AN INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) AND BIOSAFETY PROGRAM BENCHMARKING SURVEY (ID #1)

Christine M. Johnson, Karen M. Dobos, Colorado State University, Fort Collins, CO

Objectives:

- Assess of the organizational structure of IBC and biosafety programs
- Determine the scope of IBC review
- Compare the size of IBC and biosafety programs

Method: The survey consisted of 24 questions; an invitation to participate was emailed to IBC contacts and posted on the ABSA listserv, and included a link to the web-based survey. Survey results were analyzed using Microsoft Excel.

Results: 157/1157 responses were received resulting in a response rate of 13.6%.

Conclusion: The survey data revealed that IBCs most often reside under the same administrative unit (VPR/VCR) as the Institutional Animal Care and Use Committee (IACUC) and Institutional Review Board (IRB), while most Biosafety Officers (BSOs) report to a different unit (Environmental Health & Safety (EHS)). Furthermore, the survey demonstrated that most IBCs have been tasked with far more oversight duties than originally prescribed by the National Institutes of Health (NIH) Guidelines. In general, most institutions reported having fewer FTE dedicated to support their IBC, than IACUCs and IRBs. This discrepancy could be due to the higher average protocol numbers for IRBs (1137) and IACUCs (360), compared to IBCs (216), therefore necessitating more IRB and IACUC FTE. However, since many institutions (21%) manage their IBC review process on a PI basis instead of an individual project basis, it is possible that the IBC protocol numbers are artificially low. Further investigation would be required to determine if there is a true gap in IBC support staffing.

Outcomes: There were several successful outcomes resulting from the benchmarking survey. Firstly, several similarities and shared practices among IBCs and biosafety programs were discovered. Secondly, the data collected can be used by institutions as a tool to compare their program to other programs. Finally, the survey identified potential gaps in IBC support staffing, warranting further evaluation.

DEVELOPMENT OF AN OCCUPATIONAL RISK ASSESSMENT TOOL FOR LABORATORY ANIMAL FACILITIES (ID #2)

April Clayton, James Hayes, Chris Sieradzki, George Lathrop, Nathaniel Powell, Centers for Disease Control and Prevention, Atlanta, GA

Objectives:

- Illustrate the process in developing a tool to identify, prioritize, and mitigate occupational risks in vivaria
- Summarize the implementation of our tool to improve the safety of occupational tasks
- Demonstrate how critical participation from personnel is to the success of an occupational risk management program

Method: Laboratory animal facilities aim to provide excellence in animal care and welfare and support scientific research. Critical to these goals is to ensure a safe work environment for personnel comprised of veterinary and animal care, laboratory research, and maintenance staff. Thus, performing occupational risk assessments allows for evaluation of risks from identified hazards associated with a variety of tasks ongoing in laboratory animal facilities. Herein, we present the development, implementation, and execution of an occupational risk assessment tool to capture the dynamics of work performed in laboratory animal facilities, to calculate and prioritize identified risks associated with procedures and processes, and to inform and evaluate risk mitigations. Our risk assessment tool is comprised of a matrix to calculate current and adjusted risks based on likelihood and consequence severity.

Results: We also highlight the use of our designed risk management process in the refinement of sharps usage in the husbandry and care of our macaque colony.

Conclusion: Our process and framework evolves into an occupational risk management system of identifying, evaluating, and mitigating occupational risks and determining risk acceptability.

Outcomes: Essential to our model is consistently communicating and consulting with front line personnel and subject matter experts in biosafety, science, and animal care and welfare as well as continuously striving to improve and enhance the operations of laboratory animal facilities.

EVOLUTION OF A DIGITAL PAPERLESS BIOSAFETY PROGRAM (ID #3)

Justin G. Arthur, Raymond Scheetz, Penn State School of Medicine, Hershey, PA

Objectives: Development of The LabManager Program has given the ability to view all informational aspects of an academic research lab from a central dashboard. Connection of records through a digital system allows for a streamlined workflow and easier management of research compliance activities. Furthermore, the ability to provide an instant, automatic, and secure digital archive of an individual laboratory or entire institution's compliance informatics could provide a vital service in the event of an lab emergency or emergent issue. Through adapting antiquated processes into standardized & digitally interactive interfaces LabManager has shown to be an effective business practice in the reduction of paperwork and overall workflow time.

Method: An in-house program was made to provide a single dashboard for both connecting documentation/training systems and providing a compliance management tool for a biosafety program. The LabManager automatically populates and converts data to interactive metrics, i.e.: PI/Manager/staff records; lab equipment manuals/records; automatic survey/audits scheduling, tracking, and reporting; lab placard/emergency info collection/placard generation; SOP housing; linking to 3rd party systems; training record linking/automatic reminders; and link to emergency response.

Results: The LabManager system has proven to be a useful tool in our university setting to keep all essential lab, biosafety and compliance information in one location.

Conclusion: The LabManager program has the potential to increase collaborative efforts through the ease of access to research agents, equipment, and contact information.

Outcomes: Information gained from this presentation will enable labs at all institutions to properly manage the essential make up and compliance issues necessary in the management of their programs.

THE FUTURE OF ISO 35001: BIORISK MANAGEMENT FOR LABORATORIES AND OTHER RELATED ORGANIZATIONS—WHERE ARE WE? (ID #4)

Patricia Olinger, Emory University, Atlanta, GA

Objectives:

- Restate biorisk management through a quality management standard approach and how it could be utilized on your institution
- Paraphrase the history of how the ISO 35001 Biorisk Management International Standard has been developed
- Recognize the timeline for ISO 35001 and how you can begin preparing your program

Method: Starting with the CWA 15793 and under the direction of ISO, representatives from multiple countries have been developing the new ISO Standard on Biorisk Management.

Results: ISO 35001: Biorisk Management for Laboratories and Other Related Organizations is on track to be completed in 2019.

Conclusion: The new ISO Biorisk Management Standard builds upon lessons learned from implementation of the CEN Workshop Agreement 15793:2008: Laboratory Biorisk Management.

Outcomes: From conception, to the CEN Workshop Agreement CWA 15793:2008 to ISO 35001, Biorisk Management for Laboratories and Other Related Organization. In 2019, the new ISO deliverable is scheduled to be competed. This talk will discuss the history, the evolution and what this new ISO standard could mean to industries and institutions who work with biohazardous materials.

UPDATED BIOLOGICAL RISK MANAGEMENT PROGRAM AT CDC (ID #5)

Eduardo Gomez, Christopher M. Sieradzki, Centers for Disease Control and Prevention, Atlanta, GA

Objectives:

- Identify the main components of a risk management program
- Summarize the steps taken to update the risk management program
- Describe the impact of the program on the laboratories

Method: As part of the CDC continuous process towards achieving world class laboratory safety an improved risk assessment program was developed. To implement the updates to the risk management program, we have established a 6-hour course that includes lecture, interactive review, and case studies/exercises. The course includes basic concepts such as hazard, risk, inherent risk, residual risk, risk mitigation, risk matrix, severity and probability, hierarchy of controls, and risk assessment as a continuous process. Simultaneous with the training program a new risk assessment tool was developed following the steps outlined in class, including hazard identification, risk evaluation, and risk mitigation. Then a policy was enacted which required a risk assessment for all new or modified laboratory work and for the commissioning of new laboratories. Our risk management cycle also included an annual review requirement as well as record keeping and data analysis.

Results: Between 2015 and early 2018 over 400 laboratory scientists were trained in risk assessment. Of those who attended the class, 95% successfully completed the course. Other data and outcomes of the training program and the risk assessment review process will be discussed.

Conclusion: As indicated by the positive program results and increased safety awareness, the principles of risk assessment and management should be put in practice in the daily performance of duties in biological laboratories. Similar steps can be taken at other biomedical institutions to enhance their safety posture.

Outcomes: Increased awareness of risk assessment agency wide, increase in the number of risk assessments submitted for review, and a new systematic approach to risk management.

