



# An Update on *Mycobacterium Chimaera* and Cardiac Surgery Infections Due to Contaminated Sorin 3T Heater-Cooler Units

HOT TOPIC / 2018

HOT TOPIC / An Update on *Mycobacterium Chimaera* and Cardiac Surgery Infections



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## Disclosures

- None

## Utilization Message

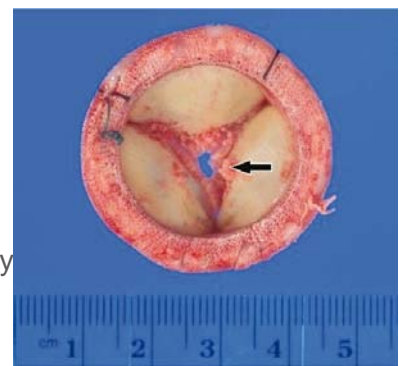
- As you view this presentation, consider the following important points regarding testing:
  - How is the test going to be used in your practice?
  - When should the tests be used?
  - How will results impact patient management?

## Objectives

- Discuss the global outbreak of *M. chimaera* infections following cardiac surgery
- Describe current knowledge about the heater-cooler units implicated as the cause of the outbreak
- Examine laboratory diagnostics for identification for detection, identification and susceptibility testing of *M. chimaera*

## First Report of Cases<sup>1</sup>

- In 2015, a group from Zurich, Switzerland reported a series of cases involving 6 patients with prosthetic valve endocarditis or vascular graft infections due to *Mycobacterium chimaera*
- First case dated back to surgery performed in 2012; reported latency of infection was 1.5 -3.6 years after surgery
- *M. chimaera* was cultured from blood, cardiac tissue and other surgical specimens for all cases
- *M. chimaera* was also cultured from heater-cooler units used for cardiac bypass during surgery and from air samples in the surgical suite



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Sattar A, Yu S, Koirala J - *Infect Dis Rep* (2015)

## A Global Outbreak

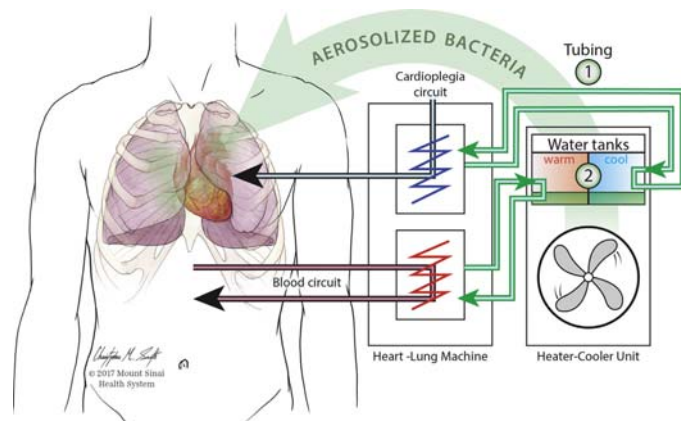
- Since the first report, >100 cases of *M. chimaera* infection have been reported in Europe, the United States and Australia
- All cases are reported from patients who have previously undergone cardiothoracic surgery
- Cases involve the use of Sorin 3T heater-cooler units (HCU); also known as the LivaNova Stockert 3T HCU, manufactured in Germany
- >250,000 cardiothoracic surgical procedures annually in the United States alone raising concern that the cases detected so far are only the beginning a larger problem



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## What is a Heater-Cooler Unit and How is it Used in Cardiac Surgery?

- Used during major heart surgery when a heart-lung bypass machine is needed
- No direct contact with the patient but it contains 2 water tanks and tubing that through indirect thermal transfer are used to warm the blood and cool the cardioplegia solution used to slow/stop the heart



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## Outbreak Investigation

- NTMs are environmental organisms frequently found in soil and water sources;
- NTMs are responsible for numerous reports of device-associated and post-surgical infections and outbreaks; found in hospital and household water sources; often resistant to disinfection.
- *M. chimaera* has been found in water from Sorin 3T HCUs used in cardiac surgeries around the world.
- *M. chimaera* isolates have been recovered from new, unused Sorin 3T HCUs and from water samples at the manufacturing site implicating the manufacturing site as the source of the microbial contamination.
- Sorin 3T HCUs account for approximately 60% of HCU units used in cardiac surgery in the U.S.

