

Addressing the Continuing Threat of Laboratory–Acquired Infections

Tom Hearn, PhD
Deputy Director

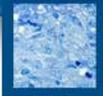
National Center for Preparedness, Detection,
and Control of Infectious Diseases (NCPDCID)

**Update: Potential Exposures to Attenuated Vaccine
Strain *Brucella abortus* RB51 During a Laboratory
Proficiency Test --- United States and Canada, 2007**

Coordinating Center for Infectious Diseases

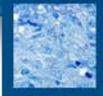
Potential *Brucella* Exposures in the CAP Laboratory Preparedness Survey (LPS)

- Laboratory survey using surrogate agents for potential bioterrorism agents sent 10/07
 - LPS specimen inadvertently sent to NYS public health laboratory (PHL)
 - Laboratory workers in NYS PHL did not follow safety precautions
 - Follow up survey of laboratories that participated in the LPS was conducted



Voluntary Survey Report

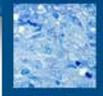
- 36 states, 2 cities, 1 county, DC
- Potential exposures:
 - 916 people in 254 laboratories
 - 679 (74%) high-risk exposures
 - 237 (26%) low-risk exposures
- No cases of brucellosis reported



Need for Attention to Safe Working Practices

- *Brucella* is most common agent in laboratory-acquired infections (LAI)
- *Shigella*, *Salmonella*, and *Staphylococcus aureus* are also common*
- Survey of hospital labs indicated LAI more frequent in >200 bed hospitals*
- Risk of LAI greatest for *Brucella*, *Neisseria meningitidis*, and *E. coli* 0157:H7 vs. community*

*Baron and Miller, *Diag Microbiol Infect Dis*, 2007



Laboratory Employees Face Greater Risks

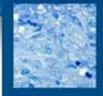
Risk of a LAI in microbiologists vs. the general population, same relative age

Organism	Risk/100 000 microbiologists	Risk/100 000 general population
<i>Brucella</i>	641	0.08
<i>Coccidioides</i>	13.7	12
<i>C. difficile</i>	0.2	8
<i>E. coli</i> O157:H7	8.3	0.96
<i>N. meningitidis</i>	25.3	0.62
<i>Salmonella</i>	1.5	17.9
<i>Shigella</i>	6.6	6.6

From: Ellen Jo Baron and J. Michael Miller “Bacterial and fungal infections among diagnostic laboratory workers: evaluating the risks” [“Diagnostic Microbiology and Infectious Disease”](#) March 2008 **60(3)**: 241-6”

Issues

- Clinical laboratories handle many specimens that may contain infectious agents
- Recent incidents indicate:
 - Laboratory personnel may not have adequate **training** to work safely with infectious agents
 - Some safety **equipment** may not be readily available in clinical laboratories
 - Safety **procedures** in clinical laboratories may need improvement



Background

Biosafety Activities

- Laboratories and professional organizations
- Training, safety, and accreditation organizations

Federal Activities

- Trans Federal Task Force for Optimizing Oversight of High Containment Laboratories
 - BSL 3 & 4 Labs
 - Research and Clinical
- BRP focused on Clinical Testing, All BSL categories

Blue Ribbon Panel Members

Dr. Ellen Jo Baron

Dr. Kathleen Beavis

Mr. William Dunn

Dr. Larry Gray

Mr. William Homovec

Dr. Michael Pentella

Dr. Bruce Ribner

Dr. William Rutala

Dr. Daniel Shapiro

Ms. Lisa Skodack–Jones

Ms. Christine Snyder

Mr. Robert Sunheimer

Ms. Christina Thompson

Regulations and Guidelines for Laboratory Safety

- OSHA General Duty Clause (29 CFR 654)
- Bloodborne Pathogens Regulations (29 CFR 1910)
- *Protection of Laboratory Workers for Occupationally Acquired Infections, CLSI M29–A3*
- *Medical Laboratories—Requirements for Safety, ISO 15190*
- State and Local Oversight

Blue Ribbon Panel

- Inaugural Meeting at CDC 5/16/08
- Broad National Representation
 - Assistance from Professional Organizations
 - Wide Range of Expertise and Experiences
- Cross-cutting interest at CDC
 - Office of the Director
 - Coordinating Center for Infectious Diseases (CCID) and the 4 National Centers in CCID
 - Office of Health and Safety
- Environmental scan and “reality testing” for CDC

Discussion Points

- Standards, guidelines, and regulations
 - Are clinical laboratories aware of these and are they being followed?
 - Are current guidelines adequate to address safety risks in the modern clinical laboratory?
 - What are the best practices to ensure implementation?
 - How should standards and guidelines be formulated and by whom?
 - How should they be evaluated and enforced?

Discussion Points

- Education and training
 - What, if any, are the requirements (e.g., per regulation, institution, accrediting agency)?
 - Is there a best practice for a training strategy?
 - Is training and education sufficient for establishing safe work practices?

Discussion Points

- Safety management program
 - Is safety management practiced in clinical laboratories?
 - Are there local, state, or national programs that deal with responses to laboratory accidents?
 - Are there policies in clinical facilities for post-exposure prophylaxis or other follow-up for laboratory accidents?

