CPB FMEA # 25 Mismatch of roller pump read out and blood flow

Friends-

OK, guys, this is an easy FMEA; Perfusion 101 material. Except that I am embarrassed to admit that I have done this on more than one occasion in the past. Working in peds we frequently change pump calibration; 3/16, 1/4, 3/8 and 1/2. The times when I failed to catch this was when I was working alone or in an emergent situation. Checklists are not fool proof, to which this fool can attest. I eventually solved this problem (and many others) by asking the hospital to hire a perfusion assistant for me. S/he would double check my checklist, among other things. Later, when we began to take students, I managed to buy Transonic flow meters for each of my CPB and ECMO pumps (10 in all). Blood flow is one of the most important parameters in perfusion and I think that redundant measurement is justified. Imagine flying on a jet airliner that had no redundant hydraulic controls. One leaking fitting could disable the rudder and everyone on board would be doomed. Or like an inaccurate airspeed reading with a bug stuck in the only pitot tube on board; bad news. (Aircraft examples courtesy of Don Sheff CCP.)

So please look this over. I am sure that I have missed some obvious factor that should be included in this. (My wife just read an article to me that says in the USA one out of every three hospital patients is subjected to some kind of medical error, most not life threatening but nonetheless mistakes.)

AmSECT Safety Committee

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FAILURE MODE AND EFFECTS ANALYSIS: CPB FMEA # 25 Roller pump mismatch to blood flow

FAILURE:

Mismatch of roller pump read out and actual blood flow delivered.

EFFECT:

1. If arterial pump is affected, there may be inadequate blood supply to the patient causing

a. Hypotension

b. Acidosis

c. Hypercapnea

d. Hypoxia

e. Shock and organ failure

2. There may be over perfusion to the patient causing

a. Hypertension

b. High arterial line pressure causing automatic pressure alarm and pump shut off.

3. Secondary pumps can fail to provide adequate cardioplegia, ultrafiltration, ventricular venting or field suckers function.

CAUSE:

1. Human error.
2. Check list error.
3. Roller-head occlusion not properly adjusted.
4. Pump read out not set to proper tubing size.
5. Defective pump operation.

PRE-EMPTIVE MANAGEMENT:

1. The blood flow of the arterial pump is continuously measured using a separate and independently operated Doppler flow meter to assure adequate flow if occlusion is too loose or pump calibration readout is incorrect. (\* Without independent flow meter measurement the Occurrence RPN = 2.)

2. Confirm with checklist the proper tubing size calibration on the pump readout. Have secondary personnel confirm. (\*\*Without double check, Detectability RPN = 2.)

3. For flow calibration, if available on certain equipment, inter link setup process when setting BSA to tubing size to provide an Index flow as part of a visual check list reminder.

4. Adjust occlusion of each pump head according to accepted practices during set-up and prime.

5. Ritualize tasks in sequence, such as 1) tubing size, 2) occlusion, 3) venous reservoir level alarm, 4) arterial bubble alarm, etc.

6. Indications for over-occlusion can be ‘Load’ light or jammed tubing.

7. Indications for under occlusion can be failure to collapse raceway while clamped on the inflow side during pump high speed RPM set up testing.

8. Secondary personnel (perfusion assistants or clinical perfusionists) are always in attendance to obtain equipment and assist in emergency procedures.

MANAGEMENT:

1. Common clinical indications for under-occlusion or improper calibration can be unexplained abnormal SVO2 values, hypotension, hypertension and acidosis.

2. Check tubing occlusion and calibration, then correct if needed.

3. If malocclusion is suspected temporarily stop pump and tighten or loosen pump head as necessary.

4. If occlusion mechanism is defective replace pump with back-up using appropriate caution. (If the arterial pump fails, clamp arterial and venous lines and transfer raceway to a back-up centrifugal pump by cutting the raceway and attaching to the C-pump head.)

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 Moderate RPN, 3.)

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. \* Without independent flow meter measurement the Occurrence RPN = 2.)

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. \*\*Without double check, Detectability RPN = 2.)

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 3\*1\*1\*3 = 9. However if an independent flow meter and double check is not used, the total RPN would be 3\*2\*2\*3 = 36.)