Australian Commission on **Safety and Quality** in Health Care

National Infection Prevention and Control Guidance

Heater-cooler devices contaminated with non-tuberculous *Mycobacterium*

This guidance outlines infection prevention and control measures designed to minimise the risk of non-tuberculous Mycobacterium (NTM) infections associated with the use of heater-cooler devices (HCDs).

Key Points

HCDs are used to regulate the temperature of blood during cardiopulmonary bypass surgery and extracorporeal membrane oxygenation (ECMO). These devices may become contaminated with *Mycobacterium* species during manufacture, repair, shipping or use. Patients can be infected when bacteria in the device's water reservoir are aerosolised through the device's exhaust vent into the environment. Infection may not be clinically apparent for up to 12 years after exposure.

Health service organisations must have systems in place to identify and manage risks associated with heater-cooler devices.

Background

HCDs contain water reservoirs that provide temperature-controlled water to heat and cool blood during cardiopulmonary bypass surgery and ECMO. HCDs have the potential for water reservoirs to become contaminated with bacteria, particularly NTM.

NTM species reported in contaminated HCDs include *Mycobacterium chimaera* (*M. chimaera*) and *Mycobacterium gordonae* (*M. gordonae*), or less frequently, *M. abscessus, M. chelonae* complex or other water-borne non-*Mycobacterium* species.[1] In late 2025, the Commission received reports of an increasing prevalence of HCD contamination with M. gordonae and M. chimaera in Australia.[1]

Patients may be infected when bacteria from the device's water reservoir is aerosolised into the environment by the device's exhaust vent. There are more than 100 patients worldwide identified as having been infected with a species of NTM following cardiac surgery.[2]

The risk of *M. chimaera* infection in patients undergoing open-heart surgery is thought to be very low and has been estimated as 0.4–16 per 10,000 patient years.[1] Infections are predominantly associated with cardiac surgery involving the insertion of prosthetic material, such as valve replacement or grafts.[3–5]

For HCD product safety reviews, visit the Therapeutic Goods Administration (TGA) website for further information.

Contaminated HCDs in Australia

The TGA has reported NTM contamination of several different HCD devices. The TGA received reports of *M. chimaera* contamination in eleven Stöckert HCDs (3T) manufactured after September 2014. The investigation into these reports did not identify a root cause. However, it is possible that contamination occurred by[1]:

- cross contamination of devices in storage
- the use of hoses and connecters that were used on contaminated heater-cooler devices
- slow growth of biofilm.

HCDs and risk

HCDs and the risk of NTM contamination and transmission of infection can vary across device types due to their design. Devices with exhaust vents are at a higher risk of transmission compared to closed systems with no exhausts.[1,6-8] While water units within HCDs used for ECMO treatment have been found to have NTM species, aerosolisation into the clinical environment is considered unlikely, and no transmission events of NTM or outbreaks associated with ECMO devices have been identified.[1,7-8]

Table 1 Recommended controls based on device type and use

Device type and use	Transmission risk	Recommended controls
HCDs used in cardiopulmonary bypass surgery.	Transmission during cardiopulmonary bypass surgery is possible, however thought to be very low. Contaminated water may be aerosolised into the clinical environment.[1–5,10]	• Follow manufacturer's maintenance instructions • Direct the exhaust vent outside of the operating room where possible (see Section 5) • Undertake routine cleaning and disinfection; follow appropriate and safe storage • Implement water quality management program and take corrective actions where contamination or adverse test results are identified • Undertake baseline microbiological testing with regular surveillance program implemented • Investigate contamination events and replace devices if remediation fails • Perform servicing away from patient care areas where practicable • Use appropriate Personal Protective Equipment (PPE) during maintenance and sampling (see Sections 1–7 for more detail).[1,4,10–12]
HCDs used for ECMO.	Water circuits can become contaminated with NTM. Aerosolisation into the clinical environment is considered unlikely during normal operation. However, exposure may occur during servicing, decontamination, emptying of reservoirs or accidental circuit breaches.	• Follow manufacturer's maintenance instructions • Undertake routine cleaning and disinfection; follow appropriate and safe storage • Consider implementation of water quality management program and take corrective actions where contamination or adverse test results are identified • Undertake baseline microbiological testing with periodic surveillance based on risk assessment • Investigate contamination events and replace devices if remediation fails • Perform servicing away from patient care areas where practicable • Use appropriate PPE during maintenance and sampling (see Sections 1–7 for more detail).[1,4]

Action for health service organisations

1. Governance

Each health service organisation where HCDs are used should designate a senior member of staff to coordinate risk management strategies, such as:

