Friends- Here is the narrative for the first ECMO FMEA.
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Narrative #1
ECMO FMEA A1 FAILURE: REDUCED OR NO APPARENT BLOOD FLOW ON CENTRIFUGAL BLOOD PUMP.
Go to the AmSECT Safety Page http://www.amsect.org/page/perfusion-safety, select ECMO FMEAs, open the PDF and scroll down to section A1 to find the detailed FMEA. This FMEA focuses on centrifugal blood pumps (CBP). Many of these same problems can occur on roller blood pumps (RBP).

EFFECTS, CAUSES and MANAGEMENT OVERVIEW;
There may be a technical failure but no real loss of blood flow and no immediate danger to the patient. The simplest effect and easiest to resolve is a failure of blood flow indicators. The flow transducer (also called a flow probe) for the CBP can be miss-calibrated or just fail to function (lose connection, dried out contact gel/cream, incorrect calibration), while the actual blood flow is still moving. The mechanical operation propelling the blood is not as clearly visible with CBP as it is with a RBP. This could temporarily fool the ECMO Specialist into thinking that the blood pump itself has malfunctioned when all that is needed is to have the flow sensor repaired or replaced. To prevent this confusion there should always be a separate, free-standing blood flow meter measuring the flow in the arterial return line after any circuit shunts. One reviewer emphasizes the need to keep record of RPM at particular flows rates in order to anticipate if the blood flow may be failing. An accidental adjustment to flow control knob may make the pump appear to be operating, but the RPMs may be too low for forward flow. This may not be clearly stated in the FMEA as a likely cause of reduced or no apparent blood flow.

It is less likely that this confusion could occur with a RBP because the visual operation of the roller head is readily apparent. However, poor occlusion or miss-calibration of the RBP could result in an actual blood flow reduction that is undetected by the ECMO Specialist. Blood flow is arguably the most important parameter on the ECMO pump and deserves to be backed up with a free-standing, independent blood flow meter. If there is an actual reduction or cessation of blood flow, it could quickly degrade the patient's physiology and result in the death of the patient.

Other causes of a real reduction in blood flow include the pre-pump pressure can become too negative, being caused by a kinked or clotted venous blood line or cannula. Likewise, the post-pump pressure can be too high. This can be caused by a kinked or clotted blood line or oxygenator. Blood lines are commonly kinked whenever a patient is moved on ECMO to surgery, radiology or some other location. The ECMO Specialist should be focused on the circuit and let others deal with the details of moving the patient.

Venous cannula displacement is another less common cause of reduced blood flow as is cardiac tamponade with all of its internal restrictive complications.

A rarer cause can be air entry into the venous line which can de-prime the cone of the CBP, stopping the blood flow. This can be caused by a number of things; a leak in the venous line or venous cannula side-hole exposure (even under the skin). I had one case where a surgeon put a needle and stitch through the lumen of the venous cannula without even knowing it. Try telling a surgeon he misplaced a stitch! It could take a day or two to convince him. And then he might only go back in to prove you are wrong. Rarely the cause can be diffuse alveolar damage which can permit air entry into the left atrium where it can migrate to the right atrium though some kind of atrial defect. (I have seen this twice when ventilator pressures were high.) Then the air is aspirated by the siphon into the CBP cone. All of these are rare occurrences but can be life threatening because ECMO often must be discontinued to rid the system of the air.

Occasionally the CBP cone may not be properly seated in the drive unit. This may be caused by pulling on blood lines, kinking or disrupting them, often during transport. This is the least risky of all this failure causes and is always the most easily prevented. This A1 #8 Management describes the mechanical configuration of a XXXXX C pump. Other pumps will differ. (Note from GG: I marked out the identity of this centrifugal pump to protect myself from legal action by the manufacturer. If you want to know the name, contact me directly.)

Finally, there may be no obvious reason for the blood flow to stop. In these situations the ECMO Specialist will likely resort to hand cranking the blood pump. Less experienced ECMO Specialists are more likely to choose this option first than a more experienced specialist who can quickly diagnose and correct one of the problems from above.

