



Public Health
England

Protecting and improving the nation's health

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

Information for healthcare providers in the UK

Version 2

A resource produced by Public Health England and partners

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health, and are a distinct delivery organisation with operational autonomy to advise and support government, local authorities and the NHS in a professionally independent manner.

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Summary

Evidence to date indicates that heater cooler units used in cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO) can generate potentially infectious aerosols containing a range of bacteria including *Mycobacterium chimaera*. NHS England and the Medicines and Healthcare products Regulatory Agency (MHRA) require providers to take all reasonable steps to mitigate risks associated with these devices, including explicit compliance with Health and Safety Executive (HSE) requirements and PHE or MHRA guidance.

The Care Quality Commission (CQC), as the lead enforcement body for healthcare in England, will expect to be provided with evidence that the following provider responsibilities have been addressed and embedded into practice. In Wales, Scotland and Northern Ireland, reporting and enforcement arrangements will differ. Refer to the local guidance published alongside this document for information.

This updated guidance includes a revised risk assessment and a new instruction for patient notification to facilitate early diagnosis of *M. chimaera* infection.

Providers 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 guidance presented here as required
3. Suitable cleaning and disinfection regimes are in use as directed by manufacturers or MHRA
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 below. 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 provider
7. Traceability of heater cooler units is ensured; the individual unit used for any surgery or ECMO should be recorded
8. Notification of heater cooler unit related issues are made to MHRA, NHS England or PHE as appropriate. This should include problems encountered in cleaning and disinfection (MHRA), patient harm (MHRA/NHS England), and new cases of *M. chimaera* infection (PHE). Refer to the local guidance published alongside this document for reporting instructions for Wales, Scotland and Northern Ireland
9. Patients are informed of the specific risk associated with these devices when they are consented for surgery

ALL providers of acute care should:

- 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
- ensure that they comply with the requirements for reporting of cases and heater cooler unit related issues. In England, this includes notifying PHE health protection teams of potential cases and MHRA of any concerns related to the heater cooler units. Refer to the local guidance published alongside this document for reporting instructions for Wales, Scotland and Northern Ireland

A retrospective notification of patients at highest risk of *M. chimaera* infection from exposure to heater cooler units should be undertaken. Providers will receive detailed information from NHS England and PHE in England, and from NHS leads and public health agencies in Wales, Scotland and Northern Ireland.

Introduction

During 2014-15, PHE were made aware of cases of *Mycobacterium chimaera* endocarditis or deep infection following cardiac surgery in Switzerland, Germany and The Netherlands^{1,2}. *M. chimaera* is a recently described species within the *Mycobacterium avium* complex, a group of environmental organisms usually associated with lung infections, or systemic infections in the immunocompromised host. A Swiss investigation implicated the Sorin (now LivaNova) 3T heater cooler unit (HCU) of the cardiopulmonary bypass equipment, with the transmission of bacteria to the surgical site by aerosolisation of contaminated water from within the unit¹. The LivaNova device is widely used in the UK and internationally. Maquet, another manufacturer of devices used in the UK, has also indicated that *M. chimaera* has been identified in its HCU water tanks and issued advice to manage any associated risk. Risk associated with HCUs from other manufacturers is currently unknown.

A national investigation was undertaken in 2015 indicating a low risk in patients undergoing valve replacement and repair and widespread contamination of devices in use in the UK³. Surveillance and microbiological investigations have been continuing since that time. A number of findings have triggered review of the UK response:

1. Increased case numbers: There are now 26 cases, 15 of whom have died, originating from 13 NHS trusts and 1 private provider. The risk is heterogeneous, and at the worst affected trust in the highest risk year, it has reached 1 in 100 patients undergoing cardiac valve surgery
2. Enlarged cohort at risk: As well as following valve surgery, cases are now recognised after coronary artery bypass graft (UK, US) and left ventricular assist device implantation (US) and transplant (US)⁴
3. Whole genome sequencing data: WGS of *M. chimaera* isolates from patients and devices in the UK, US and Europe demonstrates close relatedness between patient and device isolates, supporting the hypothesis of transmission from the HCUs and suggestive of a point source outbreak of mycobacteria within a wider potential risk of microbial transmission from this type of device
4. Diagnosis: The clinical manifestations of *M. chimaera* infection are diverse and the symptoms non-specific, often occurring many months or years after surgery. This has caused diagnostic difficulties and delays

