Executive Summary

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted a review of Legionnaires' disease (LD) at the VA Pittsburgh Healthcare System (VAPHS) at the request of the VA Secretary, Senator Robert P. Casey, Jr., Congressmen Michael F. Doyle and Tim Murphy, and the Chairmen and Ranking Members of the House Committee on Veterans' Affairs and the Senate Committee on Veterans' Affairs. They asked that OIG evaluate whether VAPHS was adequately maintaining its system for preventing LD. Additional questions regarding mitigation of risk at other VA hospitals will be addressed in a subsequent report.

VAPHS has a long history of comprehensive mitigation efforts for LD. Following the recent outbreak, VAPHS instituted numerous additional measures. However, we found that while employing copper-silver ionization systems during 2011-12, VAPHS allowed ion levels inadequate for *Legionella* control to persist. There was a lack of documentation of system monitoring for substantial periods of time and inconsistent communication and coordination between the Infection Prevention Team and Facility Management Service staff.

We also found that VAPHS did not conduct routine flushing of hot water faucets and showers, especially in areas that are infrequently used, as recommended by the copper-silver ionization system manufacturer. We found that VAPHS conducted environmental surveillance in accordance with Veterans Health Administration (VHA) Directive 2008-010. However, VAPHS responded to positive cultures by flushing distal outlets with hot water at normal operating temperatures, a corrective action not consistent with VHA or Centers for Disease Control and Prevention guidance. In addition, VAPHS did not test all healthcare-associated pneumonia patients for *Legionella* as specified by VHA guidance for transplant centers with a history of healthcare-associated LD.

We recommended that the VAPHS Director ensure that any disinfectant system in use for *Legionella* prevention is monitored and maintained in accordance with manufacturer's instructions, that hot-water faucets and showerheads are routinely flushed, and that close coordination between the Infection Prevention Team and Facilities Management Service staff occurs. Additionally we recommended that the VAPHS Director ensure that when environmental cultures are positive, actions taken comply with VHA guidelines, and that all healthcare-associated pneumonia patients are tested for *Legionella* infection.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with our recommendations and provided an acceptable action plan. (See Appendixes C and D, pages 25–30 for the Directors' comments.) We will follow up on the planned actions until they are completed.

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Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted a review of Legionnaires' disease (LD) at the VA Pittsburgh Healthcare System (VAPHS) at the request of the VA Secretary, Senator Robert P. Casey, Jr., Congressman Tim Murphy, and the Chairmen and Ranking Members of the House Committee on Veterans' Affairs and the Senate Committee on Veterans' Affairs. They asked that OIG evaluate whether VAPHS was adequately maintaining its system for preventing LD. Additional questions regarding mitigation of risk at other VA hospitals will be addressed in a subsequent report.

Background

VAPHS is part of Veterans Integrated Service Network (VISN) 4 and includes three divisions located in Pittsburgh, PA, and five community-based outpatient clinics in nearby counties. The system serves a veteran population of approximately 360,000 in western Pennsylvania, northern West Virginia, and eastern Ohio.

The University Drive (UD) division is a tertiary care facility serving as a referral center for cardiac surgery, liver and kidney transplantation, and for multiple other specialized services, including mental health, oncology, and geriatrics. In 2012, the facility performed 48 liver transplants and 39 kidney transplants.

In September 2012, inpatient and outpatient mental health services, previously located at the Highland Drive (HD) division, were relocated to UD. There are currently no patient care activities at HD. The H. J. Heinz division (Hz) is the site of a modern community living center (CLC),[1] a geriatric center of excellence, a primary care center, and a domiciliary.

Legionella and Legionellosis

Infections caused by bacteria of the genus *Legionella* have been recognized since the outbreak at a convention of the American Legion in Philadelphia in 1976. That outbreak sickened more than 200 people who had been in and around the Bellevue-Stratford Hotel, and 34 died.[2] The subsequent intense epidemiologic and microbiologic investigation led to isolation of the previously unknown organism,[3] and retrospective analyses suggest that outbreaks caused by *Legionella* had occurred decades earlier. The earliest documented outbreak, identified through testing of banked serum, was at a meat-packing plant in Minnesota in the 1950s.[4]

[1] Previously referred to as a Nursing Home Care Unit.
[2] Fraser DW, Tsai TR, Orenstein W, et al. Legionnaires' disease: description of an epidemic of pneumonia. N Engl J Med. 1977;297:1189-1197.
[3] McDade JE, Shepard CC, Fraser DW, et al. Legionnaires' disease: isolation of a bacterium and demonstration of its role in other respiratory disease. N Engl J Med. 1977;297:1197-1203.
[4] Osterholm MT, Chin TD, Osborne DO, et al. A 1957 outbreak of Legionnaires' disease associated with a meat packing plant. Am J Epidemiol. 1983;117:60-67.

Legionella is now known to be present widely in nature, particularly in aquatic environments, but also in soil.[5] Its peculiar ecology and growth characteristics explain a predilection for large buildings and make clear why it is exceptionally difficult to eradicate. *Legionella* thrives in the biofilm that lines water pipes, particularly at temperatures in the range 35-46 degrees C (95-115 degrees F). Even when present at undetectable levels at lower temperatures, it can colonize a water system and proliferate when temperature, sediment, scale, and supporting microorganisms provide optimal conditions for growth.[6]

Within the biofilm of pipes, *Legionella* occupies an ecologic niche, living inside the cells of other microorganisms where it is resistant to eradication by chemicals and heat. Growing *Legionella* in culture media in the laboratory is notoriously difficult because it is easily overwhelmed by the growth of other bacteria in the environment and because of its stringent nutrient requirements.

Although more than 50 species of *Legionella* have been described, fewer than half of these cause disease in humans. The most common species, *L. pneumophila*, includes at least 16 serogroups. *L. pneumophila* serogroup 1 is responsible for at least 70% of proven cases.[7]

Human disease caused by *Legionella* is referred to as legionellosis, which manifests either as a self-limiting illness known as Pontiac fever or as LD, a serious and potentially fatal infection of the lungs and other organs. Pneumonia is the most common manifestation of LD. In most cases, infection occurs when a susceptible person aspirates or inhales water containing the organism. The number of organisms required to cause infection is probably small. Persons at greatest risk are immunocompromised or have impaired respiratory barriers. LD is the cause of approximately 5% of community-acquired pneumonias, but may account for a much higher proportion of hospital-acquired disease.[8]

The outbreak in Philadelphia in 1976 was ultimately attributed to *Legionella* growth in a hotel's air conditioning system, but numerous other outbreaks have been attributed to colonization of drinking water, humidifiers, spas, and other sources of contaminated aerosols. Within healthcare environments, drinking water is the most common source of infection.[9]

Healthcare providers are required to report cases of legionellosis to public health authorities, and the Centers for Disease Control and Prevention (CDC) periodically

[5] Bartram J, Chartier Y, Lee JV, Pond K, Surman-Lee S, eds. *Legionella* and the prevention of legionellosis. Geneva: World Health Organization, 2007.
[6] U.S. Department of Labor. Occupational Safety & Health Administration. OSHA Technical Manual. Section III: Chapter 7, Legionnaires' Disease, January 20, 1999.
[7] Edelstein PH, Cianciotto NP. *Legionella*. In: Mandell GL, et al, eds. Principles and Practice of Infectious Diseases, 7th ed., 2009. Churchill Livingstone.
[8] Sabria M, Yu VL. *Legionella* infection. In: Longo DL, et al., eds. Harrison's Principles of Internal Medicine, 18th Edition. New York: McGraw-Hill, 2012.
[9] Lin YE, Stout JE, Yu VL. Prevention of hospital-acquired legionellosis. Curr Opin Infect Dis. 2011;24:350-6.

publishes a description of national and regional trends. Approximately three-fourths of reported cases occur in the absence of any known outbreak, most commonly in the summer and fall. The published rate of disease is believed to represent substantial underdiagnosis.[10]

From 2000 through 2009, 22,418 cases of legionellosis were reported to CDC. During this period, the age-adjusted incidence rate increased from 0.40 to 1.08 per 100,000 persons, and an increase was noted in all regions. The highest rates have consistently been reported from the Middle Atlantic Census Division (New Jersey, New York, and Pennsylvania), for which the 2009 rate was 2.6 cases per 100,000. Persons aged 50 and older accounted for 74% of confirmed cases.

Within Pennsylvania, rates of legionellosis are highest in the southwest corner of the state, and particularly high in and around Allegheny County, which includes Pittsburgh. In 2010, the rate was 5.3 per 100,000 in Allegheny County and 3.8 in the 5 adjacent counties.[11]

Mitigation of Risk

Because *Legionella* is widespread in nature, its periodic introduction into hospital water is difficult to prevent. Low numbers of the organism may enter buildings from public water sources and colonize pipes. Clinical risk is increased when conditions for growth are optimal, and the goal of mitigation is to maintain an acceptably low level of risk. The extent to which patients and the hospital environment are tested for *Legionella* influences whether hospital managers are aware of a potential problem.

