

National Infection Control Guidance

Non-tuberculous *Mycobacterium* associated with heater-cooler devices

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Second release

Background

Australian health service organisations should be aware of the infection risks associated with devices that have built-in water reservoirs. A number of microorganisms are able to colonise these reservoirs. As a general principle, health service organisations should identify infection risks associated with these devices and respond with action to mitigate these risks.

This guidance document outlines key actions that Australian health service organisations should take in relation to heater-cooler devices (HCDs) used during cardiac surgery. There is a specific risk that these devices may be contaminated with *Mycobacterium chimaera* (*M. chimaera*), and that exposure of patients to the aerosolised exhaust from these devices may cause infection. *M. chimaera* infections may not be clinically apparent for several years after exposure.

While there have been reports of infections and deaths in the US and Europe,^{1,2} the risk of infection appears to be extremely low. At 30 January 2017, three patient cases have been identified in Australia. The international literature states that infections have been predominantly associated with cardiac surgery involving the insertion of prosthetic material such as valve replacement, or a prosthetic graft.³ Infection is believed to result from aerosolised transmission of *M. chimaera* from contaminated water inside HCDs, into the operating room environment and surgical field, and during an open-chest surgical procedure.

The Therapeutic Goods Administration (TGA) provided updated advice in an Alert dated 28 October 2016⁴. The TGA continues to investigate this matter. All HCDs found to be contaminated should be reported promptly to the TGA using the Users Medical Device Incident Report (<https://apps.tga.gov.au/prod/mdir/udir03.aspx>).

This guidance provides advice for Australian health service organisations on the infection prevention and control strategies to be employed to minimise the risk of infection associated with HCDs; it has drawn from the literature and from information developed by state and territory health authorities and the TGA. Health service organisations should use this guidance in conjunction with safety notices, alerts or other local advice provided by their state and territory health authorities and the National Health and Medical Research Council's *Australian Guidelines for the Prevention and Control of Infection in Health Care*.⁵

The Australian Commission on Safety and Quality in Health Care (the Commission) will update this guidance if further information becomes available.

Action for Health Service Organisations

Because of the importance of this matter, the Commission recommends that health service organisations consider the following actions:

1. Governance

- a) Designate a senior person within the local health service organisation to coordinate actions to identify relevant equipment, as well as testing, reporting and response strategies.
- b) Ensure that the results of confirmed *Mycobacterium chimaera* contamination are reported to the TGA, the manufacturer of the device, and the relevant state or territory government contact (see Section 7 for contact details).
- c) Establish policies and procedures to minimise exposure risk to patients and to enable service continuity; guidance in this regard is provided in Sections 2 to 6.
- d) Communicate the potential for risk and local response strategies to senior management and relevant clinicians. This may include the hospital executive and staff with responsibility for infection prevention and control, infectious diseases, cardiac surgery, perfusion, anaesthesia, clinical microbiology, and anatomical pathology.
- e) Ensure systems for maintaining records of HCD testing, maintenance and use (Section 3).

2. Testing for mycobacterial contamination

- a) Undertake microbiological baseline testing of all HCDs in service, as a matter of urgency, to determine the status of the device. Testing should be performed by a laboratory specified by the relevant state or territory government contact.
- b) Two tests need to be undertaken on HCD water samples:
 - i. Heterotrophic plate count which is a surrogate measure of cleanliness/overall water quality (results usually take three to five days).
 - ii. Mycobacteria cultures (results usually take six to nine weeks).
- c) Follow-up testing should be scheduled in accordance with the manufacturer's instructions. Where information from the manufacturer is not available and the initial sample from the HCD is negative, then follow-up testing should occur at least every three months. This testing cycle should be maintained until further information about this situation becomes available.
- d) Samples should be collected as directed by the laboratory. Generally, samples (100mL/sample) should be collected from all water reservoirs, including water tanks and overflow receptacles. For HCDs with two tanks, one sample should be collected from the patient circuit and another sample should be collected from the cardioplegia circuit.

