

M. chimaera and Heater-Cooler Units:
Lessons Learned from the University of
Iowa Outbreak Response



Index patient

- 59 yo male, aortic valve replacement 10/2012 for dilated aortic root and symptomatic AI, performed at University of Iowa
- 2/2014, began to have back/chest pain, dyspnea, cough, fever, pancytopenia, ↑ LFTs, weight loss: Evaluation unrevealing
 - Extensive local ID evaluation including multiple blood cultures
- 4/2014: Clinical response to prednisone: resolution of symptoms
 - Symptoms recur after prednisone course complete
- Bone marrow and bronchoalveolar lavage cultures: *M chimaera*
- Referral back to local ID: blood culture 10/2014: *M chimaera*
- Multidrug therapy for *M chimaera* begins October 2014
- Persistent mycobacteremia (~ monthly + blood cultures) for > year
- **1/19/16: U of Iowa ID on call receives call from local ID provider**
 - Requests assistance, transfer for intractable *M chimaera* infection
 - U of Iowa ID physician notes exposure to bypass at our institution in 2012
 - Local outbreak investigation and management process begins

University of Iowa Timeline

- **1/19/2016:** Notified of *M chimaera* index pt
- **1/19/16-2/2/2016:**
 - State DOPH, CDC, FDA, TJC, LivaNova all notified
 - Initial case finding (lab and chart review)
 - Existing units removed from service
 - Water samples (HCUs, tap) obtained for culture
 - Elective surgeries requiring CPB were postponed until 2 new heater cooler units arrived 1/23/16
 - Heater cooler units moved outside the OR
 - Communication plan developed (internal/external)
 - Process for evaluation and management of pts with symptoms within 4 years of procedure
 - **Patient and provider notification**, media release

Case finding: Lookback

- All cultures positive for MAC in prior 5 years—case review
- No probable cases: 2 isolates sent for further species ID (pulmonary isolates from lung transplant pt exposed to HCU)
- No new cases identified from laboratory lookback
 - *Sterile site AFB cultures usually obtained only when recognized risk factors present*

Case Finding: Best Practice Alert (BPA)

- Epic BPA developed to identify potential cases and prompt clinicians to order mycobacterial blood cultures if appropriate
 - Identifies patients who had cardiopulmonary bypass (active or standby) in the last 4 years who now have febrile illness
- Message to clinicians:

This patient appears to have underwent a surgery within the last four years utilizing cardiopulmonary bypass (between January 1, 2012, and January 22, 2016) or had it in the operating room on standby. In addition, this patient's last documented temperature was over 101°F, or the patient has a febrile diagnosis for this encounter. Please consider ordering AFB blood culture.

As you may be aware, in October 2015 the CDC and FDA issued an advisory to hospitals regarding a bacterial contaminant that has been identified in the water reservoir of the heater-cooler devices used during cardiopulmonary bypass surgeries. Surgical site contamination results from the bacteria becoming aerosolized while the heater-cooler devices are in use, which may lead to infection. The specific bacterium has been identified by the CDC as *Mycobacterium chimaera*, a nontuberculous mycobacterium (NTM), part of the *Mycobacterium avium* Complex.

- As of 5/22/16, BPA has fired for 26 patients
 - AFB blood cultures sent for 6 patients, all negative (5 sets final)

UIHC engineering control for risk mitigation: Heater-cooler unit hose portal

Early decision to postpone
elective bypass procedures
until HCUs moved outside of
the operating room



Patient notification

- All patients exposed to a HCU since 1/1/12
 - Billing codes and OR logs used
 - no risk stratification
 - Included some liver transplant, TAVR patients
 - “Standby” cases sometimes have HCU running
- Required patient response
 - Letter with instructions to call toll-free line
 - Script and algorithm employed by nurse
 - Follow up calls to those who didn't respond
 - If symptoms: “NTM clinic”, with option to take info to their personal physician for evaluation

Excerpt from patient letter

Because NTM is a slow growing bacterium, it can take several months, even years, for symptoms of infection to develop. If you have the following symptoms and a cause has not been identified, you should share this letter with your personal doctor.

Please be alert for the following symptoms:

- Fever lasting more than one week
- Pain, redness, heat, or pus around a surgical incision
- Night sweats
- Joint pain
- Muscle pain
- Weight loss
- Loss of energy

Translated into preferred language
Translators available for patient calls

It is important that you call us toll-free at 866-514-0863 to let us know you have received this letter. We will answer your questions and arrange an appointment with one of our providers, if needed, during this call. You will not be charged for this appointment.

Enclosed are additional details about this issue, which may help answer some of your questions. They can also be found on our website: uihealthcare.org

Referring provider letter

[Date]

Dear [REFERRING PHYSICIAN],

At University of Iowa Hospitals and Clinics, our top priority is safe, high quality care. We value you as our partner and thank you for trusting us with the care of your patients. We are writing today to let you know of actions we have taken to address an issue that is affecting hospitals across the country and in Europe.

Q & A

Questions and Answers About NTM Exposure

What is the situation?

