Nontuberculous Mycobacteria and Heater-Cooler Devices: A CDC Update

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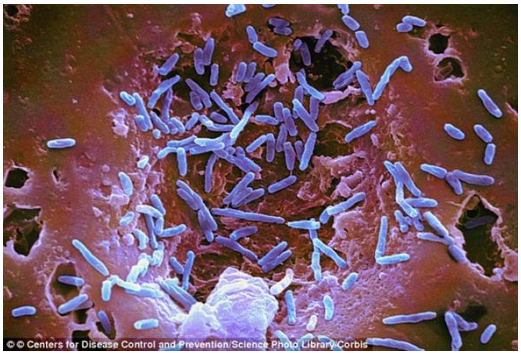
January 18, 2017

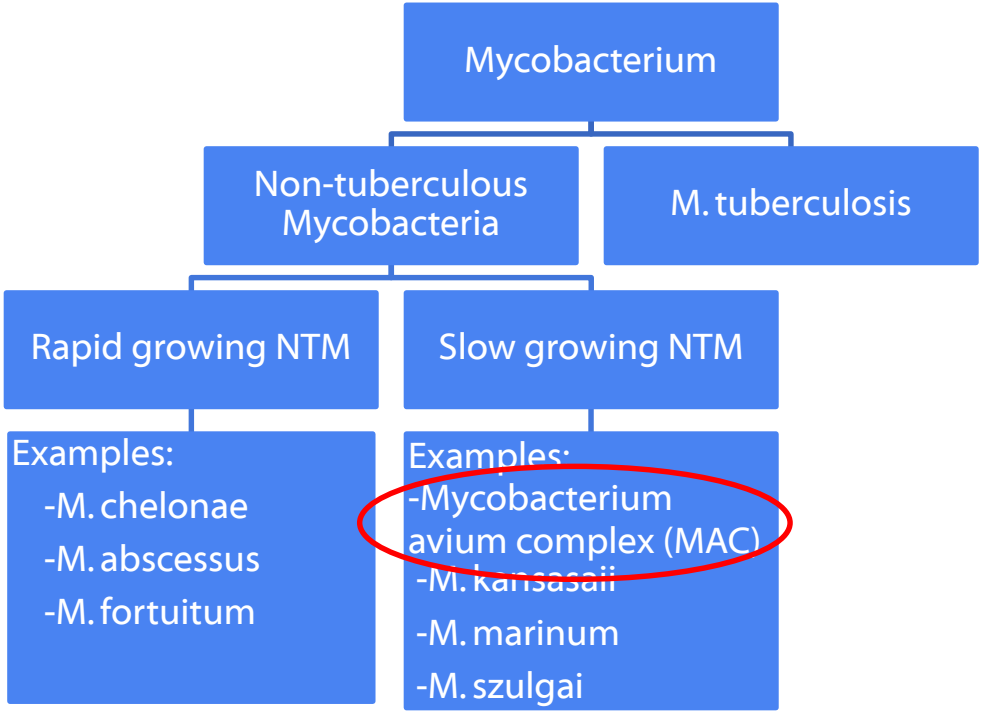
Nontuberculous Mycobacteria (NTM)

- Acid-fast bacteria
- Most common slow-growing NTM is *Mycobacterium avium complex* (MAC), which includes *Mycobacterium chimaera*
- Found in the environment: surface water, tap water, soil
- Opportunistic: immunocompromised, chronic lung disease
- Only 10% of infections are extrapulmonary
- Infections can be difficult to diagnose
- Outbreaks in healthcare settings often related to water sources



Courtesy of Meghan Lyman, MD

Nontuberculous Mycobacteria (NTM)

