Friends- Here is the narrative for the sixth ECMO FMEA. I realize that this is out of order since I inadvertently sent the seventh narrative earlier due to a glitch at my end. I thought #6 was a simple ECMO FMEA, but the reviewers had a lot to say about it. And then I realized how complicated this issue has become with the FDA and CDC getting involved.

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Narrative #6 F1 Failure: Water 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 F1 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.)

EFFECTS, CAUSES and MANAGEMENT OVERVIEW:
I wrote many of these ECMO FMEAs years ago as teaching tools. As I review these now I realize how deficient I was in discussing many relevant things and how circumstances have changed such as the revelation of water born infections associated with ECLS water heaters. For example I only list one EFFECT for this FMEA; the loss of adequate water to operate the unit and wet floor slippage by personnel but nothing about infection risks. Coming from the OR, I was always gun shy about spilled water, having suffered a fall and broken arm because of it.

If the water heater fails due to a leak or some other defect on an ECMO pump, this is about the easiest piece of equipment to replace during ECMO. One thing I did not contemplate in the original FMEA was an electrical hazard from water leaking into electrical circuits. All the platforms I used to support the pumps and water heaters were not water sealed. In hind sight, I should have used a fluid barrier like a large Chux between the platform and the water heater. I don't think that engineers ever thought that a water heater would be positioned directly over the junction boxes, power supplies and batteries for the pumps. Normally these platforms were used in open heart procedures which utilized larger, free-standing floor positioned heater/coolers (H/C). If one of these leaked it would not drip directly on the electrical circuitry below. Since I retired I have noticed new systems using pumps with self-contained batteries and power supplies that are not easily water contaminated. And newer carts put the water heater on the lowest level below any circuitry. But I know that many people are still using the old platforms with the potential for water contamination.

Lastly, I wrote this FMEA years before the issue of nontuberculous mycobacteria (NTM) infections became evident. I suppose that a water leak could expose the patient (and personnel, for that matter) to this infection. I did not deal with NTM in the effects section, but it should be addressed since the FDA and CDC have issued recommendations concerning this.

I only list two causes; a water only leak (no blood) at the water hose connections or a crack in outer plastic housing of the oxygenator not involving blood leakage. Of course a cracked oxygenator housing is going to require an oxygenator or entire circuit change out. Most of the hose leaks were either from a worn "O" ring in the Hansen connector at the oxygenator or at the hose clamps. I always secured the water hose with screw clamps, never trusting the spiked fittings alone to prevent leakage. There is also the possibility of an internal water leak in the unit, but I did not list that cause. I should have.

In discussing management I was again deficient. I should have included a pre-emptive management section. This should include routine maintenance of the unit according to the IFU. I replaced the rubber "O" rings in the Hansen connectors yearly and kept them properly lubricated. Without the lubricant to

protect them, these seals can degenerate from ambient oxidation. Remember that it was ambient conditions (low temperature) that caused an "O" ring to fail and bring down the Challenger space shuttle. I am not saying that an "O" ring failure will cause your pump to explode, but it could cause a leak with someone slipping and breaking an arm or (worst case scenario) cause an electrical short-circuit resulting in failure of the pump. Am I exaggerating the risk? The purpose of an FMEA is to identify ANY POSSIBLE failure, effect and cause and prevent or mitigate it.

Also under the pre-emptive management, a section on cleaning and specific maintenance practices to prevent NTM should also be included. The FDA and CDC are working with professional societies, public health departments, H/C manufacturers, and individual experts to develop methods for preventing infections associated with H/C devices. Just cleaning the units is not enough. Programs should be able to verify that the decontamination procedure was followed and performed by personnel with documented competency for the procedure.

Al Stammers has a good summary of the NTM problem on YouTube ("Update on Infections with Heater Cooler Devices"; https://www.youtube.com/watch?v=C-9F-0Vr7qg). He refers to an estimate that 1/8,000 cardiac surgery patients on bypass develop NTM infections. I am skeptical of this figure since the programs that first described these infections seemed to have greater numbers in smaller populations of patients.

