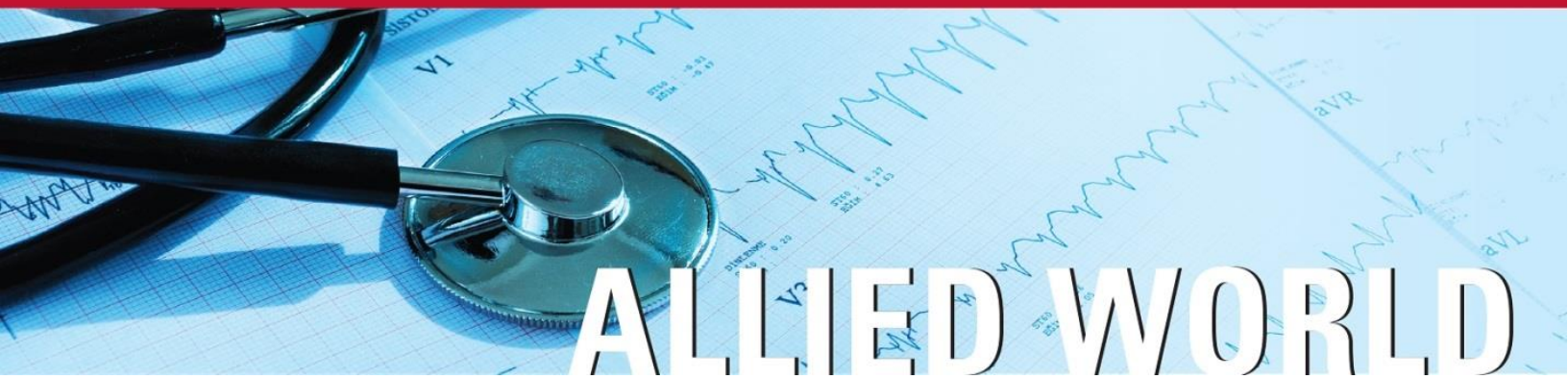

December 2016

Patients May be at Risk from Contaminated Heater-Cooler Devices Used during Cardiac Surgery

Heater-cooler devices used during cardiothoracic surgeries and other surgical procedures to warm or cool a patient have been linked with Nontuberculous Mycobacteria (NTM) infections. In Spring 2015, investigators in Switzerland reported a cluster of six patients with invasive infection of *M. chimaera*, a species of NTM commonly found in soil and water. All of the infected patients had undergone open-heart (open chest) surgical procedures that used contaminated heater-cooler devices during extracorporeal circulation. Similarly, in July 2015, a Pennsylvania hospital also discovered a cluster of invasive NTM infections among patients who had undergone open-heart surgery. The Centers for Disease Control (CDC) investigated and found that like the hospital in Switzerland, contaminated 3T heater-cooler devices had been used during the surgeries in the Pennsylvania hospital.

Between January 2010 and August 2015, the Food and Drug Administration (FDA) received 32 Medical Device Reports (MDRs) of patient infections associated with heater-cooler devices or bacterial heater-cooler device contamination. 25 of these cases were reported during 2015. Some reports described NTM infections related to cardiothoracic surgeries, but other reports did not specify the surgical procedure performed. In some cases, patients presented with infections several months or years after their surgical procedures. Important to note is that half of the 32 reports submitted described only contamination of the heater-cooler device and without known patient involvement or infections. The FDA is not aware of NTM infections that may have been acquired by hospital staff or physicians. It is also important to note that some cases may not yet have been reported to the FDA.

More than 250,000 heart bypass procedures using heater-cooler devices are performed in the United States every year. The 3T heater-cooler device linked to these infections represents about 60% of all heater-cooler devices in the country. NTM infections are difficult to treat and delays in diagnosis may further complicate a given patient's clinical condition and medical management.

Surgeries that may involve the use of a heater-cooler include:

- Heart valve replacement
- Heart transplant
- Lung transplant
- Coronary artery bypass graft (CABG)
- Extracorporeal membrane oxygenation (ECMO)
- Left ventricular assist device (LVAD) implant
- Aortic anomaly surgery
- Pulmonary artery banding
- Lung resection

On October 13, 2016, the CDC issued a health advisory alerting hospitals to notify patients who underwent open-heart surgery involving Stöckert 3T heater-cooler devices that the device was potentially contaminated, possibly putting patients at risk for a life threatening infection. Hospitals are advised to tell potentially exposed patients to seek medical care if they are experiencing symptoms such as night sweats, muscle aches, unexplained weight loss, fatigue, or unexplained fever. CDC further advised hospitals to implement a plan to communicate with potentially exposed patients and increase the awareness of healthcare providers.

