Safety Notice 005/22

Issue date
23 May 2022

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

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

Clinical Excellence Commission
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Fax. 02 9269 5599
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cec-hai@health.nsw.gov.au
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http://www.health.nsw.gov.au/quality/sabs
Intranet Website
http://internal.health.nsw.gov.au/quality/sabs

Review Date
May 2023

INFECTION POST CARDIOPULMONARY BYPASS ASSOCIATED WITH HEATER-COOLER DEVICES - UPDATE

Situation

What is new in this safety notice?

- A new case of invasive *M Chimaera infection* has been reported
- A heater cooler device has been found to be contaminated with *M Chimaera*

Serious and fatal infections with an unusual mycobacterial species, *Mycobacterium chimaera,* have been reported in patients who have had open cardiac surgery linked to contaminated heater-cooler devices (HCDs) used in cardiac bypass surgery. There have now been seven cases in NSW (most recent case in early 2022) and more than 120 worldwide of infection with *Mycobacterium chimaera.* The route of transmission is thought to be via aerosolisation of condensate through the device's exhaust vent and into the operating theatre (OT) environment.

Assessment

A specific brand of HCD, Sorin3T has been linked to these infections. HCDs manufactured before September 2014 were thought to be contaminated at time of manufacture. All Sorin3T HCDs manufactured prior to this date were replaced in NSW public hospitals. More recently an aerosol collecting device has been provided to retrofit to existing 3T HCDs to prevent aerosols leaking into the operating theatre. However, of concern, one of these newer HCDs in a private hospital has been recently identified as being contaminated with *M chimaera.*

Clinical Recommendations

All heater-cooler devices (regardless of brand) should be cleaned and maintained as per the manufacturers' instructions for use (IFU) and tested for Mycobacteria as per the Clinical Excellence Commission (CEC's) recommendations (see link below).

The overall risk of infection to individual patients is low. Most cases of invasive *M chimaera* infection present in the first six years after exposure; however, infection has now been reported up to 12 years after exposure. Along with appropriate cleaning and disinfection as per manufacturers IFU, reducing exposure to aerosols from the HCD is strongly recommended by installing the 3T aerosol collection kit and by considered placement of the HCD in the OT. Patients who present with symptoms of unexplained infection after cardiac surgery should have the possibility of *M chimaera* infection considered.

The Therapeutic Goods Administration (TGA) and the United States (US) Food and Drug Administration have 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
- https://www.fda.gov/medical-devices/what-heater-cooler-device/fdas-ongoing-evaluation-and-continued-monitoring-reports-nontuberculous-mycobacteria-infections

Clinical Recommendations cont:

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
- https://www.safetyandquality.gov.au/publications/national-infection-control-guidance-for-non-tuberculous-mycobacterium-associated-with-heater-cooler-devices/

Required actions for the Local Health Districts/Networks

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 clinicians 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 to many 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: : https://www.cec.health.nsw.gov.au/__data/assets/pdf_file/0007/349090/CEC-expert-working-group-recommendations-for-water-testing-of-HCDs.pdf
6. Ensure a system is in place to document actions taken
7. Report any related adverse events in ims+.