

PENNSYLVANIA DEPARTMENT OF HEALTH
2015– PAHAN –319 – 10-27-ADV
FDA Alert and CDC Practical Guidance about
Non-tuberculous Mycobacterium (NTM) infections
associated with Heater-Cooler Devices



DATE:	10/27/2015
TO:	Health Alert Network
FROM:	Karen M. Murphy, PhD, RN, Secretary of Health
SUBJECT:	FDA Alert and CDC Practical Guidance about Non-tuberculous Mycobacterium (NTM) infections associated with Heater-Cooler Devices
DISTRIBUTION:	Statewide
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This transmission is a “Health Advisory” that provides important information for a specific incident or situation; may not require immediate action.

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PROFESSIONAL ORGANIZATIONS: PLEASE DISTRIBUTE TO YOUR MEMBERSHIP

The Pennsylvania Department of Health (PA DOH) is sharing the following information from the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) with you.

Purpose:

CDC has identified a need for increased vigilance for NTM infections by health departments, healthcare facilities, and individual healthcare providers. FDA recently issued a Safety Communication on Nontuberculous Mycobacterium Infections Associated with Heater-Cooler Devices that addresses issues regarding the proper use and maintenance of these devices. CDC has been working with the FDA and local and state health departments to investigate heater-cooler units associated with NTM infections and/or found to be contaminated with NTM. This CDC communication is to (a) raise awareness among health departments, healthcare facilities, and healthcare providers of the possible association between NTM infections and use of heater-cooler devices and (b) to provide guidance on identifying patients with infection.

Summary:

Heater-cooler devices are commonly used during cardiac surgical procedures to warm and cool a patient's blood during cardiopulmonary bypass. NTM are slow-growing bacteria that are found in surface water, tap water, and soil. Recent reports have suggested an association between heater-cooler devices and NTM infections among patients undergoing cardiac surgery potentially through the aerosolization of bacteria from contaminated water used in these devices (1-4).

The most important action to protect patients will be to remove contaminated heater-coolers from operating rooms, and ensure that those in service are correctly maintained. Patients who might have been exposed to NTM during a surgical procedure should continue to look for signs of potential infection and keep in touch with their clinicians for further evaluation. Due to the potentially long delay between exposure to NTM and manifestation of clinical infection (up to several years), identifying infections related to the use of heater-cooler devices can be challenging.

Recommendations for health departments:

Local and state health departments should communicate with healthcare facilities that perform cardiac surgical procedures, or facilities that may provide care to patients who have undergone such procedures, to ensure that the devices have been assessed, their maintenance reviewed and any potentially contaminated devices are removed from service. Clinical staff should be alerted to maintain increased awareness in identifying NTM infections potentially associated with surgery that uses heater-cooler devices.

Health departments should track reports from healthcare facilities regarding potential infections associated with heater-cooler units, encourage facilities to report these events to FDA, and be prepared to assist healthcare facilities with further investigation as needed. CDC is available to health departments for further consultation.

Recommendations for healthcare facilities:

Healthcare facilities should immediately assess their use of heater-cooler units and ensure that they are safe and properly maintained. In addition, clinical staff should maintain heightened vigilance for possible NTM infections among patients who have undergone cardiac surgical procedures that involved the use of heater-cooler devices. Some actions that healthcare facilities should consider include:

- Ensure that your facility is following the most current manufacturer's instructions and following FDA's recommendations for maintenance, cleaning, disinfection and monitoring of heater-cooler devices
- If a heater-cooler device in your facility tests positive for NTM or if there is concern for patient infections related to the heater-cooler device, review your facility's microbiological database and records of surgical procedures to identify any patients that have had NTM-positive cultures within four years following a cardiac surgery procedure.
- If a heater-cooler device is suspected to have led to patient infections or if a heater-cooler device has tested positive for NTM, promptly notify your local health department, submit a report to FDA via MedWatch, and assess the need for notifying exposed patients in coordination with public health authorities.

Recommendations for healthcare providers:

Healthcare providers should have increased suspicion for NTM infections among patients who have signs of infection and a history of cardiac surgery. When seeing patients, actions that providers should consider include:

- Assessment for NTM infection for patients who report signs or symptoms of infection and who have had undergone cardiac surgery within the previous four years.
- Patients suspected to have an NTM infection should also be assessed for a history of cardiac surgery or exposure to a heater-cooler device. Note that other healthcare exposures such as injections, plastic surgery, and dialysis may also be associated with NTM infections and warrant consultation with public health authorities or reporting to FDA.
- Order mycobacterial culture in patients who have undergone a cardiac procedure within the previous four years who present with signs of infection.
- Patients with NTM infections following cardiac surgery have presented with a variety of clinical manifestations. Common examples include endocarditis, surgical site infection, and bacteremia. However, other clinical manifestations have included hepatitis, splenomegaly, and osteomyelitis.
- Diagnosis can be difficult due to the non-specific presentation of illness, but it is important that providers maintain an index of suspicion in patients with a history of cardiac surgery. Consider arranging consultation with an infectious disease specialist. It is also important to obtain acid fast bacteria (AFB) cultures to increase the likelihood of identification of the organism as well as to obtain an AFB smear in order to have preliminary information while awaiting culture results.

Recommendations for patients:

Patients who have recently had cardiac or thoracic surgery should contact their health care provider if they have (a) symptoms of NTM infection, which may include a combination of the following: fever: pain, redness, heat, or pus around a surgical incision: night sweats: joint pain: muscle pain: and fatigue: or (b) questions about possible or exposure to a heater-cooler device.

It is important to note that these infections typically develop slowly and treatment may not be needed right away. Those who were exposed to NTM should continue to look for signs of unexplained infection and keep in touch with their clinicians for further evaluation and tracking.

References:

1. U.S. Food and Drug Administration, Nontuberculous Mycobacterium Infections Associated with Heater-Cooler Devices: FDA Safety Communication: October 15, 2015.
2. Kohler P, Kuster SP, Bloemberg G, et al. Healthcare-associated prosthetic heart valve, aortic vascular graft, and disseminated Mycobacterium chimaera infections subsequent to open heart surgery. European heart journal. Jul 17 2015.
3. Sax H, Bloemberg G, Hasse B, et al. Prolonged Outbreak of Mycobacterium chimaera Infection After Open-Chest Heart Surgery. Clinical infectious diseases: an official publication of the Infectious Diseases Society of America. Jul 1 2015;61(1):67-75.
4. Mycobacterial infections associated with heater cooler units used in cardiac surgery: advice for providers of cardiac surgery. London: Public Health England: 2015.

Categories of Health Alert messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for a specific incident or situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of October 27, 2015, but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.