In 2016, the Centers for Disease Control and Prevention (CDC) issued a Health Advisory Notice warning healthcare providers and patients about the risk of infection from contaminated medical devices used during open-heart surgery. These heater-cooler devices were contaminated with nontuberculous mycobacteria (NTM), a naturally occurring organism found in water and soil. Prevention Strategist sat down with representatives from the CDC and U.S. Food and Drug Administration (FDA) to discuss the implications of this contamination for infection preventionists (IPs), healthcare providers, patients, and their families.

MICHAEL BELL, MD, Deputy Director, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention

SUZANNE SCHWARTZ, MD, MBA, Associate Director for Science and Strategic Partnerships, Food and Drug Administration, Center for Devices and Radiological Health
Q1: For IPs using the CDC’s “Interim Guide for the Identification of Possible Cases of Nontuberculous Mycobacterium Infections Associated with Exposure to Heater-Cooler Units” (dated 5/13/2016), will there be a revised version of this document with a more structured approach to identifying cases? Given the numbering sequence used, it appears the laboratory assessment occurs first, the clinical assessment second, and the exposure assessment last. However, if a patient was not exposed via usage of a heater-cooler device intraoperatively, the lab finding of Mycobacterium avium complex would not need to be reviewed for inclusion in this case review. This has caused confusion among IPs and led to the review of multiple cases that do not meet inclusion criteria.

CDC: The guide for identifying cases was intended to capture the greatest number of potential patients that may have had exposure and, therefore, may result in the review of cases of patients with invasive NTM infections who end up not having had the exposure of interest. CDC is also currently working with state health departments on related guidance for tracking case reports. As drafted, this guidance includes criteria to classify a case of NTM that is associated with exposure to heater-cooler devices and other data elements that may be helpful in tracking cases.

FDA: In addition to the recommendations provided in the October 2015 Safety Communication and June 2016 Safety Communication for facilities and staff using heater-cooler devices, the FDA updated its recommendations on October 13, 2016, to include the following:
• If your facility uses Stockert 3T heater-cooler (3T) devices, you should:
  o Immediately remove from service any heater-cooler devices, accessories, tubing, and connectors that have tested positive for M. chimaera or have been associated with known M. chimaera patient infections at your facility.
  o Use new accessories, tubing, and connectors to prevent recontamination when using a different heater-cooler device.
  o Direct and channel the heater-cooler exhaust away from the patient (e.g., to the operating room exhaust vent).
  o Review the recommendations in CDC’s Health Advisory Notice.
  o Be aware that heater-cooler devices are important in patient care. In appropriately selected patients, the benefits of temperature control during open chest cardiothoracic procedures generally outweigh the risk of infection transmission associated with the use of these devices.
• If your facility has 3T devices manufactured prior to September 2014, you should:
  o Strongly consider transitioning away from the use of these devices for open-chest cardiac surgery until the manufacturer has implemented strategies for these devices to mitigate the risks of patient infection. Use of these devices should be limited to emergent and/or life-threatening situations if no other heater-cooler devices are available.
  o Follow the FDA’s earlier recommendations (see first reference) to help mitigate the risks of patient infection.
• If your facility has 3T devices manufactured after September 2014, you should:
  o Follow the FDA’s earlier recommendations (see first reference) to help mitigate the risks of patient infection.
  o Be aware that testing of heater-cooler devices to identify units contaminated with M. chimaera presents technical challenges related to sample collection, the long culture time, and the high rate of false negative tests. Therefore, it is not recommended at this time.
• If your facility has 3T devices manufactured after September 2014, you should:
  o Follow the FDA’s earlier recommendations (see first reference) to help mitigate the risks of patient infection.
  o Be aware that testing of heater-cooler devices to identify units contaminated with M. chimaera presents technical challenges related to sample collection, the long culture time, and the high rate of false negative tests. Therefore, it is not recommended at this time.
The FDA takes the risk of infection very seriously and is working intensively to address it. In general, most of the heater-cooler devices have similar designs, and include vents, fans, and water tanks. All of the heater-cooler devices in distribution have design aspects that agitate the water and have fans with the potential to disrupt the laminar air flow in operating rooms.
The aerosolization of NTM and disruption of the protective airflow in operating rooms may play critical roles in patient exposure to *M. chimaera* and infection.

