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# Nontuberculous mycobacterium infection in heart surgery patients: Current protocol for Hospitals, clinicians and patients: Diagnosis and Therapy

**Robert Hurwitz***

Touro University, Las Vegas, Nevada and Hopkins Read Radiology Associates. Las Vegas, USA

## Introduction

Between January 2010 and August 2016 the U.S. Food and Drug Administration (FDA) received 91 reports of patients world-wide of patients with NTM (nontuberculous mycobacterium) infections associated with cardiac surgery. All were associated with the Stöckert 3T heater-cooler device, used in heart lung bypass units. Current name of the manufacturer is LivaNova Sorin PLC. This paper deals with the history of NTM bacteria and the recent reports of infection post-cardiac procedures. Recommendations have been made by the FDA and CDC for decontamination procedures of installed units and for diagnosis and therapy of infected patients.

## Background

Pulmonary infections due to nontuberculous mycobacteria (NTM) have been increasing world-wide. Over 150 different species of NTM have been described. NTM bacteria are ubiquitous in soil and water and normally pose no significant health threat. Laboratory, radiographic and clinical findings are required to establish the diagnosis.

Since the 1970's, publications have documented increased infections due to immune deficiency, patients on chemotherapy, and an aging world population.

Symptoms of NTM infection include night sweats, weight loss, fatigue, and unexplained fever. The pulmonary illness can require more than one year of antibiotic therapy. NTM is not contagious from person to person.

Radiographic presentation differs from classic tuberculosis. These are best depicted on the "lung windows" of CT scan of the chest. The first features are bibasilar bronchiectasis. Late features are abscess cavities. The spectrum dictates the length of antibiotic therapy [1-3].

## Recent reports of NTM in patients undergoing Cardiac Bypass Procedures.

Since 2010, the FDA has received reports from North America and Europe of cases of NTM infection in patients undergoing open heart surgery. The cause was linked to contamination during construction of the Stöckert 3T heater-cooler device before shipment to hospitals, world-wide. The heater-cooler device is a critical component in heart bypass machines. Aerosolized bacteria from the water tank is thought to enter the open surgical site for cardiac procedures.

Those patients who have had heart bypass procedures should be monitored for symptoms, which may take months or years to manifest. Culture of the bacteria may take 8 weeks (CDC website).

250,000 cardiac surgeries/year are performed in the U.S. annually. 60% of these procedures rely on the Stöckert 3T heater-cooler devices (CDC website statistics).

## Recommendations to Hospitals

The FDA and CDC recommend following the manufacturer's recommendations for sterilization, change-out of all tubings, and cleansing procedures between patient procedures. The current name of the manufacturer is LivaNova PLC. Devices manufactured prior to September 2014 may have been contaminated with *M. chimaera* during the manufacturing process. The FDA has issued numerous safety alerts to U.S. hospitals. A ban on further importation of the LivaNova 3T heater cooler is now in place. Hospitals are urged to consider eventual migration to other manufacturers.

## Recommendations to Clinicians

Clinicians should consider the possibility of *M. chimaera* infection when evaluating patients with signs of infection and a history of open chest surgery. An infectious disease specialist should be consulted for assistance with diagnosis and management.

Clinical manifestations of *M. chimaera* infection may be variable and nonspecific, and present months or even years after exposure to the contaminated device. Treatment of *M. chimaera* infection is complex and prolonged. Any delay in diagnosis and proper treatment results in poor outcomes.

Infectious disease specialists can use the treatment protocols for NTM infections established as effective in past decades. Treatment is multi-drug and may be for as long as one year.

## Recommendations to Patients

The U.S. Food and Drug Administration (FDA) and the Centers for Disease Control (CDC) have provided to Hospitals a template for notification of risk of TNM infection after cardiac bypass surgeries. Many Hospitals provide links to the FDA for further information and phone numbers to personally discuss this new issue. While the risk

***Correspondence to:*** Robert Hurwitz MD, Touro University, Las Vegas, Nevada and Hopkins Read Radiology Associates. 8805 Jeffreys St., Suite 2014, Las Vegas, NV 89123, USA, Tel: (949) 422-1453; Fax: (702) 478-6812; E-mail: Bob95Fox@aol.com

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of infection is quite low, patients need to know that symptoms may take months or years to develop. They should promptly notify their cardiac surgeon and cardiologist of new cough, unexplained weight loss, fatigue, or persistent fevers.

## Summary

250,000 open heart surgeries are performed annually in the U.S. A new development is the possibility of invasive infections with a slow-growing nontuberculous mycobacteria, *M. chimaera*. This is associated with the LivaNova Sorin 3T heater-cooler device. Recommendations for Hospitals, physicians, and cardiac patients are explained.

Any urgent concern by patients or clinicians can be addressed by contacting the CDC at 800-232-4636 or via its website.

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