## What Happened?

### Smoke Testing of Airflow in Surgical Suite During HCU Operation<sup>3</sup>

HCU placement view

Lateral view of surgical field

HCU exhaust  
directed away from  
operating field



HCU exhaust  
directed toward  
operating field



## What is Being Done?

- On June 1, 2016 the FDA advised hospitals to “determine a method for patient follow-up and establish patient surveillance in case of potential exposure”
- On October 13, 2016 the CDC said that “hospitals are advised to notify patients who underwent open surgery involving a Stockert 3T heater-cooler unit that the device was potentially contaminated, possibly putting patients at risk for a life threatening infection”.

<https://emergency.cdc.gov/han/han00397.asp>  
<https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm504213.htm>

## Patient Notification<sup>4</sup>

- At Mayo Clinic, >17,000 patients who underwent cardiac surgery at any of our sites (MN, FL, AZ, WI) within the past 5 years were notified of the recently discovered risk.
- Nurse and physician resources were made available to patients and their physicians who may have questions or concerns.
- The risk of infection appears to be low (1:100 to 1:1000) according to early reports from the CDC  
(<https://www.cdc.gov/hai/outbreaks/heater-cooler.html>)
- Patients may not experience any symptoms for months to years after the surgery (range 3 months to 5 years, median 18 months)

## Clinical Presentation<sup>2</sup>

### Most common

- Cardiac manifestations
  - Endocarditis
  - Vascular graft infection
  - Mycotic aneurysm
- Surgical site infection
  - Mediastinitis
  - Sternal wound infection
- Abscess
- Bacteremia
- Other (osteomyelitis, ocular infections, granulomatous disease mimicking sarcoid, etc)

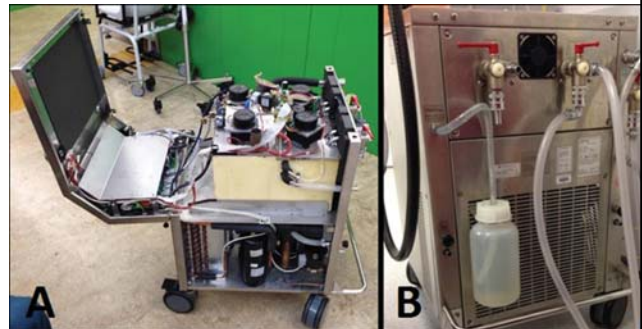
### General symptoms are nonspecific

- Fever
- Night sweats
- Weight loss
- Fatigue
- Muscle aches
- Shortness of breath

Not necessary to test asymptomatic patients just because they have had cardiac surgery

## Preventative Measures with the HCUs?

- The exact site(s) of contamination within the HCUs has not been well-defined
- Decontamination with a variety of agents has been successful in the short-term but fails to completely eradicate the organism
- Biofilm formation has been suggested
- Strict adherence to the manufacturer's decontamination protocols and replacement of internal tubing/refurbishment has been recommended
- Reliable decontamination remains difficult



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## Alternative Strategies

- Use of HCU from other manufacturers
- Positioning of the Sorin 3T outside of the operating suite and/or facing away from the surgical field has been demonstrated to reduce particle counts and disruption of the surgical air curtain (requires some construction)



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## *M. chimaera*<sup>7</sup>

- Nontuberculous mycobacterium
- Member of the *Mycobacterium avium* complex
- Known as a genetic variant called “MAC-A” until Tortoli described it as a separate species in 2004
- *M. chimaera* was the name selected since a chimera in Greek mythology is a mixture of 3 different animals and *M. chimaera* is a genetic mix between different MAC strains



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## ***M. avium* Complex Species Members**

