Memo

CLINICAL EXCELLENCE COMMISSION

CEC TRIM Ref: D16/18450

TO:	Chief Executives of Hunter New England LHD; Illawarra Shoalhaven LHD; Northern Sydney LHD; South Eastern Sydney LHD; South Western Sydney LHD; Sydney LHD; and Sydney Children's Hospitals Network		
CC	Directors of Clinical Governance of HNELHD; ISLHD; NSLHD; SESLHD; SWSLHD; SLHD; and SCHN Dr Kerry Chant, Chief Health Officer and Deputy Secretary, Population and Public Health Kathy Meleady, Director Commonwealth Programs, Australian Commission on Safety and Quality in Health Care		
FROM:	Carrie Marr, Chief Executive		
TEL:	02 9269-5500	**DATE:**	6 December 2016
SUBJECT:	**Water testing of heater-cooler devices used during cardiac bypass surgery**		

To date, one patient in Australia and more than 50 patients worldwide have been identified with *Mycobacterium chimaera* infections associated with heater-cooler devices (HCDs) used during cardiac surgery.

There is evidence to suggest that patients are infected when bacteria in the device's built-in water reservoirs becomes airborne. The risk for mycobacterial infection from contaminated aerosols from HCDs is considered to be very low compared with the overall risk of surgical and valve infection.

In September, the Australian Commission on Safety and Quality in Health Care (ACSQHC) issued attached National Infection Control Guidance relating to HCDs, which include recommendations for microbiological baseline testing of all HCDs in service.

Consistent with the guidance issued by the ACSQHC, the TGA recommends baseline testing, then follow-up testing in accordance with the manufacturer's instructions.

The Clinical Excellence Commission recently convened an expert working group to develop attached recommendations for undertaking water testing of HCDs. The working group recommends that:

- Heterotrophic plate testing (HPC) should be performed
- Water sources to test include tap water after it is filtered; the circuits for both heating and cooling; and, if used, the cardioplegia circuit
- Initially, water be tested monthly for three months; then three monthly if colony forming units (cfu) counts are consistently below an agreed minimum
- While there are currently no available international or Australian standards for water quality in HCDs, an initial cut-off of 200 cfu/ml with a review after 6 months testing would be appropriate.

The CEC strongly recommends that NSW public health facilities using HCDs during cardiac bypass surgery implement the expert working group's recommendations.

The CEC will review the results of HPC testing after six months.

Should you or your staff have any enquiries, please contact Dr Paul Curtis, Director Governance and Assurance, by phone on 9269 5569 or by email at paul.curtis@health.nsw.gov.au.

Yours sincerely

Carrie Marr
CHIEF EXECUTIVE

Locked Bag 8 HAYMARKET NSW 1240
t +61 2 9269 5500 f +61 2 9269 5599
cec-info@health.nsw.gov.au | www.cec.health.nsw.gov.au

National Infection Control Guidance

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

Date of notice: 2 September 2016

First 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 minimise the effect of 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*, 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 31 August 2016, one patient case had 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 advice in a Medical Devices Safety Update dated 2 May 2016[4] and in a Safety Alert dated 2 August 2016.[5] 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 *Australian Guidelines for the Prevention and Control of Infection in Health Care*.[6]

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 the health service organisation 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. Refer to Public Health England for further advice on sampling and testing.[7]
f) Laboratory results should be returned to the designated senior person in the health service organisation for further action and reporting.

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) 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.[8]
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.[9] Filters should be replaced at least monthly or more frequently if recommended by the manufacturer.

5. Placement and positioning of HCDs

a) 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.
b) If the above options are 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 health service organisation should consider an appropriate risk minimisation approach to the use of contaminated HCDs. Optimally, the contaminated HCD should

be removed from service and arrangements should be made for decontamination or replacement. The health service organisation should concurrently assess the risk of removing a contaminated HCD from service to determine whether disruption to non-elective cardiac surgery could lead to patient harm.

c) The additional risk posed by this issue has been reported as very low in the UK, with cases identified to date predominantly being associated with valve replacement or repair.[10] However, the actual risk of infection when a contaminated HCD is used is not clear. 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) The following actions should be considered for HCDs remaining in service, where known to be contaminated, or where the laboratory results are not yet available:
   i. Consider prioritising the use of HCD for non-elective procedures and for procedures where implantation of prosthetic material is unlikely.
   ii. Ensure that the HCD exhausts directly to the outside of the operating theatre and, where practical, undertake daily water changes to reduce microorganism concentration.
   iii. As part of the consent process, ensure that the risk of infection is communicated to patients.

