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Continuing Education Information

ACTIVITY DESCRIPTION:

This webinar will discuss evidence linking invasive Nontuberculous Mycobacterium (NTM) infections and exposure to heater-cooler units used during cardiac surgery, outline clinical manifestation of invasive NTM infections, describe diagnostic and treatment strategies for invasive NTM infections, outline steps to identify patients at risk, and steps to mitigate risk to patients.

OBJECTIVES:

- Describe infection control techniques that reduce the risk and spread of healthcare-associated infections (HAI).
- Identify unsafe practices that place patients at risk for HAIs.
- Describe best practices for infection control and prevention in daily practice in healthcare settings.
- Apply standards, guidelines, best practices, and established processes related to safe and effective medication use.
Invasive Nontuberculous Mycobacterium Infections Associated with Exposure to Heater-Cooler Units during Cardiac Surgery

Abbigail Tumpey, MPH, CHES

Associate Director for Communications Science, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention

August 29th, 2016
Featured Speakers

- Joseph Perz, DrPH, MA, Team Leader, Quality Standards and Safety, Division of Healthcare Quality Promotion, CDC
  - Risk of Invasive NTM infection from Exposure to Heater-Cooler units
Featured Speakers

- Charles L. Daley, MD, Chief, Division of Mycobacterial and Respiratory Infections, National Jewish Health
  - Clinical Manifestations of Invasive NTM Infections and Diagnostic and Treatment Strategies

- Daniel J. Diekema, MD, D (ABMM), Director, Division of Infectious Diseases, University of Iowa Carver College of Medicine
  - Identifying Patients at Risk and Mitigating Risks to Patients

CDC Disclaimer: The findings and conclusions in this presentation are those of the presenter(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
Featured Speakers

- Keith B. Allen, MD, Director of Research, Clinical Associate Professor of Surgery, Mid America Heart and Lung Surgeons
  - Perspective from a Cardiothoracic Surgeon and Member of the FDA Circulatory System Devices Panel

CDC Disclaimer: The findings and conclusions in this presentation are those of the presenter(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
Before We Get Started…

- To submit a question:
  - Use the “Chat” window, located on the lower left-hand side of the webinar screen.
  - Questions will be addressed at the end of the webinar, as time allows.

- To ask for help:
  - Please press the “Raise Hand” button, located on the top left-hand side of the screen.

- Please remember to turn-on your computer speakers for audio for today’s webinar.
Featured Speakers

- Michael Bell, MD, Deputy Director, Division of Healthcare Quality Promotion, CDC
Best intentions

- Improved efficiency
- Greater convenience
- Minimal invasiveness
- Lifesaving innovations

All intended to help patients.

But…
Unintended Consequences

- Opportunities for misuse
- Difficulties in maintenance
- Blind-spots for infection risk
BE AWARE
DON’T SHARE

Insulin pens that contain more than one dose of insulin are only meant for one person. They should never be used for more than one person, even when the needle is changed.

ONE INSULIN PEN, ONLY ONE PERSON

The One & Only Campaign is a public health campaign aimed at raising awareness among the general public and healthcare providers about safe injection practices.

For more information, please visit: www.ONEandONLYcampaign.org
Dirty scopes needlessly infected scores of patients, investigation finds
Non-tuberculous Mycobacterium (NTM) Infections and Heater-Cooler Devices
Interim Practical Guidance: Updated October 27, 2015

Purpose:

CDC has identified a need for increased vigilance for NTM infections by health departments, healthcare facilities, and individual healthcare providers. FDA recently issued a Safety Communication on Nontuberculous Mycobacterium Infections Associated with Heater-Cooler Devices that addresses...
Devices like these require:

- Correct use! – (education, onboarding, refresher training…)
- Design that promotes successful maintenance.
- Engineering specifications that include minimizing infection risk…
Nontuberculous Mycobacterium (NTM)

- NTM = mycobacteria that do not cause tuberculosis
- Slow-growing
- Found in surface water, tap water, and soil
- Opportunistic
- Healthcare
  - Immunocompromised patients
  - Breaches in normal host defenses
  - Novel exposure pathways
    - Direct and indirect exposures to water
Prolonged Outbreak of *Mycobacterium chimaera* Infection After Open-Chest Heart Surgery