- identifying and testing HCDs and attachments
- developing policies, procedures and protocols to minimise exposure risk to patients, and to enable service continuity (see Sections 2–6)
- auditing compliance with local policies, procedures and protocols to ensure usage, cleaning, storage, maintenance and testing occurs in accordance with manufacturer's instructions
- enabling systems for maintaining records of HCD testing, maintenance, and use. Ensure systems are in place for regular reporting of HCD surveillance results e.g. at the infection prevention and control committee (see Section 3)
- communicating the potential for risk and local response strategies to senior management, relevant clinicians, and primary health providers e.g. the hospital executive, infection prevention and control, infectious diseases, cardiac surgery, perfusion, anaesthesia, clinical microbiology and anatomical pathology services
- developing protocols for management of HCD-positive results, including criteria that are to be met for recommissioning machines
- reporting results of confirmed HCD contamination to the TGA, the manufacturer of the device, and the relevant state or territory government contact (see Sections 6 and 7)
- developing protocols for use of HCDs that have been sent overseas for repair
- reporting a case of NTM infection following cardiac surgery to the relevant state or territory government contact (see Section 7).

2. Testing for mycobacterial contamination

Microbiological baseline testing of all HCDs should be undertaken prior to being commissioned. Additional and routine microbiological testing is to be conducted while in service as per manufacturer's instructions. Where the manufacturer does not provide a routine testing schedule, services should undertake testing at least every three months following a negative baseline result, in line with TGA advice. Testing should be performed by a National Association for Testing Authorities (NATA) accredited laboratory and be consistent with the current Public Health Laboratory Network Guidelines.[9] There is growing evidence that detection of NTM-positive water samples in HCDs increases over time despite disinfection (see Section 6). This may be due to *Mycobacterium* biofilm formation within the device.[10,12] Recent studies have emphasised the need for design changes to increase the safety of devices and researching and developing new disinfection protocols.[10,12]

3. Record keeping

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

- HCD details, including make, model, serial number, date of manufacture and date of commissioning
- details of routine maintenance and disinfection procedures for each HCD
- bacterial surveillance details, including sampling dates, samples collected and test results
- patient details for each procedure in which a HCD has been used
- details of the specific HCD used should be documented in the patient's healthcare record
- evidence of compliance with documentation requirements e.g. audit data.

4. Routine maintenance, cleaning, and disinfection

Health service organisations should strictly adhere to all current maintenance, cleaning and disinfection instructions for HCD use and any additional guidance material provided by the manufacturer (e.g. medical device corrections, operating instructions).

The following actions should also be undertaken for all HCDs:

- follow a comprehensive quality control program for periodic maintenance, cleaning, and disinfection, including while a device is in long-term storage
- minimise the risk of aerosolisation by only filling and emptying water reservoirs outside any operating theatre or clinical space, and only emptying external circuits after the patient has left the operating theatre or clinical space[1]
- prior to use, inspect the HCD for a visible biofilm or contamination in tubing and other components, including hidden tubes such as overflow tubes. If water is cloudy or discoloured, or internal surfaces are discoloured, remove the HCD from service
- consult infection prevention and control/infectious diseases/biomedical engineering for guidance
- for HCDs that are in service and for which laboratory results are not yet available, change water daily where practical to reduce the concentration of any contamination that may be present, and to reduce the risk of microorganisms being aerosolised
- use only sterile water or tap water that has been passed through a filter of less than or equal to 0.22µm to rinse, fill, refill or top up HCD water tanks. Deionised water and sterile water created through reverse osmosis are not recommended as these may cause corrosion.[11] Water additives should be used only in accordance with the manufacturer's Instructions for Use. Similar processes should be considered when making ice for use in an HCD.
- change filters periodically in accordance with the manufacturer's instructions
- ensure each HCD has dedicated, clearly labelled hoses, accessories and connectors that are not shared between devices, and replace these components in accordance

with the manufacturer's instructions or if contamination, damage or deterioration is suspected

- consider appropriate action regarding use of contaminated HCDs (see Section 6), including storing contaminated devices away from non-contaminated devices, including hoses and connectors
- follow manufacturer’s instructions for storage of devices and accessories when not in use, including cleaning and disinfection, and remove all water from the device and tubing prior to storage.[1]

5. Placement and positioning of HCDs with exhaust vents

The optimal placement strategy is to directly exhaust the HCD outside the operating theatre by moving it into an adjacent dedicated utility room. Alternatively, consider construction of an enclosure with independent exhaust systems for use of HCDs.[3] It is advisable to contact the manufacturer or supplier of the HCD to discuss how placement and positioning will affect the functioning of the device.