Close communication between infection control professionals and facility engineers is essential in reducing risk of LD,[12] and multiple components of risk mitigation require attention. Among available strategies for limiting exposure to *Legionella* from hospital drinking water are the application of disinfectants and maintenance of elevated water temperatures. Use of disinfectants must balance the benefits of controlling bacterial growth with the potential hazards inherent when any chemical is added to drinking water. Various approaches to disinfection have been employed with some success, but only the treatment of circulating hot water with copper (Cu) and silver (Ag) ions has been systematically evaluated at multiple sites.[13] Water treated with monochloramine by utilities (as opposed to free chlorine) appears to confer a reduced risk of LD,[14] and is now being evaluated for use at the level of individual facilities.

[10] Centers for Disease Control and Prevention. Legionellosis – United States, 2000-2009. MMWR Morb Mortal Wkly Rep. 2011; 60:1083-86.
[11] Data from the Allegheny County and Pennsylvania Departments of Health.
[12] Lin YE, Stout JE, Yu VL. Prevention of hospital-acquired legionellosis. Curr Opin Infect Dis. 2011;24:350-6.
[13] Lin YE, Stout JE, Yu VL. Controlling *Legionella* in hospital drinking water: an evidence-based review of disinfection methods. Infect Control Hosp Epidemiol. 2011;32:166-73.
[14] Kool JL, Bergmire-Sweat D, Butler JC, et al. Hospital characteristics associated with colonization of water systems by *Legionella* and risk of nosocomial Legionnaires ' disease: a cohort study of 15 hospitals. Infect Control Hosp Epidemiol.1999;20:798-805.

Maintenance of hot water at temperatures sufficient to prevent *Legionella* growth throughout a hospital is challenging and requires special care to avoid scalding patients and staff. Unfortunately, episodic renovations, common in many hospitals, often involve water system modifications leading to unexpected mixing of hot and cold water. These connections can lead to dilution of disinfectants and reduced temperatures in one or more locations within a water system.

Another component of risk mitigation is careful attention to the clinical presentations of patients. Providers of care must consider the possibility of LD whenever patients present with pneumonia, especially if the pneumonia is severe or the patient has recently been hospitalized. Testing in most cases can be easily accomplished with a simple urine test. However, up to 30% of LD cases are not detected with this test and may require sputum culture for diagnosis. In addition to permitting identification of multiple serogroups of *L. pneumophila* and of other *Legionella* species, sputum cultures allow for matching of clinical isolates with isolates derived from environmental cultures.[15] Particular vigilance is required in hospitals caring for vulnerable populations, such as transplant patients, and where LD has previously been associated with the hospital environment.

Finally, risk mitigation can include monitoring the growth of *Legionella* through routine cultures of distal water outlets. The use of environmental cultures requires strict attention to procedures for the handling of samples and specialized laboratory testing. Controversy exists regarding actions to be taken in response to positive cultures.[16]

Outbreaks of Legionnaires' Disease

Outbreaks of LD have been reported prominently in the media. In 2012, eight cases and at least two deaths were linked to a contaminated whirlpool and lobby fountain at a luxury hotel in Chicago.[17] In 2011, multiple guests at two different hotels in Las Vegas contracted LD, and *Legionella* was cultured from drinking water.[18] Even in the absence of illness, *Legionella* is concerning. The Architect of the U.S. Capitol was reported to have been cited in 2000 for failure to conduct follow-up monitoring after *Legionella* was found in cooling towers; no illness was reported.[19]

Although LD has been associated with exposure to many types of water-related sources, delivery of drinking water through pipes is of particular importance. *Legionella*

[15] Mandell LA, Wunderink RG, Anzueto A, et al. Infectious Disease Society of America/American Thoracic Society consensus guidelines on the management of community-acquired pneumonia in adults. Clin Inf Dis. 2007;44:S27-72.
[16] Allen JG, Myatt TA, MacIntosh DL, et al. Assessing risk of health care-associated Legionnaires' disease from environmental sampling: the limits of using a strict percent positivity approach. Am J Infect Control. 2012;40:917-21.
[17] Smith M. Two die in Legionnaires' outbreak linked to Chicago hotel. Chicago Tribune, August 28, 2012. CNN subsequently reported a third death.
[18] Harasim P. Legionnaires' disease linked to Aria. Las Vegas Review-Journal. July 15, 2011. Valley J. Guest who stayed at Luxor dies of Legionnaires' disease. Las Vegas Sun, Jan. 30, 2012.
[19] http://www.achrnews.com/articles/*Legionella*-in-capitol-cooling-towers, accessed March 9, 2013.

has been found in water systems in homes, hospitals, hotels, and factories.[20] In healthcare environments, where vulnerable patients are exposed, outbreaks of LD garner special attention. In 2005, two separate academic hospitals in New York City were found to have *Legionella* growth in hospital drinking water, and LD was the principal cause of death for one patient.[21]

Among non-VA hospitals in Pittsburgh, two large academic hospitals have a history of health-care associated (HCA) LD.[22,23] At one of these hospitals, *Legionella* has been controlled with Cu-Ag ionization systems. At the other, persistent infections led to installation of a system for introduction of monochloramine into hospital water.

Legionnaires' Disease in VHA

For VHA, LD has been a recurring challenge and the object of systematic effort. In 1977–78, 65 persons, including 5 hospital employees, contracted the disease at the VA hospital in Los Angeles; LD was implicated in the deaths of 16 patients.[24] In the 1990s, VA hospitals experienced a marked decrease in the rate of hospital-acquired LD after VHA promulgated policies designed to increase the temperature of hot water while avoiding the risk of scalding.[25,26] Prior to 2011, VAPHS had a long history of epidemiologically-linked LD. In the early 1980s, approximately 100 cases were diagnosed, and 30 percent were fatal.[27]

In 2007, OIG surveyed VHA's inpatient facilities to characterize the risk of LD for patients at individual facilities. Thirty facilities reported obtaining water from municipal sources that use monochloramine. Twenty-five facilities reported obtaining routine, periodic environmental cultures, and 12 had specific disinfection systems in place. Eighteen acute-care facilities reported no recent diagnostic testing of patients and were categorized as being at relatively increased risk. OIG recommended that VHA ensure that inpatient facilities where bone marrow or organ transplants are performed have a written plan which addresses the prevention of LD, and that all inpatient facilities

[20] Bartram J, Chartier Y, Lee JV, Pond K, Surman-Lee S, eds. *Legionella* and the prevention of legionellosis. Geneva: World Health Organization, 2007.
[21] Lueck TJ, O'Connor A. Hospital alters conclusions in patient death. New York Times, April 27, 2005.
[22] Lee CJ. Legionnaire outbreak hits Presby: 4 patients with illness die, hospital water suspected. Pittsburgh Post-Gazette, May 12, 1992.
[23] Smeltz A. Pittsburgh's Mercy Hospital switched water treatment system after two Legionnaires' cases. Pittsburgh Tribune-Review, December 21, 2012.
[24] Kirby BD, Snyder KM, Meyer RD, Finegold SM. Legionnaires' disease: report of sixty-five nosocomially acquired cases and review of the literature. Medicine. 1980;59:188-203.
[25] Kelly AA, Danko LH, Kralovic SM, Simbartl LA, Roselle GA. *Legionella* in the Veterans healthcare system: report of an eight-year survey. Epidemiology and Infection. 2003. 131:835-9.
[26] VHA Directive 2009-009. Domestic hot water temperature limits for *Legionella* prevention and scald control, February 25, 2009.
[27] Brown A, Yu VL, Magnusson MH, Kroboth F. Nosocomial outbreak of Legionnaires' disease at the Pittsburgh Veterans Administration Medical Center. Trans Assoc Am Physicians. 1980;93:52-9. See also: Pittsburgh Tribune-Review, Feb. 23, 2013

periodically assess local risk for LD using specific guidelines developed by VHA experts.[28]

VHA convened a multidisciplinary expert working group to address the prevention of HCA LD at VHA inpatient facilities. The working group developed VHA Directive 2008-010, Prevention of *Legionella* Disease, which includes a classification of facilities based on the type of services provided – transplant, non-transplant acute care, CLC – as well as facility history of HCA LD.[29]

Algorithms for *Legionella* evaluations and action plans based on facility classification included procedures for each type of facility. The UD campus of VAPHS is a transplant center, and the Hz campus houses a CLC.

