Biosafety in CDC Laboratories: The Path Forward

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2014 Lapses in Biosafety at CDC

• Following laboratory safety incidents at CDC involving select agents, CDC conducted comprehensive internal reviews of each incident.
• During each review, an assessment of the event, contributing factors, and risk mitigation practices was completed.
• Each review resulted in a report of findings and recommendations.
Full Reports of Each Incident Available on CDC Website

- Posted at [http://www.cdc.gov/about/lab-safety/](http://www.cdc.gov/about/lab-safety/)
  - June, 2014: Lab Incident Anthrax Report [744KB, posted 7/11/14]
  - July, 2014: Report on Cross-Contamination and Shipment of a Laboratory Specimen with Influenza Virus H5N1 [608KB, posted 8/15/14]
Lab Safety Improvements Overview

- Laboratory Safety Improvement Workgroup (LSIW)
  - Charge, Accomplishments and Products
- Current Laboratory Safety Initiatives
  - External Laboratory Safety Workgroup
    - Recommendations to the Advisory Committee to the Director (ACD)
    - CDC’s progress towards the ACD’s recommendations
  - Sharing of Best Practices
LSIW Charge

• Charge Announced to CDC Staff 7/31/2014:
  o Review requests to resume transfers of biological materials (BSL-3/4 laboratories)
  o Oversee an Agency-wide inventory of biological materials
  o Engage CDC laboratory staff, stakeholders and an external group of subject matter experts to inform recommendations for laboratory safety improvements
  o Review career paths to determine how best to strengthen our culture of safety at CDC
  o **Provide recommendations to CDC Director**
LSIW Accomplishments

• Moratorium Resolution:
  o 52/53 laboratory teams have resumed operations
• External Laboratory Safety Working Group (ELSW)
• Biological Materials Inventory
• Review Data and Reports for Laboratory Incidents
• Communications:
  o Staff Engagement Sessions
  o Laboratory Consultations (Piloted in 2 Laboratories)
  o Meetings with CDC Lab-related Boards and Committees
  o Laboratory Staff Survey
• Policy:
  o Revised Procedure for Notification of Management for Laboratory Exposures
LSIW Accomplishments

Enhanced Inventory Management:

• U.S. Government Safety Stand-Down:
  o Fact Sheet on Biosafety and Biosecurity in the United States: Results of the Safety Stand-Down
    http://www.cdc.gov/about/lab-safety/factsheet.html
  o Clean Sweep Completed on 9/30/2014
  o Initiated Biological Materials Inventory
    ▪ >7.2 M samples in long-term storage inventoried

• Recommended enhanced Out-Processing procedures
LSIW Products

Communications:

• CDC Laboratory Safety Intranet Website:
  o Lab Safety-Related Reports and Findings
  o Staff Announcements
• CDC Laboratory ListServ (>1500 members)
• Lab Safety Mailbox (Monitored Daily)
• Staff Engagement Sessions
• Laboratory Safety Survey
• CDC Connects (lab safety articles)
Lab Safety Mailbox

Lab Mailbox Update by Disposition*
January 26, 2015 at 9:00 AM  
*as of July 16, 2014

- Answered: 141
- Initiated: 5
- Withdrawn: 4

Lab Mailbox Update by Campus*
January 26, 2015 at 9:00 AM  
*as of July 16, 2014

- Alaska: 2
- Cambria: 1
- Chamblee: 4
- Corporate: 5
- Ft. Collins: 1
- Morgantown: 16
- Pittsburgh: 4
- Roybal: 1

Lab Mailbox Update by Category*
January 26, 2015 at 9:00 AM  
*as of July 16, 2014

- Training: 10
- SOPs: 10
- Shipping: 1
- Safety: 4
- Occupational Health: 4
- Moratorium Release Pkg Info: 1
- Lab Security: 5
- Inventory: 2
- Incident Response: 3
- Human Resources: 5
- Equipment and Facilities: 1
- Documentation and Systems: 5
- Culture: 3
- Communications: 7
- Clean Sweep Inventory: 13
Recommendations to CDC Director

Report Completed (10/29/14):

• Associate Director for Laboratory Science and Safety (ADLSS)

• Recommendations for 7 Functional Areas:
  1. Leadership, Staffing, and Organizational Structure
  2. Training and Education
  3. Policy, Authority, and Enforcement
  4. Process and Standard Operating Procedures
  5. Facilities, Systems, and Software
  6. Communications
  7. Staff Feedback
External Laboratory Safety Workgroup

- Recommendations presented to the ACD on 1/13/15
  - Aligned with LSIW recommendations

- CDC updated the ACD on its progress towards the recommendations on 4/23/15

- CDC will continue to engage ELSW and provide updates on progress towards implementing recommendations
Leadership

• **Recommendation:**
  – Create a position for a biomedical scientist in the Director’s office to lead this (*laboratory safety programs*) effort.

• **Progress:**
  – Established an Associate Director for Laboratory Science and Safety (ADLSS), who will report to the CDC Director and provide agency-wide leadership and accountability for laboratory science, safety, and quality
  – The CDC Director is currently interviewing candidates
Leadership

• **Recommendation:**
  – Funding for laboratory safety programs and laboratory safety training should be established from a central funding source and should be considered a fundamental mission for the CDC.

