

DLS ECHO Biosafety Session: November 28, 2023

Laboratory Professional Vaccine Compliance and Effect on Safety



Michael Pentella, PhD, D(ABMM) Director, Iowa State Hygienic Laboratory at the University of Iowa Clinical Professor, University of Iowa Iowa City, IA





Agenda

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





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Learning Objectives

- At the conclusion of the session, attendees will be able to:
 - Identify effective biosafety practices that strengthen laboratory systems and advance laboratory safety.
 - Examine biosafety concepts that apply to conducting risk management when performing laboratory activities.

Risk Assessment Process



Mitigation Control Measures

- Engineering Controls: Physical changes to work stations, equipment, materials, production facilities, or any other relevant aspect of the work environment that reduce or prevent exposure to hazards
- Administrative Controls: Policies, standards and guidelines used to control risks
- Practices and Procedures: Processes and activities that have been shown in practice to be effective in reducing risks
- Personal Protective Equipment: Devices worn by the worker to protect against hazards in the laboratory

Mitigation Tools For Every Laboratory

- Biosafety Plan to Prevent Laboratory Acquired Infections:
 - Vaccinations
 - Biosafety Training
 - 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



Role of vaccine in mitigation



- Based on the risk of exposure to various microbial agents encountered in the laboratory and the availability of effective vaccines, the laboratory biosafety plan must include recommendations for the vaccination of individuals with the potential of occupational exposure.
- Determination of the vaccines to offer employees must be based on a risk of assessment of the work performed in the facility.

What vaccines to offer?

- The Advisory Committee on Immunization Practices recommends that all adults receive influenza, measles/mumps/rubella, varicella, and tetanus/diphtheria/pertussis vaccines.
- **Meningococcal vaccination** is recommended for those at risk for occupational exposure.
- Other vaccines to consider are **typhoid fever and anthrax vaccines**, for at-risk employees based on reasonable risk of exposure while performing routine job duties.
- Because of the nature of the disease and the lack of effective treatment availability, other vaccines, such as rabies and smallpox, are required as a condition for testing or handling specimens with infectious risk.
- For those individuals whose work activities place them at risk of exposure to blood and body fluids, the laboratory must provide to the employee hepatitis B virus vaccine as is required by the OSHA blood borne pathogen standards.

Hepatitis B virus (HBV) Vaccine

- HBV vaccine is recommended for all laboratorians whose work-related activities involve exposure to blood or other potentially infectious materials.
- The hepatitis B vaccine series must be made available before the employee begins work at an assignment that would place them at risk of exposure to blood and body fluids unless:
 - (1) the employee has previously received the complete series
 - (2) results of HBV antibody testing reveals that the employee is immune or immunized, or
 - (3) the vaccine is contraindicated for medical reasons
- The hepatitis B vaccine is administered as three intramuscular (IM) injections (2 dose for Heplisav-B)
 - first dose is followed in a minimum of 4 weeks by a second dose, which is followed in a minimum of 8 weeks by a third dose. There should be 16 weeks between dose 1 and 3.
- After completing the initial vaccination series, a post-vaccination hepatitis B surface antibody titer (anti-HBs) test should be performed in 1-2 months.
- If an employee is anti-HBs positive (immune), post exposure to blood or body fluids, no hepatitis B treatment is required. If anti-HBs is negative after initial vaccination, then 1-3 additional vaccine doses will be offered until anti-HBs is positive.

Tetanus-Diphtheria (Td) and Tetanus-Diphtheria-Acellular Pertussis vaccine (Tdap)

•Administer Tdap to all adults who have not previously received Tdap or for whom vaccine status is unknown. Tdap can be administered regardless of interval since the most recent tetanus or diphtheria-toxoid containing vaccine.

•Adults with an unknown or incomplete history of completing a 3-dose primary vaccination series with Td-containing vaccines should begin or complete a primary vaccination series including a Tdap dose.

•For unvaccinated adults, administer the first 2 doses at least 4 weeks apart and the third dose 6–12 months after the second.

•For incompletely vaccinated (i.e., less than 3 doses) adults, administer remaining doses.

Measles, Mumps, Rubella (MMR) vaccine

• Although laboratorians are not at a substantially increased risk for MMR infection (<u>http://www.cdc.gov/vaccines/recs/schedules/downloads/adult/adult schedule.pdf</u>) recommends that all adults born in 1957 or later with no evidence of vaccination or have no evidence of previous infection, unless they have a medical contraindication to the vaccine.