**Q2:** How will the FDA intervene to prioritize and mobilize replacement equipment coming to market for the contaminated heater-cooler units? For those hospitals that purchased these devices seeking alternatives, will there be a structured approach to ensure patient safety is not compromised during this transition? Will hospitals performing urgent/emergent open cardiothoracic cases and no alternative heater-cooler devices available receive replacement units first?

**FDA:** We are working toward an approach that minimizes patient risk and ensures patient safety. In general, when public health concerns occur, manufacturers discuss with the FDA their proposed allocation and prioritization strategies to mitigate shortages and to minimize patient risk. We encourage hospitals to work closely with the device manufacturer in the needs assessment that the manufacturer carries out.

**Q3:** Knowing the length of time from exposure to potential infection for this specific microorganism and knowing our patients may receive care from multiple healthcare systems during this time, what is the long-term plan for continued surveillance for *Mycobacterium avium* complex?

**CDC:** Currently, there are only a handful of states that have mandatory reporting of extrapulmonary NTM infections. However, given the recent global public health investigation involving invasive *M. chimaera* infections, the potential need for expanding surveillance of extrapulmonary NTM infections is being actively explored by CDC and through discussions with state health departments. CDC is also discussing and exploring options for the systematic collection of cases of NTM infection specifically related to heater-cooler exposure.

**Q4:** The FDA has recommended performing environmental air and water sampling when heater-cooler unit contamination is suspected. Besides patient infection, when should there be a suspicion a unit may be contaminated?

**CDC:** One basic indicator of potential contamination is the presence of any visible biofilm in the heater-cooler device.

**Q5:** The CDC and FDA have recommended directing the heater-cooler unit exhaust vent away from the operative field and table to mitigate the risk of aerosolizing tank water into the surgical field. Is there evidence that this sufficiently removes the risk? Should this be done for heater-cooler units made by companies other than Sorin?

**CDC:** There have been some publications over the last year that have done experiments of operating room air flow and interactions with the exhaust from heater-cooler devices that have demonstrated that exhaust from these devices can reach the surgical field. CDC is collaborating with academic partners who are exploring options for obtaining data through research to help determine how much effect this and other interventions have on decreasing risk of bioaerosols from reaching the surgical field. In general, any heater-cooler device that may have the potential to blow aerosolized particles to the surgical field should be redirected to face away from the sterile area.

**Q6:** There are other companies besides Sorin that manufacture heater-cooler units. Are the CDC and FDA reviewing these units to determine if they pose a risk of infection similar to the Sorin Stöckert 3T units that were manufactured prior to September 2014?

**FDA:** The FDA is currently working with manufacturers of heater-cooler devices to review their recommended cleaning and disinfection protocols included in the labeling.
for currently marketed devices to ensure that they are adequate and can be understood by medical staff and end users. Manufacturers are responsible for updating their labeling after their device is cleared. FDA is generally not made aware of labeling changes to an already cleared device unless, for example, modifications could significantly affect a device’s safety or effectiveness, which is why we are working with heater-cooler manufacturers to better understand their current cleaning and disinfection protocols.

If your facility has 3T devices manufactured prior to September 2014, you should:

• Strongly consider transitioning away from the use of these devices for open-chest cardiac surgery until the manufacturer has implemented strategies for these devices to mitigate the risks of patient infection.
• Limit use of these devices to emergent and/or life-threatening situations if no other heater-cooler devices are available.

Follow the FDA’s earlier recommendations (see first reference) to help mitigate the risks of patient infection.

• Be aware that testing of heater-cooler devices to identify units contaminated with *M. chimaera* presents technical challenges related to sample collection, the long culture time, and the high rate of false negative tests. Therefore, it is not recommended at this time.

If your facility has 3T devices manufactured after September 2014, you should:

• Follow the FDA’s earlier recommendations (see first reference) to help mitigate the risks of patient infection.
• Be aware that testing of heater-cooler devices to identify units contaminated with *M. chimaera* presents technical challenges related to sample collection, the long culture time, and the high rate of false negative tests. Therefore, it is not recommended at this time.

Q7: Should hospitals that own Sorin Stöckert 3T units manufactured after September 2014 plan to replace them with units from another manufacturer?

**FDA:** See FDA answer to question 1 on p. 58.

**References**


