

PROVINCIAL LABORATORY SERVICES
COMMUNIQUÉ

<http://www.healthpei.ca/laboratoryservices>

TO: Island Physicians and Nurse Practitioners
FROM: Dr. Greg German, Medical Microbiologist and Infectious Diseases Consultant
DATE: January 31, 2017
RE: **Very low risk of *Mycobacterium chimaera* infection during open-heart surgery**

Health Canada and the CDC have reported that heater cooler units used in open heart surgeries have been linked to infection caused by an environmental mycobacterium. *Mycobacterium chimaera* is a NON-tuberculosis mycobacterium that has infected approximately 50 patients in Europe and so far 2 patients in Canada during the time of their open heart/chest surgery. Time from exposure to symptoms is prolonged (3 months to 5 years; median 18 months) and only devices used after 2011 are implicated. Heater-cooler devices are required for bypass / perfusion during these procedures and the internal water circuit has been found to be contaminated in some machines, leading to exhaust airflow that could potentially infect the patient. The attack rate is uncommon to rare (between 1 in 100 to 1 in 10,000 surgeries). Steps have been taken to limit future risk, and infected patients cannot spread the organism to others.

Dr. Dorran and I are in contact with our regional partners. Patient notification occurred for those Islanders that went to Nova Scotia for their procedure (18 paediatric patients and 296 adult patients). New Brunswick (Saint John Regional Hospital) has decided to focus on alerting all clinicians in New Brunswick rather having a special letter sent to exposed patients that include 210 Islanders. Copies of these letters and additional accessory information will be provided on the Health PEI Microbiology website including off-island contact information. (www.healthpei.ca/micro). I serve as the provincial contact for suspected cases.

Only symptomatic patients should be tested for *M. chimaera* for which recent interim Canadian guidelines are summarized below. Please note that 3 or more weeks of constitutional symptoms are typically required to be considered significant to warrant special testing:

- Constitutional: Fevers, fatigue, dyspnea, weight loss, night sweats, & failure to thrive (infants)**
- Cardiac: (endocarditis / vascular graft infection),**
- Extracardiac: osteomyelitis (sternal, etc), mediastinitis, hepatitis, bacteremia, ocular...**
- Ocular: 50% of cases: panuveitits, multiflocal chorioiditis, and chorioretinitis**
- Immunologic/embolic: Splenomegaly (80% of cases), cytopenia, and sarcoid-like conditions**

Mycobacterium chimaera infections like other mycobacteria infections will not respond to many first line antibiotics. There is an importance on sending tissue for mycobacterial culture and blood using special mycobacteria/fungal blood culture bottles (two cultures separated by at least 12 hours). Please indicate query *M. chimaera* on the request form and list symptoms. Please contact me if you have further questions or concerns; I am also available for laboratory and/ or infectious diseases telephone, inpatient, or outpatient consultations (fax: 620-0483)



November 22, 2016

Dear Sir or Madam,

Nova Scotia Health Authority (NSHA) is contacting patients who have had heart surgery since January 2012 about a potential, but low risk related to their surgery.

A device used to heat and cool the blood during heart surgery has been linked to a rare bacterial infection caused by *Mycobacterium chimaera*, a type of bacteria known as non-tuberculous mycobacteria (NTM). This bacteria may have been present in the machines during manufacturing and there is potential for bacteria-contaminated water contained in the device to be transferred via aerosolization (through the air) in the operating room. The chances of getting this infection are very low (estimated to be less than one per cent).

Many hospitals across the country, as well as in the United States and Europe, use this equipment during heart surgeries and are experiencing the same concerns. We are not aware of any patients who have developed this infection following heart surgery at the QEII Health Sciences Centre. These devices first came into use at the QEII in January 2012. NSHA has followed all recommendations made by the manufacturer and Health Canada.

NTM organisms are commonly found in the environment, from sources such as water and soil. They are typically not harmful to people exposed to them and rarely cause complications. Most types of NTM that are associated with heater-cooler infections are slow-growing and it can take several months or even years for evidence of an infection to develop.

Symptoms of this infection may include the following: unexplained fever; pain, redness, warmth or pus around a surgical incision; night sweats; joint pain; muscle pain; weight loss; and fatigue.

We understand you and your family may have questions or concerns. Please discuss any symptoms or associated questions you may have with your family doctor and share this letter with your doctor.