- Evidence of immunity includes laboratory evidence of immunity to each of the three diseases, or documentation of provider-diagnosed measles or mumps disease.
- Persons who received inactivated (killed) measles vaccine or measles vaccine of unknown type during 1963-1967 should be revaccinated with 2 doses of MMR vaccine.
- This vaccine contains live virus. It should not be given during pregnancy or if employee is immunocompromised or life-threatening allergic reactions to any vaccine component, or if the employee has recently received blood products or is moderately or severely ill.

Knowledge check

- Of the following vaccines, which is required by OSHA to be offered to employees at risk of exposure at **no charge** to the employee?
 - a) Influenza vaccine
 - b) Tetanus/diphtheria/pertussis vaccine
 - c) Hepatitis B vaccine
 - d) Measles/mumps/rubella vaccine

Surveillance of laboratory exposures to human pathogens and toxins, Canada, 2022

Christine Abalos¹, Audrey Gauthier¹, Antoinette Davis¹*, Cailey Ellis¹, Nathalie Balbontin¹, Aryan Kapur¹, Samuel Bonti-Ankomah¹

- 145 reports of laboratory incidents in CY 2022
- 40 confirmed laboratory exposure incidents reports
- 2 suspected LAI
- Incidence rate 3.8/100 active licenses
- Most common agent involved in exposure incidents = Neisseria meningitidis (n=5, 11.6%)

Neisseria meningitidis

Requires BSL 2 and some BSL3 practices, BSC, aerosol/droplet





precautions.	Estimated 3,000 isolates of Nm
<u>12 out of 32</u> LAIs were fatal in lab techs preparing a suspension or doing a catalase test on the open bench.	per year. Est. attack rate= 13/100,000 lab techs vs 0.3/100,000 adults aged

Neisseria meningitidis

A significant risk to microbiologists!

TABLE 1. Years of occurrence, ages, sex, identified serogroups ofN. meningitidis, and outcomes in 16 cases of probably laboratory-
acquired meningococcal disease from 1985 to 2000

Case	Yr	Age of patient	Sex ^c	Serogroup	Outcome
1	1985			В	
2^a	1985		F	С	Fatal
3ª	1987		F	В	Fatal
4	1989		F	В	Fatal
5	1991	46	F	В	Fatal
6	1991		F	С	Fatal
7 ^a	1992	and Second and	М	В	Surviveo
8ª ·	1995		M	В	Survived
9ª	1997	40	М	В	Surviveo
10	1997		F	В	Survived
11	1998	45	F	В	Surviveo
12^a	1999		F	С	Survived
13ª	1999		F	C	Survived
14^a	2000	35	Μ	С	Fatal
15^a	2000	52	F	С	Fatal
16 ^a	2000	and the second second	F	С	Fatal
17"	2002	50	F	С	Survived
18^b	2002	21	M	A	Survived
196	2002	65	F	ĉ	Survived

Sejvar, J.J. et. al. 2005. JCM. 43: 4811-4814.

Risk Assessment Matrix for *Neisseria meningitidis*

Risk factors	Degree of Laboratory Risk			
Agent Hazards	Low to Moderate	Moderate to High	High	
Pathogenicity			Severe disease	
Virulence			Lethal disease or high infectivity	
Infective dose			<100 IU	
Transmission			Inhalation of aerosols	

Risk Assessment Matrix for N. meningitidis

Protocol Hazards	Low Risk	Moderate Risk	High Risk
Agent Concentration			>10 ⁹ IU/ml
Suspension Volume	<1 ml	1 ml – 1 L	
Generate droplets & droplet nuclei			Making a suspension for gram stain on bench top
Protocol Complexity	Standard repetitive procedures		
Use of Animals	NA	NA	NA
Use of Sharps	NA	NA	NA

Risk Assessment Matrix for *N. meningitidis*

Risk factors	Degree of Laboratory Risk			
Susceptibility to Disease	Low to Moderate	Moderate to High	High	
Potential for Exposure	Visitor to lab		Manipulating agent	
Individual Susceptibility	Effective immunization	Immunocompetent	Compromised immune status	
Availability of vaccine or other prophylaxis	Yes			
Availability of effective treatment		Yes – but serious sequelae of infection		



Evening April 27, 2012, California microbiologist, 25 y/o onset of headache, fever, neck pain, and stiffness.