PREPARING FOR THE NEXT PANDEMIC: THE DEPARTMENT OF HEALTH AND HUMAN SERVICES PREFUNDING REVIEW OF RESEARCH ON ENHANCED POTENTIAL PANDEMIC PATHOGENS (ID #6)

Patricia Delarosa, Theresa Lawrence, Kathleen Danskin, United States Department of Health and Human Services (HHS), Washington, DC

As part of its mission to enhance the health and well-being of Americans, the Department of Health and Human Services (HHS) supports research with the potential to advance our understanding of pathogens; mechanisms of disease; inform the development of medical countermeasures; prevent and treat infections; guide disease surveillance; and enhance public health preparedness activities. However, a specific subset of studies that could generate pathogens with pandemic potential have raised some concerns. On January 9, 2017, the White House Office of Science and Technology Policy issued policy guidance requiring funding agencies to have a pre-funding mechanism in place for the review of a small subset of experiments that could potentially produce an enhanced pathogen with pandemic potential (PPP). A PPP is: highly transmissible and capable of uncontrollable spread in humans; highly virulent and capable of causing significant morbidity and mortality in humans. In response, HHS has developed a multi-level, multi-disciplinary Department-level review process, called P3CO that includes a risk-benefit analysis and review of risk mitigation plans for the conduct of enhanced PPP research.

ASSESSMENT OF CLINICAL LABORATORIES BIOSAFETY PRACTICES THROUGH SITE VISITS AND RISK ASSESSMENTS (ID #7)

Melissa L. D'Amico, Michael J. Perry, Corey Bennett, David Hill, Christina T. Egan, New York State Department of Health—Wadsworth Center, Albany, NY

Objectives: Recent infectious disease events, including Ebola and Zika, have highlighted the need to review biosafety practices in state public health and clinical laboratories across New York state. Members of the biosafety team at the Wadsworth Center (WC) designed a study to determine how risk assessments are incorporated into lab practice and to identify gaps in biosafety. We conducted site visitsand reviewed risk assessments (RAs) from clincial and public health labs in New York State (NYS).

Method: To date, the safety team has studied biosafety practices and RAs at over 50 clinical and public health labs in NYS. Also, information regarding packaging/shippping training/procedures, was collected from over 250 labs in NYS.

Results: Lab visits began with emphasis on the sole purpose to promote biosafety practices, and not to conduct an official inspection. This open approach helped facilitate better and more informative dialogue between NYS and clinical labs, allowing the safety team to identify biosafety practices that labs could improve upon, as well as ways the labs could better utilize their RAs to create a safer culture. Onsite visits, including *Brucella* exposure discussions, as well as webinars, biosafety resources and other training materials, provided labs with useful information to further enhance their biosafety practices.

Conclusion: Lab visits and the collection of RAs allowed for the identification of biosafety gaps, which were addressed through development of various training materials, including biothreat agent information bench cards, biosafety training videos, and a biothreat webinar, etc., which were needed and requested by clinical labs.

Outcomes: Labs received feedback on their RAs, identifying gaps in biosafety practices, resulting in reduced risks for LAIs, and safer work environments.

USING AN ONLINE OCCUPATIONAL HEALTH INFORMATION SYSTEM TO PROMOTE BIOSAFETY AND BIOSECURITY (ID #8)

David Jones, N. Tlotleng, N. Naidoo, L. Darwin, National Health Laboratory Service/NICD, Johannesburg, South Africa
J.M. Spiegel, A. Yassi, Global Health Research Program, University of British Columbia, Vancouver, British Columbia, Canada

Objectives: The 2013 - 2015 Ebola outbreak demonstrated that healthcare workers are at risk and highlighted the need for prepared and informed public health workers as well as a means to communicate information quickly and credibly. With over 7100 employees spread across South Africa, the National Health Laboratory Service (NHLS) faces the challenge of providing and improving occupational health and safety, biosafety and biosecurity with limited resources. OHASIS, a secure online occupational health and safety information system developed by University of British Columbia is an intranet application which has been rolled out across the NHLS to assist in monitoring and communicating worker health, safety, biosafety and biosecurity. We conducted surveys in 2013, 2015, and 2018 to assess: employees' knowledge of health and safety in the workplace; awareness regarding occupational health and safety; and improvements in perceptions about health and safety.

Method: A baseline cross sectional study was conducted in 2013 among 15% of employees who were selected by stratified random sampling based on occupation type. The survey was repeated in 2015 post implementation of OHASIS; a 2018 survey is in progress. Results were considered significant if the P value <0.05.

Results: Significant improvement occurred from 2013 to 2015 including knowledge of risk assessments (53% to 68%), ease of obtaining information (26% to 40%), knowledge of emergency procedures (53% to 71%), trust of management (57% to 67%), incident reporting (69% to 86%) and use of N95 respirators (68% to 78%). 2018 data will be presented at the conference.

Conclusion: An online information system that is accessible, user friendly and connects users to the relevant expertise contributes to improving biosafety and their general wellbeing.

Outcomes: To improve occupational health and safety using online tools

THE DEVELOPMENT OF THE USDA AGRICULTURAL RESEARCH SERVICE JOB HAZARD ANALYSIS (JHA) TEMPLATE (ID #9)

Megan Kennedy, United States Department of Agriculture, Agricultural Research Service (ARS), Albany, CA

Objectives: To develop procedures for instituting JHAs as a tool to identify hazards and review job methods to reduce accidents in the conduct of ARS research. As part of this task the ARS Risk Assessment Work Group (RAWG) was formed.

Method: The RAWG is a multi-disciplinary work group assembled in spring 2017 to create a JHA template for ARS. The RAWG included scientists, safety professionals, research leaders and administrative employees to cover all areas of work. The RAWG compiled JHA forms from ARS locations and other institutions. One subgroup reviewed different forms and created a single template with instructions for use at ARS locations. A second subgroup developed an ARS policy mandating the use of JHAs to document and improve agency-wide safety management. A third subgroup created educational tools such as example JHAs, training materials and FAQs. The entire RAWG reviewed the draft template and recommended changes.

Results: Upon final review of the draft JHA template by the RAWG, two ARS locations were selected to serve as pilot sites. Employees at the pilot sites were requested to complete JHAs for a variety of tasks and submit feedback on both the process and the template.

Conclusion: After the initial five ARS locations completed their JHAs the safety professionals on the committee reviewed the JHAs and provided feedback. ARS JHA documents are in the final form and have been well-received by employees at the pilot sites. ARS employees find the new template easily to use and the template has helped them get a better grasp of the steps that need to be taken to protect employees.

Outcomes: Once the pilot testing is complete, the JHA template & instructions, FAQs and ARS policy document will be issued to all ARS locations. ARS management plans for the JHA template to be issued across the department by February 2019.

A COMPREHENSIVE REVIEW OF BIOSAFETY AND BIOSECURITY PROGRAMS IN STATE, LOCAL AND TERRITORIAL PUBLIC HEALTH LABORATORIES (ID #10)

Michael Marsico, Association of Public Health Laboratories (APHL), Silver Spring, MD

Objectives: Attendees will understand how public health laboratories (PHLs) have been utilizing Centers for Disease Control and Prevention (CDC) funding to improve biosafety and biosecurity functions in their laboratories. Attendees will learn about biosafety officers (BSOs) in PHLs and their outreach activities in engaging with clinical laboratory partners. Attendees will learn why a long-term, sustainable funding approach is needed to strengthen PHL and clinical biosafety and biosecurity programs.

Method: The 2017 survey was distributed via email with a unique survey and a copy of the survey; it was distributed to 64 state, local, territorial and US Affiliated Pacific Island (USAPI) PHLs. Data was collected using Qualtrics, a web-based survey tool and data repository. The 2017 APHL Biosafety and Biosecurity, available at APHL.org, presents aggregate survey assessment results for all questions.

Results: The 2017 Biosafety and Biosecurity Survey responses revealed: PHLs have successfully utilized CDC funding to implement risk assessments, perform outreach to sentinel clinical laboratories, deliver training courses to thousands of clinical laboratories, and design guidance documents. PHLs are facing the challenges of inconsistent funding, a diminished workforce pool, and limited buy-in from clinical laboratories.

