Current Clinical Laboratory Biosafety Practices

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State Hygienic Laboratory, Director
University of Iowa

APHL Annual Meeting
2019
Presentation objectives

• Review the clinical laboratory biosafety survey regarding biosafety practices
• Understand the needs of clinical laboratories
• Discuss the relationship between both clinical and public health laboratories in biosafety and biosecurity
College of American Pathologists: Historically: Safety – Concern

First CAP checklist in 1965

<table>
<thead>
<tr>
<th>Private Office Laboratory</th>
<th>Hospital Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Director</td>
</tr>
<tr>
<td>Others who share the income from this laboratory: (Include Degrees)</td>
<td></td>
</tr>
</tbody>
</table>

**Pathologist's role in the hospital:**
- 1. Member of the active staff?
- 2. Member of the Executive Committee?
- 3. Other Committee Memberships:
  - a. Tissue Committee
  - b. Educational Committee
  - c. Record Committee
  - d. Medical Audit Committee
- 4. Past or present staff offices:
  - a. President
  - b. Vice President
  - c. Secretary
- 5. Teaching done by Pathologist:
  - a. Number of CPC's: Weekly __ Monthly __ None
  - b. Hours per week devoted to teaching:
    - Residents
    - Interns
    - Technologists
    - Nurses
    - (Others)

**Hospital Administrator:**
- Name

(Summarize briefly the attitude of the hospital administrator toward the pathologist and the department of pathology.)

**Other Hazards (Continued):**
- b. How are stool specimens discarded?
- c. How are animal carcasses discarded?
- d. How are unpreserved tissue specimens from surgical or autopsy material discarded?
- e. How are sputum cups, contaminated sponges, sops, etc., discarded?
- f. How are contaminated bench tops, incubators, furniture and floors cleaned?

Slides courtesy of Denise Driscoll, College of American Pathologists
***DISINFECTION OF BIOLOGIC SAFETY CABINETS***

Ventilation followed by UV radiation before and after handling cultures is recommended for day to day maintenance, but it is not adequate for thorough decontamination of a system. (UV light doesn't reach filters.) Effective decontamination of the entire system in situ can be achieved by means of gaseous fumigants, such as ethylene oxide, B. propiolactone, formaldehyde or glutaraldehyde. The latter two are preferable since ethylene oxide may be explosive if combined with CO₂ and B propiolactone is carcinogenic. Vaporization of about 30 cc of 10% formaldehyde per cubic feet in a sealed cabinet left to stand overnight is said to be effective. Ref: H.R. Barlow, "Safety in the Microbiology Laboratory", Soc. for Applied Bacteriology. Tech. Series No. 6. Academic Press.

Slides courtesy of Denise Driscoll, College of American Pathologists
Then – Summer 1974

Note – no “dump picking” (#7)

**DISPOSAL OF CONTAMINATED WASTES**

The following recommendations were abstracted from the 4th quarter CDC report on Nosocomial Infections.

1. Specific policies should be developed for the handling and method of disposal of all hazardous materials.

2. Hazardous materials should be either carefully flushed down the sewage system or doubly packaged in impervious plastic bags. (Ed. note: OSHA regulations require such packages to be clearly marked as to type of hazard and who to notify in case of accidental spillage).

3. Bacteriologic wastes should be either autoclaved or incinerated. (Ed. note: Flooding of plates with disinfectant prior to disposal is also recommended).

4. Blood specimens should be either carefully poured into the sewage system or double bagged and incinerated.

5. Pathology wastes should be double bagged and incinerated.

6. Solid materials which could cause injury (needles, scalpel blades, broken glassware) should be disposed of in rigid containers. Contaminated and potentially contagious materials should be either autoclaved, or double bagged and incinerated.

7. Non burnables may be either ground up and flushed into the sewer or disposed of into a sanitary land fill. Finally, scavenging or "dump picking" should not be permitted in any dumps receiving hospital wastes.

Slides courtesy of Denise Driscoll, College of American Pathologists
Then: Inspection and Accreditation Newsletters

March 1973

a. Departmentalization: Questions regarding the physical facilities, safety, personnel, procedures, quality control and instrumentation have been written to cover each department.

Winter 1981

A new safety checklist has been added to each technical manual. This is modified for each section, but most of it repeats the questions. The redundancy is regrettable, but necessitated by our highly variable inspection chores.

