CPB FMEA # 41 Failure of checklist to prevent errors

Friends-

This week’s FMEA is one that all of you can identify with; perfusion checklists. Many decades ago, when I first started using checklists, I thought they were an annoyance that just slowed me down. I did not see much value in them (my youthful arrogance). But as I aged I began to realize that I was not infallible. There were many times when I caught myself making errors that a properly structured checklist could have prevented. Fortunately, wisdom often comes with age. I began to see the real benefits of a good checklist. Later, as I instructed students, I realized that a good checklist could help them learn the ropes of the circuit setup rather than just me repeatedly showing them how to setup. I also realized that a checklist that was too vague did not help them much and a checklist that was too complicated just confused them. It is difficult to find a happy medium for students because, unlike staff perfusionists who use the checklist every day for months or years and become very familiar with it, a student must master it in a few days if s/he expects to run the pump during their rotation. This is particularly true in a pediatric program where differently sized and configured circuits are frequently used.

Speaking of becoming very familiar with checklists, I came to realize that familiarity breeds contempt, not just with people but with checklists as well. Experienced staffers are more inclined to miss or incompletely perform a checklist task because they are working autonomically (like the autonomic nervous system) with very little conscious thought given to each task. It is more of a reflex than a thoughtful action. This can be compared to learning a musical instrument like the piano or guitar; at first it is difficult and deliberate requiring intense concentration. But later, when mastered, playing the instrument requires very little conscious thought. This can be further complicated if what little conscious attention they are using gets distracted by irrelevant things. This automaticity can be even more problematic if a relief perfusionist taking over the setup assumes that the items on the checklist are actually completed when, in reality, they have not been completed.

My solution was to require a double check system. The Amsect Guideline 4.1 states in part: ”Completion of the checklist should be performed by two people, one person being the primary perfusionist responsible for operation of the heart lung machine during the intra-operative period.” That has always seemed to work well for me. Since I implemented checklists decades ago, I don’t ever remember spilling the prime because of failing to securely connect a tube, or putting tubing in a pump backwards or not having the sweep gas system work properly when beginning CPB. These errors may be simple enough to correct. But they may be inadequately dealt with by an inexperienced perfusionist or add another layer of criticality in an emergent case.

The Joint Commission in the USA mandates a “time out” in the OR before beginning any surgery. In this FMEA I recommend a second time out just before the surgeon cuts the AV loop. The heart lung pump is a complicated life support system. Everyone in the room whose name is on the operative record should have the assurance that the pump is ready and safe to use. In the Gritten Report, the accidental CaCl2 overdose that killed the patient was in the pump prime. The iCa+2 of the prime was 12 mmole/L when it should have been 1 mmole/L. The report says that the prime was tested, but it unclear to me if the lab results were returned to the perfusionist in time before CPB was implemented or if the perfusionist just thought the CaCl2 would be harmlessly diluted after CPB was started. In either case, he was wrong headed. He should have implemented a time out and waited for the lab results. If the overdose was recognized, then the surgeon could have decided for himself if the CaCl2 would be harmlessly diluted or have the pump drained and re-primed. Why didn’t the Gritten Report perfusionist implement a time out? There were four reasons that I can see from the report. Firstly, the perfusionist and surgeon had an angry confrontation minutes before the case started, so there was already tension there. Secondly, the perfusionist took a short cut, feeling pressure that he needed to catch up with the surgeon. The perfusionist was also tired (#3) AND stressed (#4). He had been in counseling as a result of over work and emotional stress.

A pump time out is a new revelation to me. My old checklist does not list a time out. But I think all future checklists should incorporate it. Perhaps you and many others have done a routine pump time out in the past, but I doubt that it is widely used or documented. AmSECT Standard 5.1 states: “A patient-specific management plan for the cardiopulmonary bypass (CPB) procedure shall be prepared and communicated to the surgical team either during the pre-operative briefing or prior to beginning the procedure.” But I am not sure if this can be interpreted as a time out that confirms the readiness of the pump just prior to CPB. The AmSECT generic checklist does not list anything resembling a time out prior to CPB.

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FAILURE: Failure of checklist use to prevent errors during CPB.

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EFFECT: Indeterminate risk to the patient, ranging from insignificant to lethal, depending on the specific error.