You may also call NSHA's toll-free line at 1-844-874-0122. You will be asked to leave your name and phone number and someone will return your call. Additional information is also available on NSHA's website at www.nshealth.ca

Sincerely,

A handwritten signature in black ink, appearing to read "Greg Hirsch", is written over a white background.

Greg Hirsch, BA, MD, FRCSC

Head, Division of Cardiac Surgery, Queen Elizabeth II Health Sciences Centre



November 22, 2016

Dear Physician Colleagues:

We are writing to provide you with information regarding Nova Scotia Health Authority's (NSHA) decision to notify potentially impacted patients and their healthcare providers of recent findings from [Health Canada](#) and the [Centers for Disease Control and Prevention](#) (CDC) in the United States, regarding patients who have undergone open-chest cardiac surgery.

Heater-cooler devices, used in conjunction with the heart/lung bypass machine during open-chest cardiac surgery procedures, have been linked to a rare bacterial infection caused by *Mycobacterium chimaera*, a non-tuberculosis mycobacteria (NTM). According to Health Canada, this type of mycobacterium was isolated from heater-cooler devices used in some hospitals and in the manufacturing process. In the Nova Scotia Health Authority context, these Stockert 3T heater-coolers are used during open-chest cardiac surgeries performed at the Queen Elizabeth II Health Sciences Centre.

These organisms are slow growing and infections have been diagnosed between several months to several years after surgery. The CDC estimates that in hospitals where at least one infection has been identified, the risk of a patient getting an infection from the bacteria was between about 1 in 100 and 1 in 1,000.

Symptoms of NTM can be vague initially and include: persistent night sweats, weight loss, unexplained fever, fatigue, joint pain and muscle aches. Patients with suspected NTM infections following open-chest cardiac surgery have presented with a variety of clinical manifestations (e.g. endocarditis, surgical site infection, or abscesses and bacteremia).

There is no screening test to see if a patient has been exposed. When seeing patients with possible NTM infections and a history of cardiac surgery, clinicians should contact the patient's cardiac surgeon and consider consultation with an Infectious Diseases physician. The risk of infection is low and the benefit of cardiac surgery outweighs any possible infection transmission. Therefore, we do not recommend cancelling surgery due to this risk. We do not know of any cases of infection from surgeries done at NSHA to date. NSHA has followed all recommendations made by the manufacturer and Health Canada.

Patients who have had open-chest cardiac surgery requiring bypass since 2012 are being notified by letter. Patients who have had a qualifying procedure are being asked to contact their family physician for any symptoms or associated questions or call NSHA's toll-free line at 1-844-874-0122 for questions or concerns. Additional information is also available on NSHA's website at www.nshealth.ca.



Sincerely,

Greg Hirsch, BA, MD, FRCSC

Head, Division of Cardiac Surgery, Queen Elizabeth II Health Sciences Centre

Cardiac Surgery – Information Regarding Potential Infection Risk Following Open Heart Surgery

Recently, you may have heard about issues with a device commonly used in open heart surgeries in Canada, the US and Europe. This device, which is used to heat and cool blood during surgery, has been linked to a rare infection caused by a type of bacteria called Mycobacterium Chimaera.

The chances of getting this infection are so low (less than one percent) that, normally, it would not be necessary to advise you about it prior to surgery. However, because of the attention raised about this risk in recent weeks, we want to ensure our patients feel informed about and have the opportunity to ask questions prior to surgery.

Symptoms of infection may appear several months or years after surgery and may include: night sweats; muscle aches; weight loss; fatigue; unexplained fever; and redness, heat, or pus around the cut in your chest (sternal surgical incision). Following your discharge from hospital after surgery, if you experience these symptoms for more than a week, please contact your family physician; if you experience severe symptoms, please seek medical attention immediately.

We have implemented several strategies to mitigate the risk associated with this bacteria, including compliance with safety measures recommended by Health Canada and the manufacturer, and communicating with health care providers and patients to increase awareness of this risk.

New Brunswick Heart Centre

Centre cardiaque du Nouveau-Brunswick
PO/CP Box 2100
Saint John, NB
E2L 4L2

November 14th, 2016

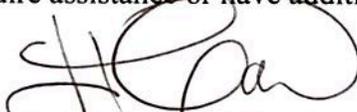
Dear Colleagues :

The New Brunswick Heart Centre and Horizon Health Network are notifying providers of recent findings from the Centers for Disease Control (CDC) and Health Canada, regarding patients who have undergone open-heart cardiac surgery.

