Friends

This is an introduction to the Extracorporeal Membrane Oxygenation (ECMO) Failure Modes and Effects Analysis (FMEA) year-long safety project. Approximately every two weeks there will be a new posting. The project is profiled below:

1. ECMO safety project introduction.

This is to introduce a new safety project sponsored by the AmSECT Safety Committee. ECMO safety is the avoidance of incidents that result in adverse patient outcomes. These may be associated with 1. malfunctioning or defective equipment and/or supplies, 2. communication failure between healthcare professionals, 3. human error or incorrect execution of procedures, 4. failure to anticipate adverse events. This project will explore these various safety aspects of ECMO by using failure modes and effects analyses (FMEAs).

2. Where to find the ECMO FMEA.

The ECMO FMEAs can be found at http://www.amsect.org/page/perfusion-safety. Click on the ECMO FMEA link for a downloadable PDF near the bottom of the page.

3. Using FMEAs to explore safety aspects.

An FMEA is a form of proactive risk assessment that dissects a potential failure (or a problem) bit-by-bit into its component parts in order to better understand it. It does this by 1) identifying potential problems in a design or process by itemizing the conceivable failures, 2) describing the consequences of the failures, 3) recognizing the specific configurations or actions that can cause the failures, 4) listing specific actions that can prevent or mitigate the failures, 5) ranking the risk of each failure. This is different than root cause analysis or trouble shooting. A definition and description of those processes can be found on page 1 of the ECMO FMEA PDF on the AmSECT Safety page (see above).

4. FMEAs written for novices.

These ECMO FMEAs are useful to experienced personnel, but they were originally written to train novice ECMO Specialists, perfusionists and physicians. The first sight of an ECMO pump can be quite intimidating to a novice. So, some of the failures are very simplistic and fundamental as befits personnel who have no prior perfusion experience. From the viewpoint of a career perfusionist or experienced ECMO Specialist, some of these things may be too basic to be of immediate value. However, as the risk increases with the passage of time, experienced personnel may have to make difficult strategic decisions about a simplistic failure in order to prevent disaster. ECMO FMEAs can also be used to document, for training purposes, those rare failures that happen so infrequently that the memory of their occurrence fades as the involved personnel move on, out of the program.

5. Risk priority numbers in FMEAs.

FMEAs are unique because they use a Risk Priority Number (RPN). An RPN determines the subjective degree of risk based on expert consensus to establish the probability that a failure will occur. Each failure mode has a RPN assigned to the following categories:

A. Harmfulness Rating Scale: how harmful the failure can be from 1. slightly harmful to 5. critically harmful.
B. Occurrence Rating Scale: how frequently the failure occurs from 1. rarely occurs to 5. commonly occurs.
C. Detection Rating Scale: how easily the potential failure can be detected before it occurs from 1. very easily detected to 5. no means of detection

D. Patient Frequency Rating Scale: how often the failure occurs in the total patient population from 1. only few patients are at risk to 3. all patients are at risk.
E. Risk Time Factor (RTF): Time period during which the patient is at risk from day 1 exposure to increasing risk as he days pass (2,3,4,5 days, etc.).

6. Risk management.

Individual ECMO FMEAs can have a multitude of RPNs that rank the different causes of each failure. Resources can then be assigned to prevent or manage those failure causes of greatest risk. Once the highest risks are identified, an ECMO program can work to reduce those risks by developing new methods to prevent or reduce risks. By quantifying the risks year after year, an ECMO program can document that risks are being assessed and actively reduced, as required or suggested by some oversight groups; i.e. in-house risk managers, the Joint Commission (JC), the Center for Medicare/Medicaid Services (CMS), insurance companies and plaintiff's attorneys.

7. Concept of risk interval.

These ECMO FMEAs introduce the concept of the risk interval into ECLS procedures. Certain adverse events following ECMO initiation can occur with increasing frequency as time passes. During ECMO, the risk of an oxygenator failing on the first day is quite rare. However as time passes, oxygenator failure becomes almost a certainty. I illustrate the risk interval concept in the ECMO FMEA by showing the total RPN for day 1 of ECMO as well as the increased risk by day 10.

8. RTF is unique to ECLS procedures.

The RTF is unique to extended ECLS procedures. The longer a patient is on ECMO the greater the risk that a failure will occur: 1) Equipment and disposables are at greater risk for failure the longer they are in continual use. 2) With multiple changes of personnel over time there is increased risk of a communication failure. 3) Human errors or incorrect execution of procedures are more likely as the skill level of personnel varies from shift to shift. 4) Less experienced personnel are less likely to anticipate adverse events. One day (24 hours) on ECMO is arbitrarily selected as one RTF. Day 1 (E1) RPNs and Day 10 (E10) RPNs can be determined subjectively by experienced personnel. RPNs constitute a progressive warning, not a statistical certainty.

