

# Biosafety in Your Health Department

Kristin Long, PhD,  
Biosecurity/Biosafety Officer

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## CDC Funding

- Epidemiology and Laboratory Capacity for Infectious Diseases (ELC)
  - State, local and territorial health departments
  - 20+ infectious disease areas
  - Strengthen public health workforce, surveillance systems, facilities and communication
- 2015 supplement to enhance PH laboratory biosafety capacity
  - Hire biosafety officers
  - Work with local public health labs and facilities to implement biosafety measures



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## NCSLPH Biosecurity Officer Roles

- Manage biosafety/select agent program at NCSLPH
- Work with other biosafety/security officers to develop policies and training materials to augment existing CDC-APHL resources
- Assess external biosafety needs in state public health groups
  - Sustainable biosafety programs
  - Continuing education and training programs

## Outline

- Case studies
  - Risk of working with unknowns
  - Lab/health care acquired infections
- Proposed OSHA Infectious Disease standard
- Biosafety basics
  - Challenges
  - Risk assessments
  - Standard operating procedures = biosafety plan
  - Examples of operational practices
  - Managing incidents

## 2001 New York

- 57 y/o female
- Presented in ER one week after onset
  - Headache, malaise, vomiting, and fever
- Five weeks symptoms persisted; multiple ER visits
- Colleagues did blood draw and Gram stain - identified *Brucella* spp.
- Wadsworth Center, NYSDOH – Reactive *Brucella* SAT

## 2002 New York

- 48 y/o female
- Presented to ER with high fever, chills, drenching sweats and weight loss
  - Treated for influenza
- Symptoms persisted- multiple ER visits
- Referred to ID specialist
  - Reactive *Brucella* SAT

## Analysis

- Index patient - 76 y/o F presented to ER where LAI #1 worked in lab
  - Fever, headache
  - Treated for UTI and discharged
  - NYSDOH found
    - Gram stain incorrectly interpreted
    - *B. melitensis* DNA identified in Gram stain material
- LAI #1
  - Blood cultures from index patient plated benchtop
  - Catalase test performed benchtop
- LAI #2
  - Handled LAI#1 blood cultures for biochemical testing on open bench

Noviello, et al. 2004. Emerg Infect Dis; 10(10)

## 2000 Alabama

- 35 y/o male
- Presented in ER with malaise, fever, myalgia
  - Tachycardic and hypotensive
  - Succumbed to infection
- Post-mortem diagnosis *Neisseria meningitidis*
  - Microbiologist in clinical lab
  - Aspirated from blood culture bottle for Gram stain on open bench
  - No BSC or PPE (eye protection or mask)

Lofgren, et al. MMWR 2002; 51(7)

## Lessons

- All personnel were following laboratory procedures
  - Were not doing anything “wrong” or purposefully violating safety rules
- Need to define Standard Operating Procedures for Biosafety
  - Site-specific risk assessment

## Lab Acquired Infection Survey 2002-2004

- All specimens start with patient
- Working with unknowns
- 33% of clinical labs reported at least 1 LAI; 41 LAIs reported
  - *Shigella* (15)
  - *Brucella* (7)
  - *Salmonella* spp. (6)
  - *S. aureus* (6)
    - (5) MRSA
  - *N. meningitidis* (4)
  - *E. coli* 0157:H7 (2)
  - *C. difficile* (1)

Baron and Miller. 2008. Diagn Microbiol Infect Dis; 60(3)

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## Exposures

- Known – unplanned, direct contact with infectious agent
  - Needle stick
  - Spill/splash into mucous membranes or cut in skin
- Potential
  - Break in PPE
  - Incorrect handling of agent determined upon identification

**Only 16% of LAIs result from known exposure**



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## Common Routes of Lab/HC Acquired Infections

1. Inoculation with needle or other contaminated sharp
2. Bites/scratches
3. Splashes to skin and mucous membranes
4. Ingestion
5. Touching mouth/eyes with fingers or contaminated objects
6. Infectious aerosols/droplets

First 5 are easy to detect but only account for 20% of all reported LAIs

MMWR Supplements 2012; 61(101)



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## OSHA Infectious Disease Protection

- [Bloodborne Pathogens standard](#) (29 CFR 1910.1030) to protect workers from occupational exposure to bloodborne pathogens (e.g., Hepatitis B, HIV)
  - Revised in response to the Needlestick Safety and Prevention Act, [Pub. L. 106-430](#).
- TB compliance directive, "Enforcement Procedures and Scheduling for Occupational Exposure to Tuberculosis" ([CPL 02-02-078](#)).



