



Public Health  
England



Protecting and improving the nation's health

# **Mycobacterial Infections Associated with Heater Cooler Units Used in Cardiothoracic Surgery**

Advice for providers of cardiothoracic  
surgery

## About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

This document has been produced by PHE in association with the Society for Cardiothoracic Surgery and the Association of Cardiothoracic Anaesthetists.

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# 1. Frequently asked questions

## What is the issue?

Switzerland, The Netherlands and Germany have reported cases of invasive infection in patients after cardiac surgery, caused by an unusual organism, *Mycobacterium chimaera*. They attribute these infections to transmission of organisms from contaminated heater cooler units used in theatre during cardiothoracic surgery, via production of an aerosol of contaminated water from the device. Case numbers in all countries are very low but infections were severe, including endocarditis and disseminated infection, with some deaths.

A UK investigation has found a similar potential risk and identified a small number of cases of *M. chimaera* and other similar mycobacteria in cardiothoracic surgery patients in the UK, including some deaths. All cases had valve replacement or repair. The link with the heater cooler unit has not been proven in the UK, however it has been shown in a laboratory evaluation that a heater cooler can generate a microbial aerosol when running.

A manufacturer of a heater cooler unit potentially associated with known cases, Sorin, is issuing a Field Safety Notice (FSN) recommending enhanced decontamination and the removal of some machines which are contaminated from service. It should be noted that the risk may not be limited to this brand of device and other devices are currently under investigation.

Based on Public Health England (PHE) investigations, a high proportion of UK devices may be contaminated, so the FSN has the potential to **significantly disrupt UK cardiothoracic surgical services**.

## What is the level of the risk?

The additional risk posed by this issue is **very low**. Cases identified to date are associated with valve replacement or repair. Around 20,000 such surgical procedures are carried out in the NHS each year. Taking a theoretical 10,000 patients undergoing valve replacement, approximately 120 would be expected to develop a surgical site infection within a year and 300-600 endocarditis within five years given the normal risks of infection in these patients. One or two additional patients of the 10,000 would be expected to be diagnosed with a *M. chimaera* infection. A full quantitative risk assessment can be found in Section 3.

## What has been done to date?

PHE and the Medicines and Healthcare products Regulatory Agency (MHRA) have worked together with NHS colleagues at a number of trusts to investigate whether there was a credible UK risk and have informed the manufacturer of the most commonly used unit, Sorin, of their findings. Investigation of other brands of heater cooler is underway.

In order to ensure safe operating of the device, it has not been possible for PHE to advise any interim alteration to the decontamination method or any other aspect of any device without manufacturer testing and approval.

## What is now planned?

Sorin has released a Field Safety Notice. This advises that microbiological testing of heater cooler units is undertaken (see page 8). A series of actions are advised by Sorin while waiting for local testing results. If machines are found to be contaminated, Sorin advises local infection control decision-making, and if mycobacteria are found in the air of the operating theatre, Sorin advises that the heater cooler is removed from service and that local infection control teams should make decisions regarding emergency surgeries.

Investigations concerning other brands of heater cooler will continue.

## What should we do if our device is found to be contaminated or generating positive air samples?

You should contact the your local manufacturer's representative immediately. Sorin has indicated that in some circumstances it may be possible for it to support you in moving the device safely further from the patient or outside the operating theatre.

Sorin is able to offer a mechanical decontamination process for contaminated machines. The turnaround time on this for the UK is not yet clear as the overall capacity in the company is limited but it could be several weeks.

If any of your devices are withdrawn or returned to the manufacturer, an adverse incident report should be sent to MHRA.

While no cases of mycobacterial infection have been linked to other brands of heater coolers, assessment of these machines is not yet complete and they cannot necessarily be considered a safer alternative.

## Should we delay surgery?

This decision must be made by the NHS trust or independent provider. The risk to the individual patient of acquiring this infection is extremely low. All known UK cases are associated with valve replacement or repair.

In most cases the risk from delaying cardiothoracic surgery, including valve replacement or repair, is likely to outweigh the infection risk. The Society for Cardiothoracic Surgery (SCTS) advises that the risk of dying or suffering other adverse events due to delay in valve replacement is likely to be significantly greater than the risk of acquiring mycobacterial infection in this context (see page 11). SCTS advises that surgeons may wish to consider on an individual case basis whether there are any planned procedures that would not be affected by delay (see page 10).

If surgery is undertaken, the trust must ensure that there are adequate mechanisms in place to follow up and investigate patients who become unwell, including mycobacterial investigations.

## Should we alert patients to this risk?

The **Duty of Candour** requires that any patient harmed by the provision of a healthcare service is informed of the fact and an appropriate remedy offered. Any patient in whom you detect an infection that may be related to this device should be informed that this is a possibility.