Conclusion: A long-term, sustainable funding strategy is needed to strengthen PHL and clinical biosafety and biosecurity programs. The funding will assist laboratories with maintaining and hiring highly skilled BSOs, improving outreach to clinical laboratories and increasing their buy-in, providing training to internal staff and external laboratories and ultimately ensuring a safe and secure place thus preventing laboratory-acquired infections.

ESTABLISHING BIORISK MANAGEMENT IN THE TUNISIAN MILITARY LABORATORIES (ID #11)

Ben Moussa Mohamed, Tunisian Military, Tunis, Tunisia
Melissa Mørland, University of Maryland, Baltimore, MD

Objectives:

- Evaluate the laboratory environment of 15 military health institutions
- Assess the current awareness of staff
- Develop and hold workshops to help train staff across the military hospitals

Method: Fifteen military hospital laboratories were visited to assess the current environment as it relates to biorisk management. In addition, staff in these laboratories completed an awareness assessment to identify training needs. Based on this needs assessment, a biorisk management workshop was held for the laboratory staff in five military hospitals. A multi-trainer approach was used and awareness was measured pre- and post-training.

Results: The laboratory assessment results showed that the design, equipment, and security in the laboratories were adequate; however, the assessment highlighted the lack of training, a need for standard operating procedures and health surveillance. After ranking the needs, we determined that training was the highest need, thus a training workshop was developed and thirteen laboratory health workers were trained in biorisk management. Pre- and post-assessments were used to measure increase in awareness at BRM training program. Results showed that the introduction of biorisk management increased the understanding of safety and security among the laboratory workers.

Conclusion: Thirteen laboratory health workers now have a basic understanding of BRM. The increase in biorisk management awareness will prevent potential threat to public health and the environment as well as reducing the risk of exposure to laboratory staff. Further training is needed for additional laboratory personnel and advanced workshops will be necessary to enhance skills and knowledge.

Outcomes: This project increased biorisk management awareness in Tunisian military health institutions; therefore, increasing safety and security in the laboratories.

HAVING A GAME PLAN: INFECTION CONTROL, PUBLIC HEALTH AND BIOLOGICAL SAFETY IN THE DEPARTMENT OF ATHLETICS (ID #12)

Danielle Scavone, Yale University, New Haven, CT

Objectives: This presentation will provide attendees with a wide range of biosafety-related issues associated with academic athletics. While seemingly benign, these issues can be overlooked. Biosafety program management should include these non-traditional sources of risk and exposure. By examining these biosafety issues, attendees will be able to identify and become familiar with tasks and exposures associated with athletics. They will then be able to properly mitigate these risks and offer alternative procedures. Attendees will be offered emergency response procedures in the event of exposure or communicable disease among athletes.

Method: Extrapolating the risks encountered in laboratory and clinical settings, a biosafety program was able to develop a plan for mitigating risks in the non-traditional setting of intercollegiate athletics.

Results: Proactive risk mitigation is a hallmark of biosafety. Using this concept with partners in athletics, enhancements have been made to an already robust program.

Conclusion: By promoting the applicability of biosafety concepts to outlying departments and disciplines on campus, an Environmental Health and Safety group can have a greater impact on safety culture throughout all disciplines.

Outcomes: Greater partnerships have been developed well beyond the walls of laboratories and clinics.

DEVELOPMENT OF A HAZARD SPECIFIC HANDBOOK FOR THE JORDANIAN ROYAL MEDICAL SERVICES (RMS) (ID #13)

Sana'a Saidat, Jordanian Royal Medical Services, Amman, Jordan
Marian Downing, Biosafety Consultant, Kemah, TX

Objectives: The RMS oversees hospitals run by the Jordanian Army as well as the Princess Iman Ctr for Research and Laboratory Sciences. This project involved gathering US Department of State Biosafety Engagement Program (BEP)-trained RMS medical personnel into a Biorisk Management Committee (BMC). The BMC would address lab agents, procedures and equipment in a hazard-specific handbook. A satisfaction survey would be conducted.

Method: The BMC met and identified the pathogens handled as well as equipment and lab procedures. The handbook includes agent hazard safety data sheets, equipment safety guidance and best practices for the lab procedures. Training sessions included lecture, demonstrations, and a training video. A post training satisfaction survey was conducted.

Results: As of 11/17, over 40 lab staff were trained on the "Hazard Specific Handbook". There was increased management and peer acceptance for improving the biorisk management program (BMP). There are new opportunities for RMS biorisk professionals to attend conferences. The project inspired other safety efforts, including training engineers in BSC certification, generating emergency call lists, appointing a BSO for each lab, generating chemical SDSs and a project poster was presented at a conference for Advancing Jordan's National Biosecurity Effort.

Conclusion: BMC and upper management commitment was critical for worker acceptance of additional training. Effective training should include multiple delivery methods. Finalizing the handbook spurred enthusiasm in the BMC to assist in training.

Outcomes: Formation of the BMC and handbook generated RMS support for biorisk management, DoS trained scientists skills were utilized, and equipment, training, SOPs, and manuals were evaluated. Goals include training additional staff, sharing the hazard handbook with other Army facilities, implementing lab inspections and promoting biorisk management at a national level.

DEPARTMENT OF HOMELAND SECURITY COMPLIANCE ASSURANCE PROGRAM OFFICE: REVIEW PROCESSES AND COMPLIANCE EFFORTS (ID #14)

David Martinson, Vittoria Smeglin, Jamie Rotimi, John Scarbeck, Perri Pleeter, Ryan Gearheart, Department of Homeland Security, S&T Compliance Assurance Program Office [Contractors}, Washington, D.C.
Chris O'Donnell, Department of Homeland Security, S&T Regulatory Compliance Program Manager, Washington, D.C.
Tamika Knight, Department of Homeland Security, S&T Compliance Assurance Program Manager, Washington, D.C.

The Department of Homeland Security (DHS) has a centralized Compliance Assurance Program Office (CAPO) to ensure all relevant Department research, development, testing, and evaluation activities are conducted in compliance with all applicable regulations. CAPO is housed within the Science and Technology Directorate, and reviews Department-sponsored activities for treaty and regulatory compliance. CAPO ensures treaty compliance by assessing new projects against the Biological and Chemical Weapons Conventions. CAPO ensures regulatory compliance by assessing new projects against DHS directives and federal law/policies, performing documentation-based reviews of existing programs, conducting biosafety-focused site visits, participating in joint inspections of select agent-registered entities with CDC and APHIS, and representing DHS in interagency discussions pertaining to oversight of biosafety and biosecurity policy. Areas of oversight include biosafety, select agent and toxin security, research involving recombinant and/or synthetic nucleic acid molecules, research involving human subjects or animals, and compliance with the Biological and Chemical Weapons Conventions. CAPO also leads DHS efforts pertaining to institutional and life sciences dual use research of concern (DURC). In addition, CAPO conducts outreach training throughout the Department.

NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES (NCIRD) NATIONAL BIOSAFETY MONTH CAMPAIGN (ID #15)

Michele Edenfield, Banks Denney, Booz Allen Hamilton, Atlanta, GA
Brandi Limbago, Centers for Disease Control and Prevention (CDC), Atlanta, GA

Objectives:

- Recognize how one program was able to raise awareness of biosafety from all levels of the organization
- Identify techniques used to inform, share and promote biosafety
- Paraphrase these methods to implement a biosafety awareness campaign

Method: National Biosafety Month (NBM) is an opportunity to encourage institutions to reinforce their attention to biosafety policies, practices and procedures by focusing on Training, Engagement and Transparency. The National Center for Immunization and Respiratory Diseases (NCIRD) at CDC used NBM to offer a range of opportunities to educate lab staff on biosafety. The NCIRD Safety Team developed a NBM Campaign complete with weekly activities including trainings, games, contests, engagement sessions, and staff recognition. Campaign success was evaluated by participation, reach, and feedback.