If the above options are not feasible, the following are recommended:

- position the HCD as far away as possible from the patient and surgical field
- direct the exhaust vent away from the patient and surgical field, and as close as possible to the suction exhaust outlet of the operating theatre to mitigate the risk of aerosolising heater-cooler tank water into the sterile field
- do not place external water overflow containers from the HCD in the path of HCD airflow (inflow or exhaust)
- Only use 3T machines if the aerosol collection set is in place and is functioning correctly. The 3T Aerosol Collection Set collects aerosols created by the heater-cooler 3T water tanks during use.

6. Contaminated HCDs

All positive NTM test results from an HCD machine constitute a contamination event and should trigger activation of local contamination management policies and procedures. Management of a positive result should include (but is not limited to):

- removal of the affected HCD from routine clinical use
- immediate notification to infection prevention and control/infectious diseases, relevant clinical stakeholders and biomedical engineering staff
- review of maintenance, cleaning, disinfection, water management and microbiological surveillance records
- cleaning, disinfection and decontamination procedures in accordance with manufacturer’s recommendations
- repeat microbiological sampling following decontamination to assess the effectiveness of remediation

- documentation of the contamination event and reporting through relevant local incident management systems, state or territory government contact (see Section 7) and the TGA via the Medical Device Incident Reporting system
- a risk assessment to determine whether patient exposure may have occurred and whether additional investigation, including patient follow-up or look-back activities, is required, including communication and notification to patients
- return to clinical service only after completion of remediation activities, negative microbiological testing and assessment that residual risk is acceptable in accordance with manufacturer instructions and local policy.

Emergency use of a contaminated device (e.g. replacement device cannot be sourced immediately) should only occur after careful consideration by relevant stakeholders (e.g. clinicians undertaking the proposed surgical procedure, infection prevention and control teams, state or territory government contact [See Section 7]) in line with local policies.

The risk of infection associated with HCDs must be discussed with the patient by the relevant clinician during the consent process.

7. State and territory contacts

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

Table 2 State and territory government contacts for further information or advice related to HCDs

State or Territory	Contact
Australian Capital Territory	**Office of the Chief Health Officer** T: 02 5124 9442 E: HCSDOCHO@act.gov.au
New South Wales	**Kathy Dempsey** NSW Chief Infection Control Practitioner/Healthcare-associated Infections Advisor, Clinical Excellence Commission T: 02 9269 5614 E: Kathy.Dempsey@health.nsw.gov.au
Northern Territory	**Senior Nursing Advisor, Infection Prevention and Management** T: 08 8944 8013
Queensland	**Queensland Infection Prevention and Control Unit (QIPCU)** T: 07 3328 9717 E: QIPCU@health.qld.gov.au CC: BelindaC.Henderson@health.qld.gov.au
South Australia	**Communicable Disease Control Branch, Infection Control Service** T: 08 742 57161 E: HealthICS@sa.gov.au
Tasmania	**Anne Wells** Nursing Director, Communicable Diseases Prevention Unit E: Anne.Wells@health.tas.gov.au
Victoria	**Amy Shields** Medical Device Recall Coordinator E: SafetyReviews@safercare.vic.gov.au
Western Australia	**Communicable Disease Control Directorate** Department of Health, Western Australia E: CDCD@health.wa.gov.au

8. Other resources

Therapeutic Goods Administration:

Infections associated with heater-cooler devices

Obligations to report an adverse event for medical devices

Australian Centre for Disease Control:

Public Health Laboratory Network (PHLN) guidance regarding *Mycobacterium chimaera* and heater–cooler units

Disclaimer

The content of this document is published in good faith by the Commission for information purposes. The document is not intended to provide clinicians or patients with guidance on particular healthcare choices. You should contact your healthcare provider for information or advice on particular healthcare choices.

This Guidance supersedes the Commission's 2022 *National Infection Control Guidance: Non-tuberculous Mycobacterium infections associated with heater-cooler devices*. The Guidance was updated in 2026 to:

- expand the scope to include the use of HCDs in ECMO
- expand on the actions to be taken when contamination is identified
- introduce a table outlining recommended control measures for different device types and uses
- incorporate *Mycobacterium chimaera* as a reportable species, following advice from the TGA
- strengthen governance and oversight measures related to the management and use of HCDs.

The Commission does not accept any legal liability for any injury, loss or damage incurred by the use of, or reliance on, this document.

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For more information

Please visit: https://www.safetyandquality.gov.au/our-work/infection-prevention-and-control

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