

External Laboratory Safety Workgroup (ELSW) Live Meeting Summary

Monday, October 5 – Tuesday, October 6, 2015

Attendees

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| ✓ Joseph Kanabrocki, PhD, CBSP – Chair | ✓ Jill Taylor, PhD |
| ✓ Kenneth I. Berns, MD, PhD – Co-Chair | ✓ Heather J. Sheeley, BA, MS, CBiol MSB, CMIOSH, FISTR |
| ✓ Debra L. Hunt, DrPH, CBSP | ✓ Thomas V. Inglesby, MD |
| ✓ Patty Olinger, RBP | ✓ Michael A. Pentella, PhD, D(ABMM) |
| ✓ Fred Sparling, MD | ✓ Sarah Wiley, ELSW DFO* |
| ✓ Domenica (Dee) Zimmerman | |

✓ *In attendance*

**CDC employee*

Call to Order, Welcome, and Introductions

Joe Kanabrocki, Chair, and Sarah Wiley, DFO, ELSW

Update: CDC Laboratory Safety

Steve Monroe, Leslie Dauphin, Mike Shaw, Joe Henderson, ELSW Members

Dr. Monroe provided the ELSW with a brief overview. As the newly appointed Associate Director for Laboratory Science and Safety, he has the following charges:

- Stand up the new Office of the Associate Director for Laboratory Science and Safety (OADLSS)
- Ensure that appropriate laboratory training is being delivered in a timely manner
- Maintain internal and external communication
- Advance a “CDC Way” of approaching safety.

Dr. Monroe also shared an update of CDC activities in response to the ELSW’s recommendations. The agency has initiated response to all of the proposed recommendations, with several actions completed and more underway.

Discussion Points

- The ELSW and Dr. Monroe discussed plans to engage with bench-level and leadership staff across CDC laboratories. A plan for a communications Road Show is already underway, to be completed by the end of 2015.
- The group discussed how the new office interacts and cooperates with existing offices and roles, such as the Office for the Associate Director for Science (ADS) and the Center-level Associate Directors for Laboratory Science (ADLS).
- The group discussed how ESHCO is currently integrated with the OADLSS and the organizational review being conducted of ESHCO. There has been considerable discussion between Drs. Monroe, Dauphin, and the OSSAM team regarding what functionally would move to the OADLSS and what would need to remain in operations to supply the support to continue to improve the culture of laboratory safety.
- The group discussed the new training efforts for laboratory staff. A working group of SMEs was to help develop the courses, and CSELS staff with expertise with in competency mapping, adult learning theory, and assembling training materials also participate. An external group will review the process for competency mapping and assembling new curricula.

- The group discussed the “CDC Way” and strengthening the culture of laboratory safety at CDC. Dr. Monroe said that to him, safety and quality ties into a culture of responsibility.

Meeting with the Chief Operating Officer

Sherri Berger, Chief Operating Officer; ELSW Members

Ms. Sherri Berger, CDC COO, indicated that her portfolio includes human resources, information technology, security, safety, asset management, and all incoming and outgoing financial resources.

In FY 2016 President’s budget, there were requests for increases in laboratory safety and science. Both the House and Senate Appropriations Committees recommended that CDC receive funding over the base. The Office of Management and Budget (OMB) recently visited CDC to discuss the FY 2017 budget request, and the agenda included laboratory safety and science.

The Office of the COO is currently working with leadership to determine what functions of ESHCO would be more appropriately housed within OADLSS, as well as the current and future state of the CDC Occupational Health Clinic. Ms. Berger is also dedicated to improving laboratory safety culture, and she believes that having Dr. Monroe as the ADLSS will help the agency continue to move in a positive direction.

Discussion Points

- The group discussed the resources given to OADLSS and how they were used. Dr. Monroe indicated that the funds supported contract staff, operations within the new office, travel for some benchmarking trips for ISO accreditation and other outreach, preparing laboratories for ISO accreditation, and technology improvements. He recognized the need to be diligent in providing value to the laboratory programs.
- The group discussed the potential creation of a CDC training center, which would initially focus on BSL-3 and BSL-4 training. The materials would be developed through the OADLSS.

Update: ELSW Laboratory Safety Survey

Liz York, Chief Sustainability Officer; ELSW Members

Ms. Liz York reported on the results of the second Laboratory Safety Survey conducted by the Program Performance and Evaluation Office on behalf of the ELSW. The survey was conducted August 3-31, 2015, and received 411 responses. There were no significant differences between this survey and the one administered in 2014 in terms of the demographic characteristics (e.g., number of years at CDC, education, type of laboratory).

