

**Mycobacterium chimaera Infections Associated with Exposure to Sorin 3T Heater-Cooler Devices during Open Chest Cardiac Surgery**

**Guidance for Physicians and Local Public Health Officials**

**Clinical Evaluation**

Physicians should consider the possibility of *M. chimaera* infection when evaluating patients who had open chest surgery during the past four years, and consult an infectious disease specialist for assistance with diagnosis and management. Clinical manifestations of *M. chimaera* infection may be variable and nonspecific. The diagnostic evaluation is determined on a case-by-case basis. Specific stains (e.g., acid fast bacillus (AFB) staining) and cultures for mycobacteria on blood and/or other invasive sample(s) are necessary. Treatment of mycobacterial infections is complex and prolonged, and guided by results of drug susceptibility testing that is typically performed at a referral laboratory.

Presenting symptoms of infection with *M. chimaera* may include fever of undetermined origin, weight loss, night sweats, malaise, myalgia and joint pain. Clinical manifestations vary, and include:

- Localized infection, including but not limited to:
  - Prosthetic valve endocarditis
  - Prosthetic vascular graft infection
  - Sternotomy wound infection
  - Mediastinitis
  - Other deep organ space infection (e.g., empyema, pocket infection around a left ventricular assist device)
- Disseminated infection, resulting in:
  - Bacteremia
  - Embolic and immunologic manifestations (splenomegaly, bone marrow involvement with cytopenias, osteomyelitis, arthritis, chorioretinitis, cerebral vasculitis, hepatitis, nephritis)

**Laboratory Evaluation**

*M. chimaera* is part of the *M. avium* complex (MAC). Specialized testing, not typically available at clinical laboratories, is needed to specifically identify *M. chimaera* and perform drug susceptibility testing.

MAC isolates from patients suspected to have *M. chimaera* infection associated with exposure to a Sorin 3T heater-cooler unit should be submitted to the Mycobacteriology Laboratory at National Jewish Health for speciation and drug susceptibility testing. The mycobacteriology requisition form may be accessed at [https://www.nationaljewish.org/getattachment/professionals/clinical-services/diagnostics/adx/ordering-tests/requisitions/ADxForm\\_Mycobacteriology\\_Form-new.pdf.aspx](https://www.nationaljewish.org/getattachment/professionals/clinical-services/diagnostics/adx/ordering-tests/requisitions/ADxForm_Mycobacteriology_Form-new.pdf.aspx) Submitters should indicate in Special Instructions (8) that the patient isolate is associated with exposure to a Sorin 3T heater-cooler unit. Mycobacterial culturing of implicated heater-cooler unit(s) is not currently recommended.

**Public Health Notification**

Healthcare providers who suspect *M. chimaera* infection or identify MAC in a patient with history of open chest cardiac surgery must notify their local public health authority (by telephone) and CDPH at [HAIProgram@cdph.ca.gov](mailto:HAIProgram@cdph.ca.gov) or 510-412-6060. The CDPH HAI Program is available to provide guidance for ensuring implementation of current operating instructions for Sorin 3T heater-cooler units and assistance in developing epidemiology investigation plans.

### Summary of Published Cases

The CDPH HAI Program summarized the European cases published in the scientific and medical literature and U.S. cases presented to an FDA advisory panel in June 2016. Seventeen patients with *M. chimaera* infections linked to exposure with a heater-cooler device were identified in Switzerland, Germany, the Netherlands and the U.S. Median patient age was 62 years (range, 1-76), 16 (94%) were male, and 16 (94%) had a procedure that involved a prosthetic implant. Surgeries occurred from 2008-2014; 6 (35%) had surgery in 2012. Surgeries included aortic valve replacement (7), mitral valve reconstruction (3), aortic root and arch replacement (3), aortic dissection and graft (1), thoracic aneurysm repair (1), heart transplant (1), and coronary artery bypass graft (1). Among fifteen patients for whom microbiology results were described, *M. chimaera* was isolated from blood (8), cardiac tissue (7), bone marrow (3), bone (3), soft tissue (2), pacemaker pocket (1), liver (1), and urine (1). Some patients had cultures from multiple sites. Time to diagnosis ranged from 12-60 months after open chest surgery; median time to diagnosis was 36 months. The mortality rate was 35% (Achermann Y, J Clin Micro, 2013; Sax H, CID, 2015; Kohler P, Eur Heart J, 2015; Haller S, Euro Surveill, 2016; and Deikema D, FDA advisory committee meeting, June 3, 2016).

If you are interested in a document with more detailed case descriptions, including the publicly described U.S. cases, please contact the HAI Program at [HAIProgram@cdph.ca.gov](mailto:HAIProgram@cdph.ca.gov).