RISK PRIOROTIES:
The risks associated with these types of problems are usually low. The highest risk is associated with inadequate patient circulating volume. This is almost certain to occur during ECMO if the run lasts more than a few days. The cause could be a low CVP (if it is being measured) or a negative fluid balance. The desire to reverse anasarca may prompt an intentional negative fluid balance. Even if the patient is in balance but continues to third-space fluid, the actual circulating blood volume could be less than adequate. This may cause a reduced blood flow with a "circling the drain" cycle of removing fluid followed by a forced blood flow reduction followed by the administration of fluid followed by the return to adequate blood flow followed by an increased anasarca followed by more fluid restriction, etc.

REVIEWER COMMENTS:

REVIEWER RG: It's important to keep a record of RPM at particular flows rates to monitor the after load to see if it is changing (up or down) or if anybody by mistake reduced the RPM.
A1 cause#1 #Flow (probe) transducer, (A1 cause #6#Aortic cannula displacement), (A1cause#8# Check for low ACT) A1 Management #8 # Ensure adequate ACT/Aptt, A1 cause # 9 RPM above 1200-1500, A1management #9 ensure RPM above 1200 reduce flow by clamp.

REVIEWER CN: At my previous institution we used the XXXXXX centrifugal pump with the XXXXX (venous return monitoring device). On multiple occasions we would have zero blood flow due to a clotted cone head which would in turn have to be changed out. We called it the "Triad" 1. Increased venous pressues (less negative) 2. No flow 3. Decreased pre and post membrane pressures. I feel this potential cause should be added onto the list. I have also used the OOOOOO centrifugal pump with the same venous return monitoring device and never had this issue. So, in my opinion it is a combination of the (venous return monitoring device) and that specific cone head. (Note from GG: I marked out the identity of the centrifugal pumps and venous return monitoring device to protect myself and the author from legal action by the manufacturers. If you want to know the names, contact me directly.)

REVIEWER DZ: I agree with your point that less experienced clinicians are definitely more likely to grab a hand pump before making sure the pump has really failed and it isn't a sensor problem too.

REVIEWER JT:
In my experience a decrease or stop of pump flow is related to: 1. Kinks or tubing or the cannula (there is memory in some cannulae, so once it happens/kinks, it may be predisposed to do it again), 2. Drainage cannula malposition or migration (which does occur over time, especially with ambulatory use or repositioning or transport of the patient, despite the best securement), 3. Centrifugal pump failure/decoupling (I have never seen this). (GG Note: This particular perfusionist has a hell of a lot of experience and never seen this. However, I have seen this several times, usually during transport.)
In some applications, certain people advocate a zero flow mode on a centrifugal pump if air has been detected in the venous, in order to prevent an air embolism. Air in the venous line does relate to what has been stated previously: excessive negative pressure, or perhaps an open IV line. In this case those that measure air on the venous line may see a trigger (Note: GG, I assume this is an in-line bubble detector). Is it worth stopping the pump, especially if there are air traps distal to the circuit (ie gas exchange device)? Do you stop the flow on the pump because of some trigger (maybe a false trigger)? Or do you allow for the system to run and have the circuit trap the air (in theory). Much of that issue is moot if the patient is on VV support, where the risk is considerably less.

REVIEWER ML: This setting is loss of visible flow readings with or without clinical deterioration of the patient? Resolution in the pathway without clinical deterioration would involve checking the flow probe connections, paste,

position to flow or securely clamped to tubing. Resolution in the pathway with clinical deterioration may involve the above actions, plus verification of blood flow with a flashlight to precede clamping the circuit, stopping the pump, unmounting and remounting the blood pump to a back up pump or manual handcrank to resume flow. This is a significant event requiring additional support staff with the possibility for advanced circulatory support in medications and chest compressions. I would stick to the facts and not introduce any conjecture regarding surgeons or other narratives. (Note: GG I highly respect this perfusionist, but I am a big fan of "conjecture". In fact, any proactive risk assessment is entirely about conjecture based on the experience of those involved.)

REVIEWER TM: At first I thought you'd be remiss to not have mentioned that a blood pump failure could be caused by a malfunctioning centrifugal console cpu or power supply, but looking ahead I see that is described in A2! The only real issue I saw was a typographical misspelling of "through" in the sentence ["Rarely the cause can be diffuse alveolar damage which can permit air entry into the left atrium where it can migrate to the right atrium though some kind of atrial defect"]. (Note: GG I rely entirely too much on "Spell check"; "through" and "though" are both words, so spell check did not catch it.)