In general, perceptions of safety were high and remained so from the 2014 survey to the 2015 follow-up. Similarly, staff responded that they find laboratory safety protocols to be helpful generally; however, fewer respondents agreed that protocols were appropriate for their work and that they were clear and easy to understand. Staff were more likely to perceive their laboratory supervisors to understand protocols and procedures, and communication about safety incidents appears to have improved. Respondents also did not appear to perceive structural barriers, like facilities and equipment, to be problematic, nor did they perceive pressure from others to not comply with safety procedures. There does still appear to be room for improvement in training, communications, and setting expectations for safety.

In the past year, CDC has worked to improve the safety of laboratories through a variety of new initiatives, including adding new processes and technology. Ms. York pointed out that because these are new initiatives, they may not yet be widely recognized.

The results of the follow-up survey provide an opportunity to assess continued efforts to improve safety as well as staff's perceptions. Although quantitative markers of safety are the essential outcome of initiatives to improve safety, the perceptions of the staff who are the focus of these efforts is important both for continued implementation and the health of the organization. Some of these results suggest that change itself is difficult, but may also point to particular groups of laboratory staff who may need further attention.

Discussion Points

The group discussed the second ELSW survey results. Points of discussion included:

- People's sense of CDC's safety culture may have decreased in the second survey period because of increased awareness of issues occurring across CDC and external laboratories.
- Given the response rate was 25 - 30%, it is possible that the staff who chose to respond were more unhappy overall and more likely to express their frustrations, potentially biasing the results.
- Responses to training competency were mixed, and the group found that more emphasis was needed on enhancing training and measuring competencies.

Meeting with the CDC Director

Dr. Tom Frieden, Director; ELSW Members

Dr. Frieden thanked the ELSW members for their focus and input and emphasized that CDC values their contributions.

To report broadly on the overall progress, Dr. Frieden highlighted several areas in which CDC has made progress in the past year or so.

- There is now a single point of accountability in the new OADLSS. One of CDC's top funding priorities in the current year is a significant increase for laboratory science and safety.
- Substantial consideration has been given to a critical control point approach. There is also now a clear verification and validation process for any materials sent out of BSL-3 and BSL-4 laboratories.
- Reporting of problems has been encouraged. The agency continues to clarify what the criteria are for reporting of incidents.

Discussion Points

Dr. Frieden and the ELSW discussed the areas of progress highlighted by the Director. Points of discussion included:

- Appropriately staffing and funding the OADLSS with biosafety professionals.
- Dr. Monroe's presence in the laboratories and interacting with staff will strengthen and maintain the safety culture in laboratories.
- Enhancing and protecting CDC's reputation for safety and quality.
- Creating a risk assessment process that is consistent, transparent, and sustainable.
- Communicating positive laboratory safety progress at the CDC to external stakeholders and communities.

Dr. Frieden's Feedback to the ELSW's Observations Regarding Progress

Several major issues identified by ELSW members that CDC should be emphasizing internally and externally included the following:

- CDC should create its own training and should not contract it out
- Restructuring of biosafety under Dr. Monroe is a major step forward
- Creation of the overall LSRB for etiologic agents is extremely important

Laboratory Information Management System (LIMS) is an ongoing issue for CDC laboratories. In terms of external inspections, CDC has considered the two main bodies that conduct inspections and has completed some fact-finding missions. All of CDC's clinical laboratories go through Clinical Laboratory Improvement Amendments (CLIA) inspections. CDC would like all of the research laboratories to be inspected as well.

Discussion Points

The Director and ELSW closed out their meeting by discussing Dr. Frieden's feedback to the ELSW's observations. Points included:

- Introducing community liaisons as a form of community building and increasing buy-in from external stakeholders.
- How to communicate to CDC staff that their work is valued to increase overall morale.
- Maintaining flexibility when new processes are implemented; if it is found that a process is not working, the CDC should move to adjust its approach.
- Good science should drive the agency's work.

Meeting with the Laboratory Safety Review Board (LSRB), Institutional Biosecurity Board (IBB), and Institutional Biosafety Committee (IBC)

Wendi Kuhnert, Ruben Donis, Tim Barrett, Kathleen Keyes, ELSW Members

The Executive Secretaries and Chairs of the LSRB, IBB, and IBC each provided an overview of their respective Board or Committee work, mission, membership, and area of risk assessed. The groups also presented current challenges they are facing. The challenges are detailed as follows:

IBC:

- Currently, the IBC does not have a central "home base." While the committee has a home within OID, it is not a resourced home. The IBC is completely voluntary and has no funding or resources to provide administrative support, provide stipends to outside members, or create an electronic database.
- There is not an overall laboratory registration system, though this would be a beneficial resource for compiling all of the IBC's work, allowing management to review the work being done, and for PIs to be able to continuously update their work.