Morning April 28, while being transported via ambulance to the ER he lost consciousness.

Upon arrival, noted petechial rash, and treated with ceftriaxone, went into respiratory arrest and died 3 hours later.

Most likely cause???...

Neisseria meningitidis group B case study

Morbidity and Mortality Weekly Report

Fatal Meningococcal Disease in a Laboratory Worker — California, 2012

Channing D. Sheets, MSEd¹, Kathleen Harriman, PhD¹, Jennifer Zipprich, PhD¹, Janice K. Louie, MD¹, William S. Probert, PhD¹, Michael Horowitz, MS², Janice C. Prudhomme, DO², Deborah Gold, MPH², Leonard Mayer, PhD³ (Author affiliations at end of text)

- What is known:
 - Probable aerosol transmission.
 - Safety training was inadequate.
 - Equipment used included plate spreader, plate scraper, flaming loops, pipettor, etc.

- Occupational Practices:
 - PPE included lab coat and gloves.
 - Worked on the open bench.
- Recommendations:
 - Work inside BSC.
 - Replace flame sterilization of loop with disposable plastic.
 - Use disposable, closed front lab coats.
 - Wear eye protection.
 - Use double gloves and dispose outer gloves inside BSC.
 - Improve training.

Meningococcal vaccine

- Microbiology staff working with *Neisseria meningitidis* cultures should receive a single dose meningococcal vaccine and repeated at 5 years.
- Clinical microbiologists and research microbiologists who might be exposed routinely to isolates of N. meningitidis should receive a single dose of MCV4 and receive a booster dose every 5 years if they remain at increased risk. (MMWR, Nov 24, 2011, Vol. 60, No.7).

a) MCV4- quadrivalent (A, C, W-135, Y) conjugate meningococcal vaccine, licensed for persons aged through 55 years.

b) MPSV4- quadrivalent (A, C, W-135, Y) polysaccharide meningococcal vaccine, for use in persons aged >55 years.

c) MenABCWY vaccine may be used when both MenACWY and MenB are indicated at the same visit. (per Oct 2023 ACIP recommendations)

Salmonella Case Study:

Let's use this published paper to think through the risk assessment



Case Report

Typhoid fever due to laboratory-acquired *Salmonella* Typhi, confirmed by core genome multi-locus sequence typing

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^c Centre for Infectious Disease Control, Diagnostics and Laboratory Surveillance (IDS), National Institute for Public Health and Environment, Bilthoven, Netherlands

Salmonella case study

- What is known:
 - Clinical microbiology technician seen an ER with FUO
 - Blood culture collected, GNR isolated in 36 hours
 - Identified as Salmonella sp.
 - Stool culture collected also positive for Salmonella sp.
 - Sixteen days before the onset of clinical symptoms, this employee had performed a serotyping of a *Salmonella* strain
 - All strains identical by whole genome sequencing
 - Index patient recently traveled to India

- Occupational Practices
 - Review of laboratory safety procedures did not reveal any breach in practices
 - Case demonstrates the need to be aware of the risk of laboratory acquired infections.
 - The laboratory does not offer the Typhoid vaccine to staff, and this patient was not immunized.
 - BSL-2 practices were used which is consistent with CDC recommendations since there was not the risk of significant aerosols.

Salmonella Typhi: Magnitude of risk

- CDC estimates 5,700 infections of *Salmonella* Typhi annually in the U.S. and 620 hospitalizations.
- Vaccination of laboratorians who work with *Salmonella* Typhi is recommended.
- A booster is required every 2 years for injectable and 5 years for oral vaccine.



https://www.cdc.gov/typhoid-fever/reports/annual-summary-2020.html#figure-1

Poll: What are the likely risks in this case?

- Select the most probable risk:
 - 1. Lack of handwashing
 - 2. Insufficient training on biosafety practices
 - 3. Surface contamination
 - 4. Ineffective disinfectant
 - 5. Cell phone use in the lab



As a follow up to the case repeat the Risk Assessment?

