

Advice 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, Institute of Clinical Pathology and Medical Research, Westmead

Marcus Bayly, Acting Perfusion Director, John Hunter Hospital

Jimmy Ng, Laboratory Scientist, Institute of Clinical Pathology and Medical Research, Westmead

This document addresses heterotrophic plate counts for heater cooler devices. This document does not address testing for mycobacteria as there are clear guidelines for testing published by the Australian Commission in Safety and Quality in Healthcare.

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 testing¹.

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 figure⁴.

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?

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>

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 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 13959:2014⁵. 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 UK⁶ and in NSW by the Acute Care Institute, NSW Health⁷. 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.

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

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 re-cleaned and samples re-sent for testing. A sample procedure is attached.

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)