



Please distribute to all physicians, dentists, oral & maxillofacial surgeons and/or podiatrists.

Date: November 25, 2016

To: AHS Medical Staff

From: Dr. Francois Belanger, VP, Quality & CMO & Dr. Mark Joffe, Senior Medical Director, Infection Prevention and Control (IPC)

Re: Potential *M. chimaera* exposure in cardiac surgery patients

Dear Colleagues:

You may be seeing reports related to *Mycobacterium chimaera* infections associated with certain types of heater cooler units used in cardiac surgeries. While rare, these infections have been associated with major patient morbidity and mortality. We will be notifying patients who have had cardiac surgery about this newly identified risk and you may start to receive questions from this patient population.

This issue is being reported globally. In the United States, the Federal Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) and in Canada, Health Canada are reporting a potential general risk due to aerosolization of this water-borne non-tuberculous mycobacterium (NTM), *M. chimaera*, from heater cooler units (HCUs) that are an essential component of open heart surgery. A specific risk of infection by *M. chimaera* through contaminated Sorin 3T HCUs manufactured before September 2014 has been identified.

Alberta Health Services (AHS) has used and continues to use the affected units, at the Foothills Medical Centre (Calgary) the Mazankowski Alberta Heart Institute and Stollery Children's Hospital (Edmonton).

On October 21, 2016, Health Canada reemphasized the importance of following the cleaning and disinfection procedures recommended by the manufacturer and has not recommended replacement of devices at this time. We are monitoring the situation closely and will follow Health Canada guidance related to the use of the affected heater cooler machines. AHS sites follow all manufacturers' instructions for use, maintenance and cleaning of the heater cooler units. We have implemented additional safety measures to further minimize risk to our patients at all sites that use these heater cooler units.

To date, there have been two documented cases of *M. chimaera* infection in Canada. None have been identified in Alberta. However, as other countries are reporting these infections, it remains a possibility in Alberta. Though we believe the risk to be extremely low (less than 1:1000), in keeping with our values, Alberta Health Services is proceeding with notification of potentially affected patients and parents/guardians of patients who have undergone cardiac surgery either in Edmonton after January 01, 2012 or in Calgary after January 01, 2013, by mail. Notifications will occur the week of November 28, 2016.

Clinicians, including cardiologists, pediatricians, general practitioners and others who take care of cardiac surgery patients before and after surgery, should be aware of the risk and consider NTM as a potential cause of unexplained illness and declining health following surgery. Patients having prosthetic valve replacements and/or aortic graft procedures are thought to be at the greatest risk of *M. chimaera* infection.

Patients may develop symptoms months or even years after surgery, at a time when patients and their physicians may not readily associate onset of symptoms with previous surgery.

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General symptoms of a NTM infection may include:

- fever
- unexplained, *persistent and profuse* night sweats
- unintentional weight loss
- muscle aches
- fatigue
- redness, heat or pus at the surgical incision site

There will likely be additional symptoms depending on which tissues are affected. Importantly, symptoms are likely to be persistent and progressive over several weeks.

M. chimaera is slow growing and causes indolent infections with onset 3 months to 5 years after surgery (most commonly 18-21 months) and may be very difficult to diagnose. Patients with NTM infections following cardiac surgery have presented with a variety of clinical manifestations, including endocarditis, surgical site infection, or abscess and bacteremia. Other clinical manifestations have included hepatitis, renal insufficiency, retinal seeding, splenomegaly, pancytopenia and osteomyelitis. It may present as a chronic inflammatory condition. Biopsy specimens demonstrate granulomas and patients have been misdiagnosed with Sarcoidosis.

M. chimaera is not spread person-to-person and there is no risk to family, friends or healthcare workers.

Clinicians and patients may not consider an NTM infection when symptoms present. Delayed diagnosis may make treating these infections even more challenging. While there is no screening test to identify individuals who may have been exposed to the bacteria at the time of surgery, those who develop infections can be diagnosed by submitting cultures for NTM to the laboratory. Where NTM infection is suspected, it is important to obtain specimens of blood, wounds, bone marrow and tissue (as appropriate) and specifically request cultures for NTM [acid fast bacilli (AFB)] utilizing a provincial lab requisition, as well as other relevant investigations. In Alberta, the Provincial Laboratory will report preliminary identification as *Mycobacterium avium* complex with definitive laboratory identification of *M. chimaera* to follow from the National Microbiology Laboratory in Winnipeg.

If you have concerns regarding a symptomatic patient, please call one of the numbers listed below for recommendations regarding diagnosis and management.

- **Stollery Children's Hospital** (pediatric patient referrals Edmonton): Phone: 780-407-3307
- **Mazankowski Alberta Heart Institute** (adult patient referrals Edmonton): Phone: 780-492-8193 or fax 780-492-8050.
- **Foothills Medical Centre** (adult referrals Calgary) Phone: 403-944-3616
- **Alberta Children's Hospital** (pediatric patient referrals Calgary) Phone: 403-955-7316

We are monitoring the situation closely and will continue to follow Health Canada guidance and direction related to the use of heater cooler units.

Sincerely,

Dr. Francois Belanger
Vice President, Quality & CMO

Dr. Mark Joffe
Senior Medical Director, IPC