Briefly, heater-cooler devices used in conjunction with the heart/lung bypass machine during open-chest cardiac surgery procedures, have been linked to a rare bacterial infection caused by Mycobacterium chimaera, a nontuberculosis mycobacteria (NTM) from the MAI family. Investigations into clusters of infections linked to exposures to LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stockert 3T heater-cooler devices during open-chest cardiac surgery have determined these devices were likely contaminated with M. chimaera during the manufacturing process. The New Brunswick Heart Centre uses these machines during bypass surgeries. This contamination problem is likely not exclusive to the "Sorin" heater cooler.

To date some infections related to Chimera have been reported in Europe, United States and in Canada (2 patients). The perceived risk of infection is low with estimation being between 1:100 to 1:1000 but difficult to ascertain given the rarity of the infection. Patients with suspected NTM infections following open-chest cardiac surgery have presented with a variety of clinical manifestations and often many months to years after surgery. At highest risk are patients who had a foreign body implanted as part of their surgery such as a valve procedure or an aortic graft. These organisms are slow growing and infections will be quite indolent. Some of the infections have been diagnosed up to 3.6 years after surgery. Symptoms of NTM can be vague initially and include: night sweats, weight loss, unexplained fever, fatigue, joint pain and muscle aches. There is no screening test to see if a patient has been exposed. Testing should only be done in symptomatic patients

The risk of infection is low and the benefit of cardiac surgery outweighs any possible infection transmission. Therefore, we do not recommend cancelling surgery due to this risk. We do not know of any cases at The New Brunswick Heart Centre to date. We have been proactive on this issue with our local team, are following current Health Canada recommendations and keeping an eye on National consensus on this issue. At this time we do not believe it is in patients best interest to be notified largely because of the paucity of information. Should you require assistance or have additional concerns please contact the New Brunswick Heart Centre at 506-648-6102.



Dr Jean-Francois Legare
Clinical Head, Department of Cardiac Surgery



Dr Vernon Paddock
Medical Director New Brunswick Heart Centre

November 18, 2016

Frequently Asked Questions

Nontuberculous mycobacteria infections associated with heater-cooler devices

Health Canada and the U.S. Centers for Disease Control and Prevention (CDC) have alerted hospitals, including the IWK, that a device used to heat and cool the blood during heart surgery, known as a heater-cooler, has been linked to a rare bacterial infection caused by *Mycobacterium chimaera*, a type of bacteria known as nontuberculous mycobacteria (NTM). The bacteria may have been present in the machines during manufacturing.

NTM are commonly found in the environment, from sources such as water and soil. They are typically not harmful to persons exposed to them, but in rare cases, NTM organisms may cause infection, particularly those with compromised immune systems, chronic diseases or biomedical devices such as a heart valve.

How are heater-cooler devices associated with infection?

Heater-cooler devices are used during heart surgery to warm or cool a patient. While the water used in this machine is not in direct contact with the patient's body or body fluids, contaminated water droplets from the tank may transmit bacteria through the air (aerosolize) and land in the operating room environment.

Does the IWK use these machines?

Yes. Like most hospitals in North America and Europe, the IWK uses heater-cooler devices and is aware of the Health Canada alert.

What is the IWK doing about this issue?

Health Canada recommends that health-care providers and facilities using heater-cooler devices implement specific measures to reduce risk of infection to patients. The IWK is following these recommendations and implementing all preventative measures recommended by national agencies, such as enhanced cleaning and disinfection. We are also working with various agencies and equipment suppliers to explore longer-term solutions to this issue.

My child had heart surgery at the IWK a few years ago. When did the IWK begin using this model?

The IWK began using this type of heater-cooler device in November 2010.

What is the risk of infection?

The risk of NTM infection is very low. It is estimated that 1 in 100 to 1 in 1000 cardiac surgery patients may get NTM infection according to the CDC.

Why not stop using the machines?

Heater-cooler devices are important in patient care. In most cases, the benefits of performing the surgery with temperature control during surgery outweigh the small risk of infection associated with these devices.

Are there any confirmed NTM cases linked to the IWK?

No. We have no known cases at the IWK to date linked to heater-cooler devices.

Can the machines be tested to see if they are contaminated?

