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Continuing Education Information

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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.

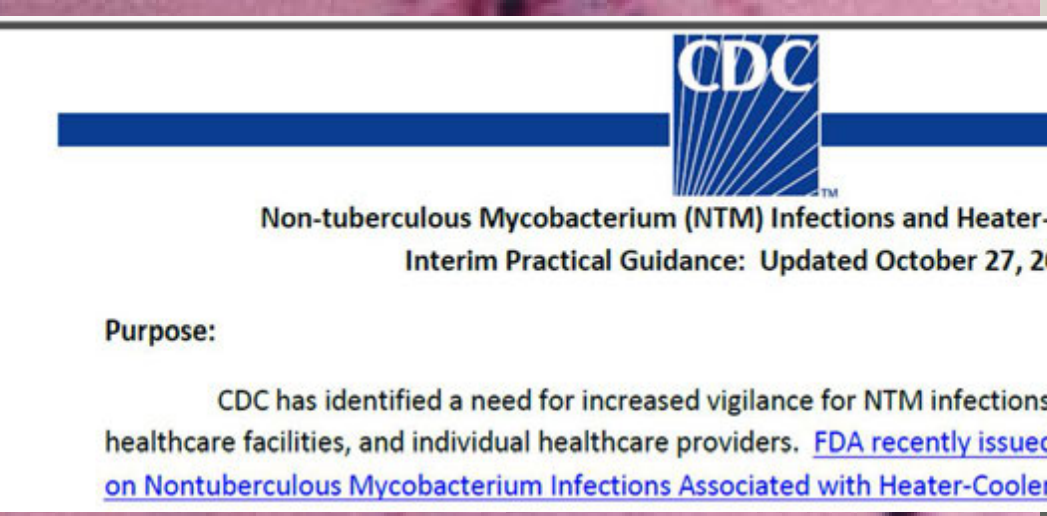
They ***should never be used for more than one person***, even when the needle is changed.

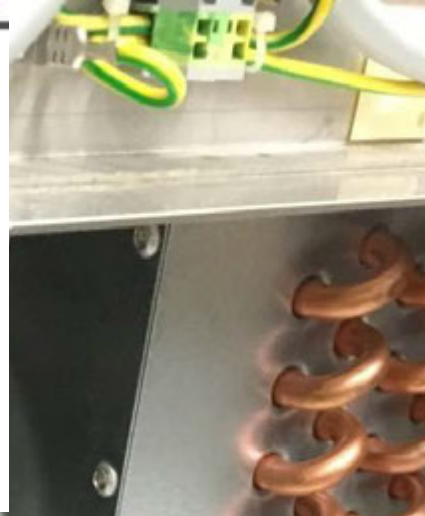
ONE INSULIN PEN, ONLY ONE PERSON

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

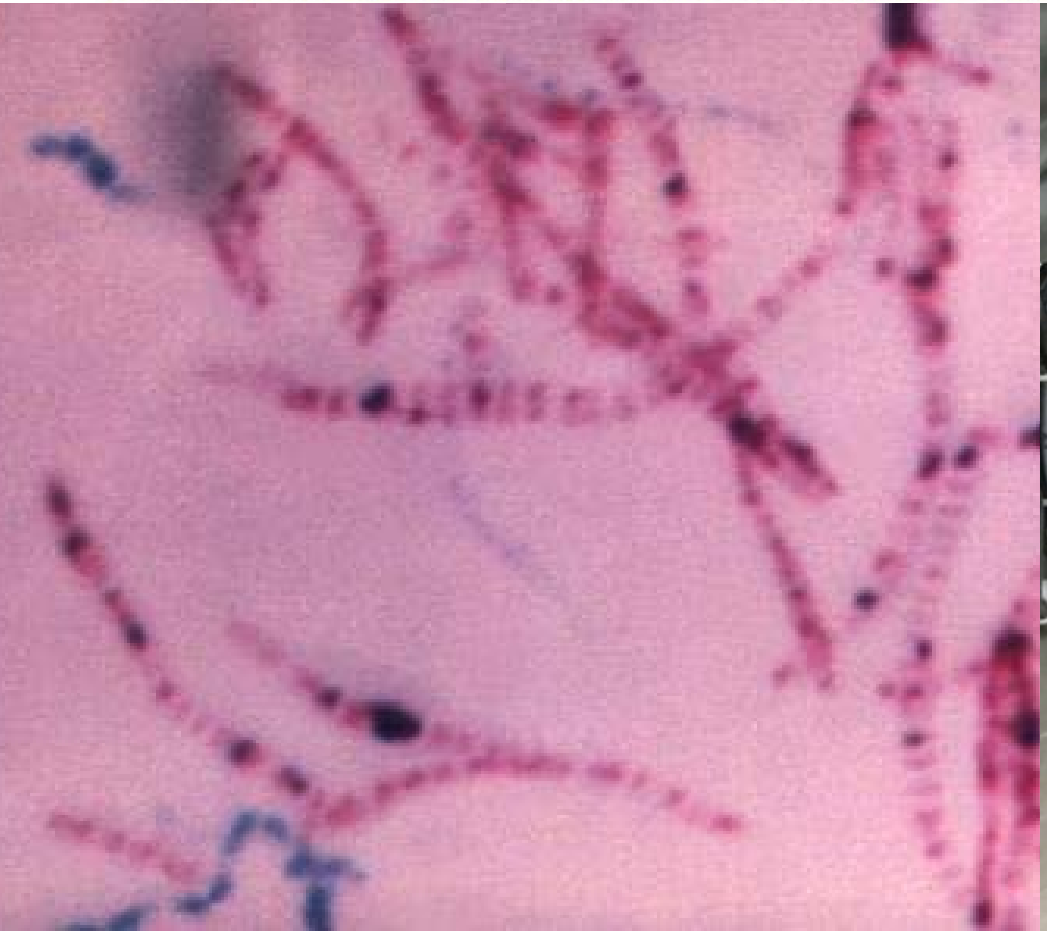




Non-tuberculous Mycobacterium (NTM) Infections and Heater-Cooler Devices
Interim Practical Guidance: Updated October 27, 2015