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## OSHA Infectious Disease Standard (10/2017)

<https://www.osha.gov/dsg/id/tab6.pdf>

- Require employers to have comprehensive infection control program and control measures for non-bloodborne (contact, droplet, airborne) infectious agent exposure
- Includes **health care, emergency response**, correctional facilities, homeless shelters, drug treatment programs, and other occupational settings where employees can be at increased risk of exposure to potentially infectious people or materials. Also **laboratories, which handle materials that may be a source of pathogens**, and to pathologists, coroners' offices, medical examiners, and mortuaries



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## Worker Infection Control Plan

- Needs to be developed, implemented and updated annually
- List of all job classifications with occupational exposure risk
- Workplace-specific SOPs for infection control measures
- Plan must be accessible to staff and trained
- Ensure visitors adhere to WICP at the same level or higher than staff



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## SOP Requirements in All Affected Workplaces

- Develop SOP consistent with recognized and generally accepted good infection control practices (CDC/HHS/HICPAP guidelines)
  - Agent hazard evaluations
  - Communication of hazards to employees
  - Use of engineering/administrative and work practice controls including PPE
  - Decontamination procedures
  - Handling and transport of contaminated materials
  - Occupational health services

## SOP Requirements – Patient Care

- Standard and transmission-based precautions to protect workers
- Methods for prompt identification and staff protection from infectious patients
- Patient isolation or transfer
  - Airborne infection isolation room operation if available

## SOP Requirements - Laboratories

- Handling and intake of contaminated materials
- Control measures to prevent or minimize transmission
- SOPs for implementing standard microbiological practices
  - Proper construction, operation, and maintenance of engineering controls
  - Measures to address release of infectious agents

## Occupational Health Requirements

- The employer would be required to make available to at-risk employee(s) at a minimum
  - Influenza (seasonal and pandemic)
  - Measles, Mumps and Rubella (MMR)
  - Tetanus, Diphtheria, and Pertussis (Tdap)
  - Varicella
  - Others specified in plan (e.g. meningococcal vaccine)
- Medical screening and surveillance of employees

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## Biosafety Definitions

- Biosafety – the discipline addressing the safe handling and containment of infectious microorganisms and hazardous biological materials
- Risk assessment – process to identify hazards, evaluate risks, determine controls, implement controls and review and adjust as necessary
  - Informs workers of risks and mitigations
  - Backbone of any biosafety program

**Risk is Never Zero**

## Risk can be Reduced/Mitigated

- Engineering
  - Facility design
  - Safety equipment
- Administrative
  - Safety practices
  - PPE
  - Standard protocols based on risk assessment

## Challenges to Biosafety in Health Departments

- Facility design and construction
  - Limited space
  - Not designed for use as laboratory/clinic
  - Not easily adapted to handle new and emerging pathogens
- Limited access to costly safety equipment – BSC, biocontainment rotors
- Personal protective equipment
  - Required assessments and training limited
- Access to biosafety expertise and training

## Challenges to Biosafety in Health Departments

- High stress, critical work
- Limited staff with high workload
- Minimal institutional support and enforcement for biosafety
- Lack of time and/or \$ for training
- “We’ve always done it that way”
- **Work conducted before risk is known**



## Risk can be Reduced/Mitigated

- ~~Engineering~~
  - Facility design
  - Safety equipment
- Administrative
  - Safety practices
  - Standard protocols based on risk assessment
  - PPE

## Risk Assessments

- Evaluate interaction between
  - Health care provider or laboratorian
  - Patient and/or specimen
  - Environment
- Identify and mitigate risks
- Operational risk assessments
  - Provides information for developing SOPs
- Agent-specific risk assessments
  - Provides training material and information for SOP development
- Personal risk assessments
  - Thought process to about your abilities and needs



## Who, What, Where, When, Why and How

- Who should participate in risk assessment?
  - Personnel who perform or who have performed the task
  - Supervisors
  - Infection control officer, SME, Biosecurity/Biosafety Officer
- Where?
  - Risk assessment is always site-specific

## What?

- Identify potential hazards from patient care/specimen collection to disposal/shipment of specimens
- Identify activities with exposure potential
  - Equipment
  - Route of transmission
  - Use of sharps
  - Biohazardous waste disposal and decontamination
  - Competencies of personnel

## When?

- Prior to beginning new procedures
- Anytime the chance of encountering a pathogen in the clinic changes
  - Zika - 216 cases in FL and 6 cases in Texas that were acquired locally
  - *Candida auris* – NY 2013-2015; 2015 NJ; 3 additional states May 2016-2017
- Anytime mitigation strategies change
  - Antibiotic resistance increases risk

## Why?

- Lack of risk identification, communication and mitigation leads to
  - Inappropriate containment measures = unsafe environment
  - Nothing occurs in a vacuum
    - Lack of information can be replaced with inaccurate information
  - Employee safety concerns

## How?

- Resources are available – CDC, APHL, etc.
- Reach out to NCSLPH
  - BTEP Lab Improvement Consultants
    - Kristi Jenkins
    - Barbie Page
  - Biosafety Officer





## Pathogen Safety Data Sheets and Risk Assessment

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

- Describe hazardous properties of human pathogens
- Recommend practices for work with agents

Determine if facilities, engineering controls, PPE, and personnel competency are sufficient to manage risks



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## Standard Operating Procedures/Protocols

- Written guidelines that allow two or more people to do the same thing, the same way, with the goal of achieving the same result
- Standard Operating Procedure for Biosafety = Biosafety Plan
- Ensure quality and safety of work

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## What should be included in Biosafety Plan?