Hugo Sax,1,a Guido Bloemberg,2,a Barbara Hasse,1,a Rami Sommerstein,1 Philipp Kohler,1 Yvonne Achemann,1 Matthias Rössle,3 Volkmar Falk,4 Stefan P. Kuster,1 Erik C. Böttger,2,b and Rainer Weber1,b

1Division of Infectious Diseases and Hospital Epidemiology, University Hospital Zurich, 2Institute of Medical Microbiology, National Centre for Mycobacteria, University of Zurich, 3Institute of Surgical Pathology, and 4Division of Cardiac Surgery, University Hospital Zurich, Switzerland

**Background.** Invasive *Mycobacterium chimaera* infections were diagnosed in 2012 in 2 heart surgery patients on extracorporeal circulation. We launched an outbreak investigation to identify the source and extent of the potential outbreak and to implement preventive measures.

**Methods.** We collected water samples from operating theaters, intensive care units, and wards, including air samples from operating theaters. Nontuberculous mycobacteria samples and *M. chimaera* specimens were studied using polymerase chain reaction and reverse transcriptase polymerase chain reaction on archived histopathological and endocarditis or vasovasostomy specimens, or other biopsy specimens connected to the demonstrated identical and strains in 2 patients.

**Results.** We identified a cular graft infection due to after surgery. *Mycobacterium chimaera* infected patients were able to be identified using a combination of clinical, microbiological, and molecular methods. We identified clusters among *M. chimaera* strains.

**Conclusions.** The epidemiological and microbiological features of this prolonged outbreak provided evidence for the airborne transmission of *M. chimaera* from contaminated heater-cooler unit water tanks to patients during open-heart surgery.

**Keywords.** outbreak; *Mycobacterium chimaera*; nontuberculous mycobacteria; open-chest heart surgery; infection control.
M. chimaera detected in heater-cooler water circuits and air samples collected w/ units operating
On June 15, 2015, Sorin Group USA, issued a Field Safety Notice, followed on July 15, 2015 by a Class II Recall:

- Stating that “although water from the heater cooler device is not intended to contact the patient directly, fluid leakage from the device or aerosolization generated by a contaminated water circuit during device operation may create conditions in which the organisms could potentially contact the patient and subsequently contaminate the surgical site.”
- Indicating an Error in Labeling, requiring revisions to instructions for cleaning and disinfection.
2015 US Outbreak Investigation

- July 20 – PA Department of Health notified of a cluster of NTM infections among cardiac surgery patients
- Heater-cooler units were removed and replaced
- CDC provided on-site assistance with investigation
- 8 cases of invasive NTM (MAC / M. chimaera) infection
- Epidemiologic and laboratory findings indicated heater-cooler units = source
- October – Hospital notified affected patients/families as well as over 1300 potentially exposed patients
Nontuberculous Mycobacterium Infections Associated with Heater-Cooler Devices: FDA Safety Communication

Scope: All heater-cooler devices

Recommendations include:

- Adhere to current manufacturer instructions
- Sterile or filtered water
- Direct exhaust away
- Remove units w/ signs of contamination
- MedWatch reporting
Aim: amplify FDA alert and provide guidance on identifying patients with infection

Summary:

Heater-cooler devices are commonly used during cardiac surgical procedures to warm and cool a patient’s blood during cardiopulmonary bypass. NTM are slow-growing bacteria that are found in surface water, tap water, and soil. Recent reports have suggested an association between heater-cooler devices and NTM infections among patients undergoing cardiac surgery potentially through the aerosolization of bacteria from contaminated water used in these devices.
Transmission of *Mycobacterium chimaera* from Heater–Cooler Units during Cardiac Surgery despite an Ultraclean Air Ventilation System

Rami Sommerstein, Christian Rüegg, Philipp Kohler, Guido Bloemberg, Stefan P. Kuster, Hugo Sax
Contamination during production of heater-cooler units by *Mycobacterium chimaera* potential cause for invasive cardiovascular infections: results of an outbreak investigation in Germany, April 2015 to February 2016

