

Managing Risk and Liability for *Legionella* and Legionnaires' Disease in Healthcare Facilities



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The Program



- Background
- Risk Factors
- Healthcare
- Guidelines and Regulations
 - ASHRAE 188
 - CDC
 - ACHD
 - ACA
 - New York
- Risk/Liability Mitigation

1976

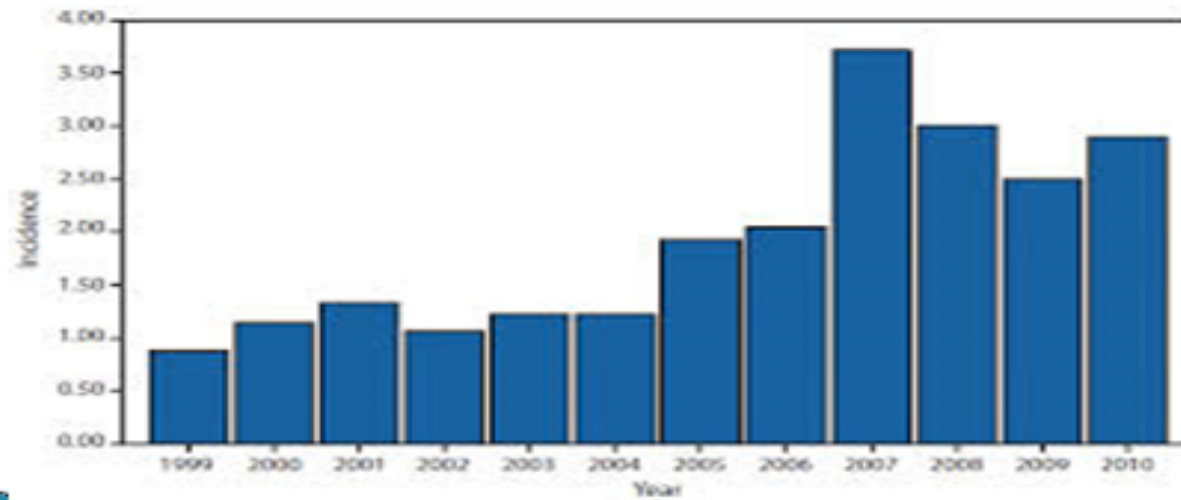


1976



What is Legionnaires Disease?

The Trend



2016 and Beyond...



- Experts predict Legionellosis cases will continue to increase across the globe...
 - Climate change- increased flooding events
 - Deteriorating infrastructure
 - Green technology encourages lower temperatures conducive to *Legionella* growth
 - Hands free devices in healthcare encourage proliferation of stagnant water
 - Increased surveillance/awareness on diagnosis
 - Improved public awareness/reporting
 - Improved laboratory processes for identification
 - Increasing aging population

2011-15



- 2011-12-32 Outbreaks associated with drinking water
 - 66% caused by *Legionella*
 - 50% in healthcare facilities
 - 56.3% surface water sources
- CDC Vital Signs- June 2016
 - People with LD grew 4x from 2000-14
 - LD deadly for 10% of those who contract it
 - Most problems preventable with good water management
- Reported cases increasing in USA, Europe, Canada, and relatively stable in Australia

Background-Risk



- **Why Should I Care?**

- Bodily Injury
- Property Damage
- Negative Publicity
- Relocation
- Remediation
- Legal Costs
- Business Interruption
- Affordable Care Act (ACA)



Risk Factors



Level/Species
Development of
Legionella

- Temperature
 - Growth Range- 68-122F
 - Dormancy- 32-77F and 122-139F
 - Death- 140F and above
- pH
 - 5.0-8.5

Risk Factors



Level/Species
Development of
Legionella

- Water Stagnation
- Complex Piping
- Dead Legs
- Long Runs
- Oversized Pipes

Risk Factors



Intensity of
Exposure
(Sources)

- Potable Water
- Non-potable Water
- Legionella is chlorine tolerant
- Incoming MUNICIPAL water with $<.5$ ppm residual chlorine and/or with excess **sediment**

Risk Factors



Intensity of Exposure- Sources

- Cooling Towers
- Potable Water Systems
- Evaporative Condensers
- Misting Systems
- Spas/Whirlpools/Hydrotherapy
- Respiratory Therapy/Bronchoscopes
- Decorative Fountains
- Showers
- Ice Machines
- Room Air Humidifiers
- Faucet Aerators
- Eye Washes
- Dental Water Lines
- Air Conditioners
- Car Washes
- And More...