VHA algorithms indicate that each facility should determine whether there has been a history of epidemiologically-linked HCA LD. "Epidemiologically-linked" refers to the association of a suspected HCA LD case with exposure to *Legionella* at the facility. Such cases include, but are not limited to, those that are temporally associated (10 or more days of continuous inpatient care prior to onset of illness) and those that are environmentally associated (that is, when *Legionella* has been isolated from the facility environment).

Following the identification of a possible case of HCA LD, an epidemiologic investigation involves several important steps. Active surveillance denotes identification of recent or ongoing cases of LD, maintaining a high level of suspicion for possible infection with *Legionella,* and performing LD testing by urine antigen testing or cultures of respiratory secretions.[30] Clinical testing of HCA pneumonia cases is advised for transplant facilities with a history of HCA LD.

During January–June 2009, concurrent with scheduled inspections, OIG assessed five non-transplant facilities considered to be at increased risk because they had hospital water not treated with monochloramine, no evidence of clinical testing for *Legionella* (with urinary antigen), and no routine environmental cultures. Three of the five facilities were in full compliance with VHA Directive 2008-010. Two facilities lacked a plan for LD prevention or had not completed a risk assessment.

In 2009, the VHA Infectious Diseases Program Office conducted a comprehensive survey to assess implementation of VHA Directive 2008-010. Although 86 percent of facilities reported "correct implementation" of guidance for environmental risk assessments, only 29 percent reported adherence to guidance for clinical risk

[28] VA OIG Report No. 07-00029-151. Assessment of Legionnaires' Disease Risk in Veterans Health Administration Inpatient Facilities, June 20, 2007.
[29] VHA Directive 2008-010. Prevention of *Legionella* Disease, February 11, 2008.
[30] Tabian OC, et al; Healthcare Infection Control Practices Advisory Committee. Guidelines for Preventing Healthcare-Associated Pneumonia, 2003. *MMWR.* 53(RR03):1-36 (March 26, 2004).

assessments. Twenty-three of 176 facilities were considered to require environmental mitigation, and 6 cases of HCA LD were reported for FY 2008.[31]

Recent outbreak at VAPHS

On August 26, 2012, a patient was admitted to the VAPHS medical intensive care unit with confirmed LD; this patient had been hospitalized at VAPHS August 15–20. Four days later, another patient was admitted with LD; this patient had also been recently hospitalized at the facility. During September 2012, two additional patients were hospitalized with LD, and environmental cultures revealed growth of *Legionella* in 1/26 samples. Cultures growing *Legionella* from the first two patients and from environmental samples collected on October 3 were sent to the CDC for analysis.

On October 29, preliminary results indicated a match between the organism isolated from patient samples and environmental specimens. A CDC investigative team conducted a VAPHS site visit November 7–16 2012. The objectives of the investigation were to identify any additional cases of LD among VAPHS patients, complete environmental assessment of LD risk and environmental sampling, and make recommendations for prevention of ongoing disease transmission. The team did not assess maintenance or effectiveness of the Cu-Ag ionization systems prior to November 2012.[32]

CDC identified 21 "probable" or "definite" cases of HCA LD during 2011–2012 (Appendix A) and found that VAPHS drinking water had widespread colonization of *Legionella*. The CDC report concluded that colonization and infection occurred despite a comprehensive risk reduction program that included use of Cu-Ag ionization systems, routine cultures of the hospital environment for *Legionella*, and disease surveillance. The report also noted that small volumes of water taken during sampling may have led to decreased sensitivity in detecting widespread colonization; that the facility relied on a 30% positive culture rate as its threshold for taking remediative action, even though in 2011, there were two outbreaks with lower positive culture rates; and that extensive construction at the facility may have introduced organic matter into the drinking water and coincided with the recent outbreak. The report described a "Failure to recognize healthcare-associated cases of LD for an extended period of time. A low index of suspicion that lab-confirmed cases were healthcare-acquired can be partially attributed to a perception that *Legionella* was being well controlled in the environment."

CDC made recommendations for both short and long-term actions. The following actions were to begin immediately and continue until remediation efforts had been shown to be effective:

[31] VHA Infectious Diseases Program Office. Report on Implementation of VHA Directive 2008-010 (Prevention of *Legionella* Disease) by VHA Facilities, and Associated Risk Assessment Findings and Actions, June 2011.
[32] CDC Epi-Aid Trip Report: *Legionnaires' Disease Among Patients at a Veterans Affairs Healthcare System in Pennsylvania*, 2011-2012 (Epi-Aid 2013-011), January 25, 2013.

- Enhance disease surveillance and test for *Legionella* in patients with possible or definite HCA pneumonia, including patients with severe illness, recent travel or hospitalization, or failure of initial antibiotic therapy.
- Restrict patient showering and drinking of hospital water; provide bottled drinking water.
- Turn off all decorative fountains and whirlpool spas.
- Install point of use filters for faucets and showerheads.
- Hyperchlorinate (≥ 2 ppm) all water and flush at distal sites and/or perform a super heat (160-170 degrees) and flush of all pipes to point of use for a minimum of ten minutes.

Long-term recommendations for control of *Legionella* at the facility were:

- Consult with experts for a reevaluation of the disinfection system.
- Map the hospital plumbing system and identify areas of potential water stagnation.
- Strive for eradication of *Legionella* from the drinking water, "...as there is no known safe level of *Legionella*."

Additional recommendations were made pertaining to surveillance for LD and methods for collecting, processing, and communicating results of environmental cultures.

The Joint Commission (JC) completed a for-cause evaluation of VAPHS on December 18, 2012, finding "Insufficient Compliance" with the requirement that "All hospital components and functions are integrated into infection prevention and control activities." JC noted that "The hospital had begun but not yet completed a mapping and inventory of the entire water piping system. This must be accomplished to identify those areas that would be considered high risk such as points of stagnation or "dead heading" for the ongoing contamination of the *Legionella* bacteria."[33]

VAPHS took the following actions in response to CDC and JC recommendations:

- Notified clinical providers of the *Legionella* outbreak and of actions to take when patients present with pneumonia. (November 16, 2012)
- Installed point-of-use filters at water outlets.
- Increased number of environmental samples and volume of water collected.
- Created a hotline and a web site with information for patients and employees.
- Established a Water Committee to monitor new plumbing installation during construction projects.
- Initiated daily meetings of VAPHS executives with the infection control team and Facilities Management Service (FMS) staff to discuss newly identified cases of

[33] JC report, December 18, 2012

LD, environmental culture results, and other issues concerning control of *Legionella*.

- Discontinued use of the Cu-Ag ionization systems and began continuous infusions of chlorine into hot and cold water. (November 2012)
- Completed emergency thermal eradication for all hot water circuits. (November 2012)
- Contracted with an expert in control of *Legionella* to assist with an evaluation of the physical plant and development of a new mitigation plan. (February 2013)
- Contracted for mixing valves for all faucets, new instantaneous water heaters, and new control software that permits the increase in hot water temperature optimal for thermal eradication.
- Began a survey of all water outlets to ascertain their usage. Outlets that are used infrequently are being removed.
- Began development of a protocol for periodically flushing all distal outlets.
- Initiated processes to hire a contractor to map all hospital water piping, including identification of areas of stagnation and mixing of hot and cold water.

Scope and Methodology

We conducted site visits January 14–17 and February 26–28, 2013. We interviewed VAPHS leaders, infection preventionists, physician staff, and FMS staff. We also interviewed staff from the Pennsylvania Department of Health (PDOH), Allegheny County Health Department, Pittsburgh-area hospitals, and representatives of water utilities in other states. We conferred with members of the epidemiology investigation team from the CDC who were on-site at VAPHS November 6-16, 2012.

For each of the three UD hot-water circuits in place throughout 2011-2012, we reviewed preventive maintenance documentation, including daily and weekly logs, quarterly Cu and Ag chemical analyses, and environmental culture results. We reviewed VAPHS policies and committee meeting minutes. In addition, we toured machine rooms housing the Cu-Ag ionization systems at the UD and Hz campuses, and the Hz water tower.

We reviewed VHA policies, JC standards, CDC[34] and American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE)[35] guidance, and a World

[34] Guidelines for Environmental Infection Control in Health-care Facilities. Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Morbidity and Mortality Weekly Reports (MMWR) 52 (RR10):1-42; 2003. See also footnote 28.

[35] American Society for Heating, Refrigerating and Air-conditioning Engineers (ASHRAE). Guideline 12-2000. Minimizing the Risk of Legionellosis Associated with Building Water Systems; 2000. See also: 2013 draft guideline. https://www.ashrae.org/news/2013/proposed-ashrae-standard-on-prevention-of-legionellosis-open-for-third-public-comment, accessed March 22, 2013.

