

Infections Associated with Heater Cooler Units Used in Cardiopulmonary Bypass and ECMO

Information for healthcare providers in the UK

Scottish appendix

Introduction

The forthcoming Patient Notification Exercise (PNE), resulting from the identification of mycobacterial infections associated with the use of heater cooler units (HCUs) within cardiothoracic surgery, is a UK wide incident. However, it has been recognized that although the overarching aims and objectives of the exercise are shared by each of the devolved nations, some of the processes detailed within the main guidance document need to be amended in order to support the systems and structures in place across each of the respective devolved nations. The following appendix has been prepared for use in Scotland and details how the aforementioned information translates across for use in a Scottish context.

Although the document refers to NHS Boards, we would hope that the guidance will also be helpful for private healthcare providers.

Summary

NHS Boards who use heater cooler units (of any brand and model) should ensure that:

1. A full local risk assessment is conducted, at a minimum reviewed annually and acted upon, and a local Quality Assurance Programme is put in place covering the use of the device
2. Devices are microbiologically monitored according to the manufacturer's instructions supplemented by the [main guidance document](#) for cardiothoracic service providers
3. Cleaning and disinfection regimes are in use as directed by manufacturers and as supplemented by MHRA via any Medical Device Alerts, etc.
4. Heater cooler units are positioned outside theatre where this is possible. If it is unavoidable that they are in the theatre, attention should be given to positioning as described in the main guidance document. Seek advice from the manufacturer in

achieving this safely without affecting device performance

5. A Legionella risk assessment for the heater cooler units has been undertaken according to the information presented in this guidance. This should include the risks to potentially exposed healthcare staff.
6. Impact on cardiothoracic surgical services is minimised. Decisions regarding delaying or continuing surgery must be made by the individual NHS Board in conjunction with the Scottish IMT.
7. Traceability of heater cooler units is ensured; the individual unit used for any surgery or ECMO should be recorded which traces the individual unit to any particular patient, time and date of use through the use of the equipment serial number.
8. Notification of heater cooler unit related issues are made to the Incident Reporting and Investigation Centre (IRIC) and/or Health Protection Scotland as appropriate. This should include problems encountered in cleaning and disinfection (IRIC), patient harm (IRIC/HPS), and new cases of *M. chimaera* infection (NHS Board Health Protection Teams and HPS).
9. Patients are informed of the specific risk associated with these devices when they are consented for surgery.

All NHS Boards should:

1. Disseminate information to relevant clinical staff and ensure that they have methods in place to diagnose mycobacterial and Legionella infections in patients and staff who have been exposed to heater cooler units.
2. Ensure that they comply with the requirements for reporting of cases (as per case definition detailed within the Scottish surveillance form) and heater cooler unit related issues. Cases should be reported to local NHS Board Health Protection Teams who will subsequently notify Health Protection Scotland. Concerns regarding HCU safety and performance issues should be reported to IRIC directly and to HPS through the Scottish IMT.

Responsibilities of NHS Boards

The responsibilities of NHS Boards are as detailed within the main guidance. One of these areas is with respect to compliance with reporting requirements. The reporting mechanisms within Scotland are detailed below:

IRIC: all NHS Boards with concerns relating to the safety and performance of HCUs or their accessories should report these to the device manufacturer **and** to IRIC via the [HFS website](#). Concerns should also be escalated to HPS through the national IMT.

HPS: report cases of mycobacterial and other infection related to HCUs to NHS Board

Health Protection Teams who will then report to HPS.

HSE: report cases of legionellosis to HSE under RIDDOR if a doctor notifies the employer; and the member of staff's current job involves work on or near heater cooler units.

The Care Inspectorate, as the lead enforcement body in Scotland, will expect to be provided with evidence that the described NHS Board responsibilities have been addressed and embedded into practice.

Risk assessment

Mycobacterial infections

The findings of the retrospective case finding exercise are described within the main guidance. Thus far, no cases of *M. chimaera* infection associated with cardiopulmonary bypass have been identified in Scotland.

