

Frequently Asked Questions

NONTUBERCULOUS MYCOBACTERIUM (NTM) INFECTIONS IN PATIENTS WHO HAVE HAD OPEN HEART SURGERY WITH CARDIOPULMONARY BYPASS

What is the possible connection between NTM infections and patients who have had open heart surgery with cardiopulmonary bypass?

- Recent advisories from the [U.S. Food and Drug Administration](#) (FDA), the [Centers for Disease Control and Prevention](#) (CDC), and findings from recent public health investigations suggest an association between heater-cooler devices and NTM infections among patients undergoing open heart surgery.
- Heater-cooler devices are commonly used during cardiothoracic surgical procedures to warm and cool a patient's blood during cardiopulmonary bypass.
- Patients do not come into direct contact with the water in the heater-cooler device's water tanks. However, NTM in the machine can potentially be transmitted during surgery by aerosols (fine spray) of contaminated water from these devices.
- NTM are usually not harmful, but can cause infections in patients who have had invasive health care procedures and those with weakened immune systems.

What is NTM?

- Nontuberculous Mycobacterium grow slowly and are commonly found in soil and water, including tap water.
- NTM are usually not harmful, but can cause infections in patients who have had invasive health care procedures and those with weakened immune systems.
- NTM may enter the body through the lungs by breathing, through the gut by eating or drinking, or through the skin by a cut or wound contaminated by water or dirt containing NTM germs.
- **NTM are not contagious and are not spread from person to person.** As the name suggests, NTM or NON-tuberculous mycobacterium are different from the bacteria that cause TB (*Mycobacterium tuberculosis*).
- NTM is treatable. Potentially exposed individuals should be aware of the symptoms and follow up with their health care providers if they show any signs of illness from NTM.

What are the symptoms of NTM?

- NTM bacteria grow slowly in the lab and in individuals. NTM is unusual in that it can take several years before people who are infected with it are diagnosed.
- Affected patients and their health care providers need to be aware of the symptoms of infections caused by NTM, including:
 - Fever;
 - Pain, redness, heat, or pus around a surgical incision;
 - Weight loss;
 - Night sweats;
 - Joint pain;
 - Muscle pain; and
 - Loss of energy.
- Affected patients should talk to their health care provider if they have any of the above symptoms so they can be further evaluated.
- It is important for affected patients and their doctors to be aware of their potential exposure to NTM and its symptoms, and the need for NTM cultures to diagnose the infection.

Have there been any NTM infections in patients in Pennsylvania?

- Yes. To date, there have been confirmed cases of NTM infections in patients who have undergone open heart surgery requiring cardiopulmonary bypass at two Pennsylvania health care facilities:
 - WellSpan York Hospital
 - Penn State Hershey Medical Center
- The first confirmed cluster of infections occurred at WellSpan York Hospital, with investigation results demonstrating a convincing link between NTM infections and the heater-cooler devices used during open heart surgeries to warm and cool a patient's blood during cardiopulmonary bypass

How many patients may have been exposed?

- The department believes that all patients who had open heart surgeries requiring cardiopulmonary bypass at **WellSpan York Hospital from October 1, 2011, through July 24, 2015**, could have been exposed to NTM.
 - Affected patients seeking more information should talk to their health care provider. More information is available from WellSpan York Hospital by calling their 24-hour nurse call center toll-free at **1-866-217-2970** or by visiting www.wellspan.org/yorkopenheart.

- The department believes that all patients who had open heart surgeries requiring cardiopulmonary bypass at **Penn State Hershey Medical Center from November 5, 2011, through November 5, 2015**, could have been exposed to NTM.
 - Affected patients seeking more information should talk to their health care provider. More information is available from Penn State Hershey Medical Center by calling their toll-free hotline at **1-877-467-7484** or by visiting www.pennstatehershey.org/open-heart.

How many patients have become ill?

- A cluster of patients have been diagnosed with NTM infections at both WellSpan York Hospital and Penn State Hershey Medical Center. These patients have also had open heart surgeries requiring cardiopulmonary bypass.
- It is the Pennsylvania Department of Health's (PADOH's) responsibility to protect patient privacy and ensure affected patients are not identified. For this reason, the department will not provide any additional information regarding ill patients.

Have any patients died from this infection?

- There have been patients from both hospitals that were infected with the NTM bacteria that have died. The cause of their death cannot be conclusively determined, as they also had other serious health complications.
- It is PADOH's responsibility to ensure patient privacy. For this reason, the department will not provide any additional information.

I had open heart surgery requiring cardiopulmonary bypass and have symptoms of NTM. What should I do?

- We understand it might be upsetting for affected patients who have any of the symptoms of infection caused by NTM.
- Affected patients should talk to their health care provider if they have any NTM symptoms so they can be further evaluated.
- It is important for affected patients and their doctors to be aware of their potential exposure to NTM and its symptoms, as well as the need for NTM cultures to diagnose the infection.

Have NTM infections occurred in other hospitals? Is this common?

- A European research paper published July 1, 2015, suggested an inconclusive link between NTM infections and heater-cooler units, but there is now increasing awareness of the potential of heater-cooler units to aerosolize or spread NTM bacteria in the air. On October 15, 2015, the FDA issued a safety communication regarding heater-cooler devices.

- The first confirmed cluster of infections occurred at WellSpan York Hospital, with investigation results demonstrating a convincing link between NTM infections and the heater-cooler devices used during open heart surgeries to warm and cool a patient's blood during cardiopulmonary bypass
- To date, there have been confirmed cases of NTM infections in patients who have undergone open heart surgery requiring cardiopulmonary bypass at two Pennsylvania health care facilities:
 - WellSpan York Hospital
 - Penn State Hershey Medical Center

What is the Pennsylvania Department of Health doing in response to these NTM infections in patients?

- The department is reaching out directly to all health care facilities in Pennsylvania that perform heart surgeries with bypass to ensure they not only know the recommended methods for cleaning these heater-cooler devices, but also how to assess if their devices show signs of contamination.
- The department is also urging health care providers to heighten their awareness of possible NTM infections among patients who have symptoms and a history of cardiac surgery.

How are hospitals regulated in Pennsylvania?

- The Health Care Facilities Act authorizes the department to license hospitals that meet state and federal standards designed to assure safe, adequate, and efficient facilities and services and to promote the health, safety, and adequate care of patients.
- The department inspects hospitals to evaluate their compliance with laws and regulations, and, if a hospital is found to be deficient or out of compliance, requires the hospital to submit a plan of correction to address each deficiency.
- In addition, the department conducts monitoring surveys and investigates all complaints filed about a hospital.

What are hospitals required to report in Pennsylvania?

- Health care facilities in Pennsylvania are required to report diseases, infections, and conditions identified in PADOH regulations as being reportable.
- They are also required to report unusual occurrences or outbreaks of infections and disease.

Will there be a class action lawsuit? Can I submit my name and contact information for one?

- The department is not collecting names for a class action lawsuit. Patients who wish to seek out an attorney to discuss their options can do so.

When will we find out more?

- The Department of Health is dedicated to protecting the public's health and safety. Public health investigations are confidential and information can only be shared if it will help prevent and control the spread of disease.
- PADOH will promptly share relevant developments as they become known and if they are needed to prevent and control the spread of disease. This will be done either by press release or by updating information on our website – www.health.pa.gov.

Where can I get more information?

- **WellSpan York Hospital** patients can call **1-866-217-2970** or visit www.wellspan.org/yorkopenheart.
- **Penn State Hershey Medical Center** patients can call **1-877-467-7484** or visit www.pennstatehershey.org/open-heart