- Risk assessments
- Safe work practices
  - Aerosol generating procedures
  - Sharps – use and disposal
- PPE
- Spill procedures
- Engineering controls
- Exposure/incident management – reporting, PEP
- Waste management and decontamination
- Safe transport of specimens

## Write Biosafety Plan for Compliance

**"A plan alone will never produce consistent results. It does not matter if a plan exists – what matters is if the workforce is following that plan"**

- Plan must be available to staff at the place where work occurs
- Plan must make sense and be easy to understand
- Plan must be trained and understanding assessed
- Plan must be based on scientific, site-specific facts

## Operational Practices

- Proper signage
- Areas kept clean and tidy; good lighting; appropriate airflow
- Work surfaces cleaned and decontaminated
- Minimize biological aerosols
- Safe transport and shipping protocols
- Incident management

## Signage

- Staff awareness
- Support personnel
- Uninvited guests



## Aerosol Containment without a BSC

- Centrifuges
  - Biocontainment rotors
  - Allow time between run and opening lid
- Work occurs away from doors, air vents, etc.
- Decontaminate work surfaces after use and at end of day
  - SOPs should contain proper disinfectant and contact time for highest possible pathogen reasonably encountered
- Decontaminate spills of biological materials immediately

## Personal Protective Equipment

- PPE worn properly fastened in patient and laboratory areas
  - Not worn in open, public areas and not stored near street clothes
- Define dress code including suitable footwear
- Identify procedures requiring eye and face protection
  - Masks
  - Face shields
  - Goggles/safety glasses
- Overtly or potentially contaminated clothing decontaminated

## Gloves

- Gloves are worn for all procedures that involve direct skin contact with known or potentially biohazardous material
- Usefulness increases exponentially with proper training
  - Protection provided
  - Proper donning and doffing
  - Good handwashing measures
  - Protocols for behaviors
    - Cell phones

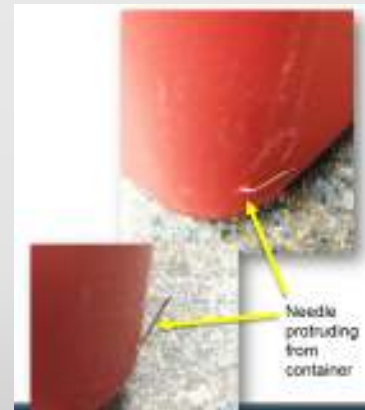


## Reporting and Incident Management

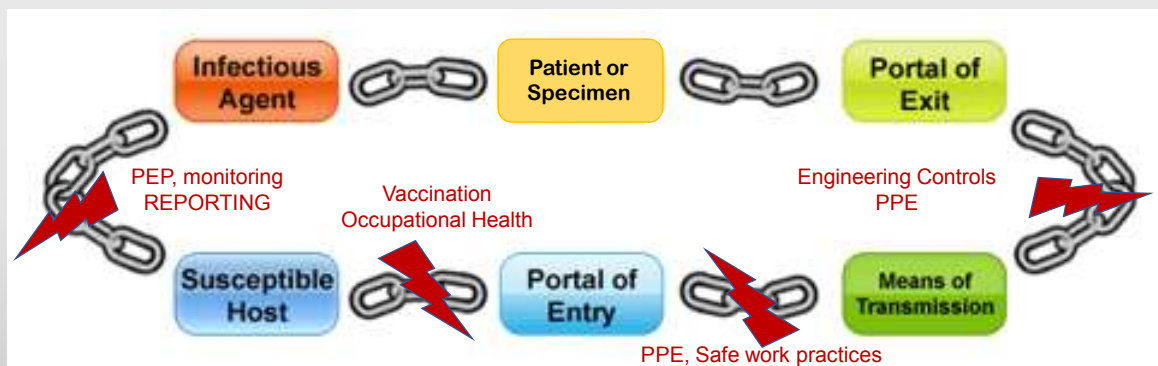
- Incident- individual occurrence or event such as spill, injury, exposure
- Near-miss - incident which under different circumstances could have resulted in an exposure, spill or injury
  - Prevent exposures by managing near miss incidents
- Safety plan describes management of incidents and near-misses
- “Culture of Safety” promotes prompt reporting of incidents and near-misses

## Case Study – Near miss

- Autoclaved sharps container
- Person processing autoclaved waste received needle stick
- Incident investigation
  - Staff this occurring frequently
  - Report could have prevented injury
    - Containers NOT autoclavable



## Break Chain of Infection



## Upcoming Training Opportunities at NCSLPH

- Eagleson Institute Training Risk Assessment and Safety Culture
  - August 23-24, 2017
- 13<sup>th</sup> Annual Clinical Lab Day, Safety Culture and Biosafety
  - Friday, October 6, 2017
  - Wake Technical Community College Main Campus
- BTEP Workshop, Preparedness Training for Clinical Laboratories
  - September 21, 2017



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## Thank you



Kristin M. Long, PhD  
Biosecurity Officer  
North Carolina State Laboratory of Public Health  
[kristin.long@dhhs.nc.gov](mailto:kristin.long@dhhs.nc.gov)  
919-807-8778 office  
919-614-2822 cell



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