Guidance

Responsibilities of NHS trusts

In view of the essential nature of HCU and the fact that it will take time to eliminate the risks associated with their use, MHRA, NHS England and the equivalent organisations in Wales, Scotland and Northern Ireland require providers to take all reasonable steps to mitigate these risks, regardless of the brand or model of HCU used. This includes explicit compliance with HSE, PHE and MHRA guidance, including:

- a full risk assessment that is reviewed at least annually and acted upon
- compliance with most recent manufacturer's instructions and/or MHRA guidance at all times
- a quality assurance programme with standard operating procedures that cover all stages and potential hazards in the use of the device, including water quality and appropriate use of water filters, refilling and draining of tanks and overflows, scheduled maintenance, replacement of consumables such as circulating tubing and water filters, and compatibility between the HCU (including its decontamination regime) and devices connected to it. Discussion with the manufacturer should take place if non-compatible components are to be used, as there may be device risks associated
- the management of this equipment to be on the same footing as that employed with endoscopy equipment, with a clear line of accountability, including staff training in cleaning, disinfection and decontamination. All processes should be routinely audited. Records of the piece of equipment used with particular patients and each device's microbiological record so that traceability is ensured in the event of a future infection
- processes to be in place to ensure that patients presenting with infection following exposure to HCUs are rapidly clinically and microbiologically investigated for mycobacterial infection
- compliance with reporting requirements. These are as follows for England, refer to the local guidance published alongside this document for reporting instructions for Wales, Scotland and Northern Ireland.

NHS England: routine reporting of any patient safety incident via local risk management system to the National Reporting and Learning System (NRLS). Any incident related to HCUs that meet the criteria of a serious incident are reported on the Strategic Executive Information System (STEIS), for example where patients suffer severe harm or death due to failure to adhere to guidance in this document.

MHRA: all providers with concerns relating to HCUs or their accessories should report these to the device manufacturer **and** to MHRA via the Yellow Card scheme (<https://www.gov.uk/report-problem-medicine-medical-device>)

PHE: investigate cases of non-tuberculous mycobacterial infection to identify cases potentially related to HCU exposure and report these and any other infection related to HCUs to health protection teams.

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 HCUs.

Providers will be notified separately of a stock take unity return as part of a fact finding exercise to enable NHS England and other stakeholders to assess service risk and take coordinated action to mitigate risk.

Commissioners and CQC, as the lead enforcement body for healthcare in England, will expect to be provided with evidence that the described provider responsibilities have been addressed and embedded into practice.

Risk assessments

Mycobacterial infections

Between 2007 and 2 November 2016, 26 probable cases of *M. chimaera* infection associated with cardiopulmonary bypass have been identified in the UK. Twenty-five of the cases identified are thought to have acquired their infection during surgery involving cardiac valve replacement or repair, sometimes as part of more complex surgery, the remaining single case having had coronary artery bypass graft surgery. From retrospective and prospective case finding beginning in 2007, the earliest cases identified were diagnosed in 2008 and the earliest implicated surgery was performed in 2007. One of the cases had their cardiac surgery in the private sector with 13 of 41 NHS cardiothoracic centres identifying at least one case to date; numbers of *M. chimaera* infection by cardiothoracic centres varied considerably. The median interval between surgery and diagnosis was 18 months but has been up to 5 years.

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.

There is a rising incidence rate from <0.2 before 2011 to 2 in 2014 per 10,000 person years of post-operative follow-up (assuming 5 years at risk after surgery). However, only one case operated on in 2015 has been diagnosed, and no case has been diagnosed who had had surgery since the introduction of the enhanced cleaning and disinfection regime. These patients may still developed symptoms at a later date, but this may provide an early indication that risk has already been reduced.

