Biosafety: Today and Tomorrow

Changing Biosafety Practices

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Presentation objectives

• Review what cultural change requires
• Understand the role of the Partner’s Forum
• Consider the future of biosafety in public health and clinical labs
Ebola cases and deaths among health care workers due to the outbreaks in West African countries as of November 4, 2015

This statistic displays the number of cases and deaths among health care workers related to the 2014-2015 Ebola outbreak in West Africa (and the DR Congo). As of November 4, 2015, there have been 378 cases among health care workers in Liberia, resulting in 192 deaths. The Ebola virus causes extremely severe hemorrhagic fever and is considered a Risk Group 4 Pathogen by the World Health Organization (WHO). The health sector will focus on cross-border regions to strengthen treatment, testing, and contact tracing.
More Ebola precautions needed, Mass. officials say

Healthcare workers are not immune to the fear of an emerging pathogen.

Nurses were motivated to make a change in biosafety practices during ebola.

- Meta analysis of all articles from 1983-1996 related to occupationally acquired infections among HCWs from English language publications
- 15 airborne infections: tuberculosis, varicella, measles, influenza and RSV
- Outbreak-associated attack rates range from 15-40%
- Most occupational transmission is associated with violation of one or more of three basic principles of infection control:
  - Handwashing
  - Vaccination of health care workers
  - Prompt placement of infectious patients into isolation
<table>
<thead>
<tr>
<th>Infection</th>
<th>Outbreak-Associated Attack Rate</th>
<th>Group of Health Care Workers Most Affected</th>
<th>Intervention</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuberculosis</td>
<td>20%–50% (6, 61)</td>
<td>Nurses (51), pathologists (61, 62), laboratory workers (63), housekeeping staff (64–66)</td>
<td>Airborne precautions with negative-pressure ventilation (67), regular skin testing (67), role of BCG vaccine not established</td>
<td>Recent deaths of several health care workers due to drug-resistant tuberculosis (6)</td>
</tr>
<tr>
<td>Varicella</td>
<td>4.4% (68)–14.5% (69)†</td>
<td>All</td>
<td>Airborne and contact precautions, vaccine (70)</td>
<td>Vaccine recently recommended (70)</td>
</tr>
<tr>
<td>Measles</td>
<td>Relative risk, 2.1–8.4 (71)†</td>
<td>Physicians, nurses (71)</td>
<td>Airborne precautions, vaccine</td>
<td>Health care workers are the source of many outbreaks (71, 72)</td>
</tr>
<tr>
<td>Influenza</td>
<td>45% (73); 3%–8% (74)†</td>
<td>Nurses (74), physicians (73, 74)</td>
<td>Droplet precautions, vaccine, amantidine</td>
<td>Compliance with vaccination is poor (75)</td>
</tr>
<tr>
<td>Rubella</td>
<td>13% (76)</td>
<td>All</td>
<td>Droplet precautions, vaccine</td>
<td>Pregnant health care workers with acute infection have opted for elective abortion (76, 77)</td>
</tr>
<tr>
<td>Mumps</td>
<td>Not available</td>
<td>Pediatricians, dentists (78)</td>
<td>Droplet precautions, vaccine</td>
<td>Respiratory precautions may be insufficient (79, 80)</td>
</tr>
<tr>
<td>Pertussis</td>
<td>43% (81)</td>
<td>All</td>
<td>Droplet precautions, vaccine, erythromycin (81)</td>
<td>Outbreaks in vaccinated persons (82); Clarithromycin and trimethoprim–sulfamethoxazole are possible alternatives (83)</td>
</tr>
<tr>
<td>Parvovirus B19</td>
<td>27%–47% (84, 87)</td>
<td>Nurses (84)</td>
<td>Droplet precautions</td>
<td>One pregnant health care worker gave birth to a normal child (88)</td>
</tr>
<tr>
<td>RSV infection</td>
<td>42%–56% (89, 90)</td>
<td>All</td>
<td>Droplet precautions, mask may be unnecessary (91–93)</td>
<td>Interventions resulted in less spread to other patients but not to staff (90)</td>
</tr>
<tr>
<td>Adenovirus infection</td>
<td>22%–39% (94, 95)</td>
<td>Staff in ophthalmology clinics (96–98), intensive care units (95, 99), long-term pediatric care facilities (94)</td>
<td>Droplet precautions, possibly contact precautions</td>
<td>Intubated patients may be more likely to transmit organisms</td>
</tr>
</tbody>
</table>

