrobactrum) species</b>	<b>(Select Agent) Classical <i>Brucella</i> species</b>
Blood and Chocolate agar	>0,5 mm 24 hours; >0.5 mm 48 - 72 hours	No growth to pinpoint at 24 hours 0.5 – 1.0 mm 48 - 72 hours
MacConkey agar	No growth to >0.5 mm at 24 hours, non-lactose fermenter >0.5 mm 48 - 72 hours	No growth at 24 hours No growth to pinpoint at 72 hours
Colony Morphology	Creamy, smooth, shiny, round, maybe mucoid, non-hemolytic	Smooth, white or translucent, glittering, round convex, non-hemolytic
Motility	Positive Motile (variable)	Negative Non-motile
Catalase	Positive	Positive
Oxidase	Positive	Positive
Urease	Positive (variable)	Positive (Can be very rapid 15 min – 24 hours)



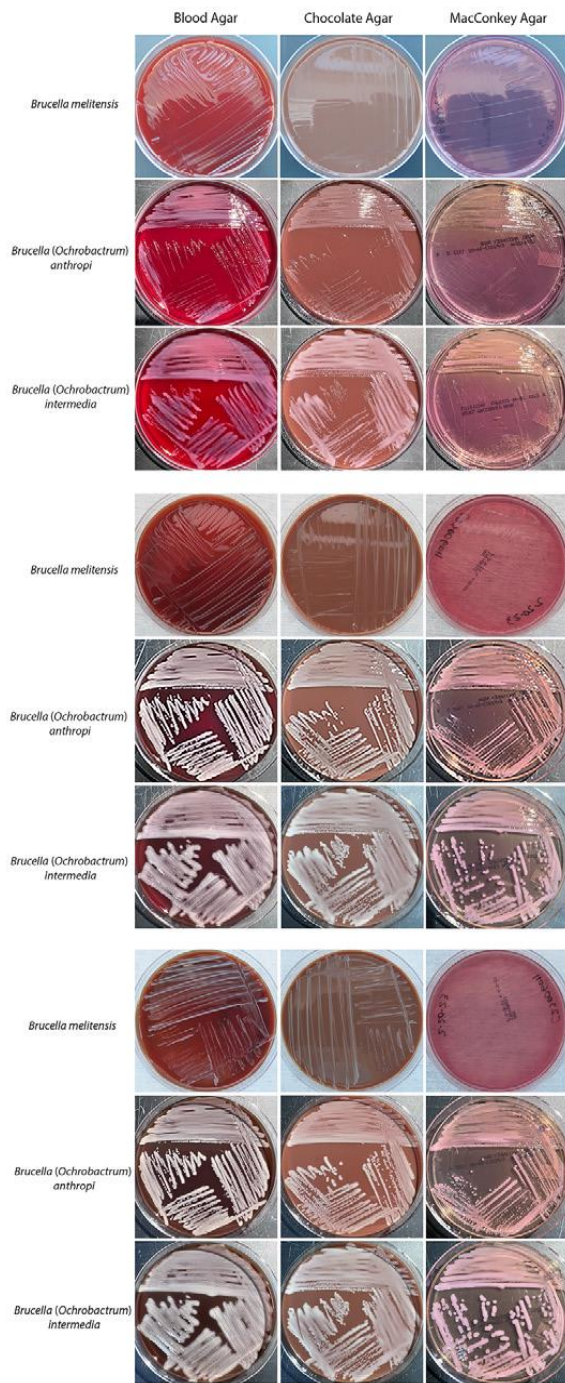
# Images from ASM Document “*Brucella* and *Ochrobactrum* Taxonomic Updates for Laboratories”



24 Hours

48 Hours

72 Hours



# Clinical Clues Can Help Differentiate



Contact the clinician to get clinical clues on exposure history, transmission risk and clinical history

- **Classical Brucella:**

- Do they work with animals or meat?
- Do they have pets?
- Do they eat unpasteurized animal products (dairy)?
- Have they traveled to Brucella endemic areas and had contact with wildlife?