The HCD should be connected and running for at least five minutes before water samples are collected. Sampling should take place immediately prior to the HCD undergoing its disinfection cycle.
- e) Sample labelling should include: date, hospital name, HCD serial number and other product identification details (e.g. asset number), sample site (i.e. which circuit), sampling time and details of a designated point of contact for results. If not processed immediately, samples should be stored between 2°C and 8°C and for no longer than 24 hours.
- f) Laboratory results should be returned to the designated senior person in the health service organisation for further action and reporting.
- g) Refer to the Australian Public Health Laboratory Network for additional guidance on testing for *Mycobacterium chimaera* associated with HCDs⁶.

3. Record keeping

Health service organisations should ensure that the following information is recorded:

- a) HCD details, including make, model, serial number, date of manufacture and date of commissioning.
- b) Details of routine HCD maintenance and disinfection procedures for each HCD.
- c) Bacterial surveillance details, including sampling dates, samples collected and test results.
- d) Patient details for each procedure in which a HCD has been used.
- e) Details of the specific HCD used should be documented in the patient's healthcare record.

4. Routine maintenance, cleaning and disinfection

- a) Ensure that maintenance, cleaning and disinfection of HCDs is performed according to the manufacturer's current instructions for use for that HCD model.
- b) Ensure that any external water overflow containers from the HCD are not placed in the path of HCD airflow (inflow or exhaust).
- c) Where possible, inspect the HCD for visible biofilm in tubing and other components. This includes hidden tubes such as overflow tubes. If biofilm is present, remove the HCD from service, test for contamination, clean and disinfect the HCD and notify the manufacturer. Consider appropriate action regarding use as indicated in Section 6.
- d) For HCDs that are in service and for which laboratory results are not yet available, undertake daily water change, where practical, until results are negative, in order to reduce the concentration of any contamination that may be present. This has been demonstrated to reduce the risk of microorganisms being aerosolised.⁷
- e) It is recommended that unfiltered tap water should not be used to rinse, fill, refill or top-up HCD water tanks as this may introduce contamination. Any water additives should be used only in accordance with the manufacturer's current instructions for use. Use only sterile water or tap water that has been passed through a filter of less than or equal to 0.22µm; similar processes should be considered when making ice for use in the HCD. De-ionised water and sterile water created through reverse osmosis are not recommended as these may cause corrosion.⁸ Filters should be replaced at least monthly or more frequently if recommended by the manufacturer.

5. Placement and positioning of HCDs

- a) For all HCDs, direct the vent exhaust away from the surgical field to mitigate the risk of aerosolising heater-cooler tank water into the sterile field.
- b) The optimal strategy is to ensure that the HCD directly exhausts outside the operating theatre. Review the feasibility of moving the HCD outside the operating theatre. Some centres overseas have also constructed enclosures for the HCDs which are independently exhausted.² It is advisable to contact the manufacturer or supplier of the HCD to discuss whether these actions will affect the functioning of the device.
- c) If the above option is not feasible then ensure that the HCD is positioned as far away as possible from the patient and surgical field in the operating theatre. Ensure that the fan exhaust is directed away from the patient and is close to the suction exhaust outlet of the operating theatre.

6. HCDs contaminated with *Mycobacterium chimaera*

- a) Ensure that positive test results indicating HCD contamination are reported to the manufacturer, the TGA and the relevant state or territory government contact (see Section 7).
- b) The TGA has recommended the following risk stratification approach⁴:
 - i. For Stöckert 3T HCDs that have been manufactured BEFORE September 2014, consider transitioning away from reliance on, and the use of, these devices

(regardless of contamination status) for open-chest cardiac surgery until the manufacturer has implemented strategies for these devices to mitigate the risk of patient infection. Use of these devices should be limited to emergent and/or life threatening situations if no other HCDs are available. Strict compliance with all other recommendations detailed in this document is essential if these devices remain in service.

- ii. For Stöckert 3T HCDs that have been manufactured AFTER September 2014 and all other HCDs, follow the recommendations detailed in Sections 1-5.
- c) The additional risk posed by this issue has been reported as between 1 in 100 and 1 in 1000 patients,⁹ with cases identified to date predominantly being associated with valve replacement or repair.¹⁰ The decision to use a contaminated device should be made in conjunction with clinicians undertaking the proposed surgical procedures and an infection control team.
- d) For all devices, ensure that the risk of infection is communicated to patients as part of the consent process.