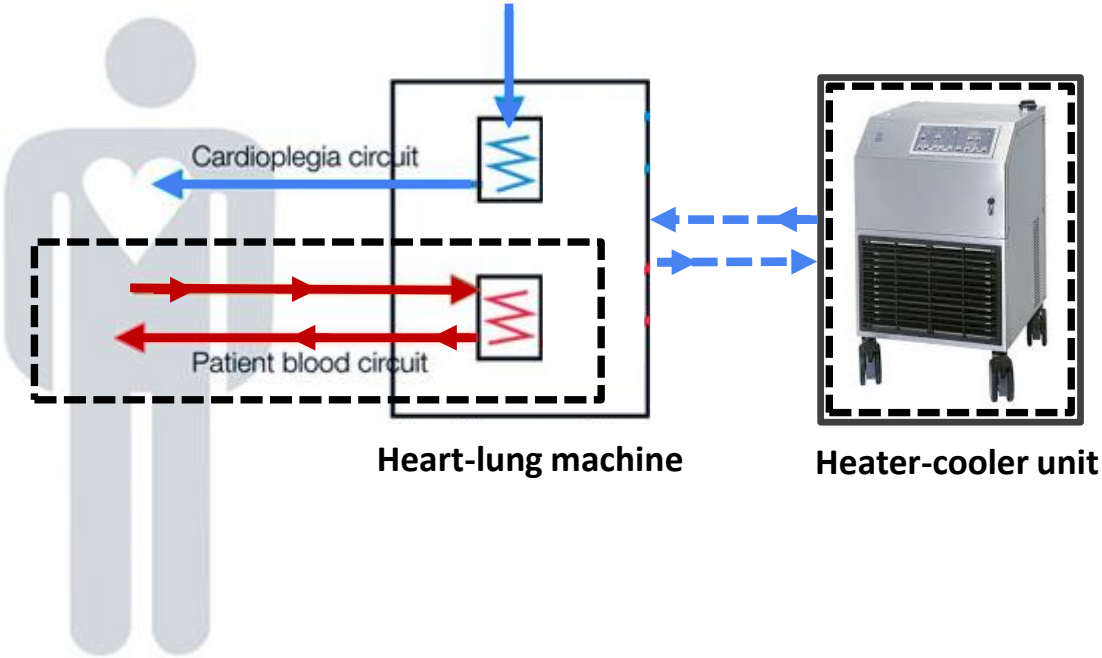


Courtesy of Meghan Lyman, MD

Prior Healthcare-associated NTM Outbreaks

- Showers
- Ice machines
- Hydrotherapy pools/personal hot tubs
- Solution used to mark surgical site
- Inadequate sterilization of surgical equipment
- Tap water used in cooling cardioplegia
- Artificial heart valves
- Injections (i.e. steroids, anesthetic, vaccines)
- Portable misting humidifiers
- Heater-cooler devices

Cardiopulmonary Bypass (CPB)

