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Impact of the California Airborne Transmissible Disease Standard: Potential National Implications

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A nighttime photograph of the Miami skyline, featuring several illuminated skyscrapers and their reflections on the water in the foreground. The scene is dark, with the city lights providing the primary illumination.

ABSA MIAMI

Do You Remember What We Did In
Miami
2009

52nd Annual
Biosafety Conference

We Were Introduced To The
California Airborne Transmissible
Disease Standard
Title 8, California Code of
Regulations , Section 5199

What Has Happened in the Last Four Years

- SF Giants Won Two World Series
- Stanford Won A Rose Bowl
- But More Importantly



**California's
Aerosol Transmissible Disease Standard
Was Implemented**

A Short Re-Cap

- The California Aerosol Transmissible Disease Standard is designed to minimize occupational exposure to inhalation hazards associated with airborne pathogens.

Key Provision

- It allows the Institutional Biosafety Committee and Biosafety Officer to make an assessment of risk and determine the appropriate level of containment for research related operations as well as require other administrative controls.

What the Standard Entails

Considerations in Content

- Key Points-objectives
 - Protect Public Health, Primarily With Regard To Health Care Workers, To Airborne Biological Hazards
 - Document Appropriate Control Measure By Use Of A Biosafety Plan
 - Protect Environment
- Safety Considerations
 - Mandatory Recordkeeping, Training, Reporting
 - Security/Safety Requirements
 - Use Of Appropriate Biological Containment
 - BSO Input On Design / Plan Review

Implementation

Key Steps

- Identify Tasks And At Risk Personnel – Similar To BBP Exposure Determination
- Treat Incoming Specimens As Containing Virulent Pathogens Until Proven Otherwise – Similar To Universal Precautions
- Develop Use Of Engineering Controls, Work Practices, Personal Protective Equipment – Similar BBP Standard

Intent and Objective

The ATD Standard Was Designed To Protect Health Care Workers And **Evolved To Cover Laboratory Workers In Research Laboratories.**

This Presentation Will Focus On Actual And Potential Impacts The Standard Has Had And Implications For The Future Through Two Case Studies.

Case Study #1: Alta Bates Hospital

- On Dec. 3, 2009, Alta Bates Summit Medical Center in Oakland received a patient with bacterial meningitis. The patient was transported by American Medical Response with the assistance of a fire department paramedic. The ambulance service responded to the home of the patient where the Oakland Police and Fire Departments had previously arrived. Employees of all three responders at scene were exposed to bacterial meningitis.

Case Study #1: Alta Bates Hospital

Alta Bates Summit Medical Center was issued citations for not

- implementing an ATD program,
- providing post exposure information to employees,
- properly fit testing employees for respirators and
- not providing medical treatment to the exposed employee.

They also received two willful citations:

- one for not reporting the meningitis case to the local health authorities and other employees in a timely manner,
- and one for failure to conduct an exposure analysis of employees exposed to bacterial meningitis for a week after the exposure.

Case Study #1: Alta Bates Hospital

- In 2010, Cal/OSHA issued \$101,485 in citations to Alta Bates Summit Medical Center in Oakland.
- Ten violations of the state safety and health standards in connection to a life-threatening exposure of bacterial meningitis.

Case Study #1: Alta Bates Hospital

- The Oakland Fire Department, whose paramedic assisted in transporting the exposed patient, was cited \$2,710 for five violations that included failure to develop and implement an ATD standard, not properly notifying the Oakland Fire Department and American Medical Response of the exposure and providing exposed employees with a copy of their medical evaluations.

None of the responding fire fighters, who all used personal respirators, developed the disease.

Case Study #1: Alta Bates Hospital

- All employers involved in the transportation and treatment of a patient exposed to bacterial meningitis are required to provide respiratory protection,
- report the case to the local health authority and to employees or other employers exposed and
- initiate appropriate medical treatment.

Investigations revealed a failure to comply with the above requirements.

