



FREQUENTLY ASKED QUESTIONS FOR PENN MEDICINE PATIENTS

What is the situation?

The U.S. Centers for Disease Control and Prevention (CDC) has notified all hospitals of a potential exposure to bacteria in patients who have undergone open chest cardiac surgery using a heart/lung bypass machine. The bacteria have been linked to heater-cooler devices used during these surgical procedures.

What type of bacteria is involved?

The bacterium is called Nontuberculous Mycobacteria, or NTM. It grows slowly and is commonly found in soil and water, including tap water. It is usually not harmful to humans, and typically only rarely has caused infections in patients with weakened immune systems. However, patients who have had open-chest heart surgery with bypass may have become exposed to these bacteria during their procedure, and could be at risk of infection.

What is a heater-cooler device and how might it be related to this problem?

A heater-cooler device is used during open-heart surgeries to warm or cool a patient's blood as part of their usual surgical care. It is never in direct contact with the patient or the patient's blood. There is a water reservoir inside the device. NTM can grow in the water in heater-cooler devices. During use, some of the water evaporates and enters the air in the operating room. It is believed that the NTM bacteria may be put in to the air by the heater-cooler device, and can then possibly enter the patient's open chest during the procedure.

Why are we contacting patients?

Recently, we have identified the NTM infection in a few patients who had certain types of open-chest heart surgery at Penn Presbyterian Medical Center. It is possible that they may have been exposed to the bacteria during their surgery. Although the risk of developing an NTM infection after cardiac surgery is very low, we want to make sure that our open-chest heart surgery patients are aware of this issue, and understand that we have resources available to our patients who may have questions or health concerns.

What types of surgeries place patients at risk for this infection?

Only open-chest heart surgeries using a heart/lung bypass machine carry this very low risk. This includes coronary artery bypass graft (CABG) surgeries, valve surgeries, and surgical procedures involving the thoracic aorta. Penn Presbyterian Medical Center used the implicated heater-cooler device between October 2013 and December 2015, and is therefore notifying patients who underwent these types of surgeries during this timeframe.

Has this happened at other hospitals?

Yes. There have been multiple cases documented in the United States and Europe. In the United States, federal health authorities, including the CDC and Food and Drug Administration (FDA) have issued health advisories to hospitals to help them prevent and detect these infections.

What action is Penn Medicine taking to protect patients?

We have always consistently followed or exceeded manufacturer guidelines for disinfecting and maintaining heater-cooler devices across our health system. Due to the recently recognized association of NTM infections with heater-cooler devices, and to address this potential risk, we replaced all of our heater-cooler devices from the manufacturer that was the focus of the FDA's investigation, with heater-cooler devices from another manufacturer. The new heater cooler devices are being maintained according to the most recent manufacturer's cleaning procedures and FDA guidelines. We are confident that the potential risk of exposure to NTM bacteria has been effectively addressed.



In addition to notifying our patients, we have created a toll-free hotline (1-800-890-6963) to provide our patients with additional information, screening, and appointments, if needed.

What are my chances of having this infection?

We estimate the risk of infection to be less than 1%. To date, patients known to have developed an invasive NTM infection following heart surgery with an open chest in our hospital, and at other U.S and European hospitals have undergone complex procedures like heart transplantation, heart valve reconstruction or surgeries involving the implantation of foreign material. This includes patients who have undergone surgeries for:

- Tissue or mechanical heart valves,
- Vascular grafts,
- Left ventricular assist devices (LVADs), or
- Total artificial heart devices.

What if I had another type of heart surgery?

Patients who had other, less invasive heart procedures – such as stents, pacemakers, defibrillators and ablations – or minimally invasive cardiac surgery procedures such as transcatheter aortic valve replacement, or TAVR, are not at risk because the heater-cooler device is not used for these procedures.

What do I need to do now?

Call us toll-free at 1-800-890-6963 with any questions or concerns. Our call center will be open 7:30 AM – 8PM Mondays –Fridays. We will ask you a few screening questions, answer your questions, and if necessary, we can arrange an appointment with a medical provider. You will not be charged for this appointment.

What are the symptoms of an NTM infection?

According to the Centers for Disease Control and Prevention, symptoms may include those associated with an unexplained infection, including the following:

- Pain, redness, heat or pus around the surgical incision on your chest
- Persistent fevers for more than 1 week without another cause
- Unexplained weight loss

These symptoms are not specific for NTM and can be due to many other causes, but NTM should be considered if you had possible exposure from open-heart surgery. NTM infection may take a long time to develop after potential exposure – from a few weeks up to four years. Therefore, those who may have been exposed to NTM should continue to look for symptoms and see their clinician for further evaluation if any develop.

Is this infection treatable?

Yes, there are effective antibiotic treatments available for this infection.

If I have been exposed or develop an NTM infection, is my family at risk of getting the infection?

No. This bacterium cannot be spread by contact with those who have been exposed to this infection.

Can I find out whether I'm infected?

If you do not have symptoms, you do not require testing. Because the bacterium grows slowly, it can take several months or years for symptoms of infection to develop. If you have or develop symptoms, it is important for your physician to know in order to arrange testing.

For further information, please visit our website at: <https://www.pennmedicine.org/ppmc-cardiac-bypass>