Health Organization (WHO) reference[36] on LD risk mitigation in healthcare facilities. We also reviewed training, operating, and maintenance manuals from the manufacturer of the Cu-Ag ionization systems, and examined all available communications between the manufacturer and VAPHS personnel. In addition, we reviewed a report of consultation provided by a second Cu-Ag system contractor.

We identified patients with LD at VAPHS and other VHA facilities from hospital discharge diagnoses, infection control records, and by searching results of laboratory testing. For categorization of patients with respect to the likelihood of having contracted LD from the VAPHS environment, we used criteria described by CDC. We reviewed the electronic health records (EHR) of affected patients.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

[36] Bartram J, Chartier Y, Lee JV, Pond K, Surman-Lee S, eds. *Legionella* and the prevention of legionellosis. Geneva: World Health Organization, 2007.

Inspection Results

1. Efforts to Mitigate the Risk of Legionnaires' Disease at VAPHS

A. Risk assessments & annual plans

VHA requires all inpatient facilities to have a written plan for the annual evaluation of LD prevention.[37] Facilities that have a history of "previous epidemiologically-linked HCA LD ever at the facility" are expected to implement an Action Plan for ongoing mitigation of *Legionella* in the water distribution system, with monitoring and evaluation of the mitigation effort. VAPHS had a written plan for *Legionella* prevention and conducted annual evaluations of LD risk for all its campuses.

Monitoring the implementation of a facility's mitigation protocol involves obtaining samples from hot water tanks and distal sites for *Legionella* culture. VHA recommends that transplant centers consider on-site availability of *L. pneumophila* serogroup 1 urinary antigen testing and ensure that if the facility collects environmental samples for *Legionella* culture it has access to a laboratory with the capability to identify multiple *Legionella* species.

VAPHS performs *Legionella* urinary antigen testing on-site. The VAPHS clinical laboratory was certified by CDC's Environmental *Legionella* Isolation Techniques Evaluation (ELITE) Program. ELITE certification indicates that laboratory procedures are consistent with federal recommendations and meet or exceed industry standards for recovery of *Legionella* in water samples.[38]

VHA expects that at least ten distal sites will be sampled at least twice yearly at transplant centers; for facilities with multiple water distribution systems each system must be included. Remedial action is implemented if the percentage of positive distal sites is above the threshold level determined by the facility. A threshold of 30% is recommended by VHA and this was the threshold applied by VAPHS. For transplant centers, remedial action is expected to include treatment of water and *Legionella* testing of all patients at the facility (not just transplant patients) who have HCA pneumonia. Water treatment for remediation may include thermal eradication or hyperchlorination. If mitigation efforts have proven to be ineffective, the facility is to reassess and modify its mitigation plan, then monitor the plan's subsequent effectiveness.

VHA requires that the following reports be submitted annually to the local Infection Control Committee: (1) total number of urinary antigen tests and clinical cultures ordered for *Legionella*, (2) total number of persons with positive results for *Legionella*, (3) water system maintenance and monitoring, (4) results of any environmental testing for *Legionella*, and (5) any *Legionella* remediation undertaken.

[37] VHA Directive 2008-010. Prevention of *Legionella* Disease, February 11, 2008.
[38] CDC Web site, https://www.cdc.gov/elite/public/memberlist.aspx, accessed March 12, 2013.

We found that the VAPHS Pathology and Laboratory Medicine Service and FMS did not submit required reports to the Infection Prevention Team (IPT)[39] for review. Although the IPT met bimonthly and discussed ongoing positive clinical and environmental testing results and activities related to water system maintenance and monitoring, no annual written reports summarizing these activities were provided to the committee. This information was therefore not readily available for use by the IPT for development of the annual LD risk assessment.

B. Use of Copper-Silver Ionization Systems

The UD campus comprises four adjacent buildings reflecting sequential periods of renovation. Water from the public utility circulates around the perimeter of the campus and is stored in two large tanks from which water is pumped throughout the facility in a complex network. There are currently four distinct hot water circuits, each with its own instantaneous water heater. At the Hz campus, water from the public utility is pumped into a water tower and then distributed to buildings throughout that campus; there are three hot water circuits at the Hz campus. At the HD campus, two hot water circuits were in place; effective September 2012, there were no patient care activities at HD campus.

Three of the four UD hot water circuits were in operation throughout 2011–12 and are the focus of this inspection. Each of these circuits is named according to the location of its hot water heater: BN211, the oldest and largest; AA114; and 7W139. The fourth circuit was put into service with the opening in 2012 of the newest building on the campus.

VAPHS employed Cu-Ag ionization systems to treat circulating hot water as part of its mitigation plan for the prevention of LD. These systems were taken out of service in November 2012 as part of the response to the recent outbreak of LD. The Hz and HD systems had been installed in 1994-95. UD systems were installed in 2002, 2010, and 2012.

Cu and Ag ions inhibit the proliferation of *Legionella*. To the extent that they reach the organism in the biofilm of water pipes, these ions form electrostatic bonds that disrupt cell wall permeability and cause protein denaturation, leading to cell death.[40]

Each Cu-Ag ionization system consists of a flow cell and a control unit. The flow cell contains bars of Cu and Ag installed in the flow of circulating hot water. The control unit displays the electric current (measured in amperes) and voltage at the flow cell. As hot water flows over the Cu and Ag bars, the controller applies a direct current across the bars, causing release of the ions into the water.[41] The control unit can be set to adjust ion release in response to changes in water flow. Operation of Cu-Ag ionization systems requires: monitoring and adjusting the flow cells as necessary; measuring the

[39] At VAPHS the Infection Control Committee is called the Infection Prevention Team.
[40] Lin YE, Stout JE, Yu VL, Vidic RD. Disinfection of water distribution systems for *Legionella*. Semin Respir Infect. 1998;13:147-59.
[41] LiquiTech® Inc, Environmental Solutions, *Installations and Operations Manual*, pp.1-2-1-4, April 28, 2009.

concentration of ions in hot water; cleaning or replacing the Cu and Ag bars; and routine flushing of hot water faucets, especially in areas of low use.

VAPHS policy[42] requires documentation of:

- Daily amperage and voltage at each flow cell.
- Weekly colorimetric testing of Cu levels.
- Quarterly reference lab testing of Cu and Ag levels.
- Quarterly flow cell maintenance and cleaning. More frequent cleaning is required if colorimetric Cu levels are low or the voltage at flow cells is high. In September 2011, FMS modified the policy, changing flow cell maintenance to monthly.

The local policy was in accord with the manufacturer's standard operating instructions, except for the absence of a procedure for routine flushing of distal outlets. Routine flushing of distal hot water outlets ensures that Cu and Ag ions reach all sites of potential *Legionella* growth and is recommended by the manufacturer.[43]

Amperage and voltage at each flow cell were checked daily and flow cell maintenance was performed as required. Weekly colorimetric testing was performed at selected sites on all campuses.

We reviewed colorimetric Cu test results for BN211, 7W139, AA114, and for the Hz campus from September 1, 2011, until the units were deactivated in November 2012. We did not review copper levels prior to September 2011 because the facility retained documentation for only one year. Colorimetric testing was not performed on any of the UD systems during June 26–July 16, 2012, because of a lack of testing reagent. We found no colorimetric testing documentation for the Hz campus.

We found multiple instances of low Cu levels. BN211 levels were low for three weeks in December 2011. 7W139 levels were low for four weeks in September–October 2011, and no results were recorded the week of March 15, 2012, or the month of April 2012. Except for three non-consecutive weeks, AA114 levels were low September 22–December 28, 2011.

According to staff we interviewed, in early April 2012, the AA114 flow control device did not work and was taken out of service; this Cu-Ag ionization system subsequently functioned in continuous mode. Manufacturer representatives visited VAPHS, analyzed the system, and made recommendations for changes. After the flow cell was moved and other changes made, colorimetric Cu levels improved.

VAPHS IPs collected quarterly water samples and sent them to a reference laboratory for ion testing. This provided validation of VAPHS's copper levels and was the only mechanism by which silver levels were assessed. In June 2012, the frequency of testing increased to bi-monthly.

[42] IC-001 *Legionella* Prevention and Control, March 17, 2011.
[43] LiquiTech® Inc, Environmental Solutions, *Installations and Operations Manual*, pp 1-1, April 28, 2009

We reviewed results from the reference laboratory for June 2011 through October 2012, and results of CDC testing in November 2012. Although only one circuit had an ion level outside the target range in October 2012, for each of the other seven dates when samples were obtained at all hot water returns, two or more levels were outside the target range. See Table 1.