However, based on the numbers of cases diagnosed in England where surgery was performed in NHS hospitals (n=23), the risk to patients was estimated as follows:

Cardiac valve repair/replacement

Between 2007 and 2015 approximately 130,000 patients underwent valve repair or replacement surgery in the NHS in England according to Hospital Episode Statistics, which means an estimated risk of **2 cases of *M. chimaera* infection per 10,000 patients (or 1 in 5,000)**. In 2014, the year with the highest number of cases reported to date, this risk increases to approximately 1 in 2,000.

Coronary artery bypass graft (CABG)

Between 2007 and 2015 approximately 186,000 patients underwent CABG surgery in the NHS in England, translating to an estimated risk of **<1 case of *M. chimaera* per 100,000 patients**, substantially lower than for cardiac valve patients.

Heart/lung transplant

Between 2007 and 2015 approximately 2,800 patients underwent heart or lung transplants in the NHS in England. No cases associated with these procedures have been identified to date in the UK. However the number of procedures is relatively small and there is less certainty around risk assessment in this group.

Congenital heart disease

Between 2007 and 2015 approximately 28,000 patients underwent surgical procedures other than valve replacement or repair on cardiopulmonary bypass as a result of congenital heart disease in the NHS in England. No cases associated with these procedures in the absence of heart valve surgery have been identified to date in the UK suggesting a very low risk of *M. chimaera* infection.

Furthermore, the risk identified above is small compared to the background risk of infection recognised following this type of surgery and as such, in this context any increased risk posed by *M. chimaera* is extremely small.

Legionella

As detailed within the main document, mycobacterial infections are not the only possible infection risks given how *Legionella* spp have been identified from HCUs indicating potential *Legionella* spp colonisation. Although the risk to patients from respiratory exposure is unlikely given the use of closed-circuit ventilation, there is a theoretical risk of deposition of *Legionella* spp in the surgical field. There is also a potential risk to staff from exposure to aerosols generated by the HCUs. In addition, in ECMO units, adjacent patients on the same unit but not on closed circuit ventilation could also be exposed.

Although *Legionella* spp have been identified in water from HCUs, enhanced surveillance undertaken by HPS between 2007 and 2016 has not identified any cases of Legionnaire's disease in healthcare workers expected to have exposure in cardiothoracic or ECMO facilities. No *Legionella* spp endocarditis cases have been reported post cardiothoracic surgery. These infections may not be detected by standard culture methods. Therefore, although *Legionella* spp have been identified in water from some heater-cooler units, the lack of any Legionnaires' disease cases identified in previous years supports an assessment that the overall risk to staff and patients is **very low**. Given the potential difficulties in diagnosing post-surgical *Legionella* infections, surveillance will continue.

Instructions on managing Legionella risk are provided on page 13 of the main guidance document.

Other infections

A range of other opportunistic pathogens such as other non tuberculous mycobacterial species, *Pseudomonas aeruginosa*, *Stenotrophomonas maltophilia* and fungi, have been isolated from the water in these devices. It is theoretically possible that such organisms could transmit via the aerosolisation of the water in the device.

The Scottish Mycobacteria Reference Laboratory (SMRL), in conjunction with HPS, is collating the positive microbiological results from the testing of each of the HCUs. The microbiological testing results from the HCUs are being utilised by local teams, and with the support of the national IMT, in the development of local risk assessments.

The ongoing monitoring of Surgical Site Infections (SSIs) incidence will continue to be undertaken through participation in the Scottish Surveillance of Healthcare Associated Infection Programme (SSHAIP) within HPS.

Microbiological monitoring

Devices must be microbiologically monitored according to instructions from the manufacturer and according to *Legionella* spp advice from HSE.

In Scotland, the Scottish Mycobacterial Reference Laboratory (SMRL) is responsible for identifying positive mycobacterial cultures from the environmental samples (both air and water) from heater cooler units sent from Boards. Charging for this service is to be confirmed.