Case Study #2: SF VA Hospital

- A 25 year old researcher contracted meningococcal disease from exposure to the bacteria in the lab where he worked.
- Symptoms began in the evening after working with *Neisseria meningitidis*, worsened the following morning and resulted in death 17 hours after symptoms first appeared

Case Study #2: SF VA Hospital

- Not clear *exactly** what went wrong
 - No evidence of spills, malfunctions in BSC
 - Co-workers indicated researcher worked “by-the-book”: was fastidious, hardworking, and followed appropriate precautions
 - No accidents reported by researcher or co-workers
- Lab remained closed for several months following researcher’s death

**MMWR publication pending*

Case Study #2: SF VA Hospital

- Unique Business Relationship
 - Researcher was an employee of the Northern California Institute for Research and Education (NCIRE) – a California NGO that had an affiliation agreement with the San Francisco Veterans Affairs Medical Center
 - Accident occurred on “Federal Turf” but to a non-Federal employee
 - UCSF employees (faculty) run the lab in which researcher worked [UCSF IBC not involved in protocol review]

Case Study #2: SF VA Hospital

- Unique Regulatory Relationship
 - California has its own OSHA agency (Agreement State)
 - Cal/OSHA and Fed/OSHA had an inter-agency working agreement, but it was – at the time of the accident – valid only in Alameda County – SF VA is in San Francisco County
 - Agreement since corrected to include all California counties
 - Fed/OSHA took the lead in investigating accident
 - Conclusions included significant input from Cal/OSHA

Case Study #2: SF VA Hospital

Findings

- Fed/OSHA issued a notice of unsafe and unhealthful working in the SF VA
- Three serious violations for failing to protect laboratory workers researching *Neisseria meningitidis*

Case Study #2: SF VA Hospital

- Workers were found inoculating live bacteria [and conducting other procedures] outside of a BSC
- Tests found strain of *N. meningitidis* being worked on was in researcher's blood, confirming a lab exposure
- “[Researcher] died because the VA failed to supervise and protect these workers adequately...”

Case Study #2: SF VA Hospital

- Three serious violations included failure to:
 1. Require workers to use a safety enclosure when performing microbiological work with a viable bacteriological culture
 2. Provide training on signs and symptoms of illness
 3. Provide available vaccines to workers potentially exposed to bacteria

A serious violation occurs when there is a substantial probability that death or serious physical harm could result from a hazard about which the employer knew or should have known.

Case Study #2: SF VA Hospital

Cal/OSHA's Published Concurrent Opinion

Cal/OSHA shares Fed/OSHA's concerns... we are saddened by this senseless loss; however, we remain hopeful that future incidents can be prevented... *This is why Cal/OSHA adopted a standard to protect workers from diseases ... that can be contracted through contaminated air in laboratories.*

Case Study #2: SF VA Hospital

- Litigation (by family of deceased) pending
- Defendants include U.S. Department of Veterans Affairs, UC San Francisco, and supervisors on researcher's shift.
- UCSF included because of faculty role as supervisors



Summary, Conclusions, Questions

- Practical
 - Some techniques may not be readily identified – *or accepted* – as generating aerosols because risk assessment not made by qualified personnel (K. Byers identified over a dozen potential techniques among *Neisseria* workers*)
 - Lack of such awareness can be deadly
 - Significant financial penalties can occur
 - Research can be suspended for significant periods of time

*K.B. Byers, *Neisseria meningitidis* exposures in clinical laboratories, Applied Biosafety **12 (1)**, 47-49, 2007

Summary, Conclusions, Questions

- Regulatory: We Typically Eschew Proscriptive Actions
 - But
 - Some regulations can be beneficial: Cal/OSHA ATD Standard includes Biosafety Officer input and references NIH Guidelines
 - Interagency jurisdictions must be clearly understood; working together is more beneficial than working in separate realms

More Conclusions

- ATD Standard could be of great national benefit – on par with BBP
- Avoidable deaths demonstrated
- Added benefits of IBC / BSC input
- Emerging diseases (novel and otherwise) plus documented airborne transmission
- Case study at VA, at the very least puts the possibility of a national standard on the radar

Thank You !

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- ATD Standard: <http://www.dir.ca.gov/title8/5199.html>



**BUT WAIT,
there's more!**



Sutter – Alta Bates Hospital

A man in a dark suit and light-colored shirt is sitting on the ground on a paved road. He has his head buried in his hands, suggesting distress or despair. He is holding a pink folder or document in his left hand. The background shows a clear blue sky and some utility poles in the distance.

