Safety Notice SN007/16

SURGICAL SITE INFECTIONS ASSOCIATED WITH HEATER COOLER DEVICES

4 August 2016

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Associate Director, Private Health Care Unit, MOH
- 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
- 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

July 2019

There have been a number of international reports of serious and fatal surgical site and other infections with an unusual mycobacterial species, *Mycobacterium chimaera,* in patients who had had open cardiac surgery. Investigations have linked infections with contaminated heater-cooler devices used in cardiac bypass surgery. As of 4 August 2016, in Australia there has been one possible patient infection with *Mycobacterium chimaera* suspected of being linked to contaminated heater-cooler devices. A specific brand of heater-cooler device, Sorin3T, has been linked internationally with these infections and published reports suggest this device was contaminated at time of manufacture. All heater cooler devices should be cleaned and maintained as per their manufacturers' instructions.

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.

The Therapeutic Goods Administration has recently urged health professional and facilities to be alert to the potential link between the use of heater-cooler devices in open cardiac surgery and infections with non-tuberculosis mycobacteria and has up-dated its advice in August. https://www.tga.gov.au/alert/non-tuberculous-mycobacterium-infections-associated-heater-cooler-devices

The US Food and Drug Administration has a brief summary of the Circulatory System Devices Panel Meeting – Heater-Cooler Devices: June 2-3, 2016 – which includes recommendations. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM505732.pdf

Local Health Districts/Networks should

1. Distribute this notice to all stakeholders in operating theatres and surgical units that undertake cardiac surgery.
2. Alert physicians that if patients develop 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 some months or even years after exposure.
3. Consult your infectious diseases unit and infection prevention and control service, ensuring capacity for adherence to the cleaning and disinfection instructions provided by the manufacturer.
4. Ensure that staff undertaking cleaning, disinfection and or maintenance of heater-cooler devices wear protective equipment; and clean, disinfect and maintain heater-cooler devices as per the manufacturer's instructions.
5. Contact the Australian sponsor of the device for further clarification if there are concerns regarding ability to follow the manufacturer's instructions.
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.
7. Ensure that any environmental sampling from heater-cooler devices is made in consultation with the local Infectious Diseases and Microbiology units and submitted to an accredited environmental laboratory.

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 IIMS