Discussion Points

- Reporting of laboratory-acquired infections
 - Is there a mechanism to report these on a local/national scale?
 - Should there be a national reporting requirement and if so, what would it look like?
 - What would encourage facilities to fully participate in a reporting system?
 - What data would be collected from each incident that would allow meaningful follow-up and resolution?
 - Where should national surveillance and analysis reside?
 - Should reporting be voluntary?

Panel's Recommendations

CDC Guidance

- CDC could and should continue to provide guidance for working safely in clinical laboratories
- Challenged CDC to:
 - publish asap in written form the 5th edition of *Biosafety in Microbiological and Biomedical Laboratories* (BMBL)
 - provide additional biosafety guidance, such as an MMWR RR, tailored specifically for clinical laboratories
 - provide information about biosafety training (e.g., lists of resources, web-based training) online and via other venues
 - provide a variety of communication tools such as posters, guideline summaries, and training materials on the CDC website that could be readily utilized by laboratories

Panel's Recommendations

Surveillance

- To reduce the incidence of laboratory-acquired infections (LAIs), it is important to determine their circumstances and root causes
- Consequently, the ability to determine and monitor the frequency of such occurrences is desirable
 - a non-punitive surveillance system would be most effective
 - the CDC-developed voluntary surveillance system for surveillance of nosocomial infections National Healthcare Safety Network (NHSN) might be leveraged to document LAIs

Panel's Recommendations Surveillance

- Challenges with using NHSN
 - NHSN is in only a fraction of US hospitals
 - Reporting LAIs would need to be required or incentivized in order to capture accurate information, and at this time there are no such requirements
 - Any system must also collect data about laboratory practices that lead to the infections in order to be of use in preventing future infections. This would require personnel from infection control or safety offices to work with the laboratory supervisor to conduct an investigation and make such determinations.

Panel's Recommendations

Training and Education

- Training & education are important for safely working in clinical labs
- OSHA requirement for training in bloodborne pathogens is insufficient to prevent LAIs
 - variably effective because many laboratorians may be offered only limited time for training
 - scope of OSHA training may not address aerosol transmissible diseases and appropriate aerosol exposure control measures
- Clinical laboratories are receptive to additional training, however,
 - funding for training is problematic
 - travelling to training is challenging because of both the time lost from work as well as the cost of travel
- Need low-cost or free training that is focused and effective
- Leverage training materials developed by others

Panel's Recommendations Research

- Additional research in the area of biosafety is needed to inform:
 - safer working practices
 - use of personal protective equipment
 - engineering controls
 - facility design
- Further research assessing the role of biosafety interventions in the reduction in rates of LAIs is also needed

Panel's Recommendations

Organizational Collaborations

- Many professional, accrediting, training, and standard-setting organizations are already making efforts to address the safety of lab workers, but more work is needed.
- Professional organizations (such as ASCP) that certify personnel should consider including safety training in their requirements
- Organizations that certify or accredit laboratories (e.g. Centers for Medicare & Medicaid Services, College of American Pathologists) could include safety, training, and incident reporting components on their inspection checklists
- Professional safety organizations such as the American Biological Safety Association could develop or provide additional biosafety training information specifically for clinical laboratory personnel

Panel's Recommendations Collaborations

- CDC could help by
 - providing additional guidance and expanding its role as a resource for credible lab safety information.
 - exploring the possibilities for surveillance and offering suggestions for development of a system.
 - CDC should consider expanding its efforts and leadership in the role of coordinating clinical laboratory biosafety efforts to create a systematic approach to reducing LAIs
- State health departments could require reporting of LAIs and support activities to reduce them

Proposed Topics for New Guideline

Clinical microbiology laboratory – biosafety concerns

- Laboratory design – open vs. closed; automatic faucets; sink locations; air flow; BSL-1 vs. BSL-2
- Worker protection
 - Training – content, frequency
 - Vaccines
 - PPE – set-up; plate reading; stains; blood cultures;
- Specimen receiving and log-in
- Set-up station
 - Biosafety cabinet
 - Specimen disposal

Proposed Topics for New Guideline

Clinical micro laboratory – biosafety concerns (cont)

- Stains and disposal
 - Gram stain
 - Trichrome stain
 - Acid-fast stains
 - Mycology stains

- Plate reading at the bench – gloves vs. no gloves
 - Plate sniffing
 - Disposal
 - Disinfection – countertops, phones, computers, etc

Proposed Topics for New Guideline

Clinical micro laboratory – biosafety concerns (cont)

- Blood culture station
- Identification instruments
- Rapid testing (kits)
- PCR testing
- Parasitology laboratory
- Mycology laboratory
- Virology laboratory
- Packaging and transport
- Disposal
 - On-site
 - Off-site

Proposed Topics for New Guideline

- Non–Microbiology Labs (Clinical Chemistry, Hematology, Blood Bank, Histology/Pathology labs)
- Reporting Laboratory Accidents
 - Role of the technologist
 - Role of the supervisor
 - Role of Infection Control

Next Steps

- Guidelines
 - Collaborators
 - Process
 - Timeline
- Clearinghouse for Training Materials
 - Available on CDC internet
- Expansion of Scope?