

## **FAQ for Open-Chest Heart Surgery Patients at Penn State Hershey Medical Center**

### **Why are you contacting patients?**

Three patients who had open-chest heart surgery at Penn State Hershey Medical Center between Nov. 5, 2011 and Nov. 5, 2015 became sick with a bacterial infection. It is possible that they may have been exposed to the bacteria during their surgery. We want to assure these patients that we continue to follow this issue and are taking precautionary steps to ensure appropriate follow-up and care.

### **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, but in some cases it can cause infections in patients who have had invasive health care procedures – such as open-heart surgery – and those who may have weakened immune systems.

### **How did this happen?**

Penn State Hershey staff became concerned about a potential association with open-heart surgery in July 2015 after patients who underwent open-heart surgery at WellSpan York Hospital were treated at our hospital for NTM infection. At about that same time, several other hospitals in Europe reported this same rare infection in open-heart surgery patients, and the manufacturer of a heater-cooler device used in open-heart surgery issued an alert about infections potentially arising from the use of the devices. Upon identifying these cases, coupled with this additional information, our Medical Center began a voluntary review of our own heater-cooler devices used in open-heart surgery. We have identified three cases (out of approximately 2,300 over four years) in which NTM infections have occurred in patients who underwent open-heart surgery at our Medical Center. We feel it is important to notify patients, providers and our community about the steps we have taken to address this issue.

### **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 not on or touching the patient. There is a water reservoir inside the device. During use, some water evaporates and enters the air. The evaporation could make contact with a patient's open wound during the procedure.

### **What action are you taking to protect patients?**

Due to the recently recognized association of NTM infections with heater-cooler devices, we replaced our devices. The new equipment is being maintained according to the most recent enhanced cleaning procedures provided by the manufacturer and FDA guidelines. In addition, the Medical Center is adhering to the highest standards of maintenance and testing for these devices.

Additionally, we have set up a dedicated clinic where we can answer patient questions and perform examinations and lab tests as needed.

### **What are my chances of having this infection?**

At Penn State Hershey, three of approximately 2,300 patients who had open-heart surgery between Nov. 5 2011 and Nov. 5, 2015 are known to have acquired the infection. This means the current occurrence rate is about 0.1 percent, or one-tenth of 1 percent.

To date, patients known to have developed an invasive NTM infection following heart surgery with an open chest at our hospital and other hospitals in the country and in Europe 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.

### **If I had open-chest heart surgery but not one of those procedures mentioned, am I still at risk for NTM infection?**

Complex surgical procedures like open-chest heart surgery carry the risk of infection generally. However we are unaware that any patients have developed invasive NTM infections after undergoing less complex heart surgeries with an open chest but without placement of any foreign material.

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.

**If my odds of having this infection are so low, why are you setting up a dedicated clinic to see patients?**

The chances of you getting this infection are extremely low, and most patients will not experience an infection from this possible exposure. However, we understand that you may still be concerned and may also want to be evaluated. This dedicated clinic is an opportunity for you to ask questions, be evaluated by a provider looking specifically for signs of NTM infection and have done any lab tests that may be recommended.

In addition, NTM is a slow-growing organism. Seeing patients in this dedicated clinic gives Penn State Hershey an opportunity to closely follow our patients until the likelihood of infection has diminished.

**How do you know when people were at risk for this infection?**

The problem seems to be relatively recently recognized, based on reports to the FDA, so we are being cautious by going back four years. In addition, infections related to the heater-cooler units have become apparent within less than four years (usually months to 3 1/2 years), so if a patient had open-heart surgery more than four years ago, the infection should have shown up by then.

**What are the symptoms of an NTM infection?**

According to the Centers for Disease Control and Prevention, symptoms may include a combination of the following: pain, redness, heat or pus around a surgical incision; fever; night sweats; joint pain; muscle pain; and fatigue. 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 could 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.

**Can this type of infection be treated?**

The infection can be treated with antibiotics.

**What should I do?**

Penn State Hershey has already been in direct contact with the patients who were diagnosed with NTM infections or their families.

If you or a loved one underwent one or more of the surgical procedures listed above, we would like you to call our 24/7, toll-free line (1-877-467-7484) to schedule an appointment to be seen in our dedicated clinic.

If you or your loved one had another type of open-chest heart surgery other than those listed above, you should continue to be followed by your primary care provider. We are asking these providers to monitor their patients for any future concerns. Additionally, we understand that even if you are in this group of patients, you may be concerned and may also want to be evaluated in our dedicated clinic. Please call our toll-free line and we will be happy to schedule you to be seen.

**My child had open-chest heart surgery during this time period. What should I do?**

Please call us at 1-877-467-7484. Your call will be referred to the Children's Heart Group, who will make arrangements to evaluate your child at a pediatric practice site that is convenient to you.

**What if I don't remember the details of the surgery that I or a family member had?**

If you are unsure what type of procedure you or your family member had at the Medical Center, please call us at 1-877-467-7484. A nurse can help to identify appropriate health care evaluations if any are needed.

**Is NTM infection contagious?**

No. An NTM infection cannot be spread to your family and friends.

**Is this heater-cooler device issue an isolated or a widespread problem?**

There have been similar infections documented in Europe. In the United States, federal health agencies are concerned the heater-cooler device-associated NTM infections could be widespread. The agencies have issued recent advisories and safety warnings to hospitals across the country in an effort to alert them of the potential problem and prevent infections in other patients. With the recent identification of NTM infections potentially associated with heater-cooler devices in southcentral Pennsylvania, Penn State Hershey infectious disease specialists agree with federal health agencies that this problem may be prevalent but not yet fully recognized in some healthcare facilities.

**If I have the infection and need to be treated, will Penn State Hershey pay for my treatment costs?**

Yes. If you are confirmed to have an NTM infection that is associated with open-heart surgery, Penn State Hershey Medical Center will provide you with the treatment necessary for the NTM infection.

**Where can I find more information?**

We have created a website, <http://www.pennstatehershey.org/open-heart>, which contains additional resources. If you have additional questions or concerns, please call our toll-free call center at 1-877-467-7484.