CDC Recommendations[i]

Healthcare providers

- Internist, infectious disease specialists, cardiologists, cardiothoracic surgeons, and other clinicians should suspect NTM infections among patients who have signs of infection and a history of open-chest cardiac surgery. Clinicians should be aware that infections can take months to cause symptoms.
- Patients with NTM infections following cardiac surgery have presented with a variety of clinical manifestations. Common examples are endocarditis, surgical site infection, or abscess and bacteremia. Other clinical manifestations have included hepatitis, renal insufficiency, splenomegaly, pancytopenia and osteomyelitis.
- Diagnosis can be difficult due to the nonspecific presentation of illness and the slow growing nature of the bacteria. Physicians should consider:
    - Consulting with an infectious disease specialist if caring for patients who have undergone an open-chest procedure and present with signs of infection.
    - Obtaining cultures for acid fast bacilli (AFB) as part of the evaluation.
    - Other specialized testing to detect *M. chimaera* may be needed and further laboratory testing should be discussed and arranged in consultation with an infectious disease specialist or health department.

Hospitals

- Hospitals performing open-chest cardiac surgery should immediately assess their use of heater-cooler devices and determine whether they are currently using—or have previously used—3T devices. Facilities should ensure that they are implementing current FDA recommendations to minimize patient risk to infections associated with heater-cooler devices. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/UCM520191.htm
- Hospitals should notify cardiothoracic surgeons, cardiologists, infectious disease physicians, internal medicine, primary care physicians, and other clinicians who evaluate patients that have had open-chest cardiac or other bypass surgery, about the risk of infection associated with 3T heater-cooler devices. CDC has sample letters available at https:/www.cdc.gov/hai/outbreaks/heater-cooler.html. Hospitals should review their facility's microbiology laboratory databased and records of surgical procedures for any positive NTM cultures in surgery patients that might indicate a possible case.
  CDC has provided guidance on case-finding:
  http://www.cdc.gov/hai/pdfts/outbreaks/Guide-for-Case-Findings.pdf.
- Hospitals should consider institution-specific strategies for alerting patients of the risk of infection related to potentially contaminated heater-cooler devices.
- Hospitals can consider prospective surveillance of patients who have undergone open-chest cardiac surgery involving a 3T heater-cooler device.
- Hospitals should consider using informed consent to educate patients of the potential NTM infection risks.
- The overall risk of *M. chimaera* infection is low relative to other complications following cardiac surgery; emergent cardiac procedures should not be delayed because of the use of 3T devices. Continued use of 3T devices should be done in accordance with the latest manufacturer's recommendations, including maintenance and proper positioning of devices to minimize the risk of patient exposure.
- Hospitals that have identified contaminated 3T heater-cooler devices or patient infections associated with devices should promptly alert their local or state health department and submit a report to FDA via Med Watch.
  http://www.fda.gov/Safety/MedWatch//HowToReport/DownloadForms.default.htm

Updated FDA Recommendations[ii]

On October 13, 2016, the FDA updated its recommendations to health care facilities and staff using 3T devices. The updated recommendations include, among other things:

- 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 the facility.

- Use new accessories, tubing, and connectors to prevent recontamination when using a different heater-cooler device.
- Be aware that device contamination also may occur from other sources such as environmental contamination or device contact with contaminated accessories.
- 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 use of these devices.
- 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.
- For facilities with 3T devices manufactured prior to September 2014, 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.

