CPB FMEA # 17 Transfusion error failure

Friends-

This week’s FMEA is about transfusion errors on CPB. I wanted to write this for a couple of reasons. Firstly, transfusion errors are one of the most frequent sentinel events according to the JC. So perfusionists should have a formal FMEA that recognizes this risk. A transfusion error will, at minimum, trigger a root cause analysis (RCA) and focus intense scrutiny on perfusion personnel and practices. Who are these perfusionists? Who is in charge of them? Who approves their P&P? Are they qualified to administer blood? Etc. A critical RCA could even jeopardize a perfusionist’s job if he/she is not protected by special P&Ps. It could also trigger a formal investigation by JC, CMMS, AABB and even the PSO. This could greatly antagonize the hospital’s administration against the perfusion staff. Outside assessors are sticklers for following procedure. I refer to this JC Patient Blood Management Guide on the FMEA (\*http://www.jointcommission.org/assets/1/6/PBM\_Implementation\_Guide\_20110624.pdf).

Secondly, perfusionists usually administer a blood transfusion on CPB under the authority of an AABB approved general transfusion P&P of the hospital. However the method of administering blood on CPB is very different than that stipulated in an accepted AABB transfusion P&P. We don’t use the recommended filters (we use better filters, but investigators don’t know that). We don’t use NS exclusively for chase fluid. We might first wash the RBCs through a cell saver to reduce preservatives, K+, free hemoglobin and glucose. (I can hear it now. Why did you do that and who authorized it?) We put the blood into the arterial system rather than the venous system. We give the blood much faster than is recommended. We document our vital signs differently and on a different record. We may not have a written order to give the blood. With all these differences and more, if an incident should occur the perfusionist may be on the hook for incorrectly performing the transfusion according to accepted P&P or in violation of the P&P. Perfusionists need a transfusion P&P that specifically relates to transfusions during CPB. So that is what this FMEA recommends for pre-emptive management.

Of course the most important aspect is patient welfare. Most perfusionists never give the incorrect blood product on CPB. But, based on my own experience, I also think that those same perfusionists have found many errors in the blood preparation and identification process that needed correction before any blood was given. It is this deliberate awareness that keeps patients safe. But any deviation from the normal CPB process such as an emergent life threatening situation when thoughts are focused elsewhere can result in an unintentional transfusion error.

This FMEA does not detail a complete ‘perfusion transfusion on CPB P&P’. These are just the high points so that programs will have some guidelines to take the initiative on their own to write comprehensive perfusion transfusion on CPB P&P.

The AmSECT Safety Committee

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FAILURE: Perfusionist related transfusion error on cardiopulmonary bypass (CPB).

EFFECT: (not necessarily in order of importance).

1. An error triggers an incident report and possible sentinel event (SE) review.
2. An SE triggers a root cause analysis, a Joint Commission citation, a review of perfusion practices by internal and outside assessors, and potentially a significant monetary penalty.
3. An error may trigger an indefensible civil law suite with significant monetary damages.
4. An error may cause a transfusion reaction: non-hemolytic or hemolytic
5. hemoglobinuria
6. DIC
7. ↓BP
8. ↑HR
9. bronchospasm
10. erythema
11. urticaria
12. fever
13. angioedema
14. bronchospasm
15. pulmonary edema
16. shock
17. anaphylaxis
18. organ failure
19. death

CAUSE:

1. Human error.
2. Failure to follow approved hospital transfusion policy and procedure (P&P).
3. Approved hospital or blood bank P&P not suitable for transfusion procedure on CPB.
4. An incompatible blood transfusion leads to a potentially massive activation of the immune and clotting systems causing shock, kidney failure, circulatory collapse, and death.
5. Idiopathic transfusion reaction of unknown cause.

PRE-EMPTIVE MANAGEMENT:

1. Develop specific P&P for transfusion during CPB approved by blood bank medical director or equivalent.
2. Stipulate acceptable variations from general AABB approved transfusion P&P in the perfusion transfusion P&P; key points source\*.
3. Ensure the proper consent is obtained.
4. Ensure the clinical indication is documented.
5. Filter type in P&P. (Pall, cardiotomy, etc.).
6. Speed of transfusion.
7. Transfusion line rinse fluid type (Plasmalyte, Normosol, LR, NS, etc).
8. Confirm physician’s order, product and recipient
9. Policy requires double verification of patient identification and product labeling prior to transfusion and confirms that a perfusionist can verify blood products.
10. Provide correct storage of blood product in OR before use.
11. Vitals monitored and documented by perfusion staff on perfusion record.
12. Completed transfusion documented on perfusion record.

MANAGEMENT:

1. Call for help if transfusion reaction is suspected.
2. Stop transfusion.
3. Disconnect donor product and IV tubing.
4. Examine blood product ID and determine if correct patient.
5. Send remaining product to blood bank.
6. Document incident per institutional policy
7. Maintain intravascular volume.
8. Maintain urine output at least 1-2 mL/kg/h.
9. Prepare for cardiovascular instability: extracorporeal support.
10. Send patient blood and urine sample to laboratory.
11. Consider the following medications:
12. Furosemide 0.1 mg/kg
13. Mannitol 0.5 grams/kg (2 mL/kg of 25% mannitol)
14. Dopamine (2-4 mcg/kg/min)
15. Epinephrine 10 mcg/kg IV
16. Diphenhydramine 1 mg/kg IV
17. Hydrocortisone 2-5 mg/kg

\*http://www.jointcommission.org/assets/1/6/PBM\_Implementation\_Guide\_20110624.pdf

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

(The problems that this failure causes are usually 5, critical.)

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

1) Remote, 2) Low, 3) Moderate, 4) Frequent, 5) Very High

(This occurs very infrequently. So occurrence should be 2, low. Transfusion errors are one of the most common sentinel events according to the Joint Commission. But among perfusionists this error is still very low.)

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

(This problem can be easy to detect when proper policy and procedure is followed; a detection RPN of 2, high.)

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.

(Only patients who receive a transfusion on CPB are at risk. So the Patient Frequency RPN should be a 2.)

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 5\*2\*2\*2 =40.)