

Friday, December 9, 2016

Dear Health Care Provider:

The Ministry of Health and Long-Term Care is informing health care providers of the emerging risk of infection by nontuberculous mycobacteria in patients exposed to a device called a heater-cooler unit during open chest cardiac surgeries that require extracorporeal circulatory systems.

Background

Heater-cooler units used during certain cardiothoracic surgeries that require extracorporeal circulatory systems have recently been linked to a rare bacterial infection caused by *Mycobacterium chimaera*, a slow-growing species of nontuberculous mycobacteria (NTM). These units include water tanks that provide temperature-controlled water to external heat exchangers or warming/cooling blankets through closed circuits. The physically separate water circuits are not intended to come in contact with the patient's blood circuits. However, recent studies have suggested that there is a potential for bacteria contaminated water in the unit to be aerosolized into the operating room environment and into the patient during open chest cardiac surgeries.

Investigation of cases of *M. chimaera* to date suggests that all, or almost all, cases have resulted from exposure to the heater-cooler unit produced by a single manufacturer—the Stöckert Heater-Cooler System 3T by LivaNova PLC (formerly Sorin)—and may have resulted from contamination during manufacturing. Patient cases have been reported from several European countries and from the United States. Although, to date, all or almost all *M. chimaera* infections associated with heater-cooler units used in cardiothoracic surgeries have been linked to one manufacturer, microbial contamination has been found in units of other manufacturers, and the potential for transmission related to other heater cooler units has not yet been ruled out.

Recently, [Health Canada](#) is investigating reports of possible *M. chimaera* infections in patients with a history of cardiothoracic surgery involving these units in Canada. Current, limited evidence suggests that the risk of acquiring infection is less than 1% at centres that have reported cases.

Clinical Manifestations

Most patients present with *M. chimaera* infection months to years after the index surgery, with the following symptoms:

- unexplained fever that persists or recurs over greater than three weeks
- night sweats
- muscle aches
- unexplained weight loss
- fatigue, and/or
- shortness of breath

Some patients are diagnosed with specific infections or conditions including (but not limited to):

- culture negative prosthetic valve endocarditis or prosthetic vascular graft infection
- para-valvular abscess
- pseudo and mycotic aneurysms
- osteoarthritis or spondylodiscitis
- sternotomy wound infection
- mediastinitis
- hepatitis
- bloodstream infection
- panuveitis, multifocal chorioiditis, chorioretinitis

Other embolic and immunologic manifestations (e.g., arthritis, osteomyelitis, bone marrow involvement with cytopenia, cerebral vasculitis, pneumonitis, myocarditis, granulomatous nephritis) have also been described. Splenomegaly is observed in approximately 80% of cases. Due to the presence of fever, multiorgan involvement, granuloma on biopsy and frequent negative routine cultures, several cases have been misdiagnosed and treated for sarcoidosis.

Recommended Actions

The Ministry of Health and Long-Term Care is recommending that all health care providers be made aware of the risk of *M.chimaera* infections in patients presenting with the above clinical manifestations after open heart surgery or implantation of cardiovascular devices.

Given the low risk of infection, asymptomatic patients do not require testing. For patients with a history of open heart surgery in the last five years with fever or other symptoms listed above, common infectious and non-infectious conditions should be ruled out first. However, in patients with prolonged symptoms, or where an alternative diagnosis cannot be made, testing for *M.chimaera* is appropriate. Additionally, it is prudent to test all patients with these clinical presentations where a diagnosis of sarcoidosis has been made.

When seeing patients with possible *M.chimaera* infection and a history of cardiothoracic surgery, health care providers should consider consulting with an infectious disease specialist. If an infection is suspected, it is important to obtain mycobacterial cultures from blood and any potentially infected tissues. Routine bacterial cultures will NOT detect *M.chimaera*. Please refer to Public Health Ontario Laboratory's [Labstrac](#) on *Mycobacterium chimaera* – Clinical Testing Guidelines for Symptomatic Persons with Potential Exposure to Contaminated Heater-Cooler Units During Open-Chest Heart Surgery for specimen and testing recommendations.

Additional Resources

For more information on *M. chimaera* infections associated with heater-cooler units, please refer to the following resources:

- 1) Government of Canada. [Heater-Cooler Devices–Risk of Nontuberculous Mycobacteria Infections](#).
- 2) Centers for Disease Control and Prevention (US). [Contaminated Heater-Cooler Devices](#).
- 3) Food and Drug Administration (US). [UPDATE: *Mycobacterium chimaera* Infections Associated with LivaNova PLC \(formerly Sorin Group Deutschland GmbH\) Stöckert 3T Heater-Cooler System: FDA Safety Communication](#).

Should you have any questions or concerns, you are welcome to contact the Hospitals Branch at HospitalsBranch@ontario.ca.

Sincerely,

Dr. Melanie Kohn
Director