Friends- Here is the narrative for the third ECMO FMEA for your review. In this narrative I explore a basic, instinctive fear at people can experience. If you think I am getting too inappropriate with this discussion, I want to know how you feel. On the other hand, if there is something you can offer along these lines, I would like to know about that as well.
Thanks for all your help. I appreciate it and I know the ECLS community appreciates it also.

Gary Grist RN CCP Emeritus

Narrative #3
ECMO FMEA C1 FAILURE: BLOOD DRIPPING ON THE PUMP OR FLOOR
Go to the AmSECT Safety Page http://www.amsect.org/page/perfusion-safety, select ECMO FMEAs, open the PDF and scroll down to section C1 to find the detailed FMEA.

This FMEA focuses on the sudden discovery of blood dripping on the ECMO pump or the floor. You wouldn't think that seeing some spilled blood, especially a small amount, would spook a well-trained ECMO Specialist or perfusionist. But sometimes, even in the most experienced personnel, the sight of blood coming from an unknown source stabs at our very genetic core…going back to our time in the bush when, as man-apes, we were in constant fear of predators or other man-apes and the sight and smell of spilled blood peaked the senses and started the adrenalin rush. In other words, it is an evolutionary fear reflex. The systematic exposure to blood as experienced by many healthcare workers may inure them to the sight of constrained blood. But the sight of uncontrolled bleeding or spurting of blood may affect even those most experienced by impairing their thinking and reaction.

"Nonsense!" you say. But even I have, on occasion, experienced an acute fear and suppressed anxiety when the loss of control led to spilled blood; during redo sternotomies that have gone terribly wrong, dissected and ruptured aortas, ruptured circuits when a raceway split or the top blew off a cardiotomy reservoir and showered everyone in the room, when an ECMO oxygenator unexpectedly blew out a temperature port and showered the bedside nurse, ECMO Specialist and the patient as well as numerous other instances.

Did I personally ever panic? No! I held it together and did my job as most professionals do. But I felt the fear. And I knew that spilled blood from an unknown and uncontrolled source on the ECMO pump could affect my nurses and ECMO Specialists as well as endanger the patient. There were even a few people over the years who resigned the ECMO team because of such a fear.

Fortunately, most of the spilled blood leaks detected during ECMO are minor. Sometimes it involves a leaking stopcock that can easily be replaced. But if the operator is unsure of where the leak originates, it could become a major problem. For example, a hairline crack in a major circuit connector may spray an almost invisible stream of blood to a distant area on the pump or floor. Then while the operator is looking for the leak source far from where it really is, the connector gives way due to fatigue or defect.

I once entered a cardiac surgery room for a routine check on one of my staff perfusionist. Her mask and upper scrub gown were covered with a fine layer of blood that she did not even notice. With my eyes and brain fresh to the situation and from a different lighting perspective, I could see a very fine spray of blood emanating from a cracked blood port on the cardioplegia set. My staffer was not even aware of the spray or the imminent failure of the CP set. We avoided catastrophe, but only just barely and by a stroke of luck (or divine guidance, which is what I prefer to believe). I have seen similar things on ECMO circuits in the past.

EFFECTS, CAUSES and MANAGEMENT OVERVIEW: The effects depend on how much blood is leaking and the source. The risks include blood loss, air embolus, oxygenator failure, circuit disruption and infection and even terminating ECMO causing patient death. I mention death here in the narrative and not in the FMEA as a possibility. I don't list any causes with a critical Harmfulness RPN. Death is a possibility only if the management is bungled. If I start listing Harmfulness RPNs based on the potential for human error, virtually every ECMO FMEA failure would be critical!

The common causes listed in this FMEA include 1) pre or post-cone (roller pump) leak in a connector or other component, 2) oxygenator leaking blood from tubing connection or 3) oxygenator leaking blood from an air vent port (not present on all oxygenators) and 4) an oxygenator leaking blood from sweep gas exhaust port. There are certainly others but I have found these to be the most common.

Correspondingly I have listed four management actions. The only pre-emptive management action is the check for leaks during wet priming. But this is not always effective since leaks can develop subsequently. So I did not include it in the FMEA. You may feel differently and want to include it in your ECMO FMEA. Management includes changing or repairing the component that is leaking. This could be as simple as securing a blood tube to a connector with a tie band or replacing a stopcock. Sometimes a small leak can be temporarily patched with a sterile bone wax plug secured with tape. Or the repair can be as complex as changing the entire circuit. The urgency depends on how much blood is leaking.