IBB:

- Updated training is needed to ensure that people have a common understanding of risk mitigation.
- Lack of dedicated structural support (e.g., administrative, IT, training, and other support).
- There are challenges with the Data Collection Tool for the Semi-annual DURC Report. The IBB Review Library and Calendar faces challenges with regard to administrative support. It is currently maintained by volunteers across the agency.

LSRB:

- Ensuring that board members are adequately trained to ensure consistency of reviews
- Receiving consistent, high-level scientific support from OADLSS as described in the charter, although having a permanent staff named should alleviate this issue
- Providing sufficient and high quality example SOPs through the SOP library to support the programs.
- Ensuring communication and guidance from the board consistently gets to the programs in a timely manner
- The need for a robust system to track and manage the process for submission, tracking, review and reporting of protocols, quarterly material transfer certificate reports, and annual reviews

Discussion Points

- Many of the agency's efforts should benefit from having a coherent approach. Splitting the reviews off to individual groups may not be productive.
- Dr. Monroe acknowledged that there are clearly gaps that the agency is working to address. Starting with inactivation at BSL-3 and BSL-4 levels that are perceived to pose the highest risk seemed like an appropriate starting point.
- The OADLSS will provide an organizational home and administrative support for the IBC, IBB, and LSRB.

Risk Assessment

Eduardo Gomez, ESHCO Interim Leadership Team; ELSW Members

Dr. Eduardo Gomez reported that there has been a risk assessment tool in use for a few years at CDC, but it was not used consistently, and there was not a risk assessment class.

The newly developed CDC class is based upon five steps that align with the BMBL: 1) identify hazards, 2) evaluate risks, 3) mitigate risks, 4) conduct a trial run, and 5) review risk assessments. Thus far, the class has been well-received. Over 160 students have taken the class so far, and many have expressed excitement about implementing risk assessment into their laboratories and sharing the information with others who have not yet taken the course.

The plan is to have a standard, systematic, uniform way of conducting risk assessments within CDC. A draft policy has been developed supporting this process. Thus, risk assessment at CDC has moved from a check-box procedure to having a process that is actually having an impact on the safety of the agency's laboratories.

Discussion Points

The group discussed the following points related to CDC's risk assessment process and training:

- The risk assessment policy is an agency-level policy, and it is in the final round of review.
- Conducting the risk assessment will be the responsibility of the laboratory supervisor. Every member of the laboratory must be aware of and read the risk assessment.
- The policy refers to all new projects being started in laboratories. At this point, risk assessments will not be retroactive. The policy spells out new procedures, new projects, or any changes to a common procedure that the laboratory is already conducting. The policy also states that there will be some type of formal process to determine whether a risk assessment should be reviewed by ESHCO or in collaboration with a board.

Laboratory Leadership Service and Laboratory Training

Michael Iademarco, Patricia Simone, Barbara Zehnbauer, CSELS; ELSW Members

Dr. Michael Iademarco, CSELS Director, explained that CSELS has two divisions that are directly engaged in the agency's response to biosafety: Division of Scientific Education and Professional Development (DSEPD) and Division of Laboratory Systems (DLS).

Dr. Patricia Simone, CSELS/DSEPD Director, oversees the division responsible for a number of the CDC scientific fellowship programs, such as the Epidemic Intelligence Service (EIS) program. Dr. Simone provided an update on the Laboratory Leadership Service (LLS) program, which was begun in 2015. The LLS is a two-year postdoctoral fellowship program for early career laboratory scientists. The focus of the program is on biosafety, quality management systems, and management and leadership competencies. In terms of the approach, the LLS program combines core PHL competency-based training with practical, applied investigations and service.

Dr. Barbara Zehnbauer, CSELS/DLS Acting Director, indicated that the DLS supports the goals of the OADLSS in terms of designing, updating, and offering the safety courses. The Laboratory Training Team establishes the learning objectives for competency-based safety training courses, designs the courses, produces videos, facilitates a functional review, pilot tests the course, facilitates clearance, and delivers the courses.

A Biosafety Best Practices Committee was recently established, which will review curricula to ensure that they have the right quality and objectives and are maintained. The team is also consulting on biosafety training for public health laboratories with regard to Ebola grants that were allocated to public health laboratories throughout the country.