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 Achermann,[1] Matthias Rössle,[3] Volkmar Falk,[4] Stefan P. Kuster,[1] Erik C. Böttger,[2,b] and Rainer Weber[1,b]

[1]Division of Infectious Diseases and Hospital Epidemiology, University Hospital Zurich, [2]Institute of Medical Microbiology, National Centre for Mycobacteria, University of Zurich, [3]Institute of Surgical Pathology, and [4]Division 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 th lomly amplified poly-morphic DNA polymerase on archived histopa-thology samples and *M. ch* rospectively surveyed.

Results. We identified e endocarditis or vas-cular graft infection due to veen 1.5 and 3.6 years after surgery. *Mycobacteri* tures, or other biopsy specimens. We were able a nits connected to the cardiopulmonary bypass, a emonstrated identical patterns among *M. chimae* id strains in 2 patient clusters.

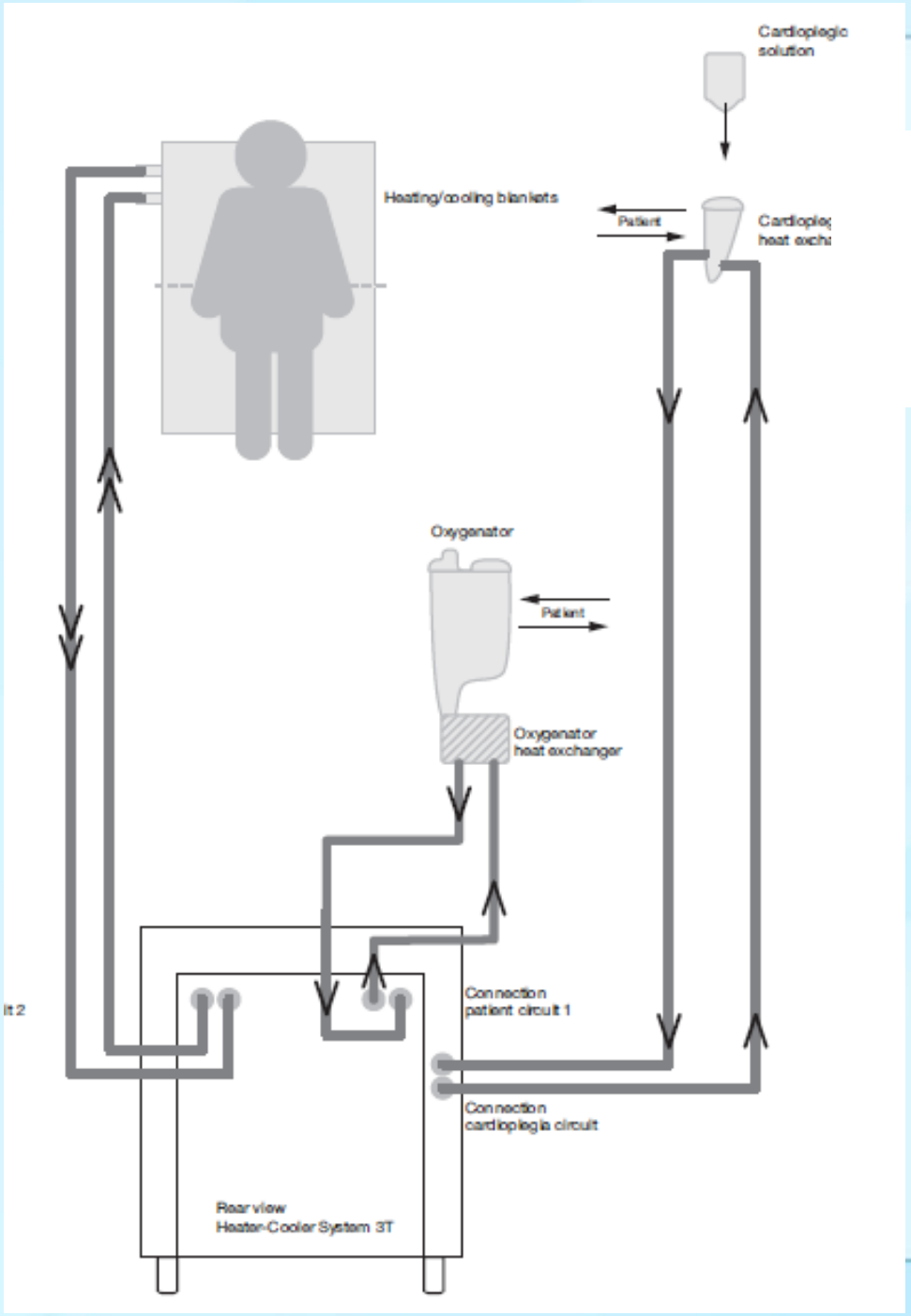
- **Invasive *M. chimaera* in 6 patients**
- **Open-chest, implants, 2008-2012**
- **Investigation of possible water sources**
- **Heater-cooler unit used for heart-lung machine and cardioplegia**

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.

Clinical Infectious Diseases 2015;61(1):67–75

M. chimaera detected in heater-cooler water circuits and air samples collected w/ units operating



www.livanova.sorin.com/products/cardiac-surgery/perfusion/hlm/3t#product_download_area

U.S. Department of **Health & Human Services** a A A

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Class 2 Device Recall STOCKERT HEATERCOOLER SYSTEM 3T

FDA Home › Medical De

CDRH SuperSearch

New Search

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.