**Apparently Didn't Learn
Their Lesson**

Sutter – Alta Bates Hospital

Cal/OSHA Findings in 2013

www.dir.ca.gov/dosh/citation.html

- Total Violations – Failure to implement ATD Standard
 - 2 Willful / Serious
 - 1 Regulatory
 - 2 General
- Proposed Penalties
 - \$142,970

- Slide agglutination testing and observing colony morphology (CDC, 2002);
- Aspirating samples from blood culture bottles, performing Gram stains, handling plates, and sub-culturing cerebrospinal fluid (CDC, 2002);
- Culturing blood and sub-culturing isolates (CDC,1991);
- Performing agar diffusion anti-biogram with sero group C strain isolated from cerebrospinal fluid (Guibordenche, 1994);
- Determining antibiotic susceptibility using a Steerstype replicating device with 10 isolates (Guibordenche,1994);
- Preparing a suspension, vortexing, seeding agar plates, and pipetting the suspension into the wells of a plate to perform a commercial identification procedure on the workbench (Paradis, 1994);
- Making a heavy suspension of *N. meningitidis* to inoculate an identification test strip using a pipette, by collecting a colony with a swab, and suspending it in saline (CDR, 1992); and
- Preparing negative stains for electron microscopy by adding 0.1 ml bacterial suspension to 0.9 ml 3.5% formalin solution (Bhatti, 1982).

A microscopic view of numerous green, rod-shaped bacteria, likely Bacillus subtilis, arranged in chains and clusters against a dark blue background. The bacteria are elongated and have rounded ends, with some showing flagella. The text is overlaid in the center of the image.

**And We're Here To Talk About
What's Happened
Since Its Implementation**

Revisions To This Standard

- The Standard Now Includes The Following:
 - Agents Listed In Appendix D Of The Standard;
 - Agents For Which BMBL Recommend BL3 Containment;
 - Experiments That The Biosafety Officer And The IBC Recommend Inclusion Under The Standard;
 - Novel, Emerging Or Unknown Pathogens That Demonstrate A Potential For Airborne Transmission.

What the Standard Entails

8 CCR Section 5199

- Similar to the Bloodborne Pathogen Standard
- The Context of The Standard
 - Scope, Applicability
 - Permit Requirements
 - Definitions
 - Exposure Criteria
 - Mitigation to Exposure
 - Written Procedures Biosafety Plan
 - PPE, Engineering Controls, Work Practices
 - Toxic gases, disinfection,
 - Respiratory protection
 - Disposal of Waste
 - Medical Considerations
 - Training, Recordkeeping

Two Case Studies

- Alta Bates: April 2010, One Year After The ATD Standard Was Implemented
- San Francisco Veterans Administration Hospital: April 2012, At A “Dual Employer” Facility

Case Study #1: Alta Bates Hospital

- The Oakland Police Department, which had an officer hospitalized in the Intensive Care Unit of another hospital for five days with bacterial meningitis, was cited \$31,520 for nine violations that included failure to develop and implement the required ATD standard, failure to properly notify the Oakland Fire Department and American Medical Response of the exposure, not obtaining a medical evaluation of the exposed employee, failure to report the officer's hospitalization to Cal/OSHA, and for not notifying the exposed employee of his exposure to meningitis.

Case Study #2: SF VA Hospital

- Vaccines available since the '60's for several strains of *N. meningitidis*, but not against serotype B strains which was the type the researcher was working with the week before his death
- Tests confirmed the presence of serotype B *N. meningitidis* in researcher's blood, confirming a lab exposure

Summary, Conclusions, Questions

- Philosophical
 - We are addressing a “Once-in-a-lifetime-experience”
 - Best to prepare for the most reasonable worst case scenario

Still More Conclusions

- Needs support of Biosafety Professional community
- Avoid obvious mortality and morbidity consequences, and substantial financial penalties and embarrassment
- Keep eye out for potential legislation for the following reasons:
 - Make sure it's written correctly
 - Does not go overboard (as CA initially did)

Case Study #1: Alta Bates Hospital

- The exposure resulted in the emergency hospitalizations of an Alta Bates employee and an Oakland police officer.
- Cal/OSHA was notified on Dec. 15 by Alta Bates that a respiratory therapist, who directly treated the patient, was hospitalized at another hospital and in the Intensive Care Unit being treated for bacterial meningitis. The respiratory therapist was hospitalized for 11 days.

Implementation

Key Steps

- Prepare Emergency Medical Procedures – Consistent With IBC Risk Assessment
- Training, Inspections And Hazard Communication – Similar To The California Injury Illness & Prevention Program (IIPP)
- Recordkeeping
- Plan Review: BSO Required To Review Design /Construction

In Summary, Most Labs Are Already Doing The Required Procedures; This Standard Makes The Connection Specifically For Airborne Transmissible Pathogens...