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

State / Territory	State or Territory Contact
WA	**Paul Armstrong, WA Health** Department of Public Health Communicable Disease Control Directorate P: 08 9388 4800 E: paul.armstrong@health.wa.gov.au

References

1. Food and Drug Administration. FDA Executive Summary. Nontuberculous Mycobacterium (NTM) Infections Associated with Heater-Cooler Devices (HCD) during Cardiothoracic Surgery. [Online] 2016 [cited 15 August 2016]; Available from: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM503716.pdf.
2. Sax H, Bloemberg G, Hasse B, et al. Prolonged outbreak of *Mycobacterium chimaera* infection after open-chest heart surgery. *Clin Infect Dis*. 2015; 61: 67-75.
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6. National Health and Medical Research Council. Australian Guidelines for the Prevention and Control of Infection in Healthcare. 2010 [cited Available from: http://www.nhmrc.gov.au/guidelines/publications/cd33.
7. Public Health England. Protocol for environmental sampling, processing and culturing of water and air samples for the isolation of slow-growing mycobacteria: standard operating procedures. [Online] 2016 [cited 16 August 2016]; Available from: https://www.gov.uk/government/publications/isolation-of-slow-growing-mycobacteria-environmental-and-air-sampling.
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9. 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.
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.

Water testing of Heater Cooler Devices

Expert working group

Dr Kate Clezy, Clinical Advisor HAI Program, Clinical Excellence Commission

Professor Richard Morris, Director of Perfusion, Director of Anaesthetics, St George Hospital

A/Professor Vitali Sinchenko, Director of Microbiology, ICPMR

Marcus Bayly, Acting Perfusion Director, John Hunter Hospital

Jimmy Ng, Laboratory Scientist, ICPMR

Background

The recent association of infection with non-tuberculous mycobacteria (NTM) with contaminated heater cooler devices used in cardiac bypass surgery has raised the issue of water quality and testing of these devices. The Australian Commission in Safety and Quality in Health Care has released advice reducing risk to patients and this includes advice on testing every three months for *Mycobacteria (including M chimaera)* and recommends heterotrophic plate testing (HPC) but without sufficient detail for facilities to manage testing[1].

Currently water used in dialysis is subject to HPC on a monthly basis with UK and US guidelines agreeing to a cut-off of between 100 and 200 cfu/ml[2,3]. There is published data that provides some evidence for this cut-off figure[4].

Although the pathogenesis of infection is different between heater cooler devices and dialysis machines, it is reasonable to use existing testing protocols and cut-offs to inform decisions about testing of water within heater cooler devices used in cardiac bypass surgery.

As the testing around NTM appears clear and agreed, this was not discussed further. The questions the working group considered were as follows

1) Should HPC testing be done?
2) Which water to test?
3) How often should water be tested?
4) What is a reasonable cut-off in cfu that would reflect adequate cleaning and disinfection?
5) When should results of water testing be reviewed?
6) Should air-sampling be performed?

Should HPC testing be performed?

The group agreed HPC testing should be performed given the risk of water contamination due to inherent design issues of these machines. Water is stored in tanks which are kept at a variety of temperatures, some of which will allow bacterial growth; filtered tap water is used to fill the water tanks; biofilms can form in either the tanks or tubing and water is aerosolised when the machine is in operation. Decontamination is a multistep process which also contributes to the potential for

[1] http://www.safetyandquality.gov.au/wp-content/uploads/2016/09/National-Infection-Control-Guidance-for-Non-tuberculous-Mycobacterium-Heater-Cooler-Devices-PDF.pdf
[2] http://www.bcrenalagency.ca/resource-gallery/Documents/1a-Microbial-Testing-of-Dialysate-Final_2013.pdf
[3] http://www.renal.org/docs/default-source/default-document-library/raandartguidelineversion-12647da131181561659443ff000014d4d8.pdf?sfvrsn=0
[4] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4596525/pdf/nihms-726710.pdf

contamination. It is likely that because of these factors, HPC testing is being recommended in other jurisdictions and internationally.

