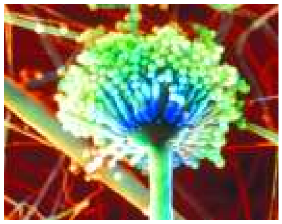
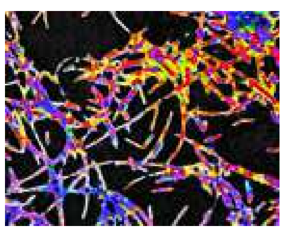


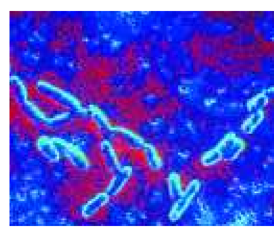


BASIC FACTS ABOUT

COMMON WATERBORNE PATHOGENS

SOURCES, RISKS AND CONTROL MEASURES





This brochure has been created to provide healthcare professionals with information about the role that tap water plays in patient morbidity and mortality. Point-of-Use filtration technology minimizes patient and hospital staff exposure to waterborne pathogens and contributes to shorter lengths-of-stay, reduced antimicrobial costs and better patient quality of life during treatment.

Pall Medical is committed to helping the medical community address growing concerns for contamination in biological fluids, water, drugs and air as sources of infection. We hope that you find this booklet to be a valuable information resource. For more information, please visit www.pall.com/healthcarewater