Healthcare Risk



- **Healthcare Facilities- A Special Case**
 - Greatest risk due to susceptible population
 - Greatest liability (VA Hospital litigation)
 - Conflicting Approaches to Risk Mitigation



Healthcare Risk



- **Healthcare**

- Risk Exposure Points

- ✦ Higher probability of infection based upon:

- Intended use of water based processes
- Vulnerability of patients
- Estimate likelihood of legionellosis

- ✦ Areas with greatest risk should get greatest scrutiny:

- All clinical support areas (dietary, central sterile, etc.)
- All patient care areas (including dialysis, respiratory/hydrotherapy)
- All water use end points (spas, whirlpools, ice machines, cooling towers, pools, etc.)

Legionella Regulations/Guidelines



- ASHRAE 188- Regulation
 - Guidelines... Until Now
 - ASHRAE 2000, CDC 2003, AIA 2001, EPA 1991, WHO 2007, OSHA 1996, JCAHO 2001, AIHA 2015, CDC 2016, EPA-2016 and other state/local guidelines, ACHD
 - New York State Regulations
 - Affordable Care Act (ACA)
- Code Ready Language (potential legal force where adopted into building codes)
- Standardizes risk assessment, prevention, and management
- Compliance may be best defense to allegations of negligence/*Legionella* claims
- Requires a **Water Management Plan** (WMP) to control *Legionella*
- *American Society of Heating, Refrigerating, and Air Conditioning Engineers

ASHRAE 188



- **Where Does ASHRAE stand?**
 - Pro-active approach
 - Identifying and controlling the risk at critical control points should effectively manage the quality of the water with appropriate verification and validation
 - Position on testing left ambiguous in the absence of disease/problems but clearly testing can be utilized for validation
 - AIHA 2105- recommends testing for hazard recognition even though the presence does not necessarily equate with disease.

ASHRAE 188



Does
ASHRAE
188
Apply To
Me?

- **Do I Need a WMP?**
- Multiple housing units with central potable water heater;
- Buildings more than 10 stories (including any sub-levels);
- In patient (>24 hours) healthcare facility;
- Senior housing (over the age of 65); OR
- Buildings housing/treating high risk individuals (burn victims, cancer patients, solid organ transplants, renal disease, chronic lung disease, diabetes, immunocompromised).

ASHRAE 188



Does
ASHRAE
188
Apply To
Me?

- Whirlpools or spas on site
- Ornamental fountains, misters, air washes, atomizers, humidifiers or other nonpotable water systems or devices releasing water aerosols
- Open or closed circuit cooling towers or evaporative condensers providing cooling or refrigeration

ASHRAE 188



What
Do We
Need
To Do?

- Designate Multi-Disciplinary Team
 - Maintenance
 - Engineering
 - Risk Management
 - Infection Prevention (healthcare facilities)
 - Consultants ???
 - Suppliers ???
 - Contractors ???
 - Legal
 - Administration

ASHRAE 188



What Do We Need To Do?

- Review as-built drawings for potable/non-potable water systems
- Compare drawings with current conditions
- Amend/change as necessary ensuring drawings reflect current conditions
- Develop accurate facility specific water system flow diagrams

ASHRAE 188



What
Else
Does
188
Require?

- Specifications for system start up/shut down- especially critical for new construction
- System maintenance
- Water treatment
- Emergency response

Legionella Testing



- ***Legionella* Testing- A Hot Topic**
 - Water testing is NOT specifically required under ASHRAE 188 in the absence of disease although verification/validation might actually imply a testing requirement for compliance
 - This is NOT applicable to New York
- **Testing in the Presence of Disease**
 - Select culture locations based upon disease history at the facility
 - Physical plant structure
 - Likely sources
 - Enact emergency response/remediation protocol
 - Follow CDC or other national guidelines and established infection control processes

CDC



- Testing in the Presence of LD-CDC-2016
 - Test ALL patients with HA pneumonia for LD
 - ✦ Urinary antigen
 - ✦ Lower respiratory culture
 - Perform full investigation* for *Legionella* if:
 - ✦ 1 case of definite HA LD in patient who spent the ENTIRE 10 days prior to onset in facility OR
 - ✦ 2 cases of possible HA LD in patient who spent PART of the 10 days prior to onset in facility WITHIN 6 months of each other

CDC



- Patient Testing Without Disease- CDC-2016
 - Positive environmental tests for *Legionella*
 - Changes in water quality that may lead to *Legionella* growth:
 - ✦ Low chlorine levels
 - ✦ Construction start up/shut down
 - ✦ Water main breaks
 - ✦ Changes in municipal water quality, source, sedimentation
 - ✦ Difficulty in maintaining water quality within control limits
 - ✦ Prior history of LD in facility

CDC vs. ACHD



ACHD Potable Water

- ✓ Environmental survey of all hot water tanks and a % of distal sites every year
- ✓ Disinfection of water distribution system is needed if 30% or greater of distal sites are positive for *Legionella*

