U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Nontuberculous Mycobacterium Infections Associated with Heater-Cooler Devices: FDA Safety Communication

Date Issued: October 15, 2015

Audiences:

- Health Care Providers who use heater-cooler devices
- Hospital staff who are responsible for operating and maintaining devices
- Infection Control Practitioners
- Infectious Disease Specialists
- Surgeons
- Perfusionists
- Operating Room Managers, Directors and Staff
- Risk Managers

Medical Specialties: Cardiothoracic Surgeons, Cardiovascular Surgeons, Orthopedic Surgeons, Neurosurgeons, General Surgeons, Anesthesiologists, Infection Control, Infectious Disease Physicians, Intensive Care Physicians

Product: All heater-cooler devices. Heater-cooler devices provide heated and/or cooled water to 1) oxygenator heat exchangers, 2) cardioplegia (paralysis of the heart) heat exchangers, and/or 3) warming/cooling blankets.

Purpose:
The FDA wants to heighten awareness about infections associated with heater-cooler devices and steps health care providers and health facilities can take to mitigate risks to patients.

Summary of Problem and Scope:
Heater-cooler devices are used during cardiothoracic surgeries, as well as other medical and surgical procedures to warm or cool a patient to optimize medical care and improve patient outcomes. Heater-cooler devices include water tanks that provide temperature-controlled water to external heat exchangers or warming/cooling blankets through closed circuits. Although the water in the circuits does not come into direct contact with the patient, there is the potential for contaminated water to enter other parts of the device or transmit bacteria through the air (aerosolize) through the device's exhaust vent into the environment and to the patient.

Through the FDA's analysis of adverse event reports, the medical literature, and information from national and international public health agencies, we are aware that the use of heater-cooler devices has been associated with Nontuberculous Mycobacteria (NTM) infections, primarily in patients undergoing cardiothoracic surgical procedures. NTM organisms are widespread in nature and can be found in soil and water, including tap water sources. They are typically not harmful, but in rare cases may cause infections in very ill patients and/or in individuals with compromised immune systems.

Between January 2010 and August 2015, the FDA received 32 Medical Device Reports (MDRs) of patient infections associated with heater-cooler devices or bacterial heater-cooler device contamination. Twenty-five of these MDRs were reported to the FDA in 2015. Some reports describe NTM infections related to cardiothoracic surgeries, but other reports do not specify the procedure the patient was undergoing. Eight reports were related to 3 events describing patient infections occurring in U.S. health care facilities. The remaining 24 reports involved health care facilities outside the United States, most of these in Western Europe. In some cases,

patients presented with infections several months to years after their surgical procedures. It is important to note that half of the 32 reports submitted to the FDA describe bacterial contamination of the heater-cooler device without known patient involvement or infection. The FDA is not aware of NTM infections acquired by hospital staff.

It is possible that some cases have not been reported to the FDA. It is challenging for a health care facility, health care provider, manufacturer, or patient to recognize that infections, particularly NTM infections, may be associated with the use of or exposure to a particular medical device. The FDA continues to evaluate reports through follow up with health care facilities and manufacturers to determine which factors may have contributed to the reported events.

Recommendations for Health Care Facilities and Staff
In addition to following standard precautions, the FDA recommends that facilities and staff using heater-cooler devices consider implementing the following measures to reduce risk to patients:

- Strictly adhere to the cleaning and disinfection instructions provided in the manufacturer's device labeling. Ensure you have the most current version of the manufacturers' instructions for use readily available to promote adherence.
- Do not use tap water to rinse, fill, refill or top-off 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. Deionized water and sterile water created through reverse osmosis is not recommended because it may promote corrosion of the metal components of the system.
- 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 and exposing the patient.
- Establish regular cleaning, disinfection and maintenance schedules for heater-cooler devices according to the manufacturers' instructions to minimize the risk of bacterial growth and subsequent patient infection.
- Develop and follow a comprehensive quality control program for maintenance, cleaning, and disinfection of heater-cooler devices. Your program may include written procedures for monitoring adherence to the program and documenting set up, cleaning, and disinfection processes before and after use.
- 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.
- Consider performing environmental, air, and water sampling and monitoring if heater-cooler contamination is suspected. Environmental monitoring requires specialized expertise and equipment to collect and process samples, which may not be feasible in all facilities.
- Health care facilities should follow their internal procedures for notifying and culturing patients if they suspect infection associated with heater-cooler devices.
- Submit a report to the manufacturer and to the FDA **via MedWatch (/Safety/MedWatch/HowToReport/ucm2007306.htm)**, as described below, if you suspect heater-cooler devices have led to patient infections.