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PALL® Medical

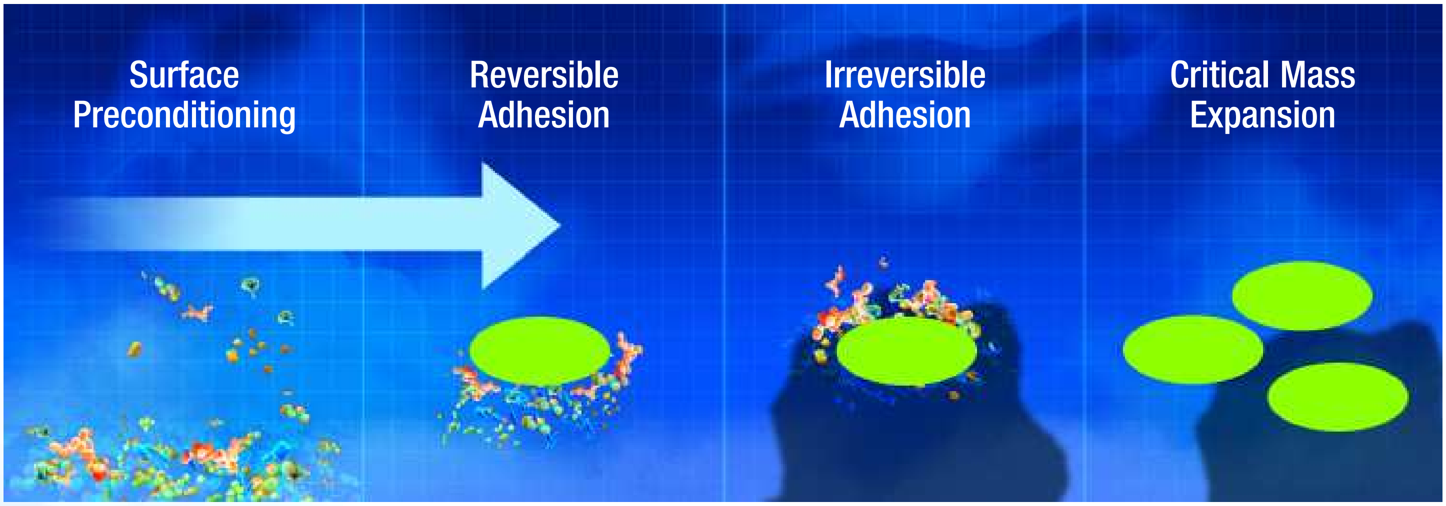
Water & Biofilm

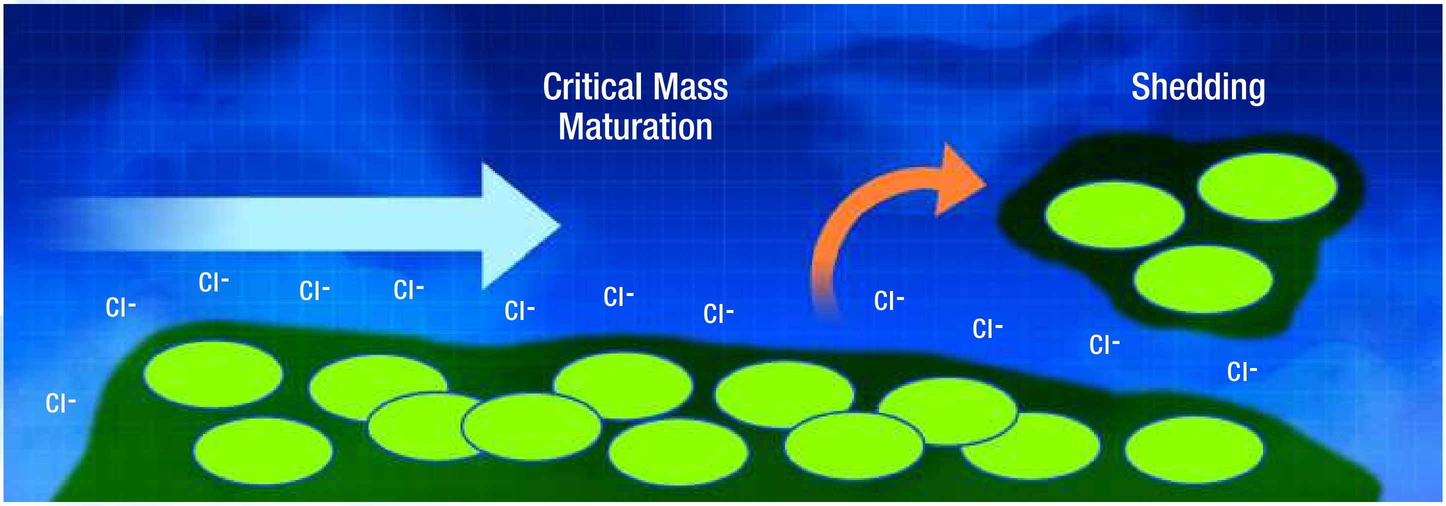
Water is the essence of life, and we naturally associate it with purity and cleanliness.

We rarely think of tap water as harmful, but in the healthcare setting, water can be the carrier of morbidity and mortality. Many different bacteria, fungi, and parasites can be found in tap water.

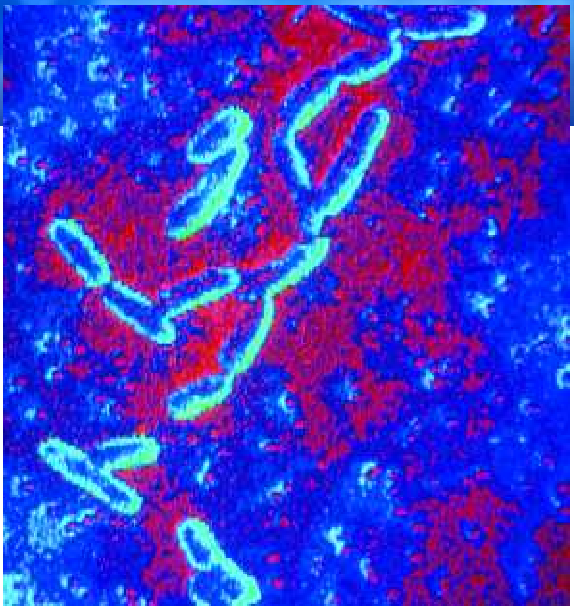
Originating at the municipal water supply or local aquifer, hospital water containing low levels of microbes is diverted to hot and cold water supply systems. Although different types of free-floating microbes may predominate in hot and cold water, they have the common ability to anchor themselves to internal pipe surfaces, faucets, and shower heads. Once they irreversibly attach to an internal plumbing surface,they multiply and produce a sticky extracellular matrix. This highly organized and well-characterized aggregate of numerous types of microbes that flourish within the matrix is called a biofilm. As microbes within a biofilm multiply and the biofilm enlarges,the shearing forces of flowing water break off microbe-containing fragments and transport them to distant locations in the water distribution system through processes known as seed dispersal, streaming, detaching, rolling, and rippling.

