Friends- Here is the narrative for the fourth ECMO FMEA for your review.

I would like to post the reviewed narrative by September 21. So if you could get your comments to me by then I would be very grateful.

Thanks for all your help. I appreciate it and I know the ECLS community appreciates it also.

Gary Grist RN CCP Emeritus

Narrative #4

ECMO FMEA D1 FAILURE: Venous blood line jerking a/k/a chugging.

Go to the AmSECT Safety Page <u>http://www.amsect.org/page/perfusion-safety</u>, select ECMO FMEAs, open the PDF and scroll down to section D1 to find the detailed FMEA. (Any opinions expressed in this communication are solely my own and not necessarily those of the Safety Committee or AmSECT.)

This failure is either very common or very uncommon depending on the cause with Occurrence RPNs of either 4 or only 1. Chugging can represent the degradation of venous return that can result in inadequate perfusion support and its associated complications, such as organ failure, organ damage or failure to improve

EFFECTS, CAUSES and MANAGEMENT OVERVIEW:

Chugging results in poor blood flow, often cutting out and even blood damage due to hemolysis. I listed six causes including cannula malposition, kinked tubing, flow knob inadvertently moved, patient condition, malfunctions with the cannula, or the cannula being too small, which is really a problem with the surgeon. I think that any other causes I did not list can probably be categorized in one of these six classifications. Cause #4 is really the catch all since it refers to the myriad physiologic and anatomical problems that ECMO patients have that can affect venous return. For that reason, in Management #4 I refer to ECMO FMEA Section H. PATIENT PROBLEMS. For example, hemothorax, pneumothorax, cardiac tamponade and even mediastinal shift sometimes seen in diaphragmatic hernia patients can all cause chugging. I write that kinking commonly occurs spontaneously with VV double lumen cannulae. This was written before improvements were made in various cannulae after I retired. I do not know if this is a serious problem anymore. I also mention a cannula flow chart. This should always be available at the time of cannulation. We did extensive in-house in vitro testing of cannula flow ranges using the same ECMO circuit and pumps we used clinically. This is important to know should it be necessary to increase blood flow beyond what is anticipated. This might qualify as pre-emptive management

I did not list any pre-emptive management actions by the perfusionist or ECMO Specialist. The best pre-emptive management is a good surgeon who knows how to put the proper sized cannulae in the proper place. The management actions focus on neck cannulations. I probably should have included more on open chest cannulations and femoral cannulations. Perhaps some of you can contribute more in this area. I have never had any experience with axial cannulations, but I have heard that some surgeons favor this approach.

RISK PRIOROTIES: With this failure the risk can vary greatly depending on the cause. With cause #3, the risk is very low and may never occur during the ECMO run. With other causes, the risk is very high and is almost a certainty within a 10 day period. I did not list death as an Effect, although that may be a possibility if venous return problems cannot be properly managed. Correspondingly, I did not include a Harmfulness RPN of 5 – Critical.

REVIEWER COMMENTS:

REVIEWER CN:

D1 Failure: Venous blood line jerking a/k/a chugging.

D1 Effect #1: The degradation of venous return can result in inadequate cardiovascular support and its associated complications, such as organ failure or organ damage.

D1 Cause #1: Venous/cephalic catheter mal-positioned.

D1 Cause #2: Kink in venous blood tubing between the patient and the pump.

D1 Cause #3: Flow knob inadvertently increased: assess RPMs

D1 Cause #4: Inadequate venous return due to patient condition; patient agitated/active, hypovolemia, pericardial tamponade, increased abdominal pressure, seizures, etc.

- D1 Cause #5: Cannula kinked or obstructed:
- 1. Assess CXR.
- 2. Steel reinforcing wire within cannula compressed when inserted.
- 3. Securing suture is too tight around cannula.
- 4. Kinking commonly occurs spontaneously with VV double lumen cannulae.

D1 Cause #6: Cannula too small: assess blood flow capacity of the cannula. See cannula flow chart.

D1 Management #1: Adjust patient head and neck position:

- 1. Midline or extend head and neck.
- 2. Prop up patient; R or L side.
- 3. Check CXR for venous cannula position.
- 4. Call surgeon for cannula revision.

D1 Management #2: Remove kink and secure tubing to prevent further problems.

D1 Management #3: Reduce RPMs in indicated

D1 Management #4: This is not a condition related to the mechanical function of the ECMO pump. SEE SECTION H. PATIENT PROBLEMS:

- 1. Manipulate pump as indicated to optimize blood flow as much as possible.
- 2. Evaluate the patient as indicated.
- 3. Apply appropriate medical/surgical remedies.

D1 Management #5:

- I. If neck cannulation, extend neck.
- 2. May require surgical intervention to repair.

D1 Management #6:

- 1. Reduce blood flow from target flow.
- 2. Increase medication or ventilator support to compensate for lower blood flow.

3. Surgical replacement, if applicable

.RPN	Α.	В.	C.	D.	E1.	E10.
D1#1	3	4	2	3	72	720
D1#2	2	4	1	3	24	240
D1#3	2	1	1	З	6	60
D1#4	З	4	1	З	36	360
D1#5	4	1	З	З	36	360
D1#6	3	1	2	3	18	180