Results: The NBM Campaign was a success! NCIRD had 123 lab staff take the offered trainings, 10 contest finalists, all 8 lab branches conducted engagement sessions, and many more participated in the weekly activities. This campaign reached lab staff and leadership in our center, other centers and other agencies. As a result, we have had requests to extend our trainings for more frequent offerings. Lab staff and leadership shared valuable insight during the engagement sessions and we are building programs to act on that feedback.

Conclusion: Using NBM to raise awareness for biosafety helped to reach all levels of the NCIRD organization, as well has external groups. This campaign helped to connect lab staff to leadership and to raise biosafety awareness.

Outcomes: This event helped to bring safety to the forefront of our minds and provided opportunities for lab staff to learn about safety, practice hands-on training, and engage with leadership. We have this will open the lines of communication around safety and get everyone more involved, on all levels.

AWARENESS AND ATTITUDES OF RESEARCH STUDENTS TOWARDS DUAL USE RESEARCH OF CONCERN (DURC) IN PAKISTAN: A CROSS SECTIONAL QUESTIONNAIRE SURVEY (ID #16)

Samreen Sarwar, Madiha Rafique, University of Health Sciences Lahore, Lahore, Pakistan
Sadaf Ilyas, Australian National University, Canberra, Australia
Bilal Ahmed Khan, Dow University of Health Sciences Karachi, Karachi, Pakistan
Danielle C. Lohman, University of Wisconsin—Madison, Madison, WI
Saleha Hafeez, National University of Sciences and Technology, Islamabad, Pakistan

Objectives:

- Assess the level of awareness and attitudes of research students towards dual use research of concern
- Measure the level of consideration regarding DURC while publishing data and experimental protocols
- Identify preferred method to learn about DURC

Method: A cross-sectional study was conducted to evaluate the level of awareness and attitudes of research students towards dual use research of concern (DURC) in more than twenty-five universities in four provinces, federal area and Azad Jammu and Kashmir region of Pakistan.

Results: Across the geographic areas targeted, 933 students responded. Most of the respondents (58.2%) never heard of DURC; while 18.5% had heard of the term, but were unsure of its meaning. Irrespective of the prior knowledge, a higher percentage of students (68.6%) felt an obligation to report research misuse. Considering the need for DURC training, 94.1% of the respondents agreed that the principal investigator should train students on DURC at the start of a research project. Almost half (46.2%) of the students indicated that they prefer to learn about DURC through workshops. Few were supportive of learning about DURC using an online approach (5.1%), or as part of the course curriculum (6.3%), and a minority (2.7%) showed no interest in learning about DURC. In case of experimental results having dual use potential, 69.1% indicated they would publish with limited protocol, with 43.5% indicating they would publish the limited protocol only if there was a way for scientists to access their data.

Conclusion: DURC awareness among researchers across Pakistan is greatly limited. It is important to note that the respondents, although not formally educated about DURC, were quite aware of its impact.

Outcomes: The survey results identified significant knowledge gaps. The information will be very valuable in addressing country-specific awareness and training needs.

IS YOUR INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) PREPARED TO REVIEW CLINICAL TRIALS INVOLVING HUMAN GENE TRANSFER? (ID #17)

Esmeralda L. Meyer, Kalpana Rengarajan, Patricia Olinger, Emory University, Atlanta, GA

Objectives:

- Discuss four representative cases involving the use of human gene transfer (HGT) based on changes to the 2016 National Institutes of Health (NIH) Guidelines
- Identify the roles and interactions among institutional committees
- Summarize the example of a decision making flow when determining the type of review needed for the clinical study involving HGT

Method: This is an experience-based presentation with the overarching goal of sharing our experience at Emory University when the IBC was challenged with various scenarios associated with the review of clinical trials involving HGT when Emory University was an initial site or an added site. Examples from each of these scenarios will be presented and discussed with special emphasis in the decision making process utilized to determine the type of review most appropriate for each study.

Results: Case 1 and case 2 are a comparison of two studies where the institution was an initial site using different investigational products. Case 3 and case 4 are a comparison of two studies where the Institution was an added site using different investigational products.

Conclusion: The 2016 NIH Guidelines shifted the determination of whether a study would benefit from Recombinant DNA Advisory Committee (RAC) review from the NIH to the IBC. Therefore, new work flows needed to be developed to accommodate the added responsibilities. Clear interaction between the IBC, Institutional Review Board (IRB), research coordinators, and principal investigators is critical for a successful review process and outcome. To successfully manage the submission and required review of clinical trials involving HGT it is important to have a comprehensive review of the study and associated documents.

Outcomes: This presentation will provide a first-hand account on how an IBC manages the review of clinical trials involving HGT following the 2016 NIH Guidelines.

SERIOUSLY, AN INSECTARY AT A PRIMATE CENTER? (ID #18)

Kalpana Patel, Maureen Thompson, Yerkes National Research Primate Center, Atlanta, GA

Objectives: In 2016, it was identified that an insectary was needed to meet the research needs for Malaria projects at Yerkes National Primate Research Center. A team was assembled to determine the feasibility of renovating an existing nonhuman primate facility to serve as a mosquito insectary. As the team assessed available facilities while referring to Arthropod Containment Level-2(ACL-2) guidelines, it was determined that a space previously used for Non-human Primate (NHP) testing (ABSL-2) could safely be retrofitted to accommodate the mosquito insectary. Once the facility was renovated, a risk assessment was conducted to determine operational procedures, PPE, and training requirements.

Method: Team members where recruited representing Malaria researchers, biosafety professionals, entomologists, facilities as well as outside consultants with expertise in the operation of an insectary. The team determined that the facility would meet all of the recommendations outlined in the 2003 ACL-2 guidelines. Construction began in 2017. The plans included addressing issues to control mosquitos, construction near NHP housing, security and mapping out the work flow for mosquito feeding, rearing and dissection. Standard operating procedures (SOPs) were developed. Personal protective equipment requirements were determined and training was provided for the varying access levels.

Results: The insectary construction was completed. SOPs were approved. Involved personnel were trained. Regularly scheduled facility inspection were implemented by the safety office. The facility went live with the first mosquito rearing on February 2018 and first mosquito feeding on March 2018.

Conclusion: When research and biosafety work together using risk assessment it is possible to modify existing ABSL-2 NHP space to become an mosquito insectary.

Outcomes: A fully functioning mosquito insectary is working to support NHP malaria research.

HIGH-CONTAINMENT VS HIGH-CONFINEMENT RESEARCH FACILITIES: ARE THEY THE SAME? WHAT ARE THEIR UNIQUE ATTRIBUTES? (ID #19)

Paul Hansen, Flad Architects, Madison, WI
Jared Machala, WSP USA, Houston, TX

Objectives:

- Recognize the criterion that influence confinement facility design and operation
- State the key engineering elements and controls that differentiate confinement facilities from bio-containment facilities
- Review industrial hygiene needs and operational hazards demanded and presented by facilities of this type

Method: Confinement facilities' goals are to confine, secure, and safely manipulate hazardous material and its associated waste and to minimize the risk of cross-contamination, while biocontainment facilities maintain containment systems, preventing the release of pathogenic material. Utilizing relevant projects, the team will present and discuss the planning, programming and design attributes of chemical and radiological confinement facilities. This presentation will highlight recently designed and constructed facilities, discussing their unique features and the extent these facility types draw from biocontainment industry concepts.

Results: An understanding of the unique attributes of confinement labs, as compared to their bio-containment counterparts, including the type(s) and allowable quantities of materials housed, material surety considerations, regulatory criteria, health physics considerations, primary and secondary confinement approach, cross-contamination considerations, lab room integrity, and engineering systems attributes.

Conclusion: An understanding of the lab and engineering systems and considerations that influence the design, construction, and operation of high-confinement facilities.

Outcomes: Understand the difference in regulatory, programmatic, and safety needs between confinement facilities and biocontainment spaces.

