

M. chimaera

**Q. What is *M. chimaera*?**

A. *M. chimaera* belongs to a group of bacteria called “non-tuberculous mycobacteria” or NTM. NTM are commonly found in the environment, and may grow very slowly.

**Q. What is the risk of infection?**

A. The Centers for Disease Control estimates the risk of infection to be very low – less than 1%

**Q. How long does it usually take for these infections to show up?**

A. Non-tuberculous mycobacteria (NTM) such as *M. chimaera* are slow-growing bacteria and infections may take months to develop. Cases associated with the heater cooler device have been diagnosed within months and up to several years after an open-heart surgery.

**Q. What are the symptoms of *M. chimaera* infection?**

A. Symptoms of *M. chimaera* infection are typically last longer than one week and can include night sweats, muscle aches, weight loss, fatigue and fever.

**Q. Can a person who develops *M. chimaera* infection spread it to others, such as family members?**

A. No, the bacteria cannot be spread from person to person.

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

A. The Centers for Disease Control does not recommend antibiotics for patients “just in case”. There is no data this will prevent an infection. 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 cause of antibiotic resistance, which can put patients at risk for antibiotic-resistant infections later.

**Q. How long does it take to find out if an infection is being caused by *M. chimaera*?**

A. *M. chimaera* is a slow-growing species of NTM that can take eight weeks and sometimes longer to grow and allow final identification. There is no specific test which will detect an infection in an individual who does not have symptoms.

Heater cooler devices

***Q. What is a heater-cooler device?***

A. From the FDA: “Heater-cooler devices are often necessary for use during surgeries to warm or cool patients as part of their care. They are especially important tools for surgeries involving the heart, lungs, esophagus, and other chest organs (cardiothoracic surgeries). Heater-cooler devices include tanks that provide temperature-controlled water to external heat exchangers or to warming/cooling blankets through closed water circuits.”

***Q. How did the heater-cooler devices become contaminated?***

A. Non-tuberculous mycobacteria (NTM) such as *M. chimaera* are common in water and soil. Recent Centers for Disease Control 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.

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

A. 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, *M. chimaera* could reach a patient's surgical site. Heater-cooler devices are critical for life-saving surgery.

NYU response

***Q. What has NYU done to prevent these infections?***

A. NYU has followed all maintenance steps as recommended by the manufacturer and adopted any new recommendations after this problem was identified. The machines have been tested for the bacteria and were negative, but the CDC warns a negative test does not rule out contamination. NYU has conducted extensive additional tests within our operating rooms to ensure the machines are safe.

***Q. Will NYU pay for the diagnosis and treatment of these infections?***

A. If you identify any concerning symptoms during our call today, NYU will refer you to one of our providers – this appointment will not incur any out of pocket expense. As always, if you feel ill or are concerned, please see your primary care provider and give them the “dear doctor” letter we included in our mailing to you.

***Q. Why wasn't I notified earlier of the risk?***

A. CDC and the FDA released advisories regarding *M. chimaera* and the heater cooler devices late in 2016. NYU has immediately implemented all recommendations from these agencies. Prior to alerting the over 3,000 patients who underwent open heart surgery at NYU since 2012, we conducted a risk assessment and look back to identify possible cases of infection.

***Q. Have other institutions reported infections?***

A. Yes, this is a worldwide problem linked to these types of devices. A recent abstract presented at a scientific meeting indicated over 50 institutions have had infections related to the heater cooler devices, with the majority caused by NTM.

***Q. I have symptoms – where do I go if I need to be evaluated?***

A. I am happy to refer you to one of our providers to be evaluated at no out of pocket expense to you. As always, you should also contact your doctor if you don't feel well.

***Q. I don't have symptoms – do I need to be evaluated?***

A. I'm glad you feel well. You don't need to be evaluated at this stage, but monitor for the following symptoms lasting longer than one week night sweats, muscle aches, weight loss, fatigue and fever. As always, you should also contact your doctor if you don't feel well.