Nontuberculous Mycobacterium Infections Associated with Heater Cooler Devices – Perspective from CDC

Joseph Perz, DrPH MA
Team Leader, Quality Standards and Safety
Prevention and Response Branch
Division of Healthcare Quality Promotion

FDA
June 2, 2016

The findings and conclusion in this report are those of the authors and do no necessarily represent the official position of the Centers for Disease Control and Prevention.

CDC's Role in Investigation

- **PA Field Investigation (July – August 2015)**
- **Issued Interim Practical Guidance (October 2015)**

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

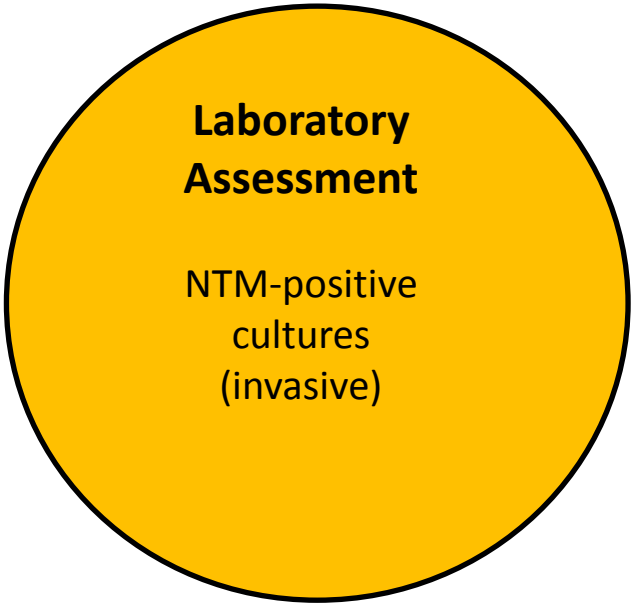
Purpose:

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 found to be contaminated with NTM. This CDC communication is to (a) raise awareness among health departments, healthcare facilities, and healthcare providers of the possible association between NTM infections and use of heater-cooler devices and (b) to provide guidance on identifying patients with infection.

