Nebraska Department of Health and Human Services

HEALTH ALERT NETWORK Advisory

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DEPT. OF HEALTH AND HUMAN SERVICES

TO: Nebraska primary care providers, cardiologists, cardiac surgeons, infection preventionists, infectious disease, and public health

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RE: *Mycobacterium chimaera* Infection

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The Healthcare Associated Infections/Antimicrobial Resistance Division of the Epidemiology and Informatics Unit, Nebraska DHHS, recently received a report of a third case of *Mycobacterium chimaera* infection following open heart surgery utilizing a LivaNova 3T (previously called Sorin) heater-cooler device created before 2014. All 3 of the Nebraska patients have died. In at least 2 of the cases the *M.chimaera* infection was a contributing factor. Since this infection can be difficult to detect, with a long incubation period (up to six years) and an insidious onset of infection with non-specific symptoms, there is a risk of delayed diagnosis in patients with this complication. This Health Advisory is intended to remind the cardiovascular team and the primary care providers of these patients of this risk and to enhance early diagnosis and treatment. The risk is primarily confined to patients who underwent cardiac surgery utilizing the 3T LivaNova heater-cooler device between January 1, 2012 and October 2016 at Nebraska Heart, Bryan, Methodist and Nebraska Medicine, the 4 facilities using these devices.
Prior communications have included:

- In October 2015 and June 2016, the CDC published Safety Communications for facilities utilizing heater cooler devices during open heart surgery. https://emergency.cdc.gov/han/han00397.asp
- On October 13, 2016 the FDA updated recommendations and issued a warning of *M. chimaera* infections related to 3T LivaNova heater-cooler devices that included: removal of these devices from service, use of new accessories/tubing and, direction/channeling of the exhaust away from the sterile field. http://wayback.archive-it.org/7993/20171115052210/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm520191.htm
- On December 6, 2016, Nebraska DHHS released an initial HAN to inform Nebraska cardiac surgeons, cardiologists, infection preventionists, and hospital epidemiologists of the potential threat. http://dhhs.ne.gov/publichealth/HAN/han%20Documents/UPDATE120616.pdf
- The four affected Nebraska facilities identified and notified patients who underwent cardiac surgeries utilizing the 3T LivaNova heater-cooler device between January 1, 2012 and October 2016.
- All 3T LivaNova devices in Nebraska manufactured before 2014 have either been decommissioned or have undergone specialized cleaning as per FDA requirements.

Approximately 50 to 80 annual reports of *M. chimaera* infection related to this heater-cooler device have been identified in the United States, with a 46%-64% mortality rate (1). These infections are difficult to treat and delays in diagnosis complicate patients' management. The attack rate in the at-risk surgical population appears to be **1 in 100 to 1 in 1000** (1,2). Since

many Nebraska patients had cardiac surgery remote from their residence and source of their primary care, we are directly contacting primary care providers in addition to cardiologists and cardiac surgeons with the reminder that while the risk is decreasing, it is still present. Please consider this diagnosis in anyone who underwent surgery with one of these devices between January 1, 2012 and October 2016 who presents with any of the symptoms listed below.

Clinical Presentation, Diagnosis, and Treatment

- Highest risk of disseminated infection post prosthetic valve, graft or LVAD surgery.
    - Dissemination can involve the liver, spleen, bone marrow, kidney, eye, bones, and/or joints (1,2).
- Patients often present with nonspecific symptoms, most commonly severe fatigue, fever, sweats (60%), dyspnea, weight loss (1,2).
    - The last two patients in Nebraska presented with significant weight loss and fevers and then developed pancytopenia.
- Infections following coronary artery bypass grafting are typically localized such as sternal wound, mediastinum or pleural space infection (2).
- Detection is difficult. Growth takes between 2 and 8 weeks and requires specific culture-based methods. Quantitative polymerase chain reaction (PCR) may be preferred (1). Any nontuberculous mycobacterial culture result in this patient population should trigger further bacteriologic testing and clinical review.
- Recommended treatment:
    - 3-4 drug regimen, but a multidrug regimen that includes four to five antibiotics has also been used (1).
    - Include a macrolide, rifamycin, ethambutol, and another oral agent, such as moxifloxacin or clofazimine, as well as a parenteral agent, such as amikacin, added to the oral regimen initially (1).
    - Optimal duration of therapy is unknown. Often 12 months, up to 24 months (1).

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Resources

For more information about risk mitigation, clinical presentation and management, and communication with patients:

1. Kasperbauer, SH, Daley, CL; *Mycobacterium chimaera* Infections Related to the Heater-Cooler Unit Outbreak: A Guide to Diagnosis and Management. Clinical Infectious Disease 2018;XX(XX):1-7.
2. Marra, AR, Diekema, DJ, Edmond MB; *Mycobacterium chimaera* Infections Associated With Contaminated Heater-Cooler Devices for Cardiac Surgery: Outbreak Management. Clinical Infectious Disease 2017;65(4):669-674.
3. Bell, M, Schwartz, S; Contaminated heater-cooler devices used during open-heart surgery. Prevention Strategist 2017;56-60.
4. CDC FAQs: https://www.cdc.gov/hai/outbreaks/heater-cooler.html#quest
5. CDC Toolkit: https://www.cdc.gov/hai/outbreaks/heater-cooler.html#hct