

Lessons from the Field: Surveillance Cultures of Heater Cooler Units in Cardiothoracic Surgery

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Background

- Our institution is a community-based tertiary teaching hospital Level 1 Trauma Center in Western Pennsylvania having >500 beds
- In June 2015, our institution received a field safety notice from our Heater Cooler Unit (HCU) vendor recommending revision of disinfection practices¹
 - The notice was in response to the vendor's investigation of non-tuberculous mycobacterium (NTM) infections in cardiac surgery cases where the HCU was used
 - The risk is associated with fluid leakage or aerosolization of water from the HCU
 - This safety notice included recommendation on microbiological monitoring of the water quality in these HCUs (meet microbiological drinking-water quality standards)
- In 2015, we had 96 cardiac surgery cases for which the HCU was used, however, our institution had no associated infections
- In January 2015, we had one HCU in which we were using sterile water per Instructions For Use (IFU)
- In June 2015, we received updated instructions regarding disinfection and maintenance procedures

Objective

- Evaluate adherence to the IFU and implement surveillance cultures pre-disinfection and post-disinfection of the HCU
- Assess the cost of water quality cultures for our community-based hospital

Methods

- A multidisciplinary team was formed in July 2015 to obtain cultures as indicated in the field notice. The team comprised of a Perfusionist, Infection Preventionists, Hospital Epidemiologist, Surgical Services and Chair of Pathology
- We implemented a bi-weekly microbiological monitoring of the water quality, including monitoring for non-tuberculous mycobacteria. The samples were taken pre and post disinfection
- The Lab Director identified a local environmental lab that sent the specimens to another lab (Lab A) that provided genus and species identification which included testing for *Pseudomonas* and additional organisms beyond the recommendations in the field safety notice. Our cultures revealed bacteria in the pre and post HCU disinfection samples, which led us to modify our workflow
- The Infection Preventionist observed the Perfusionist perform the specimen collection for compliance with aseptic technique
- This protocol was revised on two occasions to incorporate techniques necessary to improve the collection process for aseptic technique
- We performed a Gap Analysis based on the PA Department of Health guidance²
 - Multiple samples collected by the Perfusionist were sent to a local environmental lab (Lab A) in July 2015 through March 2016. In December 2015, additional testing was scaled back to include only the recommendations from the field safety notice – heterotrophic plate count, coliform bacteria, *P. aeruginosa* and non-tuberculous mycobacteria
 - Sorin recommends water testing to confirm:
 - Heterotrophic Plate Count (HPC): is less than 500 cfu/ml (acceptable level according to U.S. drinking water standard)
 - Non-tuberculous Mycobacteria: is not detectable in 100ml
 - Coliform bacteria: is not detectable in 100ml
 - Pseudomonas aeruginosa*: is not detectable in 100ml
- Results of *Pseudomonas non-aeruginosa* led our Lab Director to identify a second environmental lab (Lab B) that was certified and sent samples simultaneously to Lab A and B in February 2016 for comparison. We also quarantined the HCU from which we identified *Pseudomonas non-aeruginosa*
- We reviewed our sample collection techniques and had conference calls with staff of Lab A and Lab B and reviewed their workflow and sample processing and culturing
- As of March 2016, our samples are only being sent to Lab B

Results

- To date we have had no positive cultures of NTM, coliform or *Pseudomonas aeruginosa* on the pre and post disinfection HCU
- The approximate cost for one set of cultures for one HCU is \$524.



HCU is used to transfer heat or cold to the patient's blood in the bypass circuit to maintain a set body temperature



Obtaining culture of water sample from HCU



Disinfection process



Filling HCU with tap water prior to disinfection

Conclusion

- Working with a multidisciplinary team and your product vendor is crucial
- Monitoring your approach based on results is dependent on accountability and drives sustainability
- We continue with our surveillance program to mitigate risk of infection
- We have added NTM culturing to clinical specimens for suspected mediastinitis

Disclosure Statement: None of the authors have any conflicts of interest

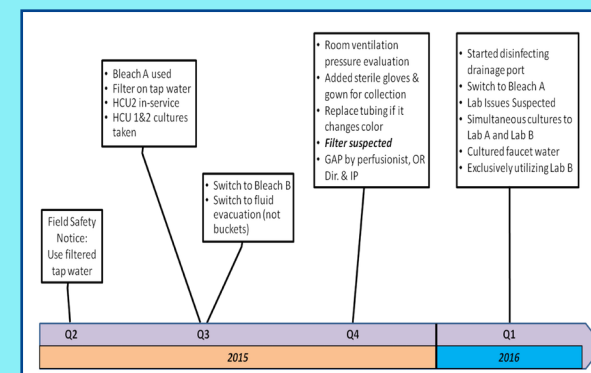


Figure 1: Timeline of Heater Cooler Unit Interventions

References

1. "Cardiac Surgery Mycobacterium Risks Disinfection and Cleaning of Sorin Heater Cooler devices" - Sorin Field Safety Action - June 2015
2. PADOH and PSA Guidance Regarding Nontuberculous Mycobacterium (NTM) Infections among Patients Undergoing Open Heart Surgeries on Cardiopulmonary Bypass.



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