Managing legionella risk: Advice from the Health and Safety Executive

Duties under the Health and Safety at Work Act (HSWA) extend to risks from legionella arising from work activity, with legionella bacteria coming under the scope of the Control of Substances Hazardous to Health Regulations 2002. HSE has confirmed that NHS Boards are responsible for managing risks associated with these devices, as with any other known legionella risks in the healthcare environment. NHS Boards, in conjunction with the national IMT, must consider their duties under HSWA and undertake a local assessment of the risks associated with infections from these devices and consider HSE's Approved Code of Practice (L8): The control of legionella bacteria in water systems; and associated Legionella Technical Guidance HSG274.

NHS Boards should include *Legionella* spp testing in the management of HCUs. Legionella testing should be conducted once the enhanced cleaning and disinfection regimens are in place in order to most accurately assess the ongoing risk. Culture based methods are recommended and it is suggested that devices are tested in rotation in order to minimise operational impact. In accordance with [HSE guidance](#), any detection of legionella should be investigated and the appropriate actions taken. Immediate decontamination should be conducted according to the local procedure for the device. Providing the decontamination includes a process believed to be active against *Legionella* spp, the device may then be reinstated to service followed by repeat testing. The manufacturer should be contacted to determine whether any further control measures are available.

It should be noted that detection of *Legionella* spp may be difficult in devices with high total viable counts, and retesting may be required. Further advice can be obtained from the Scottish *Haemophilus*, *Legionella*, Meningococcus and Pneumococcus Reference Laboratory (SHLMPRL).

Legionella risk management in ECMO setting

In addition to the above, adjacent patients, staff, and visitors in the ECMO setting may be exposed to HCUs for longer periods. If HCUs required for ECMO are demonstrated to contain legionella, this should be investigated and the risk assessment should take into account the ECMO setting. HPS advice is that clinicians should consider testing adjacent patients for *Legionella* infection should they develop hospital acquired pneumonia. Testing should be by urinary antigen, and if negative and no other cause of pneumonia is identified, *L. pneumophila* PCR (or *Legionella* spp PCR if available) and culture should be performed on a lower respiratory specimen.

Legionella infection in healthcare staff

In the event of a Legionella infection in a healthcare worker exposed to HCUs, individuals will be promptly diagnosed and treated in conjunction with local occupational health teams.

Informing patients: required actions

Patients who are undergoing surgery on cardiopulmonary bypass

Patients who are considering surgery which will or may involve cardiopulmonary bypass must be informed of this small but known risk of *M.chimaera* infection. All consent should be informed by an understanding of the risks and benefits of any proposed intervention. The risk of not intervening should always be part of that process.

Over time the onus on deciding how much information to consider and who should decide on whether or not to proceed with the intervention has shifted from the doctor or health care provider to the patient. This cultural shift in society has been matched by regulation and legislation, [Montgomery](#) being the most recent high profile case.

It is now recognised that it is the patient taking the risk and who is the one therefore to decide how much information to receive and consider. Importantly, the impact of any specific risk and the associated weight a person places on it when making decisions about treatment will depend on the individual patient.

Consent is therefore an individualised process. This makes it challenging when designing consent documents and mandates supplementation of any generic form with:

- a) separate guidance for the surgeon and
- b) information sheets for the patient.

The benefit of such an approach is that it enables the supplementary guidance to change as understanding of the issue changes while keeping the generic consent form relatively constant, requiring less frequent updating.

In this specific instance the consideration is the bio-burden associated with cardiothoracic surgery. This includes, but is not limited to, transfusion transmissible disease, early prosthetic valve endocarditis due to endogenous or exogenous transmission of commensal flora and mycobacterial infection from contaminated water in HCUs.

While the overall risk of being affected by *M. chimaera* is low, the potential impact is high and a small number of deaths have resulted from this infection. Furthermore there is much that is unknown in relation to this organism and the means of contamination of the HCU. For these reasons the decision has been made that all patients being consented for surgery must be made aware of the risk.

