

Medical Device Alert

MDA/2015/022

Issued: 11 June 2015 at 11:00

Heater-cooler devices used during cardiac surgery: risk of infection with *Mycobacterium* species. All manufacturers.

Summary

There is a low risk of *Mycobacterium* infection in patients undergoing cardiac surgery, associated with heater-coolers used in conjunction with cardiopulmonary bypass machines. The cause of the infection may come from *Mycobacterium*-contaminated water in the heater-coolers.

Action

- Follow the manufacturer's instructions for use at all times, in particular for cleaning and disinfecting these devices and the sterile components used in the system.
- Review, update and follow the local protocols for water management practices, water quality, environmental hygiene, vigilance, and maintenance of these devices.
- Review, update and follow your local risk assessments for the safe operation of the heater-coolers.
- Identify whether there are any practices which may lead to transmission of organisms via aerosolisation where there is water contact with other cardiac surgery equipment.
- Have systems in place to notify the manufacturer and MHRA if you observe specific risks associated with the use of any of these devices.
- Have systems in place to contact [Public Health England](#) (PHE), or in the case of the Devolved Administrations their respective health protection agencies, if you have new cases of mycobacteria infections.

Action by

All medical and nursing staff who use these devices or who are responsible for maintaining devices used in cardiac surgery.

Deadlines for actions

For systems to be in place

Actions underway: 02 July 2015

Actions complete: 06 August 2015

Problem / background

A small number of patients who underwent cardiac surgery, where cardiopulmonary bypass was used, developed endocarditis and/or septicaemia associated with *Mycobacterium avium* species.

A study suggests that a possible source of contamination is colonisation by bacteria of the water used in the heater-coolers. Study Reference:

Sax H, Bloemberg G, Hasse B, Sommerstein R, Kohler P, Achermann Y et al (2015). Prolonged outbreak of

Mycobacterium chimaera infection after open-chest heart surgery. Clin Infect Dis

Mycobacterium avium complex is usually described as causing respiratory infections and disseminated infections in immunocompromised patients.

The overall risk of infection is difficult to quantify as current practices for monitoring the environmental integrity of operating theatres may not identify this slow-growing, resistant organism. It is important that you are aware of the mycobacteria risk to patients undergoing cardiac surgery.

For England: PHE issued a health protection report serial number 2015/020 in March 2015 to all microbiology and cardiothoracic centres to raise awareness of mycobacteria infection and for hospitals to undertake a local risk assessment of their cardiac bypass machines or devices using a water system. The original report and updates is on: <https://www.gov.uk/government/publications/health-protection-report-volume-9-2015/hpr-volume-9-issue-15-news-30-april>

Additional information is available from PHE's [website](#).

For Scotland: Content of the PHE report was circulated in Scotland by Health Protection Scotland (HPS) – Reference 2015/008.

For Northern Ireland: The Public Health Agency (PHA) in a letter dated 24 March 2015 contacted trust microbiologists and the BHSC Cardiothoracic Unit highlighting this issue and actions required. Contact the PHA duty room on 03005550119 for further information.

For Wales: Content of the PHE report and additional information was circulated to all Health Boards in Wales by Public Health Wales on 17 April.

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Adult intensive care units
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Clinical governance leads
- Clinical governance leads
- Clinical perfusionists
- Health and safety managers
- Infection control departments
- Infection prevention and control directors
- Infectious diseases paediatricians
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Microbiologists
- Operating department practitioners

- Paediatric cardiologists
- Paediatric intensive care units
- Respiratory departments
- Risk managers
- Theatre managers
- Theatre nurses
- Theatres

NHS England area teams

CAS liaison officers for onward distribution to all relevant staff including:

- Practice managers

Independent distribution**Establishments registered with the Care Quality Commission (CQC) (England only)**

- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2015/022** or **2014/007/016/081/003**.

Technical aspects

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Clinical aspects

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Reporting adverse incidents in England

Through Yellow Card <https://yellowcard.mhra.gov.uk/>

Northern Ireland

Alerts in Northern Ireland are distributed via the [NI SABS system](#).

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
CMO Group
Department of Health, Social Services and Public Safety
Tel: 028 9052 3868
Fax: 028 9052 3900
Email: NIAIC@dhsspsni.gov.uk
<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

Reporting adverse incidents in Northern Ireland

Please report directly to NIAIC using the [forms on our website](#).

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre, Health Facilities Scotland, NHS National Services Scotland
Tel: 0131 275 7575
Fax: 0131 314 0722
Email: nss.irc@nhs.net

Reporting adverse incidents in Scotland

NHS Boards and Local Authorities in Scotland – [report to Health Facilities Scotland](#).

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – [report to Health Facilities Scotland](#).

Private facilities providing care to private clients report to the [Care Inspectorate](#) and [MHRA](#).

Wales

Enquiries in Wales should be addressed to:
Healthcare Quality Division, Welsh Government
Tel: 01267 225 278 / 02920 825 510
Email: Haz-Aic@wales.gsi.gov.uk

Reporting adverse incidents in Wales

Report to MHRA through Yellow Card <https://yellowcard.mhra.gov.uk/> and follow specific advice for reporting in Wales in [MDA/2004/054 \(Wales\)](#).