CDC links patient infections to potentially contaminated heater-cooler devices
Hospitals advised to notify at-risk patients

Embargoed for media until Thursday, Oct. 13, at 1 pm ET

The Issue

The Centers for Disease Control and Prevention (CDC) has informed us that Stöckert 3T Heater-Cooler devices manufactured by LivaNova PLC (formerly Sorin Group Deutschland GmbH) may have been contaminated with Mycobacterium chimaera (M. Chimaera) in the manufacturing process, and that patients for whom these devices were used during cardiac surgery may be at risk of developing infections. On Thursday, Oct. 13, CDC will publish information in the Morbidity and Mortality Weekly Report detailing its research about this potential device-related infection risk and issue a Health Advisory.

CDC is advising hospitals to alert patients who have had open-heart surgery involving a Sorin Stöckert 3T heater-cooler device that they might be at risk for developing a life-threatening infection from M. Chimaera. To assist hospitals in their outreach, CDC has developed the attached toolkit, which includes: a sample notification letter to patients, as well as a letter for patients to take to their health care providers; a letter for clinicians; and a questions-and-answers document. The CDC has embargoed the toolkit for media until Thursday, Oct. 13, at 1:00 p.m. ET but agreed to share it with hospitals today to help them prepare for questions from patients and the media. Please do not share the materials outside of your organization.

The Food and Drug Administration (FDA) also plans to release a Safety Communication on Oct. 13 providing updated device-specific recommendations to help prevent the spread of infections related to the use of these devices.
**NEXT STEPS**

Hospitals should review and determine how best to follow the recommendations in the CDC Health Advisory and the FDA Safety Communication that will be published on Oct. 13. We will forward both of these documents to member hospitals. We also suggest hospitals take the following steps:

- Develop procedures for how to process questions from patients who may learn of their potential exposure either through outreach efforts made by your organization or media reports. Prepare staff to work with patients who may be concerned about the risk of infection, and ensure staff have proper information, training and referral sources. It may be helpful to identify a small team of individuals who can work with patients at risk.

- Educate your clinical staff, as well as providers in the community, about *M. Chimaera* screening and monitoring of post-surgical patients.

- Prepare your media team for inquiries from the media on the potentially contaminated devices. It may be helpful to designate a spokesperson. See the media talking points included below in this advisory.

- Work with your communications and social media teams to post relevant materials to your website, patient portals and other communications with patients.

Even if your hospital has not used the device, we encourage you to share the CDC educational materials with your clinical staff members, as well as physicians and practitioners in the community. These efforts can alert health care providers of the need to consider *M. Chimaera* infection among patients with relevant symptoms and a history of cardiac surgery.

**FURTHER INFORMATION**

The CDC and FDA held a call yesterday with hospital members of the American Hospital Association, the Federation of American Hospitals, the Association of American Medical Colleges and America’s Essential Hospitals. A recording of the call will be posted shortly on the following websites:

- FAH – [http://fah.org/members-only/members-only](http://fah.org/members-only/members-only)
- AAMC – [www.aamc.org/hospitalpaymentandquality](http://www.aamc.org/hospitalpaymentandquality)
- AEH – [https://essentialhospitals.org/quality/](https://essentialhospitals.org/quality/)
For further questions, contact:

- Evelyn Knolle, American Hospital Association, at eknolle@aha.org
- Jayne Hart Chambers, Federation of American Hospitals, at JChambers@FAH.org
- Maryellen Guinan, America’s Essential Hospitals, at mguinan@essentialhospitals.org
- Scott Wetzel, Association of American Medical Colleges, at swetzel@aamc.org

**TALKING POINTS**

This news has the potential to prompt media inquiries, so your organization may want to designate a spokesperson. Below are sample talking points, which should be modified based on the practices, actions and circumstances of each hospital or health system.

- Patient safety is the top priority for hospitals and health systems.

- We take this and all possible safety events very seriously and have thoroughly reviewed the CDC materials to determine how they apply to our hospital or health system.

- Our clinical teams will continue their vigilant patient safety process prior to, during and after procedures.

For hospitals that have used the devices involved:

- Our hospital is working to notify patients who may be affected. (*Provide details on how you are contacting patients.*) [*If your hospital has already taken action based on previous FDA reports about these devices, such as post-surgical monitoring of patients, describe these efforts in general terms.*]

- If a patient or family member has any questions, they should contact: (*Provide details on who patients should contact with any questions.*)

- We have provided/will be providing educational materials from CDC to our clinical staff and physicians in the community about how to identify the signs of an infection in post-surgical patients.

- As a standard practice, we have and will continue to monitor reports from CDC and FDA detailing concerns about *any type* of medical device.
• Although the possibility of transmission is low, even one infection is too many. That is why we are taking proactive action to notify patients and clinicians.