Date Posted	
Recall Status[1]	
Recall Number	
Recall Event ID	
Premarket Notification 510(K) Number	
Product Classification	Controller, Temperature, Cardiopulmonary Bypass - **Product Code** DWC
Product	Sorin Stockert Heater-Cooler 3T, 120 V / 60 Hz Temperature control for extracorporeal

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

October 15, 2015

Product: All heater-cooler devices. Heater-cooler devices provide heated and/or cooled water to 1) oxygenator heat exchangers, 2) cardioplegia (paralysis of the heart) heat exchangers, and/or 3) warming/cooling blankets.

Purpose:
The FDA wants to heighten awareness about infections associated with heater-cooler devices and steps health care providers and health facilities can take to mitigate risks to patients.

Summary of Problem and Scope:
Heater-cooler devices are used during cardiothoracic surgeries, as well as other medical and surgical procedures to warm or cool a patient to optimize medical care and improve patient outcomes. Heater-cooler devices include water tanks that provide temperature-controlled water to external heat exchangers or warming/cooling blankets through closed
potentia ze)
through
Throug
internat with
Nontub dures.
NTM or ey are
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Betwee
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surgeri d to
3 events describing patient infections occurring in U.S. health care facilities. The remaining 24 reports involved health care facilities outside the United States, most of these in Western Europe. In some cases, patients presented with infections several months to years after their surgical procedures. It is important to note that half of the 32

- **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**

www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm466963.htm

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 issues regarding the proper use and maintenance of these devices. CDC has been working with the FDA and local and state health departments to investigate heater-cooler units associated with NTM infections and/or a) raise awareness among f the possible association betwe e guidance on identifying patien

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.[1,2,3,4,5]

www.cdc.gov/HAI/pdfs/outbreaks/CDC-Notice-Heater-Cooler-Units-final-clean.pdf

RESEARCH

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

Emerg Infect Dis; 2016;22(6):1008-13.

SURVEILLANCE AND OUTBREAK REPORT

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 [1], M Abu Sin [1], DL Monnet [4], D Plachouras [4], T Eckmanns [1]

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

Date	Type of sample	Source of sample
16 Jul 2014	Water (100 mL)	Used HCU from Switzerland
29 Jul 2014	Water (100 mL)	New HCU from manufacturing site
5 Aug 2014	Water (100 mL)	New HCU from manufacturing site
11 Aug 2014	Water (100 mL)	New HCU from manufacturing site
19 Feb 2015	Water (100 mL)	Used HCU from the Netherlands
10 Jun 2015	Water (volume not specified)	Sample taken in pump assembly area at the manufacturing site

Euro Surveill 2016;21(17): pii=30215

FDA Issues Recommendations for Healthcare Facilities and Staff June 2016

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):

http://www.cdc.gov/hai/pdfs/outbreaks/Guide-for-Case-Finding.pdf

FDA Advisory Committee
June 2016

→ Despite outreach efforts, awareness of heater-cooler infection risks is low and needs to be escalated across the clinical community

http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM503716.pdf

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

National Jewish Health
Science Transforming Life

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)

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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

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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

