BUILDING BIOSAFETY AND BIOSECURITY
CULTURAL COMPETENCIES

Dana Perkins, PhD
Regional Occupational Health Conference
It’s a Small World: From Global to Local Threats
Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, 22 Oct 2016
‘Guided by Science’
President Obama Visits NIH, Touts Progress in Ebola Vaccine Effort
By Carla Garnett
On the front page...

In his Dec. 2 visit to NIH, President Barack Obama revealed two things about his approach to problem-solving: The U.S. will respond with compassion and science will lead the way. He used his time at what he calls “America’s laboratory” to congratulate scientists for delivering a potential Ebola vaccine and to champion scientific research once again as the nation’s most powerful weapon against global health threats.

“We are going to be guided by the science—not by speculation, not by fear, not by rumor, not by panic—by science,” said President Obama, in a 22-minute address to a packed Masur Auditorium. Earlier he had visited two NIAID senior investigators (see sidebar) and their labs in the Vaccine Research Center. With the briefings in Bldg. 40 and the speech in the Clinical Center, he spent about 90 minutes on campus.

“One of the things that has always marked us as exceptional is our leadership in science and our leadership in research,” the President said. “Here at NIH, you have always been at the forefront of groundbreaking innovations.”
“We are fortunate that biological threats have not yet resulted in a catastrophic attack or accidental release in the United States… we cannot be complacent but instead must take action to ensure that advances in the life sciences positively affect people of all nations while we reduce the risks posed by their misuse”.

National Strategy for Countering Biological Threats
Biosafety and Biosecurity Regulations, Standards, and Guidelines

**All Workplace Hazards**
OSHA General Duty Clause & other relevant standards (Regulatory)

**Certain Infectious Agents**
Transport, Export, Import DOT, DOC, CDC, APHIS (Regulatory)

**Bloodborne Pathogens**
OSHA Standard (Regulatory)

**Infectious Agents**
NIH/CDC BMBL (Voluntary)

**Select Agents**
HHS/USDA FSAP (Regulatory)

**Recombinant & Synthetic DNA**
NIH Guidelines (NIH funding condition)

**DURC policies**
(USG funding condition)

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The Federal Experts Security Advisory Panel (FESAP) was established on July 2, 2010 by Executive Order 13546 to provide recommendations related to the security of biological select agents and toxins (BSAT) to the Secretaries of Health and Human Services and Agriculture and the Attorney General.

The FESAP successfully completed the tasks enumerated by Executive Order 13546 and released the FESAP Recommendations Concerning the Select Agent Program report on November 2, 2010.

http://www.phe.gov/Preparedness/legal/boards/fesap

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Federal Experts Security Advisory Panel

- In Sep 2014, National Security Council tasked FESAP to make recommendations to enhance biosafety and biosecurity

- Report published in Dec 2014 contains:
  - 8 recommendations on actions and regulatory changes to improve biosafety and biosecurity;
  - 8 recommendations on optimizing biosafety, biosecurity, oversight, inventory management, and control of BSAT; and
  - An approach to determine the appropriate number of high containment labs required to possess, use, or transfer BSAT.

http://www.phe.gov/Preparedness/legal/boards/fesap
Identification of Actions and any Regulatory Changes to Improve Biosafety and Biosecurity

- FESAP Recommendations -

- Add a specific requirement for the documentation of the drills and exercises required in sections 11 (Security), 12 (Biosafety), and 14 (Incident Response) of SAR.

- Add a specific requirement to section 15 (Training) to include how a trainee can access the U.S. Department of Health and Human Services Office of the Inspector General (OIG) Hotline to anonymously report a safety or security concern.

- Address enhancements to the SAR Guidance

- Support the U.S. Occupational Safety and Health Administration (OSHA) Infectious Diseases Standard.
OSHA Infectious Diseases Standard

- OSHA is considering a program standard to address worker exposure to infectious diseases transmitted by routes (i.e., contact, droplet, airborne) other than the bloodborne route.

- Examples of infectious agents primarily transmitted by each of the three other transmission routes include:
  - Contact-transmissible agents (e.g., MRSA, noroviruses)
  - Droplet-transmissible agents (e.g., influenza viruses, B. pertussis)
  - Airborne-transmissible agents (e.g., M. tuberculosis, SARS-CoV)

- Examples of workplaces and job duties that will be covered:
  - Acute care hospitals  • Long-term care facilities
  - Home health care  • Ambulatory surgical centers
  - Physician’s offices  • Hospice care
  - Clinics embedded in non-healthcare settings (e.g., schools, prisons)
  - Mortuaries
  - Medical equipment reprocessing facilities
  - Research, diagnostic, and production laboratory facilities


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Infectious Diseases Rulemaking

Introduction

The healthcare and social assistance sector is among the largest of the industrial sectors in the U.S. As of 2013, there were 18.6 million employees in this sector, 11.7 million of those are classified as healthcare workers (HCWs). HCWs work in a great variety of settings. A large proportion of these HCWs provide direct patient care (i.e., they provide healthcare services with face-to-face or hands-on contact with patients) and have occupational exposure to infectious agents during the performance of their duties. Depending on the workplace setting and the job tasks, workers performing ancillary tasks (e.g., laboratorians, medical examiners, medical waste handlers) also have occupational exposure to infectious agents.

