



Department
of Health

10 NYCRR Part 4 - Protection Against *Legionella*

Subpart 4-2, Health Care Facilities

Today's Presentation

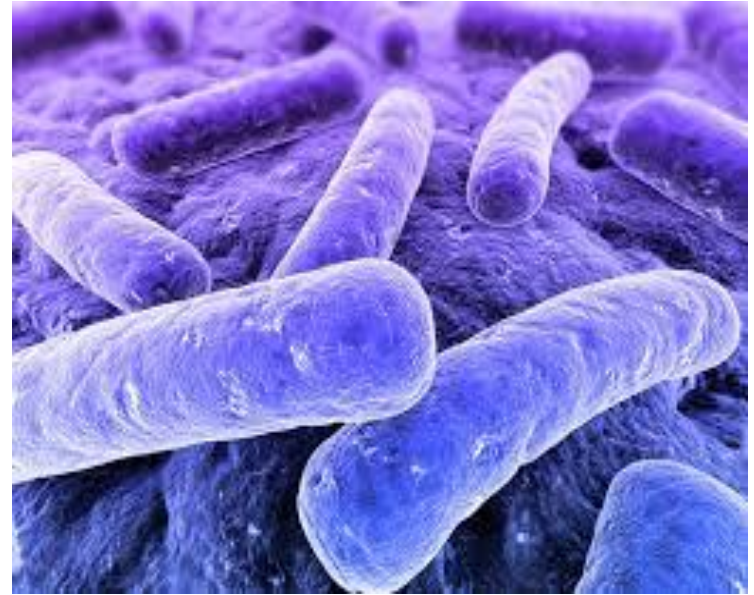
- Brief overview of *Legionella* and Legionnaires' disease
- Clinical guidelines
- Infection prevention and control guidelines
- Part 4 regulatory requirements
 - Subpart 4-2: Healthcare Facilities
- Some guidance for Subpart 4-2

Legionellosis

- A bacterial infection causing:
 - Legionnaires' disease
 - Progressive pneumonia
 - 2-10 day incubation period
 - Pontiac Fever
 - Self-limiting, flu-like illness (no pneumonia)
 - 1-2 day incubation period
 - Rarely, can infect other sites

Legionella

- Ubiquitous, aquatic organism
- First isolated in the lab in 1943
- Facultative intracellular parasite



Legionnaires' Disease (LD)

- American Legion convention in Philadelphia, 1976
 - 200+ ill
 - 20+ deaths
 - Illness linked to hotel air conditioning system

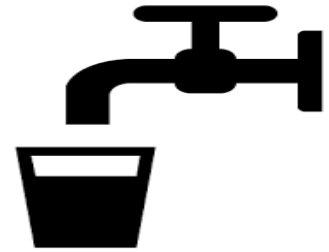


Epidemiology

- *L. pneumophila* causes 90% of infections
 - Serogroup 1 most common cause of disease
 - Serogroups 2-6 also can cause disease
- *L. micdadei*, *L. bozemanii*, *L. dumoffii*, *L. longbeachii*, *L. anisa* also cause human disease

Epidemiology

- *Legionella* prefers aquatic environments
 - Ideal growth at 77-115° F (25 - 46° C)
- LD cases have been linked to:
 - Potable water systems
 - Cooling towers
 - Showers/faucets
 - Hot tubs, whirlpool spas
 - Respiratory therapy equipment
 - Room-air humidifiers



Epidemiology

- Human host factors
 - Greatest risk group: Immunosuppression
 - Organ transplant, hematologic malignancies, end-stage renal disease
 - Moderate risk group: Other factors
 - Diabetes mellitus
 - Chronic lung disease
 - Non-hematologic malignancies
 - HIV
 - Elderly (≥ 50 years)
 - Tobacco smoking
 - Rare among children