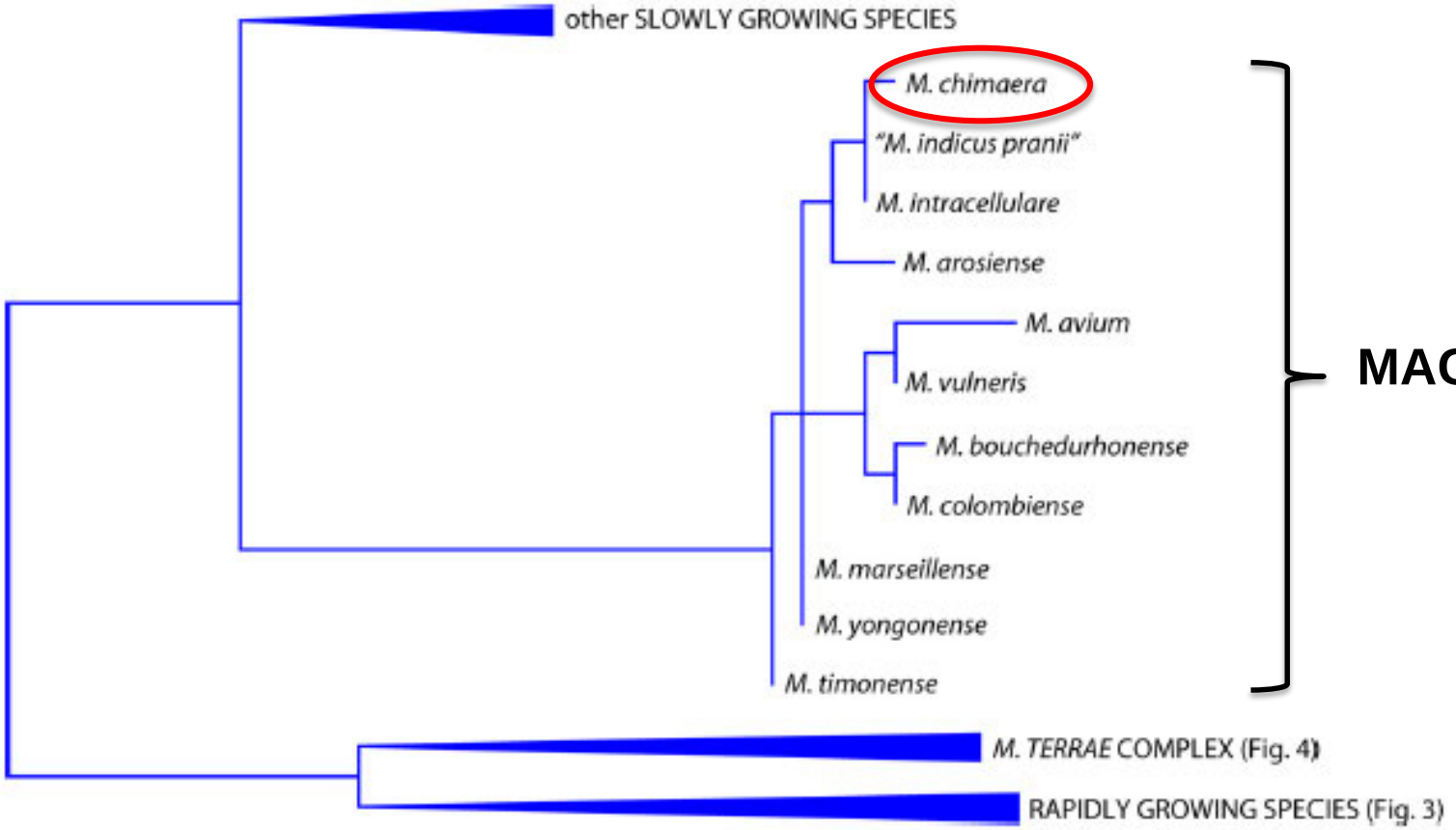

FIG 5 Phylogenetic tree, based on the 16S rRNA gene, for the species belonging to the *M. avium* complex.

Tortoli E, et al. J System Evol Micro 2004;54:1277-1285
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

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Schweickert B, et al. Emerg Infect Dis 2008;14:1443-1446

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

24.4%	*M. abscessus* group	
19.9%	*M. avium*	42.3%
16.4%	*M. intracellulare*	
6.0%	*M. chimaera*	
5.1%	*M. fortuitum*	
3.8%	*M. gordonae*	
3.7%	*M. chelonae*	

Source: Max Salfinger, MD

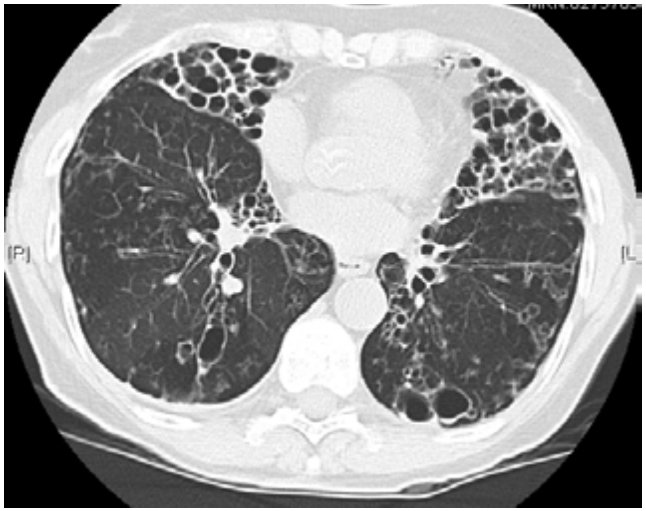
Mycobacterium avium Complex What's in a Name?

- **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*

Schweickert B, et al. Emerg Infect Dis 2008;14:1443-1446.
Wallace RJ, et al. J Clin Micro 2013;51:1747-1752
Koh WJ, et al. Chest 2012:142:1482-1488
Boyles DP, et al. AJRRCM 2015:191:1310-1317

Clinical Presentation
Pulmonary Infection

Symptoms	**Chronic cough** **Fatigue**, Fever, Weight loss, Shortness of breath
Signs	Thin in stature Adventitious breath sounds
Laboratory Values	Lymphocytopenia, Elevated CRP Normal immunological tests (immunoglobulins, lymphocyte phenotyping)



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)

Symptoms	Fever, Fatigue, Weight loss, Shortness of breath
Signs	Splenomegaly Chorioretinitis
Laboratory Values	Anemia, Lymphocytopenia, Thrombocytopenia, Elevated CRP Elevated transaminases Elevated creatinine

Achermann Y, et al. J Clin Microbiol 2013;51:1769
Sax H, et al. Clin Infect Dis 2015;61:67 Kohler P, et al. Eur Heart J 2015;36:2745

Manifestation of Disseminated Infections

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

Achermann Y, et al. J Clin Microbiol 2013;51:1769
Sax H, et al. Clin Infect Dis 2015;61:67 Kohler P, et al. Eur Heart J 2015;36:2745

Delays in Diagnosis

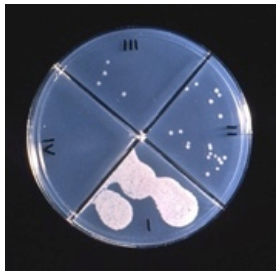
- Long period from index surgery to clinical presentation
- Various clinical manifestations
- Lack of appropriate cultures at presentation
- Slow growth of *M. chimaera*
- Disbelief on behalf of provider

Diagnosis of NTM Infections

Routine Methods Take a Long Time!

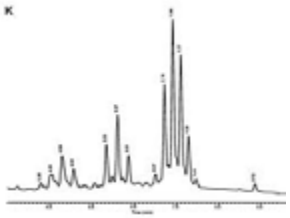
Think about it!