S Haller ¹, C Höller ², A Jacobshagen ³, O Hamouda ⁴, M Abu Sin ¹, DL Monnet ⁴, D Plachouras ⁴, T Eckmanns ⁴

*Mycobacterium chimaera*-positive samples from environmental investigations at the manufacturing site of new HCU’s and of used HCU’s from at the manufacturer’s service centre, July 2014 to June 2015

<table>
<thead>
<tr>
<th>Date</th>
<th>Type of sample</th>
<th>Source of sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>16 Jul 2014</td>
<td>Water (100 mL)</td>
<td>Used HCU from Switzerland</td>
</tr>
<tr>
<td>29 Jul 2014</td>
<td>Water (100 mL)</td>
<td>New HCU from manufacturing site</td>
</tr>
<tr>
<td>5 Aug 2014</td>
<td>Water (100 mL)</td>
<td>New HCU from manufacturing site</td>
</tr>
<tr>
<td>11 Aug 2014</td>
<td>Water (100 mL)</td>
<td>New HCU from manufacturing site</td>
</tr>
<tr>
<td>19 Feb 2015</td>
<td>Water (100 mL)</td>
<td>Used HCU from the Netherlands</td>
</tr>
<tr>
<td>10 Jun 2015</td>
<td>Water (volume not specified)</td>
<td>Sample taken in pump assembly area at the manufacturing site</td>
</tr>
</tbody>
</table>
Potential M. chimaera contamination in Sorin 3T Units shipped < September 2014

Recommendations for Facilities, Staff, and Patients
Updated CDC Guidance for Identifying Patients at Risk
May 2016

Interim Guide for the Identification of Possible Cases of Nontuberculous Mycobacterium Infections Associated with Exposure to Heater-Cooler Units

The following guidance is intended to assist facilities in identifying patients with nontuberculous mycobacterium (NTM) infections associated with exposure to heater-cooler units in order to help ensure timely diagnosis and treatment of patients.

Institutions performing surgeries requiring cardiopulmonary bypass should consider taking the following steps to identify patients at risk. Patients meeting the following criteria may represent heater-cooler unit-associated infection and may warrant additional investigation.

1) Laboratory assessment:

Identify NTM-positive cultures obtained from an invasive sample (blood, pus, tissue biopsy, or implanted prosthetic material) using facility’s microbiologic database or other appropriate sources. Time period for review is institution dependent. Some institutions have used a four-year time period to conduct laboratory review whereas other facilities have opted for a longer time frame.

2) Clinical assessment:

Cross reference NTM-positive cultures with medical and surgical records to identify patients who meet the following clinical criteria (any one of the following):

Despite outreach efforts, awareness of heater-cooler infection risks is low and needs to be escalated across the clinical community.
Clinical Presentation, Diagnosis and Treatment of Disseminated *Mycobacterium chimaera*

Webinar: *Invasive Nontuberculous Mycobacterial Infections Associated with Exposure to Heater-Cooler Units During Cardiac Bypass Surgery*

Centers for Disease Control and Prevention
August 29, 2016

Charles L. Daley, MD
National Jewish Health
University of Colorado, Denver
Conflict of Interest Disclosures

• Investigator in multicenter randomized placebo controlled clinical trial of inhaled liposomal amikacin in pulmonary NTM infections (Insmed)
• Investigator in Bronchiectasis and NTM Research Registry (COPD Foundation)
• Investigator, Colorado CF/NTM Research Development Program (Cystic Fibrosis Foundation)
• Investigator in randomized controlled trial of clofazimine in the treatment of pulmonary MAC (FDA)
Outline

• What's in a name – *Mycobacterium chimaera*
• Clinical Presentation - When to suspect disseminated disease
• Diagnosis – A Clinical Laboratory Perspective
• Treatment – Challenging under any circumstance
**Mycobacterium avium** Complex

- Slow-growing nontuberculous mycobacteria
  - Over 170 species and subspecies of NTM,
- Ubiquitous in environment
  - Surface water, tap water, and soil
- Low virulence, opportunistic pathogens
  - Chronic lung infection, mostly among those with underlying lung disease (bronchiectasis, COPD)
  - Disseminated disease described with extreme immune compromise (AIDS and post transplant)
**Mycobacterium avium** Complex

*FIG 5* Phylogenetic tree, based on the 16S rRNA gene, for the species belonging to the *M. avium* complex.