- **Brucella(Ochrobactrum):**

- Environmental organisms found in/on water, soil, plants, animals
- Typically cause infections in immunocompromised individuals
- HAIs associated with contaminated invasive equipment





# Laboratory Work-up

Slow growing  
isolate – no  
growth on MAC

- Work at BSL-2 with additional BSL-3 precautions and perform rule-out testing
- Contact clinician
- Notify and submit to WSLH if unable to rule-out
- Package and ship as a suspect Cat A infectious substance

Rapid ID of  
Brucella or  
Ochrobactrum  
any species

- Work at BSL-2 with additional BSL-3 precautions and perform rule-out testing
- Contact clinician
- Notify and submit to WSLH if unable to rule-out
- Package and ship as a suspect Cat A infectious substance

MALDI ID of  
Brucella or  
Ochrobactrum  
any species

- Work at BSL-2 with additional BSL-3 precautions and perform rule-out testing
- Contact clinician
- Notify and submit to WSLH if unable to rule-out
- Package and ship as a suspect Cat A infectious substance

# Reporting of Non-Classical *Brucella* or *Brucella (Ochrobactrum)*



- **Lab** - document in the internal laboratory patient workup (not the patient report) how classical select agent *Brucella* was ruled-out
- **Lab** - accurately report the organism detected to support appropriate treatment
  - If entering an explanatory comment in the patient report make sure it transfers to the patient chart
  - See handout for some suggest comments
- **Lab** - provide clear communication on the clinical and public health risks of the organism
  - Consider providing education to care providers and infection prevention on the clinical significance of the new *Brucella(Ochrobactrum)* name
    - Emphasize these organisms are distinct from *Brucella* species that cause Brucellosis
- **Clinician** - do not treat for Brucellosis, but rather treat for Ochrobactrum infection if see report of *Brucella (Ochrobactrum)*
- **State and local epidemiologists** - do not report as Brucellosis if see report of *Brucella (Ochrobactrum)*



# Lesson 2

# Using WSLH Bioterrorism Exercises to Teach and Prepare



- Twice a year, someone in every participating laboratory receives a letter by email telling you when the exercise is shipping **This is an exercise and not proficiency testing.**
  - Letter includes reminder that participation in the exercises is required as per the “*Definition of Sentinel Clinical Laboratories*” to help laboratories practice rule-out testing: <http://www.slh.wisc.edu/wp-content/uploads/2018/11/Sentinel-Clinical-Laboratories-Definition-Updated-April-2018-.pdf>
  - Letter provides links to documents/tools you should use for the exercise.
    - APHL/LRN/ASM Bench cards: [Biothreat Agents Identification Bench Cards for Sentinel Laboratories \(For Print\) \(aphl.org\)](#)
    - “*Sentinel Level Clinical Laboratory Guidelines for Suspected Agents of Bioterrorism and Emerging Infectious Diseases*” located on the ASM website at <https://asm.org/Articles/Policy/Laboratory-Response-Network-LRN-Sentinel-Level-C>
    - APHL/ASM “*Clinical Laboratory Preparedness and Response Guide*”: [BlueBook Layout 4 2016-04-18 Word \(wisc.edu\)](#)
- Make sure the person performing the exercise gets a copy of the letter.
- Once the exercise is completed, results are submitted and you have received the exercise results, you can use the 2<sup>nd</sup> residual swab for training staff.



# Read the Instructions That Come with the Specimens!



## Initial Steps:

**(Perform all work in a biosafety cabinet until all BT agents are ruled out)**

1. Do not use your magic wand to help you rule-out the BT agents
2. Use the provided scenario and the initial Gram stain to help determine which BT agent the exercise is trying to help you practice identifying
3. Set up culture on Blood, Chocolate, and MacConkey agar
4. Always subculture any growth twice before performing rule-out testing
5. Don't use the growth rate alone to rule-out BT agents as these are organisms meant to simulate the BT agents and may grow more rapidly
6. Do note which agar the organism grows on and note any hemolysis
7. Gram stain the isolate growth
  - a) If a Gram Positive bacillus, is it large and boxcar shaped like Bacillus or small and thin?
  - b) If a Gram negative coccobaccili/bacilli go to page 13 in the "*Recognize. Rule-out. Refer. Biothreat Agent Bench Cards for the Sentinel Laboratory*". (Use the flowchart to help you determine which agent(s) you need to rule-out.)



