Biosafety Practices in Sentinel Clinical Laboratories: What’s New in the Era of Terrorism?

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Objectives

- Describe biosafety issues confronting Sentinel Laboratories in an era of “bioterrorism”

- Suggest areas for additional training by public health entities to facilitate biosafety in clinical laboratories

- List resources for sentinel laboratories in the area of biosafety
Issues 1: Current areas confronting sentinel laboratories

- Naturally emerging/resurging infectious diseases
- Incidental/accidental infections (following disasters or uncommon occurrences)
- Intentional threats or cases of infectious diseases

- These frequently overlap and frequently involve uncommon agents
- All pose infection risks to laboratorians
To paraphrase Forrest Gump..

- Microbiology is like a box of chocolates…

- You never know what you are going to get! (and you don’t always recognize what you have)
Recent references on LAIs

- Baron and Miller. DMID 60:241 (2008)
- Vesley and Hartmann. AJPH 78(9): 1213 (1988)
- Belgian Biosafety Server: www.biosafety.be/CU/LAI/Intro_LAI.html
Baron and Miller (2008)

- Shigella
- Brucella*
- Salmonella
- S. aureus (MRSA)
- N. meningitidis*
- E. coli O157*
- Coccidioides
- C. difficile
- B. anthracis

- 21/88 (~25% reported an exposure

- 29/88 (~33%) reported an LAI

Risk greater than for general public
What are the risks for exposure and infection?

- Percutaneous
- Ingestion
- Skin and mucous membrane contact
- (Animal contact)
- Aerosol
Infection risk characteristics

- Routes are not mutually exclusive
- Less than 20% due to 1-4, 50% source unapparent, 18-30% "careless error"
- Currently clinical 45% of LAIs, research 51% in contrast to 1979 with 59% research, 17% clinical
- Infection rates higher in clinical than public health labs (also true for injury rates)
- Numbers higher in larger labs but rates higher in smaller labs
- Information on exposures not readily available
Issue 2: Where do we stand with awareness and training?

- All SPHLs have a working relationship with SCLs
- 67% have a bioterrorism advisory committee
- 98% have rapid communication means
- 98% have a database of SCLs
- 90% have ready access to contact information
- 83% have conducted drills
Training, continued

- 98% have a state training coordinator, but only 37% are fulltime
- 100% have a BT laboratory coordinator, but only 65% are fulltime
- 88% offer courses (588 to 8500 laboratorians, increased in 2008 including 130 biosafety classes to 2300 laboratorians)
- 75% have a performance measurement system
- ONLY 10% have awarded “Sentinel lab certificates” (increased to 39%, 860 labs in 2008)

What % of this training activity is dedicated to biosafety and how important is it?
Issue 3: What is an advanced sentinel laboratory?

- CLIA certified
- Inspected successfully
- P&P for “rule out and refer”
- Class II BSC
- BSL 2 practices
- “2.5” as necessary
- LRN Sentinel Laboratory P&P
- Trained personnel in SL P&P
- Trained in packing and shipping
- Adequate waste decontamination
- Comply with AIA guidelines for negative pressure
- Terminal on-site decontamination

http://www.asm.org/Policy/index.asp?bid=6342
Virtually every area relates to biosafety practices
Evaluating processes: The laboratory test triangle model
The laboratory biosafety triangle

Pre-exposure

BIOSAFETY

Exposure

Post-exposure
Training opportunity 1: Pre-exposure activities

- Risk assessment
- Education
- Communication
- Vaccination
- Baseline analysis
- Periodic assessments
- Shipping and handling
Risk assessment process:

Depends on:
- Organism load
- Pathogenicity
- Host state
- Therapy or vaccine
- Individual setting

Includes:
- Identify microbial hazards and risks
- Identify lab risks
- Determine BSL and BSL+
- Evaluate staff competency
- Review with a professional

Multiple exposures to “unknown” invasive N. meningitidis resulted in process changes:
1. + bloods and sterile fluids in BSC and 2. CID's in BSC
Microbiologist vaccinations and evaluations

- HBV
- HAV
- MMR
- TDap
- Pneumococcus
- Meningococcal*
- Influenza
- TB skin test or LFT

MMWR Quick Guide to adults, October 19, 2007; 56(41)
*Meningococcal unique to microbiologists; does not currently include B
Training opportunity 2: Exposure mitigation

- Hand hygiene
- Universal precautions
- PPE for BSL-2
- Aerosol protection in “BSL 2.5”
- Surface hygiene
- Waste management
- Procedural controls
Hand hygiene: Could it be better?

