Addressing Legionella and Waterborne Pathogens in Healthcare with a Water Risk Management Plan

APIC Tri-Valley

November 14, 2012
Disclosure

I am employed by Pall Medical, a manufacturer of filtration, separation, and purification technologies for healthcare, biopharm, and industry.
Goals for Today

1. Recognize potable water as a source for gram negative infections.
2. Understand the impact of Waterborne Pathogens
3. What Waterborne Pathogen risks should you be concerned about.
4. What is ASHRAE Standard188
5. The scope of Standard188
6. Understand what is HACCP.
8. Who will be involved.
Healthcare-Associated Infections (HAIs)

1 of 22 US hospitalized patients will suffer an infection.

Total of 1.7 million persons will be infected.

$10+ Billion to treat these infections.

Approximately 99,000 will die from these infections.

According to the CDC$^1$
CDC Baffled By Legionnaire's Disease Cases Way Up In The US

19 Aug 2011
While older people and those living in the Northeast are most at risk, Legionnaire's disease occurs in all age groups and regions. Men account for 60% of the cases overall.

The number of cases reported to the CDC Prevention rose from 1,110 in 2000 to 3,522 in 2009. The incidence rate increased from 0.39 to 1.15 per 100,000 people during that time.

http://www.medicalnewstoday.com/articles/233072.php
Annual average percentage of legionellosis cases occurring annually, by month and U.S. Census region* --- United States, 2000--2009

Source: MMWR © 2011 Centers for Disease Control and Prevention (CDC)
Waterborne Pathogens Represent an Unrecognized Risk

Attempts to culture waterborne microbes using nutrient-rich media for short incubation periods (24-48 hours at 37°C) are often unsuccessful.

In addition, waterborne pathogens such as Legionella have even more specialized growth requirements. Legionella requires buffered charcoal yeast extract agar for cultures.

Waterborne microbes are adapted for survival in a nutrient-poor environment.

Waterborne pathogens can also transfer into a viable but non-culturable status (VBNS); not detectable by cultures. Only molecular analysis like PCR (Polymerase Chain Reaction) or FISH (Fluorescent In Situ Hybridization) are capable of detecting VBNS.

Successful culturing of waterborne microbes involves special media (R2A) and extended incubation periods (E.g. 25°C for 14-28 days).
Tap Water - A Reservoir for Risk

Tap water harbors potentially pathogenic microorganisms from biofilm on internal surfaces of pipes and fixtures.

High risk patients are among those at the greatest risk of infection caused by waterborne pathogens.¹

¹CDC (2003) Guidelines for Environmental Infection Control in Healthcare Facilities. MMWR, 52 (RR10);1-42
Drinking Water Supply Chain

Source → Water Plant → City Pipes → End User
Waterborne Microbial Pathogen Transmission

- Surface Corrosion
- Inorganic/Organic Nutrients
- Warm Temperature

Biofilm Growth and Shedding à Waterborne Pathogens

Tap Water

- Drinking Water
- Bathing/Showering
- Hand Washing
- Ice Production
- Rinsing Medical Equipment

Healthcare Workers

Environmental Surfaces

Patients
Sources of Waterborne Pathogen Exposure

- Direct contact with water streams
- Aerosols from showers and faucets
- Improperly reprocessed medical devices
- Ice from ice machines

Waterborne microbes enter into the healthcare environment via:
Biofilm Definition

A Microbially-derived sessile community.

Irreversibly attached to substratum, interface, or each other.

Exhibit altered growth rate and transcription phenotype.

Embedded in matrix of extracellular polymeric substances.
Hospital Water Distribution System

- Municipal Water Supply
- Hot Water Boiler
- Water Distribution Point
- Hot Water Recirculation
Biofilm release

- Water turbulence
  - A break in water main
  - Modifications/alteration to the building water system
  - Pump shut down & activation
  - Dynamic changes in flow
- Natural dissemination
- Other complex mechanisms
Amoeba - The Trojan Horse

- Amoeba-resistant organisms are not destroyed by free-living amoeba.
- Amoeba cysts are resistant to chlorination, adverse pH, osmotic pressure, and temperature.
- Amoeba have been recovered from drinking water, cooling towers, and hospital water networks.