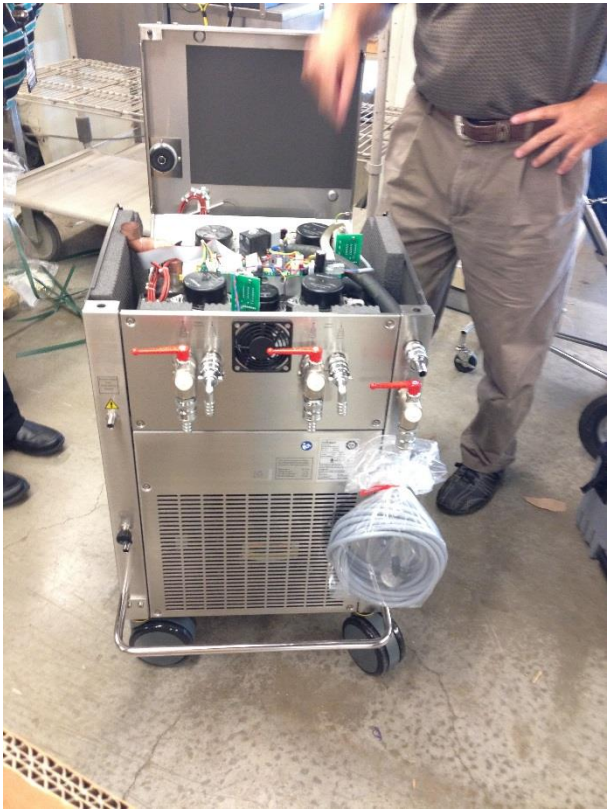


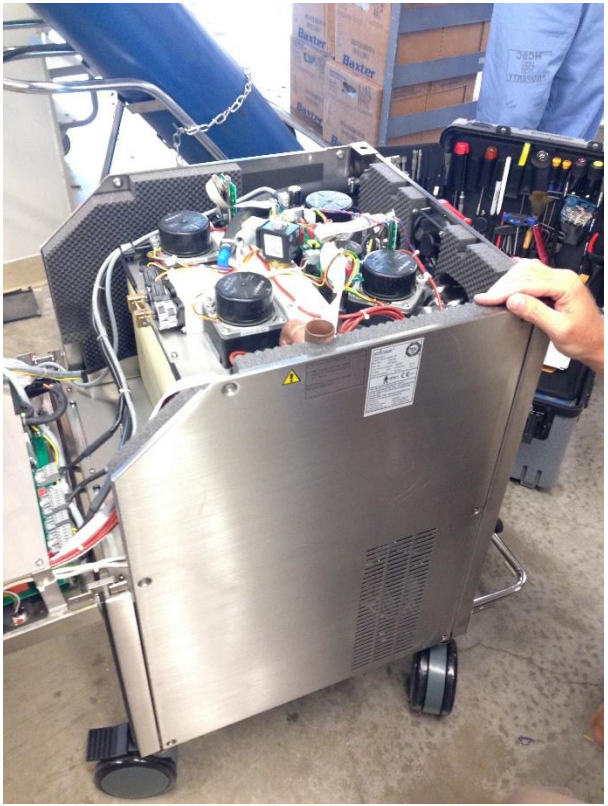
http://www.fda.gov/medicaldevices/productsandmedicalprocedures/cardiovasculardevices/heater-coolerdevices/default.htm

Courtesy of Meghan Lyman, MD

Heater-cooler Device

Heater-cooler Device





Greenville, SC Investigation 2014

GHS infection probe focuses on water

Liv Osby, losby@gannett.com 8:40 p.m. EDT July 12, 2014

Federal health officials say they are focusing on water as the potential source of the bacteria that infected 15 patients at Greenville Memorial Hospital in recent months and which may have contributed to the deaths of three of them.

- Total cases = 18, Majority but not all cardiac surgery patients (abdominal, neurological)
- *M. abscessus*
- Conducted patient notification

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 … …ween 1.5 and 3.6 years after surgery. *Mycobacteri*… …tures, or other biopsy specimens. We were able … …nits connected to the cardiopulmonary bypass, a… …emonstrated identical patterns among *M. chimae*… …d strains in 2 patient clusters.

Conclusions. The epid… …ak provided evidence for the airborne transmission of *M. chimaera* from contaminated heater-cooler unit water tanks to patients during open-heart surgery.

- **Invasive *M. chimaera* in 6 patients**
- **Open-chest, implants, 2008-2012**
- **Investigation of possible water sources**
- **Heater-cooler device**
- **Up to 3.6 yrs following exposure**

Keywords. outbreak; *Mycobacterium chimaera*; nontuberculous mycobacteria; open-chest heart surgery; infection control.

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

Cluster of NTM Infections, Pennsylvania, 2015

- July 20, 2015, Wellspan York Hospital reported a cluster of NTM infections among cardiothoracic surgery patients
- Recent reports of an association between heater-cooler devices (HCDs) and risk for NTM infections
- Hospital replaced their HCDs and attached devices
- Pennsylvania Department of Health (PADOH) and CDC investigated the cluster

Courtesy of Meghan Lyman, MD

Investigation

- Performed direct observations
- Reviewed infection control policies and procedures
- Conducted comprehensive case-finding
- Described cohort, developed case definition
- Conducted case-control study to identify risk factors for infection among cardiovascular surgery patients
- Collected environmental and clinical isolates

Courtesy of Meghan Lyman, MD

Rate of NTM Infections by Surgery Type

	Number of NTM+ patients	Rate of NTM+ patients (per 10,000 surgeries)
All surgeries	48	4.8
Cardiothoracic	20	20.2
General	19	7.7
Orthopedic	8	5.0