REVIEWER LP: 1. One of the first interventions I would undertake is to look at the patient and see if he/she is affected by the apparent reduced or no blood flow. This is a first indicator of where the problem might be and how fast you need to react. (Note: GG I left this out…mea culpa. The first rule of intensive care is to look at the patient first before intervening.) 2. Cause #3: post pump pressure too positive. One of the causes of a high post pressure pump can be arterial hypertension of the patient, or, depending on the cannulation site, too much output from the patient. Also, the position of the patient, causing kinks in cannulae or tubing. Of course, all of this with a Centrifugal BP.

REVIEWER DJ: Pertains more to new bedside specialists I think. A1 Cause 4 RPM's that are too high combined with low volume status is another issue that can be seen. We drill our staff on backing off RPM's to see if flow is returned and giving volume helps. A1 Cause 3 Clot is not just post pump- we have had clot pulled in the venous line. Management- We had also had clot stop the impeller/cone on centrifigal pumps. By removing and re-seating the pump head we were able to reestablish flow. Cause - The other scenario we have seen is if there is a bridge in line that was opened by mistake. Especially in the neonate setting - or not enough RPM's. Which brings up another scenario we drill on. That is having two flow probes with the XXXXXX monitor to measure differential flow with a bridge open - but that doesn't really pertain to the pump failure FMEA. (Note: GG I again blanked the manufacturer's name. If you want to know it, please contact me directly.)

REVIEWER TM: (NOTE: GG I have reproduced the review below in its entirety because it represents EXACTLY the kind of discussion your program and personnel should have when writing and reviewing ECMO FMEAs.)

Here's my review for the A1 material.
A1 Cause #2 and #3 are probably not named well since they would also be the same as other causes (e.g. #2 and #4 are both pre-pump pressure too negative). I would rename #2 and #3 to be inlet and outlet obstruction, respectively since they refer to a mechanical interruption in the fluid path.
A1 Cause #6 contains too much detail. None of the other causes include "clinical signs and symptoms" like you included for tamponade (also, tamponade only has 1 "n").
AI1 Cause #7 should be entitled: De-primed cone
A1 Cause #8: I don't see what "pulling on blood lines, kinking or disrupting them" has to do with drive unit not properly locked into position. Kinking or disrupted lines would fall into #2 or #3 and not here. This should simply be that the centrifugal head is not aligned into the housing; now, this whole thing might be better suited for A2 where you have a decoupling of the rotor from the motor. However, I can see instances where there is poor (and very loud) interaction with the centrifugal head and that results in poor blood flow.
A1 Management #8 is VERY pump specific. I don't know which pump you are referring to, but the 3 combined make me think it's not one of the popular ECMO ones (XXXXX, OOOOOC, ZZZZZ or QQQQQ). Only 1 has a locking knob that is tightened; the rest have locking springs or latches. I don't know what "2. location with the proper cone orientation in close proximity to the emergency drive" has anything to do with it; other than basic safety in the

event of a pump failure. “3. Position the drive unit to prevent fluid from entering the ventilation ports.” Doesn’t make sense to me; I don’t’ know what pump you’re referring to.

I don’t agree with the automatic multiplication of time for E1 and E10. Things that are purely mechanical and have little to do with temporal events can be considered independent events and therefore history doesn’t come into play (e.g., there is no such thing as a gambler being “due” since all hands at all times are an independent random probability). The only things that would have changing risk factors are those that have a limited “lifespan” such as the MO or a demonstrative track record of a temporal dependence that can be calculated through a probability density function (probably of having a line infection is something that should have a defined PDF that could be used). Those things that have a proven temporal lifespan or changing PDF should have those corrections applied at column B and cannot simply multiply on top of the existing terms (e.g., A*B*C=10; let’s say that the probability of B increases by 10 on day 10. A*(B+10)*C does not equal A*B*C*10). What you are essentially stating is that on day 10, any of the items is 10x’s more likely, which is a gross overestimation of the true rates of occurrence. Currently, ELSO is collecting the dates of occurrence for most of their listed complications. I think it would be prudent to provide a true PDF for the various failures as a basis for folks to start; realizing that the institutional rates are not all the same.