



## RAPID RISK ASSESSMENT

# Invasive cardiovascular infection by *Mycobacterium chimaera* potentially associated with heater-cooler units used during cardiac surgery

30 April 2015

### Main conclusions and options for response

Since 2011, cases of infection caused by *Mycobacterium chimaera* have been detected in patients having previously undergone cardiac surgery in Europe (1-3).

Healthcare providers involved in caring for patients who have undergone open-heart surgery should be vigilant for cases of endocarditis or other cardiovascular infection of unidentified origin and consider testing specifically for slow-growing non-tuberculous mycobacteria such as *M. chimaera*. Regulatory bodies in charge of licensing and agencies monitoring the safety of such devices should be aware of the potential association of invasive cardiovascular infections caused by *M. chimaera* with heater-cooler units and relevant information should be disseminated to all centres performing cardiac surgery.

ECDC is maintaining vigilance for additional information that can be used to further evaluate the public health risk of invasive cardiovascular infection by *M. chimaera* associated with heater-cooler units and will update its risk assessment as new evidence is obtained.

### Source and date of request

ECDC internal decision, 13 April 2015.

### Public health issue

Assess the risk of invasive cardiovascular infection by *Mycobacterium chimaera* potentially associated with heater-cooler units used during cardiac surgery in Europe.

### Disease background information

*Mycobacterium chimaera* is a slow-growing non-tuberculous mycobacterium (NTM) distinguished as a species within the *Mycobacterium avium* complex in 2004 (4). Identification requires molecular diagnostic testing. *M. chimaera* has been linked to lung infections in patients with underlying lung disease, such as chronic obstructive pulmonary disease. Colonisation of water sources, aided by the formation of biofilm, is possible.

## Event background information

Since 2011, cases of invasive cardiovascular infection caused by *M. chimaera* in patients having previously undergone cardiac surgery in Switzerland, the Netherlands and Germany have been reported by the relevant authorities (1-3, 5).

Switzerland has reported six *M. chimaera* infections: three cases of endocarditis, one bloodstream infection and two vascular graft infections. Two of the six had fatal outcomes related to the infection (2). The clinical manifestations included osteomyelitis and involvement of multiple organs such as the eye and spleen. The Netherlands reported one fatal *M. chimaera* infection in a patient following cardiac surgery (1, 6). A case has also been reported in Germany. Investigation in Switzerland included microbiological examination of environmental samples that identified *M. chimaera* contamination in heater-cooler units used during cardiac operations, including water samples from the units. Air sampling cultures became positive for *M. chimaera* when units were running but not if they were turned off. Some strains from air and water samples showed matching Random Amplified Polymorphic DNA (RAPD)-PCR patterns (2, 3). This suggests *M. chimaera*-contaminated heater-cooler units as a potential source of infection (2). Heater-cooler units are used to regulate the temperature of the blood during extracorporeal circulation and use filtered tap water as a heat exchanger.

A number of control measures have been implemented. In the Netherlands, several elective heart surgery procedures were postponed until measures had been taken, such as placing devices that may spread the bacteria outside of operating rooms, although acute cardiac surgery was not postponed. By 12 February 2015, the regular programme of operations had resumed at these centres (1).

In Switzerland, cleaning and decontamination of the heater-cooler units was followed by recontamination. A new heater-cooler unit that initially tested negative for *M. chimaera* at the hospital tested positive three months after purchase and installation. In a Zurich hospital, a maintenance protocol was applied that included daily water change (using 0.2µm bacterial filters). The hospital also started building customised housing units for these devices inside operating rooms, with high-efficiency particulate air filters connected (2).