# Which Select Agent considered to be a Gram negative coccobacillus can sometimes stain Gram positive?

- A. *Francisella tularensis*
- B. *Yersinia pestis*
- C. *Burkholderia pseudomallei*
- D. *Burkholderia mallei*
- E. *Brucella* species



# Which Select Agent considered to be a Gram negative coccobacillus can sometimes stain Gram positive?

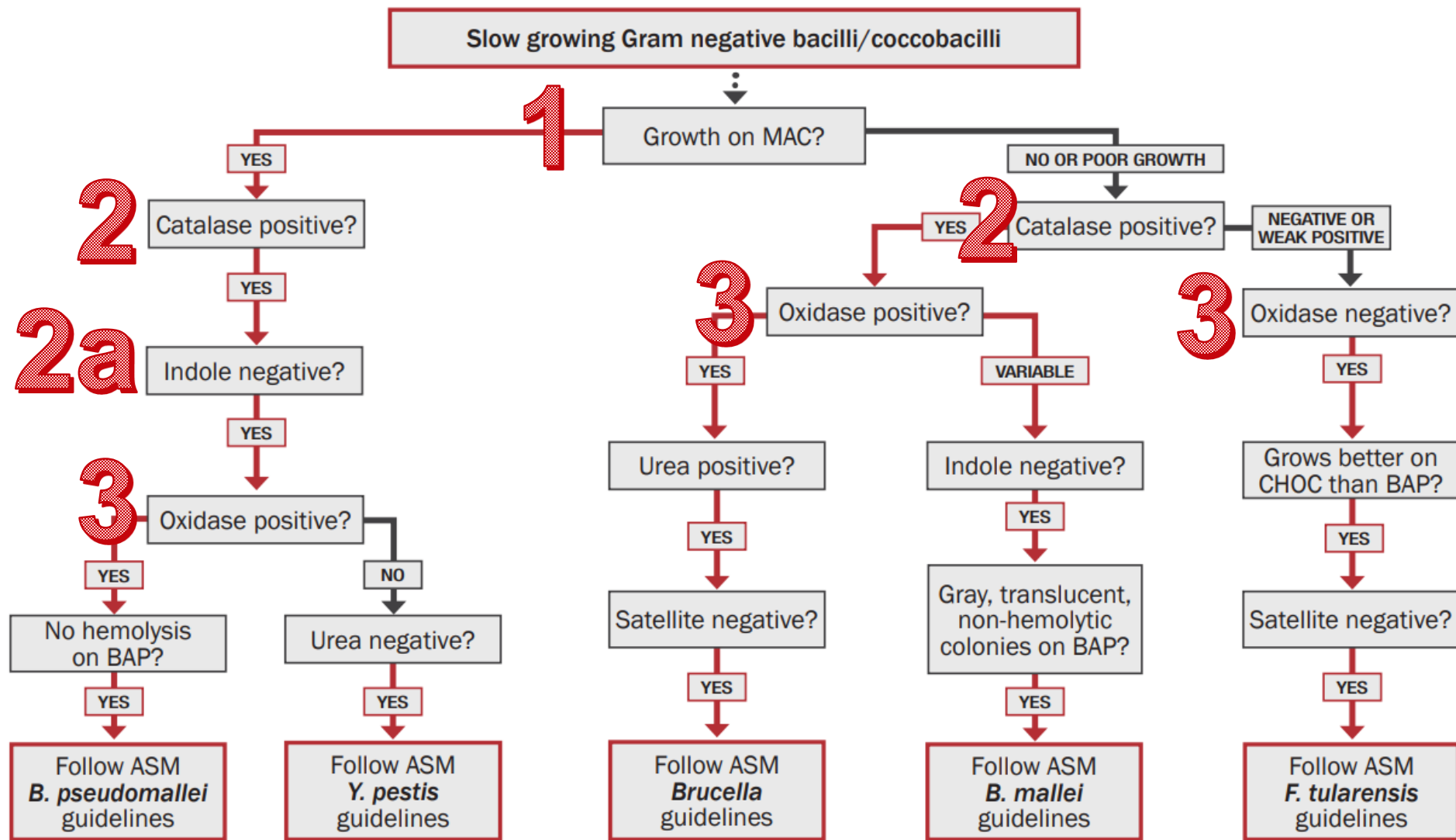
- A. *Francisella tularensis*
- B. *Yersinia pestis*
- C. *Burkholderia pseudomallei*
- D. *Burkholderia mallei*
- E. *Brucella* species**



# BIOTHREAT AGENT IDENTIFICATION

## Gram Negative Bacilli/Coccobacilli Rule-Out Algorithm

Biothreat Agents Identification Bench Cards for Sentinel Laboratories (For Print) ([aphl.org](http://aphl.org))