Methods for sampling and microbiological testing of heater-cooler devices for NTM are neither reliable nor timely. Therefore, negative test results do not necessarily indicate that devices are not presently contaminated or that they have not been contaminated in the past.

If my child has been exposed to NTM during heart surgery, what are the chances they have been or will get infected?

While the risk of infection after surgery is thought to be very low, NTM infections can occur. Although the risk is very low, if you are concerned that your child had cardiac surgery at the IWK since 2010 and is unwell, please contact 1-555-495-2273 (IWK CARE) or the Halifax local number at (902) 470-7435. Alternatively, you can send an email to feedback@iwk.nshealth.ca

What types of infections have been reported in other organizations?

Infections after surgery have been reported and include heart infections, wound infections, chest infections and bloodstream infections.

What are the symptoms of NTM infections?

Most NTM bacteria grow slowly, so it can take several months or even years for symptoms of an infection to develop.

Symptoms associated with the NTM infection linked to the heater-cooler device may include any of the following: prolonged, unexplained fever; night sweats; unexplained weight loss or failure to thrive in infants; and chest pain.

NTMs may also be a cause of surgical site infections not responsive to usual antibiotic therapy. Signs of surgical site infection include pain, redness, heat or pus around a surgical incision. If your child has any of these symptoms you should seek medical attention.

Non-specific signs and symptoms include nausea, vomiting, muscle/joint pains and fatigue. These are common signs and symptoms experienced by children and are likely due to common childhood illnesses.

What should I do if my child is experiencing symptoms?

Contact your health-care provider if your child is experiencing symptoms and inform them that your child had heart surgery and you received information from the hospital about nontuberculous mycobacteria (NTM). Physicians will follow their usual routine to rule out the most common causes of fever or other symptoms in children. Your local care provider can refer your child for evaluation prior to referral for testing for NTM.

Can NTM infection be treated?

NTM infections can be treated with combinations of specific antibiotics. Most patients who are infected need prolonged treatment (from months to years). Additionally, although rare, some patients who develop NTM infections after having heart surgery may require additional surgery.

Should everyone who was exposed to these devices be tested for this bacteria just in case?

No, testing for this type of bacteria is not recommended when there are no signs or symptoms of infection present. Symptoms associated with this type of infection may include a combination of the following: prolonged, unexplained fever; night sweats; unexplained weight loss or failure to thrive in infants; a surgical wound that does not heal; and chest pain. If your child has any signs and symptoms for infection you should seek medical attention.

Should everyone who was exposed to these devices receive antibiotics just in case?

The risk that patients will develop an infection following exposure to a contaminated heater-cooler unit is extremely low. Although antibiotics can be life-saving drugs, preventative antibiotics are currently not recommended.

Can I become infected through contact with someone who is infected with NTM?

No. This type of NTM infection is not spread from person-to-person.

For updates to this FAQ please visit www.iwk.nshealth.ca



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November 18, 2016

Dear Patient/Family,

The IWK Health Centre is notifying patients who had open heart surgery with cardio-pulmonary bypass, about a potential infection risk related to their surgery. We are contacting you today because your child has been identified in our clinical records as a patient who had this type of heart surgery and therefore might be affected.

A device used to heat and cool the blood during heart surgery has been linked to a rare bacterial infection caused by *Mycobacterium chimaera*, a type of bacteria known as nontuberculous mycobacteria (NTM). The bacteria may have been present in the machines during manufacturing and there is potential for bacteria-contaminated water contained in the device to be transferred via aerosolization (through the air) in the operating room environment. The chances of getting this infection are extremely low. The American Centers for Disease Control and Prevention (CDC) estimates the risk to be less than one percent. We are not aware of any patients who have developed this infection following heart surgery at the IWK. Many hospitals across the country, as well as the United States and Europe, use this equipment during heart surgeries and are also contacting patients who might have been exposed to this machine. Investigations are continuing into the cause of these infections and Health Canada and the CDC are providing advice to hospitals on an ongoing basis. NTM organisms are commonly found in the environment, from sources such as water and soil. They are typically not harmful to persons exposed to them and rarely cause complications. Most types of NTM that are associated with heater-cooler infections are slow-growing and it can take several months or even years for evidence of an infection to develop.

Features of this infection may include the following: unexplained fever; pain, redness, warmth or pus around surgical incision; night sweats; joint pain; muscle pain, weight loss; and fatigue; as well as failure to thrive in infants.

