Safety Notice SN004/17

INFECTION POST CARDIOPULMONARY BYPASS ASSOCIATED WITH HEATER-COOLER DEVICES

3 March 2017

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director, Regulation and Compliance Unit
- Chief Health Officer, MOH
- HAI Expert Advisory Committee, CEC

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Directors of Surgery
- Directors of Anesthetics
- Directors of Cardiac Services
- Directors of Emergency Departments
- Operating Theatre Managers
- Infection Prevention and Control Services
- Infectious Disease Units

Content reviewed by:

- Healthcare Associated Infections Expert Advisory Committee
- Office of the Chief Health Officer

Clinical Excellence Commission

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Internet Website:
http://www.health.nsw.gov.au/quality/sabs

Intranet Website
http://internal.health.nsw.gov.au/quality/sabs

Review date

March 2019

There have been a number of reports of serious and fatal surgical site and other infections with an unusual mycobacterial species, *Mycobacterium chimaera,* in patients who have had open cardiac surgery. Investigations have linked infections with contaminated heater-cooler devices used in cardiac bypass surgery. As of 1 February 2017, there have been over 70 cases internationally and three in Australia (2 in NSW) of infection with *Mycobacterium chimaera* suspected of being linked to contaminated heater-cooler devices. A specific brand of heater-cooler device, Sorin3T, has been linked to these infections and published reports suggest devices manufactured before September 2014 were contaminated at time of manufacture. It is recommended that use of Soren3T HCDs manufactured BEFORE September 2014 should be limited to emergent and/or life threatening situations if no other HCDs are available.

All heater-cooler devices (regardless of brand) should be cleaned and maintained as per the manufacturers' instructions and tested as per the CEC's recommendations (see link below). The exact route of transmission to patients is currently unknown. Studies suggest that if bacterial contamination of the water within the device occurs, there is the potential for the device to transmit bacteria through the air (via aerosolisation) through the device's exhaust vent and into the operating environment.

While the overall risk to individual patients is thought to be very low, in patients presenting three months to five years post cardiac surgery with symptoms of unexplained infection, the possibility of *M. chimaera* infection should be considered.

The TGA and the US Food and Drug Administration have continually released updates regarding infections relating to the heater-cooler devices. These can be located at:

- https://www.tga.gov.au/alert/non-tuberculous-mycobacterium-infections-associated-heater-cooler-devices
- http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM505732.pdf
- Additional NSW Health resources for clinicians and patients can be found at: http://www.health.nsw.gov.au/Infectious/alerts/Pages/M-chimaera-and-surgery-alert.aspx alert.aspx
- https://www.safetyandquality.gov.au/publications/national-infection-control-guidance-for-non-tuberculous-mycobacterium-associated-with-heater-cooler-devices/

Local Health Districts/Networks should

1. Distribute this notice to all stakeholders in operating theatres and surgical units that undertake cardiac surgery, cardiologists and infectious diseases units.
2. Alert physicians that if patients develop culture-negative endocarditis, surgical site infection or systemic illness suggestive of infection after cardiac surgery, mycobacterial infection should be considered in the differential diagnosis and to consult with infectious diseases. Note that infection may be slow growing and present months or even years after exposure.
3. Notify the Clinical Excellence Commission (CEC) of any probable or confirmed cases via cec-hai@health.nsw.gov.au (HAI Program).
4. Ensure that staff undertaking cleaning, disinfection and or maintenance of all heater-cooler devices wear protective equipment; and clean, disinfect and maintain heater-cooler devices as per the manufacturer's instructions. Contact the Australian sponsor of the device for further clarification if there are concerns regarding ability to follow the manufacturer's instructions.
5. Ensure that environmental sampling from heater-cooler devices is undertaken according to the recommendations from the Clinical Excellence Commission at http://www.cec.health.nsw.gov.au/patient-safety-programs/assurance-governance/healthcare-associated-infections/heater-coolers.
6. Undertake a risk assessment of procedures to direct the heater-cooler's vent exhaust away from the surgical field to mitigate the risk of aerosolising heater-cooler tank water over the sterile field and exposing patients. Contact the Australian sponsor of the device and discuss the proposed method to ensure it will not affect the functioning of the device. The CEC will provide further advice when available.

Further information

Can be obtained from the CEC at cec-hai@ health.nsw.gov.au and Ministry of Health at http://www.health.nsw.gov.au/Infectious/alerts

Actions required by Local Health Districts/Networks

1. Forward this safety notice to the appropriate area for action.
2. Ensure a system is in place to document actions taken.
3. Notify any adverse events in the Incident Information Management System (IIMS).