The CDC investigation team collected 11 water samples for Cu and Ag levels, 7 from distal outlets and 4 from before or after flow cells. Although 7 of 11 water samples had ion levels in the target range, only 2 of these were taken at hot water returns.[44]

	Copper-silver ionization unit					
	AA		BN		7W	
	Copper	Silver	Copper	Silver	Copper	Silver
Date	Ion concentration, parts per million*					
Jun-11	**0.14**	**<0.005**	2.93	0.080	0.43	0.104
Aug-11	**0.08**	**<0.005**	6.75	0.428	0.32	0.216
Sep-11	**0.17**	**<0.005**	**0.16**	**0.005**	**0.15**	**0.013**
Dec-11	**0.15**	**<0.005**	0.64	0.107	**0.18**	**0.013**
Apr-12	1.56	0.041	0.72	**0.012**	**0.14**	0.031
Jun-12	0.38	0.123	**0.17**	**0.010**	**0.12**	**<0.005**
Aug-12	0.37	0.084	1.31	0.156	**0.17**	**<0.005**
Oct-12	0.20	0.057	0.24	0.026	0.20	**0.015**
Nov-12	Not done		0.27	0.020	0.35	0.023

Table 1. Copper and silver ion levels for samples collected at hot water returns. Analyses were performed by Analytics Corporation, Ashland, VA, except samples collected in November 2012, which were analyzed by the Pittsburgh Water and Sewer Authority. The target concentration range for copper is 0.2-0.8 ppm; for silver, the target range is 0.02-0.08. Numbers in bold indicate concentrations below the target range.

We found little documentation regarding any actions taken to correct ion levels that were outside the target ranges. Communication and coordination between VAPHS IPs and FMS staff was inconsistent. FMS supervisors inconsistently received testing results and informed staff about what needed to be done.

FMS staff sometimes spoke directly with IPs regarding the need for Cu-Ag ionization system adjustments. However, we found documented changes on only two occasions, one each for the BN211 and AA114 circuits. We also found very limited communication from FMS staff to IPs regarding actions taken. We found documentation of one call to the manufacturer and actions taken by FMS staff in response to recommendations.

[44] CDC Epi-Aid Trip Report: *Legionnaires' Disease Among Patients at a Veterans Affairs Healthcare System in Pennsylvania*, 2011-2012 (Epi-Aid 2013-011), January 25, 2013.

VAPHS contacted two manufacturers to evaluate its Cu-Ag ionization systems. Both companies submitted proposals to the facility for remote monitoring and control of the systems. VAPHS entered into no contracts with these manufacturers.

C. Environmental Cultures

Legionella is present in natural and artificial water environments worldwide. Infection with *Legionella* is more likely to occur when bacteria proliferate in water systems and when exposure via aerosolization occurs, especially in immunocompromised individuals.[45] Experts agree that the risk of disease is decreased when the concentration of bacteria in drinking water is low, but there is no clear dose-response relationship between the concentration of *Legionella* in water and *Legionella* outbreaks. Despite the uncertainty about a threshold level of *Legionella* needed to cause disease, monitoring the level of *Legionella* in a hospital's water system is considered to be a relevant indicator of risk.

VHA Directive 2008-010 requires that transplant centers with a history of epidemiologically linked HCA LD develop an Action Plan for ongoing mitigation, and monitor mitigation efforts twice yearly.

The VAPHS plan called for collection and testing of water from distal sites every other month (more frequently than specified by the Directive). VAPHS used VHA's recommended 30 percent threshold of positive results as a trigger for instituting remedial action. Its plan called for FMS to perform a 30 minute monthly flushing of all hot water distal outlets in the areas where cultures were positive, until culture results return to an acceptable level (less than 30%).

Because the facility continued water treatment with Cu-Ag ionization, its approach was in accordance with the Directive. However, flushing hot water outlets at usual hot water temperatures[46] and without hyperchlorination is not an accepted practice and will not eradicate *Legionella*, even temporarily. Further, the facility responded inconsistently to positive cultures exceeding the 30 percent threshold. In February 2011, selected distal sites were flushed at usual hot water temperatures, while in September 2011, thermal eradication was implemented in all three hot water circuits.[47]

Although applied at many healthcare facilities, the appropriateness of the 30 percent threshold has recently been questioned by researchers who concluded that relying on a

[45] Bartram J, Chartier Y, Lee JV, Pond K, Surman-Lee S, eds. *Legionella* and the prevention of legionellosis. Geneva: World Health Organization, 2007.
[46] VHA Directive 2009-009. Domestic Hot Water Temperature Limits for *Legionella* Prevention and Scald Control, February 25, 2009. Hot water at distal sites is generally maintained at less than 120 degrees F. Higher temperatures are possible with the use of distal mixing valves, but these were not widely employed at the facility before 2013.
[47] Thermal eradication entails raising hot water temperature to at least 160 degrees F and flushing all distal outlets for 30 minutes.

30% positivity measure could lead to inadequate *Legionella* control.[48] CDC guidelines address prevention of *Legionella* in transplant centers and differ from VHA guidelines regarding routine environmental cultures. CDC does not recommend routine environmental cultures, but rather states that transplant centers *can* [emphasis added] perform periodic distal site culturing as part of a prevention plan. CDC further states that if a transplant center does utilize environmental cultures, (1) "no recommendation can be made about the optimal methods (i.e., frequency or number of sites) for environmental surveillance cultures in transplant units;" (2) corrective measures are aimed at maintaining *undetectable* [emphasis added] levels and (3) that even when cultures are negative, the transplant center should maintain a high level of suspicion for HCA LD pneumonia.[49]

From January 2011 through Dec 2012, VAPHS met or exceeded the requirement for environmental cultures at all three campuses. Ten or more samples were collected five times in 2011 and five times in 2012 at Hz; four times in 2011 and nine times in 2012 at UD; and three times in 2011 and two times in 2012 at HD.

IPT committee meeting minute documentation and our interviews with VAPHS staff revealed a lack of clarity about actions actually taken. The phrase "heat and flush" sometimes indicated thermal eradication of at least one hot water supply circuit, but at other times indicated the local flushing protocol—running hot water at normal temperatures through a faucet for 30 minutes.

In February 2011, 6/16 (38 percent) environmental cultures obtained in the MICU and SICU were positive, exceeding the threshold for remedial action. March 2011 IPT minutes noted, "heat and flush of the area was completed." However, thermal eradication was not done; flushing was done at normal hot water temperatures. Monitoring for success of "heat and flush" included re-culturing the MICU and SICU areas monthly until sites were found to be negative. May 2011 IPT minutes noted negative culture results in these areas; however, records of these culture reports were not available.

In September 2011, positive environmental cultures again exceeded the threshold for remedial action, and IPT minutes noted, "a heat and flush of all areas was completed." On this occasion, FMS records documented thermal eradication.

D. Clinical Surveillance

VHA requires transplant centers that have a history of "epidemiologically-linked HCA LD ever" to routinely test all patients (not just transplant patients) with HCA pneumonia for LD. We found that VAPHS lacked requirements or procedures for routinely testing all patients with HCA pneumonia. In contrast to the routine testing expected by VHA,

[48] Allen JG, Myatt TA, MacIntosh DL, et al. Assessing risk of health care-associated Legionnaires' disease from environmental sampling: the limits of using a strict percent positivity approach. Am J Infect Control. 2012;40:917-21.
[49] Tabian OC, et al; Healthcare Infection Control Practices Advisory Committee. Guidelines for Preventing Healthcare-Associated Pneumonia, 2003. *MMWR*. 53(RR03):1-36 (March 26, 2004).

VAPHS's risk assessment included monitoring for HCA LD only following identification of positive environmental cultures.

In September 2011, following the isolation of *Legionella* from environmental cultures, the VAPHS Chief of Staff advised clinicians to order urinary antigen testing for all patients with HCA pneumonia. It was also advised that clinicians order sputum testing for *Legionella* culture from those patients producing sputum. Follow-up monitoring of environmental cultures continued to reveal positive distal site cultures. However, our review of LD testing performed during October–December found LD testing for only 7 of 17 of patients identified as having HCA pneumonia.

2. Legionnaires' Disease Patients

From January 1, 2011, through December 31, 2012, 34 VAPHS patients were found to have LD by diagnostic testing or discharge summary diagnosis. For an additional patient, the diagnosis was made at a non-VA hospital. All of the patients were male. Twelve patients had no exposure to VAPHS within 14 days of illness onset and were considered to have community-acquired disease. For one patient the diagnosis was not confirmed. Based on CDC epidemiologic criteria, 5 patients were considered to have "definitely HCA" and 17 "probably HCA" LD. See Figure 1.

During 2011–2012, 948 *Legionella* urinary antigen tests and 651 *Legionella*-specific cultures were performed for patients at VAPHS. Thirty-one (3.3 percent) antigen tests and 11 (1.7 percent) cultures were positive.