.../2

We would like to suggest the following actions on your part:

- 1) If your child is experiencing these symptoms, contact your health-care provider. Your health-care provider can contact the Children's Heart Centre. Please bring this letter to your health care provider.
- 2) If your child is well, but you do have questions, please contact our toll free Feedback line at 1-855-495-2273 (IWK CARE) or the Halifax local number at 902-470-7435. You will be asked to leave your name and phone number and someone will return your call within 48 hours. Alternatively, you can send an email to feedback@iwk.nshealth.ca

To assist in answering additional questions you may have, we have enclosed a "Frequently Asked Questions" sheet.

Sincerely,



Dr. David Horne, MBChB, DCH, FRCS(C)
Congenital Cardiovascular Surgeon
Children's Health Centre, IWK Health Centre



Joanne M Langley MD, MSc, FRCPC
Professor of Pediatrics and Community Health and Epidemiology, Dalhousie University
Active Medical Staff, Pediatric Infectious Diseases, IWK Health Centre
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Interim laboratory testing guidelines for the detection of non-tuberculous Mycobacterium (NTM) infections in post-operative patients exposed to heater-cooler units

Antonation K (Federal Co-Chair)¹, Patel S (Provincial Co-Chair)², Trumble Waddell J¹, Guillaume Poliquin P¹, Alexander DC³, Hoang L⁴, Farrell D⁵, Garceau R⁶, Haldane D⁷, Jamieson F², Marchand R⁸, MacKeen A⁹, Marcino D⁹, Theriault S¹, Tyrrell GJ¹⁰, Zahariadis G¹¹, Zelyas N¹⁰ on behalf of the Canadian Public Health Laboratory Network

Abstract

The advice contained in this document should be read in conjunction with relevant federal, provincial, territorial and local legislation, regulations, and policies. Recommended measures should not be regarded as rigid standards, but principles and recommendations to inform the development of guidance.

This advice is based on currently available scientific evidence and adopts a precautionary approach where the evidence is lacking or inconclusive. It was approved for publication on December 5, 2016. It is subject to review and change as new information becomes available.

The main changes to this version include additions to: Case load reported to date, Sarcoidosis-like disease as an Indicator, Whole Genome Sequencing effort, links to Provincial and Territorial Lab Services and Health Canada reporting.

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Scope

This document outlines laboratory testing criteria and specimens to be collected for symptomatic persons with history of exposure to heater-cooler units during cardiothoracic heart surgery performed from November 1st, 2011 onward.

Background

A recent outbreak of *Mycobacterium chimaera* has been detected globally in patients who have undergone cardiothoracic heart surgery while in the presence of contaminated heater-cooler units. At this point in time, 52 cases of non-tuberculosis Mycobacterium (NTM) have been detected in Europe, and 2 within Canada (11).

There are many areas of uncertainty with respect to: 1) the magnitude and factors affecting infection risk, 2) clinical presentations of disease and 3) ideal management of devices.



At this time the risk to patients is thought to be low as evidenced by small number of cases reported globally. Risk estimates will be supplied as more information becomes available.

The Canadian Public Health Laboratory Network and its partners are working to support the laboratory response through the production of these *interim* recommendations.

This guidance document will focus on 1) defining patients at risk to establish criteria for testing and 2) recommendations related to the sample collection and testing for detection of *M. chimaera* in patients.

Clinical presentations* associated with post-operative non-tuberculous *Mycobacterium* infection

The majority of patients present three months to five years (median 18 months) after the index surgery, with symptoms of fever, fatigue, shortness of breath, night sweats, joint or muscle pain and unexplained weight loss (1,3,7). Cardiac manifestations include prosthetic valve endocarditis (PVE), prosthetic vascular graft infection (PVG), paravalvular abscess, and pseudo and mycotic aneurysms (7,10). Extracardiac manifestations include bone infection (osteomyelitis, spondylodiscitis), sternotomy wound infection, mediastinitis, hepatitis, and bloodstream infection (BSI) (3,7,10). Ocular manifestations due to emboli (panuveitis, multifocal chorioiditis, chorioretinitis) are observed in approximately 50% of patients (3). Immunologic manifestations include arthritis, cerebral vasculitis, pneumonitis, myocarditis, granulomatous nephritis (7,10). Splenomegaly is observed in approximately 80% of cases (3) as well as bone marrow involvement with cytopenia. Recent recommendations have raised awareness for granulomatous diseases, particularly those that resemble sarcoidosis (11). There have been case reports of *M. chimaera* patients who were initially diagnosed with sarcoidosis.