- *M. chimaera*
- "*M. indicus pranii*"
- *M. intracellulare*
- *M. arosiense*
- *M. avium*
- *M. vulneris*
- *M. bouchedurhonense*
- *M. colombiense*
- *M. marseillense*
- *M. yongonense*
- *M. timonense*

- *M. TERRAE COMPLEX (Fig. 4)*
- RAPIDLY GROWING SPECIES (Fig. 3)


Tortoli E. Clin Micro Rev 2014;27:727-752
Occurrence and Clinical Relevance of *M. chimaera*, Germany

- 97 patients from Charité University Hospital between 2002-2006 and
- 69 isolated provided by National Reference Laboratory (Borstel, Germany)
  - 166 *Mycobacterium intracellulare* strains identified by 16s rRNA-based methods
  - 143 (86%) were *Mycobacterium chimaera* by sequencing 16S-23S ITS region

### Nontuberculous Mycobacteria at National Jewish Health

> 8,800 isolates were analyzed using rpoB gene sequencing

Seven *Mycobacterium* species accounted for ~80% of all isolates tested

<table>
<thead>
<tr>
<th>Species</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>M. abscessus</em> group</td>
<td>24.4%</td>
</tr>
<tr>
<td><em>M. avium</em></td>
<td>19.9%</td>
</tr>
<tr>
<td><em>M. intracellulare</em></td>
<td>16.4%</td>
</tr>
<tr>
<td><em>M. chimaera</em></td>
<td>6.0%</td>
</tr>
<tr>
<td><em>M. fortuitum</em></td>
<td>5.1%</td>
</tr>
<tr>
<td><em>M. gordonae</em></td>
<td>3.8%</td>
</tr>
<tr>
<td><em>M. chelonae</em></td>
<td>3.7%</td>
</tr>
</tbody>
</table>

Source: Max Salfinger, MD
Mycobacterium avium Complex
What's in a Name?

• Acquisition of infection
  – *M. avium* and *M. chimaera* are found in water. *M. intracellulare*?

• Pathogenicity
  – *M. intracellulare* ≥ *M. avium* > *M. chimaera*

• Clinical Presentation
  – *M. intracellulare* presents with more advanced disease

• Treatment outcomes
  – *M. chimaera* and *M. avium* may have a higher rate of clinical recurrence than *M. intracellulare*

# Clinical Presentation

## Pulmonary Infection

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Chronic cough, Fatigue, Fever, Weight loss, Shortness of breath</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signs</td>
<td>Thin in stature, Adventitious breath sounds</td>
</tr>
<tr>
<td>Laboratory Values</td>
<td>Lymphocytopenia, Elevated CRP, Normal immunological tests (immunoglobulins, lymphocyte phenotyping)</td>
</tr>
</tbody>
</table>

Dissemination outside of the lung does not occur unless severely immunocompromised.
Clinical Presentation
Disseminated *M. chimaera* Infection

Time to Presentation – median 21 months (5-40)

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Fever, Fatigue, Weight loss, Shortness of breath</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signs</td>
<td>Splenomegaly, Chorioretinitis</td>
</tr>
<tr>
<td>Laboratory Values</td>
<td>Anemia, Lymphocytopenia, Thrombocytopenia, Elevated CRP, Elevated transaminases, Elevated creatinine</td>
</tr>
</tbody>
</table>

Manifestation of Disseminated Infections

- Prosthetic valve endocarditis
- Vascular graft infection
- Manifestations of disseminated disease:
  - Emboli
  - Bone marrow involvement
  - Splenomegaly
  - Nephritis
  - Myocarditis
  - Osteomyelitis

Delays in Diagnosis

• Long period from index surgery to clinical presentation
• Various clinical manifestations
• Lack of appropriate cultures at presentation
• Slow growth of *M. chimaera*
• Disbelief on behalf of provider
Diagnosis of NTM Infections
Routine Methods Take a Long Time!

- Collect a specimen
- Microscopic examination
- Culture (liquid and solid media)
- Identification
- Drug susceptibility
- Diagnosis 8 + weeks

Think about it!
Diagnosis of NTM Infections
Routine Methods Take a Long Time!