• Whenever someone identifies a new potential risk and requests a repeat assessment

Changes in personnel After a lab move or renovation W

Changes to L consumables of or M manufacturer, supplier of consumables (e.g. PPE, Container, waste disposal materials, media)

After an accident, LAI, theft, or security violation National or regional changes in disease status

Special Circumstances and vaccination

- Anthrax Rabies
- Smallpox

• Ebola



CDC Guidelines for the Prevention and Treatment of Anthrax, 2023

Recommendations and Reports / November 17, 2023 / 72(6);1-47

Anthrax vaccine:

- Pre-exposure vaccination is recommended for laboratorians at risk for repeated exposure to fully virulent *B. anthracis* spores, such as those who ... handle environmental samples that might contain powders and are associated with anthrax investigations" or who "work in other settings where repeated exposures to *B. anthracis* aerosols may occur."
- 2) Vaccination is offered to personnel who:
 - a) Are designated for performing testing as part of the biothreat response efforts working on:
 - 1. Clinical Bacillus species isolates or
 - 2. Unknown powders that may contain anthrax
 - 3. Who may be involved in the processing of environmental specimens as part of a biothreat response scenario.

https://www.cdc.gov/mmwr/volumes/72/rr/rr7206a1.htm?s_cid=rr7206a1_e&ACSTrackingID=USCDC_921-DM117184&ACSTrackingLabel=MMWR%20Recommendations%20and%20Reports%20%E2%80%93%20Vol.%2072%2C%20November%2017%2C%202023&deliveryName=USCDC_921-DM117184

Smallpox vaccination

- Uses live vaccinia virus. Must take precaution post vaccination to prevent spread.
- Smallpox vaccination is required for all laboratory personnel who perform variolaspecific PCR testing, and all personnel who could be involved with processing specimens referred for possible smallpox testing. Personnel who decline vaccination are not permitted to perform variola testing or specimen processing.
- Smallpox vaccination must be given to laboratory workers who directly handle cultures of non-highly attenuated vaccinia virus, or other orthopox viruses that infect humans (e.g.: monkeypox, cowpox, vaccinia strains, or variola) (MMWR 2001 ;50 (No. RR-10)
 - Vaccination is required at 3-year intervals.

Use of a Modified Preexposure Prophylaxis Vaccination Schedule to Prevent Human Rabies: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022

Agam K. Rao, MD¹; Deborah Briggs, PhD²; Susan M. Moore, PhD²; Florence Whitehill, DVM^{1,3}; Doug Campos-Outcalt, MD⁴; Rebecca L. Morgan, PhD⁵; Ryan M. Wallace, DVM¹; José R. Romero, MD⁶; Lynn Bahta, MPH⁷; Sharon E. Frey, MD⁸; Jesse D. Blanton, DrPH¹

- 1) Rabies vaccination is required for all employees working in areas where rabies virus testing occurs (including the animal necropsy laboratory and the laboratory where direct fluorescent antibody testing is performed).
- 2) Two does are given IM on days 0 and 7.
- 3) Check titers every 6 months; booster if titer <0.5 IU/mL.
 - Following completion of the initial vaccination series and semi-annually thereafter, the ACIP recommended Rapid Fluorescent Focus Inhibition Test (RFFIT) method is used to demonstrate rabies antibody response, and a protective level of immunity.

<u>MMWR Recomm Rep.</u> 2021 Jan 8; 70(1): 1–12. Published online 2021 Jan 8. doi: <u>10.15585/mmwr.rr7001a1</u>

Use of Ebola Vaccine: Recommendations of the Advisory Committee on Immunization Practices, United States, 2020

Mary J. Choi, MD,^{II} Caitlin M. Cossaboom, DVM, PhD, ¹ Amy N. Whitesell, MPH, ¹ Jonathan W. Dyal, MD, ¹ Allison Joyce, MSc, ¹ Rebecca L. Morgan, PhD, ² Doug Campos-Outcalt, MD, ³ Marissa Person, MSPH, ¹ Elizabeth Ervin, MPH, ¹ Yon C. Yu, PharmD, ¹ Pierre E. Rollin, MD, ¹ Brian H. Harcourt, PhD, ¹ Robert L. Atmar, MD, ⁴ Beth P. Bell, MD, ⁵ Rita Helfand, MD, ¹ Inger K. Damon, MD, PhD, ¹ and <u>Sharon E. Frey</u>, MD ⁶

- ACIP recommends use of the rVSVΔG-ZEBOV-GP Ebola vaccine (Ervebo)
- FDA approved live attenuated recombinant vesicular stomatitis virus (VSV) in which the gene encoding the glycoprotein of VSV was replaced with the gene encoding the glycoprotein of Ebola virus species *Zaire ebolavirus*
- HCW at designated Ebola treatment centers or laboratorians working in BSL-4 labs

Polling Question

- With regards to your organization:
 - a) There is an inhouse occupational health service?
 - b) Occupational health is a contract service?
 - c) Do not have occupational health resources?