CDC- Potable Water-2016

- ✓ Consider environmental testing when:
 - ✓ Control limits exceeded
 - ✓ Prior history of LD
 - ✓ Caring for patients at increased risk of LD
- ✓ Consider testing all patients with HA pneumonia when:
 - ✓ LD identified in patient(s)
 - ✓ Positive environmental test for LD
 - ✓ Changes in water quality that may lead to *Legionella*

Affordable Care Act (ACA)



- Affordable Care Act
 - Pay for Performance not Fee for Service
 - ✦ Hospital Readmissions Reduction Program- (up to 3% penalty)
 - ✦ Hospital Acquired Conditions- (1% penalty)
 - ✦ Value Based Purchasing (+/- 2% based upon Total Performance Score heavily weighted on patient satisfaction/safety/outcomes)
 - 6% total at stake plus deductions under the Deficit Reduction Act based upon differential payments and present on admission conditions)
 - Hospital Inpatient Quality Reporting does not yet include *Legionella* but list grows yearly

Affordable Care Act (ACA)



- Affordable Care Act

- So What Does 6% amount to anyway????
- Average Penalties- 2015
 - ✦ VBP- \$91,873
 - ✦ HACs-\$541,9896
 - ✦ Readmissions- \$161,240

TOTAL= \$795,009

**BUT IF YOU WERE LOWER THAN AVERAGE THE
TOTAL COULD BE AS HIGH AS \$8,570,333**

- **AND THERE WENT YOUR RAISE AND BONUS !!!**

New York Regulations



- **New York – (323% increase in legionellosis-05-14)**
 - Owners of cooling towers must electronically register towers with DOH
 - Must test and inspect for *Legionella* and report at least every 90 days (and must inspect prior to seasonal start up)
 - Also requires bacterial testing every 30 days while operational
 - Immediate testing following events (i.e. loss of biocide, power failure, cases of legionellosis, etc.)
 - Must use ELAP certified lap and qualified inspector
 - Limits (> or equal to 20 CFU/mL but <1000 CFU/mL) require treatment plan review and immediate disinfection and retest
 - Limits (>1000 CFU/mL) requires DOH notification, disinfection/retest
 - Must use EPA and/or NYS approved biocide
 - Documentation- must have maintenance program/plan and maintain records on site for 3 years
 - DOH may inspect/sample at will
 - Failure to comply-civil/criminal penalties

New York Regulations



- New York-Healthcare Facilities (Art. 28 PH Law)
- Applicable to residential healthcare facilities/hospitals
 - Must perform an environmental assessment with annual updates and sampling plans
 - ✦ More frequently if construction/renovation/plumbing modifications, 1 or more cases of legionellosis, impact to transplant units, or any other conditions specified by DOH
 - Must perform culture **sampling of potable water systems** at least 90 days after initiation and every 90 days for the first year following adoption- thereafter on an annual basis.
 - ✦ Immediately if one or more cases of legionellosis
 - ✦ More frequently if construction/renovation, impact to transplant units or any other conditions specified by DOH (every 90 days or less for applicable transplant units)
 - Civil/criminal penalties and DOH may inspect at any time
 - Must retain documentation for 3 years

New York Regulations



- **New York- Healthcare Facilities**
 - Criteria- Using the $>$ or equal to 30% impact rule- i.e. institute control measures (heat and treat, hyperchlorination, etc.), retest within 7-28 days and if persistent problem, implement long term controls (supplemental disinfection methods)
 - Regulation left vague as DOH may require additional sampling/testing/investigation under “other conditions specified by the department.”

Risk Mitigation



- Environmental Testing Without Disease
 - CAUTION: Do NOT perform environmental testing for *Legionella* unless you have a program in place establishing *Legionella* testing criteria and response protocol (if *Legionella* is found) and have the resources available to fully comply with your facility plan.
 - Establish testing frequency, locations, limits, controls

Risk Mitigation



- **Testing Without Disease-Strategy**
 - Inventory water systems
 - Identify testing locations (based upon amplification hazard)
 - ✦ Conducive water temperatures-dead legs, biofilms, etc.
 - ✦ Water sources capable of exposure
 - ✦ Locations of susceptible occupants
 - ✦ Areas of recent construction
 - Conduct sampling
 - ✦ Viable cultures-ISO Method 11731:1998
 - ✦ PCR- rapid detection but does not speciate
 - ✦ No correlation with heterotrophic bacteria counts
 - Identify control methods once sample results received

Risk Mitigation



- Testing

- Results

- ✦ Goal- non-detect but may not be possible due to source water content
- ✦ OSHA Guidelines
 - Humidifiers/Misters/Fountains/Whirlpools- <1 CFU/mL
 - Potable Water/Industrial Sources- <10 CFU/mL
 - Cooling Towers- <100 CFU/mL
 - Stricter standards if high risk occupants on site

