CPB FMEA #18 Heater/cooler contamination

Friends-

The announcements by the FDA (http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm466963.htm)

and the CDC (http://www.cdc.gov/HAI/pdfs/outbreaks/CDC-Notice-Heater-Cooler-Units-final-clean.pdf) on heater/coolers (H/C) used during CPB and other surgical procedures has created a lot of chatter on perfusion list servers. Specifically the CDC is looking at nontuberculous mycobacteria (NTM) growing in H/Cs and the association with some NTM infections in surgical patients. Most of these infections were in Europe. Only three were reported in the USA. Only about half of the reported infections were associated with cardiac patients, but since NTM was cultured from those patients’ H/Cs, they have singled out the H/C as one source of infection.

I have not seen a Root Cause Analysis on the source of the infections from the FDA, CDC or anybody else. It could be that the source that contaminated the patient was also the same source that contaminated the H/C. As an example I want to relay a story about H/C and infections. At my hospital back in the 1980's a few of our ECMO babies developed Pseudomonas infections. The Infection Control (IC) people cultured the ECMO pumps and found the bug growing in our ECMO water heaters. The IC people thought that, somehow, bacteria were jumping from the water heater reservoir into the blood. I tried to explain the impossibility of that, but they did not understand how the system worked. I had to jump thru a lot of hoops to clear the bug from the H/C. When we thought the problem was solved some more ECMO babies caught the bug as well as some other babies who were not on ECMO. After that, IC cultured everything they could think of in the NICU without success. But the bug kept showing up in the ECMO water heaters. Finally I asked them to remove the aerators from all the hand washing faucets in the NICU and culture those. Almost all of them were positive cultures. This is what was happening. The nurses and docs would wash their hands and then rinse them under the faucets, probably picking up some bugs from the aerators and then transferring the bugs to the babies by contact. The faucets with the aerators were also the water source for the ECMO water heaters. I suspected the aerators because years before, in the OR, we traced surgical infections to the use of aerators at the scrub sink faucets. Some hospital bean counter had decided that using aerators saves water and never figured that they could be a source of bacterial colonization. If you don’t believe me, go take the aerator off your own kitchen or bathroom faucet and look at the crud in the screen. Then look at your garden hose spigot without an aerator; no crud.

Initially, the IC people were quick to blame my ECMO water heaters as being the source of the infection. But after we removed all the aerators from the NICU faucets the infections went away. My point is that the H/C may not be the original source of the NTM infections, especially if the OR faucets use aerators. So if the CDC suggests taking a culture only from the water bath reservoirs, they need to look further than just our H/C. One independent report states that NTM infections in the general population have been steadily growing and now exceed tuberculosis infections in some areas. It is also difficult to believe that with all the common pathogens in hospitals like S. aureus, P. aerginosa and E. coli that can potentially grow in a H/C, that these infections are not more frequent in cardiac surgery patients than H/C associated NTM if H/C really are a source of infections.

AmSECT is taking action by notifying their membership about these infections. However, according to the JC Leadership Standard LD 5.2, that is only a reactive response. There must also be a proactive process review. Because these infections are dangerous and because this risk has been identified by both the FDA and CDC, we need to respond with an FMEA as a proactive risk assessment and process review. With both the CDC and FDA involved, it is just a matter of time before JC and CMMS, as on-site assessors, will want to get involved and impose their own set of standards on us if we have not already addressed the issue with an FMEA. In addition, the following is language directly from the CDC Non-tuberculous Mycobacterium (NTM) Infections and Heater-Cooler Devices Interim Practical Guidance: Updated October 27, 2015 – “Local and state health departments should communicate with healthcare facilities that perform cardiac surgical procedures, or facilities that may provide care to patients who have undergone such procedures, to ensure that the devices have been assessed, their maintenance reviewed and any potentially contaminated devices are removed from service.” So you might even have a visit from a local or state government health representative to check on your compliance with the CDC/FDA recommendations.

Most of the pre-emptive management and interventional management items in this FMEA come from the FDA and CDC recommendations. I just shortened them. They have a lot of deficiencies. For example, they refer to “following the manufacturers’ IFU”, but do not say if the programs reporting the infections were compliant with those instructions. If the programs were compliant, then that would be evidence that the IFUs are ineffective. If the programs were not compliant, why make any additional suggestions beyond the IFUs? Just enforce the current IFUs. We don’t know the circumstances one way or the other. They also recommend using sterile ice but make no recommendations on how to make ice in large quantities from sterile water. What are perfusionists who use ice based H/Cs supposed to do? Stop doing cases until they buy compressor based units? And now that the FDA has pontificated on the use of sterile ice, do programs that continue to use ice from unsterile water have an increased liability?

The most practical suggestion so far comes from Don Floyd CCP who thinks that an ultraviolet light sanitizer used during H/C use would be the most helpful. I agree with this. A small UV light sanitizer can be easily attached to any H/C, ice based or compressor based, and inserted into the water line. This would keep bacterial growth under control during use without personnel being exposed to toxic chemicals. It would also exceed the CDC/FDA recommendations.

The AmSECT Safety Committee

Contributor: Gary Grist

CPB FMEA #16 Heater/cooler contamination

FAILURE:

Contaminated water from the heater/cooler (H/C) may:

1. enter the sterile parts of the circuit, oxygenator or cardioplegia heat exchanger along an unknown pathway.