BIOSAFETY OF PLANT RESEARCH IN GREENHOUSES AND OTHER SPECIALIZED CONTAINMENT FACILITIES (ID #20)

Dann Adair, Conviron, Pembina, ND
Sue Tolin, Ruth Irwin, Virginia Polytechnic Institute and State University, Blacksburg, VA
Anne K. Vidaver, University of Nebraska, Lincoln, NE

Minimal biosafety guidance regarding plant science impacts present needs and offers little to assist emerging needs resulting from new technologies. An important distinction must be recognized: plant research focuses on environmental protection whereas traditional biosafety is about worker and subject protection. To address this need for guidance, a chapter, bearing the name of this presentation, in *Biosafety, Principles and Practices, 5th* edition, ASM Press, 2017 was created. The chapter describes agency regulations and guidelines for working with plants and related organisms grown in containment facilities. Containment related to biotechnology is seldom a regulated situation but the guidance offered in the NIH Guidelines is universally accepted. A basic understanding of what constitutes containment and examples of containment facilities and specific design elements are presented. Management practices, including the need for appropriate signage, are also illustrated. Collaboration with leading professionals (co-authors Tolin, Vidaver, and Irwin) was key to assembling the chapter. Literature reviews and consultations with relevant agencies and professionals were the basis for compiling regulatory and guidance materials. Experience on design teams and facility management contributed to the thorough understanding of specialized facility features. Discussions at an annual biosafety course indirectly solicited the community resulting in a new plant containment symbol. This new symbol serves to counter the misapplication of the universal biohazard symbol. While it is important to identify plants grown under containment, seldom is there a risk to humans. Reserving the universal biohazard symbol for the appropriate risk ensures its validity.

TITLE PREVALENCE OF TUBERCULOSIS INFECTION AMONG PARAMEDICAL STAFF WORKING IN LAB
(ID #21)

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Objectives: The risk of infection for health care workers is higher as compared to other careers, and people working in laboratories are at higher risk. The increasing prevalence of drug-resistant TB is alarming. Healthcare workers in hospitals perform in the absence of appropriate infection control policy and practices. This lack of standardized procedures creates a favorable environment for the transmission and spread of TB from hospital patients to hospital workers.

Method: A survey was performed along with blood sample analysis (for the presence of tuberculosis) of 150 laboratory workers. Mtb antibodies were detected by the Quantiferon T.B Gold Elisa method. Positive test results were confirmed by a PCR method using specific primers. All workers directly dealing with processing and disposal of clinical samples within last three years were included. All paramedic staff with pre-exposure with TB infection were excluded.

Results: After performing the Elisa test on 150 lab workers'samples, 29 were found to be positive for the presence of TB antibodies. 25 samples were confirmed further by PCR testing. Demographic data showed that 78% of workers did not receive any prior biosafety training, while 66% of workers had no access to proper PPE. Prior vaccination was not available for employees either.

Conclusion: Absence of appropriate infection control policy and biosafety practices in labs of hospitals created a favorable environment for transmission and spread of TB among hospital patients and hospital workers. Surviliance studies and infection control measures are needed for the workers' well being.

Outcomes: The survey has highlighted the importance of biosafety for the welfare of health care workers, with a special focus on laboratory workers.

AMPOULE OPENING DEVICE: LESSONS LEARNED FROM INCIDENT STUDY OF SHARP INJURIES (ID #22)

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Anastasia Shutov Petit, British Standards Institution (BSI), Reston, VA

Objectives: High incident of injury exists when opening a glass ampoule without employing a safety device. Not all safety opening devices ease the opening of a glass ampoule, and may actually introduce a hazard. Reoccurring education and training are critical.

Method: Gaithersburg Safety, Health, and Environment (GB SHE) department conducted an investigation of an incident involving the opening of a glass ampoule containing a 16% Paraformaldehyde (PFA). Following further research, it was determined that a common practice amongst the research staff for opening ampoules was by free-hand handling techniques. The risk for a sharp injury was high when not using an ampoule opening device. The objective of this assessment was to determine a safer method for opening glass ampoules and to spread awareness to other employees in prevention of sharps injuries.

Results: An alternative device for opening an ampoule was researched and tested by the GB SHE group and research staff.

Conclusion: It was concluded that not all ampoule opening devices provide ease-of-use and should be tested prior to implementing into laboratory procedures.

Outcomes: Incidence of injury from opening glass ampoules drastically dropped.

ANALYSIS OF FERRET BITE INCIDENTS AT CDC (ID #23)

Christopher M. Sieradzki, William Taylor, George W. Lathrop, Jr., Nathaniel Powell, Jr., Eduardo Gomez, Centers for Disease Control and Prevention, Atlanta, GA

Objectives:

- Outline the analysis of laboratory incidents involving ferret bites
- Identify common factors leading to these incidents
- Describe safety recommendations for safe handling of ferrets in laboratory setting

Method: Ferrets (*Mustela putorius furo*) are commonly used as an animal model in biomedical studies, including research on several infectious agents. However, their unpredictable behavior and occasional aggressiveness can lead to bites and scratches incurred by animal care/veterinary personnel. Laboratory incidents involving ferrets occurring at CDC during the past 5 years (2013-2017) were reviewed and analyzed. This included evaluation of incident risks, sustained injuries, potential for exposure to infectious agents, root-cause, and findings with corrective actions.

Results: Between Jan. 1, 2013, and Dec. 31, 2017, over 4000 ferrets were housed and used for research at CDC vivaria. During the same period, 11 ferret-related incidents were reported. Most injuries (hand/finger bites) occurred during routine ferret handling/treatment and involved naïve animals, thus presented no or very low risk of infection. Institutional SOPs were followed and the appropriate PPE was used. Root cause analysis revealed that the incidents were primarily caused by aggression.

Conclusion: Given the anatomic features of the ferrets (making mechanical restraining difficult), the understanding of the ferret behavior is the key to the application of safe manual restraint performed on this species. Considering the challenges posed by the large numbers of ferrets housed and handled at CDC and their unpredictable nature, the low frequency of incidents involving these animals indicates safe management of the CDC animal program ferret operations.

Outcomes: Increased awareness of risks and the application of risk mitigation protocols related to work with the ferrets.

TITLE CENTRIFUGE BIOSAFETY IN BL-2 RESEARCH LABORATORIES AND UPGRADES; CASE STUDY
(ID #24)

David M. Ndegwa, Karen B. Byers, Melissa McCullough, Dana Farber Cancer Institute, Boston, MA

Objectives: Compliance with the OSHA Bloodborne Pathogen Standard 1910.1030 containment equipment section (e)(2)(iii)(A), requiring "centrifuge safety cups, sealed centrifuge rotors shall be used for all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols." Improvement of centrifuge safety/biocontainment procedures. Use of a consolidated biosafety response to address problems flushed out with an internal audit.

Method: 254 biological research registration documents were reviewed to determine the number of laboratories centrifuging human primary samples. A list of 167 labs in 9 buildings was generated. 145 centrifuges were checked to verify that safety bucket covers were available and functional gaskets present on sealed rotors. Quotes were obtained for needed bucket covers, gaskets, and safety features from 5 vendors and funds were requested.

Results: 71 out of 145 centrifuges required buckets covers, gaskets, or lid support repairs. A request for funding was approved to correct the deficiencies. One obsolete centrifuge was confiscated. Supplies were delivered, and training provided to laboratory staff at that time. Stickers were applied to centrifuge lids to reinforce of proper practice.

Conclusion: This exercise generated goodwill with the laboratories, and improved both regulatory compliance and centrifugation safety.

Outcomes: This exercise established safer centrifugation engineering control, generated goodwill with the laboratories, and improved both regulatory institute-wide compliance and centrifugation safety.

DEVELOPMENT OF A BIOLOGICAL SAFETY CABINET TRAINING FOR AFRICAN PUBLIC HEALTH LABORATORIANS (ID #25)

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Philip Lee, Florida Department of Health, Jacksonville, FL
Maureen Sullivan, Minnesota Department of Health, Saint Paul, MN
Lucy Atieno Mambo, Association of Public Health Laboratories, Nairobi, Kenya

Objectives: With the assistance of the Association of Public Health Laboratories (APHL) and as part of the Global Health Security Agenda (GHSA), a biological safety cabinet (BSC) training was developed for hospital laboratorians in Ethiopia, Kenya, Tanzania, Uganda, and Ghana. The training addressed gaps in biosafety practices through hands-on learning. Attendees were evaluated on their ability to identify risks and consequences associated with improperly using a BSC to process infectious materials. Laboratorians were provided assessment tools to incorporate during the training which highlighted safe work practices.