A fuller account of the investigation has been published³.

International context: Our estimate has a high degree of uncertainty since it is not standard practice in the UK to look for mycobacteria in cardiac or post-surgical infections. Risk estimates from The University Hospital of Zurich are around 1 per 500 cases and estimates from hospitals in the US where cases have been identified range from 1 per 100 to 1 per 1000^{5,6}. National data from these countries is not published. Their individual centre risks are similar to the risks seen in our centres with cases in the years with the highest risk (from 1 per 1000 to 1 per 100).

***M. chimaera* compared to other surgical infection risks:** The risk identified above is small compared to the background risk of infection recognised 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 of surgery. Literature suggests 3- 6% of patients develop a prosthetic valve infection within five years of valve replacement. As such, the additional elevation in risk is small.

Legionella

Legionella spp, including *Legionella pneumophila*, have been identified from HCUs by culture and PCR. These results indicate that these devices can be colonised by *Legionella* spp. There is a potential risk of exposure to legionella if staff are exposed to aerosols from the HCUs. It is anticipated that patients undergoing cardiothoracic surgery would be on closed-circuit ventilation during the operation of these units and so respiratory exposure would be unlikely. There is a theoretical risk of deposition of *Legionella* spp in the surgical field. In ECMO units, in addition to staff, adjacent patients on the same unit who are not on closed circuit ventilation may be exposed to potential aerosols.

PHE enhanced surveillance data (1 January 2007 to 1 November 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.

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. Centres should consider the microbiology results from the testing of their own HCUs, and rates and aetiologies of infection in their cardiothoracic surgical patients, in their local risk assessment.

Ongoing monitoring of SSI incidence through participation in the PHE Surgical Site Infection Surveillance Service should be considered as a means to monitor rates of infections following cardiac surgery.

Mitigation of risk

Cleaning and disinfection advice from MHRA

MHRA advised healthcare professionals through an MDA in June 2015 <https://www.gov.uk/drug-device-alerts/heater-cooler-devices-used-in-cardiac-surgery-risk-of-infection-with-mycobacterium-species>. The June 2015 MDA remains current. Additional operational management advice was issued in an MDA in December 2016 <https://www.gov.uk/drug-device-alerts/heater-cooler-devices-used-in-cardiac-surgery-risk-of-infection-with-mycobacterium-species-update>. This advice also reflects recommendations issued by LivaNova and Maquet. Providers should ensure that they are aware of the most current MHRA advice and Field Safety Notices from the relevant manufacturers.

If it is feasible to remove contaminated HCUs from service then that is optimal, however this may not be possible given service demands. Cleaning and disinfection must follow the manufacturer's advice and/or MHRA guidance, including Field Safety Notices.

Chemical disinfection may not fully disinfect devices with existing biofilms, however it is likely to reduce counts of organisms in circulating water and so temporarily reduce risk. Contact the relevant manufacturer for machines which are demonstrably contaminated as in some cases a mechanical decontamination process may be available. In the interest of reducing the likelihood of patient infection, an ongoing cleaning regime should be maintained, following manufacturer guidance.

Providers experiencing problems with recommended cleaning and disinfection regimes should report this promptly to the manufacturer and MHRA. There has been limited evidence of degradation of the coating of heat exchange coils in some units following the latest guidance on cleaning. In the face of the current overriding need to protect patients from infection and preserve cardiac services, any such degradation should be considered a secondary issue. Assessments made by the manufacturer have assessed the potential for serious adverse consequences from degradation as minimal. If devices exhibit signs of degradation, the user should advise the manufacturer and report the issue to MHRA.

Attention should also be paid to cleaning and/or replacing accessories, tubing and connectors to prevent recontamination or cross contamination between devices.

Microbiological monitoring

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

In England, PHE offers a laboratory service for water microbiology including mycobacteria and Legionella in water samples from HCUs. Contact your nearest PHE Food Water and Environment laboratory for more information. For Wales, Scotland and Northern Ireland, refer to the local guidance published alongside this document.