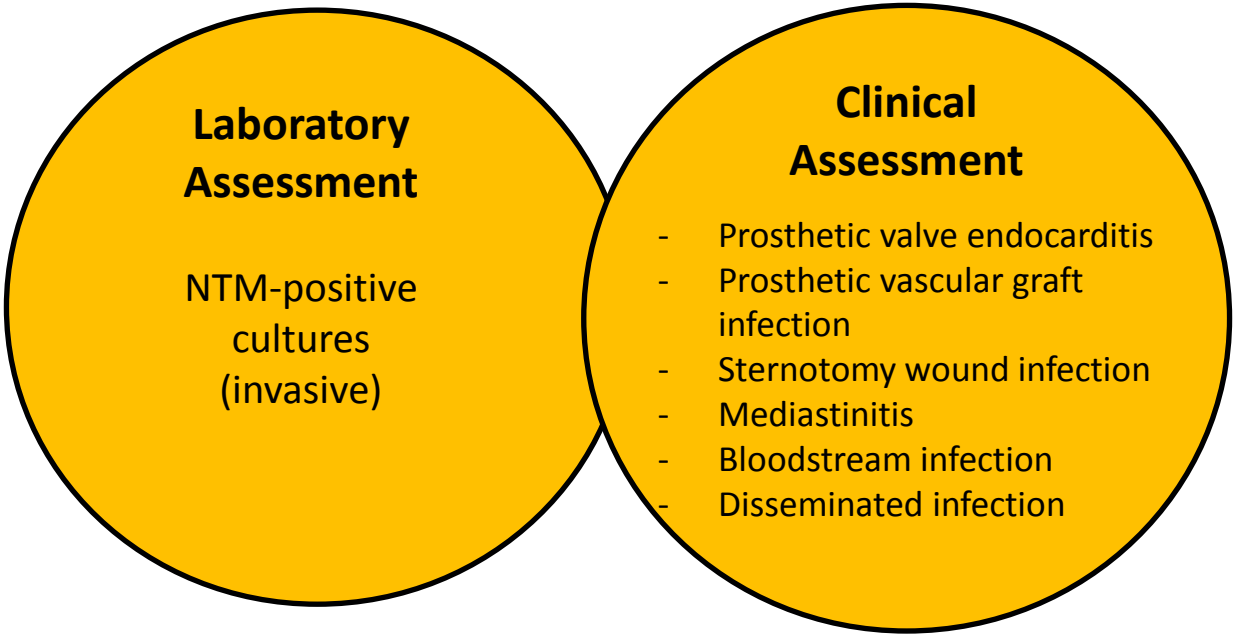
CDC's Role in Investigation

- **Outreach to partners (Fall 2015)**
  - Phone calls with >dozen professional associations including those representing various infectious disease, surgery and perfusion specialties, large healthcare systems, and other state/federal partners
  - Blast email (CDC GovDelivery)
- **Healthcare Infection Control Practices Advisory Committee (HICPAC)**
  - November 2015 and March 2016
- **Ongoing engagement with**
  - FDA, EU partners (ECDC), state and local health departments, facilities, other clinical and laboratory partners

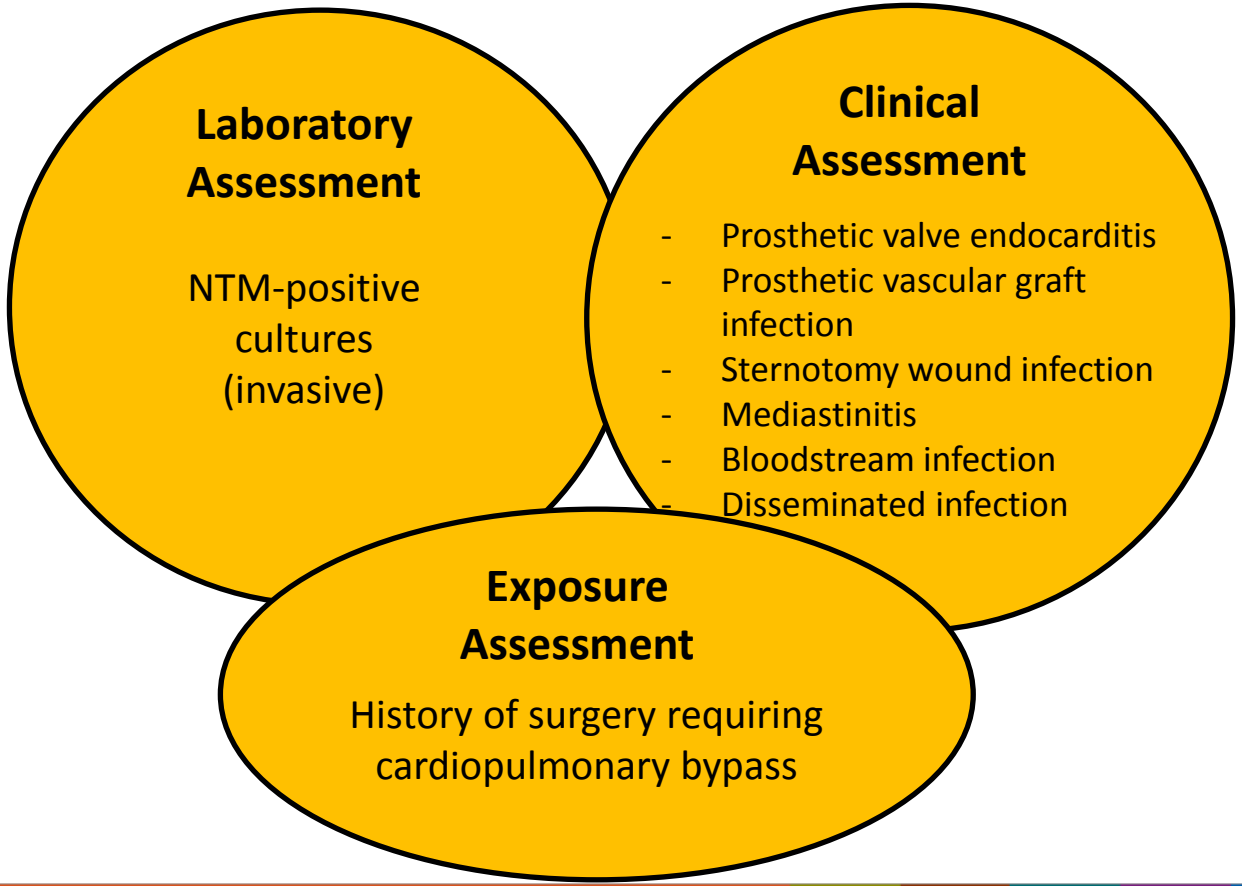
Identifying Possible Cases of NTM Infections Associated with Exposure to Heater-Cooler Devices



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



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



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

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):

www.cdc.gov/hai/outbreaks/

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