Diagnosis
8 + weeks

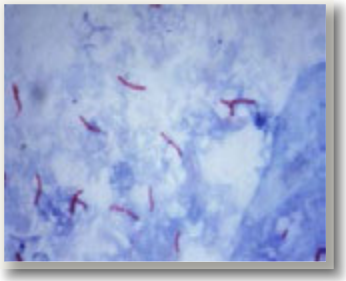


Drug susceptibility

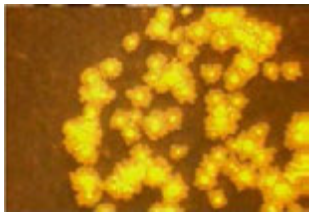
Collect a specimen



Identification



Microscopic examination



Culture (liquid and solid media)

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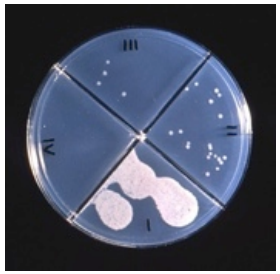
Diagnosis of NTM Infections

Routine Methods Take a Long Time!



Drug susceptibility

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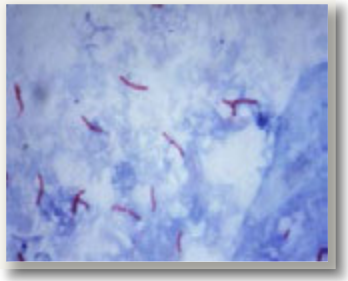
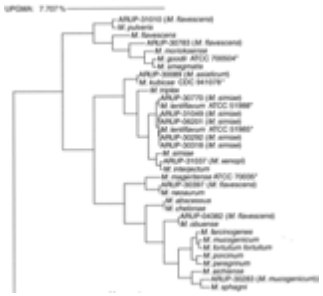
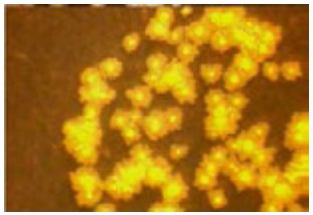


Microscopic examination



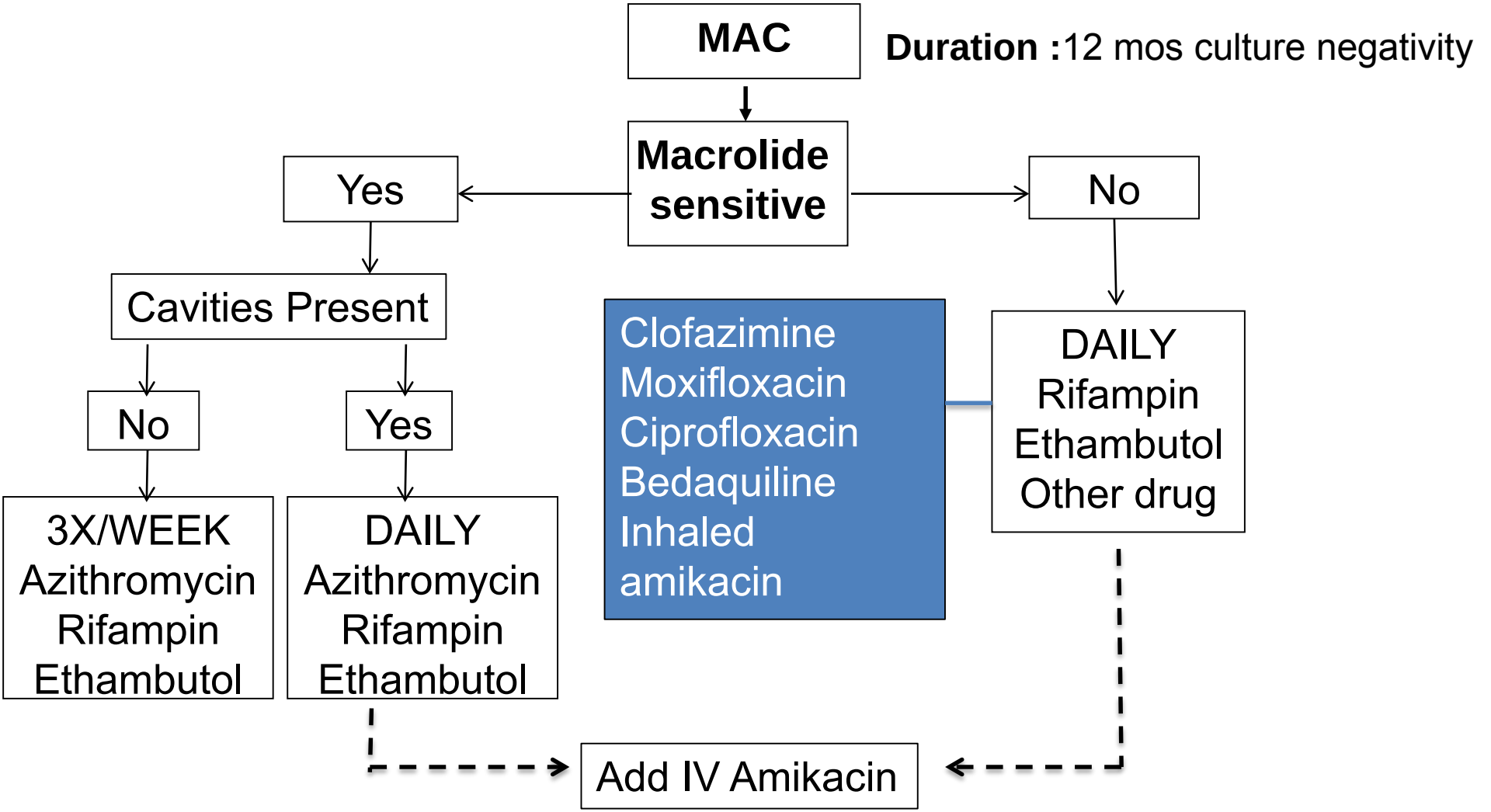
Sequencing (rpoB)



Culture (liquid and solid media)