Patient testing criteria

Criteria 1: Risk exposure

Patients must have had cardiothoracic surgery in the past. Due to the prolonged incubation time, patients who have had surgery from November of 2011 onward would be considered to meet this criterion.

Caveat: Some isolated reports involve patients without cardiothoracic surgery, but in a room with an active heater-cooler unit on standby. While these patients are not routinely felt to be at risk, such patients could be considered for NTM testing if a compatible clinical syndrome was present (see below).

* Prior presentations: Published literature from Germany (5 cases)², Switzerland (6 cases)¹ and the United Kingdom (17 cases)⁹ demonstrate that the majority of patients presented with endocarditis, paravalvular abscess, site infection or bacteremia associated with artery bypass graft, valve replacement or repair. Common accompanying signs and symptoms were fatigue, fever, hepatitis, renal insufficiency, splenomegaly and pancytopenia.

Criteria 2: Compatible clinical syndrome

Overall patients tend to present with non-specific symptoms, making the distinction of NTM infection from other, more common causes of these symptoms difficult. To that end, a compatible syndrome is defined as presence of:

- **Constitutional:** recurrent or prolonged fever, fatigue, shortness of breath, weight loss, night sweats, joint or muscle pain
- **Cardiac:** prosthetic valve endocarditis and/or prosthetic vascular graft infection
- **Extracardiac:** bone infection, sternotomy surgical wound infection, mediastinitis, hepatitis, bloodstream infection, ocular infection (panuveitis, multifocal chorioiditis, chorioretinitis)
- **Immunologic/embolic:** splenomegaly, cytopenia
- **Infants:** febrile episodes and failure to thrive

Symptoms must have either: 1) appeared post-surgery or, 2) if present prior to surgery, must have significantly worsened following surgery AND symptoms should have been present \geq three weeks. Persistence of these non-specific symptoms beyond three weeks helps to eliminate other infections that generally are diagnosed or resolved within that time span. In the absence of a diagnosis (both infectious and non-infectious) patients with unexplained symptoms should be investigated for possible *M. chimaera* infection.

Important testing considerations

- Asymptomatic individuals who have undergone cardiothoracic surgery should not undergo testing for *M. chimaera*, based on current evidence.
- It may be impractical to wait ≥ 3 weeks, either due to severe illness or when patient follow-up will be complex due to frailty or geographic access. Under these exceptional circumstances, one can consider proceeding to NTM testing without waiting.

Specimens

The following specimens should be submitted for mycobacterial cultures from eligible patients, as identified by the testing recommendations:

Clinical samples from sterile sites (**Table 1**), such as, but not restricted to, blood, purulent drainage, or fresh tissue should be sent for mycobacterial culture and acid fast bacilli (AFB) smear with accompanying requisition (**Appendix 1**: Links to local laboratory services). Please note, *M. chimaera* is a slow growing organism and detection through culture can take up to 6-8 weeks incubation. If it is early in the infection, *M. chimaera* may not be detected.

Positive cultures identified as *M. avium-intracellulare* complex microorganisms must be sent forward to a [reference laboratory for 16S](#) (or alternative such as hsp65/ITS) gene sequencing to confirm as *Mycobacterium chimaera* species at <https://cnphi.canada.ca/gts/reference-diagnostic-test/5054?labId=1004>. Sending pure culture on solid or in a liquid (minimum 4mL) medium is optimal for the reference laboratory.

Isolates potentially tied to this outbreak are currently undergoing whole genome sequencing as part of a national collaborative effort. Results are pending.



Table 1: Clinical testing for identifying potential cases of non-tuberculous *Mycobacterium* (NTM) following cardiac surgery