In patients who are being consented for cardiothoracic surgery, SCTS advises that surgeons inform their patients of the specific risk but also that the risk of delaying surgery is significantly greater. The risk of other infections also remains much higher than that of mycobacterial infection.

## Should we test cardiothoracic patients routinely for mycobacterial infection?

If patients develop endocarditis, surgical site infection or systemic illness suggestive of infection after cardiothoracic surgery, diagnostic tests should be discussed with the local infection specialist to ensure appropriate sampling and analysis is carried out. Further details are provided on page 9. The maximum time between surgery and presentation in reported cases so far is five years.

## Should we look retrospectively for cases if we find that our machines are contaminated?

It is advisable to review any patients with prosthetic valve endocarditis or other relevant infections after cardiothoracic surgery, who have not had a microbiological diagnosis, to see if mycobacterial investigations may be relevant as this diagnosis would alter management. Liaison with an infection specialist is recommended. Case definitions are available from PHE if required (see Contact section). Please notify PHE of any cases identified retrospectively and send an adverse incident report to MHRA.

## Are healthcare staff at risk?

Non-tuberculous mycobacteria are found very widely in the environment, including in tapwater. Most people are exposed on a regular basis with no adverse consequences. However these organisms do cause infection of the respiratory tract in the presence of pre-existing damage to the respiratory tract, or an impaired immune response, and the particle size generated by the heater cooler in one evaluation is such that the particles could be inhaled to the deep lung. Theatre staff should be advised of the issue and if they have pre-existing lung conditions or impaired immune response including on immunosuppressive therapy, should be offered occupational health review.

## Where else are heater cooler units used?

The same heater coolers may be used to provide extracorporeal membrane oxygenation (ECMO) and hyperthermic isolated limb perfusion. No cases associated with these functions have been reported to date, however an investigation is ongoing in ECMO patients.

## 2. Background information

### What is *Mycobacterium chimaera*?

*Mycobacterium chimaera* is one of the species within the *Mycobacterium avium* complex, a group of common slow-growing environmental organisms that sometimes cause respiratory infections or severe disease in immunocompromised patients. They have not been previously recognised as common causes of cardiothoracic surgical infections. It is not clear at present why *M. chimaera* is associated with many of these devices, and it is also possible that other organisms are being transmitted by the device.

### Which devices are involved?

The device that has been implicated by the Swiss report is manufactured by Sorin. The device tested by PHE, and in use in many UK centres, is the Sorin 3T. It is not yet clear whether other brands of heater cooler are associated with similar risk. There is limited evidence to suggest some other brands of heater coolers may have detectable mycobacteria within the water circuit. Investigations continue.

### What is the evidence that heater cooler units are a source of infection?

**Switzerland:** Following a cluster of six *M. chimaera* invasive infections after surgery in a Swiss hospital, a **published investigation** demonstrated *M. chimaera* in the water within the heater cooler units, and found that *M. chimaera* could be cultured from the air in the operating theatre when the machine was running but not when it was off. Some air and water strains were matched by microbiological typing.

**UK:** Retrospective case finding has identified 13 patients in the UK with mycobacterial endocarditis, aortic root abscess, sternal wound infection or disseminated infection subsequent to cardiothoracic surgery. Ten have been confirmed to date as being *M. chimaera*. These cases have not been definitively linked to the device as they have been identified long after the surgery was undertaken. Mycobacterial investigation is not routine in post surgical infections and this infection may be under-diagnosed.

Microbiological sampling of heater cooler devices at several NHS sites has demonstrated a range of bacteria in the water within the device, including *M. chimaera* in many cases. Experimental testing of a machine has demonstrated that a microbial aerosol is generated.



## Which patients may be affected by this risk?

**Type of surgery:** The six published Swiss cases underwent heart valve replacement/repair or aortic graft. The 13 probable cases in the UK underwent repair or replacement of heart valves. Their surgery was undertaken in eight different NHS trusts. The earliest cases underwent surgery in 2007 and the most recent case in 2013.

**Patient factors:** Environmental mycobacteria more commonly cause severe infections in immunocompromised patients. Two of the six Swiss cases are described as immunocompromised, one with low CD4+ T cell count of unknown cause, one on corticosteroid treatment. Investigations on the UK cases continue.

## How should we test a device for contamination?

Sorin provide brief instructions for general bacteriology and mycobacterial testing in the FSN. For other brands of heater coolers, this may be available in the instructions for use or directly from the company. For mycobacterial investigations, PHE has issued a supplementary environmental sampling standard operating procedure. This is available at <https://www.gov.uk/government/collections/mycobacterial-infections-associated-with-heater-cooler-units>.