Risk Mitigation



Healthcare Defense Strategy

- What is the value of determining the presence/absence of *Legionella* in hospital water systems?
- What actions will be taken if sampling is positive/negative since no dose/response relationship has been established?
- Any sampling/sampling data is potentially discoverable documentation that can later be used in court
- Facilities must determine the purpose of testing and how the results will be managed PRIOR to testing
- If sampling-determine sample locations, methodology, frequency, number and CRITICAL LIMITS (i.e. proportion of positive sites vs. degree of colonization vs. high risk locations)
- **EXCEPT IN NEW YORK !!!**

Legionella and the Law



- **Must Prove**
 - Exposure to specific bacteria
 - At defendant's premises
 - Due to the negligence of defendant
 - Resulting in disease caused by the exposure
- **Tort Liability**
 - Grounded in negligence
 - Defense-reasonable due care in prevention and compliance with guidelines/standards/local regulations
 - Punitive damages possible
- **Contractual Liability**
 - Breach of express/implied warranty-manufacturers/product defect
- **Pollution Exclusion and Insurers?**

Risk Mitigation



What Do I Do If I Have a Problem? Emergency Response

- Establish emergency disinfection response program/plan
- Assemble team of experts
- Assess exposure points (cooling towers, fountains, whirlpools, etc.) and potential causes (temperature, stagnation, sediment, etc.) and obtain baseline serology (MUST TEST FOR *Legionella* presence)
- Initiate emergency response procedures to control and prevent exposures- bottled water, point of use (POU) filtration, thermal shock
- Select disinfection method to be utilized and obtain cost estimates- labor/materials
- Healthcare- determine if full investigation needed-CDC and report case to local health department

Risk Mitigation

- Point of Use (POU) Filtration



Risk Mitigation



Emergency Disinfection

- Primary Options
 - Thermal Shock- Maintain water temperature at 160-170F through each outlet for 30 minutes/REGROWTH-major issue unless combined with secondary disinfection. Water temperatures >140F inhibit but won't prevent growth.
 - Chemical Treatment- Shock halogenation for a minimum of 2 hours. Confirm levels are within EPA limits prior to restarting water systems
- Monitor, Monitor, Monitor
- Document, Document, Document
- INTERIM MEASURE ONLY !!!!

Risk Mitigation



- Other Disinfection Methodologies
 - Complete eradication of *Legionella* on a continuous basis from water supply systems is VERY DIFFICULT to achieve without physical modification of water systems.
 - EPA-Technologies for *Legionella* Control- 2016



Risk Mitigation



Secondary Disinfection Systems

Copper-Silver Ionization

Ultra Violet (UV) Light

Chlorine Dioxide

Great residual effect

Not dependent upon water temperature for effectiveness

Non corrosive

Works throughout the system-even dead legs

Must maintain pH within certain parameters

Only effective where water passes point of radiation

No residual effect-organisms that escape recolonize

Fewer negative effects than hyper-chlorination

Removes biofilms and kills bacteria

No corrosion

pH parameter issues

Ineffective in hot water loops

Risk Mitigation



- *Legionella* WMP template
 - Multi-disciplinary water management team including CIC/MS (if healthcare) and assign responsibilities
 - Up to date as-built plumbing drawings/water process flow diagrams for all buildings on campus
 - Evaluate all physical/chemical conditions in water flow process where hazardous conditions could occur and where control measures could be applied
 - Risk Analysis- including patient (if healthcare)/occupant vulnerability and water process exposure
 - Determine legionellosis potential from risk analysis
 - Identify: Control locations/Control limits
 - Identify: Monitoring procedures/Corrective actions
 - Document actions-Verification/Validation

Liability Mitigation



- Compliance with ASHRAE 188/CDC/AIHA/New York Regulations
- Multi-disciplinary team in place
- Water management program in place along with emergency response program
- Documentation of compliance with plan
- Key: Correlating elevated risk for *Legionella* (when control measures are not controlling the hazards) with increased disease surveillance and vice versa based upon knowledge where risks are greatest at your facility

Summary



The
Following
Statements
are TRUE

- Recent studies indicate that water systems colonized with *Legionella* are common
- *Legionella* can be present in a water system without being associated with disease
- Most LD is the result of exposure to contaminated potable water systems as well as cooling tower water reservoirs and is therefore preventable
- It is important to identify the species of *Legionella* present because some are much less likely to cause illness

Summary



ASHRAE 188 Implications

- In states that adopt the guidelines into building codes- will have the force of law
- Compliance will provide additional protection from allegations of negligence and failure to maintain systems/protect occupants
- Compliance will be a valid defense especially in cases where the precise exposure point (source) of *Legionella* cannot be identified
- Will establish benchmarks for threshold, type, level, intensity of exposure and may impact claim validation/dismissal
- Plaintiffs can use noncompliance as proof of negligence
- Insurance carriers may consider compliance as a factor in coverage determination

Summary