In any event, assistance should always be called if only to provide a second set of eyes and hands and a fresh brain to assess the situation. Air vent port leaks were fairly common on the oxygenator we used. A stopcock could be affixed to the port and closed with no further action required. If the sweep gas exhaust port dripped pink tinged condensate, the oxygenator was changed as convenient if it was a hollow fiber oxygenator. The small fiber size prevented the leak from increasing in size. However on older, sheet membrane oxygenators, even only a tinged leaked was replaced immediately due to the risk of the sheet membrane ripping wide open. But, even on a hollow fiber oxygenator, if the exhaust port was dripping red whole blood, the oxygenator or circuit was changed ASAP, just in case it was more than just a fiber or two leaking. It could also be a header seal or a heat exchanger leak. Again, always be calling for assistance to provide a fresh brain, and another set of eyes and hands.

RISK PRIOROTIES: These kinds of risks are very low. Even after 10 days of ECMO, they may never rise to a level of certainly the way that a failing or clotted oxygenator might. But, as I once heard an investigator from the National Transportation Safety Board say when talking about airline accidents; “Low probability events happen all the time!” He commonly dealt with fatal events which could often have been prevented with the proper pre-emptive management. Blood leaks on ECMO do not have effective pre-emptive management actions, so a minor event can easily escalate to a major problem if not managed quickly and correctly.

REVIEWER COMMENTS:

REVIEWER LP: Maybe it’s in Cause #1,or this is what you meant by not mentioning human error, but a badly screwed on stopcock, or a three way stopcock turned in the wrong direction, may be a plausible cause to me. Action would then simply be to screw the luer locks on tighter or turn it in the right way. (GG Note: Your comment is very pertinent. I tried to classify the leaks into four categories; 1. an easily replaced component (human error in attaching the component or component was damaged but not detected during priming), 2. a main circuit defect (cracked connector or blood port), 3. a defect in a specific kind of oxygenator that can be easily mitigated (plugging an air vent) and 4. a defective oxygenator requiring change out (fiber bundle or defective casing). Maybe I should have spelled that stuff out better. Of course I was heavily influenced because this FMEA was written for my ECMO Specialists in particular.

REVIEWER GH: My only question is with the solution of the bone wax. Is that really a viable solution? I assume by the next step of call for assistance that it is a temporary measure, but wondered about the legitimacy of bone wax working with a leak so large that it really just needs to be changed or the potential of pushing bone wax into the circuit itself…maybe I’m off base. (GG Note: Now to your question about bone wax. It is meant to only be a temporary fix until help arrives. A little bone wax can stop a leak. It can reduce the patients' exposure to infection from a disrupted circuit and reduce the ECMO Specialists' exposure to a hazardous waste (blood). Of course, it would not be useful in a catastrophic leak, like a ruptured casing (or cardiotomy reservoir in CPB). I have seen several of those that I can remember. Conceptually, it would be possible to push some wax into the blood flow. But the way I have used it is to "press and seal" rather than dig it into the leak like surgeons do to the sternum cut edges. I admit it is pretty crude, but should an operator allow a leak to drip until help arrives? Or should an

operator attempt a repair alone without knowledgeable assistance? I guess the answer to that question is program dependent and whether the operator is willing to take the risk of having to terminate ECMO. That exposes the patient to injury or death and exposes the operator to a potential PTSD incident. I always taught my specialists that if one part of the circuit required the attention of an operator for any lengthy time, then another operator should be available to run the pump. This is the same concept used by air line pilots; one does the trouble shooting while the other one focuses on flying the plane.)

REVIEWER GH: I understood it (bone wax) to be a very temporary measure as well given the real solution is change out, and I think you are also right about it being center dependent. We would call the "primer" to the bedside stat for an urgent/emergent change. Do you think the bone wax approach deserves to be noted with the specialist initial check if indeed that is the center's approach until the Calvary comes? (GG Note: I think that any intervention that is carried out, particularly one out of the ordinary, should be thoroughly documented. I am not sure what you mean by "deserves to be noted with specialists initial check".)

