CPB FMEA #2: C pump failure to initiate bypass.
The AmSECT Safety Committee
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This week's Failure Mode is below:

I. Failure Mode: Centrifugal pump works during priming but when connected to the arterial cannula and bypass initiation is attempted there is no forward flow.

II. Potential Effects of Failure:
1. Inability to initiate bypass
2. Backflow with entrainment of air into the aorta around aortic cannula purse stings.
3. Possible hypotension if patient inadvertently drains into the venous reservoir before bypass can be initiated.
(Can you suggest other problems that can occur?)

III. Potential Cause of Failure:
1. RPM too low for forward flow.
2. Level senor or auto clamp set incorrectly.
3. Failure to verify line patency.
4. Line pressure control set too low.
5. Flow probe set or placed incorrectly.
6. Defective one way valve.
7. Purge or recirc line left open.
8. VAVD negative pressure set too negative.
9. Pump head magnetic coupling failure.
10. Down ramp safety feature values set out of the limit range.
(What other things can cause this particular failure?)

IV. Interventions to Prevent or Negate the Failure:
PRE-EMPTIVE MANAGEMENT:
1. All new critical equipment (including blood pumps) should be wet lab tested under as close to clinical conditions as possible prior to use.
2. Competency of all perfusionists should be fully documented prior to using new equipment clinically.
3. Maintain standby equipment necessary to change out a pump including adequate circuit tubing slack.
4. Centrifugal circuit should have a one way valve to prevent complications of backflow.
5. Centrifugal pumps heads should be tested against a high back pressure (300 mmHg) prior to the initiation of bypass.
6. Ensure adequate RPMs before initiating bypass.
7. Check alarm limit setting prior to bypass after servicing by maintenance personnel
8. Initiate alarm systems one by one after initiating bypass.

MANAGEMENT:
1. Come off attempt to initiate bypass. If patient drained volume into venous reservoir, infuse volume by hand crank to prevent hypotension.
2. Aggressively hand crank pump head to determine if forward flow can be manually achieved.
3. Disable all alarm features, confirm forward flow via the recirculation line and then attempt to initiate bypass.
4. If failure still occurs splice in standby pump.

V. Risk Priority Number (RPN): (select the number from each category that you feel best categorizes the risk).

A. Severity (Harmfulness) Rating Scale: how detrimental can the failure be:
1) Slight, 2) Low, 3) Moderate, 4) High, 5) Critical
(The main result of this failure is a delay in proceeding with the surgery and the extended anesthesia time. The Harmfulness RPN should be only a 2.)

B. Occurrence Rating Scale: how frequently does the failure occur:
1) Remote, 2) Low, 3) Moderate, 4) Frequent, 5) Very High
(This is a rare problem. So the Occurrence RPN should 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
(This problem become obvious immediately and can be detected without harming the patient. So the detection RPN should be 1.)

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.
(This could happen to any patient. So the Patient Frequency RPN should be a 3.)

Multiply A x B X C X D = RPN. The higher the RPN the more dangerous the Failure Mode.
The lowest risk would be 1 X 1X 1 X 1 = 1. The highest risk would be 5 X 5 X 5 X 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 X 1 X 1 X 3 = 6 which is very low but the risk could be totally avoided with proper training of the pump at issue.)

The take home lesson from this FMEA is to ensure that all new critical equipment is wet lab tested as close to clinical conditions as possible. Just having a manufacturer's representative present for first use is not adequate. What is critical equipment? Any equipment whose failure to function properly will not allow the safe progression of the procedure is critical.