



# Update: Mycobacterial infections associated with heater cooler units used in cardiac surgery

July 2017

## Background

There is a risk that heater cooler perfusion units (HCUs), predominantly used in cardiac bypass surgery, may be contaminated with *Mycobacterium chimaera*, and that exposure of patients to the aerosolised exhaust from these units in the operating theatre may lead to the development of a serious infection up to several years post-surgery. A small number of cases of serious *Mycobacterium chimaera* infections have been reported in the United States, the UK/Europe and Australia.

National guidance on this issue was published in September 2016 by the Australian Commission on Safety and Quality in Health Care, and most recently in June 2017 the Therapeutic Goods Administration (TGA) again revised its information and advice (see References). The TGA's safety investigation into heater cooler devices is ongoing and has been expanded to include devices used for extracorporeal membrane oxygenation (ECMO). However, while contamination has been detected in ECMO devices, there have been no infections linked to the use of ECMOs.

## What's happening in Victoria?

Recently in Victoria a patient who underwent cardiothoracic surgery in 2016 was diagnosed with a *Mycobacterium chimaera* infection. This is the first case report for Victoria. The patient responded well to treatment with antimicrobials and was discharged home.

Safer Care Victoria is continuing to seek specialist advice and liaise with national/international experts and organisations as required to minimise risk and maximise safety for cardiac bypass surgery patients.

## Testing

The Victorian public health laboratory, Microbiological Diagnostic Unit (MDU), developed and validated a test for *Mycobacterium chimaera* early in 2016. Testing HCU water samples from health services is continuing, with a specified three monthly testing schedule introduced in January 2017. Refer to the separate document *Health service testing of heater cooler units used in cardiac surgery*.

## Record keeping

Records are now to be kept for all heater cooler units if this is not already done. Details to be recorded should include:

- Heater cooler unit details including make, model, serial number, date of manufacture and date of commencement of use at health service
- Dates and sufficient detail of all maintenance and disinfection procedures
- All microbiological test results
- Patient medical records must include details of the individual heater cooler unit used in the procedure

Note that record keeping is the responsibility of the health service. While the department will also monitor and record microbiological test data from Victorian health service heater cooler units over the next 1-2 years, this does not take the place of health service records.

## Contingency planning

It is advised that health services develop a local contingency plan for the ongoing provision of cardiac surgery in the event of a positive test result for *Mycobacterium chimaera*. This may include sourcing a back-up or loan heater cooler unit and/or working with other health services. If you think the provision of cardiac surgery at your health service will be affected, please contact the department.

## Patient data review

Health services carried out an extensive patient data review if their HCU(s) tested positive for *Mycobacterium chimaera*. Using the Victorian Admitted Episodes Dataset, the department identified cardiac surgery patients who had procedures involving the use of an HCU over the last five years and who had been subsequently readmitted with clinical features possibly suggestive of *Mycobacterium chimaera* infection. Relevant patient data were then forwarded to health services for more detailed case file reviews.

Affected health services completed this review in late 2016, with no patient infections identified via this process.

It is anticipated that health services will continue to prospectively undertake detailed reviews of any cardiac surgery patients readmitted with a suspected infection until further notice.

## Patient communication and information

Information for patients was developed which describes the potential risk of infection, signs and symptoms to be aware of, what measures are being taken to protect patient safety and where to go for further information. This document is available from the department's *Better Health Channel* website at: <https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/infection-risk-cardiac-surgery-and-mycobacteria>.

Additionally, in February 2017, health services wrote to patients who had undergone cardiac surgeries most likely to be at risk of infection to inform them of the possible risk, signs and symptoms to look out for and where to go for further information.

## Summary of recommended actions for health services

### Testing of heater cooler units

1. Undertake three monthly testing of all heater cooler units in accordance with the Victorian testing schedule detailed in *Health service testing of heater cooler units used in cardiac surgery*.
2. Inform the department of all microbiological test results (whether positive or negative) from heater cooler units until further notice.
3. Ensure maintenance records and any microbiological sampling results are kept for all heater cooler units.
4. Report any confirmed *Mycobacterium chimaera* infections suspected to be associated with heater cooler unit use to the department, the TGA and to the manufacturer of the unit.