**4** Go to the specific flow chart for the agent(s) you are trying to rule out



# What Do I Do If My Laboratory Doesn't Have All the Biochemicals I Need to Rule-Out all the Select Agents?



- **All laboratories must be able to perform, at a minimum, Gram stain, catalase and oxidase rule-out testing on an isolate.**
- Laboratories may not have, tube motility, urea, indole and other rule-out biochemicals.
- Do not perform testing that isn't indicated for the agent you are trying to rule out (**This is for biosafety measures and to prevent exposures**).
- Perform all indicated tests that you have the ability to do and record your results.
- If the test isn't indicated for the agent you are trying to rule out, report "Test not indicated". Do not use the exception code "Procedure/source not performed in-house".
- If a test is indicated but you don't have the ability to perform the test in your laboratory, use the exception code "Procedure/source not performed in-house". Additionally, record in a comment why you would perform the test, if you could, and what the test would tell you about the suspect agent.
- **Use the comment section** to help walk us through what you did and why, to help us understand your thought process. If you perform an unnecessary test and don't provide an appropriate supporting comment explaining why you did it, you will receive a failing score for that test.



# Reading Culture Plates

- For example:



WSLH Proficiency Testing  
 2601 Agriculture Drive  
 Madison, WI 53718  
 1-800-462-5261  
[www.slh.wisc.edu/proficiency](http://www.slh.wisc.edu/proficiency) PService@slh.wisc.edu

WSLH PT Event Bioterrorism Prep  
 Worksheet

## Result Recording Worksheet Module 6010, 6015 – Bioterrorism Preparedness Exercise – For use of APHL Sentinel Guidelines

IMPORTANT: Have instructions, clinical histories, and the publication by APHL/LRN/ASM “Recognize. Rule-Out. Refer - Biothreat Agent Bench Cards for the Sentinel Laboratory” while performing testing [https://www.aphl.org/programs/preparedness/Documents/2018\\_BiothreatAgents\\_SentinelLab\\_BenchCards\\_print\\_092019.pdf#search=agents%20of%20bioterrorism](https://www.aphl.org/programs/preparedness/Documents/2018_BiothreatAgents_SentinelLab_BenchCards_print_092019.pdf#search=agents%20of%20bioterrorism)

Perform all testing in a certified biosafety cabinet. Make sure organism has been subcultured twice & colonies are 24 – 48 hours old before using for biochemical testing.

Procedure	Online choices	Comments for Sample: _____	Comments for Sample: _____
Growth on Blood agar at 35°C	24 hours / 48 hours / >48 hours / No growth <sup>#</sup>	Slight growth at 48 hrs	
Growth on Chocolate agar at 35°C	24 hours / 48 hours / >48 hours / No growth <sup>#</sup>	Slight growth 24 hrs	
Growth on MacConkey / EMB at 35°C	24 hours / 48 hours / >48 hours / No growth <sup>#</sup>	No growth at >48 hrs	
Hemolysis description	Beta-hemolytic / Not beta-hemolytic / No growth on BAP		
Gram stain (from agar growth)	Gram positive: bacilli, large bacilli, cocci Gram negative: bacilli, small bacilli, coccobacilli, small coccobacilli, cocci	Tiny GNGB	
STOP! Consider possible BT agents based on the agar growth/no growth, and/or Gram stain result.	BT agents ruled out so far: _____	GNGB R/O <i>B. anthracis</i> ; N/G on MAC R/O <i>Yersinia</i> and <i>B. pseudomallei</i>	
	BT agents not ruled out so far: _____	<i>Brucella</i> , <i>B. mallei</i> , better growth on Choc suspect <i>Francisella</i>	

**ORGANISM NOTE:** The organisms sent in this exercise are surrogate organisms meant to mimic BT agents, & may grow faster than BT agents typically would in a laboratory. It is recommended NOT to use growth rate as a reason to rule out a BT agent IN THIS EXERCISE.

**PROCEDURE NOTE:** Only perform procedures appropriate for the suspected bioterrorism agent(s) not ruled out by growth and/or Gram stain, following the flow chart in the APHL Sentinel Guidelines. For any procedures not appropriate for the suspected agent use result choice “Test not indicated”. \* TNI = Test not indicated.



# Biochemical Testing

- For example (ruling out *Brucella* sp, *B. mallei*, and *F. tularensis*)

**PROCEDURE NOTE:** Only perform procedures appropriate for the suspected bioterrorism agent(s) not ruled out by growth and/or Gram stain, following the flow chart in the APHL Sentinel Guidelines. For any procedures not appropriate for the suspected agent use result choice "Test not indicated". \* TNI = Test not indicated.

