

WellSpan York Hospital Open Heart Surgery Infections

Frequently Asked Questions (FAQ) for Physicians & APCs

How many patients have you 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.

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.

What specific open-heart surgery procedures were involved in these NTM 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.

Are patients who had non-invasive heart procedures – such as stents, pacemakers, defibrillators and ablations – also at risk?

No. The heater-cooler device is not used for these procedures. Patients who had one of these non-invasive heart procedures are not considered to be at risk for this infection.

What are the chances of acquiring this infection for open-heart surgery patients whose procedures occurred between October 1, 2011 and July 24, 2015?

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.

I have a patient who is among the 1,300 who were potentially exposed to NTM during open-heart surgery at WellSpan York Hospital? What is the recommendation for monitoring and treatment?

For most patients who were potentially exposed to this bacteria, we are advising awareness and vigilance in monitoring for symptoms. Primary care physicians and APCs should continue to monitor for symptoms and contact our nurse case managers, toll-free at (866) 217-2970, with any questions.

What should I do if follow-up care is needed for one of my patients?

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

What health issues can the bacteria cause?

Although NTM typically poses no harm, it can – in very rare cases – cause infections in post-operative surgical patients, especially in people with weakened immune systems. These could include respiratory infections or more serious infections in patients with weakened immune systems.

Is there testing for patients who are symptomatic?

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.

What are the symptoms of an NTM infection?

Symptoms of the infection 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 CDC, symptoms of this NTM (bacterial) 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 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.

Is there a way to treat patients prophylactically with antibiotics, if a patient asks whether he/she can take medication to prevent infection?

Because the bacteria is already prevalent in the environment and the risk of clinical infection in surgically exposed patients is thought to be less than 1 percent, antibiotic prophylaxis is not recommended by the CDC or DoH. In consultation with the infection control department of Johns Hopkins Hospital we affirmed that prophylaxis is not believed to have benefits that exceed the risk for patients with intact immune systems. For patients who are immunosuppressed and under treatment for MAC prophylaxis, the conventional macrolide antibiotic prophylaxis should be sufficient for *Mycobacterium chimaera* also.

What specific type of bacterium 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. While frequently not further identified beyond the NTM group, the specific bacteria identified by the CDC was *Mycobacterium Chimaera*, which is part of the *Mycobacterium Avium Complex* (MAC). It is generally treated like any other MAC infection.

Is the bacterium contagious?

No. This organism is 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.

How did these patients get infected with the bacteria?

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 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 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.