For hospitals that HAVE NOT used the devices involved:

• None of the machines identified by the CDC were used in surgeries at our hospital. However, we will be working with our clinicians, including our emergency department doctors and those in the community, to help them identify the symptoms of *M. Chimaera* infections in patients who may have had surgery elsewhere so they may provide the proper course of treatment.

• While we do not use the device identified by the CDC at our hospital, we will continue to monitor alerts about any heaters-coolers to ensure we take all appropriate action.
October 11, 2016

Dear Colleagues:

The Centers for Disease Control and Prevention (CDC) has identified additional laboratory information in its ongoing investigation into heater-cooler units used during open-chest cardiac surgery. The new laboratory findings demonstrate that the Stöckert 3T heater-cooler devices manufactured by LivaNova PLC (formerly Sorin Group Deutschland GmbH) linked to outbreaks in several states, were likely contaminated during the manufacturing process. These units represent about 60 percent of the heater-cooler devices currently in use in the United States, and may be putting patients at risk for severe infection from slow-growing bacteria known as *Mycobacterium chimaera*.

**CDC is advising hospitals to alert clinicians and patients of this risk and advise patients to seek immediate medical evaluation if they have had open-chest cardiac surgery and are experiencing symptoms such as night sweats, muscle aches, weight loss, fatigue, or unexplained fever.**

Infections with *Mycobacterium chimaera*, a species of nontuberculous mycobacterium (NTM), can be challenging to diagnose and treat. The bacteria are slow-growing and patients may not experience symptoms for months or even years after surgery. Clinicians and patients may not immediately consider an NTM infection when symptoms present. Delayed diagnosis may make treating these infections even more challenging. There is no test to determine whether a person has been exposed to the bacteria. Infections can be diagnosed by detecting the bacteria by laboratory culture; the slow growing nature of the bacteria can require up to two months to rule out infection.

**As CDC’s valued healthcare partner, we are sharing the attached clinician & patient notification toolkit to aide in alerting clinicians and patients about the risk of infection from these heater-cooler units.**

Attached you will find:

- Modifiable patient notification letter
- Letter to alert clinicians
- Letter for patients to take to their healthcare provider
- Questions and answers document
These materials can be customized by healthcare facilities and/or health departments and are designed to be sent directly to clinicians and patients. CDC will make updates to these materials as additional information becomes available.

Sincerely,
Centers for Disease Control and Prevention
Division of Healthcare Quality Promotion

Additional Resources:
- Link to Sorin 3T website: http://www.livanova.sorin.com/products/cardiac-surgery/perfusion/hlm/3t
Key Points

Summary
- CDC recently found that a device used during open-heart (open-chest) surgery might have been contaminated with a rare bacteria during manufacturing.
  - The heater-cooler devices: Stöckert 3T manufactured by LivaNova PLC (formerly Sorin Group Deutschland GmbH)
- Patients who have had open heart surgery and who are experiencing symptoms such as night sweats, muscle aches, weight loss, fatigue, or unexplained fever should seek a medical evaluation.
- In particular, CDC is advising hospitals to alert patients who have had open-heart surgery involving a Sorin Stockert 3T heater-cooler devices that they might be at risk for developing a life-threatening infection from *Mycobacterium chimaera*.

About the bacteria
- Nontuberculcous mycobacterium (NTM) are a type of bacteria often found in soil and water but rarely make healthy people sick.
  - The specific type of NTM involved is called *Mycobacterium chimaera*
- Transmission of NTM from environmental sources to people can occur, but usually only among immunocompromised patients.
- NTM infection is also linked with getting medical care because of necessary procedures (such as surgery) that, by their nature, require breaches of patients’ normal immune system defenses.
- NTM are often recognized as a cause of chronic lung infection, mostly among people who have underlying lung disease such as bronchiectasis or COPD.

About heater-cooler devices
- Heater-cooler devices are essential pieces of equipment that enable doctors to perform life-saving procedures.
- These devices are used during cardiac surgery when cardiopulmonary bypass is needed to help regulate the temperature of the patient’s blood.
  - The machine uses water to warm or cool the blood as it is circulated outside of the patient’s body.
- The device’s design includes a fan, which researchers now believe can disperse aerosolized bacteria into the operating room. The bacteria can then move through the air and enter the patient’s open chest cavity.

Common Questions
- **What is the risk of infection?**

  Overall, the risk is thought to be very low. In hospitals where at least one infection has been identified, the risk of infection was between about 1 in 100 and 1 in 1,000 patients. Initial information suggests that patients who had prosthetic implants are at higher risk. It is possible that not all of the devices introduced these bacteria into the operating room or exposed patients.
• How long does it usually take for these infections to show up? What’s the shortest amount of time it’s
taken for an infection to occur following exposure to a contaminated heater-cooler device during bypass
surgery? The longest?