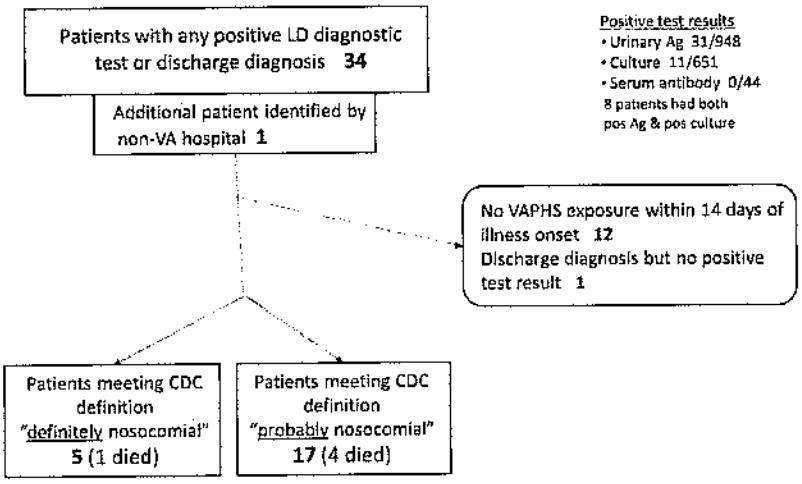


Figure 1. Identification of patients with Legionnaires' disease at VAPHS, 2011-12.

For 15 of the 34 patients whose diagnosis was confirmed, the diagnosis of LD was made during March–November 2011; one of these 15 was categorized as "definitely HCA," 8 as "probably HCA," and 6 as community-acquired. The remaining 19 patients had the diagnosis confirmed during May–Dec 2012; 4 of these were categorized as "definitely HCA," 9 as "probably HCA," and 6 as community-acquired. See Figure 2.

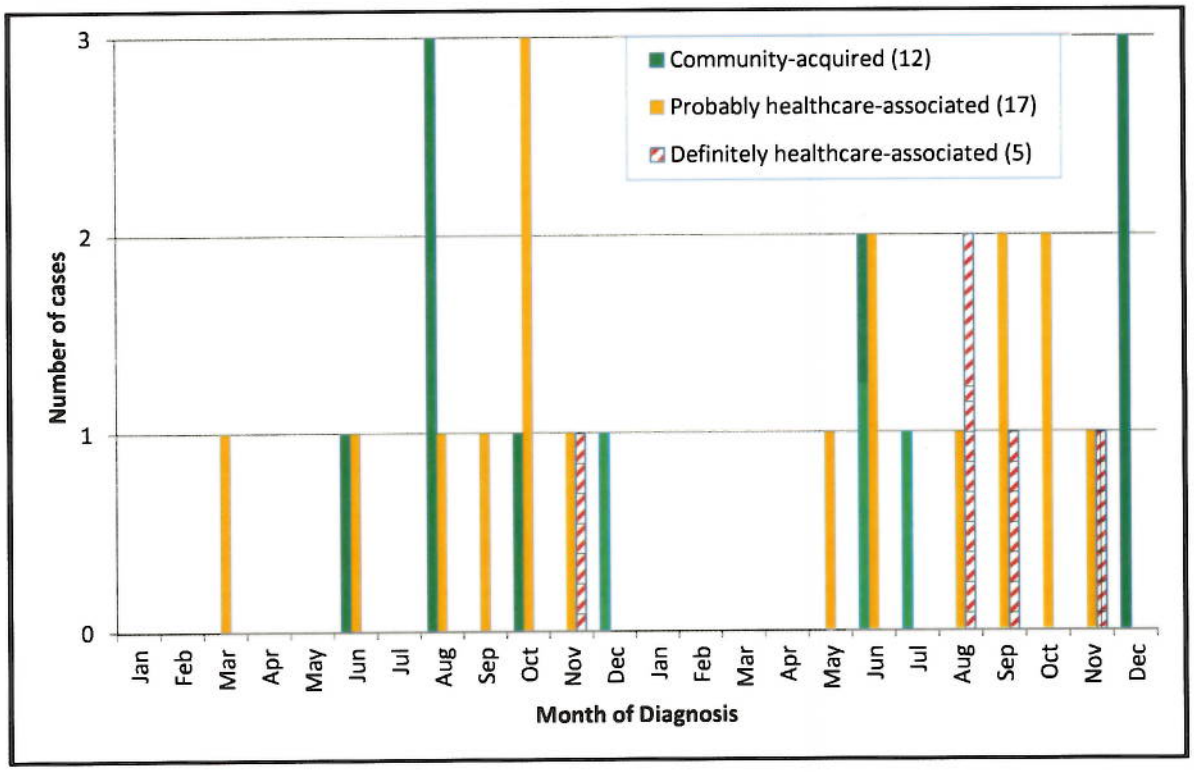


Figure 2. Cases of Legionnaires' disease (n = 34), VAPHS, 2011-12.

For the 22 patients considered to have HCA LD ("definitely" or "probably"), the median age was 67 (range, 53-87). Twelve of these patients had VAPHS exposure exclusively in outpatient settings. All of the patients had one or more risk factors for LD, but none had undergone organ transplantation. See Table 2.

Among the five patients categorized as "definitely HCA," three patients had *Legionella* isolated from sputum cultures that matched isolates cultured from environmental samples; these three patients survived. Two patients were categorized as "definitely HCA" because they were continuously hospitalized at VAPHS for at least 10 days prior to onset of LD; one of these patients died.

Patient	Risk Factors *	Exposure site †	Health care environment	Days from illness onset to death	Urinary antigen	Sputum culture for *Legionella*	Comment
1	Ca, Imm, DM, CLD	UD	Outpatient	566	Positive	Not done	
2	DM, Smok	Hz	Nursing home	24	Positive	Not done	
3	DM	UD	Outpatient	n/a	Positive	Not done	
4	Ca, Imm, Smok	UD	Outpatient	499	Positive	Not done	
5	Ca, Imm	UD	Outpatient	34	Positive	Positive	
6	Imm, CKD	UD	Outpatient	n/a	Positive	Negative	
7	Smok, CHF	Hz	Outpatient	n/a	Positive	Not done	
8	Imm, DM, Smok, CLD,	UD, Hz, HD	Hospital	n/a	Positive	Positive	Definite: resided at VAPHS
9	DM, Smok, CLD	UD	Outpatient	n/a	Positive	Not done	
10	CLD	UD	Outpatient & Hospital	n/a	Positive	Not done	
11	Smok	UD	Hospital	n/a	Positive	Not done	
12	Ca, Imm, CLD	UD, Hz	Outpatient & Hospital	8	Positive	Positive	
13	Ca	Hz	Outpatient	n/a	Positive	Not done	
14	DM, CLD	UD	Outpatient & Hospital	n/a	Positive	Positive	Definite: DNA match
15	DM, Smok	UD	Outpatient & Hospital	n/a	Positive	Positive	Definite: DNA match

Patient	Risk Factors *	Exposure site †	Health care environment	Days from illness onset to death	Urinary antigen	Sputum culture for *Legionella*	Comment
16	CLD	UD	Outpatient	n/a	Positive	Not done	
17	DM, Smok	UD, Hz	Outpatient	n/a	Positive	Positive	Definite: DNA match
18	DM, CKD	UD	Hospital	26	Positive	Not done	
19	Ca	Hz	Outpatient	n/a	Positive	Not done	
20	DM, Smok	UD, Hz	Outpatient	n/a	Negative	Positive	
21	CLD, Smok	UD	Nursing home	61	Positive	Negative	
22	CHF	UD	Hospital	4	Positive	Not done	Definite: in hospital during entire incubation period

Table 2. Cases of Legionnaires' Disease, VAPHS, 2011–2012. These cases met CDC criteria for "definite" or "probable" healthcare-associated LD. All of the patients were male.
* Risk factors: Ca, active malignancy; Immun, immunosuppressive medication taken within 30 days; DM, diabetes mellitus; CLD, chronic lung disease; Smok, active smoking or ≥ 20 pack-year history; CKD, chronic kidney disease; CHF, congestive heart failure.
† Exposure site: UD, University Drive; Hz, Heinz; HD, Highland Drive.

In January 2013, two additional VAPHS patients were found to have LD. The first patient had diabetes and chronic kidney disease and was brought to the UD Emergency Department (ED) because of fever, chest pain, cough, and shortness of breath. He had been hospitalized one month earlier for an infection of the bones of his foot. In the ED, he was found to have pneumonia, treated with broad-spectrum antibiotics, including medications appropriate for LD, and admitted to the hospital. A *Legionella* urinary antigen test was collected and the following day returned negative; this test was repeated on the eighth hospital day and again returned negative. Five days later, the patient suffered cardiopulmonary arrest, resuscitation efforts were unsuccessful, and the patient died. An autopsy was performed and culture of lung tissue grew *L. pneumophila* serogroup 1. The isolate was analyzed by CDC and found to be a strain that was different from the strain associated with the recent VAPHS outbreak. This strain is a known cause of outbreaks throughout the United States, and CDC recommended remediation of the patient's home.

