CPB FMEA #37 Repairable circuit component failure

Friends-

This week’s FMEA is a very simple failure. I am amazed at how often a connector or component fails during CPB and needs changing. When I first started in perfusion there were no plastic circuit components. All the connectors and stopcocks were stainless steel and reusable after cleaning and sterilizing. Nowadays, something as simple as changing a cracked plastic connector or leaking stopcock can divert a perfusionist’s attention long enough to cause an accident. I guess that sometimes there is a price to be paid for the convenience of disposability.

Some people will say that his type of failure is so minor and the repair is so ‘common sensical’ that an FMEA is not needed. However I feel anything that takes a perfusionist’s attention away from running the pump has the potential to be a part of a larger and more dangerous problem. This is called a cascading failure. A complicated system such as a heart lung pump with a minor failure can trigger a failure in other areas by diverting the perfusionists’ attention. This is a risk that must be formally recognized.

John Nance is an airline safety expert. He says that airliners have two pilots for several reasons. Firstly, two pairs of eyes are better than one in identifying a potential failure. Secondly, when a problem does occur one pilot devotes his attention to ‘flying the airplane’ while the other pilot troubleshoots the problem. This is because, unlike an automobile with a mechanical problem, an airplane can’t be pulled to the side of the road and stopped. It must keep flying until it reaches the airport before it crashes. Similarly, a heart lung pump cannot be stopped mid-CPB while minor repairs are made. A perfusionist working by himself with no trained assistance immediately available is at a higher risk of a cascading failure than if help is immediately available.

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FAILURE: Component or connector failure leading to partial loss of circuit integrity but amenable to immediate repair.

EFFECT:

1. Perfusionist’s attention diverted.
2. Blood loss
3. Embolization
4. Hypoperfusion
5. Blood transfusion

CAUSE:

1. Plastic connector, stopcock or other component failure due to poor manufacturing.
2. Split or ruptured tubing.
3. Incorrect assembly or connection within circuit.
4. Clamping tubing over a connector.
5. Rolling the pump over a component during moving.
6. Exposure to high traffic area causing unintentional circuit contact damage.
7. Poor circuit or engineering design.

PRE-EMPTIVE MANAGEMENT:

1. After priming, the circuit is recirculated at high pressure to check for component failures before CPB is initiated.
2. Extreme care is taken when moving a pump with an assembled circuit.
3. Have replacement connectors and components readily available.
4. Have tools needed for repair readily available (clamps, sterile prep materials, sterile tubing cutters, tie bands, protective gloves, eye protection, etc.)
5. Have ancillary personnel readily available to assist. (\*If no ancillary personnel immediately available, increase the Harmfulness RPN to 4.)

MANAGEMENT:

1. Depending on the location of the component or connector, CPB may need to be emergently terminated and the part replaced.

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 Low RPN, 2. \*If no ancillary personnel immediately available, increase the Harmfulness RPN to 4.)

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

1) Remote, 2) Low, 3) Moderate, 4) Frequent, 5) Very High. (The Occurrence is Remote. So 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 3.)

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 would be at risk for this failure so the Patient 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 = 2\*1\*3\*3 = 18 unless there is no immediate assistance available. Then the RPN would be 4\*1\*3\*3 = 36.)