

Policy Applies to:

Credentialed specialists, and staff who provide or support cardiac surgery.

Related Standards:

- New Zealand Infection Control Standard NZS 8143.3:2008
- EQuIP criterion 1. 5. 2

Rationale:

Heater cooler units have been associated with both water contamination and patient infections with *Mycobacterium chimaera* (*M. chimaera*). *M. chimaera* infections may not be clinically apparent for several years after exposure.

Objective:

To minimise the risk of infection from water contamination associated with Cardiac Heater Cooler Units (HCU's).

To ensure correct water safety management of the water contained within the tanks and hosing of the heater cooler machine, best practice cleaning and disinfection and monitoring requirements will be followed.

Implementation:

Record keeping

Equipment

- The HCU details, including make, model, serial number, date of manufacture and date of commissioning will be included on the organisational asset register
- HCU instructions for use manual will be located where the unit is stored and an electronic copy stored with the maintenance equipment records
- The HCU will have a current Warrant of Fitness and details of routine maintenance and/ or repairs will be documented and held by Biomedical Services.

Patient Records

- Patients will be informed by their specialist of the risk of infection, including *M. chimaera*, associated with cardiac surgery as part of their pre-admission information and the risk management strategies in place
- Details of the specific HCU used will be documented on the patient's clinical perfusion record by the perfusionist.

Routine maintenance, cleaning and disinfection

- Cleaning and disinfection of HCU's will be performed according to the 'manufacturer's instructions for use' for the HCU model
- Cleaning and disinfection will be tasked to a designated health care professional, (the cardiac perfusionist) who has completed competency training

- A documented log sheet (Appendix Two) will be used to record the HCU water changes, the cleaning and disinfection and will be signed by the healthcare professional undertaking the cleaning. The log sheet will be available at the point of use and electronic copies archived with the HCU audits
- A bacterial water filter (0.2µm) will be used, on the fit for purpose water tap, when obtaining the water for filling the tanks. Filters will be replaced at least monthly and recorded in the log
- Permanent tubing inspected for integrity as part of scheduled cleaning and will be replaced as required or annually
- Disposable tubing is changed after every patient.

Bacterial surveillance

A documented water sampling schedule for *Mycobacterium chimaera* will be undertaken quarterly by the perfusionist with laboratory results logged and reviewed by the Theatre Manager and Infection Prevention Nurse.

Microbiological Testing

Laboratory cultured water samples will be taken on the HCU to test for the presence of *Mycobacterium chimaera* and other non-tuberculous mycobacteria and test water quality as per testing cycle criteria utilising recommended testing procedures. (Appendix One)

Laboratory test dates and results will be recorded on the cleaning and disinfection log sheet.

Positive microbiological results

In the event that microbiological testing reveals contamination, either by heterotrophic plate count (HPC) >200cfu and/or positive culture for, *Mycobacterium chimaera*, procedures for response action and reporting must be followed (Appendix One).

Evaluation

- An annual audit will be completed by the Infection Prevention Nurse to report on compliance and reported to the Infection Prevention and Control Committee this will include the;
 - Cardiac Heater Cooler Cleaning and Disinfection audit report
 - HCU maintenance, cleaning and disinfection log records
 - Mycobacteria culture and heterotrophic plate laboratory results
 - Infection Prevention and Control Committee bi-monthly reports - Theatre and Infection Prevention
 - Patient clinical records – consent and record of HCU serial number
 - Biomedical Service HCU maintenance test reports.

Associated Documents

External

- National Infection Control Guidance Non-tuberculous Mycobacterium associated with heater-cooler devices, 3 February 2017, (Australian Commission on Quality and Safety in HealthCare D16-45631)
- Medsafe: <http://www.medsafe.govt.nz/safety/EWS/2016/H&C.asp>
- TGA (Therapeutic Goods Administration, Australia): <https://www.tga.gov.au/alert/infections-associated-heater-cooler-devices> (update 18 August 2017)
- USFDA: <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/default.htm>
- PHE (Public Health England): https://www.gov.uk/search?q=heater+cooler&show_organisations_filter=true&filter_organisations%5B%5D=public-health-england
- Public Health Laboratory Network. PHLN guidance regarding Mycobacterium chimaera & heater-cooler units: <http://www.health.gov.au/phln>
- Public Health Laboratory Network. PHLN survey regarding Mycobacterium chimaera & heater-cooler units. <http://www.health.gov.au/phln>

Appendix One:

HCU Microbiological testing procedures and response to positive results

Two water sample tests must be undertaken on HCU:

1. Mycobacteria cultures (results available in approximately 8-9 weeks) to test for the presence of *Mycobacterium chimaera* and other non-tuberculous mycobacteria
2. A heterotrophic plate count (results available in 3-5 days) as a surrogate measure of cleanliness/overall water quality.

Frequency of testing

Three monthly testing will be carried out for Mycobacteria cultures and water quality and test dates will be recorded on the HCU Cleaning, Disinfection Log sheet.

- Samples for mycobacterial culture should be collected in the morning of a Monday-Thursday, to enable transport to Wellington SCL for processing
- Samples for heterotrophic plate counts should be collected in the morning, Monday to Friday.

Specimen collection

- a) The HCU must be connected and running for at least five minutes before water samples are collected
- b) Sampling must occur before the HCU's disinfection cycle
- c) In HCUs with two tanks, two samples must be collected from each tank (i.e. from the patient 'arm' and the cardioplegia 'arm' of the circuit)
- d) Each sample must be of at least 100 ml (i.e. 200ml from each tank) and must be collected into a sterile container supplied by the laboratory
- e) Sample labelling & the specimen request form must include: date of collection, HCU serial number, sample site (which arm/circuit) and details of a designated point of contact for results
- f) Immediately send samples to the laboratory.

Laboratory processing

- a) Samples must be stored at 2-8°C and for no longer than 24 hours before processing
- b) Heterotrophic plate counts will be performed in Dunedin as per the usual protocol
- c) Samples for mycobacterial culture will be sent on the same day to Wellington SCL for processing. Chiller packs should be included in the chillybin.

Laboratory Sampling Results Reporting

Laboratory test results will be provided to the Theatre Manager and Infection Prevention Nurse and reported to the Infection Prevention and Control Committee.

Positive microbiological results

In the event that microbiological testing reveals contamination, either by HPC >200cfu and/or positive culture for *Mycobacterium chimaera*, the following actions must be taken:

- If the results test positive for *Mycobacterium chimaera* or other non-tuberculous mycobacteria the heater cooler unit is not to be used.
 - Discuss immediately with infection control specialist, cardiac surgeon and theatre manager
 - Make alternative equipment HCU plans for cardiac patients until HCU is cleared for use
 - Review, cleaning and disinfection procedures.
- For heterotrophic plate counts, no absolute criteria for interpretation exist. Trends, rather than absolute numbers of organisms, should be followed for this monitoring.
 - Discuss immediately with infection control specialist, cardiac surgeon and theatre manager
 - Review, cleaning and disinfection procedures.