Slides courtesy of Denise Driscoll, College of American Pathologists
LABORATORY ACQUIRED INFECTIONS

Many of us continue to treat safety precautions in cavalier fashion. Some laboratories, unfortunately, "smarten up" only around inspection time. There is always a lurking killer and disbelievers are urged to read Fatal Salmonellosis Originating in a Clinical Microbiology Laboratory, Blaser, M.J. and Lofgren, J.P. J Clin Microbiol 13:855-858, May 1981.

Slides courtesy of Denise Driscoll, College of American Pathologists
An Experience with *Brucella*
Recounted by Joselyn Pribble
Biosafety Practices and Needs in Clinical Laboratories Survey

- Launched in June 2018
- Purpose: to determine needs in clinical laboratories
- Estimated target audience of 5,000 laboratories: 489 laboratories responded
- 376 stated they were defined as a sentinel clinical laboratory
- 147 stated they identified an Ebola Assessment Hospital
- 21 stated they identified as an Ebola Treatment Center
489 Labs Responded

Responses ranged from

- A high 11% in Georgia and New York
  (54 laboratories each)

- A low of 0.2% in Alaska, Alabama, Colorado, Kentucky, Michigan, Nebraska, and New Mexico
  (1 laboratory each)
Does your institution have staff who are responsible for biosafety?

34.7%, Yes, includes full time or part time

54.4%, No full time staff dedicated to biosafety but responsibility is allocated to multiple staff across all institutional laboratories

10%, No
How many staff in your facility are currently certified in safe packaging/shipping of International Air Transport Association (IATA) Division 6.2 Category A Infectious Substances?

<table>
<thead>
<tr>
<th>n</th>
<th>Total</th>
<th>Average</th>
<th>Median</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>489</td>
<td>2,743</td>
<td>6</td>
<td>4</td>
<td>0</td>
<td>100</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Range</th>
<th>Percentage</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-9</td>
<td>76.9%</td>
<td>376</td>
</tr>
<tr>
<td>10-24</td>
<td>11.2%</td>
<td>55</td>
</tr>
<tr>
<td>25-49</td>
<td>1.8%</td>
<td>9</td>
</tr>
<tr>
<td>50-74</td>
<td>0.4%</td>
<td>2</td>
</tr>
<tr>
<td>75-100</td>
<td>0.4%</td>
<td>2</td>
</tr>
</tbody>
</table>

No One 9.2%, n = 45
Does your institution have a biosafety plan in place?

YES = 91.4%
   n = 447

NO = 8.6%
   n = 42
Are you aware of the following Competency Guidelines?

YES  
55.2%  
N = 217

No  
39.7%  
N = 194
Have you developed safety-specific competencies for laboratory staff?

YES = 84.9%
   n = 415

NO = 15.2%
   n = 74

The majority were incorporation into their annual general competencies review. Other responses included laboratories were unaware of safety specific competencies and not being able to develop them due to time constraints.
From May 2015 to May 2018, did your institution complete risk assessments?

**YES = 56.4%**  
**n = 276**

- Yes at least one = 37.4% 183
- Yes - at least two = 19% (33)
- Yes – other = 10.6% (52)

**NO = 32.9%**  
**n = 161**

Annual risk assessments and general laboratory risk assessments, or utilizing risk assessments and evaluating risks when conducting LPX.
Has your staff received training on the following topics: 100% - 95%

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>YES</th>
<th>N</th>
<th>No</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sharps Hazard</td>
<td>99.6%</td>
<td>487</td>
<td>0.4%</td>
<td>2</td>
</tr>
<tr>
<td>Bloodborne Pathogens</td>
<td>99.4%</td>
<td>486</td>
<td>0.6%</td>
<td>3</td>
</tr>
<tr>
<td>Personal Protective Equipment (PPE)</td>
<td>99.2%</td>
<td>485</td>
<td>0.8%</td>
<td>4</td>
</tr>
<tr>
<td>Spill Prevention, Control, and Countermeasure</td>
<td>97.5%</td>
<td>477</td>
<td>2.5%</td>
<td>12</td>
</tr>
<tr>
<td>Chemical Hazards</td>
<td>95.9%</td>
<td>469</td>
<td>4.1%</td>
<td>20</td>
</tr>
</tbody>
</table>
Has your staff received training on the following topics: 94%-90%