9. ECMO FMEAs harder than CPB FMEAs.

This project is a lot harder than a CPB FMEA. CPB is like a checkers game whereas ECMO is more like chess. Both require tactical thinking to solve immediate problems within a few hours. ECMO, however, requires long term strategic thinking for days or weeks. For example, during CPB the oxygenator rarely fails. However, with ECMO an oxygenator failure is almost a certainty as time (days or weeks) passes. If a perfusionist or ECMO Specialist thinks the oxygenator may need changing but the patient is improving rapidly enough to come off tomorrow or the next day, should s/he make the change out knowing that it may set the patient back and expose the patient to the hazards of changing an oxygenator or circuit (air emboli, infection, etc). There may be an additional complicating factor. Unlike checkers or chess there may be more than two players (or stakeholders and decision makers), particularly with ECMO. They may have different training, experience and priorities. They may not always all agree on the best course of action in either the short term (trouble shooting) or the long term. So having a plan like an ECMO FMEA before problems occur is even more important.

10. Tabletop scenarios.

Simulation is a beneficial training tool. However those ECMO programs without formal simulation facilities sometimes find it difficult to organize and setup simulation exercises. Often all that is available

is a wet circuit setup with pretend situations and make-believe monitor readouts. Nonetheless these can be very valuable, especially when training novice personnel. Some problems like inconsistent ACTs, oliguria, hemolysis and seizures do not lend themselves easily to equipment focused simulation. However an additional tool is a tabletop scenario which does not require the hardware to be setup. This is an exercise in which personnel in both management and clinical roles can gather in a non-intimidating environment to discuss failure modes without the stress of critical observation or performing incorrectly in front of others.

11. How do ECMO FMEA tabletop scenarios work?

Participants must be willing to engage in cordial, non-threatening conversation to challenge themselves and others. It is OK to not have an answer during a tabletop discussion since all the known answers are available to the participants in the FMEA. Those leading the tabletop discussion can control the pace and flow of the exercise and not worry about technical breakdowns. Discussion leaders can draw out those of the group who are less confident or just let them listen and absorb. They can assess the risks and how they can be reduced. ECMO personnel can recognize their own strengths and identify areas that need improvement. This can sometimes lead to policy and procedural improvement. Tackling just one ECMO FMEA for a 5-10 minute tabletop discussion can be a part of any staff meeting without special equipment or personnel preparations.

12. Simulation vs. Tabletop Scenarios.

ECMO FMEA tabletop scenarios do not upend the role of a trained simulation team but provides an alternative method for studying interventions and crisis prevention. Simulation participants are focused on getting the correct answers to bring the exercise to a successful conclusion followed by a critique of their actions. Whereas a tabletop discussion can be more free ranging and exploring; looking at the causes of failures that may overlap each other. ECMO FMEA tabletop scenarios lack the situational awareness recognition and muscle memory training of hands-on simulation. But they can be utilized much more frequently than expensive and time consuming equipment centered exercises.

13. Posting narratives rather than formal FMEAs.

I will not post the detailed ECMO FMEA on the list server or discussion board because they are in table form and would be difficult to post in a normal prose configuration. Those detailed ECMO FMEAs can be found on the AmSECT Safety page (http://www.amsect.org/page/perfusion-safety). Rather a narrative describing the individual ECMO FMEAs will be posted about every two weeks. The narrative for individual FMEAs will also summarize salient points. I hope that these will generate interest, discussion and criticism that can benefit the ECLS community at large.

14. ECMO FMEAs and oversite agencies.

The CMS does not mandate the use of FMEAs but they highly recommend their use; <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/downloads/GuidanceForFMEA.pdf> . The JC requires each member hospital to select at least one high-risk process for a proactive risk assessment using an FMEA every 18 months at a minimum <https://www.jcrinc.com/assets/1/7/PS17.pdf.> The JC further recommends that hospitals, in their role as learning organizations, constantly work to identify other high-risk processes for proactive risk assessment as well. There are not many processes risker than ECMO. An ECMO FMEA can fulfill this JC proactive risk assessment requirement. The Extracorporeal Life Support Organization recommends continuing education and quality improvement for ECMO programs to become and maintain their Centers of Excellence designation. ECMO FMEA tabletop scenarios can provide credible documentation of compliance and risk management to this recommendation.

Gary Grist RN, CCP Emeritus
garygrist@comcast.net