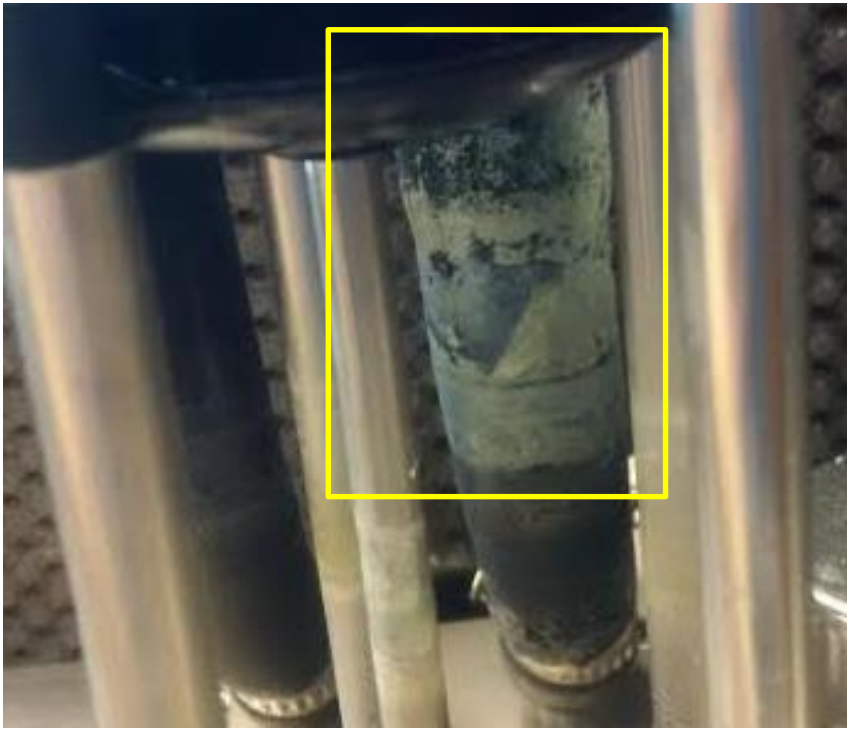
Courtesy of Meghan Lyman, MD

Case-control study: Surgery Characteristics

Surgery Characteristics	n (%) Case patients (n=10)	Control patients (n=48)	Odds Ratio	95% CI
Cardiopulmonary bypass	8 (80)	20 (42)	5.6	1.1-29.2
Length of HCU exposure (cumulative operating time with HCU present)				
0 hours	2 (20)	28 (58)	ref	ref
>0–4 hours	1 (10)	9 (19)	1.6	0.1-19.2
>4–5 hours	1 (10)	6 (13)	2.3	0.2-30.1
>5 hours	6 (60)	5 (10)	16.8	2.6-108.1

Courtesy of Meghan Lyman, MD

Infection Control Assessment



Courtesy of Meghan Lyman, MD

Laboratory Testing Results

Description	Sample Type	Species identified
Patient Isolates		
Case-patient #1	Blood	M. chimaera
Case-patient #2	Blood	M. chimaera
Case-patient #3	Blood	M. chimaera
Environmental Sampling		
HCU #1	Water	M. chimaera
HCU #2	Water/Swab	M. chimaera
HCU #3	Water	M. chimaera
Ice machine	Ice	M. mucogenicum/phocaicum; M. gastri
Scrub sink	Water	M. avium
Air Sampling with HCU operational	Air	M. chimaera

Courtesy of Meghan Lyman, MD

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-coo… to
warm or co… er
tanks that …
closed circ…
potential fo…
through the…

Through th…
internation…
Nontuberc… es.
NTM orgar… re
typically no…
compromis…

Between J…
infections …
these MDRs were reported to the FDA in 2015. Some reports describe NTM infections related to cardiothoracic surgeries, but other reports do not specify the procedure the patient was undergoing. Eight reports were related 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 fo raise awareness among h he possible association betwee guidance on identifying patients

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

Case Series in Europe – October 2015

European Heart Journal (2015) **36**, 2745–2753
doi:10.1093/eurheartj/ehv342

FASTTRACK CLINICAL RESEARCH
Cardiovascular surgery

Healthcare-associated prosthetic heart valve, aortic vascular graft, and disseminated *Mycobacterium chimaera* infections subsequent to open heart surgery

Philipp Kohl
Michelle Fra
Markus J. W
Sylvia B. Del
Margreet C.
Erik C. Bött
and Barbara

10 Cases described in Switzerland, Germany, and the Netherlands

- **Estimated a minimum of 1-2 *M. chimaera* infections per 1000 patients undergoing open-heart surgery.**
- **17/25 hospitals detected *M. chimaera* in the water system of their HCUs**
- **All surgeries involved prosthetic material**
- **5/10 cases died**

Iowa Investigation

Controversies in Hospital Infection Prevention

Wherein we ponder vexing issues in infection prevention and control, inside and outside the hospital.

