Safety Information Message

Reference: SIM2209 **Issued:** 11 August 2022 **Review Date:** 11 August 2023

UKHSA investigation into potential contamination of bioprosthetic heart valves with Mycobacterium chelonae

Summary

This safety information message highlights the attached UK Health Security Agency (UKHSA) Briefing Note 2022/058 issued on 21 July 2022. Note that actions in Scotland differ from those in the Briefing Note (see below).

Action in Scotland

1. Clinicians are asked to consider the possibility of mycobacterial infection in patients presenting with signs or symptoms suggestive of infective endocarditis following cardiac surgery/implantation of **any bioprosthetic material** (particularly after multiple or "redo" surgeries), and to undertake appropriate investigations including mycobacterial blood cultures which should be processed locally. At present there is insufficient evidence to recommend enhanced follow up of patients who have received BioIntegral products.

2. All explanted bioprosthetic products, regardless of manufacturer, are recommended to undergo direct microscopy for Acid Fast Bacilli, with mycobacterial culture of the homogenate using automated liquid culture systems plus conventional solid media, at both 30ºC and 37ºC, extended to 12 weeks. It is recommended to retain an aliquot for pan-mycobacterial molecular testing if subsequently required. Please ensure all explanted bioprosthetic products are submitted for histology.

3. Clinicians, practitioners and microbiology staff are asked to notify ARHAI Scotland, as per Chapter 3 of the National Infection Prevention and Control (NIPCM), upon new identification of laboratory confirmed mycobacterial infection (any mycobacteria species), or where histology is strongly suggestive, in any individual who has previously received a bioprosthetic implant: National Infection Prevention and Control Manual: Chapter 3 - Healthcare Infection Incidents, Outbreaks and Data Exceedance (scot.nhs.uk)

4. Mycobacterial isolates (or specimens where solid culture cannot be undertaken locally) (any mycobacteria species) from individuals known to have had prior bioprosthetic implants should be sent to the Scottish Mycobacteria Reference Laboratory as per routine referral pathways labelled 'bioprosthetic implant recipient'.

5. Clinicians should report any device-related adverse incidents, including explant due to early valve failure, to their local adverse event management system (usually called Datix or Ullyses) and to IRIC at https://www.nss.nhs.scot/health-facilities/incidents-and-alerts/report-an-incident/

Suggested onward distribution

Cardiology
Cardio-Thoracic Surgery
Infection Control Staff
Laboratories
Microbiology
Operating Departments
Risk Management
Supplies/Procurement

Enquiries

Enquiries and adverse incident reports should be addressed to:

Incident Reporting & Investigation Centre (IRIC)
NHS National Services Scotland
Tel: 0131 275 7575 Email: nss.iric@nhs.scot

Accessibility: Please contact us using the above details if you are blind or have a sight impairment and would like to request this alert in a more suitable format.

IRIC remit: general information about adverse incidents, safety alerts and IRIC's role can be found in CEL 43 (2009), *Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities,* issued 30 October 2009.

Report an incident: Information on how to report an adverse incident

NHS National Services Scotland is the common name for the Common Services Agency for the Scottish Health Service https://www.nss.nhs.scot/

UK Health Security Agency

Serial number 2022/058 **Date 21/07/2022**

Event: UKHSA investigation into potential contamination of bioprosthetic heart valves with *Mycobacterium chelonae*

Notified by: HCAI, Fungal, AMR, AMU & Sepsis Division and National Mycobacterial Reference Service

Authorised by: Shona Arora (Director of Health Equity and Clinical Governance)
Colin Brown (Deputy Director CEI)
William Welfare (Pan Regional Directorate)

Contacts: **UKHSA.NICC69@ukhsa.gov.uk**

NIERP Level: Standard Response

Incident Directors: James Elston and Russell Hope

Background and Interpretation

UKHSA is currently investigating potential contamination of bioprosthetic heart valves produced by BioIntegral Surgical, Inc. with *Mycobacterium chelonae*. BioIntegral Surgical issued a Field Safety Notice (FSN) on 13 April 2022 following identification of *Mycobacterium chelonae* contamination in explanted bioprosthetic heart valves from four cardiac patients in two countries over three years. Testing of a small number of new / unused bioprosthetic valve products in Germany also revealed the presence of *Mycobacterium chelonae* through molecular methods, but no viable organisms were recovered.

The FSN requested a hold to be placed (i.e. immediate cessation of all implantations and sales) on the following bioprosthetic heart valve products whilst investigations are conducted: (1) No-React® BioConduit (NRAC), (2) No-React® BioPulmonic Conduit (NRPC), (3) No-React® Injectable BioPulmonic (NRIP), (4) No-React® BioMitral (NRM), (5) No-React® BioAortic (NRA).