- Guideline and Hygiene in Health-care Settings: MMWR10/25/2002; Vol. 51(RR-16)
- Study of laboratory compliance:
  - Compliance at end of duty was 100%
  - 36.7% wore a ring, 46.9% a watch, 6.1% a bracelet → Pathogens exclusively on hands of those with jewelry
- What about other “handheld objects?”
- Implications for surface decontamination

Hand hygiene among laboratory workers
Infection Control and Hospital Epidemiology September 2006, 27(9): 978
What is appropriate PPE for a “2.5 BSL”?

- Role of gloves controversial although at least one study has shown reduced Brucella exposure with gloves
- What is the best respiratory protection strategy including appropriate use of N-95 or higher masks?
- How does one safely and effectively use BSCs?
Waste management?

- Is there a need for on-site terminal decontamination?


  “Biosafety Level 1 and 2 laboratories should develop strategies to inactivate amplified microbial cultures and stocks on-site…”

- Implications for select agents
Procedural controls:
Lessons from the “RB51 incident”

High risk:
- Manipulated outside of BSC or w/in 5 feet
- Spot tests
- Streaking
- Sniffing
- Aerosol generating activities*

➤ PEP plus medical monitoring

Low risk
- In lab but not in high risk category
  ➤ Medical monitoring only

No risk
- All procedures within BSC

* Aerosol generating: Splashes, Pipeting, Centrifugation, Grinding, Blending, Shaking, Mixing, Sonicating, Opening containers of liquids, Flaming loops

NOTE: The assessment and PEP guidelines were NOT uniformly accepted
Training opportunity 3: Post-exposure activities

- First aid plan
- Reporting (institutional and national/international)
- Post exposure prophylaxis*
- Post-testing
- Medical surveillance
- After action planning

*PEP recommendations may change with emerging resistance:
Note FQ resistance Group B N. meningitidis, MMWR 2/22/2008; 57(7):173

Note: Infectious agent MSDSs at http://www.phac-aspc.gc.ca/msds-ftss/
Training opportunity 4: Overarching activities

- Licensure/Regulation/Accreditation requirements
- Guidelines and recommendations available
- Training in all aspects of biosafety
- Information dissemination to Sentinel Laboratories (eg LOCS)
- Biosafety plan development
Resources for biosafety planning

- CDC (www.cdc.gov BMBL-5 and other Biosafety resources)
- CLSI (M29-A3; Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body fluids, and Tissue.
- APHL (www.bttrain.org)
- ASM (www.asm.org, Bioterrorism resource documents)

No single resource is comprehensive for sentinel laboratories
What is still needed?
A model template for a biosafety plan

- Biosafety Program Scope
- Program Policy
- Roles, responsibilities, and authorities
- Significant biohazards
- Legal and other related requirements
- Objectives and targets
- Training plans

- Communication Plan
- Documents and records
- Operational Control
- Emergency response
- Monitoring and measuring
- Audit procedure
- Program and management review

Biological Safety and Principles
New educational activities

- CDC Symposium on Biosafety (February 2008)
- “Blue ribbon panel” on Biosafety and Biosecurity
- State Health Laboratory continuing role in training sentinel laboratories

NOTE: Dr. Larry Gray is the ASM representative for biosafety planning
Ultimate goal

- We want to be sentinels for emerging infectious disease…

- …not canaries in a coal mine without protection
Final thought

- Biosafety is not biosecurity

- We have an obligation to protect ourselves, our co-workers, and the public