REVIEWER BM: Very relatable Gary! I feel like the component that I'm always worried about on our ECMO circuit in regard to blood dripping on the floor/leaks is our recirculation bridge b/c currently we operate with a three-way high flow stopcock on the outflow side of the circuit connecting to tubing going to a three-way high flow stopcock on the inflow side. I feel like those connections do get loose at times either opening or closing the bridge when we want/need to increase flow through the oxygenator for babies or through just gross manipulation and movement of the lines and circuit around the bedside. We are in the process of redesigning those connections to potentially being wye's. Ultimately with the goal being less luer connections and reduction of right angle flow through the stopcocks when open. Thoughts? I think circuit design could play a huge part in this particular FMEA since most of the blood dripping that I see is from connections that require manual twisting. Also, following up on the bone wax topic… I've definitely seen that used for temporary fixes and it's always in the back of my mind. Also, there is that industrial grade Flex Tape that I have seen on commercials that can patch holes in large containers that hold lots and lots of fluid. Maybe keeping a roll of that around would be beneficial for the same temporary use? Just an idea- can't wait to share these with the Cincinnati Children's Perfusion Team as well as our ECMO specialists/clinicians! (GG Note: Any stopcocks on our circuit were attached using a pigtail. I have seen too many stopcocks attached directly to a circuit be accidentally snapped off. Attaching it by pigtail greatly reduces this problem. After removing our wye-wye bridge, we replaced it with two straight connectors with luer locks. The connectors were located in the arterial and venous lines fairly close to the patient. We then attached a pigtail stopcock to each connector. The stopcocks could be connected with a male/male connector if a bridge was needed. Problem then was deciding on how often the pigtails needed flushing. The venous side was no problem, but there was worry about flushing directly into the arterial line past any bubble traps. Then we realized that there was never a time when we needed to use the bridge emergently. If the patient needed to come off ECMO emergently, the lines were clamped between the connectors and the patient. If the circuit needed to be recirculated, we leisurely attached a short 1/8" line to each connector at the luer ports. Any air introduced was easily handled by recirculating it back into the pump. After that we could leave the small, short bridge in or remove it, depending on the situation. But we rarely had to take a patient off emergently or even use the bridge on most cases. But the connectors were there if we needed them. As far as using industrial tape (Flex tape or Gorilla glue tape?) to hold bone wax in place, if you needed to remove the tape for some reason it could be a problem. I just used good ole' adhesive tape with courtesy tabs bent on the loose end.

REVIEWER DJ: I have to say that looking back to issues we have had since 1985, the majority has involved some type of "leak" most being minor and a few being major. For our bedside specialists seeing blood from a leak is usually the one that gets them amped up more than anything. So I really appreciate Gary's statement about gearing his FMEA to his bedside specialists. (GG Note: Dread of uncontrolled blood loss is a primal fear common to many people, including perfusionists and ECMO Specialists.)

As perfusionists we all have our own routine for scanning a circuit during conduct of CPB. Putting an ECMO specialist at the bedside and getting them to do the same and finding small issues before they become a more critical one and panic sets in takes time. By decreasing the workload (connections, stopcocks, shunts) to check,

the probability of missing something "should" decrease. Standardizing different size circuits to the same design patterns and minimizing components also decreases the workload and minimizes the possibility of most minor leaks. (GG Note: Circuit scanning is an important ritual, even more important than a hand off checklist which can often become a rote activity. I think that circuit design is extremely important in mitigating leaks. I never thought of a circuit design FMEA. I think that is an excellent idea, particularly as new components frequently become incorporated into a circuit; "How can this new sensor possibly screw things up - leaks, clots, settling out, need for replacement, infection exposure, circuit disruption, false readout, etc?")

Some "leaks" are preventable. Some are not, as in a oxygenator leak. Many times by noticing leaks early makes the difference between an urgent change out and a full blown emergency. A lot of the "leaks" we have seen have been used to modify our packs to minimize them in the future. So maybe my comments may be more pertinent for circuit design FMEA's or training standards, but being preemptive in this area i think should include more than just checking a circuit after priming. Design can also decrease human or operational issues that come into play with some of the leaks.