In this way, biofilm serves as a repository for the sustained release of bacteria into flowing water. In order to eradicate waterborne microbes, water systems are periodically disinfected either chemically or with extremely hot water. Although these methods may achieve a measure of short-term success, that success rarely extends to the long-term because these methods cannot access and destroy every biofilm community, nor are they sufficient to cope with occasional bursts of elevated microbial levels in incoming water. Also, in complex plumbing systems, improper design or facility renovations result in “dead ends” where water stagnates and disinfectants cannot attain adequate concentrations to eradicate biofilm. Biofilm in plumbing “dead end” regions constantly seeds the formation of new biofilm communities elsewhere in the plumbing system.





Waterborne Pathogens



According to the U.S. Centers for Disease Control, nearly two million patients per year contract infections during their stays initals (about 10% of all hospitalized patients), resulting in significant morbidity, mortality, and financial burden[1]. Healthcare-associated infections (HAIs) in the U.S. resulted in 88,000 deaths in 1995[1]. Their annual cost is estimated to be as much as $5.7 billion[2], with patient costs of up to $50,000 per episode[3-6].

Microbes in healthcare facility water can cause HAIs. Tap water used for drinking, showering, bathing, ice preparation, and rinsing medical devices presents a potential hazard, especially to at-risk patients such as those in the following units:

- Bone Marrow Transplant
- Burn
- Hematology/Oncology
- Neonatal Intensive Care
- Pediatric Intensive Care
- Solid Organ Transplant
- Surgical Intensive Care
- Medical Intensive Care
- Cardiac Intensive Care
- Respiratory Intensive Care

Faucets and showers are also a source of aerosolized tap water. They produce vaporized water droplets that migrate on almost imperceptible air currents to distant locations within the healthcare environment. The water droplets, which carry bacterial, fungal, and protozoan pathogens, then settle on surfaces and contact patients and staff through touch contamination or inhalation by susceptible individuals.

Waterborne Pathogen Facts:

- Contamination of the healthcare facility water supply with potentially pathogenic organisms is very common.
- The magnitude of the problem presented by waterborne pathogens is widely recognized but undetected because proper culturing methods are not routinely performed.
- The scientific literature has detailed a considerable number of studies that have established a genetic link between waterborne pathogens and patient infection[7-13].
- Common waterborne pathogens of primary clinical significance include:

Bacteria:
- *Pseudomonas aeruginosa*
- *Legionella pneumophila*
- *Acinetobacter spp.*
- *Klebsiella spp.*
- *Nocardia spp.*
- *Mycobacterium avium complex*

Parasites:
- *Cryptosporidium parvum*
- *Giardia lamblia*
- *Acanthamoeba spp.*

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

Waterborne Pathogens and Point-Of-Use Filtration:

Point-of-use 0.2 micron filters for water faucets, showers, ice machines, and water sources used for rinsing of medical devices provide a cost-effective alternative for managing waterborne pathogens that would otherwise enter the healthcare environment.

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Biofilm Facts

A biofilm is a microbially derived sessile community characterized by cells that:

- are irreversibly attached to a substratum, interface, or to each other
- are embedded in a matrix of extracellular polymeric substances that they have produced
- have exhibited an altered phenotype with respect to growth rate and gene transcription[1].