Although the Patient Notification Exercise was a targeted exercise towards the patients at highest risk, all patients who are considering surgery which may involve cardiopulmonary bypass should be consented with respect to the risks of *M.chimaera* infection.

It has been agreed that a standard consent process should be implemented across Scotland.

Cardiothoracic surgical teams must therefore:

- advise patients of the contemporaneous knowledge of the risks associated with *M. chimaera*. The risk assessment will be regularly reviewed and updated by PHE in conjunction with health protection leads from each of the devolved nations.

This should include information regarding any known cases at that specific provider and where available a risk ratio. At the current time there have been no cases of *M. chimaera* infection associated with the use of heater cooler units during cardiothoracic surgery in Scotland. As such, the risk estimates provided earlier in this document should be used to support discussions.

This must be done with the provision of information sheets about their surgery. An example of such an information sheet is provided in Appendix A

At the time of discharge patients must also be provided with information regarding the symptoms of infection with *M. chimaera* and how to seek help, even if this is many years after the surgery. A suggested information leaflet for use at discharge is found in appendix B.

Reporting of cases of infection related to HCUs

Infection specialists should report to their local health protection team (HPT) and IPCT any cases of non tuberculous mycobacterial infection in patients who have had cardiothoracic surgery or ECMO, and also of any cases of other infections which are strongly believed to be linked to heater cooler units. The HPT will request information for a short case report form which should be submitted to HPS.

Any cases of Legionnaires' disease with an exposure to a heater cooler unit in the 14 days prior to onset should be reported as per normal procedure to the local health protection team. The local health protection team will complete the standard Legionnaires' disease surveillance form, noting the details of the heater-cooler exposure on the form. The national Legionnaires' disease surveillance team within HPS will collate this information.

Appendix A: Example patient information for use in consent discussion

The following is an example of patient information which centres may wish to use to assist in the consent process.

Why am I receiving this information?

You are considering, or have decided to have, surgery that will or may require the use of the heart lung bypass machine during your operation. Your surgical team will discuss the risks and benefits of your proposed surgery with you and your family. These are detailed in the consenting process which the surgical team will take you through.

This information sheet is to provide you with information, in line with the new NHS duty of candour, on the risk of infection associated with your planned surgery. A risk of infection with a bacteria called *Mycobacterium chimaera* has been identified in relation to heart and/or lung surgery. This is a very rare but potentially serious infection.

The risk of infection has been linked to a device used to heat and cool the blood during some types of heart surgery. All the cases identified in the world to date have been linked to devices produced by one manufacturer.

Tests on these heater/cooler units in Europe and the UK have revealed a growth of a type of bacteria commonly found in the environment, which does not frequently cause human infections. This bacteria is a non-tuberculous *Mycobacterium* species. It is not TB and is not passed on from person-to-person.

What is the risk of infection?

This risk is thought to be small. There have been no cases identified in Scotland. However, information from Public Health England indicates that approximately [*x in 10,000 – refer to current PHE national risk data*] patients having this type of surgery might be affected. This level of risk is so small that surgery should not be delayed, as the risks of delaying surgery are greater than proceeding.

What is NHS Scotland doing to reduce the risk of further infections?

Following the identification of this possible risk, hospitals that undertake heart surgery have put in place extra precautions to reduce the chances of *Mycobacterium* infection. It is possible there's still a very small risk though.

All cardiothoracic centres have now increased their cleaning and disinfection procedures for the heater cooler units and are testing their devices for evidence of growth of micro-organisms. No cases of the infection have been found in patients who have had open heart surgery since these measures were put in place.

There is no evidence that extra antibiotics during surgery, in most cases, will give any further protection. Your surgical team will discuss with you whether additional antibiotics would be required in your particular case

Will I get tested for this infection after my surgery?

The symptoms of this infection can take up to five years to appear. It is not possible to be tested to see if you will develop symptoms in the future.

