WellSpan York Hospital Open Heart Surgery Infections

Frequently Asked Questions (FAQ)

What do I need to do now?

If you are among the 1,300 individuals had open-heart surgery at WellSpan York Hospital between Oct. 1, 2011 and July 24, 2015, you should have received additional information from the hospital, providing recommended steps for you to take. For most of these patients who were potentially exposed to the bacteria, we have recommended that they make an appointment with their primary care doctor to discuss the issue. If you have any further questions regarding this issue, please call one of our nurse case managers toll-free at (866) 217-2970.

What should I do if follow-up care is needed?

A special NTM clinic has been provided for those patients needing further follow-up. The NTM clinic offers comprehensive medical evaluations, which will include documenting clinical history, conducting a focused physical examination, and, if clinically appropriate, providing laboratory testing. The clinic evaluations are recommended for patients who had the following specific procedures:

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

If you had one of these procedures between Oct. 1, 2011 and July 24, 2015, and you have not yet been evaluated by a WellSpan Infectious Disease clinician, please call (866) 217-2970 to schedule an appointment.

What specific type of bacteria is involved in these infections?

The bacterium is called Non-tuberculous Mycobacterium (NTM), which is commonly found in the environment, such as in soil and drinking water. Although NTM typically is not harmful, it can – in very rare cases – cause infections in post-operative surgical patients, especially in people with weakened immune systems.

If I've been exposed to this bacteria, what are the chances that I have, or will get, this infection?

The chances of acquiring this infection are extremely low. Currently, approximately 1 percent of the patients who had open-heart surgery at WellSpan York Hospital between October 1, 2011 and July 24, 2015 have acquired the infection. That means approximately one out of every 100 patients, on average, has acquired this infection.

Is this infection treatable?

The infection can usually be treated successfully once it is identified. Unfortunately, because the bacterium grows slowly, it can take up to several months for it to develop into an infection and years before the infection is correctly diagnosed, unless patients and their clinicians are alert to the possibility of NTM infection.

If I've been exposed to this bacteria, is my family at risk of getting the infection?

No. This organism can be commonly found in the environment and only rarely causes infections. It is not contagious, meaning it cannot be spread by contact with others with this infection.

If I've been exposed to this bacteria, how do I find out whether I'm infected?

There is no simple way to test for this bacterial infection. If you had open-heart surgery at WellSpan York Hospital at any time between Oct. 1, 2011 and July 24, 2015, we recommend you consult with your primary care physician to discuss this issue and determine if you have symptoms that could be associated with an NTM infection.

What are the symptoms of an NTM infection?
Symptoms may be very general. If a patient has had open-heart surgery within the past four years, and unexplained infection symptoms are present, this bacteria should be considered as a possible cause. According to the U.S Centers for Disease Control and Prevention (CDC), symptoms of this NTM infection "may include a combination of the following: fever; pain, redness, heat, or pus around a surgical incision; night sweats; joint pain; muscle pain; and fatigue. Those who were exposed to NTM should continue to look for signs of unexplained infection and keep in touch with their clinicians for further evaluation and tracking."

Is there testing for patients who do not have symptoms?
Unfortunately, the bacteria generally can only be found if the patient shows symptoms and a source of the infection in the body to test. It is important to be aware of the possibility of this infection so that patients and health care providers can be vigilant in identifying symptoms and pursuing appropriate care.

Is there testing for patients who may have symptoms?
If a patient has symptoms and a source is suspected, then testing could occur. As with any infection, the area of the body where the infection exists is where the test would occur. Due to the slow-growing nature of the bacteria and the testing that is required, final test results may take as long as eight weeks. If you had open-heart surgery at WellSpan York Hospital at any time between Oct. 1, 2011 and July 24, 2015, we recommend you consult with your primary care physician to discuss this issue and to determine if you have symptoms that could be associated with an NTM infection.

How many patients have been notified regarding potential exposure to NTM bacteria during open-heart surgery at WellSpan York Hospital?
WellSpan York Hospital has sent letters to approximately 1,300 patients who may have been exposed to this bacteria during their open-heart surgery procedure. The letters encourage those patients to consult their primary care physician should they have any concerns about their health – particularly within four years following the date of their most recent open-heart surgery at the hospital.

If it is determined that I may have been exposed to this bacteria during open-heart surgery at WellSpan York Hospital, will WellSpan pay for my care and treatment related to this matter?
Yes. WellSpan York Hospital sincerely regrets any distress this issue has caused you and your family. We will provide you with the care and treatment you need regarding this issue, at no cost to you.