Clinical Considerations

- LD is not clinically distinguishable from pneumonia caused by other agents
 - Incubation period 2-10 days
 - Pneumonia developing 48+ hours after admission is considered healthcare facility-associated
 - Maintain heightened awareness in all healthcare facility-associated pneumonia, especially persons at greatest or moderate risk

Clinical Considerations

- Diagnostic work up should include the following:
 - Chest radiograph
 - Respiratory cultures for *Legionella* spp.
 - Requires special laboratory techniques; routine sputum culture will not grow *Legionella* spp.
 - Alert lab that *Legionella* is suspected!
 - *Legionella* urinary antigen test (UAT)
 - Not reliable for serogroups other than *L. pneumophila* 1



Clinical Considerations

- Additional lab testing
 - Direct fluorescent antibody (DFA) staining
 - Polymerase chain reaction (PCR)
 - Identifies both living and dead organisms
 - Presents challenge in diagnosis and comparison of clinical and environmental isolates
 - Serology
 - Requires acute and convalescent phase sera 2-4 weeks apart
 - Not helpful in a timely manner

Clinical guidelines

- When isolates are positive for *Legionella* spp.:
 - Submit to NYSDOH Wadsworth Laboratories
 - Facilities within NYC should submit to NYCDOHMH Public Health Laboratory
 - Notify infection control within the facility



Infection Control

- Close collaboration with multidisciplinary team is essential
 - Infection control
 - Physical facilities management
 - Engineering
 - Clinicians
 - Laboratory
 - Hospital Management

Infection Control

- Residents at greatest or moderate risk should be tested for *Legionella* if they develop a healthcare facility-associated pneumonia
- Report all community- and healthcare facility-associated cases to public health within 24 hours of diagnosis

Infection Control

- Respiratory devices/equipment
 - Use sterile water for rinsing or filling reservoirs
 - If reusable, follow manufacturer instructions for cleaning and disinfection
 - This includes patient equipment brought from home



Infection Control

- Guidelines for “protective environments” are outlined in the NYSDOH document released 8/10/15
 - Does not apply to most nursing homes
 - Pertain to protecting patients with stem cell and solid organ transplants from exposure to potentially contaminated water

Infection Control

- If single or multiple cases of LD detected
 - Report to NYSDOH and local health department
 - NYSDOH will provide consultation
 - Investigations in NYC conducted jointly with NYCDOHMH

Surveillance

- Investigations of one or more healthcare facility-associated cases might involve:
 - Retrospective and prospective surveillance for additional cases
 - Review of facility's potable water and cooling systems
 - Molecular analysis of clinical and environmental cultures
 - Reinforcement of published prevention guidelines
 - Tap water restrictions for immunocompromised residents
 - Resident notification