Positioning

Users should follow instructions from the relevant manufacturer, including Field Safety Notices, and should seek assistance from the manufacturer as required to effect changes. The basic principles are as follows:

If it is possible and safe to do so, position the HCU outside the theatre. This has been achieved in a number of European hospitals.

If not possible, review the positioning of the HCU within the theatre. In November 2016, LivaNova issued specific advice regarding positioning their 3T systems. In the Sorin (LivaNova) 3T device evaluated in a PHE laboratory, aerosol was detected outside the rear fan on the device. The HCU exhaust, thought to carry the majority of airborne microbes originating from the HCU, should be directed away from both the patient and exposed instruments and if possible towards the theatre air exhaust⁵.

The location of aerosol production, if any, from other makes and models of devices is currently unknown.

Use of ultraclean ventilated theatres

Ultraclean ventilation (UCV) systems are validated as resisting the ingress of particles as part of the theatre's commissioning procedure. However, there is evidence that the airflow from the HCU exhaust can compromise the effect of the UCV airflow pattern.⁷ There is current debate about the risks and benefits of ultraclean ventilation as a general measure for surgical site infection prevention and insufficient evidence to recommend using it for the prevention of heater cooler related infection.⁸

Delaying cardiothoracic surgery

Decisions regarding continuing or delaying cardiothoracic surgery must be made by the provider.

In most cases the risk from delaying cardiothoracic surgery is likely to outweigh the infection risk. The highest risk is associated with valve replacement or repair. The 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. If mitigating measures are currently being implemented, 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.

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.

Traceability of devices

The individual HCU used in a patient's surgery should be recorded so that the device can be traced in the event of a later infection. A record of microbiological test results and a log of cleaning and disinfection should also be kept for each individual device. There should be a clear management structure within the unit for managing this process.

Choice of devices

There is currently insufficient data to determine the potential risk associated with other makes and models of devices. *M. chimaera* has been detected in some of these devices and transmission risk cannot be excluded.

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 trusts are responsible for managing risks associated with these devices, as with any other known legionella risks in the healthcare environment. Trusts, in consultation with the Water Safety Group, 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.

Trusts 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 (<http://www.hse.gov.uk/pubns/priced/hsg274part2.pdf> - **Special considerations for healthcare premises**), 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. Contact the manufacturer 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. Contact your testing laboratory for further advice.

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. PHE 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) should be performed on a lower respiratory specimen.

Legionella infection in healthcare staff

Providers should work with their occupational health department to ensure that Legionella infection in healthcare staff exposed to HCUs will be promptly diagnosed and treated.

Informing patients: required actions

Patients with infection believed to be related to heater cooler units

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

Patients who have been exposed to risk of infection from heater cooler units in the past

Patients that are at the highest risk should be notified as part of a retrospective notification exercise. Providers will receive the timeframe for this exercise and other additional information from NHS England and PHE, or the relevant national services in the devolved administrations.

This notification is to enable patients to appropriately seek medical advice if they become unwell with symptoms associated with infection by this organism, and to alert healthcare workers to the need for the appropriate investigation when the patient presents. As the risk has now been well substantiated, this is also in keeping with the Duty of Candour.

The notification exercise will include patients who had valve replacement or repair surgery, including procedures undertaken as part of congenital heart disease repair, from January 2013 onwards. Centres that have used Sorin/LivaNova devices exclusively since Jan 2013 or used a mixture of devices including Sorin/LivaNova must undertake the notification. Centres that have **exclusively** used other HCU brands (such as Maquet) since January 2013 do not need to undertake notification. A list of the included procedures is provided alongside this guidance. Patients for whom the cardiopulmonary bypass equipment was kept on standby but not used during their surgery should also be included. Patients who had specific information about this risk included in their informed consent do not need a further notification.

Patients who have undergone heart/lung transplant, and patients who have had non valve related congenital heart disease repair, will usually have remained under routine follow up and appear to be at lower risk. They do not need notifying by letter, but information will be issued to the relevant clinical centres so that the centre can communicate with them directly as most appropriate, for example at their routine review.

A national helpline will be provided for patients who require further information.