Simple things like banding certain connections and eliminating bridges or not putting them in until they are actually used have taken care of a lot of our past issues. Also putting double stopcocks on pigtails and only using the end one. The inside stopcock then allows for change outs without coming off ECMO for the minor leaks. Having a standardized "pattern" for circuit design makes everyone more comfortable doing their routine scans of the circuit. The same pattern design also allow for the same steps for emergent component changes, only the size of the component is different. Minimizing circuit components to mitigate the possibility of leaks is an important consideration for this FMEA. I have been surprised by the numbers of connectors on some of the circuits on patients we have received from outside facilities in the past. Leaks (for the most part) to me are usually a sign that a human has missed something in action or design rather than a component failure. (GG Note: In all my years of ECMO I never thought of a two stopcock pigtail. What a great idea! Wish I known about it decades ago. But your comment will definitely help in spreading the word. As far as having excess connectors in the circuit, at one time we used the “Galveston diamonds” in our circuit. This bone-headed idea was actually recommended in a credible perfusion text book: Cardiopulmonary Bypass: Principles and Practice, 2nd Ed. May 2000, Chapter 31: “Any failing membrane should be changed immediately on recognition to prevent an air–blood leak. A double-diamond tubing arrangement with dual connectors, both pre- and post-oxygenator, allows in-line replacement of the oxygenator without interruption of ECMO flow.” After using the diamonds for a year or so we realized that the 4 extra wye connectors in-line caused a lot of circuit clotting that we could not control with our anti-coagulation regimen. Because of them we changed a lot more clotted circuits than failing oxygenators before abandoning their use. Perhaps a circuit design FMEA would have helped us avoid those problems at the time. I don't mean to offend anyone still successfully using the diamonds. If they work for you, you are definitely not a bone-head!)

REVIEWER DZ: I agree with your points too (REVIEWER DJ). A little prevention (ie pigtails before stopcocks instead of putting the stopcock directly on the lure, tie-banding, etc) goes a long way towards not having to scramble down the road. I think that is the way most perfusionist’s brains work, but some of the ECMO specialists we all encounter don’t necessarily always think that way. This has been a good discussion on what to do when you find “blood on the floor” with ECMO and I think most perspectives on this seem to have been covered. I only have a couple brief thoughts to add. I have used sterile bone wax a few times over the years on CPB to get me through a case, but I think it’s only a plausible option for a “slow” drip. If it’s a positive pressure connection, I don’t think any bone wax will get into the blood path. If it’s on the venous side, I guess it would be possible but you would probably see more air being pulled in than an active drip. By far the most common cause I’ve found for a blood leak in either an ECMO or CPB circuit over the years has been cracked, cross-threaded or loose stopcocks. I personally have grown to hate the stopcocks with the collars that need to be tightened down because they often back off over time. I liked the old-fashioned stopcocks better that you just screwed down tight like any other lure connection, but they don’t seem to be very common anymore. (GG Note: I haven't liked stopcocks since they stopped making them out of stainless steel decades ago. I often think that the term luer "lock" should be changed to luer "loose lock", particularly if they are to remain in place for days or weeks.)

REVIEWER ML: In section C1: Circuit Blood Leaks, column 3; Potential Cause of Failure; C1 Cause #1: Consider to remove "pre-cone" as an option for a blood leak as this is an area of negative pressure. C1 Management #2: Consider adding, to first decrease flows temporarily to a lower acceptable level prior to initiating a repair as a means to reduce circuit pressure during repair. Consider adding or replacing a tie band before the bone wax repair option. C1 Management #4: Consider adding a statement to increase the frequency of "sighing" the oxygenator prior to "change oxygenator as convenient". (GG Note: Great thoughts! Particularly about lowering the flow. This is another one of those things that I just assumed the ECMO Specialist would know to do.....but you know what happens when assumptions are made. So it should be better explained when the ECMO FMEA is rewritten. But I want to give a little bit of push back on the blood leaks on the venous side of the pump. You are correct when you say this is normally operating under negative pressure, particularly at full flow and with a restrictive venous cannula. But sometimes, if you lower the transducer to the level of the pump inflow port, the pressure will be positive. So sometimes there can be blood leaking out. This might be something that ECMO Specialists need to understand more fully; the transducer at the phlebostatic axis might be reading a negative pressure. But the inflow pressure at the level of the blood port might be positive, with the potential for a blood leak rather than air aspiration.)