



# *Mycobacterium chimaera* in heater cooler devices – information for clinicians

This information is intended to provide advice to general practitioners and specialists caring for patients who may have been exposed to the bacterium *Mycobacterium chimaera* while undergoing cardiac bypass surgery in the past five years.

## Background

*Mycobacterium chimaera*, one of the non-tuberculous mycobacteria (NTM), is a slow growing environmental organism. It is usually of low pathogenicity and is an occasional cause of pulmonary infection in immune-compromised patients.

Since being first reported in Switzerland in 2013,<sup>1</sup> there has been a number of *M. chimaera* infections (predominantly prosthetic valve endocarditis) reported from countries in Europe and the United States related to the use of heater-cooler devices (HCDs). These devices are used to regulate the temperature of the patient's blood during cardiopulmonary bypass surgery. The transmission route from the HCD to the patients appears to be linked to biofilm that develops inside the unit's water reservoir, allowing growth of environmental bacteria such as *M. chimaera*.<sup>2</sup> The microorganisms are subsequently aerosolised into the theatre environment by the unit's fan during use.<sup>3</sup>

Infections with *M. chimaera* have predominantly been associated with a particular model of HCD from one manufacturer (LivaNova, formerly called Sorin, Germany). This Sorin 3T HCD has been used at all hospitals in Western Australia (WA) that perform cardiac bypass surgery.

The Therapeutic Goods Administration (TGA) first issued a *Medical Devices Safety Update* in May 2016,<sup>4</sup> advising of the issue and listing recommended actions that hospitals should take. A further update was issued in October 2016 confirming one case of *M. chimaera* infection in a Queensland patient that was potentially linked to a contaminated unit.<sup>5</sup> As of 20 February 2017, two further cases have been identified in New South Wales. There have been no reports of any patients in WA developing *M.chimaera* infection from contaminated HCDs.

The Australian Commission for Safety and Quality in Health Care (ACSQHC) has issued national infection control advice on this issue.<sup>6</sup>

At a meeting of Chief Health Officers from around the country on 15 December 2016, it was agreed that all states and territories that have patients at risk would undertake a patient notification exercise to ensure a nationally-consistent approach to this issue.

## Risk assessment

Available information indicates that the infections are almost always associated with surgery involving the insertion of some form of prosthetic material e.g. heart valves or aortic grafts. Patients who have had coronary bypass grafting, transplantation, or other cardiac procedures without any prosthetic

implants appear to be at an extremely low risk of NTM infection from HCDs. The time to diagnosis can be up to 5 years following exposure to this organism, although the median time to symptoms in the identified cases from overseas is approximately 18 months.

Estimates of the absolute risk for an individual patient have varied widely, however, the overall risk is considered to be very low. Public Health England estimated the risk to be of approximately one case of *M. chimaera* infection for every 10,000 patients undergoing open heart surgery,<sup>7</sup> although a more recent Swiss study from a particular hospital network estimated the risk to be about 1 in 500 for patients with prosthetic implants.<sup>8</sup>

WA patients at potential risk of exposure include those who have had their cardiac surgery within the past five years at Fiona Stanley Hospital, Fremantle Hospital, Princess Margaret Hospital, Royal Perth Hospital, the Mount Hospital, and St John of God Subiaco Hospital. The HCDs used at Sir Charles Gairdner Hospital were purchased at an earlier date than other HCDs used in WA and have repeatedly tested negative for *M.chimaera* over many months.

## **Actions taken by the WA health system**

WA hospitals that perform cardiac bypass surgery have tested all HCDs to determine the presence of *M.chimaera*. Hospitals that identified contaminated HCDs have implemented risk mitigation strategies recommended by the TGA, the ACSQHC and the Centres for Disease Control and Prevention in the United States. All contaminated HCDs used in WA have either undergone extensive disinfection processes to remove the bacterium, or been replaced with new HCDs. Testing of the HCDs is ongoing at all hospitals and no further positive results have been reported.

## **Patient assessment**

### **Clinical Presentation**

Patients with *M.chimaera* infections following cardiac surgery have presented with a variety of clinical manifestations. Most have had prosthetic valve endocarditis, prosthetic vascular graft infection, surgical site infection, abscess or bacteraemia. Less common manifestations have included hepatitis, renal insufficiency, splenomegaly, pancytopenia, and osteomyelitis. Patients have also presented with granulomatous disease that imitates sarcoidosis.

Symptoms of *M. chimaera* infection are non-specific and may include any one or more of the following, occurring for a period of two weeks or more:

- unexplained fevers
- night sweats
- unexplained weight loss
- increasing shortness of breath
- joint or muscular pain
- nausea, vomiting or abdominal pains
- malaise (note: fevers or night sweats or weight loss should also be present with malaise)
- pain, redness, heat or pus around the surgical site.

### **Initial assessment**

Patients with a history of cardiac surgery who present with this symptom complex are more likely to have causes other than *M.chimaera* infection. Before referral and specialised testing for mycobacterial infection, these more common causes need to be considered. Conventional blood cultures should always be performed when patients present with the above symptom complex.

## Assessment for mycobacterial infection

Diagnosis of prosthetic valve endocarditis (PVE) or disseminated infection due to *M. chimaera* is based on:

- detailed patient history
- physical examination – for signs of valvular pathology, splenomegaly and retinal involvement
- routine blood tests: FBE, biochemistry, CRP (disseminated NTM infections should be considered in the symptomatic patient with unexplained anaemia, thrombocytopenia, pancytopenia or unexplained elevated liver function tests)
- imaging studies guided by signs and symptoms
- echocardiography including transoesophageal echocardiography
- biopsy of any tissues as may be implicated with a systemic infection (include request for mycobacterial culture).

It is strongly recommended that an infectious diseases physician or clinical microbiologist be consulted prior to requesting specialised tests for mycobacteria, especially as laboratory capacity to provide such testing is very limited. Such specialised testing includes blood culture for NTM (acid fast bacilli (AFB) blood culture) and bone marrow culture for NTM. When recommended, two MycoF lytic bottles should be collected on separate days.

HCD-associated infections have not included pulmonary infections, and sputum cultures for mycobacteria are not indicated (in the absence of other features of pulmonary disease).

### Investigation is not indicated for asymptomatic patients

Only patients who have signs and symptoms consistent with PVE or a disseminated infection should be investigated. There is no indication to investigate asymptomatic patients for possible systemic NTM infection, including the ordering of AFB cultures. There is no recommended screening laboratory test, culture or imaging modality for the asymptomatic patient.

## Management of patients with mycobacterial infection

Management of *M. chimaera* infections requires an interdisciplinary approach and is best managed and co-ordinated by an infectious diseases physician or clinical microbiologist experienced in the treatment of mycobacterial diseases.

Treatment for NTM infection requires prolonged combination antibiotic therapy based on susceptibility testing. Antibiotics used to treat common bacterial infections are usually not active against *M. chimaera*. The optimal duration of therapy is unknown, however, 12 months is commonly cited. Revision cardiac valve surgery in addition to antibiotic therapy may be required for cure in some cases.

There is no antimicrobial prophylaxis treatment for the potentially exposed patient. In this instance, antimicrobial prophylaxis could promote resistance if subclinical disease is already present.

### Notification of patients with *M. chimaera* infection

All patient cases of *M. chimaera* following cardiac surgery should be notified to the Director, Communicable Disease Control Directorate on (08) 9388 4801, Public Health Division, Department of Health Western Australia, and to the TGA.

## References

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