Regulatory Background

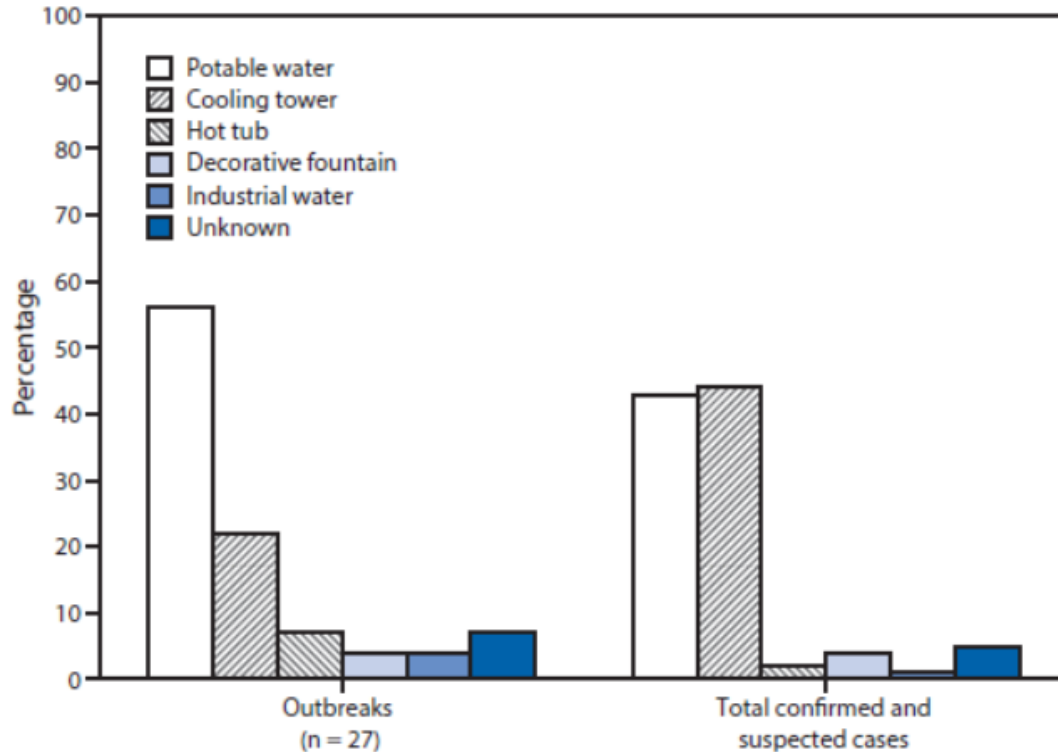
Why is it important to regulate *Legionella*?

Water in the home, workplace, healthcare facilities, or aerosol-producing devices in public places can be potential sources of exposure to *Legionella*.

- **Cooling towers (Subpart 4-1):** Proper maintenance of cooling towers is needed to prevent the growth and dissemination of *Legionella*.
- **Healthcare facilities (Subpart 4-2):** Patient surveillance along with the proper monitoring for *Legionella* in the potable water systems at general hospitals and residential health care facilities can also help decrease patient exposures and illness.

CDC Data

Percentage of Outbreaks and Cases of Legionnaires' Disease, by Environmental Source – North America, 2000-2014



Definitions

Covered Facilities

- General hospitals
- Residential healthcare facilities
- Defined in Article 28 of Public Health Law

Potable Water System

- A building water distribution system
- Provides water intended for human contact or consumption

Regarding Article 28 Facilities

In accordance with the definitions of “general hospital” and “residential healthcare facility” set forth in section 2801 of the Public Health Law, 10 NYCRR Subpart 4-2 applies to:

- Buildings of general hospitals that provide in-patient services or to buildings of residential healthcare facilities providing a “health related service,” such as lodging, board, and physical care.
- 10 NYCRR Subpart 4-2 does not apply to administrative buildings of such facilities, general hospital buildings that only provide out-patient services, or to diagnostic and treatment centers providing only out-patient services.

Environmental Assessment

- All covered facilities must perform or update an environmental assessment by September 1 of each year
- The environmental assessment must be updated annually or under certain conditions including completion of construction or repair activities that may affect the potable water system
- The Environmental Assessment Form (EAF) is posted on the Health Commerce System (HCS) and can also be found on the Department's website at: <http://www.health.ny.gov/forms/doh-5222.pdf>



Environmental Assessment of Water Systems in Healthcare Settings

1. Type of Assessment (check as appropriate)

On-site assessment Telephone assessment Mailed/emailed prior to telephone conference

2. Information about the person doing the assessment

Name

Job title

Facility name

PFI (Permanent Facility Identifier)

Facility address

Date of assessment

3. Contact information

Telephone number (work and/or cell)

FAX number

Email

Instructions and Notes to the User (please read)

Please complete this form and keep it with your records. You do not need to submit it to NYSDOH. You will need to produce this form at the request of NYSDOH as part of a routine inspection or during the investigation of an outbreak.