Procedure	Online choices	Comments for Sample: _____	Comments for Sample: _____
Catalase (tube or covered preferred)	Positive / Negative / TNI*	Tube catalase weakly positive (2 bubbles in tube)	
Oxidase	Positive / Negative / TNI*	Negative oxidase (rules out <i>Brucella</i> sp.)	
Indole	Positive / Negative / TNI*	TNI	
Motility	Positive by tube / Positive by wet mount / Negative by tube / Negative by wet mount / TNI*	TNI	
Urease	Rapid positive ( $\leq 2$ hours) / Positive / Negative / TNI*	TNI	
Satellite test	Positive / Negative / TNI*	Exception code	
Colistin disk	Resistant / Susceptible / TNI*	TNI	
Polymyxin B disk	Resistant / Susceptible / TNI*	TNI	
Penicillin disk	Resistant / Susceptible / TNI*	TNI	
Amoxicillin-clavulanate disk	Resistant / Susceptible / TNI*	TNI	
Beta-lactamase	Positive / Negative / TNI*	Exception code	
Growth at 42°C	Growth / No growth / TNI*	TNI	

**EXCEPTION CODES:** Each procedure must have either a result or an exception code chosen during online result entry! Use Exception Code "Procedure/source not performed in-house" if that test is not available at your facility. Exception Codes may be added by clicking the yellow E next to the drop down menus.

**COMMENTS:** Participants are encouraged to use the Comments section for each test/organism during online result entry to describe why it was or was not performed or ruled out. Comments may be added by clicking the yellow C next to the drop down menus.

Worksheet continued on next page



- For example

Rule out organisms	Online choices		Comments for Sample: _____	Comments for Sample: _____
	Comment on why each organism was ruled out/not ruled out			
<i>Bacillus anthracis</i>	Ruled out	Not ruled out	R/O by Gram Stain	
<i>Brucella species</i>	Ruled out	Not ruled out	R/O by negative oxidase and	weak positive catalase
<i>Burkholderia mallei</i>	Ruled out	Not ruled out	R/O by negative oxidase and	weak positive catalase
<i>Burkholderia pseudomallei</i>	Ruled out	Not ruled out	R/O by no growth MAC	
<i>Francisella tularensis</i>	Ruled out	Not ruled out		
<i>Yersinia pestis</i>	Ruled out	Not ruled out	R/O by no growth MAC	

**RULE OUT NOTE:** Participants are encouraged to use the Comments section for each organism during online result entry to describe why it was or was not ruled out. Comments may be added by clicking the yellow C next to the drop down menus.

Reporting & Referral Protocol (if this were a patient sample)	Online choices		Comments for Sample: _____	Comments for Sample: _____
Immediately notify, and then refer to LRN reference lab?	Yes*	No		
Report to local public health department?	Yes /	No		
Report to state public health department?	Yes /	No		
Refer to routine reference lab?	Yes*	No		

\* Please specify the LRN and/or routine reference lab using the Comments function (clicking the yellow C next to the drop down menus) during online entry.

# After You Receive the Exercise Results



- Use any extra remaining swabs to teach staff and students about BT agents
  - **Practice** performing rule-out testing safely (E.g. tube catalase versus slide catalase)
- You don't want your staff to be performing testing for the first time on a suspect isolate from an actual patient
- Review the results with all employees so everyone learns from the exercise
- If there were any failed items, review the problem and document your corrective actions



**Wingardium Leviosa**

# But What About Real Patient Culture Work-Up?



Know your possible BT agent indicators or stopping points!

**(MOVE WORK INTO A BIOSAFETY CABINET!)**

- Working on blood, wound (includes animal bites), or lower respiratory culture
- Gram stain shows large, boxcar GPB, small pleomorphic GNR, or tiny, faint GNGB
- Slow growing culture
  - From blood – bottle first positive > than 24 hours
  - From isolate growth – teeny tiny haze to tiny colonies at 24 hours, or no growth until 48 hours
  - Better growth on CHOC agar than BLD agar
  - No growth on MAC





# Rule-Out Testing

**(DON'T USE AN AUTOMATED ID SYSTEMS OR MALDI-TOF UNLESS YOU HAVE RULED-OUT BT AGENTS!)**



1.) Perform the required rule-out testing you have available in your laboratory according to the APHL bench card flowchart

2.) Consult with the clinician to see if patient has symptoms consistent with a possible BT agent infection

3.) Notify the WSLH of the situation and if suspicion is high for a select agent, notify state and local public health, infection prevention, and employee health

4.) Package isolate as a suspect Category A specimen and ship to the WSLH for further testing. Stop work on any other cultures from the patient and isolate all media.

