Biosafety in Your Health Department

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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
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

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)
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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  - *C. difficile* (1)

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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
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

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)
- TB compliance directive, "Enforcement Procedures and Scheduling for Occupational Exposure to Tuberculosis" (CPL 02-02-078).
OSHA Infectious Disease Standard (10/2017)

- 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

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
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
Outline

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  - Risk assessments
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  - Examples of operational practices
  - Managing incidents

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
- 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

Reinforcing the CDC Way of Risk Assessment

Risk Assessment Process:
- Identify hazards
- Reassess risk
- Conduct procedure
- Mitigate risk
- Evaluate risk
Pathogen Safety Data Sheets and Risk Assessment


- 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

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
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

• 13th 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

Thank you

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