Method: During the training, gaps in biosafety practices were identified including a lack of training on proper safety procedures. This was reinforced after visiting local hospital laboratories to observe the workflow and utilization of BSCs in a clinical setting. Based on observations during these visits, training material was adapted for each country based on need.

Results: Over 80 attendees of varying experience and education received extensive didactic and hands-on experience in how to safely work within a BSC, BSC operation and decontamination procedures. Attendees gained knowledge in how a BSC could better protect laboratorians, the environment, and the samples being processed.

Conclusion: The successful implementation of this training has initiated the first step to a safer biosafety program. Many Attendees noted that while they have BSCs, they preferred working on benchtops since they had never received training on how to work within a BSC. They now have a better understanding on why and how BSCs should be used while processing.

Outcomes: This program can be utilized for the development of a train-the-trainer program or as a model for other regions within Africa. The course was well received by each of the nations' health ministries and has been requested as an annual training.

BIORISK MANAGEMENT VACCINE FIELD GUIDE FOR THE JORDANIAN VETERINARY SERVICES (ID #26)

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Marian Downing, Biosafety Consultant, Kemah, TX

Objectives:

- Extend the biorisk management knowledge and practices among field workers for vaccination efforts
- Create written comprehensive guidelines
- Restate the knowledge among workers to protect themselves, farmers, other farms and the community

Method: Obtained approval for the project, and performed an oral pre-assessment of the field workers knowledge to ascertain any gaps in knowledge and behaviors related to safe field vaccination practices. Subsequently, a written questionnaire was administered to determine workers knowledge and a review of pre-existing documentation and published references on relevant topics. Using the results from the pre-assessment and the written questionnaire, a draft of the field vaccination guide was prepared and reviewed by various stakeholders to assess its comprehensiveness. Finally, a satisfaction survey was administered, followed by completion and distribution of the field guide.

Results: Our findings showed a great disparity in the knowledge of field workers about the biological risks associated with vaccination management. This disparity was evident among veterinarians and paraprofessionals. These findings were a key driver for the development of this field guide. Reviewers of the initial draft of the guide have emphasized that the guide will have a great impact on increasing the knowledge of field workers and will help to develop skills and raise awareness of the need to protect themselves and others from these biological hazards in the future.

Conclusion: This project demonstrated the importance of developing a comprehensive field guide to help protect field workers and enhance their knowledge and performance in the future

Outcomes: The field guide will be disseminated and distributed at 55 veterinary centers in Jordan, and will greatly benefit field work. Future plans include training to maximize the effect and achieve proper implementation.

DEVELOPMENT OF A LABORATORY-SPECIFIC BIORISK MANAGEMENT MANUAL FOR THE LABORATORY OF CLINICAL VIROLOGY AT THE PASTEUR INSTITUTE OF TUNISIA (IPT) (ID #27)

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Eilyn Fabregas, United States Department of Agriculture—APHIS, Riverdale, MD

Objectives:

- Build capacity and raise awareness
- Develop hazard-specific BRM policies, manual and training
- Mitigate biorisks, including general safety hazards

Method: Identified and prioritized topics to be included in a BRM manual based on biorisks and their level of severity. All LCV staff received training on the BRM manual. Training effectiveness and functionality of this manual was assessed using a tailored questionnaire whereby staff's level of understanding was evaluated.

Results: BRM manual included three main parts: general safety, policy and risk management system. We specified the purpose, principle, context, as well as definitions and roles and responsibilities of all the employees. The policy was written according to the LCV's core mission and value and the objectives that are needed to be accomplished. The laboratory chief committed to provide adequate resources, and ensure that biological agents are handled, stored and disposed of in a safe, secure and responsible manner. The manual was written following the AMP model and describes the procedure to be followed for the management of equipment, infrastructure, personnel, waste management, biosecurity, incidents and accidents, and spills. Also, SOPs were established in the local language, appropriate PPE and general safety equipment were purchased, and biological spill kits were developed. An evaluation questionnaire showed a high level of understanding of the manual and a good perception of its utility.

Conclusion: A BRM manual can change the safety culture, as well as mitigate risks, in the LCV. The ease of understanding the BRM manual and continuous training of the staff will be an asset to enhance the biosafety and biosecurity system in the laboratory, and IPT as an institution.

Outcomes: BRM manual, training, biorisk and general safety risk-mitigating activities, identification of needed PPE and other equipment, spill kits, etc.

APPLICATION OF A HAZARD ANALYSIS TOOL (HAT) FOR UNDERGRADUATE STUDENTS AND INSTRUCTORS IN MICROBIOLOGY TEACHING LABORATORIES AT THE HIGH INSTITUTE OF BIOTECHNOLOGY IN THE UNIVERSITY OF MONASTIR (ID #28)

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David E. Harbourt, United States Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD

Objectives:

- Develop risk assessment training for undergraduate students and instructors in the College Microbiology course laboratories at the High Institute of Biotechnology in the University of Monastir
- Design a risk assessment and hazard analysis worksheet for undergraduate students and instructors in the College Microbiology course laboratories along with a powerpoint presentation on the risk assessment process
- Evaluate course effectiveness using metrics obtained by pre and post assessment surveys

Method: Many students both in the United States and overseas receive extensive training in microbiology and other scientific disciplines but lack any formal risk assessment training. Here, we developed both a risk assessment training program along with formal worksheets to allow students and instructors to identify and mitigate risks in the laboratory. Pre and post assessment surveys were conducted for each class of students and instructors to evaluate course effectiveness.

Results: All students and instructors completed the formal risk assessment training along with the pre and post assessment surveys. Data analyzed from the surveys indicates a significant difference ($p<0.05$) between risk assessment understanding in both the student and instructor cohorts. Students also were able to complete the hazard analysis worksheet which has aided their understanding of laboratory hazards.

Conclusion: Understanding the risk assessment process is vital for all laboratory personnel and can improve laboratory safety practices and research institute support for safety.

Outcomes: The development of this training program and worksheets can serve as a model for formal risk assessment training in laboratory hazards both in the United States and abroad.

DEVELOPMENT OF A NATIONAL TRAINING PROGRAM FOR BIOSAFETY AND BIOSECURITY IN PAKISTAN (ID #29)

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Furqan Ahmed, Javed Muhammad, Pakistan Biological Safety Association, Islamabad, Pakistan
Lexy Jamison, Stacey Knobler, Zeba A. Rasmussen, National Institutes of Health, Bethesda, MD

Objectives:

- Articulate PBSA's missions and goals
- Restate PBSA's activities
- List PBSA's accomplishments

Method: Life sciences research is rapidly increasing in institutions across urban and rural Pakistan. The Global Health Security Agenda denotes that laboratories need expert training in biorisk practices. The Pakistan Biological Safety Association (PBSA) was established to disseminate biorisk training and has collaborated with Fogarty International Center (FIC) since 2013 to train professionals in biosafety and biosecurity protocols. PBSA and FIC have conducted training workshops throughout Pakistan, teaching ~730 health professionals from >250 institutions and producing 36 master trainers. PBSA and FIC have designed biorisk management curricula and implemented regional/national training workshops with external consultants. The program has grown in scope through deliberate selection of institutions from remote areas. Social media and online resources have been employed to boost impact. Outstanding Attendees are selected to be trained as master trainers.

Results: PBSA engages universities and private sector institutions in biorisk training. Public-private partnerships are created for sustained impact. Provincial chapters conduct outreach activities with local master trainers. Curricula have been translated into Urdu (national) and regional languages. Workshops include biosafety awareness, training-of trainers, ISO 35001, IBCs, HROs, and biosafety cabinets. Long-term impact will be evaluated. We plan to develop a state-of-the-art national biorisk training center. PBSA is now part of the Pakistan National Laboratories Working Group and has over 20 IFBA certified professionals.

Conclusion: The progress PBSA has made in bringing biosafety to remote and under-resourced areas in the country is novel.