5.) If identified by the WSLH as a BT agent perform exposure assessment, destroy all isolates, report to Select Agent Program



# Lesson 3





# What would you do if you are working on the weekend or on 2<sup>nd</sup> or 3<sup>rd</sup> shift and you believe you were exposed to a BT agent?

- A. I would leave a note for my laboratory supervisor where he/she would see it the next day
- B. I would go to the ER
- C. I wouldn't do anything until I get a definitive identification on the isolate
- D. I would make an appointment with my personal doctor ASAP
- E. I would check the biosafety plan and follow any guidance on what to do if you think you may have been exposed to a high risk agent



# Who would you do if you are working on the weekend or on 2<sup>nd</sup> or 3<sup>rd</sup> shift and you believe you were exposed to a BT agent?

- A. I would leave a note for my laboratory supervisor where she would see it the next day
- B. I would go to the ER
- C. I wouldn't do anything until I hear a definitive identification of the isolate
- D. I would make an appointment with my personal doctor ASAP
- E. I would check the biosafety plan and follow any guidance on what to do if you think you may have been exposed to a high risk agent**

# How Do You Determine Whether or Not You've Had Lab Exposures?



**It Takes a Team of Partners**



**Determine Who is Responsible for What**



# Do you have a biosafety plan that includes information on what to do if there is a laboratory exposure?

- A. Yes, we have a biosafety plan and it has information on what to do if there is a laboratory exposure to an infectious agent
- B. Yes, we have a biosafety plan, but it doesn't have information about what to do if there is a laboratory exposure to an infectious agent
- C. No, we don't have a biosafety plan, but this is covered in our accident policy
- D. No we don't have a biosafety plan or any plan about what to do if we have experienced an exposure
- E. I have no idea whether we have a plan, or what is in it



# Do you have a biosafety plan that includes information on what to do if there is a laboratory exposure?

- A.** Yes, we have a biosafety plan and it has information on what to do if there is a laboratory exposure to an infectious agent
- B.** Yes, we have a biosafety plan, but it doesn't have information about what to do if there is a laboratory exposure to an infectious agent
- C.** No, we don't have a biosafety plan, but this information is covered in our accident policy
- D.** No we don't have a biosafety plan or any plan about what to do if we have experienced an exposure
- E.** I have no idea whether we have a plan, or what is in it

# Lumos!

- Let's shed some light on what should be in your laboratory biosafety plan



# Tools Every Laboratory Must Have and Utilize



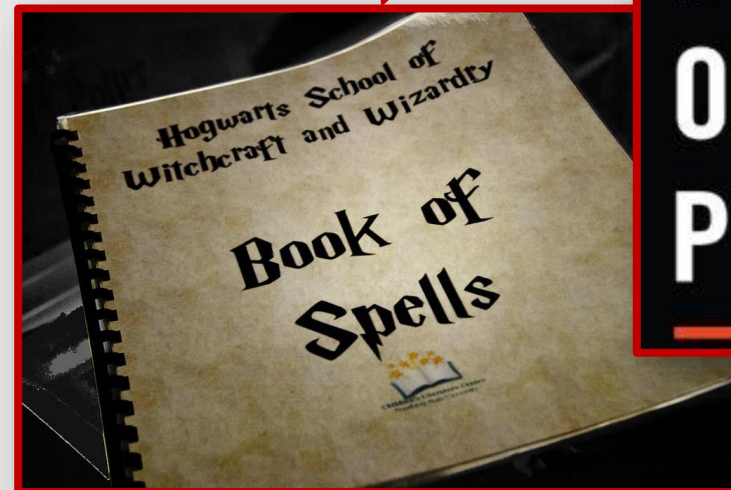
- **Biosafety Plan:**

- Vaccinations
- Biosafety Training
- Biosafety Competency Assessment
- Risk Assessment and Mitigation Steps Tool
- Exposure Assessment Tool
- Incident Report
- Names and contact information for Occupational Health/Incident response team
- Root Cause Analysis Tool



No

Yes



**STANDARD  
OPERATING  
PROCEDURE**

# Have You Done Your Risk Assessment?



- Things to consider:
  - What are you working with?
  - How hazardous is the specimen?
  - Where will you be working?
  - Will others be working nearby?
  - What are the testing steps and how will you manipulate the specimen?
  - What is your immune status?
  - What is your mental status?
- Who performs the risk assessment?
- Risk assessment requires continual re-assessment





# Exposure Assessment and Monitoring Tool



## CLINICAL LABORATORY BIOLOGICAL EXPOSURE EVALUATION TOOL

### Potential Exposure Event Summary

Date of Potential Exposure: \_\_\_\_\_ Exposure Location(s): \_\_\_\_\_

Multiple people exposed?  No  Yes. Complete this form for each person to determine individual exposure risk.