Tuesday, February 2, 2016

M. chimaera infections associated with cardiopulmonary bypass

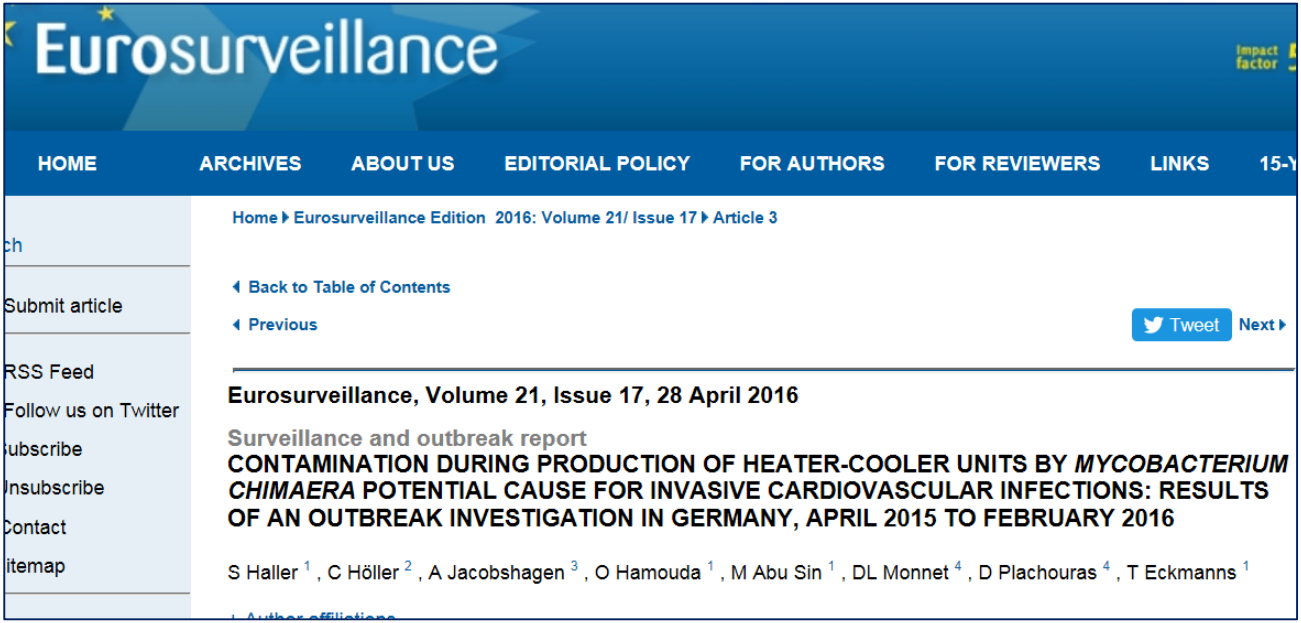
Dan Diekema

- Facility performed lookback for cases followed by patient notification
- Identified cases as a result of PROVIDER notification
- Moved heater-cooler devices outside of the OR as has been done in multiple European hospitals

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



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Eurosurveillance, Volume 21, Issue 17, 28 April 2016

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]

- *M. chimaera* typing results from the HCDs from 3 different countries almost identical to samples obtained from manufacturing site in Germany "unpublished data"

Smoke Dispersal Experiment with Heater-Cooler Device

https://www.youtube.com/watch?v=YZ41aLoHrhQ&feature=youtu.be

Sommerstein R et al. Emerg Infect Dis 2016;22(6).

