

Heater-cooler Notification
CDC Key Messages
December 2016

Summary

- CDC recently found that a device used during open-heart (open-chest) surgery might have been contaminated with a rare bacteria during manufacturing.
 - The heater-cooler devices: Stöckert 3T manufactured by LivaNova PLC (formerly Sorin Group Deutschland GmbH)
- Patients who have had open heart surgery and who are experiencing symptoms such as night sweats, muscle aches, weight loss, fatigue, or unexplained fever should seek a medical evaluation.
- In particular, CDC is advising hospitals to alert patients who have had open-heart surgery involving a Sorin Stockert 3T heater-cooler devices that they might be at risk for developing a life-threatening infection from *Mycobacterium chimaera*.

About the bacteria

- Nontuberculous mycobacterium (NTM) are a type of bacteria often found in soil and water but rarely make healthy people sick.
 - The specific type of NTM involved is called *Mycobacterium chimaera*
- Transmission of NTM from environmental sources to people can occur, but usually only among immunocompromised patients.
- NTM infection is also linked with getting medical care because of necessary procedures (such as surgery) that, by their nature, require breaches of patients' normal immune system defenses.
- NTM are often recognized as a cause of chronic lung infection, mostly among people who have underlying lung disease such as bronchiectasis or COPD.

About heater-cooler devices

- Heater-cooler devices are essential pieces of equipment that enable doctors to perform life-saving procedures.
- These devices are used during cardiac surgery when cardiopulmonary bypass is needed to help regulate the temperature of the patient's blood.
- The machine uses water to warm or cool the blood as it is circulated outside of the patient's body.
- The device's design includes a fan, which researchers now believe can disperse aerosolized bacteria into the operating room. The bacteria can then move through the air and enter the patient's open chest cavity.

Common Questions

- **What is the risk of infection?**

Overall, the risk is thought to be very low. In hospitals where at least one infection has been identified, the risk of infection was between about 1 in 100 and 1 in 1,000 patients. Initial information suggests that patients who had prosthetic implants are at higher risk. It is possible that not all of the devices introduced these bacteria into the operating room or exposed patients.
- **How long does it usually take for these infections to show up? What's the shortest amount of time it's taken for an infection to occur following exposure to a contaminated heater-cooler device during bypass surgery? The longest?**

NTM are slow-growing bacteria and infections may take months to develop. Cases associated with this device have been diagnosed within months and up to several years after an open-heart surgery involving heater-cooler unit exposure.

- **Can a person who develops one of these NTM infections spread it to others, such as family members?**

No, the bacteria cannot be spread to others from an infected patient. Also, it is important to keep in mind that NTM is common in soil and water but rarely makes healthy people sick.

- **Should everyone who was exposed to these devices during open-heart surgery receive antibiotics just in case?**

The risk that patients will develop an infection following exposure to a contaminated heater-cooler unit is very low. There is also no evidence that giving antibiotics just prior or during surgery with a potentially contaminated heater-cooler device will prevent infection.

Although antibiotics can be life-saving drugs, there is no antibiotic treatment available to ward off this specific infection and antibiotics are also not without risk themselves. Antibiotics put patients at risk for allergic reactions and a potentially deadly diarrheal infection caused by the bacteria *Clostridium difficile*. Antibiotic use is also a key driver of antibiotic resistance, which can put patients at risk for antibiotic-resistant infections later.

- **How long does it take to find out if an infection is being caused by NTM?**

M. chimaera is a slow-growing species of NTM that can take eight weeks and sometimes longer to grow and allow final identification.

- **Why are these infections so deadly?**

Symptoms of infection can take months to develop, and are often general and nonspecific. As a result, diagnosis of these infections can be missed or delayed, sometimes for years, making these infections more difficult to treat. Clinicians may not immediately consider an NTM diagnosis. Delayed diagnosis can result in more widespread disease in a patient. This, combined with underlying health problems such as heart disease can make these infections difficult to treat.

- **How do you think the devices got contaminated?**

NTM is common in water and soil. Recent CDC findings are consistent with previous reports suggesting that the heater-cooler units were contaminated during production. Testing conducted by the manufacturer in August of 2014 found *M. chimaera* contamination on the production line and water supply at the 3T manufacturing facility.

- **Have these devices ever been recalled? Why aren't they being recalled now?**

In 2015, the manufacturer recalled the instructions for use, but not the device itself. Information provided by the manufacturer reminded users that while water from the device itself is not intended to contact the patient directly, under certain circumstances, due to fluid leakage and/or aerosolization, NTM could reach a patient's surgical site. Heater-cooler devices are critical for life-saving surgery. A national recall could result in patients not getting life-saving surgeries that are needed now.

New heater-cooler equipment, manufactured by a different company, has been purchased and is now in use at McLaren Port Huron.