Name/Identifier of Person Potentially Exposed: \_\_\_\_\_

Individual's Predispositions:  Pregnant  Immunocompromised  Other: \_\_\_\_\_

### Interactions with Organism

Individual worked with organism:  Within BSC  Outside BSC  Did not work directly with organism

Individual did not work with organism, but was:  Within five feet  More than five feet away  Unsure

Individual wore:  Gloves  Lab coat/gown  Safety glasses  \_\_\_\_\_

Individual performed the following activities or types of manipulation with

- |  |  |   |
|--|--|---|
| <input type="checkbox"/> Removed caps or swabs from culture containers, opened lyophilized cultures or cryotubes | <input type="checkbox"/> Flamed a loop         | <input type="checkbox"/> Examined       |
| <input type="checkbox"/> Manipulated needles, syringes or sharps   | <input type="checkbox"/> Wet preps             | <input type="checkbox"/> Smear          |
|  | <input type="checkbox"/> Rapid antigen testing | <input type="checkbox"/> Centrifugation |
|  | <input type="checkbox"/> Blood culture bottle  | <input type="checkbox"/> _____          |

What work was done by whom, where and what PPE was worn? Who else was present and how close were they?



### Exposure Event Follow-up

#### Treatment and Monitoring

Post Exposure Prophylaxis (PEP):  Will begin PEP  Declined PEP  N/A

Serological Monitoring:  Will begin serological monitoring  Declined  N/A

Fever Watch:  Yes  No  N/A

Other Notes:

What treatment is needed and who will be monitoring the treatment?



#### Corrective Actions and Mitigations

Use the risk assessment determinations above to evaluate the overall risk of exposure according to the likelihood of occurrence and severity of consequences.

# Complete Exposure Assessment Section



- Determine who will do the exposure assessment
- 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 is the level of risk.
- Determine what post-exposure follow up steps will be taken



# Determine Root Cause

- Ask 5 “whys” to get to the underlying root cause?

## Problem:

Why was there an exposure?

Why?

Aerosol created when making a Gram stain slide outside of a biosafety cabinet

Why?

Tech didn't realize that she was working on the open bench with *Francisella tularensis*

Why?

Didn't look at the culture to see when the blood culture bottles 1<sup>st</sup> turned positive

Why?

Short of staff because someone called in sick and the individual was rushing to get through reading all the plates

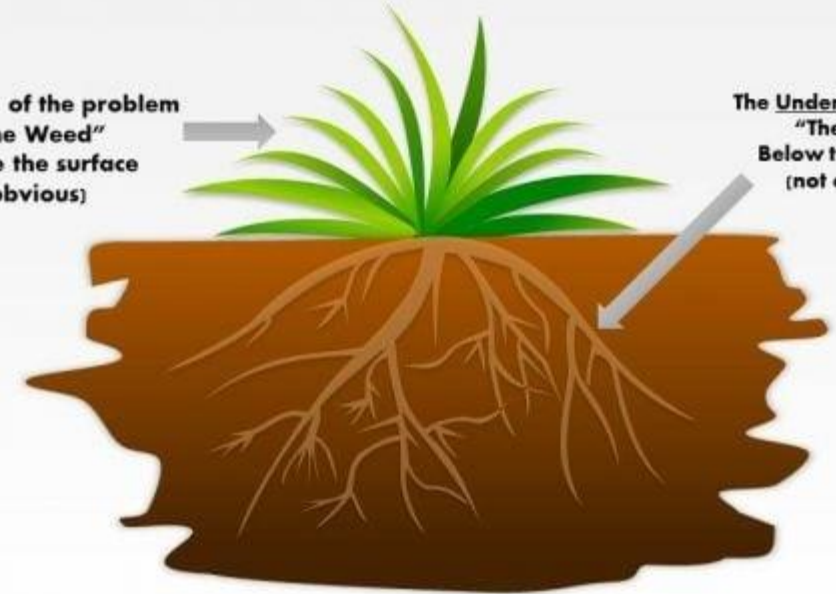
Why?