Biofilm formation is a critical factor influencing the contamination of tap water. Biofilms are prone to form on the internal lumens of plumbing systems, due to the availability of nutrients in the water and other factors such as[2]:

- Water chemistry
- Water flow
- Water stagnation
- Water temperature
- Surface materials of construction
- Degree of surface corrosion
- Degree of shear stress over the surface
- Degree of surface flushing

Biofilm and Antimicrobial Resistance:

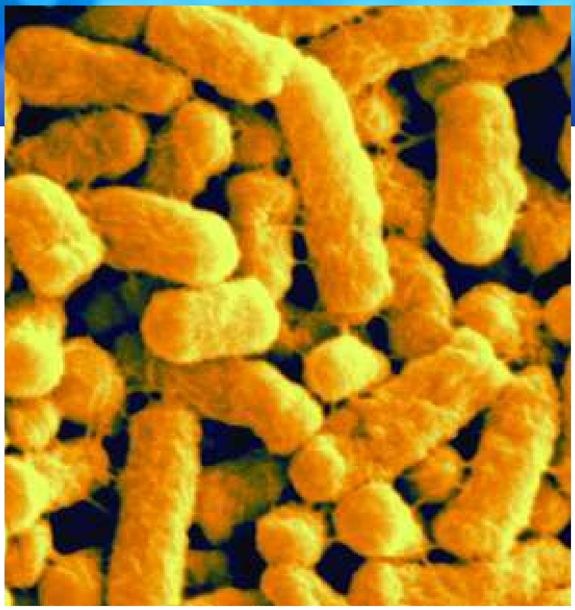
Some biofilm-associated bacteria display a higher level of resistance to antimicrobial agents than planktonic (free-floating) bacteria[1-3]. Their increased level of antimicrobial resistance can be attributed to the failure of the antimicrobial agent to reach target biofilm cells due to its inability to[1]:

- penetrate biofilm's extracellular polymeric matrix
- penetrate dense cell aggregates and microcolonies
- bind to the extracellular polymeric matrix

Biofilm and Systemic Water Disinfection Methods:

Systemic water treatment methods such as hot water flushing, hyperchlorination, chlorine dioxide, copper-silver ionization, ozonation, ultraviolet light, and monochloramines are generally unable to permanently eradicate biofilms from healthcare facility plumbing systems over the long-term[2]. These treatment methods do not respond effectively to sudden, unanticipated infusions of hospital water systems with high concentrations of pathogens due to[2]:

- Facility renovation projects
- Municipal water system breakdown and repair activities
- Seasonal water quality variations



Biofilm Facts:

The stages of biofilm formation include[2]:

- Surface preconditioning
- Reversible adhesion
- Irreversible adhesion
- Maturation
- Shedding

Biofilm and Point-Of-Use Filtration:

- Point-of-use 0.2 micron filters for water faucets, showers, ice machines, and water sources used for rinsing of medical devices can either provide cost-effective insurance against the inadequacies of systemic water treatment methods or replace them entirely.

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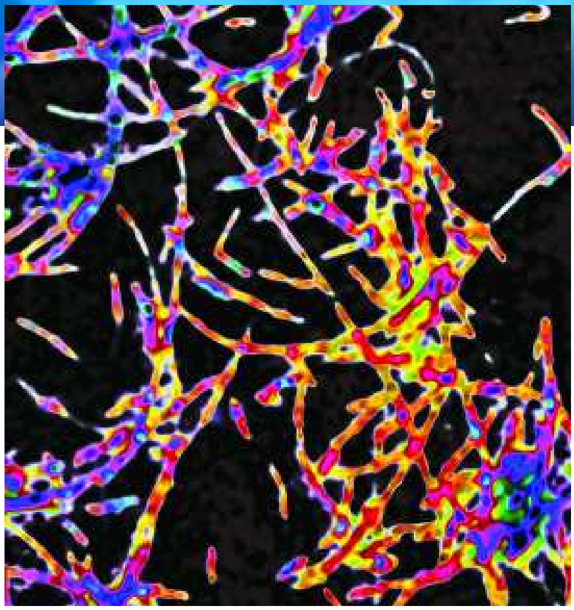
Legionella

Legionnaires' disease was first identified and named in 1976 when a group of American Legion conventioneers at the Hotel Bellevue in Philadelphia, PA were taken ill, some fatally, from a contaminated air conditioning system[1,2]. For the majority of people exposed to *Legionella* bacteria, the outcome is benign. However, for sensitive populations such as newborns, the elderly, those recovering from burns or recent surgery, or those suffering from cancer or chronic lung disease, the outcome can be serious and life threatening[3]. Immunocompromised patients such as allogeneic and autologous bone marrow transplant recipients, solid organ transplant recipients, and HIV-positive patients are also at high risk for *Legionella* infection[4].