Point Source Contamination of *M. chimaera*

Morbidity and Mortality Weekly Report

October 2016

Notes from the Field

Whole genome sequencing points to concerns for point source contamination of LivaNova (formerly Sorin) 3T HCDs

***Mycobacterium chimaera* Contamination of Heater-Cooler Devices Used in Cardiac Surgery – United States**

Kiran M. Perkins, MD[1]; Adrian Lawsin, MS[1]; Nabeeh A. Hasan, PhD[1]; Michael Strong, PhD[2]; Alison L. Halpin, PhD[1]; Rachael R. Rodger, MPH[2]; Heather Moulton-Meissner, PhD[1]; Matthew B. Crist, MD[1]; Suzanne Schwartz, MD[3]; Julia Marders, MS[3]; Charles L. Daley, MD[2]; Max Salfinger, MD[2]; Joseph F. Perz, DrPH[1]

all sequences across a core genome of approximately 5 million base pairs revealed a maximum of 38 SNPs between any two isolates related to the outbreak investigation, versus a minimum of 2,900 SNPs between any single outbreak isolate and

CDC Advises Hospitals to Alert Patients at Risk from Contaminated Heater-Cooler Devices Used during Cardiac Surgery

HAN HEALTH ALERT NETWORK

Distributed via the CDC Health Alert Network

October 13, 2016, 13:00 ET (1:00 PM ET)

CDCHAN-00397

This is an official CDC HEALTH

UPDATE: Mycobacterium chimaera Infections Associated with LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stöckert 3T Heater-Cooler System: FDA Safety Communication

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CDC Advises Patient Notification

HAN
HEALTH ALERT NETWORK
Distributed via the CDC Health Alert Network
October 13, 2016, 13:00 ET (1:00 PM ET)
CDCHAN-00397

This is an official CDC HEALTH ADVISORY

Summary

The Centers for Disease Control and Prevention (CDC) is advising hospitals to notify patients who underwent open-heart (open-chest) surgery involving a Stöckert 3T heater-cooler that the device was potentially contaminated, possibly putting patients at risk for a life threatening infection. New information indicates that these devices, manufactured by LivaNova PLC (formerly Sorin Group Deutschland GmbH), were likely contaminated with the rare bacteria

Q.How far back in time should hospitals go to notify patients?

A. Hospitals should consider notifying patients **in writing** if they were exposed to the Stöckert 3T devices during open-chest cardiac surgery at their institution since **January 1, 2012**. Hospitals that did not use the Stöckert 3T device during this entire time period should adjust the patient notification timeframe accordingly.

~ 600,000 patients

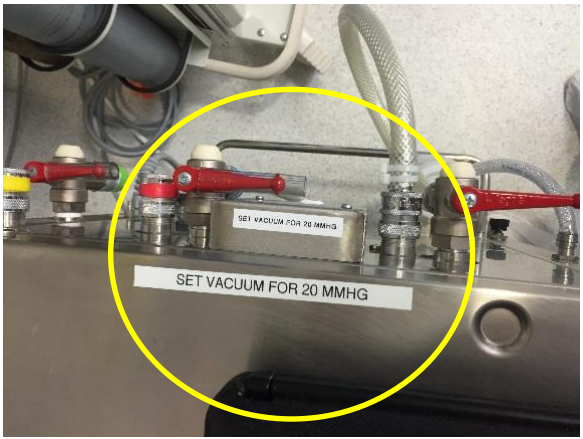
Case tracking

- Health departments advised to track reports of potential infections
  - Invasive NTM infections - NTM-positive specimen from:
    - normally sterile body site
    - skin soft tissue, or drainage from a wound or abscess, or
    - lymph nodes
  - Data elements:
    - Demographics
    - Diagnosis
    - Exposure history
    - Outcome
- Reporting to CDC voluntary
- Facilities should report all cases to FDA

FDA Recommendations: 3T Devices October 2016

- **Any 3T device:**
  - Remove devices, accessories, tubing, & connectors that have tested positive for *M. chimaera* or associated with *M. chimaera* infections
  - Use new accessories, tubing, & connectors to prevent recontamination
  - HCD exhaust should be directed/channeled away from patient
  - Consider risk/benefit
- **3T manufactured before September 2014:**
  - Transition away from using the device until risk mitigation strategies implemented by manufacturer
  - Limit use to emergent and/or life-threatening situations if no other available options
  - Testing HCDs for *M. chimaera* not recommended
- **3T manufactured after September 2014:**
  - Follow FDA recommendations to mitigate risk
  - Testing of HCDs for *M. chimaera* not recommended