Outcomes: PBSA is a success story that can serve as a model for other countries.

BIOSAFETY AND BIOSECURITY CONCEPTS AND ISSUES FOR THE MALIAN PUBLIC HEALTH COMMUNITY AND PROMOTION OF MALIAN ASSOCIATION FOR BIOSAFETY AND BIOSECURITY (MABB). (ID #30)

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Objectives:

- Develop three flyers to increase awareness of biosafety and biosecurity concepts and issues to the general public community, hospital and laboratory workers in Mali
- Design a satisfaction survey to provide information and an evaluation on how effective the flyers were in regards to Institutional and public awareness of biosafety and biosecurity
- Assess the usefulness of the flyers through satisfaction surveys using developed survey questionnaires

Method: We have developed tools to increase awareness of biosafety and biosecurity issues and concepts. We are providing these flyers to the public health community of Mali in order to introduce the proper biosafety and biosecurity concepts to the Malian community and to promote the Malian Association for Biosafety and Biosecurity (MABB) to the Public Health community as an expert resource.

Results: Three flyers were developed for this purpose: A flyer defining biosafety and guidance on how it can help prevent unintentional exposures by providing guidelines for proper PPE, guidelines for proper removal of gloves and guidelines for proper hand washing. A flyer defining biosecurity, why access control and inventory control are important and how these controls relate to the public health labs in Mali and a flyer promoting the Malian Association for Biosecurity and Biosafety (MABB) by providing the community with information regarding the vision, mission, fundamental values, partners and services provided by MABB.

Conclusion: These flyers were distributed to the Malian Public Health community and satisfaction surveys were provided and collected. We were able to ascertain that the flyers benefited and raised awareness to the Malian public health community.

Outcomes: The concept of biosafety and biosecurity is new to Malians. We sensitized people to differences between the two concepts.

WASTE MANAGEMENT AND CONTROL IN ANIMAL HOUSE ISOLATION BUILDING OF CLEVB: EVALUATION OF DISPOSAL OF SPECIMENS AND BIRD CARCASSES AFTER CHALLENGE WITH VIRULENT BACTERIAL STRAINS. (ID #31)

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Selim Salama, Central Lab for Evaluation of Veterinary Biologics (CLEVB), Cairo, Egypt

Objectives:

- Identify hygienic methods for handling of lab animal carcasses and specimens post challenge with virulent bacterial strains
- Determine effective methods for safe decontamination of contaminated clothing and equipment, and disposal of carcasses and specimens
- Protect the workforce and external environment from contamination

Method: Evaluated the strategies applied for waste management in order to protect people and environment from contamination: hygienic disposal of the dissected carcasses by incineration in the animal house isolation building; effective cleaning of equipment and buildings with detergents; and disinfection using phenolic compound, aldehydes, oxidizing agents, halogens or quaternary ammonium compounds. Tested and monitored the biological safety cabinet after use (after re-isolation of challenge strain), lab benches and the building work site after disinfection by distribution of TSA medium plates then incubated overnight.

Results: The ability to recover viable organisms following treatment of the building and biosafety cabinet with disinfectant was varied according to the disinfectant used (details mentioned in table). In case of bacterial growth, cleaning and disinfection should be repeated.

Conclusion: Disposal of biological wastes, especially carcasses and biological specimens, need more attention. Efficient treatment and a good understanding of waste management and control is necessary to avoid putting people at risk of fatal diseases and to avoid exposure of the environment to hazardous materials.

Outcomes: Effective cleaning and disinfection are needed for necropsy areas and carcass disposal to prevent workforce and environmental hazards. It is important to raise awareness of all contact persons and to increase public health interest concerning exposure to hazardous materials.

STEAM STERILIZATION OF POLYTETRAFLUOROETHYLENE (PTFE) FILTERS ON PLUMBING VENTS USING A PORTABLE STEAM GENERATOR (ID #32)

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Objectives:

- State how infectious aerosols from a biosafety level 3-agriculture (BSL3-Ag) room could reach a plumbing vent
- Describe a polytetrafluoroethylene (PTFE) filter assembly design
- Successfully apply steam as a PTFE filter housing sterilization method

Method: The Kansas State University Biosecurity Research Institute houses a large biocontainment facility. Drains from the BSL-3Ag area connect to a plumbing vent to accommodate gas expansion and release of unexpected pressure in the plumbing. Each vent location has two PTFE filter assemblies, in series. These filters prevent aerosols from entering the environment, if any, inadvertently pass through drain traps and enter the plumbing vent. A method was needed to decontaminate PTFE filters before evaluating filter integrity by conducting water intrusion tests or before filter change out. A portable electric boiler was used to develop this procedure. Biological indicators (BIs) were placed inside the PTFE filter assembly and on the inlet and outlet ports. The assembly was isolated by closing appropriate valves. Hoses were attached to the top and bottom valves of the housing and to the valve on the inlet side to drain condensate. A gauge was placed on the top side of the assembly to monitor pressure. Outer surface temperature was monitored using a thermocouple device. Steam was slowly introduced through the outlet side of the housing until the temperature reached 120°C. Air within the system was bled out through the valve on top of the assembly. Pressure was adjusted using the bottom valve of the housing. Condensate was collected into a bucket containing disinfectant. Steam was applied for a minimum of 30 minutes at 120°C and 15 psi.

Results: All BIs were negative for growth.

Conclusion: Using a portable steam generator is a practical method for PTFE filter housing sterilization.

Outcomes: This method is routinely used at K-State BRI for PTFE filter assembly sterilization.

RISK ASSESSMENT OF DECONTAMINATION PROCEDURES AT PRINCESS HAYA BIOTECHNOLOGY CENTER (PHBC) IN JORDAN (ID #33)

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Objectives: The present study was to evaluate effectiveness of decontamination procedures and to identify the gaps in the current process. To use risk assessment results to influence mitigation measures to prevent disease transmission, and to decrease risks of improper decontamination. To move a step forward added to other efforts to improve the biosafety program at PHBC based on the results of risk assessment.

Method: Several methods were used including observation of the working situations, evaluation of previous problems, revision of standard operating procedures (SOP), and interviews. All collected data were used to develop a survey questionnaire to assess the level of awareness, practices, training, and risk perception. The data from the survey was checked for consistency and completeness, managed using Microsoft Excel, and statically analyzed using SPSS software.

Results: Results analysis showed some gaps in the decontamination though no previous problems were reported. The results showed that 43% of attendees trusted the effectiveness of decontamination, 67% were not using chemical disinfection appropriately, 50% didn`t know decontamination procedures for different items, 66% thought that they have SOP but they didn`t, 25% were not immunized against HBV, and 77% need more signs and training. The statistical analysis results approved significant correlations (P value <0.05) between awareness, training, practices and perception.

Conclusion: Improving safety does not cost a lot, but failure to take simple precautions can cost a lot more. The next steps are to assess biorisks for other activities, and to look for validation methods to ensure that the system is working safely.

Outcomes: The designed mitigation plan included writing SOP, training, posting signs, and a program to vaccinate staff against HBV, to improves the decontamination procedures and provide higher protection.

CHEMICAL DECONTAMINATION STRATEGY FOR AN EFFLUENT DECONTAMINATION SYSTEM (EDS) USED IN A LARGE SCALE POLIO VACCINE MANUFACTURING FACILITY (ID #35)

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Ingrid Abbott-Permell, Biosafety Consultant, Toronto, Ontario, Canada

Objectives:

- Develop a road map to chemically decontaminate a large scale, Effluent Decontamination System (EDS) prior to decommissioning
- Determine the concentration and exposure time necessary to chemically inactivate Poliovirus using sodium hypochlorite (NaClO)
- Establish a simple method for measuring free chlorine concentrations during decontamination

Method: Decontaminating a large scale EDS used in Poliovirus Vaccine manufacturing can present a considerable biosafety challenge. At Sanofi Pasteur Limited, an overkill strategy was developed in order to safely decontaminate approximately 1300L of residual poliovirus contaminated waste, in a 4000L collection tank. After reviewing the CDC recommendations for the chemical treatment of poliovirus, the internal poliovirus inactivation study, along with a review of the current literature, an overkill method using 1.2% NaClO over a 24 hour contact time was developed. A road map, outlining the process, helped to identify risks, while commercially available test strips were used to monitor the levels of free chlorine.