Disregarded SOP requiring working with blood cultures in a biosafety cabinet

## Root Cause Analysis Testing

Symptom of the problem  
“The Weed”  
Above the surface  
(obvious)

The Underlying Causes  
“The Root”  
Below the surface  
(not obvious)



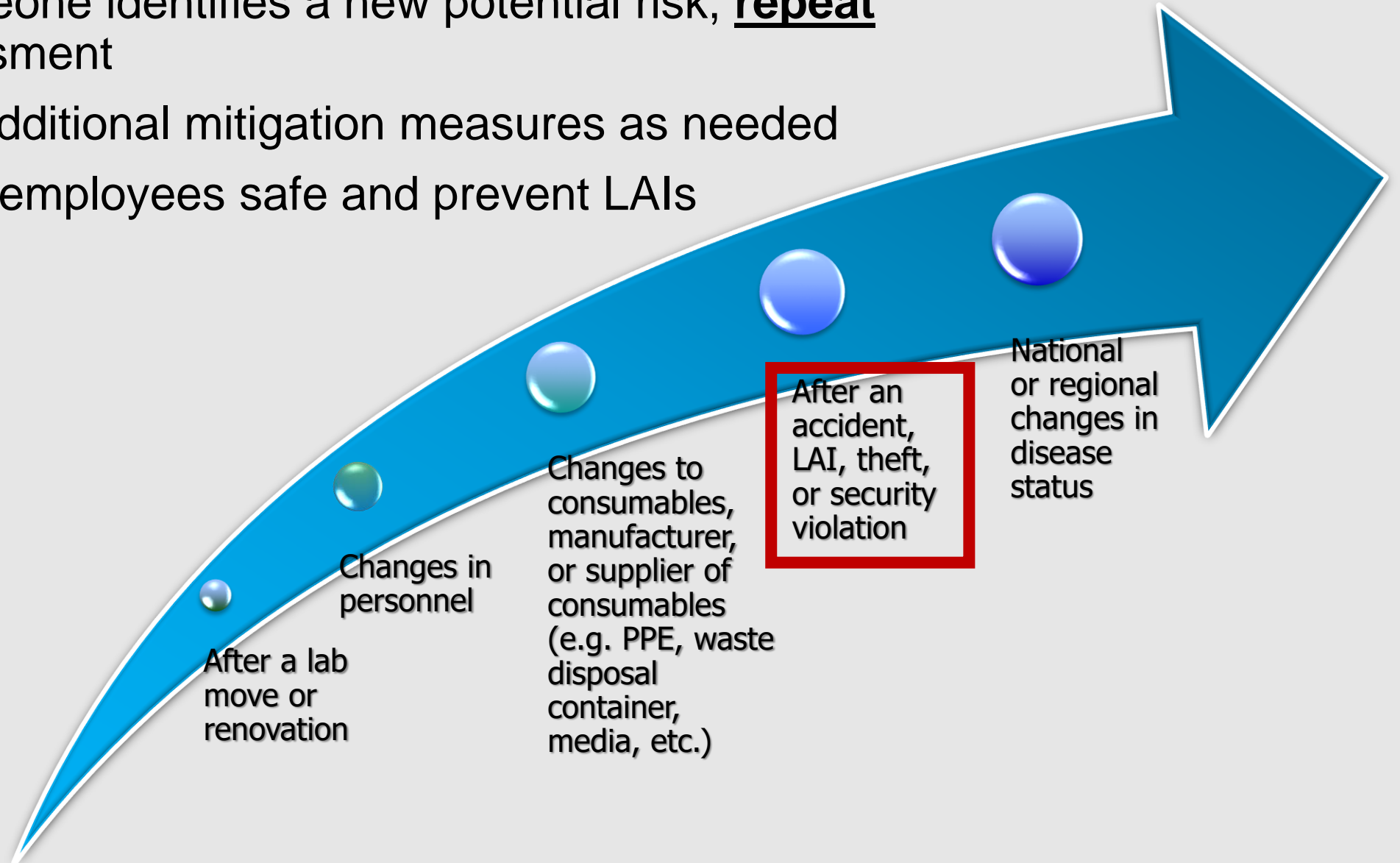
The word root, in root cause analysis, refers to the underlying causes, not the one cause.

**Root Cause: Employee didn't follow the SOP**

# When Do You Repeat a Risk Assessment?



- Whenever someone identifies a new potential risk, repeat your risk assessment
- Modify or add additional mitigation measures as needed
- Goal is to keep employees safe and prevent LAIs



# Don't Wait, Teach and Prepare Now!