The second patient presented to a Community Based Outpatient Clinic with fever, cough, and shortness of breath. He had a long history of cigarette smoking and continued to smoke. His most recent contact with any VAPHS facility in Pittsburgh was more than 6 months earlier. From the CBOC, he was transported by ambulance to UD, where a chest x-ray revealed pneumonia. He was treated with an antibiotic appropriate for LD and admitted to the hospital. On the day following admission, a urinary antigen test was positive for *Legionella*; sputum culture was negative. He was discharged home after a 3-day hospitalization and at a routine clinic visit 1 month later he was well.

Findings related to maintenance of the Cu-Ag ionization systems, environmental cultures, and clinical cases are summarized in Appendix B.

Conclusions

VAPHS has a long history of comprehensive mitigation efforts for LD. Following the recent outbreak, VAPHS instituted numerous additional measures. However, while employing copper silver ionization systems during 2011-12, VAPHS allowed ion levels inadequate for *Legionella* control to persist. There was a lack of documentation of system monitoring for substantial periods of time and inconsistent communication and coordination between the Infection Prevention Team and Facility Management Service staff.

VAPHS did not conduct routine flushing of hot water faucets and showers, especially in areas that are infrequently used, as recommended by the Cu-Ag ionization system manufacturer.

VAPHS conducted environmental surveillance in accordance with VHA Directives. However, VAPHS responded to positive cultures (6/16 sites positive) in February 2011 by flushing distal outlets with hot water at normal operating temperatures, a corrective action not consistent with VHA or CDC guidance.

VAPHS did not test all healthcare-associated pneumonia patients for *Legionella* as expected according to VHA guidance for transplant centers with a history of healthcare-associated LD.

Recommendations

Recommendation 1: We recommended that the VA Pittsburgh Healthcare System Director ensure that any disinfectant system in use for *Legionella* prevention is monitored and maintained in accordance with manufacturer's instructions.

Recommendation 2: We recommended that the VA Pittsburgh Healthcare System Director ensure routine flushing of hot-water faucets and showerheads.

Recommendation 3: We recommended that the VA Pittsburgh Healthcare System Director ensure close coordination between the Infection Prevention Team and Facilities Management Service staff.

Recommendation 4: We recommended that the VA Pittsburgh Healthcare System Director ensure that when environmental cultures are positive, actions taken comply with Veterans Health Administration guidelines.

Recommendation 5: We recommended that the VA Pittsburgh Healthcare System Director ensure that all healthcare-associated pneumonia patients are tested for *Legionella* infection.

Appendix A

CDC Case Definitions for Legionnaires' Disease associated with VAPHS

Cases required at least one item from Signs or Symptoms AND Laboratory confirmation AND Exposure

<table>
<tr><th>Signs or Symptoms of Pneumonia</th><th>Laboratory Criteria</th><th>Exposure to VAPHS</th></tr>
<tr><td rowspan="4">1. Cough or shortness of breath,
AND at least one of the following:
• fever (temperature ≥100.5°F)
• nausea
• diarrhea
• confusion
• malaise
• headache

OR

2. Physician diagnosis of pneumonia,

OR

3. Chest x-ray consistent with pneumonia.</td><td rowspan="4">1. Isolation of any Legionella organism from any of these:
• respiratory secretions
• lung tissue
• pleural fluid
• other normally sterile fluid

OR

2. Detection of Legionella pneumophila serogroup 1 (Lp1) urinary antigen using validated reagents,

OR

3. Fourfold or greater rise in antibody titer to Lp1 using validated reagents.</td><td>Definitely healthcare-associated</td></tr>
<tr><td>1. Continuous hospitalization at VAPHS for the entire 14 days prior to onset

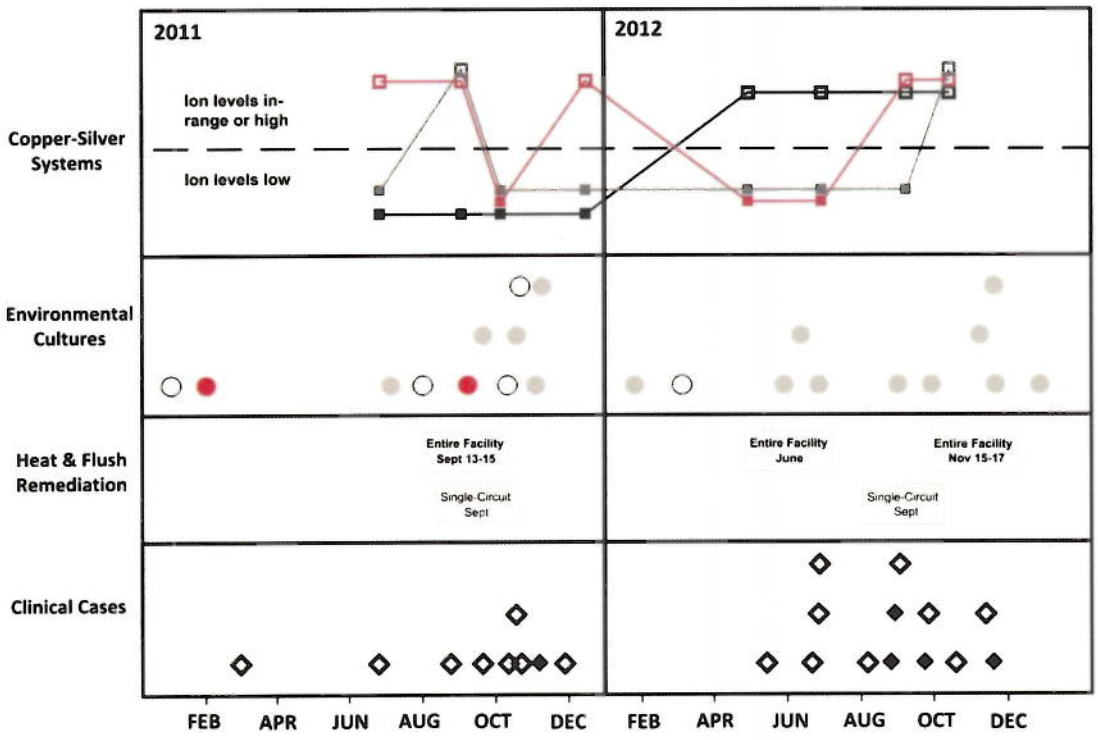
OR

2. Exposure to VAPHS during the 14 days prior to onset
AND
a clinical respiratory isolate matching an environmental isolate from VAPHS by molecular methods.</td></tr>
<tr><td>Probably healthcare-associated</td></tr>
<tr><td>Exposure to VAPHS including but not limited to:
• overnight stay
• outpatient visit
• visitor
• employee
• volunteer
during a portion of the 2-14 days prior to onset.</td></tr>
</table>

Appendix B

Management of Legionnaires' disease at VAPHS, 2011-12.

Copper-silver ionization systems: Each line represents a distinct hot water circuit.
Environmental cultures: Each circle indicates environmental sampling: Closed red circles, at least 10 distal sites sampled, with at least 30 percent of sites positive; closed gray circles, positive cultures, with at least 10 distal sites sampled but fewer than 30 percent positive or less than 10 sites sampled; open circles, no positive cultures.
Clinical cases: Closed diamonds, "definite" healthcare-associated LD; open diamonds, "probable" cases



Appendix C

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: April 11, 2013

From: Director, VA Healthcare Network (10N4)

Subject: **Healthcare Inspection – Legionnaires' Disease at the VA Pittsburgh Healthcare System, Pittsburgh, PA**

To: Assistant Inspector General for Healthcare Inspections (54)

Director, Management Review Service (VHA 10AR MRS)

I have reviewed the information provided by the VA Pittsburgh Healthcare System and I am submitting it to your office as requested. I concur with all responses and target dates.

If you have any questions or require additional information, please contact Barbara Forsha, VISN 4 Quality Management Officer at 412-822-3290.

(original signed by:)
Michael E. Moreland, FACHE

Appendix D

VAPHS Director Comments

Department of Veterans Affairs **Memorandum**

Date: April 11, 2013

From: Director, VA Pittsburgh Healthcare System (646/00)

Subject: **Healthcare Inspection – Legionnaires' Disease at the VA Pittsburgh Healthcare System, Pittsburgh, PA**

To: Director, VA Healthcare Network (10N4)

1. The findings from the Healthcare Inspection – Legionnaires' Disease at the VA Pittsburgh Healthcare System reviewed by the Office of the Inspector General (OIG) conducted during two site visits January 14-17 and February 26-28, 2013 have been reviewed.