Clinical symptoms/ exposure	Specimen and testing recommendations
Asymptomatic AND Cardiothoracic surgery after Nov 1, 2011	None
Symptomatic¹ <ul style="list-style-type: none"> Constitutional: recurrent or prolonged fever, fatigue, shortness of breath, weight loss, night sweats Cardiac: prosthetic valve endocarditis and/or prosthetic vascular graft infection Extracardiac: bone infection, sternotomy surgical wound infection, mediastinitis, hepatitis, bloodstream infection, ocular infection (panuveitis, multifocal chorioiditis, chorioretinitis) Immunologic/embolic: splenomegaly, cytopenia Infants: febrile episodes and failure to thrive AND <ul style="list-style-type: none"> Open-chest surgery 3 months to 5 years prior to illness onset 	<ul style="list-style-type: none"> Blood: Request mycobacterial blood culture at local, commercial or reference laboratory as available (Appendix 1) <ul style="list-style-type: none"> Specific incremental yield of multiple blood cultures is not known at present. A set of 2 cultures collected 12 hours apart is a reasonable option with more specific recommendations to follow as data becomes available. NTM isolation from a sterile site is highly likely to be clinically significant (12) Tissue (including bone), and fluid: Request mycobacterial culture and acid fast staining at local, commercial or reference laboratory as available <ul style="list-style-type: none"> Aseptically collect and submit in sterile container without fixative Submit to laboratory with appropriate requisition indicating patient history Refer culture to reference laboratory as necessary for species level discrimination

¹ Symptomatic is defined as: Investigation of NTM infection in patients with prolonged illness (≥3 weeks) AND absence of alternative diagnosis through routine investigation to eliminate common etiologic agents

Testing of heater-cooler units and surrounding environment

The authority to advise on the testing of heater-cooler units resides with [Health Canada](http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2016/60662a-eng.php#issue-problem) (<http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2016/60662a-eng.php#issue-problem>).

Reporting of adverse events from medical devices

Health Canada encourages healthcare professionals to report any cases of patient infection thought to be associated with the use of devices. The [Medical Devices Problem Report Form and Guidelines](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/index-eng.php) (<http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/index-eng.php>) can be found on the Health Canada Web site.

Acknowledgements

The authors would like to acknowledge members of the Public Health Agency of Canada's Infection Prevention and Control Expert Working Group for their advice and contribution to the development of these interim laboratory testing guidelines.

In addition, the authors would like to thank Kathleen Dunn from the Public Health Agency of Canada for her contribution to this work.

Conflicts of interest

None

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- Infections associated with heater cooler units used in cardiopulmonary bypass and ECMO – information for healthcare providers in England. Version 1. – October 2015.
- EU protocol for case detection, laboratory diagnosis and environmental testing of *Mycobacterium chimaera* infections potentially associated with heater-cooler units: case definition and environmental testing methodology – August 2015.
- European Centre for Disease Prevention and Control. Invasive cardiovascular infection by *Mycobacterium chimaera* associated with 3T heater-cooler system used during open-heart surgery – 18 November 2016. Stockholm: ECDC; 2016.
- Griffith DE et al. An official ATS/IDSA statement: diagnosis, treatment and prevention of nontuberculous mycobacterial diseases. *Am J Respir Crit Care Med*. 2007 Feb 15;175(4):367-416.



Appendix 1: Link to provincial laboratory services

	Link to Laboratory Services	Laboratory Contact(s)
British Columbia	http://www.bccdc.ca/health-professionals/professional-resources/laboratory-services	mel.krajden@bccdc.ca
		mabel.rodrigues@bccdc.ca
Alberta	http://www.provlab.ab.ca/guide-to-services.pdf	greg.tyrrell@albertahealthservices.ca
		cary.shandro@albertahealthservices.ca
Saskatchewan	http://sdcl-testviewer.ehealthsask.ca/	paul.levett@health.gov.sk.ca
		dfarrell@health.gov.sk.ca
Manitoba	http://dsmanitoba.ca/	arendina@dsmanitoba.ca
		dswidinsky@dsmanitoba.ca
Ontario	http://www.publichealthontario.ca/en/ServicesAndTools/LaboratoryServices/Pages/Index.aspx	frances.jamieson@oahpp.ca
		kevin.may@oahpp.ca
Quebec	https://www.inspq.qc.ca/lspq/repertoire-des-analyses	hafid.soualhine@inspq.qc.ca
Newfoundland	www.publichealthlab.ca	kessica.kafka@easternhealth.ca
		robert.needle@easternhealth.ca
Nova Scotia	http://www.cdha.nshealth.ca/pathology-laboratory-medicine/laboratory-client-support-center	david.haldane@nshealth.ca
		darlene.mcphee@nshealth.ca
New Brunswick		hope.mackenzie@HorizonNB.ca
		janet.reid@HorizonNB.ca
Northwest Territories		caroline_newberry@gov.nt.ca
Nunavut		smarchand@gov.nu.ca