CPB FMEA #44 Heater/cooler hose failure

Friends-

I chose this FMEA because of the recent FDA Summary on heater/coolers (H/Cs). See the web site below. I anticipate that all future H/Cs will need to incorporate a variety of new safety features which could include an internal heat sterilization system, UV lights, carbon/DI filters, sub-micron filters and aerosol suppression systems. So I think one of two things will happen. 1. The H/Cs will become much more complicated, more expensive and require much more maintenance. Or 2, manufacturers will just stop making H/Cs to avoid the government regulation hassle. I think these same regulations will eventually apply to all water heating/cooling blankets in the OR as well.

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM503716.pdf>

What about those thousands of H/Cs still in use? They are going to come under greater scrutiny by hospital risk managers. Patients who get sternal wound infections or other types of infections are going to consider legal action and the H/Cs will be at the center of the struggle. (I have already seen trial lawyer commercials on TV about this very thing.) So perfusionists are going to do their best to eliminate any possibility that their H/Cs are the source of any infection. The most visible sign that a H/C may be dirty is the water lines, many of which are transparent polyvinyl chloride (PVC). I think the scum that deposits inside the lines is mostly mineral deposits from tap water. But it can also look like biofilm. So perfusionists are going to want to change those lines frequently. This is going to increase the risk of gross water contamination of the sterile field if the hose connection has a stream leak under pressure or blows completely off the connector and sprays water all over the room.

This only happened to me once (and once is enough). Back in the days when I was using wall water, the hose came completely off the oxygenator and sprayed all over the room, wiggling like a snake. The sterile operative field and table personnel were completely contaminated. Fortunately, the incision had not been made. But the entire setup had to be torn down and reset. The patient was unharmed except for having additional anesthesia time and no electronic equipment was damaged. Needless to say the other team members were quite pissed off. Nonetheless I thanked my lucky stars that the procedure had not started. From that time onward I always obsessed about H/C water lines and ensuring that they were secure throughout the case.

Over the years I have seen high pressure stream leaks around the hose clamps that were strong enough to reach the table. And also an incident when a perfusionist, pushing the pump around, pulled a water hose off a connector while the H/C was running. I always taught my students to pick up the water lines to take any strain off the hose connections and to prevent the hose from being run over whenever the pump was moved near the table. The students told me that no other site instructed them to do that.

Now days, as perfusionists begin to frequently change their H/C water lines to keep them clean, there will be an increased risk for improperly secured tubing with the risk of stream leaking or the line pulling off or blowing off. So that's what this FMEA is about. It has the lowest RPN of any FMEA I have written. Even though the risk is small, it is still there. And with the scrutiny that H/Cs will be under in the years to come, I think it is worth discussing.

On the other hand, the frequent water line changes are also an opportunity to make sure the connections are secure. My guess is that water line changes have been infrequent at most programs in the past. And whatever hose coupling system was being used (hose clamps, crimped connections, screw on pressure fittings, compression fittings, etc.) could have become loosened without being noticed over an extended period.

A water hose blowing off in the middle of a case might be considered a freak accident. A freak accident is a harmful incident that occurs under unusual and improbable, but not necessarily unpredictable, circumstances. FMEAs are written to anticipate any failure that the human mind can conceive as a possibility. So a freak accident like this might be prevented by an FMEA.

Gary Grist RN CCP, contributor

AmSECT Safety Committee

garygrist@comcast.net

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FAILURE:

Heater/cooler (H/C) water hose disconnected or ruptured.

EFFECT:

1. Non-sterile water spray over sterile operative field.

2. Potential for infection.

3. Potential for water damage to electrical equipment.

CAUSE:

1. Failure to secure water lines properly to oxygenator or cardioplegia heat exchangers.

2. Disconnecting water lines with the water pump running.

3. Loose adjustable hose clamp or other types of tubing connectors or leaking 'O' ring seal.

4. Tubing blow off under pressure.

5. Tubing pull off if pump rolled over tubing during case.

6. Water tube or connection defect.

PRE-EMPTIVE MANAGEMENT:

1. Checklist item for securing water lines to heat exchangers and testing for leaks.

2. Maximize water system pressure and flow prior to priming to stress test for component failure before CPB.

3. Document stress testing on checklist prior to initiation of CPB.

4. Have backup H/C system readily available.

5. Have ancillary personnel readily available to assist.

6. Perform routine maintenance on the H/C system and water lines.

7. If maintenance personnel are responsible for hose replacement and other repairs, the perfusionist should test the H/C for function and leaks prior to bringing it into a clinical area and using it clinically.

8. Have applicable tools and replacement parts readily available for quick repairs, particularly if no backup equipment is readily available..

MANAGEMENT

1. Tighten or replace components or replace water circuit.

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

(I would give this failure a Slight Harmfulness RPN of 1.)

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

1) Remote, 2) Low, 3) Moderate, 4) Frequent, 5) Very High. (This would be a rare freak accident. So the Occurrence is Remote. The RPN would be a 1.)

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 Detectability RPN equals 1 because it is easy to determine if water hose connections are secure.)

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 perfusionists are at risk. So the Frequency RPN would be 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 low at 1\*1\*1\*3 = 3.)