

Frequently Asked Questions for Patients regarding nontuberculous mycobacteria infections in surgeries using heater-cooler machines

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) have recently issued updated advisories regarding heater-cooler machines used in open-chest surgery. The machines used to heat and cool the blood during surgery have been linked to a rare bacterial infection caused by *Mycobacterium chimaera*, a slow-growing species of nontuberculous mycobacteria.

What is nontuberculous mycobacterium (NTM)?

NTM is a type of slow-growing bacteria that can be found in surface water, tap water and soil. This bacteria rarely causes infections in patients.

What surgical procedures utilize these heater-cooler machines?

Open-heart surgery is the most common type of surgery where the heater-cooler machines are used. They are also utilized in some liver transplant and vascular surgeries.

What is the risk of infection?

For patients who have had surgeries utilizing the heater-coolers, the chances of getting this infection are very low – the CDC estimates the risk to be less than 1 percent. 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 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?

Nontuberculous Mycobacteria (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 a surgery involving heater-cooler unit exposure.

Why are these infections so concerning?

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 or cancer can limit treatment choices and make these infections difficult to treat.

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 someone who has had surgery utilizing one of these heater-cooler devices be treated?

The risk that patients will develop an NTM infection following exposure to a contaminated heater-cooler unit is very low. Patients should only be treated if they develop signs or symptoms of infection. Although antibiotics can be life-saving drugs, there is no antibiotic treatment available to ward off this specific infection, and antibiotics are 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.

If a patient is planning on having open-chest surgery should they receive any treatment prior to surgery to minimize risk?

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 specific to this infection just prior, during or immediately after 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.

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

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

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.

What are the symptoms I need to watch out for?

Symptoms which could indicate infection include:

- Unexplained fever
- Night sweats
- Unintentional weight loss
- Excessive fatigue
- Signs of infection at your surgical site such as redness, warmth or increased drainage/pus

What treatments are available if a patient is found to have NTM infection?

Treatment for NTM infections should be managed by a physician specializing in infectious diseases. Treatment typically involves multiple antibiotics and the course of antibiotics may be prolonged.

Patients who have had open-heart surgery, vascular surgery or liver transplant surgery and are having symptoms should seek medical care. While risk of infection is low, it is important to consult with your surgeon, cardiologist or primary care doctor.