Treatment

M. avium complex Pulmonary Infection



Treatment Outcomes for Pulmonary MAC

	Culture Conversion
Macrolide susceptible	
Non cavitary	80%
Cavitary	<50%
Macrolide resistant	
No surgery/aminoglycoside	5%
Surgery + aminoglycoside*	80%

* ≥ 6 months IV aminoglycoside

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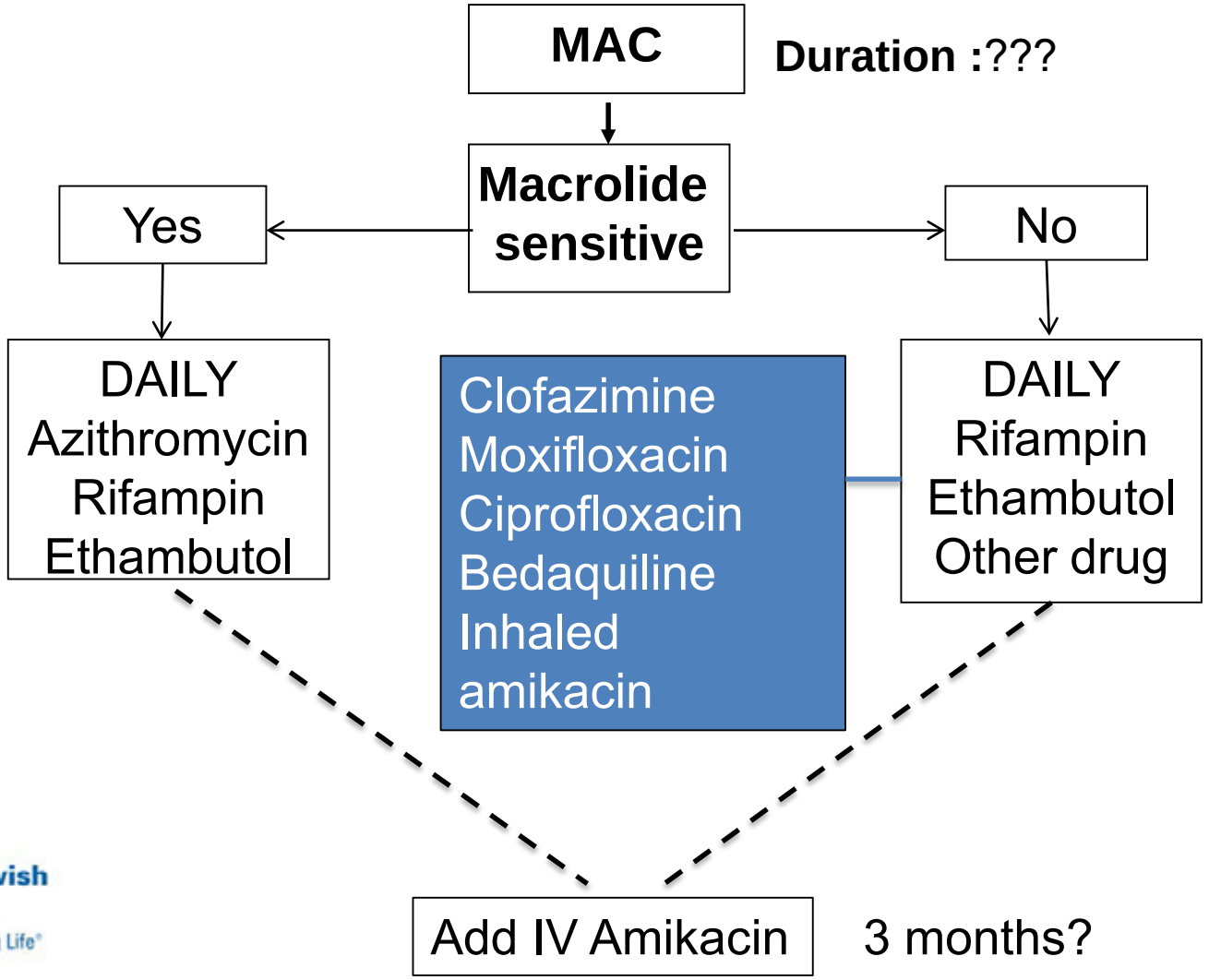
Griffith DE, et al. AJRCCM 2006;174:928
Wallace R, et al. Chest 2014:146:276-282
Jeong BH, et al. AJRCCM 2015:191:96-103