The U.S. Centers for Disease Control and Prevention (CDC) has notified all hospitals of a potential bacterium exposure to patients that has been linked to heater-cooler devices on heart/lung bypass machines.

What specific type of bacterium is involved?

The bacterium is Nontuberculous Mycobacterium (NTM). This bacterium is common in the environment and typically is not harmful. In rare cases, NTM can cause infections in patients who have had certain major heart, lung, or liver surgeries.

How are heater-cooler devices believed to be associated with NTM exposure during surgery?

University of Iowa News Release

February 2, 2016

UI Hospital and Clinics notifies patients of infection risk

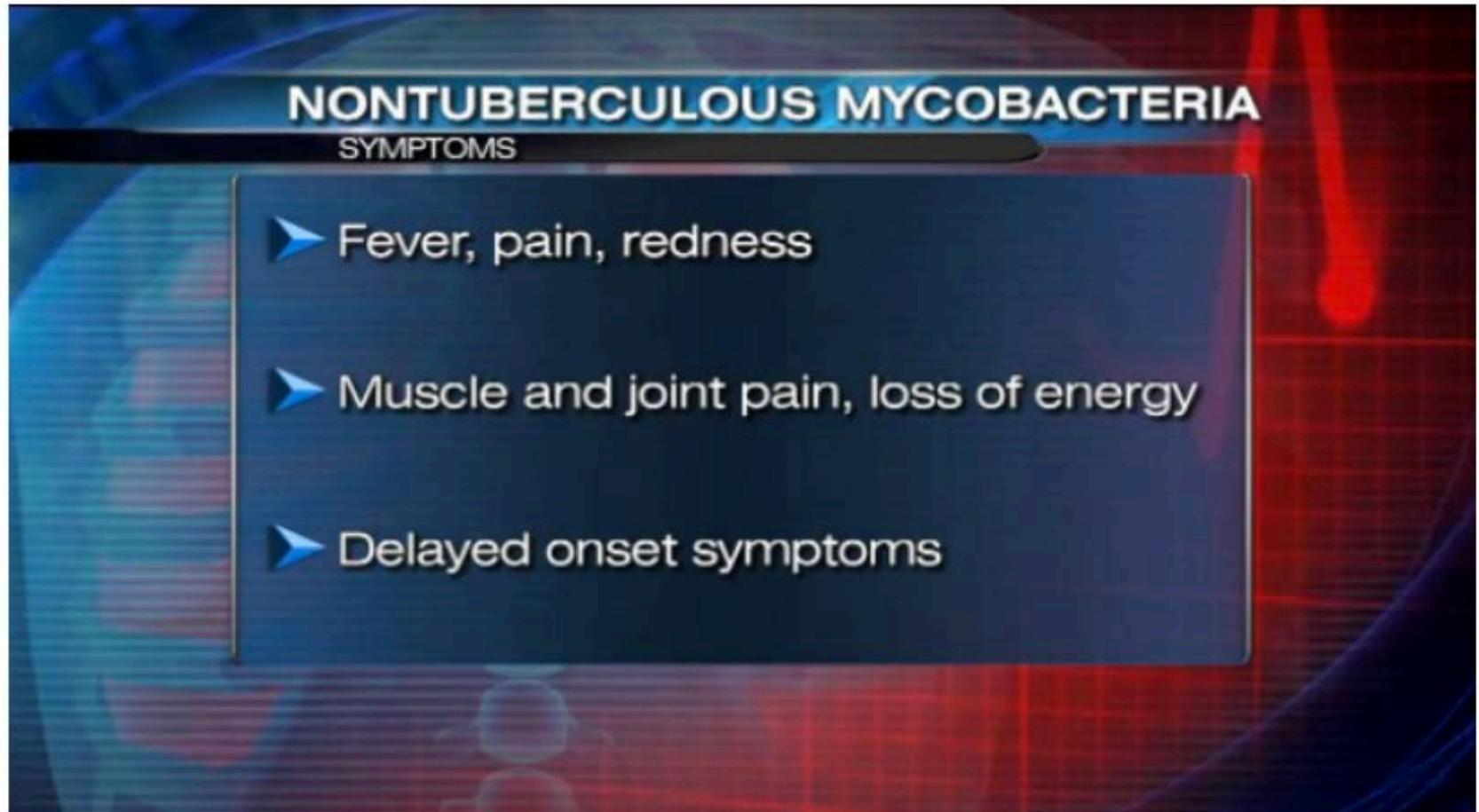
Safe and high quality care is the top priority for University of Iowa Hospitals and Clinics in Iowa City. Hospital leaders recently began notifying about 1,500 patients of possible exposure to a bacterium during certain major surgeries that took place between January 1, 2012, and January 22, 2016.

The very low risk of infection has been limited to patients who underwent certain major heart, lung or liver surgeries within the past four years. The issue only affects those patients who have undergone surgery that involves the use of heart-lung bypass machines with heater-cooler systems.

Patients who had other procedures - such as stents, pacemakers, defibrillators, ablations, biopsies and other surgeries - are not at risk.

The bacterium - Nontuberculous Mycobacterium, (NTM) - is commonly found in nature, including soil, water, and even tap water. Although it typically is not harmful, it can cause infections in rare cases.

