CPB FMEA # 28 Blood line pull-off or blow-off.

Friends-

 Anyone interested in perfusion safety should visit the Australian & New Zealand College of Perfusionists website (http://www.anzcp.org/index.htm) and read the Perfusion Incident Report System (PIRS) entries. The objectives of the PIRS are to 1) increase confidential incident and accident reporting in the perfusion community, 2) provide feedback on incidents, 3) provide the means for proactive and reactive safety review, and 4) create a safety culture. They have been collecting data since 2005 and have complete reports dating back to 2012. I currently organize CPB FMEAs into only 12 categories, but the PIRS uses 27 categories for perfusion incidents and accidents. If you think that some of the hypothetical failures used in my FMEAs are far-fetched, just spend time reading the PIRS reports that describe the incredible real-life failures that have actually occurred. Many of them could have been prevented by better pre-emptive management. Some of the most common incidents include drug and medication incidents and air in the circuit. But by far the most commonly reported incidents involve circuit disruptions.

Reading the PIRS entries, the question arises; what is the difference between a ‘failure’ and an ‘accident’? Some might say that a failure is avoidable and an accident is not; some accidents being beyond a perfusionist’s control. I dispute that. The whole reason behind an FMEA is to envision any accident that could conceivably occur and plan Pre-Emptive Management techniques to prevent the occurrence or use Management techniques to mitigate the problem if it does occur.

One of the recent PIRS circuit disruption reports states “…arterial pump boot connection started to leak on the positive pressure side connector. Touched it to see how much blood was coming out and it hosed a fine jet out. Decided not to touch it again…..watched it for a few minutes, gauging the leak. Was nervous about using the tie gun on the pulsing shaking connector, thought it might fail dramatically. Turned the flow right down briefly and put a further tie on the connector next to the one already on. Increased flows, no further leaking.” This incident just missed causing serious patient harm. Under the PIRS preventative plan the author recommends using glue and additional ties at manufacture. Ties, yes, but I don’t agree with the glue. Was this incident a failure or an accident? Was it avoidable or inevitable; i.e., beyond the perfusionist’s control? You decide.

In deference to this particular PIRS I decided to write this FMEA dealing with a simple pull-off or blow-off between a blood line and connector or blood port. The most fundamental task of a perfusionist is to assemble, inspect and test an extracorporeal circuit before it is used on a patient. Despite this, there are a lot of failures like the one described above. Please give me your take on how to make this FMEA better and more relevant.

AmSECT Safety Committee

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FAILURE MODE AND EFFECTS ANALYSIS: CPB FMEA # 28 Blood line pull-off or blow-off.

FAILURE:

Pull-off or blow-off failure between a blood line and a connector or blood port.

EFFECT:

1. Interruption of CPB.
2. Blood loss; exsanguination.
3. Circuit contamination
4. Embolization
5. Hypoperfusion
6. Blood transfusion

CAUSE:

1. Failure to secure tubing to connector or blood port. Without a proper match between tubing (durometer and wall thickness) and connectors, tubing can be a) pulled off due to traction-type tension, b) blown off from a pressure spike, c) or leak.
2. Shape and placement of barbs combined with tubing flexibility determine the force required to connect the blood line. If it is too difficult or too easy to push the blood tubing on, the tubing will not grip properly causing a leak or disconnect.
3. A connector barb or blood port barb is a sharpened ridge or bump that is used to grip the inside of the blood line and seal the connection. As a tube is pushed over the barb it expands, gripping and sealing the connection as the tube returns to its original diameter behind the barb.
4. Multi-barbed connectors are more difficult to properly connect and may require significant strength to properly secure.
5. Improperly placed cable ties may be over the tubing but not behind the barb; the place needed to provide additional holding power.
6. Pull‐off resistance: Blood lines tend to contract and grab more tightly when pulled. But the tensile strength characteristics will differ for different sizes and grades of tubing and connectors and may allow a blood line and connector to unexpectedly disengage with minimal pulling force.
7. Blow‐off resistance: Spikes in hydraulic pressure make blood lines expand, potentially loosening the grip of the barb. Larger blood lines (3/8” and ½”) are more susceptible to elevated pressure blow-off than smaller lines (1/4” and 3/16”).
8. A mold seam that produces a slight imperfection on the connector or blood port may cause a failure.
9. Blood lines and connectors that are wet before assembly are more prone to pull-off or blow-off.
10. Certain blood line coatings may be more prone to pull-off or blow-off.

PRE-EMPTIVE MANAGEMENT:

1. Utilize pre-assembled circuits with manufacturer-made connections when possible.
2. Apply cable ties at vulnerable connections.
3. Double check circuit for potential disconnects if equipment is transported.
4. After priming, the circuit is recirculated at high pressure to check for potential pull-off or blow-off sites.
5. Test circuit for pressure/pump servo-regulation during priming to prevent blow-off.
6. Ensure proper tubing position and occlusion in roller pump heads during priming.
7. At the minimum, use cable ties on 3/8” or greater connections.
8. Use checklist to confirm that all connections have been tested and are secure prior to CPB.

MANAGEMENT:

1. Depending on the location of the disconnection, CPB may need to be emergently terminated and the disconnection secured, being careful to minimize the risk of blood loss, contamination and embolus.
2. If arterial roller pump raceway or centrifugal pump connections are involved, stop CPB and clamp arterial and venous lines until repaired.

3. If ancillary pump raceway is involved, it may not be necessary to discontinued CPB.

4. Secure disconnection.

5. De-air circuit as needed and resume CPB.

6. A cable tie remover tool should be available should an emergency arise wherein the ties need removal.

7. Glue bonding of the tubing to the connector should be avoided should an emergency arise requiring the tubing to be removed.

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 High RPN, 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 in this example, but may be higher or lower depending on the adequacy of circuit preparation. An outright careless performance of the task by an ill or emotionally distraught perfusionist or during emergent situation where procedural corners are cut might make the Detectability RPN a 5. If a meticulous approach is made, even during an emergency, the Detectability RPN might be a 1. Past perfusion staff performance and the Occurrence RPN are the best indicators of the Detectability RPN score. This means that incidents like this should be tracked over time.)

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. 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 4\*1\*3\*3 = 36. However this score could be as high as 4\*1\*5\*3 = 60 or as low as 4\*1\*1\*3 = 12, depending on the conditions described above.