Waterborne Microorganisms of Primary Clinical Significance

**Bacteria**
- *Pseudomonas aeruginosa*
- *Legionella pneumophila*
- Acinetobacter spp.
- Non-tuberculous Mycobacterium
- *Stenotrophomonas maltophilia*

**Fungi**
- *Aspergillus fumigatus*
- *Fusarium solani*

**Parasites**
- *Cryptosporidium parvum*
- *Giardia lamblia*
- Acanthamoeba spp.
Upon exposure to waterborne pathogens, several factors determine whether or not infection will occur:

- **Pathogen concentration**
- The **virulence** of the pathogen
- The **immune condition** of the patient
At-Risk Patient Populations

- Solid Organ Transplant
- Bone Marrow Transplant
- Burn
- Neonatal Intensive Care
- Pediatric Intensive Care
- Hematology/Oncology
- Surgical Intensive Care
- Medical Intensive Care
- Cardiac Intensive Care
- Respiratory Intensive Care
Waterborne Pathogens are Found in Both Cold and Warm Water in Transplant Units

<table>
<thead>
<tr>
<th>Cold Water</th>
<th>Warm Water</th>
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<tbody>
<tr>
<td>16.6° C (8.3° C – 28.9° C)</td>
<td>56.2° C (37° C – 74.6° C)</td>
</tr>
<tr>
<td>Legionella spp., 47%</td>
<td>Legionella spp., 55%</td>
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<tr>
<td>L. Pneumophila, 35%</td>
<td>L. Pneumophila, 45%</td>
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<tr>
<td>Protozoa, 42%</td>
<td>Protozoa, 70%</td>
</tr>
</tbody>
</table>

Environmental Surveillance and the Risk of Healthcare-Associated Legionellosis

- 20 hospitals without documented Legionellosis included.
- 5 water analyses within 2 years, at least 10 sample sites per test cycle.

Results:

- 14 of 20 hospitals (70%) were colonized with Legionella.
- 6 of 14 (42%) were highly contaminated (>30% of outlets).
- In 4 of 6 highly contaminated hospitals clinical Legionellosis was detected.

Polling Question 1

The presence of Legionella and other waterborne pathogens can be easily ruled out by simply submitting a water sample to the hospital microbiology laboratory for routine culture.
A. True
B. False
**Pseudomonas aeruginosa - A Critical Hospital Pathogen**

- *Pseudomonas aeruginosa* is responsible for up to 10-20% of HAIs in Intensive Care Units (Pneumonia, wound infections, blood stream infections and urinary tract infections).¹

- Several studies revealed that up to 40% of healthcare acquired *Pseudomonas aeruginosa* infections are derived from contaminated water distribution systems.

- POU filtration is a simple, successful, and highly cost-effective strategy to lower endemic *P. aeruginosa* infections in a Surgical ICU.²

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Non-Tuberculosis Mycobacterium – An Emerging Pathogen

Pseudo-Outbreak of “Mycobacterium paraaffinicum” Infection and/or Colonization in a Tertiary Care Medical Center

She-Hua Wang, MD, MPH/IM: Preeti Pancholi, PhD; Kurt Stevenson, MD, MPH: Mitchell A. Yek니, MS, MPH; W. Ray Butler, MS; Larry S. Schlesinger, MD; Julie E. Mangano, MD

OBJECTIVE. To investigate a pseudo-outbreak of “Mycobacterium paraaffinicum” (an official strain) infection and/or colonization, using isolates recovered from clinical and environmental specimens.

DESIGN. Outbreak investigation.

SETTING. University-affiliated, tertiary-care hospital.

METHODS. M. paraaffinicum, a slow-growing, non-tuberculosis species of mycobacteria, was recovered from 21 patients and an ice machine on a single patient care unit over a 2.5-year period. The clinical, epidemiological, and environmental investigation of this pseudo-outbreak is described.

RESULTS. Twenty-one patients with pulmonary symptoms and possible risk factors for tuberculosis were admitted to inpatient rooms that provided airborne isolation conditions in 2 adjacent hospital buildings. In addition, 1 outpatient had induced sputum cultured for mycobacteria in the pulmonary function laboratory. Of the samples obtained from these 21 patients, 26 isolates from respiratory samples and 1 isolate from 1 food sample were identified as M. paraaffinicum. Environmental isolates obtained from an ice machine in the patient care unit where the majority of the patients were admitted were also identified as M. paraaffinicum.

CONCLUSIONS. An epidemiological investigation that used molecular tools confirmed the suspicion of a pseudo-outbreak of M. paraaffinicum infection and/or colonization. The hospital water system was identified as the source of contamination.