The FDA also recommends that healthcare facilities and staff using any type of heater-cooler device (including the 3T) continue to follow all recommendations presented in the October 15, 2015 FDA Safety Communication. These recommendations include, among other things:

- Strict adherence to the cleaning and disinfection instructions provided in the manufacturer's device labeling. Ensure you have the most current version of the manufacturer's instructions for use readily available to promote adherence.
- Do not use tap water to rinse, fill, or top-off heater-cooler water tanks since this may introduce NTM organisms. Use only sterile water or water that has been passed through a filter of less than or equal to 0.22 microns. When making ice needed for patient cooling during surgical procedures, use only sterile water or water that has been passed through a filter of less than or equal to 0.22 microns.
- Direct the heater-cooler's vent exhaust away from the surgical field to mitigate the risk of aerosolizing heater-cooler tank water into the sterile field.
- Establish regular cleaning, disinfection and maintenance schedules for heater-cooler devices according to the manufacturer's instructions to minimize the risk of bacterial growth and subsequent patient infection.
- Immediately remove from service heater-cooler devices that show discoloration or cloudiness in the fluid lines/circuits, which may indicate bacterial growth. Consult your hospital infection control officials to perform the appropriate follow up measures and report events of device contamination to the manufacturer.

Other Risk Management Considerations

- Maintain documentation of biomedical inspections including the date and time of the inspection and name of the technician who performs the inspection.
- If a contaminated heater-cooler device is identified notify the FDA via Med Watch report and also notify the manufacturer of the unit.
- Do not release the device to the manufacturer if requested. Require the manufacturer to perform their inspection at the hospital and monitor the inspection that is performed. Establish a chain of custody for any tubing, connectors or parts that are replaced.
- Develop a plan to transition away from the 3T device per FDA guidance.
- Follow manufacturer's recommendations for disinfection and cleaning, as well as guidance issued by the FDA.
- Ensure perfusionists and other staff are following FDA recommendations for the use and maintenance of 3T devices to reduce exposure risks.
- Establish a team to develop the hospital's plan of action to notify patients and physicians and to conduct training for physicians and employees. Include the hospital risk manager on the planning and implementation team.
- Share CDC and FDA advisories, alerts and guidance with physicians and employees.
- Develop the patient notification letter and implement the plan for notifying patients and the public. Involve media relations. Maintain a database that identifies each patient notified. Determine how returned mail undelivered will be addressed and the additional measures the hospital will take to notify potentially exposed patients.
- Inform employees of the hospital's plan of action and how employees should manage any inquiries presented to them by concerned patients or community members.
- Notify risk management of all patients identified infected with *M. chimaera*.
- Submit a notice of potential loss report to the facility's professional liability insurance claim representative for all *M. chimaera* infected patients identified. Report any threat of legal action regardless of infection to the facility's professional liability insurance claim representative.
- Notify the facility's directors and officers (D&O) and errors and omissions (E&O) carrier(s) of all *M. Chimaera* infected patients identified as well as any threats of legal action regardless of infection.

Resources

[i] CDC Health Alert Network, CDC Health Advisory, October 13, 2016, 13:00 ET

[ii] UPDATE: Mycobacterium chimaera infections with LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stöckert 3T Heater-Cooler system: FDA Safety Communication; October 13, 2016. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm520191.htm

Additional Resources

Sax H, Bloemberg G, Hasse B, et al. prolonged outbreak of Mycobacterium chimaera Infection After Open-chest Heart Surgery. Clin Infect Dis 2015; 61:67-75. http://cid.oxfordjournals.org/content/early/2015/04/14/cid.civ198.full.pdf.

Sommerstein R, Ruegg P, Bloemberg G, et al. Transmission of Mycobacterium chimaera from heater-Cooler Units during Cardiac Surgery despite an Ultraclean Air Ventilation System. Emerg Infect Dis, 22(6), 1008-1013. http://doi.org/10.3201/eid2206.160045.

CDC resources

Notification Toolkit; https://www.cdc.gov/HAI/outbreaks/heater-cooler.html

Morbidity and Mortality Weekly Report (MMWR) Notes from the Field: Mycobacterium chimaera Contamination of Heater-Cooler Devices Used in Cardiac Surgery – United States; October 14, 2016/65(40); 1117-1118. https://www.cdc.gov/mmwr/volumes/65/wr/mm6540a6.htm?s_cid=mm6540a6_w

FDA resources

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/ucm492590.htm.

Author

Gwen R. Stokes, BSN, MPH, CPHQ, CPHRM, DFASHRM
Vice President, Healthcare Risk Management Group
AWAC Services Company, *a member company of* ***Allied World***