### Maintenance

5. Provide the department with the contact details of a designated person from your health service who has been allocated the responsibility of responding to this issue.
6. Advise the department of the brand, model, serial number and age of all heater cooler units in use at your health service, including new units as they are purchased/received.
7. Ensure that all heater cooler units in use at your health service are cleaned and disinfected strictly according to the manufacturer's instructions for use. Seek clarification from the manufacturer if the instructions are unclear.

### Patient care

8. Ensure the heater cooler unit is positioned as far away from the patient as possible in the operating theatre and ensure that the fan exhaust is directed away from the patient and is close to the suction exhaust outlet of the operating theatre. Seek assistance from the manufacturer if required in order to accomplish this safely and effectively.
9. Ensure patient records include a reference to the individual heater cooler unit used for their procedure to facilitate tracing if required.
10. Consider amending patient consent information to include the (low risk, <1%) possibility of developing serious infections postoperatively up to several years after cardiac surgery.
11. Consider the possibility of *Mycobacterium chimaera* infection for cardiac surgery patients presenting postoperatively with symptoms of unexplained infection; seek infectious diseases specialist advice to assist diagnosis and management.

### Contingency plans

12. Undertake local contingency planning for the ongoing provision of cardiac surgery in the event of a positive test result for *Mycobacterium chimaera*.

## Contacts

### Safer Care Victoria

Jonathan Prescott, Manager, Clinical Safety & Monitoring  
Ph: (03) 9096 7258, email: [jonathan.prescott@dhhs.vic.gov.au](mailto:jonathan.prescott@dhhs.vic.gov.au)

### Sampling and testing inquiries

Microbiological Diagnostic Unit Public Health Laboratory,  
University of Melbourne, Parkville VIC  
Ph: (03) 8344 5701

### Reporting of a suspected adverse event relating to a medical device

Therapeutic Goods Administration Medical Devices Branch  
Ph: 1800 809 361, email: [iris@tga.gov.au](mailto:iris@tga.gov.au)

## Further information and references

American Thoracic Society, 2007. An Official ATS/IDSA Statement: Diagnosis, Treatment, and Prevention of Nontuberculous Mycobacterial Diseases. Available at:  
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Kohler P, Kuster SP, Bloemberg G et al. Healthcare-associated prosthetic heart valve, aortic vascular graft, and disseminated *Mycobacterium chimaera* infections subsequent to open heart surgery. *European Heart Journal*, 2015: 36, 2745-2753.

Public Health England webpage, updated May 2017. Mycobacterial Infections Associated with Heater Cooler Units. Investigation updates, sampling protocol and guidance updates for health services available to download. <https://www.gov.uk/government/collections/mycobacterial-infections-associated-with-heater-cooler-units>

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Stewardson AJ, Stuart RL, Cheng AC, Johnson PD. *Mycobacterium chimaera* and cardiac surgery. *Medical Journal of Australia*, 2017: 206(3), 132-135.

Therapeutic Goods Administration, updated June 2017. Infections associated with heater cooler devices. <https://www.tga.gov.au/alert/infections-associated-heater-cooler-devices>

US Centers for Disease Control and Prevention information on contaminated heater cooler devices, including background information, health alert, question and answers, press release etc. Updated November 2016. <https://www.cdc.gov/HAI/outbreaks/heater-cooler.html>

US Food and Drug Administration safety communication, June 2016. Mycobacterium chimaera Infections Associated with Sorin Group Deutschland GmbH Stöckert 3T Heater-Cooler System: FDA safety communication. Available at: <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm504213.htm>

US Food and Drug Administration safety communication update, October 2016. Mycobacterium chimaera Infections Associated with LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stöckert 3T Heater-Cooler System: FDA safety communication. Available at: <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm520191.htm>

*Investigations are ongoing and this guidance may be revised. Updates will be available at:  
<https://www2.health.vic.gov.au/hospitals-and-health-services/quality-safety-service/infection-prevention/healthcare-associated-infection>*