Vaccines to protect in shared work-spaces

- All employees should be offered the Influenza vaccine through the annual facility wide immunization clinic or through employee's private health care provider
- Also consider SARS-CoV-2 and RSV



Ethical assessment of mandatory vaccination

<u>Clin Chim Acta.</u> 2020 Nov; 510: 421–422. Published online 2020 Aug 7. doi: <u>10.1016/j.cca.2020.08.003</u> PMCID: PMC7410812 PMID: <u>32771485</u>

Ethical and organizational considerations for mandatory COVID-19 vaccination of health care workers: A clinical laboratorian's perspective

Raffick A.R. Bowen

- Compelling patient safety concerns
- Least restrictive approach to achieving patient safety
- Opt-out criteria based on religious beliefs or medical contraindications
- Alternative methods for prevention, i.e., PPE or reassignment
- New employees should be informed of policy and consequences of noncompliance
- Mandatory vaccination policies transparent
- Vaccinate at no cost and easily accessible

Polling Question

- What vaccines does your organization offer (select all that apply)?
 - a) Influenza
 - b) COVID-19
 - c) Td or Tdap
 - d) MMR
 - e) Meningococcal
 - f) Typhoid
 - g) Rabies
 - h) Anthrax
 - i) Smallpox



Conclusion: Vaccines are an important part of an organization's Biosafety Plan and contribute to the culture of safety for the laboratory.

Facilitated Discussion – The situation...

- The laboratory is in a large metropolitan area with an international airport and several large teaching hospitals. It is known as a destination for individuals seeking medical care in the U.S. from many global destinations.
- You're a new BSO. There has been a long gap between the last BSO leaving and your start date. One of the first questions you receive is from a staff member asking about the need to get influenza vaccine. Which gets you to thinking, what vaccines do you want people to receive?
 - Where do you start your considerations?
 - What information do you need to make your recommendation?



The laboratory tests human samples.

- What is the first vaccine that everyone is required to have?
- How will you select which vaccines to offer?



The first step is to perform the risk assessment and review the hazards that the laboratory staff can reasonably be expected to encounter.

- What data will you need to do you risk assessment?
- What governmental agencies could be of help?



The lab has these sections: Chemistry, hematology, microbiology, immunology, urinalysis, toxicology, and sample receiving.

- Based on the risk assessment, what likely mitigation tools will you select?
- What data and information do you need to determine the vaccines that might be offered?



The laboratory has contracted with an occupational health clinic which is located offsite.

- When do you contact the occupational health clinic?
- What services will you need from the occupational health clinic to provide the vaccines?



The laboratory has a safety committee which has a charter and meets monthly. The Biosafety Officer cochairs the committee with the Chemical Safety Officer. One of the roles of the committee is to review the policies and procedures. The committee also reviews all laboratory exposures and other incidents.

- What is the role of the committee in selection of vaccines?
- What actions do you expect the committee to take?

You observe through conversation with some staff that the knowledge level regarding biosafety is minimal.

- Before implementing the vaccine program, what is necessary to make it successful?
- What tools will you use to message about the program?



Vaccine hesitancy is a well-known problem among healthcare workers including laboratorians. It has the potential to be detrimental to the vaccination program

• How will you deal with vaccine hesitancy?





About News/Events Publications/Resources Career Growth (Q)



https://absa.org/

- N=590 LAI
- Clinical Laboratories = 120
- Articles About Fatal Cases = 22



Laboratory-Acquired Infection (LAI) Database Search Tips

You can search partial terms using the asterisk (*)	
example: pseud*	
results: Pseudoalteromonas, pseudomycoides,	
Pseudallescheria. etc.	

input any term that might appear in a report (examples: 2014, virus, goggles, texas, dengue, etc.)

Search LAI Database

Search

A searchable laboratory-acquired infection database.

Gillum, David, Partha Krishnan, and Karen Byers. *Applied Biosafety 21.4 (2016)*: 203-207.

You can use Boolean operators OR, AND syringe AND gloves student OR teacher



Questions?

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