7. State or territory government contacts

If you require further information or advice on issues related to HCDs please contact your state or territory government contact listed below.

State / Territory	State or Territory Contact
ACT	Peter Collignon, ACT Health ACT Pathology P: 02 6244 2891 E: Peter.Collignon@act.gov.au
NSW	Paul Curtis, Clinical Excellence Commission Clinical Governance P: 02 9269 5569 E: Paul.Curtis@health.nsw.gov.au
QLD	Kirstine Sketcher-Baker, Queensland Health Patient Safety Unit P: 07 3328 9424 E: Kirstine.Sketcher-Baker@health.gov.au
SA	Irene Wilkinson, SA Health Communicable Disease Control Branch P: 08 7425 7170 E: Irene.Wilkinson@sa.gov.au
TAS	Annie Wells, Department of Health and Human Services Public Health Services P: 03 6166 0605 E: tipcu@dhhs.tas.gov.au
VIC	Jonathan Prescott, Department of Health and Human Services Safety Programs P: 03 9096 7258 E: jonathan.prescott@dhhs.vic.gov.au
WA	Paul Armstrong, WA Health Department of Public Health, Communicable Disease Control Directorate P: 08 9388 4800 E: paul.armstrong@health.wa.gov.au

8. Other resources available

Therapeutics Goods Administration

Alert, dated 28 October 2016: <https://www.tga.gov.au/alert/infections-associated-heater-cooler-devices>

Alert, dated 2 August 2016: <https://www.tga.gov.au/alert/non-tuberculous-mycobacterium-infections-associated-heater-cooler-devices>

Medical Devices Safety Update, dated 2 May 2016: <https://www.tga.gov.au/publication-issue/medical-devices-safety-update-volume-4-number-3-may-2016>

Public Health Laboratory Network

<http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-phln-guidance-survey-mycobacterium-heater-cooler.htm>

References

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3. Haller S, Holler C, Jacobshagen A, et al. Contamination during production of heater-cooler units by *Mycobacterium Chimaera* potential cause for invasive cardiovascular infections: results of an outbreak investigation in Germany, April 2015 to February 2016. *Eurosurveillance*. 2016; 21: 1-6.
4. Therapeutic Goods Administration. Infections associated with heater-cooler devices. Alert - updated advice for health professionals and facilities. [Online] 2016 [cited 22 December, 2016]; Available from: <https://www.tga.gov.au/alert/infections-associated-heater-cooler-devices>.
5. National Health and Medical Research Council. Australian Guidelines for the Prevention and Control of Infection in Healthcare. [Online] 2010 [cited 2 September 2016]; Available from: <http://www.nhmrc.gov.au/guidelines/publications/cd33>.
6. Public Health Laboratory Network. PHLN Guidance and Survey regarding *Mycobacterium chimaera* & heater-cooler units. [Online] 2016 [cited 22 December, 2016]; Available from: <http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-phln-guidance-survey-mycobacterium-heater-cooler.htm>.
7. Sommerstein R, Ruegg C, Kohler P, Bloemberg G, Kuster SP and Sax H. Transmission of *Mycobacterium chimaera* from heater-cooler units during cardiac surgery despite an ultraclean air ventilation system. *22*. 2016; 6: 1008-13.
8. Food and Drug Administration. Information for health care providers. [Online] 2016 [cited 16 August 2016]; Available from: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/ucm492583.htm>.
9. Centers for Disease Control and Prevention. CDC Advises Hospital to Alert Patients at Risk from Contaminated Heater-Cooler Devices Used during Cardiac Surgery. [Online] 2016 [cited 22 December 2016]; Available from: <https://emergency.cdc.gov/han/han00397.asp>.
10. Public Health England. Infections associated with heater cooler units used in cardiopulmonary bypass and ECMO: information for healthcare providers in England. [Online] 2015 [cited 24 August 2016]; Available from: <https://www.gov.uk/government/publications/infections-associated-with-heater-cooler-units-used-in-cardiopulmonary-bypass-and-ecmo>.