2. Attached are the facility responses addressing each recommendation, including actions that are in progress and those that have been completed.

(original signed by:)
Terry Gerigk Wolf, FACHE
Director

VAPHS Director Comments to OIG's Report

The following comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

Recommendation 1. We recommended that the VA Pittsburgh Healthcare System Director ensure that any disinfectant system in use for *Legionella* prevention is monitored and maintained in accordance with manufacturer's instructions.

Concur **Target Completion Date**: August 31, 2013

Response: VAPHS used a copper-silver ionization system throughout its patient care campuses until the system was taken off-line entirely in November 2012. Over the years, the system received regular monitoring and maintenance but maintaining ion level within the range specified by the manufacturer required frequent adjustments and ion levels would fluctuate between those adjustments. When ion levels fell out of range, the vendor was contacted for the appropriate adjustment in settings. After those adjustments were made, the system would cycle for a period of time before repeat ion levels were taken and further adjustments made as needed. The system was also impacted by water pH, dissolved solids, and flow over the copper-silver cells. During the collaborative review with the CDC, *Legionella* bacteria were discovered growing in water samples with adequate copper and silver ion levels.

Consequently, VAPHS replaced this system with a direct chlorine infusion system. Chlorine readings are taken daily from each of the plumbing loops as well as from multiple distal water outlets at all three campuses. Electronic chlorine analyzer and control systems (trim analyzers) have been installed in each of the plumbing loops at the two patient care campuses in order to permit accurate control of chlorine levels in a range between 0.5 and 4.0 parts per million (PPM). VAPHS has standardized the maintenance and monitoring of these systems in accordance with manufacturer's instruction and maintains competency validation records for the employees who work with it. These competency validation records will be audited for completeness and appropriateness. VAPHS awarded a contract for a consultant to assist in developing a hazard analysis and critical control point (HACCP) plan. Work started in the first week of April 2013 and involves facilities management, executive leadership, infection control and prevention, and research staff. The goal will be to produce a series of water maintenance processes which will ensure consistent disinfection levels, appropriate monitoring activities, and rapid intervention for needed adjustments in order to prevent wide fluctuation in chlorine levels. The HACCP plan will serve as a template for policy and procedures for maintaining proper chlorine levels.

Recommendation 2: We recommended that the VA Pittsburgh Healthcare System Director ensure routine flushing of hot-water faucets and showerheads.

Concur **Target Completion Date**: December 31, 2013

Response: VAPHS has more than 2,700 water outlets with varying levels of usage. Historically, thermal eradication and flushing of various outlets occurred where positive cultures were identified throughout the healthcare system. VAPHS recognizes the importance of water temperature as the primary *Legionella* remediation method, but also the balance that must be achieved between that and mitigating any risk of scalding by staff or patients. The current plumbing system could not support sustained high temperatures recommended in the VHA directive in order to prevent rapid growth of *Legionella* at all distal sites.

In order to address water temperature concerns (sufficiently high water temperatures to prevent growth of Legionella and safe water temperatures flowing from the faucets and showers to prevent scalding), a contract has been developed to include installation of mixing valves on every point of use showerhead and faucet to allow circulating water temperatures to be increased to a point sufficient to prevent rapid growth of *Legionella*. As part of this contract, instantaneous hot water heaters have been purchased and will be strategically placed at distal sites to insure temperatures remain at or above the VHA recommended level. The contract for this project was awarded on February 8, 2013 and work is expected to start in April 2013. The goal is for project completion by August 31, 2013.

Additionally, VAPHS developed a scope of work to map the entire plumbing system, update blueprints, and identify unused plumbing sections ("dead legs") in the system. That contract was awarded April 10, 2013 with an estimated completion date of December 31, 2013. The goal is to eliminate areas of water stagnation that could lead to *Legionella* amplification. Once the plumbing mapping is complete, a comprehensive flushing protocol can be developed and implemented to assure all water systems are properly flushed and maintained. In the interim, underutilized water outlets are being taken out of service to inhibit *Legionella* growth and environmental management staff are flushing water fixtures in patient care areas during room cleaning.

Recommendation 3: We recommended that the VA Pittsburgh Healthcare System Director ensure close coordination between the Infection Prevention Team and Facilities Management Service staff.

Concur **Completion Date**: January 31, 2013

Response: The VAPHS has had an established Infection Prevention Committee for many years which meets every other month. Their responsibility is to address any healthcare acquired infections or any failures in the healthcare system that may expose Veterans, visitors and employees to increased risk of infection. The committee is comprised of individuals from varying disciplines with *Legionella* suppression addressed as a frequent agenda topic. Prior to January 2013, Facility Management Service

maintained close communication with the committee but since that time they have become active members.

Due to the complexities of maintaining the water system of a multiple site campus, VAPHS recognized the need for a committee that is tailored to address only water related issues. A Water Safety Committee was chartered on January 22, 2013 and the first meeting was held on January 31, 2013 with regular meetings held twice a month. The committee is led by a member of the executive leadership team and contains representatives from facilities management, infection prevention and control, laboratory, the safety office, the research department, environmental management and local union officials. All aspects of *Legionella* control including water testing, water remediation, construction projects, and issues with water quality from the local water authority are discussed and interventions implemented where appropriate. This committee reports to the VAPHS Executive Leadership Board of the healthcare system.

A small subgroup of the water safety committee has been tasked to study variables such as heat, pH, dissolved solids, and other organic matter that may impact the concentration of chlorine present in various sections of the plumbing system. The subgroup consists of VAPHS researchers with expertise in epidemiology and healthcare database design as well as the facilities manager, and representatives of facility leadership. A consultant specializing in the evaluation of plumbing systems utilizing chlorine-based *Legionella* prevention will also be included. The purpose will be to assess what relationships exist between chlorination levels in various plumbing segments and other variables present in the water such as temperature, pH, dissolved solids, and other organic matter. The findings will be informative for VAPHS policy and may lead to knowledge that can be informative for other healthcare facilities.

Recommendation 4: We recommended that the VA Pittsburgh Healthcare System Director ensure that when environmental cultures are positive, actions taken comply with the Veterans Health Administration guidelines.

Concur **Completion Date**: February 7, 2013

Response: Past practice for addressing positive Legionella culture results at VAPHS included thermal eradication, local fixture sanitation, or spot flushing at the water outlets. Since these actions involve substantial coordination, VAPHS recognized the necessity for standardizing the documentation process. A database project was developed which involved labeling every distal water outlet in the facility with its own number and barcode. When water samples are taken, the individual sink or shower is identified, linked to the specific sample, and recorded in the database with other metrics related to water quality such as temperature, biocide (chlorine) levels, and pH levels.

In the event that a sample is returned with a result positive for *Legionella*, an electronic work order is placed by a member of the infection control and prevention team. The identification number of that work order is linked to the uniquely identified distal site and its corresponding sample so that the remediation may be specifically identified, linked to the correct distal water outlet, and fully described. This system facilitates tracking and

randomization of sampling sites as well as queries into areas where remediation has taken place so that trends may be identified. The database also creates a documentation trail, which is searchable and easily monitored and audited. Capability exists to add events such as construction activities and newly installed distal water outlets. The database was implemented February 7, 2013.

VAPHS follows the mitigation protocol as outlined in the VHA Directive. Infection control and Facilities Management continue to work collaboratively on appropriate remediation strategies immediately upon discovering a positive culture. When a site tests positive, infection control reviews the results as well as the water qualities recorded at the time of sampling and enters a work order for the appropriate local remediation action. Infection Control also obtains cultures from adjacent sites in order to determine if a local remediation is adequate or if a system-wide remediation is required.

Recommendation 5: We recommended that the VA Pittsburgh Healthcare System Director ensure that all healthcare-associated pneumonia patients are tested for *Legionella* infection.

Concur **Completion Date**: November 16, 2012

Response: Historically, VAPHS tested for *Legionella* in suspected pneumonia cases at a higher rate than most medical facilities in the community. Additionally, infection prevention and control staff members reviewed, on a daily basis, all inpatient chest X-rays suspicious for pneumonia in order to make patient care decisions.

Since November 16, 2012, VAPHS has created a formal process, which requires that all patients presenting with symptoms of pneumonia, regardless of the source or type, undergo urine antigen testing as well as a sputum specimen in order to test for *Legionella*. Embedded within this process is a requirement that the laboratory staff review all specimen submissions, on a daily basis, in order to ensure that both the urine antigen and sputum culture are ordered for each suspected case. If a patient is unable to produce a sputum specimen, respiratory therapy staff will be contacted to assist with obtaining a specimen.

OIG Contact and Staff Acknowledgments

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Appendix F

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