Which water to test?

The possible water sources to test include the following

- Tap water after it is filtered. The reason for testing this is to ensure the integrity of the 0.2um filter. These filters are designed to be changed once a month and it would be appropriate to test water at or about the time the filter is due to be changed.
- Both patient circuits: the circuits for both heating and cooling are tested separately
- Cardioplegia circuit (if used)

How often should water be tested?

As water has not been routinely tested in this environment, initially there is a recommendation that water be tested monthly for three months; then three monthly if cfu counts are consistently below an agreed minimum. Whether testing should fall to lesser frequency would be reviewed after 6 months along with a review of National and/or International recommendations.

What is a reasonable cut-off in cfu that would reflect adequate cleaning and disinfection?

There are currently no available international or Australian standards for water quality in HCDs. The manufacturer's instructions for the Sorin machine state < 500 cfu/ml, which is the standard for safe drinking water. The closest device related information is with respect to dialysis water. The Food and Drug Administration recognized standard, ANSI/AAMI 13959:2014[5]. Water for haemodialysis and related therapies, sets limits for microbial counts in water used for haemodialysis. The standard indicates that total viable microbial counts in dialysis water shall be less than 100 cfu/ml or lower if required by national legislation or regulations. This is also the cut-off set in the UK[6] and in NSW by the Acute Care Institute, NSW Health[7]. The limit is based on rates of pyrogenic reactions related directly to the number of bacteria in dialysis fluid.

All of these documents include an action level set based on knowledge of the microbial dynamics of the system. Typically, the action level will be 50 % of the maximum allowable level or 50 cfu/ml. The action level was established to allow the user to initiate corrective action before levels exceed the maximum levels established by the standard.

The FDA provided a report from a Panel Meeting on June 2-3, 2016 and their summary of this issue was *"When asked what water standard should be utilized for HCDs, the informal vote was split between 100 cfu/ml and 500 cfu/ml."*

It is therefore difficult to provide a cut-off that will be clinically relevant, however an initial cut-off of 200 cfu/ml with a review after 6 months testing is available, would be an appropriate place to start. The action level would therefore be set at 100cfu/ml.

If a HCD had a HPC result of > 100cfu/ml then the cleaning of the HCD would be reviewed, the machine recleaned and samples re-sent for testing. A sample procedure is attached.

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[5] https://dialysiswatersolution.com/regulations-and-guidelines/ansiaami/ansiaami-13959-water-for-hemodialysis-and-related-therapies/

[6] http://www.renal.org/docs/default-source/guidelines-resources/RA_and_ART_Guideline_on_Water_Treatment_Facilities_and_Water_Quality_for_Haemodialysis_26_06_11.pdf?sfvrsn=0

[7] http://www.aci.health.nsw.gov.au/__data/assets/pdf_file/0007/306088/water-for-dialysis-2016.pdf

When should results of water testing be reviewed?

The Clinical Excellence Commission would be reviewing the results of HPC testing after 6 months. The purpose of this review would be to see what the usual cfu counts were and whether testing could be conducted less frequently.

Should air-sampling be performed?

This was discussed and because of the variability in testing and difficulty interpreting results this would not be currently recommended but an ongoing review of international recommendations would occur and would continue to inform this decision.

Summary

This expert group recommended HPC testing on HCDs but with a review process after 6 months of testing to ensure this recommendation was appropriate.

Action plan chart for bacterial contamination (CFU) of Heater Cooler Devices

Review of culture results

- **Levels < 100cfu/ml:**
    - no further action required, sample as usual

- **Levels > 100cfu/ml:**
    - Notify relevant medical staff, perfusionist and others as required
    - Review sampling, cultures and disinfection log
    - Usual disinfection process repeated

- **Redraw sample**
    - Levels < 100 cfu/ml, sample as usual
    - Levels > 100 cfu/ml
        - Notify relevant staff; notify medical director
        - Determine whether to remove equipment from patient use
        - Evaluate cleaning and disinfection; sampling and equipment
        - Consider enhanced cleaning and disinfection (more frequent)