NTM are slow-growing bacteria and infections may take months to develop. Cases associated with this
device have been diagnosed within months and up to several years after an open-heart surgery involving
heater-cooler unit exposure.

• Can a person who develops one of these NTM infections spread it to others, such as family members?

No, the bacteria cannot be spread to others from an infected patient. Also, it is important to keep in mind
that NTM is common in soil and water but rarely makes healthy people sick.

• Should everyone who was exposed to these devices during open-heart surgery receive antibiotics just in
case?

The risk that patients will develop an infection following exposure to a contaminated heater-cooler unit is
very low. There is also no evidence that giving antibiotics just prior or during surgery with a potentially
contaminated heater-cooler device will prevent infection.

Although antibiotics can be life-saving drugs, there is no antibiotic treatment available to ward off this
specific infection and antibiotics are also not without risk themselves. Antibiotics put patients at risk for
allergic reactions and a potentially deadly diarrheal infection caused by the bacteria *Clostridium difficile*.
Antibiotic use is also a key driver of antibiotic resistance, which can put patients at risk for antibiotic-
resistant infections later.

• How long does it take to find out if an infection is being caused by NTM?

*M. chimaera* is a slow-growing species of NTM that can take eight weeks and sometimes longer to grow and
allow final identification.

• Why are these infections so deadly?

Symptoms of infection can take months to develop, and are often general and nonspecific. As a result,
diagnosis of these infections can be missed or delayed, sometimes for years, making these infections more
difficult to treat. Clinicians may not immediately consider an NTM diagnosis. Delayed diagnosis can result in
more widespread disease in a patient. This, combined with underlying health problems such as heart disease
can make these infections difficult to treat.

• How do you think the devices got contaminated?

NTM is common in water and soil. Recent CDC findings are consistent with previous reports suggesting that
the heater-cooler units were contaminated during production. Testing conducted by the manufacturer in
August of 2014 found *M. chimaera* contamination on the production line and water supply at the 3T
manufacturing facility.

• Have these devices ever been recalled? Why aren’t they being recalled now?

In 2015, the manufacturer recalled the instructions for use, but not the device itself. Information provided
by the manufacturer reminded users that while water from the device itself is not intended to contact the
patient directly, under certain circumstances, due to fluid leakage and/or aerosolization, NTM could reach a
patient’s surgical site. Heater-cooler devices are critical for life-saving surgery. A national recall could result
in patients not getting life-saving surgeries that are needed now.
SAMPLE LETTER FOR PATIENTS TO TAKE TO THEIR HEALTHCARE PROVIDER

Dear Healthcare Provider:

Your patient has undergone open-chest cardiac surgery at [hospital] and has been notified of a potential risk of a rare infection related to this surgery. In our letter to patients, we encourage them to discuss any symptoms with their healthcare provider.

Heater-cooler devices used during certain open-chest cardiac surgeries that require the use of a heart/lung bypass machine have recently been linked to a rare bacterial infection caused by *Mycobacterium chimaera*, a slow-growing species of nontuberculous mycobacteria (NTM). Investigations conducted by Centers for Disease Control and Prevention (CDC) and Federal Drug Administration (FDA) assessed several clusters of infections that were linked to exposures to LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stöckert 3T heater-cooler devices during cardiac surgery. It was determined that these devices were likely contaminated with *M. chimaera* during manufacturing.

CDC is recommending that clinicians, including cardiologists and general practitioners who take care of cardiac surgery patients before and after their surgery, be aware of the risk and consider NTM as a potential cause of unexplained chronic illness. These NTM infections are slow-growing bacteria and infections may take months or even years to cause symptoms.

Symptoms of an NTM infection may include:
- night sweats
- muscle aches
- weight loss
- fatigue
- unexplained fever

Patients with NTM infections following cardiac surgery have presented with a variety of clinical manifestations. Common examples include endocarditis, surgical site infection, or abscess and bacteremia. Other clinical manifestations have included hepatitis, renal insufficiency, splenomegaly, pancytopenia, and osteomyelitis.

The bacteria are slow-growing and patients may not experience symptoms for months or even years after surgery. Clinicians and patients may not immediately consider an NTM infection when symptoms present. Delayed diagnosis may make treating these infections even more challenging. There is no test to determine whether a person has been exposed to the bacteria. A test can identify infection once symptoms begin, but results can take about two months.

When seeing patients with possible NTM infections and a history of cardiac surgery, clinicians should consider arranging consultation with an infectious disease specialist. If an NTM infection is suspected, it is important to obtain acid fast bacilli (AFB) cultures from an infected wound and/or blood to increase the likelihood of identification of the organism and to obtain an AFB smear in order to have preliminary information while awaiting culture results.

