CDC Coordinating Center for Infectious Diseases

Future Directions for Biosafety
Attention to Biosafety

- **GAO investigation** of proliferation and oversight of BSL-3 and BSL-4 laboratories (2007)
- **House Hearing** and GAO preliminary report (Oct. 2007)
- **Congressional Research Service report** (2009)
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U.S. Government Response to Biosafety Issues

- Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight
  - HHS, USDA co-chair
- Blue Ribbon Panel for Issues of Clinical Laboratory Safety
  - CDC

**Must ensure each effort does not conflict with the other**
Trans-Federal Task Force

• HHS announced establishment at October 2007 hearing
• 11 federal agencies involved
  – USDA and HHS co-chair
• Report to be presented to HHS and USDA secretaries for their consideration
Trans-Federal Task Force

Scope

- High and maximum containment (BSL-3 and 4) research laboratories in all sectors
  - Pathogens that affect humans, zoonotic agents, toxins, and agricultural pathogens
  - Outside scope: diagnostic and treatment facilities (non-research); licensed biomedical production facilities
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Trans-Federal Task Force
Charge

- Develop report that:
  - Reviews current framework for biosafety and biosecurity
  - Develops objectives and options for improvement
  - Develops specific recommendation(s) to address each objective
Trans-Federal Task Force Timeline

- Writing group began work in January 2008
- Public meeting Dec. 8-9, 2008
- Final recommendations due to Secretaries of HHS and USDA
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Trans-Federal Task Force
Areas Identified for Improvement

• Training
• Reporting laboratory incidents
• Reviewing protocols
• Biosafety guidelines
• Infrastructure
• Oversight
• Research
• Communication
Concepts Explored by the TFTF
BSL-3 and -4 Laboratories

- Coordination of biosafety oversight
- Identification of senior responsible official
- Biosafety review of all research protocols
- Available credentialed biosafety professionals
- Accreditation of biosafety management programs
- Effective infrastructure
- Effective public communication
- Training requirements
- Incident/accident reporting
Blue Ribbon Panel

- Charged to look at laboratory biosafety in clinical labs
- 13 invited participants
- Discussed biosafety concerns
- Key Question: What can CDC do to reduce risk of lab-acquired infections?
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Issues

- Clinical laboratories handle many specimens that may be infectious
- Recent reports indicate:
  - Biosafety training may be inadequate
  - Safety equipment may not be available
  - Safety procedures may need improvement
- Biosafety guidelines for clinical laboratories are needed
Clinical Laboratory Workers Are at Higher Risk for Certain LAIs

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<th>Organism</th>
<th>Risk/100,000 microbiologists</th>
<th>Risk/100,000 general population</th>
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<tr>
<td>Shigella</td>
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</table>

Regulations and Guidelines for Laboratory Safety

- OSHA General Duty Clause (29 CFR 654)
- Bloodborne Pathogens Regulations (29 CFR 1910)
- *Biosafety in Biomedical and Microbiological Laboratories*
- *Protection of Laboratory Workers for Occupationally Acquired Infections, CLSI M29-A3*
- *Medical Laboratories—Requirements for Safety, ISO 15190*
- State and local
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Recommendations from Blue Ribbon Panel to CDC

- Provide guidance for laboratory biosafety tailored for clinical laboratories
- Provide communication tools
- Provide information about biosafety training opportunities
- Develop a non-punitive surveillance system for LAI
- Expand role as source of credible information on laboratory biosafety
Other Recommendations

- Personnel certification programs could add safety training or continuing education to requirements
- Professional organizations could develop training programs and/or lab aids
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Guideline for Clinical Laboratory Safety (Proposed)

- Provide information about working safely with specimens potentially containing infectious agents
- Addresses issues specific for the laboratory discipline
- Recommends responsibilities of all involved
- Provides a risk assessment template
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Overlaps between BRP and TFTF

- Training
- Reporting laboratory infections/incidents
- Guidelines
- Research
- Culture of responsibility
Likely Next Steps

Biosafety

• Development of CDC guidance on laboratory biosafety for clinical laboratories—CDC
• Dissemination of Trans Federal Task Force document—HHS and USDA
• Development of a voluntary, non-punitive reporting system for LAIs—Unknown
Additional Issues Regarding Biosecurity

• Concerns about mishandling of select agents:
  – Bruce Ivins and Amerithrax investigation
  – Heightened awareness of increase in numbers of BSL-3 and -4 laboratories

• Reauthorization of the Select Agent regulation
Current Activities in Biosecurity

- Executive Order 13486—Strengthening Laboratory Biosecurity in the United States
- NSABB Working Group on Personnel Reliability
Executive Order Working Group

- **Chairs**: Department of Defense, HHS
- **Also**: State, Commerce, Attorney General, USDA, Transportation, Energy, Homeland Security, EPA, National Intelligence, NSF
Executive Order Activity

• Review and evaluate efficiency and effectiveness of:
  – Existing laws, regulations, and guidance for physical, facility, and personnel security and assurance
  – Practices with respect to physical, facility, and personnel security and assurance
Executive Order Sub Groups

• Transportation
• Select Agent Rule (risk stratification, inventory, accountability)
• Physical/Facility Security
• Oversight and Inspection Standard
• Personnel Security/Reliability
Executive Order

Activities

• Sub groups providing reports to inform a final report

• Public meeting in Bethesda MD, May 13-14, 2009

• Final report to President July 9, 2009
NSABB Working Group
Personnel Reliability

- Charged by Homeland Security Council Senior Director for Biodefense
- Recommend strategies for enhancing personnel reliability among those who have access to select agents
NSABB Working Group
Personnel Reliability (PR)

• Examined current government PR programs
• Identified optimal characteristics of reliable personnel
• Held public consultation April 3, 2009
• Full NSABB approved recommendations April 29, 2009
• Final recommendations to be transmitted to HHS
NSABB PR WG Recommendations

- Enhance extant personnel reliability measures; a formal PR program is not necessary
- Strengthen SRA process
- Enhance culture of responsibility and accountability at institutions
- Encourage professional societies to promote personnel reliability concepts
- Reduce or stratify list of select agents
U.S. Government to Consider Recommendations

- Trans Federal Task Force report
- Executive Order Report
- NSABB Recommendations
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Improving Biosafety and Biosecurity is Everyone’s Responsibility

• **Federal entities**: regulations and national level guidelines; coordination; oversight
• **Professional organizations**: standards, credentialing, certification
• **State entities**: specific regulations and guidelines; licensing and certification
• **Local entities**: implementation of rules and regs; oversight and accountability
• **Individuals**: safe and ethical conduct of research; compliance with regulations, guidelines and policies
For more information:

Janet K.A. Nicholson
Senior Advisor for Laboratory Science
CCID
jnicholson@cdc.gov