*For more detailed information about isolation precautions, consult reference 93. Numbers given in parentheses are reference citations. BCG = bacille Calmette-Guérin.
† Annual incidence, not associated with outbreak.
‡ Risk relative to age-matched controls who were not health care workers.
§ Rate on one ward.
|| Hospital-wide rate for all physicians and all nurses.
Interesting findings

- HCW who die of an occupationally acquired illness receive little public attention, yet CDC calculates that HBV causes 125-190 deaths/yr among HCW’s in the U.S.
  - Compare to very high profile of deaths in policemen (n=157) and firefighters (n=100)

- Data on HCW infections is also in short supply
<table>
<thead>
<tr>
<th>Group of Health Care Workers</th>
<th>Infection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Laboratory workers (205–207)</strong></td>
<td><em>Neisseria meningitidis</em> infection (208, 209), brucellosis (210), Q fever (211), hepatitis (205), typhoid fever (205), tularemia (205), tuberculosis (205), dermatomyositis (205), Venezuelan equine encephalitis (205), psittacosis (205), coccidioidomycosis (212), rickettsiosis (213), arbovirus infection (214)</td>
</tr>
<tr>
<td><strong>Animal workers†</strong></td>
<td>Cryptosporidiosis (141, 142), cutaneous larva migrans (213), toxocaral infection (216), lymphocytic choriomeningitis (217–219)</td>
</tr>
<tr>
<td><strong>Primate handlers (220)</strong></td>
<td>B virus infection (11), hepatitis A (220), yellow fever (220), Marburg virus infection (220), tuberculosis (220), simian immunodeficiency virus infection (221), shigellosis (222)</td>
</tr>
<tr>
<td><strong>Pregnant health care workers (223, 224)†</strong></td>
<td>Rubella, parvovirus B-19 infection, cytomegalovirus infection, varicella, echovirus infection, coxsackievirus infection</td>
</tr>
<tr>
<td><strong>Pregnant veterinarians (225)‡</strong></td>
<td>Brucellosis, tuberculosis, cryptococcosis, listeriosis, lymphocytic choriomeningitis, Q fever, toxoplasmosis, Venezuelan equine encephalitis</td>
</tr>
<tr>
<td><strong>Pathology workers</strong></td>
<td>Tuberculosis (226, 227), HIV infection (?) (228), hepatitis B (228), Creutzfeld–Jakob disease (228), Legionnaires disease (228), Lassa fever virus infection (228), anthrax (228), group A streptococcal infection (228), tetanus (228), typhoid fever (228)</td>
</tr>
<tr>
<td><strong>Surgery workers</strong></td>
<td>Hepatitis B (8), other infections caused by bloodborne pathogens (?) (229–231)</td>
</tr>
<tr>
<td><strong>Dentists</strong></td>
<td>Hepatitis B (57, 232), hepatitis C (16, 17), herpetic whitlow (197, 233), mumps (234), tuberculosis (235, 236)</td>
</tr>
<tr>
<td><strong>Anesthesia workers</strong></td>
<td>Hepatitis B (237), rhinovirus infection (238)</td>
</tr>
<tr>
<td><strong>Laundry workers</strong></td>
<td>Smallpox (239), salmonellosis (129), hepatitis A (131), scabies (193), Q fever (240)</td>
</tr>
</tbody>
</table>

* Numbers in parentheses are reference numbers. HIV = human immunodeficiency virus.
† Includes veterinarians and animal laboratory workers.
‡ Incidence not increased but potential risk posed to fetal development.
An Example of a dangerous profession:

U.S. Law Enforcement Fatalities in 2017 = 129/765,000 sworn officers = 0.17/Million
Working in a clinical laboratory is dangerous work. Our culture has come to accept the danger.