CAUSE:

1. Action error: These errors occur when a frequent and routine task becomes a rote, autonomic and habitual action that bypasses the active thought process. These errors also occur if attention is diverted resulting in an incomplete or unintended action.
2. Slip: Error of commission failure.
3. Lapse: Error of omission failure.
4. Non-compliance error:
5. Routine failure: Deliberate deviation from procedures. Attitude: “I like my way better.”
6. Situational failure: Taking short cuts or failing to properly follow procedure to save time or effort on a particular case. Attitude: “I need to catch up with the surgeon.”
7. Exceptional failure: A well-meaning, but misguided procedural error on many cases. Attitude: “I am under pressure by my boss to get the job done.”
8. Exacerbating factors:
9. Fatigue
10. Stress
11. Hunger
12. Illness
13. Perfusion checklists also fail to catch errors due to their poor design, poor wording or being too short or overly long.

PRE-EMPTIVE MANAGEMENT:

1. Checklists are executed using a verbal challenge and response format.
2. Verbalize task, even if being the sole operator. Verbalizing the task helps to stimulate the thought process and inhibit the autonomic response.
3. Physically complete task
4. Check mark the item on the list only after the task is complete using repeat verbalization.
5. Avoid irrelevant distractions and interruptions when possible. Otherwise complete a specific checklist task before addressing the outside distraction.
6. Ensure sufficient time to complete checklist.
7. Employ a double check confirmation process with secondary personnel. (\*Without double check confirmation the Detectability RPN should be increased to 4, making the Total RPN 3\*2\*4\*3 = 72.)
8. Perform time out before cutting the AV loop.
9. Describe modifications to circuit and procedure based on surgeon preference.
10. Describe any circuit prime lab test results required during priming, reporting any abnormalities.
11. Describe any contingency perfusion support preparations anticipated based on the patient condition; blood availability, auto-transfusion, IABP/ ECMO/VAD readiness, secondary personnel availability, etc.
12. Be prepared to delay CPB implementation if circumstances warrant.
13. Ensure compliance to checklist procedure by staff:
14. Raise awareness of purpose and non-compliance consequences.
15. Employ frequent audits and active review to document compliance.
16. Revise checklists annually or as necessary with staff input.
17. Either the checklist or the perfusion record should list the type and serial numbers of the equipment used and the type and lot numbers of supplies used.
18. Consider checklist use during the entire peri-operative period; pre-bypass, CPB initiation, CPB termination, post CPB with potential resumption or use of other support methods.

MANAGEMENT:

1. If a checklist related failure occurs:
2. Trouble shoot the failure as needed.
3. Notify Risk Manager after the case of the need to perform a Root Cause Analysis if appropriate.
4. Prepare a Failure Mode and Effects Analysis to prevent future incidents, modifying the checklist and its use.

RISK PRIORITY NUMBER (RPN):

A. Severity (Harmfulness) Rating Scale: how detrimental can the failure be:

1) Slight, 2) Low, 3) Moderate, 4) High, 5) Critical

(I would give this failure a Moderate RPN, 3.)

B. Occurrence Rating Scale: how frequently does the failure occur:

1) Remote, 2) Low, 3) Moderate, 4) Frequent, 5) Very High. (The Occurrence is Low. So the RPN would be a 2.)

C. Detection Rating Scale: how easily the potential failure can be detected before it occurs:

1) Very High, 2) High, 3) Moderate, 4) Low, 5) Uncertain. (The Detectability RPN equals 2 on the premise that a double check system with two people is used. If only one person completes the checklist the Detectability RPN would be 4.)

D. Patient Frequency Scale: 1) Only a small number of patients would be susceptible to this failure, 2) Many patients but not all would be susceptible to this failure, 3) All patients would be susceptible to this failure. (All patients would be at risk. So the Frequency RPN would be 3.)

Multiply A\*B\*C\*D = RPN. The higher the RPN the more dangerous the Failure Mode.

The lowest risk would be 1\*1\*1\*1\* = 1. The highest risk would be 5\*5\*5\*3 = 375. RPNs allow the perfusionist to prioritize the risk. Resources should be used to reduce the RPNs of higher risk failures first, if possible. (The total RPN for this failure is = 3\*2\*2\*3 = 36. If there is no double check system used the total RPN would be 3\*2\*4\*3 = 72.)