



STATE OF HAWAII
DEPARTMENT OF HEALTH
P. O. BOX 3378
HONOLULU, HI 96801-3378

In reply, please refer to:
File:

October 17, 2016

MEDICAL ADVISORY: POSSIBLE ASSOCIATION OF NON-TUBERCULOUS MYCOBACTERIA INFECTIONS WITH HEATER-COOLER DEVICE USED IN OPEN-CHEST CARDIAC SURGERY

Dear Healthcare Provider:

The Hawaii Department of Health (HDOH) has been advised regarding the potential for non-tuberculous mycobacteria (NTM) infections occurring in patients who have undergone open-chest surgery utilizing the Stöckert 3T Heater-Cooler System (3T) device. Although hospitals in Hawaii have, since 2015, either discontinued use of this device or implemented measures to prevent such infection, Hawaii clinicians are advised to monitor their patients for possible signs and symptoms of NTM infection, which may develop months to years after exposure.

Previously, the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) distributed notifications and guidance regarding heater-cooler devices,^{1,2,3} frequently used during cardiothoracic surgeries and occasionally in other procedures, and the possible risk of NTM infections. More recent data⁴ have demonstrated epidemiologic and laboratory linkage of the Stöckert 3T Heater-Cooler System (3T) device, in particular, to invasive *Mycobacterium chimaera* infections following cardiothoracic surgery. Contamination of these devices, which have been used in hospitals in Hawaii as well as on the mainland, is thought to have occurred in the manufacturing plant.

Although the risk of infection is likely low, especially as safeguards have been implemented by Hawaii hospitals, HDOH advises clinicians to be aware of the potential infection risk in their patients. *M. chimaera* is a ubiquitous, slow-growing NTM which lives in soil and water. Persons are not normally at risk for infection; however, exposure and possible infection likely occurs intraoperatively by aerosolization of contaminated water from the device reservoir through its exhaust vent to the patient's open surgical wound. The majority of patients have presented in the first several years after surgery, and manifestations have reportedly included surgical site infections, abscesses with bacteremia, and endocarditis.

Clinicians should suspect possible NTM infection in patients who have a history of open-chest (cardiac) surgery and present with signs of infection (fever, fatigue, night sweats, malaise, pain, inflammation or pus at the surgical site, weight loss, nausea, and vomiting), especially in the absence of other clear explicative etiology. Patients with implanted prosthetics may be at increased risk of infection. Clinicians suspecting invasive NTM infection in their patient should obtain cultures (blood or from wound, if applicable) for acid-fast bacilli (AFB) as part of the diagnostic workup, and infectious disease consultation should be considered. More information can be found at CDC's website:

¹ <https://www.cdc.gov/HAI/pdfs/outbreaks/CDC-Notice-Heater-Cooler-Units-final-clean.pdf>

² <https://www.cdc.gov/hai/pdfs/outbreaks/Guide-for-Case-Finding.pdf>

³ <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm466963.htm>

⁴ https://www.cdc.gov/mmwr/volumes/65/wr/mm6540a6.htm?s_cid=mm6540a6_w

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<https://www.cdc.gov/HAI/outbreaks/heater-cooler.html>.

Although isolated NTM infections are not a reportable condition in Hawaii, any suspected cases of NTM infection in the setting described above should be reported to HDOH by calling the disease reporting line at (808) 586-4586.

We appreciate your assistance in preventing infections among Hawaii's residents.

Sincerely,

A handwritten signature in blue ink, appearing to read "Sarah Y. Park".

Sarah Y. Park, MD, FAAP
State Epidemiologist
Hawaii Department of Health