Any environmental samples should be processed in the local microbiology laboratory as directed in the SOP. Any positive mycobacterial cultures should be sent to the regional mycobacterial reference laboratory for identification. Whilst the current investigation is ongoing, regional reference laboratories will refer any samples identified as *M. intracellulare* to the National Mycobacterial Reference Laboratory for further testing for *M. chimaera*.

Device testing is part of local maintenance and infection control and is not funded by PHE.

## How should patients be tested for possible mycobacterial infection?

If patients develop endocarditis, surgical site infection or systemic illness suggestive of infection after cardiothoracic surgery, mycobacterial infection should be considered in the differential diagnosis. Sampling and testing should be discussed with an infection specialist. We suggest testing any non-repeatable samples from these patients (eg valve tissue, bone or other surgical samples) for mycobacteria directly, by mycobacterial culture and 16S rRNA gene sequencing. In the case of more accessible samples, such as blood cultures in suspected endocarditis, it may be preferable to start with standard

investigations, and if these are negative, continue to three sets of mycobacterial blood cultures in the appropriate bottles, incubated for six weeks.

Please note there have been supply issues with some mycobacterial blood culture bottles recently. Laboratories which cannot perform mycobacterial blood cultures should contact the regional mycobacterial reference laboratory.

## 3. Quantitative risk assessment

### Risk of acquiring *M. avium* complex infections after cardiothoracic surgery

To date 13 probable cases have been identified in the UK. All cases have had valve replacement or repair, some as part of more complex surgery. In six cases the infection manifested as endocarditis or other cardiac infection, in five cases as disseminated or non-cardiac infection, and in two cases as surgical site infection.

- in the NHS, approximately 56,000 procedures likely to involve cardiopulmonary bypass are carried out per year. Last year, this included around 20,000 valve replacements
- infection is a recognised risk following this type of surgery. PHE surgical site surveillance indicates that 1.2% of patients undergoing procedures to heart valves or septum develop a surgical site infection within the first year after surgery. There is no national surveillance targeted at prosthetic valve endocarditis, however studies suggest 3-6% of patients develop a prosthetic valve infection within five years after valve replacement
- 13 probable cases have been identified from all surgeries undertaken in the NHS likely to have been on bypass, over seven years, approximately totalling 560,000 years of living post operation. Thus, at present the crude incidence rate is 0.2 (95% confidence interval 0.1 to 0.4) per 10,000 years of post-operative follow-up. Patients previously receiving extracorporeal circulation may remain at risk from this organism and if it is assumed that the risk of developing a frank infection is constant over time, and remains for seven years post-operation (which may equate roughly to life expectancy in these patient) then there is approximately an additional 420,000 years at risk. This equates to an additional five to 17 such infections that could manifest themselves over the next six years, giving an estimate of the eventual total number of cases between 18 and 30
- this risk is extremely small compared to the overall 3-6% of patients who have infections by five years after surgery
- uncertainty is introduced by the fact that it is not standard practice to look for mycobacteria in cardiac or post-surgical infections, thus, an upper limit on this risk is difficult to quantify

- an approximate rate of 6.7 (95% confidence interval 2.4 to 14.5) per 10,000 years of follow-up, can be estimated from data published from the University Hospital of Zurich (six cases arising between 2008 and 2012 from approximately 600 patients receiving extracorporeal circulation per year). This is nearly 29 times the incidence estimated currently in the UK
- of 10,000 cases undergoing valve replacement, approximately 120 would be expected to have surgical site infections and 300-600 would have endocarditis by five years due to the normal risks of infection. One could be expected to have diagnosed infection related to the current risk. A total of 30-60 microbiologically undiagnosed cases of endocarditis could be expected, some of which could potentially be mycobacterial

### Risks of delaying valve replacement surgery

- acute significant valve lesions are poorly tolerated and urgent surgery is required, with poor short-term prognosis if untreated
- for chronic valve lesions, if the patient is symptomatic with severe stenosis or regurgitation of left sided valves then medium prognosis without surgery is poor, and risk of delay would far outweigh the potential risk of acquiring this infection, eg two year survival is only 40-50% for severe symptomatic aortic valve disease
- the only subset of patients who may have an elective choice to delay with some safety, where their one year prognosis would be good (>95% survival) without intervention are: Truly asymptomatic (class 1) aortic stenosis (or aortic regurgitation) with preserved left ventricular function and dimensions (left ventricular end systolic diameter <5cm), asymptomatic mitral stenosis and asymptomatic chronic mitral regurgitation with preserved left ventricular function and dimensions (left ventricular end systolic diameter <3.5cm)

## 4. Contacts

### PHE

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These Q&As may be updated. Updates and further information will be available at <https://www.gov.uk/government/collections/mycobacterial-infections-associated-with-heater-cooler-units>

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