• **Progress:**
  – Identified funding in FY 2015 for development of a new general safety and laboratory safety training curriculum
  – The FY 2016 budget requests an increase of $20 million to help advance CDC’s laboratory safety and capacity
Governance

• **Recommendation:**
  – Establish governance structures that provide accountability and oversight authority to a central entity for laboratory safety and compliance committees with ultimate authority in the Office of the Director.

• **Progress:**
  – In March 2015, CDC established a Laboratory Safety Review Board to conduct safety reviews of laboratory protocols for work in BSL-3 and BSL-4 laboratories
    ✓ Oversight and support will be in the Office of the ADLSS
    ✓ Members are from all centers with laboratory programs to ensure accountability and consistency of practices across the agency
Risk Assessments

• **Recommendation:**
  - Risk assessments should be performed for experimental work being done at CDC. The benefits and risks of proposed experimental work should be documented before the work is undertaken.

• **Progress:**
  - Piloted a new Risk Assessment Course on 2/24/15 to teach staff how to conduct and document risk assessments:
    ✓ Course evaluation completed on 3/9/15; revised course (based on evaluation data) taught on 4/15/15
  - Post-training evaluations are scheduled to assess competency and implementation
  - Development of new policy to require the use of risk assessments for experimental work is underway
Laboratory Safety Training

**Recommendation:**
- Establish a standardized lab safety training curriculum across CDC with standardized methods for competency skills mapping and refresher training.

**Progress:**
- Establishing a standardized, competency-based, core safety training curriculum across CDC
  - Identified and documented competencies for core safety training (1/28/15)
  - Evaluated 23 CDC safety training courses to map competencies and identify gaps (3/6/15)
  - Developed a prioritized list of courses for a standardized safety training curriculum (3/20/15)
  - Developed learning objectives for priority courses (4/12/15)
Laboratory Safety Training

**Recommendation:**
- Establish a fellowship/internship program to train scientists to serve as laboratory safety professionals who serve as liaisons between the labs and ESHCO or other central lab safety entity.

**Progress:**
- Established the Laboratory Leadership Service (LLS), a new laboratory fellowship at CDC, to begin in July 2015
  - LLS will be a 2-year postdoctoral fellowship program combining core public health laboratory competency-based coursework with practical, applied research and service
  - 7 fellows matched with 7 host laboratories for the 2015 class
  - The fellows participated in the 64th EIS Conference
  - Development of competency-based curriculum is in progress
Culture of Safety/Incident Reporting

**Recommendation:**
- Reporting is important for facilitating the analysis of incidents and the establishment of corrective actions to mitigate repeat occurrences. Lessons learned should be shared with the community.

**Progress:**
- Established methods to share lessons learned and promote transparency with the community, including:
  - Posting of reports and updates for laboratory-related incidents on CDC websites (internal and external);
  - Proactive communications with the CDC laboratory community via the Laboratory ListServ;
  - Meetings and updates with external partners (e.g., APHL)
Culture of Safety/Incident Reporting

• **Recommendation:**
  – In this culture of safety response, ensure that scientists operating safe laboratories are recognized.

• **Progress:**
  – Implemented a new program, *Laboratory Safety Champion*, to recognize staff (through a CDC Connects story) who promote laboratory safety and best practices. The first *Champion* was featured on 3/12/15, and the second was featured on 4/20/15.
  – Utilizing the Laboratory ListServ of more than 1600 staff to acknowledge and commend staff who demonstrated responsible and safe actions in the laboratory.
Biosafety and Occupational Medicine

• **Recommendation:**
  – Develop a division liaison program, where each division identifies individuals who can represent their needs to a centralized ESHCO committee.

• **Progress:**
  – Identified a representative from each of the infectious disease centers to represent program needs related to safety consultations and risk assessments to ESHCO.
Progress Reporting and Laboratory Accreditation

• **Recommendation:**
  - CDC laboratories should go through an external review and accreditation process for all labs.

• **Progress:**
  - Pilot project to begin in 2015 to attain external accreditation to International Organization for Standardization (ISO) 17025 standards.
    - Conducted stakeholder engagement sessions to solicit input and recommendations (report completed 2/26/15)
    - Conducted benchmarking interviews with ISO-accredited government laboratories (report completed 3/31/15)
    - Implementation Plan is under review
    - ISO standards training for CDC pilot beginning May 2015
Sharing Best Practices

1) Laboratory Safety Review Board:
   – Review laboratory protocols for safety critical control points

2) Laboratory Consultations:
   – Peer review laboratory audit program
   – Piloted in 2 CDC laboratories

3) Laboratory Procedure Library:
   – Searchable library of approved protocols for inactivation and transfer of pathogens
   – Currently in development
Summary

• LSIW conducted a series of targeted activities to develop recommendations to the CDC Director, including:
  – ADLSS
  – Recommendations in 7 Functional Areas

• LSIW and ACD recommendations were aligned in several areas

• Current Activities:
  – Engagement of the ELSW
  – Expansion of Biosafety Training
  – External Accreditation Pilot
THANK YOU FOR THE OPPORTUNITY TO PROVIDE UPDATES!

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