Emerging Infectious Diseases Vol. 11, No. 7, July 2005
The challenge of convincing clinical laboratories to invest time in Biosafety

- Barrier to getting the change in culture is for clinical labs to accept that investment in biosafety now will provide pay back in the future

IDEAL

WE ENVISIONED THAT TRAINING WOULD SOLVE THE PROBLEM

REALITY

Bang Head Here

WHAT IT FEELS LIKE
Biosafety is an organizational culture change.

• How long does organizational change actually take?
  • Compares getting an organization into shape is similar to getting one’s self into shape
    • The length of time it takes depends on where you are starting from
  • You can never really stop – the never-ending journey that depends on the goals, habits etc.
  • Most large organizations take about 3 years for change to occur

Changing culture is a collaborative project

• Execute culture change by doing four things:
  • **Research phase** – understand the current culture of biosafety in order to move to a new culture
  • **Convince leaders** that culture change can happen – many efforts in this area to educate leaders about biosafety
  • **Teach leaders** how to change it – in biosafety that is performing the risk assessment
  • Have a **formal “handoff”** – have someone in the clinical lab take ownership

Commitment from leadership  Commitment from employees  Innovation  Time  Ownership
APHL Biosafety Change Process Investment

CULTURE OF BIOSAFETY CHANGE PROCESS

1. Hire Biosafety Officers
2. Train Them
3. Risk Assessments for Public Health Labs
4. Build a Community of Practice
5. APHL & Biosafety Officers outreach to Clinical Labs
6. Provide training opportunities for Clinical Labs
7. Risk Assessment for Clinical Labs
8. Reassess and Adjust
9. Continue outreach to Clinical Labs

APHL Partners
- Forum
- Webinars

APHL Builds
- Tools

APHL Holds
- Regional Meetings

APHL Supports
- BSO COP
Partners Forum: A collaboration for culture change

- APHL led collaboration between Federal and private sector partners connected with clinical laboratories engaged in evaluating and improving PH and clinical lab biosafety and biosecurity practices in the US

- Convene an annual in person meeting (2016 and 2017) and 6 month follow up call
Biosafety and Biosecurity Partners Forum

Clinical Laboratory Biosafety Risk Management Program Assessment Checklist

Clinical Laboratory Survey

Disinfectant Webinar

Slide courtesy of Michael Marsico
Partners Forum Activities

• Beginning Challenges
  • Reviewed state of biosafety in clinical labs
  • Lack of familiarity with biosafety risk assessment process
  • Unknown risk of new technology ex. MALDI-TOF

• Future Activities
  • Potential regulatory action by some organizations
  • Adding additional biosafety items to checklists already in place
  • Continue to promote biosafety awareness
Current state of biosafety practice:

Many of the current biosafety practices are based on experience and expert judgment.

How can this be changed in the future?
In contrast, infection control practices are based on studies and collaborative discussions.
Research Needs

• Ritterson and Casagrande. March 2017. Basic Scholarship in Biosafety is Critically needed to reduce risk of laboratory accidents. mSphere. Applied and Environmental Science.
  • Article focuses on gain of function research for influenza, MERS and SARS
  • Biosafety assessment faced limitations because of missing data that results in stunning gaps in knowledge
  • “Governments invest billions in biological research; at least a small fraction of this support is warranted to prevent biological accidents.”
Identified Gaps: Lack of human reliability data

- No data on LAI caused by human error
  - Publicly available quantitative biosafety risk assessments done by others focused primarily on detailed measurements of equipment and mechanical failure rates, and omitted a quantitative treatment of human error entirely
    - Ex. motor control mistake results in spill or needle stick
    - Ex. the median chance of an exhaust fan failing is significantly less than someone improperly responding when the alarm sounds for the failure
  - Other industries (ex. airlines) invest heavily in studying human error
Lack of historical biosafety incident data

• Laboratory-acquired infections (LAIs) are important for evaluating the effectiveness of biosafety.
• There is no data on how mistakes have been made despite a clear need for record keeping.
• Other industries have a centralized tracking of incidents (ex. airlines, nuclear power and chemical manufacturing industries) and sharing the information industry wide in a no-fault system of reporting incidents and mistakes, no matter how minor.
• Reporting correlates with a decrease in risk.
Benefits of gathering these data

