DATE: October 14, 2016

TO: Acute Care Facilities, Local Health Departments, and NYSDOH Regional Epidemiologists

FROM: NYSDOH Bureau of Healthcare Associated Infections

Health Advisory:
Non-tuberculous Mycobacterium (NTM) Infections and Heater-Cooler Units

Please distribute immediately to: Administration, Cardiothoracic Surgeons, Operating Room management, Infectious Disease Department, Infection Prevention, Perfusionists, Laboratory Service, Clinical Technology Department, Purchasing Department

New York State Department of Health (NYSDOH) is distributing the attached Centers for Disease Control and Prevention (CDC) Health Alert Network Advisory from October 13, 2016: CDC Advises Hospitals to Alert Patients at Risk from Contaminated Heater-Cooler Devices Used During Cardiac Surgery. https://emergency.cdc.gov/han/han00397.asp. This advisory details recommendations related to specific heater-cooler units used for extracorporeal circulation during open-heart surgery.

The Department is recommending that hospitals:

- Review and follow the attached CDC recommendations.
- Ensure heater-cooler units in use at your facility are maintained per the latest Federal Drug Administration (FDA) recommendations: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/UCM520191.htm.
- Identify and report any extrapulmonary, non-tuberculous mycobacterium infections among patients who had surgeries where the heater-cooler device of concern was used until further notice. Cases should be reported to your NYSDOH Regional Epidemiologist or to the NYSDOH Bureau of Healthcare Associated Infections, Healthcare Epidemiology and Infection Control Program Central Office.
- Clinical laboratories should hold any relevant isolates, pending discussion with and instruction from NYSDOH.

NYSDOH Regional and Central Office Contact Information:
Western Regional Office (716) 847-4503
Central New York Regional Office (315) 477-8166
Metropolitan Area Regional Office (914) 654-7149
Capital District Regional Office (518) 474-1142
Central Office (518) 474-1142

If you have any questions about this advisory, please call the Bureau of Healthcare Associated Infections at 518-474-1142.
CDC Advises Hospitals to Alert Patients at Risk from Contaminated Heater-Cooler Devices Used during Cardiac Surgery

Summary
The Centers for Disease Control and Prevention (CDC) is advising hospitals to notify patients who underwent open-heart (open-chest) surgery involving a Stöckert 3T heater-cooler that the device was potentially contaminated, possibly putting patients at risk for a life threatening infection. New information indicates that these devices, manufactured by LivaNova PLC (formerly Sorin Group Deutschland GmbH), were likely contaminated with the rare bacteria *Mycobacterium chimaera* during manufacturing. Hospitals should advise 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. In addition, hospitals that use or have used this device are strongly encouraged to make and execute a plan to communicate with potentially exposed patients and to increase awareness among healthcare providers.

Background
In the spring of 2015, investigators in Switzerland reported a cluster of six patients with invasive infection of *M. chimaera*, a species of nontuberculous mycobacterium (NTM) commonly found in soil and water. The infected patients had undergone open-heart surgery that used contaminated heater-cooler devices during extracorporeal circulation (1). In July 2015, a Pennsylvania hospital also identified a cluster of invasive NTM infections among patients who had undergone open-heart surgery. CDC assisted in a field investigation that used both epidemiologic and laboratory evidence to identify an association between invasive *Mycobacterium avium* complex, (including *M. chimaera*) infections and exposure to contaminated 3T heater-cooler devices, consistent with the Swiss report (2).

The water circuits in these heater-cooler devices that are used to regulate temperature during cardiopulmonary bypass do not come into direct contact with the patient’s circulating blood; however, these reports suggest that *M. chimaera* can be aerosolized by the devices and result in infections (1,2). The Food and Drug Administration (FDA) and CDC have issued alerts about the need to follow updated manufacturer’s instructions for maintenance and use of the devices, evaluate the devices for contamination, remain vigilant for new infections, and continue to monitor reports from the United States and overseas (2).

CDC in collaboration with National Jewish Health completed a whole-genome sequencing analysis and results demonstrate that *M. chimaera* isolates from patients with heater-cooler associated infections and from the 3T heater-cooler devices from several U.S. hospitals (in Pennsylvania and Iowa) are all highly related to each other (3). This evidence for likely point-source contamination of the 3T heater-cooler devices is consistent with recent reports from Europe (http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm504213.htm) that describe matching of *M. chimaera* sequences from environmental isolates at the device production site in Germany and isolates from patients and devices in Europe.

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 the heater-cooler devices in the country (2,4). In hospitals where at least one infection has been identified, the risk of infection was between about 1 in 100 and 1 in 1,000 patients. Initial information suggests that patients who had prosthetic material implanted are at highest risk for NTM infections. These infections are difficult to treat and delays in diagnosis further complicate patients’ clinical management. Therefore, it is
imperative that patients and providers are informed about the risk of infection associated with use of the
3T device and the need for appropriate diagnostic evaluation to facilitate timely diagnosis and treatment.

Recommendations

Healthcare providers
1. Internists, 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.
    - 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.

2. 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 cardiac procedure and present with signs of
     infection.
   - Cultures for acid fast bacilli (AFB) should be obtained 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
1. 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).
2. Hospitals should notify cardiothoracic surgeons, cardiologists, infectious disease physicians,
   internists, 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.htm.
3. Hospitals should review their facility’s microbiology laboratory database 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/pdfs/outbreaks/Guide-for-Case-
   Finding.pdf.
4. Hospitals should consider institution-specific strategies for alerting patients of the risk of infection
   related to potentially contaminated heater-cooler devices. CDC has sample patient notification letters
5. Hospitals can consider prospective surveillance of patients who have undergone open-chest cardiac
   surgery involving a 3T heater-cooler device.
6. Hospitals should consider using informed consent to educate patients of the potential NTM infection
   risk.
7. 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.
8. 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
**Health Departments**

1. Health departments should communicate with healthcare facilities that perform cardiac surgery using heater-cooler devices about the risk of *M. chimaera* infection associated with open-chest cardiac surgery involving use of the 3T heater-cooler devices. Health departments should direct facilities to CDC and FDA heater-cooler guidance documents in these communications.
   - CDC guidance documents can be found here:
   - FDA guidance documents can be found here:
     - [http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm504213.htm](http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm504213.htm)
     - [http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm466963.htm](http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm466963.htm)
     - [http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/UCM520191.htm](http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/UCM520191.htm)

2. Health departments should track reports from healthcare facilities about potential infections associated with heater-cooler devices and encourage facilities to report these events to FDA.

3. Health departments should be prepared to assist healthcare facilities with further investigation; CDC is available for further consultation as needed.

**Patients**

1. Symptoms of NTM infection, including *M. chimaera* infection, can take months to appear. Patients should be aware of the symptoms of NTM infection which can include persistent or unexplained fever; night sweats; redness, heat, or pus around a surgical incision; muscle aches; unexplained weight loss; or fatigue.

2. Patients who have had cardiac surgery should seek medical evaluation if they have one or more of these symptoms or have questions about possible exposure to a heater-cooler device.

**References**


The Centers for Disease Control and Prevention (CDC) protects people’s health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

---

Categories of Health Alert Network messages:
- **Health Alert** Requires immediate action or attention; highest level of importance
- **Health Advisory** May not require immediate action; provides important information for a specific incident or situation
- **Health Update** Unlikely to require immediate action; provides updated information regarding an incident or situation
- **HAN Info Service** Does not require immediate action; provides general public health information

---

## This message was distributed to state and local health officers, state and local epidemiologists, state and local laboratory directors, public information officers, HAN coordinators, and clinician organizations##