

September 2017

National *Mycobacterium chimaera* (cardiac surgery) case definitions

Infection of open-heart cardiac surgery patients with *Mycobacterium chimaera* associated with heater-cooler devices was first recognised in 2012 in Switzerland. Exposure of patients to these units in the operating theatre has led to infections that appear from three months up to five years after the surgery. Six cases of invasive *M. chimaera* infections after open-heart cardiac surgery have been reported in Australia.

The Australian Commission on Safety and Quality in Health Care has developed [National Infection Control Guidance](#) in relation to heater-cooler devices, and the TGA has provided alerts on this issue.

The Communicable Diseases Network Australia (CDNA), in consultation with representatives from the Australian Government's Public Health Laboratory Network and the Australian Society for Infectious Diseases, has developed a set of definitions to classify confirmed, probable and suspected cases of *M. chimaera* infections. These definitions were endorsed by the Australian Health Protection Principal Committee (AHPPC) of the Australian Health Ministers' Advisory Council (AHMAC) in August 2017.

Reporting

Confirmed, probable and **suspected** cases should be reported to the relevant state or territory health department (who will also advise on reporting to the Therapeutic Goods Administration).

Case definitions

All case categories require **a history of surgery requiring cardiopulmonary bypass in any facility in the five years prior to the onset of symptoms AND clinical evidence**, which is any one or more of the following:

- Prosthetic valve endocarditis
- Prosthetic vascular graft infection
- Sternal wound infection
- Mediastinitis
- Manifestations of disseminated infection including embolic and immunologic manifestations, such as splenomegaly, arthritis, osteomyelitis, bone marrow involvement with cytopenia, chorioretinitis, cerebral vasculitis, pneumonitis, hepatitis, nephritis, myocarditis, and/or sarcoidosis-like illness.

Confirmed case

A confirmed case also requires

- Laboratory-definitive evidence (A) **and** exposure-definitive evidence (D).

Probable case

A probable case also requires

- Laboratory-definitive evidence (A), **or**
- Laboratory-probable evidence (B) **and** exposure-definitive evidence (D).

Suspected case

A suspected case also requires

- Laboratory-probable evidence (B), **or**
- Laboratory-suggestive (C) evidence **and** exposure-definitive (D) evidence.

Case definition components [A to D]

A. Laboratory-definitive evidence

Mycobacterium chimaera detected by culture and confirmed by whole-genome sequence comparisons to match strains isolated from contaminated heater-cooler units, in an invasive sample (blood, tissue biopsy or implanted prosthetic material) or in pus from a deep wound sample.

B. Laboratory-probable evidence

M. chimaera detected by specific direct PCR or amplified DNA sequencing in an invasive sample (blood, tissue biopsy or implanted prosthetic material) or in pus from a deep wound sample,

OR

Histopathological detection of non-caseating granuloma and foamy/swollen macrophages with acid-fast bacilli in cardiac or vascular tissue in the proximity of the prosthetic material or in a specimen from the sternotomy wound

AND

Routine bacterial cultures negative, and negative/non-diagnostic serological tests for Q fever, bartonellosis and legionellosis.

C. Laboratory-suggestive evidence

Mycobacterium avium complex (MAC) detected by culture or direct PCR from an invasive sample (blood, tissue biopsy or implanted prosthetic material), or in pus from a deep wound sample, where further identification to species level is not feasible (e.g., retrospective identification of cases)

AND

Routine bacterial cultures negative and negative/non-diagnostic serological tests for Q fever, bartonellosis and legionellosis.

D. Exposure-definitive evidence

A history of surgery requiring cardiopulmonary bypass in a facility known to have used Stockert 3T heater-cooler devices manufactured prior to September 2014 (or any other heater-cooler device with a confirmed detection of *M. chimaera*) in the five years prior to the onset of symptoms of infection.

Decision matrix

In patients with a history of surgery requiring cardiopulmonary bypass in any facility in the five years prior to the onset of symptoms AND clinical evidence AND:

A+D	Confirmed case
A	Probable case
B+D	Probable case
B	Suspected case
C+D	Suspected case