

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

Summary Brief

Invasive infections due to a specific type of slow-growing mycobacteria, *Mycobacterium chimaera*, have been identified in patients in Europe and the U.S. after open-chest surgery using a heater-cooler device, the Sorin Stockert 3T. In September, 2016, the CDPH HAI Program was informed by a local public health agency of a patient with *M. chimaera* infection who underwent cardiothoracic surgery using a Sorin 3T device in a California hospital in 2014.

M. chimaera is a slow growing nontuberculous mycobacterium (NTM) in the mycobacterium avium complex (MAC) group. Diagnosis requires specific stains and cultures, e.g., AFB, which are rarely ordered for working up invasive or post-operative infections. Specialized testing in a reference laboratory is needed to specifically identify *M. chimaera*.

Heater-cooler devices are used in operating rooms with cardiopulmonary bypass machines to control core body temperature during cardiac surgery. The devices have closed water systems that do not contact the patient. A contaminated device can aerosolize mycobacteria into the operating room.

Most of the *M. chimaera* infections have been diagnosed 2-4 years after surgery. Clinical manifestations include sternal wound infections, endocarditis, osteomyelitis, disseminated granulomatous disease, persistent bacteremia. Physicians should consider the possibility of *M. chimaera* infection when evaluating and treating patients who had open chest surgery in the past four years and consult an infectious disease specialist.

On June 1, 2016, FDA issued a safety alert indicating that Sorin 3T devices manufactured prior to September 2014 may have been contaminated with *M. chimaera* during the manufacturing process. Hospitals with a Sorin 3T heater-cooler device manufactured prior to September 2014 need to inform cardiothoracic surgeons that their patients may have been infected with *M. chimaera*, and determine a method for surveillance and follow-up of patients who may have been exposed.

On October 13, 2016, FDA updated the safety alert and recommended that hospitals with Sorin 3T devices manufactured prior to September 2014 strongly consider transitioning away from the use of these devices for open-chest cardiac surgery until the manufacturer has implemented strategies for these devices to mitigate the risks of patient infection. Use of these devices should be limited to emergent and/or life-threatening situations if no other heater cooler devices are available.

On October 13, CDC distributed a health alert advising hospitals to alert patients at risk from contaminated Sorin Stockert 3T heater cooler devices, and published a toolkit to provide sample letters for clinician and patient notification.

Healthcare providers who identify a mycobacterium or MAC infection in a patient who had open chest cardiac surgery need to report it as an occurrence of unusual disease to the local health authority and CDPH. Public health will provide instructions for testing at a reference laboratory.