**Nontuberculous Mycobacteria Infections Associated with Heater-Cooler Devices**

Public health and healthcare practitioners are familiar with *Mycobacterium tuberculosis*, which continues to cause tuberculosis cases and deaths throughout the world. Other related species may be less well known. One nontuberculous Mycobacterium species was recently the focus in an investigation of healthcare-associated infections.

**Background**

Nontuberculous Mycobacteria (NTM) organisms are found in the environment from sources such as water and soil. These species are not commonly pathogenic for humans. In rare situations, NTM organisms have caused infections in vulnerable patients such as those with significant illnesses or compromised immune systems. Factors influencing transmission of NTM from the environmental reservoirs to humans are poorly understood. Inhalation of aerosols appears to be the primary transmission route for NTM pulmonary infections, usually as a result of exposure to artificial water environments such as hot tubs and showers. The incubation period can be long, lasting up to years after exposure.

*Mycobacterium chimaera* was distinguished within the Mycobacterium avium complex (MAC) as a novel species in 2004. Infections have been identified mainly in persons with cystic fibrosis, presenting as pulmonary infections. Extrapulmonary infections are rare with this species.
Cluster Investigation

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Heater-cooler units were recently implicated as a source of exposure to *M. chimaera* which caused surgical site infections. The first report was from Switzerland in 2012 where investigators reported a cluster of infections in six post-operative patients. The cases had undergone open heart surgery procedures that used heater-cooler units during extracorporeal circulation. In 2015 in the United States, several states reported clusters of infections with *M. chimaera* that were healthcare associated. Epidemiologic and laboratory evidence was used to identify an association between the NTM infections and exposure to contaminated heater-cooler devices, all one model manufactured by a single company.

Risk for NTM post-operative infection is low, estimated as between 1 in 100 and 1 in 1000 in hospitals where cases have been identified. Diagnosis is challenging because infected patients have presented with a variety of clinical manifestations such as endocarditis, surgical site infection, or abscess and bacteremia. Other manifestations have included hepatitis, renal insufficiency, splenomegaly, pancytopenia, and osteomyelitis. Specific mycobacterial cultures must be ordered to diagnose the infection, which will not be identified on routine bacterial cultures.

Heater-cooler units are used to regulate the blood temperature during the cardiac bypass phase of cardiothoracic surgery (e.g., coronary surgery, valve replacement) or liver transplants. Although a patient and the circulating blood have no direct contact with the unit’s water, there is the potential for the contaminated water to enter other parts of the device or to escape through vent(s) into the operating room environment. The result could be contaminated water reaching a patient’s open surgical cavity.

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**Figure 1:** Schematic representation of heater–cooler circuits tested for transmission of Mycobacterium chimaera during cardiac surgery despite an ultraclean air ventilation system. Blue arrows indicate cold water flow, and red arrows indicate hot water flow and patient blood flow.

[http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/ucm20082725.htm](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/ucm20082725.htm)
During the 2015 cluster investigation, *M. chimaera* isolates were obtained from patients and devices in the U.S. outbreak. Results from whole genome sequencing completed on isolates from 11 patients and from five heater-cooler devices from hospitals in Pennsylvania and Iowa strongly suggested a point source contamination of the devices rather than the devices becoming independently contaminated within the healthcare facilities. A recent report from Germany noted that preliminary typing results of *M. chimaera* isolated from heater-cooler devices from three European countries were almost identical to samples obtained from the manufacturing site for the devices, further supporting the likelihood of point-source contamination during production.

In a Health Alert Network advisory from October 13th, 2016, the Centers for Disease Control and Prevention (CDC) notified the country’s healthcare community that a specific brand of heater-cooler devices used during cardiothoracic surgeries may have been contaminated with *M. chimaera* at the manufacturing facility. As a result, any patient who has undergone cardiothoracic or other surgery which involved use of a LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stöckert 3T heater-cooler devices should be made aware of the risk for NTM infection.

The CDC advised hospitals to notify patients who may have been exposed to the heater-cooler devices during surgery. Such patients should seek medical care if they are experiencing symptoms such as night sweats, muscle aches, unexplained weight loss, fatigue or unexplained fever. CDC also issued guidance on identifying patients potentially at risk to ensure timely diagnosis and treatment. The CDC advised a patient notification time frame of four years and is therefore recommending that hospitals notify patients exposed after January 1st, 2012. Hospitals are also advised to perform retrospective case-finding for post-cardiac survey NTM infections back to January 1st, 2012.

In the alert, CDC recommended that physicians order mycobacterial cultures for any patient who had undergone a cardiac procedure in the past four years using a heater-cooler and who presents with signs consistent with an infection with NTM. The physician should also consider a consultation with a specialist in infectious disease. Because diagnosis by laboratory culture for mycobacteria can take up to two months, initiation of treatment has often been delayed.

Washington State Department of Health requests that facilities and providers report newly diagnosed extrapulmonary NTM infections to local health jurisdictions.

There are over 250,000 cardiopulmonary bypass procedures annually in the United States. The implicated device has a large share of the market. CDC resources for impacted healthcare facilities and healthcare providers include sample notification letters for providers and patients, frequently asked questions for hospitals, and a video. The CDC and the FDA are continuing their investigations.
Resources

[http://cid.oxfordjournals.org/content/early/2015/04/14/cid.civ198.full.pdf](http://cid.oxfordjournals.org/content/early/2015/04/14/cid.civ198.full.pdf)


CDC resources

[https://www.cdc.gov/HAI/outbreaks/heater-cooler.html](https://www.cdc.gov/HAI/outbreaks/heater-cooler.html)

FDA resources

[http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/ucm492590.htm](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/ucm492590.htm)

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