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.

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. (www.supremecourt.uk/decided-cases/docs/UKSC_2013_judgement.pdf)

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, including lethal risks to the patient. 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.

In England, the generic NHS consent form will be amended to include the following paragraph (refer to local guidance published alongside this document for Wales, Scotland and Northern Ireland):

“All surgery carries a risk of infection. Some patients (such as those with reduced immunity due to their illness or as a side-effect of their treatment) and some types of operation carry a higher risk of such infection than others. In some instances an infection acquired during operation can have a serious impact on your quality of life or even lead to death. Your surgeon will inform you if your operation is associated with specific risks and / or you have a condition which makes you particularly susceptible.”

Additionally cardiothoracic surgical teams must:

- advise patients of the contemporaneous knowledge of the risks associated with *M. chimaera*. The risk assessment will be regularly reviewed and updated by PHE
- this should include information regarding any known cases at that specific provider and where available a risk ratio
- 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.

Advice on diagnosis and clinical management of *M. chimaera* or similar infections

In the first instance, clinical advice should be obtained from the local infection team. Infection teams requiring specialist advice in England should contact the nearest PHE National Mycobacterial Reference Service team (London or Birmingham):

National Mycobacterial Reference Service – South (London)

Tel 020 8327 6957

Email: eliza.alexander@phe.gov.uk; copying nmrl@phe.gov.uk

National Mycobacterial Reference Service – North and Central (Birmingham)

Tel 0121 424 3247 or 0121 424 2500

Email grace.smith@phe.gov.uk, copying esther.robinson@phe.gov.uk

Out of hours Tel 0121 424 2000 and request the duty microbiology or infectious diseases consultant

In Wales, Scotland or Northern Ireland, refer to the local guidance published alongside this document.

Reporting of cases of infection related to HCUs

The following arrangements cover cases identified in England. For arrangements for Wales, Scotland and Northern Ireland, please refer to the local guidance published alongside this document.

Infection specialists should report to their local health protection team (HPT) 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 HCUs. The HPT will request information for a short case report form which will be submitted to the Healthcare-Associated Infection and Antimicrobial Resistance department at PHE Colindale. Aggregate national information on cases and outcomes will be shared at <https://www.gov.uk/government/collections/mycobacterial-infections-associated-with-heater-cooler-units>

Any cases of Legionnaires' disease with an exposure to an HCU 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 in the "any other relevant information" field on page 2 of the form. The national Legionnaires' disease surveillance team 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 use to assist in the consent process. It was developed by an NHS trust.

Dear Patient

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. The surgical team will discuss the risks and benefits of your proposed surgery with you and your family and these are detailed in the consenting process

This information sheet is to provide you with new information, in line with the new NHS duty of candour, on the risk of infection associated with your planned surgery. Although the overall infection risk remains unchanged, all hospitals have been informed by Public Health England (PHE) of an infection risk associated with all heart and/or lung surgery that requires the use of a cardiopulmonary bypass machine.

This risk is thought to be small. Approximately [*x in 10,000 – use a centre specific risk or 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.

Further information:

- during heart (and some lung) operations the body is cooled and warmed by the heart lung machine (cardiopulmonary bypass machine). To do this the bypass machine is connected to a heater/cooler unit, which is kept in the operating theatre

Tests on these heater/cooler units in Europe and the UK have revealed a growth of a non-tuberculous *Mycobacterium* species (which is a type of bacteria that is common in the environment but does not frequently cause human infections), with the potential for growth of other organisms. There have been reports of a particular organism called *Mycobacterium chimaera* causing serious infections in a very small number of patients having operations on their heart valves, in some cases several years after the operation. In the UK a small number of such infections have been reported since 2007. Given that around 35,000 heart operations on bypass are performed each year of which approximately 15,000 have been heart valve operations, this represents a very small risk.

- all cardiothoracic centres have now increased their cleaning and disinfection procedures for HCUs used in all heart and lung surgery. All centres are testing their heater/cooler units for evidence of growth of micro-organisms
- 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

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

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

Further information is available at:

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

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