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)

3) **Exposure assessment:**

   For patients identified using the criteria above, assess for a history of surgery requiring cardiopulmonary bypass prior to diagnosis of NTM infection.

Additional considerations:

1) Consider institution-specific strategies for alerting patients and providers for the risk of infection given exposure to potentially contaminated heater-cooler units.
2) Order acid-fast bacilli (AFB) culture in any patient with exposure history and meeting the clinical criteria, or presenting with signs or symptoms of NTM infection such as recurrent or persistent fever of unknown etiology, night sweats, joint or muscle pains, weight loss, or fatigue. If AFB culture is positive for mycobacterium avium complex, consider sending sample for further speciation to an NTM reference laboratory.
3) Submit FDA MedWatch Report for positive cases.
4) Alert the appropriate local or state health department.

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