University of Iowa Hospitals and Clinics Notifies Hundreds of Patients of Infection Risk



By Mark Carlson, KCRG-TV9 | Posted: Thu 12:11 PM, Feb 04, 2016 | Updated: Thu 5:36 PM, Feb 04, 2016



IOWA CITY, Iowa (KCRG-TV9) - Officials at the University of Iowa [Hospitals](#) and Clinics are notifying 1,500 patients about a possible infection risk linked to a machine used during certain heart, lung or liver surgeries.

Dedicated website established at time of patient, provider and media notification



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Potential Infection Risk in Major Heart and Lung Surgeries

Important Information

On this page

- [Questions and Answers](#)
- [News Release](#)
- [Information for Medical Professionals](#)
- [Government Resources](#)

Did you receive a letter from University of Iowa Hospitals and Clinics about a possible bacterial exposure during surgery? If so, it is important that you call us toll-free at 866-514-0863 to let us know that you have received the letter. We will answer your questions and, if needed,

State and Federal Resources Regarding NTM Bacteria and Heater-Cooler Units

- [CDC Safety Communication - \[.pdf\]](#)
- [FDA Notice](#)
- [U.S. National Library of Medicine](#)

<https://www.uihealthcare.org/ntm/>

Dedicated NTM evaluation clinic

- Staffed by a physician's assistant
- Directed by an ID clinician
- Checklist developed with input from ID and external experts: trigger for cultures
 - Symptoms, signs, lab results (elevated LFTs, pancytopenia), prior workup all included
- Updated policy for AFB blood cultures
- Additional bottles ordered and distributed

Lab capacity

- U of Iowa mycobacteriology laboratory
 - Culture and identification (DNA probe)
 - MTB complex, MAC, *M. goodii*
 - Send out for species level ID to *M. chimaera*
 - Send out for susceptibility testing
 - Initial evaluation exceeded capacity of blood culture instrument, converted to manual Isolator method
 - Most cultures now final



Patient notification and evaluation status

- 1,500 patients potentially exposed
 - All procedures using HCU since 1/1/2012
- Confirmed contact (by phone) required
- Vendor employed to help identify contact info for ~200 patients we're unable to reach
- 131 symptomatic patients underwent evaluation in "NTM clinic"
 - no additional cases yet diagnosed from this clinic
- 3 cases identified to date
 - Index case, + 2 identified via **provider notification**

How were additional patients detected?

- Case 2:
 - Referred from local provider for systemic granulomatous inflammatory process (liver and bone marrow bx: noncaseating granulomas)
 - UI hepatologist heard presentation and ordered AFB blood cultures
- Case 3:
 - Followed at UI after complicated course for cardiac transplantation, failure to thrive
 - Transplant cardiology and Transplant ID coordinated AFB blood cultures
 - Prior AFB blood cultures during earlier ID eval negative

University of Iowa *M. chimaera* Infections

Confirmed Cases

	Case 1	Case 2	Case 3
Age, gender	59 yo M	62 yo M	65 yo M
Procedure	AVR	Thoracic aortic aneurysm repair	VAD placement VAD replacement/AA repair VAD replacement Heart transplant
Procedure date	October 2012	March 2013	November 2011 June 2012 July 2012 December 2012
Sites of positive cultures	Blood, bone marrow, BAL	Blood	Blood
Time to symptom onset	14 months	15 months	??
Time to diagnosis	39 months	35 months	40 - 53 months
Current status	Died May 2016	Under treatment	Under treatment

Environmental microbiologic surveillance

- Water samples (1 L each) sent to National Jewish mycobacteriology laboratory for cultures:

Sample	Date in service	1/28/16	4/14/16
Tap water	Not applicable	Negative	Negative
HCU 1	11/29/10	<i>M. chimaera</i>	<i>M. chimaera</i>
HCU 2	11/29/10	Negative	<i>M. chimaera</i>
HCU 3	11/29/10	Negative	<i>M. chimaera</i>
HCU 4	01/09/12	Negative	<i>M. chimaera</i>
HCU 5	01/23/16	Fungal overgrowth	Negative
HCU 6	01/23/16	Negative	Pending

Challenges

- Case finding
 - Many receive follow-up care locally, not at the hospital where surgery performed
 - Symptoms are nonspecific (fever, fatigue, wt loss), and can present months to years after the exposure
 - Mycobacterial cultures are not routinely performed, but are required for diagnosis
- Risk mitigation
 - Units at high risk of being colonized, no disinfection method proven reliable
 - Water cultures have ?? negative predictive value
 - Safest approach is separation of HCU exhaust air from OR air

Essential next steps

- **Find current cases**
 - Improve clinician awareness!
 - National provider and patient notifications
 - Identify indicators to prompt workup
 - FUIO, sarcoid diagnosis after bypass procedure, etc.
- **Manage identified cases**
 - More clinical information (management, outcome) to help guide clinicians' and patients' decision-making
- **Prevent additional cases**
 - Remove implicated units from OR (short term)
 - Separate exhaust air from OR air
 - Long term issues: engineering solutions