Nebraska Department of Health and Human Services

HEALTH ALERT NETWORK

Update

TO: Medical Directors, Infection Control Committee Chair, Chief of Cardiac Surgery, Infection Preventionists, and Public Health

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RE: Contamination of Open Heart Surgery Heater-Cooler Devices with *M. chimaera*

DATE: December 6, 2016

This notice is being addressed to all Nebraska hospitals performing cardiac surgery. FDA and the CDC have recently notified all hospitals of the potential for infection due to contamination of certain types of heater cooler devices with a non-tuberculous mycobacterial strain (*M. chimaera*), and cases that have occurred because of this contamination (https://www.cdc.gov/mmwr/volumes/65/wr/mm6540a6.htm?s_cid=mm6540a6_w).

To address this problem in Nebraska, we are asking you to assign a member of your staff to complete a survey being used by many state public health agencies regarding this outbreak. We have copied the lead infection preventionist and other related personnel at your institution who might be able to assist in completing the survey.

This survey is both to ascertain your response to date and to guide you through the latest advisories of the CDC, the FDA and our Healthcare Associated Infections (HAI) program here at Division of Public Health. Because this is a challenging and complicated situation, a collaborative approach might further our mutual interest in assuring patients that their safety and welfare is of paramount importance. We wish to offer any assistance we can in case-finding, developing patient notification letters or even completing the survey. In addition we have provided some more recent information from the CDC that you may find helpful.

Lastly, since all positive mycobacterial and nonmycobacterial lab results are reportable in Nebraska, we are accessing our reportable disease database to identify all cultures positive for M.chimaera or M. avium intracellulare. M. chimera is difficult to identify so it is often classified in the avium-intracellulare group. We are prepared to cross reference this database against a list of patients who underwent surgeries with the specified devices at your institution over the at-risk time periods. Please let us know if you wish us to do this for your facility.

The survey is accessible by using the following link: **https://www.surveymonkey.com/r/NTMinfections**

Please call us with questions, advice, or assistance.

From 10-16-2016

CDC Advises Hospitals to Alert Patients at Risk from Contaminated Heater-Cooler Devices Used during Cardiac Surgery

Recommendations

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
- These are useful forms to utilize in case findingd
  - 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
    - Latest recommendations from CDC/FDA lean heavily on alerting patients

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Frequently Asked Questions for Hospitals Notifying Patients of Risk from Contaminated Heater-Cooler Devices Used During Cardiac Surgery

Q. How far back in time should hospitals go to notify patients?
A. Hospitals should consider notifying patients **in writing** if they were exposed to the Stöckert 3T devices during open-chest cardiac surgery at their institution since **January 1, 2012**. Hospitals that did not use the Stöckert 3T device during this entire time period should adjust the patient notification timeframe accordingly.
Q. What is the rationale for active patient outreach? Why use this time frame?
A. Based on our current understanding, the majority of patients who become infected from exposure to these devices will develop symptoms within months of their exposure. Pursuing active patient outreach using a

longer time frame of approximately 4 years is expected to benefit most of the patients who have developed symptoms but have not yet been diagnosed. However, any patient who has had cardiac surgery with the Stöckert 3T device – including patients who had their surgery prior to 2012 – should be aware of this risk in the event that they develop concerning symptoms. Other forms of patient outreach (e.g., through advocacy channels or the media) will be helpful in this regard. Likewise, ongoing efforts to raise awareness among clinicians is expected to benefit all patients, regardless of when their exposure occurred.

Q. Our hospital acquired a Stöckert 3T device after September 2014. Should we still notify patients?

A. Patients who were exposed to Stöckert 3T devices manufactured after September 2014 should also be notified**.** While the risks associated with these newer devices may be lower, some have tested positive for *M. chimaera* (see FDA Safety Alert), possibly as a result of cross contamination from accessory devices.

Q. Our hospital conducted retrospective case-finding and we did not identify any probable cases – do we still need to send patient letters?

A. Yes, while case finding is important, negative results cannot be relied upon to determine an absence of risk.

Q. Our hospital conducted retrospective case-finding and we identified a probable case that had surgery before January 1, 2012. Do we need to extend the time period of our notification?

A. Decisions to extend notification farther back in time using individualized patient letters may best be considered on an institution-specific basis. The likelihood of identifying undetected infections diminishes with time. However, directly notifying individual patients who have been identified as having actually acquired an infection from a contaminated heater cooler device is advisable regardless of when the exposure occurred.

Q. Are only patients who have had prosthetic material implanted during their cardiac surgery at risk for *M. chimaera* infections? Should our hospital only notify patients who have had prosthetic material implanted?

A. Although there is some evidence that patients who have prosthetic material implanted during their open-chest cardiac procedure may be at higher risk of developing infection, heater-cooler device associated NTM infections have also occurred among patients who did not have placement of prosthetic material. Therefore, hospitals should not determine which patients to notify based on whether they have had the placement of prosthetic material during their procedures.

Q. In 2015, our hospital took measures to mitigate risk to patients by following updated manufacturer's recommendations for disinfection and cleaning and updated guidance from the FDA. Do we still need to notify patients?

A. Yes, hospitals should still notify patients. A possible exception pertains to hospitals that have taken additional steps (e.g., moved the Stöckert 3T device out of the operating room) to eliminate patient exposure to the exhaust from these devices. These hospitals may consider not notifying patients who had surgery after these interventions if they are confident that the risk was abated.

Q. The Stöckert 3T device(s) at our hospital tested negative for *M. chimaera*. Should we still notify patients?

A. Yes, hospitals should still notify patients. In general, methods for sampling and microbiological testing of heater-cooler devices for *M. chimaera* are neither reliable nor timely. Therefore, negative test results do not necessarily indicate that devices are not presently contaminated or that they have not been contaminated in the past.

Q. How do I diagnose a patient with *M. chimaera* infection? How do I treat a patient with an *M. chimaera* infection?

A. Initial experience from clinicians indicates that these infections can be challenging to diagnose and treat. CDC recommends that physicians consult with an infectious disease specialist for specific clinical concerns regarding these infections. CDC hosted a webinar on August 29th which included a presentation by clinical experts on the diagnosis and treatment of *M. chimaera* infections. The recorded webinar can be found here: https://www.youtube.com/watch?v=zPSLD3Um0sw