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>YES</th>
<th>N =</th>
<th>No</th>
<th>N =</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biological Safety Cabinets (BSCs) and other Engineering Controls</td>
<td>92.6%</td>
<td>453</td>
<td>7.4%</td>
<td>36</td>
</tr>
<tr>
<td>BSL-2 safe practices (fundamentals of biological materials safety practices, excluding bloodborne pathogen training)</td>
<td>91.6%</td>
<td>448</td>
<td>8.4%</td>
<td>41</td>
</tr>
<tr>
<td>Regulated Waste Management</td>
<td>90.8%</td>
<td>444</td>
<td>9.2%</td>
<td>45</td>
</tr>
<tr>
<td>Emergency Management and Response</td>
<td>90.2%</td>
<td>441</td>
<td>9.8%</td>
<td>48</td>
</tr>
<tr>
<td>Continuous Quality Improvement (review, improvement, and implementation)</td>
<td>90.2%</td>
<td>441</td>
<td>9.8%</td>
<td>48</td>
</tr>
</tbody>
</table>
Has your staff received training on the following topics:  89%-30%

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>YES</th>
<th>N =</th>
<th>No</th>
<th>N =</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certification in packaging/shipping of IATA Division 6.2 infectious</td>
<td>89.4%</td>
<td>437</td>
<td>10.6%</td>
<td>52</td>
</tr>
<tr>
<td>substances (Category A)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decontamination</td>
<td>87.5%</td>
<td>428</td>
<td>12.5%</td>
<td>61</td>
</tr>
<tr>
<td>Biological Risk Assessment</td>
<td>69.3%</td>
<td>339</td>
<td>30.7%</td>
<td>150</td>
</tr>
<tr>
<td>Select Agent Regulations</td>
<td>67.1%</td>
<td>328</td>
<td>32.9%</td>
<td>161</td>
</tr>
<tr>
<td>Biosecurity Plan</td>
<td>64.6%</td>
<td>316</td>
<td>35.4%</td>
<td>173</td>
</tr>
<tr>
<td>BSL-3 safety practices</td>
<td>44.4%</td>
<td>217</td>
<td>55.6%</td>
<td>272</td>
</tr>
<tr>
<td>Safe Handling and Use of Cryogenic Liquids</td>
<td>30.5%</td>
<td>149</td>
<td>69.5%</td>
<td>340</td>
</tr>
</tbody>
</table>
### Additional training needs

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>%</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biosecurity Plan</td>
<td>16.2%</td>
<td>79</td>
</tr>
<tr>
<td>Select Agent Regulations</td>
<td>15.1%</td>
<td>74</td>
</tr>
<tr>
<td>Biological Risk Assessment</td>
<td>14.9%</td>
<td>73</td>
</tr>
<tr>
<td>Certification in packaging/shipping of IATA Division 6.2 infectious substances (Category A)</td>
<td>12.9%</td>
<td>63</td>
</tr>
<tr>
<td>BSL-3 safety practices</td>
<td>11.7%</td>
<td>57</td>
</tr>
<tr>
<td>Continuous Quality Improvement (review, improvement, and implementation)</td>
<td>9.4%</td>
<td>46</td>
</tr>
<tr>
<td>BSL-2 safe practices (fundamentals of biological materials safety practices, excluding bloodborne pathogen training)</td>
<td>7.8%</td>
<td>38</td>
</tr>
</tbody>
</table>
### Additional training needs

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>%</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency Management and Response</td>
<td>7.4%</td>
<td>36</td>
</tr>
<tr>
<td>Decontamination</td>
<td>7.2%</td>
<td>35</td>
</tr>
<tr>
<td>Regulated Waste Management</td>
<td>5.1%</td>
<td>25</td>
</tr>
<tr>
<td>Safe Handling and Use of Cryogenic Liquids</td>
<td>4.1%</td>
<td>20</td>
</tr>
<tr>
<td>Biological Safety Cabinets (BSCs) and other Engineering Controls</td>
<td>3.3%</td>
<td>16</td>
</tr>
<tr>
<td>Spill Prevention, Control, and Countermeasure</td>
<td>2.0%</td>
<td>10</td>
</tr>
<tr>
<td>Personal Protective Equipment (PPE)</td>
<td>1.0%</td>
<td>5</td>
</tr>
<tr>
<td>Sharps Hazard</td>
<td>0.6%</td>
<td>3</td>
</tr>
<tr>
<td>Bloodborne Pathogens</td>
<td>0.6%</td>
<td>3</td>
</tr>
</tbody>
</table>
If public health laboratory training was available to you at no cost, would you choose the following areas/topics?