This information collection tool may be used where a thorough understanding of the potable water system of a healthcare facility is needed during a public health investigation. It can be used by a hospital multi-disciplinary group that includes: a hospital epidemiologist, infection control practitioner, engineer, facility manager or other individual(s) engaged in efforts to reduce the risk of legionellosis associated with the facility. It may also be used to assist the facility in efforts to minimize the risk of legionellosis in the absence of evidence of human disease or when a facility is reviewing/implementing the NYSDOH guidance document on hospital-associated legionellosis. It should be completed in as much detail as possible. Some information requested by the tool may not be applicable for every healthcare facility.

For very large, complex healthcare facilities, completing the form may take several hours. Please keep in mind that this initial investment of time is quite important and will be a time-saving device during periodic re-assessments. If follow-up with the facility is needed in subsequent months or years, the information contained in this form will be very valuable. **Please do not leave sections blank. If a question doesn't apply, write N/A. If a question can't be answered please explain why.** Where applicable, please specify the unit of measurement being used (e.g., ppm). It is recommended that if you are completing the form electronically, you use a different font and/or italics for your answers. This will make the form much easier to read if additional information is added in the future to an existing form.

Environmental Assessment Form



Sampling and Management Plan

Implementation and Updating

- Plans for covered facilities should have been implemented by December 1, 2016
- New facilities must adopt a plan prior to providing services
- The plan must be updated annually and following specific conditions

Requirements

- Routine *Legionella* culture sampling and analysis at intervals not to exceed 90 days for the first year and annually thereafter (with the exception of hematopoietic stem cell transplant or solid organ transplant patient units)
- Provisions for non-routine sampling for *Legionella* culture sampling and analysis following disease, construction, and other conditions
- Culture analysis by a NYS ELAP-approved laboratory



Expected Elements – Sampling and Management Plan (S&MP)

Additional elements of the S&MP include details regarding, for example:

- Facility information
- Personnel roles and responsibilities
- Description of the building water system
- Monitoring / Environmental culture sampling
- Response to >30% *Legionella* culture results
- Preventative measures



***Legionella* Culture Results (Appendix 4-B)**

- < 30% of *Legionella* test sites positive
 - Maintain environmental assessment and *Legionella* monitoring
- \geq 30% of *Legionella* test sites positive
 - Immediately institute short-term control measures
 - Resample in 1 to 4 weeks
 - For persistent results, implement long-term control measures

Health Advisory *Guidance* – Attachment 3

August 10, 2015

Guidance on environmental sampling is provided in Attachment 3 of the Advisory:

- At least 10 sites (taps/showers) are recommended in hospitals with <500 beds; 2 sites per 100 beds is recommended for facilities with >500 beds.
- During outbreaks the number of samples would likely be increased

Health Advisory *Guidance* – Attachment 3

August 10, 2015

The recommended sampling sites should include but not be limited to:

- One water sample of the inlet of the heating system(s)
- One water sample of the outlet of the heating system(s)
- One sample of the inlet of the cold water supply
- Floors that housed ill patients/residents, as well as additional floors, should be sampled. Samples should be collected from each floor. This is normally done in the following fashion:
 - Tap closest to first delivery of hot water from the riser
 - One sample from the middle of the system
 - One sample from the last outlet before the water returns to heaters



Additional Provisions

Recordkeeping

- The EAF, sampling and management plan, and sampling results shall be retained on-site for three years

Enforcement

- The Department may conduct an assessment or *Legionella* culture sampling of the potable water system at any time

Variations and Waivers

- A facility may submit a written application to the Department for a variance from any provision, for a period not to exceed 90 days
- The Department may issue a written general or specific waiver, where the Department is satisfied that such a waiver will not present a danger to public health

Questions?

Environmental

- Subpart 4-1:
Cooling.tower@health.ny.gov
- Subpart 4-2:
HCF.legionella@health.ny.gov
- Phone: (518) 402-7650

Clinical

- ICP@health.ny.gov
- Phone: (518) 474-1142