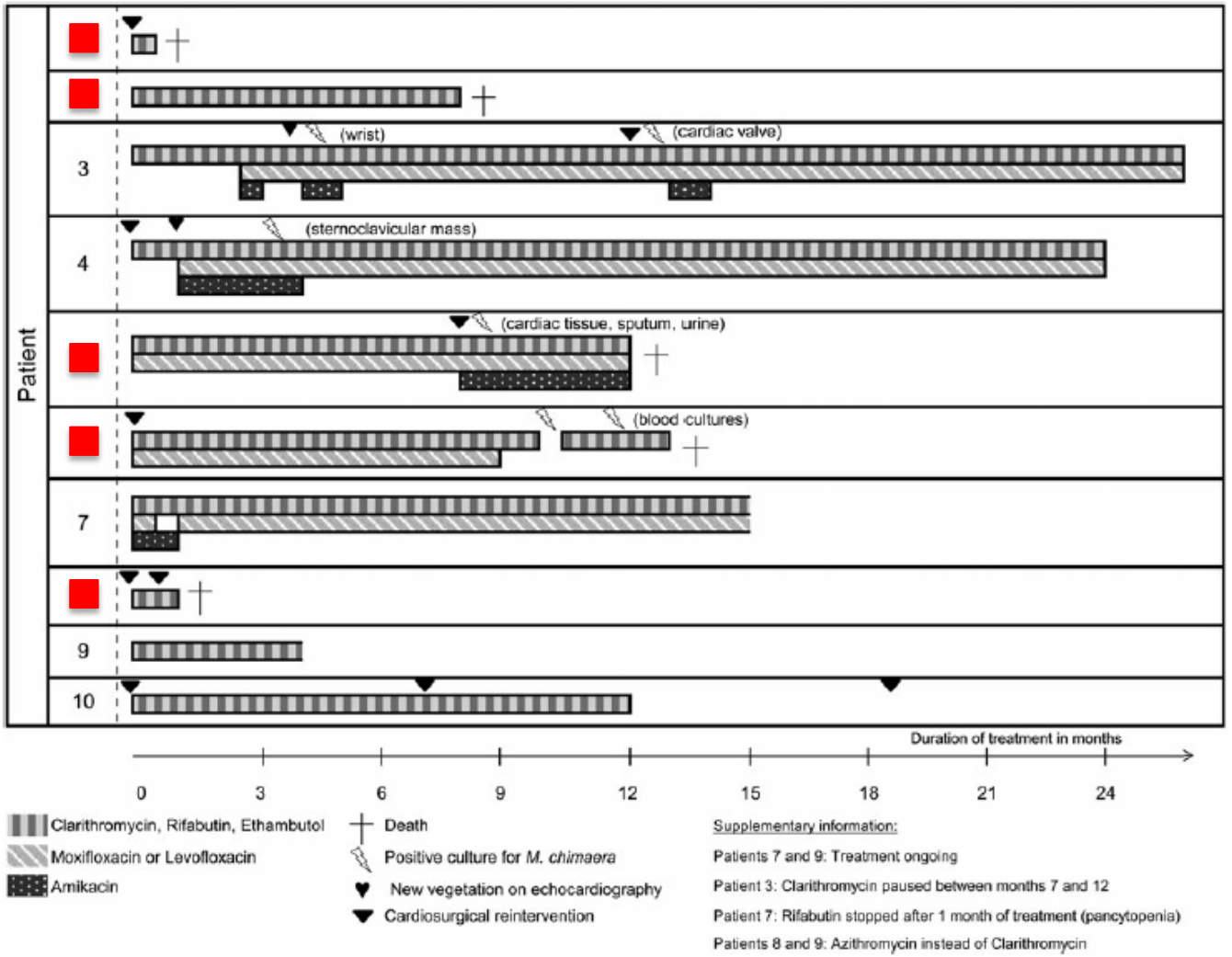
Treatment

Disseminated *M. chimaera*



National Jewish Health
Science Transforming Life

Clinical Outcomes of Disseminated *M. chimaera* Infections



Kohler P, et al. Eur Heart J 2015;36:2745

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!

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Science Transforming Life®

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.

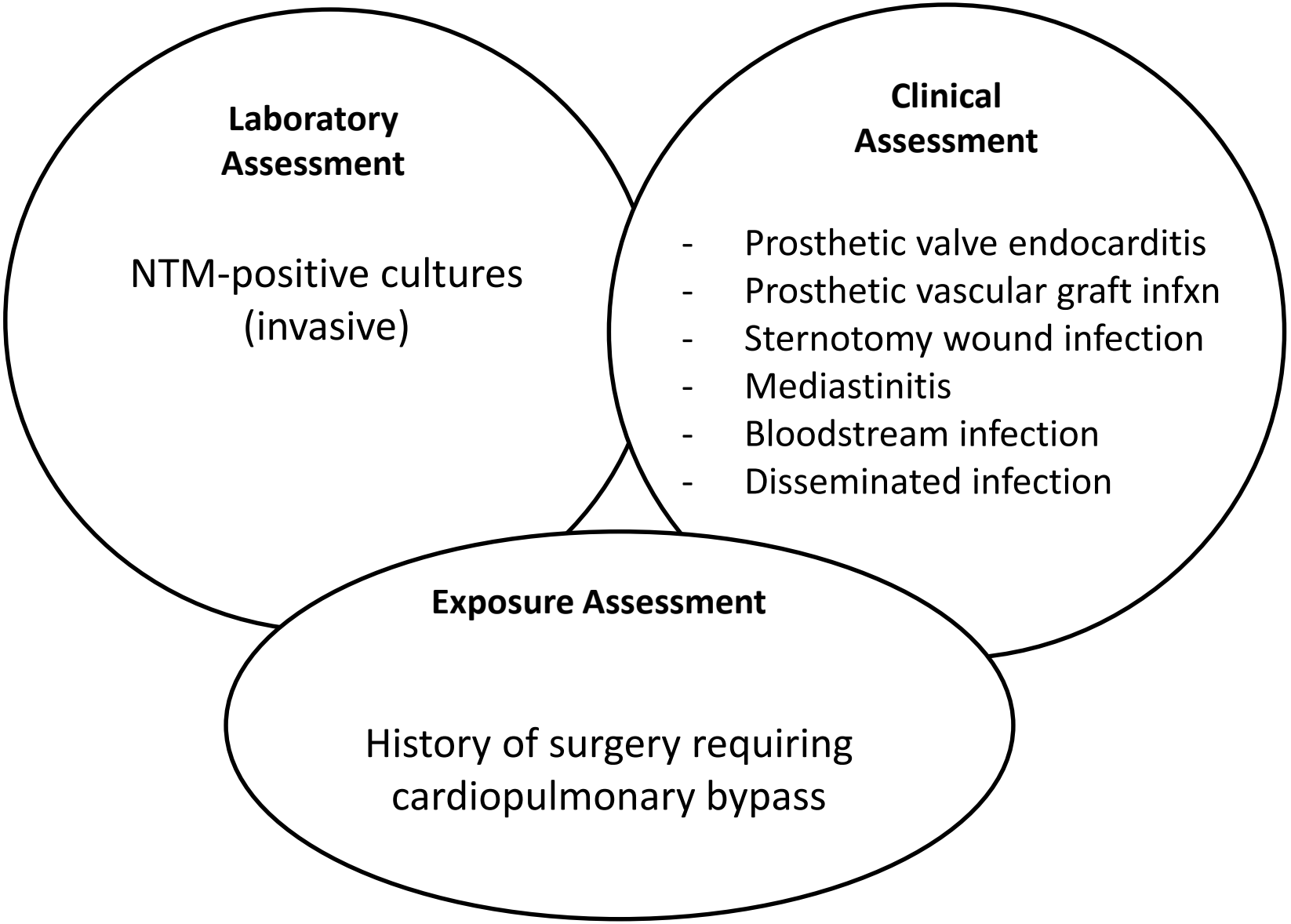
2) **Clinical assessment:**

   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)