Infect Control Hosp Epidemiol 2009; 30(S4):862-863
Polling Question 2

What percentage of Healthcare Acquired Pseudomonas cases in an ICU can be directly linked to potable water

A. 2%
B. 10%
C. 25%
D. 40%
So What Do We Do?
Proposed ASHRAE Standard 188

Prevention of Legionellosis Associated with Building Water Systems
Basics of Propose Standard 188

• Identify the hazards
  – Waterborne pathogen - *Legionella Spp.*

• How do you control the hazards
  – Validation

• How do you know the controls are working
  – Verification
The Guiding Principle

Hazard Analysis and Critical Control Points (HACCP)

– Began with NASA in the ’60’s
– Adopted by the food industry
– Has Seven Principles
Seven Principles of HACCP

• **Principle 1: Conduct a Hazard Analysis**
  – Create a Water Management Team
    • Should include stakeholders from multiple disciplines
    • Involve third parties as well.
  – Perform a Risk Assessment
    • Includes a Process Flow Diagram of Potable and Process water systems.
Seven Principles of HACCP

- **Principle 2: Identify Critical Control Points (CCP’s)**
  - Decide which are Critical.
  - Confirm accuracy by on-site inspection.
Seven Principles of HACCP

- **Principle 3: Establish Critical Limits for each CCP**
  - Regulatory requirements
  - Guidance and GMPs
  - Examples
    - Maintain temperature in hot water tank between X and Y °F.
    - Delivery hot water at faucets no hotter than X °F but less than Y °F.
    - Change Point of Use filters per specifications.
Seven Principles of HACCP

• Principle 4: Establish CCP Monitoring Procedures
  – Who does the monitoring?
  – What are you monitoring?
  – How often do you monitor?
Seven Principles of HACCP

- **Principle 5: Establish Corrective Actions**
  - Once monitored, if the CCP is outside of the Critical Limits
    - Follow the corrective action plan to bring the CCP back into specification
    - Document the actions taken
Seven Principles of HACCP

• Principle 6: Establish Record Keeping Procedures
  – Plan Development
  – Operations of Systems
    • Records of CCPs
    • Monitoring records
    • Corrective actions taken
  – Without recordkeeping, problems are more likely to recur
# HACCP Form

## HACCP PLAN

**PROCESS CATEGORY:**

**PRODUCT EXAMPLE:**

<table>
<thead>
<tr>
<th>CCP# and Location</th>
<th>Critical Limits</th>
<th>Monitoring Procedures and Frequency</th>
<th>HACCP Records</th>
<th>Verification Procedures and Frequency</th>
<th>Corrective Actions</th>
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**Signature:** ____________________________  **Date:** ____________________________
Seven Principles of HACCP

- Principle 7: Establish Procedures for Ensuring the HACCP System is Working as Intended
  - Validation of your site’s “Real Word” conditions
    - Review of your Process Maps
    - Review your CCP’s
    - Has there been changes?

<table>
<thead>
<tr>
<th>Product: Potable Water Processing Steps</th>
<th>System/subsystem</th>
<th>Identify potential hazard introduced, enhanced or controlled at this step</th>
<th>Risk and Severity Significant?</th>
<th>Basis for the Risk Characterization</th>
<th>What controls could be applied to eliminate, reduce or prevent the hazard from causing harm?</th>
<th>CP</th>
<th>CCP</th>
</tr>
</thead>
</table>
| P1 RECEIVING                           | General system   | **B = Biological Hazards**
Coliforms, Legionella, viruses, and protzoa
**C = Chemical Hazards**
Lead, other metals, and disinfection by-products
**P = Physical Hazards**
Radon                                      | No               | Low risk because water is treated to US Standards for drinking water given in the Code of Federal Regulations | Obtain product from sources that are certified to the National Primary Drinking Water Regulations (NPDWR)
Obtain water quality test results from the water provider every six months | B | No |
| S1 RECEIVING                           | Fire suppression | B = microbial growth due to stagnant water in FS system                    | No                             | Low risk because limited exposure | Wear PPE during routine maintenance and periodic flushing | B | No |
| P2 HEATING Steam Tables                | General system   | B = Growth of microbes in the heating system                               | No                             | Medium risk because no storage tanks | Maintain temperature in hot water loop above 140°F
Thermal flush hot water loop >120 °F periodically | B | NO |
| P3 DISTRIBUTION                        | General system   | B = Microbial growth in the potable water distribution system which could be transmitted by faucets and showerheads
**C = Toxins** could be transmitted by ingestion
**P = Scaling**                                      | Yes               | Low or medium risk because municipal water source has a measurable halogen residual in the building water system | Flush system x times per year
Chlorinate x times per year | B | YES |


Seven Principles of HACCP

• Principle 7: Establish Procedures for Ensuring the HACCP System is Working as Intended
  – Verification that your plan is working as intended.
    • Testing for Legionella bacteria.
    • Observation of your patient population (surveillance)
Summary of Key Points

- Create a Water Management Team
- Conduct a HACCP risk management survey.
- Document water systems and operation & maintenance as it relates to reducing/controlling Legionella bacteria.
- Maintain documentation of efforts.
- Verify that the controls are in “check.”
- Validation that the hazard (Legionella) is under control.
Polling Question 3

ASHRAE Standard 188 states that a healthcare facility is required to test for Legionella bacteria.

A. True
B. False
Thank You! - Questions?

steve_ebersohl@pall.com

239-220-8272