Legionella Facts:

- *Legionella* present one of the most pressing and high-profile problems with respect to waterborne healthcare-associated infections[5].
- Pediatric hospitals, rehabilitation centers, and long-term care facilities have reported healthcare-associated infections linked to the potable water supply[4].
- The correct diagnosis of healthcare-associated Legionnaires' disease is easily overlooked, since it is difficult to distinguish from other forms of pneumonia. In addition, specialized microbiological studies are necessary to detect it[5].
- Legionnaires' disease had occurred at two institutions for periods of 12 and 17 years, respectively, before intervention measures were applied. Most of the cases were diagnosed retrospectively, with some only being diagnosed at autopsy[6,7].
- Contamination of intensive care unit tap water led to a cryptic epidemic of ventilator-acquired pneumonia caused by *L. anisa*[8].
- The U.S. Centers for Disease Control recently amended their guidelines to stipulate that water in areas housing transplant patients should not contain any *Legionella* bacteria[11].

Challenges to controlling *Legionella* in healthcare facility systems:

- *Legionella* are constituents of biofilms that contaminate the internal plumbing of hospital water systems[4].
- *L. pnemophila* is amoeba-resistant, meaning that is it able to grow and multiply within an amoeba[12].
- Studies have confirmed that free-living amoebae are necessary for *Legionella* multiplication in water biofilms, although they may survive in a latent state in biofilms without amoebae[13].
- When an amoeba encysts to protect itself from adverse environmental conditions, it may protect *L. pneumophila* from the effects of chlorine[12].
- Recolonization of *Legionella* is very likely to occur in the long-term after systemic water treatment technologies have been implemented[4].

Legionella and Point-Of-Use Filtration

- Sheffer et al. evaluated the Pall-Aquasafe™ water filter in a hospital building with chronic *Legionella* contamination and determined that point-of-use filters completely eliminated *Legionella pneumophila*[9].
- Vonberg et al. evaluated the performance of point-of-use tap water filters in three intensive care units. Without filtration, it was shown that over 90% of 32 samples collected were positive for *Legionella* at concentrations ranging from 1-106 cfu/ml. In contrast, 250 out of 251 samples recovered from taps fitted with filters for seven days failed to recover any *Legionella.* In the single positive sample, the residual *Legionella* concentration was only 1 CFU/mL[10].
- *Legionella* species measure 0.3-0.9 microns wide by 2 microns long[14]. They and the larger amoeba which they inhabit are easily retained by point-of-use 0.2 micron filters.

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Pseudomonas

Pseudomonas aeruginosa is ubiquitous in water. It can be carried by touch contamination[1]. As an opportunistic microorganism, it rarely causes harm to the immune competent individual. However, *P. aeruginosa* is commonly recognized as one of the more virulent microorganisms among immunocompromised patients both in and out of the hospital setting[2]. It has been shown to be responsible for fatality rates approximating 30% among those with pneumonia and septicemia[3], and when the causative agent of ventilator-associated pneumonia, mortality may be as high as 38%[4]. Among AIDS patients, *P. aeruginosa* can effect 50% fatality rates[5], and it is lethal in 60% of the highly susceptible burn patient population[4]. Cystic fibrosis patients are particularly susceptible, with virulence and antibiotic resistance having been well studied[6].

Pseudomonas Facts:

- The U.S. National Nosocomial Infection Surveillance system report issued in 2000, comprising data from 205 medical and surgical intensive care units collected over a seven-year period and involving 500,000 patients with 29,000 healthcare-associated infections, stated that *P. aeruginosa* ranked among the top five most frequently encountered organisms responsible for healthcare-associated infections[7].
- A principal factor in the establishment and maintenance of virulence in *P. aeruginosa* is its resistance to antibiotics[2].
- *P. aeruginosa* is a common constituent of biofilms[2].
- Studies in the scientific literature have linked healthcare-associated infections to drug-resistant *P. aeruginosa* in the hospital water supply[8].
- Recent data suggest that *P. aeruginosa* found in hospital water is a significant source of healthcare-associated infections[9].
- During a six-month period in a 16-bed surgical intensive care unit, Trautmann et al. demonstrated through DNA-based typing techniques that 5/17 (29%) of invasive *Pseudomonas* infections were caused by strains isolated from the tap water in the intensive care unit[10].
- 36-42% of healthcare-associated Pseudomonas aeruginosa infections are possibly due to contaminated tap water[11].
- A study by Blanc et al. concluded that the water systems of the intensive care units investigated was the primary reservoir of patient colonization and infection with *P. aeruginosa* in a substantial proportion of patients[12].
- A three year prospective study of intubated ICU patients colonized with *P. aeruginosa* observed that the source of strains was predominately environmental, in most cases the tap water from the patient's room.[13].

Pseudomonas and Point-Of-Use Filtration:

- Exposure to *P. aeruginosa* can be managed with point-of-use bacterial retention filters at faucets and showerheads as an adjunct to or replacement for existing systemic water disinfection regimens.

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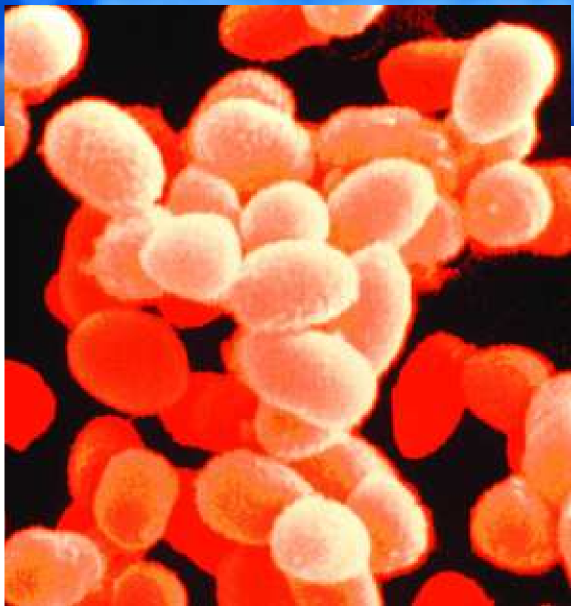
Mycobacteria



As opposed to *M. leprae* and members of the *M. tuberculosis complex*, environmental opportunistic mycobacteria are normal inhabitants of municipal water and water aerosols[1]. In addition, they may grow and replicate within protozoa like *Acanthamoeba spp.*, which protect them from conventional water disinfection regimens. Their prevalence in municipal drinking water is directly related to their high innate resistance to chlorine and biocides[1]. Systemic water treatment technologies such as ozone and chlorine have even been found to cause a shift in the population of waterborne microbial flora away from the original distribution to a greater predominance of members of the *Actinomyces* family, which includes *Mycobacterium*[2].

Water is a likely source of *M. avium* complex infection in humans, as evidenced by a study in which DNA-based fingerprints of *M. avium* isolates from AIDS patients were found to be identical to those of isolates recovered from their drinking water[3]. Furthermore, environmental *Mycobacteria* such as *M. fortuitum*, *M. chelonae*, and *M. avium* are capable of forming biofilm, which enable their populations to persist in a water distribution system in spite of their slow doubling time, which can range from 2-48 hours[1].

Mycobacteria Facts:

- Mycobacteria possess an extraordinary ability to survive in tap water[4,5].
- Mycobacteria are tolerant of extreme temperatures[6] and can therefore survive in both hot tap water and ice machines. The most thermoresistant species include *M. avium complex*, *M. xenopi*, *M. phlei*, and *M. chelonae*[1].
- *M. avium* exhibits higher chlorine resistance than other environmental mycobacteria, but even weaker mycobacterial species such as *M. aurum* are 100-fold more chlorine tolerant than *E. coli*[7,8].
- They have a complex, lipid-rich cell wall that renders them hydrophobic. Their hydrophobicity assists in their attachment to the internal surfaces of plumbing systems, where they are thought to be biofilm formation "pioneers"[9]. It also causes them to migrate to the surface of an air-water interface, from which they are readily aerosolized[1].
- *M. avium*, *M. fortuitum*, and *M. marinum* have been shown to be amoeba-resistant, namely able to survive phagocytosis by amoeba such as *Acanthamoeba*[10]. This characteristic has been linked to a higher degree of virulence and enhanced resistance to antimicrobial agents[10,11]. *M. avium* surviving within an amoeba have even been shown to survive the amoeba's encystment in response to adverse environmental conditions and subsequent excystment when more favorable survival conditions emerged[12].
- A definitive genetic link was established between *M. mucogenicum* isolates from a hospital shower and a bacteremic hospital patient[13].
- A genetic link was established between *M. simiae* isolates found in a home shower and various hospital water sites to those found in patients who had contracted *M. simiae* pulmonary disease[14].

Mycobacteria and Point-Of-Use Filtration:

- Exposure to environmental mycobacteria can be managed with bacterial retention filters mounted to faucets and shower heads, as well as the incoming water supply of ice machines and sprayers used for medical device reprocessing.

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Aspergillus

Aspergillus is a group of molds that are ubiquitous in nature and common to water environments. They are also resistant to many water disinfection treatment methods. Failure of disinfection methods to eradicate waterborne *Aspergillus* can lead to dissemination of their spores. In water distribution systems, *Aspergillus* can quickly flourish at sites of biofilm development[1,2].

Invasive aspergillosis is now considered to be the second most common fungal infection requiring hospitalization in the United States[3]. In patients with positive fungal cultures, *Aspergillus spp.* are the second most common isolates after *Candida sp.*[3]. Invasive aspergillosis has been associated with a 60% overall mortality rate, and a mortality rate of 80-90% among severely immunocompromised patients[4].

Aspergillus Facts:

- In a three-year prospective study conducted by Anaissie et al. at a 350-bed teaching hospital, a total of 416 water samples were drawn from both municipal and hospital water sites. Aspergillus species were recovered from 33% of municipal water sites, 55% of hospital water sites, and 21% of patient care area faucet and shower sites[5]. Data from the same study indicated that in patient rooms with properly functioning laminar airflow systems, the concentrations of airborne *Aspergillus* in the bathrooms adjoining patient rooms was six-fold higher than the concentrations in the rooms themselves. This finding suggested that *Aspergillus*-containing aerosols generated by the bathroom showers produced the elevated concentrations of airborne *Aspergillus*.
- The 2003 Centers for Disease Control Guidelines for Infection Control in Health Care Facilities suggests minimizing the exposure of severely immunocompromised patients to activities that might result in their exposure to fungal spores[6]. It stands to reason that point-of-use water sources such as faucets and showers should also be a matter of concern.

Aspergillus and Point-Of-Use Filtration:

- Point-of-use 0.2 micron filters on faucets and showers can assist in managing patient exposure to waterborne pathogens such as *Aspergillus sp.*

Infections caused by *Aspergillus spp.* are associated with high rates of morbidity and mortality, especially in the following patient populations:

- Allogeneic hematopoietic stem cell transplant recipients
- Patients receiving chemotherapy for non-hematologic malignancies.
- Heart and lung transplant recipients
- AIDS patients
- Severe burn patients

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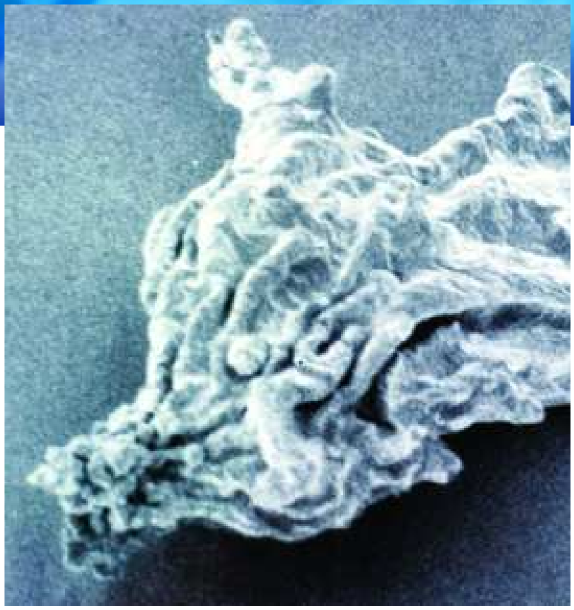
Amoeba-Resistant Microbes

