

Heater-cooler devices and NTM infections: Information for Clinicians as of December 2018

Heater-cooler devices and nontuberculous mycobacterial (NTM) infections:

- Heater-cooler devices are routinely used during cardiac surgery procedures, a small percentage of lung transplants, and a portion of thoracoabdominal vascular surgery and other procedures to warm and cool a patient's blood during cardiopulmonary bypass. These devices are used for both adult and pediatric patients.
- Nontuberculous mycobacteria (NTM) are slow-growing bacteria that are found in surface water, tap water, and soil.
- Reports over the last few years have confirmed an association between Sorin Stöckert 3T heater-cooler devices and NTM infections (primarily due to *Mycobacterium chimaera*) among patients undergoing cardiopulmonary bypass, potentially through the aerosolization of bacteria from these devices. The affected heater-cooler devices are believed to have become contaminated with NTM at the time they were manufactured.

U-M response to this matter has included the following:

- Cardiovascular Perfusion Services has maintained all heater-cooler devices according to manufacturer and CDC/FDA recommendations.
- As of August 23, 2016, Perfusion has replaced all Sorin Stöckert 3T heater-cooler devices at Michigan Medicine with alternative devices.
- In November 2016, letters informing of the potential risk and clinical presentation of NTM infection were sent to referring physicians and primary care providers of all patients who had procedures using heater cooler devices from June 2011 through August 22, 2016, when these devices were in use at Michigan Medicine.
- In November 2016, letters were sent to all patients who had procedures using heater cooler devices from June 2011 through August 22, 2016 with information related to clinical symptoms of infection and recommendations for follow-up including a patient hotline.
- We have now identified a small number of U-M patients who have developed NTM infection among the nearly 7,000 patients who had surgery potentially using the Sorin Stöckert devices.
- In December 2018, letters were sent to a small subset of patients (84 in total) who underwent procedures using a specific heater cooler device that was implicated in an NTM infection reminding them of the clinical symptoms of infection and recommendations for follow-up including a patient hotline. These letters were also shared with referring physicians and primary care providers.

What clinicians need to know:

- Clinicians should maintain a high index of suspicion for NTM infection in adult and pediatric patients who have undergone procedures involving cardiopulmonary bypass between June 2011 and August 22, 2016, particularly those who have received valves or other implanted devices. These symptoms can present years later (literature suggests that this can be as long as 6 years).
- A wide range of clinical presentations has been described in patients with NTM infection after cardiopulmonary bypass, including sternal wound drainage or redness, bacteremia/endocarditis,

and disseminated infection. NTM infection should be suspected in patients who have persistent unexplained fever, prolonged fatigue, night sweats, weight loss, or muscle aches after undergoing cardiac surgery. Laboratory abnormalities may include leukopenia and LFT elevation.

- NTM can be detected only with special cultures for acid-fast bacilli (AFB). AFB cultures should be performed on tissue samples obtained during operative debridement procedures for sternal wound infection or other cardiac or graft infections (note that AFB cultures cannot be performed on swab samples). For patients who present with persistent fever of unclear etiology after cardiac surgery, AFB blood cultures and imaging to evaluate for disseminated infection should be considered. Bone marrow aspiration may also be useful.

If you have a clinical question pertaining to one of your patients, or if you have a symptomatic patient who requires additional evaluation for potential NTM infection, please call M-LINE at (800) 962-3555 or internally at 936-3856 to speak to one of our designated providers who can answer your heater-cooler related questions.

We have also established a hotline for patients who may call us directly at 855-336-5900. Representatives are available Monday through Friday from 8 a.m. to 5 p.m.

Additional information can be found at:

<http://www.med.umich.edu/heater-cooler/index.html>