It is therefore important that you are aware of the symptoms of a *Mycobacterium chimaera* infection and to see your GP if you develop any of these. Treatments for *Mycobacterium chimaera* infection are available.

What will happen after my operation?

Your recovery will be monitored as part of your routine care.

Further information on this infection will be given to you as part of your hospital discharge information.

If you have any further concerns or questions please speak to your consultant.

Further information is also available at:

<https://www.gov.uk/government/collections/mycobacterial-infections-associated-with-heater-cooler-units>

Appendix B: Example patient information for use as part of hospital discharge information

Why am I receiving this information?

Before your operation your medical team will have discussed the infection risks of the surgery. This will have included information about the very small risk of an infection with a bug called *Mycobacterium chimaera* (*M.chimaera*).

Investigations carried out across the UK have identified that a machine used to heat and cool the blood during some types of heart surgery has been linked to infection with *M. chimaera*. This is a very rare but potentially serious infection.

What is the risk of infection?

The risk of infection is very low. There have been no cases identified in Scotland. However, information from Public Health England indicates that approximately [*x in 10,000 – refer to current PHE national risk data*] patients having this type of surgery might be affected. This

level of risk is so small that surgery should not be delayed, as the risks of delaying surgery are greater than proceeding.

However, for patients who do develop infection, it can be slow to develop and difficult to diagnose. It is possible to develop symptoms years after surgery which is why it is important to be aware of what symptoms to look for.

Will I get tested for this infection now that I have had my surgery?

The symptoms of this infection can take up to five years to appear. It is not possible to be tested to see if you will develop symptoms in the future.

It is important that you are aware of the symptoms of a *Mycobacterium chimaera* infection and to see your GP if you develop any of these. Treatments for this infection are available.

What are the symptoms of *M. chimaera*?

Symptoms of an infection with this bacteria have many of the same features of other illnesses. Therefore, if you experience any of the following, while it is unlikely to be caused by this bacteria, it should be considered as a possibility that needs to be excluded when you are seen by your GP or other health care professional.

Symptoms to be aware of include:

- Unexplained fevers
- Unexplained weight loss
- Increasing shortness of breath
- Waking up with bed sheets showing signs of sweating (night sweats)
- Joint or muscular pain
- Nausea, vomiting or abdominal pain
- Abnormal levels of tiredness / fatigue
- Pain, redness, heat and / or pus around the surgical site.

There are many other causes for these symptoms so should you experience any of these there is no need to be alarmed – just report these to NHS 24/your General Practitioner.

Please note this infection cannot be spread from person-to-person.

What should I do if I have symptoms from the list you have provided?

If you feel unwell and have one or more of the symptoms listed above, please contact your GP. If you are diagnosed with the infection, treatments are available.

What about future heart surgery?

In the event that any further heart surgery may be recommended for you in the future, it is important to stress that the risks of infection from this bacteria are very low and much lower than the risks involved in not having appropriate surgical treatment.

What is the NHS in Scotland doing to reduce the risk of further infections?

The device used to heat and cool the blood is essential for some types of surgery. However, the risk of infection is very low and much lower than the risks involved in not having surgical treatment.

The low risk of infection is an issue that has affected this type of machine across the world and not just the UK. Following the identification of this possible risk, hospitals that undertake heart surgery have put in place extra precautions to reduce the chances of Mycobacterium infection. All cardiothoracic centres have now increased their cleaning and disinfection procedures for the heater cooler units and are testing their devices for evidence of growth of micro-organisms.

No cases of the infection have been found in patients who have had open heart surgery since these measures were put in place.

What should I do when I go home?

If you are well and have no symptoms you do not need to do anything specific as a result of this situation. However, you should be aware of the symptoms, particularly because the infection can take up to five years after surgery to appear.

Further information about this infection can be found on the NHS Inform website (<https://www.nhsinform.scot/campaigns/mycobacterium-chimaera>). There, you will find a video which explains all you need to know, as well as other relevant details.