The FDA and CDC include water heater devices used with ECMO as well as blanket warmers in their mandatory requirements and suggested recommendations. No NTM infections have been associated with ECMO water heaters. But ECMO patients are known to have been contaminated with NTM bacteria from an unknown source without developing active infections. If an ECMO patient does become infected with NTM and the requirements from the FDA and CDC were not followed as pre-emptive management, who knows what could happen to the responsible parties and in civil litigation.

Under management, I list mainly replacing the unit. Trying to fix the water heater during a clinical procedure is not a management action, it is reckless. If the oxygenator is defective, its replacement is the only choice.

RISK PRIORITIES:
The risk is low that a water leak is going to injure a patient. Neither cause that I list approaches certainty after 10 ECMO days. However, the cause I did not list (an electrical circuit blowout due to a short circuit from a water leak) could pose a high risk if ECMO were stopped unexpectedly at a critical time. I am not sure how an NTM infection should be risk scored; certainly rare, but harmfulness is critical (50% mortality).

REVIEWERS

REVIEWER LP: With regards to NTM, if protocol for H/C disinfection has been followed, there should be no concern. Don't know if bone wax will help in this situation (it does require some interaction with blood, no?), but I just reviewed a case report where Dermabond was used to seal a leaking arterial cannula on ECMO (pressure of 240 mmHg), so that might work to seal a (water) leak. Maybe also have "Clean up spilled water" in the Management Section.

REVIEWER RM: Are most ECMO centers using 3T for heating and cooling? We use the Hemotherm and do not perceive the same issues. The units are wiped down with bleach wipes after ICU use. Sorry that I

do not have much more to add. Our Biomed Department takes care of cleaning the units. (NOTE GG: I don't know what is commonly used for ECMO water heaters today. But it doesn't really matter. The FDA recommendations apply to any water heater used with CPB or ECLS. It doesn't sound like just wiping the unit down with bleach is going to pass muster. Here is just one of the many FDA recommendations: "Develop and follow a comprehensive quality control program for maintenance, cleaning, and disinfection of heater-cooler devices. Your program may include written procedures for monitoring adherence to the program and documenting set up, cleaning, and disinfection processes before and after use." If you (or your Biomed Dept) are not doing that and the other FDA recommendations and your patient gets an NTM infection, there could be hell to pay legally. Before that happens it is more likely that the JC is going to show up and want to see if you are following the FDA recommendations.)

REVIEWER JT: It is important to know that the different water recirculation units used for ECMO temperature control vary widely. Briefly, the devices used for ECMO as reported by active ELSO centers to Extracorporeal Life support Organization break down as follows: Cardioquip 29%, CSZ 33%, Maquet 20 %. Less than 1% of reported units are the Sorin/Livanova devices (such as the 3T). There are others that are not cleared for use in the USA, but used internationally. Some units are new (Cardioquip) and others quite old in which they are not supported by their vendors. Many devices used are not intended for ECMO use, but are used (ie Blanketrol, Gaymar) and modified anyway. Old dinosaurs including the MDT Biocal 370 and the Seabrook ECMO unit are still in use at some centers. One can also expect to see updates regarding recommendations for cleaning and reuse for these devices published in the peer review literature next year. (NOTE GG: Thanks, JT. Very informative on an issue that perfusionists and ECMO Specialists are struggling with.)

REVIEWER DZ: Gary, I think your current FMEA F1 Failure: Water on the Floor is straightforward and easy to understand. I also think your narrative will generate some good discussion about the preventive management (cleaning) of the HC units to avoid NTM infections, and that can be used to develop a section on that topic in your existing FMEA.

One other factor I think we need to think about with respect to minimizing the chance of HC associated infections is to minimize the clinicians' interactions with the HC unit during an ECMO case to only those that are absolutely necessary. An ECMO program I was involved with in the past had their bedside Specialists physically check the water level in the HC every 8 hour shift even though the unit had a low water alarm. When the reports of NTM infections with HCs on bypass started coming out they stopped that practice. They even went as far as covering their small HC units with a clear Plexiglass cover to provide a physical barrier.

Another point you made in your narrative that isn't talked about as much but we should be aware of is the potential electrical hazard of having a small HC sit on a heart lung machine base that has openings in it for cables. Those bases obviously weren't designed with that purpose in mind, and I think the concern about a significant water leak being an electrical hazard is a legitimate one.