• Data gathering from human reliability and historical incident record keeping is a powerful tool to lowering risk
• Training, equipment and safety systems can be redesigned to prevent common mistakes before they happen
• It will also establish the risk assessment process in every facility
Ritterson and Casagrande recommendations

- Establishment of a national incident reporting system
- Primary research on human reliability
- Sharing best practices
  - “Given the vast gaps in knowledge that exist, a significant return on investment could be expected in terms of reduced biosafety risk in the near term, making this one of the safest research investments the federal government could make.”
Transforming biosafety into a quantitative practice

• We need evidence based data as the basis for recommendations
• Risk assessments identify mitigation needs but there is no data on which to base the mitigation selected
  • Ex. Risk of aerosols from some lab procedures
  • Ex. What is the benefit of PPE in certain testing circumstances
• Data on the containment effectiveness of equipment and laboratories are scarce and fragmented.
• The tendency is to over protect which leads some to disregard the recommendation
• Using evidence based data will enhance the effectiveness of biosafety measures as well as compliance with these measures
Future vision: Never ending process of continuous improvement - 10K foot view

1. Collection of data on human reliability
2. Collection of data on biosafety incidents
3. Evidence based data to support decisions
4. Develop mathematical models to support further development of knowledge of biosafety
Value of avoidance

• Unable to calculate the value of not having an exposure or not experiencing a lab acquired infection.

• The cost to prevent, control, and treat occupationally acquired infections is considerable, in terms of both dollars spent and lives affected.

• Incurring the risk for occupationally acquired infection is necessary for daily health care delivery.

• The willingness of health care workers to accept this risk is, in many ways, as important to health care as their professional skills.
## Costs for Lab Acquired Infections

<table>
<thead>
<tr>
<th>Costs</th>
<th>Time Range (min)</th>
<th>Direct Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MIN</td>
<td>MAX</td>
</tr>
<tr>
<td><strong>Exposure</strong></td>
<td>Inci</td>
<td>on</td>
</tr>
<tr>
<td>Notification</td>
<td>Inci</td>
<td>on</td>
</tr>
<tr>
<td>Incident occurs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occupational health, HR, supervisor, biosafety officer, laboratory director</td>
<td>15</td>
<td>$14</td>
</tr>
<tr>
<td>Notification</td>
<td>Initia</td>
<td>&amp; c</td>
</tr>
<tr>
<td>Initiate &amp; complete first report of injury, including witnesses (25 min, 5 min)</td>
<td>60</td>
<td>$55</td>
</tr>
<tr>
<td>Documentation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Review: first report of Injury by Safety Committee, director, biosafety officer, supervisor</td>
<td>120</td>
<td>$110</td>
</tr>
<tr>
<td>Travel</td>
<td>Travel to occupational health site</td>
<td>10</td>
</tr>
<tr>
<td>Patient/Physician Time</td>
<td>Review</td>
<td>exposure, review history, identify treatment</td>
</tr>
<tr>
<td>Review: follow-up Occupational Health</td>
<td>35</td>
<td>$32</td>
</tr>
<tr>
<td>Travel</td>
<td>Travel to pharmacy/Pick-up</td>
<td>10</td>
</tr>
<tr>
<td>Documentation</td>
<td>Costs of Rx</td>
<td></td>
</tr>
<tr>
<td>Lost Work Time</td>
<td>Lost productivity and reallocation of other workforce (175-235 per person)</td>
<td>350</td>
</tr>
<tr>
<td>Total</td>
<td>Total</td>
<td>760</td>
</tr>
<tr>
<td>Total (HRS)</td>
<td>Total (HRS)</td>
<td>12.7</td>
</tr>
</tbody>
</table>

**Other Costs**
- Emotional stress
- Review of protocols (individual, supervisory/management, Safety Comm)
- Retraining (individual, group, division)

**KEY**
- Patient Time
- Physician Time
Biosafety at a crossroads

• The funding is scheduled to end but we are hopeful that it will continue
• Through BSO efforts many more labs recognize the importance of biosafety
• Through the Partners Forum, other organizations are considering changes that will keep biosafety in the forefront