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>YES (%)</th>
<th>N =</th>
<th>NO (%)</th>
<th>N =</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biological Risk Assessment</td>
<td>89.8%</td>
<td>439</td>
<td>10.2%</td>
<td>50</td>
</tr>
<tr>
<td>Biosecurity Plan</td>
<td>87.1%</td>
<td>426</td>
<td>12.9%</td>
<td>63</td>
</tr>
<tr>
<td>Certification in packaging/shipping of IATA Division 6.2 infectious substances (Category A)</td>
<td>84.9%</td>
<td>415</td>
<td>15.1%</td>
<td>74</td>
</tr>
<tr>
<td>BSL-2 safe practices (fundamentals of biological materials safety practices, excluding bloodborne pathogen training)</td>
<td>80.8%</td>
<td>395</td>
<td>19.2%</td>
<td>94</td>
</tr>
<tr>
<td>Continuous Quality Improvement (review, improvement, and implementation)</td>
<td>76.5%</td>
<td>374</td>
<td>23.5%</td>
<td>115</td>
</tr>
<tr>
<td>Select Agent Regulations</td>
<td>76.3%</td>
<td>373</td>
<td>23.7%</td>
<td>116</td>
</tr>
<tr>
<td>Emergency Management and Response</td>
<td>75.3%</td>
<td>368</td>
<td>24.7%</td>
<td>121</td>
</tr>
</tbody>
</table>
If public health laboratory training was available to you at no cost, would you choose the following areas/ topics?

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>YES</th>
<th>N</th>
<th>NO</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decontamination</td>
<td>67.5%</td>
<td>330</td>
<td>32.5%</td>
<td>159</td>
</tr>
<tr>
<td>BSL-3 safety practices</td>
<td>64.4%</td>
<td>315</td>
<td>35.6%</td>
<td>174</td>
</tr>
<tr>
<td>Biological Safety Cabinets (BSCs) and other Engineering Controls</td>
<td>63.8%</td>
<td>312</td>
<td>36.2%</td>
<td>177</td>
</tr>
<tr>
<td>Chemical Hazards</td>
<td>61.8%</td>
<td>302</td>
<td>38.2%</td>
<td>187</td>
</tr>
<tr>
<td>Regulated Waste Management</td>
<td>58.9%</td>
<td>288</td>
<td>41.1%</td>
<td>201</td>
</tr>
<tr>
<td>Spill Prevention, Control, and Countermeasure</td>
<td>57.5%</td>
<td>281</td>
<td>42.5%</td>
<td>208</td>
</tr>
<tr>
<td>Bloodborne Pathogens</td>
<td>57.3%</td>
<td>280</td>
<td>42.7%</td>
<td>209</td>
</tr>
<tr>
<td>Personal Protective Equipment (PPE)</td>
<td>50.5%</td>
<td>247</td>
<td>49.5%</td>
<td>242</td>
</tr>
<tr>
<td>Sharps Hazard</td>
<td>45.0%</td>
<td>220</td>
<td>55.0%</td>
<td>269</td>
</tr>
<tr>
<td>Safe Handling and Use of Cryogenic Liquids</td>
<td>36.2%</td>
<td>177</td>
<td>63.8%</td>
<td>312</td>
</tr>
</tbody>
</table>
How satisfied are you with the services and support provided by your public health laboratory biosafety officer?

n = 489
Briefly describe your rating of the public health laboratory biosafety officer.

• The majority rated the PHL biosafety officer very highly,
  – BSO very knowledgeable and communicate regularly, sending pertinent information on available trainings and available at all times for questions.

• Respondents saw the site visits as very useful.

• Some stated that they have not directly interacted with their PHL biosafety officer as of yet and would like more involvement and information from their biosafety officers.
What are your needs of a public health laboratory biosafety officer?

• More guidance and communication around laboratory biosafety was needed.

• Some stated that more in-person communications and visits across the laboratory would be helpful.
Training: What training materials do you use?

- Public Health Laboratory Provided Training: 67.7% n = 331
- Self Developed Training: 63.0% n = 308
- Purchased training: 32.5% n = 159
- Other - CDC and CAP developed training materials and trainings offered through hospital and health care systems: 16.6% n = 81
What training mechanism(s) do you currently use?

<table>
<thead>
<tr>
<th>Answer</th>
<th>%</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-Person/Classroom</td>
<td>65.6%</td>
<td>321</td>
</tr>
<tr>
<td>Online/Archived Webinar</td>
<td>58.1%</td>
<td>284</td>
</tr>
<tr>
<td>Online/Live Webinar</td>
<td>47.6%</td>
<td>233</td>
</tr>
<tr>
<td>Virtual Course</td>
<td>32.3%</td>
<td>158</td>
</tr>
<tr>
<td>Other - responses included hands-on drills, tabletop exercises and written procedures.</td>
<td>10.8%</td>
<td>53</td>
</tr>
<tr>
<td>Telephone (no web component)</td>
<td>4.5%</td>
<td>22</td>
</tr>
</tbody>
</table>
How do you identify biosafety training needs?