Results: At the end of the decontamination, the pH was measured between 6.2-6.4, and the free chlorine ranged between 200-500mg/L. This chlorine value was compared to the CDC recommended values, stipulated in the report entitled, “Effect of Chlorination on Inactivating Selected Pathogens” which recommended a minimum free chlorine level of 0.5 mg/L and exposure time of 12 minutes, to achieve 99.99% inactivation. Since both NaClO and exposure time were both well in excess, decontamination was successfully achieved prior to disposal, and long-term shutdown.

Conclusion: By developing a structured road map, a safe and effective chemical overkill method to decontaminate the EDS was achieved.

Outcomes: A well-defined structured road map outlining the process, PPE and engineering requirements needed to treat large volumes of contaminated waste.

LARGE-SCALE DECONTAMINATION AND DECOMMISSIONING OF A VINTAGE HIGH-CONTAINMENT EFFLUENT DECONTAMINATION SYSTEM (EDS), PLANNING THROUGH EXECUTION (ID #36)

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Objectives:

- State and layout the various requirements needed to properly decontaminate and decommission (D&D) the vintage facility
- Obtain buy-in from key stakeholder groups early on in the process to define methods and the final expected end-state of the D&D facility
- Recognize the complexities of executing the planned work

Method: Perform a risk assessment based on the pathogens processed through the EDS and the feasibility of various decontamination options within the spaces to develop a decontamination plan for the facility. Separate the decontamination process for the facility into discrete tasks that are initially designed to reduce the overall risk with the facility and the EDS components, including primary containment piping and vessels. Remove all extraneous material and equipment from the facility. Depending on the pre-determined end state of the facility perform final D&D of the facility.

Results: Decontamination of the existing EDS facility has been broken into several discrete sub-systems and tasks. Several of these tasks can occur in parallel vs. series, reducing the impact to the overall schedule. The proposed approach has received buy-in from both internal and external SME's and management, while the end-state of the facility is still to be determined.

Conclusion: The complexities for decontaminating and decommissioning vintage high-containment spaces are well-known and understood by personnel working in them. Although the approaches are understood, the decontamination and decommissioning of the vintage EDS facility has unique challenges and depends on tailoring them to the facility, with considerations given to available infrastructure, risk tolerance, and final disposition.

Outcomes: Understand the complexities of decontaminating and decommissioning vintage high-containment facilities based on a case study of decontamination and decommissioning a vintage EDS facility.

EVALUATION OF DISINFECTION TECHNIQUES IN A MICROBIOLOGICAL LABORATORY (ID #37)

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Objectives:

- Measure environmental contamination at the Microbiological Laboratory, National Center for Disease Control and Prevention (NCDC) before decontamination
- Determine biochemical characteristics and antibiotic susceptibility of environmental isolates
- Measure decontamination effectiveness

Method: Following routine analyses of patient samples at the Microbiological Laboratory of NCDC, environmental samples were collected. Air samples were collected through sedimentation on Nutrient agar for 20 min or Mannitol Salt agar for 40 min. Surface samples were collected through washouts using MacConkey broth. Surfaces were disinfected with 70% ethanol, and the bactericidal ultraviolet lamp was operated for 1 hr; additional samples were then taken in the same locations using the same methods. Samples were grown in/on selective and differential media for 24-48 hrs at 37°C under aerobic atmospheric conditions. Isolates' oxidase and catalase production and antibiotic susceptibility were tested. Morphological, biochemical, and fermentative features and zones of inhibition of patient and environment samples were compared.

Results: In 2016-2017, surface samples from laboratory benches (80), door handles (36), and thermostat doors (72) and laboratory air samples (24) were analyzed. Prior to decontamination, 32 surface samples (17%) were positive for *Escherichia coli*; 8 air samples (33%) were positive for *Staphylococcus aureus*. Isolates' biochemical and antibiotic susceptibility characteristics matched those from patient samples. All samples taken after disinfection with 70% ethanol and bactericidal lamp operation were negative.

Conclusion: Current disinfection procedures in the Microbiological Laboratory kill *E. coli* and *S. aureus*.

Outcomes: Disinfection and decontamination rules and other biosafety requirements must be heeded to protect the laboratory, staff, and environment.

DEVELOPMENT OF A DECONTAMINATION AND BIOLOGICAL WASTE MANAGEMENT PROGRAM FOR THE ANIMAL HEALTH LABORATORIES IN THE JORDAN MINISTRY OF AGRICULTURE (ID #38)

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Melissa A. Mørland, University of Maryland, Baltimore, MD

Objectives:

- Establish a decontamination and biological waste management program for the animal health laboratories
- Develop standard procedures for biological waste handling, transport, and final destruction
- Design guidelines for decontamination of surfaces, equipment and materials

Method: A needs assessment was conducted to document current decontamination practices and gaps in training, documentation, validation, waste storage, and transport containers. During the assessment, agents processed in the laboratories were identified to determine if current detergent/decontamination methods were adequate. Based on the needs assessment, a hazardous waste manual and a disinfection and decontamination manual were developed. In addition, proper decontamination and waste practices were promoted through education and training as well as signage in the laboratories. Following the training, the laboratories were reassessed.

Results: The pre-assessment identified a number of gaps including: lack of training, use of the wrong disinfectants for biological agents, inappropriate contact times, segregation issues, and improper personal protective equipment for waste handling. Less than 10% of individuals had been trained and less than 50% were using appropriate PPE. Following the development of manuals and training, compliance in all areas showed a marked increase on reassessment.

Conclusion: The implementation of a disinfection and biohazardous waste management program in the animal health laboratories in Jordan Ministry of Agriculture will prevent potential threat to public health and the environment as well as reducing the risk of exposure to laboratory staff.

Outcomes: Proper documentation and training will ensure best practices are always in place to reduce the risk to both laboratory staff and the greater community.

FILTER-CAPTURE DNA ISOLATION: A FILTER STERILIZATION AND NUCLEIC ACID PREPARATION METHOD FOR THE DETECTION OF BURKHOLDERIA PSEUDOMALLEI IN URINE (ID #39)

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Objectives: The filter-capture DNA isolation (FCDI) method is a DNA preparation method for the rapid and sensitive detection of *Burkholderia pseudomallei* (Bp) by PCR in human urine samples. In the US, laboratory work with cultures of Bp must be performed in BSL-3 facilities. However, Bp DNA lysates are often transferred to BSL-2 for PCR analysis after confirmation of lysate sterility. The objectives of the current study were to evaluate: the sterilization performance, total operational time, and PCR detection range and sensitivity of FCDI.

Method: As a surrogate for clinical samples, we spiked human urine with the non-virulent Bp laboratory strain Bp82. FCDI lysates were prepared from the spiked urine samples by centrifugation using 0.1µm pore-size spin filter microfuge columns for cellular capture and lysis of the captured organisms directly on the filters. Some FCDI lysates (100% volume) were cultured on agar media for 5 days at 35^0C to evaluate the exclusion of viable bacterial cells. Additionally, FCDI lysates were used as templates for PCR to determine Bp82 detection range and sensitivity.

Results: The FCDI method was completed in less than one hour. No growth was observed from 20 cultured lysates after 5 days incubation on agar, and PCR yielded a detection range and sensitivity of 6.8 X 10^7 to 680 CFU/ml.

Conclusion: FCDI is a rapid and effective laboratory method for detection of Bp82 in spiked human urine at high to low cellular concentrations. Additionally, FCDI lysates are free of viable Bp82. Only minimal sample volume (450µl) and common laboratory equipment are required. FCDI reagents are also shelf-stable at room temperature.

Outcomes: The FCDI method yields DNA lysates of Bp82 that are free of viable bacterial cells. For labs that perform routine PCR detection of Bp, downstream DNA analysis of FCDI lysates could occur at BSL-2.