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Perfusion | *Clinical Alert*

Up-to-Date Information on Cardiopulmonary Bypass Heater-Cooler Devices as a Source of Nontuberculous Mycobacterium Infection

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Summary
Last week, on June 2-3, the U.S. Food and Drug Administration (FDA) convened a Circulatory Devices Panel dedicated to examining information associated with infections originating from heater-cooler devices (HCD) utilized during cardiopulmonary bypass. This panel, a part of the Medical Devices Advisory Committee, met to provide recommendations concerning the use of HCDs that have been implicated in patient injury, including death, related to the outbreak in infections of nontuberculous mycobacterium (NTM) in patients who had previously undergone cardiac surgery (1-5). The Panel consisted of members from various medical specialties, including infectious disease specialists from the Centers for Disease Control (CDC) and the FDA. There were two perfusion thought leaders on the panel, Alfred Stammers, MSA, CCP, Director for Quality and Research, SpecialtyCare, and Jeffrey Riley, MHPE, CCP, Director of Perfusion Services, Mayo Clinic. Below is a summary of the current situation, and a list of recommendations to reduce the risk for infection.

Background from the FDA panel
Airborne transmission of NTM occurs through the dissemination of aerosolized bacteria contained in contaminated water droplets emitted from the HCD and distributed by the exhaust fan of the device. Genomic sequencing has confirmed that the organisms existing in the HCD are implicated in the infections. While all patients may be susceptible, cardiac surgical patients undergoing valvular or aortic surgery are especially at risk. The FDA has identified over 180 reports of infections throughout the United States and Europe. Expression of symptoms may take several years due to the latency period for this organism after initial exposure, making it difficult to identify the infection and link it to the operative procedure.

Due to design characteristics, all HCD, regardless of manufacturer, are susceptible to the deposition of bacteria creating a coating (biofilm) on the synthetic surfaces that are exposed to water and contamination. The rate of reported incidents among different machine types is proportionate to the volume of market share of each manufacturer, and changing devices may not alleviate the problem. No device has been found to be less susceptible to biofilm deposition than another, and appropriate maintenance of the device by strict adherence to IFU guidelines are paramount in addressing the problem.

SpecialtyCare Assistance
SpecialtyCare has established a policy for the evaluation of water samples obtained from HCD to assess the adequacy of disinfection procedures. Benchmark Environmental Labs, Inc., of Columbus, Ohio, is a testing facility that will process samples, when requested, performing assays such as heterotrophic plate counts, as well as culturing for pseudomonas aeruginosa and NTM.

Below are recommendations that have been generated through an examination of the presented evidence and through thoughtful discussion that should be considered to mitigate the risk of this infection relative to HCD. The SpecialtyCare Medical Department, our clinical associates, and Al Stammers, MSA, CCP (Al.Stammers@specialtycare.net) are available to discuss with you at any time any issue concerning these recommendations.

Priority Recommendations to Limit the Occurrence of NTM Infections in the OR
1. All HCD will be maintained using hospital, federal, and state regulatory policies, and in accordance with manufacturer's labeled use.
2. All HCD should be used in accordance with established policies by the facility and by the manufacturer's Instructions-for-Use (IFU).
3. All policies and procedures for disinfecting and cleaning the devices need to follow the manufacturer's IFU.
4. As has been our practice, SpecialtyCare associates will complete a "Checklist" for disinfecting and cleaning HCD and save this with the service documentation for each device. The checklist will be maintained by each hospital according to bioengineering guidelines.
5. All individuals involved in disinfecting and cleaning HCD that SpecialtyCare either owns or maintains have completed and will continue to complete annual clinical competencies established by SpecialtyCare.
6. Identification and documentation of each HCD by serial number will be maintained for each procedure for which they have been used.
7. Document utilization of HCD in non-cardiac procedures such as liver transplantation, lung transplantation, vascular surgery, and ECMO, following same standards for use for cardiac surgical procedures.
8. All water to be utilized for HCD will undergo filtration using a 0.22 micron filter.

Suggested Recommendations to Limit the Occurrence of NTM Infections in the OR (not possible in all sites)
1. Monitor HCD for bacterial growth through heterotrophic plate count (HPC), pseudomonas, and coliform bacteria, based on hospital infectious disease recommendations.
2. Reduce open entry points on oxygenator venous reservoirs by closing all luer ports not necessary for venting, and omit the use of syringes as "funnels" for the delivery of solutions either during priming of the circuit or throughout the case.

3. Where possible, position heart-lung machine in the laminar flow area of the OR table.
4. Limit turning on HCD to the times when needed.
5. Position HCD at the end of the OR bed at patient's feet.
6. Do not empty tubing attaching HCD to heat exchanger(s) until AFTER the patient has left the OR.
7. Use gas evacuation system to capture air circulated at the HCD exhaust fan into hospital waste system.
8. Omit the use of non-disposable mounting system (holders) for oxygenators and cardioplegia heat exchange couplers.
9. At regular disinfection and cleaning cycles sterilize quick-disconnects (Hansen Couplers) according to hospital policy for instrumentation.

Additional Considerations for Limiting the Occurrence of NTM Infections in OR

1. Consider an alternate location of HCD outside of the OR.
2. Place HCD in encased housing.
3. When system is in use, place blanket over exhaust area of HCD, assuring that the device does not malfunction by limiting exhaust and over-heating.

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