(NOTE GG: Your comment about clinician interaction with the HC is intriguing. That did not occur to me as being a problem. What is an ECMO HC but an incubator sitting on the pump for many days without change? It is a perfect Petrie dish for bacterial growth; warm, moist, and dark. As you know, infections are common on ECMO and who knows from where they originate?

Forty-five years ago, in my hemodialysis days, sterilizing the artificial kidney machine (AKM) was very important. Although the semipermeable membrane prevented bacteria from entering the blood of the patient, it did not stop pyrogens (toxins) from crossing and causing a severe febrile reaction. This sometimes led to shock and even arrest. I saw that many times. So we developed methods to kill the bacteria in the equipment. We used three methods. 1. After use, the internal water/dialysate circuit was filled with formalin. I don't think that is still done today because I think formalin is now considered a carcinogen. And there are now other caustic solutions used to kill the bugs but not harm the equipment in AKM. 2. We used UV lighting contained within the water circuit which was on continuously when the equipment was in use to inhibit bacterial growth. 3. Lastly, we had some AKM that could self-sterilize. After use, the AKM could recirculate water within their water/dialysate circuits using the built-in heater to warm it up to 185 F. It ran for 1-2 hours and pasteurized any bacteria. I think the last two methods could certainly be built into future H/C of all types.

In another personal experience, more than three decades ago just after our ECMO program started there developed a Pseudomonas outbreak in our NICU. Several babies were infected including some ECMO babies. The entire nursey was cultured to try to find the source of the bug. A positive culture came back for all three of my ECMO water heaters. So I sterilized the units with formalin. The medical director felt confident that he had found the point source of the Pseudomonas, but I strongly disagreed. I felt that my heaters had somehow become contaminated from the original point source. Sure enough, the Pseudomonas outbreak continued even with the bugs removed from my heaters.

Then one brilliant nurse cultured the inside of the aerators on the water faucets at the bedside used to wash care givers hands. Sure enough, there was Pseudomonas in it and most of the other faucet aerators. It seems that about a year earlier, the hospital added aerators to the faucets to decrease water usage and lower the water bill. But the aerators became a perfect nest for the bugs to grow. After removing all the aerators, the infections stopped. How did my ECMO water heaters become contaminated? The water we used to fill the units prior to use came from those same faucets.)

REVIEWER DJ: Is heater failures and use addressed elsewhere (in another ECMO FMEA)? If not then we need to consider more than a water leak. My medical director had a case at another institution where the heater failed. Patient eventually became bradycardiac and arrested after patient cooled to 32. (Lack of monitoring patient temp is a separate issue). We too have had heater failures but the temp monitor alarmed on the Cardiohelp to catch this before it became an issue. Also do we need to address cooling and rewarming for post cardiac arrest patients? Or do we leave this as an institutional policy? Also given that some heaters are used as an “off the shelf” application -CZW Microtps have a default setting of 42C setting. This must be adjusted every time the unit is turned on. Just my two cents. But these are issues we touched on through the years in our quarterly drills with our bedside specialists. (NOTE GG: I did not address the issue of a heater failure in this particular FMEA. I was primarily worried about leaks which seem a lot more common. I can't remember if I did write an FMEA about an actual heater failure causing hypothermia or hyperthemia. I certainly think that blood temp monitoring is important, but redundant H/C monitoring for both hot and cold should also be available. I think our ECMO water heaters only had high temp alarms.

I can see how a patient on VV ECMO with cool blood entering their right heart could fibrillate, even before the peripheral patient temp sensor responded. How would that be dealt with? CPR of course, but what would you do to get the H/C back on line? If you stayed on ECMO until the water heated up, that could take some time to do, provided the unit is working properly. Or if you stayed on ECMO after

removing the H/C, how is the patient's heart going to get warm? Of course, a replacement H/C should always be standing by. But it would still take a few minutes to get it warmed up as well.

An overheating unit would be much easier to deal with; pour cold water in it or just remove it. I hope neither of these situations ever happens to anyone. But if we can conceive it happening, someday it might.)