Discussion Points

The ELSW and CSELS representatives discussed their feedback to the current status of laboratory training. Points of discussion included:

- LLS host laboratory selection requirements. CSELS selects laboratories that have a supervisor and secondary supervisor who can devote the amount of time necessary to provide a good experience for the trainees. The decision is based upon laboratory interest, commitment, and activities that would be good for the laboratory and the fellow.
- Course development status and evaluation of completed and outstanding trainings.

Day 1 Wrap-Up and Discussion

ELSW Members

The ELSW engaged in a discussion pertaining to what they learned throughout the day from the presentations, deliberations, and staff engagement sessions.

Discussion Points

The group discussed the most salient points of feedback from the first day's meeting. They included:

- The current and future organizational structure of OADLSS, and how ESHCO fits in to the structure based on needs and functions.
- The challenge is to ensure that the OALDSS is the focal point of the biosafety effort. How that is technically parsed out requires additional work.

Engagement Sessions: Laboratory Staff

Throughout the two days of the meeting, ELSW members met with a diverse range of laboratory staff members to gain insight into the laboratory safety efforts that have been implemented since the last in-person meeting. CDC staff who met with ELSW members are listed below.

Meeting with the Office of the Associate Director for Communication

Katherine Lyon Daniel, Associate Director for Communication (ADC); Kate Galatas, Deputy ADC;
ELSW Members

Dr. Katherine Lyon Daniel, Associate Director for Communication, expressed her appreciation for the time that the ELSW members put into this effort. For communication efforts there are three particular groups of audiences: public health partners, policymakers, and CDC laboratory staff.

The OADC is working very closely with the OADLSS and will continue to do so. In addition to health messaging, the OADC views agency reputation and maintaining credibility as paramount.

Dr. Daniel outlined a few of the strategies from the communication plan that has been developed for the work with the OADLSS.

- Core messaging about CDC's work to save lives, protect people, and keep the nation healthy and secure, as well as some of the specifics with regard to laboratory work.
- The agency is receiving major coverage when there is a problem. OADC and OADLSS have been working to develop a video that primarily features laboratory workers talking about the work that they do and why it is so important.

Discussion Points

The group discussed communication efforts at OADC related to laboratory safety. Points of discussion included:

- Three primary areas of focus identified were:
 - Develop a national notifiable incidents/accidents for laboratory-acquired infections
 - Advocate for research on biosafety issues
 - Look beyond infectious disease and microbiology laboratories into other areas of laboratories.
- Enhancing and supporting CDC messaging about how laboratory work is one of the key values of the CDC's overall mission.
- Dr. Daniel observed that the ELSW's top priority appeared to be scientific communication—communication about the core of the science and the leadership within the field of science. This will take a close collaboration with Dr. Monroe's office.

Final ELSW Discussion

During this session, the ELSW reflected on the two days of the meeting and compiled a list of preliminary observations to present during their final discussion of the afternoon with CDC leadership. It was agreed that the final report should be structured in the same manner as the original recommendations.

Final Discussion with CDC Leadership

Anne Schuchat, Principal Deputy Director; Rima Khabbaz, Deputy Director for Infectious Diseases; Steve Monroe, ADLSS; Joe Henderson, Director, OSSAM; ELSW Members

Dr. Kanabrocki, ELSW Chair, reported on the ELSW's preliminary observations made during this in-person meeting. He emphasized the ELSW's recognition that addressing the recommendations they made could not all be done overnight, particularly those related to cultural changes. He encouraged CDC to remain patient with the process, to remember the importance of getting it right versus being too hasty, and to stay the course.

The ELSW members observed a great deal of progress, and were pleased with many of the efforts. They categorized their comments into the following topic areas:

- **Leadership:** Dr. Monroe was a good choice for the ADLSS position. He is trusted, is very well-respected, has great knowledge of CDC, has an extensive background as a scientist, others recognize his excellence and like his style, and he is an effective communicator with his audience.
- **Governance:** The concept of laboratory safety functions being placed within the OADLSS is a positive move.
- **Risk Assessment:** Good progress has been made on risk assessment training for front-line staff. While the risk assessments are being documented, the next step is to determine what is being done to follow-up on the findings of the risk assessments.
- **Laboratory Safety Training:** There is a clear commitment from CDC leadership to develop training. The development of training that is timely and appropriate for specific tasks and individuals is a work in progress, but progress is being made.