- *M. avium* subsp. *avium*
- *M. intracellulare*
- also
- *M. avium* subsp. *silvaticum*
- *M. avium* subsp. *paratuberculosis*
- *M. avium* subsp. *hominissuis* (non-validated subsp.)
- *M. arosiense*
- *M. bouchedurhonense*
- *M. chimaera*
- *M. colombiense*
- *M. marseillense* (caution – do not confuse with *M. massiliense*)
- *M. paraintracellulare*
- *M. timonense*
- *M. vulneris*
- *M. yongonense*

## **Laboratory Diagnostics for *M. chimaera***

- Slowly growing, non-pigmented, acid-fast mycobacterium
- Direct detection methods from patient specimens are not available in most clinical laboratories
- Acid-fast smear and mycobacterial culture recommended followed by identification to the species level for positive cultures
- Not all isolates of *M. chimaera* are clinically significant
  - MAC often isolated from respiratory specimens
  - MAC in respiratory specimens can be a pathogen, a commensal or a contaminant
  - in our experience, approximately one-third of MAC isolates from respiratory specimens can be further identified as *M. chimaera*

## Common Questions for the Lab

- What type of specimen should I submit?
  - It depends on the clinical presentation
  - Consult your local ID specialist for help
  - Common samples: blood, purulent drainage (no swabs please!), tissue

## Common Questions for the Lab

- Should we do environmental testing on the HCU unit? Should we perform air sampling in the surgical suites?
  - Probably not
  - Consult your local Infection Control specialist
  - Literature has already firmly established that Sorin 3T HCUs manufactured prior to September, 2014 are likely to be contaminated with *M. chimaera*
  - Negative environmental cultures do not rule out *M. chimaera* contamination and do not negate the need to consider *M. chimaera* infection in patients with prior cardiac surgery and the appropriate clinical presentation

## Identification of *M. chimaera* from Culture Isolates

- Hologic/GenProbe AccuProbes for *M. avium* complex and for *M. intracellulare* will be positive but cannot identify to the species level
- Hain GenoType NTM-DR LiPA can differentiate *M. chimaera* from other MAC members
- MALDI-TOF mass spectrometry standard libraries cannot distinguish between *M. intracellulare* and *M. chimaera*
  - Software-based algorithm has been recently reported<sup>8</sup>
- Sequencing of the 16S gene yields a single nucleotide mismatch with *M. intracellulare* at position 403; alternate targets are *hsp65* and ITS.

## Mycobacterial Blood Cultures for *M. chimaera*

- Yield from performing multiple blood cultures is unknown at present; general recommendation is to collect 1 to 3 blood cultures per patient
- Consult Microbiology Lab if large numbers of blood cultures will be collected to avoid rapidly exceeding available capacity
  - Mycobacterial blood cultures require prolonged incubation times



Mayo Clinic Microbiology Lab  
Photos

## Susceptibility Pattern for *M. chimaera*

- AST should always be performed on clinically significant isolates
- Use CLSI-recommended panel for slowly growing mycobacteria
- *M. chimaera* is generally susceptible to clarithromycin
- No CLSI interpretive breakpoints for drugs other than clarithromycin; amikacin breakpoints coming soon
- Combination therapy with clarithromycin, rifabutin and ethambutol has been used; amikacin often added for first 3 months;
- ATS/IDSA guidelines - a minimum of 12 months of therapy for disseminated MAC disease; little data on cardiac implants infected with MAC so optimum therapy/duration of therapy is evolving

## Summary

- *M. chimaera* is a NTM involved in a global outbreak event caused by use of Sorin 3T HCUs in cardiac surgery
  - Patient notification of possible exposure should follow CDC and FDA guidance
- CDC website is a good site for the most up-to-date information on the outbreak and they provide a toolkit to assist with patient notification
  - (<https://www.cdc.gov/hai/outbreaks/heater-cooler.html>)
- *M. chimaera* is a member of the *M. avium* complex; identification to the species level and AST should be performed by qualified laboratories for clinically significant isolates from patients with prior cardiac surgery

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## Questions or requests...

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