FDA Activities:
The FDA is actively engaged with stakeholder groups to better understand the causes and risk factors for transmission of microbial agents associated with these devices and to develop strategies to minimize patient exposure. Our ongoing activities include:

- Working with health care facilities and professional medical societies to understand their experiences with heater-cooler devices.
- Evaluating information about documented and potential infections from multiple sources, including **medical device adverse event reports (/MedicalDevices/Safety/ReportaProblem/ucm2005291.htm)** submitted to the FDA, the medical literature, international public health agencies and federal partners.

- Collaborating with medical device manufacturers to review their existing cleaning and disinfection protocols provided in the instructions for use for currently marketed devices.

FDA continues to actively monitor this situation and will provide updates as appropriate.

Reporting Problems to the FDA:
Device manufacturers and user facilities must comply with the applicable **Medical Device Reporting (MDR) regulations (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)**.

Health care personnel employed by facilities that are subject to the **FDA's user facility reporting requirements (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)** should follow the reporting procedures established by their facilities.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with the use of medical devices. Health care providers should submit voluntary reports of infection transmission associated with heater-cooler devices or reports describing difficulty following the manufacturers' instructions for use to the agency via the **Medical Device Reporting (MDR) (/MedicalDevices/Safety/ReportaProblem/ucm2005291.htm)** process. If a health care provider suspects bacterial contamination of the heater-cooler device following use, we encourage the health care provider to file a voluntary report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program (/Safety/MedWatch/HowToReport/ucm2007306.htm)**.

Additional Resources:
American Thoracic Society. **An Official ATS/IDSA Statement: Diagnosis, Treatment and Prevention of Nontuberculous Mycobacterial Diseases: (https://www.thoracic.org/statements/resources/mtpi/nontuberculous-mycobacterial-diseases.pdf) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** 2007.

European Centre for Disease Prevention and Control (ECDC). **Rapid Risk Assessment: Invasive cardiovascular infection by *Mycobacterium chimaera* potentially associated with heater-cooler units used during cardiac surgery: (http://ecdc.europa.eu/en/publications/Publications/mycobacterium-chimaera-infection-associated-with-heater-cooler-units-rapid-risk-assessment-30-April-2015.pdf) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** April 30, 2015.

References:
Kohler, P.; Kuster, SP.; Bloemberg, G. **Healthcare-associated prosthetic heart valve, aortic vascular graft, and disseminated *Mycobacterium chimaera* infections subsequent to open heart surgery. (http://eurheartj.oxfordjournals.org/content/ehj/early/2015/07/16/eurheartj.ehv342.full.pdf) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** Eur Heart J. 2015 Jul 17. *(Abstract)*

Sax, H.; Bloemberg, G.; Hasse, B.; et al. **Prolonged outbreak of *Mycobacterium chimaera* infection after open chest heart surgery. (http://cid.oxfordjournals.org/content/early/2015/03/11/cid.civ198.abstract) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** Clin Infect Dis. 2015 Mar 11. *(Abstract)*

Falkinham JO.; Pruden A.; Edwards M. **Opportunistic Premise Plumbing Pathogens: Increasingly Important Pathogens in Drinking Water. (http://www.mdpi.com/2076-0817/4/2/373/pdf) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** Pathogens 2015;4(2):373-386.

Contact Information:
If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at **DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV)**, 800-638-2041 or 301-796-7100.

More in Safety Communications (/MedicalDevices/Safety/AlertsandNotices/default.htm)

Information About Heparin (/MedicalDevices/Safety/AlertsandNotices/ucm135345.htm)

Preventing Tubing and Luer Misconnections (/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm)