US EPA ARCHIVE DOCUMENT

US EPA ARCHIVE DOCUMENT

Potential Exposures to Attenuated Vaccine Strain *Brucella abortus* RB51 During a Laboratory Proficiency Survey — United States and Canada, 2007

LCDR Rebecca Noe MN, MPH, FNP
CDC Division of Bioterrorism, Preparedness, and Response

Joint EPA and DHA Conference on Real-World Applications and Solutions for Microbial Risk Assessment
April 8, 2008

Laboratory Preparedness Survey (LPS)

- Bi-annual voluntary laboratory proficiency test
- Established in 2002 and revised in 2006
  - CAP, APHL, and CDC
- Simulate select agents encountered during BT event
- Tests capabilities to:
  - Safely handle samples
  - Rule in/rule-out BT agents
  - Execute referral protocols

CDC

LPS October-November 2007

- 1316 participating labs – US and Canada
- LPS kit included:
  - 5 samples – 1 vaccine strain *Brucella* abortus RB51
  - Written instructions describing handling procedures

AND

BSL-3 primary barriers
+
safety equipment

CDC

Brucella abortus

- RB-51 vaccine for cattle against brucellosis
  - Accidental human exposure to RB51
  - Uncommon but exposures ⟶ disease*
- Human brucellosis
  - Flu-like illness
    - Fever, sweats, headaches, and/or back pains
  - Severe infections meningitis and endocarditis
  - Chronic symptoms
    - Recurrent fevers, joint pain and fatigue

* Ashford et al Vaccine 22(2004) 3435-3439

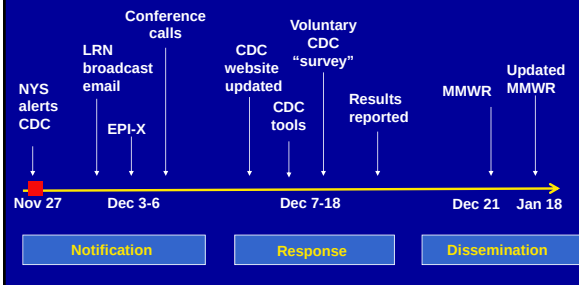
CDC

Initial Incident - New York State

- Nov 2007 a single LPS-RB51 sample mislabeled as a routine clinical specimen
  - Submitted to NYS bacteriology laboratory
  - Manipulated on an open bench
  - Resulted in 24 laboratorians potentially exposed
- Further NYSDOH investigation of LPS-participating laboratories
  - 17 of 25 labs reported potential RB51 exposures

CDC

RB51 Response Timeline



CDC

US EPA ARCHIVE DOCUMENT

CDC Tool 1
Questionnaire to Assess BioSafety Practices

- 5-pages - check off boxes
- Specific handling questions
  - Under the Class II BSC under BLS-3
    - Exemptions were:
      - Carrying a closed culture plate to an incubator
      - Observing a fixed/stained slide under a microscope
      - Observing a closed culture plate
  - Outside the Class II BSC under BLS-3
    - Manipulations (e.g. Open flame, performing catalase test or prep for automated identification methods)
    - Major aerosol generating events (e.g. vortexing, centrifuging without sealed carriers)

NOTE: If there are any questions regarding interpretation of the risk assessments and recommendations provided in this table, please do not hesitate to contact CDC at (404) 639-1711.

Table: Risk assessment and post-exposure prophylaxis (PEP) for potential exposure to RB51

Risk level	Risk area	Definition defining risk	PEP** considerations
High	Individual	Individual working with RB51 specimen 1. Sniffed culture plate, 2. Mouth pipetted specimen material, OR 3. Worked in class II biosafety cabinet, but WITHOUT using BSL-3 precautions	Recommended for the individual(s) working with RB51 specimen
	5 foot radius of work with RB51	Work (beyond that defined in "Individual" risk above) with RB51 outside of class II biosafety cabinet on an open bench BUT work DID NOT involve widespread aerosol generating procedures*	Recommended for those within 5 feet of the work with RB51 on open bench while the implicated work occurred.
	Laboratory room	Work with RB51 outside of class II biosafety cabinet on an open bench INVOLVING widespread aerosol generating procedures*	Recommended for those present in laboratory room while widespread aerosol generating procedures involving RB51 specimen were conducted
Low	Laboratory room	Present in the lab at the time of manipulation of RB51 on an open bench, but who do not have high-risk exposures as defined above	May be offered to those present in laboratory room while work involving RB51 specimen was conducted
None	Laboratory room	Handling and testing of RB51 in a class II biosafety cabinet using BSL-3 precautions	None