2. transmit bacteria through the air (aerosolized) from the H/C water pump or compressor cooling fan exhaust vent into the environment and subsequently to the patient.

3. be transmitted by the operator coming in contact with contaminated H/C water and then introducing the bacteria into the blood circuit by routine contact.

EFFECT:

1. Infections from Nontuberculous Mycobacteria (NTM) or other bacteria related to cardiothoracic surgeries.

2. Some patients may not present with infections for several months or years after their surgical procedure.

3. This diagnostic delay may cause a failure to communicate critical information in a timely manner to the perfusionist for quality control purposes.

4. Hospital staff does not seem to be at risk for NTM or other bacterial infections from H/Cs.

5. Indeterminate risk to patient welfare which may include death:

a. A CDC survey found an overall surgical site infection rate of 1.9% with a mortality rate of 3% of those infected patients.

b. Deep sternal wound infection complication after median sternotomy has a frequency of 1 to 5% with a mortality rate ranging from 10% to 47%.

c. There is no systematic reporting of NTM infections and precise incidence data are lacking. Several state health departments report that the number of isolates of NTM has surpassed the number of M. tuberculosis isolates. (De Groote M, Huitt G. Infections Due to Rapidly Growing Mycobacteria. Clinical Infectious Diseases Volume 42, Issue 12, pgs 1756-1763. )

CAUSE:

1. NTM organisms as well as other bacteria are widespread in nature and can be found in soil and water, including tap water sources.
2. NTM bacteria are typically not harmful, but in rare cases may cause infections in very ill patients and/or in individuals with compromised immune systems.
3. Other bacteria such as Pseudomonas aeruginosa are known pathogens causing serious and fatal infections.

PRE-EMPTIVE MANAGEMENT:

1. Follow standard universal precautions.
2. \* \*\*Strictly adhere to the cleaning and disinfection instructions provided in the manufacturer’s Instructions for Use (IFU).
3. \*Do not use tap water to rinse, fill, refill or top-off water tanks since this may introduce NTM and other organisms.
4. \*Use only sterile water or water passed through a filter of 0.22 microns or less.
5. \*Ice used for patient cooling should be from sterile water or water passed through a 0.22 micron or smaller filter. (Note: the FDA recommendations to use sterile water or to make ice from sterile water in quantities needed for H/C operation is an impracticality for many perfusion programs.)
6. \*Deionized water and sterile water created through reverse osmosis may corrode the metal components of the H/C.
7. \*Direct the H/Cs vent exhaust away from the surgical field to reduce aerosolizing H/C tank water into the sterile field.
8. \*Establish regular cleaning, disinfection and maintenance schedules for H/C according to the manufacturer’s IFU.
9. \*Develop quality control program for maintenance, cleaning, and disinfection of H/Cs.
10. Consider installation of an ultraviolet light water sanitizer in the H/C water lines.

MANAGEMENT:

1. \*Immediately remove from service any H/Cs with discoloration or cloudiness (biofilm) in the water lines and circuit components which may indicate bacterial growth.
2. \*Consult in-house Infection Control officials for follow up measures.
3. \*Report events of H/C contamination to the manufacturer.
4. \*Consider performing environmental, air, and water sampling and monitoring if H/C contamination is suspected. (Environmental monitoring requires specialized expertise and equipment to collect and process samples, which may not be feasible in all facilities.)
5. \*\*Health care facilities should follow their internal procedures for notifying and culturing patients if they suspect infection associated with H/C.
6. \*Submit a report to the manufacturer and to the FDA via MedWatch if H/C contamination has led to patient infections.
7. \*Hospitals obligated to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.
8. \*Perfusionists should submit voluntary reports of infection transmission associated with H/C or reports describing difficulty following the manufacturers’ IFU to the Medical Device Reporting process.

\*FDA recommendation.

\*\*CDC recommendation.

RISK PRIORITY NUMBER (RPN):

A. Severity (Harmfulness) Rating Scale: how detrimental can the failure be:

1) Slight, 2) Low, 3) Moderate, 4) High, 5) Critical

(The problems that this failure causes are usually 3, moderate.)

B. Occurrence Rating Scale: how frequently does the failure occur:

1) Remote, 2) Low, 3) Moderate, 4) Frequent, 5) Very High

(These infections occur very infrequently. So, occurrence should be 1, remote.)

C. Detection Rating Scale: how easily the potential failure can be detected before it occurs:

1) Very High, 2) High, 3) Moderate, 4) Low, 5) Uncertain

(The potential for infection is impossible to detect during individual cases; a detection RPN of 5, uncertain.)

D. Patient Frequency Scale:

1) Only a small number of patients would be susceptible to this failure, 2) Many patients but not all would be susceptible to this failure, 3) All patients would be susceptible to this failure.

(All patients are at risk. So the Patient Frequency RPN should be a 3.)

Multiply A\*B\*C\*D = RPN. The higher the RPN the more dangerous the Failure Mode.

The lowest risk would be 1\*1\*1\*1\* = 1. The highest risk would be 5\*5\*5\*3 = 375. RPNs allow the perfusionist to prioritize the risk. Resources should be used to reduce the RPNs of higher risk failures first, if possible.

(The total RPN for this failure is 3\*1\*5\*3 =45.)