It is unclear currently whether the presence of *M. chelonae* conveys any risk to patients, and to date viable *M. chelonae* has not been cultured from valve tissue or other patient samples for up to 14 weeks . An update on the latest test results can be found in the second FSN issued by Biointegral Surgical on 14th July 2022. Follow-Up FSN (July 2022)

UKHSA have established a national standard incident response to undertake risk assessment and investigation to inform any relevant public health actions. UKHSA is working with partners to progress urgent investigation incorporating microbiological and epidemiological approaches.

MHRA is investigating the validity of possible *M. chelonae* contamination on the range of BioIntegral Surgical implantable medical devices, to ensure that the benefits of these devices continue to outweigh any potential risks, relative to alternative devices or treatments, and that any risks are being reduced as far as possible. Simultaneously the MHRA is undertaking separate discussions with the wider biological valve industry. *M. chelonae* is a rapidly growing, nontuberculous mycobacterium (NTM), which is ubiquitous in the environment. *M. chelonae* grows optimally at 30-33°C and may be challenging to culture using standard methods. *M. chelonae* primarily causes skin and soft tissue infections (including post-surgical wounds), with infection of long-term intravenous catheters and medical devices described. Clinical presentations may have prolonged incubation periods and disseminated disease may result in the immunocompromised. Infective endocarditis or graft failure caused by this organism would be expected to result in high associated morbidity and mortality. Treatment is challenging; *M. chelonae* is intrinsically resistant to many antibiotics and requires prolonged

therapy with multiple agents. *M. chelonae* is not a notifiable organism and cases in general will be underestimated in the population at large.

UKHSA is requesting additional measures, outlined below, to understand the incidence of *M chelonae* among patients implanted with bioprosthetic cardiac implants from any device manufacturer, and to inform risk assessment for this incident.

Implications and recommendations for UKHSA Regions

UKHSA Regions, particularly Health Protection Teams (HPTs) are requested to use their relevant networks with NHS Trust microbiology, infection prevention control, infective endocarditis teams / Infectious Disease physicians, and relevant clinical networks to promote awareness of the FSN and cascade this briefing note and to request the following

- Clinicians are asked to consider the possibility of mycobacterial infection in patients presenting with signs or symptoms suggestive of infective endocarditis following cardiac surgery/implantation of any bioprosthetic material (particularly after multiple or "redo" surgeries), and to undertake appropriate investigations including mycobacterial blood cultures which should be processed locally. At present there is insufficient evidence to recommend enhanced follow up of patients who have received BioIntegral products.
- All explanted bioprosthetic products regardless of manufacturer are recommended to undergo direct microscopy for Acid Fast Bacilli, with **mycobacterial culture of the homogenate using automated liquid culture systems plus conventional solid media, at both 30ºC and 37ºC degrees**, extended to 12 weeks. It is recommended to retain an aliquot for pan-mycobacterial molecular testing if subsequently required. Please ensure all explanted bioprosthetic products are submitted for histology.
- Clinicians, practitioners and microbiology staff are asked to notify the relevant UKHSA Health Protection Team upon new identification of laboratory confirmed mycobacterial infection (any mycobacteria species), or where histology is strongly suggestive, in any individual who has previously received a bioprosthetic implant.
- Mycobacterial isolates (any mycobacteria species) from individuals known to have had prior bioprosthetic implants should be sent to the relevant mycobacterial reference laboratory as per routine referral pathways labelled 'bioprosthetic implant recipient'.
- Clinicians should report any device-related adverse incidents, including explant due to early valve failure to the MHRA https://yellowcard.mhra.gov.uk/

HPTs are asked to investigate/follow up as appropriate such cases, ensure isolates are submitted to the relevant mycobacterial reference laboratory and liaise with the incident team via UKHSA.NICC69@ukhsa.gov.uk.

Implications and recommendations for UKHSA sites and Services

UKHSA Sites and Services are requested to use their relevant networks particularly with NHS Trust microbiology, infection prevention control teams and relevant clinical networks to promote awareness of the FSN and cascade this briefing note to cardiology and cardiothoracic surgery, infection specialities, emergency medicine, and other relevant clinical colleagues.

Diagnostic laboratories (UKHSA, NHS Trusts, and independent sector) are asked to submit mycobacterial isolates from individuals known to have had prior bioprosthetic implants to the relevant mycobacterial reference laboratory as per routine referral pathways labelled 'bioprosthetic implant recipient', until further notice.

Implications and recommendations for local authorities

Not applicable.

UK Health Security Agency

References / Sources of Information

- UK SMI: B 40 Investigation of specimens for Mycobacterium species (publishing.service.gov.uk)
- Communicable disease threats report, 12-18 June 2022, week 24 (europa.eu).