* Widespread aerosol generating procedure include, but are not limited to, centrifuging without sealed carriers, vortexing, sonicating, and accidents resulting in spillage or splashes (i.e. breakage of tubs containing specimen). Other manipulations such as automated pipetting of a suspension containing the organism, grinding the specimen, blending the specimen, shaking the specimen or procedures for suspension in liquid to produce standard concentration for identification may require further investigation (i.e. inclusion of steps that could be considered major aerosol generating activities).

** Post-exposure prophylaxis should include doxycycline 100 mg orally twice daily for at least 21 days. For those with contraindication to doxycycline, trimethoprim-sulfamethoxazole 160

CDC Tool 2
Risk Assessment Table

Stratify by 3 levels of exposure (High, Low, None)

- Risk Area
- Definition of Risk
- PEP

Risk Assessment Tool 2: High Risk

Risk area	Definition defining risk	PEP considerations
Individual	Individual working with RB51 specimen 1. Sniffed culture plate, 2. Mouth pipetted specimen material, OR 3. Worked in class II biosafety cabinet, but WITHOUT using BSL-3 precautions	Recommended for the individual(s) working with RB51 specimen
5 foot radius of work with RB51	Work (beyond that defined in "Individual" risk above) with RB51 outside of class II biosafety cabinet on an open bench BUT work DID NOT involve widespread aerosol generating procedures	Recommended for those < 5 feet of the work with RB51 on open bench while the implicated work occurred
Lab room	Work with RB51 outside of class II biosafety cabinet on an open bench INVOLVING widespread aerosol generating procedures*	Recommended for those present in laboratory room while widespread aerosol generating procedures involving RB51 specimen were conducted

Voluntary CDC Survey

- 5 questions
- Summary information
- Facilitated reporting to the state
- CDC contacted states for information
- No summary information from Canada

CDC Survey Questions

1. All LPS-participating labs contacted in your state?
2. # of labs with potential exposures?
3. # individuals identified as high risk and low risk?
4. # identified were recommended prophylaxis?
   - High risk of exposure? _____
   - Low risk of exposure? _____
5. Any persons with symptoms that may be consistent with brucellosis? If so, how many?

Results of CDC Survey

- Surveys conducted at state-level
- Voluntary reporting to CDC
  - 44 states and D.C. provided information
  - 281 laboratories had 1 or more exposures
  - 991 persons identified with potential exposure (715 with high-risk)
  - Incomplete PEP information reported
  - No cases of brucellosis report to CDC to date

US EPA ARCHIVE DOCUMENT

Limitations

- CDC provided risk assessment tools but the level of assessment done in each laboratory is unknown
- Not all States/laboratories reported their results
- Of those states that reported-some incomplete reporting

CDC

Discussion

- Risk assessment tools
  - Assess exposure risk and provided guidance for PEP
- Decision to recommend PEP
  - RB51 exposure has resulted in disease
  - RB51 no measurable antibody response
  - Consequence of "watching and waiting"

Conclusion and Recommendations

- Persons with high-risk exposures recommended PEP
- Persons with low-risk exposures offered PEP or symptom monitoring
- Establish and review diagnostic protocols (e.g. ASM) and adhere to during handling and testing specimens including PT samples
- Train laboratorians on characteristics of particular agents

CDC

Acknowledgments

- CDC
  - Division of Bioterrorism, Preparedness, and Response
  - Bacterial Zoonotic Branch
- New York State Department of Health
  - Dale Morse
- College of American Pathologists (CAP)
- The Association of Public Health Laboratories (APHL)
- All Participating State and Local Health Departments

For Further Information

MMWR
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5702a2.htm

Questions?

CDC