Think about it!

Diagnosis
8 + weeks

Drug susceptibility

Sequencing (rpoB)

Collect a specimen

Microscopic examination

Culture (liquid and solid media)
Treatment

*M. avium* complex Pulmonary Infection

**MAC**

Duration: 12 mos culture negativity

Macrolide sensitive

- **Yes**
  - Cavities Present
    - **No**
      - 3X/WEEK Azithromycin, Rifampin, Ethambutol
    - **Yes**
      - DAILY Azithromycin, Rifampin, Ethambutol

- **No**
  - DAILY Rifampin, Ethambutol, Other drug

Clofazimine, Moxifloxacin, Ciprofloxacin, Bedaquiline, Inhaled amikacin

Add IV Amikacin
## Treatment Outcomes for Pulmonary MAC

<table>
<thead>
<tr>
<th></th>
<th>Culture Conversion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Macrolide susceptible</strong></td>
<td></td>
</tr>
<tr>
<td>Non cavitary</td>
<td>80%</td>
</tr>
<tr>
<td>Cavitary</td>
<td>&lt;50%</td>
</tr>
<tr>
<td><strong>Macrolide resistant</strong></td>
<td></td>
</tr>
<tr>
<td>No surgery/aminoglycoside</td>
<td>5%</td>
</tr>
<tr>
<td>Surgery + aminoglycoside*</td>
<td>80%</td>
</tr>
</tbody>
</table>

* ≥ 6 months IV aminoglycoside

Griffith DE, et al. AJRCCM 2006;174:928
Treatment
Disseminated *M. chimaera*

MAC

Duration: ????

Yes

Macrolide sensitive

DAILY
Azithromycin
Rifampin
Ethambutol

No

DAILY
Rifampin
Ethambutol
Other drug

Clofazimine
Moxifloxacin
Ciprofloxacin
Bedaquiline
Inhaled amikacin

Add IV Amikacin

3 months?
Clinical Outcomes of Disseminated *M. chimaera* Infections

Why so Difficult to Treat?

• Delay in diagnosis resulting in widespread disseminated infection
• Endovascular infection involving foreign material (biofilm)
• Largely bacteriostatic drugs
• Low serum drug concentrations
• Co-morbidities
Thank you!
M. chimaera and Heater-Cooler Devices: Finding cases, communicating risk, and reducing risk
University of Iowa Response

• Notified of *M chimaera* index patient in January 2016
• Hospital Emergency Incident Command activated:
  – **Case finding**
    • Laboratory look-back
    • Process for notification and evaluation of exposed patients
  – **Communication plan**
    • State DOPH, CDC, FDA, TJC, LivaNova all notified
    • Patient, provider and media notifications coordinated
  – **Investigation and risk mitigation**
    • Existing heater-cooler units removed from service
    • Water samples (HCDs, tap) obtained for culture
    • Elective surgeries requiring CPB were postponed
    • All heater cooler devices moved outside the OR
• FDA Safety Communication issued June 1, 2016
• If use Sorin/LivaNova 3T HCD from pre-September 2014
  • Perform provider notification regarding exposure risk
  • Implement method for patient follow up and surveillance
    • Follow CDC guidance for case finding
  • Follow most current instructions for use

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm504213.htm
Interim Guide for the Identification of Possible Cases of Nontuberculous Mycobacterium Infections Associated with Exposure to Heater-Cooler Units

The following guidance is intended to assist facilities in identifying patients with nontuberculous mycobacterium (NTM) infections associated with exposure to heater-cooler units in order to help ensure timely diagnosis and treatment of patients.

Institutions performing surgeries requiring cardiopulmonary bypass should consider taking the following steps to identify patients at risk. Patients meeting the following criteria may represent heater-cooler unit-associated infection and may warrant additional investigation.

1) Laboratory assessment:

Identify NTM-positive cultures obtained from an invasive sample (blood, pus, tissue biopsy, or implanted prosthetic material) using facility’s microbiologic database or other appropriate sources. Time period for review is institution dependent. Some institutions have used a four-year time period to conduct laboratory review whereas other facilities have opted for a longer time frame.