Employees in health care and other high-risk environments face long-standing infectious disease hazards such as TB, influenza and MRSA, as well as new and emerging infectious disease threats. OSHA is considering the need for a standard to ensure that employers establish a comprehensive infection control program and control measures to protect employees from exposures to infectious agents that can cause significant disease. Although the Bloodborne Pathogens standard has been very effective in protecting workers, it does not address infectious diseases transmitted by other routes (e.g., contact, droplet and airborne). In addition, OSHA believes that a standard is needed because transmission-based infection control guidelines, though readily available, are not consistently followed.

The Agency has thus far published an Infectious Diseases Request for Information (RFI), held stakeholder meetings, conducted site visits, and completed the SBREFA process. Feedback from these sources helped the Agency to further refine its development of a Notice of Proposed Rulemaking regarding an Infectious Diseases standard that is scheduled for publication in March 2017 TBD.
Create and strengthen a culture that emphasizes biosafety, laboratory biosecurity, and responsible conduct in the life sciences.

This culture of responsibility should be characterized by individual and institutional compliance with biosafety and laboratory biosecurity regulations, guidelines, standards, policies and procedures, and enhanced by effective training in biorisk management.
Implementation Plan

1) Develop and incorporate bioethics modules and quality system training into laboratory biosafety and laboratory biosecurity training and/or research design.
   • The training should include discussions of ethical and legal considerations, as well as the social relevance of life science research, and the range of dual-use concerns that arise due to the impact of science and technology on society, health, and national security.

2) Promote bioethics and quality system training (creating and implementing quality planning and assurance, as well as quality control and quality improvement) that includes curricula on conduct that incorporates fundamental safety and security responsibilities expected of all life scientists.

3) Develop semi-quantitative methods to evaluate the efficacy of training, education, codes of conduct, and similar interventions to reduce risk and improve safety in domestic research laboratories housing infectious agents and toxins

FESAP 1.1. Working Group

- U.S. Department of Health and Human Services (ASPR, CDC, NIH, FDA)
- U.S. Department of Agriculture (OSEC, APHIS, ARS, FSIS, NIFA)
- U.S. Department of Defense (USAMRIID, USUHS)
- U.S. Department of Homeland Security
- Environmental Protection Agency
- Federal Bureau of Investigation
- National Science Foundation
- Sandia National Laboratories

Co-Chairs: Dana Perkins, PhD (HHS/ASPR) and Eilyn Fabregas, PhD (USDA/APHIS)

Non-governmental experts participated in deliberations and provided feedback (AALAS, ABSA, APHL, ASM, Behavioral-Based Improvement Solutions, Elizabeth R. Griffin Foundation, Colorado State University, UTMB National Biocontainment Training Center, University of Georgia/CITS, National Academies of Sciences, North Carolina State University/CHSEMA, Emory University, Gryphon Scientific, Chrome Biological Risk Management Consulting, etc.)
Select resources

- **Developing a Culture of Safety in Scientific Research Webinar (ABSA)**
- BioSafe360 Weekly Program - *Leading a Culture of Safety Excellence* (Behavioral-Based Improvement Solutions, LLC)
- **A guide to implementing a SAFETY CULTURE in our universities** (APLU, 2016)
- **A Biosafety Checklist: Developing A Culture of Biosafety** (APHL, 2015)
- **On Being a Scientist: A Guide to Responsible Conduct in Research** (National Academy of Sciences, 2009)
- **Building a Global Biosecurity Culture - The Role of Biosafety Associations** (IFBA, 2016)
- **Doing Global Science: A Guide to Responsible Conduct in the Global Research Enterprise** (InterAcademy Partnership, 2016)

http://bioethics.gov/node/5678
Definition of Culture

An assembly of beliefs, attitudes, and patterns of behavior of individuals and organizations that can support, complement or enhance operating procedures, rules, and practices as well as professional standards and ethics designed to prevent the loss, theft, misuse, and diversion of biological agents, related materials, technology or equipment, and the unintentional or intentional exposure to (or release of) biological agents.
Foundational values of an organizational culture that emphasizes biosafety, biosecurity, and responsible conduct

- Research excellence
- Bioethics
- Biosafety and biosecurity

http://apps.who.int/iris/bitstream/10665/70507/1/WHO_HSE_GAR_BDP_2010.2_eng.pdf

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What elements should we consider for strengthening the organizational culture?

1) Management systems which prioritize biosafety, biosecurity, and responsible conduct

2) Behavior of leadership and personnel that fosters more effective biosafety and biosecurity

3) Principles for guiding decisions and behavior as they relate to biorisk management

4) Beliefs and attitudes on biosafety and biosecurity
Culture matters!

- Regulations or guidelines alone cannot ensure safe, secure, and responsible practices in the laboratory.

- A strong culture of biosafety, biosecurity, and responsible conduct includes willingness to report concerns, response to incidents, and communication of risks.
Working group-developed educational materials

- Fact Sheet
- *In Hindsight: Scenarios that Illustrate the Importance of a Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences Research*
- Slide deck template for training / outreach
- Guiding Principles to Promote a Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences in the context of bioethics and laboratory quality management training (pending)
- Crossword puzzle

https://www.absa.org/ttMiscHandoutsPosters.html

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Building culturally competent organizations

- Develop guiding principles for communication and outreach, education and training, capacity development, raising awareness of norms and standards

- Define organizational culture indicators (and associated assessment - monitoring tools) to measure: a) outcome for evidence-based decision-making (e.g. on staffing, areas for improvement, choice of training programs); b) ability to detect changes associated with a particular intervention; and establish an ongoing evaluation framework

- Identify, collect, analyze, and disseminate lessons and best practices

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