Amoebae pose a unique threat to the healthcare environment. Not only are they pathogenic in their own right, but they can also function as "Trojan horses" that can harbor and safely transport Amoeba-resistant strains of bacteria, viruses, and occasionally fungi[1]. Amoeba-resistant organism*s* are defined as those microbes that have evolved to resist destruction by free-living amoeba[1]. Some Amoeba-resistant microbes cannot be engulfed by amoeba, while others can survive and grow after internalization and subsequently return safely to the environment[1].

Amoebae have been recovered from drinking water, cooling towers, and hospital water networks[1]. They often live on biofilm and other water-soil, water-air, and water-plant interfaces[3]. When they are confronted with harsh environmental conditions that threaten their survival, they convert to a resting form known as a cyst[1]. Amoeba cysts are resistant to chlorination, adverse pH, osmotic pressure, and temperature[1]. Free-living amoebae have demonstrated resistance to hyperchlorination treatment of complex water delivery systems[2].



Some waterborne amoeba-resistant microorganisms include the following:

- *Legionella pneumophila*
- Other *Legionella spp.*
- *Pseudomonas aeruginosa*
- *Burkholderia cepacia*
- *Burkholderia pseudomallei*
- *Mycobacterium avium*
- *Mycobacterium fortuitum*
- *Mycobacterium simiae*
- *Flavobacterium spp.*

Amoeba-Resistant Microbe Facts:

- Studies have confirmed that free-living amoebae are necessary for *Legionella* multiplication in water biofilm, although they may survive in a latent state in biofilm without amoebae[4]
- Microbes that are engulfed by amoebae are encased in internal structures called vesicles. A single vesicle inside an amoeba may harbor thousands of *Legionella* bacteria[5,6].
- When an amoeba containing *L. pneumophila* encysts to protect itself from adverse environmental conditions, it may protect *L. pneumophila* from the effects of chlorine[7].
- The survival of *Mycobacterium avium* within amoeba cysts has been well documented[8,9].
- Contamination of intensive care unit tap water led to a cryptic epidemic of ventilator-acquired pneumonia caused by an amoeba-resistant strain of *L. anisa*[10].

Amoeba-Resistant Microbes and Point-Of-Use Filtration:

- Free-living *Acanthamoeba spp.* measure 15-45 microns in diameter, while their cysts measure 10-25 microns in diameter[11]. They and the Amoeba-resistant microbes that they might harbor are therefore easily retained by point-of-use 0.2 micron filters.

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Water and At-Risk Patients

Patients with weakened immune systems are particularly vulnerable to direct contact with pathogens

Patients with weakened immune systems are particularly vulnerable to direct contact with pathogens in contaminated water, whether it be in the form of a liquid stream, an inhaled aerosol, the ice in a beverage, contact with a staff person who has just washed her hands, or with a reprocessed medical device that has been rinsed with water. When water enters the hospital room environment from a faucet or shower, tiny water droplets containing biofilm contaminants separate from the main water stream and are spread by air currents in all directions. Some are then inhaled as aerosols, while others condense onto surfaces where they can be transferred to patients and staff through touch contamination. Although these aerosols may not pose a threat to a healthy individual, they can very seriously affect the health of an immunocompromised patient.

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- Have significantly contributed to reductions in the monthly rate of P. aeruginosa infections in the clinical setting[1-4].
- Are an infection control measure that has contributed to the dramatic decline of P. aeruginosa-derived NICU infections[6].
- Can generate drinking water that is much less expensive than bottled water or bottled sterile water[5].
- Can enhance the qualify of life for seriously immunocompromised patients by permitting them to bathe and shower.
- Can be used with water-based hand disinfectants for effective removal of C. difficule spores.

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