- **Surveys:** While both versions of the survey were very informative to the ELSW and to CDC to understand the research activities in the agency's laboratories, additional surveys are not necessary at this point.
- **ESHCO:** The ELSW recognized that this group is a work in progress. Staffing ESHCO with appropriate SMEs is extremely important, as is the selection of good leadership.
- **Laboratory Registration System:** Though not one of the ELSW's original observations, they strongly encouraged CDC to develop a laboratory registration system that would enable the agency to know which PI has what pathogens in which location and what they are doing with it.

Discussion Points

The group closed its in-person meeting by discussing the primary areas of feedback and observation from the ELSW. Points included:

- Standardization of guidance from the OADLSS and agency in relation to laboratory safety.
- A central laboratory registration system.
- Developing a robust training program for all staff.
- Dr. Schuchat thanked the ELSW and acknowledged that all of their observations and suggestions seemed very reasonable.
- Dr. Kanabrocki emphasized how proud the ELSW is of the CDC as well.

CDC Staff Present

Timothy Barrett, PhD

Assoc. Director for Laboratory Science (Acting)
National Center for Immunization and Respiratory
Diseases

Sherri A. Berger, MSPH

Chief Operating Officer

Mary Brandt, PhD

Chief, Mycotic Diseases Branch
Division of Foodborne, Waterborne & Environmental
Diseases
National Center for Emerging and Zoonotic
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Daniel Browning, MS (via teleconference)

Interim Leadership Team, ESHCO
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National Institute for Occupational Safety and Health

Alan Czarkowski, MD

Medical Director
Occupational Health Clinic

Inger Damon, MD, PhD

Director, Division of High-Consequence Pathogens
and Pathology
National Center for Emerging and Zoonotic
Infectious Diseases

Katherine Lyon Daniel, PhD

Associate Director for Communication

Leslie Dauphin, PhD

Deputy Director, OADLSS

Ruben Donis, PhD

Assoc. Dir. for Policy, Evaluation & Preparedness
Influenza Division
National Center for Immunization and Respiratory
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Thomas R. Frieden, MD, MPH

Director, CDC
Administrator, Agency for Toxic Substances and
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Kata Galatas, MPH

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Craig Hooper, PhD

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National Center for Birth Defects and Developmental
Disabilities

Michael F. Iademarco, MD, MPH

Director, Center for Surveillance, Epidemiology, and
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Office of Public Health Scientific Services

Joanne Jones, MPH

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Suzy Kalb, PhD

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Kathleen Keyes, BS, MS

Safety and Occupational Health Manager
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Rima Khabbaz, MD

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Associate Director for Laboratory Science
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Steve Monroe, PhD

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Missy Brykailo Pearce

HCL Manager

Jim Pirkle, MD, PhD

Director, Division of Laboratory Sciences
National Center for Environmental Health

Nathaniel Powell, DMV

Chief, Animal Resources Branch
Manager, CDC Laboratory Animal Medicine
Residency Program

Ann Powers, PhD (via teleconference)

Laboratory Chief
Arboviral Diseases Branch
Division of Vector-Borne Diseases
National Center for Emerging and Zoonotic
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Lori Rowe, PhD

Microbiologist
Biotechnology Core Facilities Branch
National Center for Emerging and Zoonotic
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Anne Schuchat, MD

Principal Deputy Director, CDC and ATSDR

Michael Shaw, PhD

Senior Advisor for Laboratory Science
Office of Infectious Diseases

Paul Siegel, MD

Associate Director for Science
Health Effects Laboratory Division
National Center for Chronic Disease Prevention and
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Patricia M. Simone, MD

Director, Division of Scientific Education and Professional Development
Center for Surveillance, Epidemiology, and Laboratory Services

David Sue, PhD

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Sarah Wiley, MPH

Senior Advisor, Office of Infectious Diseases
ELSW Designated Federal Official

Liz York, BS, MS, AIA, LEED AP, CNU-A

Chief Sustainability Officer
Office of Safety, Security, and Asset Management

Barbara Zehnbaauer, PhD

Acting Director
Division of Laboratory Sciences
Center for Surveillance, Epidemiology, and Laboratory Services

Others Present

Julia Bell

Deloitte Consulting, LLP, Contractor
Centers for Disease Control and Prevention
Business Integrity and Strategic Management Unit (BISM)

Kendra Cox, BS, MA

Medical & Scientific Writer/Editor
Environmental Scientist
Cambridge Communications, Training, & Assessments, Inc. (CCTA)

Stephanie Wallace, PhD, MS

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