National regulatory authorities for medical devices have been notified in countries that have reported infections. In the Netherlands, authorities reported the incident to the Health Inspectorate which sent information to professional associations, including the Dutch Association for Cardio-Thoracic Surgery (NVT) and the Dutch Society for Medical Microbiology (NVMM), and to the public via a press release (1). In Switzerland, the Federal Office of Public Health issued a public alert in July 2014, following an alert to all 16 Swiss hospitals that perform this type of cardiac surgery and to cardiac surgeons via the Swiss Society for Cardiac and Thoracic Vascular Surgery (3). In Germany the regional authorities were informed and comprehensive investigations were initiated (5). In the UK, Public Health England (PHE) are working with the Medicines and Healthcare Products Regulatory Agency (MHRA) to assess whether there is any historic or ongoing risk to patients who have had or are undergoing cardiac surgery. PHE has also alerted cardiothoracic centres, microbiologists and public health services across the UK to their investigation (7).

## ECDC threat assessment for the EU

ECDC is gathering information in collaboration with affected countries to evaluate the public health risk of cardiovascular-surgery-associated invasive infections with *M. chimaera* potentially linked to heater-cooler units, and will update its risk assessment as new evidence is obtained. Healthcare providers involved in caring for patients who have undergone open-heart surgery or other surgery involving cardiopulmonary bypass such as lung transplant should be vigilant for cases of endocarditis or other cardiovascular, deep-surgical-site or disseminated infection of unidentified origin. They should also consider testing specifically for slow-growing non-tuberculous mycobacteria such as *M. chimaera*. Regulatory bodies in charge of licensing and agencies monitoring the safety of such devices should be aware of the potential association of invasive cardiovascular infections caused by *M. chimaera* with heater-cooler units and relevant information should be disseminated to all centres performing cardiac surgery.

## References

1. Inspectie voor de Gezondheidszorg (IGZ). Hartcentra nemen maatregelen om hartoperaties veiliger te maken [20 April 2015]. Available from: [http://www.igz.nl/actueel/nieuws/hartcentra\\_nemen\\_maatregelen\\_om\\_hartoperaties\\_veiliger\\_te\\_maken.aspx](http://www.igz.nl/actueel/nieuws/hartcentra_nemen_maatregelen_om_hartoperaties_veiliger_te_maken.aspx).
2. Sax H, Bloemberg G, Hasse B, Sommerstein R, Kohler P, Achermann Y, et al. Prolonged Outbreak of *Mycobacterium chimaera* Infection After Open-Chest Heart Surgery. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America*. 2015.
3. Swiss Agency for Therapeutic Products. *Mycobacterium* risks in cardiac surgery – Heater Cooler Devices [20 April 2015]. Available from: [https://www.swissmedic.ch/rueckrufe\\_medizinprodukte/00833/01630/02299/index.html?lang=en](https://www.swissmedic.ch/rueckrufe_medizinprodukte/00833/01630/02299/index.html?lang=en).
4. Tortoli E, Rindi L, Garcia MJ, Chiaradonna P, Dei R, Garzelli C, et al. Proposal to elevate the genetic variant MAC-A, included in the *Mycobacterium avium* complex, to species rank as *Mycobacterium chimaera* sp. nov. *International journal of systematic and evolutionary microbiology*. 2004;54(Pt 4):1277-85.
5. Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM). Möglicher Zusammenhang zwischen Hypothermiegeräten und Infektionsrisiko mit Mykobakterien bei der Herzchirurgie 2015 [cited 2015 30 April]. Available from: <http://www.bfarm.de/SharedDocs/Risikoinformationen/Medizinprodukte/DE/Hypothermiegeraete.html?nn=3495216>.
6. Isala. Isala heeft melding gedaan van besmetting hartpatiënt met *M. chimaera* bij Inspectie [23 April 2015]. Available from: <http://www.isala.nl/over-isala/nieuws/isala-melding-besmetting-hartpatient-m-chimaera-inspectie>.
7. Public Health England. Investigation of *Mycobacterium chimaera* infection associated with cardiopulmonary bypass 2015 [cited 2015 30 April]. Available from: <https://www.gov.uk/government/publications/health-protection-report-volume-9-2015/hpr-volume-9-issue-15-news-30-april>.