http://www.cdc.gov/hai/pdfs/outbreaks/Guide-for-Case-Finding.pdf

Identifying Possible Cases of NTM Infections Associated with Exposure to Heater-Cooler Devices



http://www.cdc.gov/hai/pdfs/outbreaks/Guide-for-Case-Finding.pdf

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

http://www.cdc.gov/hai/pdfs/outbreaks/Guide-for-Case-Finding.pdf

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

Translated into preferred language
Translators available for patient calls

It is important that you call us toll-free at 866-[redacted] 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

Hospital Administration

Office of the Chief Medical Officer
200 Hawkins Drive, 1309-A JCP
Iowa City, IA 52242-1009
319-467-5700 Tel
319-356-3862 Fax
www.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.

Referring provider letter

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

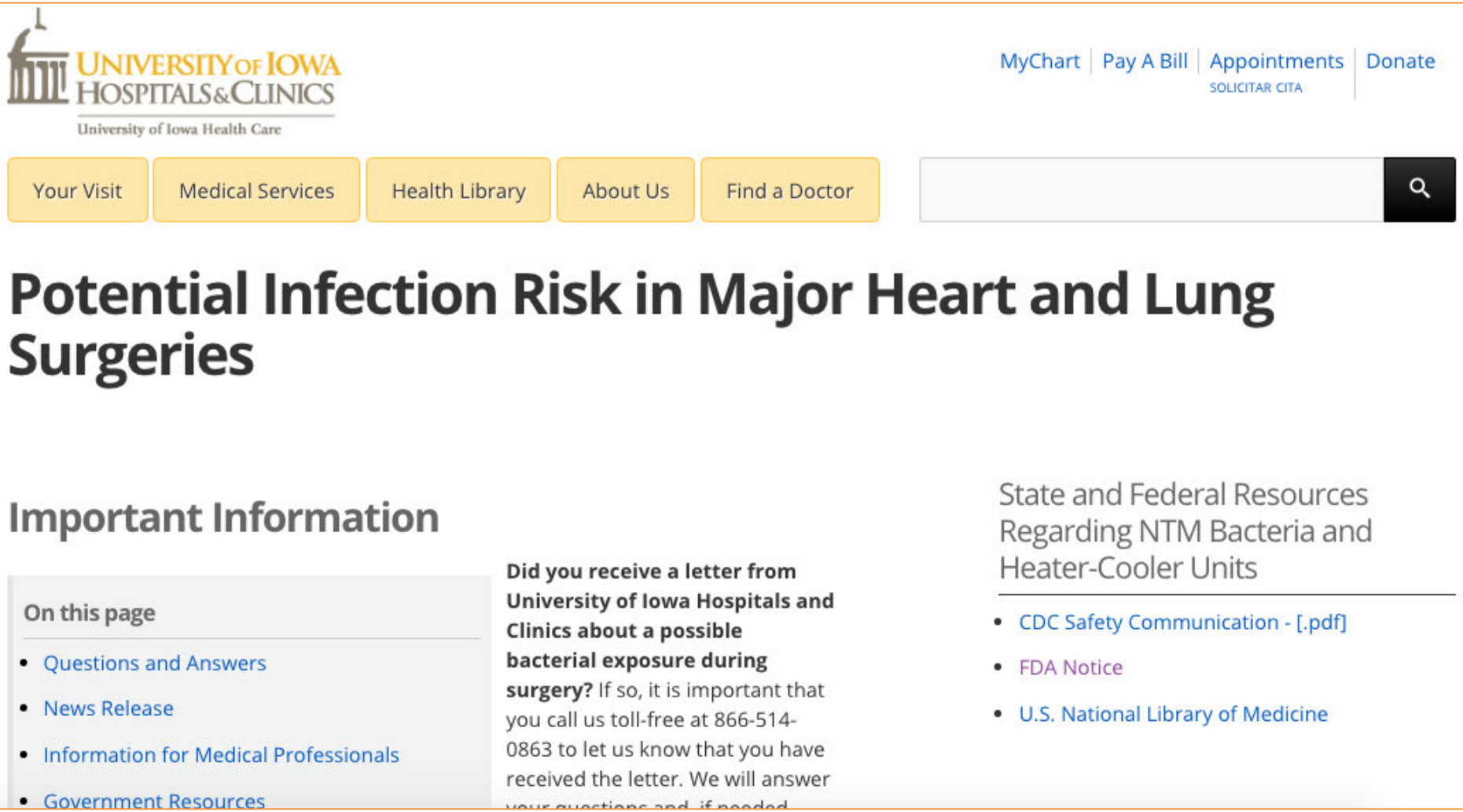
Safe and high quality care is the top priority for University of Iowa Hospitals and Clinics in Iowa City. Hospital leaders recently began notifying about 1,500 patients of possible exposure to a bacterium during certain major surgeries that took place between January 1, 2012, and January 22, 2016.

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.

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



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 (*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 *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