Update: Mycobacterial infections associated with heater cooler units used in cardiac surgery
December 2016

Background

There is a risk that heater cooler perfusion units (HCUs) used in cardiac 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 one case in Australia (Qld).

National guidance on this issue was published in September 2016 by the Australian Commission on Safety and Quality in Health Care, and in October the Therapeutic Goods Administration (TGA) updated its information and advice (see References).

What’s happening in Victoria?

There have been no clinical cases of infection with Mycobacterium chimaera associated with HCUs reported in Victoria.

The Department of Health and Human Services (the department) is continuing to seek specialist advice and liaise with national/international experts and organisations as required to minimise risk and maximise safety for cardiac 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 testing schedule for four times a year to be introduced from January 2017. Refer to the separate document Health service testing of heater cooler units used in cardiac surgery.

Record keeping

Records must now be kept for all heater cooler units if this is not already done. Records must include as a minimum:

- 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.

Furthermore, the October 2016 update from the Therapeutic Goods Administration advises that health services consider transitioning away from reliance on and the use of Stöckert 3T Heater-Cooler System devices manufactured prior to September 2014 (regardless of contamination status) for open-chest surgery until the manufacturer has implemented strategies for these devices to mitigate the risks of patient infection. This advice is based on information from the United States Food and Drug Administration (FDA) investigation, which concluded that the contamination had occurred at the Sorin manufacturing facility in Germany up until September 2014, by which time the manufacturer had identified and taken steps to rectify this issue.

**Patient data review**

The department is coordinating an extensive patient data review in health services where HCUs have tested positive for *Mycobacterium chimaera*. Using the Victorian Admitted Episodes Dataset, the department has identified cardiac surgery patients who have had procedures involving the use of an HCU over the last five years and who have been subsequently readmitted with clinical features possibly suggestive of *Mycobacterium chimaera* infection. Relevant patient data have then been forwarded to health services for more detailed case file reviews. This process has been progressing effectively. Affected health services are at different stages of completing the review process, but no cases of *Mycobacterium chimaera* have yet been confirmed.

**Patient Information**

Information for patients has now been 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 will be circulated to all stakeholders and will be available from the department’s Better Health Channel website.
Summary of recommended actions for health services

Testing
1. Undertake three monthly testing of 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 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

Department of Health and Human Services
Jonathan Prescott, Manager, Safety Programs
Ph: (03) 9096 7258, email: 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

Investigations are ongoing and this guidance may be revised. Updates will be available at:
Further information and references