If you have a clinical question pertaining to one of your patients, or if you have a symptomatic patient who requires additional evaluation for potential NTM infection, please call ______________ and speak to ______________.
If you have any questions about talking to your patients or anything else regarding this infection, please do not hesitate to contact us.

Sincerely,

NAME
TITLE
Sample Patient Notification Letter

Dear Sir or Madam,

[HOSPITAL] is currently notifying patients who have received open-heart cardiac surgery, of a potential infection risk related to this surgery. We are contacting you today as you or a member of your family has been identified in clinical records as a cardiac surgery patient that may be at risk for a rare infection.

The Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) are investigating reports that during certain open-heart surgeries the device used to heat and cool the blood has been linked to a rare bacterial infection caused by *Mycobacterium chimaera*, a species of bacteria known as nontuberculous mycobacterium (NTM). For patients who have had one of these surgeries, the chances of getting this infection are very low. CDC estimates the risk to be less than 1 percent. Of the [number of patients] at [HOSPITAL], who have had open heart surgery, we are aware of [number] of patient(s) who have developed this infection.

This infection is very slow growing and difficult to diagnose. It is possible to develop symptoms years after surgery, so it is imperative to know the symptoms to look for and to discuss any symptoms or questions you may have with your primary care doctor. This infection cannot be spread person-to-person.

Symptoms of an NTM infection may include:

- night sweats
- muscle aches
- weight loss
- fatigue
- unexplained fever

We understand that you and your family may have additional questions or concerns about the information you have received. To help answer them, we have established a hotline at [(555) 555-5555]. The hotline will be available starting [DATE]. You may also obtain additional information on the [HOSPITAL NAME] website at [http://www.website.com].

Sincerely,

NAME

Chief Health Officer
SAMPLE PRIMARY HEALTHCARE PROVIDER NOTIFICATION LETTER

Dear Healthcare Provider:

[HEALTHCARE FACILITY] is notifying providers of recent findings from Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) regarding patients who have undergone open-chest cardiac surgery. Heater-cooler devices used during certain major surgeries that require the use of a heart/lung bypass machine have recently been linked to a rare bacterial infection caused by Mycobacterium chimaera, a slow-growing species of nontuberculous mycobacteria (NTM). Investigations into several clusters of infections linked to exposures to LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stöckert 3T heater-cooler devices during cardiac bypass surgery have determined that these devices were likely contaminated with M. chimaera during manufacturing.

CDC is recommending that clinicians, including cardiologists and general practitioners who take care of cardiac surgery patients before and after their surgery, be aware of the risk and consider NTM as a potential cause of unexplained chronic illness. Infections can take months to years after surgery to develop, and symptoms are often general and nonspecific. As a result, diagnosis of these infections is often missed or delayed, making these infections especially difficult to treat. There is no test to determine whether a person has been exposed to the bacteria. A test can identify infection once symptoms begin, but results can take about two months.

Symptoms of an NTM infection may include:

- night sweats
- muscle aches
- weight loss
- fatigue
- unexplained fever

Patients with NTM infections following cardiac surgery have presented with a variety of clinical manifestations. Common examples include endocarditis, surgical site infection, or abscess and bacteremia. Other clinical manifestations have included hepatitis, renal insufficiency, splenomegaly, pancytopenia, and osteomyelitis. M. chimaera are slow-growing and patients may not experience symptoms for months or even years after surgery. Clinicians and patients may not immediately consider an NTM infection when symptoms present. Delayed diagnosis may make treating these infections even more challenging. There is no test to determine whether a person has been exposed to the bacteria. Infections can be diagnosed by detecting the bacteria by laboratory culture; the slow growing nature of the bacteria can require up to two months to rule out infection.

When seeing patients with possible NTM infections and a history of cardiac surgery, clinicians should consider arranging consultation with an infectious disease specialist. If an NTM infection is suspected, it is important to obtain acid fast bacilli (AFB) cultures from an infected wound and/or blood to increase the likelihood of identification of the organism and to obtain an AFB smear in order to have preliminary information while awaiting culture results.

In our letter to patients, we encourage them to discuss any symptoms with their primary care physician or to call ______________ if they have any questions or concerns.

If you have a clinical question pertaining to one of your patients, or if you have a symptomatic patient who requires additional evaluation for potential NTM infection, please call ______________ and speak to ______________.
We are working with the _________ Department of Health to guide our response, and will continue to partner with CDC and FDA to ensure we are following all safety recommendations. We believe that with our current practices we can continue to provide patients who need this device with safe, high-quality care.

If you have any questions about talking to your patients or anything else regarding this infection, please do not hesitate to contact us.

Sincerely,

NAME
TITLE