Risk Mitigating Strategies



Outreach

- **Hospitals**
  - CDC calls with AHA and other hospital associations
  - FDA/CDC Stakeholder call (11/1/16) with over 1,100 participants
  - Active engagement by many health departments
    - Calls/webinars, hospital surveys, all facilities letter
- **Clinicians**
  - CDC hosted webinar (8/29/16) with > 1,900 participants and >3,400 subsequent views
  - CDC calls with >20 professional societies ahead of the MMWR, encouraging additional outreach to members
    - E.g., Society of Thoracic Surgeons (STS), American Thoracic Society (ATS), other surgical societies, perfusionists

Outreach

- **Patients**
  - Tools on website for patients
    - FAQs
    - Sample letter to present to PCP
  - Media (CDC press release)
  - YouTube Video (> 4,400 views)

CDC Heater-Cooler Website

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

SEARCH

CDC A-Z INDEX

Resources for hospitals, clinicians, and patients

Healthcare-associated Infections

- Healthcare-associated Infections (HAI)
- Data and Statistics +
- Types of Infections +
- Diseases and Organisms +
- Preventing HAIs +
- Map: HAI Prevention Activities
- Research +
- Patient Safety
- Outpatient Settings
- Laboratory Resources +
- Outbreak and Patient Notifications −
  - *B. cepacia* – Saline Flush
  - **Contaminated Heater-Cooler Devices**
  - *B. cepacia* – Docusate
  - CDC Statement LA CRE
  - Multistate Meningitis Outbreak +
  - Outbreaks in Outpatient Settings +
  - Outbreak Resources for State Health Departments +

CDC > Healthcare-associated Infections (HAI) > Outbreak and Patient Notifications

Contaminated Heater-Cooler Devices

Update: CDC has updated the notification toolkit to include frequently asked questions for hospitals notifying patients of risk from contaminated heater-cooler devices used during cardiac surgery.

Alert: CDC issued a Health Alert Notice to patients and hospitals regarding the risk of NTM infections from Stöckert heater-cooler devices used during open-heart surgery.

Patients who have had open-heart surgery and are having symptoms should seek medical care. While risk of infection is low, it is important to consult with your doctor.

Contaminated Devices Putting Open-Heart Surgery Patients at Risk

CDC encourages hospitals to take action, advises patients to seek care if ill

The Centers for Disease Control and Prevention (CDC) is warning healthcare providers and patients about the potential risk of infection from certain devices used during open heart (open-chest) surgery.

Patients who have had open heart surgery should seek medical care if they are experiencing symptoms associated with infections, such as night sweats, muscle aches, weight loss, fatigue, or unexplained fever. This advice follows new information indicating that some LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stöckert 3T heater-cooler devices, used during many of these surgeries, might have been contaminated during manufacturing which could put patients at risk for life-threatening infections.

More than 250,000 heart bypass procedures using heater-cooler devices are performed in the United States every year. Heater-cooler units are an

More Information

- Notification Toolkit
- Questions and Answers
  - General
  - For Hospitals
- CDC Health Alert
- CDC MMWR
- FDA Safety Alert
- CDC Press Release
- Heater-Cooler Unit Webinar [1:05]

Concerned Patients

- Important information for heart surgery patients

- Questions and Answers

Ongoing Opportunities/Challenges

- **Outreach**
  - Need for continued/targeted outreach efforts
  - Expanding hospital surveys to measure awareness and uptake of CDC and FDA recommendations
- **Managing identified cases**
  - Guidance to aid clinical management
  - CDC exploring consultation services with experts
- **Tracking of *M. chimaera* infections**
  - Making extrapulmonary NTMs reportable (currently reportable in few states)
  - CDC exploring case registry
- **Assessing effectiveness of various risk mitigation strategies in the field**

Thank you

heatercoolerunits@cdc.gov

KPerkins@cdc.gov

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.