How many open-heart surgery patients at WellSpan York Hospital have been identified with this infection?
The calculation of the number of potentially infected patients identified at WellSpan York Hospital is based on class definitions developed while working with the CDC and the Pennsylvania Department of Health (DoH). These class definitions were developed for the purpose of capturing all potentially related infections even where an infection is not necessarily confirmed by laboratory testing. Using these class definitions, WellSpan York Hospital has identified fourteen "probable" cases and three "suspect" cases of NTM infections.

What is the status of the patients who are confirmed to have acquired this NTM infection?
Hospital officials have reached out to all patients with identified infections and their families to notify them about these infections and to offer any additional information, treatment or care they may need. This group of confirmed "probable" cases currently includes eight living patients and six patients who are now deceased. One of the eight living patients is no longer experiencing symptoms of infection and is not in active treatment. The remaining seven patients are in active treatment.

How has this bacteria caused infections in a small number of open-heart surgery patients?
Based upon the results of a joint review by the CDC, DoH and WellSpan York Hospital, we have learned that NTM infections might be caused by a heater-cooler device used during open-heart surgery to regulate the temperature of a patient's blood. The problem identified by WellSpan York Hospital, and the correlation between this heater-cooler device and NTM bacterial infections, has affected hospitals around the world and has resulted in a widespread and ongoing investigation by the U.S. Food and Drug Administration (FDA), the

CDC, and similar organizations in Europe. In the United States, the FDA has issued two safety notices and conducted a two-day hearing about this previously unknown phenomenon.

What kind of open-heart surgery procedures were involved in these infections and exposures?
There is limited risk of infection for patients who underwent open-heart surgery at WellSpan York Hospital between Oct. 1, 2011 and July 24, 2015. These procedures included surgery to treat an aortic valve defect and, in some cases, coronary bypass surgery. It is believed that patients who had these types of procedures during the above time period were at limited risk for these infections. This is because the heater-cooler device was used in these procedures.

What about other heart procedures, such as stents, pacemakers, defibrillators and ablations? If I had one of these procedures, am I at risk for this infection?
No. Those are not open-heart procedures, and the heater-cooler device is not used for these procedures. If you had one of these non-invasive heart procedures, you are not considered to be at risk for this infection.

What role does the heater-cooler device have in the infection?
Heater-cooler devices are used during cardiac surgeries to warm or cool a patient as part of their care. There is the potential for the bacteria to grow in a water reservoir in the heater-cooler units. It is important to note that the water in the heater-cooler unit never comes into contact with the patient's blood or body fluids. When the water evaporates, the bacteria escapes the device with the water. Once it hits the open air, the bacteria then becomes aerosolized and can then make contact with a patient's open wound during surgery.

Were there issues identified with the maintenance of the heater-cooler device?
Yes. An internal review conducted by the hospital identified that its maintenance protocols for the heater-cooler devices did not align perfectly with the original specifications provided by the device manufacturer. The heater-cooler device consists of a sealed water system filled with sterile water that does not come into contact with the patient, so staff members did not perceive there to be a health risk. With the risks now evident, the manufacturer recently alerted customers across the United States of enhanced cleaning procedures to address NTM contamination concerns. The FDA, the CDC and the DoH have recently issued advisories regarding this risk of NTM contamination with these devices. The manufacturer also issued a Class II recall of the device in July 2015. In addition, the FDA has issued a warning to the manufacturer of these devices, based on issues concerning the risk of contamination.

What has WellSpan York Hospital done to address these issues related to the heater-cooler device?
Immediately upon consultation with the DoH and the CDC, WellSpan York Hospital completely replaced its heater-cooler devices with new equipment on July 25, 2015. Since that time, continued concerns related to these specific devices prompted WellSpan York Hospital to replace all of these devices with those manufactured by a different company. The primary heater-cooler devices now used at WellSpan York Hospital are provided by a different device manufacturer. The hospital is adhering to the highest standards of disinfection, maintenance and testing for these devices.

Is WellSpan York Hospital the only hospital with this problem?
No. Several hospitals have since announced similar NTM infections and exposures, including Penn State Hershey Medical Center, which notified 2,300 of its open-heart surgery patients that they might have been exposed to the same bacteria. In February 2016, the University of Iowa Hospitals & Clinics announced that it had notified approximately 1,500 open-heart surgery patients of potential NTM exposure, with one confirmed infection. Also, in August 2016, Mercy Medical Center in Des Moines, Iowa announced that it had notified 2,600 of its patients that they may have been exposed to NTM during open-heart surgery there. Spectrum Health in Grand Rapids, Mich. has also disclosed that it had two patients infected with NTM. Federal authorities have issued health advisories to hospitals across the country to alert them of this issue and prevent infections in other patients. There also have been other similar infections documented in Europe. In late December 2015, the FDA issued a Warning Letter to the leading manufacturer of the heater-cooler devices, noting concerns related to potential NTM contamination.