



Heater-Cooler Device Questions and Answers (Q & A) for Patients

November 3, 2016

Key Points

The Centers for Disease Control and Prevention (CDC) recently notified state health departments that a heater-cooler device used during cardiac surgery may have been contaminated with a bacteria during the manufacturing process. The heater-cooler device, Sorin/Stockert 3T, has been linked to *Mycobacterium chimaera* (*M. chimaera*), infections in cardiac patients.

New Jersey Department of Health (NJDOH), along with the New Jersey Hospital Association, has been in contact with the hospitals in the state that perform cardiac surgery. Of the 18 hospitals in New Jersey that perform cardiac surgery, 16 use or have used the Sorin/Stockert 3T heater-cooler device. NJDOH has recommended that hospitals notify all patients who had cardiac surgery where the Sorin/Stockert 3T device was used during the procedure, or was on standby for possible use during the procedure (i.e., it was turned on and running in the same room as the surgery).

While the risk is low, patients who have had cardiac surgery using the Sorin/Stockert 3T device should be notified about the potential for infection. *M. chimaera* is a slow growing bacteria and symptoms may not appear until months or years after surgery. Persons who have undergone a cardiac procedure at a New Jersey hospital that currently use or have used the Sorin/Stockert 3T device should monitor themselves for symptoms and discuss any changes in their health with their health care provider.

Questions and Answers

What is *Mycobacterium chimaera* (*M. chimaera*)?

Mycobacterium chimaera (*M. chimaera*) is a specific type of nontuberculous mycobacterium (NTM) and is found in soil and water. NTM rarely makes healthy people sick. People may get NTM from an environmental source, but usually only among those with weak immune systems. *M. chimaera* is a slow growing bacterium. Because of this, it might take months or years before an infection develops.

What are the symptoms of NTM infection?

Symptoms may include those associated with an unexplained infection, including the following:

- Fatigue (feeling very tired)
- Fever
- Pain, redness, heat or pus around the surgical site on the chest
- Night sweats
- Unexplained weight loss
- Nausea
- Vomiting
- Muscle or joint pain

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 cardiac surgery with a heater-cooler device. NTM infection may take months or years to develop after an exposure. Contact your health care provider if you have any symptoms.

There may be an increased risk of infection if you received a heart valve, graft, left ventricular assist device (LVAD), or any other prosthetic product/materials or had a heart transplant.

What is a heater-cooler device?

Heater-cooler devices are essential equipment used in certain cardiac procedures. These devices are used during cardiac surgery to help regulate the temperature of the patient's blood. The machine uses water to warm or cool the blood as it is circulated outside of the patient's body. There is a fan in the device. It is believed that the fan can aerosolize (turns liquid into a fine spray or mist) bacteria in the operating room. The bacteria can then move through the air and enter the patient's open chest cavity during the surgery. If the heater-cooler device is not used during the surgery, but is prepared and in the room during surgery, there is the potential for bacteria to become aerosolized (turned into a fine mist), move through the air and land on surgical tools/instruments.

What is the risk of infection?

The risk is thought to be low, but not zero. At this time, it is thought that patients who had prosthetic (artificial) implants such as valves are at higher risk for infection. It is possible that not all Sorin/Stockert 3T devices are contaminated. Out of an abundance of caution, patients are being notified about the possible risk for developing an NTM infection.

Can a person who develops an NTM infection spread it to others?

No, the bacteria cannot be spread to others from a person who is infected. It is important to keep in mind that NTM is common in soil and water but rarely makes healthy people sick.

If I had heart surgery and am at risk, should I ask my doctor to give me antibiotics just in case?

The risk that patients will develop an infection following exposure to a contaminated heater-cooler device is low. There is no evidence that giving antibiotics prior to or during surgery with a potentially contaminated heater-cooler device will prevent infection.

Antibiotics are medications and have their own side effects. Monitor yourself for symptoms and talk with your health care provider.

How long does it take for a NTM infection to appear?

M. chimaera is a slow-growing type of NTM that can take months or years to grow. Symptoms of *M. chimaera* infection are often general and nonspecific. For these reasons, infections may be missed or delayed making them difficult to treat. Clinicians may not immediately consider NTM diagnosis. NJDOH has alerted the medical community about the potential for NTM in patient's that have undergone cardiac surgery.

Is there testing that can tell me whether or not I have the NTM infection?

If you do not have symptoms, you do not require testing. Because the *M. chimaera* is a slow growing bacteria, it can take months or years for symptoms to develop. If you have symptoms or develop symptoms, contact your health care provider immediately.

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

Cardiac procedures that use a heart/lung bypass machine carry this risk. This includes coronary artery bypass graft (CABG) surgeries, valve surgeries, and surgical procedures involving the thoracic aorta, such as a transcatheter aortic valve (TAVR) or transcatheter aortic valve implantation (TAVI).

I had cardiac surgery more than four years ago and I feel fine. Should I be concerned?

The Food and Drug Administration (FDA) findings indicate that the Sorin/Stockert 3T devices may have been contaminated when they were manufactured.

In New Jersey, the Sorin/Stockert 3T has been used in some facilities since 2009. NJDOH is recommending that hospitals notify all patients who have had cardiac surgery where the Sorin/Stockert 3T heater-cooler was used. Patients are advised to monitor themselves for symptoms and discuss any changes in their health with their health care provider.

Should I post-pone my cardiac surgery until the hospital purchases new heater-cooler devices?

This is a talk you should have with your health care provider. Hospitals that perform cardiac surgery where a heater-cooler device was used are aware of the issues with the Sorin/Stockert 3T devices. Heater-cooler devices are important in patient care. In selected patients, the benefits of temperature control during cardiac surgery where the heater-cooler device is used, may outweigh the risk of infection associated with the use of these devices.

Not all hospitals in New Jersey use the Sorin/Stockert 3T device. Those facilities that do use the Sorin/Stockert 3T device are recommended to inform patients about the risk of infection associated with the device prior to their surgery.

If the Sorin/Stockert 3T devices are contaminated, why are hospitals still using them?

In 2015, the manufacturer of the Sorin/Stockert 3T device recalled the instructions for use, but not the device itself. Heater-cooler devices are critical for life-saving surgery. A national recall could result in patients not getting life-saving surgeries that are needed now. New Jersey hospitals with Sorin/Stockert 3T devices are aware of the recall of the instruction for use and are taking additional steps to reduce the risk of infection associated with the use of the devices.

Did the hospitals know that the devices were contaminated when they bought/used them?

Sorin/Stockert 3T devices have been used in New Jersey since 2009. In July 2015, the manufacturer issued a recall for instructions for use, including new cleaning instructions to all facilities across the country that use the device. In October 2016, the CDC reported that the Sorin/Stockert 3T devices have been linked to infections in several states and in Europe. As a result, NJDOH is recommending that hospitals are notifying patients who had cardiac surgery where a heater-cooler device was used, about their risk for developing an NTM infection.

If I didn't receive a letter from the hospital where I had my cardiac surgery, then I do not have to worry, right?

NJDOH recommends that all hospitals in New Jersey that use or have used the Sorin/Stockert 3T devices for cardiac surgery notify all patients about being exposed to the bacteria. If you had cardiac surgery where a heater-cooler device was used in New Jersey and have not received a letter from the hospital where you had your procedure, you were not exposed or you may wish to follow up with your cardiologist.