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CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network
October 13, 2016, 13:00 ET (1:00 PM ET)
CDCHAN- 00397

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

- 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.
- 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 fact 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

- 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 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.
- 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 available at https://www.cdc.gov/hai/outbreaks/heater-cooler.html
- Hospitals can consider prospective surveillance of patients who have undergone open-chest cardiac surgery involving a 3T heater-cooler device.
- Hospital should consider using informed consent to educate patients of the potential NTM infection risk.
- 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 MedWatch. http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm

Health Departments

- 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:
        - http://www.cdc.gov/hai/pdfs/outbreaks/Guide-for-Case-Finding.pdf
        - http://www.cdc.gov/HAI/pdfs/outbreaks/CDC-Notice-Heater-Cooler-Units-final-clean.pdf
    - FDA guidance documents can be found here:
        - 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/UCM520191.htm

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

Patients

- 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.
- 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

1. 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.
2. Food and Drug Administration. Nontuberculous Mycobacterium (NTM) infections associated with heater-cooler devices (HCD) during cardiothoracic surgery. Gaithersburg, MD; FDA Circulatory System Devices Panel of the Medical Devices Advisory Committee; June 2-3, 2016. http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/ucm485091.htm.
3. *Mycobacterium chimaera* Contamination of Heater-Cooler Devices Used in Cardiac Surgery — United States MMWR Morb Mortal Wkly Rep 2016;65:1117–1118. DOI https://emergency.cdc.gov/han/han00397.asp
4. The Society of Thoracic Surgeons. Adult cardiac surgery volumes and procedures. Adult Cardiac Surgery Database 2015.

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