<table>
<thead>
<tr>
<th>Answer</th>
<th>%</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Accreditation/Certification checklist</strong></td>
<td>71.6%</td>
<td>350</td>
</tr>
<tr>
<td>Gap risk assessment</td>
<td>41.1%</td>
<td>201</td>
</tr>
<tr>
<td>None, do not evaluate</td>
<td>11.5%</td>
<td>56</td>
</tr>
<tr>
<td><strong>Other - individual staff competency assessments, review of public health laboratory resources, institutional safety inspections and site visits by consultants and public health laboratory staff, and mock drills and exercises.</strong></td>
<td>11.2%</td>
<td>55</td>
</tr>
</tbody>
</table>
CAP 2019: Safety – Major Laboratory Concern

LABORATORY GENERAL INDEX
Safety policies, procedures and records
Bloodborne Pathogens
Other Infectious Hazards
Fire Prevention and Protection
Electrical Safety
Chemical Safety
Compressed Gases
Radiation Safety
Environmental Safety
Other Hazards
Waste Disposal

MICROBIOLOGY CHECKLIST
Biosafety
Laboratory Safety
CAP: Biosafety GEN.74000

- Infection Control policies must comply with OSHA Bloodborne Pathogens Standard
- Engineering and Work Practice Controls to reduce or eliminate exposure to bloodborne pathogens

- 1991 OSHA Bloodborne Pathogen Standard requires
  - an employer must implement an exposure control plan ...

Slides courtesy of Denise Driscoll, College of American Pathologists
• Specific PPE requirements, with exception of glove use, is determined by facility and based on “reasonably anticipated exposure”

• Records of training/instructions for use of PPE

• If tasks are identified and required PPE stipulated, practice must match policy

• 1991 OSHA Bloodborne Pathogen Standard requires
  – ...ensure the use of personal protective clothing and equipment, provide training, medical surveillance, hepatitis B vaccinations, and signs and labels,...
Hand cleaning
- Personnel remove gloves, use an effective antimicrobial method
  - After manipulating biological samples
  - After each patient contact

1994 OSHA Hand Protection standard (29 CFR 1910.138) requires employers to select and ensure that workers use appropriate hand protection when their hands are exposed to hazards.

Slides courtesy of Denise Driscoll, College of American Pathologists
CAP GEN.75000

• Sterilizing Device Monitoring
  – Frequency must be defined
  – Biologic or chemical indicator
  – Test performed under conditions that simulate actual use

CAP Now - GEN.77900

Biohazard Disposal Containers
• All infectious wastes are discarded in labeled containers
• Container must be leak proof with solid tight-fitting covers
• Compliant with local regulations

Slides courtesy of Denise Driscoll, College of American Pathologists
MIC.19035, 19010

- MIC.19035 Safe Specimen Processing
  - Written policies and procedures
  - Tight sealing containers
  - Spills
  - PPE

- Benchtop Decontamination
  - Daily, with records

MIC.19840, 20520

- Biological Safety Cabinet
  - available per biosafety level
  - maintained
  - certified annually, with records
  - meets minimum requirements for testing performed

Slides courtesy of Denise Driscoll, College of American Pathologists
Briefly describe biosafety training needs for your facility and plans to address them.

- Packaging and shipping,
- Risk assessments
- Proper personal protective equipment usage.
- Biosafety plans,
- Biosafety competencies
- Regulatory requirements.

- Plans to address these needs included
  - online and in-person courses available through public health laboratories,
  - CDC
  - Consultants.
What top three conferences would you or your colleagues attend to strengthen your biosafety knowledge, skills and abilities?

• The majority of responses included
  – American Society for Microbiology (ASM) Microbe,
  – CDC International Biosafety Symposium
  – American Biological Safety Association Annual Biosafety and Biosecurity Conference.
APHL/CDC Biosafety Forums: Public Health Laboratory Outreach, Clinical Laboratory Engagement and Needs

- Regional one day forums inviting clinical laboratories from a jurisdiction
- Discuss the effectives of biosafety outreach programs and ongoing needs from public health labs and clinical labs
- Minnesota, North Carolina, US Affiliated Pacific Islands and California
- Aggregate report this summer
Thank you!

State Hygienic Laboratory at the University of Iowa
www.shl.uiowa.edu