2) Clinical assessment:

Cross reference NTM-positive cultures with medical and surgical records to identify patients who meet the following clinical criteria (any one of the following):

- Prosthetic valve endocarditis
- Prosthetic vascular graft infection
- Sternotomy wound infection
- Mediastinitis
- bloodstream infection
- Disseminated infection, including embolic and immunologic manifestations (e.g. splenomegaly, arthritis, osteomyelitis, bone marrow involvement with cytopenia, chorioretinitis, lung involvement, hepatitis, nephritis, myocarditis)
Identifying Possible Cases of NTM Infections Associated with Exposure to Heater-Cooler Devices

**Laboratory Assessment**
- NTM-positive cultures (invasive)

**Clinical Assessment**
- Prosthetic valve endocarditis
- Prosthetic vascular graft infection
- Sternotomy wound infection
- Mediastinitis
- Bloodstream infection
- Disseminated infection

**Exposure Assessment**
- History of surgery requiring cardiopulmonary bypass

Case finding: Lab Look-back

• Unclear how far back to look (4+ years)
• Lab-based look-back alone is low yield for two reasons:
  – Sterile site AFB cultures usually obtained only when recognized risk factors present
  – Prior exposure to cardiopulmonary bypass in otherwise immune-competent patient only recently described as a risk factor

• Active case finding is also required
Identifying Possible Cases of NTM Infections Associated with Exposure to Heater-Cooler Devices

- Acid-fast bacilli (AFB) cultures may be indicated for patients with exposure history and:
  - Clinical criteria*
  - Recurrent or persistent fever of unknown etiology
  - Night sweats
  - Joint or muscle pains
  - Weight loss
  - Fatigue

- Consider sending *Mycobacterium avium* complex positive cultures to NTM reference laboratory

* Clinical criteria as outlined in previous slide which includes prosthetic valve endocarditis, prosthetic vascular graft infection, sternotomy wound infection, mediastinitis, bloodstream infection, or disseminated infection, including embolic and immunologic manifestations

Case Finding: Practical approaches

- Review of all patients with diagnosis codes for sarcoidosis and culture-negative PVE
  - Consider AFB cultures if meet exposure criteria
- Electronic medical record:
  - Best Practice Alert (BPA) developed to identify potential cases and prompt clinicians to order AFB cultures
  - Identifies patients who had cardiopulmonary bypass in the last several years who now have diagnosis codes c/w febrile illness, or fever without known cause
Case Finding: Patient notification

• All patients exposed to an HCD
  – Billing codes and OR logs used
  – Highest risk are those with prosthetic implants
  – “Standby” cases may have HCD 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

It is important that you call us toll-free at 866-123-4567 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
[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.

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

Potential Infection Risk in Major Heart and Lung Surgeries

Important Information

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]
- FDANotice
- 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

• Mycobacteriology laboratory
  – What is your current capacity?
  – For most labs, species-level ID (\emph{M chimaera}) and susceptibility testing is a send out
  – Our initial evaluation exceeded capacity of blood culture instrument, so we converted to manual Isolator method temporarily
  – Created \emph{M chimaera} order set

• Discuss with lab director!
Investigation and Risk Mitigation: Heater-cooler devices

- Removed HCDs from OR
- Sampled all HCDs for culture
- Meet/exceed existing IFU
- Engineering solutions needed
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

• Communication
  – Still many unknowns about infection risk, variables associated with risk, disease management, outcomes

• Risk assessment and mitigation
  – Once colonized, no disinfection method proven effective
  – Water cultures have unknown negative predictive value
  – Goal should be separation of HCU exhaust air from OR air
Summary

- Life-saving device we continue to need
- Large number of potentially exposed patients
- Non-specific presentation
- Slow growing pathogen with specific diagnostic requirements
- High index of suspicion
- Culture for AFB
- Look-back assessments
- Interim solutions for location of machine
Before We End Today’s Webinar…

- **Question and Answer Session**
- **Continuing Education**
  - A link to the post-test and evaluation will appear on your screen as soon as today’s webinar concludes.
  - If you exit out of the webinar prior to taking the post-test and evaluation, you can access these links in an email we will send to you following today’s webinar.

THANK YOU